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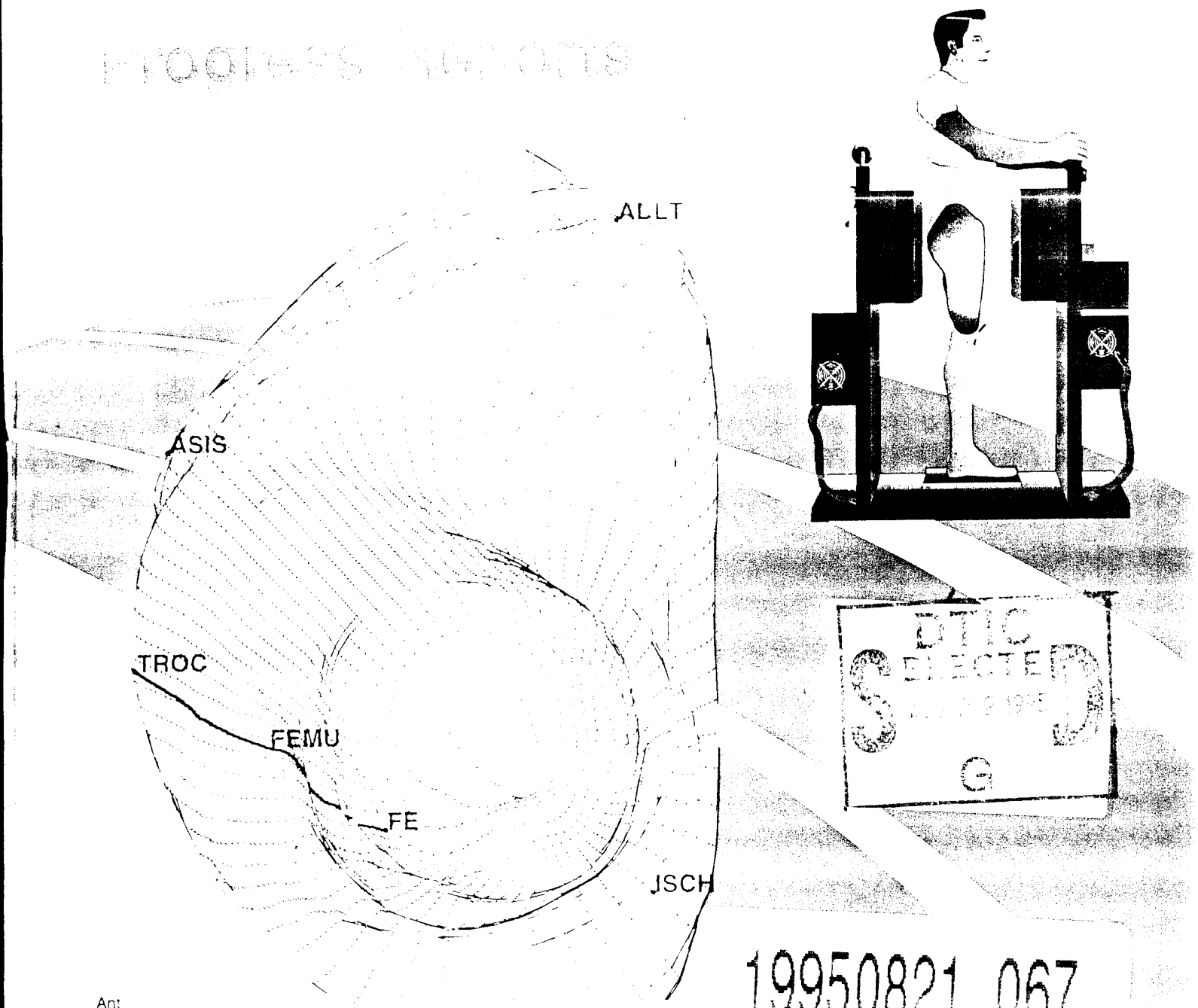
Rehabilitation R&D Progress Reports



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Vol 32, June 1995
Veterans Health Administration
Rehabilitation Research and Development Service

ON THE COVER

Research and development sponsored by the Department of Veterans Affairs, Rehabilitation Research and Development Service, is featured on the front cover. This research is being performed at the Manhattan VA Medical Center, by Principal Investigator Vern Houston, Ph.D. The anterodistal view of an unmodified plaster wrap cast measurement of a residual limb of a test subject with a right AK amputation is shown electromechanically digitized and is depicted on the left. Depicted in the right upper portion of the cover is a drawing of a clinical application of the VA-Cyberware Optical Laser Digitizer in measurement of the special geometry and surface topography of a residual limb of a test subject with a right AK amputation. The Progress Report of this study may be found on page 215. A complete and detailed paper is published in the *Journal of Rehabilitation Research and Development, Vol. 32 No. 1,* starting on page 55.

THE EDITOR

Cover design, illustration and production by Frank Vanni, Scientific and Technical Publications Section, Rehabilitation Research and Development Service, Department of Veterans Affairs, Baltimore, MD.

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Each report must include the following information:

1. Full names, titles, and addresses (including e-mail if available) of the principal investigator and co-authors and location of the research activity, including zip or postal codes.
2. Telephone number, e-mail address, and fax of the principal investigator.
3. Full name and address of the sponsoring organization(s), as well as the specific funded program. Include name of organization's director, if applicable (not necessary of VA facilities).
4. Complete and accurate publications resulting from this research for 1994 and 1995 (i.e. exact title, author(s), publication, title, volume, issue number, date, and page numbers). Incomplete citations will be deleted.
5. A list of key words.
6. A suggested category listing (based on categories included in this book).

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Text of reports may not exceed 600 words. Progress reports are published solely as statements of investigators on the current status of their work, and not as short research papers. Reports must be typed, double-spaced, with clearly marked page numbers. Two hard copies are required. A copy of the same material on diskette (nonreturnable) must be included. We use files save in pure ASCII format under MS-DOS, either 5 1/4 or 3 1/2-inch diskettes. To expedite submission, progress reports may also be submitted via e-mail, followed up by the hard copy/diskette package (refer to our e-mail addresses below).

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Rehabilitation R&D Progress Reports

1994

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Rehabilitation R&D Progress Reports 1994

Contents

1	*Section I.*	***PROJECT PROGRESS REPORTS*** Progress reports are arranged in appropriate subject categories. Reports are numbered in brackets preceding the title. VA-sponsored reports are presented first and are followed by those of other sponsoring organizations in alphabetical order. (*See next page for a topical listing with sequence numbers.*)
331	*Section II.*	***SPONSOR INDEX WITH SELECTED PROGRAM SUMMARIES*** ***A. Department of Veterans Affairs*** ***B. Non-VA Sponsoring Organizations*** This section contains the name and location of all sponsoring organizations and an index of the titles and page numbers of the projects sponsored by each.
348	*Section III.*	***AUTHOR INDEX*** The names of all progress report investigators are listed with corresponding page numbers.
357	*JRRD On-Line*	Information on accessing *Progress Reports* and *JRRD* electronically.

Section I
Project Progress Reports

I. Amputations and Limb Prostheses

A. General

1 Additive Fabrication Technique for the CAM of Prosthetic Sockets
2 Software and Equipment Development for Improved Computer-Aided Prosthetic Socket Design
3 Lighter Weight Electric Prehensor
4 Loads in a Prosthetic Pylon Using Strain Gauges
5 Assessment of the Accuracy and Reliability of Three Hand-Held Infrared Temperature Probes for Clinical Use
6 Skin Perfusion Pressure Response Monitor

B. Upper Limb: General

7 Direct Muscle Attachment: Multifunctional Control of Hands and Arms
8 Improving Prosthetic Prehension
9 Electric Humeral Rotator

C. Lower Limb: General

10 Clinical and Laboratory Study of Amputation Surgery and Rehabilitation
11 Developing a Biomechanical Model of the Interface between the Residual Limb and the Prosthesis for Trans-Femoral Amputees
12 Dynamic Response Prosthetic Feet and Their Role in Human Ambulation
13 Stepping Over an Obstacle: A Comparison of New and Experienced Prosthesis Users
14 Dynamic Diagnostic Socket/Skin Interface Monitoring Using a Prosthesis Mounted Video Camera
15 Finite Element Models to Assist Prosthetic Socket Design

D. Lower Limb: Above-Knee

16 Femoral Displacement in Above-Knee Sockets
17 Investigation of 4-Bar Linkage Knees as an Aid to Floor Clearance
18 Waterski for a Bilateral Above-Knee Amputee
19 Update on the Elastic Strain Energy Discus Leg
20 Prosthetic Design for Dysvascular Below-Knee Amputees

E. Lower Limb: Below-Knee

21 Practical Applications of New CAD and CAE Techniques to Socket Design
22 Neuropathic Foot in Leprosy
23 Computer-Aided Prosthetic Alignment System Using Neural Networks
24 Trans Tibial Suspension Evaluation
25 Artificial Limb Design: Assistant System Using Knowledge-Based Expert System
26 Neural Network Models to Assist Medical Imaging Systems for Prosthetic Fabrication

II. Biomechanics

A. Bone and Joint Studies

27 Functional Electrical Stimulation of Spinal Cord Injury Patients
28 Skeletal Changes after Spinal Cord Injury and Cast Immobilization
29 Biomechanics of Cervical Diagnostic Maneuvers: A Pilot Study
30 Effects of Spinal Fusion with Instrumentation on the Stabilized Spine: A Pilot Study
31 Effect of Surgical Procedures on the Stability of the Lumbar Motion Segment
32 Subtalar and Transverse Tarsal Joint Mechanics
33 Dynamic Response of Spinal Segments: Experimental and Analytical Studies
34 Synovial Joint Biomechanics and the Pathogenesis of Osteoarthritis
35 Calculation of Knee Ligament Loads during Rehabilitation Exercises

B. Human Locomotion and Gait Training

36 Pinned Polymer Model of Posture Control
37 Anatomical Frame Definition, Determination, and Exchange in Movement Analysis
38 Experimental Artifacts in Movement Analysis
39 Postural Control in Parkinson's Disease
40 Model of the Neuro-Musculo-Skeletal System for Human Posture and Gait
41 Model for the Dynamic Postural Control System
42 Biomechanical Evaluation of the Effects of Load Carrying on Dynamic Balance Control
43 Effects of Head Injury on Open-Loop and Closed-Loop Postural Control Mechanisms
44 Effects of Spaceflight on Open-Loop and Closed-Loop Postural Control Mechanisms
45 Development of a Direct Ultrasound Ranging System for the Quantification of Ambulation
46 Controlling Neuronal Noise Using Chaos Control
47 Using Chaos Control to Control Non-Chaotic Systems
48 Initiation of Human Walking
49 Stepping Over an Obstacle: Effect of Reduced Visual Field
50 Effect of Reduced Optic Flow on Gait
51 Effects of Robotic-Assisted Weight Support on Gait and Energy Expenditure

52 Surface EMG Signal Analysis in Normal and Pathological Subjects during Gait by Means of a Novel Algorithm for On-Off Timing Detection
53 Optimal Rigid Body Degrees of Freedom Estimation in Movement Analysis
54 Gait Analysis in TKR Patients

C. Other

55 Wheelchair Propulsion Performance in Young, Middle-Aged, and Elderly
56 Characterization of Normal and Pathological Sway Dynamics
57 Quantitative Functional Anatomy of the Upper Extremity
58 Coordination of Muscles in Gait

III. Functional Assessment

59 Ranked-Ordered Regulation of Motor Units
60 Common Drive of Motor Units: In Numero Experiments
61 Effects of Hand Dominance on Motor Unit Firing Behavior
62 Firing Patterns, Firing Rate Behavior, and Force Generation of Motor Units
63 Biomechanical Analysis of the Sit-to-Stand Motion: A Pilot Study
64 Correlates of Motor Unit Size, Recruitment Threshold, and H-Reflex Jitter
65 Development of an Adult Clinical Version of the Tufts Assessment of Motor Performance (TAMP)
66 Assessment of the Reliability and Validity of the Pediatric Evaluation of Disability Inventory (PEDI)
67 Integrated, Computer-Managed System for Clinical Motor (DIS)Ability Assessment
68 Synchronous Behavior of Motor Unit Firings
69 Motor Unit Control Properties during Sustained Isotonic Isometric Contractions
70 Control of Muscle Fibers: How Does a Muscle Regulate Force?
71 Relation of Rehabilitation Intervention to Functional Outcome
72 Development of Protocols and Models Used to Quantify Functional Capabilities of Persons in Response to the American with Disabilities Act (1992)
73 Development of Mathematical Models to Quantify Joint Velocity, Torque, and Power during Lifting Tasks
74 Assessment of Ambulation Motion Parameters for Clinical Evaluation
75 Use of Joint Torque, Energy, and Power in Clinical Gait Evaluation
76 Mechanisms Underlying Compliant Behavior of the Limbs
77 Central Nervous System Control Rules for Voluntary Movement
78 Assessing Individuals' Predispositions to the Use, Avoidance, or Abandonment of Assistive Technologies
79 Evaluation of Carpal Tunnel Syndrome

IV. Functional Electrical Stimulation

A. General

80 High Charge Density, Bipolar Electrodes for Chronic FNS
81 Rehabilitation of Respiratory Paralysis: Accessory Muscle Stimulation
82 New Bioelectric Method for Early Diagnosis of Delayed Fracture Healing
83 Neuroprosthetic Control of Bladder and Bowel in Spinal Injury Patients
84 Electrical Activation of Diaphragm for Ventilatory Assist
85 Evaluation and Optimization of FES Techniques for Exercise
86 Perineum Stimulation for Control of Urge Incontinence and Frequency
87 Rehabilitation of Urinary Incontinence Using Stimulated Muscle Flaps
88 Restoration of Muscle Activity through FES and Associated Technology: The Raft Project, A Concerted Action
89 Kinesthetic Perception in the Hand and Arm
90 Implantable Stimulation, Telemetry, and Transducer System for Neural Control
91 Management of Urinary Disorders in SCI
92 Development and Dissemination of a Resource Guide on Functional Electrical Stimulation (FES) for Persons with Spinal Cord Dysfunction
93 Fatigue and Recovery of FES-Activated Paralyzed Muscles

B. Upper Limb Applications

94 Functional Neuromuscular Systems for Upper Extremity Control
95 Thin-Film Peripheral Nerve Electrode
96 Mechanical Effects of Muscle Tendon Transfer and Functional Neuromuscular Stimulation

C. Lower Limb Applications

97 Restoration of Standing Pivot Transfer for Quadriplegic Patients Using a Totally Implanted FNS System
98 Functional Paraplegic Walking with Electrical Stimulation
99 Restoration of Sit-to-Stand Function in Elderly Patients Using FNS
100 Restoration of Gait for the Stroke Patient
101 Development of an On-Line Correction Capability for FNS Locomotion

102 Relationship Identification between Electrical and Muscle Stimulus Torque for FES Optimization in Paraplegic Patients
103 Paraplegic Walking Made Practical with FNS and Orthoses
104 Rehabilitation of Paralyzed Muscles by Surface FES

V. Geriatrics

105 Upper Body Motion Analysis for Amelioration of Falls in the Elderly
106 Effects of Strength Training on Functional Ability of Older Adults
107 Balance Training in Elderly Fallers and Nonfallers
108 Applicability of Accessibility Codes to Meet the Needs of Elderly People
109 Age-Related Changes in the Triceps Surae Stretch Reflex and Postural Control
110 Aged Muscle Metabolic Adaptations to Resistance Exercise
111 Age-Related Changes in Open-Loop and Closed-Loop Postural Control Mechanisms
112 Vestibular System Dysfunction and Quiet-Standing Postural Control
113 Effects of Muscle Strength on Balance during Movement in the Elderly
114 Does Leg Strength Influence Rising from a Chair in Older Adults?
115 Do Changes in Strength Influence Measures of Balance and Function in Elderly Men and Women?
116 Demonstrating the Efficacy of Memory Training
117 Manipulating Joint Compliances and Ground Reaction Forces to Predict Falling Potential: A Pilot Study
118 Swallowing Dysfunction in Elderly Head and Neck Cancer Patients
119 Effects of Age on Oropharyngeal Swallowing
120 Age-Related Changes in Sensory-Motor Performance
121 AARP Evaluation of Assistive Devices for the Bathroom
122 White Matter Hyperintensities
123 Use of Technology Services to Maintain Employment among People Aging with a Disability
124 Role of Training to Enhance Utilization of In-Home Support: A Comparison between Older Hispanics and Anglos with a Disability
125 Assessment of Residential Care Facilities as an Alternative Community Service Model for Disabled Older Adults
126 Variations in Secondary Conditions, Risk Factors, and Health Care Needs for Four Groups of Persons Aging with Physical Disability
127 Study of Policy Barriers Impeding Use of Assistive Technology by Persons Aging with Disabilities

VI. Head Trauma and Stroke

128 Computer-Assisted Treatment of Hemi-Inattention in R-CVA Patients
129 Bicycle Ergometry to Improve Ambulation in Hemiplegic Stroke Patients
130 Muscle Denervation and Recovery following Phenol-Induced Peripheral Nerve Block
131 Communicative Partners: Integrating Aphasic Adults Back into Society
132 Fetal Transplants and Repair of Stroke in Adult and Aged Rats
133 Quantification of Upper Limb Synkinesis in Hemiparetic Subjects
134 Prospective Study on the Use of Bolus Intrathecal Baclofen for Spastic Hypertonia Due to Acquired Brain Injury
135 Prevention of Thromboembolism in Stroke Rehabilitation Patients
136 Comorbidities and Complications in Stroke: Incidence, Risk Factors, and Effects on Outcomes
137 Course of Recovery of Cognitive-Communicative Problems in Right-Brain-Damaged Individuals
138 Predictive Value of Cognitive/Behavioral Measures in Patients after Stroke in Assessing Functional Outcome
139 Reducing Motor Disability in Hemiparetic Stroke by Manipulation of Sensory Input from the Paretic Upper Limb: A Quantitative Evaluation
140 Controlled Study of the Effects of EMG Feedback and Electrical Stimulation on Motor Recovery in Acute Stroke Patients
141 Effects of Aerobic Exercise on Young Persons Post-Stroke
142 Effectiveness of a Telephone Support Group for Stroke Caregivers
143 Improving Vocational Outcomes of Individuals Who Have Sustained a Stroke
144 Aftercare Program Focused on the Postconcussion Syndrome following Mild Traumatic Brain Injury
145 Processing Spatial Information

VII. Independent Living Aids

A. General

146 Design of New Toilet Prototypes for Elderly and Disabled Veterans
147 Assisting Community-Based Rural Independent Living Programs
148 Life Satisfaction of People with Physical Disabilities: Relationship to Personal Assistance, Disability Status, and Handicap
149 Use of Personal Assistance Services by Persons with Spinal Cord Injury
150 Variables Affecting Independent Living for Persons with Physical Disabilities
151 New Grip Aid for Leprosy Patients

152 Special Projects and Demonstration: Applications of Technology to Enhance Quality of Life—A Community Model
153 Trans-Train: Transdisciplinary Training of Rehabilitation Personnel in Assistive Technology

B. Robotics
154 Vocational Training Facility
155 Improving the Functional Utility of Rehabilitation Robotics through Enhanced Sensory Feedback: The Virtual Headstick
156 Rehabilitation Robotics Technical Assistance and Outreach
157 Developing a Robotically Aided Science Education Laboratory for Students with Severe Physical Disabilities
158 Multimodal Control of a Rehabilitation Robot
159 Development of a Control System for Robots

C. Communication Methods and Systems
160 Recognition of Hand Gestures by People with Motor Impairments: A Pilot Study
161 Engaging, Recruiting, and Retaining Students with Disabilities in Science, Engineering, and Math
162 Selecting Items from Lists and Menus in Information Systems
163 Uni-Flex: A Universal-Flexible Human Interface Protocol
164 Development of Cross-Disability Access Techniques for Database Systems
165 Development of Extensions for Standard Computers and Operating Systems to Allow Access by Users with Motor Impairments
166 General Input Device Emulating Interface (GIDEI) Standard Version 2
167 Augmentative and Alternative Communication Technical Assistance and Outreach Program
168 Research in Interface Methodologies for AAC

D. Private and Public Programs
169 Evolution of Independent Living Programs: A Longitudinal Study
170 Development of an Instrument to Measure Adequacy of Personal Assistance Services
171 Effect of Personal Assistance Services on the Long-Term Health of a Rehabilitation Hospital Population: Perceptions of Rehabilitation Professionals
172 Demonstrating a Model Approach to Independent Living Center-Based Assistive Technology Services
173 Increasing the Ability of Independent Living Centers to Serve the Population of African Americans with Disabilities
174 Collaboration between Medical Rehabilitation Programs and Independent Living Centers in Facilitating Independent Living by Persons with Recently Incurred Spinal Cord Injury
175 Relationships among Age at Onset, Adequacy of Personal Assistance, Negative Health Incidents, and Health Care Utilization for Persons with Physical Disabilities
176 Assessing the Capabilities of Independent Living Center Staff to Deliver ADA-Related Services

VIII. Muscles, Ligaments, and Tendons

A. Muscles
177 Physiological Basis of Strength following Surgical Tendon Transfer
178 Biochemical and Myoelectric Events during Fatigue
179 Effects of Muscle Fiber Size on Surface EMG Parameters
180 Muscle Adaptation following Limb Unloading and Its Influence on EMG Parameters
181 Influence of Resistance Exercise Training on the Determinants of Glucose Tolerance
182 Effects of 2 Weeks of Oral Albuterol on Insulin Sensitivity and Lipoprotein Lipids in Healthy Men
183 Modeling of EMG Signals: The Effect of Layered Media
184 Effects of Spaceflight on Human Muscle Performance
185 Patient Management and Rehabilitation Protocols following Major Hip Surgery Based on Quantitative in Vivo Data
186 Quantifying Co-Contraction in Agonist/Antagonist Muscles: A Force Instrumented Endoprosthesis
187 Muscle Fiber Damage Due to Eccentric Contractions
188 Skeletal Muscle Reaction to Growth and Immobilization
189 Skeletal Muscle Length Force Characteristics during Maximal and Submaximal Activation

B. Ligaments and Tendons
190 Combined Functional Loading and Laser Photostimulation of Regenerating Tendons
191 Simulation of Distal Tendon Transfer of Arm and Forearm Muscles

IX. Neurological and Vascular Disorders

A. General
192 Artificial Nerve Graft: Union of Cellular and Noncellular Components
193 Nerve Rubbing in the Symptomatic Treatment of Ulnar Nerve Paresthesiae
194 Neuromuscular Function in Postpolio Subjects: A 5-Year Follow-Up Study
195 Comparison of Symptoms between Swedish and American Postpolio Individuals and Assessment of Lower Limb Strength: A Four-Year Cohort Study

196 Development of a Procedure for the Assessment of Motor Behavior in Young Children under Natural Conditions
197 Podiatric Evaluation of the Neuropathic Foot in Leprosy
198 Kinematics of Human Tremor Using Stereophotogrammetry

B. Low Back Pain

199 Development of a Clinical Database for the Back Analysis System
200 Development of Test Protocols to Assess the Behavior of Back Muscles
201 Back Analysis System Update
202 EMG Spectral Parameters as a Treatment Outcome Measure for Low Back Pain
203 Muscle Performance in the Back Analysis System Compared to Lifting Tasks
204 Spectral Parameters of Lumbar Back Muscle Electromyography at Different Contraction Levels
205 Alterations in EMG Characteristics Coinciding with Low Back Pain
206 EMG Parameters of Lumbar Back Muscles
207 Normative Database for Low Back Pain Evaluation in Blue Collar Workers
208 Predictability of the Susceptibility to Low Back Pain
209 Evaluation of Low Back Pain Treatment Outcome
210 Vermont Rehabilitation Engineering Research Center for Low Back Pain

C. Swallowing Disorders

211 Determining Response Curve for Tactile-Thermal Application: A Pilot Study
212 Comparison of Manofluorography, the Modified Barium Swallow, and Biomechanical Analysis in the Post-Surgical Pharynx
213 Biomechanical Effects of Tracheostomy Tubes
214 Biomechanics of Swallow After Head and Neck Cancer
215 Effects of Surgical Reconstruction on Speech and Swallowing
216 Assessment of Performance Outcome in Laryngeal Cancer Patients

D. Vascular Disorders

217 Feasibility of a Dynamic Dermofluorometer to Monitor Skin Fluorescence: A Pilot Study
218 Noninvasive Measurement of Changes in Muscle Oxygen with Claudication
219 Measurement of Plantar Foot Soft Tissue Properties of Patients with Diabetic Neuropathy for Prediction of Plantar Foot Pressure and Assessment of Plantar Ulceration Risk
220 Measuring the Effects of Vestibular Stimulation on Children with Cerebral Palsy

X. Oncology

221 Strength of Human Cortical Bone with Simulated Metastatic Defects

XI. Orthopedics

A. General

222 Mechanical Regulation of Skeletal Tissue in Normal and Prosthetic Joints
223 Hip Fracture Risk Assessment Using Automated 3-D Finite Element Modeling
224 Biochemistry of Cartilage in a Model of Disuse and Different Types of Recovery: A Pilot Study
225 Predisposing Factors in Disc Prolapse
226 Pulsed Laser Deposited Hydroxyapatite Coating for Prosthesis-Bone Bonding
227 Diagnosis of Cartilage Degeneration: Quantitative Surface Spectroscopy
228 Comparison of Events in Bone Healing Influenced by CCEF and PEMF Signals
229 New Strategies for Long-Term Performance of Femoral Prosthesis
230 Factors Affecting Streaming Potentials in Healing and Remodeling Bone
231 Biochemical Analysis of Synovial Activation in Joint Dysfunction
232 Origin and Character of Regenerate Bone
233 In Vivo Measurement of Vertebral Displacement after Lumbar Fusion
234 Prediction of Bone Adaptation Based on Damage and Repair in Bone
235 Three-Dimensional Reconstruction of Scoliotic Deformities and Evaluation of Treatments
236 Effect of a Plaster Cast on Lumbosacral Joint Motion
237 Finite Element Models Generated from Magnetic Resonance Images

B. Hip Implants

238 Suitability of Titanium Alloy as a Joint Replacement Bearing Surface
239 Effect of Femoral Collar Geometry in Hip Replacement
240 Wear Debris Generation in Hip Modular Head and Neck Components
241 Changes in Bone Blood Flow Associated with Intramedullary Nailing
242 Bone Cement Collar (BCC) for Sealing the Femoral Canal around Non-Cemented Prostheses: A Pilot Study
243 Optimized Surface Bonding and Stiffness of Femoral Endoprostheses
244 New Methods to Treat Impaired Fracture Healing Using Growth Factors
245 Continuation of the Center for the Examination of Retrieved, Orthopedic Prostheses

246 Hip Joint Biomechanics: The Effects of Femoral Head Endoprosthetic Replacements

C. Arthritis

247 Individual Adaptability and Its Relation to Recovery after Therapeutical Interventions in Patients with Rheumatoid Arthritis

XII. Orthotics

248 FES-Aided Paraplegic Gait Using a Controlled-Brake Orthosis
249 Developmental Enhancement and Application of the VA-Cyberware Prosthetics-Orthotics Optical Laser Digitizer
250 Computer-Aided Design and Computer-Aided Manufacturing of Orthopedic Footwear
251 Gait Analysis of Paraplegic Patients Walking with Mechanical Orthoses and FES
252 Criteria for Interfacing and Control of a Powered Upper Extremity Orthosis
253 Design and Evaluation of a Triceps Orthosis for C5/C6 Quadriplegics
254 Orthotic Foot Appliances for Leprosy Patients: A Study Based on Podiatric Principles

XIII. Psychological and Psychosocial Disorders

255 Effects of Expectation, Reward, and Activity on Subtypes of Schizophrenia: Status Report
256 Sexuality Issues among Women with Physical Disabilities
257 Development and Evaluation of a Treatment Program Directed at the Improvement of Psychosocial Behavior following Stroke

XIV. Sensory, Cognitive, and Communication Aids

A. Hearing Impairment

258 Signal Processing and Hearing Aid Design
259 Optokinetic Testing for Diagnosis and Rehabilitation of Balance Disorders
260 Evoked Otoacoustic Emissions for Ototoxic Monitoring in Adults
261 Effect of Presence versus Absence of Prolonged Amplification on Audition
262 Effect of Lack of Amplification on Persons with Unilateral Hearing Loss
263 Programmable Hearing Aids: Evaluation and Prediction of Benefit
264 Assessment of Nonauditory Factors in Hearing
265 Evaluation of a New Nucleus Cochlear Implant Speech Processor: A Pilot Study
266 Early Detection of Hearing Loss from Ototoxic Agents by High-Frequency Auditory Evaluation
267 Efficacy of an Auditory Rehabilitation Program: A Pilot Study
268 Hearing Aid Research: Improving the Selection, Fitting, and Evaluation Process
269 Showsounds and Soundsentry: Access to Computers and Information Systems for People Who Are Deaf or Hard-of-Hearing

B. Speech Impairment

270 Evaluation of Word-Recognition Performance with Sentence Material
271 Computer-Assisted Speech Evaluation Expert System
272 Using Self-Monitoring to Improve Communicative Efficiency in Aphasia
273 Characteristics of Connected Speech in Aphasic Adults
274 Aphasic Naming Deficits: Effects of Deep- and Surface-Level Treatments
275 Analysis of a Treatment for Apraxia of Speech in Adults with Aphasia
276 Conversational Skills Training for Aphasic Subjects
277 Measurement and Prediction of Benefit from Amplification
278 Restoration of Oral Function with Maxillary Bone Grafts and Implants
279 Treatment of Dysphagia in Age-Related Disease: Stroke
280 Cricopharyngeal Myotomy Study

C. Vision Impairment

281 Design and Testing of an Electronic Travel Aid for Blind Persons
282 Evaluating the Efficacy of a Peripheral Vision Expander System: A Pilot Study
283 Design and Evaluation of Liquid Crystal (LC) Dark-Adapting Eyeglasses for Persons with Low Vision
284 National Survey of Impact of Low Vision Aid Use among Veterans
285 Environmental Information Needs for Wayfinding by Special Populations
286 Development of a Predictive Model of Driving Performance in Stroke Patients
287 Stimulation of Retinal Photoreceptor Function with Arrayed Subretinal Microphotodiode Implants: A Pilot Study
288 Touchscreen Access for Individuals Who Are Blind: "Talking Fingertip" Strategy
289 Identification of Skills and Knowledge Necessary for People with Visual Impairments Beginning Jobs after Graduating from Postsecondary Institution
290 Identification of Skills, Knowledge, and Steps Necessary for Students with Visual Impairments Entering Postsecondary Institutions
291 The Head Reader—A Display for Sensory Impaired Bowlers

XV. Spinal Cord Injury and Related Neurological Disorders

A. General

292 Multimodality Image Registration of the Cervical Spine
293 Wheelchair Exercise and Digital Echocardiography for the Detection of Heart Disease
294 Effect of Supported Standing and Upper Body Exercise on Lower Extremity Spasticity in Persons with Spinal Cord Injury
295 Corticospinal System
296 Carbohydrate Metabolism and Cardiovascular Risk Factors in Persons with Spinal Cord Injury
297 Effect of Quadrugby on Physical Capacity and Physical Strain among a Group of Subjects with Cervical Spinal Cord Injury
298 Causes and Costs of Unplanned Rehospitalizations among Persons with Spinal Cord Injury
299 Immune Responses to Pneumococcal Vaccine in Spinal Cord Injury
300 Adjustment after Spinal Cord Injury: The 20-Year Minnesota Longitudinal Study
301 Prediction of Mortality after Spinal Cord Injury: A 20-Year Prospective Study
302 Secondary Conditions after Spinal Cord Injury: Relationship to Life Adjustment
303 Performance Capacity and Physical Strain in Subjects with a Spinal Cord Injury
304 Employment Status among Persons with Spinal Cord Injury: Associations with Need to Work, Creativity, and Need for Stimulation
305 Study of Employers: Experiences and Attitudes of Upper Management and Its Relationship to the Hiring of Persons with Mobility Impairments
306 Modification of Trombone Trigger Allows Performance on the Trombone by Persons with Spinal Cord Injuries

B. Treatment and Rehabilitation

307 Noninvasive Urodynamic Evaluation of Vesicourethral Function: A Pilot Study
308 Functional Restoration of Gasp: A Pilot Study
309 Management of Musculoskeletal Complications of Spinal Cord Injury
310 Vertebral Fusion by New Osteogenic Agents to Accelerate Rehabilitation
311 Spinal Cord Injury-Induced Bone Loss
312 Rehabilitation of the Colon after Spinal Cord Injury: A Pilot Study
313 Advanced Technology Neural Information Sensors for Prosthetic Control by Quadriplegics
314 Device for Treatment of Peripheral Nerve Injury
315 Prokinetic Agents for Constipation in Spinal Cord Patients: A Pilot Study
316 Exercise Testing and Training of Multiple Sclerosis Patients
317 Improving Exercise Performance of Quadriplegics
318 Objective Assessment of Spasticity in Spinal Cord Injury
319 Minimizing Hypertonus to Improve Recovery after Spinal Cord Injury
320 High-Frequency Magnetic Stimulation of the Bladder and Bowel: A Pilot Study
321 Baclofen Pump: Functional and Neuropsychological Impact
322 Longitudinal Analysis of Well-Being in Persons with Spinal Cord Injury and Their Caregivers
323 Ultrasound for Urinary Tract Surveillance of Persons with Spinal Cord Injury
324 Natural History and Clinical Course of Urinary Tract Complications in Patients with Spinal Cord Dysfunction
325 Motor Complete Spinal Cord Injury: Prognosis for Ambulation
326 Recovery of Upper Extremity Muscles following Cervical Spinal Cord Injury
327 Vasopressin and Blood Pressure Control in Spinal Cord Injury Patients
328 Bacteriuria in Patients with Neurogenic Bladder Treated with Intermittent Catheterization
329 Effects of Surgical Decompression on Impairment and Disability Parameters in Cervical Spondylotic Myelopathy
330 Complications of Anterior Cervical Fusion with Plate and Screw Fixation

C. Spinal Cord Regeneration

331 Application of Electric Fields to Enhance Recovery following Spinal Cord Injury: Behavioral Studies
332 Application of Electric Fields to Enhance Recovery following Spinal Cord Injury: Electrophysiological Studies
333 Enhanced Carbon Filament Prostheses as Substrates for Regrowth of Injured Spinal Cord: Recovery of Function
334 Enhanced Carbon filament Prostheses as Substrates for Regrowth of Injured Spinal Cord: Electrophysiological Recovery
335 Electric Field Effects on CNS Axonal Transport in SCI: A Pilot Study
336 Tubular Prostheses to Enhance and Direct Neuronal Regrowth in SCI
337 Neuron-Glia Interaction and CNS Regeneration

XVI. Wheelchairs and Powered Vehicles

A. General

338 Clinical Workstation for Reducing Wheelchair Propulsion Injuries
339 Electrical Control of Bladder and Bowel following Spinal Cord Injury
340 Design and Selection Guidelines for Wheelchair Ride Comfort
341 Toward the Design of a New Prone Cart: A Pilot Study

I. Amputations and Limb Prostheses

A. General

[1] ADDITIVE FABRICATION TECHNIQUE FOR THE CAM OF PROSTHETIC SOCKETS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A711-DA)*

PURPOSE—We seek to develop a device that can be used with computer-aided design/computer-aided manufacturing (CAD/CAM) systems to automatically produce sockets for artificial limbs from quantitative data. The device should not use intermediary steps in fabrication (e.g., mold making), should use clinically acceptable thermoplastics (e.g., polypropylene), and should produce sockets in clinically practical times (e.g., less than 1.5 hours).

METHODOLOGY—The system under development builds sockets using a plastic deposition technique. A plastics extruder melts raw plastic material and dispenses it through a nozzle. The moving dispensing nozzle is under computer-guidance allowing plastic to be deposited in thin layers of predetermined contour. Multiple layers are deposited, one upon another, to create the shape of the desired socket. The socket-building process is automatic and executed in accordance with the numerical data provided by a prosthetics CAD system.

PROGRESS—The system has been prototyped and tested using standard test methods to determine the strength and the durability of the the fabricated sockets. Two persons with trans-tibial amputation have been fitted with sockets made using the prototype machine.

RESULTS—The prototype uses an extrusion welder to melt and dispense plastic. The extruder is mounted upon a computer numerically controlled (CNC) milling machine which manipulates the plastic bead during deposition. The extruded plastic is forced through an extrusion die with rectangular cross-section to form a continuously flowing ribbon of melted plastic. Ribbon dimensions are 0.75 mm thick and 5 mm wide, corresponding to the plastic layer thickness and socket wall thickness. The layer spacing is sufficiently fine to give the socket wall a smooth finish. A 9-in (22.86 cm) socket consisting of 300 layers can be fabricated in 90 min.

Standard ASTM tensile specimens were used to evaluate the experimental fabrication system using two common prosthetics plastics; polypropylene homopolymer (PPH) and polypropylene copolymer (PPC). Specimens were prepared from rectangular pseudosockets fabricated by the experimental device. Tensile strengths of samples produced with the experimental system were within the range of published values for PPH and PPC. Specimen failure was not, in general, at the interlaminar boundaries.

Fatigue tests were carried out wherein tensile specimens were continuously and repetitively loaded to determine service life of sockets produced with the experimental system. For PPH, specimens underwent "unlimited" (i.e., over 1,000,000) loadings at stress

levels of 2250 psi or less, but showed "limited" life above 2650 psi. For PPC, stress levels of 1550 psi and below demonstrated "unlimited" life, while stress levels of 1750 psi and higher have "limited" life. Maximum fatigue stress levels in sockets were estimated at 1330 psi using the Draft International ISO Standard (ISO/DIS 10328-1) and typical socket dimensions.

Two sockets were fitted to persons with transtibial amputation. The first socket was fit after tensile strength testing but before tensile fatigue testing. That socket was used for routine activities for 3 months and then visually examined; no signs of mechanical failure were found. The second socket was fitted after concluding the fatigue tests and has been in use for a period of 1 month. The subject continues to use the test socket at the time of this writing and uses it exclusively and for all activities.

A Request for Evaluation (RFE) is being prepared for submission to the VA. If approved, the fabricating device will begin a period of precommercial evaluation with the goal of bringing the device to market as a commercial product.

FUTURE PLANS—Production of clinically usable prototype machines will begin upon approval of the RFE or similar preproduction evaluation or development proposal. Feedback from the use of these preproduction units will be incorporated into the design of socket fabricating machines for commercial release.

RECENT PUBLICATIONS FROM THIS RESEARCH

Additive fabricator for high-speed production of artificial limbs. Rovick JS. In: Proceedings of the Fifth International Conference on Rapid Prototyping, Dayton, June 1994.

New CAM technique for the direct automated fabrication of sockets. Rovick JS. In: Proceedings of the Nineteenth Annual Meeting of the American Academy of Orthotists and Prosthetists, Las Vegas, March-April 1993.

Plastic deposition fabricator for the CAM of sockets: material strengths and clinical experience. Rovick JS, Uellendahl J. In: Proceedings of the Twentieth Annual Meeting of the American Academy of Orthotists and Prosthetists, Nashville, March 1994.

[2] SOFTWARE AND EQUIPMENT DEVELOPMENT FOR IMPROVED COMPUTER-AIDED PROSTHETIC SOCKET DESIGN

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PURPOSE—The objective of this project is to develop clinically effective and efficient equipment and software enabling computer-aided design and manufacture (CAD/CAM) of more intimately fitting, comfortable, and functional prosthetic sockets for US veterans with below-knee amputations.

METHODOLOGY—To achieve this objective, the following research protocol has been established:

1) Develop transducers and instrumentation to measure socket/residual limb interface stresses for analysis of residual limb tissue loading as a function of socket design geometry and material.

2) Develop software for automatic detection, identification, and registration of anatomical landmarks from optical digitizer camera output intensity measurements for input to and use in CAD design.

3) Adapt a commercial, diagnostic ultrasound unit for digitization and characterization of below-knee amputees' residual limb skeletal, tendonous, and ligamentous morphology.

4) Develop software for integration of optically digitized residual limb surface measurements and ultrasonically digitized subsurface measurements.

5) Develop models of, and instrumentation to measure, the nonlinear, nonstationary, nonhomogeneous, anisotropic, viscoelastic behavior of soft tissues for prediction and analysis of stress distributions in residual limb tissues subjected to static and dynamic prosthetic loads.

PROGRESS—A 1360 element force-varying resistive transducer for measurement of socket/residual limb interface normal and gradient shear stresses has been designed and fabricated. Comprehensive laboratory testing of the "P-Scan" measurement system incorporating this transducer has been conducted. Design refinements to improve the performance of the transducer and P-Scan system are being implemented. Clinical tests with the P-Scan system with two subjects with BK amputation have been performed. Prosthetics CAD software for analysis and visualization of the resulting measurement data is being developed.

Laboratory tests have been conducted with the NY VAMC Department of Radiology clinical diagnostic ultrasound unit. A prototype stepper motor driven scanning fixture has been fabricated, and ultrasonic measurements of a test subject's residual limb and three nonamputee control subjects' lower limb segments have been performed. From the results of these tests, specifications for a prosthetics ultrasonic digitizer have been formulated.

An image processing algorithm for automatic residual limb landmark detection from optical digitizer camera output intensity information has been developed. An artificial intelligence blackboard pattern recognition algorithm for automated landmark detection, identification, and registration from integrated optical and ultrasonic residual limb measurements is being investigated.

A nonlinear, biphasic viscoelastic model for characterization of the nonlinear, nonstationary, nonhomogeneous, anisotropic, viscoelastic mechanical properties of bulk, soft tissues is being investigated. Tests with a prototype indentor for measurement of the mechanical properties of soft tissue are being conducted, and compared with the results predicted by the nonlinear, biphasic viscoelastic model.

FUTURE PLANS—Refinement and enhancement of the project P-Scan transducer and stress measurement system shall continue. Firmware for quantitative CAD system feedback of socket design of socket/residual limb interface stresses resulting from given socket designs and materials shall be developed. Construction and testing of a prototype prosthetics ultrasonic digitizer is planned. In addition, utilization of the results and knowledge obtained in this project, together with results obtained by the investigators in their other research in tissue mechanical property characterization, measurement of static and dynamic loading, and foot/ankle biomechanics, is planned for development of new, improved, biomechanically based CAD socket designs.

[3] LIGHTER WEIGHT ELECTRIC PREHENSOR

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—One of the most effective configurations for a transhumeral prosthesis is the hybrid prosthesis, which combines a cable-actuated, body-powered elbow and an electric-powered prehension device. The cable linking the elbow to the movement of the physiological shoulder provides direct control the position, speed, and acceleration of the elbow, as well as perception of those quantities through the proprioception of the shoulder. The electric-powered prehension device produces high grip forces; these are in excess of 89 N at the fingertips compared to the maximum of 22 or 27 N possible with a cable-actuated split hook. The electric prehensor also allows maintenance of low forces (for delicate handling) without physiological effort to sustain the gripping force. A body-powered voluntary opening prehensor always requires physiological effort to maintain grip forces below the maximum possible. The powered prehensor and body-powered elbow enable prehension and elbow function to be independent, making simultaneous action possible.

The hybrid configuration is typically not appropriate for persons with short residual limbs because of the high forces associated with flexing the mechanical elbow against the weight of the electric prehensor. As a consequence, it is often necessary to utilize an electric elbow with this level of amputation or to use a

complete body-powered prosthesis with a lightweight mechanical prehensor (having low gripping force). Although there have been advances in cable-actuated control of electric elbows, clinical implementations of these systems have yet to achieve the refined control possible with cable-actuated body-powered elbows.

We are proposing to develop a lighter-weight electric prehensor (LEP) that will make possible the fitting of the hybrid configuration to a broader range of persons with upper-limb amputations, especially persons with short transhumeral limbs.

METHODOLOGY—The LEP will be based on the design of our laboratory's intermediate-size electric prehensor (ISEP). The ISEP was derived from the design of our synergetic prehensor (SP) but intended for older children and adolescents. This prehensor used 10X Hosmer Dorrance hook fingers rather than the APRL hook fingers of the SP. The ISEP also had lower performance characteristics in comparison to the SP, so as to achieve a smaller package and simpler mechanical arrangement. It was capable of producing a prehension force of 44 N at the finger tips.

To develop the LEP for adults, the hook-like fingers of the ISEP will be converted from the #10 (child) to the #5 (adult) size. The gear drive will be modified to produce a maximum grip force of at least 44 N at the tips of the longer hook fingers. Speed of finger movement, which is approximately 40°/sec with a 6-volt battery (65°/sec with a 9.6-volt transistor-type battery), may have to be reduced to achieve the specified grip force while maintaining low weight. If reduction is necessary, slower finger closing speed is believed to be an acceptable tradeoff for higher grip force.

With the #5 size hook fingers, we expect the LEP to weigh 230 gm, two-thirds the weight of the Steeper Powered Gripper or Centri Ultralite Hand. In a typical adult transhumeral prosthesis with a body-powered elbow, it would require less than 1.7 Nm to flex the elbow against this weight at the end of an adult-size forearm.

PROGRESS—A preliminary design for the LEP has been completed. The finger speed is estimated at 0.93 radians/second (53.2°/second) and the grip force at the tips is expected to be 11.1 pounds (49.4 N). Maximum opening at the finger tips will be 4.0 inches (101.6 mm), the same as the 5XA split hook.

Part drawings for the prehensor have been completed, and we are fabricating two units to be used in our initial evaluation.

FUTURE PLANS—Our first test subject had been an evaluator of the earlier ISEP and has continued to use this device since 1989. The evaluation period will be 3 months. The next phase of the project will depend on the outcome of this first evaluation.

[4] LOADS IN A PROSTHETIC PYLON USING STRAIN GAUGES

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Sponsor: *None listed*

PURPOSE—A realistic measurement of the forces transferred to the residual limb via the prosthetic socket needs to be known. As there are only rigid connections between the socket and the pylon, a method to measure these forces was devised concentrating on strain measurement at the pylon.

METHODOLOGY—Using a strain gauge direct connect card that provided signal conditioning, 10 strain gauges were configured on a standard 30 mm aluminium prosthetic pylon. The configuration was designed to provide axial load, torsion, anterior/posterior bending moment at the distal end of the pylon, anterior/posterior bending moment at the proximal end of the pylon, and distal medial lateral bending moment.

A single 30-way ribbon cable connected the strain gauges to the data acquisition card. Real time data analysis was obtained using LabTech Notebooksoftware, which includes software programmable gains, and the acquired data were displayed in graphical format. The data can also be stored in ASCII format for further analysis. A data logger would pro-

vide a more mobile system, removing the limitations of the cable.

This system was fitted to a 290 mm long pylon. It is possible to mount these strain gauges on a shorter pylon, where the minimum length is approximately 50 mm between the pylon adaptors. After calibration the pylon was fitted onto a trans-tibial endoskeletal prosthesis.

RESULTS—Initial results compared well with literature. It was also tested on the Rehab Tech fatigue machine, which mimics normal gait.

IMPLICATIONS—The forces measured can be used to determine the shock absorption properties of prosthetic feet, as well as the component forces in relation to proposed ISO standards forces while running. It will also provide the actual forces at the distal end of the socket, useful for FEA (Finite Element Analysis) of the socket. The advantage of using strain gauges instead of load cells is that there is no need to modify the prosthesis, while the properties of the pylon remain unchanged.

[5] ASSESSMENT OF THE ACCURACY AND RELIABILITY OF THREE HAND-HELD INFRA-RED TEMPERATURE PROBES FOR CLINICAL USE

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Sponsor: *None listed*

PURPOSE—The accuracy and reliability of an industrial infra-red temperature probe (Fluke 80T-IR) were compared to those of two similar probes in current clinical use (First Temp Genius and Invotech Biotherm).

METHODOLOGY—The accuracy was determined using a Platinum Resistor Temperature Sensor (PRT) as a reference. Reliability was also examined in the short term (reading to reading) and the medium term (day to day). The probes were assessed across the biological range (24 to 40°C).

RESULTS—The average accuracies of the probes were First Temp (−1.9°C), Invotech (−1.2°C) and Fluke (+3.7°C). Reliability was expressed as standard deviation of results. The overall standard deviations were First Temp (0.7°C) Invotech (0.7°C) and Fluke (0.9°C).

IMPLICATIONS—Where the highest degree of accuracy is required, the Fluke would not be a suitable replacement for the clinical devices across the biological range of temperatures. However, the Fluke may be a worthwhile cheap alternative to the First Temp and Invotech devices as it is less than half the price of the other two temperature probes. It also can be used at higher temperatures (up to 260°C) such as those found in prosthetic manufacturing processes. This study provides a basis for skin and socket temperature studies clinically, including the area of prosthetics and orthotics.

[6] SKIN PERFUSION PRESSURE RESPONSE MONITOR

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Sponsor: *None listed*

PURPOSE—An instrument to apply known pressures to the skin was required, to measure re-perfusion behavior of small blood vessels in skin. Design criteria included: low cost; simple operation; accuracy; reliability; incorporation of Laser Doppler Flowmetry; operation across the biological range of pressures; and applicability to a variety of body sites.

PROGRESS—The resulting design consists of a pneumatic circuit, pressure transducer, chart recorder, mercury manometer, housing for blood flow and temperature probe, and a stand to rest subject's upper limb on. The pressure is applied vertically to the limb that rests horizontally on the stand. Pressure can be applied or released as required. A continuous output of local pressure, blood flux and temperature is obtained at the same point. The blood flux and temperature readings are acquired using a Moor Instruments DRT4 Laser Doppler Perfusion and Temperature Monitor.

IMPLICATIONS—This device facilitates a wide range of research projects. It will initially be used to establish a skin re-perfusion response, or stress test in controls. Subsequent projects would then involve various patient groups.

B. Upper Limb: General

[7] DIRECT MUSCLE ATTACHMENT: MULTIFUNCTIONAL CONTROL OF HANDS AND ARMS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A306-4DC)*

PURPOSE—To achieve a significant improvement in the function of electric-powered upper-limb prostheses, we believe it is necessary to develop better control interfaces with inherent sensory feedback. We suggest that small tunnel cineplasties, or other surgical procedures such as the tendon exteriorization cineplasty developed by Robert W. Beasley M.D., which externalizes the force and excursion of the muscle, can provide this superior control. The muscle would be connected to the prosthetic component through a controller that embodies Dr. David C. Simpson's concept of extended physiologic proprioception (EPP). The physiological sensory feedback inherent in the skin, muscle, and other tissues of the cineplasty would inform the user of the state of the prosthesis in a somewhat subconscious and natural manner. For persons with long transradial amputations or wrist disarticulations, we envision multiple tunnel cineplasties (small) or exteriorized tendons, each with an EPP controller, providing independent multifinger control of hand prostheses. At higher levels, such as the short transhumeral or shoulder disarticulation level, small pectoral or deltoid tunnel cineplasties could augment existing control sources to improve control of multi-

functional total arm prostheses. The goal of this research was to quantify the control capabilities of subjects with pre-existing tunnel cineplasties and to develop prostheses to test these ideas.

PROGRESS—All the control quantification experiments have been completed. Three subjects with biceps tunnel cineplasties and a single subject with two forearm tendon exteriorization cineplasties took part in our experiments. Fifteen subjects with biceps tunnel cineplasties were located who were willing to participate in our research. Of these, three participated in the current study. Additionally, one subject who has two tendon exteriorizations of forearm muscles was also tested. The testing procedure consisted of having the subjects perform pursuit tracking of a randomly moving target displayed on an oscilloscope screen. Using movement of the cineplastized muscle to control a follower, they attempt to match the path of the target. A mathematical relationship between the follower's and target's paths provides a measure of control performance. With this measure, dynamic control capability of the tunnel cineplasty was compared with other control methods. Pursuit tracking was repeated using glenohumeral flexion and a conventional above-elbow control harness, and again using the subject's contralateral elbow. Blind positioning experiments were performed to quantify static positioning capability in comparison to other control methods. Finally, the characteristics of each subject's tunnel cineplasty were recorded for isometric and isotonic muscle contractions.

We have also developed a prototype EPP electric hand prosthesis for the subject with the exteriorized tendons. Control cables from the tendon tunnels are linked to the hand's mechanism. Contraction of the flexor muscle closes the hand and contraction of the extensor muscle opens it. The device requires approximately 6 mm of tendon excursion and a range of 225 to 500 grams-force for operation.

RESULTS—Our results for the pursuit tracking experiments show that the dynamic performance of the muscle tunnel is statistically similar to that of the conventional control harness. Tracking performance with the intact contralateral elbow was superior to both.

For the blind positioning trials, the static positioning capabilities of the elbow, cineplasty, and glenohumeral flexion with harness were the same and showed no bias. Without vision, there was a tendency for subjects to overshoot the closest target and to undershoot the furthest target. The accuracy, or bias, of the contralateral elbow, without vision, was superior to either the cineplasty or the glenohumeral flexion with harness. The biases for the cineplasty and glenohumeral flexion with harness were similar, with the cineplasty showing more scatter.

Within the context of prosthesis control as a whole, work done in our laboratory in 1984 by James Doubler showed the superiority of position control over velocity control in pursuit tracking tasks. Our new results show that control by tunnel cineplasty is as good as control using glenohumeral flexion with a harness. This indicates that control by tunnel cineplasty should, as a consequence of Doubler's work, be superior to velocity-control techniques. In addition, tunnel cineplasty offers a number of advantages over control using glenohumeral flexion and conventional harness arrangements. Tunnel cineplasties, or exteriorized tendons, in conjunction with electronic EPP controllers may provide both force and excursion amplification while retaining a physiologically appropriate proprioceptive sense of position, velocity, and force; they may eliminate the need for proximal harnessing and consequent encumbrance of an otherwise intact physiological joint for certain prosthetic configurations; they may provide an additional control source to supplement other, more conventional control sources in the fitting of total arm prostheses; and they may make possible the direct control of individual fingers in prostheses for persons with wrist disarticulation or long transradial amputations.

[8] IMPROVING PROSTHETIC PREHENSION

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Sponsor: *National Center for Medical and Rehabilitation Research, National Institutes of Health*

PURPOSE—The purpose of this research is to improve both body-powered and externally powered prehensors. Because the current grant has expired, additional funding will be explored to bring these devices closer to the clinical arena. Projects include:

Vector prehensor. We are developing a voluntary opening prehensor with grip force which can be easily adjusted to the demands of the task, improving efficiency of grasping and reducing mechanical energy demands.

Variable mechanical advantage (VMA) prehensor. We are also developing a voluntary-closing device with enhanced gripping efficiency (i.e., rapid sizing with minimal cable excursion coupled with large grip force generation).

General prehension research. We are seeking improvements to prehension applicable to any type of prehensor, including anthropomorphic fingers with nonlinearly compliant structure and variable hardness finger materials.

Quantification of prehensor performance. We explore methods to quantify grasping performance in the laboratory, including the degree of force and torque that can be effectively applied.

RESULTS—Recent work has focused on vector prehensors. The first prototype, reported on in a previous progress report, performed well and was positively evaluated in field testing by three amputees. However, the device was too bulky because it utilized conventional prosthetic elastic bands. In order to minimize prehensor bulk, we have been developing custom elastomeric power modules which can provide high tension in a minimal volume. Target specifications are for a unit with a spring rate of 75 lbs/inch (13.39 kg/cm) which will fit within a volume measuring 0.375 in by 0.75 in by 1.3 in (1.9×3.3×0.95 cm). Materials tested include natural rubber, neoprene, and polyurethane in a variety of geometries and material formulations. Preliminary work has produced units which can meet the stiffness and volumetric requirements, but so far have inadequate fatigue life.

Two new prototypes have been designed and fabricated. The Vector Grip is comparable in size and configuration to the TRS Grip II, a voluntary-closing prehensor. Like its predecessor, it generates a tip grip force from 1 to 15 lb. (0.45 to 6.8 kg), depending on the setting of an easily adjusted lever. This range of grip force allows an amputee to hold a tomato for slicing in the lowest setting and do demanding physical tasks in the highest setting.

The Vector Hook has canted hook-shaped fingers and is comparable in volume to the Sierra Two-Load Hook. It uses the same power modules and adjusting mechanism as the Vector Grip and has comparable grasping performance.

FUTURE PLANS—We believe that the vector concept is one that offers significant functional advantages to wearers of voluntary-opening body-powered prehensors. Therefore, future plans will focus on producing prototypes that can be evaluated clinically on a more comprehensive basis. Specific improvements are required to make the prehensors more reliable and cost effective. Further research and development of an elastic power module with longer fatigue life would address the first issue, and redesign with an emphasis on manufacturability would address the second.

RECENT PUBLICATIONS FROM THIS RESEARCH

Body powered prehensor with variable mechanical advantage. Frey DD, Carlson LE. Prosthet Orthot Int, 1994:18:118-23.

[9] ELECTRIC HUMERAL ROTATOR

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—It is recognized in prosthetics practice that humeral rotation\Minward and outward rotation of the forearm along the axis of the humeral section\Mis generally helpful to the person with a unilateral amputation at a level above the elbow and essential to the person with bilateral amputations. Currently, this motion is achieved using a passive rotating friction joint proximal to the elbow mechanism. Positioning of the joint is done manually if an intact limb is present, or by pushing the forearm of the prosthesis against objects in the environment. Our goal is to develop an electric-powered humeral rotator so that the forearm and prehensor of a trans-humeral or shoulder disarticulation prosthesis can be positioned independently by the user. Positioning would be possible at any elbow angle, during dynamic activities, and without pushing or pulling the forearm against external objects. The rotator would also enable persons with high-level bilateral amputations to move their forearms inward or outward simultaneously, to bring the prehensors together, or to separate them. This capability would make bimanual manipulations more practical and easier to perform.

METHODOLOGY—The rotator design utilizes multiple, miniature, permanent-magnet, DC gearmotors to provide active powered rotation and powered locking. Two gearmotors driving (in parallel) an internal gear attached to the proximal plate of an elbow component provide torque for positioning the forearm. A third gearmotor drives a single-lead worm that mates with a worm gear attached to the shaft of one of the drive motors. When humeral rotation stops, this third motor and geartrain provide positive locking against further motion. The design parameters are a no-load output speed of 1.2 radian per second and a stall torque of 2.3 N-m. A high-friction coupling provides a safety "breakaway," allowing the forearm to rotate if external forces, such as from falling on the prosthesis, are greater than 8.1 N-m.

The rotator design can be used with either body- or electric-powered elbows. It can be accommodated in prostheses for short transhumeral or higher-level amputations and can be used unilaterally or bilaterally.

PROGRESS—A laboratory test stand has been fabricated to simulate the multimotor humeral rotator. The motors, gearheads, bearings and gear-trains are identical to those planned for the actual rotator. This simulated rotator has been operated at various loads and input voltages to determine its optimum operating parameters.

The tests indicate that the system functions at its highest efficiency when the locking-motor operates at a slightly lower voltage than the drive-motors. When the control circuitry was modified to accommodate this characteristic, the system efficiency remained nearly constant at varying input voltages.

On the basis of the test stand results, a prototype rotator has been constructed that could be incorporated into a prosthesis. The completed prototype has a maximum no-load speed of approximately one radian per second (at 7.5 volts). We are presently testing the prototype rotator to verify that its efficiency (with the electronic control circuit) is similar to the efficiency measured on the test stand mechanism.

FUTURE PLANS—If our laboratory tests confirm that the performance of the humeral rotator meets the design criteria, we will proceed with development of a second, lighter-weight prototype. Most of the weight reduction will be accomplished by removing material from the rotator housing. This prototype will be used for a preliminary clinical evaluation by a single individual. This subject's experience will determine if any design changes are needed before we proceed with additional, longer, clinical trials.

C. Lower Limb: General

[10] CLINICAL AND LABORATORY STUDY OF AMPUTATION SURGERY AND REHABILITATION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A092-7RC)*

PURPOSE—The mission of the Prosthetics Research Study (PRS) is to advance and improve the care for veterans having, or at risk of, limb loss. We are providing this service to the field of amputations and prosthetics by engaging in fundamental prosthetics research, clinically implementing new technologies, and providing education in state-of-the-art techniques. Our research objectives fall into four main areas: automated fabrication of mobility aids (AFMA), amputation management, assessment of functional outcomes, and treatment of the limb at risk. Current projects at PRS involve the development of: 1) an AFMA training center, 2) tools for alignment and cosmesis design and fabrication within the AFMA system, 3) a video gait simulator of amputee gait patterns, 4) a system for the automated fabrication of insoles/footwear for diabetics, 5) postoperative AFMA protocols, 6) tools for functional outcome evaluation, and 7) a gait activity monitor for clinical use.

PROGRESS—*1) AFMA Training Center:* To achieve the goal of technology transfer of the AFMA system to the VA clinical service, we developed the PRS/VA AFMA training program. This training program included a 5-day, intensive course of formal instruction at our center, followed by a personal 3- to 5-day on-site visit to each of the students' clinical facilities. PRS has now trained 46 VA prosthetists, and directly assisted 31 new VAMC sites with the installation of AFMA, and the incorporation of AFMA in patient care.

2) AFMA Alignment and Cosmesis: To achieve the goal of improved automation of alignment and prosthetic cosmesis, software has been completed and tested which allows for bench alignment of prosthetic sockets using a computer. The software directly imports VA/Seattle ShapeMaker socket files and then allows the user interactive control of the alignment fixture distal to the socket. Measurement of the alignment is made relative to the surface position of the two-point landmark of the long bone contained in the socket, for example, femur, tibia, humerus. The user has discrete control of alignment in adduction or abduction angle as well as translation in the A-P or M-L planes. Prototype software to automate the design of the cosmesis for an AFMA prosthesis is now being tested and refined.

3) Video Gait Simulator: To improve the teaching and understanding of amputee gait, and prosthetic alignment, the first version of the video gait simulator of amputee gait has been completed. It provides a computer simulated gait training area for the user to interact with a tireless virtual patient. The user can adjust alignment of a prosthesis on the computer screen and instantly see pre-recorded video of the amputee with that alignment. For training, this system can present to the student an amputee with various gait deviations for the student to correct. Multiple patients and pathologies can be represented on a single computer compact disk (CD-ROM) for widespread inexpensive distribution. CD-ROM disks of the above-knee simulator will be made this year for testing by interested parties.

4) Automated Insole Design and Fabrication: Veterans with diabetes mellitus who lack foot sensation are at increased risk for foot ulcers and amputations. Our data indicate improper footwear precipitates many diabetic foot ulcers. To address this problem, we have developed a foot digitizer which provides a 3-D plantar foot image. By extending the principles of the AFMA system to the foot, we have developed templates that correspond to foot structures and contours, and can now make custom, milled insoles. Our current insole design fits exactly with the prototype shoe we have developed in conjunction with NIKE over the last year, specifically for diabetic males with foot insensitivity. Pilot testing of the shoes and insoles is ongoing.

5) Postoperative AFMA Protocols: We are writing a revised edition of the PRS VA Amputee Management Text of 1969 and are currently preparing for publication on CD-ROM format. The surgical techniques sections have been written by Drs. Smith and Burgess. Schematic drawings are complete, and new intraoperative and postoperative photographs are currently being taken. We will add sections on preoperative considerations, early postoperative techniques (weeks 1\N8), and first year prosthetic techniques. Early and first year prosthetic techniques will emphasize AFMA protocols.

6) Functional Outcome Evaluation: We are creating new questionnaire-based instruments to better evaluate the functional outcomes of amputation surgery and prosthetic intervention. After completing focus group interviews and individual interviews of amputees, we constructed our first draft of the visual analog based scales to evaluate amputations, prosthetics, and general health. After the drafts were piloted on 10 amputation clinic patients, our multidisciplinary team modified the tools by refining instructions, verbiage, and format. We have collected additional data on a formal pilot survey of 25 amputees, but have not yet analyzed this data. We have completed a system of automated computer data entry from the visual analog scales and the SF-36 forms.

7) Gait Activity Monitor: To achieve our goal of improved objective measurement of gait in nonlaboratory, real world conditions, we have developed the Gait Activity Monitor. Two working prototypes underwent repeated tests for accuracy and reliability. Specifications were established for the next generation prototype to be fabricated. Methods for analyzing and interpreting Gait Activity Monitor output have been developed. Testing of a final prototype will begin upon receipt of the new device.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Does awareness of high risk status for lower extremity amputation alter patient and provider foot care practice? Del Aguila M, Reiber GE, Koespell TD. Diabetes Care 1994:17:1050-4.

Who is at risk of limb loss and what to do about it? Reiber GE. J Rehabil Res Dev 1994:31(4)357-62.

Amputations. Smith DG, Burgess EM. In: Harry Skinner, ed. Current orthopaedic diagnosis and treatment. Norwalk: Appleton & Lange: In press.

Numerical comparison of 3-d shapes: application to the insensate foot. Borchers RE, Boone DA, Joseph AW, Smith DG, Reiber GE. J Prosthet Orthot. In press.

Prosthetic history, prosthetic charges, and functional outcome of the isolated, traumatic below-knee amputee. Smith DG, Horn P, Malchow D, Boone DA, Reiber GE, Hansen ST. J Trauma. In press.

[11] DEVELOPING A BIOMECHANICAL MODEL OF THE INTERFACE BETWEEN THE RESIDUAL LIMB AND THE PROSTHESIS FOR TRANS-FEMORAL AMPUTEES

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Sponsor: *Engineering and Physical Sciences Research Council*

PURPOSE—This program of research will be directed toward the generation of a finite element (FE) model of the residual limb of an amputee. Such a model would be capable of predicting the pressure distribution at the patient/prosthesis interface. The benefit in having this knowledge would be the ability to predict quality of socket fit prior to manufacture. This should allow a reduction of fitting errors and hence improve delivery of service to the physically disabled population.

METHODOLOGY—The authors have collaborated with the Institue of Neurological Sciences at the Southern General Hosipital in Glasgow to obtain geometrical detail of the residual limb using magnetic resonance imaging (MRI) techniques. Six trans-femoral amputees will participate in this study, which will include MRI scans, providing enhanced geometrical descriptions for the creation of FE models.

The actual loading on the amputees' lower limbs, during standing and during gait, will be obtained

using force platforms and a motion analysis system. These realistic loading and boundary conditions will act as input to the FE model. The FE models created will be verified by measuring interface pressures between the socket and the residual limb using specially adapted strain gauge transducers.

PROGRESS—Currently patients are being selected for inclusion in this study.

RECENT PUBLICATIONS FROM THIS RESEARCH

Mechanical behaviour of amputee stump/socket using finite element method. Lee VS, Solomonidis SE, Paul JP. In: Proceedings of the International Society of Biomechanics XIVth Congress; July 1993. Paris, 1993:774-5.

Biomechanical modelling of the interface between residual limb/prosthesis interface for transfemoral amputees unsing finite element analysis. Lee VS, Solomonidis SE, Spence WD. In: Proceedings of the 8th International Conference on Biomedical Engineering; Dec 1994. Singapore, 1994:333-5.

Generic geometrical model of the femur using anthropometric scaling. Lee VS, Solomonidis SE, Spence WD. In: Proceedings of the 8th International Conference on Biomedical Engineering; Dec 1994. Singapore, 1994:502-4.

[12] DYNAMIC RESPONSE PROSTHETIC FEET AND THEIR ROLE IN HUMAN AMBULATION

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—The primary objective is to understand the role of dynamic response prosthetic feet in trans-tibial prosthetic gait and to determine how the mechanical characteristics of footwear affect this role. This understanding will allow prosthetists to prescribe prosthetic feet more objectively, more accurately, and with greater cost effectiveness. Additionally, this knowledge may indicate ways to improve foot design.

METHODOLOGY—Methods for foot characterization and amputee walking trials have been established. A specially designed prosthetic foot-loading apparatus, consisting of a steel support frame, prosthetic foot mounting jig, and wooden loading beam, was used to perform characterization studies. Foot deflection, and the magnitude and location (center of pressure) of the applied force were obtained from dynamic and quasi-static tests on 11 different prosthetic foot types in several orientations of contact.

A single subject with a unilateral trans-tibial amputation walked with seven different prosthetic foot conditions: five different foot types (Flex Foot, SACH, Seattle Lightfoot, Carbon Copy III, and Reflex VSP), and an additional keel stiffness variation with two of the feet (Seattle Lightfoot and Carbon Copy III). The goal was to characterize the center of pressure progression and the kinematics of foot shape during prosthetic stance phase. Three-dimensional data of three markers placed on the prosthesis, and ground reaction forces were measured during self-selected walking trials.

PROGRESS—Static and dynamic characterization of 11 prosthetic foot types has been completed for 3 foot/ground contact orientations: heel contact (–15° shank angle), heel off (0° shank angle), and forefoot (+15° shank angle). Data acquisition has been completed on the amputee walking trials. Analysis of the data is continuing.

RESULTS—The foot characterization results include force versus deflection and center of pressure versus force graphs, and a table containing the calculated damped resonant frequency, damping ratio, and energy efficiency for all feet or foot/shoe combinations. For all three orientations, the static characterization data show a wide spread of deflection and center of pressure properties; the deflection ranges are two to three times that of the smallest deflection at a particular orientation, while center of pressure values vary by as much as four to six cm at equivalent loads. There is no direct correlation between deflection and center of pressure data. The dynamic data indicate that the feet are largely undamped, or essentially spring-like

(damping ratio from 0.019–0.137). The results of testing footwear on several prosthetic feet in the heel off orientation indicate that shoes tend to make the foot/shoe combination stiffer, but this is caused by a simultaneous posterior shift in the center of pressure, which we feel is essentially an alignment alteration. Shoes also increased the damping and energy losses.

FUTURE PLANS—We plan to characterize prosthetic feet in an orientation analogous to terminal double support, with and without shoes. Walking studies will be enlarged to include several more amputees. A dynamic model of the foot will be created.

RECENT PUBLICATIONS FROM THIS RESEARCH

Do shoes influence the forefoot mechanics of prosthetic feet? Childress DS, Sandifer A, Knox E. In: Proceedings of the 8th World Congress of the International Society for Prosthetics and Orthotics; Melbourne, Australia, April 1995. In press.

[13] STEPPING OVER AN OBSTACLE: A COMPARISON OF NEW AND EXPERIENCED PROSTHESIS USERS

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Sponsor: *St. Maartenskliniek*

PURPOSE—Walking in a normal environment requires that an individual modulates his or her locomotion in order to avoid various obstacles. This study compares how new and experienced prosthesis users react to reduced visual information in such a locomotor task. To this end, subjects were required to step over an obstacle with 0 cm height while the lower portion of the visual field was blocked.

METHODOLOGY—Two approach steps and the step over the obstacle were studied. In the reduced visual field condition, the subjects wore a pair of safety goggles (that could fit over corrective glasses) in which the lower rim and the sides were covered. In addition to eliminating the lower portion of optic flow, this manipulation ensured that when the subject fixated straight ahead, (s)he could not see the obstacle in the last approach step and as (s)he stepped over it. Subjects were tested with and without the goggles for two levels of task difficulty. In the first level, the subjects could look where they wished; in the second level, they were required to fixate on a sticker positioned at eye height 5 m beyond the obstacle.

Two video cameras of the 3-D motion analysis system PRIMAS registered passive markers on a head frame enabling the angle of the head in relation to the floor to be calculated; further, passive markers were attached to the neck and the back of the shoes. Subjects stepped over a flat piece of cardboard located on a 10 m walkway in a well-lit laboratory. The width of this obstacle was adjusted to be half of the subject's normal step length. From this data, step length and velocity could be calculated as well as the distance from the approach foot to the obstacle (DTO) and the distance from the obstacle to the heel of the foot which steps over the obstacle (DHO).

Two groups of prosthesis users with mean experience of 2.1 months (n=8) and 17.2 years (n=10) were tested. The mean age for the two groups were 41.6 and 45.5 years, respectively.

RESULTS—Preliminary analysis of the data indicates that both prosthesis groups make adjustments in the two approach steps, regardless of the amount of visual information. The experienced prosthesis group is consistent in the amount that the step over the obstacle is lengthened when visual information is reduced. With visual information reduced to only peripheral vision, the 'safety margin' (DTO plus DHO) increases to 20 percent. When visual field is restricted by the goggles, the increase in the safety margin is 23 percent; this increases only to 28 percent when fixating on the sticker with the goggles. For the young adults, these values are 16, 12, and 37 percent, respectively. The new prosthesis users have safety margins of 19, 2, and 43 percent, respectively.

IMPLICATIONS—Prosthesis training should include stepping over obstacles and navigating with limited visual information. Prosthesis users (even those with just a few weeks experience) are not limited to just one step length pattern; they can vary their step length by 30 to 40 percent.

FUTURE PLANS—Other kinematic variables are now being analyzed, and the data is now being analyzed to determine the amount of visual information used per step.

[14] DYNAMIC DIAGNOSTIC SOCKET/SKIN INTERFACE MONITORING USING A PROSTHESIS MOUNTED VIDEO CAMERA

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Sponsor: *None listed*

PURPOSE—Clear diagnostic sockets have become a frequently used instrument for the assessment of cast modifications in the final stages of fitting a prosthetic socket. In the case of the lower extremity, a diagnostic socket can give a limited subjective pressure map of the socket/skin interface by nature of the skin discoloration under load. More recently diagnostic sockets have been used at the dynamic trial stage in an attempt to provide feedback to the practitioner in both the areas of fit and dynamic function. Problems arise in both situations, static and dynamic, in terms of the assessment of fit. Statically the socket/skin interface can be viewed clearly, but in this case the loading pattern is limited. Dynamically the loading pattern is more desirable, but in this case the socket/skin pressure interface cannot easily be viewed.

By mounting a video camera onto the prosthesis, the frame of reference of the socket/skin interface remains static. The loading pattern changes dynamically as the patient walks.

METHODOLOGY—A number of different "lipstick" cameras were mounted onto the prosthesis and assessed in terms of resolution, clarity, and field of vision. The signal from the cameras was plugged into a video recorder, ensuring the cable did not get in the way of the patient. Telemetry between the camera and video recorder was also tried. A third method (untried) was to mount a small video recorder onto the patient and record the output signal. The first two methods give a real time image as well as the option of recording.

RESULTS—In the initial trial the patient did not feel that the camera and mounting influenced his use of the prosthesis. The subjective opinion of the prosthetist involved was that he could clearly detect aspects dynamically that would influence his modification. These aspects could not previously be detected.

The image can be observed in real time, recorded as part of the ongoing clinical information or mixed into a special effects generator to mix the image with that of the patient walking or to color enhance the image of the socket/skin interface.

[15] FINITE ELEMENT MODELS TO ASSIST PROSTHETIC SOCKET DESIGN

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Sponsor: *None listed*

PURPOSE—In the prosthesis, the socket provides the interface of the mechanical support system for the residual limb. The design and fit of the custom-fabricated socket largely determines the utility and acceptance of the prosthesis. In the past decade, although a considerable research effort has been directed toward data acquisition systems and CAD/CAM of the socket, very marginal attention has been given to understanding the socket-stump interface, the distribution of forces in the residual limb, and characterizing the comfort of the prosthetic limb. Understanding the socket-stump interface is important in ensuring an effective design of the socket and circumventing discomfort due to skin breakdown.

In order to fully understand the socket-residual limb interface, it is necessary to study the force distribution (normal and shearing stresses) throughout the residual limb, and its deformation under dynamic load (i.e., normal gait). This can be achieved by using finite element modeling (FEM), developed to study stress distribution in mechanical and structural systems, of the residual limb. Recently, some studies have considered this issue but employ only very basic approximate models (some studies consider the stump to be a regular geometric shape, such as a cylinder or a cone) and they focus on the stress and deformation of the socket, rather than on the residual limb itself. Major problems with this approach are the rather ad hoc nature of these studies and the very crude representation of the materials (soft tissue, bone, etc.) constituting the residual limb.

METHODOLOGY—In this research, we propose to develop a FEM of the residual limb to evaluate the contact forces (normal stress and shearing stress) and deformation of the amputee's residual limb. The analysis involves conceptually dividing the body under study into small homogeneous segments called ''elements.'' A mathematical representation is then developed for this linked collection of elements considering the material properties (which may vary from element to element). Impact of subjecting this linked collection of elements to external force (during the different phases of gait) can be analyzed using numerical methods. The analysis will be performed using the ANSYS software package, regarded as the industry standard for FEM analysis.

In general, pain, discomfort, and skin-breakdown are caused by stress concentration and non-uniform stress distribution. Contact stress on the contact surface between the residual limb and the prosthetic socket must be analyzed for stress distribution using theories of mechanics. This is a 3D contact problem, and the topology of the contact surface is the complex free-form topology of the residual limb. In an effort to evaluate the contact stresses, we cross-cut the stump and femur to form a mechanical model. The model has different material (bone, soft tissue, and so forth) and hence capture effects of different materials that were overlooked by previous studies. For simplicity, we assume that the materials are isotropic and linearly elastic, but have different elasticity modulus, and different poisson ratio. We employ a 3D surface-to-surface contact (with friction) element model.

This research will provide insight into the impact of prosthetic limb loading on the patient's residual limb. The model developed will estimate the stress distribution in the various elements of the residual limb. It will be a very useful insight into the design of the optimal socket. Socket material, wall thickness, size of the socket, and socket/residual limb interface can be optimized using the insights gained in this study. This will minimize the occurrence of blood clots, skin breakdown, sores, gangrenes, and so forth on the residual limb. Most of these problems occur because of stress levels exceeding the tolerance limits.

D. Lower Limb: Above Knee

[16] FEMORAL DISPLACEMENT IN ABOVE-KNEE SOCKETS

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—The purpose of this development work is to produce an ultrasonic device that will enable us to estimate the location of bony structures of the body with respect to prosthetic/orthotic structures while a prosthesis or orthosis is being used. Our aim is to develop portable ultrasonic devices that persons with prostheses or orthoses can carry with them during ambulation. We are interested, for example, in using transducers of this kind to track the movement of the femur with respect to the above-knee socket during walking.

METHODOLOGY—The ultrasonic measurement device operates on the basis of detection of a reflected wave from the bone in the tissue. The ultrasonic transducer is mounted in the wall of the prosthesis or orthosis and coupled to the skin with a paste. The time from the initial pulse until the reflected pulse is received is the basis for determination of the distance from the transducer to the bone. An output pulse is generated which is ''on'' from the time the ultrasonic pulse is initiated until the reflected pulse is received. The ''on'' time of this output pulse is made to correspond linearly to an output voltage between 0 and 10 volts. Knowing the speed of sound in tissue (~1540 m/sec), the output voltage can be used to establish the distance measurement.

PROGRESS—We now have a functioning device, although has not been calibrated. The signal-to-noise ratio is around 20 db, and we have been able to estimate distances from the skin surface to the humerus in the arm and to the femur in the leg. We are now working on portability. Certain modifications have been made over the past year. For example, the large current requirements of the ultrasonic transducer have made it necessary to use D-cell batteries to power the transducer. Also, our test tank proved to be too small and too symmetrical for the performance of accurate testing.

FUTURE PLANS—The major goals for the next year include testing the system for accuracy using the reflected signal from the other side of the leg. This will be accomplished by clamping the thigh in a vice-like device which will have the transducer mounted on one side and a metal reflector mounted on the other side. Since the distance can be measured, the device can be calibrated and accuracy can be determined.

[17] INVESTIGATION OF 4-BAR LINKAGE KNEES AS AN AID TO FLOOR CLEARANCE

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PURPOSE—The stance-phase advantages of 4-bar knees (i.e., voluntary control and cosmesis) are well known; however, another advantage is their ability to increase floor clearance above that possible with a single-axis knee during the swing phase of walking. The purpose of this project is to investigate the ability of commercially available 4-bar linkage knees to increase floor clearance beyond that of single-axis knees

for a given knee flexion angle. This additional floor clearance may allow an amputee to walk with less concern for floor contact during prosthetic swing. These knees may especially be helpful for those above-knee and hip-disarticulation amputees who have trouble with floor clearance. Using a computer model of an above-knee prosthesis, we have performed kinematic analyses of commercially available 4-bar knees to determine the amount of added floor clearance achieved.

METHODOLOGY—Four-bar linkage knees were selected on the basis of three criteria. The knees were commercially available during 1994, they were all endoskeletal units, and their linkages all had constant length throughout knee flexion range.

The following knees have been included in our study: the Hosmer VC4, the Hosmer UltraRoeLite, the Ohio Willow Wood Pendulum Senior, the Otto Bock 3R23 Knee Disarticulation, the Otto Bock 3R36 Habermann, the Otto Bock 3R60, the Otto Bock 3R70, and the USMC OHC.

The computer model was based upon an above-knee prosthesis for an average-size man. The alignment of the leg was recommended by a certified prosthetist. Data pertaining to each knee were stored in a data file, which could be read by the computer program for knee evaluation. Once the knee was ''inserted'' into the computer model, toe clearance was calculated for each hip and knee combination as the joints were rotated through their full ranges of motion. Other parameters of interest that were calculated include the hip-toe distance, the knee's instant center of rotation, and the foot trajectory.

PROGRESS—We have developed a computer model of an above-knee prosthesis that allows us to ''insert'' a representation of any 4-bar linkage knee for evaluation. Quantitative information regarding a particular knee design is read into a computer program, which simulates hip and knee rotation of the prosthesis in the sagittal plane and calculates kinematic parameters of interest. We have analyzed eight commercially-available 4-bar knees.

RESULTS—Contour plots were created that show the first 5.0 cm of floor clearance as a function of the hip and knee angle for each knee analyzed. From these plots it is possible to find the amount of floor clearance for a given hip/knee combination. These values are compared with those for a single-axis knee to demonstrate the ability of the 4-bar knee to increase the amount of floor clearance for a given knee flexion angle. The 4-bar knees were found to increase floor clearance by 2–4 cm beyond that of a single-axis knee at a knee flexion angle of 50°. Some of the knees had as much floor clearance at 30° of knee flexion as the single-axis knee had at 50°.

FUTURE PLANS—We have finished analyzing the 4-bar knees, and we are now writing a series of technical reports that contain the data for each knee. We will share the data with the companies who participated in our study. We plan to publish the results from this work as a journal article in the near future.

RECENT PUBLICATIONS FROM THIS RESEARCH

Investigation of 4-bar linkage knees as an aid to floor clearance during swing. Childress DS, Gard SA, Uehllendahl JE. In: Proceedings of the 8th World Congress of the International Society for Prosthetics and Orthotics; Melbourne, Australia, April, 1995. In press.

[18] WATERSKI FOR A BILATERAL ABOVE-KNEE AMPUTEE

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Sponsor: *None listed*

PURPOSE—A 19-year-old male with bilateral above knee amputation had shown interest in competitive water skiing. He used a KanSki designed for paraplegic use, consisting of a very large slalom ski with a deck chair type harness. This dampened his control, forcing him to rely entirely on upper body weight

distribution. He had to use his lower lumbar spine as the mobile joint for shifting weight for control and weight distribution, and this limited his ability to transfer load to the ski for more complex maneuvers. The Victorian Disabled Water Ski Association, through the Transport Accident Commission, and REHAB Tech combined to design a more suitable ski.

METHODOLOGY—The skier's style was videotaped and analyzed. Based on our analysis, we developed a ski according to two key parameters: the ski must allow the skier to utilize distal joints for control and weight distribution, and the ski's design must be safe.

PROGRESS—Elastic restraints were used together with a polypropylene, custom-moulded seat in a neutrally bouyant harness system that mimicked those found on regular skis, one that released readily in crash situations. The seat was mounted to an adjustable frame to optimize the height and position, and the whole device could also be mounted on different types of skis.

This harness system increased his ability to transfer even small body movements to the ski via weight transfer and residual limb movement, giving him far more control and maneuverability than previous systems. Using this sytem, the skier trained with the Disabled Water Skier Association and qualified for the National Disabled Waterski titles held on Melbourne's Yarra River during the Moomba festival. Having come second overall in his class, he competed in the World Titles in France in 1993, finishing fourth.

[19] UPDATE ON THE ELASTIC STRAIN ENERGY DISCUS LEG

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Sponsor: *None listed*

PURPOSE—John Eden is the only known above knee amputee who does a full rotation when throwing the discus or shot. In March 1992, a prosthesis was developed for him by the Central Development Unit at the Heidelberg Repatriation Hospital.

METHODOLOGY—Extensive biomechanical assessment was carried out at the Australian Institute of Sport in Canberra on both Mr. Eden and a nondisabled discus thrower. A conventional polypropylene socket was fitted to the patient and a custom designed prosthesis was attached. Although the actual composition of the prosthesis cannot be described (due to commercial reasons), it consists of a curved, cantilevered composite leaf. Knee flexion and extension are achieved not by means of a mechanical joint but through the force-deflection capabilities of the material from which the prosthesis is made. The weight of the prosthesis is minimized which assists with speed through the rotation section of the throw.

PROGRESS—Initial evaluation has been positive, but has been hampered by durability. Mr. Eden competed at the Barcelona Paralympics and won a silver medal. The interest generated by his new leg was enormous: he could not appear anywhere without 10 minutes of photo-taking and interviews.

REHAB Tech has since taken over this project and further efforts have improved the durability enormously. Mr. Eden is currently the world champion as well as holding the world record.

IMPLICATIONS—The application of a prosthesis that can give active knee extension (and active plantar flexion) has enormous consequences for all amputees. REHAB Tech has been developing this concept in a power sport application but prototypes are already being developed which would have for walking and running an application. These prototypes are for below knee and above knee amputees as well as footwear.

E. Lower Limb: Below Knee

[20] PROSTHETIC DESIGN FOR DYSVASCULAR BELOW-KNEE AMPUTEES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington DC 20420 (Project #A735-RA)*

PURPOSE—Recent studies have demonstrated inefficiency at the hip and knee during the loading response phase of walking, regardless of the type of prosthetic foot component. The mechanics of the prosthetic heel (heel rocker) results in excessive forward tibial acceleration, which induces hip and knee instability. This demand requires increased muscular stabilization that the weakened dysvascular amputee has difficulty meeting. The primary purpose of this study is to develop design criteria for a prosthetic foot component which will facilitate knee stability during loading response and reduce the muscular demand of ambulation.

METHODOLOGY—This work centers on three main areas: 1) classification of persons with dysvascular below-knee amputation by walking ability and strength of the weight bearing musculature; 2) quantitated definition of the gait of those persons, focusing on the mechanics of loading response and the demands imposed by three classes of prosthetic feet; and 3) development of optimal design criteria for a prosthetic foot for the dysvascular patient with below-knee amputation. Thirty such persons will be tested for strength of both limbs, as well as stride analysis and joint motion during free and fast walking. Ten additional subjects with dysvascular below-knee amputation will undergo EMG and kinetic analysis during free and fast walking, wearing three different prosthetic feet (Flex-foot, Seattle and Single-axis). A comparison of the loading mechanics, joint moments, and muscle activity between these three feet and nondisabled individuals will be made.

PROGRESS—Twenty subjects with dysvascular below-knee amputation have undergone stride and motion analysis, and strength assessment of both the residual and sound limbs. Stride characteristics and joint motion testing as well as EMG and kinetic analysis has been completed on three additional subjects while wearing the three different prosthetic feet. Data from 10 nondisabled controls have also been collected. Data collection, processing, and analysis continue.

RESULTS—Preliminary stepwise regression analysis has identified sound limb knee extensor strength and amputated limb hip abductor strength as significant predictors of free walking velocity ($r=0.79$). Sound limb knee extensor strength was the best predictor or stride length ($r=0.63$), while residual limb hip abductor strength significantly correlated with cadence ($r=0.67$). Residual limb hip abductor strength was the only significant predictor of fast walking velocity ($r=0.72$), and cadence ($r=0.64$).

Analysis of the loading response mechanics between the normal and amputee subjects has revealed a significant delay in reaching the stable foot flat posture in the amputee group. Foot flat did not occur until 19 percent of the gait cycle compared to 9 percent of the gait cycle for the normals ($p<0.01$). During this interval the amputee is maintaining an unstable heel only posture. Compared to the control group, maximum loading response knee flexion in the amputee group was reduced (9.4 vs. 16.0 degrees; $p<0.05$) and delayed (17 percent vs. 14 percent of the gait cycle; $p<0.05$). The same trends were found for fast walking. These preliminary results suggest that the amputee prosthetic foot is unstable while the knee is flexing. This is consistent with the increased knee extensor activity utilized to provide stability during weight acceptance. In contrast, peak loading response knee

flexion in normal individuals occurs after foot flat, providing a more stable base of support during this phase of the gait cycle.

RECENT PUBLICATIONS FROM THIS RESEARCH

Below-knee amputee gait in stair ambulation: a comparison of stride characteristics using five different prosthetic feet. Torburn L, Sweiger G, Perry J, Powers CM. Clin Orthop 1994:303:185-92.

Effects of prosthetic foot design on sound limb loading in adults with below-knee amputations. Powers CM, Torburn L, Perry J, Ayyappa E. Arch Phys Med Rehabil 1994:75:825-9.

Energy expenditure during ambulation in dysvascular and traumatic below-knee amputees: a comparison of five different prosthetic feet. Torburn L, Powers CM, Guiterrez R, Perry J. J Rehabil Res Dev. In press.

[21] PRACTICAL APPLICATIONS OF NEW CAD AND CAE TECHNIQUES TO SOCKET DESIGN

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A521-3DC)*

PURPOSE—This work intends to continue refinements in the application of the finite element analysis (FEA) technique to the design of below-knee prosthetic sockets based upon models of the prosthesis and the residual limb. Additionally, we intend to develop computer design guidelines based upon prosthesis and limb mechanics during gait as well as incorporate new techniques for determining complete below-the-knee limb geometry that do not rely on CT imaging.

METHODOLOGY—Contact problem formulation was applied to an existing simple problem to verify the accuracy of the solution. The axisymmetric residual limb/socket approximation built and modeled by Reynolds (1988) was reformulated as a contact problem using the Marc finite element code.

PROGRESS—An approximation made previously in our FEA modeling was that the limb and socket interface was fixed, where no slippage or loss of contact may occur. We have begun work to model this interface more accurately, using the contact problem capabilities of the Marc FEA code.

In addition to accounting for slippage at the interface during the gait cycle, contact problem modeling will also be used to more accurately model donning of the socket. This will provide a means of quantifying the stresses produced by wearing of the socket independent of weight bearing.

Software is being developed to convert existing limb/socket FEA models to contact problems. This will save the time of redeveloping the modeling method for this new technique and allow quick determination of the proper implementation of the contact problem to our current models. Upon completion of this software, the final step will be to incorporate the contact algorithm into dynamic FEA modeling of the socket during gait.

Investigation into the use of geometry data obtained via an ultrasonic digitizer developed by Drs. Ping He and Kefu Xue of Wright State University is proceeding with encouraging results. The data obtained from ultrasonic scans includes both bone and tissue boundaries and is thus well suited for finite element model generation. They have provided us with their first ultrasonic scan of an amputee containing 50 sections at 5 mm intervals. Working with the Wright State group, we were able to incorporate the ultrasonic scan data of the amputee limb directly into our procedure for creating finite element models.

Information and results from these projects have been made available on the World Wide Web at http://www.repoc.nwu.edu/

RESULTS—Initial results showed similar stress distribution to both Reynolds predicted and experimentally determined values. In addition, some variation of the surface friction coefficient was investigated and the expected result of increasing shear with increasing friction was evident. These initial models provided confidence in the contact capabilities of the FEA code.

FUTURE PLANS—We will extend the modeling capabilities to three dimensions by modeling a slightly more complex system of our own design. A physical model of the residual limb is being designed and constructed of silicone for this purpose. This model will possess material characteristics similar to soft tissue and will also contain an internal solid geometry to approximate the internal bony prominences of an amputated limb.

A slightly rectified socket will be fitted to this limb model in a controlled manner, so the loading process may be modeled exactly. Pressure transducers within this socket will record the stresses at fixed locations for comparison to model values. Correlation between the physical model and FEA model will validate the use of contact modeling for pre-stress determination. This also will give an estimate of the magnitude of tissue pre-stresses due to socket donning.

[22] NEUROPATHIC FOOT IN LEPROSY

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PURPOSE—In the process of evolution the human foot has achieved a specific function of weight bearing, locomotion, and keeping balance. In standing, the foot serves as a base to support the body above it, and in walking it maintains intrinsic postural stability with a minimum of energy expenditure by means of its specialized anatomy, an aspect important during ambulation.

In leprosy this specialized anatomy gets disturbed following the involvement of peripheral nerve trunks. Loss of protective sensations, muscular paralysis, autonomic disturbance, and weakened bony and ligamentous structure due to disease itself make the neuropathic foot more vulnerable to injury. Repetitive microtrauma go unnoticed, leading ultimately to secondary complications like trophic ulceration and tarsal disintegration (TD).

Negligence of neuropathic foot can eventually lead to marked instability of the ankle with the ultimate resort to amputation making the individual more handicapped. Proper rehabilitation of such a foot is therefore essential and starts right from the time of diagnosis, and involves both control of the disease and the prevention of further complications following anaesthesia.

PROGRESS—We have successfully treated all types of the neuropathic foot from the mildest (sensory loss only) to the most severe (TD with sepsis and unstable ankle) through the use of preventive rehabilitation.

Preventive rehabilitation works to: minimize nerve damage by steroids and physical therapy, thereby preventing deformities; correct established deformities by timely reconstructive surgery; prescribe proper footwear or orthoses; and educate the patients about their health.

We use anti-leprosy, anti-inflammatory drugs, and steroids to control nerve damage. We use physical therapy to prevent further paralysis, maintain range of motion in joints, and strengthen the weakened musculature. We employ tibialis posterior transfer to correct established foot drop later on and treat plantar ulcers by sterile dressings and plaster casts. Tailor-made micro-cellular footwear are prescribed in all the cases along with modifications as and when necessary, and plaster casts followed by fixed-ankle-brace (FAB) appliances are used for TD.

During the regular foot clinics, high risk groups of patients are segregated and health education is emphasized. Instructions include advising the patients to walk with slow and short steps and to refrain from strenuous activities like prolonged standing, walking, and running, as well as from squatting on ground. This posture imposes a tremendous strain on the already weakened talo-navicular junction. Sitting cross-legged is also to be avoided to prevent lateral malleolar ulceration.

The patient is also instructed to practice a daily self care regime as a part of domiciliary therapy; for his own well-being, he must:

1. Look: inspect for any injuries, redness, or sores;
2. Soak: soak feet for 20 min in plain water;
3. Scrape: remove callosities with rough stone;
4. Oil: apply oil to retain the moisture gained by soaking;
5. Exercise: perform simple exercises to maintain range of motion and prevent disuse atrophy;
6. Dress: apply clean dressings of wounds;
7. Protect: use micro-cellular rubber footwear to guard from injury and infection.

[23] COMPUTER-AIDED PROSTHETIC ALIGNMENT SYSTEM USING NEURAL NETWORKS

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Sponsor: *San Antonio Area Foundation*

PURPOSE—San Antonio has more than 55 percent Hispanic population, and a large number suffer from diabetes; in fact, the prevalence of diabetes tends to be 2 to 3 times higher in Hispanics than in non-Hispanic whites. A sizable number of diabetic patients have amputations of their extremities due to poor blood circulation. However, with the aid of a prosthesis, a large number of these patients can stand, walk, run, and climb. A typical prosthesis, a mechanical extension to the residual limb, has a pair of alignment devices at either end. The alignment devices allow for optimal positioning of the artificial foot relative to the stump or residual limb.

Optimal alignment ultimately determines the comfort, stability, suspension, energy conservation of the prosthesis, and hence, the utility of the prosthesis. Suboptimal alignment, even with a perfectly fitting socket, may lead to instability and excessive energy consumption, resulting in fatigue and skin breakdown. In one recent study, 30 percent of patients developed complications such as stump pain, pressure ulcers, and stump infection, due to poor fitting and improper alignment of prosthesis.

The objective of this project is to develop a neural network-assisted below-knee prosthetic alignment system. The proposed system exploits the underlying relationship between the demographics of the patients and their gait patterns, using neural networks. Neural networks emulate human cognition and thinking processes, and consist of groups of relatively simple units, called neurons, that perform complex tasks, such as pattern recognition and classification.

METHODOLOGY—In this research, we exploit the underlying relationship between the demographics of the patients and their gait patterns using neural networks. A neural network model with a back propagation architecture will be trained by a random optimization algorithm. Consistent with our overall objectives of developing better-fitting light-weight prosthesis, we use pyramid-type titanium alignment devices for this project.

We will train the neural network with the random optimization algorithm. Demographic and stump features, which could affect the alignment, are inputs and the alignment measures are outputs of the neural network. Randomly selected 20 BK amputees with mature stumps will be fitted with endoskeleton prosthesis with pyramid type components by a pool (to minimize any individual biases) of expert prosthetists. The data will be used as the training set for the network. The prosthetists will also perform the static and dynamic alignment using the traditional visual observation approach.

The alignments suggested by the trained neural network are validated against the final dynamic alignment done by a pool of expert prosthetists. In an effort to maintain integrity and reliability of the neural network model, the validation data is independent and separate from the training data sets. An independent set of five BK amputees will be used to validate the model. The alignment performed by the prosthetists will be compared with the alignment suggested by the neural network model using Analysis of Variance. If the results are favorable, the neural network will be

fine tuned using a larger training data, and statistical validation will be evaluated over a larger and diverse population sample.

FUTURE PLANS—This research is a major step toward the development of an Automated Intelligent Prosthetic Design System, alleviating the problem of acute shortage of prosthetists in developing countries. As more data becomes available from prosthesis designed for patients, the neural network will continue to be trained to improve its precision. Further research work is needed at exploring other training algorithms, and better methods of characterizing and measuring prosthetic alignment.

RECENT PUBLICATIONS FROM THIS RESEARCH

Neural network models for customized alignment of endoskeleton BK prosthesis. Chahande AI, Faulkner VW, Billakanti SR, Walsh NE. In: Proceedings of the IEEE International Conference on Neural Networks, 1994:3507-11.

[24] TRANS TIBIAL SUSPENSION EVALUATION

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Sponsor: *None listed*

PURPOSE—Below knee prosthetic suspension systems can be categorized into four classes: vacuum, anatomical, strap, and hinged. While there have been many claims about the relative effectiveness of the various techniques for suspension, there have been few comparative studies of them. An experiment was devised which could be used to quantify the effectiveness of various suspension systems.

METHODOLOGY—To standardize the experiment, a below knee (BK) prosthesis was constructed to have similar anatomical features and skin surface characteristics as an anatomical residual limb. To this prosthesis, vacuum, strap, and anatomical suspension BK sockets could be attached. By using a tensile tester, a graph of the tensile force required to displace the socket a given distance can be obtained. Extensive video footage was used to see how the suspension systems released from the "limb." This tensile force can be related to the radial force produced by a prostheses of known weights at a variety of walking speeds.

PROGRESS—A clinical trial was then conducted using the same four suspension techniques on a single patient. The results of both the clinical and technical trial indicated that at walking velocities the displacement for all suspension techniques was minimal.

IMPLICATIONS—The graph gives a comparison of various suspension classes for a given situation. This can complement other clinical considerations in the type of prosthesis prescribed for a given patient.

[25] ARTIFICIAL LIMB DESIGN: ASSISTANT SYSTEM USING KNOWLEDGE-BASED EXPERT SYSTEM

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Sponsor: *None listed*

PURPOSE—A number of engineering design tools in the form of prosthetic CAD/CAM software have been developed to assist the prosthetist in the design phase. However, these tools still require a seasoned prosthe-

tist to work on the CAD system, using his/her expertise and evaluating the effects. In view of the shortage of skilled prosthetists, this has not solved the problem completely. In this research, we aim to develop a knowledge-based assistant system for the computer-aided design of below-knee artificial limb that can assist and guide a ''not-so-trained'' prosthetist and augment his/her skills in the design and fabrication of customized prosthetic limb sockets.

METHODOLOGY—An expert system is a computer program using artificial intelligence to make logical decisions based on the input data. Input for this system consists of: 1) limited individual demographic information such as age, weight, time period since amputation, and proportion of torso to length of legs; 2) the conditions of residual limb such as strength of bone, residual limb length, and condition of skin; and 3) additional information such as activity level and material of socket. The expert system approach uses a non-algorithmic framework to represent and manipulate an expert's knowledge and reasoning. The inference system sequentially uses a combination of forward and backward chaining and performs both exact and approximate reasoning.

In designing the socket, we must consider the following criteria to maximize user satisfaction: (1) minimal energy expenditure, (2) efficient distribution of stump-socket contact pressure, (3) natural gait pattern, (4) comfortable weight-bearing ability, (5) control of edema through distal residual limb pressure, and (6) total contact socket. Since most of the decision rules are based on skill and expertise, they are inherently fuzzy and stochastic in nature. Thus, suitable uncertainty management techniques and fuzzy logic will have to be deployed. When the project is done, the system will consist of a database, a knowledge-base (a store of prosthetic design rules, principles, and expertise acquired by seasoned prosthetists through extended experience), the inference engine, the user interface, and knowledge update and explanation facilities. The system will be also useful in the standardization of socket design techniques and a valuable assisting instrument for junior prosthetists.

[26] NEURAL NETWORK MODELS TO ASSIST MEDICAL IMAGING SYSTEMS FOR PROSTHETIC FABRICATION

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Sponsor: *None listed*

PURPOSE—In the prosthesis, the socket provides the interface of the mechanical support system for the residual limb. The design and fit of the socket largely determines the utility and acceptance of the prosthesis. The traditional approach is to use a plaster mold of the residual limb, which has a very high degree of variability and lacks reproducibility. Digitizers and noncontact video laser scanner are common enhancements, but provide only surface topology, with anatomical markers (bony prominences) being manually added.

In the past decade, although considerable research effort has been directed toward data acquisition systems, marginal attention has been given to automating (even partially) the identification of load-bearing and pressure-sensitive areas. Such identifications are important in ensuring an effective design of the socket and circumventing discomfort due to skin breakdown.

The socket is the result of biomechanical alterations of the model of the residual limb to relieve pressure from the pressure sensitive areas and provide load-bearing regions at the pressure tolerant areas. Pressure directly over pressure sensitive areas (bony prominence) will cause immediate skin breakdown and discomfort to the patient. The weight-bearing areas are identified by their proximity to the underlying tendons and ligaments, which can be subjected to considerable compression forces and bending moments without resulting in failure. Currently, the prosthetist determines the location of the load-bearing areas by anatomical markers, based on experience and physical feel of the residual limb, recorded during the casting (plaster molding) or imaging phase.

It is hypothesized that a relationship exists between surface topology and the underlying bone structure. Some researchers have used surface curvature analysis of the surface topology for identifying the bony prominence. The algorithms used are heuristic-based and perform very poorly for oversized and fat residual limbs, since the curvature change is not significant and hence may result in improper identification of the areas. We propose to use a neural network model to exploit this relationship. Neural computing provides an approach that is closer to human perception and recognition. Since our approach does not rely on surface curvatures, the performance does not deteriorate with extreme case topologies (i.e., very skinny or fat residual limbs).

METHODOLOGY—The proposed model exploits the relationship between the surface topology and the underlying bony prominence. The input to the neural network model is the surface topology and the output is the pressure sensitive and pressure tolerant regions. The neural network is trained using data collected from CT scans, which provide excellent images of the human anatomy. The model is tested and validated using an independent set of data also acquired from CT scans. A number of neural network models will be compared using a variety of training algorithms. Finally, the effectiveness of the models will be compared with results from a trained prosthetist using data with manually added anatomical markers. A neural network model will be designed and implemented using the package NeuralWorks. We begin by considering a standard three-layer model that will be progressively modified to improve the performance of the models.

Volunteers with one below-knee amputation of average residual limb size and reasonably good health condition will be recruited. Their residual limbs will be scanned using the CT scan and the noncontact laser scanner. The CT data will be processed and filtered to convert it to a machine-readable format. This data will then be converted to the input and output variables of the neural network using the preprocessing algorithms/routines. The output from the neural network will be post-processed and incorporated in the original image (surface topology). This forms the ''Image Enhancement'' component of the Intelligent Prosthetic Design System. An automated intelligent prosthetic design system will not be a viable to the human prosthetist unless the data acquisition system can capture all the data available to the human decision maker.

RECENT PUBLICATIONS FROM THIS RESEARCH

Identification of load bearing areas for prosthetic limbs in a below-the-knee amputee using neural networks. Chahande A, Billakanti S. In: Proceedings of the 15th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 1993:1290-1.

II. Biomechanics

A. Bone and Joint Studies

[27] FUNCTIONAL ELECTRICAL STIMULATION OF SPINAL CORD INJURY PATIENTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B603-RA)*

PURPOSE—The potential benefits from functional electrical stimulation-induced ergometry of lower extremities (FESIELE) for SCI patients are: enhanced functional capabilities, improved cardiovascular fitness, decreased blood cholesterol levels, increased muscle tone, increased bone mineralization, prevention of joint contractures, and improvement of peripheral adaptations to exercise, including increased muscle mass, energetics, and blood flow. The purpose of this project is to study the effects of FESIELE on complete, spastic SCI subjects to determine the therapeutic benefits and associated risks of this rehabilitative therapy.

METHODOLOGY—Subjects participate in a 48-session training protocol on a computerized REGYS ergometer powered by lower extremity muscles activated by cutaneous electrodes. Fifteen (15) subjects have participated in various phases of the project.

RESULTS—*Muscle Tone (Spasticity).* Muscle tone was assessed using an isokinetic dynamometer that measures the resistance to passive movement. Data from 10 nondisabled, 12 spastic, and 6 flaccid subjects demonstrated significant differences between the spastic and the other two groups for peak torque during knee flexion. The discriminant analysis correctly classified 100 percent of the spastic, 90 percent of the nondisabled, but only 67 percent of the flaccid subjects. Separation of observations was good between flaccid and nondisabled groups and spastic and nondisabled groups, but some overlap existed between spastic and flaccid groups. The time course effect of FESIELE on the spasticity of 10 spastic patients immediately after, 2 hours after, and the next day following FESIELE suggests only immediate decreases in muscle tone, not lasting more than 2 hours. Assessment of FESIELE effects on spasticity using H-reflex measurements is being quantified.

Bone Density. Dual Energy X-ray Absorptiometry (DEXA) studies have been completed to assess bone density before and after training. Significant training effects have been found in the lumbar spine region, and correlations between body weight and the change before and after training are being investigated. Loads, nondisabled and orthogonal to the pedal surface, are measured and joint reaction forces and muscle torques calculated during FESIELE in three

SCI subjects using pedals instrumented with standard foil strain gauges. Changes in seat position to reduce high tensile forces are being explored.

Muscle Mass. Computerized tomographic and magnetic resonance imaging studies before and after training to assess muscle mass changes in the thigh (stimulated muscles) and in the shank (nonstimulated muscles) are underway in 15 subjects. With training, the muscle mass showed a significant increase in the anterior compartment of both thighs, while the right thigh muscle mass also showed significant increases in the posterior compartment. Data of shank muscle mass is currently being analyzed.

Metabolic Studies. VO_2 kinetics results obtained from 9 subjects during a 10-min session of FESIELE indicate that the VO_2 time constant is significantly longer in paralyzed subjects than in sedentary controls or elderly subjects. Significant improvements in maximal aerobic capacity (peak VO_2) and recovery VO_2 kinetics, however, indicate improved cardiovascular fitness, peripheral muscular adaptations, and endurance capacity. Lipid profiles show that subjects tend to have normal levels of cholesterol, but very low levels of HDL and high ratios of CHOL/HDL suggesting that paralysis and lack of aerobic exercise increase the risk of heart disease. Creatine kinase (CK) values during FES leg training (Phase I-quadriceps muscle FES only) and Phase II (FESIELE, less than 30 min/session) were at the high end of the normal range (u/l=40–280), while during Phase III (FESIELE, 30 min/session for 24 sessions) CK values were above the normal range.

FUTURE PLANS—Plans to complete work with the remaining subjects in all areas, as well to as expand areas of the effect of FES on muscle blood flow using PET scans, hybrid leg-arm exercise metabolic studies, and lipid profiles are underway.

RECENT PUBLICATIONS FROM THIS RESEARCH

Determination of the effect of functional electrical stimulation induced ergometry on muscle tone in spinal cord injury subjects. Scremin AME, Perell KL, Woodrow RB. In: Proceedings of the American Paraplegia Society Annual Meeting, September 1994, Las Vegas, 29.

Effect of functional electrical stimulation (FES) leg training on the creatine kinase (CK) levels of subjects with complete spinal cord injury. Scremin AME, Mutton DL, Kunkel CF, Cagle TG. Arch Phys Med Rehab 1994:75(9):1033.

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Investigation of joint reaction forces and movements produced during functional electricla stimulation induced cycling. Franco J, Gregor RJ, Scremin AME. In: Proceedings of the International Rehabilitation Medicine Association, April 1994, Washington, A136.

Pulmonary gas exchange kinetics in subjects with complete spinal cord injury during leg cycle exercise injuced by functional electrical stimulation (FES). Mutton DL, Scremin AME, Kunkel CF, Cagle TG, Whipp BJ. FASEB J 1994:8:A288.

Recovery oxygen uptake kinetics in subjects with complete spinal cord injury before and after training with leg cycle exercise injuced by functional electrical stimulation. Mutton DL, Scremin AME, Barstow TJ, Kunkel CF, Cagel TG. In: Proceedings of the American Paraplegia Society Annual Meeting, September 1994, Las Vegas, 9.

[28] SKELETAL CHANGES AFTER SPINAL CORD INJURY AND CAST IMMOBILIZATION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B802-RA)*

PURPOSE—The objective of this study is to use high resolution QCT imaging of lower limb bones and a novel method of monitoring daily physical activity level to develop a new noninvasive, human model for the study of functional adaptation of bone tissue. By charting the time course of bone loss or gain within small volume elements of bone in recent SCI patients and fracture cast immobilized subjects, we will inves-

tigate for the first time the nature of bone remodeling within and among bones and the related issue of reversibility of changes in bone density and structure in cancellous and cortical bone. Through a comparison of results obtained from two subject groups and results from model simulations, we will address a number of important questions with this study. The answers to these key questions will provide important new insights for better understanding the basic mechanisms of bone adaptation. These insights, in turn, should suggest new and improved clinical treatment strategies.

METHODOLOGY—We will use a combined experimental and computational approach to investigate skeletal changes in the lower limb bones of 15 spinal cord injured subjects and 15 cast immobilized subjects. The experimental phase of the project will involve the use of QCT and dual-energy x-ray absorptiometry (DXA) to measure serial changes in bone mass. The accomplishment of the experimental phase of the study involves five specific tasks: the registration (spatial repositioning) of serial CT scans of whole bones for each subject; the accurate and precise determination of bone density using QCT throughout the calcaneus, proximal tibia, and distal femur; the determination of the local remodeling rate throughout the volume of each bone using the registered QCT scan data; the monitoring of the daily loading history after cast removal; and the measurement of urine and serum markers of bone resorption and formation.

The registration task will be accomplished by adapting and refining existing algorithms developed at Stanford University. The determination of bone density and local remodeling rate will be accomplished by scanning subjects using a GE Hi-Speed Advantage CT scanner and state-of the-art QCT techniques. To measure the daily loading history, we will use a new device that continuously records the ground reaction force during daily activity. Lastly, we will assay urinary pyridinoline and serum osteocalcin levels as biochemical indicators of bone resorption and formation. In the computational component of the study, we will use three-dimensional finite element models of the calcaneus, proximal tibia, and distal femur to simulate skeletal adaptation using a bone remodeling theory developed in our laboratory in combination with the daily loading histories.

RESULTS—Development and adaptation of the CT registration software is underway. Bone-mineral-equivalent QCT phantoms have been designed and will be constructed from plexiglass and solutions of dipotasium phosphate.

[29] BIOMECHANICS OF CERVICAL DIAGNOSTIC MANEUVERS: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #B91-214AP)*

PURPOSE—Specific objectives of this research were to conduct *ex vivo* experiments on cadaveric spine specimens to determine the vertebral displacements and the stretches of the representative neck tissues (intertransverse ligament, anterior longitudinal ligament and vertebral artery at C1-C2 level) during vertebral artery provocation (VAP) testing, designed to challenge these structures in extreme extension and rotation; and to develop a computer model of C1-C2 motion segment that can be used to estimate the vertebral displacements, the stretches of the ligaments and the vertebral artery, and loads on the ligaments during the simulated VAP test.

The long-term goal of the project is to quantify and describe the biomechanical events that occur during orthopedic diagnostic testing conducted on neck pain patients. This information is useful in identifying the tissues that are challenged during the diagnostic

maneuvers and provides useful information for validating the underlying hypotheses of these diagnostic procedures.

METHODOLOGY— The *ex vivo* experiments were conducted on five, fresh human cadaveric cervical spine specimens consisting of the head and C0-C4 to measure the vertebral displacements, ligament stretches, ligament loads, and vertebral artery stretch at the C1-C2 joint level. These measurements were based on an optoelectronic three-dimensional motion-analysis system, a miniature Hall-effect stretch transducer, and differential variable reluctance transducers. The stretch transducers were used to measure the stretches of the anterior longitudinal ligament (ALL), capsular ligament (CL), and the vertebral artery under simulated VAP testing, which involves the loading of the head and the cervical spine in combined motions of extension and rotation. The computer model idealizing the ligamentous structures at the C1-C2 joint level was developed by incorporating the geometry and the material properties of the cervical spine to predict the biomechanical response under loading conditions of extension and rotation similar to the VAP diagnostic test.

PROGRESS—All cadaveric experiments and computer simulations were successfully carried out. This pilot study demonstrates that the vertebral displacements and the ligament stretches can be studied under the diagnostic maneuvers as proposed in the pilot study.

RESULTS—The C1-C2 joint mean displacements were 10.9° in extension and 33.3 ° in rotation. The mean ligament stretches were 2.83 mm for ALL and 2.87 mm for CL, and the mean stretch for the vertebral artery was 0.9 mm. The model predictions correlated well with experimental values for the displacements and ligament stretches, but they did not correlate well with the vertebral artery stretches. The inability of the model to predict the vertebral artery stretch may be attributed to the following two reasons: the artery does not contain the blood during the *ex vivo* experiments, thus loosing its true elasticity and the artery does not rigidly attach to C1 or C2 vertebrae. Future studies may consider perfusion of the artery during the *ex vivo* experiment to simulate *in vivo* elasticity of the artery.

FUTURE PLANS—The computer model development can be extended to include several vertebrae and the connecting ligaments, discs, and facet joints. Future studies would be to develop the similar protocols to investigate other diagnostic maneuvers commonly used in the case of neck-pain patients.

[30] EFFECTS OF SPINAL FUSION WITH INSTRUMENTATION ON THE STABILIZED SPINE: A PILOT STUDY

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PURPOSE—The purpose of this study was to investigate the effects of spinal instrumentation on biomechanical properties of the intervertebral disc adjacent to the stabilized segment.

METHODOLOGY— Ten male mongrel dogs (weight: 25-30 kg) were used in this study. Five experimental dogs (age 1.5 yrs) underwent posterior fusion with Isola transpedicular instrumentation from L5 to sacrum, and were euthanized after 30-week follow-up period. Five control dogs (age 2 years) were euthanized at the beginning of the study. A 3-D motion analysis system consisting of cameras and a workstation was used to obtain the load-displacement data of the harvested spines via load controlled tests to define the flexibility of each motion segment within L4-sacrum region for the following cases: intact control, the control stabilized with Isola, the experimental group

with Isola, and experimental group after removing Isola instrumentation.

Afterward, the L4-5 motion segment adjacent to the fusion was separated and its posterior bony elements and ligaments were dissected to leave the body-disc-body unit intact. The prepared specimen underwent biomechanical tests to quantify the viscoelastic properties of the L4-5 disc in terms of the relaxation and cyclic load-displacement responses. For the relaxation test, the specimen was subjected to a constant strain of 8 percent, and the total relaxation test period was 1 hour. A three-parameter standard linear solid model was used to quantify the viscoelastic parameters. In the cyclic test, the load-unload cycles were repeated 50 times at 10±2 percent strain for 0.1 and 1 Hz testing frequencies. The last three load-displacement loops were used to determine the dynamic stiffness and hysteresis. Following testing, the L4-5 discs were sectioned to investigate gross anatomic or degenerative changes.

PROGRESS—The animal model was developed and the biomechanical tests were performed as planned.

RESULTS—No complications were observed during the follow-up period, but loosening at the rod-screw connection was observed at the sacrum level in four out of five dogs at sacrifice. Tests on control specimen showed that Isola instrumentation provided a statistically significant acute stabilization across L5-sacrum in all modes of loading. Control specimens showed a significantly larger flexibility at the lumbosacral junction as compared to the other lumbar segments. The flexibility data from the experimental group indicated a solid fusion across L5-L7 levels but nonunion at the L7-sacrum segment. There were no statistically significant differences in the flexibility and viscoelastic parameters of the L4-5 segment between the control and experimental groups. No gross signs of degeneration were observed at the L4-5 disc space.

FUTURE PLANS—The results of our study suggest the following questions: 1) What are the changes in biochemical composition and nutrition of the disc adjacent to fusion? Although biomechanical changes were not detected at the end of 30 weeks, fusion may induce changes in the biochemical and nutritional environments, which may indicate a degeneration process. 2) Are the biomechanical properties of the adjacent disc significantly affected in the presence of a solid fusion at the lumbosacral junction? In the pilot study we were unable to study this effect due to the nonunion at the L7-sacrum level, which has the greatest segmental flexibility in the dog lumbar spine. In order to study this question we will have to develop a method to achieve solid lumbosacral fusion in the dog model. Further investigations are being planned to address these questions.

[31] EFFECT OF SURGICAL PROCEDURES ON THE STABILITY OF THE LUMBAR MOTION SEGMENT

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PURPOSE—Many surgical procedures of the lumbar spine require removal of tissue from the motion segment, for example, laminectomy and discectomy. When large amounts of tissue are removed, the stiffness of the motion segment is reduced to a degree that there is an abnormal response to an applied load. To compensate for this decrease in stiffness, which in addition to creating pain may present a risk to neurological structures, fusion surgery is sometimes performed. At the present time, there is a clinical controversy about when a fusion should or should not be performed. The question of whether to fuse or not is important since the fusion procedure increases the morbidity from spinal surgery. Further, when one mo-

tion segment is fused, the adjacent segments receive increased stress, placing these segments at risk of future injury.

The overall hypothesis is that when parts of a motion segment are resected for clinical purposes, its stiffness decreases in a nonlinear manner; and that there is a critical magnitude of resection at which a large stiffness decrease occurs (the breakpoint), thereby making the segment unable to meet the load-bearing requirements of everyday activities, and making restabilization (fusion) necessary.

The purpose of this research is to quantify the breakpoints for the commonly used surgical techniques of facet and disc resection through a combination of experimental and analytical techniques. The information generated in this study will be used as a basis for developing recommendations concerning when to fuse and when not to fuse.

METHODOLOGY—The study will be conducted in three phases. In the first phase, we will perform experiments on human cadaveric lumbar spine specimens to determine the effects of surgical procedures on the load-displacement behavior of lumbar motion segments. The experiments will simulate 18 unique combinations of surgical procedures, including unilateral and bilateral facet removal and disc denucleation. Each simulated surgical procedure will be tested under four types of loads: compression, flexion, lateral bending, and axial torsion. In the second phase, we will validate an existing finite element model of a lumbar motion segment by modeling the experimental simulations of 18 combinations of facet removal and disc denucleation, each subjected to four types of loads. In the third phase, we will use the validated finite element model to conduct a detailed parametric study of the effects of surgical procedures on the change in stiffness of the lumbar motion segments. Seventy-five unique combinations of unilateral and bilateral facet removal and disc denucleation will be simulated, each subjected to compression, flexion, lateral bending, and torsion. The finite element model will also be used to determine how disc height and facet orientation influence changes in the stiffness of the motion segment caused by different surgical procedures. The simulation results will be analyzed to determine the critical magnitude of surgical resection that causes a large decrease in the stiffness of the lumbar motion segment (breakpoint).

PROGRESS—We are in the process of fabricating and testing the spinal loading device. We are also conducting sensitivity analysis using the existing finite element model of a lumbar motion segment to determine the sensitivity of the model's response to the various assumptions concerning the model geometry and material properties.

FUTURE PLANS—During the first year fresh human cadaveric lumbar spines will be acquired and experiments will be performed on 30 specimens. After completing the sensitivity analysis on the finite element model, validation studies will be initiated.

[32] SUBTALAR AND TRANSVERSE TARSAL JOINT MECHANICS

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PURPOSE—The overall aim of this research is the characterization of the mechanical function of the joints of the hindfoot and midfoot. The goal of the first part of the research is to develop a testing system to determine 3-D kinematics of the tarsal bones under normal conditions. This will allow testing of the effectiveness of some commonly performed surgical treatments that alter the mechanical properties of the foot. The second component of the study is to clarify the role of the talus in distributing load between the hind foot and the midfoot and determine the effects of the same fusion procedures studied kinematically.

METHODOLOGY—For kinematics, a three-channel spatial sensor system is used to record the position and orientation of the tarsal bones with respect to the calcaneus in six degrees of freedom, as well as to digitize the anatomical landmarks of these three bones relative to their respective sensors. A force and torque transducer is used to record applied loads. "Orthokine" software, written by coinvestigator Sidles, takes the raw input from the sensors and facilitates transforming the sensor-based coordinates into user-defined anatomy-based coordinates. Algorithms estimate the mechanical center of the subtalar joint, and offer quasi-real-time computation of rotational and linear displacements from reference positions. Anatomic and positional data are employed to draw computer images of bones and to animate the movement of these images with respect to each other. A workstation receives image, position, and motion output from the Orthokine software and produces animated color images that can be viewed from any desired perspective.

For contact charactersitics, a load is applied through a pneumatic cylinder at a controlled rate. Measurements of the contact pressure between joint surfaces is made using two grades of pressure sensitive film, that was cut with a die made from a template of the joint to be studied. The layers of film were assembled and sealed in clear waterproof tape, making a transducer of 0.305 mm thickness. A quantitative analysis is produced by scanning the film along with calibration strips using a desktop scanner at 256 grey level resolution. The resulting image is analyzed using an image analysis program in a personal computer.

PROGRESS—The feasibility of the testing techniques has been established. The data collection has been completed for normative kinematic data and isolated disruption of single joint function. Data collection has also been completed for the contact pressures in the talonavicular joint, but it is not yet analyzed.

RESULTS—From the motion studies, an "Inman style" uniaxial model best described motion in all four hind foot articulations. The orientations of the rotational axes define the relative coupled motions between adjacent bones. Strong coupling of motion in the subtalar, talonavicular, and calcaneocuboid joints was found between inversion (angular rotation of the inferiorly directed axis toward the medial axis) and adduction (anteriorly directed axis toward the medial axis). Calcaneocuboid range of motion was only 35 percent of that of the talonavicular joint. Fusion of the calcaneus and cuboid had relatively little effect on the angular axes and ranges of motion of the other articular articulations. The main effect was a loss of 10° of talonavicular motion.

FUTURE PLANS/IMPLICATIONS—The same procedure will be used to study the effects of talonavicular fusion and combined calcaneus-cuboid-navicular fusions, and to look at the effect of muscle imbalances that occur with strokes and other neurologic diseases.

RECENT PUBLICATIONS FROM THIS RESEARCH

Contact characteristics of the subtalar joint: the effect of calcaneus fracture misalignment. Sangeorzan BJ, Ananthakrishnan D, Tencer A. J Orthop Trauma. In press.

[33] DYNAMIC RESPONSE OF SPINAL SEGMENTS: EXPERIMENTAL AND ANALYTICAL STUDIES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Core Funds)*

PURPOSE—Epidemiological studies suggest that when prolonged loading is combined with low-frequency vibration (e.g., vertical oscillations in operating a motor vehicle), the incidence of low-back pain complaints is significantly increased. In these environments, a spinal segment experiences static and dy-

namic loads in axial compression, bending and shear, that occur due to the natural curvature of the spine. This is particularly applicable to the L4–L5 and L5–S1 discs, where the lordotic anatomic configuration predetermines the presence of a large shear component. Clinical observations that these discs are most commonly implicated in low back disease suggest that shear may play a significant role in affecting the disc's ability to sustain compressive loads in static as well as dynamic loading environments.

The purpose of this study was to determine: the responses of lumbar discs to prolonged loading and low-frequency vibration in anterior shear and in compression; the effect of combined loading in the sagittal plane on the shear and compressive responses; and the effects of disc degeneration on the behavior of the lumbar discs in shear, compression, and combined loading.

METHODOLOGY—Fresh human cadaveric lumbar discs were tested in pure shear, pure compression, and combined modes. In each loading mode, the static and dynamic stiffness, hysteresis, and load relaxation behavior of each specimen were measured. The degeneration grade of each disc was quantified using T2-weighted images of sagittal section MRI scans. Data were analyzed using repeated measures ANOVA.

PROGRESS—Eleven lumbar disc specimens have been tested and the data analyzed as described above.

RESULTS—The responses of lumbar discs to prolonged loading and low-frequency vibration in shear were significantly different than those in compression. The relaxation time constant in pure shear was 36 percent smaller than the value in pure compression ($p<0.05$). The percent load relaxation in pure shear was 40 percent smaller than in compression ($p<0.01$). The instantaneous and equilibrium stiffness values in shear were smaller than the values in compression by 75 and 60 percent, respectively ($p<0.001$). The dynamic stiffness in pure shear was 60 percent smaller than in compression ($p<0.001$). In pure shear, the hysteresis value tended to be smaller than in pure compression ($p=0.08$).

Disc degeneration affected the response of lumbar discs to prolonged loading and low-frequency vibration in pure shear and compression. Increasing disc degeneration (grade 1 vs. 3) significantly reduced the instantaneous, equilibrium, and dynamic stiffness, and increased the load relaxation and hysteresis of lumbar discs in shear. Similar trends were observed for the response in compression.

The responses of lumbar discs in compression were significantly affected in the presence of combined loading. The instantaneous and equilibrium compressive stiffness decreased by 52 and 23 percent, respectively ($p<0.01$). The compressive load relaxation decreased by 48 percent in the combined loading mode ($p<0.01$). The combined loading mode also caused a decrease of 37 percent in the dynamic compressive stiffness ($p<0.01$). The energy dissipation characteristic in compression decreased significantly ($p<0.05$) as a result of combined sagittal plane loading.

The structure of the intervertebral disc appears significantly better suited for resisting prolonged and dynamic loads in compression than in shear. The ability of the disc to resist compression is adversely affected by combined shear and compression loading. The presence of a large shear at the L4–5 and L5–S1 discs may explain the increased incidence of disc injuries at these levels.

FUTURE PLANS—Further studies are planned to investigate the effects of different shear/compression ratios, and to correlate disc responses to disc structure and composition.

[34] SYNOVIAL JOINT BIOMECHANICS AND THE PATHOGENESIS OF OSTEOARTHRITIS

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PURPOSE—Many theories have been advanced in the effort to explain how the relatively soft cartilage matrix in skeletal joints can accommodate motion with very low friction when loaded and either last a lifetime or fail in the degenerative disease, osteoarthritis. This project, using a combined experimental and analytical approach, offers convincing evidence that the synovial joint is a self-pressurized, hydrostatic bearing, a concept first proposed by McCutchen in 1957.

METHODOLOGY—This project benefits from prior unique instrumentation which produces detailed pressure maps of acetabulae cartilage, both *in vitro* and *in vivo,* and ultrasonically based techniques for measuring cartilage layer, geometry, permeability, and modulus *in situ.* Cadaver acetabulae are step-loaded with a pressure-instrumented pseudoendoprosthesis to produce a time record of pressure distribution. The same cartilage is then loaded in the same way with an identical endoprosthesis which monitors ultrasonically the time consolidation of the joint, permitting detailed calculation of the time evolution of the cartilage-layer geometry. A finite-element, analytical model applies these experimental boundary conditions (pressure and geometry) to calculate the fluid flow, both tangentially in the cartilage and radially from the cartilage into, and then through, the interarticular space. The calculation iteratively matches the boundary conditions.

RESULTS—The combined experimental and analytical approach quantifies the fluid flow radially into the interarticular space, evaluates the conductance of that interarticular space relative to the conductance tangentially through the cartilage layer and thereby establishes, without qualification, that the joint operates as a self-pressurized fluid bearing. The pressure gradient in the cartilage is from deep in the cartilage to the interarticular space, challenging the ''boosted'' theory of cartilage tribology. The matrix stress on the collagen-proteoglycan structure is shown to be a small fraction of a megapascal in magnitude. Thus as long as the interarticular seal maintains the pressures we have measured *in vitro* and *in vivo* in the human hip joint, the matrix is never at risk. However, if the seal is breached by fibrillation of the cartilage structure, the fluid pressure cannot be maintained, the cartilage matrix is subjected to the imposed load, and is destroyed, as in the osteoarthritic process.

IMPLICATIONS—Future research must address threats to the sealing of the fluid within the cartilage. Failure is likely to occur either at the superficial layer or at the tide mark, the normally fluid-impervious interface between ossified cartilage and bone. Excessive leakage at either the top or bottom of the cartilage layer will put the matrix at risk. Studies of the nature of the interarticular seal should be pursued; it is now believed to be a consequence of the first-order variations (approximately 75 microns RMS) on the normally spherical shape of the femoral or acetabulum. A recent estimate of the average radial width of the interarticular space over the load-bearing area indicated a clearance of 10 to 20 microns.

RECENT PUBLICATIONS FROM THIS RESEARCH

Cartilage stresses in the human hip joint. Mann RW. J Biomech Eng 1994:116:10-8.

[35] CALCULATION OF KNEE LIGAMENT LOADS DURING REHABILITATION EXERCISES

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Sponsor: *None listed*

PURPOSE—Effective rehabilitation is critical to the success of knee ligament reconstruction. In order to devise rational rehabilitation protocols, one should understand the patterns of ligament loading during remedial exercises, so that the most suitable load environment for the ligament graft can be achieved. *In-vivo* measurement of ligament forces is difficult and has only been done for very small numbers of subjects. *In-vitro* measurement is not suitable, since it is impossible to reproduce many of the active movements carried out as rehabilitation exercises. Therefore we have decided to calculate the ligament forces mathematically. However, due to the mechanical indeterminacy of the knee joint, this is not a trivial task. The purpose of this study is to develop a procedure for calculating ligament forces and to use that procedure to determine the forces carried by the ligaments during a range of rehabilitation exercises.

METHODOLOGY—In the preliminary stages, the exercise investigated was isokinetic flexion/extension. An isokinetic dynamometer applies to the tibia a known external force, which is automatically varied so as to keep the angular velocity of the tibia nominally constant (hence isokinetic). A stereophotogrammetric system is used to record the positions of markers on the limb segments during the exercise and the line of action of the applied force. From the smoothed and filtered time-histories of the marker positions, it is possible to calculate the acceleration of the tibia and the exact knee flexion angle at any given time. This data can be used to calculate the resultant force and moment at the joint. A computerized two-dimensional geometrical model of the knee is then used to calculate moment arms and lines of action of muscle, ligament and contact forces, reducing the indeterminacy of the system. The model incorporates the quadriceps, hamstrings, and gastrocnemius muscle groups, the anterior and posterior cruciate ligaments, and the patello-femoral joint. Passive motion is governed by a planar four-bar linkage. The ligaments are taken to be extensible and antero-posterior (a-p) tibial translation due to elastic deformation of the ligaments can also be modeled. It is possible to determine three forces and the value of the a-p tibial displacement simultaneously. In total there are six possible forces included in the model. Therefore, we take combinations of three out of the six forces in turn, setting the other three to zero, and calculate their values. Any combinations that yield tensile contact forces or compressive muscle forces are discarded, as they are physiologically impossible. This reduced the number of admissible solutions considerably. The remaining combinations are compared with temporal EMG signals recorded during the exercise.

PRELIMINARY RESULTS—All possible single-muscle solutions were calculated. These solutions represent the limiting cases for the ligament forces; if co-contractions occur, the true ligament forces will be lower than the calculated values. At each flexion angle, up to two valid solutions were found. EMG supported the assumption of single muscle activity for quadriceps contractions, but suggested that hamstrings and gastrocnemius are active concurrently. Preliminary values from three subjects for the mean peak ligament forces are: 0.31 (SD 0.03) body-weight (BW) for the ACL and 1.33 (SD 0.61) BW for the PCL, both occurring at a nominal angular velocity of 100°/sec. No significant differences between peak values at different velocities have been established. During the exercise, the angular velocity of the tibia is rarely constant, which shows that an isokinetic dynamometer does not produce a true isokinetic contraction.

FUTURE PLANS—Further subjects will be evaluated in order to improve the statistical power of the study. A variety of other exercises, such as isometrics and isotonics, will also be investigated.

RECENT PUBLICATIONS FROM THIS RESEARCH

Redundant nature of locomotor optimization laws. Collins JJ. J Biomech 1995:28(3):251-67.

Bi-articulating two-dimensional computer model of the human patellofemoral joint. Gill HS, O'Connor JJ. Clin Biomech. In press.

B. Human Locomotion and Gait Training

[36] A PINNED POLYMER MODEL OF POSTURE CONTROL

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Sponsor: *National Science Foundation; Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E756-RA)*

PURPOSE—In our earlier posturographic studies, it was demonstrated that the time-varying displacements of the center of pressure (COP) under the feet of quietly-standing subjects could be represented as a stochastic process. This motivated the use of mathematical tools from nonequilibrium statistical mechanics. Accordingly, the objective of this study was to develop a phenomenological stochastic model for posture control, one which yields physiologically-relevant parameters and output that corresponds to experimental posture data.

METHODOLOGY—Guided by the posturographic data and the biomechanical constraints of the human body, we derived a stochastically driven partial differential equation to model posture control. This equation considered the upright body to be a stochastically-driven pinned polymer. A polymer is a flexible string under tension; it is a coarse-grained approximation of the body. The pinning represents the corrective actions of the postural control system, which work to keep the body upright.

RESULTS—The model reproduced the correlation functions computed from the experimental data and characterized posture control in terms of four physiologically relevant parameters. With the pinned polymer model, the response to a perturbing force could also be calculated and characterized using the parameters derived from the quiet-standing data. This feature of the model is important from a motor control standpoint because it allows one to test the hypothesis that quasi-static posture control and dynamic posture control are governed by the same mechanisms.

[37] ANATOMICAL FRAME DEFINITION, DETERMINATION, AND EXCHANGE IN MOVEMENT ANALYSIS

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Sponsor: *C.E.C. programme AIM - CAMARC II*

PURPOSE—This research deals with methodological problems in reconstructing the position and orientation of the human pelvis and the lower limb bones in space during the execution of locomotion and physical exercises using stereophotogrammetric systems. In order to make movement analysis effective in the solution of rehabilitation and clinical problems, a structured conceptual background is needed in addition to

standardized definitions and methods. Technical solutions that make data sharing and relevant data banks possible are also of primary importance. This research study makes suggestions in this context.

METHODOLOGY—For practical purposes, the bone-embedded frames ought to meet the following requirements: 1) their determination from experimental data should be repeatable both inter- and intra-individually; 2) they should possibly incorporate suitable axes with respect to which both rotations and translations of the joint may be defined; and 3) they should permit an easy estimation of the body segment center of mass and principal axes of inertia. Their identification will therefore be based on the location of a number of anatomical landmarks.

A number of selected anatomical landmarks has been identified, according to established anatomical literature and our own experience in gait analysis. Based on these landmarks, anatomical systems of axes for the pelvis and lower limb segments have been defined and are proposed for standardization. In order to enrich relevant knowledge and help the user in the anatomical landmarks' trajectories reconstruction during movement, the experimental protocol called ''Calibrated Anatomical System Technique'' (CAST) has been developed. Anatomical landmark location may be determined using a pointer, on which a minimum of two markers has been mounted at an adequate distance. The experimenter points the tip of the pointer onto the anatomical landmark so that the markers on the pointer and the relevant body segment technical markers are visible to the cameras. Through obvious geometric calculations and using the reconstructed position of the pointer markers, the location of the anatomical landmarks may be determined.

Finally a proposal of a preprocessed gait data (PGD) format, which refers to the position and orientation in space of the body segments involved during the movement, was proposed for standardization. This data file is intended for use in exchange between laboratories and to be fed into concerted data-processing software.

RESULTS—The CAST method is usually more practical than the classical ones, especially when the anatomical landmark is in an awkward position. The PGD lexicon reduces the redundancies and makes the kinematic variables of each body segment easily shared between laboratories, without involving knowledge on the specific set-up used. Thus it is now possible to exchange data, or to create a shared database of gait data.

RECENT PUBLICATIONS FROM THIS RESEARCH

Position and attitude in space of bones: calibrated anatomical system technique. Cappozzo A, Catani F, Leardini A. In: Proceedings of 8th Annual East Coast Clinical Gait Conference; Rochester, 1993.

Position and orientation in space of bones during movement: anatomical frame definition and determination. Cappozzo A, Catani F, Della Croce U, Leardini A. Clin Biomec. In press.

[38] EXPERIMENTAL ARTIFACTS IN MOVEMENT ANALYSIS

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Sponsor: *C.E.C. programme AIM - CAMARC II*

PURPOSE—This study deals with experimental problems in reconstructing the position and orientation of the human pelvis and the lower limb bones in space during the execution of locomotion and physical exercises using stereophotogrammetric systems. Stereophotogrammetry is limited by accuracy in experimental errors associated with the skin marker movement artifacts, which make the estimation of small but clinically relevant angular and linear joint movement critical. This research is intended to contribute to the solution of this problem.

METHODOLOGY—Quantitative information regarding the so-called skin movement artifact was collected from experiments on eight subjects, who had suffered fractures and were wearing either femoral or

tibial external fixators. Clusters of markers attached to these latter devices, and relevant local coordinates of suitable anatomical landmarks, allowed the calculation of anatomical frames which could be assumed to be rigid with the underlying bones. Markers were located above typically used anatomical landmarks: greater trochanter (GT), lateral epicondyle (LE), head of the fibula (HF) and lateral malleolus (LM). Clusters of markers were also attached to the lateral aspect of the instrumented segment, at first directly on the skin surface and later on rigid plates strapped to the segment using elastic bands.

Several cycles of level walking at a natural cadence, of cycling on a cyclette, and of elementary joint rotation were analyzed. For each experiment, the displacement of the skin markers in the relevant bone anatomical frame could then be determined during movement. Moreover, in order to gain insight into the effect that the artifacts may have on the estimation of joint angles, the orientation vector of the anatomical system of axes was calculated from the clusters of technical markers (with respect to the bone anatomical frame) in each sampled instant of time.

In order to assess qualitative information about the same artifact in subjects with intact musculoskeletal structures, videofluoroscopy was used in nondisabled subjects. Sagittal digital videofluroscopic images of hip, knee, and ankle were collected at a rate of 6 per second, from four nondisabled subjects, while the subject was performing a flexion movement of the joint.

RESULTS—Both external fixator and videofluroscopy experiments have confirmed that skin marker artifacts are usually overwhelming when compared to photogrammetric errors. GT, LE, HF, and LM skin markers underwent displacements in the range of 10 to 30 mm, proportional to the closest joint rotation. The trajectories of the same anatomical landmarks reconstructed using plate mounted markers have shown better results. The cluster skin markers artifact affected the estimation of the knee joint kinematics during walking, by inaccuracies which, for flex/extension, ad/abduction and inter/external rotation, roughly amount to 10, 50, and 100 percent of the respective movement range angle.

FUTURE PLANS—Although, at present, skin marker artifacts are larger than desired and affect significantly the kinematics evaluation of joint, a better design of the coupling between body segment and the relevant markers to be collected would significantly improve the reliability of the estimation of the position and orientation in space of bones using stereophotogrammetry.

RECENT PUBLICATIONS FROM THIS RESEARCH:

Calibrated anatomical system technique in 3D motion analysis: assessment of artifacts. Cappozzo A, Catani F, Della Croce U, Leardini A. In: Proceedings of II International Symposium on 3D Analysis of Human Movement; Poiters, 1993.

Skin movement artifacts in human movement photogrammetry. Cappozzo A, Catani F, Leardini A. In: Abstracts of XIV Congress of the ISB; Paris, 1993.

[39] POSTURAL CONTROL IN PARKINSON'S DISEASE

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Sponsor: *Hebrew Rehabilitation Center for Aged; National Institute on Aging; Boston University*

PURPOSE—Parkinson's disease (PD) is a common neurodegenerative condition in the elderly. Postural instability is the hallmark of advanced disease and can result in significant morbidity manifested by falls, decreased mobility, and functional decline. Despite the frequency and severity of this problem, the postural dyscontrol associated with PD remains a poorly understood phenomenon. The objective of this study was to use stabilogram-diffusion analysis to gain an increased understanding of the postural impairments associated with PD.

METHODOLOGY—We obtained clinical data from 22 patients with PD and 25 nondisabled elderly sub-

jects. The two groups were matched for age and gender. Each individual's postural stability was evaluated by using a force platform to measure the movements of the center of pressure (COP) under his/her feet. The individuals were tested under eyes-open conditions for multiple 30-sec trials. The COP trajectories were parameterized according to stabilogram-diffusion analysis. Standard statistical analyses were used to compare the results for the PD patients with those from the nondisabled subjects.

RESULTS—We found that: 1) the stochastic activity of the open-loop and closed-loop postural control mechanisms in the mediolateral (ML) direction was significantly greater in the PD patients, 2) the ML/AP (anteroposterior) ratio of postural stochastic activity was increased in the PD patients, 3) the PD patients utilized open-loop postural control schemes over a greater distance in the ML direction, and 4) a higher ML/AP ratio of postural stochastic activity during quiet stance correlated with poorer performance on clinical measures of physical function, such as functional reach, habitual gait speed, and a comprehensive clinical balance scale. Our finding that PD patients have a greater tendency to sway mediolaterally may be the consequence of rigidity at the ankle joint which is restricting the typical anteroposterior movement of quiet stance. This functional change could predispose a PD patient to impairments of balance and physical function.

[40] MODEL OF THE NEURO-MUSCULO-SKELETAL SYSTEM FOR HUMAN POSTURE AND GAIT

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Sponsor: *Japan Society for the Promotion of Science*

PURPOSE—Computational models can be developed and used to gain insight into the complex interactions that exist between the neuromuscular and biomechanical components of the human motor control system. In an earlier study, one of us proposed that the dynamic stability of gait is established through the global entrainment between neural dynamics and musculoskeletal dynamics. The objective of this study was to extend the aforementioned work and create a theoretical framework for understanding both posture and gait. We hypothesized that there are separate mechanisms responsible for static and dynamic stability and that there exist flexible interactions between these mechanisms which generate integrated movements, depending upon the environmental and task constraints. In this study, we considered stepping in place, which is a task that involves both static balance and dynamic limb movements.

METHODOLOGY—The sagittal-plane model of the human body consisted of eight segments and single-joint muscles. The neural model was composed of a posture controller (PC) with two neural units for each limb and a central pattern generator (CPG) with six neural oscillators for each joint. The PC produced coactivation signals for all the muscles, while the CPG generated reciprocal activation of the antagonistic muscles. The PC was excited when the ipsilateral foot was on the ground and inhibited when the ipsilateral CPG was active. We used a computer program based on this model to conduct a series of simulations.

RESULTS—We obtained stable stepping with the model. The coactivation of the stance-limb muscles by the PC maintained posture, while the reciprocal activation of the swing-limb muscles by the CPG produced stepping movements. This result supports the hypothesis that integrated movements are produced by the interplay between static and dynamic controllers. We plan to extend this work by studying how transient states are controlled during the transitions between quiet standing and stable walking.

[41] MODEL FOR THE DYNAMIC POSTURAL CONTROL SYSTEM

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Sponsor: *Liberty Mutual Insurance Company*

PURPOSE—This project is designed to develop a physiologically-based, mathematical model of the dynamic postural control system. In our earlier posturographic investigations, we proposed that open-loop and closed-loop neuromuscular control mechanisms are involved in the regulation of undisturbed, upright stance. The objective of this study was to conduct *in numero* experiments to test the above open-loop/closed-loop postural control hypothesis and to explore the functional roles of related neural and biomechanical factors.

METHODOLOGY—The computer model we developed can take the form of a single-link or multi-link inverted pendulum. The joints of each pendulum are constrained by spring-dashpot systems and noisy force actuators. The software package permits the user to set interactively each parameter affecting the modelled system. The computer model is enabled to explore the effects of various control systems, such as: 1) a proportional, derivative, accelerative feedback controller, 2) a variable-gain feedback controller, 3) a sampled data system, and 4) an ON/OFF feedback controller with an error dead-zone. The output of the system consists of the time-varying position of the system's center of mass and center of pressure. In this preliminary study, we conducted a series of computer experiments to explore the possible role of active stiffness (arising from activated postural muscles) and passive stiffness (arising from soft-tissue elements, such as tendons and ligaments) in the maintenance of upright stance.

RESULTS—We found that the baseline active and passive stiffness values reported in the literature were insufficient to maintain the model in an upright stance. Importantly, the inverted-pendulum model was based on realistic anthropometric parameters. With larger stiffness values (ones which were not physiologically reasonable), it was possible to stabilize the system, for a range of initial conditions and in a noisy environment. These findings suggest that the maintenance of quiet standing does not rely simply on stiffness mechanisms.

[42] BIOMECHANICAL EVALUATION OF THE EFFECTS OF LOAD CARRYING ON DYNAMIC BALANCE CONTROL

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Sponsor: *Liberty Mutual Insurance Company*

PURPOSE—A number of movement-related injuries in the workplace are associated with load-carrying tasks. There is a need to gain an increased understanding of how different load-carrying situations affect the "dynamic" postural control system. There is a related need to develop an objective test for evaluating quantitatively an individual's risk for slipping and falling while carrying a weight. Information derived from such investigations could be used to redesign potentially-dangerous work tasks (e.g., by establishing safety limits for the weights to be carried). The objective of this project was to conduct analyses of the effects of load carrying on dynamic balance control.

METHODOLOGY—We developed an experimental protocol for evaluating an individual's ability to initiate walking while carrying different weighted boxes. With this protocol, a force platform is used to measure the displacements of the center of pressure (COP) under an individual's feet, and a motion analysis system is utilized to measure the subject's lower-limb kinematics during the gait-initiation period. EMG sig-

nals are also recorded from selected lower-limb muscles. During the testing, each subject is instructed to stand on the platform for a brief period while holding a weighted box. They are then instructed to walk forward off the platform and to continue walking for several steps. Multiple trials are conducted for each load-carrying condition.

RESULTS—To date, we have completed the development of analytical software for extracting a number of parameters from the kinetic and kinematic data, including: 1) the maximum displacement of the COP under the subject's feet, 2) the relative timing of foot-contact events, and 3) the relative time to the maximum angular deflection of the hip, knee, and ankle of the subject's swing leg. These parameters will be analyzed to determine how an individual modifies the behavior of their dynamic postural control mechanisms to compensate for the fact that they are carrying a load. In addition, we have collected preliminary data on four subjects, each of whom were tested under unloaded conditions. We plan to examine a total of 20 nondisabled young subjects aged between 21 and 30 years. All subjects will be tested under loaded and unloaded conditions.

[43] EFFECTS OF HEAD INJURY ON OPEN-LOOP AND CLOSED-LOOP POSTURAL CONTROL MECHANISMS

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PURPOSE—Head injuries are often the result of accidents that occur during a variety of daily activities, such as descending stairs or driving a motor vehicle. These injuries can lead to a series of long-term movement and balance problems. It is surprising, therefore, that only a small number of posturographic investigations have reported on means for evaluating the severity and dysfunction due to head injury. The objective of this study was to use stabilogram-diffusion analysis to gain an increased understanding of the functional neuromuscular changes that result from head injuries.

METHODOLOGY—We examined 10 patients with head injuries recruited from the Spaulding Rehabilitation Hospital. Each patient's postural stability was evaluated by using a force platform to measure the movements of the center of pressure (COP) under his/her feet. The patients were tested under eyes-open and eyes-closed conditions for multiple 30-sec trials. The COP trajectories were parameterized according to stabilogram-diffusion analysis. Standard statistical analyses were used to compare the results from the head-injured patients with those from age-matched nondisabled individuals.

RESULTS—We found that the operational characteristics of the open-loop and closed-loop postural control mechanisms for the patients were significantly different from those for nondisabled individuals. For instance, we found that the stochastic activity of the open-loop and closed-loop postural control mechanisms was higher in the head-injured patients. In addition, we discovered that the patients utilize the open-loop postural control schemes for longer periods of time and over larger areas of the base of support during periods of undisturbed stance. This work clearly demonstrates that head injuries result in changes in the functional behavior of the open-loop and closed-loop postural control mechanisms and that these changes can be characterized quantitatively during periods of undisturbed stance.

[44] EFFECTS OF SPACEFLIGHT ON OPEN-LOOP AND CLOSED-LOOP POSTURAL CONTROL MECHANISMS

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PURPOSE—Astronauts returning from spaceflight typically exhibit postural difficulties. Few static posturographic investigations, however, have demonstrated pre-flight/post-flight differences in the postural sway of astronauts tested under eyes-open conditions. The objective of this study was to examine how the sensorimotor systems underlying quasi-static balance control adapt to prolonged periods in microgravity.

METHODOLOGY—Four crew members and two alternates from the 14-day Spacelab Life Sciences 2 Mission were included in the study. An instrumented force platform was used to measure the time-varying displacements of the center of pressure (COP) under each subject's feet during quiet standing. Each subject was tested under eyes-open conditions on multiple pre-flight and post-flight days. The COP trajectories were parameterized according to stabilogram-diffusion analysis.

RESULTS—We found that the stochastic activity of the open-loop postural control mechanisms in three of the four crew members was increased following spaceflight. We interpreted this result as an indication that there may be in-flight adaptations to higher level descending postural control pathways. We also found that the crew members, as a group, did not exhibit any consistent pre-flight/post-flight differences in the steady-state behavior of their closed-loop postural feedback mechanisms. Likewise, we found that the crew members, as a group, did not exhibit any consistent pre-flight/post-flight differences in the spatial or temporal interaction of their open-loop and closed-loop postural control mechanisms. We interpreted these results as indications that although there may be in-flight adaptations to the vestibular system and/or proprioceptive system, input from the visual system can compensate for such changes during undisturbed stance.

[45] DEVELOPMENT OF A DIRECT ULTRASOUND RANGING SYSTEM FOR THE QUANTIFICATION OF AMBULATION

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PURPOSE—Most gait analysis devices are not suitable for use in a clinical setting because of their complexity and high cost. We are attempting to develop a direct ultrasound ranging system (DURS) for the quantitative evaluation of ambulation in a simple and economical manner. The DURS operates by emitting an ultrasound and infrared pulse simultaneously from a transmitting unit at a sampling frequency of 22 Hz. The receiver unit then measures the time difference between the arrivals of the light and sound pulses. By calibrating for the speed of sound, this time difference is then converted into a measurement of the distance between the transmitting and receiving units. These distance samples are then stored in a computer and processed through a differentiation algorithm to obtain an estimate of the velocity profile of the body trunk. From this velocity profile, additional gait parameters such as gait speed, cadence, stride length, and step time can be calculated. This device is similar to one developed at the University of Ljubljana in Slovenia.

PROGRESS—We have completed prototype development of the first DURS. This prototype interfaces with a personal computer through the parallel port,

and the calibration for the speed of sound is accomplished manually through the hardware. In addition, the software has been written to implement a three point differentiator followed by a two point time averager to convert the distance samples obtained from the device into velocity samples. The time averager was implemented to smooth the velocity data as the process of differentiation tends to enhance discontinuities and sharp edges.

With this first prototype, velocity measurements were taken on the ambulation of subjects with normal gait. These velocity profiles were then compared with velocity profiles obtained from the CODA 3 system in our Human Mechanics Measurement Laboratory to test the accuracy of the DURS.

RESULTS—The velocity profile obtained from the DURS and the CODA 3 system are very similar. Both devices accurately measure the periodic fluctuation in the forward velocity of the body trunk that results from the rising and falling of the center of mass during normal gait. The gait speed determined from the DURS was consistently within 3 percent of the gait speed determined from the CODA 3 system. Similarly, the average cadence measured with the DURS was consistently within 3 percent of the CODA-3 measured values. Average step time and average step length measurements were also compared between the two devices and the measured values from the DURS were respectively within 3 and 6 percent of the CODA-3 measured values. These preliminary results suggest that the DURS can be utilized to accurately quantify certain parameters of ambulation.

FUTURE PLANS—In the next stage of the DURS development, we will modify the first prototype to improve its operation. The first modification will be to improve the transmission and reception of the infrared light, since this is the limiting signal in the receptive field of the device.

A second modification which will be attempted is to have the computer measure the time difference between the arrivals of the infrared and ultrasound signals at the receiver unit. Therefore, the conversion of the time measurement into a distance measurement and the calibration for the speed of sound will be done in software instead of hardware. This will greatly reduce the circuitry required in the receiver unit.

Finally, the software will be improved to make the device easier to operate and to facilitate the calculations of the desired gait parameters. The system will then be modified to run on a lap-top computer to increase its portability.

[46] CONTROLLING NEURONAL NOISE USING CHAOS CONTROL

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Sponsor: *National Science Foundation*

PURPOSE—In a recent study, chaos control techniques were utilized to control spontaneously bursting neuronal networks. It was assumed that these networks were chaotic in nature. However, the identification of chaos in experimental systems, particularly physiological systems, is a difficult and often misleading task. The objective of this study was to determine whether or not chaos control techniques could be used to control a noise-driven, nonchaotic neuronal model with a level of success similar to that reported for the aforementioned neuronal networks.

METHODOLOGY—We implemented the FitzHugh-Nagumo neuronal model. In this case, the model neuron was driven by both tonic and noisy inputs. The system parameters were chosen such that the additive noise did not induce chaos. We applied chaos control techniques to the model in an attempt to control its firing rate.

RESULTS—We found that the chaos criteria used in the aforementioned study could falsely classify our noise-driven, nonchaotic neuronal model as being cha-

otic. Moreover, when we applied chaos control techniques to the model, we obtained results which were similar to those reported for the aforementioned neuronal networks. These novel findings challenge the claim that the aforementioned neuronal networks were chaotic and suggest that chaos control techniques may be applicable to a wider range of experimental systems than previously thought.

[47] USING CHAOS CONTROL TO CONTROL NONCHAOTIC SYSTEMS

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PURPOSE—Chaos control techniques constrain the output of a chaotic system by exploiting the system's extreme sensitivity to small perturbations. These techniques have been used to control a number of different chaotic systems. However, to our knowledge, these methods have never been used to control a nonchaotic system. The objective of this study was to explore the possibility of using chaos control techniques to control nonchaotic systems. Work of this sort could open up a number of new, real-world applications for chaos control.

METHODOLOGY—In this study, we examined the stable, periodic orbits of the Hénon map in its nonchaotic regime. We used additive white noise to locate the underlying lower-order, unstable periodic orbits of the system. These orbits were required for the application of chaos control. We then used chaos control techniques to compute and apply adaptive parameter perturbations to the system. These perturbations were determined and applied so as to constrain the system within a selected unstable periodic orbit.

RESULTS—We discovered that chaos control techniques could be used to control the output of the noisy, nonchaotic Hénon map. We also found that chaos control techniques could be used to shift the output of the noise-free Hénon map from a stable high-period orbit to lower-order unstable periodic orbits. In this case, control could be achieved using only small parameter perturbations. This work challenges the generally accepted notion that large parameter changes are needed to alter the qualitative dynamics of nonchaotic systems. From a practical standpoint, these novel developments suggest that chaos control may offer an efficient means for removing higher-order periodicities from the output of a nonchaotic, experimental system. From a physiological standpoint, this could be important given that a number of pathological conditions are associated with the appearance of unwanted higher-order oscillations.

[48] THE INITIATION OF HUMAN WALKING

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PURPOSE—It has been hypothesized that gait initiation, the transition from quiet stance to steady-state walking, is governed by a motor program. Moreover, it has been proposed that this motor program controls several sub-tasks during gait initiation, including the generation of forward momentum. The objective of this project was to test this hypothesis. The information derived from this study could eventually be utilized in the development of a clinical technique for evaluating and characterizing posture and movement disorders.

METHODOLOGY—We examined 10 nondisabled young subjects (aged 20 to 30 years). Subjects initiated walking under three different speed conditions (slow, normal, fast) from a force platform, which

measured the ground reaction forces and displacements of the center of pressure under the subject's feet. Simultaneously, a motion analysis system measured the movements of the subject's body segments, and electromyographic (EMG) signals were recorded from eight lower limb muscles.

RESULTS—Our preliminary results indicated that gait initiation in several individuals may be governed by a motor program, as previously suggested. Moreover, our analyses indicated that the initial muscle activity governed by this program is used to generate forward momentum, and that the amount of momentum generated is based on the target speed. It is important to note, however, that a number of subjects did not exhibit EMG patterns which were indicative of a motor program. This issue requires further study. We plan to extend this work by testing additional nondisabled young subjects, as well as nondisabled elderly subjects.

[49] STEPPING OVER AN OBSTACLE: EFFECT OF REDUCED VISUAL FIELD

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PURPOSE—Walking in a normal environment requires that an individual modulate his (her) locomotion in order to avoid various obstacles. This study investigates the use of visual information in such a locomotor task. To this end, subjects were required to step over an obstacle with 0 cm height while the lower portion of the visual field was blocked.

METHODOLOGY—Two approach steps and the step over the obstacle were studied. In the reduced visual field condition, the subjects wore a pair of safety goggles (that could fit over corrective glasses) in which the lower rim and the sides were covered. This manipulation ensured that when the subject fixated straight ahead (s)he could not see the obstacle in the last approach step and as (s)he stepped over it. Subjects were tested with and without the goggles for two levels of task difficulty. In the first level, the subjects could look where they wished; in the second level, they were required to fixate on a sticker positioned at eye height 5 m beyond the obstacle.

Two video cameras of the 3-D motion analysis system PRIMAS registered passive markers on a head frame enabling the angle of the head in relation to the floor to be calculated; further passive markers were attached to the neck and the back of the shoes. Subjects stepped over a flat piece of cardboard located on a 10 m walkway in a well-lit laboratory. The width of this obstacle was adjusted to be half of the subject's normal step length. From this data, step length and velocity could be calculated as well as the distance from the approach foot to the obstacle (DTO) and the distance from the obstacle to the heel of the foot which steps over the obstacle (DHO).

Three groups of healthy adults with mean ages of 26.0 (n=10), 65.6 (n=11), and 75.9 (n=9) years were tested.

RESULTS—Preliminary analysis of the data indicates that the oldest group is most affected by the reduced visual information. In this group, DTO increases significantly when only peripheral visual information is available (task X age interaction is significant ($p<0.000$). This group seems to show a change in strategy. With full visual information, adjustments in the two approach steps are made so that the approaching foot lands close to the obstacle; the heel of the foot stepping over the obstacle is placed relatively close to the obstacle. With reduced visual information, there is minimal adjustment in the two preceding steps. The step over the obstacle is lengthened. The 'safety margin' (DTO plus DHO) increases by at least 35 percent. When the subjects are restricted to peripheral vision by fixating on the sticker without the goggles, the increase is more than 40 percent; when fixating on the sticker with the goggles, it is 64 percent. For the youngest group these values are 12, 16, and 37 percent, respectively; for the group with mean age of 65.5, these values are 7, 30, and 29 percent, respectively.

IMPLICATIONS—The above results call into question the advisability for the elderly of walking in unfamiliar or uneven environment with bifocal or trifocal corrective glasses.

FUTURE PLANS—Other kinematic variables are now being analyzed, and the data is now being analyzed to determine the amount of visual information used per step.

[50] EFFECT OF REDUCED OPTIC FLOW ON GAIT

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PURPOSE—This study investigates the effect of optic flow on the regulation of locomotion. Numerous studies have shown that a moving visual field can induce the feeling of motion in a stationary subject. Until now, the modulation in locomotion produced by the visual field moving at an apparent velocity that differs from the actual movement velocity of the subject has only been studied in artificial environments for extreme differences (50 percent) between the two velocities. In this study a manipulation was used to create an apparent visual velocity which was slightly different than the subject's actual velocity.

METHODOLOGY—The subjects wore safety goggles (that could fit over corrective glasses) in which the lower rim and the sides were covered with black felt. This blocked at least the first 0.75 m (1.0 m average, range 0.75 to 2.0 m) of the floor when the subject focused straight ahead, thus eliminating the lower part of the optic flow. Since the flow is radial, the amount of change is greatest at the periphery. The subject had no chance to discover how much of the flow is missing and, therefore, would not have been able to correctly interpret how to scale the change that occurs in the visible optic flow.

Two video cameras of the 3-D motion analysis system PRIMAS registered passive markers attached to the neck and the back of the shoes as the subjects walked over a 10 m walkway in a well-lit laboratory. From this data, step length, velocity, and step frequency could be calculated.

Three groups of healthy adults with mean ages of 26.0 (n=10), 65.6 (n=11), and 75.9 (n=9) years were tested.

RESULTS—Preliminary analysis of the data indicates that the decorrelated optic flow created by eliminating the lower portion of optic flow appears to create an apparent visual velocity that is slower than the subject's actual velocity. This resulted in an increased step length. A two-way repeated measures analysis showed that all subjects increased step length in the decorrelated optic flow condition ($p<0.028$). A paired t-test for increase in step length for the oldest group is significant ($p<0.011$). For the oldest group, the increase in velocity in the decorrelated optic flow condition is also significant ($p<0.011$). Other kinematic variables are now being analyzed.

IMPLICATIONS—The effect of optic flow on the modulation of locomotion seems to increase with increasing age.

[51] EFFECTS OF ROBOTIC-ASSISTED WEIGHT SUPPORT ON GAIT AND ENERGY EXPENDITURE

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Sponsor: *None listed*

PURPOSE—Bed rest associated with disease, surgery, or medical treatment results in significant decrements in physiological functions. To facilitate early ambulation by allowing secure posture support and prescribed weight-bearing, a rehabilitation robot, REHABOT®, was developed. The purpose of this study was to validate the functional performance of this device and the physiological responses of the subject by measuring knee joint range of motion, ground reaction forces, gait temporal parameters, and oxygen consumption while walking under prescribed weight bearings. In the first phase of the study, 14 healthy normal subjects ambulated in a circular path around the REHABOT at 0 percent body weight support (BWS), then at 20, 40, and 60 percent. In the second phase of the study, a treadmill was added to the REHABOT to eliminate the circular path, and all the above mentioned parameters were studied and compared with the previous results.

METHODOLOGY—A weight-relieving device (REHABOT) manufactured by the Japan E.M. Co. was used in this study. This device supports the patient's body in an upright position, and reduces body weight by applying a prescribed lifting force through a harness attached to a robotic arm, while allowing the patient to walk in a circular path. Fourteen healthy normal subjects (20–40 years of age) were studied and data was collected at 0 percent, 20, 40, and 60 percent BWS. After placing foot switches under the shoes and mounting triaxial electrogoniometers on knee joints, the subjects were supported by the harness. The subjects were asked to walk eight trials, stepping successfully on the force plates at the four different BWS. Twenty-six channels of analog data were digitized through an A/D converter. Expired gas samples were also collected and VO_2 was analyzed. The same experiment was repeated after adding a treadmill and the same subjects were used. The average speed was the same for both the treadmill and the circular path.

PROGRESS—The first phase of this study has been completed, and data for the second phase has been collected concerning the combination of a treadmill with the REHABOT.

RESULTS—Stance phase duration was longer at 0 percent BWS and decreased with the increase in BWS. At 60 percent BWS the decrease was maximum. Significant difference between the inner and outer stance phase occurred with all increased BWS. Swing and double stance phases followed the reverse pattern. Knee kinematics showed no statistically significant difference between 0 percent to 40 percent BWS, however, at 60 percent BWS, significant changes occurred in mid-stance flexion and total sagittal motion . As for ground reaction analysis, the relevant patterns were similar to normal walking at all the different weight supports. However, the circular pathway produced remarkable changes in the anterior-posterior shear forces, which were lower in the inner leg. The medio-lateral shear force showed a modified pattern due to the circular pathway (e.g., higher mean shear force on the outer leg).

Oxygen consumption showed a gradual decrease from 0 percent to 40 percent BWS ($p<0.05$); however, at 40 percent BWS there was a rise. Comparison between treadmill and circular walking for cadence, stance, swing, and double support duration at the above-mentioned four different weight bearings for right and left legs did not show much difference. As for knee kinematics, both midstance and total flexion slightly increased. Oxygen consumption showed a gradual decrease with increased weight support after using the treadmill with the REHABOT.

[52] SURFACE EMG SIGNAL ANALYSIS IN NORMAL AND PATHOLOGICAL SUBJECTS DURING GAIT BY MEANS OF A NOVEL ALGORITHM FOR ON-OFF TIMING DETECTION

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Sponsor: *None listed*

PURPOSE—In motion studies, the surface myoelectric signal analysis is commonly used to estimate muscle on-off timing in order to correlate muscle activity with the joint kinematics and kinetics. Surface electrodes are comfortable, even during dynamic contraction, and are easy to use and safe. Unfortunately, this technique often leads to poor signal-to-noise ratio and is exposed to crosstalk. Relative movements among active fibers and detection surfaces can also cause large variations in signal amplitude. Typically, on-off timing is obtained by first extracting the signal envelope and then observing time intervals during which the envelope crosses an arbitrarily chosen threshold that discriminates background noise from the signal. This procedure does not allow the user to choose the sensitivity and the specificity of the detection, and this results in unpredictable shapes of the estimated activation pattern.

Our goal is to apply a novel algorithm to obtain on-off timing, based on the statistical properties of the surface EMG signal during gait in normal and pathological conditions. This approach is appealing, because it allows the user to set the specificity and sensitivity of the detector.

METHODOLOGY—Five nondisabled subjects (mean age 32) and 10 total knee replacement (TKR) patients (mean age 64.8) were assessed at 3 and 6 months, 1 and 2 years post-op. Raw surface EMG signals (homolateral and contralateral longissimus dorsii, gluteus medius, rectus femoris, hamstrings, tibialis anterior and gastrocnemius) were acquired by means of an eight-channel system and processed by means of the statistical detection algorithm mentioned above for on-off time detection. The processing chain consists of a whitening filter that relies on the Burg algorithm and a statistical detector based on a double threshold technique.

RESULTS—The surface detected myoelectric on-off pattern on the nondisabled population for the explored muscles agreed with data previously reported in the literature, which had been obtained by means of indwelling electrodes. A high intra-subject repeatability of activation intervals was found. With respect to the linear envelope obtained from the same signals, in which we found a high variability of the profiles, the timing component detection of the muscular activity is very reliable and repeatable. In the patients who had TKR, the first post-op muscle activation pattern is remarkably different from the nondisabled one.

The patients displayed in the early follow-up prolonged activity of most muscles, and particularly of the homolateral and contralateral longissimus dorsii, rectus femoris and hamstrings during stance phase, tibialis anterior until late stance phase, and a premature activation of gastrocnemius. This pattern tends to normalize at 1 and 2 years post-op mainly with respect to the lumbar and the shank muscles activity, but a prolonged activity of rectus femoris and hamstrings seems to persist for a long time.

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[53] OPTIMAL RIGID BODY DEGREES OF FREEDOM ESTIMATION IN MOVEMENT ANALYSIS

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Sponsor: *None listed*

PURPOSE—Obtaining reliable estimates of the degrees of freedom (DOF) of human body segments represents a critical feature that normally concerns every laboratory of movement analysis. This study deals with accurate estimation of the 6 DOF of a human body segment, starting from landmark trajectories acquired with a suitable measurement system, using smoothing algorithms and optimization techniques. Its aim is to suggest methods to reduce the effects of the instrumental inaccuracies concerning human movement analysis.

METHODOLOGY—The study began with the implementation of a smoothing algorithm derived from a widely known digital filter obtained by using a second-order Butterworth filter bidirectionally. The innovative feature was the algorithm's capability to self-determine the optimal cut-off frequency by maximizing a residual's whiteness measure. Filter algorithm performances have been compared with those of a heptic spline function smoothing scheme, based on the generalized cross-validation criterion (GCVC). After that, an iterative algorithm which estimates the translation and orientation vectors of a moving rigid body from noisy marker measurements through a weighted least-squares (WLS) procedure was introduced.

If markers are mounted on a rigid framework and the local model of the array is known, it can be used to assess the body segment DOF in each sampled instant of time. That can be done by calculating the translation and rotation which, frame by frame, match, in the best possible way, the array model to the actual array as it has been observed by the measurement system. Both rigidity constraints and anisotropic properties of measurement noise were taken into account in order to improve estimation quality.

A method for estimating the unknown array rigid model starting from the markers trajectories was also introduced. It is essential, especially when the array is not rigid as in the case of skin placed markers. Both the optimization and the filtering routines have been singularly tested and validated on simulated and collected data.

Finally, the performances of four different strategies, combining smoothing and optimization techniques in different ways, were evaluated. The reconstruction and smoothing schemes were analyzed and tested and their performances were compared with each other and with those of a more traditional technique that does not incorporate any optimization criteria. Testing has been carried out on synthetic sequences, which simulate the trajectories of four plate-mounted markers fixed on a thigh and video-recorded during the execution of physical exercises. The test signals have been then corrupted by adding normally distributed random sequences, simulating additive measurement noise.

RESULTS—The filter performances have been superior to GCVC, especially when considering signal derivatives and time requirements. The use of WLS method has shown good results when implemented in situations where the array model is easily settled. The results of combining schemes have shown that filtering the segment DOF previously reconstructed from rough coordinates can be as effective as reconstructing the DOF after filtering the marker coordinates. Moreover, they suggest that the use of an optimization routine provides a visible improvement in DOF reconstruction.

RECENT PUBLICATION FROM THIS RESEARCH

New weighted least squares and smoothing scheme for kinematic analysis: application to instanteneous helical axis determination. Angeloni C, Cappello A, Magnani G, Leardini A. In: Proceedings of II International Symposium on 3D Analysis of Human Movement; Poiters, 1993.

Optimal estimation of rigid body position and attitude from noisy marker coordinates. Magnani G, Angeloni C, Leardini A, Cappello A. In: Abstracts of XIV Congress of ISB; Paris, 1993.

Selection and validation of skin array technical references based on optimal rigod model estimation. Cappello A, Leardini A, Catani F, LaPalombara F. In: Proceedings of III International Symposium on 3D Analysis of Human Movement; Stockolm, 1994.

[54] GAIT ANALYSIS IN TKR PATIENTS

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Sponsor: *None listed*

PURPOSE—Gait performance after total knee replacement (TKR) has been evaluated by many different authors, who point out some residual postoperative gait disfunctions. The problems they examined included implant geometry, ligament sparing, patellar resurfacing, proprioception alterations, muscular weakness, preoperative gait pattern, and other joints arthritic involvement. The aim of this work is to assess gait in patients who underwent TKR and were followed post-operatively; to verify that the amount of time needed for normalization of the kinematics, the dynamics, and the myoelectric activity of the agonist and antagonist muscles of the operated knee; and to verify that neither the knee joint nor the adjacent joints were subjected to overloading.

METHODOLOGY—Twelve TKR patients (mean age 64.8) operated for primary osteoarthritis have been assessed. The TKR patients were assessed at 3 and 6 months, 1 and 2 years post-op. The type of prosthesis used is not cemented, is posterior cruciate ligament sparing, and enables early weight-bearing. No patellar replacement was performed. Patients underwent, in different follow-ups, a functional rehabilitation program aimed at restoring a sufficient range of motion, strenghtening quadriceps, and improving proprioceptive control. Gait analysis was performed through an ELITE System (BTS) for kinematics, a KISTLER Platform for GRF and a TELEMG (BTS) for surface EMG. Both the calculation of the position of anatomical landmarks during movement with the experimental procedure "Calibrated Anatomical System Technique" (CAST), and the design of relative anatomical reference systems were obtained according to the systems decribed by Cappozzo.

PROGRESS—Thorough review of relevant literature has been accomplished. Gathering of walking data from the patients is in progress for the latest follow-up at 2 years.

RESULTS—To date results obtained demonstrate that: 1) 1 year after surgery, the operated knee presents almost normal joint kinematics in conjunction with reduced velocity; 2) a reduction in knee flexion during midstance and a reduction in the flexion joint moment is present, a pattern which seems to be due both to a deficiency of the extensory apparatus and to an attempt to stabilize knee joint in order to reduce contact and shear forces; 3) the kinematics in the horizontal and frontal planes are almost physiological, indicative of a good prosthetic design; 4) the adduction moment is normal or reduced after 1 year, demonstrating a physiological load in the medial compartment; 5) the extensory knee pattern during the loading response phase and the midstance phase is associated with prolonged activity of quadriceps and hamstrings in co-contraction, which is probably due to different causes including a reduction in the strength of quadriceps, a pattern of walking learned before the operation, an attempt to reduce the joint compressive and shear forces, the presence of pain, and an alteration in proprioception; and 6) there is not any overloading of the adjacent joints.

RECENT PUBLICATIONS FROM THIS RESEARCH

Quadriceps activation pattern evaluation during gait in subjects operated on TKR. Catani F, Benedetti MG, Battistini A, Leardini A, Marcacci M, Giannini S. Gait Posture 1994:2(1):63.

Gait analysis in patients operated on TKR, Catani F, Marcacci M, Benedetti MG, Battistini A, Leardini A, Giannini S. J Biomec 1994:27(6):827.

TKR extensor mechanism during gait in a short follow-up: 3-6 months and 1 year post-op, Catani F, Marcacci M, Benedetti MG, Battistini A, Leardini A, Giannini S. In: Proceedings of the Second World Congress of Biomechanics, Amsterdam, July 1994.

Valutazione funzionale delle protesi d'anca, ginocchio e tibio-tarsica, Giannini S, Catani F, Benedetti MG, Leardini A, Ghetti M. G Ital Orthop T 1994:20(Suppl 2):769-81.

C. Other

[55] WHEELCHAIR PROPULSION PERFORMANCE IN YOUNG, MIDDLE-AGED, AND ELDERLY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B764-RA)*

PURPOSE—Results from a pilot study of wheelchair propulsion suggested some age-related trends in wheelchair propulsion and that certain interventions (i.e., therapeutic exercises that stretch or strengthen certain muscle groups) might prevent specific types of overuse injuries. The purpose of this 3-year continuation research program is twofold: to investigate how wheelchair performance compares among three different age groups of disabled (lower-limb impaired) wheelchair users; and to test a specific exercise intervention for its effectiveness in reducing potential injury-producing biomechanical characteristics and excessive physiologic stresses.

METHODOLOGY—A total of 60 wheelchair users in three age groups of n=20 (20–39, 40–59, and 60–79 years) will participate in this study. Body measurements, muscle strength, neuromuscular assessments, and wheelchair propulsion testing are performed before and following exercise training. The first wheelchair graded exercise test includes incremental increases in wheelchair handrim resistance to determine peak physiologic responses. The second test is a prolonged fatigue test consisting of wheelchair propulsion exercise at 75 percent peak oxygen consumption (VO_2) until volitional fatigue is achieved. Handrim force, wheel velocity, heart rate, and VO_2 are monitored during each data collection session.

Upper-extremity and trunk movement are videotaped using a three-dimensional motion analysis system to obtain kinematic data. Surface electromyography is used to document upper-extremity muscle activity patterns during testing. Shoulder, elbow, and wrist joint kinetics (joint moments and joint reaction forces) are calculated from the motion and handrim force data. After initial testing, each subject participates in a specific intervention program of therapeutic exercise (stretching/strengthening and aerobic training) 3 times weekly for 6 weeks. Wheelchair tests are repeated at the end of the training program to determine changes in stresses.

PROGRESS—A total of eight subjects have completed the pretesting (using the specially designed wheelchair ergometer), 6-week training period, and post-testing. The program has now been transferred to Baltimore VAMC. All testing and training equipment is being reassembled and calibrated. Institutional review board approval has been obtained and subject recruitment has been initiated.

PRELIMINARY RESULTS— The first eight subjects were paraplegic individuals (age 47±14 yrs; weight 78±24 kg; lesion level T3-L5; six male, two female), nonathletes, and had been wheelchair users for 3 to 38 yrs (19±12 yrs). Results for these subjects showed a significant increase in weights for all free weight exercises (mean increase of 97 percent) during the 6-week training period. VO_2 significantly increased following training from 1.0±0.3 to 1.4±0.1 mL/m. Increases in time to fatigue and power output were not significant for this small sample. Analysis of kinematic and kinetic data is in process. These preliminary data support the efficacy of this exercise intervention program for reducing stresses in everyday wheelchair users.

FUTURE PLANS—Testing and exercise training will continue until the desired sample size is reached (n=60). Determination of age-related characteristics, which are related to high joint stresses, and evaluation of potential injury-reducing interventions are expected

to provide the necessary foundation for improving wheelchair function.

RECENT PUBLICATIONS FROM THIS RESEARCH

Initial findings from an exercise program for nonathletic wheelchair users. Rodgers MM, Gayle GW, Gupta SC, Figoni SF, Parker WD, McCarty T, Glaser RM. In: Proceedings of the APTA Combined Sections Meeting. In press.

Biomechanics of wheelchair propulsion during fatigue. Rodgers MM, Gayle GW, Figoni SF, Kobayashi M, Glaser RM. Arch Phys Med Rehabil 1994:75:85-93.

Three-dimensional dynamic analysis of joint reaction forces and moments during wheelchair propulsion. Rodgers MM, Tummarakota S, Lieh J, Schrag DR. J Biomech 1993:26:346.

[56] CHARACTERIZATION OF NORMAL AND PATHOLOGICAL SWAY DYNAMICS

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Sponsor: *The Fund for the Promotion of Research at the Technion*

PURPOSE—This is a continuation of a previous study in which the dynamic patterns of postural sway were characterized for normal and pathological populations, using the bilateral foot-ground reactions forces. A biomechanical model, based on closed-loop dynamics is being developed. The purpose of this model is to enable us to predict the dynamics of postural sway from the previously defined and developed parameters. Additionally, the muscle forces responsible for producing these dynamics are being evaluated. Model criteria for the characterization of pathological postural sway dynamics are being developed.

METHODOLOGY—Postural sway is measured by two force platforms collaterally installed for adjacent positioning of the feet during standing. The parameters monitored include: all components of the foot-ground reaction forces, the center of pressure of the vertical forces, and EMG of the muscles of the lower legs. Defined parameters including sway activity, asymmetry, weight-bearing imbalance, and relative sequence of the forces are being correlated with the variations in center of pressure and with the EMG and incorporated into a closed loop dynamics model including five body segments.

RESULTS—The results obtained so far are from 32 nondisabled subjects, 14 persons with below-knee amputations (BKA), 16 post-stroke patients, and 10 patients after cranio-cerebral injuries (CCI). It is shown that there exists a typical swaying pattern for each of the groups studied. Furthermore, it is concluded that the swaying parameters can be used as indicators for monitoring and for prognosis of the locomotor functional outcome of post-stroke and CCI patients. The postural stability of BKA's is shown to be initially affected due to a proprioceptive deficit as a result of partial limb loss. However, this effect tends to gradually decrease with time due to the development of compensation processes. The preliminary model results enable us to predict the swaying frequency and amplitude for given conditions of asymmetry and weight-bearing imbalance.

FUTURE PLANS—It is planned to complete the developed model. Data on the reactive forces will be used to input the boundary joint torques. Solution of the model will provide the resulting body sway for the patterns identified. When combined with the EMG measured data, it will be possible to study the role of the leg muscles in controlling body sway.

RECENT PUBLICATIONS FROM THIS RESEARCH

Influence of prosthesis alignment on the standing balance of below-knee amputees. Isakov EK, Mizrahi J, Susak Z, Onna I, Hakim N. Clin Biomech 1994:9:258-62.

[57] QUANTITATIVE FUNCTIONAL ANATOMY OF THE UPPER EXTREMITY

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PURPOSE—Our goal is to collect the musculoskeletal parameters for the shoulder and arm for biomechanical modelling of the upper extremity. Much of the clinical and ergonomical problems in the shoulder are the result of the complex coordination of the muscles involved in the control of shoulder movements and joint stabilization. This complexity of the human shoulder and arm can not directly be studied, but needs the application of a biomechanical model. In addition, the three-dimensional nature of upper extremity motion and the covert motions of the scapula, require a highly sophisticated three-dimensional movement analysis.

Quantitative data on the morphology of shoulder and arm are needed as a basis for:

1. analysis of the load on the shoulder and arm, based on arm movement registration in wheelchair propulsion, activities of daily living (ADL) and vocational activities;
2. analysis of the outcome of shoulder arthrodeses;
3. interpretation of *in-vivo* human palpation data.

PROGRESS—To date, morphological parameters have been collected on the shoulder mechanism. These data form the basis for a three-dimensional biomechanical model of the shoulder. With the use of the model, it is now possible to calculate muscle forces, tensions in ligaments, and reaction forces in joints of the shoulder. In addition, data on the morphology of the elbow and forearm, as well as accurate joint descriptions, have been collected; these are presently being included in the model. Parallel to the model development, 3-D measuring techniques have been developed.

RESULTS—The program has been proven to be useful in the development of a sophisticated 3-D model of the shoulder mechanism that has been applied in the prediction of optimal fusion angles of shoulder arthrodeses after injury of the brachial plexus, in the analysis of the positioning of endoprostheses and operation techniques used, and in the quantification of mechanical load on the shoulder joint in manual wheelchair propulsion.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Muscle power in the shoulder girdle during wheelchair propulsion. Scheijndel PAM van, Baan Hofman M, Veeger HEJ, van der Helm FCT. Abstract: 2nd World Congress on Biomechanics, Amsterdam, 1994:II-307b.

Quasi-static analysis of muscle forces in the shoulder mechanism during wheelchair propulsion. van der Helm FCT, Veeger HEJ. J Biomech. In press.

[58] COORDINATION OF MUSCLES IN GAIT

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Sponsor: *Netherlands Organization for Research, Foundation of Biophysics*

PURPOSE—The coordination of lower limb muscles has been studied in explosive movements of the lower limb. Rules for coordination of biarticular leg muscles were formulated and tested in movements and in sim-

ulation studies. Recently the work has been extended to arm functioning. Neuronal network modelling is used for studying the learning aspects of coordination.

METHODOLOGY—Inverse dynamic modeling of running and walking in combination with simulation of various forms of jumping are used. For modeling, data are acquired with high speed film and (from 1991 onward) by using VICON system, force platform and EMG. For simulation, a SPACAR package is used.

PROGRESS—Biarticular muscles play a unique role in transporting rotational energy from proximal to distal segments when a person jumps up. The muscles contribute to the mechanical goal of the movement: maximizing effective power at take off. They compensate for the diminishing contribution to translation of the body's center of gravity by extension (rotation) of lower limb segments.

Timing of the activation of these muscles, as well as the fact that they co-contract with their antagonists, is important. In bicycling it appeared essential that such co-contractions were instrumental in producing thrust, as well as direction of movement in the extending limb.

These concepts were validated in human walking and running by experimenting and modeling. In gait, biarticular hamstring and rectus femoris muscles are active in early stance. They co-contract with monarticular hip and knee extensors, and tune hip and knee movements while the leg is shortening and lengthening (knee flexion in early stance), regulating the level of potential energy.

RESULTS—Simulation proved most of the above mentioned concepts. A sensitivity analysis, concentrating on length of momentarms of biarticular muscles, was conducted. In simulations of jumps, disturbances are not corrected by changes in stimulation patterns but by mechanical properties of muscles. Various starting positions result with one stimulation program in nearly optimal performance. From the study of running it appeared that biarticular muscles distribute net moments in ballistic leg extensions. Optimal coordination is regulated with the aim of efficiency of expenditure of mechanical energy by monoarticular and biarticular muscles. Arm movements are studied in which the directions of force application and movement are not identical.

FUTURE PLANS—Learning of the optimal stimulation pattern will be analyzed by conducting simulations of a mechanical nature and simulations of neural networks. Wheelchair propulsion will be analyzed.

RECENT PUBLICATIONS FROM THIS RESEARCH

The influence of the biarticularity of the gastrocnemius muscle on vertical jumping achievement. Van Soest AJ, Schwab AL, Bobbert MF, Van Ingen Schenau GJ. J Biomech 1993:26(1):18.

III. Functional Assessment

[59] RANK-ORDERED REGULATION OF MOTOR UNITS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B749-RA); Liberty Mutual Insurance Company*

PURPOSE—This study was undertaken to investigate the firing rate behavior of motor units in the whole force range of the muscle. The relationship, if any, between the recruitment threshold and firing rate behavior is an important issue that has significant bearing on the control of motor units in the generation of muscle force. A thorough understanding of the mechanisms involved in normal force generation will be the groundwork for developing tools to diagnose and treat individuals with impaired motor function.

METHODOLOGY—Myoelectric signals were detected from the tibialis anterior muscle of five nondisabled subjects with a special quadrifilar needle electrode during voluntary isometric contractions. The subjects generated isometric forces that linearly increased up to the maximal voluntary level. The firing behavior of motor units were studied by plotting average firing rates as a function of the corresponding force output. The use of specialized data acquisition and processing techniques enabled the investigation of a wide range of motor units, in contrast to previous studies which had been limited to only the low-threshold motor units due to technical difficulties.

RESULTS—The analysis of data revealed a highly rank-dependent ordering of various parameters of a motor unit, such as the mean firing rate, initial firing rate, and the response to the requirement to increase the force output. In other words, the properties of motor units did not appear to be randomly distributed but highly rank-ordered as a function of recruitment threshold. This observation supports the previously advanced theory of common drive, which states that motor units of a motoneuron pool are controlled not by individual control signals but by a common command signal. The rank-ordered distribution of motor unit properties would make it possible for motor units to respond differently even though they receive the same input.

RECENT PUBLICATIONS FROM THIS RESEARCH

Common drive of motor units in regulation of muscle force. Erim Z, DeLuca CJ, Mineo K. Trends Neurosci 1994:17(7):299-305.

[60] COMMON DRIVE OF MOTOR UNITS: IN NUMERO EXPERIMENTS

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PURPOSE—The concept of common drive is based on the observation that motor units active in a contraction modulate their firing rates in a highly interdependent manner, whereby an increase or decrease in the firing rate of one motor unit is accompanied by similar changes in the firing rates of other units. It is important to understand this behavior of motor units if we are to understand how muscles generate force. The

objective of this study was to conduct a series of computer experiments to explore the phenomenon of common drive.

METHODOLOGY—We developed a software package, called NEUROSIM, which simulates a population of motoneurons that receive signals from a common drive and independent sources (i.e., excitatory and inhibitory sources). The software package permits the user to set interactively each parameter affecting the modeled system. In this study, NEUROSIM was used to test the following null hypotheses concerning the possible form of the common drive: 1) it is a (noisy) tonic activation signal, 2) it is a (noisy) periodic signal, 3) it is a (noisy) quasi-periodic signal, and 4) it is a correlated noise signal. These hypotheses were tested by comparing the output of the computer model with experimental motor unit firing data.

RESULTS—We found that the first three null hypotheses could be rejected: the numerical results for each case were significantly different from the experimental motor unit firing data. However, the forth null hypothesis could not be rejected: the numerical results for a common drive made up of correlated noise were not significantly different from the experimental data. In order to match the experimental results closely, we found that the correlation time of the common-drive noise had to extend over several motor unit firings and each motor unit also had to be influenced by a particular level of independent noise. These novel findings provide insight into the possible functional organization and regulation of populations of motor units.

[61] EFFECTS OF HAND DOMINANCE ON MOTOR UNIT FIRING BEHAVIOR

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PURPOSE—Preferential use of a muscle has been shown to alter its physiological and mechanical properties. Our previous studies, as well as the work of other investigators, suggested a higher fatigue resistance and possibly a higher percentage of slow-twitch fibers in the dominant hand. The present study is aimed at revealing any differences in the physiology and control properties of contralateral muscle pairs in individuals who show a clear preference for one hand. The results of this study will enhance our understanding of skilled motor activity and the relationship between physical exercise and control properties of motor units.

METHODOLOGY—The first dorsal interosseous muscle in the dominant and nondominant hand of three right-handed and four left-handed male subjects was tested at a force level of 30 percent of the maximal voluntary contraction.

RESULTS—The firing rates of motor units in the dominant hand were lower when compared to motor units of similar recruitment threshold in the nondominant hand. The lateral difference in average firing rates was statistically significant in right-handed but not in left-handed subjects, possibly due to a certain level of ambidexterity among the latter. Common fluctuations of mean firing rates for pairs of motor units did not differ in phase or amplitude with respect to handedness, but the force had a greater delay with respect to motor unit firing rates in the dominant hand. No difference was seen in maximal voluntary contraction strength between the dominant and nondominant sides. The observations of lower firing rates and greater firing rate-to-force lead times in the dominant hand are consistent with the notion of an increased percentage of slow twitch fibers in the preferentially used muscle. Slow twitch fibers are capable of twitch fusion at lower contractile rates, allowing the motor units of the dominant muscle to generate force at lower firing rates in comparison to the nondominant muscle.

[62] FIRING PATTERNS, FIRING RATE BEHAVIOR, AND FORCE GENERATION OF MOTOR UNITS

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PURPOSE—We know that the motor units of healthy muscles are controlled by a common drive. We wish to categorize the behavior of the firing rates of motor units so that ultimately the normal behavior may be used as a point of reference to distinguish and quantify abnormal behavior in diseased and dysfunctional muscles.

METHODOLOGY—A series of muscle contractions collected from the first dorsal interosseous muscle of normal subjects was collected to obtain information about the firing times of a group of motor units. Additionally, we investigated the associated force produced by their firing and the relationship between their size (measured by macro electromyography) firing times and the force (the electromechanical lag). The raw firing data were converted from asynchronous time series to regular interval firing sequences through an interpolation algorithm. The resulting sequences were analyzed both individually and in comparison with the force data.

RESULTS—Analysis of the firing rate sequences for a group of motor units revealed that when the average of instantaneous firing rates of all the active units is subtracted from their individual firing rates, the residuals fall into a Gaussian distribution around the mean. Further, the average itself follows a Gaussian distribution. When this average is plotted, it generates a histogram similar to that of the force plot, albeit with the force lagging about 100 ms after the firing rates (the electromechanical lag). Additionally, when peaks of individual firings of motor units are compared to peaks in the force, an electromechanical lag emerges which can be measured for each unit. This varied between 90 to 120 ms in our subjects. Since the average of the instantaneous firing rates is common to all the active units, we surmise that it bears a relationship to the common drive itself.

[63] A BIOMECHANICAL ANALYSIS OF THE SIT-TO-STAND MOTION: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #A92-487AP)*

PURPOSE—The ability to rise from a seated position is critically important for maintaining independence. Elderly people and people with neurologic dysfunction, such as Parkinson's disease or stroke, commonly have difficulty completing the sit-to-stand motion. The purpose of this pilot project is to develop and validate a system to characterize the fundamental differences between successful and unsuccessful performance of the sit-to-stand motion. The system will be used to identify elements of the sit-to-stand motion that are essential to successfully rise from a chair.

METHODOLOGY—An adjustable instrumented chair has been designed and fabricated. After calibration, the chair will be used to characterize the sit-to-stand motion in conjunction with existing systems that measure three-dimensional kinematics and ground reaction forces. We will collect data during the sit-to-

stand motion for 10 patients with Parkinson's disease and 10 age-matched nondisabled controls.

Objective measures of the sit-to-stand motion will be developed using the three-dimensional kinematics and the reaction forces on the chair seat, armrests, and ground. These measures will be used to characterize performance differences between the patients with Parkinson's disease and the controls, and between unsuccessful and successful trials of the patients with Parkinson's disease.

PROGRESS—We have designed and fabricated an adjustable instrumented chair as part of a system to evaluate the sit-to-stand motion as a complete functional task. The chair is instrumented to independently measure the vertical and horizontal forces on the seat and each of the armrests. Strain gage-based triaxial force transducers were designed and fabricated for the seat of the chair. Signal conditioning circuits have been designed and fabricated for the force transducers, and incorporated into the data acquisition system for the chair. The height of the seat, the height and spacing of the armrests, and the anterior-posterior position and height of the back support are independently adjustable. All of these adjustments can be made while a subject is seated in the chair. The seat and armrest surfaces will accommodate a variety of padding and grip materials. We are currently calibrating the force transducers and data acquisition system. Also, we are working with the Physical Medicine and Rehabilitation Service to finalize the subject testing protocol, and with the Neurology Service to identify prospective patients with Parkinson's disease for participation in this study.

IMPLICATIONS—This pilot project will serve as the basis for future research to develop and assess the effectiveness of rehabilitation programs for patients whose independence is compromised by their inability to safely rise from a chair. These treatment/intervention strategies can be integrated into the health care provided at VA Medical Centers, including Adult Day Health Care and Nursing Home Care Units. The system developed in this pilot project will also be used in future studies to evaluate modifications in chair design to facilitate the successful performance of the sit-to-stand motion. The advances in rehabilitation treatments, intervention strategies, and chair design resulting from this research will help to prolong functional independence in veterans with impaired functional abilities.

[64] CORRELATES OF MOTOR UNIT SIZE, RECRUITMENT THRESHOLD AND H-REFLEX JITTER

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Sponsor: *Boston VA Medical Center*

PURPOSE—The H-Reflex jitter is related to various properties of the anterior horn cell (AHC). It can be a function of its input resistance, its recruitment threshold, ascending and descending influences on it, and of the synaptic transmission itself. This study allowed us to shed some light on the following questions: How does the H-Reflex jitter relate to all these variables; and how is it affected by them? Would its study give us information about the size and recruitment behavior of the AHC? Is there a difference in H-Reflex jitter between men and women, and does the central synapse age in the same fashion as the peripheral, neuromuscular synapse? These measurements may provide an avenue for the investigation of AHCs *in situ* in patients with spasticity, and AHC disease as well as the study of the effect of different drugs on AHC and central synaptic function.

METHODOLOGY—The H-Reflex was studied in the flexor carpi radialis muscle by stimulating the median nerve at the elbow and recording from the belly of the muscle using a single fiber electromyographic electrode. Twelve men and 7 women, aged 20 to 80 years were studied. An action potential in the 15 to 25 ms latency range was sought at low stimulation strengths (25 to 100 V). The subject was then given a

series of shocks at 0.5 pulses per second. After 50 stimuli, single fiber H-Reflexes were superimposed, 10 at a time, and their jitter was calculated.

RESULTS—The mean H-Reflex jitter was 137.99±58.89 μs. H-Reflex jitter increased with age (while the M-Reflex jitter did not) and was greater in men than in women. There was a direct correlation between the H-Reflex jitter and the AHC's input resistance with smaller AHCs, with high input resistance, showing a greater H-Reflex jitter than larger AHCs with low input resistance. The H-Reflex jitter can be used as a direct indicator of AHC size. When subjects fell asleep, the H-Reflex jitter increased more than 10 fold over the baseline value, raising the possibility of an alternative, oligosynaptic pathway for the H-Reflex.

[65] DEVELOPMENT OF AN ADULT CLINICAL VERSION OF THE TUFTS ASSESSMENT OF MOTOR PERFORMANCE (TAMP)

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PURPOSE—The Tufts Assessment of Motor Performance (TAMP) was designed to provide a diagnosis-independent clinical assessment of human functional motor performance and to provide a comprehensive evaluation of physical function across all disability types and across all ages. Its purpose is to examine motor performance in sufficient detail to assist with treatment planning and to adequately describe and identify meaningful clinical change in motor abilities. The TAMP is a standardized measurement tool that samples a broad range of physical skills in the areas of mobility, activities of daily living (ADL), and physical aspects of communication. Multiple measurement dimensions are employed to assess various levels of disability.

Experience has shown that the TAMP as designed was not fully applicable to young children, and because of its length not practical in clinical settings. A version practical for use in clinical settings was created specifically for the pediatric population. This version, the Pediatric Evaluation of Disability Inventory or PEDI, was developed for clinical evaluation of children with physical disabilities and is currently being used in many pediatric clinical rehabilitation settings. Because the PEDI was designed specifically for the evaluation of children, it is not applicable for the evaluation of adults. The purpose of the current project is to develop a revised version of the research TAMP specifically designed for clinical use in adult rehabilitation populations.

METHODOLOGY—The TAMP is administered by having subjects perform a number of motor tasks. Each task is broken down into three components. Subjects are evaluated by a physical or occupational therapist on their ability to complete each segment, as well as being timed on the entire task.

PROGRESS—Testing to date has been completed on 80 adult subjects including pilot testing. Data collection will last until May 1995 with the minimum goal of 120 subjects. Rasch analysis will be a primary analysis technique. Data will be analyzed to develop an item hierarchical model, item difficulty estimates, and interval level summary scores. Repeat testing will occur for some subjects in order to develop inter-rater reliability and test-retest estimates. TAMP data will be compared to FIM data collected on a subset of subjects to cross-validate the TAMP.

FUTURE PLANS—A manual is being developed for the final version of the Adult Clinical TAMP which will include all instructions necessary to utilize the test in a variety of clinical environments. A computer software program is also being developed to automatically store and score TAMP data. Further dissemina-

tion of the TAMP will be in the form of publications in peer reviewed journals and presentations at national rehabilitation meetings. Final development of the Adult Clinical TAMP and administrative/scoring manual is expected to be completed by October of 1995.

[66] ASSESSMENT OF THE RELIABILITY AND VALIDITY OF THE PEDIATRIC EVALUATION OF DISABILITY INVENTORY (PEDI)

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Sponsor: *The Hospital for Sick Children Foundation*

PURPOSE—The recently developed Pediatric Evaluation of Disability Inventory (PEDI) is a functional assessment measure intended for evaluation of young children (ages 6 months to 7 years) with chronic illness or physical disability. The PEDI is a judgment-based assessment completed by rehabilitation professionals and parents as they reflect on the function of children in their home, school, and therapy environments.

The PEDI includes three domain areas comprised of eight self-care areas, seven mobility areas, and five social function areas; it is divided into three theoretical measurement dimensions: Functional Behaviours and Skills (Part 1), Assistance by Caregivers (Part 2), and Modifications/Adaptive Equipment Required (Part 3). It has been standardized on a sample of non-disabled children between the ages of 6 months and 7 years. We undertook in this study to evaluate the PEDI's reliability, validity, and responsiveness when used with 40 children with varying severities of cerebral palsy, aged 3 to 7 years inclusive, seen as clients at the Hugh MacMillan Rehabilitation Centre or at Bloorview Children's Hospital, both in Toronto, Canada.

METHODOLOGY—A 3-week test-retest interval was chosen for assessment of intra- and inter-rater reliability of Parts 1 and 2. The PEDI was completed on two separate occasions by the child's primary caregiver, physiotherapist, occupational therapist, and classroom teacher. Data were analyzed according to these four respondent groups for the inter-rater reliability component. Concurrent validity evaluations included estimation of the strength of correlations between PEDI scores and those of actual performance of the PEDI tasks, as well as on two validated measures: the Gross Motor Function Measure (GMFM) and the Battelle Developmental Inventory Screening Test (BDIST). Responsiveness was estimated using change scores obtained from administration of the PEDI 6 months after the baseline evaluation.

PROGRESS—The test-retest reliability of Part 1 was excellent within each respondent group for all of the three domains of self-care, mobility, and social function ($0.80<ICC<0.98$; $SEM<4.0$). Inter-rater reliability estimates at baseline for the various respondent group comparisons (i.e., PT vs. parent) were fair to excellent for the three domains ($0.72<ICC<0.86$; $SEM<8.5$). Differences between Part 1 scores by PTs/OTs and parents were significant ($p<0.001$), perhaps reflecting differences in abilities in the classroom and in the home. For Part 2, there was good inter and intra-rater agreement (weighted kappas >0.65). In both Parts 1 and 2, reliability estimates were highest for the Self-Care domain, and lowest for Social Function, which respondents noted was harder to rate.

Results from the validity assessments included the following: PEDI total score and GMFM total, $r=0.75$; PEDI mobility domain and GMFM total, $r=0.85$; PEDI total and BDIST total, $r=0.81$; PEDI social function domain and BDIST total, $r=0.59$. The data also confirmed the PEDI's responsiveness to change over a 6-month time period in rehabilitation settings in which small, gradual gains are expected. Evaluation is still needed with children in whom greater change may occur, to give estimates of maximum responsiveness.

IMPLICATIONS—It is essential to have valid instruments to measure change in functional abilities in the cerebral palsy population in order to assist with

both treatment planning and service evaluation. Results from this study indicated strong inter-rater reliability for the Pediatric Evaluation of Disability Inventory. The influence of the environmental context on inter-rater reliability warrants further investigation. Evidence of good concurrent validity of the PEDI has also been documented. Given these satisfactory reliability and validity results, the PEDI has strong potential as a clinical, research, and evaluation instrument for use with children with cerebral palsy up to the age of 7 years.

RECENT PUBLICATIONS FROM THIS RESEARCH

Critique of the pediatric evaluation of disability inventory (PEDI). Reid DT, Boschen K, Wright V. Phys Occup Ther Pediatr 1993:13:57-87.

Pediatric evaluation of disability inventory (PEDI): validation of a new functional assessment outcome instrument. Wright V, Boschen KA. Can J Rehabil 1993:7:41-2.

[67] AN INTEGRATED, COMPUTER-MANAGED SYSTEM FOR CLINICAL MOTOR (DIS)ABILITY ASSESSMENT

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PURPOSE—The definition of disability given by WHO is of poor use to devise a procedure for (dis)ability assessment. It is more effective, instead, to define disability as the breakdown of a motor skill: the poorer the motor skill, the lower the automaticity in performing a motor task (i.e., the stronger the dependence on cognitive and/or perceptual guidance). The system we have implemented is based on the evaluation of this dependence in level walking by assessing the residual motor ability. The most relevant kinematic and dynamic parameters of gait are obtained by using the procedures and the already existing instrumentation for movement analysis (MA). In order to investigate how much the recovered motor skill still depends on the cognitive and perceptual systems, auditory and/or visual disturbances (secondary tasks) are reproduced during the performance of motor tasks (primary task). A few ad hoc tools have been devised to implement perceptual and cognitive tasks. It was mandatory to exploit telecontrol and telemetry to limit the influence of system-patient interaction on the motor response.

METHODOLOGY—The system is composed of four functional blocks: a set of tools to implement the perceptual/cognitive tasks, movement data acquisition instruments, a trial manager through which all these devices operate, and a data analysis module. The following secondary tasks have been used. To determine visual dependence, impaired vision has been simulated by means of liquid-crystal spectacles that can be turned transparent or opaque by means of a radio control. To determine cognitive dependence, an auditory task has been implemented by means of a voice synthesizer and recognizer device, radio-linked to a headphone-microphone set. The patient has to recognize the pitch of a message, which could not correspond to the meaning of the message itself. Response correctness and delay are recorded. To determine sensory-motor adaptability, the patient is asked to approach a step and to walk on it without decreasing velocity, or to step right or left in response to a randomly activated light signal managed by computer via radio link. Movement acquisition instruments are: a 3-D opto-electronic system, a force platform of any kind, and a 2.5 m long pressure platform.

PROGRESS—Preliminary trials revealed that, even in healthy subjects, the cognitive/perceptual task interferes with the motor task, and that subjects are better off not knowing what type of task they will be asked to perform. This avoids artifacts due to anticipation. Walking velocity, stride breadth, pelvic rotations, step length and frequency, and the score of the auditory task are the most significant parameters. The method was first applied to nondisabled subjects. Patient cate-

gories that present a well-known pathology (e.g., amputees) have been selected. The degree of variability of the motor response is closely correlated to the level of rehabilitation, which indicates a certain amount of reautomatization of gait.

FUTURE PLANS—The dual task approach seems to be a promising technique for (dis)ability assessment. A few drawbacks emerged during our early experiments: the anticipatory response cannot be avoided completely, but its effects must be minimized further on, and the number of trials and hence the number of tasks should be reduced to not fatigue the patient too much. Our system is intended as a workbench to validate the approach while improving the implementations of the secondary tasks. Meanwhile, it will allow us to gather information useful to design more specific, cost-effective instruments for clinical use.

[68] SYNCHRONOUS BEHAVIOR OF MOTOR UNIT FIRINGS

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PURPOSE—The physiological purpose of the synchronization of motor units has been questioned by many researchers. If motor units were to fire synchronously, muscle contractions would not be smooth. From a functional point of view, therefore, synchronization of motor units is not desirable, yet it is consistently observed in low levels in concurrently active motor units. To gain further insight into the phenomenon of synchronization, we are investigating it under different experimental paradigms. The information obtained, in addition to shedding light into the mechanisms responsible for motor control, will provide a means of identifying altered behavior among compromised motor units.

METHODOLOGY—A total of 446 motor unit pairs identified in contractions of the first dorsal interosseus and tibialis anterior muscles in humans were analyzed for synchronization. The Synchronization Ratio and Motor Unit Synchronization, described previously, were used to quantify and compare the synchronization changes. The effects of various parameters on synchronization were considered. These parameters included the force level and duration of the contraction, the recruitment threshold, and average firing rate, as well as the difference in the recruitment thresholds and in the average firing rates of motor unit pairs.

RESULTS—Preliminary findings indicate that the synchronization level is affected by the force level, and that over time, synchronization does not appear to have a consistent pattern. The physiological origins of these results and whether synchronization serves a functional purpose or whether it occurs as a side effect of other physiological mechanisms, are still under consideration.

[69] MOTOR UNIT CONTROL PROPERTIES DURING SUSTAINED ISOTONIC ISOMETRIC CONTRACTIONS

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PURPOSE—We previously reported that during sustained constant-force contractions at 30, 50, and 80 percent of maximum voluntary strength, motor units in the tibialis anterior (TA) and the first dorsal interosseous (FDI) muscles showed a continual decrease of mean firing rates. Our studies have established that

the rate of the decrease was proportional to the contraction level and, within single contractions, proportional to the recruitment threshold of the motor unit. This project addressed the question of how the force output of the muscle can be maintained constant when the firing rates are shown to decrease. This information regarding the mechanisms which control the behavior of motor units will provide a basis for repairing dysfunctional muscles.

METHODOLOGY—The ability to sustain muscle force in the presence of decreasing firing rates could possibly be due to three mechanisms: recruitment of additional motor units, compensatory activity in the agonist or antagonist muscle groups, and twitch potentiation. In order to investigate which of these mechanisms prevailed, electromyographic (EMG) data recorded in 85 constant-force contractions of the TA and FDI muscles were searched for recruitment of motor units. Wrist extensor and flexor muscles were employed to investigate the presence of compensatory action, such as a decrease in antagonist activity or an increase in agonist activity, during sustained force output.

RESULTS—In isotonic contractions, no recruitment was observed after the aimed force level was initially reached. Recruitment of additional motor units was observed only in contractions where the force was increased above the already achieved plateau level. In this case, the already active motor units also increased their firing rates. This ruled out the possibility that recruitment was responsible or necessary for maintaining a constant force level. No compensatory activity in the agonist or antagonist muscles was observed. Without recruitment or complementing agonist/antagonist activity, twitch potentiation remained as the only acceptable mechanism that could cause the firing rates to decrease during sustained contractions.

[70] CONTROL OF MUSCLE FIBERS: HOW DOES A MUSCLE REGULATE FORCE?

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PURPOSE—Our previous work addressed the architecture of the motoneuron pool and the inherent characteristics of individual motor units. In the present study we attempt to gain insight into the input signals that drive the motor units, given the formerly established pool architecture and input/output properties. This work is intended to increase our knowledge of the normal control of motor units so that better procedures may be established to diagnose and rehabilitate persons with neuromuscular deficiencies.

METHODOLOGY—Myoelectric signals were detected from the tibialis anterior muscle of six subjects with a special quadrifilar needle electrode while the subjects generated isometric forces at 20, 50, 80, or 100 percent of maximal voluntary contraction. These signals were later analyzed by our Precision Decomposition Technique.

RESULTS—The investigation of the coefficient of variation and standard deviation of the interspike intervals as a function of recruitment threshold led to the suggestion that at a given force, the coefficient of variation of the interpulse intervals may be the parameter which the system controls and maintains constant. It was observed that the coefficient of variation increased with increasing target levels.

The joint behavior of pairs of motor units were investigated by cross-correlating the continuous mean firing rate signals of pairs of motor units. The results confirmed our conviction of the previously discussed concept of common drive pertaining to the unison control of motor units active in a given contraction. If the inputs received by a motor unit are modeled as a common drive shared by all motor units and a noise input specific to that unit, the findings of this study suggest that common drive increases faster relative to the noise component as higher muscle forces are produced.

[71] RELATION OF REHABILITATION INTERVENTION TO FUNCTIONAL OUTCOME

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PURPOSE—A clear relationship between medical rehabilitation therapy and functional outcome has not been demonstrated. It is assumed that "more of the right kind" of therapy results in better functional outcome; however, there is little objective evidence to support this assertion. Importantly, we do not know objectively what the "right" kind of therapy is. Cost-effective, competitive rehabilitation services will be based on a clear understanding of what resources and strategies result in the most desirable outcomes at least cost. It is the purpose of this project to objectively measure and then demonstrate relationships between therapy type and extent of functional outcomes, based on recently developed methods.

Our preliminary studies have illustrated the motor and cognitive recovery attained by patients undergoing comprehensive medical rehabilitation and moderate correlations with nursing time and certain billed services but not others, such as physical and occupational therapy. Further study is needed to identify relationships between impairment and disability, the extent to which rehabilitation goals are met, and barriers to goal attainment and functional recovery.

The specific aims of this 4-year study are to:

1. Document the characteristics of functional improvement during inpatient rehabilitation
2. Describe the relationships between type, intensity and duration of rehabilitation interventions and functional improvement
3. Evaluate differences between patients with specific kinds of impairments in functional improvement
4. Describe extent and rate of functional improvement in terms of therapeutic goals and activities, barriers to rehabilitation process, and comorbidity.

METHODOLOGY—Three impairment groups will be included: Patients with stroke, traumatic brain dysfunction, and spinal cord dysfunction. These groups are among the largest populations served by inpatient rehabilitation programs. A minimum of four inpatient rehabilitation programs will collect patient data. All will be subscribers to the Uniform Data System for Medical Rehabilitation. A sample of 100 patients per impairment group (a minimum of 400 total) will be collected; each hospital will provide data on 100 patients, 33 per impairment group.

For each patient, FIM scores will be assessed weekly by nursing staff; nursing activities will be collected during a 24-hour period weekly; therapy hours will be extracted from patient bills and totaled for weekly periods; and, therapy activities and goals, comorbidities, and barriers will be summarized weekly.

PROGRESS—An advisory group at the Rehabilitation Institute of Chicago identified, reviewed, and approved a list of rehabilitation goals, therapy activities and interventions, barriers to goal attainment, and comorbidities. Pilot data were collected through February, 1995. The advisory group will reconvene through March, 1995, to review the pilot data, to discuss procedural difficulties, and to revise instruments and procedures to assure that full-scale data collection proceeds smoothly. Full scale data collection will begin in March 1995, and continue through January 1997. Data analysis and report writing will begin in February 1997, and continue through August 1997.

RESULTS—Study in progress; no results yet available.

RECENT PUBLICATIONS FROM THIS RESEARCH

Functional status and therapeutic intensity during inpatient rehabilitation. Heinemann AW, Hamilton BB, Linacre JM, Wright BD, Granger CV. Am J Phys Med Rehabil. In press.

[72] DEVELOPMENT OF PROTOCOLS AND MODELS USED TO QUANTIFY FUNCTIONAL CAPABILITIES OF PERSONS IN RESPONSE TO THE AMERICAN WITH DISABILITIES ACT (1992)

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PURPOSE—Title I of the ADA prohibits employment discrimination against people with disabilities who are qualified to do "the essential functions of a job." Employers must demonstrate that a medical test or inquiry is job-related and consistent with the business necessity and that performance cannot be achieved with reasonable accommodations. Consequently, job task analysis and job demand profile necessity have become crucial in the industry.

The objective of this project has been to develop a series of models that could be used in the process of employment and rehabilitation of injured workers under the ADA. More specifically, the goal was to develop a protocol and models that could be used to predict the functional capabilities (i.e., joint velocity, torque and power generation capabilities) of an individual.

METHODOLOGY—Twenty subjects (10 males and 10 females) were tested using the KIN-COM 125E Plus muscle testing and training system from Chattecx Corp. Isometric, isokinetic, and isoresistive modes of testing were used to study the velocity, torque, and power capabilities for each of the isolated joints: trunk, shoulder, elbow, hip, knee, and ankle. From the angle and velocity dependent data, surfaces of the joint torque capability were generated. These surfaces will be used to predict the joint torque generation capability for any combination of angle and velocity within the scope of the model.

PROGRESS—All subjects have been tested, and the data analysis is ongoing. A database has been constructed of the angle and velocity dependent joint torque capabilities. Foremost in the groups' progress has been the inclusion of normal female subjects into the database. Despite the continuous increase in the percentage of women who are involved in MMH tasks in the work-force, few studies address the quantification of strength profiles and functional capacity for females. In addition, most traditional jobs were designed based on male strength characteristics and anthropometry which increases the risk for female injuries.

RESULTS—In an attempt to answer the question of how to best assess strength, it was found that the isokinetic mode of testing was a more systematic and efficient method of characterizing the strength profiles as a function of joint position and velocities. The isoresistive mode, on the other hand, resulted in sparse data sets due to the fact that in this latter mode there is no prior knowledge what combinations of positions and angular velocities will be observed. Additionally, 3-D surface responses of joint strengths as a function of angular position and velocity were constructed for the trunk, shoulder, elbow, hip, knee, and ankle joints. Such data presentation is more accurate and gives better insight about the individual strength profiles.

Combined with an analysis of the job-specific joint requirements, the quantification of functional capabilities of an individual will answer the following questions: Can subject/patient A perform task B? What about task B is most limiting? Is there any modification in task B that makes the demands within the feasible and acceptable range of subject/patient A's functional capabilities? What is the limiting functional unit for performing task B? Which tasks or jobs in the designated set of tasks are feasible and acceptable, given the known functional capabilities of subject/patient A?

RECENT PUBLICATIONS FROM THIS RESEARCH

Comparative evaluation of isotonic and isokinetic modes of testing with ergonomic and rehabilitation perspective. Khalaf K, Parnianpour M, Sparto P. In: Proceedings of the RESNA International '94; 1994 June 17-22, Nashville, TN. Washington, DC: RESNA Press, 1994:176-8.

Development of 3-D surface response of trunk strength as a function of trunk position and angular velocity. Khalaf K, Parnianpour M, Sparto P. In: Proceedings of the American Society of Biomechanics Annual Meeting, 1994:59-60.

[73] DEVELOPMENT OF MATHEMATICAL MODELS TO QUANTIFY JOINT VELOCITY, TORQUE, AND POWER DURING LIFTING TASKS

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PURPOSE—The Americans with Disabilities Act (ADA) of 1992 ensures both equal access to public accommodations and services and equal opportunity in employment for the 43 million Americans who have disabilities. Title I of ADA became effective for companies with 25 or more employees on July 26, 1992. Title I of the ADA prohibits employment discrimination against people with disabilities who are qualified to perform the essential functions of a job. This prohibition applies to all aspects of employment such as: hiring, retention, promotion, benefits, and training opportunities.

The objective of this project has been to develop a series of models that could be used in the process of employment and rehabilitation of the injured workers given the ADA. More specifically, the goal is to develop models that can successfully predict the requirements of industrial tasks. These models would be used for both analysis and simulation purposes. Once these models are validated, they could be used along with documentation of a subject's functional capabilities to prescribe job-specific rehabilitation programs and/or assistive devices, that would allow individuals to perform the essential functions of the job.

METHODOLOGY—Healthy nondisabled subjects and low back pain patients are to perform a variety of lifting and lowering tasks in order to quantify what joint motion and strength capabilities are needed in order to complete the tasks. Subjects will be tested while the speed of lift, lifting style, load of lift, and duration of task are varied for lifts occurring in the sagittal plane. Video kinematic analysis and biomechanical modeling will provide estimates of required joint velocity, torque, and power needed to perform the tasks. Mathematical models will be developed that will be used to predict what is required in terms of joint velocity, torque, and power, given any arbitrary set of lift speed, load, and lifting style within the scope of the model.

PROGRESS—Twenty nondisabled subjects (10 female, 10 male) have been tested. The data analysis has been completed for the male subjects and started for the female subjects. A normative database is being constructed consisting of the joint velocity, torque, and power generation requirements for each of the simulated lifting tasks.

RESULTS—The speed of lift, lifting style, and load of lift all significantly affected the joint velocity, torque, and power generation and distribution. For example, the power generated by the knee and hip muscles is less for a stoop lift than for a squat lift, while the reverse is true for the lower back muscles. The development of a normative database and valid models are important for the prescription of rehabilitation programs and assistive devices for disabled individuals. The use of biomechanical analysis for quantification of task requirements is integral to this goal.

RECENT PUBLICATIONS FROM THIS RESEARCH

Effects of load, speed, and mode of lift on the joint energetics during unconstrained lifting and lowering activities. Sparto P, Parnianpour M, Khalaf K. Advances in Bioengineering, ASME-BED 1993:26:467-70.

More quantitative approach to classification of impairments, disabilities, and handicaps. Parnianpour M, Engin A. J Rheumatol Med Rehabil 1994:5(1):52-64.

Applications of quantitative assessment of human performance in occupational medicine. Parnianpour M. In: Bronzino J, ed. Handbook of Biomedical Engineering. Boca Raton, FL: CRC Press, 1994.

Effects of load, mode, and speed of lift on the power generation, absorption and transfer during a multi-link coordinated lifting task. Sparto P, Parnianpour M, Khalaf K. In: Proceedings of the RESNA International '94; 1994 June 17-22, Nashville, TN. Washington, DC: RESNA Press, 1994: 182-184.

[74] ASSESSMENT OF AMBULATION MOTION PARAMETERS FOR CLINICAL EVALUATION

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PURPOSE—This project seeks to develop and assess quantitative parameters, which are computed from motion laboratory data and can be used in clinical decision-making processes. Development of useful parameters requires substantial reduction of large volumes of motion data (e.g., kinematic and electromyographic (EMG) data). Resulting parameters should be understandable to clinical personnel, so that such personnel can utilize them properly in patient care. This project involves the following objectives: propose candidate parameters and indices; evaluate the computation of these parameters with respect to assumptions required and to sources of error and variability; examine the feasibility of implementing these parameters in clinical data processing; assess the usefulness of these parameters in clinical decision making; and develop databases of values for these parameters.

Initial efforts have been directed largely toward development of parameters to assist orthopedic surgeons in determining the amount of lengthening to obtain, when lengthening musculotendon units in children with cerebral palsy (CP). Toward this end we have established two objectives: the identification of thresholds at which dynamic spasticity becomes present in young children with CP and the determination of a scaling factor to relate the age of the child with CP to the amount of musculotendon lengthening to be obtained. We have continued to collect motion laboratory data for substantial numbers of clinical patients, consistent with the need for establishing appropriate databases.

METHODOLOGY—To estimate threshold levels for dynamic spasticity onset, we will need to determine musculotendon unit length when dynamic spasticity becomes present, as well as the concurrent rate of change of musculotendon unit length. We also need to evaluate two additional quantities: the force produced by the spastic musculotendon unit when dynamic spasticity becomes present, and the concurrent rate of change in force produced. To determine scaling factors that relate age to the needed amount of lengthening of the specific musculotendon unit, we need to combine pre-surgery and post-surgery gait data with measured changes in the length of specific musculotendon units.

We have obtained biomechanical simulation software with the flexibility to recreate the dimensions of any individual's lower extremity by scaling the bone elements of the general lower extremity model. The musculotendon units can be scaled similarly. This software also includes the flexibility to modify the origins and insertions of any musculotendon unit, and thus alter its length. We have modified some of our standard data formats in order to effect compatibility with this software package. Such modifications have permitted use of our existing database, at least in the initial stages of our investigations.

Modifications have been made to allow the simulation software to accept data from our database in the Gait Analysis laboratory. We have been able to enter certain gait parameters and observe the force generated by certain musculotendon units, as well as observe the changes in the length of any unit as a function of time. We also have been able to estimate moments about each joint during the gait cycle as they relate to one or several musculotendon units, based entirely upon kinematic and electromyographic data. In addition, we can observe strains experienced by different musculotendon units during the gait cycle.

RESULTS—Results to this point indicate that kinetic variables are very sensitive variables. In other words, the force generated by a spastic musculotendon unit and the moments this unit can produce about the joints it acts upon, are the most sensitive parameters when an operation that results in lengthening of the musculotendon complex has been performed. However, to this point our results are based on estimated lengthenings of the musculotendon units in question.

[75] USE OF JOINT TORQUE, ENERGY, AND POWER IN CLINICAL GAIT EVALUATION

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PURPOSE—This project is a study of the potential use of lower limb joint kinetics, including torque, energy, and power data, to assist rehabilitation professionals in evaluating disabling and potentially disabling conditions which affect ambulation. We are investigating these parameters with respect to their value in making or refining diagnoses, making clinical decisions regarding interventions, prognosing long term function, and assessing disability levels.

METHODOLOGY—Activities of this project have involved a number of subject groups. We have evaluated kinetic data of patients (primarily with spastic cerebral palsy) who utilize ankle bracing. Initial evaluation of lower limb joint moment patterns, performed by an orthopaedic surgeon specializing in gait data interpretation, had suggested that bracing provided substantial benefits to some patients, had negligible impact on others, and had detrimental effects on the rest. In subsequent investigation of these subjects' kinetic data, we computed the braced and unbraced joint power trajectories for all lower extremity joints. From the joint power trajectories we determined the joint energy absorbed and the joint energy expended for each joint under each condition (i.e., braced and unbraced). Subsequently, we obtained the differences in joint energy absorptions and expenditures, between the braced and unbraced conditions, for each joint and for all joints combined.

Additionally, we have evaluated kinetic data collected from patients, with suspected loose prosthetic femoral stems, in order to overcome the difficulty of using kinematic data to determine whether these components are loose. Preliminary kinematic data has suggested that transverse plane hip joint rotations (i.e., internal/external rotations) may be increased in patients with loose prosthetic femoral stems. It was difficult, however, to determine the amount of an internal/external hip joint rotation that could be attributed to relative rotation between the prosthetic femoral head and the prosthetic acetabular cup (not problematic), and the amount of transverse hip rotation that could be associated with relative rotation between the femoral canal and the prosthetic femoral stem (very problematic). We have speculated that, during single limb stance phase (i.e., from opposite foot off to opposite foot contact) overall change of transverse hip joint moment per unit change of transverse hip rotation would be less for a hip joint with a loose prosthetic stem. Based on this speculation we have been estimating transverse plane hip joint stiffness, during single limb stance, as the slope of transverse hip moment versus transverse hip rotation.

RESULTS—To date, joint energy data indicate that, with bracing, joint energy absorptions are increased at the hip and contralateral ankle, and for all joints combined. Joint energy absorption is primarily associated with eccentric muscular activity. Some investigators have suggested that eccentric muscular activity is more fatiguing than concentric activity; however, others have reported that eccentric activity is better for strengthening.

For the subjects with loose prosthetic femoral components, the plots of dynamic rotational joint stiffness suggest that these subjects exhibit substantially smaller joint stiffness peaks on the limb with a loose prosthetic stem, compared with the peaks for the contralateral limb. Conversely, stiffness peaks appeared similar for both limbs, when prosthetic femoral component looseness was not present (as determined at subsequent surgery). These results appear to suggest strongly the potential use of dynamic rotational joint stiffness at the hip for distinguishing loose prosthetic femoral stems from those that are rigidly fixed.

[76] MECHANISMS UNDERLYING COMPLIANT BEHAVIOR OF THE LIMBS

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Sponsor: *National Institutes of Health*

PURPOSE—The fact that our limbs generate forces in response to externally imposed displacement is a manifestation of their compliant properties. This compliance is essential both to postural stability and to graceful performance of all voluntary motor activity. It is important to understand the mechanisms that are responsible for creating and maintaining compliance.

METHODOLOGY—Compliance was studied in the elbow by imposing perturbations to the limb with a torque motor, using a specially designed manipulandum that was controlled by a pair of small computers. The forces and the effects of those forces on the motion of the limb were measured and analyzed. Simultaneously, the concurrent electrical activity of the muscles (electromyography) was recorded from the skin with surface electrodes. This allowed us to partition the responses into components that were produced by intrinsic muscle properties, by reflex mechanisms, and by the intervention of higher functions of the nervous system.

RESULTS—Experiments show that during sudden perturbations and during rapid movement, limb compliance is primarily due to the velocity-sensitive, force-producing mechanisms of the muscle's contractile mechanism. During postural maintenance, however, it is the length-sensitive mechanisms that are most important. These intrinsic muscle mechanisms are supported by rapidly acting reflex mechanisms that can alter the activity of the muscles to oppose the effects of the perturbations. Neither is sufficient, however, to prevent limbs from being displaced by external perturbations. The motor system relies on the corrective actions of higher centers, including conscious ones, to provide a complete and adequate response.

[77] CENTRAL NERVOUS SYSTEM CONTROL RULES FOR VOLUNTARY MOVEMENT

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Sponsor: *National Institutes of Health*

PURPOSE—To understand how the brain directs the limbs to perform purposeful movement, we need to know what kinds of commands are sent to the muscles and what variables are used to plan and construct them. For example, does the control system plan a movement's path and velocity through space and then from this plan compute the forces necessary to produce the movement? Does the system plan a path and rely on neurophysiological feedback mechanisms to generate the desired forces? Or does it plan forces that from past experience it expects will produce a satisfactory movement, and then monitor the outcome to see if it was correct? The work of the Motor Control Lab focuses on this third alternative and performs experiments to test its hypotheses and implications. We expect that not only will a better understanding of brain function emerge from this research, but that it will lead to new insights and a better way of evaluating patients with motor deficits.

METHODOLOGY—Subjects were asked to make simple pointing movements, either in a special apparatus that limits motion to a single joint (the elbow or wrist) or unconstrained movement of the whole limb. The motion was measured by our apparatus and the concurrent electrical activity of the muscles (electromyography) was recorded from the skin with surface electrodes.

RESULTS—The electromyographic patterns of the muscles are modulated in a highly systematic fashion when the subject is instructed to vary the distance, speed, location, or the load of the movement. This has led to the development of a model in which movement planning occurs in terms of muscle activation patterns. Muscle forces are produced, and, from these, movement characteristics emerge. Reflexes play a supportive and adaptive but subordinate role in this process. Movement skill emerges from practice in which individuals learn the proper muscle activation patterns by trial and error.

[78] ASSESSING INDIVIDUALS' PREDISPOSITIONS TO THE USE, AVOIDANCE, OR ABANDONMENT OF ASSISTIVE TECHNOLOGIES

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PURPOSE—The rate of abandonment of assistive technologies (AT) remains high: 6 to 75 percent, depending on the AT. The PI's past research has categorized AT use as depending upon characteristics within four major areas: a) the particular technology (e.g., design, service delivery); b) the person's abilities and personality (e.g., aptitudes, outlook, expectations); c) the nature of the disability (e.g., type, severity); and d) the person's psychosocial environment (e.g., support from family and friends, life experiences, education). When variables within each of the above areas are organized by category of technology use (optimal and partial/reluctant) and non-use (avoidance and abandonment), individuals can be profiled according to the likelihood of a good match with a particular AT.

METHODOLOGY—The Assistive Technology Device Predisposition Assessment (ATD PA) is a consumer self-report checklist with items of varied format, including 5-point Likert scales. Its purpose is to identify potential sources of person and technology mismatches for early intervention. The ATD PA has subscales to separately assess characteristics of the AT, the individual's temperament, and the environment in which the person will use the AT. A companion form completed by professionals assesses shared perspectives between consumer and professional. Both forms were revised in 1994 to: a) facilitate the assessment of multiple AT use for any given consumer, and b) simplify the scoring. Side One of the consumer form consists of questions given per consumer on temperament, psychosocial resources, and views of "disability"; Side Two contains 10 questions for consumers to complete per technology on their views of and expectations for that particular AT. Companion professional forms are similarly constructed.

PROGRESS—*Validity studies.* A study is being conducted of 21 persons with mixed diagnoses discharged from an acute inpatient rehabilitation unit between March and October 1994. They were administered the 1994 revised forms of the ATD PA-C at time of discharge and will complete the forms again at 6-month follow-up. Other research efforts included the administration of the ATD PA consumer form to individuals precategorized into five groups according to level of hearing loss. Additional studies are being conducted by researchers at other sites throughout the United States.

Reliability studies. Studies of the reliability (primarily inter-rater) are on-going. Case examples of individuals being matched with an AT (consisting of narrative case histories, the consumers' responses on the ATD PA-C, and videotaped interview segments) are presented to groups of professionals and students who then complete the professional form of the ATD PA. The percent agreement and mean deviation from the mode are calculated for each item.

RESULTS—All results will be presented as data analyses are completed. Previous studies have shown that the consumer and professional forms of the ATD PA are valid and reliable, and it is anticipated that the 1994 revised forms will evidence improved validity and reliability.

IMPLICATIONS—Reasons for and predispositions to AT abandonment are clarified when reviewing the results obtained from the ATD PA. It is hoped that this information will lead to better person-technology matching and enhanced consumer AT use and training for use.

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Measuring the relationship of equipment use and functional status at follow-up. (Abstract). Cushman LA, Scherer MJ. Arch Phys Med Rehabil 1994:75(6):724.

[79] EVALUATION OF CARPAL TUNNEL SYNDROME

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Sponsor: *NeuroMuscular Research Center*

PURPOSE—Carpal tunnel syndrome, resulting from the compression of the median nerve at the carpal tunnel, is thought to result from repetitive motion, sustained loads, awkward joint positioning, and vibratory forces. In 1990, the Bureau of Labor Statistics reported 240,000 new cases, adding to the 1.89 million Americans already afflicted with carpal tunnel syndrome. In spite of its common occurrence, the clinical tests currently used to assess the syndrome are subjective and often inconclusive. The purpose of this project is to design an objective, quantitative, and noninvasive method to evaluate a patient's involvement with the carpal tunnel syndrome.

METHODOLOGY—In order to keep our procedures as noninvasive and comfortable for the patient as possible, we have opted for a measurement system employing only surface electromyography and force measurements. We hypothesized that if a subject is asked to produce a combined force that can be generated as a sum of force contributions from two muscles (one being more directly impaired by the carpal tunnel syndrome), the unaffected muscle will be activated more intensively in order to make up a greater portion of the force as compared to that of a healthy person.

RESULTS—An arm and hand restraint device was built that enables surface electromyographic and force measurements from the thenar and hypothenar muscle groups. This device allows the combined output force to be displayed on-line to the subject for visual feedback. Our next step will be to test five healthy subjects and five carpal tunnel patients and compare the results in order to verify the usefulness of the technique in quantifying involvement with carpal tunnel syndrome.

IV. Functional Electrical Stimulation

A. General

[80] HIGH CHARGE DENSITY, BIPOLAR ELECTRODES FOR CHRONIC FNS

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PURPOSE—The purpose of this research includes: characterizing *in vivo* environments and developing stimulating waveforms to minimize electrode corrosion; evaluating high strength lead materials for percutaneous and intramuscular electrodes; developing improved *in vitro* environments for evaluating electrodes; and using activated iridium oxide (AIROF) coatings for electrodes.

METHODOLOGY—Variable impedance bath *in vitro* studies were conducted in a sand/electrolyte bath using a three-electrode arrangement consisting of the test electrode, Pt counter electrode, and standard calomel reference electrode. Studies evaluated the effects of pulse protocols, potential transients, buffers, and protein on the corrosion response. Chronic pulsing studies were conducted in our standard bath without addition of protein for 1 year at a charge injection density of 20 $\mu C/cm^2$.

In vivo studies were conducted in SCI cats. Studies consist of performing a laminectomy over T-7, implanting 2 Pt counter electrodes and approximately 20 test electrodes, and inserting a chronic bladder catheter. Both anodic and cathodic-first pulsing were evaluated for their effects on the corrosion response and electrical transients of 316LVM electrodes.

PROGRESS—We have continued the evaluation of fluid, electrolyte, and impedance on the corrosion response of electrodes pulsed *in vitro*. AIROF coated electrodes have been made with preliminary evaluation of charge injection characteristics. Injection densities up to 200 μC/cm2 appear suitable. However, adhesion of the coating to the metal remains a concern.

RESULTS—The effect of protein on the corrosion response of 316LVM electrodes was investigated *in vitro*. The data indicated that the presence of protein added to the fluid/electrolyte bath did not effect the corrosion response or electrical transients. In the presence and absence of protein, light microscopy revealed slight tarnishing uniformly across each electrode's surface. This finding was confirmed using SEM.

The effect of impedance on the corrosion response of monophasic, capacitively coupled 316LVM electrodes pulsed with a charge injection of 40 μC/cm2 was investigated. Studies were conducted both *in vitro* and *in vivo*. Increased corrosion rates and impedances were observed for pulsed electrodes *in vivo*. The impedance of the *in vitro* bath was increased to mimic the *in vivo* environment by using a bath filled with sand and a small amount of fluid and electrolyte. Pulsing in the sand bath resulted in increased corrosion rates similar to *in vivo*. These increased corrosion rates were also reflected in the electrical transients. These results show that corrosion rates may be high in the body, requiring lower charge injection densities.

The effect of chronic (1 year) continuous stimulation on the corrosion response of 316LVM electrodes was investigated in the standard low impedance, non-protein-fluid/electrolyte bath. Despite the low charge

injection density of 20 μC/cm2, tarnishing was observed on electrodes pulsed with either anodic or cathodic-first pulsing.

FUTURE PLANS—We plan to conduct detailed *in vitro* and *in vivo* evaluations of high charge capacity coatings of Ir (AIROF) as a means of achieving bipolar charge injection capacities exceeding those presently available with uncoated alloys.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Effects of long term stimulation on the corrosion responses and electrical transients of 316LVM stainless steel electrodes. Riedy L, Walter JS. An Biomed Eng 1994:22:202.

[81] REHABILITATION OF RESPIRATORY PARALYSIS: ACCESSORY MUSCLE STIMULATION

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PURPOSE—Electrical activation of the diaphragm via phrenic nerve stimulation has successfully maintained resting levels of alveolar ventilation in spinal cord injured and selected hypoventilating patients. Although technical improvements have provided for long-term care, the lack of coordinated contractions of accessory muscles has severely limited the usefulness of this technique. Normally, chest wall enlargement acts synergistically with the diaphragm to inflate the lungs. With diaphragm stimulation alone, the chest wall collapses. This overburdens the diaphragm and contributes to fatigue. Electrical activation of the chest wall inspiratory muscles would assist the diaphragm and increase the efficiency of diaphragm pacing. Electrical activation of expiratory muscles would provide further enhancement and demonstrate the feasibility of inducing an electrically generated "cough." The goals of the present study are to develop techniques that could be applied in the clinical setting to coordinate diaphragm pacing with accessory muscle stimulation.

METHODOLOGY—In acute dogs following anesthesia, suture-type intramuscular electrodes were inserted in each hemidiaphragm close to the entry of the phrenic nerves. Accessory muscle stimulation was obtained from intramuscular implantation of stainless wire electrodes with a small hooked end inserted through a 27-gauge needle. The needle containing the electrode was pulsed through the skin and into the superficial muscle. We had little if any success with subcutaneous electrodes no matter the location.

RESULTS—We have demonstrated the effectiveness of stimulating accessory respiratory muscles using intramuscular electrodes. Bilateral stimulation of electrodes in the 3rd to 6th interspace were the most effective. Within this region electrodes placed in the lateral or sternolateral regions next to rib margins produced the greatest response. Electrodes placed in the caudal intercostal spaces produced little change or collapsed the chest wall. Intramuscular electrodes in the rectus abdominus and external obliques when stimulated consistently increased intra-abdominal pressure and supported expiration.

FUTURE PLANS—Studies are in progress to test the effectiveness of intercostal muscle stimulation to assist the breathing of people with quadraplegia.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Diaphragm and accessory respiratory muscle stimulation using intramuscular electrodes. Dunn RB, Walter JS, Walsh J. Arch Phys Med Rehabil. In press.

[82] A NEW BIOELECTRIC METHOD FOR EARLY DIAGNOSIS OF DELAYED FRACTURE HEALING

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PURPOSE—To develop a procedure of skin-surface measurements of endogenous electricity for early identification of delayed healing fractures.

METHODOLOGY—Based on our studies using canine models, we propose the following hypothesis: normal and delayed healing fractures have distinct electrical signatures represented by different temporal patterns of skin-surface electrical activity during the first 8 weeks after fracture. The skin-surface voltages will be measured over the fracture site within 24 to 48 hours after initial treatment. These measurements will be repeated at 1, 2, 3, 4, 6, 8, 12, 16, and 24 weeks after the first measurement, and at 2-month intervals subsequently. Magnitude and rate parameters that characterize the changes in voltage, as well as time parameters characterizing sign changes in voltage, will be compared for groups of patients in whom the fractures have been clinically judged to be normally healing or delayed at 4 months after fracture. Thus, we will determine if these early electrical measurements can predict whether or not the fracture will heal normally.

Statistical design of the study is intended to test the hypothesis that there is no difference in electrical signatures of normal healing (NH) and delayed healing (DH) fractures, under the condition α=0.01 and β=0.1, using the results of our canine study as test data. Minimum sample size is 10 patients for each class of fracture (e.g., DH fractures of the tibia). Only patients with single fractures of arms or legs treated at the Omaha VAMC, the Creighton University Medical Center, and the University of Nebraska Medical Center will be included in the study.

Instrumentation and procedure for bioelectric measurements described previously for the canine study will be followed, using EKG-type miniature Ag/AgCl electrodes. Based on X-ray, stress fluoroscopy, and pain assessment, we will classify fractures at 4 months into NH and DH groups. This will be repeated, if needed, at 2-month intervals until the "healing time" (Th) is reached when the fracture is determined to be healed.

The temporal patterns of voltages will be described in terms of rate parameters (e.g., rate of initial decay of the would potential), magnitude parameters and time parameters, as indicated above. The relationship between these parameters and Th will be analyzed to develop indices that represent electrical signatures for NH and DH groups. Data will be tested for normality (Rankit Test) and approximate equality of standard deviations (F-Test) before choosing parametric or nonparametric methods to test for statistical significance of differences in these indices for normal and delayed healing.

PROGRESS—Six patients have been enrolled so far in the study, five with femoral fractures and one with a fracture of the tibia.

RESULTS—It is too early to determine the predictive value of the electrical measurements.

FUTURE PLANS—Additional patients are being enrolled to attain the minimum sample size in each group. If these electrical measurements prove to have predictive value, delayed healing fractures may be identified earlier and additional treatments started sooner to reduce the duration of disability.

[83] NEUROPROSTHETIC CONTROL OF BLADDER AND BOWEL IN SPINAL INJURY PATIENTS

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PURPOSE—To evaluate the Finetec-Brindley electrical stimulator for evacuating the bladder and bowel following spinal cord injury (SCI) in 20 subjects. Veterans with SCI require considerable health care resources for prevention and treatment of bladder and bowel complications. The greater independence, improved health, and sense of self worth that implantation of the sacral nerve anterior root stimulator will provide, in present form or in future design, will allow veterans to achieve a significant reduction in need for support staff, nursing care physicians, and treatment. Our ultimate goal is the production of an improved neuroprosthetic device to control bladder and bowel function.

PROGRESS—In general, results have been very satisfactory. As of January 1994, five subjects (three quadriplegic and two paraplegic) have received Brindley implants at the Veterans Administration Medical Center in Cleveland, Ohio. Three of these patients have also undergone posterior sacral rhizotomy.

METHODOLOGY—Finetec-Brindley (F-B) stimulators will be implanted in a total of 20 SCI subjects. Clinical and laboratory investigation will assess bladder emptying, infection, urodynamic parameters, and vesico-ureteric reflux. Colorectal studies will assess effectiveness of defecation and colorectal motility. Analysis and statistical evaluation of success in restoring bladder, bowel, and penile function will be made. Subjects will be assessed before and 3, 6, and 22 months after implantation of the neuroprosthesis. Experiments in subjects being implanted with the F-B stimulator will determine whether new electrical stimulatory procedures using quasitrapezoidal wave forms can cause selective activation of small parasympathetic nerve fibers. These should contract the colonic and bladder wall musculature without causing external sphincter contraction. Perioperative studies to be conducted during implantation of the device will permit temporary placement of new cuff electrodes and use of new stimulatory parameters, to be evaluated using intraluminal pressure transducers placed in the colon, rectum, bladder, and their sphincters. This will determine whether the new electrode design allows lower currents and more selective activation than the F-B electrodes, and whether micturition can be produced more effectively than with existing techniques.

RESULTS—Prior to operation, two subjects had long-term indwelling urethral catheters, two were dependent on staff or relatives for intermittent catheterization, and one performed intermittent self-catheterization. Five subjects had chronic urinary tract infection and one had early unilateral hydroureter. Two had had external sphincterotomy performed in an attempt to improve bladder emptying, but prior to placement of the neuroprosthesis, they remained dependent on intermittent catheterization and/or indwelling catheterization respectively.

After operation, all subjects are using their implant 4 to 6 times per day to evacuate the bladder, both in the hospital and at home, with low residual volumes of urine (<50 ml). None of the subjects require use of intermittent or indwelling catheterization. The paraplegic male and low quadriplegic male have dispensed with urine collection devices; the higher quadriplegic males continue to use a condom and leg-bag because of limited hand function for using a urine bottle. Time for bowel evacuation is reduced in all to approximately thirty minutes. No malfunctions of prostheses have been detected.

FUTURE PLANS—We plan to test, perioperatively in human subjects, neuroprosthetic techniques developed at this institution with potential for improving control of bladder and bowel evacuation. If successful, this will lead to design and testing of a new improved neuroprosthesis for bladder and bowel control in SCI patients.

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Spinal Cord Injury. Bodner DR, ed. Urology Clinics of North America. Philadelphia: W.B. Saunders, 1993.

[84] ELECTRICAL ACTIVATION OF DIAPHRAGM FOR VENTILATORY ASSIST

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B634-2RA)*

PURPOSE—The objective of this project is to develop a diaphragm pacing system for clinical applications. We propose to develop endoscopic methods to place stimulating electrodes on or in the diaphragm muscle, using an abdominal approach to access the diaphragm muscle, and to evaluate the suitability of the methods and devices for clinical applications.

METHODOLOGY—A mapping electrode, attached to the diaphragm muscle by vacuum, has been found to be highly effective in facilitating electrode placement. Video assist technology is under development to add additional accuracy to determination of the "ideal" electrode position. The vacuum attach device was also constructed to act as the carrier of the epimysial electrode, permitting the electrode to be attached to the diaphragm muscle by commercially available staples. The implant procedure for the epimysial electrode has been found to be very easy and attractive for clinical implementation.

PROGRESS—We have focused on two electrode configurations, epimysial and intramuscular. Techniques have been developed to determine the site for electrode placement. Tools have been developed to facilitate electrode implant. Electrodes have been implanted in or on dog diaphragms for periods of at least 90 days. During the period of implant, pulmonary tests were conducted on a biweekly basis to measure the ventilatory efficacy of the device. At the termination of the chronic implants, tissue was removed for pathological examination.

RESULTS—Examination of the harvested tissue, from the vicinity of the epimysial electrode, has shown a pattern that suggests relative movement between the contracting muscle and the electrode with its silicone rubber housing is a continuing source of cell irritation. Continued cell irritation suggests continued growth of connective tissue between the muscle and the electrode that is, at least for now, considered undesirable. As a result of these experiences, we have renewed our interest in the intramuscular electrode because of its better tissue response. The main problem to overcome with the intramuscular electrode is placement in the diaphragm without entering the thorax. A tool has been developed and preliminary testing is underway to evaluate electrode placement with the device. At this point we still have unresolved problems with the implant tool and procedure. We will continue to work with the implant tool to correct problems for the intramuscular electrode and will be exploring alternative designs for the epimysial electrode.

IMPLICATIONS—The procedure we are developing, aside from being minimally invasive, poses very little, if any, danger to the phrenic nerve. Successful development will make electrical activation of phrenic nerves available to a broad range of patients.

[85] EVALUATION AND OPTIMIZATION OF FES TECHNIQUES FOR EXERCISE

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PURPOSE—The purpose of this continuation program is to provide effective functional electrical stimulation (FES) exercise techniques for improving health, physical fitness, and rehabilitation outcome of individuals with spinal cord injury (SCI). Objectives are: 1) to continue evaluation of acute and chronic physiologic responses (musculoskeletal, aerobic metabolic, and cardiopulmonary) to existing FES exercise modes, including knee extension (KE), leg cycle ergometry (LCE), and combined FES-LCE + voluntary arm-crank ergometry (HYBRID), as well as to determine biomechanical characteristics of these therapies to assess potential benefits and risks to persons with SCI; 2) to modify the design of existing FES exercise devices to optimize muscular, aerobic metabolic, and cardiopulmonary responses to the various FES exercise modes, while maintaining user safety; and 3) to design more progressive FES exercise training protocols to optimize adaptations of the muscles utilized and the cardiopulmonary system.

METHODOLOGY—Groups of subjects with SCI are administered a series of exercise stress tests to determine the initial performance (i.e., strength and endurance) of their paralyzed lower-limb muscles for FES, and their arm muscles, as well as to determine their peak metabolic and cardiopulmonary responses. Subjects are then assigned to participate in a series of 12-week exercise training programs using the various FES exercise modes and protocols. They are again exercise stress tested after each training program to determine changes in fitness. Modifications to the FES instrumentation design are tested to optimize the physiologic responses and enhance training effects. Biomechanics of each exercise mode is studied to determine the appropriateness of the limb movements and to evaluate orthopedic risks. A questionnaire is used to assess changes in medical problems during participation in FES exercise programs.

PRELIMINARY RESULTS— With respect to improving therapeutic FES technology, we found that KE exercise performance and LCE exercise performance (as indicated by resistive load accomplished and metabolic and cardiopulmonary responses) can be markedly improved, in most cases, by increasing the FES current limit from 150 up to 300 mA. LCE can be further improved by incorporating the calf muscles. Thus, we have modified our instrumentation to permit these operating parameters where appropriate. We also developed an electronic circuit to permit adjustment of LCE load resistance during pedaling (without stopping and reprogramming) so that power output could be progressively increased or decreased in small increments (e.g., 1.5–3 watt rather than 6 watt) to optimize exercise session results, and to permit interval training program (ITP) protocols to be used. Furthermore, we obtained custom ROM chips for our leg cycle ergometers to widen the FES firing angles up to fourfold. This has resulted in smoother operation, but more rapid onset of fatigue in untrained subjects. It appears that combinations of these modifications may elicit accelerated and greater physiologic training adaptations.

We used a questionnaire and interviews to gain information on the incidence of medical problems that occurred previous to and during participation in FES exercise programs. The demographics of the 19 subjects who responded were: 16 male and 3 female, mean (+SD) age = 36.6+9.5 yr, 9 paraplegics and 10 quadriplegics, mean time since injury = 10.5+4.8 yr, time participating in FES exercise = 4.8+2.6 yr. Previous to FES participation, reported physician visits were: 11 for genitourinary problems, 4 for miscellaneous problems (i.e., cancer, calcium deposits in leg), 3 for neuromuscular problems, 3 for skin problems, 3 for orthopedic problems, and 1 for psychological problems. During FES participation, only 5 problems were reported (i.e., genitourinary, cancer, and arm in-

jury). Also notable is that 13 of the 19 respondents reported reductions in medication usage for spasticity, bowel problems, and antibiotics for urinary tract infections.

FUTURE PLANS/IMPLICATIONS—We are now conducting a comprehensive FES-LCE training program that will compare training effectiveness for the original LCE and established exercise protocol to the modified LCE (indicated above) and an ITP protocol. We will also continue data gathering on medical problems that occur prior to and during FES participation in FES exercise programs. Our results thus far suggest that SCI patients should derive benefits from FES exercise including increased levels of physical fitness, reduced incidence of secondary medical complications, and improved rehabilitation outcome.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[86] PERINEUM STIMULATION FOR CONTROL OF URGE INCONTINENCE AND FREQUENCY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Core Funds)*

PURPOSE—The primary objective is to determine if electrical stimulation, with surface electrodes applied to the perineum, can significantly reduce urge symptoms and incontinence in adults and elderly. The secondary objectives include: the evaluation and assessment of patient perception of treatment and outcome; the assessment of long-term effects of treatment with follow-up; the assessment of whether there are subgroups that can be correlated with the outcome based on characteristics such as patient history, weight, age, and the determination of the percent of patients who come under incontinence control during each part of the study, and to assess other aspects for the feasibility of a long-term study. These aspects will include: the adequacy of patient accrual, the patient acceptance of therapy arms, and the ability to measure incontinence, frequency, and ensuing complications with precision and accuracy.

METHODOLOGY—Surface stimulation will be conducted with a small battery powered stimulator and self-adhering surface electrodes. Stimulation will be conducted acutely and chronically during home use. Several features of the stimulator make it suitable for these clinical trials: it is a small device that can fit into the patient's pocket or clip to the belt; it has an on-off switch for continuous stimulation and a light source to indicate that the stimulation is on; its frequency and pulse duration are custom set for optimum stimulation effect with minimum of pain; and it has a single dial with friction resistance that will allow the user to easily turn on and off the stimulator but will limit unwanted changes in the stimulating current.

For home use, the patient will turn the stimulator on and off and adjust the current to the highest comfortable current. Although effectiveness is thought to be related to higher currents, the strength of the elec-

trical stimulation will be kept below the level that the patient indicates an uncomfortable sensation or pain. As the patient becomes used to the current, he/she may be able to increase the current. Thus, painful stimulation will be avoided.

PROGRESS—Patients are beginning to be enrolled.

FUTURE PLANS—Placement of the stimulating electrodes over the anal sphincter is being considered. This location has been reported to have a positive outcome and it is an area with sensory innervation from the third sacral nerve, a nerve involved with bladder function.

[87] REHABILITATION OF URINARY INCONTINENCE USING STIMULATED MUSCLE FLAPS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Core Funds)*

PURPOSE—This study will evaluate the effectiveness of stimulated skeletal muscle flaps in elevating urethral closure pressure in the dog model. Urethral ischemia and stricture formation is a known complication of urethral wrap procedures and these complications will be evaluated. This project has two overall purposes: to demonstrate in the dog model the effectiveness and reliability of an electrically stimulated skeletal muscle flap urethral sphincter for the establishment of increased urethral and leak point pressure and to assess whether a skeletal muscle urethral sphincter composed of two separate and independently stimulated muscles will provide high urethral closure pressure suitable for maintaining continence while minimizing urethral ischemia and stricture formation. These goals are particularly relevant to the patient following radical prostatectomy where urinary incontinence can be a problem.

METHODOLOGY—Two groups of male dogs will be used in this study. Group 1 will be composed of three dogs that will undergo continuous stimulation of a single sartorius muscle neosphincter. Group 2 will be composed of dogs that will undergo alternating stimulation of two independent and separate sartorius muscle neosphincters. Alternate stimulation of the two independent and separate neosphincters will eliminate continuous pressure on a single segment of urethra and should decrease the risk of urethral ischemia and stricture formation. Efficacy of the neosphincters will be determined with urethral and leak point pressure measurements and videourodynamic techniques. Urethral stricture formation will be assessed with urethrography and urethral histology.

PROGRESS—The feasibility of stimulated skeletal muscle flap was evaluated in one dog using a single muscle wrap around the sphincter. We have developed recording methods to evaluate the urethral flap.

RESULTS—Stimulation of the skeletal muscle flap in one dog did not increase urethral pressure. At autopsy, necrosis of the skeletal muscle was observed around the urethra indicating failure of the flap.

FUTURE PLANS—A reevaluation of the methodology is being conducted. The mechanics of a muscle wrap around a small urethra are being evaluated. Suitability of abdominus rectus muscle for the skeletal muscle flap is under consideration.

[88] RESTORATION OF MUSCLE ACTIVITY THROUGH FES AND ASSOCIATED TECHNOLOGY: THE RAFT PROJECT, A CONCERTED ACTION

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Sponsor: *Commission of the European Communities*

PURPOSE—The concerted action, restoration of muscle activity through FES and associated technology (RAFT), has been approved by the European Community in the frame of the ongoing program BIOMED II, aimed at promoting medical research in the European Community.

This 3-year project started in January 1993, with the objective of stimulating research into reactivating paralyzed or poorly controlled muscle function in order to permit patients with a wide range of disabling conditions to perform activities of daily living more effectively. This will in turn lead to an increase in their independence and reduce the financial burden of the support upon the various European national social security arrangements.

RAFT builds on the work completed under the MORE program by using the valuable network of centers which are already collaborating effectively in the areas of FES and paraplegic ambulation, as evidenced by the six workshops and numerous personnel interchange visits made under this program, the publication of a book, and the identification of three main objectives as major research topics.

METHODOLOGY—The nerves going to the muscles are made of a mixed population of fibres, including motor and sensitive pathways. Given this organization, the stimulation of a nerve trunk does not allow good selectivity in terms of reaching the right muscle and obtaining a reliable modulation of force by recruiting the different motor units. Special investigations on animals and stimulation modality are required for that. In order to obtain acceptable movement, it is also important to adapt the control strategies to the individual patient. This goal can be obtained a priori by considering the type and level of the lesion, the anthropometric, physiological, and anatomical characteristics of each patient in conjunction with the results of specific tests for spasticity, paresis, and so forth. From the dynamic point of view, the optimal adaptation can be reached by quantitative analysis of performance and by using simulation techniques in order to choose the best rules for muscle recruitment.

The selection of patients and the definition of a proper training before and after the implantation is key to attaining good results. Since the SCI patient cannot feel sensations of muscular fatigue and since the composition of fibers (fast and slow) is very often modified in these patients, it is important to detect the fatigue in order to avoid the muscle damage by FES.

It is important to provide a multidisciplinary evaluation during the concerted action of all the clinical and research achievements. This is to be made mostly from the clinical trials, organized within the European clinical network in the different SCI centers.

PROGRESS—In order to reach the objectives of the concerted action, three topical workshops have been held: in Milano on motor restoration by FES: patient evaluation and spasticity control, in Montpellier on neuromuscular electrode interface in implanted FES: surgical implications, and in Enschede on walking restoration by FES: patient evaluation and spasticity control.

Moreover, in the last meeting a detailed protocol for clinical surgical and rehabilitation aspects was presented.

RECENT PUBLICATIONS FROM THIS RESEARCH

Functional electrical stimulation for restoration of movement. Pedotti A, Ferrarin M, eds. Commission of the European Communities COMAC BME, Milano. Amsterdam: IOS Press, 1994.

[89] KINESTHETIC PERCEPTION IN THE HAND AND ARM

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Sponsor: *National Institutes of Health; National Institute of Neurological Disorder and Stroke*

PURPOSE—The control of normal arm movement and hand grasp depends on precise integration of sensory information and motor commands. Afferent and efferent signals, and their normal interactions, are lost or corrupted as a result of spinal cord injury (SCI), peripheral neuropathy, and other neuromuscular diseases. Assistive devices such as limb prostheses and neuroprostheses, and robotic manipulators typically provide some motor function but little or no tactile or kinesthetic information. Integration of the sensory information that is available requires careful attention and effort by the user. The goal of this project is to investigate sensorimotor behavior in the hand, and to develop an integrated model of motor control and kinesthetic perception. The model is intended to provide a better framework for the development of advanced assistive devices incorporating sensory information both subconsciously (reflexively) and consciously.

METHODOLOGY—In the past year, three experiments have been completed using different methodologies, yet arrive at a consistent results. In the first experiment, subjects matched the effort used to squeeze either isometric or anisometric (compliant) loads in two hands. Subjects made symmetric matches (equal loads in both hands) or asymmetric matches (one hand anisometric, the other isometric). Systematic differences in the resulting forces were made in the asymmetric conditions. In the second experiment, subjects made bilateral force halving and doubling judgments of isometric pinch. In the third experiment, subjects pinched a pneumatically activated manipulandum and were instructed to "not intervene" to applied force perturbations. Changes in force and finger span were used to calculate the mechanical stiffness of pinch as a function of the initial force at a constant initial span.

PROGRESS—All three experiments have been completed on separate groups of subjects. The perturbation results are only preliminary and the protocol is being revised for a subsequent and more complete experiment.

RESULTS—The results from all three experiments can be explained quantitatively by assuming that the subjects made all judgments of effort, rather than force, and that changes in effort are manifested by shifts in a control variable corresponding to the threshold of the tonic stretch threshold (lambda). The final force and span result from the equilibrium between the external load and the compliance of the grasp. The common result from both the psychophysical experiments and the physical measurements of stiffness is an inferred or measured compliant characteristic where force is an accelerating function of span with an exponent of 1.5 to 1.8, consistent with previous measurements at single joints such as the elbow or ankle.

FUTURE PLANS—Although the different experiments all result in similar estimates of the grasp compliance, it will be necessary to repeat the different protocols simultaneously on a single group of subjects. Furthermore, the experiments will need to be repeated under different sets of instructions regarding judgments of effort versus force or span to determine the interplay of the motor commands and afferent-based judgments under a range of tasks.

RECENT PUBLICATIONS FROM THIS RESEARCH

Individual differences in perceived pinch force and bite force. Van Doren CL. Percept Psychophys, 1993:53(5):483-8.

Cross-modality matches of finger span and line length. Van Doren CL. Percept Psychophys. In press.

[90] IMPLANTABLE STIMULATION, TELEMETRY, AND TRANSDUCER SYSTEM FOR NEURAL CONTROL

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Sponsor: *National Institutes of Health; Paralyzed Veterans of America, Spinal Cord Research Foundation*

PURPOSE—The aim of this project was to develop and evaluate an integrated, implantable, neuroprosthetic system to provide electrical stimulation of paralyzed muscles and sensor information from joints and muscles. Ongoing VA-sponsored, multicenter, upper-extremity, clinical trials utilize an implanted stimulator radio, controlled by an external computer, to provide quadriplegic individuals with restored grasp and release function. Users control the system with voluntary movements sensed by an externally mounted transducer. The implantable stimulator/telemeter (IST) developed in this project extends the capabilities of the existing Cleveland implantable stimulator by increasing the number of stimulus channels available and adding the capability to transmit externally information about implanted sensors and device.

The increased number of stimulus channels will allow improved or additional functions such as: finer hand control, active extension of the elbow, active rotation of the forearm, and improved strategies for providing artificial sensation.

An implantable joint angle transducer (IJAT) was also developed as an integral component of the implantable system. The IJAT is used to sense movement of joints such as the wrist in C6-level injuries or the shoulder in C5-level injuries. The IJAT can be used to provide command control information from a joint with remaining volitional control, such as the wrist in persons with C6 tetraplegia or the shoulder in persons with C5 tetraplegia, or as a feedback control source to stabilize and control the wrist in persons with C5 tetraplegia. This will eliminate external orthoses currently used in the hand neuroprosthesis and provide additional hand function. The implanted stimulator/telemeter and joint angle transducer developed in this project will eliminate many of the mounting and usage problems associated with externally mounted transducers. Status information received from the implant will help to maximize battery life of the external control computer and will alert the user if problems arise in the radio-control link.

METHODOLOGY—The initial prototype ISTs provide ten channels of stimulation, one joint angle transducer, and system status information. Miniaturization of the circuitry was accomplished by utilizing an application specific integrated circuit (a custom made "smart chip"), and hybrid circuit technology. The design seals the miniature circuit inside a small titanium box that can be implanted in the body. Leadwires run down the arm, beneath the skin, to connect the stimulator/telemeter to an implanted transducer and electrodes implanted at the muscles. The implant and chip were designed to accommodate additional stimulus and transducer channels, as well as the capability of sensing muscle contractions, to allow future expansion of the clinical capabilities of the system.

PROGRESS—Prototype ISTs and IJATs have been built, packaged, and tested. Software was developed for a laboratory computer to control the IST for bench and animal testing. One complete IST and IJAT system have been implanted in the wrist, forelimb, and shoulder of a dog, and tests are ongoing to establish its performance prior to implantation in humans. At this writing, the system had been implanted for seven weeks, and continued to function properly.

FUTURE PLANS—The IST design is undergoing some minor mechanical redesign revisions. Upon completion, additional bench and animal test data will be collected to accompany an Investigational Device Exemption (IDE) application to the FDA for beginning human clinical testing.

RECENT PUBLICATIONS FROM THIS RESEARCH

Data transmission from an implantable biotelemeter by load-shift keying using circuit configuration modulator. Tang Z, Smith B, Schild JH, Peckham PH. IEEE Trans Biomed Eng. In press.

[91] MANAGEMENT OF URINARY DISORDERS IN SCI

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PURPOSE—This project has two overall purposes: to apply functional electrical stimulation (FES) techniques for bladder voiding and incontinence management after spinal cord injury (SCI), and to use new monitoring capabilities of implantable neuroprosthetics for continuous recording of lower urinary tract functions. These goals are particularly relevant to the SCI patient where control over voiding functions is lost. Moreover, current treatments such as intermittent catheterization, continuous catheterization, or external catheterization are not always effective and can have significant, even life-threatening, side effects such as autonomic dysreflexia, urinary tract infections, and upper urinary tract problems.

METHODOLOGY—Direct bladder stimulation was evaluated before and after SCI in male cats. Animals have received either an upper motor neuron lesion or a lower motor neuron lesion. Animals were instrumented under anesthesia with five "suture" type electrodes consisting of multistranded 316LVM stainless steel with a needle placed at the electrode tip and sutured into the serosa of the bladder wall. Four electrodes were implanted anterior to the trigone and on the dome, and a fifth was placed on the dome. Additional instrumentation consisted of two suprapubic bladder catheters for recording bladder pressure and bladder filling, and a peritoneal balloon for recording abdominal pressure. EMG recording electrodes were implanted in the pelvic floor and leg quadriceps.

PROGRESS—The feasibility of direct bladder stimulation has been evaluated in seven male cats. We have developed suitable tethering procedures and effective micturition has been shown.

RESULTS—Responses to direct bladder stimulation were recorded during a 2-week period in tethered animals before SCI without anesthesia. All of the cats responded to direct bladder stimulation using a single 3 sec stimulation period, at 40 pps, 1 ms pulse duration and a stimulating current from 7.5 to 40 mA. The maximum voiding rates were from 0.5 to 1.5 ml/sec with complete bladder emptying, particularly after the first 2 or 3 weeks. Peak detrusor pressures were from 40 to 70 cm H_20. Voiding was obtained without discomfort.

Stimulation also induced voiding after SCI in all of the animals, particularly after the first 2 or 3 weeks. Voiding with stimulation was observed after 1 and 3 weeks in two animals. Maximum voiding rates after SCI were similar to before SCI but the volume voided was reduced to 4 to 10 ml at peak detrusor pressures from 40 to 70 cm H_20. Repeated stimulation completely emptied the bladder in three of the cats. Similar responses were seen after upper and lower motor neuron lesions. Impedance monitoring was effective for determining bladder volume and EMG was determined to be a good measure of urethral resistance.

In conclusion, we believe that direct bladder stimulation offers an alternative method of promoting voiding following SCI. Potential advantages or new directions in direct bladder stimulation are that the pudendal nerve in the pelvic floor may not be directly stimulated, and that the large surface area "suture" electrode may be an improvement in electrode design. However, problems related to clinical trials of direct bladder stimulation include: SCI patients must be continent and their high urethral resistance must be managed and acute evaluation procedures must be developed that will show which patients will benefit from direct bladder stimulation. If these issues can be addressed, and this is the area of our current research, direct bladder stimulation may become more widely available to the SCI patient.

FUTURE PLANS—This project will be completed in the next 6 months. Plans are to initiate clinical trials with stimulation for urogenital function and monitoring lower urinary tract function. Acute studies with percutaneous wires are being proposed to stimulate the bladder directly for voiding, the pelvic floor for bladder inhibition, and the cavernosus nerve for management of sexual function.

[92] DEVELOPMENT AND DISSEMINATION OF A RESOURCE GUIDE ON FUNCTIONAL ELECTRICAL STIMULATION (FES) FOR PERSONS WITH SPINAL CORD DYSFUNCTION

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Sponsor: *Buckeye Chapter, Paralyzed Veterans of America; Paralyzed Veterans of America, Spinal Cord Injury Education and Training Foundation*

PURPOSE—Functional electrical stimulation (FES) is a technique that can maximize health and function in persons with spinal cord injury (SCI) or spinal cord disease, such as multiple sclerosis (MS), regardless of age, race, sex, or length, level, and completeness of injury. In medically appropriate cases, FES can be used for persons with SCI or disease to restore upper and lower extremity mobility, improve respiratory functions, restore bowel and bladder functions, restore male sexual function, and to treat and help prevent secondary complications such as pressure ulcers, deep-venous thrombosis, contractures, spasticity, deconditioning due to lack of exercise, bone demineralization, and muscle atrophy. In some instances, FES can significantly improve physical and emotional health in ways that cannot be achieved by other methods available today. Persons with SCI or disease need specialized information about FES to build a knowledge base that permits them to understand, identify, and pursue appropriate treatment options to maximize their independence, function, and health.

METHODOLOGY—The objectives of the project are to increase the knowledge base of persons with SCI or disease on the use of FES, to increase access for such persons to FES providers, and to increase their ability to make informed decisions regarding the appropriateness of FES interventions. To accomplish the objectives, in cooperation with the National Spinal Cord Injury Association and ABLEDATA, we will develop and disseminate to the SCI/disease community, a resource guide on FES. The guide will serve as a "one-stop-shop" for such persons seeking information about FES options.

The tutorial section of the guide will include: 1) a description of the purpose of the FES application and a review of non-FES alternatives to accomplish the same objective; 2) a discussion of the status of the FES application; 3) criteria outlining who is medically suitable for the application and any contraindications; 4) the typical cost and time course of the application and the extent to which insurance typically pays; and 5) a discussion of realistic expectations, including identification of potential problems. A comprehensive referral section will include descriptive listings that profile the availability of FES clinical and applied research programs, so that individuals and their caregivers can identify FES programs that meet their needs.

To gather this information, a survey of clinicians and clinical researchers will be conducted. The guide will also include a section that provides references to additional resources in FES for SCI or disease and a comprehensive index. The guide will be printed in a spiral bound format for ease of use by persons with limited dexterity and strength. A baseline and a follow-up survey assessing the project objectives and usefulness of the guide will be distributed to a representative sample of users to determine the extent to which the objectives of the project have been reached.

PROGRESS—A draft of the tutorial section of the guide has been completed and will be reviewed by a committee of experts in the field. The data collection survey instrument and the distribution mailing list have been completed and the survey will be conducted at the beginning of 1995.

FUTURE PLANS—The FES resource guide is expected to be available in the last quarter of 1995.

[93] FATIGUE AND RECOVERY OF FES-ACTIVATED PARALYZED MUSCLES

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Sponsor: *The Segal Foundation; The Walter and Sandra Kaye Fund*

PURPOSE—In this work we study the relation between force, EMG, and metabolic parameters of FES-activated paralyzed muscles.

METHODOLOGY—The lower limb of a patient with paraplegia can be analyzed as a dynamically determinate system, since the muscles there are isolated from voluntary control. Hence, when activated by functional electrical stimulation (FES), the only nonzero muscle forces are those of the actually stimulated muscles. This unique situation allows the calculation of the muscle force from the externally measured torques and the correlation of this direct muscle output to parameters of another nature, such as metabolic or myoelectric.

Force is being measured by especially designed load cells during either isometric or isotonic muscle contraction. Metabolic parameters are measured using P-31 NMR spectroscopy from which information on phosphocreatine, inorganic phosphor, and intracellular pH is obtained. EMG is measured using an especially developed stimulus artifact suppressor. The measurements are taken both during the course of stimulation and during the recovery process.

A musculo-tendon model for fatigue is developed and incorporated in the dynamic model of the activated limb. In parallel, muscle fatigue in FES is being modeled by artificial neural networks.

RESULTS—The metabolic profiles obtained serve to incorporate fatigue and recovery functions into the musculo-tendon model. The model solution allows prediction of the muscle force under dynamic activation and at various levels of stimulation. Estimated muscle parameters have the following values for the quadriceps muscle: 60–64 N/cm^2 for the muscle stress and slack length ratio of 0.952, 0.935, 0.920, and 0.901 for 0, 30, 60, and 90° of knee angle, respectively. The results obtained for the EMG-force relationship indicate the conditions under which surface EMG can be used to noninvasively monitor the quadriceps muscle fatigue during stimulation. The neural networks results have shown that by using appropriate architecture, one can represent information from FES experiments in recruitment and fatigue by training the weights of the network.

FUTURE PLANS—Future plans in this work include further investigation of the relationship between fatigue and the ability of the muscle to recruit. Additionally, the recovery characteristics of the EMG parameters will be studied in comparison to those of the mechanical/metabolic parameters. The neural networks modeling will compare the performance of one- and two-layer feedforward simulations to learn the forward dynamics model of the force produced in the muscle.

RECENT PUBLICATIONS FROM THIS RESEARCH

In vivo P-31 NMR studies of paraplegics muscles activated by functional electrical stimulation. Levy M, Kushnir T, Mizrahi J, Itzchak Y. Magn Reson Med 1993:29:53-8.

Musculo-tendon model of fatigue profiles of paralyzed quadriceps muscle under FES. Giat Y, Mizrahi J, Levy M. IEEE Trans Biomed Eng 1993:40:664-74.

Stimulus artifact suppressor for EMG recording during FES by a constant current stimulator. Minzly Y, Mizrahi J, Hakim N, Liberson A. Med Biol Eng Comput 1993:31:72-5.

EMG as an indicator of fatigue of isometrically FES-activated paralyzed muscles. Mizrahi J, Levy M, Ring H, Isakov E, Liberson A. IEEE Trans Rehabil Eng 1994:2:57-65.

Modeling isometric FES muscle fatigue by artificial neural networks. Dornay M, Yadid-Pecht O, Mizrahi J, Isakov E, Susak Z. In: Proceedings of the 24th Annual Meeting of the Society for Neuroscience, Miami Beach, Florida, November 1994:1205.

Myoelectric and force characteristics in transcutaneous isometric FES. Mizrahi J, Isakov E, Susak Z. Basic Appl Myol 1994:4:154.

B. Upper Limb Applications

[94] FUNCTIONAL NEUROMUSCULAR SYSTEMS FOR UPPER EXTREMITY CONTROL

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B011-5RA)*

PURPOSE—The objective of this project is to deploy and quantitatively evaluate implantable functional neuromuscular stimulation systems to restore hand grasp and release in C5 and C6 quadriplegic patients.

METHODOLOGY—Multichannel implantable stimulator systems are surgically implanted in patients with C5 and C6 quadriplegia to provide grasp and release. An implant stimulator is placed in a subcutaneous pocket overlying the pectoralis major muscle. Seven epimysial electrodes are placed on muscles of the hand to provide motor function, and an eighth is placed in the supraclavicular area to provide sensory feedback. Augmentative surgical procedures also may be performed, including tendon transfers of voluntary and paralyzed muscles. Postsurgery, subjects are casted for 3 to 4 weeks and then undergo a period of muscle conditioning using electrical stimulation. Subsequently, during a 3-week inpatient rehabilitation stay, grasp patterns and control parameters are customized, subjects are trained to use the neuroprosthesis, and their functional ability with and without the device is evaluated.

A variety of assessments were utilized to measure impairment, disability, handicap, quality of life and device utility. Impairment was measured by range of motion, pinch force, and ability to grasp and release objects. Disability is measured by ability of the hand to perform activities of daily living. Handicap was measured using the Craig Handicap Assessment and Reporting Technique and Reintegration to Normalized living Index. Quality of life was measured by Rosenberg Self-Esteem scale, and the Mental Health Inventory. Utility was measured by a usage survey, data logging, and a satisfaction survey. In addition, a set of system assessments are also performed in order to evaluate potential deficiencies, including: 1) Static Recruitment Characteristics, which are the input/output properties of each electrode as a function of stimulus level; 2) Input/Output Properties of Hand Grasp, which are the overall relationship between the subject's command and the force and position of the digits; and 3) Specific Task Analysis, which combines simultaneous command/control and task performance assessment.

PROGRESS—A total of 22 subjects have received implant stimulators at six cooperating sites, and the multicenter clinical trial has been transferred to industry. In Cleveland, 9 subjects have received implant stimulators (6 males, 3 females; 4 C5 subjects, 5 C6 subjects), and an additional 3 subjects are scheduled for surgery in early 1995. Seven subjects have completed the majority of the training and functional evaluations (GRT, ADL Test, Telephone Interview), as well as the system assessment evaluations. The 2 remaining subjects are currently undergoing the postoperative protocols.

RESULTS— Briefly, patients generate lateral and palmar pinch strengths in the range of 2.5–30 Newtons. In a six-task grasp and release test, patients can typically manipulate two or three objects with their tenodesis grasp alone, and can manipulate five or six objects with the neuroprosthesis. The number of completions in a given time is always higher with neuroprosthesis for the larger and heavier objects. Patients demonstrate the ability to perform activities of daily living with less assistance with the neuroprosthesis than without it. This includes the reduction or removal of physical assistance, the removal of adaptive equipment, and/or the reduction in the need for self assistance (such as using the mouth to manipulate a utensil). Patients consistently indicate a prefer-

ence for using the neuroprosthesis for a variety of tasks. Patient surveys indicate consistent use of the neuroprosthesis at home, with eating and office tasks being the most frequently performed with the neuroprosthesis. Patients generally indicate a high level of satisfaction with the neuroprosthesis. Preliminary results indicate that the neuroprosthesis reduces impairment and disability, and that the device shows good usage and satisfaction. We expect that the neuroprosthesis will reduce handicap and improve quality of life.

FUTURE PLANS—Human studies for the hand neuroprosthesis will continue through 1995. In addition, animal studies for an advanced neuroprosthesis, incorporating an implanted joint angle sensor and telemetry capabilities, will continue through 1995, with human studies to follow in 1996.

RECENT PUBLICATIONS FROM THIS RESEARCH

Analysis of the reliability of percutaneous intramuscular electrodes in upper extremity FNS applications. Memberg WD, Peckham PH, Thrope GB, Keith MW, Kicher TP. IEEE Trans Rehab Eng 1993:1:126-32.

Restoration of functional grasp-release in tetraplegia with implantable neuromuscular stimulation and tendon transfer. Peckham PH, Keith MW, Stroh KC, Kilgore KL, Hart RL. Electrophysiol Kinesiology 1993:5:269-74.

Development of a quantitative hand grasp and release test for patients with tetraplegia using a hand neuroprosthesis. Wuolle KS, Van Doren CL, Thrope GB, Keith MW, Peckham PH. J Hand Surg 1994:19A:209-18.

Instrumented assessment of FNS hand control during specific manipulation tasks. Burelbach JC, Crago PE. IEEE Trans Rehab Eng 1994:2:165-76.

Surgically-implanted intramuscular electrode for an implantable neuromuscular stimulation system. Memberg WD, Peckham PH, Keith MW. IEEE Trans Rehab Eng 1994:2:80-91.

[95] THIN-FILM PERIPHERAL NERVE ELECTRODE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Core Funds)*

PURPOSE—Complex hand movements might be obtained with direct median nerve stimulation through an implanted multielectrode nerve cuff. The direct nerve stimulation should induce repeatable hand responses and result in no injury to the nerve. The electrode is comprised of a multielectrode circumneural cuff interfaced to a multichannel implantable stimulator and associated control algorithms.

METHODOLOGY—Electrodes are being fabricated by vacuum depositing Pt-Ir films on thin sheets of fluorocarbon polymer and photolithographic patterning and etching to form the leads and charge injection sites. The patterned substrate is then selectively covered with a second polymer layer. Four charge injection sites in a "round about" geometry, similar to that being investigated for phrenic nerve stimulation, are being evaluated.

In preparation for studies with the new nerve cuff electrodes, it became apparent to us that we needed more experience with electromyographic (EMG) recording from the forearm muscles as well as experience with recording the torque responses of different hand movements. Therefore, we requested and received authorization from our Institutional Animal Review Committee, to conduct one-day studies in the raccoon under anesthesia. The studies used sterile percutaneous electrodes for stimulation and recording. Electrode wires were inserted with a small 27G needle.

PROGRESS—Four raccoons have been evaluated with the percutaneous method on 8 different days and we have established our stimulation and recording techniques. The animals have recovered without adverse responses.

RESULTS—Electromyographic recording techniques have been established to show selective stimulation of muscles. Bipolar stimulation and recording electrodes

were inserted in the muscle pronator teres. Recording the EMG to stimulation revealed a stimulation artifact and an "M" wave of approximately 40 μs in duration. The EMG record was electronically modified to suppress the artifact and to record the full-wave rectified voltage. This value was suitable for recording on a strip chart recorder as a measure of muscle contractile activity. Chart recordings from the pronator teres showed increasing responses to increasing stimulating currents; whereas, other muscles such as flexor digitorum superficialis did not have an EMG response to pronator teres stimulation.

A torque recording platform constructed in our model shop held the raccoon arm and allowed free digit movement. The paw was clamped to allow for only a single movement such as wrist flexion, wrist pronation, or phalanges flexion. Torques were recorded in response to direct muscle stimulation with the percutaneous electrodes. Pronator teres stimulation resulted in pronation of the hand. Flexor digitorum profundus had a more general response with hand pronation, flexion, and phalanges flexion. Thus, torque measures are less specific for individual muscles than the EMG recordings.

FUTURE PLANS—The multielectrode cuffs will be evaluated on the median nerve using techniques developed during our current percutaneous procedures. Acute studies will be followed by chronic studies with an implantable stimulator.

[96] MECHANICAL EFFECTS OF MUSCLE TENDON TRANSFER AND FUNCTIONAL NEUROMUSCULAR STIMULATION

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Sponsor: *The Whitaker Foundation*

PURPOSE—Tendon transfer surgery is often performed in individuals with C6-C7 quadriplegia to restore voluntary control over elbow extension, wrist extension, and thumb pinch (key grip), and can be combined with functional neuromuscular stimulation (FNS) to restore hand function in individuals with C5 quadriplegia. The general objectives of this study are to quantify the ability of these procedures to restore the intended function, to assess the mechanical and neural impact of these surgical reconstructions on the other movement functions of the upper extremity, and to evaluate the role of FNS in complementing such surgical procedures. In particular, the effects of transfer surgeries to restore voluntary control over elbow extension, wrist extension, and thumb pinch on the more proximal joints of the limb (elbow and shoulder) will be examined during both posture and movement, both at the single joint and whole-arm level.

METHODOLOGY—The ability of individuals with spinal cord injury and subsequent tendon transfer surgery to perform arm movements both alone and in conjunction with the performance of a restored hand function, will be examined using a specialized robotic manipulator that has been developed for the study of arm movements. It can resist movements in a controlled manner and can be used to impose small forces to the end of the limb during posture and movement. The ability of these subjects to learn to use the donor muscle in its new function will be quantified both in terms of forces generated and by electrical activity in the donor during execution of the restored task. In particular, however, the adaptation of the other muscles of the limb to compensate for the new function of the donor will be assessed both by recording electrical activity during execution of the restored function and by characterizing the mechanical properties of the arm.

Mechanics will be characterized by imposing small force perturbations onto the end of the limb, measuring the resulting movements, and using system identification analysis procedures to estimate the endpoint impedance of the arm, which is important both functionally and as an indicator of the overall mechanical state of the limb. Analysis techniques have been developed for characterizing endpoint impedance both during posture and during movement; these will be used here to quantify the mechanics of the limb for a

range of different tasks, different external loads, and different subject populations. In particular, however, the effects of a restored hand function (i.e., thumb pinch) on the neural and mechanical properties of the rest of the limb will be examined. Nondisabled subjects and SCI subjects with tendon transfer for restoration of wrist extension and elbow extension will also be studied, for a range of tasks and external loads.

PROGRESS—Software for data analysis and system identification has been developed. The robotic manipulator has been assembled and debugged. Control software for the robotic manipulator is nearly finished, and initial experiments will begin when the software is complete.

C. Lower Limb Applications

[97] RESTORATION OF STANDING PIVOT TRANSFER FOR QUADRIPLEGIC PATIENTS USING A TOTALLY IMPLANTED FNS SYSTEM

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PURPOSE—This project is designed to investigate the use and effectiveness of an implanted eight-channel functional neuromuscular stimulation (FNS) system to provide or facilitate the ability to perform a standing pivot transfer to individuals with incomplete spinal cord injuries (SCI) at low-cervical levels. An FNS-assisted standing transfer system may decrease the need for heavy lifting on the part of family members or personal assistants, thereby reducing the burden of care and risk of back injury. In nursing homes and institutions, persons with quadriplegia outnumber those with paraplegia and depend on health care professionals for their transfers and physical mobility. FNS addresses the motor deficits that contribute to this dependency and may postpone or eliminate the need for institutionalization.

METHODOLOGY—Temporary systems consisting of up to 12 percutaneous intramuscular electrodes are implanted in the hip, knee, and trunk extensors. The percutaneous systems are primarily for exercise and training in the operation of the custom stimulation devices. Subjects begin immediately with a program of exercise with FNS. When sufficient levels of strength and endurance are achieved, functional stimulation patterns are developed and standing activities are attempted. Each subject participates in up to three one-on-one training/exercise sessions per week to refine the standing transfer maneuver and reduce the number of electrodes required. The temporary systems are then replaced by more permanent electrodes with removable percutaneous leads that mate with an external stimulator/controller for initial trials in the home or community.

Once an optimal and stable eight-channel system has been identified that provides safe and reliable standing transfers, an in-line connector allows the percutaneous portion to be replaced by an implanted receiver/stimulator. All procedures, including introduction of the implantable receiver/stimulator, are performed on an out-patient basis. Follow-up by self report and regularly scheduled visits to the laboratory continue after discharge with the implanted system.

PROGRESS—To date, four volunteers with incomplete tetraplegia have participated in the study. All have been provided with FNS systems for exercise or functional use outside of the laboratory. The first three subjects were able to stand with FNS and have demonstrated the ability to perform a pivot transfer

with minimal stand-by assistance. The fourth is in the initial stages of implantation and exercise.

The first subject has completed the course of testing and training and has received the implanted receiver/stimulator. The following two subjects are in the process of having their percutateous systems replaced with more permanent electrodes in preparation for conversion to the implanted system.

Alternative command inputs have been devised to provide users with limited manual dexterity with the ability to operate the system independently. A portable folding walker that can be opened and closed without assistance has also been designed for use with the system.

PRELIMINARY RESULTS—No technical problems have been encountered with the implant receiver/stimulator; one electrode exhibited altered recruitment properties that did not adversely affect the performance of the standing transfer. Users generally require assistance with donning/doffing the system. Although several subjects are able to exercise and stand independently, most rely on others to activate the stimulator and provide stand-by assistance. This suggests that the system may be better suited for facilitating an assisted transfer in this population. Few subjects appear able to assume or maintain a stable upright "C" posture due to activation of the rectus femoris. This does not seem to compromise the ability to transfer, although it may affect the stability and independence of the maneuver.

FUTURE PLANS—Conversion to implantable systems for the two more experienced volunteers will continue, with implantation of the receiver/stimulator to follow shortly thereafter. For the most recent subject, exercise and initial standing/transfer training is scheduled to be completed within the next 6 months. Plans are currently being formulated to review of the technology and implementation/evaluation procedures in preparation for transfer to a clinical setting for larger scale trials.

RECENT PUBLICATIONS FROM THIS RESEARCH

Augmentation of transfers for a quadriplegic patient using an implanted FNS system. Case report. Marsolais EB, Scheiner A, Miller PC, Kobetic MS, Daly JJ. Paraplegia 1994:32:573-9.

[98] FUNCTIONAL PARAPLEGIC WALKING WITH ELECTRICAL STIMULATION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B681-RA)*

PURPOSE—The purpose of this research is to develop a practical functional electrical stimulation system (FES) for walking in paraplegia. This includes development of electrodes and surgical techniques to implant them, hardware and software to deliver electrical pulses, stimulation patterns of coordinated sequences of electrical pulses for control of trunk, hips, knees, and ankles.

METHODOLOGY—Percutaneous double helix intramuscular electrodes are implanted in volunteers with paraplegia in all major muscles of trunk and lower extremities. Soft tissue endoscopic techniques are being developed to implant either intramuscular or nerve cuff electrodes for stimulation of iliopsoas, gluteal, and hamstring muscles under direct vision to improve reliability and precision of the placement. The muscles are conditioned with electrical exercises and programmed for movements. Available clinical muscle and gait evaluation techniques are being adapted to individuals with paraplegia. When sufficient functions are achieved, kinematic, kinetic, and metabolic energy evaluations are performed and movements are integrated into activities of daily living.

Using endoscopy, an operating space was created in soft tissue. This allowed implantation of a modified intramuscular electrode with a loop for fixation at the nerve or of the Huntington cuff electrode. This technique has the potential to eliminate electrode failures due to imprecise placement or movement after implantation. Application of endoscopy will allow recruitment of the iliopsoas in isolation and eliminate

problems with current implantation technique that activates, in addition, adductor longus, a muscle that causes an extension moment at large hip flexion angles and thereby limits the hip flexion movement in implanted persons with paraplegia.

Thirteen basic rules were found useful in tuning template stimulation patterns to individual needs. Muscle fatigue was found to affect the strength and timing of joint movements during walking. Timing of hip extensor activation and forward lean were found to be the most critical for progression. At least 16-channels of stimulation were needed for reasonable stability for walking with a walker.

PROGRESS—All subjects were implanted with double helix percutaneous intramuscular electrodes. Soft tissue endoscopic techniques and tools were developed and tested. Muscle strength with FES in paraplegia was quantified. Stimulation patterns for walking with rules for tailoring them to individuals have been generated. and the resulting paraplegic gait was quantified with a video-based motion analysis system.

RESULTS—A total of 25 subjects with paraplegia have been implanted. All but two, who did not achieve sufficient quadriceps strength, were able to stand. Fifteen were able to walk or make a few steps and eight were able to climb stairs.

A subject who used his FES walking system daily showed the most symmetric gait and the least variability between days in stride and step length. His physiologic cost index was also the lowest.

FUTURE PLANS—We plan to further develop the endoscopic technique and tools to improve electrode implantation and fixation at the motor point. Guidelines for modifying stimulation patterns will be implemented on a PC in a user friendly software for use by clinicians. The percutaneous FES system will be replaced with a radio frequency-driven, multichannel implant for clinical trials of the walking system in paraplegia. Electrically driven movements will be further integrated into activities of daily living.

RECENT PUBLICATIONS FROM THIS RESEARCH

Advancing step by step. Kobetic R. IEEE Spectrum, October 1994:27-31.

Endoscopic electrode implantation for enhanced stimulation of the hamstring branches of the sciatic nerve. Osman SG, Marsolais EB. Arthroscopy 1994:10(3):270-4.

Design and clinical application of a double helix electrode for functional electrical stimulation. Scheiner A, Polando G, Marsolais EB. IEEE Trans Biomed Eng 1994:41(5):1-7.

Function and strength of electrically stimulated hip flexor muscles in paraplegia. Kobetic R, Marsolais EB, Miller PC. IEEE Trans Rehab Eng 1994:2(1):11-7.

Synthesis of paraplegic gait with multi-channel functional neuromuscular stimulation. Kobetic R, Marsolais EB. IEEE Trans Rehab Eng 1994:2(2):66-79.

[99] RESTORATION OF SIT-TO-STAND FUNCTION IN ELDERLY PATIENTS USING FNS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E698-RA)*

PURPOSE—The objective of this project is to test the hypothesis that functional neural stimulation (FNS) can restore sit-to-stand transfer capability for the geriatric patient. Many geriatric patients would be able to remain at home if they were able to perform the sit-to-stand transfer independently or with minimal assistance. Quantification of the efficacy of rehabilitation techniques will provide needed rationale and justification for treatment procedures.

METHODOLOGY—For baseline purposes five non-disabled elderly subjects were tested; their sit-to-stand transfer was characterized using video records, force plate data, and EMG data. In the second phase of the study, nine subjects were provided with one of two treatment protocols for transfer dysfunction, either transfer training and exercise for strengthening and coordination, or surface FNS for exercise/coordination training in addition to the treatment provided the first group.

RESULTS—We have determined the pattern of muscle activity during sit-to-stand for five nondisabled elderly subjects. Five muscles were monitored: gluteus maximus, hamstrings, quadriceps, gastrocnemius/soleus, and anterior tibialis. Muscle on/off times were calculated in reference to each of the following five biomechanical events: initial body movement, seat-off, hands off, acceleration/deceleration change, and final knee extension. ANOVA was used to determine extent of universality of muscle on/off times across these five normal elderly subjects. A neuromuscular control model for sit-to-stand has been derived from this data.

A sit-to-stand rating scale has been created, validated, and tested for inter-rater reliability (r=0.99). This scale will be used for evaluation of changes in transfer capability for the patients treated in the study; in addition, the scale is suitable for clinical use.

Four subjects received conventional rehabilitation only. Preliminary data analysis indicates that two of four subjects improved in the sit-to-stand transfer. A video of functional outcome for each subject was made and will be subjected to analysis according to the sit-to-stand scale developed for this study. Five subjects received surface FNS exercise and coordination training. Preliminary analysis indicates that three of the five improved in the sit-to-stand transfer. Data will be analyzed as described for the first group.

IMPLICATIONS—Prior to entry into the study, all nine of the subjects had completed a 3-month (or longer) rehabilitation program, and all nine of the subjects had experienced a period (3 months or more) of either decline in transfer capability or no change in transfer capability. Five of the nine subjects in both groups improved in their transfer capability after the research treatment protocol. This finding is clinically significant because of two implications. First, it is possible that geriatric patients can benefit from periodic rehabilitation programs and that functional decline in transfer capability is not solely a result of age or disease, but also a result of a suboptimal activity level. Second, it is possible that in order to obtain improvements in transfer capability, the rehabilitation program must address in a specific way the components of movement inherent in the transfer maneuver.

RECENT PUBLICATIONS FROM THIS RESEARCH

Coordination of the sit-to-stand transfer for older individuals. Daly, Jacobs J, Jaeger RJ, Rosenberg J, Hall RJ. In: Proceedings of Aging and the Aged Conference, Case Western Reserve University, October 1994.

EMG and biomechanics of the sit-to-stand transfer for older individuals. Daly, Jacobs J, Jaeger RJ, Rosenberg J, Marsolais EB. In: Proceedings of Neural Prostheses: Motor Systems IV Conference, Engineering Foundation, July 1994.

[100] RESTORATION OF GAIT FOR THE STROKE PATIENT

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PURPOSE—We are testing a new multichannel, implanted functional neuromuscular stimulation (FNS) system for stroke rehabilitation. We are comparing conventional physical therapy treatment with FNS treatment using implanted electrodes.

METHODOLOGY—Six chronic (1 year or more post stroke) stroke subjects will be studied, each subject serving as his own control. Phase A is a baseline period of no treatment. The three treatments will be: Phase B, conventional neurorehabilitation for motor retraining; Phase C, FNS exercise/FNS gait training; Phase D, provision of totally implanted FNS orthotic system (optional, according to subject request and results of previous treatments), and monitoring of carryover effects post FNS treatment for those subjects not receiving the implanted FNS orthotic device.

Outcome measures are classified into three tiers of physical function of increasing difficulty. The first tier is voluntary movement at a single joint with the body in a static position. The second tier is voluntary motor control during walking. The third tier is func-

tional capability at home and work. EMG, kinematic data, kinetic data, gait description data, manual muscle test, coordination, balance, and functional capability data will be collected.

PRELIMINARY RESULTS—Four subjects have been admitted into the study. All four have completed conventional physical therapy treatment and have had three to five intramuscular electrodes implanted in the involved lower extremity. Preliminary analysis indicates that following conventional physical therapy: two subjects improved in either walking speed or muscle strength; and two subjects showed no change in either gait parameters or muscle strength following conventional rehabilitation. Following FNS treatment intervention using implanted electrodes, one subject demonstrated improved stance knee control, improved stance weight shift, and improved swing phase limb flexion. Sufficient data on three subjects is not yet available.

IMPLICATIONS—Results of this study have the potential to provide the following clinically applicable information: the efficacy of FNS exercise/gait training as compared with conventional neurorehabilitation techniques and as compared with no treatment; the suitability of an array of FNS stimulator subject command controls for use during rehabilitation procedures and home use; and the preliminary predictive criteria established regarding suitability of stroke patients for the implanted FNS orthotic system.

RECENT PUBLICATIONS FROM THIS RESEARCH

Efficacy of physical therapy treatment for two patients more than one year post stroke. Hull JJ, Daly, Jacobs J, Ruff RL. In: Proceedings of the Applied Neural Control Research Conference, Case Western Reserve University, May 1994.

[101] DEVELOPMENT OF AN ON-LINE CORRECTION CAPABILITY FOR FNS LOCOMOTION

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PURPOSE—The purpose of this research is to develop and evaluate improved methods of neuromuscular stimulation (FNS) for locomotion in subjects with complete paraplegia. The goal of this improvement is to make possible the use of FNS systems outside of the laboratory by compensating automatically for perturbations such as changing surfaces, disturbances, and internal changes (such as muscle fatigue). By reducing the time currently required by technical staff to maintain the FNS system, the practicality and clinical acceptance of these systems will be greatly enhanced.

METHODOLOGY—Work on this project has focused on several technical objectives. First, a computer biomechanical simulation of both normal and paraplegic human gait with 23 degrees-of-freedom has been developed; this model is driven with biomechanical data from laboratory experiments and simulates the complete gait cycle, including foot-floor contact. The results of this study showed that stable, repeatable gait is possible for FES-induced gait in persons with paraplegia (at 0.2 m/s) with limited ranges of muscle torques; in addition, the resulting joint angle trajectories follow closely with measured quantities. This model is being extended to simulate stair climbing and descent.

PROGRESS—A system to evaluate the phase of gait and detect anomalies in walking on-line has been developed. Using data obtained from joint angle goniometers, and using fuzzy logic rules derived from clinical observations of gait phase, every phase of gait for walking paraplegic subject has been estimated, with only a small (but varying) time delay. Rules to detect several anomalies during walking have also been developed and tested; these include both

"internal" system changes, as well as external (environmental) effects on the walking. These rules use processed signals from analog sensors (joint angle goniometers, solid-state accelerometers, and force-sensitive resistors). To date, two anomalies during FES gait have been successfully detected using sensor measurements: toe drag during the swing phase of gait, and the presence of walking on a 10° inclined slope. Similar rules are currently being developed to provide corrections to the electrical stimulation patterns to compensate for these disturbances.

Hardware and software for a microprocessor-based stimulation parameter controller have been developed. This unit is based upon a Pentium PC, which acquires and processes up to 64 channels of analog signals, and communicates with the existing portable microprocessor-controlled 48-channel external stimulator, using a high-speed digital interface. Software for gait event and anomaly detection operates in real time to adjust the stimulation patterns and other stimulation parameters on-line during walking.

FUTURE PLANS—Within the next year, we anticipate performing experiments to test and validate stimulation adjustment rules based upon observed gait anomalies. These rules will also be validated on the computer simulation of gait. A portable version of the computer hardware/software system will be developed to allow for experimentation and development of correction rules in conditions outside of the laboratory. Finally, the rule base for detection of anomalies and adjustment of stimulation patterns will be expanded to include additional deficits of paraplegic gait.

RECENT PUBLICATIONS FROM THIS RESEARCH

Fuzzy vs. non-fuzzy rule base for gait event detection. Ng SK, Chizeck HJ. In: Proceedings of the Annual Conference IEEE EMBS, October 1994.

[102] RELATIONSHIP IDENTIFICATION BETWEEN ELECTRICAL STIMULUS AND MUSCLE TORQUE FOR FES OPTIMIZATION IN PARAPLEGIC PATIENTS

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PURPOSE—This study aims at determining the relationship between the electrical stimulus parameters applied to quadriceps muscle through surface electrodes and the torque at the knee joint generated by stimulated muscles. Our ultimate goal is to develop a general tool for the optimization of stimulation pattern in walking restoration of paraplegics with functional electrical stimulation (FES).

METHODOLOGY—A mathematical model of the knee joint, has been developed in terms of linear viscosity and an exponential elasticity. The unknown parameters (visco-elastic properties) have been estimated from kinematic data (captured with an ELITE system) acquired during passive pendular motion of the leg and using optimization procedure. Using these estimated parameters and the kinematic data acquired during knee movement due to transcutaneous electrical stimulation of quadriceps, the net torque generated by stimulated muscles has been computed. Repeating this procedure with different stimulation parameters (frequency, impulse duration, and their modulation), a nonlinear relationship between torques and these parameters has been estimated. The stimulating device is an eight-channel programmable system linked to a personal computer on which all controlling software has been implemented.

RESULTS—Experiments on five nondisabled subjects have been performed in order to test both the experimental and the analytical procedure. Elastic property of muscles seems to be better expressed by an exponential function than by a linear one, the latter being better for muscle viscosity. A single-pole transfer function with frequency-depending gain can well identify the relationship between torque produced by electrical stimulation and stimulus duration. A difference in pole values has been found between contrac-

tion (increasing stimulus) and relaxation (decreasing stimulus) phases as well as between ramp and step stimulation pattern.

Trials performed on paraplegic patients showed that both passive (elastic component) and active (pole values) behaviors of paralyzed muscles are different if compared with sound muscles.

FUTURE PLANS—Trials with electrical stimulation of muscle induced to track a set of previously analyzed voluntary movements will be performed, using the inverse of the transfer function between current and torques. The next step will be the development of closed loop system to control knee movement using artificial sensors for angular displacement detection. The final goal is to use the same approach for all muscles stimulated by a future multichannel implanted system, and to combine these models with a comprehensive simulation model of human walking, in order to have a general tool for stimulation pattern optimization and control strategy development.

RECENT PUBLICATIONS FROM THIS RESEARCH

Evaluation of the muscle torque at the knee joint resulting from electrical stimulation by using kinematic analysis. Ferrarin M, Baglioni P, Campisi A, Rabuffetti M, Pedotti A. In: Edwards J, ed. Muscular components in functional electrical stimulation. Proceedings of EEC BIOMED RAFT Concerted Action; Salford, June 1993. Salford, UK: University College Salford Publications, 1993:26-35.

Evaluation of the torque at the knee joint due to electrical stimulation using kinematic analysis. Campisi A, Baglioni P, Ferrarin M, Rabuffetti M, Pedotti A. In: Proceedings of the Ljubljana FES Conference; August 1993, Ljubljana, Slovenia, 1993:115-8.

[103] PARAPLEGIC WALKING MADE PRACTICAL WITH FNS AND ORTHOSES

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Sponsor: *National Institute of Child Health and Human Development, the National Institute of Neurological Disorders and Stroke, the National Institutes of Health*

PURPOSE—The purpose of this research is to determine whether the combination of eight channels of implanted functional neural stimulation (FNS) and a proposed functionally activated trunk-hip-knee-ankle-foot orthosis can result in a practical mobility aid for use in the complete paraplegic individual.

METHODOLOGY—The methodology employs the combination of the existing Case Western Reserve University (CWRU) 8-channel, radio frequency controlled and powered, implantable stimulator with a to-be-designed programmable orthosis. CWRU has demonstrated the capability of generation of strong, fatigue resistant, reproducible muscle forces in both upper and lower extremities using the implantable FNS. This will be combined with expertise in electromechanical brace design from CWRU, Henry Ford Hospital of Detroit, and New York University.

Six complete paraplegic individuals will be implanted, first with percutaneous systems and then with the RF powered and controlled implants. The use of FNS and an orthosis, the combination referred to as a hybrid orthosis, will be assessed. Training and conditioning will take place in the Motion Studies Laboratory. Prototype orthoses will be constructed to test locking mechanism/stimulator interface and control schemes, along with appearance and functional ability while in use.

PROGRESS—Two subjects have been fitted with traditional reciprocating gait orthoses (RGO) and have multiple electrode percutaneous electrode systems in place. Development of open loop control strategies for the combination RGO and FNS is progressing. Walking speeds of 0.5 m/s have been sustained for 320 m. Both walker and crutch-assisted walking have been demonstrated.

FUTURE PLANS—The primary focus of this work is to provide sufficient control to the existing FNS capability to allow meaningful functions as crutch walking and stair climbing. This will be done in a manner acceptable to the patient and society from the aspects of functions provided, reliability, safety, ease of use, appearance and cost.

[104] REHABILITATION OF PARALYZED MUSCLES BY SURFACE FES

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Sponsor: *The Segal Foundation; The Walter and Sandra Kaye Fund; The L. and L. Richmond Research Fund*

PURPOSE—The purpose of this study is to apply surface FES on patients with paralyzed muscles for the activation of their paralyzed limbs. The population of patients includes paraplegics and children suffering from cerebral palsy (CP). In the paraplegic population whenever it is indicated, supported standing and walking are aimed. In the CP populations, the feasibility of FES for muscle strengthening and for control of spasticity is examined. Proper evaluation techniques are developed.

METHODOLOGY—A micro-processor controlled six-channel stimulation device with surface electrodes has been developed. This stimulator is fully programmable and can be operated in either one of the two following control modes: local or remote (hosted by a PC). An instrumented walker was designed to serve as a support. The patients are evaluated clinically, biomechanically, myoelectrically and physiologically, to monitor performance and to optimize stimulation. CP children are also video-taped prior to and following 4 weeks and 3 months of home treatment.

RESULTS—Over 25 paraplegics have so far been treated and evaluated. Eight of these patients were exercised while seated only. The remaining 17 patients were able to stand up, of whom 12 achieved reciprocal gait as well: 1 with forearm crutches, 5 with a walker, and 6 between parallel bars. One 24-month-old diplegic CP child was treated with gradual increments of both stimulation intensity and treatment period. The less functional limb was subject to treatment, while the other was used as a control. The results obtained, though not conclusive, indicate a developing asymmetry between the legs with increased spasticity in the treated leg.

FUTURE PLANS—It is planned to continue to develop evaluation methods and apparatus and to improve the stimulator device for implementation on more patients.

RECENT PUBLICATIONS FROM THIS RESEARCH

Computer controlled portable stimulator for paraplegic patients. Minzly Y, Mizrahi J, Isakov E, Susak Z, Verbeke M. J Biomed Eng 1993:15:333-8.

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Stimulus artifact suppressor for EMG recording during FES by a constant current stimulator. Minzly Y, Mizrahi J, Hakim N, Liberson A. Med Biol Eng Comput 1993:31:72-5.

EMG as an indicator of fatigue of isometrically FES-activated paralyzed muscles. Mizrahi J, Levy M, Ring H, Isakov E, Liberson A. IEEE Trans Rehabil Eng 1994:2:57-65.

V. Geriatrics

[105] UPPER BODY MOTION ANALYSIS FOR AMELIORATION OF FALLS IN THE ELDERLY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E601-2RA2)*

PURPOSE—The sense of balance declines with age due to combined vestibular, proprioceptive, and visual losses, resulting in impaired mobility and increased risk of injurious falls. We are developing a wearable accelerometric instrument to record movements outside the laboratory, identify motion patterns that accompany loss of balance before a fall occurs, warn the individual of pre-fall behavior, and signal that the wearer has fallen. We anticipate clinical use of accelerometric instrumentation to occur, first, as a diagnostic tool to quantify hitherto qualitative measures of balance; second, as a biofeedback device during therapy; and third, as a fall-prevention aid, a balance orthosis for fall-prone elderly individuals.

METHODOLOGY—The accelerometric motion detection system consists of two small 3-axis sensors attached to both corners of eyeglass frames to measure head motion, and a sensor above each hip on a belt at the waist. Also on the belt is a self-contained data-acquisition package that digitally records sensor outputs. An infrared remote control is used to command the wearable unit, so the wearer is unencumbered by cables. Data are transferred for analysis to a fixed computer using pattern-recognition algorithms. In a typical test, subjects perform 65 tasks in 8 categories derived from qualitative balance assessment protocols, including: stand eyes open, then closed, 15 sec; ascend stairs, turn, then descend; rise from and sit in chair; normal walk 10 m; tandem (toe-to-heel) walk 3 m; walk over obstacles 1 m apart.

PROGRESS—The project is continuing application of accelerometric body motion analysis to problems of the elderly:

Hardware Development. Advances in computer and sensor technology have improved the size, speed, and power consumption of the equipment. By changing the clock frequency of the microprocessor, data sampling rates have been increased from 50/sec to 200/sec. Design of a second-generation computer with built-in digital signal processing is underway.

Post-test Data Analysis. We are developing algorithms for treating the head and trunk as coupled rigid bodies, extracting rotation centers, and distinguishing between gravitational and inertial components of acceleration. A team of students at Stanford explored pattern recognition applied to the acceleration signal, resulting in a new algorithm for encoding repetitive activities and a technique for identifying the transition between motion patterns (e.g., standing and walking) based on frequency content. We have also had a volunteer engineer characterizing different strategies people employ (particularly horizontal rotation of the head or trunk) when reaching upward or to the side.

Building a Motion Database. We are expanding the range of tasks to include: activities of daily living, various kinds of perturbation, and disability-related tasks such as walking with crutches or a cane. We have measured standing tasks with simultaneous accelerometric and force platform data acquisition, to confirm the hypothesis that horizontal acceleration at the waist is equivalent to change of center of pressure on a force plate.

Expanding Range of Fall-prone Etiologies. We are enrolling subjects having hip arthroplasty (these patients are required to restrict flexion of the repaired hip and so have distinct motion signatures during rising from a chair and climbing stairs), Parkinsonism, post-hospitalization deconditioning, and post-stroke

hemiplegia. To study actual falls in an unimpaired young population, we have made a device for braking a subject's foot at a selected quartile of the gait cycle while walking on a straight 10-meter padded course: the object is to investigate how momentum is transferred to the trunk and head during the early (100 to 200 milliseconds) part of the induced fall.

Multi-site Research Collaborations. We have formalized the exchange of software, raw data, and interpretation techniques among 12 groups of researchers who have requested accelerometric motion analysis equipment for testing of diverse elderly populations. We are continuing to exchange data and procedural information with collaborators at the Travelers Center on Aging at the University of Connecticut Health Center, the Motion Studies Laboratory at Cleveland VA Medical Center, and Bolton School of Nursing of Case Western Reserve University. We have recently agreed to provide a system to Barbara Myklebust, Zablocki VAMC, Madison, WI. Researchers at Yale and Boston Universities will also receive equipment on loan.

IMPLICATIONS—In addition to its use as a diagnostic and therapeutic tool for balance-impaired elderly individuals, real-time accelerometric pattern analysis and feedback can be applied to prevention of re-injury following occupational rehabilitation, and to athletic training.

RECENT PUBLICATIONS FROM THIS RESEARCH

Accelerometric motion analysis of standing older subjects during floor perturbation. Sabelman EE, Gadd JJ, Chesney D, Winograd CH. In: Proceedings of RESNA International '93; 1993 June; Las Vegas, NV. Washington, DC: RESNA Press.

[106] EFFECTS OF STRENGTH TRAINING ON FUNCTIONAL STABILITY OF OLDER ADULTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E721-RA)*

No report was received for this issue.

[107] BALANCE TRAINING IN ELDERLY FALLERS AND NONFALLERS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E542-RA)*

No report was received for this issue.

[108] APPLICABILITY OF ACCESSABILITY CODES TO MEET THE NEEDS OF ELDERLY PEOPLE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E629-RA)*

No report was received for this issue.

[109] AGE-RELATED CHANGES IN THE TRICEPS SURAE STRETCH REFLEX AND POSTURAL CONTROL

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E723-RA)*

No report was received for this issue.

[110] AGED MUSCLE METABOLIC ADAPTIONS TO RESISTANCE EXERCISE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E724-RA)*

PURPOSE—The specific aim of this project is to determine the effects of age and race on skeletal muscle contractile performance and anaerobic metabolism during high intensity resistance exercise. This work will result in the development of strengthening programs that will improve skeletal muscle force generating capacity and the physical capacity of old persons.

METHODOLOGY—Healthy Caucasian and African American men, 20 to 35 years of age (adult) and 69 years of age and older (old) participate in this study. Forces produced by the subjects' right quadriceps femoris muscles are measured using an electromechanical dynamometer during a single bout of maximal isokinetic resistance exercise and during 12 weeks of high intensity resistance training. Needle biopsies of the subjects right vastus lateralis muscles are performed prior to and following the exercise bout and prior to and following the 12 weeks of training. Anaerobic substrate and metabolite concentrations are determined in mixed and single fast- and slow-twitch muscle fiber preparations.

PROGRESS—Investigation of quadriceps femoris muscle group force production and vastus lateralis anaerobic metabolism in adult and old Caucasian and African American men during a bout of 35 maximal contractions performed at an angular velocity of 3.14 radians/second have been completed. The findings have been reported in previous progress reports. Investigation of the effects of 12 weeks of high intensity isotonic resistance training of the quadriceps femoris muscle on the muscle groups force production and on vastus lateralis muscle anaerobic metabolism are being conducted in adult and old Caucasian and African American men. Training is performed at 80 percent of the muscle groups one repetition maximum (1 RM).

RESULTS—Preliminary results suggest that the percent increase in quadriceps femoris RM following 12 weeks of high intensity resistance training is similar in both the adult and old groups. Prior to and following training and every 2 weeks during training, however, the 1 RM muscle force in the adult group is significantly higher than in the old group. The old group 1 RM following training was similar to the adult group 1 RM prior to training. In addition, in the adult group, the increase in 1 RM muscle force occurs during the first 4 weeks of training. In contrast, in the old group, the increase in 1 RM does not occur until the last 8 weeks of training. Similar increases in adult and old vastus lateralis muscle adenosine triphosphate, creatine phosphate, and glycogen concentrations occurred during training. There was no effect of race on the results.

Thus, 12 weeks of high intensity resistance training results in a significant increase in quadriceps femoris muscle strength and vastus lateralis muscle anaerobic substrate concentrations in healthy, untrained

adult and old Caucasian and African American men. However, when during the training period the increase in strength occurs appears to be different in adult and old individuals.

RECENT PUBLICATIONS FROM THIS RESEARCH

Effects of age and gender on quadriceps femoris muscle force production during a bout of isokinetic exercise. Scalzitti DA, Pidcoe PE, Brauner DJ, Svanborg A, Hopp JF. Phys Ther 1994:74:S20.

[111] AGE-RELATED CHANGES IN OPEN-LOOP AND CLOSED-LOOP POSTURAL CONTROL MECHANISMS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E720-RA)*

PURPOSE—In an earlier posturographic study, we demonstrated that the natural aging process is associated with significant changes in the quasi-static dynamics of the postural control system. The objective of this study was to determine whether or not some of these age-related differences in postural control may have been due to subtle, undetected disease in the elderly subjects.

METHODOLOGY—A physician trained in geriatric medicine performed a complete medical evaluation of the 25 elderly subjects (aged 71 to 80 years) included in our earlier study. Specific attention was paid to clinical findings associated with impaired balance and gait. An independent panel of geriatric specialists with expertise in falls established *a priori* criteria for increased risk of impaired balance. Subjects who met criteria for potential balance impairment were designated as 'at risk for falls'. The other subjects were classified as 'healthy'. Thirteen of the 25 elderly subjects included in the study were classified as 'at risk for falls'. Consequently, we separated the population of elderly subjects into two groups: 'healthy' elderly (N=12) and 'at-risk' elderly (N=13). Standard statistical analyses were used to perform pairwise comparisons between the posturographic results for both elderly groups and a population of 25 nondisabled young subjects (aged 19 to 30 years).

RESULTS—We found that the steady-state behavior of the open-loop postural control mechanisms in the 'at-risk' elderly was significantly different from that of the 'healthy' elderly. We also found that the number of posturographic parameters indicating significant young-elderly differences in variance and group mean, respectively, was reduced substantially with the separation of the aged population into the two groups. This latter result confirms the need for using careful screening procedures and strict inclusion criteria in future posturographic studies of older persons.

RECENT PUBLICATIONS FROM THIS RESEARCH

Age-related changes to open-loop and closed-loop postural control mechanisms. Collins JJ, DeLuca CJ, Burrows A, Lipsitz LA. Exp Brain Res. In press.

[112] VESTIBULAR SYSTEM DYSFUNCTION AND QUIET-STANDING POSTURAL CONTROL

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E720-RA)*

PURPOSE—Dysfunction of the vestibular system adversely affects the performance of activity. It is particularly debilitating to the execution of skilled motor tasks. The objective of this project was to evaluate the ability of stabilogram-diffusion analysis to discriminate between healthy individuals and patients with bilateral vestibular deficits (BVD).

METHODOLOGY—We examined 12 patients with BVD recruited from Braintree Hospital. Each patient's postural stability was evaluated by using a force platform to measure the movements of the center of pressure (COP) under his/her feet. The patients were tested under eyes-open conditions for multiple 30-sec trials. The COP trajectories were parameterized according to stabilogram-diffusion analysis. In order to evaluate the ability of stabilogram-diffusion analysis to discriminate between healthy individuals and patients with BVD, we utilized discriminant function analysis. We developed a preliminary computer program based on this technique, and applied the analysis to the BVD population and to a sample of age-matched healthy individuals.

RESULTS—We found that the above procedure was able to achieve good to excellent classification results in determining whether a subject is a member of a BVD patient population or a member of a healthy population. Preliminary results showed that it was possible to achieve an 88 percent correct classification rate based on four stabilogram-diffusion parameters. This work suggests that stabilogram-diffusion analysis may be capable of detecting impairment to an individual's vestibular system.

[113] EFFECTS OF MUSCLE STRENGTH ON BALANCE DURING MOVEMENT IN THE ELDERLY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E642-RA)*

No report was received for this issue.

[114] DOES LEG STRENGTH INFLUENCE RISING FROM A CHAIR IN OLDER ADULTS?

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E760-RA)*

PURPOSE—Difficulty in rising from a chair is a significant problem for many older veterans. The purpose of this research is to investigate, biomechanically, why many older persons have chair-rise difficulty.

METHODOLOGY—In order to more fully understand the muscle strengths required to rise from a chair, we strove to analyze the joint torque strengths used to rise in a series of chair-rise tasks that presumably varied in level of difficulty. We then examined the success or lack of success in performing the chair-rise tasks, and when subjects were successful, the muscle strengths used to rise. Finally, we compared the knee extension torques used to rise with the actual maximal voluntary knee extension strengths available. We hypothesized that the joint torques used would not differ substantially between different tasks and between the young and the old for each task. If there was any difficulty with a task, as defined by the inability to successfully perform a chair-rise task, we hypothesized that the difficulty would not be due to insufficient muscle strength available.

We analyzed healthy young adults (YA, n=22, mean age 22), healthy old adults (OA, n=23, mean age 71) as they rose from an instrumented laboratory chair under carefully controlled conditions. Subjects performed 12 chair-rise tasks that were designed to increase in difficulty as seat height, handle use, foot support, and rise speed were varied. Using an optoelectronic camera system to acquire joint motion, and force plates at the seat and feet, we calculated the maximum joint torque strengths (MT) at the ankle, knee, and hip used during the rise. We also compared knee MT used to the maximum available knee torque strength measured isokinetically on the MERAC dynamometer at 120°/s.

PROGRESS—Initial data analyses have been completed for MT and range of motion used. Pending analyses of additional variables include hand force magnitude and direction, force asymmetry at the hands and feet, momentum, kinetic energy, center of mass and center of reaction excursions, and joint angular velocity.

RESULTS—Most OA successfully rose during all tasks, except when the foot support was reduced to a narrow beam (success rate 9 percent OA vs. 82 percent YA, $p<0.001$). There were few age-related differences in MT used to rise during each task, although the lowered seat required increased MT in both groups. The MT used by the YA to successfully rise on a narrow beam was within the range of MT demonstrated by the OA on other successful rises.

The mean isokinetic torques were significantly lower in the OA than the YA (81 vs. 130 Nm in extension, $p<0.001$). The percent of maximum available knee strength used for each task was higher in the OA than the YA (YA range 19–49 percent, OA range 35–87 percent, p per task generally <0.001).

IMPLICATIONS—Healthy YA and OA do not differ in the leg strengths that they use to perform a series of chair-rise tasks. Both apparently have sufficient strength to perform even the most challenging rise tasks. Nevertheless, there are situations where OA have adequate strength to rise from a chair but are limited by other factors, perhaps postural control. OA, as compared to YA, generally utilize a greater percentage of their knee strength available to rise from a chair, sometimes near maximal levels. Consequently, there are situations where large amounts of strength are required, such as when rising from a low seat; frail OA with insufficient leg strength may be unable to rise in these situations.

RECENT PUBLICATIONS FROM THIS RESEARCH

Does leg strength influence rising from a chair in older adults? Alexander NB, Gu MJ, Branch M, Schultz AB, Ashton-Miller JA, Gross M. Gerontologist 1994:34:319.

[115] DO CHANGES IN STRENGTH INFLUENCE MEASURES OF BALANCE AND FUNCTION IN ELDERLY MEN AND WOMEN?

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PURPOSE—Our purpose was to test whether lower extremity strength gains are associated with improvements in balance and function in frail elderly men and women. Specifically we predicted that strength gains would be associated with improvement in measures of balance (latency, sway, and functional reach) and measures of functional performance (6-min walk, 10-m walk time, mobility skills, and chair rise).

METHODOLOGY—We recruited 100 persons (50 men, 50 women) 65 and older who reside in the community and meet criteria for frailty (functional impairment defined as inability to ascend/descend stairs step over step without holding onto railing). Exclusionary criteria included: any lower extremity amputation, terminal cancer, progressive or other major neurologic disease, unstable angina or other cardiac disease, or the primary physician disapproval of patient's participation in exercise program.

We tested this population with measures of strength (isokinetic and isometric dynamometry), balance (sway and tibialis anterior latency, functional reach), physical performance (6-min walk, 10-m walk time, and chair rise), and disability (MOS-36 and Falls Efficacy Scale). These were recorded before and after a 10-week trial during which the exercise group was supervised in a lower extremity strengthening program in their homes and the control group continued their normal routine. After the 10-week control period, controls were offered the exercise intervention. Those who took this option were asked to return for a third testing session after the exercise intervention ended. These data will be not be used in the primary analysis but will be used for validation of models proposed in the primary hypothesis and for secondary questions.

PROGRESS—All 100 persons (50 men, 50 women) completed testing by June 1994. All data has been double entered and cleaned for data entry errors. Thirteen participants dropped out of the program for health-related reasons. The mean age of the participants was 77.6 (±7.4, range 66 to 97), mean education was 10.3 years (±4.2), 66 percent were white, 34 percent black, mean cognition was 24.3±4.1 as measured by the Folstein Minimental State Exam. Multivariate logistic regression techniques were used to examine whether change in strength is related to change in the dependent variables described above after controlling for age, depression, cognition, and baseline level of strength. A correlational analysis on the baseline data was used to determine the most appropriate measure of strength for use as the independent variable in the multivariate analysis.

RESULTS—Results show that the home-based strengthening exercise program was effective in increasing strength in this population. ($p<0.05$). Preliminary analysis show that change in strength was a significant predictor of change in mobility skills ($p=0.007$), after controlling for age, depression, baseline strength, and level of frailty. In addition, strength gain appears to be a significant predictor ($p=0.05$) of improvement in chair rise ability in the most frail participants but not in those who were higher functioning. Point estimates lack precision due to a relatively small sample size. Strength change was not a significant predictor of change in functional reach, static sway, 10-m walk time, or 6-min walk distance. In addition, change in the more distal outcome measures, Falls Efficacy Scale, and the MOS-36 (question 3) was not predicted by change in lower extremity strength. Thus, results indicate that a home-based strengthening program is effective in increasing strength in a frail, community-dwelling elderly population and that increasing strength is linked to improvement in chair rise and mobility skills but not to improvement in walking or balance tasks.

FUTURE PLANS—More studies are needed to further elucidate the relationships among impairment, physical performance, and disability in community-dwelling elders. Future studies should carefully target the population that has the greatest potential for change in the specific performance tasks of interest. Our study suggests that, although all participants were functionally impaired, those that demonstrated greater deficits in functional performance may have benefited the most from strength training. Future studies should be directed toward identifying the most appropriate population for the target intervention in order to clarify relationships between impairments and disability.

RECENT PUBLICATIONS FROM THIS RESEARCH

Choosing outcome measures that reflect physical performance. Duncan PW, Rose D, Chandler JM, Studenski S. Gerontologist 1994:34(10):151.

Choosing the best strength measure: How do we capture the effects of strength training in a frail population? Chandler JM, Duncan PW, Studenski SA, Rose D. Gerontologist 1994:34(10):151.

Predictors of strength gain following lower extremity exercise in frail elders. Vandenburg P, Duncan P, Studenski S, Chandler J, Sanders L. Gerontologist 1994:34(10):152.

[116] DEMONSTRATING THE EFFICACY OF MEMORY TRAINING

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No report was received for this issue.

[117] MANIPULATING JOINT COMPLIANCES AND GROUND REACTION FORCES TO PREDICT FALLING POTENTIAL: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #E91-355-AP)*

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[118] SWALLOWING DYSFUNCTION IN ELDERLY HEAD AND NECK CANCER PATIENTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E726-GA)*

PURPOSE—Surgery, and curative radiotherapy, are primary interventions for carcinomas of the head and neck region. Patients who have received either or both types of treatments for their tumor are often left with

iatrogenic impairments. While residual impairments, including dysphagia, after surgical treatment are documented, radiotherapy-induced functional changes are not. In addition, the relationship between patients' nutrition, speech production, and quality of life have not been systematically assessed. The purpose of this study is to describe the types of dysphagia in head and neck cancer patients after resection or radiotherapy, and the relationship of the treatment to the concurrent speech, immunological, or quality of life problems. A second objective is to determine whether pretreatment function is a predictor of post-treatment outcome.

METHODOLOGY—The protocol called for assessment of swallowing, speech, immunological, and quality-of-life outcomes in head and neck cancer subjects, at three points in time: before definitive cancer intervention (baseline), immediately after this treatment, and at an interval after complete recovery. The subjects were recruited from two populations: those receiving surgery as their primary intervention, and those receiving curative radiotherapy.

Swallowing. Videofluoroscopic swallowing studies were performed at each interval. Parameters selected to assess functional change during the study were bolus velocity and durations of discrete phases of the oro-pharyngeal swallow. Preliminary findings suggest systematic differences between the two groups at the follow-up interval in both parameters. Radiation-treated subjects produced greater bolus velocities after recovery than they did before treatment, whereas surgically treated subjects remained slower. Both velocity and duration measures supported this finding. Spontaneous compensatory strategies employed by the subjects may have produced these changes.

Speech. Video and audio taped recordings of subjects were collected at each data point, with each subject producing sentence and conversation level utterances. Eight novice listeners were trained to judge "understandability" of these recorded speakers, by writing the words understood from the sentence task, and by rating the sentence and conversation level task using a four point scale. Preliminary data suggest that listeners rate their ability to understand unintelligible speakers higher than their actual ability to understand them, and that most treated oral cancer subjects are relatively understandable after recovery, despite marked changes in acoustic intelligibility.

Immunological. Data were collected at the first and final data points. *In vitro* assays performed were: (a) mononuclear cell fraction (**T** and **B** cell enumeration (FACS)), mitogen response (ConA, PHA, and pokeweed mitogen), and natural killer cell function (cytotoxicity and K562 targets); and (b) plasma fraction, consisting of immunoglobulin level, and specific antibody (anti-influenza). To date, findings indicate compromised immune function in cancer subjects prior to treatment.

Quality of Life. Data were collected at the first and final data points. Each subject completed the *Functional Assessment of Cancer Therapy* instrument. This instrument was chosen as it targets cancer patients. Preliminary data suggest that cancer patients deny significant quality-of-life deficits before and after treatment, and that most problems encountered relate specifically to physical changes; loss of taste and salivary function among radiation subjects or reduced swallowing ease and appearance among surgery subjects.

PROGRESS—Twenty seven subjects underwent initial assessment for this protocol, 16 completed the protocol, and 11 were excluded after treatment or lost to follow up.

FUTURE PLANS—An abstract of the findings has been submitted and accepted for presentation in a technical session at the American Speech Language Hearing Association annual conference in November 1994. In addition, data collection from new head and neck cancer patients receiving radiotherapy as a curative modality continues, and a 1- to 2-year follow up of the original subjects will be attempted.

[119] EFFECTS OF AGE ON OROPHARYNGEAL SWALLOWING

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PURPOSE—The long-term objective of this project is to increase understanding of the effects of aging on swallowing physiology in an effort to advance the diagnosis and treatment of swallowing disorders in age-related disease. One of the hypotheses to be tested is that maximum tongue strength differs for young and old nondisabled individuals and that this decline in isometric pressure generation puts older individuals at risk for dysphagia.

PROGRESS—Our preliminary data set for two groups of nondisabled men (GP 1=25 years, GP 2=75 years) has been analyzed. That experiment was conducted using the Iowa Oral Performance Instrument (IOPI) to measure lingual pressures at the tip, blade, and dorsum. Pressures were recorded at each site during two tasks: maximal isometric gestures and saliva swallowing. Videofluoroscopic recordings of swallowing with radiopaque pellets fixed to the tongue tip, blade and dorsum were obtained as were MRI scans of the brains of participants.

RESULTS—The work confirmed our hypothesis that maximal lingual pressures decline with age. Only the blade placement site was significantly reduced in the older group with dorsum and tip pressures tending to be lower with increased age as well. Peak swallowing pressures did not decline with age; however, the difference scores (maximal isometric pressures minus swallowing pressures) significantly differentiated the groups. This difference score comparison may be interpreted to reflect changes in "functional reserve" with increased age. These findings suggest that older individuals, who are more likely than the young to encounter a condition that may compromise oromotor function (stroke, degenerative disease, and so forth), are more at risk for dysphagia.

While the IOPI, a single air-filled pressure-sensitive bulb served our preliminary purpose, development of an intraoral instrument designed specifically to measure tongue strength simultaneously at the tip, blade, and dorsum is under way in our laboratory. Preliminary testing of flexible plastic air-filled bulbs of discrete sizes that measure pressures as applied by the tongue against the hard palate at multiple points along the midsagittal line appear promising. Preliminary measurements can be made statically (isometric) and modifications for dynamic (during a swallow) pressure measurements are necessary.

FUTURE PLANS—Development of an intraoral pressure sensitive instrument designed for use during swallowing will continue to completion. Also, kinematic analyses of the videofluoroscopic swallow studies are underway to determine the relationship between lingual pressure and bolus transit as a function of age.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Swallowing after unilateral cerebral stroke. Robbins JA, Levine RL, Maser A, Rosenbek JC, Kempster GL. Arch Phys Med Rehabil 1993:74:1295-1300.

Study of dysphagia treatment efficacy. Robbins JA, Logemann JA. Dysphagia 1994:9:88-9.

Aging effects on lingual pressure generation as a risk factor for dysphagia. Robbins JA, Levine RL, Wood JL Roecker EB, Luschei ES. J Gerontol. In press.

Penetration-aspiration scale. Rosenbek JC, Robbins JA, Roecker EB, Coyle JL, Wood JL. Dysphagia. In press.

[120] AGE-RELATED CHANGES IN SENSORY-MOTOR PERFORMANCE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A390-3RA)*

PURPOSE—Our goal is to establish an integrated understanding of sensory-motor performance changes in aging, and to differentiate between performance deficits in nondisabled elderly controls and fallers. Performance measures in controls define a template against which to compare deficits in elderly persons who fall or are unsteady. We hypothesize that: 1) objective performance measures differ between healthy elderly subjects and fallers; 2) elderly subjects are heterogeneous in the type and extent of performance changes; 3) falling is a multifaceted problem, which differs between people; and 4) biomechanical and neurophysiologic changes become risk factors for falls in the elderly; compensatory mechanisms are used to cope with deficits.

METHODOLOGY—We evaluate performance measures in controls and fallers from the VA Nursing Home Care Unit and the community using the neurological exam, objective measures of reflexes, joint compliance, voluntary reaction times, SSEPs, standing balance, gait, and standard questionnaires about activity level, self-perception of steadiness, and falls history.

PROGRESS—Our studies of performance differences in the elderly suggest that some risk factors for falls may be gender-specific. We have redefined risk factors for falls: impairments in sensation; dyssynergia; absent/impaired DTRs; significantly impaired ankle compliance; delayed voluntary reaction times; slowness/variability in gait kinematic measures; limited toe clearance; large standing sway velocities; and significantly limited exercise tolerance.

RESULTS—We have tested 27 fallers and 102 controls (45 years and older); 66 subjects are 65 to 75 years. Longitudinal studies have been performed on 42 subjects.

Neurologic Examination. Neither longitudinal nor cross-sectional studies have shown decreased gross muscle strength in the healthy elderly. Glabellar and palmomental reflexes and dyssynergia are not uncommon. DTRs of 52 controls (65-75 years) are unremarkable in 60 percent of the cases, and depressed or absent in 40 percent. EMG recordings demonstrate reciprocal excitation in 5 cases, and reflex irradiation in 22.

Gait Studies. Cross-sectional and longitudinal analysis of free speed walking of 61 controls (65 to 87 years) demonstrates: slowed kinematic measures with increasing age; increased gait cycle duration and percent stance time; decreased stride length and velocity by approximately 27 percent; and shorter stride lengths and lower velocities in females than males up to 75 years. Most subjects demonstrated at least one deviation in tandem walking, sensation, SSEP, reflexes, joint compliance, voluntary reaction times or standing sway area and/or velocity.

Postural Steadiness. We characterize balance with measures of center of pressure with eyes-open (EO) and eyes-closed (EC). Our studies show: significant age-related changes in time- and frequency-based measures; 45 percent decrease in mean velocity of sway in healthy elderly subjects; more age-related changes with EC than with EO; and many significant measures are noncollinear and noncorrelated, suggesting that more than one process causes age-related changes.

Voluntary Movements. Voluntary reaction times and peak velocity of movement are significantly reduced in elders. Some subjects are unable to make fast plantarflexions to a 20 degree target.

SSEPS. In 58 subjects, onset latency of the SSEP is significantly prolonged. Latencies are even more prolonged with vibratory/proprioceptive deficits.

Controls versus Elderly Fallers. Cerebellar signs, delayed or absent SSEPs, and decreased reflexes are common among fallers. Voluntary ankle movements are very slow, with significant variability. Joint compliance and gait kinematics are significantly impaired.

FUTURE PLANS—Targeting patients at risk for falls is key to injury prevention. Heterogeneity of sensory-motor performance is a feature of healthy elders.

We test relationships among performance deficits that differentiate healthy elders and fallers. Our goal is to identify predictive markers of risk factors for falls to guide therapeutic interventions to minimize fall risk.

RECENT PUBLICATIONS FROM THIS RESEARCH

Characterization and modeling of postural steadiness in the elderly. Prieto TE, Myklebust JB, Myklebust BM. IEEE Trans Rehab Eng 1993:1:26-34.

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Postural control as a nonlinear dynamical system. Myklebust J, Prieto T, Myklebust B. Scientific and Engineering Applications of the Macintosh SEAM '93 Technical Conference; CD-ROM, 1993.

Effect of an abdominal binder during wheelchair exercise. Kerk JK, Clifford PS, Snyder AC, et al. Med Sci Sports Ex. In press.

Somatotopic mapping of the human primary motor cortex with functional magnetic resonance imaging. Rao SM, Binder JR, Hammeke TA, et al. Neurology. In press.

[121] AARP EVALUATION OF ASSISTIVE DEVICES FOR THE BATHROOM

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Sponsor: *American Assocation of Retired Persons*

PURPOSE—The purpose of this study is to improve the quality of life for older adults by providing a body of information about assistive devices for the bathroom and their benefits and limitations for mature consumers and caregivers. The main objectives are to: 1) identify and describe abilities, problems, and solutions of mature consumers regarding their ability to perform bathing and toileting activities with and without use of assistive devices; 2) identify, describe, and provide a list of sources for aids for bathing and toileting; 3) evaluate and compare the benefits and limitations of specific assistive devices for bathing and toileting when used by mature consumers and caregivers; 4) evaluate and compare the construction, installation procedures, maintenance and cleaning requirements of assistive devices for the bathroom; and 5) analyze input from letters written by mature consumers about their experiences in overcoming obstacles when bathing and toileting.

METHODOLOGY—There were four major components to the study. First, a meeting of manufacturers of assistive equipment for bathing, showering, and toileting was held to inform manufacturers of the study, gain their input and insight into the design of the study, and to solicit their participation. Second, all of the assistive equipment submitted by manufacturers was reviewed by a panel consisting of formal caregivers, older adult informal caregivers, and ITD researchers with the objective of identifying criteria and features important for preparation and use of the products and selecting product features to be evaluated by end-users. Third, features of assistive equipment for bathing, showering, and toileting were evaluated by a population of 32 older adults representative of likely end-users of such products. Researchers gathered data to provide consumers, caregivers, professionals, and Home Aide volunteers with comparative information about products and their usability, to help them make informed choices about products that can help prevent injury and provide convenience, independence, and safety. And fourth, letters from AARP Bulletin readers were solicited to learn difficulties they have encountered in using the fixtures and features of their bathrooms, information about any methods and/or products they have used or purchased to help alleviate problems, and specific information about the product, whether or not it has been effective, and their recommendations for others based on their experiences.

PROGRESS—A report documenting the procedures and results of this study has been sent to AARP, and ProMatura will continue the support of the AARP liason who will write a consumer report based on the results of this study.

RESULTS—AARP will release the results in a consumer product report.

[122] WHITE MATTER HYPERINTENSITIES

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Sponsor: *National Institute on Aging*

PURPOSE—This recently funded investigation constitutes a component project for a much larger research program, entitled, The Aging Brain: Vasculature, Ischemia, and Behavior. The purpose of this project is to conduct an interdisciplinary, prospective, longitudinal, and hypothesis-driven investigation of the pathophysiologic and functional significance of white matter signal hyperintensities (WMSH), a highly prevalent finding in brain MRIs of both normal and demented elderly persons.

METHODOLOGY—Several pathophysiologic models of WMSH will be tested using quantitative structural imaging, physiologic imaging (PET) and neuropathologic findings. A novel sensory-motor reaction time paradigm will also be used to test a functional model of WMSH.

PROGRESS—Accomplishments since the inception of the project in October of 1994 have focused primarily on the development and implementation of a statewide sample recruitment program. The goal is to identify a prospective subject pool of between 1,000 and 2,000 individuals, 55 years of age or older.

[123] USE OF TECHNOLOGY SERVICES TO MAINTAIN EMPLOYMENT AMONG PEOPLE AGING WITH A DISABILITY

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—Workers with a disability drop out of the labor force in increasing numbers as they age. This may be due, in part, to deteriorating physical conditions of disabled workers. While the impact of late onset physical complications on employment has been relatively unexplored, it is believed that many of these decreasing abilities can be offset by the provision of appropriate job accommodations, and that these accommodations will prolong the potential for employment of workers with disabilities. The purposes of this study are to document the changing needs for job accommodations as individuals with disability age, and to assess the current level of unmet need for accommodations. This project, under the Rehabilitation Research and Training Center (RRTC) on Aging with a Disability, will focus on individuals who have a prior history of poliomyelitis and those who have rheumatoid arthritis. In addition, individuals with spinal cord injury will be included through an identical project supported through the RRTC on Aging with Spinal Cord Injury.

METHODOLOGY—Information about accommodation needs will be gathered through a questionnaire and personal interviews. One hundred and fifty subjects who are working or have been unemployed less than 2 years will be recruited from the RRTC shared database. Of the total, 50 subjects from each of the three disability categories will be recruited. For each participant who is currently working, a worksite evaluation will also be conducted to assess current needs and determine if there are accommodations that will meet these needs. Results of the data collection will be disseminated and possible strategies for providing job accommodation services will be identified.

PROGRESS—A consumer advisory committee was formed. Working with this committee, the instruments were developed. A pilot test of these materials is underway. Sample selection criteria were established.

[124] ROLE OF TRAINING TO ENHANCE UTILIZATION OF IN-HOME SUPPORT: A COMPARISON BETWEEN OLDER HISPANICS AND ANGLOS WITH A DISABILITY

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—This project will investigate the use of paid in-home support by Anglo and Hispanic older adults with functional impairment or disability, and identify the preferred sources of support and methods of service delivery. Based on these empirical findings, a training program will be developed to enhance successful use of in-home care by both Anglos and Hispanics. This project was undertaken as one method of preventing premature institutionalization of disabled elderly individuals and assisting them to remain in their own homes.

METHODOLOGY—Data collection and training development will occur in three phases. Phase I of the project will use a field study design to collect information on the problems and needs of disabled older adults who now use in-home support services. Data will be collected in the three categories: service delivery preferences, psychological issues and concerns associated with using in-home supportive services, and preferred levels of family and professional involvement. Utilizing the findings from Phase I, Phase II will develop training programs to educate older adults on the successful use of paid in-home support. These programs will include relevant knowledge about the services, and skills and techniques to utilize services effectively and comfortably. In Phase III, training program effectiveness and outcomes will be tested by assessing satisfaction with training and the application and outcomes of skills and knowledge learned.

PROGRESS—Accomplishments since project inception in August 1993 have been the creation and Spanish translation of the interview questionnaire, composed of 75 percent created questions that address the crucial domains and variables of service delivery and preferences when using a paid attendant, and 25 percent existing scales to measure personality traits, psychological state, social and family integration, and acculturation. For future participant recruitment purposes, contacts have been established with senior citizen organizations that serve either Hispanic or Anglo elders, and a list of Rancho Los Amigos Medical Center geriatric patients seen over 5 years has been compiled into a database.

[125] ASSESSMENT OF RESIDENTIAL CARE FACILITIES AS AN ALTERNATIVE COMMUNITY SERVICE MODEL FOR DISABLED OLDER ADULTS

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—The purpose of this project is to investigate how residential care facilities for the elderly (RCFEs) operate as a community-based service model for disabled older adults no longer able to remain in their homes. The goals of the project are to: determine how well RCFEs accommodate the needs of residents with varying degrees of physical limitations or disability; provide a comprehensive understanding of activities provided by RCFEs and what physical, psychosocial, and empowerment dimensions they address; and examine the interrelationships between facility traits and services, and resident characteristics and resources, as they influence outcomes of resident health and psycholgical well-being.

METHODOLOGY—This study will combine an environmental assessment of RCFEs with a needs assessment of residents. RCFEs to be included in the

survey will be recruited from Los Angeles and Orange County. These two counties contain approximately one-third of all RCFEs within the state of California.

PROGRESS—A consumer-oriented research advisory committee was created to allow a format for consumer and service provider input on this project, and an opportunity to incorporate their expertise into the project's development to insure its practical relevance. A computerized sampling pool of RCFEs within Los Angeles and Orange County has been compiled and will be used for stratified sampling in the future.

[126] VARIATIONS IN SECONDARY CONDITIONS, RISK FACTORS AND HEALTH CARE NEEDS FOR FOUR GROUPS OF PERSONS AGING WITH PHYSICAL DISABILITY

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—Funded in 1993, the purpose of this study is to respond to the gaps in our knowledge regarding the new health problems and functional limitations experienced by persons aging with cerebral palsy (CP), polio, rheumatoid arthritis (RA), and stroke, and the consequences of these secondary conditions for quality of life outcomes and service needs. These four disabling conditions were selected to represent differences in the average age or developmental stage of the life course when disability occurs, ranging from infancy (CP) and childhood (polio) to young adulthood (RA) and mid- to later-life (ptroke). Specific objectives of the study include: 1) describing variations in the type, prevalence, magnitude, and timing of secondary conditions; 2) documenting the impact of functional health changes on social support, family relations, community integration, productivity, and psychological well-being, 3) examining race/ethnic differences and sociodemographic correlates of who is most at risk for functional declines and identifying the psychosocial and environmental factors that mediate the negative consequences of these secondary conditions, and 4) investigating the impacts of changes/declines in functional health status, social support, and community integration on utilization of and need for health and supportive services.

METHODOLOGY—This study combines a cross-sectional consumer survey with secondary analysis of medical records, and utilizes a cross-sequential design based on chronological age and duration of disability (or age of acute onset) to detect variations in aging-related changes within and between disability groups. The study is being conducted in two phases. Phase 1 involves the identification and recruitment of subjects from two study populations: a clinic-based population of approximately 1,500 low-income patients receiving medical care from a county rehabilitation hospital and a community-based population of approximately 800 patients receiving care through private physicians. To be eligible for inclusion, candidates must meet minimum age and duration of disability criteria which vary by condition. Eligible subjects from Phase 1 will be used as the sampling framework for Phase 2 and to establish a longitudinal panel that can be followed over time through medical records to assess changes in health and functional status in a larger sample. Phase 2 of the study involves the development and implementation of a cross-disability survey instrument. The survey will be conducted via telephone and by face-to-face structured interviews with approximately 1,000 respondents randomly selected within disability by gender, race/ethnicity, and chronological age.

PROGRESS—Accomplishments to date include the formation of a cross-disability consumer advisory committee to involve consumers and family members as decision-makers in all stages of the research process, the completion of subject identification and coding of medical records in conjunction with development of the Phase 1 clinic-based study population, the

preliminary analysis of data from eligible clinic-based subjects, and the development and pilot testing of the interview protocol for the Phase 2 consumer survey. Launching of the Phase 2 consumer survey will be staggered across 6 months, beginning June 1995 for the polio subsample and ending November 1995 for the CP group.

RESULTS—Consistent with the life course perspective guiding this investigation, preliminary analyses of clinic subjects identified to date suggest that the timing of acute onset of disability affects the life chances of individuals. For example, members of the polio (N=470) and RA (N=178) subsamples, with mean ages of onset of 7.4 and 40.1 respectively, were significantly less likely to be married at time of baseline coding compared to stroke patients (N=166) with an average onset of 56 years.

RECENT PUBLICATIONS FROM THIS RESEARCH

Aging with long-term disability: a life course perspective. Campbell ML. Maximizing Hum Potential 1994:1(3):1-3.

[127] STUDY OF POLICY BARRIERS IMPEDING USE OF ASSISTIVE TECHNOLOGY BY PERSONS AGING WITH DISABILITIES

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—In 1993 the project on policies for aging with disabilities (PAD) was funded to investigate current policies and practices that affect the availability, affordability, and utilization of assistive technology that support employment and maintain community-based living among middle-aged and older persons with long-standing disabilities. Our focus is on the acquisition and use of assistive technology: the equipment items, product systems, or services that maintain the independence and employment of persons aging with disability by increasing, maintaining, or improving functional performance. We will describe patterns of assistive technology use among persons aging with disability; examine the relative impact of use; assess unmet needs associated with changing functional status; and document the extent to which current federal and state policies and practices are responsive to these needs.

METHODOLOGY—Data will be collected and analyzed at three levels through a consumer survey, a national survey of state agencies, and through case studies involving consumer and national state agency respondents. Currently the consumer survey is in progress and the national survey is in the early stages of development. Case studies will be conducted in the final phase of the project to fill in the gaps in our knowledge identified in the earlier surveys.

The consumer survey employs a multimethod, group comparison, cross-sectional design with primary data collection based on a cross-sectional retrospective survey of consumers. The sample consists of four groups of persons aging with disability: rheumatoid arthritis (N=250), cerebral palsy (N=120), postpolio (N=400), and stroke (N=225). The sample is clinic and community-based and will be stratified by age, gender, and race. Assistive technology devices and services are grouped according to four major functional needs: personal care, mobility, communications, and home modification. Our questions investigate the following assistive technology issues: information-seeking related to acquisition; use of devices; funding patterns; maintenance/repair, customization, and replacement; and unmet needs.

PROGRESS—The consumer survey is currently in progress with data collection beginning in June 1995. A report of preliminary findings will be available in late 1995. Our national survey of state-level agencies is in development with data collection beginning in fall 1995. A report of our preliminary findings is projected for June 1996.

FUTURE PLANS—A national mail and telephone survey of state-level agencies providing assistive technology devices and services will be conducted in 1995. Our questions will include: types of assistive technology services provided and eligibility requirements; working linkages with other agencies and private sector organizations; programs of health professional, provider, and consumer education and outreach; mechanisms for periodic assessment of changing needs; and financing mechanisms.

RECENT PUBLICATIONS FROM THIS RESEARCH

Incorporating independent living outcomes within rehabilitation agencies: older disabled persons as an underserved population, Sheets DJ, Wray LA, DeJong F. J Phys Occup Ther, 1994. In press.

VI. Head Trauma and Stroke

[128] COMPUTER-ASSISTED TREATMENT OF HEMI-INATTENTION IN R-CVA PATIENTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B610-2RA)*

PURPOSE—A primary risk factor for falls among right hemisphere stroke patients (R-CVA) is hemi-inattention (e.g., neglect, hemispatial neglect) to left space. Previously we showed the effectiveness of using our computer-assisted training program to teach subjects to compensate for neglect-related problems during simulated, high accident, risk activities (e.g., wheelchair propulsion), and thus to reduce patients' accident proneness. Presently, we are in the first stage of comparing the effectiveness of large versus small screen projections of the computer-assisted program on accident rates.

METHODOLOGY—Subjects were wheelchair-bound, R-CVA patients who showed hemi-inattention to left space. With the aid of computer programs, subjects were trained to sit at true vertical, systematically scan into left space, and to fully scan into left hemispace while performing computer simulations of risky activities, including propelling a wheelchair through a cluttered runway. Computer simulation has been used so that training could begin even if the subject could not drive a wheelchair at the outset of therapy. Subjects were alternately assigned to receive this training using either: a CRT screen or an LCD image projected onto a 6' x 8' screen. Training was initiated within the first week of admission to the rehabilitation service.

PROGRESS—We have screened 25 subjects for the study; training was completed with 16 subjects who met criteria for participation. In addition, we have completed a training manual and revised computer programs to make them more user friendly.

RESULTS—Eight subjects completed training in each of the described conditions. We have just begun preparation to analyze differences between training conducted on the small versus the large screen. Initial findings continue to support the effectiveness of training on the large screen in reducing patients' falls.

FUTURE PLANS—We plan to continue training patients on the small computer monitor system in order to compare findings with the projection LCD system. In addition, we are preparing to begin Phase 2 of the study, which will involve training OT's in the use of the system.

RECENT PUBLICATIONS FROM THIS RESEARCH

Predictors of falls among right-hemisphere stroke patients in the rehabilitation setting. Rapport LJ, Webster JS, Flemming K, et al. Arch Phys Med Rehabil 1993:74:621-6.

Effect of attentional bias to right space on wheelchair mobility. Webster JS, Rapport LJ, Godlewski MC, Abadee PS. J Clin Exp Neuropsychol 1994:16:129-37.

Hemispatial neglect in simulated wheelchair obstacle course performance. Roades LA, Webster JS, Morrill B, Rapport LJ, Lopez, M. Clin Neuropsychologist 1994:8(3):347.

Indices of hemispatial deficits on the Rey figure copy. Rapport LJ, Dutra RL, Webster JS, Charter R, Morrill B. Clin Neuropsychologist 1994:8(3):347.

Spatial attentional factors associated with digit span performance in hemispatial neglect. Rapport LJ, Webster JS, Dutra R. Neuropsychologia 1994:32(5):517-26.

Spatial and attentional factors underlying digit span performance and hemineglect. Rapport LJ, Webster JS, Dutra R. Clin Neuropsychologist 1994:8(3):349-50.

[129] BICYCLE ERGOMETRY TO IMPROVE AMBULATION IN HEMIPLEGIC STROKE PATIENTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B763-RA)*

PURPOSE—Hemiplegia is a major consequence of stroke that contributes to significant movement dysfunction. One primary goal of rehabilitation is to restore symmetrical control over force production output and timing in the lower extremities. Rehabilitation of bilateral, lower extremity function in hemiplegic persons will result in improved daily function for many activities (i.e., standing, walking, and stair climbing). Currently there are few, if any, rehabilitation approaches that utilize biomechanical principles of movement control as a basis for providing feedback of performance to both the clinician and patient.

The application of our current understanding of neuromuscular control of bilateral, cyclical movements (such as pedaling an ergometer) should result in improved methods for training hemiplegic persons to efficiently regain lower extremity function. Our long-range goal was to improve lower extremity function in hemiplegic persons. We believed that this can be accomplished by training them to pedal an ergometer more symmetrically. Our short-term objectives in this 1-year project included first identifying pedaling asymmetries in six hemiplegic persons, then demonstrating improvement of symmetrical pedaling performance, and, finally, demonstrating improved gait parameters after 9 weeks of a pedaling exercise regimen.

METHODOLOGY—Within the 1-year period, we used existing experimental and computer modeling methods developed in our laboratory. Ten hemiplegic subjects pedaled an ergometer modified to provide added comfort and safety. Pedal reaction forces were measured by dual strain gauge transducers mounted in each pedal. Comparisons of pedal force variables (i.e., maximum peak force amplitude and phase, and single limb work output) were made between both lower extremities.

After the pedal force asymmetries were characterized, the hemiplegic subjects underwent one of two training protocols designed to demonstrate improvement in symmetrical force production. One group (seated) trained by pedaling on a seated ergometer with feedback of force symmetry performance over 27 training sessions. The other group (non-seated) pedaled while reclined against a backrest, without sitting on a bicycle seat, and also received performance feedback. Improvement was evaluated by comparing baseline measurements of pedaling variables with measurements taken after the completion of the treatment regimen. In addition, gait parameters such as speed, step length, and reaction forces were compared before and after the treatment period.

RESULTS—Evidence gathered in a small group of hemiplegic subjects showed a strong correlation between motor recovery level and pedaling force symmetry. Further evidence supported the ability of stroke patients to improve symmetrical force production while pedaling an ergometer with visual force feedback. However, the symmetry is generally achieved in only select phases of the pedaling cycle, most notably the downstroke phase. Gait parameters of step length and speed improved in both intervention groups; however, the most significant changes occurred in the nonseated pedaling group. Further evidence for improved lower extremity function was provided by improvements in functional tasks such as stair climbing and sideways walking.

FUTURE PLANS—Our results demonstrate improved lower extremity function in persons with hemiplegia who undergo at least 12 weeks of training on a bicycle ergometer. Future studies must include: controlled trials with patients in an acute setting, and studies that investigate the efficacy of pedaling exercise as an adjunct to traditional physical therapy regimens.

RECENT PUBLICATIONS FROM THIS RESEARCH

New method for improved pedal forces during pedaling in hemiplegia. Brown DA, Burgar CG, Dairaghi CA. In: Proceedings of

the American Academy of Physical Medicine and Rehabilitation, November, 1993. Miami Beach, FLA.

Improving lower extremity force symmetry in individuals with hemiplegia. Brown DA, Burgar CG, Kautz, Dairaghi CA, Dunn-Gabrielli. In: Proceedings of 12th International Gait and Posture Meeting. Matsumoto City, Japan, October 1994.

[130] MUSCLE DENERVATION AND RECOVERY FOLLOWING PHENOL-INDUCED PERIPHERAL NERVE BLOCK

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PURPOSE—Peripheral nerve block with phenol has proven to be an invaluable tool for the management of spasticity following stroke and traumatic head injuries. It is generally thought that phenol produces an axonotmetic lesion which subsequently produces a temporary but reversible peripheral nerve block without permanent loss of function. Clinical results, however, have shown a highly variable duration of action and some cases of permanent muscle weakness. The purpose of this study was to assess the recovery of the soleus muscle following application of phenol to the sciatic nerve of the rat. Two methods of application and two concentrations of phenol were used to produce the peripheral nerve block and compared.

METHODOLOGY—Fifty adult Sprague-Dawley rats were assigned to one of six experimental groups. Half of the animals underwent sciatic nerve block by intraneural injection of 20 µl of phenol and half were blocked by perineural bathing of the nerve in phenol for 20–30 min. For each application technique, three different concentrations of phenol were used: high (7 percent) (N=10), low (3 percent) (N=10), and control (0 percent) (N=5). *In situ* isometric and isotonic contractile testing of the soleus muscle was performed at 8 weeks post block. In addition, the conduction velocity of the sciatic nerve was measured. Following testing, the soleus muscle was removed and frozen for immunohistochemical analysis. Monoclonal antibodies against laminin and the isoforms of the myosin heavy chain (MHC) were used to obtain fiber size and fiber type of individual fibers. A two-way analysis of variance was perfomed to assess the effect of application method and phenol concentration. Significance was chosen as α=0.05.

PROGRESS—We have completed these studies and have found that peripheral nerve blocks with phenol can cause extensive and permanent injury to the injected nerve and denervated muscles. The extent of the injury was strongly affected by the concentration of phenol used, but not the application method. Based on these studies, a low concentration (e.g., 3 percent) would be preferred over a high concentration (e.g., 7 percent) for clinical application.

RESULTS—Application of phenol to the sciatic nerve produced axonal degeneration and muscle denervation. Eight weeks following the block, the muscles distal to the nerve block had become reinnervated. The conduction velocity of the sciatic nerve was significantly reduced in both experimental groups 8 weeks following the block: 38 percent of control in the 3 percent phenol group and 35 percent of control in the 7 percent phenol group. Contractile testing at 8 weeks revealed that the maximum isometric tension of the soleus was significantly reduced following the block. There was a significant effect of phenol concentration, but no effect of application method. The Po of the 7 percent group averaged 37 percent of control, while the Po of the 3 percent group averaged 69 percent of control. The mean fiber area of the soleus was also significantly reduced. The fiber areas of the 7 percent and 3 percent treated animals were 58 percent and 72 percent of control, respectively. The speed characteristics of the soleus were moderately affected. The maximum shortening velocity of the 7 percent and 3 percent groups was 141 percent ($p<0.001$) and 115 percent ($p=0.07$) of control, respectively. This shift in Vmax corresponded with a higher percentage of fibers expressing fast MHCs.

FUTURE PLANS—These data suggest that phenol may produce an injury that damages the endoneurial connective tissue resulting in more extensive damage than previously expected. The damage produced by phenol is greater than that produced by a nerve crush. Future studies will examine the mechanism of damage and the specificity of reinnervation.

[131] COMMUNICATIVE PARTNERS: INTEGRATING APHASIC ADULTS BACK INTO SOCIETY

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PURPOSE—Adults with acute aphasia typically return to residential settings with less use of language/communication. What is more perplexing and concerning is that this reduced use is often less than existing capabilities. The decline of communicative use in natural settings (i.e., a reduction or absence of stimulus or response generalization) is often viewed as a shortcoming of current treatment methods. Whereas careful attention and management of variables that change from clinical to natural settings are important, there is reason to question whether another entity, psychosocial well-being, may be equally influential. That is, perhaps adults with aphasia fail to communicate outside the clinical setting, NOT because they can't, but because they view themselves as either inadequately prepared or unworthy as a communicative or social partner.

The purpose of this study was to assess a novel aphasia treatment plan aimed at enhancing communication and psychosocial well-being in such adults. The novelty of this plan derives from the use of community volunteers to establish activities of choice outside the patient's home.

METHODOLOGY—Treatment triads consisting of an adult with aphasia (AWA), a community partner (CP), and a prime caregiver (C), were enrolled in an 8.5 month, multiple-baseline design. Treatment was divided into teaching community volunteers how to communicate with a paired aphasic partner and undertaking patient-selected activities in the community. Planned activities in the community were idiosyncratic to the aphasic partner's desires (e.g., volunteering as a gardener, helping at a preschool daycare center, taking adult noncredit art courses, or learning to drive a car). Dependent variables included standardized tests of language, communication, and psychosocial well-being. Several nonstandardized tests were included to assess communicative readiness and use and psychosocial adjustments specific to their aphasia.

PROGRESS—Ten treatment triads have completed the study to date; three more triads will finish the study protocol in the next two months.

RESULTS—AVOVAs with repeated measures and cross correlations between outcome measures were completed on the existing data. The findings from these analyses with respect to pre-/post-treatment comparison were: 1) no statistical differences for standardized tests; 2) numerous statistical differences for both nonstandardized tests (communication readiness and use and psychosocial well-being) when analyzed categorically according to question content; 3) Cs noted greatest changes communicatively in AWAs' readiness and use with strangers; AWAs felt the greatest changes in this realm came from use with family members; 4) both AWAs and Cs indicated that AWAs felt much better about life and themselves; and 5) sustained participation in a chosen activity appears to be a prime indicator in whether this treatment approach is beneficial or not.

IMPLICATIONS—Demonstrated improvement in clinical treatments is no longer always sufficient to justify their reimbursement. Such treatments, whether oriented toward communication or not, often must enhance life as well. Communication Partners, as judged from the preliminary analyses of the data, appears to be one viable option in this regard.

[132] FETAL TRANSPLANTS AND REPAIR OF STROKE IN ADULT AND AGED RATS

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PURPOSE—The purpose of this project was to investigate the possibility of fetal cortical transplantation into adult and aged animals following focal ischemic stroke. Stroke is a significant contributor to morbidity and mortality and remains the third leading cause of death in the United States with approximately 2 million survivors left with permanent neurologic disability. Although neuronal transplantation has been used as an important research tool in various other conditions, there are few research reports investigating the role of neuronal transplantation in stroke. Since there is no treatment for stroke at this time, the possibility of fetal transplantation and providing functional recovery after stroke is being investigated.

METHODOLOGY—Long Evans, black hooded rats were used for these experiments. Anesthestized adult or aged animals were placed in a stereotaxic instrument. Using an operating microscope, a craniotomy was made in the parietal bone and the distal branches of the middle cerebral artery were identified. The artery was followed to the region of the rhinal sulcus where a permanent occlusion was made using microcautery. One week after this procedure, animals were reanesthetized and donor tissue from rat fetuses (gestational age 14 to 16 days) was grafted into the stroke region. The animals were then returned to their own cages and after an 8-week survival period the animals were reanesthetized and neuronal connectivity between host and donor tissue was studied using either an anterograde tracer, biocytin, or a retrograde tracer, fast blue.

PROGRESS—The feasibility of this project has been proven in that animals were found to survive stroke lesions permitting the ability to graft fetal neuronal tissue after a 1-week survival period. Furthermore, the grafts were found to grow and develop within the ischemic region.

RESULTS—Our preliminary results show that simply implanting one fetal block of tissue into an ischemic region is not adequate. Therefore, in future experiments we will exclusively use two to three blocks of fetal tissue per animal. To date 15 adult animals have undergone ischemic lesions, received transplants, and undergone anatomical tracing methodology. Results indicate that the host tissue sends afferent fibers into the graft tissue. These have been found to be cholinesterase positive fibers as well as serotonergic fibers. Furthermore, preliminary results show that the fetal graft tissue is unable to send neuronal fibers out of the graft tissue into the surrounding host tissue.

FUTURE PLANS—The focal stroke model for neuronal transplantation has been successfully developed. We will continue to work on the anatomical studies to determine transplant afferent and efferent connectivity. Furthermore, methods to enhance efferent connectivity with the host brain will be developed. Another important measure to be studied in the future is a behavioral test to show possible behavioral effects of transplant tissue following stroke as an indicator of functional recovery after ischemic lesions.

[133] QUANTIFICATION OF UPPER LIMB SYNKINESIS IN HEMIPARETIC SUBJECTS

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PURPOSE—Synkinesis observed in patients with a cerebro-vascular accident consists of involuntary movements of the paretic limbs following an effort on the affected or unaffected side. It has been observed

that the capacity of hemiparetic patients to control these synkineses is an index of their motor recuperation. In addition, treatment approaches currently used to ameliorate motor performance of hemiparetic patients are aimed at reducing the synkinetic movement, or used to promote movement. Considering their clinical importance, the purpose of this project is to elaborate a method, based on static measurements of torques exerted at two joints, to quantify synkinesis in hemiparetic subjects.

METHODOLOGY—A dynamometer was constructed to measure torques exerted simultaneously at the shoulder and at the elbow in all anatomical planes. Orthogonal arm and forearm forces were recorded with strain gauge transducers. Using a desktop computer and an acquisition card, force values were sampled at a frequency of 100Hz. Lever arms were measured and the torques exerted at the shoulder and elbow calculated in real time using static equilibrium equations.

During the experiment, hemiparetic (n=10) and nondisabled (n=5) subjects were asked to exert one maximal voluntary contraction (MVC) in flexion-extension, adduction-abduction at the shoulder and in flexion-extension at the elbow on the paretic side. A hand-held dynamometer, interfaced with the computer, was used to measure maximal grip force on the unaffected side. Using visual feedback, subjects were instructed to exert a 5-second force ramp reaching to 100 percent of their maximal grip force. Three trials were repeated at 1-min intervals.

RESULTS—Dynamometric measurement of orthogonal torques exerted simultaneously at the shoulder (flexion-extension [S1], adduction-abduction [S2], internal-external rotation [S3] and elbow (flexion- extension [E1], pronation-supination [E2] were used as measures of synkinesis. Mean torques recorded at maximal exertion in S3 internal rotation were larger in hemiparetic than in nondisabled subjects. However, the only difference in torque that was significant ($p<0.05$) was E1 and S1 (flexion). Hemiparetic subjects were then divided into two groups (moderate [MD] and severe disorder [SD] based on their Fulg-Meyer score for the upper limb (t-test=–5.162, $p<0.01$). Univariate ANOVAS revealed that SD subjects had greater synkinesis in E1 (flexion) than MD and normal subjects at maximal contralateral grip exertion ($F[2, 12]=11.38$, $p<0.01$). Average synkinesis in E1 (flexion) for SD subjects represented 94 percent of their maximal voluntary torque in elbow flexion on the paretic side.

IMPLICATIONS—The results of this study indicate that synkineses recorded during a contralateral grip task are more pronounced at the elbow and that they vary with the degree of motor performance of the patient.

FUTURE PLANS—As a long-term goal, we hope that the method and technologies described here will contribute to the evaluation of these patients as well as ameliorating the rehabilitation treatments offered to this population.

RECENT PUBLICATIONS FROM THIS RESEARCH

Method for the quantification of synkineses in hemiparetic subjects. Boissy P, Bourbonnais D, Brule N, Keagi C, Goyette M. In: Proceedings of the 2nd Conférence nationale de recherche en réadaptation: recherches évaluatives, 1993.

Characterization of upper limb synkineses in hemiparteic subjects. Boissy P, Bourbonnais D, Brule N, Keagi C. Neurosci Abstr, 1994.

[134] PROSPECTIVE STUDY ON THE USE OF BOLUS INTRATHECAL BACLOFEN FOR SPASTIC HYPERTONIA DUE TO ACQUIRED BRAIN INJURY

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—The goal of this research is to determine if the intrathecal delivery of baclofen will decrease spastic hypertonia due to brain injury. Baclofen, 4-amino-3 (p-chlorophenyl) butyric acid, is structurally

similar to gamma-amino-butyric acid (GABA) and binds to presynaptic GABA-B receptors within the brainstem, dorsal horn of the spinal cord, and other central nervous system sites. The oral form of baclofen has had poor success in the treatment of patients with spastic hypertonia secondary to brain injury. Oral baclofen reaches relatively low concentrations in the spinal cerebrospinal fluid, even after large oral doses due to its incomplete penetration across the blood brain barrier. The result is a low concentration of the drug at the site of action within the nervous system. Thus, many patients experience central side effects such as drowsiness or confusion at the dosages required to reduce spasticity. Recently, continuous infusion of intrathecal baclofen has been reported to be useful in treating spastic hypertonia of spinal origin. The delivery system consists of a subcutaneously placed pump with a reservoir. The pump is programmable to deliver various rates of medication via a catheter placed in the lumbar space. It not only decreases spastic hypertonia but has been reported to reduce detrusor-sphincter dyssynergy. The intrathecal delivery of baclofen to the lumbar area concentrates the medication in the lower area of the spinal cord cerebrospinal fluid at a much higher level than attainable via the oral route. Thereby, it avoids the cognitive side effects of oral delivery such as drowsiness, confusion, and lethargy.

METHODOLOGY—Eleven patients, more than 1 year out from their brain injury with disabling lower extremity spastic hypertonia, were randomized in a double blind, placebo-controlled cross over study to receive a bolus injection of either intrathecal normal saline or 50 μg of baclofen. Data for Ashworth rigidity scores, spasm scores, and deep tendon reflex scores were collected for both the upper extremities (UE) and lower extremities (LE). Changes over time were assessed via Friedman's test. Differences between the placebo and active drug at any given time were assessed via Wilcoxon signed-rank.

RESULTS—Four hours after injection with the active drug (maximum effect) the average LE Ashworth score decreased from 4.2±1.0 to 2.1±0.8 ($p<0.001$), spasm score from 2.9±1.1 to 1.1±0.8 ($p<0.001$), and reflex score from 3.3±0.7 to 1.0±1.4 ($p<0.001$). The average UE Ashworth score decreased from 3.3±1.5 to 1.9±1.0 ($p<0.001$), spasm score from 1.8±1.5 to 0.6±1.1 ($p<0.01$), and reflex score from 2.7±0.7 to 1.7±0.4 ($p<0.01$). No trend was observed over time with placebo administration. There were significant reductions in the average for LE Ashworth ($p<0.005$), spasm ($p<0.005$), and reflex ($p<0.005$) scores and for UE Ashworth ($p<0.005$) and spasm ($p<0.025$) scores observed over 4 hours time (maximum effect) with active drug administration. No significant differences were noted between before active drug or placebo administration in the LE Ashworth scores, or LE and UE spasm or reflex scores. The 0.2 point difference in UE Ashworth score is not clinically significant. There were significant differences between the active drug and placebo at 4 hours after administration for LE and UE Ashworth, spasm and reflex scores ($p<0.01$).

FUTURE PLANS—Intrathecal injection of baclofen is capable of lowering the spastic hypertonia associated with brain injury. Further studies to evaluate the use of continuous infusion pumps similar to those used in patients with in-spinal related causes of spastic hypertonia is clearly the next step.

RECENT PUBLICATIONS FROM THIS RESEARCH

Use of intrathecal baclofen in brain injury patients. Meythaler JM. Arch Phys Med Rehabil, 1994:75:1036.

[135] PREVENTION OF THROMBOEMBOLISM IN STROKE REHABILITATION PATIENTS

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Sponsor: *National Institute on Disability and Rehabilitation Reseach*

PURPOSE—Deep vein thrombosis and pulmonary embolism are important causes of morbidity and mortality in patients who have survived a recent stroke. Complicating the efforts of rehabilitation is a vulnera-

bility to thromboembolism, which has been shown to affect 60 to 75 percent of elderly stroke patients. This study compares two methods of thromboprophylaxis (calf compression boots and low molecular weight heparin) to see which is most safe and effective. The end points will be to determine efficacy as the presence or absence of thrombus, as defined by venous flow studies, venography, positive V/Q scan, or pulmonary angiography, to determine the safety by the presence or absence of bleeding, either intracranial (positive CT scan or MRI), or elsewhere (decline in hematocrit of >5 percent, hemoglobin >2 g).

PROGRESS—Currently, 12 subjects have been enrolled in the study and subject recruitment is continuing. It is too soon for any conclusions.

[136] COMORBIDITIES AND COMPLICATIONS IN STROKE: INCIDENCE, RISK FACTORS, AND EFFECTS ON OUTCOMES

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PURPOSE—Individuals who sustain a stroke may be as disabled by the consequences of associated medical conditions as by the stroke itself. This study is designed to investigate clearly and systematically the incidence, risk factors, and impact on rehabilitation outcomes of pre-existing conditions and medical complications of stroke.

The major goal of this study is to develop a risk assessment technique to enable clinicians to identify stroke patients at risk for medical complications and to determine the effects of medical problems on rehabilitation outcome. Specifically this project will:

1. Describe the prevalence of pre-existing medical conditions, laboratory abnormalities, and secondary intercurrent medical conditions in individuals with stroke;
2. Investigate the predictive accuracy of the occurrence of pre-existing conditions and existing illness severity scales for assessing risk of acute complications during rehabilitation;
3. Develop and evaluate a complication risk assessment index specific to the rehabilitation setting; and
4. Determine the interdependence between the pre-existing conditions, secondary complications, rehabilitation outcomes, and cost effectiveness of rehabilitation.

PROGRESS—Currently, there have been 412 new stroke patients enrolled into the stroke database. Preliminary data analysis is underway, although it is still too soon to draw any conclusions.

[137] COURSE OF RECOVERY OF COGNITIVE-COMMUNICATIVE PROBLEMS IN RIGHT-BRAIN-DAMAGED INDIVIDUALS

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PURPOSE—Historically, it was assumed that only left hemisphere damage resulted in language deficits while right hemisphere damage had no important effect on communication. However, recent evidence suggests that the right hemisphere makes an important contribution to language processing, and it is now widely acknowledged that right hemisphere stroke also results in impairments in communication. Right hemisphere communication impairments are believed to result from underlying deficits in attention, mem-

ory, and perception. However, the precise relationship between communication impairment and deficits in these cognitive processes is not well understood. Appropriate rehabilitation interventions cannot be designed until a better understanding of the relationship between communication and these cognitive processes emerges. There also is very little data regarding the course of recovery of cognitive-communicative problems in patients with right hemisphere damage. Increased knowledge about the rate, amount, and patterns of recovery of communication problems in right hemisphere stroke patients is needed to facilitate the selection of effective rehabilitation interventions.

The purpose of the present study is to describe the variety of communicative impairments associated with right hemisphere stroke, measure the natural history of changes in communicative effectiveness over time, and assess whether subgroups of right hemisphere communicatively impaired patients might be identified as a function of underlying deficits in attention, memory, and/or perception or of lesion location.

PROGRESS—Subject recruitment has been progressing steadily. The charts of all consecutive admissions to RIC with unilateral right hemisphere stroke are reviewed weekly. At this time, 20 subjects have met the criteria for the project: a total of 16 subjects have been recruited and have participated in the initial evaluation session. Of the 11 subjects who are eligible for the 6-month follow-up session, 8 have been retested. In addition, 12-month testing has been completed on one subject. Preliminary data analysis is also underway. The transcripts from all subjects have been transcribed. They are presently being segmented into smaller units (T-units), and scored in terms of informational content and cohesion.

[138] THE PREDICTIVE VALUE OF COGNITIVE/BEHAVIORAL MEASURES IN PATIENTS AFTER STROKE IN ASSESSING FUNCTIONAL OUTCOME

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Sponsor: *National Institute on Disability and Rehabilitation Reseach*

PURPOSE—The major objective of this study is to examine the efficacy of neurological tests in predicting functional outcome for stroke patients. A battery of neuropsychological tests will be administered to each subject early post-stroke. Functional outcome will be measured at 1, 3, 6, and 12 months post-stroke. Analyses will be done to determine the critical variable or set of variables related to functional outcome.

METHODOLOGY—*Subject sample.* Aphasics were excluded from some previous studies. This study will include aphasics, and the cognitive battery includes tests which can be performed by these patients.
Study design. This study will be longitudinal instead of cross-sectional.
Statistical strategy. A common strategy in previous studies was to put all the predictors into one correlational analysis, then simply list the variables which had the strongest correlation with outcome. We would like to do further analyses, where indicated, to get a more precise picture of the role of cognitive abilities in functional independence.

A broad range of cognitive domains will be tested, allowing us to determine if there are critical, limiting cognitive factors.

PROGRESS—Subject recruitment is underway. It is still too early to draw any conclusions.

[139] REDUCING MOTOR DISABILITY IN HEMIPARETIC STROKE BY MANIPULATION OF SENSORY INPUT FROM THE PARETIC UPPER LIMB: A QUANTITATIVE EVALUATION

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PURPOSE—The disability of the upper limb after a hemiparetic stroke is often perceived as one of the most frustrating experiences by stroke survivors. There are well defined reasons for the disproportionate impact of cerebral stroke in upper limb function, such as the greater relative area of cortex devoted to upper limb control coupled with the fact that arm motions play a major role in activities of daily living. A large number of neurotherapeutic techniques claim that the effect of their respective interventions creates the best results. However, because of the absence of quantitative measures to evaluate the effect of these therapeutic interventions on limb motor behavior, little progress towards the determination of the optimum intervention protocols for impaired limb motion has been made.

The broad objective of our research is to quantify how sensory input can reduce disturbed muscle synergic relations and/or spasticity and thereby improve function of the impaired limb.

PROGRESS—To study disturbances in muscle coactivation patterns observed after stroke during isometric contractions in different directions and of different magnitudes, sensory manipulations with topical drugs which create skin analgesia have been initiated; however, results are still inconclusive because the eutectic drug mixture of Lidocaine and Prilocaine (EMLA) hasn't been examined yet.

In our focus on the determination the optimum sensory stimulation parameters for spasticity reduction in hemiparetic stroke subjects, we have studied the effects of transcutaneous muscle and skin electrical stimulation on the severity of spastic hypertonia in the upper limbs of adult spastic hemiparetic subjects. Several electrical stimulation parameters have been investigated over the course of the last 12 months to determine the optimum stimulation procedures for the reduction of spasticity in the upper extremity of hemiparetic stroke subjects. In that period we have examined a total of 6 hemiparetic subjects. For the current grant, experimental data has been collected during 12 experimental sessions from these 6 subjects.

Pre-stimulation torque responses of the impaired upper limb were measured during slow ramp perturbations of the elbow from our hemiparetic test population and compared with torque responses obtained immediately following stimulation over the antagonistic muscle. In addition, EMG signals of biceps, brachioradialis, and triceps muscles were collected for subsequent analysis. The electrical stimulation was applied to skin over the biceps muscle for a period of 10 min at a 20 Hz frequency, with an intensity level below motor threshold but above sensory threshold. The joint extension protocol was performed immediately after electrical stimulation, and subsequently at several intervals up to 1 hour after cessation of the stimulation.

In some cases, subjects were again given electrical stimulation, but at a level which was just above motor threshold with a duty cycle of 2.5 seconds 'on,' 2.5 seconds 'off,' so as to avoid muscle fatigue. We observed a significant reduction of spasticity in 8 of the 10 subjects we have studied to date. In two subjects, no reliable stretch reflex could be obtained with our current set-up (the stretches couldn't be performed with enough speed); hence, no alterations in the spastic state could be measured. We also investigated whether voluntary activation of arm muscles after the stimulatory protocol would again increase spasticity to pre-stimulatory levels. Preliminary results to date indicate that this is not the case. The implications of this finding are important for functional arm movements which could be impaired due to the presence of spasticity.

Our study of the effect of sensory manipulation on arm movements consisted mostly of gathering of additional control data from normal and hemiparetic stroke subjects. To date, eight stroke subjects have been studied. Four of them, with mild to moderate motor deficits, showed abnormal movement trajectories in reaching and retrieval directions where inter-

segmental coupling torques are most significant. The remaining four subjects, with moderate to sever motor deficits, showed abnormal movement trajectories coinciding with the onset of stretch reflex activity due to spasticity in elbow flexor and/or extensor muscles. The implications of these findings are significant in that a reduction of spasticity through pharmacological or physical means could potentially result in a more normal movement trajectory in the impaired upper limb. The sensory perturbation of cutaneous afferents has not been included in our protocol yet. However, if attenuation of spasticity in elbow muscles does result because of stimulation of skin afferents, it is likely to result in more direct movement trajectories performed at higher velocities, which is certain to improve motor performance of the impaired upper limb.

[140] A CONTROLLED STUDY OF THE EFFECTS OF EMG FEEDBACK AND ELECTRICAL STIMULATION ON MOTOR RECOVERY IN ACUTE STROKE PATIENTS

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Sponsor: *National Institute on Disability and Rehabilitation Reseach*

PURPOSE—Despite conventional rehabilitation efforts, loss of upper extremity control continues to be one of the main limiting factors determining functional independence in stroke survivors. The restoration of motor control relies on the convergence of at least three types of physiologic information: central representations of motor output encoding the goal of movement, afferent input to provide the means to monitor movement progress, and relevant data from motor memory.

The main objective of this project is to investigate in a controlled manner whether more normal muscle synergistic relations can be encouraged in acute stroke patients by using either EMG feedback, functional electrical stimulation, or a combination of these therapeutic interventions. Subject recruitment and testing are underway.

PROGRESS—Currently five patients with low motor function have been randomized. Four of these patients have completed 18 to 20 treatment sessions. Pre- and post-evaluation data is currently being analyzed.

[141] EFFECTS OF AEROBIC EXERCISE ON YOUNG PERSONS POST-STROKE

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Sponsor: *National Institute on Disability and Rehabilitation Reseach*

PURPOSE—Forty young stroke survivors will participate in an aerobic fitness program to determine the effects of aerobic exercise on fitness levels, ambulatory speed, and life satisfaction. This program was designed to meet the needs of the young stroke population responding to a survey assessing outcomes after discharge from a rehabilitation hospital.

METHODOLOGY—Subjects will participate in a 10-week aerobic walking program after completing a 10-week control period in which they will be instructed to maintain their normal daily routine. A second 10-week control phase will follow the exercise portion to allow each subject to serve as his or her own control. Fitness tests will be performed throughout the control and exercise portions of the program using a treadmill and metabolic cart. The exercise program will occur three times per week and will include a weekly educational component. The goals of this study are to demonstrate improvements in fitness

levels, functional ambulatory measures, and quality of life. An emphasis will be placed on promoting independence and facilitating re-entry into the community.

PROGRESS—The first group of four subjects has completed all three 10-week phases of the research protocol and the data compiled is currently undergoing analysis. A second group of four subjects has completed the first control phase and exercise phase of the research design. A final exercise test will be scheduled for these participants. A third group of six subjects has been recruited and has undergone the first treadmill test. This group is in the first control phase of the research design. Upon completion of this phase, subjects will begin the aerobic walking program. These participants will be contacted as to the starting date for the 10-week walking program.

[142] THE EFFECTIVENESS OF A TELEPHONE SUPPORT GROUP FOR STROKE CAREGIVERS

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Sponsor: *National Institute on Disability and Rehabilitation Reseach*

PURPOSE—This study explores the effectiveness of a unique intervention from the stress of caring for a stroke survivor.

METHODOLOGY—One hundred thirty-six older, spousal caregivers of stroke survivors will be randomly assigned to a treatment or control group. The control group will receive written material on caregiver stress and assessed upon recruitment and after 6 months. The treatment group will participate in an 8-week, professionally led, educational/support group held mostly by telephone conference calls. They will be assessed upon recruitment, after the group intervention, and at six months. It is hypothesized that the treatment group will show less depression, loneliness, burden, and increased healthy behavior and competence.

PROGRESS—In the first year, approximately 300 people have been solicited to participate in the study by these strategies. Approximately 195 people could be located for definite agreement or decline to participate. Thirty-three caregivers have been recruited: 16 were randomized to the treatment group, 13 were randomized to the control group, and 4 are in stages of initial assessment. Three support groups have been conducted thus far, involving 11 participants.

Of the 162 who declined, 25 percent refused due to lack of interest or being too busy; 9 percent due to the caregiver's poor health, and only 2 percent declined to participate because of living too far away from the hospital. It is notable that in 20 percent of the cases, the stroke survivor had died, making the caregiver no longer eligible. Of the total number of people solicited, 9 percent were unable to be contacted.

[143] IMPROVING VOCATIONAL OUTCOMES OF INDIVIDUALS WHO HAVE SUSTAINED A STROKE

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Sponsor: *National Institute on Disability and Rehabilitation Reseach*

PURPOSE—The overriding goal of vocational rehabilitation is to assist individuals with a disability in attaining vocational goals (i.e., return to work) at a level appropriate to their abilities. The vocational

functioning and status of individuals who have sustained a stroke are significantly less than those of individuals with other disabling conditions. It is strongly felt that there currently exists a lack of a focused, succinct assessment to assist the professional in providing cost-effective, high quality services to increase successful vocational outcomes.

The broad objective of this project is to develop a good assessment tool for proper diagnosis for vocational rehabilitation and improve the probability of positive vocational outcomes for individuals who have sustained a stroke. Specific objectives of this study are to investigate and evaluate the Functional Assessment Inventory (FAI) for its suitability for application to the stroke population and to identify appropriate areas of the FAI which require modifications to improve the assessment tool for the stroke population.

PROGRESS—By the end of 1994, data collection for the 110 control cases has been completed. The only remaining data which needs to be collected for the control group is the amount of vocational services provided. This has been obtained for 1 year out of the 2 year time period. To date, a total of 43 subjects of the experimental group have completed the modified FAI.

[144] AN AFTERCARE PROGRAM FOCUSED ON THE POSTCONCUSSION SYNDROME FOLLOWING MILD TRAUMATIC BRAIN INJURY

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Sponsor: *Stichting Fonds Johannastichting*

PURPOSE—The purpose of this investigation is to prevent the development of secondary complaints in individuals who have suffered a mild traumatic brain injury. These complaints seem to be caused not only by the injury itself but also by post-traumatic reactions, so-called secondary complaints (due to anxiety disturbances, lack of comprehension for the resultant behavioral deficits, and uncertainty). The effect of such complaints manifests itself in changing jobs, marital problems, changing school type, losing employment, persistent ''medical shopping,'' and so forth.

METHODOLOGY—During the first stage, the hospital stage, the patients are submitted to a neuropsychological examination shortly after the injury, as soon as PTA and confusion are over. The results of this examination are discussed with the patient shortly before discharge. In addition, the outpatient receives an information booklet. In this booklet patients are informed about the long-term sequelae concerning deficits which might arise on the levels of physical, psychological (cognitive, affective, psychomotoric), and social functioning. During the second stage of the investigation, the home stage, patients are periodically followed for 2 years. Patients fill out complaint lists (the Sickness Impact Profile and the Symptom Check-List 90); the results from these questionnaires are discussed at each session. At the end of the program (2 years post onset), patients are neuropsychologically reassessed. The results of this investigation will be compared with a control group consisting of individuals who suffered a traumatic brain injury but who, during the first year of recovery, do not receive any information concerning outcome except a neuropsychologic assessment during the hospital stage. In this way, both populations will be compared in order to measure the effectiveness of the aftercare program.

PROGRESS—Data are being collected. In 1997 the first comparisons will be made between the experimental group and the control group.

[145] PROCESSING SPATIAL INFORMATION

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Sponsor: *St. Maartenskliniek*

PURPOSE—Adequate processing of spatial information is essential for normal sensorimotor behavior. In stroke patients with a lesion in the right posterior cerebral cortex, very specific defects, concerning the processing of spatial information, can be observed. These include neglect for contralateral space. Although this disorder is clinically well documented, there are few studies on the way motor preparatory processes have been impaired in these patients. In the present project a series of experiments have been performed focused at the understanding of neglect in the context of sensorimotor processes.

METHODOLOGY—Two clinical neuropsychological experiments have been performed. In one experiment an attempt was made to disentangle in- and output aspects of unilateral neglect in 10 stroke patients, in a series of reaction time tasks. Visual target detection and the organization of a directed movement were manipulated, in a factorial design.

A second experiment completed this year considered the problems that can occur in patients with unilateral neglect, in navigation in the environment: they tend, for instance, to bump into objects. Nine stroke patients with adequate walking abilities, of whom 5 had visual neglect, and 18 normal, age-matched controls, were observed while they were walking through an aperture. The width of the aperture was varied, and in some trials a colored cue was attached to one of the sides, in order to increase the salience of that side. Furthermore, subjects were required to tell whether they could pass the aperture.

PROGRESS—The data acquisition has been completed, and the various experiments are being submitted to international neuropsychological and rehabilitation journals.

RESULTS—In the Reaction Time study, there was a clear target side effect, which was, however, similar across all conditions. There were no effects of movement directionality or stimulus uncertainty on the neglect scores, suggesting that intentional factors did not contribute to the impairment. Moreover, in the second experiment of this series, a similar movement was to be made following an auditory start signal and there was no effect of movement direction, either. Hence, it can be concluded that there was no evidence for an independent impairment in initiating a leftward directed movement in this sample of patients with neglect.

In the navigation study, it was observed that patients with neglect bumped into the sides of the aperture much more often than the patients without neglect or the controls (N=18). The colored cue had no effect on the number of collisions. The number of collisions correlated highly with paper and pencil tests of neglect. The results showed that there are differential patterns of performance. Three patients with mild neglect bumped into the left side, and two others with more severe neglect bumped predominantly into the right side. An important indicator of the coupling between perception and action is rotation of the shoulders while passing a narrow aperture. Although the patients were able to do so, they often failed to rotate their shoulders when this was required for a smooth passage, thus indicating an impairment at the level of perception-action coupling. This is even more interesting because patients were very well able to estimate the width of the aperture at the verbal level. The main findings are discussed in terms of a contralateral attentional deficit and an ipsilateral release of 'intentional' processes.

RECENT PUBLICATIONS FROM THIS RESEARCH

Walking through doorways: An analysis of navigation skills in patients with neglect. Tromp EH, Dinkla A, Mulder Th. Neuropsychological Rehabil. In press.

VII. Independent Living Aids

A. General

[146] DESIGN OF NEW TOILET PROTOTYPES FOR ELDERLY AND DISABLED VETERANS

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PURPOSE—This study is concerned with improving the ability of older veterans and those with disabilities to carry out routine daily activities independently and safely. Difficulty in toileting independently is common among both older people and people with disabilities. Moreover, loss of independence in toileting is one of the most common predictors of an elderly individual's relocation from the community to a nursing home. In response to these problems, the purpose of this project is to design and test new toilet and grab bar prototypes that will enhance independent and safe toileting among older veterans and those with disabilities.

METHODOLOGY—Prototype designs were based on an analysis of previous research and anthropometric data in order to develop criteria for new toilets designs (e.g., data collected on physiological and functional abilities of users, data on toilet fixture design, manufacturing processes, and toilet room configurations). Full-scale mockups of the prototypes were then constructed based on the design criteria, and subjects were videotaped getting on and off of the prototypes and post-trial questionnaires were administered. Expert assessment of participant performance as well as analyses of post-trial self-report data will be used to evaluate the independence and safety associated with each of the prototypes.

PROGRESS—Based on an analysis of previous research and anthropometric data, four prototypes were designed, constructed and tested. One of the prototypes is a wall or floor mounted toilet (a straddle toilet) with integral grab bars and hand holds. The straddle toilet is intended to be used by positioning the wheelchair in front of the toilet and then sliding over the front of the fixture. The other three prototypes are toilet seat inserts that are designed to replace the toilet seat by mounting them to the floor and covering an existing toilet. Two of the retrofit designs are intended for wheelchair access; the third is for ambulatory access. The inserts differ according to the type of built-in handles (side, recessed, and vertical handles).

The four prototypes were installed and tested in a portable bathroom testing facility. Sixty-eight subjects (34 nonambulatory and 34 ambulatory) in Atlanta and Milwaukee were videotaped simulating toileting activities on each of the prototypes (i.e., getting on and off the toilet). Videotape data of the test trials have been coded and data is being entered into the computer for statistical analysis.

PRELIMINARY RESULTS—Preliminary analyses of data indicate that people with paraplegia perceive that the prototypes enable safer transfers and better accommodate bowel care than do existing toilets. In addition, older individuals with mobility impairments indicated that it was easier to get on and off the toilet using the inserts than typical raised toilet seats.

FUTURE PLANS—Final analysis of data will be completed. Based on the data analysis, modifications to the prototypes will be assessed and working models will be constructed and evaluated in-use at the VA Research and Evaluation Unit.

[147] ASSISTING COMMUNITY-BASED RURAL INDEPENDENT LIVING PROGRAMS

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PURPOSE—Under a 3-year grant from NIDRR, ILRU identified community-based programs that are engaged in the delivery of independent living and supportive services to persons with disabilities who live in rural areas. Criteria were established for exemplary operational practices, and programs were selected that best meet these criteria. Materials were solicited from exemplary programs for inclusion in ILRU's Resource Materials Directory. Six programs (two in isolated rural communities, two in moderately rural communities, and two in urban settings that do outreach to rural communities) were selected as demonstration sites for receiving intensive supportive services by ILRU over the duration of the project. The outcome of these efforts was assessed using a comprehensive approach to evaluation. The final goal is to make rural-focused technical assistance services and supportive materials available to all rural independent living programs.

PROGRESS—An advisory committee composed of persons representing the Association of Programs in Rural Independent Living (APRIL), the National Council on Independent Living (NCIL), the Council of State Administrators of Vocational Rehabilitation (CSAVR), researchers and practitioners in rural rehabilitation service delivery, and the Research and Training Center on Rural Rehabilitation Services has been established. A Delphi questionnaire was prepared and sent out to independent living programs requesting the staff to list the five most pressing problems confronting providers of independent living services to rural areas. Next, a composite listing of these problems was sent to these programs, asking that they rank order the top ten problems.

Five exemplary rural service providers were identified, and two emerging rural independent living centers were selected as demonstration sites for technical assistance and materials. Five monographs were written about the most problematic areas for rural centers; they are currently in production. Cluster analysis was completed and three distinct profiles of rural independent living centers identified. An article is currently in progress.

RESULTS—A questionnaire sent to independent living programs in 1991 identified 300 programs that offer services to people with disabilities residing in rural areas. These programs received a second questionnaire covering center location, service delivery, and staff and board with and without disabilities, and budget; 123 centers responded. Analysis of the Delphi survey revealed the top five problems faced by rural ILCs to be attitudes, transportation, housing, funding, and accessibility. Cluster analysis based on five criteria: 1) total annual budget in proportion to the number of consumers served, 2) percentage of staff time spent providing services in the consumer's home rather than at the center, 3) number of miles traveled to deliver in-home services in proportion to the number of staff traveling annually, 4) number of miles traveled to deliver in-home services in proportion to the number of consumers served annually, and 5) number of information and referral requests received during the past fiscal year.

Of the 123 respondents, 100 met the criteria to fit into one of three profiles: 1) Prototype profile, representing the typical center providing services to rural areas, with the smallest budget to spend per consumer and the highest percentage of consumers with mobility impairments served (n=77); 2) Outreach profile, with the highest rate of travel to deliver in-home services and the highest percentage of elderly consumers (n=13); and 3) Peak expenditure profile, the most atypical, with few in-home services and the highest average budget per number of consumers served (n=10). Overall differences between profiles were highly significant at $p<0.00001$.

[148] LIFE SATISFACTION OF PEOPLE WITH PHYSICAL DISABILITIES: RELATIONSHIP TO PERSONAL ASSISTANCE, DISABILITY STATUS, AND HANDICAP

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—The preponderance of available studies indicate that persons with chronic physical impairments rate their satisfaction with life somewhat lower than nondisabled individuals. To understand how chronic physical conditions affect life satisfaction, this study is intended to explore possible moderating factors that are associated with those conditions and with life satisfaction. Three possible moderating factors were investigated: 1) level of disability, 2) level of handicap, and 3) self-appraised adequacy of personal assistance.

PROGRESS—Staff in eight centers for independent living in Federal Region VI recruited subjects for the study and distributed questionnaire packets. The questionnaire consisted of demographics, the Personal Assistance Satisfaction Index (PASI), the Arthritis Impact Measurement Scale (AIMS) to assess disability, the Craig Handicap Assessment and Reporting Technique (CHART) to assess handicap, and the Life Satisfaction Index-A. Approximately 81 percent of subjects returned surveys and participated in telephone interviews. A sample of 45 respondents used personal assistance. Data analysis is complete, and a manuscript presenting the results has been submitted for publication.

RESULTS—Self-appraised adequacy of personal assistance in terms of availability, quality, consumer control, and cost was found to be a significant factor in the life satisfaction of people with severe disabilities. Appraisal of personal assistance was not associated with whether assistance was obtained through a formal agency or whether it was provided on a paid or unpaid basis. Life satisfaction was positively related to social integration and occupation, two measures of handicap. Life satisfaction was not related significantly, however, to severity of physical disability. Whereas environmental or social limitations associated with disability had an adverse impact on life satisfaction, functional limitation had little impact. People who were mobile in their homes and communities and involved in occupational and avocational interests were generally satisfied with their lives. These findings suggest that satisfaction with personal assistance positively impacts life satisfaction, an effect that is relatively stable across disability levels.

RECENT PUBLICATIONS FROM THIS RESEARCH

Life satisfaction of people with physical disabilities: relationship to personal assistance, disability status, and handicap. Nosek MA, Fuhrer MF, Potter C. Rehabil Psych. In press.

[149] USE OF PERSONAL ASSISTANCE SERVICES BY PERSONS WITH SPINAL CORD INJURY

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—This study is designed to examine patterns of usage of personal assistance among a community-based sample of 284 persons with spinal cord injury (SCI) and to assess the relationship of the pro-

vision of personal assistance by family with the independence and productivity of persons with disabilities.

PROGRESS—The Baylor College of Medicine Research and Training Center on Spinal Cord Injury and Independent Living Research Utilization (ILRU) have used a registry of 661 persons with SCI to assess relationships between living arrangement and provision of personal assistance by family, nonfamily, or a combination of both. This now comprises the control group for all subsequent studies of quality, control, availability, and cost of personal assistance services. The sample for the present study was a subset of 284 individuals who reported needing assistance with self-care activities on structured telephone interviews. Data were analyzed and correlates of the amount of personal assistance received and arrangements for receiving personal assistance were identified. Productivity was categorized as 1) high (full-time worker, student or volunteer, homemaker, or both part-time worker and part-time student), 2) moderate (part-time worker, student, or volunteer), or 3) low (retired, other).

RESULTS—More than half of participants had only relatives providing their assistance while 46 percent paid for some or all of their assistance. Although there was a significant relationship between having nonrelatives provide assistance and having paid assistance, it is notable that 24 percent of relatives were paid, and that of the nonrelatives who assisted, 34 percent were not paid.

No significant relationships were found between living alone or with parents, friends, or attendants and whether or not paid assistants were used.

Only two demographic variables had a strong relationship with who provides assistance: marital status and educational attainment. Those who were married predictably relied on relatives more than those who were single. Those who were more highly educated tended to rely more on nonrelatives. Productivity did not have a statistically significant relationship with who assists or payment for services.

RECENT PUBLICATIONS FROM THIS RESEARCH

Use of personal assistance services by persons with spinal cord injury: policy issues surrounding reliance on family and paid providers. Nosek MA, Fuhrer MJ, Rintala DH, Hart KA. J Disabil Policy Studies 1993:4(1):1-11.

[150] VARIABLES AFFECTING INDEPENDENT LIVING FOR PERSONS WITH PHYSICAL DISABILITIES

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Sponsor: *The National Welfare Grants Program, Human Resources Canada*

PURPOSE—The purpose of this study was to identify the factors that facilitate independent living (IL) for persons with physical disabilities. It has been proposed that IL outcomes are influenced by factors from both the environment and from within the individual with the disability. However, the complex nature of individual IL circumstances has made it difficult for researchers to identify specific combinations of factors affecting successful IL. The study participants were 547 men and women with spinal cord injuries, aged 19 to 79, living in Ontario communities.

METHODOLOGY—A self-administered survey called the "Independent Living Questionnaire" (ILQ) was developed, based in large part on the Personal Independence Profile (PIP). It was hypothesized that variables from each of the four domains of demographic, disability, psychosocial, and environmental influences would predict successful IL. The outcome variables, related to living arrangements, productivity, overall independent living, and success was defined as satisfaction with these outcomes. Descriptive, correlational, factor, and regression analyses were conducted.

RESULTS—IL outcomes are influenced by a constellation of factors from each of the four domains of demographic, disability-related, psychosocial, and environmental variables. The constellation varies from person to person.

IMPLICATIONS—A broad range of support services addressing all components of IL must be available, and flexible enough to address individual needs. The built environment must be made more accessible, adapting the surroundings to the individual as well as the individual to the environment.

Locus of control (individual personal control) and social support (family, friends, acquaintances) were important factors related to successful IL for all participants in this study.

A direct funding approach is strongly recommended. Peer counseling, such as that typically provided by IL Centers, should be widely available. Family supports and community connectedness need to be strengthened by government, social service agencies, voluntary groups, and community groups.

Those who are more productive are more educated, healthier, and have greater functional ability. They are more likely to have independent transportation, and an accessible home environment and immediate community. However, it is not possible to say whether increased productivity precedes or follows from these other factors.

To facilitate productivity, it is necessary to ensure: integrated education, focusing on academics, vocational and life skills, and work readiness; health promotion for all; development of technical aids; adequate financial support for personal transportation and/ or greater access to public transportation.

Those who rank their life as independent have greater functional ability, access to affordable and accessible housing, support of friends and family, and a feeling of personal control over their lives.

Functional ability can be enhanced by assistive devices and environmental control systems, both of which require further research and development funds. Accessible and affordable housing options need to be increased in both urban and rural regions. Early education in the areas of advocacy, assertiveness, self-esteem, and social skills is strongly recommended, preferably in the context of peer support and self-help groups as well as through rehabilitation, social services, and educational avenues.

[151] NEW GRIP AID FOR LEPROSY PATIENTS

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PURPOSE—In a hand affected with leprosy, insensitivity interferes with the correct pressure judgment in manipulating objects of different size and shape. Intrinsic muscle denervation and the subsequent lack of feedback from the specialized sensory end organs, in combination with cutaneous sensory loss, categorize the neuropathic hand under high risk.

In the characteristic ulnar-median claw hand of leprosy, the functional area of the hand is reduced and only certain specific areas come in contact with objects, which quite often slip from the hand. In order to compensate for the weak grip, the patient tries to hold the object more firmly; this results in overloading specific areas. Repetition of activities in such a manner have a harmful cumulative effect on the neuropathic hand, predisposing the claw hand to anesthetic injuries. Activities of daily living are thus difficult to perform and movements become clumsy. A new grip aid, called Modulan Grip Aid (MGA), has helped in overcoming this problem.

PROGRESS—MGA is comprised of two separate components, a yellow epoxy resin and a blue hardener. The two components are thoroughly mixed together in equal proprotions to form a uniform green putty. The putty is applied to desired object and the patient grips it for a short while. The putty sets in 12 hours and the object can be used.

We have tried MGA on spoon handles, pens, tooth-brushs, specific vocational tools, scalpels and

knife handles and other objects for patients with mobile claw hands, those having absorbed phalanges, and those with severely deformed hands unfit for surgery.

RESULTS—MGA has been found extremely beneficial and safe for the anaesthetic hands. It sticks to any surface except oily or greasy and can be tried on various objects of daily living. MGA is chemically inert and retains its shape once formed. It does not break easily even if it slips from an insensitive hand. MGA improves the grasp of the object by increasing the surface area of the hand, thereby enabling the individual to handle various objects more safely and smoothly.

[152] SPECIAL PROJECTS AND DEMONSTRATION: APPLICATIONS OF TECHNOLOGY TO ENHANCE QUALITY OF LIFE—A COMMUNITY MODEL

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PURPOSE—The project focuses on demonstrating that the education and rehabilitation planning processes for individuals with the most significant disabilities can be enhanced with functional applications of technology. Specifically, the project intends to demonstrate that persons with severe disabilities using customized adaptations (assistive devices) can participate more meaningfully in integrated work, school, and other community settings and that educators, rehabilitation counselors, case managers, teachers, parents, and employers will not only consider, but actually develop and use, adaptations to meet program and service goals. We provide the resources and support so that IPP teams will be able to design, fabricate, and evaluate adaptations for persons with the most severe disabilities and increase the community's capacity to respond to technology needs of individuals with severe disabilities through exposing students in engineering and related fields, community volunteers with technical expertise, and high school students with technical interests to assistive technology. Finally, we wish to develop a replicable community approach for enhancing and broadening the applications of assistive technology through direct service, information collection and dissemination, and referrals.

PROGRESS—The goals delineated above are being realized through several avenues. To identify individuals who could benefit from customized technical adaptations, the project staff has worked closely with teachers and resource specialists of the San Diego Unified School District as well as with staff from a number of locally supported employment and living agencies. The project has specifically targeted transition-aged students (18 to 22 years) and young adults who, with suitable individualized assistive technology, could become more active participants in school, work, and community settings. Resources have been directed toward building up the technical capabilities of local schools and service agencies, expanding the network of rehabilitation and assistive technology professionals, and reducing possible duplication.

One key project component used to implement the development of functional assistive adaptations has been the use of multidisciplinary Tech Teams, individually organized to the specific needs of the consumer. The Tech Teams may include friends, family members, interested volunteer engineers, and employers in addition to the special educators, engineering students, OTs/PTs, speech therapists, and community-based rehabilitation technologists who are enrolled in a special seminar jointly taught by the Departments of Special Education and Electrical Engineering. In addition to providing valuable hands-on experience of designing and fabricating a customized assistive device, the class fosters exchanges of ideas and viewpoints between persons from varied backgrounds. A Technology Mini-center coordinates various demonstration, training, research, and dissemination activities associated with the project while also serving as a repository of numerous reference materials available for use by the community.

RESULTS—Major accomplishments of the initial 18 months include: more efficient collaboration with the school district, supported employment, and supported living agencies through better utilization of each others' assistive technology resources and expertise; expanding key intra-state and inter-state linkages; the design, construction, and delivery of over 40 customized technical adaptations; the documenting of completed individualized adaptations with photographs, videotape, technical drawings, and case study descriptions; the making of over 40 presentations at the local, state, and national levels; and the evaluation of the completed projects in terms of the reasons for success or failure.

Examples of adaptations that have enhanced integration include: 1) a work stool with customized padding and supports to allow a disabled student to work at a chemistry lab bench, 2) a sliding hand support to increase keyboard accuracy and endurance for persons with upperlimb weakness, 3) a customized work station that increases the independence of a person (with limited reach, stamina, and mobility) when using a computer, editing videotapes, and dialing a telephone, 4) a switch operated electromechanical ball launcher for inclusion into physical education classes, 5) a custom-made jacket harness that allows a student to transport his electronic communication device while leaving it readily usable, 6) a single-switch-operated staple remover and single-switch-operated automatic ticket hole puncher, 7) a modified seat and trunk support for a jet ski, and 8) a cardboard lunch box folder for someone with limited manual dexterity.

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[153] TRANS-TRAIN: TRANSDISCIPLINARY TRAINING OF REHABILITATION PERSONNEL IN ASSISTIVE TECHNOLOGY

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PURPOSE—Project TRANS-TRAIN seeks to provide preservice and inservice training to rehabilitation personnel in Assistive Technology. It is a university-based program that combines academic classroom instruction with experiential field activities. Although discipline specific training will occur, TRANS-TRAIN is fundamentally a transdisciplinary project that will establish a series of courses, guided design projects, and internships that focus on the development and use of assistive technology. Six- to nine-unit curricula sequences will be offered and co-listed in the Departments of Special Education and Rehabilitation graduate degree and certificate programs and in the Electrical and Computer Engineering undergraduate and graduate degree programs. To complement an existing certificate program in "Supported Employment and Transition," a specialization area in "Rehabilitation Technology" will be developed.

METHODOLOGY—Because students entering this program can come from various educational and vocational backgrounds, such as engineering, special education, rehabilitation counseling, communicative disorders, and social work, the certificate program will be customized to fit their backgrounds, skills, interests, and intended application areas. In addition to the six- to nine-unit curricula (supported in part by project funds), students seeking a "Certificate in Assistive Technology" must complete six units of formalized discipline-specific course work from within their

home departments and three to six units of transdisciplinary seminars covering a broad range of rehabilitation technology competencies and knowledge. For hands-on experience, students will participate in a number of internships, off-campus and on-campus, under the supervision of professors and practicing professionals in rehabilitation engineering, special education and rehabilitation, and communicative disorders by working at some local agencies such as the Sharp Rehabilitation Hospital, SDSU's Assistive Device Assessment Program, Creative Support Alternative, United Cerebral Palsy of San Diego, and Toward Maximum Independence.

One key component used to train personnel in the development of customized assistive adaptations is the use of multidisciplinary Tech Teams individually organized according to the specific needs of an individual with disabilities. The Tech Teams can include friends, family members, employers, and interested volunteer engineering professionals plus special educators, engineering students, OTs/PTs, speech therapists, and community-based rehabilitation technologists enrolled in TRANS-TRAIN sponsored special classes or seminars. In addition to providing the experience of designing and fabricating a customized assistive device, the class fosters multidisciplinary exchanges of ideas and viewpoints among persons from varied backgrounds. To monitor progress and insure that the assistive technology services envisioned will be consumer-driven and integrated into the planning processes, a series of twelve milestones—from a request for assistance, research and data collection, design, prototype construction, field-testing, to evaluation—have been used. To promote dissemination and replication by others, customized adaptations designed and constructed through this project are being incorporated into a database that will track information about each adaptation. Detailed case studies will be completed for those adaptations that are more innovative or have multiple applications.

PROGRESS—During the initial 6 months of this project, 4 undergraduate and 4 graduate engineering students and 11 graduate students with backgrounds in special education, rehabilitation counseling, and/or occupational therapy enrolled in the first transdisciplinary seminar. Guest lectures and tours of local rehabilitation agencies supplemented lectures by project staff.

Four Tech Teams were formed, based on the needs of four interested individuals with disabilities (two high school students and two adults) and the students' interests and technical skills. These Tech Teams designed, fabricated, field tested, and delivered the following: 1) a customized work station that increases the independence of a person (with limited reach, stamina, and mobility) when using a computer, editing videotapes, and dialing a telephone, 2) a custom-made vest harness that transported a student's electronic communication device while leaving it readily usable, 3) a cardboard lunch box folder for someone with limited manual dexterity, and 4) various environmental adaptations that enhanced independence (e.g., telephone receiver modification, a new remote controlled self-locking and unlocking automatic front door, a new book holder, and an improved remote light switch).

FUTURE PLANS—During the next 12 months, TRANS-TRAIN will establish a certificate program in Assistive Technology under the auspices of Department of Special Education and Rehabilitation. TRANS-TRAIN will offer an advanced version of the transdisciplinary seminar in assistive technology, set up internships at local agencies with appropriate experts, and offer an engineering class in electronic assistive devices. Two key ongoing tasks include the recruiting of students and the refinement of procedures and tracking forms.

RECENT PUBLICATIONS FROM THIS RESEARCH

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B. Robotics

[154] VOCATIONAL TRAINING FACILITY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B635-DA)*

PURPOSE—The goal of the Vocational Training Facility Project (VTF) was to develop and test a novel curriculum concept to train students with high-level quadriplegia vocational skills in desktop publishing. These skills were taught in a workstation setting, using adaptive access equipment and devices, including a voice-controlled robot for manipulation assistance.

METHODOLOGY—The VTF included the implementation of three robot-equipped workstations. Each workstation provided multimedia presentation of curriculum materials to teach skills for entry-level positions in desktop publishing and presentation. Videodisc materials supplemented instructional software to provide an accessible, integrated learning environment. A total of 16 students were tested; 3 students at a time received 4-month training sessions. In addition to conventional batteries of test instruments, software records of computer usage and robot actions have permitted subsequent analysis of the effectiveness of the VTF concept.

The workstations were equipped with a variety of interface devices for individualized access by students with quadriplegia. In addition, the robot was able to perform all needed daily-living (e.g., lunch, beverages, medication) and vocational support (e.g., printer output, mouthstick, phone) tasks while the student was at the workstation. With these supports, as well as the multimedia curriculum design, each student was able to perform self-paced learning of vocational skills. The VTF tested this approach in a study including high-level and low-level quadriplegic veterans as well as a control group of paraplegic students.

PROGRESS—The hardware, software, and training materials have been procured; three robot workstations for the set of VTF equipment configured and programmed; local companies contacted for Task Force involvement and internship placement; core instructional software necessary for the curriculum written; three DTP videodiscs edited and pressed; and the VA Spinal Cord Injury Service and the California State Department of Rehabilitation has been provided with materials and enlisted to identify prospective disabled veterans.

RESULTS—A total of 16 students have been recruited. The outcome "success" of the project was defined as the ability to participate in the 12-week course, complete an internship, and pursue a job opportunity. Of the 16, 2 did not complete the course due to medical reasons. Seven completed one or more internships. Currently, 7 of the 16 are engaged in follow-on education or gainful employment (either following the internship phase or directly after VTF training), while six are actively pursuing educational, internship, or job opportunities.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Comparison of computer access devices for persons with high level spinal cord injuries. Shafer D, Hammel J. Proceedings of RESNA International '94; 1994 June; Nashville, TN. Washington, DC: RESNA Press: 394-6.

[155] IMPROVING THE FUNCTIONAL UTILITY OF REHABILITATION ROBOTICS THROUGH ENHANCED SENSORY FEEDBACK: THE VIRTUAL HEADSTICK

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PURPOSE—A major advantage of mouth-sticks and head-sticks as extension devices for people with disabilities is that these devices provide extended proprioception, allowing the user to directly feel forces and other perceptual cues present at the tip of the stick. The conventional mouth-stick is especially effective for two reasons: it is in intimate contact with the user's mouth, which is rich in tactile and proprioceptive sensing ability, and it is lightweight and very stiff, therefore conveying tactile and kinesthetic information from the environment with high bandwidth. Unfortunately, traditional mouth-sticks are limited in workspace and in the mechanical power that can be transferred because of limitations of the user's head-neck mobility and strength.

We are developing an alternative implementation of the head-stick using the idea of a virtual head-stick, which is a head-controlled telerobot with force or position reflection. In the virtual head-stick system, the end effector of the slave robot moves as if it were at the tip of an imaginary extension of the user's head. The design goal is for the enhanced sensory feedback so that the virtual head-stick may have the same intuitive operation and extended proprioception as a regular head-stick effector, but with augmentation of workspace volume and mechanical power.

METHODOLOGY—We are using techniques developed for bilateral teleoperation to guide the design of the system. The system consists of two kinematically different robots, with controllers, kinematics and control software, and a high-speed communication link. The master robot (controlled by the consumer) is a 6 degree-of-freedom (DOF) force-reflecting hand-controller robot, modified by the manufacturer to function in an inverted configuration as a head input/output device. The slave robot is a 6 DOF force-controllable light industrial robot. The system is modelled using both analytical techniques, such as Hybrid Parameter models, and numerical simulation to gain a better understanding of factors affecting the quality of the sensory feedback such as system bandwidth and the effect force/position gains.

PROGRESS—We have successfully implemented both Cartesian and joint space control schemes with force reflection. Since the two robots are kinematically dissimilar, implementing the Cartesian mode involved analyzing and implementing the forward and inverse kinematics of the one for which the manufacturer did not provide kinematic routines. We are currently implementing closed-loop impedance controllers for both the master and slave robot in order to more precisely control the apparent mass, damping, and stiffness of both the master and slave. These quantities are important in determining the user feel of the system. As a precaution, a mechanical safety mechanism has been constructed, which will prevent excessive feedback forces from being applied to the user. We anticipate evaluation by consumers in terms of user acceptance of the system, quantitative psychophysical measurement (e.g., minimum detectable forces), and ergonomic and task effectiveness of the system.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[156] REHABILITATION ROBOTICS TECHNICAL ASSISTANCE AND OUTREACH

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PURPOSE—We seek to serve as a leading source of materials and assistance to professionals, consumers, families, and agencies dealing with rehabilitation robotics. In addition to disseminating technical reports and articles on research results obtained by ASEL staff, this program will also participate in activities to promote dissemination in the areas of technical assistance, consumer advocacy efforts, support to manufacturers, and support to other researchers.

METHODOLOGY—Dissemination tools to be developed include: an annual videotape depicting many international rehabilitation robotics research laboratories and their projects; a World Wide Web server that includes an electronic information base entitled "Assistive Technology On-Line;" a compilation of commercially available robotics devices and contact information for each; the Rehabilitation Robotics Newsletter, published quarterly; and a chapter in the *1995 Atlas of Prosthetics and Orthotics* entitled "Electronic Aids and Robotics."

PROGRESS—The researchers in rehabilitation robotics have produced 30 publications for dissemination through the information program. Inquiries from other researchers, clinicians, therapists, consumers, teachers, and families are each answered with a personal response and appropriate information materials. The Fourth International Conference on Rehabilitation Robotics (ICORR '94) was hosted, and its Proceedings published, by ASEL in Wilmington. Approximately 100 robotics researchers, manufacturers, and engineers gathered for this meeting. The 1994 Videotape Review of Rehabilitation Robotics was completed and disseminated to all Tech Act state projects and rehabilitation robotics laboratories. Video clips are now being collected for the 1995 version. "Electronics and Robotics Aids" was completed and submitted for inclusion in the *Atlas*. Cataloging and database creation of robotics literature and books continues in an effort to provide World Wide Web access to this information.

[157] DEVELOPING A ROBOTICALLY AIDED SCIENCE EDUCATION LABORATORY FOR STUDENTS WITH SEVERE PHYSICAL DISABILITIES

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PURPOSE—The intention of this project is to assist children with severe physical disabilities with the development of a functional, stand-alone, educational robotic system complete with a prototype robot, assessment and educational curriculum materials, and other supportive documents. The goals of the project include prototype development, therapeutic assessment, training and education, and dissemination. Pilot implementations to investigate the feasibility of the system in a series of field tests are under way in classroom settings in a New Castle County School and the Columbus Public Schools by the Applied Sciences and Engineering Laboratories (ASEL) and Ohio State University (OSU), respectively. The proposed prototype research and development project expands upon an extant foundation, providing for the eventual integration of the science laboratory, accessible instruments, software tools, and the robotic manipulation

abilities into a complete science laboratory environment. This setting will someday enable young learners with severe physical disabilities to work with greater independence within a powerful laboratory-based setting incorporating the best tools and instructional strategies available.

METHODOLOGY—A mixed methodological approach that integrates quasi-experimental and qualitative methodologies will be used to gather data on the academic performance and cognitive, psychomotor, and affective impact of using the prototype laboratory environment. One of the primary functions of this project is to develop a science educational curriculum that is field-tested and validated. The framework of the educational curriculum involves a two-phase process in which students are first trained to use the robot hardware and software using simple object manipulation activities. The second phase involves the development of science education activities followig the specified sequence of: explore, observe, think, find out, and record. Each of these areas are used to develop a contextualized understanding of the scientific phenomenon that are under investigation, in addition to doing the hands-on experimentation using the robotic system. There will be a total of 35 students taking part in the research during the 1994–1995 school year, that includes the selected student in the ASEL pilot project. The students include both disabled and non-disabled students who will be working in research teams at the field sites in the schools.

PROGRESS—At this time, we have completed five instructional activities within the first phase of the curriculum involving the training of students to use the robotic hardware and software. The prototype robotic workstation has been installed at the Colerain Elementary School, and the student research teams have completed two lessons. The design of the student workstation involves a multilayered set of safety features unique to the use of robots in any school-based setting. A pilot implementation of the hardware and software system is also underway in Delaware.

RESULTS—Data gathering is ongoing but results will be presented by a case study design and single subject analysis procedures.

RECENT PUBLICATIONS FROM THIS RESEARCH

Design of an integrated interface to an educational robotic system. Beitler MR, Stanger CA, Howell RD. In: Proceedings of RESNA International '94; 1994 June, Nashville, TN. Washington, DC: RESNA Press: 448-50.

Robotically-aided science education for children with disabilities. Howell R, Stanger C, Chipman C. In: Proceedings of the Fourth International Conference on Rehabilitation Robotics, 1994:165-8.

[158] MULTIMODAL CONTROL OF A REHABILITATION ROBOT

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Sponsor: *National Institute on Disability and Rehabilitation Research; Nemours Research Programs, A.I. duPont Institute*

PURPOSE—Conventional prototype interfaces have taken two approaches to achieving effective use of robotic devices by individuals with disabilities. Many have commands issued by the user to activate the robot to perform preprogrammed tasks. Others have sought to give the user control of the manipulator's motions. In this project, a new hybrid interface strategy is designed. This new man-machine interface combines command and control approaches to provide for user direction of the robot through the use of multiple modes of interface in conjunction with sophisticated capabilities of the machine. Users of this system use gestures, pointing to indicate locations, and spoken commands to identify objects and actions. The use of multiple modes of control and command allows the user to operate the robot in a manner that more closely matches the user's needs. The operation is expected to be superior to conventional methods

since it capitalizes on the user's abilities and coordinates these abilities with software and hardware sophistication of the robot and computer technology.

METHODOLOGY—This multimodal approach is based on the assumption that the world of the user is unstructured, but that objects within that world are reasonably predictable. There are two major components of this hybrid interface strategy, including a system that determines the three-dimensional contours of objects and surfaces in the immediate environment, and an object-oriented knowledge base and planning system that superimposes information about common objects in the three-dimensional world. The effectiveness of this approach can be demonstrated in the following example. An individual who uses an electric wheelchair and a portable robot arm wishes to move the pen, which is on the desk, to a box. Using a head laser pointer, he or she points to the pen and says "move." and then points to the box and says "there." The combination of pointing and commands tells the robot to pick up an object at a specific location and where to place it.

PROGRESS—The test bed for this project has been built to study the feasibility of the multimodal user-supervised control concept. The test bed currently has four major subsystems, namely, the 3D stereo vision system, voice command system, manipulator, and knowledge-based planning system. Several vision system software packages in C language have been developed for camera-robot system calibration, light spot locating, and object 3D contour measurement. A shape extraction program is developed to provide a mechanism for deriving a set of shapes from a large number of point-wise measurements from the vision system on the surfaces of the different objects in the scene. A graphics simulator has been written to display and manipulate articulated geometric figures to study the intricacies of the interactions between the user and the envisioned multimodal user direction system. Experiment trials in coordinating the vision system, voice command interface, and the gestural control interface have been made in the past to test and evaluate the designed software and the communication links. The system shows a robust performance in locating the light spot directed by the user in the three dimensional robot space.

RECENT PUBLICATIONS FROM THIS RESEARCH

Multimodal direction of a robot by individuals with a significant disability. In: Chen S, Foulds R, Kazi Z, Chester D. Proceedings of ICORR '94; Wilmington, DE: 55-64.

[159] DEVELOPMENT OF A CONTROL SYSTEM FOR ROBOTS

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PURPOSE—This research involves the development of a real-time, flexible control system for rehabilitation/assistive robots for use by disabled individuals. The control system is based on both voice recognition capabilities and an infrared sensor system placed within the robot grippers. This system is designed to augment menu-based, fixed-task robot functions by providing flexible motion and gripping controls for instances where preprogrammed tasks are inappropriate. This would include tasks that are not on the preprogrammed menu or emergency settings where rapid, flexible controls are required.

PROGRESS—The voice recognition system is based upon modified commercial systems, including those by Dragon Systems and Votan Voice Systems. Recent research in voice recognition for a disabled population has centered on the ability of such systems to recognize slurred speech common to many disabled individuals with poor motor and vocalization skills. In addition, several methods to analyze and subtract ambient noise have been studied in order to optimize the voice recognition system design. Methods to integrate flexible, voice activation systems into other menu-driven, fixed-task systems have also been analyzed. The infra-

red sensor system has been designed and tested to provide automatic gripping of nearby objects. This function is elicited by a single voice command and produces a gripping function of both stationary and moving objects. A neural network control system is being analyzed to incorporate both voice and infrared data into a robot motion/gripper control scheme.

RESULTS—The voice recognition system has been tested for a wide variety of speech abnormalities and accents. The commercially based systems have been modified to incorporate several speech classifications resulting from various disabilities. Several sources of ambient noise have been analyzed for amplitude and frequency content. Various electronic and computational noise cancellation procedures have been developed as integral components of the modified voice recognition system. The infrared gripper control system has been designed, constructed, and tested on several types of small robots. Initial tests have demonstrated the ability to grip objects several feet from the gripper for both static and moving targets. The gripper system consists of many infrared emitters and receivers that determine the location and range of the target, and controls the robot motion and gripping function to grasp the nearest object. Depth perception is being incorporated into the eye tracking robotics gripper based on reflection of infrared light from the human lens of the eye.

FUTURE PLANS—The voice recognition component to the overall robot control system is to be analyzed for potential integration with existing fixed-task, preprogrammed robot controllers in development at other rehabilitation research centers. The infrared gripper system will be tested for a wide variety of ambient conditions including light, target color and shape, target motion, and range from target to gripper. A neural network control algorithm is being continually studied to optimize robot motion and gripping function. The overall goal is to develop a flexible control system which can serve as an adjunct to fixed-task systems. The flexible version is being developed to allow disabled individuals and their assistive robots to cope with emergency situations where pre-programmed tasks cannot provide adequate support.

RECENT PUBLICATIONS FROM THIS RESEARCH

Communication and integration software. Miller GE, Etter BD. In: Manufacturing engineer's reference book. London: Butterworth Scientific Publishers, 1993.

Rehabilitation engineering design projects. Miller GE. In: Proceedings of the Biomedical Engineering Society Annual Meeting, Tempe, AZ, October, 1994.

C. Communication Methods and Systems

[160] RECOGNITION OF HAND GESTURES BY PEOPLE WITH MOTOR IMPAIRMENTS: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #C92-453AP)*

PURPOSE—The purpose of this research is to study the feasibility of two methods for computer recognition of hand gestures in the presence of noise caused by athetoid or spastic movements. We will study a feasibility scheme based on neural networks and statistical pattern recognition techniques. Our overall objective is to demonstrate the effectiveness of one or both of these techniques in recognizing hand gestures made by people with athetoid or spastic movements.

METHODOLOGY—To establish baseline data, 10 mixed-gender subjects with no motor abnormalities

have been trained on 21 gestures from the American Sign Language, using the DataGlove for sensing finger articulation and a Polhemus Isotrack for 3-D spatial position and orientation. Subjects repeat the gesture 20 times each, using both the recognition and neural network algorithms, with data subjected to multiple analysis of variance to determine intersubject and intrasubject separability. This data will be compared to the same set of data taken on a pool of 10 persons with athetoid hand movements. Additionally, the Jebsen-Taylor test is used as the standard test battery for both nondisabled and impaired persons.

PROGRESS—We have successfully completed testing on 10 normal subjects and 2 affected subjects. The limiting factor is the availability of research test subjects.

FUTURE PLANS—We plan to continue recruiting patients and to evaluate the results.

[161] ENGAGING, RECRUITING, AND RETAINING STUDENTS WITH DISABILITIES IN SCIENCE, ENGINEERING, AND MATH

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Sponsor: *National Institute on Disability and Rehabilitation Research; Nemours Research Programs, A.I. duPont Institute*

PURPOSE—Individuals with disabilities are currently underrepresented in science, engineering, and math (SEM) academic programs and professions. This fact has been confirmed in over 100 reports and studies conducted over the last decade. While this underrepresentation is due to many factors, several impediments are clear: attitudinal, physical, and curricular barriers combine to cause individuals with disabilities to be stymied in both SEM education and professions. Currently, attitudinal barriers reside not only in school counselors, teachers, and employers, but also in the students themselves and their family members. Similarly, physical barriers manifest themselves not only in the way classrooms are set up, but also in the way information is conveyed in both lectures and experiments. Moreover, SEM curricula are often designed in such a way that individuals with disabilities are barred from being active participants in the learning process. This project specifically targets each of these attitudinal, physical, and curricular barriers, and is designed to allow individuals with disabilities to flourish in SEM.

METHODOLOGY—Individual attitudinal barriers are broken down by providing positive SEM experiences and through a mentoring program. The positive SEM experiences will be obtained by adapting existing SEM programs to allow full participation by students with disabilities. The mentoring program utilizes the Internet as a 'distance free' pathway for communications over which students and mentors can communicate. The attitudes of school counselors and teachers, which currently discourage students with disabilities from pursuing SEM curricula, are changed through education and abilities demonstrations. Similar methods are used to educate and change the attitudes of family members and employers. Physical and informational barriers are broken down through the design and construction of innovative virtual laboratories. These virtual laboratories are both physical and information barrier free, and are designed to allow full and equal immersion in SEM experiments by all students. The utility of the virtual laboratories is further enhanced by teaching methods, such as problem-based learning, which allow full inclusion of all students.

PROGRESS—Existing SEM programs that are collaborating on this project have been identified. We are working with these programs to assess and improve their accessibility to students with disabilities. Students will then be enrolled in these programs starting in the summer of 1995. The Internet mentoring program is active as is a listserver focusing on these activities. Interested parties are encouraged to send e-mail to either sem-info@asel.udel.edu for information or majordomo@asel.udel.edu to subscribe to the listserver. These programs focus both on students with

physical and learning disabilities. To address the problems effecting teachers, counselors, and families, a workshop series has begun focusing on assistive technology, education, and college transition. Research into the virtual laboratories is being conducted, and alternative interfaces such as audio and tactile are being investigated for the use in science experiments.

[162] SELECTING ITEMS FROM LISTS AND MENUS IN INFORMATION SYSTEMS

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—A new generation of information systems is emerging on the marketplace. It includes a variety of systems in the home, workplace, and community, such as: electronic information kiosks, automated transaction machines (ATMs), and set-top boxes for interactive TV systems. Because these systems are dedicated to a particular function, not modifiable by the user, and frequently located in public places, they are difficult or impossible to modify for the needs of individual users. If these systems are to be made accessible to people with disabilities, accessibility must be integral to the systems' initial designs. Access for users with disabilities must be on par with (and not interfere with) access by people without disabilities.

Particular components of information system user interfaces need to be studied to determine how equivalent access can be provided for people with disabilities. This study focuses on mechanisms for selecting items from a list, a common user control structure in information systems.

METHODOLOGY—The study will record data from 24 subjects, 8 with blindness, 8 with low vision, and 8 with a physical impairment that requires the individual to look at the keyboard and away from the computer screen when typing. Three selection strategies will be tested and compared: selection by first letter of choice, selection by unique letter of choice, and selection by typing choice name until enough letters have been typed to distinguish the choice from others. The choices are made on a standard computer keyboard, with feedback provided in digitized voice. A 4×2 experimental design will be used. Presentation order will be randomized. To measure the mental load, a secondary task will be introduced, requiring the subject to press a switch in response to random-interval auditory tones. Response times will be measured and subjects will also be asked to report preferences and subjective impressions.

PROGRESS—A research prototype has been constructed and pilot subjects have been run. Based on feedback from subjects who are blind, the research instrument was modified to provide faster speech response times. Subjects for the study are currently being run.

RESULTS—This experiment is not yet completed. Results will contribute to information system design guidelines being developed by the Trace Center.

[163] UNI-FLEX: A UNIVERSAL-FLEXIBLE HUMAN INTERFACE PROTOCOL

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PURPOSE—A new generation of information systems is emerging on the marketplace. It includes a variety of systems in the home, workplace, and community, such as: electronic information kiosks, automated transaction machines (ATMs), and set-top boxes for interactive TV systems. Because these sys-

tems are dedicated to a particular function, not modifiable by the user, and frequently located in public places, they are difficult or impossible to modify for the needs of individual users. If these systems are to be made accessible to people with disabilities, accessibility must be integral to the systems' initial designs. Access for users with disabilities must be on par with (and not interfere with) access by people without disabilities. One possible set of design approaches is being developed by the Trace Center, and referred to as the Uni-Flex (for Universal Flexible) interface.

METHODOLOGY—The Uni-Flex project is focused on bringing together various techniques and strategies for making information systems accessible, and developing a set of strategies that work together. There is not necessarily one perfect solution for accessibility; however, the Uni-Flex approach will be based on the best available knowledge and techniques, and will be tested for effectiveness and consumer satisfaction. The Uni-Flex interface will consist of a suite of design strategies, including some alternative options for some aspects of design. By following the Uni-Flex standard, information system designers will be able to be certain that their design is accessible. At the same time, consumers will know what they can expect from systems that follow this standard.

PROGRESS—An initial document has been developed, listing the constraints under which the Uni-Flex protocol will have to operate. A process has begun for collecting information about existing interface strategies that might address these constraints. A series of studies is being initiated, focusing on evaluating the efficiency and effectiveness of different design strategies for different types of disabilities.

RESULTS—The result of this project will be a documented protocol for making information systems designs accessible to people with disabilities while not adversely affecting their usability for all users.

[164] DEVELOPMENT OF CROSS-DISABILITY ACCESS TECHNIQUES FOR DATABASE SYSTEMS

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—Various electronic databases have been created to provide information on assistive technology and other disability issues. Electronic information, however, requires a user interface for presentation. Basic issues in the design of this interface must be resolved in order to assure the databases are optimally effective for all potential users. The strategies developed will apply not only to the particular databases currently being created, but also to other public information systems, such as electronic kiosks, automated teller machines, and cable-TV information services.

METHODOLOGY—Databases must be simple and obvious for all users (disabled and nondisabled), especially novice users with little or no computer or database experience. They must allow independent use by people with disabilities.

The need for databases to be easy for novices to use is being met through extremely user-friendly database designs, including: familiar visual analogies on screen (such as book pages and index cards); context-sensitive instructions; prompts to the user to seek instructions; and location of geographic information by direct selection on a map.

To meet the need for databases to be accessible to users with disabilities, the Trace Center has developed interfaces which circumvent visual or movement-based features that may be difficult or impossible for users with visual or movement impairments. Some examples of strategies for users with visual impairments are: text enlargement; presentation of information and instructions in synthesized voice; and control from the keyboard rather than the mouse. Users with physical impairments are accommodated through providing alternatives to mouse movement.

The goal of this effort is to implement functioning examples of the Seamless Human Interface Protocol. This protocol, being developed by the Trace Center, defines how a user interface can integrate different modes for users of widely varying abilities (e.g., mouse/keyboard, large print/standard print). Under the protocol, each mode of operation provides equivalent access to the functions of the software, but each mode is optimized for the needs of the users at whom it is aimed.

PROGRESS—Accessibility features are being incorporated into the Trace Center's Cooperative Electronic Library on Disability, an integrated collection of disability resources in electronic form.

RESULTS—The first implementation of the Seamless Human Interface Protocol was released as part of a prototype, Publications, Media, and Materials (PMM) database. This prototype was part of the Seventh Edition of the Co-Net CD-ROM, published by the Trace Center and containing the full Cooperative Electronic Library on Disability. The interface features will become part of a formally released PMM on the next Co-Net CD-ROM. This and other accessible databases will be provided as working models for information technology industries (such as makers of electronic kiosks) for making their products accessible.

[165] DEVELOPMENT OF EXTENSIONS FOR STANDARD COMPUTERS AND OPERATING SYSTEMS TO ALLOW ACCESS BY USERS WITH MOTOR IMPAIRMENTS

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Sponsor: *IBM Corporation; Apple Computer, Inc.; National Institute on Disability and Rehabilitation Research*

PURPOSE—The most effective technique for providing access to computers for persons with disabilities is to have the computer designed in such a way that it is already accessible when manufactured. The purpose of this program is to develop extensions to operating systems that can be used to demonstrate to computer and operating system manufacturers how their systems could be modified to make them more accessible.

METHODOLOGY—Our method for getting accessibility features incorporated into standard computers and operating systems proceeds in three stages: 1) development and testing of accessible designs; 2) creation of proof-of-concept models, including actual add-on software for operating systems; and 3) working with manufacturers to build accessibility features directly in.

PROGRESS—The Trace Center has worked on the development of eight principle access features for computers, and worked for their adoptions as standard parts of computer operating systems: *StickyKeys* gives the user the capability to execute multiple key operation (such as Shift-key) with a single finger, headstick, or mouthstick. *RepeatKeys* and *SlowKeys* allow the user control over auto-repeat of keys and over the amount of time a key must be pressed before the computer accepts it as input. *BounceKeys* prevents accidental multiple keypresses (''bouncing'' on a key), and *MouseKeys* provides the option of using the numeric keypad on the keyboard to perform all mouse functions on the computer. *SerialKeys* gives the user control of keyboard and mouse from an external assistive device (such as communication aid) connected to the computer's serial port. *ToggleKeys* sounds audible tones to indicate the status of the caps lock, num lock, and scroll lock keys, and, for the hearing impaired, *SoundSentry* flashes visual indication of computer sounds (such as warning beeps).

RESULTS—We have been working with Apple Computer in their efforts to implement access features. *StickyKeys, RepeatKeys, MouseKeys* and *SlowKeys*

are now shipped as a standard part of every Macintosh sold. A version of *SerialKeys* is planned; a prototype implementation has been developed and demonstrated. We have developed the "Access Pack" for Microsoft Windows, including all eight features. The Access Pack is currently available from Microsoft Corporation, (206) 637-7098. Microsoft plans to incorporate the features directly into the upcoming Windows 95 and Windows NT. The Trace Center recently worked with IBM to develop AccessDOS, including all eight features. It is available free from IBM, (800) 426-7282. With the release of DOS 6.0, Microsoft is also distributing and supporting the AccessDOS features. For the Unix/X Window System, the Trace Center has created a set of accessibility features for the X Window graphical user interface. This "Access X" package, originally add-on software, was incorporated directly into the X Window System with release X11R6. The Trace Center is also working with the Disability Access Committee for X (DACX) on system hooks for screen magnification and screen reading, plus an X version of *SerialKeys*.

[166] GENERAL INPUT DEVICE EMULATING INTERFACE (GIDEI) STANDARD VERSION 2

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PURPOSE—Certain people with physical disabilities cannot operate standard input devices for commercially available computers. Many of these individuals can, however, operate a special communication or computer access aid, using a control system such as an optical headpointer or a single switch. The aid in turn can be interfaced to the computer and used as an input device.

In the past, a keyboard emulating interface (KEI) was used to allow a special communication aid to connect to a computer as an input device. KEIs, however, could not be developed for the Apple Macintosh or IBM PS/2 computers since keyboard access by itself would not provide full access to these computers. The general input device emulating interface (GIDEI) standard was proposed to handle the wider range in computer input devices.

The GIDEI standard defines both a connection and data communication protocol between alternate input devices and an emulating interface. Using this protocol, the alternate input device transmits information to the computer. Then SerialKeys, or another suitable emulating interface, processes that information to determine which keystrokes to type or what mouse actions to perform on the computer.

METHODOLOGY—The GIDEI Standard contains specifications for directing actions to be performed with the keyboard and mouse using a standard protocol. Communication and computer access aid manufacturers whose devices do not directly emulate input devices as a built-in feature are encouraged to design their devices with the capability to use the standard. Manufacturers who create general purpose emulating interfaces are also encouraged to support the GIDEI communication protocol.

PROGRESS—Version 1 of the GIDEI was released in 1991. The extension of the GIDEI to cover non-U.S. keyboards has been underway at the Trace Center for the past year. Version 2 of the GIDEI Standard was released in late 1994. It includes improved support for non-U.S. keyboards.

RESULTS—The GIDEI standard has been incorporated into several commercial products, including the Trace Transparent Access Module or T-TAM (now sold by Prentke Romich Company) and the Ke:nx and Darci Too computer interfaces. The GIDEI is also a part of the Access Pack keyboard/mouse adaptations developed by the Trace Center for the Microsoft Windows operating system, as part of a feature called "SerialKeys." The feature will become a standard part of Windows with the release of Windows 95. SerialKeys is also included in the AccessDOS accessibility software developed by the Trace Center for IBM

Corporation for use with DOS. A version of SerialKeys for the Macintosh is currently being explored.

FUTURE PLANS—Versions of SerialKeys for the Macintosh and X Window System are being explored.

[167] AUGMENTATIVE AND ALTERNATIVE COMMUNICATION TECHNICAL ASSISTANCE AND OUTREACH PROGRAM

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Sponsor: *National Institute on Disability and Rehabilitation Research; Nemours Research Programs, A.I. duPont Institute*

PURPOSE—Our goal is to serve as a leading source of materials and assistance to professionals, consumers, families, and agencies dealing with augmentative and alternative communication (AAC). In addition to disseminating technical reports and articles on research results obtained by ASEL staff, this program will also participate in activities to promote dissemination in the areas of technical assistance, consumer advocacy efforts, support to manufacturers, and support to other researchers.

METHODOLOGY—Dissemination tools to be developed include 1) a flipchart of features of portable communication devices, with accompanying vendor information notebook and color slide set; 2) a World Wide Web server, which includes an electronic information base entitled ''Assistive Technology On-Line;'' 3) a collection of consumer stories demonstrating various advocacy strategies undertaken by consumers to acquire their assistive technology; and 4) a special report on funding streams and strategies to acquire AAC. The information program will also serve as a catalyst for a regional support network of individuals who use communication devices and their families, and as support to ''Tech Act'' state projects in the AAC arena.

PROGRESS—AAC researchers have produced 24 publications for dissemination through the program. Inquiries from other researchers, clinicians, therapists, consumers, teachers, and families are each answered with a personal response and appropriate materials. Initial outlines of the flipchart are completed and staff is gathering and analyzing information on all devices to be included on the chart, which is to be completed by August. Fifteen research staffers traveled throughout Pennsylvania and Ohio visiting several AAC device manufacturers to discuss practical issues of design that should be considered at the research and development stage. Cataloging and database creation of AAC literature and books continues in an effort to provide World Wide Web access to this information. ASEL has been selected to host the International Conference on Spoken Language Processing in Philadelphia in October 1996. Plans for this major scientific conference are well underway.

[168] RESEARCH IN INTERFACE METHODOLOGIES FOR AAC

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PURPOSE—We seek to explore new and innovative methods for human interaction with augmentive and alternative communication (AAC) devices. This program is comprised of projects in two areas. One is

basic research in developing methods for human gesture to be used as an interface for AAC devices. The other is a human factors study in the use of eye movements to control an AAC device.

METHODOLOGY—*Gesture Project:* This project explores the use of gloves and other sensors, such as those used in virtual reality applications, as input devices to control an AAC device. Input taken from the gloves and sensors is fed into trained neural networks, which attempt to extract meaning based on hand shape, hand position, and movement in space. Both formal gestural systems (such as American Sign Language) and informal gestural systems are being studied.

Eye Movement Project: This project re-examines the use of eye gaze to control an AAC device. The first part of the project attempts to define human factor parameters related to eye gaze. Later parts of the project will examine the trade-offs in using head-mounted versus remote trackers in terms of accuracy and usability. The final phase of the project involves studying the effects of oculomotor disabilities on the performance of individuals with disabilities in their use of an AAC device using eye gaze.

PROGRESS—*Gesture Project:* The researchers have developed methods for computer recognition of the American Manual Alphabet (used in fingerspelling). The methods used here are being refined for use in recognizing hand shapes in general. Preliminary work has also been done in recognizing hand movement and position in space.

Eye Movement Project: Progress has been made in the use of motorized mirrors to track eye movement, allowing a limited range of head motion in the user. A software tool that can be used to simulate eye gaze experiments was also developed. Work on developing a head-mounted tracker suffered setbacks when further work uncovered major flaws in the original design. Other methodologies to overcome these flaws are being pursued.

D. Private and Public Programs

[169] EVOLUTION OF INDEPENDENT LIVING PROGRAMS: A LONGITUDINAL STUDY

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—The purpose of this project is to maintain a database on the status of independent living programs (ILP) nationally, and to identify trends in the development of ILPs, the emergence of issues encountered in the delivery of independent living services, and changes in the characteristics of consumers of these services.

PROGRESS—Profiles of each program responding to a full-length survey have been published in the ILRU Registry of ILPs. In early 1992, a revised and updated survey instrument was mailed to 475 programs listed in the ILRU Directory of Independent Living Programs. Information was solicited concerning populations served, services provided, characteristics of persons providing services, methods by which services are provided and programs administered, sources and amounts of funding, and relationships between programs and their communities. Responses from 257 programs were received and analyzed, an improved response rate compared to previous years. A follow-up telephone interview of these respondents was conducted to obtain more in-depth information about funding, perceived needs of centers and boards, and ADA-related services provided. Data have been analyzed, and a short report of results targeted to con-

sumers, as well as a journal article for professionals, are in preparation.

RESULTS—Although most of the results were similar to those in 1988, average total number of paid staff, particularly those with disabilities, increased. Mean funding amounts for various budget categories also changed significantly, with more centers receiving other direct federal funds, private contributions and dues, fees for service, and other business activities in 1992. Mean dollar amounts of other direct federal funds, state funds, and city and county government funds increased in 1992, while amounts of Federal Title VII Part A funds and private contributions decreased. Of those centers that charge fees for service, only 28.5 percent charge consumers and 62.5 percent charge other organizations, 62.7 percent actively market their services to the community, and 68 percent are developing consultant services for the ADA. Some 90.4 percent of centers provide services to consumers with a variety of disabilities, while 9.6 percent serve a single disability group, such as blindness. Nearly all respondents provide the five core independent living services of peer counseling, independent living skills training, information and referral, individual advocacy, and community advocacy.

Of the 182 centers responding to the telephone interview, 85.7 percent offer ADA technical assistance services to the community, center staff have received ADA-related training in 88.6 percent, and 48 percent are developing their own ADA educational materials. The majority (88.4 percent) of centers provide ADA services to consumers with disabilities, nearly all (92.1 percent) provide services to businesses, 12.3 percent to nonprofit organizations, and 18.5 percent to government agencies. A mean of 36.6 percent of ADA service clients are consumers. About half of centers charge for ADA services, and a typical cost is $50 per hour.

FUTURE PLANS—The Directory of Independent Living Programs is updated and reissued approximately five times per year. ILRU staff will continue to update the Directory and respond to specific inquiries with individualized data runs and reports. Analysis will continue on the ILRU National Database on ILPs, with trends published as they emerge. A new survey reflecting changes in minimum requirements for independent living centers based on reauthorization of the Rehabilitation Act in 1993 is underway. New data describing independent living centers will be published in a monograph in 1995.

RECENT PUBLICATIONS FROM THIS RESEARCH

Independent living centers and private sector rehabilitationists: a dynamic partnership for implementing the ADA. Howland CA, Walden E, Nosek MA. NARPPS J 1993:8(2).

[170] DEVELOPMENT OF AN INSTRUMENT TO MEASURE ADEQUACY OF PERSONAL ASSISTANCE SERVICES

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—This series of studies was designed to develop and test an instrument for assessing the adequacy of various systems for delivering personal assistance services to persons with diverse severe physical disabilities, their satisfaction with these services, and the effects of personal assistance on employability and health.

PROGRESS—A working draft of the instrument, the Personal Assistance Satisfaction Index (PASI), has been used in several studies to evaluate model personal assistance services and to assess the role of personal assistance in the health and employability of people with severe disabilities. Statistical analyses to determine the internal validity of indicators and factor

analysis to test the validity of criteria categories have been performed, and a final version of the instrument has been completed.

RESULTS—Literature review revealed 9 factors that influence the effectiveness of personal assistance services: source of control, source of funding, focus of training, scope of services, intensity or availability of services, flexibility of options, characteristics of assistants, eligibility criteria, and efficiency of services. A universe of items defining each of the 9 factors comprised the first draft of the instrument. Item analysis and ratings by a panel of 12 experts indicated the construct of satisfaction with personal assistance services to be composed of 4 salient elements: availability, cost, control, and quality. Reliability studies were done by administering the instrument to 100 consumers recruited by 10 independent living centers nationwide. Cronbach alpha of 0.91 established the reliability of 16 items, which comprise the final PASI. Concurrent validity was established by correlating the PASI's mean score with the mean score of the Life Satisfaction Index; the moderate correlation ($r=0.43$) found between the two instruments was highly significant at $p<0.0005$.

Of the 88 consumers who responded to the PASI, 92 percent paid for personal assistance and three-quarters obtained their assistants through an agency. Respondents had been using paid personal assistants for a mean of 8 years (range 1–33 years). To pay for personal assistance, one-fourth used personal or family funds, 79 percent got funds from a personal assistance agency, and 15 percent obtained payment through an insurance agency. Persons who needed more than 2 hours of assistance with personal hygiene daily were more likely to use paid assistance for these tasks.

Sixty-one percent of respondents used unpaid assistance, either exclusively or in combination with paid assistance. Of the 54 respondents who used unpaid assistance, 74 percent used relatives and 43 percent used nonrelatives, with 17 percent using both. Respondents had been using unpaid assistants for a mean of 15 years.

Significant relationships were found between: 1) who provides assistance and whether they are paid ($p<0.00001$), 2) living with spouse ($p<0.001$) or children ($p<0.05$) and using unpaid assistance, 3) who provides assistance and with whom participants live ($p<0.00001$), 4) amount of assistance received and severity of disability ($p<0.00001$), and 5) amount of assistance received and number of assistants used ($p<0.01$).

FUTURE PLANS—The PASI is being used to assess satisfaction with personal assistance of 150 persons with severe disabilities who use at least an hour of assistance daily, as part of a study of adequacy of personal assistance, negative health incidents, and health care utilization.

RECENT PUBLICATIONS FROM THIS RESEARCH

Personal assistance services: the hub of the policy wheel for community integration of people with severe physical disabilities. Nosek MA, Howland CA. Policy Studies J 1993:21:789-800.

Matching available options for receiving personal assistance services to the needs of adults with severe physical disabilities. Nosek MA, Sonehara J, Sanbonsugi. Studies on Social Work (Japanese). In press.

[171] EFFECT OF PERSONAL ASSISTANCE SERVICES ON THE LONG-TERM HEALTH OF A REHABILITATION HOSPITAL POPULATION: PERCEPTIONS OF REHABILITATION PROFESSIONALS

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—This study was designed to test the hypothesis that personal assistance with activities of daily living significantly affects the ability of persons with severe physical disabilities to maintain good physical health.

PROGRESS—A sample of 41 subjects recruited through the American Congress on Rehabilitation Medicine (ACRM) were interviewed by phone. Interviewees consist of 7 physicians, 10 nurses, 9 social workers, 8 physical therapists, and 7 occupational therapists from 5 medical rehabilitation centers. Frequency analysis was conducted on all responses to questions, and techniques of qualitative analysis were used to code comments and establish a grounded theory.

RESULTS—Results have supported our hypothesis; rehabilitation professionals believe that inadequate personal assistance contributes to poor physical and mental health for individuals with severe physical disabilities and their families. The most commonly cited health condition was skin breakdown, followed by urinary tract infections, pulmonary infections, and contractures. Inadequate personal assistance also led to extended hospital stays, threats to safety, poor nutrition, and poor personal hygiene. Nearly all those interviewed considered reliance on family alone for assistance to be inadequate, common effects being burnout, family role changes, and economic strain.

The more the time commitment and the more sophisticated the tasks needed, the more difficult it was obtaining sufficient assistance. Families were often unable to provide adequate assistance due to a pre-existing struggle to survive, a dysfunctional family structure, or an unwillingness to fill the role of assistant. Persons with the best health seemed to have a combination of family and nonfamily providing assistance. More than half of those interviewed observed the lack of agencies providing affordable, comprehensive, home services. Also needed is a pool of screened personal assistants available for respite and emergency backup. Quality of assistance was compromised by inadequate training, unreliability, turnover, and regulations limiting hours and tasks assistants are allowed to perform. Nearly half also mentioned lack of financial resources as a major cause of inadequate personal assistance. Regulations that require medical supervision of assistance with basic activities of daily living unnecessarily inflate fee scales and limit the options for receiving assistance from outside the family. When outside assistance is available, persons with disabilities often lack the ability to locate, interview, hire, instruct, supervise, terminate, and otherwise manage personal assistants.

Solutions suggested for improving adequacy of personal assistance focused on establishing a comprehensive system for delivering services that could coordinate services from home health agencies, independent living centers, and rehabilitation hospitals. Most interviewees advocated reform of current insurance policies, including Medicare, to allow coverage of expenses for personal assistance services.

FUTURE PLANS—More sensitive measures of health status and extent of personal assistance needed must be developed. The effects of the inability to control the quantity and quality of personal assistance received on individuals who desire to take charge of their health also needs to be studied.

RECENT PUBLICATIONS FROM THIS RESEARCH

Personal assistance: its effect on the long-term health of a rehabilitation population. Nosek MA. Arch Phys Med Rehabil 1993:74:127-32.

[172] DEMONSTRATING A MODEL APPROACH TO INDEPENDENT LIVING CENTER-BASED ASSISTIVE TECHNOLOGY SERVICES

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—This project is designed to establish, operate, and evaluate the effectiveness of an independent living center-based assistive technology service. The main objectives of this service are to: provide appropriate, timely, and affordable repair of assistive equipment and devices; teach preventive maintenance practices to increase the longevity of assistive equipment and devices; refer consumers whose equipment is ir-

reparable to appropriate service providers or vendors who can assist them in obtaining new equipment; counsel consumers about sources of sponsorship for equipment repair or the acquisition of new equipment. In addition to wheelchairs, assistive technology includes telecommunication devices for hearing-impaired persons, computerized communication boards for persons with aphasia, environmental control systems for persons with movement restriction, and microprocessor controls on wheelchairs.

PROGRESS—Surveys have been completed to identify gaps between consumer need and technology services available in the Houston areas. The Houston Center for Independent Living (HCIL) interviewed 30 consumers from various parts of the city and 22 vendors of equipment and equipment repair services. ILRU staff surveyed independent living centers (ILCs) who responded affirmatively to the equipment services questions in the 1988 ILRU national survey of ILCs.

Based on the results of these surveys, a wheelchair maintenance clinic is held monthly at TIRR as a demonstration model service. A system is now in place where HCIL advertises the clinic, schedules appointments, maintains a database on equipment repair services and resources, does intake when consumers arrive at the clinic, offers counseling and referral services while they wait, and documents maintenance services received. TIRR rehabilitation engineers recruit volunteer workers, supervise and instruct volunteers during the clinic, and perform some of the more complicated maintenance services. ILRU research staff supervises the clinics and conducts evaluation activities.

The first clinic, held at TIRR in January 1992, is now operating at capacity, serving 25 to 30 consumers every month. The first satellite clinic, in the Clear Lake area, was implemented in February 1993 and now provides services for 4 to 8 people monthly.

A 25-item questionnaire was sent to all consumers of the wheelchair clinics in May 1993 to evaluate the service. Results have been analyzed and accepted for publication.

RESULTS—The experience of ILCs nationwide shows equipment repair services are difficult and cost-ineffective to offer, generally operating at a deficit. The foremost problem identified from the survey of consumers was the unavailability of preventative services and the costly nature of repair services offered through commercial vendors. Transportation problems further complicate efforts to obtain repairs; few vendors offer pick up/delivery or in-home services. The result is that consumers postpone seeking repairs until equipment problems reach crisis proportions. By that time repairs are very costly and consumers are often without their equipment and immobile for long periods of time.

Follow-up satisfaction surveys of consumers who used the wheelchair maintenance clinic showed exceptionally positive responses to the helpfulness of volunteers, quality of services, relatively short waiting time, and extent to which they learned something new about their equipment. Of the respondents, 97 percent felt the preventive maintenance clinic was a worthwhile program. These clinics have saved consumers hundreds of dollars in unnecessary repairs. Before the clinic began operations, only 25 percent of respondents did preventive maintenance on their wheelchairs.

FUTURE PLANS—We plan to continue the wheelchair clinics at the present locations because evaluations indicate they have been highly successful. The service schedule for clinics will be evaluated to ensure that it is accessible to the largest number of consumers. New ways will be explored for marketing the program to the community. Information will be sent to community vendors on how they can be more responsive to consumer needs and desires. Periodic follow-up telephone calls will be made to randomly selected consumers to determine consumer satisfaction with the program and responsiveness of the program to overall consumer needs.

RECENT PUBLICATIONS FROM THIS RESEARCH

Demonstrating a model approach to independent living center-based mobility technology services. Nosek MA, Krouskop TA. Assist Technol. In press.

[173] INCREASING THE ABILITY OF INDEPENDENT LIVING CENTERS TO SERVE THE POPULATION OF AFRICAN AMERICANS WITH DISABILITIES

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—This project will investigate the role of family in supporting the independence of African-Americans with disabilities. Objectives are to offer research training in independent living to African American students in the Department of Family Life and Home Economics at Texas Southern University and assess the quality of the learning experience in terms of knowledge, skill enhancement, and satisfaction with the experience. It will also characterize appropriate roles that persons with preparation in family life and home economics might play in facilitating delivery of independent living services to persons with disabilities.

PROGRESS—Dr. Hammonds-Smith and two students have recruited African-American students with disabilities at TSU and are conducting interviews to address issues of personal care skills, interpersonal skills, and consumer skills such as managing personal assistance, advocacy, and participation in support groups. Principal investigator Margaret Nosek has presented to Dr. Hammonds-Smith's home economics class on concepts of independent living, in order to train family life specialists to be part of the team of human services professionals that arrange services for disability populations.

FUTURE PLANS—Results from interviews will be used to: identify skills that will lead to a more independent lifestyle for African Americans with disabilities; ascertain how family members can help students with disabilities gain independence; develop a Field Placement Model to expose family life and home economics students to independent living situations that include rehabilitation or other human services fields; integrate independent living concepts into existing courses in the human services and consumer sciences curriculum.

[174] COLLABORATION BETWEEN MEDICAL REHABILITATION PROGRAMS AND INDEPENDENT LIVING CENTERS IN FACILITATING INDEPENDENT LIVING BY PERSONS WITH RECENTLY INCURRED SPINAL CORD INJURY

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—During the period immediately after discharge from a medical rehabilitation program, health maintenance and independent living skills taught during hospitalization must be put into practice, and adjustment problems must be resolved that could not be prepared for adequately during hospitalization. Yet knowledgeable assistance is difficult to obtain on a timely, affordable basis during the postdischarge period. Independent living centers can provide vital services in facilitating transition of the individual with a recently incurred spinal cord injury from hospital-based rehabilitation to an independent, productive life in the community. Differences in program philosophy and style of service delivery, however, may make it difficult for medical rehabilitation programs and independent living services to work together effectively. This project is designed to develop, implement, and systematically evaluate a cooperative re-entry program involving a medical rehabilitation program and an independent living center for facilitating the

posthospitalization life adjustment of persons with recently incurred, ventilator-dependent spinal cord injury.

PROGRESS—Thirty subjects with quadriplegia have been selected from a database of ventilator users kept at the Institute for Rehabilitation and Research (TIRR), while another 30 who do not use ventilators have been selected from a spinal cord injury registry to serve as matched controls. They are being interviewed about issues they faced re-entering the community after hospitalization for rehabilitation and the extent two which HCIL assisted them with that process.

FUTURE PLANS—Data from the interviews will be analyzed and the results will be used to create a coordinated, comprehensive discharge program between TIRR and HCIL, incorporating factors that persons with spinal cord injury found to be the most useful in re-entering the community with severe disability.

[175] RELATIONSHIPS AMONG AGE AT ONSET, ADEQUACY OF PERSONAL ASSISTANCE, NEGATIVE HEALTH INCIDENTS, AND HEALTH CARE UTILIZATION FOR PERSONS WITH PHYSICAL DISABILITIES

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—The purpose of this longitudinal study is to determine the strength of relationships among age at onset of disability, use of personal assistance services for activities of daily living, health status, and use of health care services by persons with a variety of severe physical disabilities.

METHODOLOGY—Survey packets were mailed to 120 subjects with the objective of having at least 100 complete the study, allowing for attrition.

PROGRESS—To date, 120 persons ages 18 to 65, living independently in the community, who use at least 1 hour of personal assistance daily have been recruited to complete weekly checklists recording any changes in their personal assistance or health status, visits to hospitals, emergency rooms, or physicians, and (when health incidents occur) effects on productivity and levels of distress. Special efforts were made to oversample persons from minority ethnic backgrounds. Subjects were given a choice of reporting by written checklist, telephone, or computer to accommodate disability-related limits in communication method. All survey instruments have been developed and were pilot tested on 10 subjects.

FUTURE PLANS—Data collected will be used to construct a profile on each participant and his/her health service use and health conditions over a 12-month period. These profiles will be used to identify differences between participants divided into four categories based upon whether the disability was acquired in childhood or adulthood and whether personal assistance services are provided either exclusively by family members or by nonproviders alone or supplementing family assistance. In year 2, open-ended, qualitative interviews will be conducted with two subsets of the original sample: with 10 participants whose scores on the Personal Assistance Satisfaction Index (PASI) fall into the top quartile and 10 in the bottom quartile, and with 10 participants whose total number of negative health incidents fall into the top and 10 in the bottom quartile. The sample for this segment of the study will be strictly limited to 40 participants to allow in-depth exploration of PAS and health issues.

[176] ASSESSING THE CAPABILITIES OF INDEPENDENT LIVING CENTER STAFF TO DELIVER ADA-RELATED SERVICES

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Sponsor: *US Department of Education*

PURPOSE—Since the passage of the Americans with Disabilities Act (ADA), independent living centers have been getting requests for information from persons with disabilities who want to know what ADA will mean to them, and from employers, businesses, and service organizations who want to know what will be required to comply with the new law. Under a 3-year grant from the US Department of Education, ILRU will investigate the types of ADA-related services offered by independent living centers and the capability of their staff to deliver these services.

PROGRESS—ILRU conducted an open-ended, paper-and-pencil survey of independent living center involvement in ADA service delivery; 22 centers responded. These data have been analyzed and published.

An ADA Scale Pre-Test consisting of 50 multiple choice, true and false, and matching items was constructed to compare independent living center staff (N=124) knowledge of the ADA to that of 89 controls. Item analysis was conducted using factor analysis to assess scale and item dimensionality, IRT modeling to determine item discrimination and difficulty and scale reliability. Groups were then compared using the independent sample t-test on three methods of scoring the primary scale dimension. Based on these results, the test was revised and readministered after training intervention.

RESULTS—According to the results of the in-depth study of 22 subjects, the executive director is the staff member who is most likely to answer ADA-related inquiries. Centers receive the most frequent telephone inquiries about access to public accommodations, evaluation of structural barriers, implementation dates of different sections of the ADA, and how to define reasonable accommodation. The segment of the population who makes the most ADA-related inquiries per month is consumers (M=7.30), followed by rehabilitation professionals (M=4.40), government entities (M=4.35), businesses that are public accommodations with more than 25 employees (M=3.30), community or social service organizations (M=2.80), and building owners or managers (M=2.40). The vast majority of ILCs (86.36 percent) claim that the number of ADA-related inquiries received per month is increasing.

The majority of center-sponsored ADA-related workshops have been for center staff (27 percent), consumers (23 percent), and small businesses (19 percent). Other workshop recipients have included Chambers of Commerce, hospital social workers, representatives of the local deaf community, personnel directors, building design professionals, city, state, and county government representatives, and public and private schools.

Staff of ILCs obtain information on the ADA from training programs, hotlines, and written or videotaped materials from such organizations as the Department of Justice, the Department of Transportation, the Equal Employment Opportunity Commission (EEOC), the Architectural and Transportational Barriers Compliance Board, the Disability Rights Education and Defense Fund (DREDF), the President's Committee on the Employment of People with Disabilities, and the U.S. Chamber of Commerce.

Dimensionality analyses of the pre-test responses indicated one prominent dimension, with no indication that response format contributed to the dimensionality of the data. A subset of 17 items, including the matching section, did not load on the primary dimension and were thus excluded from the post-test. The final recommended scale consists of 33 items from all of the response formats. Since these items contain a preponderance of low-to-middle-ability items, thus providing poor measurement for subjects high in knowledge of the ADA, 7 difficult items were added to the post-test. Results indicate that independent living center staff need more ADA training and library materials.

RECENT PUBLICATIONS FROM THIS RESEARCH

Independent living centers and private sector the ADA. Howland CA, Walden E, Nosek MA NARRPS J 1993:8(2).

VIII. Muscles, Ligaments, and Tendons

A. Muscles

[177] PHYSIOLOGICAL BASIS OF STRENGTH FOLLOWING SURGICAL TENDON TRANSFER

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A745-RA)*

PURPOSE—The purpose of this project is to understand the biomechanical design of the human wrist. In the first stage of the work, biomechanical properties of human wrist tendons were measured under loads predicted to be experienced by those tendons under physiological conditions. This information will be used to design optimal surgical tendon transfers for wrist reconstruction.

METHODOLOGY—Architectural properties of the five prime wrist movers—extensors carpi radialis brevis (ECRB), extensor carpi radialis longus (ECRL), extensor carpi ulnaris (ECU), flexor carpi radials (FCR), flexor carpi ulnaris (FCU)—were measured and their maximum tension (Po) predicted using a specific tension value of 22.5 N/cm^2.

RESULTS—Loading the corresponding tendons to Po resulted in significantly different strain among tendons ($p<0.01$) with the largest strain observed in the FCU (3.68=0.31 percent) and the smallest strain observed in the ECRL (1.78=0.14 percent). Further, strain magnitude was significantly correlated positively with the tendon length-to-fiber length ratio of the muscle-tendon unit, a measure of the intrinsic compliance of the muscle-tendon unit. Theoretical modeling of the magnitude of muscle sarcomere shortening expected based on the measured biomechanical properties revealed a maximum sarcomere length decrease of about 0.6 fm for the FCU to a minimum of about 0.2 fm for the ECRB at Po. Thus, tendon compliance may, but does not necessarily, result in significant modification of muscle force generation. These data indicate that muscle-tendon units show remarkable specialization and that tendon intrinsic properties accentuate the muscle architectural specialization already present.

RECENT PUBLICATIONS FROM THIS RESEARCH

Relationship between muscle fiber types and sizes and muscle architectural properties in the mouse hindlimb. Burkholder TJ, Fingado B, Baron S, Lieber RL. J Morphol 1994:221:177-90.

Tendon biomechanical properties enhance human wrist muscle specialization. Loren GJ, Lieber RL. J Biomech. In press.

Tendon biomechanical properties enhance human wrist muscle specialization. Loren GJ, Lieber RL. Trans Orthop Res Soc 1994:19:691.

[178] BIOCHEMICAL AND MYOELECTRIC EVENTS DURING FATIGUE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B749-RA); the Liberty Mutual Insurance Company*

PURPOSE—*In vitro* research studies are being conducted using a rat animal model to provide a better understanding of how the biochemical events associated with fatigue influence the median frequency and conduction velocity estimates of the electromyographic (EMG) signal. This approach accurately measures biochemical correlates of fatigue, while controlling for processes that typically confound similar studies in humans. Our studies are currently focused on how the fiber type composition of a muscle influences the EMG signal and its spectral parameters. These results are a first step toward predicting the fiber type percentages in humans using similar surface EMG procedures.

METHODOLOGY—Whole muscles and nerves were surgically removed and placed in a test chamber in which the muscle temperature, oxygenation, and extracellular ionic fluid were maintained. EMG signals and isometric twitch and tetanic forces during elicited contractions were detected and sampled by a workstation. Muscles were then prepared for later histochemical analysis and fiber typing.

RESULTS—Neuromuscular preparations from two different hindlimb muscles of the rat and the diaphragm muscle have been studied to date. Results from over eight specimens of each muscle show that muscles with fast glycolytic enzyme content produce M-waves that are modified to a greater extent during fatigue than muscles with slow oxidative enzyme content. Time and amplitude scaling coefficients using wavelet analysis were significantly different for these muscles. Differences in the initial values and rate of decay of the median frequency and conduction velocity paralleled the distinct differences in the fiber type composition of these muscles. We were able to estimate the fiber type percentages of these muscles to a high degree of accuracy using just the EMG parameters.

[179] EFFECTS OF MUSCLE FIBER SIZE ON SURFACE EMG PARAMETERS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B748-RA)*

PURPOSE—We hope to strengthen the underlying scientific basis for assessing muscle disorders by surface electromyographic (EMG) techniques. One means of attaining this goal is to gain a better understanding of the relationship between the EMG signal and the muscle fiber cross sectional area (CSA). Previous studies have been successful in this regard, but were limited primarily to isolated, single fibers. We have expanded upon these earlier studies by investigating the effect of muscle fiber CSA on EMG signals detected from whole muscle, which more closely approximates the clinical use of surface electromyography.

METHODOLOGY—An *in vitro* method, similar to that described last year, was implemented for testing whole muscle sections from the rat. EMG signals were recorded from the soleus, diaphragm, and extensor digitorum longus muscles during tetanic contractions. The average muscle fiber CSA and muscle fiber type were determined by histochemical analyses.

RESULTS—The results were analyzed by pooling the data for all three muscles to provide a broader range of muscle fiber CSA to study. In contrast to previous reports for single fiber work, the muscle fiber CSA was not related to either the initial median frequency

or the initial conduction velocity. However, when proportional differences in fast fiber type for these three muscle groups were accounted for by calculating a weighted measure of CSA, a significant, positively correlated relationship was observed. This finding suggests that the proportional area of fast fibers in a whole muscle has a strong influence on surface EMG median frequency and conduction velocity.

[180] MUSCLE ADAPTATION FOLLOWING LIMB UNLOADING AND ITS INFLUENCE ON EMG PARAMETERS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B749-RA)*

PURPOSE—Electromyographic (EMG) signal analysis may provide a noninvasive method of monitoring muscle adaptations associated with disuse. To meet this objective, further information must be gained to determine how specific changes in muscle physiology associated with disuse affect the EMG signal. In this study, *in vitro* techniques were applied to compare the changes in muscle fiber type with alterations in the EMG signal from muscles exposed to long and short-term muscle unloading.

METHODOLOGY—A tail suspension model, in which the hindlimb muscles of the rat are unloaded, was utilized to induce changes associated with disuse. Hindlimbs were unloaded for either 7 or 21 days. Neuromuscular preparations of the soleus and extensor digitorum longus muscles from the hindlimb were surgically removed and placed in an *in vitro* oxygenated bath. EMG signals were recorded directly from the muscle membrane during tetanic contractions. A control group that did not undergo unloading was also studied. Following EMG signal detection, muscles were histochemically analyzed to determine the muscle fiber type cross-sectional area.

RESULTS—Preliminary results demonstrated that the initial median frequency of the EMG signal was significantly decreased in unloaded muscles compared to controls. There was also a marked decrease in the peak to peak amplitude of the signals from the unloaded muscles. These changes were likely the result of factors related to the extreme reduction in muscle fiber cross-sectional area caused by hindlimb unloading. Unloaded muscles also changed their fiber type percentages toward fast fiber characteristics, however, this more moderate change did not predominate.

[181] INFLUENCE OF RESISTANCE EXERCISE TRAINING ON THE DETERMINANTS OF GLUCOSE TOLERANCE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Core Funds)*

PURPOSE—Glucose tolerance is determined by the interaction of insulin secretion and clearance, insulin action, and glucose effectiveness (Sg). The latter term refers to the ability of an increase in plasma glucose concentration to enhance clearance of glucose from the plasma, independent of the effects of insulin. Sg represents a composite of the effects of elevated plasma glucose to enhance tissue glucose uptake and suppress glucose output by the liver. Since skeletal muscle is the primary site responsible for the increase in glucose uptake due to hyperglycemia, it seems reasonable to explore the effects of alterations in skeletal muscle mass on Sg. This study was designed to test the hypothesis that Sg would change in parallel with

changes in skeletal muscle mass induced by resistance exercise training.

METHODOLOGY—Healthy male college students have been recruited from Northern Illinois University. A training group underwent 12–16 weeks of isotonic progressive resistance training designed to increase whole-body skeletal muscle mass as part of a weight training course. A comparable control group participated in the testing but did not train. Evaluations completed at the beginning and end of the protocol included an intravenous glucose tolerance test for assessment of insulin sensitivity, insulin secretion, and Sg; body composition analysis; and strength testing.

RESULTS—Data analysis is underway. Currently no results are available.

IMPLICATIONS—Loss of skeletal muscle mass may be a factor partially responsible for the progressive deterioration of glucose tolerance that accompanies aging. This is potentially of clinical importance since it may be possible to delay or reverse age-related muscle atrophy in the elderly through appropriate exercise, dietary, and pharmacologic intervention. This pilot project represents the initial step toward the goal of testing the Sg/muscle mass hypothesis.

FUTURE PLANS—In the event that this project yields positive findings, we plan to conduct additional studies in elderly and glucose intolerant subjects.

[182] EFFECTS OF 2 WEEKS OF ORAL ALBUTEROL ON INSULIN SENSITIVITY AND LIPOPROTEIN LIPIDS IN HEALTHY MEN

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Core funds)*

PURPOSE—Beta2-selective adrenergic agonist medications are used clinically for the treatment of bronchial asthma and preterm labor. These drugs have well-known anabolic effects on skeletal muscle tissue and thus have potential therapeutic applications in rehabilitation and the management of conditions associated with muscle weakness and atrophy. Acute administration of beta2 agonists such as albuterol or terbutaline produces increased plasma glucose, insulin, and free fatty acids, and reduced serum potassium. Concern has been expressed that chronic use of this class of medication may induce glucose intolerance and/or dyslipidemia. Therefore, the present study was designed to evaluate the effects of 2 weeks of oral administration of a beta2-selective adrenergic agonist (albuterol) on serum lipids and insulin sensitivity in healthy nonsmoking men.

METHODOLOGY—Fasting serum lipoproteins and electrolytes, fasting plasma glucose and insulin, and pulmonary function were evaluated in eight healthy nonsmoking men. These tests were completed in duplicate on separate days at baseline (BL), during 14 days of oral albuterol administration (Proventil™ Repetabs, 8 mg twice daily: ALBTx), and during a 7-day washout (WO). During the final visits of the BL and ALBTx periods, insulin-modified intravenous glucose tolerance tests were also administered. The glucose and insulin profiles from these tests were submitted to a mathematical modeling program to generate indexes of whole-body insulin sensitivity and insulin-independent glucose disappearance.

PROGRESS—This pilot study has been completed.

RESULTS—During ALBTx, significant changes ($P \leq 0.01$) were observed in total cholesterol (–9.1±2.5 percent), low-density lipoprotein cholesterol (–15.0±2.9 percent), high-density lipoprotein cholesterol (+10.4±3.2 percent), the total/high density lipoprotein cholesterol (–17.4±2.6 percent), and the low density/high density lipoprotein cholesterol ratio (22.9±2.4 percent). During WO, lipid values returned to pretreatment levels except for high density lipoprotein cholesterol which remained 5.8±2.4 percent ($P<0.05$) above the BL concentration. Serum potas-

sium and magnesium concentrations were slightly depressed ($P<0.05$) during ALBTx. No significant alterations were noted in glucose clearance, insulin sensitivity, or non-insulin mediated glucose disposal. In conclusion, two weeks of oral albuterol administration resulted in potentially favorable alterations in the serum lipid profile without adversely altering glucose tolerance or its physiologic determinants.

[183] MODELING OF EMG SIGNALS: THE EFFECT OF LAYERED MEDIA

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Sponsor: *Chamber of Commerce of Torino, Italy*

PURPOSE—This work is focused on understanding how the electromyographic (EMG) signal is affected by the physiological solution surrounding a muscle in an *in vitro* preparation, and by the layer of fat between the muscle and skin in an *in vivo* situation. The results will improve our ability to utilize mathematical models to understand how specific muscle properties influence the EMG signal.

METHODOLOGY—To investigate the effect of the physiological solution, the muscle was modeled as an anisotropic conductor, and the solution as an isotropic conductor, with the electrodes placed between the two media. The potential distribution over the surface of discontinuity was studied and the effect of media parameters was investigated. *In vitro* experiments on rat muscles were conducted to assess model predictions. To investigate the *in vivo* situation, a similar approach was used in which the muscle and fat layers were modeled as anisotropic and isotropic layers respectively, with the electrode located above the two media. This first approximation does not yet account for the second discontinuity between fat and air.

RESULTS—In the first case, the presence of the solution reduces the effect of the muscle's anisotropy by increasing the contributions from fibers lateral to the electrode. As expected, the higher the conductivity of the solution, the lower the signal amplitude. Empirical data from the *in vitro* preparation supports these findings. Similar results were obtained from the second case, with the additional effect of the thickness of the isotropic layer introducing attenuation and spatial filtering. For example, isopotential curves due to a single point source in an isotropic medium are circular, but they become elliptical when the medium is anisotropic. As the detection electrode moves away from the anisotropic region into a layer of isotropic material, the potential curves become more circular.

[184] EFFECTS OF SPACEFLIGHT ON HUMAN MUSCLE PERFORMANCE

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Sponsor: *NASA through MIT Man-Vehicle Laboratory; Liberty Mutual Insurance Company*

PURPOSE—We have completed the second of two recent ground-based studies for the NASA Spacelab Life Science program (SLS-01 and SLS-02). These missions represented the first space shuttle flights dedicated entirely to studying the medical and biological effects of microgravity on the body. Our experiment focused on surface electromyographic (EMG) techniques to noninvasively measure the effects of spaceflight on antigravity muscles of the lower limb.

METHODOLOGY—Changes in strength, endurance, and surface EMG indices of fatigue were measured for the tibialis anterior, a dorsiflexor muscle, and the gastrocnemius and soleus, two plantar flexor muscles.

Measurements were conducted pre-flight and immediately post-flight on four shuttle crew members from each mission and two astronaut control subjects.

RESULTS—A comparison of results for SLS-01 (a 9-day mission) and SLS-02 (a 14-day mission), demonstrated that impairments in strength and endurance following spaceflight were influenced by spaceflight duration and were more persistent for dorsiflexor muscles than plantar flexors. Changes in the post-flight EMG signal appeared mostly in the tibialis anterior muscle which produced increased signal amplitude and median frequency for contractions sustained at pre-flight force levels. The pattern of functional loss and the changes in the EMG signal suggest that muscle atrophy and fiber type modifications cannot completely account for these results.

[185] PATIENT MANAGEMENT AND REHABILITATION PROTOCOLS FOLLOWING MAJOR HIP SURGERY BASED ON QUANTITATIVE IN VIVO DATA

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Sponsor: *National Institutes of Health*

PURPOSE—Surgical reconstruction or replacement of the human hip joint following trauma or arthritis involves over 400,000 procedures each year in the United States alone. Procedures include the total replacement of both femoral acetabular components, the replacement of only the femoral component, and osteotomies where the natural components of the joint are retained but realigned. Whatever the intervention, the patient must be managed during an immediate post-surgical period, and then must undergo a process of rehabilitation. This process includes the use of supplementary supports and then more demanding movement patterns up to the activities of daily living. Contemporary patient management and physical therapy protocols vital to the rapid, safe, and full recovery of the patient currently rest solely on qualitative observations and *ex post facto* outcomes. *De novo,* quantitative, objective data are now available to evaluate these traditional processes and consider alternatives.

METHODOLOGY—Instrumented prostheses with 12 to 14 pressure sensors integral with the femoral head of an endoprosthesis have now measured local pressures on acetabular cartilage on two subjects over a total period of 8 years. Data have been acquired during surgery, post-operative recovery, immobilization, mobilization while in bed, early muscle exercise, all stages of ambulation (parallel bars, walker, crutches, and cane) and then during normal gait and other movement patterns, such as rising from a chair, stair climbing, descent, and jogging. During movement protocols, the telemetered pressure data are complemented with kinematic and kinetic data. Pressures far higher than the average pressure cited in the literature (2-to-3 megapascals)—and considerably higher than *in vitro* tests with comparable instrumentation—are experienced: typically 5 megapascals in gait and up to 17 megapascals rising from a chair and while descending stairs.

RESULTS—Some of these data challenge traditional rehabilitation procedures; for example, most present immobilization practices produce higher maximum pressures than pedaling a stationary bicycle, a common early mobilization procedure. Muscle contraction exercises in bed prior to ambulation produce pressures of the same magnitude as do later normal level walking. Longitudinal comparisons for the same protocol indicate a leveling of pressures, presumably a sign of normalization; for example, no further rise in stance phase pressure was indicated after 6 months of gait, which correlated with the clinical observation of having achieved normal gait. During rising from a chair, pressures continued to change until about 1 year.

RECENT PUBLICATIONS FROM THIS RESEARCH

In vivo acetabular pressures in two patients: acute post-operative recovery data. Krebs DE, Mann RW, Hodge WA. Abstract,

Arthritis Foundation Research Conference, Phoenix, AZ, June, 1993.

In vivo hip joint pressures while using one or two canes. Neumann DA, Krebs DE, Riley PO, Mann RW. Abstract, Second Joint APTA/CPA Congress, Toronto, Canada, June, 1994.

Spare the back and spoil the hip: hip stress during leg and back lifting. Lueponsak N, Krebs DE, Riley PO, Mann RW. Abstract, Second Joint APTA/CPA Congress, Toronto, Canada, June, 1994

[186] QUANTIFYING CO-CONTRACTION IN AGONIST/ANTAGONIST MUSCLES: A FORCE INSTRUMENTED ENDOPROSTHESIS

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Sponsor: *National Institutes of Health*

PURPOSE— The contact across any synovial joint (like the hip or knee) can be higher than the forces imposed by external loading and any dynamic (inertial) contribution due to acceleration of body segments. If opposing muscle groups (agonist/antagonist) across a joint generate equal moments about the joint (called co-contraction), the group force on the joint will be increased by the *sum* of these co-contracting muscle forces. Co-contraction increases the stiffness or impedance of the joint. The *difference* between opposing muscle force—generated moments—produces rotation of the joint. Motion analysis studies will not detect co-contraction since the joint kinematics can be the same whether or not co-contraction is occurring. This project builds upon the prior experience of this group with pressure-instrumented endoprostheses. The pressures measured *in vivo* during certain movements were found to be significantly higher than the pressures for corresponding *in vitro studies* (e.g., during rising from a chair, cartilage pressures in excess of 17 megapascals were measured).

Concurrent joint force estimation from kinematic-kinetic data using inverse Newtonian formulations and direct total joint force measurement using a force-instrumented implant would permit quantification of the co-contraction component by subtraction of the force estimation from the direct force measurement.

Although some implant force data has been reported from total hip replacement prostheses, there have yet to be reports of experiments in which the instrument force and the external motion analysis are acquired concurrently.

METHODOLOGY—Of all instrumentation approaches, the endoprosthesis provides the best assurance of maintaining the natural geometry of the joint and that of the surrounding musculature. In total joint replacement, bone stock is removed changing joint geometry, and the musculature geometry is frequently changed to reduce the force on the artificial joint.

Based on this group's experience with the pressure-instrumented endoprothesis, a new force-instrumented prosthesis has been designed and fabricated. A hollow femoral neck accommodates semi-conductor, strain-gage rosettes which measure axial force and two-plane bending. The telemetry system in the hermetically sealed femoral head uses the same pulse-amplitude modulated FM telemetry system which has operated successfully for over 8 years in the pressure-instrumented devices. To avoid the use of batteries and to provide data acquisition potential for as long as desired, energy is fed into the prosthesis only during test sessions by electromagnetic coupling of 100 Kilocycle power from a garter worn about the thigh of the subject to the antenna at the distal end of the prosthesis stem.

A material change from the cobalt-carbon used in the pressure-instrumented devices to titanium for the force-instrumented design resulted from procurement and fabrication difficulties with the prior material and required extensive finite-element analysis followed by fatigue and strength testing of prototypes.

PROGRESS—Two force-instrumented prostheses, with 48- and 50-millimeter head diameters, are approaching completion. Following calibration and the identification and consent of appropriate subjects, im-

plantation will occur. In our continuing study of patient management and rehabilitation protocols, we will acquire data during postsurgical immobilization, during early mobilization, throughout rehabilitation, and on into the activities of daily living. When the subjects are fully recovered, we will concurrently acquire internal force measurements from the prosthesis together with external kinematic, kinetic data with which to make inverse Newtonian estimations of the non-co-contraction components of hip joint force. Subsequently, we plan to incorporate this quantification of the co-contraction component into enhanced musculoskeletal models of the lower extremity.

RECENT PUBLICATIONS FROM THIS RESEARCH

In vivo acetabular pressures in two patients acute post-operative recovery data. Krebs DE, Mann RW, Hodge WA. Abstract, Arthritis Foundation Research Conference, Phoenix, AZ, June, 1993.

Direct evidence of acetabular joint preloading during locomotion. Krebs DE, Riley PO, Carlson KL, Hodge WA, Mann RW. Abstract, International Society of Biomechanics, Paris, France, July, 1993.

[187] MUSCLE FIBER DAMAGE DUE TO ECCENTRIC CONTRACTIONS

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Sponsor: *National Institute of Arthritis and Musculoskeletal and Skin Diseases*

PURPOSE—The purpose of these studies was to determine the long-term changes in skeletal muscle after eccentric contraction-induced muscle injury. Having identified mechanical causes of muscle injury, we were interested in the physiological and structural changes which occur in the next 28 days. The effect of flurbiprofen, a nonsteroidal anti-inflammatory drug (NSAID), was also determined on muscles subjected to exercise-induced injury.

METHODOLOGY—Cyclic eccentric exercise was produced by increasing the tibiotarsal angle of the rabbit while activating the peroneal nerve using transcutaneous electrodes. Muscle properties were measured 1, 2, 3, 7, 14, and 28 days following exercise to define the time course of muscle changes after injury. A control group receiving only isometric contraction was used to study the effect of cyclic activation itself. After eccentric contraction-induced muscle injury, one group of rabbits was treated with orally administered flurbiprofen, two times/day × 6 days while the other group of rabbits remained as an untreated control.

RESULTS—The most prominent morphological changes in the injured muscle fibers were the loss of antibody staining for the desmin cytoskeletal protein and deposition of intracellular fibronectin, even when the injured muscle fibers retained their normal complement of contractile and enzymatic proteins. The presence of fibronectin inside the myofibers indicated a loss of cellular integrity. Invasion by inflammatory cells was apparent, based on the localization of embryonic myosin. Thus eccentric exercise initiates a series of events which results in disruption of the cytoskeletal network and an inflammatory response which could be the mechanism further deterioration of the contractile response. Flurbiprofen administration also resulted in a dramatic sparing of the intermediate filament protein desmin. After 3 days, a significantly greater proportion of EDL fibers (34=4.1 percent) lost desmin staining while fewer NSAID-treated fibers (2.9=1.7 percent) lost desmin staining ($p<0.001$), which supports the concept of a short-term protective effect. However, the flurbiprofen-treated muscles still mounted a dramatic regenerative response as indicated by the expression of embryonic myosin. Early in the recovery period (3 days) significantly fewer flurbiprofen-treated EDL fibers (2.2=1.4 percent) expressed embryonic myosin compared to untreated EDL muscles (11.8=1.9 percent, $p<0.001$). These results may prompt rethinking of the liberal prescription of NSAIDs for muscle injury.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Biomechanical basis of muscle cellular damage. Lieber RL, Friden J. Basic Appl Myol 1994:4:25-34.

Structural basis of muscle cellular damage. Friden J, Lieber RL. Basic Appl Myol 1994:4:35-42.

Antiinflammatory medication after muscle injury provides a short-term improvement but subsequent loss of muscle function. Mishra DK, Schmitz MC, Giangreco C, Friden, J, Lieber RL. J Bone Joint Surg. In press.

[188] SKELETAL MUSCLE REACTION TO GROWTH AND IMMOBILIZATION

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Sponsor: *Netherlands Organization for Research, Foundation for Biological Sciences*

PURPOSE—The purpose of this project was to study the reaction of skeletal muscle to immobilization at short length in relation to muscle architecture.

METHODOLOGY—Effects were studied for 4- and 6-week periods of growth and immobilization. Experimental effects were considered for immobilized as well as contralateral muscles, which were compared to control muscles. In addition to variables of muscle geometry (i.e., fiber length, aponeurosis length, and fiber and aponeurosis angles), number of sarcomeres in series within fibers, and filament length parameters were considered.

RESULTS—Myofilament length parameters were unchanged. Indications were found for changes in the inhomogeneity of sarcomere length of different fibers, particularly in muscles from the contralateral (non-immobilized leg). In soleus muscles growth as well as immobilization caused changes of number of sarcomeres in series within fibers. Immobilization induced atrophy was not higher in SOL than in GM.

IMPLICATIONS—A major adaptation to immobilization is shifting muscle optimum length to the immobilized length. The major effect of short-length immobilization is atrophy. Depending on the degree of pennation of the muscle, this will lead to a varying degree of muscle shortening. In highly pennate muscle this shortening will be much larger than in less pennate muscle. To obtain the shift of muscle optimum length in very pennate muscle, this shift due to atrophy is sufficient. In contrast, in less pennate muscle adaptation of number of sarcomeres is necessary as well. This decrease of number of sarcomeres affects muscle length and range of active force exertion.

RECENT PUBLICATIONS FROM THIS RESEARCH

Growth and immobilization effects on lengths of sarcomere components and number of sarcomere in series of adult rat muscles: a comparison between gastrocnemius and soleus. Heslinga JW, te Kronnie G, Huijing PA. Eur J Appl Physiol. In press.

[189] SKELETAL MUSCLE LENGTH FORCE CHARACTERISTICS DURING MAXIMAL AND SUBMAXIMAL ACTIVATION

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Sponsor: *None listed*

PURPOSE– The purpose of this project was to make a link between results of experiments studying muscle properties under maximal activation and *in vivo* properties of muscle which are rarely characterized by

maximal activation. For that purpose several conditions of submaximal activation will be imposed for a systematic analysis.

METHODOLOGY—In addition to variables of muscle geometry (i.e., fiber length, aponeurosis length, and fiber and aponeurosis angles), the number of sarcomeres in series within fibers and the filament length parameters were determined.

In fully recruited muscle submaximal activity was induced by changing stimulation frequencies; stimulation frequencies between 100 and 15 Hz were imposed. This was performed for constant frequencies or decreasing frequencies. Submaximal activity was induced in partially recruited muscle by simultaneous stimulation of the nerve by a tripolar set of electrodes: one for 100 Hz supramaximal current and one for 600 Hz optimal effect current and a common cathode. Variation of the current of the 600 Hz stimulation causes variation of recruitment of active motor units, in a sequence according to the size principle (block stimulation). Submaximal activity was also induced by varying the stimulation current: lowering stimulation current to a bipolar electrode on the nerve results in only a part of the motor units remaining active.

RESULTS—Length force characteristics of submaximally active rat medial gastrocnemius muscle differ from that of the maximally active muscle. With all motor units active, the force decreased at lower stimulation frequencies and muscle optimum length shifted to higher muscle lengths. If the low stimulation frequencies followed higher ones (history effects), the decrease in force was smaller (i.e., potentiation occurred). The shift of optimum length was also smaller in this case. With fewer motor units active, the optimum length (i.e., the length at which maximal active force was generated) was found to occur at higher muscle lengths during block stimulation. For submaximal current the results indicated shifts of optimum length to both lower and higher lengths.

IMPLICATIONS—Length-force and force velocity properties of submaximally active muscle are likely to be very much dependent on the degree of activation. This allows the central nervous system an extra dimension of control in the execution of movements. In effect, it creates the need for a control which may referred to as intramuscular coordination. For functional electrostimulation (FES) these findings will have important implications as well.

RECENT PUBLICATIONS FROM THIS RESEARCH

Comparison of rat EDL and GM muscle architecture and length force characteristics. Huijing PA, Nieberg SM, van de Veen EA, Ettema GJC. Acta Anatomica 1994:149:111-20.

Decreasing stimulation frequency dependent length-force characteristics of rat muscle. Roszek B, Baan GC, Huijing PA. J Appl Physiol 1994:77:2115-24.

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Heterogeneity of mean sarcomere length in different fibres: Effects on length range of active force production in rat muscle. Willems MET, Huijing PA. Eur J Appl Physiol 1994:68:489-96.

Length force characteristics of the aponeurosis in the passive active muscle and in isolated condition. Zuurbier CJ, Everhard AJ, van der Wees P, Huijing PA. J Biomech 1994:27:445-53.

Mechanical and geometrical properties of the rat semimembranosus lateralis muscle during isometric contractions. Willems MET, Huijing PA. J Biomech 1994:27:1109-18.

Hip joint position and architecture on rat semimembranosus: implications for length force characteristics. Willems MET, Huijing PA. Acta Anat. In press.

B. Ligaments and Tendons

[190] COMBINED FUNCTIONAL LOADING AND LASER PHOTOSTIMULATION OF REGENERATING TENDONS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A534-2RA)*

No report was received for this issue.

[191] SIMULATION OF DISTAL TENDON TRANSFER OF ARM AND FOREARM MUSCLES

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Sponsor: *The Segal Foundation; The Walter and Sandra Kaye Fund*

PURPOSE—The purpose of this study is to examine the kinetic activity in the upper limb when the insertion location of arm and forearm muscles is altered.

METHODOLOGY—The upper limb is modeled as a two-bar linkage moving in the vertical plane of the scapula. A Huxley type musculo-tendon actuation system is modeled in terms of five muscles moving in three-dimensional space. The muscles of which the tendon transfer is being studied are excited maximally, while the other muscles are left passive and included as such in the analysis. The limb kinematics is then solved in different insertion locations of the muscles studied. Data on the elbow kinematics, muscle tension histories, muscle length-tension and velocity-tension relationships, and joint forces are produced.

RESULTS—Present results include the distal tendon transfer of the biceps brachii and the brachialis. They indicate that when the new insertions of these muscles are located further away from the elbow joint axis, the moments of these muscles about the joint axis increase. However, the shortening velocities of these muscles are increased as well, which results in a reduced tension. In addition, the magnitude of the compressive force, the tangential forces and the torsional and bending moments are reduced. These results suggest that, whenever surgically possible, reinsertion of ruptured distal tendons of the biceps brachii and the brachialis more distally to the location of their tuberosities should be beneficial.

FUTURE PLANS—It is intended to apply the methodology developed to study the effect of muscle reinsertion in cases of upper limb amputation. Factors such as muscle flapping around the stump and variations in anthropometric data due to amputation will have to be included.

RECENT PUBLICATIONS FROM THIS RESEARCH

Simulation of distal tendon transfer of the biceps brachii and the brachialis muscles. Giat Y, Mizrahi J, Levine WS, Chen J. J Biomech 1994:27:1005-14.

IX. Neurological and Vascular Disorders

A. General

[192] ARTIFICIAL NERVE GRAFT: UNION OF CELLULAR AND NONCELLULAR COMPONENTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B588)*

PURPOSE—The goal of this project is to improve the results of nerve repair, especially after nerve injuries that result in the loss of segments of nerve, by developing a multicomponent artificial nerve graft (ANG) composed of a conduit made of glycolide trimethylene carbonate (GTMC), oriented collagen, and cultured Schwann cells.

METHODOLOGY—The experimental model consists of a 10 to 15 mm gap in the rat peroneal nerve. Short-term (3 months) animals are evaluated by qualitative histology only, while long-term (12 months) animals are evaluated by repeated noninvasive walking pattern analysis and by qualitative histology, transmission electron microscopy, fiber diameter histogram, and electrophysiology at the end of the regenerative period.

A new organ culture technique has been tested. A neonatal rat dorsal root ganglion (DRG) is placed into one end of a 5 mm GTMC tube and provides a source of neurons. Whole-mount staining for axons and collagen matrix is performed, followed by conventional and scanning electron microscopy.

PROGRESS AND RESULTS—Dr. Rosen's new facility at White River junction has concentrated on isolation and stimulation of proliferation of adult Schwann cells from rat and human sources. GTMC tubes have also been fabricated having a variety of diameters, wall thicknesses and porosities.

In a typical *in vivo* experiment, autografts and five different ANGs were implanted for 3 to 9 months in 38 Fisher rats, into a 10 mm peroneal nerve gap. ANGs consisted of Aquavene® conduits containing live neonatal Schwann cells, dead Schwann cells, or mixed fibroblasts and Schwann cells suspended in 0.8 percent collagen type 1, collagen only, and saline. Ten out of 14 live Schwann cell-containing repairs regenerated across the repair site and contained distal myelinated axons for a 71 percent success rate, while 57 percent of collagen-only repairs regenerated. The 5 autografts were 100 percent successful, while 60 percent of fibroblast-containing ANGs regenerated. Only 20 percent of saline-filled tubes supported regeneration. Upon autopsy it was apparent in 15 failures that a proximal or distal stump was dislodged from the conduit, while in three cases cause of failure could not be determined.

At Palo Alto, simplified methods of mixing cells and collagen, which results in a homogeneous sponge-like network, have been used in all implanted ANGs to date. Orientation of collagen is being pursued by coextrusion of stranded collagen, cell-containing matrix, and channels for axonal regeneration. The objective is to reproduce the Schwann-cell-lined parallel channels known as B;auungner bands in autografts.

The following organ culture experiments have been done: 1) Cell-containing tubes were cultured for 7 to 14 days. Cell viability was assayed by cutting into end and middle pieces and subculturing the matrix.

Results suggest better survival of cells in the middle of semipermeable tubes compared to nonporous tubes. 2) DRGs were placed at one end of resorbable tubes which had been previously coated internally with collagen type I or laminin, or had been left uncoated. Elongation of axon/fibroblast bundles was most rapid on laminin coatings and least on uncoated tubes. 3) DRGs were placed at random locations on oriented collagen type I strands. DRGs stained with IW-antibody to GAP-43 extended bundles of axons preferentially aligned along the collagen strand axis; the bundles exfoliated near ends of cut strands.

FUTURE PLANS—One necessary experiment still to be conducted *in vivo* is labeling of Schwann cells in the graft so that they can be distinguished from host cells; the most sensitive method is incorporation of ^{3}H-thymidine into nuclear DNA. Non-radioactive methods include a fluorescent label in donor cell membranes (1,1'-di-octadecyl-3,3,3',3'-methyl-indocarbocyanine Perchlorate).

RECENT PUBLICATIONS FROM THIS RESEARCH

Evaluation of an artificial nerve graft consisting of Schwann cells, collagen and a biopolymer for the repair of peripheral nerve. Keeley R, Sabelman EE, Kadlcik P, et al. Restor Neurol Neurosci. In press.

Artificial peripheral nerve grafts with collagen matrix: comparison of polyglycolic acid and glycolide trimethylene carbonate resorbable tubes. Rosen JM, Padilla JA, Sabelman EE, Nguyen KD, Pham HN. J Appl Biomat. In press.

[193] NERVE RUBBING IN THE SYMPTOMATIC TREATMENT OF ULNAR NERVE PARESTHESIAE

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Sponsor: *Boston VA Medical Center*

PURPOSE—A procedure named "Nerve Rubbing" is described in the treatment of ulnar sensory paresthesiae, which relieves the symptoms in patients without a significant amount of atrophy or axonal loss.

METHODOLOGY—The procedure was performed as follows: The ulnar nerve was located at the elbow, and rubbed up and down inside the groove (along its longitudinal axis) for approximately 5 minutes.

RESULTS—To date, 20 patients have improved by the end of a 1-month trial of rubbing the nerve for 5 min three times a day. In the beginning, most patients were mildly apprehensive because the rubbing induces, or worsens, their symptoms. Within a couple of minutes, however, they begin to experience relief, describing a decrease in the paresthesiae, and a sense of warming of the hand. After 5 min, they all reported an improvement, and in some instances, disappearance of their symptoms. In one instance, a patient who had a partial flexion of the fifth digit was able to open it following the rubbing. Our patients were all asked to repeat the procedure at home for a few minutes two to three times a day, for as long as the symptoms persist. Most had improved by the end of 1 month and reported a general reduction in their symptoms by at least 50 percent. Paresthesiae and neuropathic symptoms of pressure neuropathies are usually caused by local venous stasis. It is presumed that nerve rubbing works by mobilizing the venous stasis and promoting blood flow, thus reversing the ischemia, and the symptoms which result from it.

[194] NEUROMUSCULAR FUNCTION IN POSTPOLIO SUBJECTS: A 5-YEAR FOLLOW-UP STUDY

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Sponsor: *National Institute of Disability and Rehabilitation Research*

PURPOSE—The purpose of this research is to determine whether unstable postpolio subjects (those acknowledging progressive loss in muscle strength) lose strength, endurance, work capacity, or ability to recover strength after activity at a greater rate than stable postpolio (those not acknowledging progressive loss in muscle strength) or control (non-postpolio) subjects over a 5 year period of time.

METHODOLOGY—24 unstable postpolio, 13 stable postpolio, and 25 control subjects were evaluated. Subjects were assessed initially and at yearly intervals for 5 years. Isometric peak torque was determined in the quadriceps femoris muscles. An isometric endurance test was performed at 40 percent of maximal isometric strength of the quadriceps until the subject could no longer maintain torque at the assigned level. Isometric "work capacity" was defined as the product of torque and time during the endurance test. Relative recovery of isometric strength (percent of maximal isometric strength) was determined 30 sec after the endurance test. Analyses were by ANOVA and repeated measures ANOVA.

RESULTS—The initial measures showed significant ($p<0.05$) deficits in muscle strength and "work capacity" in the unstable postpolio group as compared to the stable postpolio and control groups. The other two variables (endurance and relative recovery of strength) were not significantly different ($p>0.05$) initially among the three groups. The mean strength of the quadriceps in the unstable postpolio group was only 50 to 60 percent of the control value. The mean "work capacity" in the unstable postpolio group was less than 50 percent of the control value. All variables in the stable postpolio group were similar ($p>0.05$) to the control values. Over time, all three groups significantly ($p<0.05$) lost strength in the quadriceps, but no significant ($p>0.05$) difference was found among groups in rate of change. Endurance, "work capacity," and relative recovery of strength did not significantly ($p>0.05$) change over the 5-year time interval in any group. We conclude that the unstable postpolio group does lose strength in the quadriceps musculature over a 5-year period of time. The loss of strength, however, appears to be gradual rather than rapid and may be related to aging as no difference was found in rate of change comparing the unstable postpolio group to that of the stable postpolio and control groups.

FUTURE PLANS—Obviously, further research is required. We have just recently completed the sixth year of yearly follow-up in this group and data will soon be analyzed. We are presently in the process of assessing our subjects for the seventh consecutive year of yearly follow-up. We plan to continue this for several more years to better delineate decline in function in our postpolio groups as well as for our control group.

RECENT PUBLICATIONS FROM THIS RESEARCH

Acoustic myography compared to electromyography during isometric fatigue and recovery. Rodriquez AA, Agre JC, Knudtson ER, Franke TM, Ng AV. Muscle Nerve 1993:16:188-92.

Effect of human growth hormone on serum IGF-I in poliomyelitis survivors. Gupta KL, Shetty KR, Agre JC, Cuisinier MC, Rudman IW, Rudman D. Arch Phys Med Rehabil 1994:75:889-94.

[195] A COMPARISON OF SYMPTOMS BETWEEN SWEDISH AND AMERICAN POSTPOLIO INDIVIDUALS AND ASSESSMENT OF LOWER LIMB STRENGTH, A 4-YEAR COHORT STUDY

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Sponsor: *National Institute on Disability and Rehabilitation Research; The Swedish Medical Research Council; King Gustav Vth 80 Years Foundation; The Swedish Association for Traffic and Polio Victims*

PURPOSE—The purpose of this research is to compare postpolio individuals living in Sweden and the United States and to determine whether lower limb musculature becomes weaker over time and to determine whether individuals with complaints of postpolio syndrome, new weakness, fatigue, walking or stair climbing difficulty were weaker or lost more strength over a 4-year interval of time those individuals without such complaints.

METHODOLOGY—Seventy-eight postpolio volunteers (41 Swedish and 37 American subjects) between the ages of 34–65 years were recruited to participate. Dynametrically measured knee extensor and flexor strength, body weight, and questionnaire data were obtained initially and 4 years later.

RESULTS—The two cohorts were found to be quite similar; however, the American subjects were found to gain significantly ($p<0.05$) more weight over the 4 year interval. Both groups lost significant ($p<0.05$) knee extensor strength (approximately 8 percent), but the loss was not significantly different ($p>0.05$) between the groups. Knee flexor strength did not significantly change over time. Subjects acknowledging new strength loss were not significantly ($p>0.05$) weaker than those denying strength loss; however, they lost significantly ($p<0.05$) more isometric knee extensor strength than the other subjects. Subjects acknowledging new fatigue, walking, or stair climbing difficulty were significantly ($p<0.05$) weaker in both muscle groups than those without the complaints. Subjects acknowledging postpolio syndrome were significantly ($p<0.05$) weaker than those denying this symptom, but amount of loss of strength over time was not significantly ($p>0.05$) different. We conclude that the two cohorts are quite similar. Knee extensor strength decreased during the study interval. Individuals acknowledging postpolio syndrome had weaker knee extensor musculature. Subjects with new fatigue, walking difficulty, or stair climbing difficulty were weaker in both the knee extensor and flexor musculature than the other subjects. Subjects reporting new muscle weakness also had a larger decline in isometric knee extensor strength during the study interval than those without such complaint.

RECENT PUBLICATIONS FROM THIS RESEARCH

Acoustic myography compared to electromyography during isometric fatigue and recovery. Rodriquez AA, Agre JC, Knudtson ER, Franke TM, Ng AV. Muscle Nerve 1993:16:188-92.

Changes in muscle morphology, strength and enzymes in a four-five-year follow-up of subjects with poliomyelitis sequelae. Grimby G, Hedberg M, Henning G-B. Scand J Rehab Med 1994:26:121-30.

Disability in poliomyelitis sequelae. Grimby G, Thorén-J;auonsson A-L. Physical Therapy 1994:74:415-24.

Effect of human growth hormone on serum IGF-I in poliomyelitis survivors. Gupta KL, Shetty KR, Agre JC, Cuisinier MC, Rudman IW, Rudman D. Arch Phys Med Rehabil 1994:75:889-94.

[196] DEVELOPMENT OF A PROCEDURE FOR THE ASSESSMENT OF MOTOR BEHAVIOR IN YOUNG CHILDREN UNDER NATURAL CONDITIONS

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Sponsor: *Dr. Phelps stichting voor Spastici*

PURPOSE—The aim of the project is to implement a new method for the assessment of fine motor skills in children between 2 and 6 years of age. The test enables clinicians to record fine motor behavior in an easy, objective way in a game-like setting. The test makes it possible to show whether a child has problems in motor control on theoretically relevant aspects. By repeating the test, changes in the motor performance of a child (e.g., due to an intervention) can be revealed.

METHODOLOGY—Children have to make goal-directed movements under several different conditions using a special puppet. A digitizer connected to a personal computer can record the position of the puppet with a sample frequency of 200 Hz. Movements can be characterized by velocity, acceleration, movement time, corrective movements, and errors. Manipulated in the tasks are, for example, target size, target distance, stationary or moving target, flexion or extension movement.

To motivate the children to make these movements, little stories are told. The stories are supported by cartoons shown on a monitor by the computer program before and after the movement. Based on the actual movement, the computer decides whether a movement was correct or not. A correct movement is followed by a picture clearly showing the success of the movement. After an incorrect movement, a rather boring picture is shown indicating no success.

FUTURE PLANS/IMPLICATIONS—The tasks were performed by 100 children aged between 2 and 6 years. Large differences between different age groups on the kinematic variables were found. The effects of the manipulations were stronger for the younger children, suggesting these manipulations are along dimensions relevant for motor development.

The next 2 years will be spent collecting data with a large group of healthy children and designing a user interface for all the actions a clinician will need for application of the test to a child.

RECENT PUBLICATIONS FROM THIS RESEARCH

Developmental trends of fine motor performance in primary school children: a kinematic analysis. Kosterman B, Westzaan PSH, Van Wieringen P. In: Faure C, Keuss P, Lorette G, Vinter A, eds. Selected papers of the Sixth International Conference on Handwriting and Drawing, Paris, July 1993. North Holland: Elsevier, 1994.

Method for objective recording and evaluation of fine motor performance in children. Westzaan PSH, Mulder T. In: Maarse FJ, Kattenpoel Oude Heerink KMG, eds. Computers in Psychology. Lisse: Swets & Zeitlinger. In press.

[197] PODIATRIC EVALUATION OF THE NEUROPATHIC FOOT IN LEPROSY

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PURPOSE—Prevention and treatment of plantar ulceration in leprosy has always been a challenge. The problem of recurrence and the associated stigma that make the patient an outcast lead ultimately to "dehabilitation." Prevention of the very first ulcer has to be emphasized. It is well known that the altered stresses and strains during walking on an insensitive foot are significant factors contributing to the development of plantar ulceration. However, there could be inherent morphological changes in the bones of the foot present from birth which may affect the biomechanics of the foot. The aim of this study is to

know whether pathomechanical alterations in the foot—inherent or caused by motor paralysis due to leprosy—predispose the insensitive foot to plantar ulceration.

The problem of plantar ulceration in leprosy patients still continues even after the leprosy infection is cured/brought under control. Those patients having neuritis are likely to suffer from plantar ulceration. This study is being conducted in order to devise a simple orthosis for prevention of plantar ulceration in leprosy.

PROGRESS—This type of study was conducted for the first time in the field of leprosy, and included measurement of subtalar neutral, resting and neutral calcaneal stance position, forefoot, deviation, range of motion of subtalar, mid-tarsal and ankle joints, along with recording of plantar ulcers (site and duration).

METHODOLOGY—Simple instruments in the form of protractor, tractograph, and foot gonicmeter were used for taking these measurements.

Ideally the forefoot must be parallel to rear-foot when the rear-foot is in subtalar neutral. Any angle deviation from this parallel is called fore-foot deviation. So maintaining subtalar neutral is very important as the subtalar joint is considered the key joint. The neutral position is defined as the one in which the subtalar joint is neither in inversion or eversion. Subtalar joint pronation increases mid-tarsal and fore-foot mobility, enhancing adaptability in early mid-stance. If, however, this motion is excess, hyperpronation results. This is an indication of disturbed mechanism of talo-navicular and calcaneo-cuboid joints due to weakening of the supporting structures. The hyperpronation posture imposes a great strain on the medial ray of the foot and prevents locking of the foot during heel-off, an aspect important for the foot's function as a rigid lever during propulsion. At subtalar and mid-tarsal joints the inversion to eversion ratio is 2:1. Alteration of this ratio indicates abnormal pathomechanics.

All these biomechanical aspects have been studied in detail. A total of 400 feet have been evaluated.

RESULTS—The patients were studied in two groups: those having only plantar anesthesia but no ulcer and those having anesthesia and plantar ulcer. The data are being processed.

If any direct corelation between altered foot structure and incidence of plantar ulcer is seen, patients having altered structure in the first group can be categorized as under high risk.

FUTURE PLANS—Further plans include preparation of a suitable orthosis for both groups to maintain the proper rear and fore-foot alignment.

[198] KINEMATICS OF HUMAN TREMOR USING STEREOPHOTOGRAMMETRY

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Sponsor: *None listed*

PURPOSE—Tremor is a common neurological disorder and may affect many different parts of the body. The frequency analysis of tremor bears an important role in understanding the nature of the underlying neurological mechanisms. Relevant literature shows that, in order to classify tremor and monitor the effects of treatments, linear accelerometers or EMG techniques have been mainly used. The aim of this work has been to reach a method for the amplitude and frequency analysis of tremor using a stereophotogrammetric system and an experimental protocol, in order to easily describe the multijoint kinematics of tremor and to quantify both frequency and amplitude content of each joint in the relevant anatomical axes.

METHODOLOGY—Patients were examined during three trials of an appropriate posture, relatively to pathology and behavior circumstances for which tremor is evoked. A rigid plate of balsa, mounting four retroreflective markers, was respectively strapped to the hand, forearm, arm, trunk, pelvis, thigh, shank and foot. From the collected marker trajectories the posi-

tion of a number of anatomical landmarks and the anatomical reference frames for each evaluated segment were reconstructed using the CAST experimental protocol and proposals. The three-dimensional rotations of wrist, elbow, shoulder, pelvic girdle, hip, knee, and ankle were then calculated.

Discrete Fourier Transform (DFT) analysis of the obtained anatomical angles was then carried out in order to evaluate the tremor amplitude spectrum. The amplitude and frequency value of the relevant dominant peak can be easily computed for each subject trials. In order to evaluate the reliability with which the stereophotogrammetric system collects marker trajectories even for very small displacements and high frequencies, different tests of single marker movements with known trajectories were performed. Also, kinematic analysis of voluntary elementary rotations of the human joints involved was carried out with a controlled frequency.

RESULTS—The results of realiability tests seem to suggest that stereophotogrammetric systems and CAST anatomical protocol are able to detect small joint rotations in a frequency range typical of the human pathological tremor. The patients were not disturbed by the experimental set-up and the measuring procedure, which was tolerated by all of them. The useful benefit for the clinical evaluation of tremor in obtaining frequency and amplitude characteristics of many joint angles at the same time, expressed in the well established anatomo-physiological terminology, seems to compensate the drawbacks of the entire procedure, that may be found in the stereophotogrammetric system cost and in the great amount of collected data.

FUTURE PLANS—Due to the critical dependency on the choice of the observation interval of the DFT procedure, the use of model-based parametric techniques for signal spectrum analysis could represent a convenient choice in the future research allowing thus for a lower noise sensitivity and a shorter observation interval, without loosing frequency resolution.

RECENT PUBLICATIONS FROM THIS RESEARCH

Computerized TV-method for three dimensional multi-segmental kinematic analysis of tremor. Liguori R, Benedetti MG, Paniccia M, et al. Can J Neurol Sci 1993:20(4S1):S270.

Stereophotogrammetric approach for the study of total body kinematics of human tremor. Benedetti MG, Liguori R, Leardini A, et al. In: Proceedings of III International Symposium on 3D Analysis of Human Movement; Stockolm, 1994.

B. Low Back Pain

[199] DEVELOPMENT OF A CLINICAL DATABASE FOR THE BACK ANALYSIS SYSTEM

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B748-RA)*

PURPOSE—A comprehensive database of surface electromyographic (EMG) parameters is needed to develop a classification system for muscle impairments from tests performed in the Back Analysis System (BAS). Individual test results are compared to a normative database to identify an impairment classification profile for the subject. Our efforts to establish a comprehensive database for specific clinical populations with low back pain (LBP) will help to identify the role of muscle impairment in these syndromes.

METHODOLOGY—Amplitude and spectral information from six EMG electrode sites are processed and stored into a database for each of several sustained isometric contractions specified by the BAS protocol. Other parameters, such as patient diagnosis,

physical characteristics, occupation, and back muscle strength, are also recorded. Data acquisition is conducted at several clinical sites in the Boston area as well as at the NeuroMuscular Research Center.

RESULTS—This year alone we have added over 100 new subjects to our database. Many of these subjects were drawn from an elderly population, some with significant co-morbidity or significant structural spinal organic disease such as ankylosing spondylitis. We have measured the extent to which age, gender, and physical characteristics influence the EMG parameters used to classify impairments. The relational database structure for providing a framework for data storage, retrieval, and clinical report generation has been specified and software implementation is in progress. As a result, we are significantly closer to realizing the long-term goal of having a comprehensive system available for clinical use.

[200] DEVELOPMENT OF TEST PROTOCOLS TO ASSESS THE BEHAVIOR OF BACK MUSCLES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B749-RA); Liberty Mutual Insurance Company; Boston University*

PURPOSE—Current test protocols used at the NeuroMuscular Research Center to evaluate the function of back muscles in different populations are based on the concept of fatiguing muscles during high level force contractions. Subjects in acute pain at the time of testing have problems complying with such procedures. We are currently in the process of investigating complementing protocols based on the concept of load sharing to assess the function of back muscles. We predict this will increase our knowledge about muscular function in acute phases of pain, thus improving specificity of diagnosis and allowing for better individualized treatment.

METHODOLOGY—The behavior of electromyographic (EMG) spectral and amplitude parameters has been investigated during different types of low level force contractions. Spectral parameters, including median frequency (MF) and amplitude (RMS) of EMG signals were monitored during isometric trunk extension using the Back Analysis System (BAS). Two kinds of tasks, low level long-duration contractions at constant force and stepwise incrementing "staircase" contractions for short durations at nonfatiguing force levels, were studied.

RESULTS—During long duration contractions, results in control subjects indicated the presence of different phases of EMG parameter behavior. Initial increases in RMS occurred as MF decreased; then RMS reached a plateau while MF continued to decrease; and toward the end of the contraction, RMS decreased while MF stabilized at a low level. RMS decrease was most marked in the multifidus muscle. If the contraction was maintained beyond this point, the force dropped to a lower level with concurrent reductions in RMS. Patients, however, displayed a much more rigid behavior. Their RMS and MF parameters appeared to stay more constant until the subject ended the task due to pain or discomfort. During staircase contractions, patients displayed specific unbalanced load sharing patterns as compared to control subjects. The results suggest that test protocols based on the concept of load sharing may be used to assess information related to the function of lumbar back muscles.

[201] BACK ANALYSIS SYSTEM UPDATE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B749-RA); Liberty Mutual Insurance Company; Boston University*

PURPOSE—We are continuing to refine the Back Analysis System (BAS), a technique and device that objectively measures back muscle deficits in individuals with and without low back pain. This project is directed at developing a reliable and valid system for clinical use.

METHODOLOGY—The BAS is a computerized surface electromyographic (EMG) system coupled to a postural restraint device that isolates and stabilizes the musculature of the trunk. The BAS analyzes the patterns of muscle activity observed during isometric fatiguing contractions of the back. Our approach, unlike other techniques, measures the EMG fatigue pattern produced by back extensor muscles and compares them to a normative database to characterize the presence of impairment. Test results may also be compared to previous results to monitor the progression of the subject's low back pain.

RESULTS—The new BAS prototype is near completion and is being readied for in-house and beta site testing. The device incorporates new technology and applications software that will assist the clinician in formulating appropriate diagnosis and treatment outcome measurements for back muscle dysfunction. We have redesigned and constructed the key elements of the new prototype: the postural restraint apparatus, an improved digital signal processing system, and enhanced interactive software. A digital signal processing card calculates the EMG spectral parameters in real time and interacts with a relational database for patient data storage and retrieval. The new software guides the clinician and patient through the entire assessment procedure and has safeguards that insure proper operation. The culmination of each test is a detailed written report of the patient's performance and clinical progress.

In conjunction with these technological developments, we are continuing our evaluation of the current BAS protocols at selected clinical sites. Our results from these beta sites will further validate the use of this technique for objective clinical assessment of muscular performance and dysfunction in the lower back.

[202] EMG SPECTRAL PARAMETERS AS A TREATMENT OUTCOME MEASURE FOR LOW BACK PAIN

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B749-RA)*

PURPOSE—Our interest in implementing the Back Analysis System (BAS) for clinical use prompted us to evaluate its efficacy among patients with lower back pain (LBP). The focus of this work is to study the relationship between changes in BAS measurements following treatment intervention and clinical signs of physical impairment and disability.

METHODOLOGY—We are currently conducting clinical trials of the BAS by integrating its use into several local rehabilitation programs for LBP. The clinical facilities provide diverse patient populations and rehabilitation programs needed to fully evaluate the efficacy of the technique among the population at large. We have recruited male and female LBP pa-

tients spanning a broad range of ages, clinical diagnoses and occupations. Testing is typically conducted at baseline and at fixed intervals during and following rehabilitation. Additional data from standard physical capacity assessments and disability scales are collected at the time of BAS testing for concurrent validation of the BAS technique.

RESULTS—Our results to date have demonstrated that significant changes occur in the EMG signal and force parameters following rehabilitation. These changes indicated significant gains in back muscle endurance, strength, and the reduction of muscle inhibition associated with pain. Patients with the greatest improvements in strength and endurance following rehabilitation also had the most improvements in their LBP diagnosis as determined by the BAS. The sensitivity and specificity of the baseline BAS test for LBP was close to 90 percent accurate.

[203] MUSCLE PERFORMANCE IN THE BACK ANALYSIS SYSTEM COMPARED TO LIFTING TASKS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B748-RA); Liberty Mutual Insurance Company; Boston University*

PURPOSE—Health care providers are seeking more objective ways of measuring functional limitations due to impairments of the musculoskeletal system. Surface electromyographic (EMG) techniques, such as the Back Analysis System (BAS), provide measures of impairment that may also predict functional ability. For instance, back muscle impairment may limit the ability to function during tasks requiring forceful or repetitive trunk extension. To explore this possibility further, we have completed a pilot study to determine whether muscle performance during a constrained task such as the BAS is related to muscle performance during a functional activity such as lifting.

METHODOLOGY—We compared EMG measures of fatigue for tests using the BAS and a standardized dynamic lifting device. EMG signals from extensor muscles of the trunk and legs were monitored during the standard test protocol of the BAS, which specifies isometric, constant-force contraction for a fixed period of time. EMG signals were also recorded during the repetitive lifting task. Changes in the median frequency and amplitude of the EMG signals were analyzed to compare the characteristic patterns of fatigue and muscle activation for the two tasks.

RESULTS—Results to date from seven healthy adults demonstrated that EMG median frequencies from different muscle groups were highly correlated between tasks even though the magnitude of these parameters was significantly different for the two tasks. This may indicate that repetitive lifting produced similar patterns of fatigue for static and dynamic lifting, and the magnitude of fatigue was greater for the repetitive lifting task.

[204] SPECTRAL PARAMETERS OF LUMBAR BACK MUSCLE ELECTROMYOGRAPHY AT DIFFERENT CONTRACTION LEVELS

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PURPOSE—Spectral parameters of the surface electromyographic (EMG) signal from lumbar back muscles assessed during a fatiguing isometric contraction can be used to classify different categories as well as sub-categories of low back pain patients and normal control subjects. In our current protocol, subjects perform a fatiguing isometric contraction of the back muscles at 80 percent of a maximal voluntary contraction (MVC). Since this protocol is based on the subject producing a true maximal effort, this study was designed to investigate the effect of a nonmaximal MVC on the classification score.

METHODOLOGY—Highly motivated normal control subjects were tested in the Back Analysis System (BAS) during 30-sec contractions at levels between 20 and 80 percent of MVC. Surface EMG signals were collected from six sites of the lumbar back muscles according to standard BAS protocols previously developed at the NeuroMuscular Research Center. We are currently analyzing the behavior of the initial median frequency (IMF) and the rate of decrease of the median frequency (MF slope) at these different contraction levels. Parameters from all contraction levels will be entered into a previously developed classification function to simulate the effect of low MVC assessments on the classification score.

RESULTS—Fatigue, as indicated by a significant negative MF slope, appeared at 30 to 40 percent of MVC for the L1 and L5 muscle sites and at 40 to 50 percent of MVC for the L2 sites. There was a strong correlation between percent MVC and MF slope (i.e., the higher the force, the steeper the slope). The IMF decreased with increasing force level, especially at the L5 site. Classification scores show that most subjects were correctly classified at force levels above 40 to 50 percent of MVC indicating a wide safety range in the assessment of MVC.

[205] ALTERATIONS IN EMG SIGNAL CHARACTERISTICS COINCIDING WITH LOW BACK PAIN

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Sponsor: *Liberty Mutual Insurance Company; Boston University*

PURPOSE—When a muscle is injured, a cascade of events is triggered which include acute inflammation and pain. In a complex system where several muscles act as synergists, the central nervous system may, through feedback mechanisms, minimize the effects of pain by redistributing the activation between the different muscles, thus solving the task of maintaining a certain force. The aim of this project is to study activation characteristics of muscles in the lumbar back in different categories of subjects with and without pain in an attempt to better understand muscular function in the presence of acute pain. Such knowledge may assist the clinician in decisions regarding intervention and treatment for patients with acute low back pain.

METHODOLOGY—Back pain patients with asymmetric pain patterns in the lumbar back, as well as normal subjects with muscular low back pain induced through strenuous physical exercise (delayed onset muscle soreness), were tested in the Back Analysis System (BAS) during different low level isometric contractions. Surface electromyographic (EMG) sig-

nals collected from six sites of the lumbar back muscles were analyzed and spectral symmetry parameters were extracted and compared between pain and non-pain conditions. Magnetic resonance images (T2-weighed echo planar MRI) were then obtained from pain and non-pain muscle sites.

RESULTS—Preliminary results indicate that significant spectral EMG imbalances commonly coincide with the site of pain both in normal subjects with induced pain as well as in back pain patients. Pain site specific changes in T2-weighed MR image intensity consistent with muscular damage have also been observed. Our results suggest that the presence of muscular back pain, in these categories of subjects, alters activation characteristics in a way specific to the location of the pain, and that these alterations are detectable with surface EMG techniques.

[206] EMG PARAMETERS OF LUMBAR BACK MUSCLES

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PURPOSE—The presence of an interaction between the activation of different muscles of the lower back during a sustained contraction may be monitored as changes in spectral properties of the surface electromyographic (EMG) signals. Previous analysis of surface EMG signals assessed with the Back Analysis System (BAS) were mainly focused on the behavior of the initial median frequency (IMF) and the rate of decrease of the median frequency (MF Slope) during fatiguing contractions. Results have suggested the presence of spectral imbalances between muscles of the lower back in patients with lower back pain (LBP) as compared to control subjects. In this project, new parameters are being investigated that further describe these imbalances. Discrimination scores between different categories of patients with LBP and controls should improve as a result of this study.

METHODOLOGY—Cross-correlation techniques were applied to extract parameters from the root mean square (RMS) of the surface EMG signal. The behavior of ratios between spectral properties in contralateral as well as ipsilateral pairs of muscles of the lower back were also investigated. Parameters with clinical relevance describing segmental imbalances and bilateral compensations in spectral parameters were introduced. The behavior of these parameters was monitored using the BAS during isometric contractions at 40 percent of maximal voluntary contractions (MVC) in a group of 96 LBP patients and 23 controls.

RESULTS—Preliminary results for control subjects show distinct patterns of periodically occurring positive cross-correlations between contralateral muscles of the lumbar back. The behavior appeared to become more pronounced during the contraction. This pattern is not present between simulated EMG signals or between EMG signals from different subjects. A discriminant analysis using RMS and MF ratio parameters successfully classified 81 percent of the subjects in the study. Overall, patients displayed more segmental imbalances and fewer compensations as compared to controls. Further results suggest a similar behavior of these parameters in test protocols using several different, low level force contractions.

[207] NORMATIVE DATABASE FOR LOW BACK PAIN EVALUATION IN BLUE COLLAR WORKERS

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Sponsor: *Liberty Mutual Insurance Company*

PURPOSE—Our goal of utilizing the Back Analysis System (BAS) to identify muscle impairment in patients with low back pain requires that we establish a normative data profile that encompasses a broad spectrum of occupations that may have different baselines of back muscle capability. Our current normative database evolved from a study begun several years ago in which there were limited numbers of men and women representing blue collar occupations. Because many blue collar trades involve the daily use of back extensor muscles to a greater degree than sedentary occupations, we needed to extend our normative database to encompass this segment of the population. With the acquisition of this normative database, we will be better able to identify muscle impairment categories in patients from similar blue collar occupations.

METHODOLOGY—To date, we have recruited 34 male and female subjects from a variety of occupations requiring manual labor. Testing was conducted at several of our beta sites as well as in-house. We have also formulated an improved database management software for the next prototype version of the BAS.

RESULTS—The results of this study demonstrate that back muscles from normal, pain-free populations of blue collar workers function according to a recognizable pattern of EMG parameters derived from specific back muscle sites. We have recognized the extent to which these parameters are influenced by the subject's age, gender, and body size. The study has also resulted in the specification of a relational database structure that will provide a useful framework for making comparisons to clinical low back pain data. As a result, we will be better able to generate clinical reports that categorize individuals into low back pain and normal groups for industrial applications.

[208] PREDICTABILITY OF THE SUSCEPTIBILITY TO LOW BACK PAIN

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Sponsor: *Liberty Mutual Insurance Company*

PURPOSE—We have completed the fifth year of a prospective study to determine if electromyographic (EMG) spectral parameters from lumbar muscles can correctly predict individuals who will develop low back pain (LBP). The study has focused on novice and experienced collegiate rowers because of their high risk for developing LBP. By identifying EMG parameters predictive of LBP, it may be possible to screen subjects with a tendency toward back injury and modify their training accordingly.

METHODOLOGY—Back Analysis System (BAS) tests are conducted biannually on male and female members of two local collegiate crew teams. To date, we have recruited 111 rowers, approximately 60 percent of whom were novices. We have analyzed a subset of this population, consisting of 15 rowers who developed LBP during the course of the study and an equal number who did not. We analyzed the initial test for each of these rowers to determine which BAS parameters could best predict the onset of LBP.

RESULTS—A two-group step-wise discriminant analysis procedure correctly classified all of the rowers who developed back pain, and misclassified two that did not. The discriminating parameters from this

analysis were predominantly EMG measures of fatigue recovery. These were the same parameters identified in an earlier published study on elite rowers with and without LBP. Further analysis is being conducted to include other parameters of the EMG signal, examine other subsets of the population, and monitor the influence of training on muscle performance and resistance to LBP.

[209] EVALUATION OF LOW BACK PAIN TREATMENT OUTCOME

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Sponsor: *Liberty Mutual Insurance Company*

PURPOSE—Providers of medical care are demanding that treatment regimens for low back pain be evaluated on the basis of quantitative, objective outcomes. To address this need, we have developed a system of surface electromyographic (EMG) measurement of back muscle function that is referred to as a Back Analysis System (BAS). We have undertaken a longitudinal study to assess the efficacy of this technique for monitoring treatment progression and predicting outcome following low back pain (LBP) rehabilitation. The results from this work will determine the most effective way of incorporating this technique for clinical use.

METHODOLOGY—The research is focused on low back pain injury in the workplace, targeting chronic lower back pain patients who are participants in either multidisciplinary work-hardening or workreconditioning programs. These patient groups are typically in a structured rehabilitation program where a number of physical, psychological, and functional parameters are routinely recorded and correlated to the BAS measurements. Patients are tested in the BAS at baseline and again at fixed time intervals into their rehabilitation program.

RESULTS—Our first series of tests were completed at the Liberty Mutual Medical Service Center as a part of their LIMBER program for back pain management. With the discontinuation of this program, we have completed preliminary BAS testing at the Center for Occupational Rehabilitation at the Braintree Hospital and at the private orthopedic practice of Howard Taylor. The EMG data and correlate measures of pain, physical performance, and disability have been processed and are being entered into a clinical database for further analysis.

RECENT PUBLICATIONS FROM THIS RESEARCH

Spectral EMG assessment of back muscles in patients with LBP undergoing rehabilitation. Roy SH, DeLuca CJ, Emley M, Buijs R. Spine 1995:20(1):38-48.

[210] VERMONT REHABILITATION ENGINEERING RESEARCH CENTER FOR LOW BACK PAIN

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PURPOSE—The Vermont RERC is committed to improving employability of people with back disorders through basic and applied research and information services. Activities include device design and development, and clinical and workplace intervention. Objectives of this multidisciplinary center include the following: developing and testing assistive devices to improve function and employability; developing and

testing workplace adaptations and modifications; identifying and minimizing workplace risks for back pain and injury; developing and testing models to help improve return to work of back-injured workers; disseminating research findings, facts and figures, and information about goods and services to people with back disorders, their families and employers, as well as state and government agencies, centers, and services.

PROGRESS—The RERC is engaged in ongoing engineering design and development projects in several areas:

Posture. Sustained or repeated postures that deviate from an upright position usually produce discomfort and may put extra stress on muscles and ligaments. This project addresses relationships among postures, discomfort, fatigue, and work performance. Results will help researchers measure muscle fatigue and assess job tasks.

Seating. Awkward or inappropriate sitting postures often lead to low back discomfort, particularly when lumbar lordosis is not maintained. The research team is improving techniques for evaluating seated postures and developing accommodations for those who sit on the job.

Vibration. Driving a car imposes strain on the low back, especially for those who drive, or ride, 20 miles or more a day. Many researchers believe that regular and prolonged exposure to whole-body vibration can damage the lumbar spine. The Vermont RERC is developing a simple, low-cost vibration assessment system to be used by employers or employees, themselves.

Manual Material Handling. A device to measure lifting capacity, effort, acceleration, and jerk is being tested to determine whether lifting characteristics can be used to distinguish between experienced and inexperienced lifters. Accommodations for workers who must lift frequently are also being developed.

Worksite Assessment. Research engineers are developing a system to help employers, industrial health and safety officers, and others evaluate their own work environments for back injury risk factors. An Expert System will help both to prevent injuries and specify worker accommodations.

Comparative Study of Exercise Programs. This project compares a program of exercises that address physical signs and symptoms with one that does not. Patient participants in the two programs will be compared in terms of functional ability.

Evaluation of an Assistive Device for Drivers. A backrest that provides continuous passive motion to the low back has been shown to induce back motion and to increase seated comfort. Researchers are now conducting a prospective study to see whether using the device reduces back pain, injury, and lost work time.

Statewide Program for Reducing Disability among Back-Injured Workers. Three strategies for reducing chronic occupational back disability are being tested: a Disability Prediction Questionnaire, a physician surveillance program, and a rehabilitation engineering intervention program.

Evaluation of a "Smart Corset." The Smart Corset, a gravity-based inclinometer that emits a beep when the wearer bends too far, takes the place of a traditional cloth corset. Current research will determine its effectiveness in reducing back pain and in improving function, comfort, and satisfaction.

In addition to conducting research and evaluation, the Center also disseminates information through a variety of activities in information and referral, publications, education and training, public relations and research evaluation. The Vermont RERC offers assistance in locating programs and provides information search services.

C. Swallowing Disorders

[211] DETERMINING RESPONSE CURVE FOR TACTILE-THERMAL APPLICATION: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #C93-689AP)*

PURPOSE—A critical need in dysphagia is for randomized clinical trials to determine treatment efficacy. There are many treatment procedures available to improve impaired swallowing. One widely used treatment method is tactile-thermal application (TTA). However, the efficacy of this treatment has not been established. One difficulty in establishing clinical trials to judge the efficacy of TTA is the absence of data establishing the number of trials of TTA necessary for a treatment effect. It is the purpose of this pilot study to develop a response curve for TTA by randomly assigning hospitalized, dysphagic stroke patients to treatment groups of 150, 300, 450, or 600 trials per week for 2 weeks. This response curve is necessary to complete planning of a multicenter, randomized clinical trial to determine the efficacy of TTA.

METHODOLOGY—The study population consists of medically stable hospitalized, dysphagic stroke patients. All patients will have the presence of stroke-caused dysphagia with onset between 1 and 12 weeks prior to enrollment in the study. Each subject will be randomly assigned to one of four treatment groups. Group I will receive 150 trials, group II will receive 300 trials, group III will receive 450 trials, and group IV will receive 600 trials. A trial consists of three rubs of tactile-thermal application on each of the faucial pillars and one swallow.

Videofluoroscopic examinations (VFE) will be conducted at intake, at the end of the first treatment week, and at the end of the second treatment week. Each exam will consist of five 3-ml thin liquid boluses and five 10-ml thin liquid boluses. The initial VFE will show evidence of dysphagia characterized by abnormally long duration of stage transition (DST) measures and abnormal penetration-aspiration measures on at least one swallow. If it is the first swallow, it must also be present on at least one of the next nine swallows. Treatment is conducted on at least 3 out of 5 days during each treatment week. No treatment is conducted for at least 2 hours prior to the VFE conducted on the fifth day of each week.

PROGRESS—Forty-eight subjects from 11 hospitals have been enrolled in the study to date. Differences in the therapeutic effects of 150, 300, and 450 trials have not emerged from the data.

RESULTS—Six hundred trials is contratherapeutic. Swallowing performance improves after 1 week but returns to baseline by the end of the second week. In addition, clinicians are unable to complete the required numbers of trials per week. The study continues.

RECENT PUBLICATIONS FROM THIS RESEARCH

Penetration aspiration scale. Rosenbek JC, Robbins J, Roecker E, Coyle J, Wood J. Dysphagia In press.

Swallowing after unilateral cerebral stroke. Robbins JA, Levine RL, Maser A, Rosenbek JC, Kempster G. Arch Phys Med Rehabil 1993:74:1295-1300.

[212] COMPARISON OF MANOFLUOROGRAPHY, THE MODIFIED BARIUM SWALLOW, AND BIOMECHANICAL ANALYSIS IN THE POST-SURGICAL PHARYNX

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Sponsor: *National Institutes of Health; National Cancer Institute*

PURPOSE—This project compares the data generated from manofluorographic (MFA) studies of oropharyngeal swallow with that collected with modified barium swallow (MBS) and biomechanical analysis (BMA). Currently, many patients receive videofluoroscopic examination of swallow (MBS) which provides information on the movement of food and the movement of structures. However, no pressure information is collected, and swallowing is a pressure phenomenon. Also, no measures of structural movement are made. We hypothesize that patients who have undergone particular types of head and neck cancer surgical procedures may be better evaluated with combined videofluoroscopy and manometry, or with biomechanical analysis than with modified barium swallow, since the more objective measures from biomechanical analysis and/or manofluorography (which also assesses pressure) may provide us with information which is more revealing regarding the nature of their altered swallow physiology and the effects of treatment strategies.

METHODOLOGY—The swallow physiology of 60 surgically treated head and neck cancer patients will be evaluated using simultaneous manometry and fluoroscopy (manofluorography). Data from the combined procedures will be analyzed with manofluorography while the video recording of fluoroscopy will be analyzed as a modified barium swallow and biomechanically. Results of each analysis will be compared to determine which technique provides most information regarding the swallowing ability of particular types of cancer patients, and to determine whether objective measures provide us with additional information over observations of swallow.

PROGRESS—We are completing Year 3 of a 4.8-year funding period. We have collected data on 9 patients with simultaneous manometry and videofluoroscopy and are in process of completion of data reduction of these recordings. By year's end, we anticipate collecting data on 6 additional subjects, reaching our target accrual of 15 patients for Year 3. All of the human subjects forms have been approved for this project. The methods remain unaltered. Since data reduction is still underway, no analyses have been completed of the data from these 20 subjects. A study of pharyngeal manometry, alone, has been completed.

FUTURE PLANS—In the coming year we expect to complete patient accession of 15 patients and to complete data reduction and analysis of all 15 subjects.

RECENT PUBLICATIONS FROM THIS RESEARCH

Interpretation of pharyngeal manometric recordings: limitations and variability. Ergun GA, Kahrilas PJ, Logemann JA. Dis Esophagus, 1993:6:11-16.

[213] BIOMECHANICAL EFFECTS OF TRACHEOSTOMY TUBES

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PURPOSE—This project examines the functional and biomechanical effects of tracheostomy on swallow in head and neck surgical patients who are about to be decannulated. Since many surgically treated head and

neck cancer patients receive a tracheostomy at some point in their care, as do patients with various respiratory diseases, spinal cord injuries, and other neurologic disorders, and since there is little quantified information and great divergence of clinical opinion regarding the effects of tracheostomy, this project proposes to examine and quantify the systematic effects of tracheostomy in particular types of head and neck surgical patients with tracheostomy who are about to be decannulated.

METHODOLOGY—Swallowing function of 40 head and neck cancer patients with tracheostomy who are about to be decannulated will be studied with simultaneous videofluoroscopy and endoscopy with the tracheostomy in place and after decannulation. Another 40 head and neck cancer patients will be studied with simultaneous pharyngeal manometry and videofluoroscopy. We hypothesize that tracheostomy changes the biomechanics of swallow, particularly laryngeal elevation and anterior movement, laryngeal closure and cricopharyngeal opening. By comparing the biomechanical and pressure characteristics of swallow, bolus transit measures, and vocal fold movement patterns in these groups, we will be able to define any systematic effects of tracheostomy and the interaction of a tracheostomy with particular swallowing disorders and head and neck surgical procedures.

PROGRESS AND PRELIMINARY RESULTS—We are completing Year 3 of a 4.8-year funding period. Seventeen patients have been accrued during Year 3. Results of the videofluoroscopic studies of these patients continue to reveal differences in swallow function with the tracheostomy occluded versus nonoccluded. When the tracheostomy was occluded, aspiration was reduced, as the patients could cough and clear the airway. Biomechanical and temporal analyses of these radiographic studies are underway. In addition, two studies of laryngeal and respiratory function in normal subjects without a tracheostomy have been completed.

FUTURE PLANS—During the coming year we shall access 25 patients for Year 4 and complete data analysis on these 25 subjects, including biomechanical analysis of airway closure and cricopharyngeal opening.

RECENT PUBLICATIONS FROM THIS RESEARCH

Coordination between respiration and swallow: respiratory phase relationships and temporal integration. Martin BJW, Logemann JW, Shaker R, Dodds WJ. J Appl Physiol. In press.

[214] BIOMECHANICS OF SWALLOW AFTER HEAD AND NECK CANCER

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Sponsor: *National Institutes of Health; National Cancer Institute*

PURPOSE—This project examines the biomechanical effects of head and neck surgical procedures on swallowing function and on the patient's ability to exert voluntary control over specific aspects of the swallow. A biomechanical analysis system will enable us to define the changes in muscle pull created by head and neck surgical procedures and to develop more effective swallow interventions, including surgical reconstruction.

METHODOLOGY—Videofluoroscopic swallowing studies of nondisabled subjects and specific groups of surgically treated head and neck cancer patients, collected 3 points in time post surgery, will be quantified biomechanically to identify the ways in which these surgical procedures produce voluntary swallow rehabilitation maneuvers, as compared to nondisabled subjects. This project utilizes a computerized biomechanical analysis process for the oropharyngeal swallow

developed specifically for this purpose. This system provides important information on the ways in which structural movements relate to one another and to bolus movement during the physiology of nondisabled oropharyngeal deglutition.

PROGRESS/PRELIMINARY RESULTS—We are completing Year 3 of a 4.8-year funding period. The focus of work in the last 12 months has been:

1) Accrual of 16 head and neck cancer patients and 14 age-matched nondisabled subjects, achieving the targeted number of accruals in Year 3; we anticipate collecting data on 10 more female nondisabled subjects in the last 2 months of Year 3;
2) Digitization and analysis of swallowing data on supraglottic laryngectomee patients and anterior floor of mouth patients from the archived data from the first 6 years of the project;
3) Analysis of laryngeal closure in nondisabled subjects and the effects of voluntary maneuvers to close the airway at the entrance and at the vocal folds;
4) Completion of the manuscripts and presentations documenting the effects of airway closure maneuvers and the Mendelsohn maneuver to improve laryngeal elevation.

These studies advance our knowledge of nondisabled swallow physiology as a basis for developing new swallow maneuvers and other therapy procedures, and in understanding the effects of these therapies on treated head and neck cancer patients. Our studies of spontaneous pharyngeal wall compensation in anterior floor of mouth patients defined a potential physiological mechanism to improve pharyngeal wall movement in treated head and neck cancer patients. We are following this study with several other investigations in nondisabled and disordered patients to further define the effects of this new "maneuver." In a study of postural techniques, more than 70 percent of the head and neck patients who aspirated on liquid were able to take liquids safely with no aspiration when the postural strategies were introduced. Without the postures, these patients would have been required to take liquids nonorally.

FUTURE PLANS—In the coming year, we shall complete a study of the efficacy of swallow maneuvers, particularly the super-supraglottic swallow, in conjunction with postural techniques in head and neck cancer patients, and we shall access 12 head and neck patients and 12 age-matched nondisabled subjects for Year 4.

RECENT PUBLICATIONS FROM THIS RESEARCH

Effects of postural change on aspiration in head and neck surgical patients. Logemann JA, Rademaker AW, Pauloski BR, Kahrilas PJ. Otolaryngol Head Neck Surg, 1994:110:222-7.

Mechanisms of recovery of swallow after supraglottic laryngectomy. Logemann JA, Gibbons PJ, Rademaker AW, et al. J Speech Hear Res, 1994:37:965-74.

Biomechanical analysis of the pharyngeal swallow in post-surgical patients with anterior tongue and floor of mouth resection and distal flap reconstruction. Pauloski BR, Logemann JA, Cheng JF, Colangelo LA. J Speech Hear Res. In press.

[215] EFFECTS OF SURGICAL RECONSTRUCTION ON SPEECH AND SWALLOWING

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Sponsor: *National Institutes of Health; National Cancer Institute*

PURPOSE—This study examines the effects of surgical reconstruction for oropharyngeal cancer as a first-line rehabilitation strategy in oral cancer patients. It is our hypothesis that particular surgical reconstruction can facilitate speech and swallowing or cause a further decrement in function. This project will follow 15 groups of surgically treated oral cancer patients to examine the effects of surgical reconstruction on early and late functional outcomes of speech and swallowing. This project is a continuation of a previously funded 6-year study.

METHODOLOGY—Each patient will be followed for 3 months postoperatively. All patients will be

studied preoperatively, at 1 month and 3 months posthealing. At each of these data collection points, each patient will receive a videofluoroscopic assessment of swallowing and speech, an articulation test, and recording of conversational speech for later intelligibility rating.

PROGRESS—We are completing Year 3 of a 4.8-year funding period. Patient accruals have progressed well. We have accrued 32 patients to date this year. We anticipate accruing at least an additional 6 patients in the last 2 months of Year 3, giving us more patients than we anticipated accruing in Year 3. We are continuing to examine the database to develop manuscripts regarding effects of surgical reconstruction on speech and swallowing, as well as to reduce data on new patient accruals.

RESULTS—The significance of this work lies in our increased understanding of surgical reconstruction effects in order to improve functional outcomes for patients. Our study of T-stage and its relationship to function determined that function deteriorated as T-stage increased. Our study of 12 month follow-up of patients from this study indicates that function was no better at 12 months than at 3 months postoperatively. These data support the need for more therapy to improve speech and swallowing in these patients.

FUTURE PLANS—In the coming year we shall access 34 patients and follow them for 3 months, complete data reduction on these 34 patients, and continue analysis of subsets of the large data set from the first 6 years of the project in order to define effects of surgical resection and reconstruction on speech and swallowing.

RECENT PUBLICATIONS FROM THIS RESEARCH

Speech and swallow function after tonsil/base of tongue resection with primary closure. Logemann JA, Pauloski BR, Rademaker AW, et al. J Speech Hear Res, 1993:36:918-26.

Speech and swallowing function after oral and oropharyngeal resections: One year follow-up. Pauloski BR, Logemann JA, Rademaker AW, et al. Head Neck Surg, 1994:16:313-22.

Surgical variables affecting postoperative swallowing efficiency in oral cancer patients: a pilot study. McConnel FMS, Logemann JA, Rademaker AW, et al. Laryngoscope, 1994:104:87-90.

[216] ASSESSMENT OF PERFORMANCE OUTCOME IN LARYNGEAL CANCER PATIENTS

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Sponsor: *National Institutes of Health; National Cancer Institute*

PURPOSE—The specific aims of the project are: 1) to evaluate the performance outcome of laryngeal cancer patients as a function of treatment type and time since surgery, 2) to develop "expected performance profiles" for laryngeal cancer patients, 3) to determine the relationship between observable functional impairments and physiological measures, and 4) to identify and begin to develop profiles for other groups of head and neck cancer patients.

METHODOLOGY—A total of 383 laryngeal cancer patients representing four treatment types will be assessed at four points in time, within 2 weeks of surgery, at 6 weeks, at 12 weeks, and at 6 months posthealing. The assessment will consist of administration of the Performance Status Scale for Head and Neck Cancer (PSS-HN) as well as the collection of relevant medical and personal demographic data. Objective measures of swallowing (modified barium swallow) and speech (percent intelligibility) will also be available for some patients and will be compared to ratings on the PSS-HN.

PROGRESS—Twenty-five (25) laryngeal patients were entered in the longitudinal study, 7 in each of 3 treatment groups (total laryngectomy: Group 1, hemilaryngectomy: Group 2, radiation only: Group 4) and four in the supraglottic laryngectomy group

(Group 3). Thirty-two one-time assessments have been completed, with 4 week follow-up data available on eight.

Preliminary analysis of longitudinal data is underway. Groups 1 and 2 show significant improvements on the Diet, Speech and Eating in Public subscales of the PSS-HN as well as on the Karnofsky; rates of recovery varied across subscales. Group 1 recovered most slowly without achieving normal functioning by 6 months. In contrast, most of Group 2 returned to normal functioning within 3 months. Analysis of quality of life data and the relationship between quality of life and performance is ongoing.

RESULTS—This study represents one of the first longitudinal investigations of quality of life and performance in head and neck cancer patients. Such a determination of the degree, duration, and rate of recovery across multiple life arenas is critical to patient education efforts, the development and evaluation of rehabilitation programs, and the identification of patients whose recovery falls short of expected levels. The data analyzed to date indicate significant long term deficits in certain groups of patients and underscore the importance of repeated multidimensional assessment to accurately categorize the nature and time course of specific areas of deficit. The measures employed in the current study are extremely useful clinical screening instruments which tap more specific areas than the Karnofsky.

FUTURE PLANS—The longitudinal component of the project has been completed and data analysis and manuscript preparations are underway. Accrual to the one-time assessment arm will continue, with the addition of the 4 week follow-up data point. Accrual to this arm will continue until a total of 25-30 patients have been assessed at 4 week follow-up. The relationship between the performance scores and physiological measures will then be examined.

D. Vascular Disorders

[217] FEASIBILITY OF A DYNAMIC DERMOFLUOROMETER TO MONITOR SKIN FLUORESCENCE: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #A91-260AP)*

PURPOSE—Local tissue perfusion is a critical parameter for the assessment of viability for skin flaps, strangulated bowel, and burns. In addition, patients with diabetes and arteriosclerotic peripheral vascular disease often have impaired local circulation in an extremity. The goal of this pilot study is to evaluate the feasibility of a new, rapid-sampling fluorometer for measuring skin fluorescence. Such an instrument should increase the diagnostic information provided by fluorescence tissue measurements when incorporated into a pharmacokinetic model of dye distribution.

METHODOLOGY—We have designed a new two-channel optical system for detecting fluorescein dye in subcutaneous tissue. In this system optical energy from a flash lamp is filtered at 490 nm and directed via a bifurcated fiber-optic bundle (5 mm diameter) to two optical beamsplitter modules. Each module contains a dichroic beamsplitter that directs optical signals with a wavelength often less than 510 nm to the sensing optical fiber (also 5 mm diameter). Fluorescent light emitted by fluorescein at wavelengths greater than 510 nm returns through the sensor fiber and beamsplitter to a photomultiplier tube with an

input fluorescence emission filter centered at 517 nm. This optical system is interfaced to a Macintosh Quadra 700 computer using the Labview 2 software.

For the clinical studies, a bolus injection of sodium fluorescein (0.5, 1, or 2 ml of 10 percent solution) was given through an indwelling venous catheter in the antecubital vein. Fluorescent signals were recorded from two optical fibers positioned on the skin of either the right forearm or calf for 30 min from the time of injection.

PROGRESS—The feasibility of this device has been proven in a series of animal studies and clinical trials using nondisabled volunteers. We have developed an instrument that is now suitable for diagnostic studies of patients with peripheral vascular disease.

RESULTS—A series of animal experiments were performed using 20 rats to confirm that the dermofluorometer can measure optical signals in the skin in subjects administered sodium fluorescein at doses of 4 to 5 mg/kg. A comparison of the uptake and washout kinetics of carboxyfluorescein and sodium fluorescein demonstrated that both dyes have similar uptake kinetics but that sodium fluorescein is eliminated from the body more slowly. Clinical tests of the dermofluorometer were conducted on four nondisabled volunteers at the Danville VA Hospital. The fluorescent signal intensity rose to a plateau with a time course characterized by a simple rising exponential, with a time constant of approximately 2 min. The amplitude of the signals was approximately 2 v per ml of sodium fluorescein injected (approximately 1 mg/kg). These measurements demonstrated the capability of the dermofluorometer to monitor washin kinetics of sodium fluorescein at approximately one-fifth of the dose used in standard opthalmic procedures.

FUTURE PLANS—We plan to use this instrument in a clinical study of diabetic patients at the Danville VA Medical Center who have impaired local blood flow in the lower extremities.

[218] NONINVASIVE MEASUREMENT OF CHANGES IN MUSCLE OXYGEN WITH CLAUDICATION

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PURPOSE—The purpose of the study is to assess oxygen in deep tissues of the limb when a patient experiences disabling claudication. The tissue oxygen saturation measurements utilize a small-diameter light beam at the surface of the skin. Differential light reflectance on the skin surface at dual source-detector separations and at dual wavelengths provides selective information on oxygen saturation. The laboratory portion of the study has examined the hypothesis that oxygen saturation measurements correlate with transcutaneous oxygen and with wound oxygen tension. In the clinical portion of the study, the hypothesis is being tested that changes in oxygen saturation measured by light reflectance will be a more sensitive predictor of claudication onset distance and absolute walking distance than surface measurements of transcutaneous oxygen.

As the veteran population ages, the effects of obstructive vascular disease are increasingly seen, with claudication being a chronic and disabling manifestation of the disease process. This study will assist in identifying quantitatively those aspects of the process that are due to ischemia and those factors that may be attributed to other processes. A sensitive and specific testing method developed in this study would make possible the evaluation of management alternatives for claudication such as cessation of smoking, exercise regimens, weight loss effects, and therapeutic agents.

METHODOLOGY—The animal component of this research involved the measurement of muscle oxygen in hind limbs of 12 canines during arterial occlusion and of 6 rhesus monkeys with application of a tourni-

quet. The muscle oxygen measurements were made with a custom designed oximeter with sensor/detector separations of 1, 2, and 3 cm. Standard transcutaneous partial pressure of oxygen, subcutaneous polarographic oxygen (wound oxygen), and laser Doppler flowmetry measurements were also taken.

The clinical component of the research involves examining muscle oxygen during exercise for normal subjects and subjects with a history of claudication, all with informed consent. Other measurements include transcutaneous oxygen and segmental Doppler measurements.

PROGRESS—The animal component of the study has been completed. Data are being analyzed and prepared for reporting. The human component of the study is in progress, using equipment that has been custom-designed for measurements at three subject sites during patient exercise.

RESULTS—The canine data show patterns of oxygen changes and light reflectance changes that are consistent with arterial occlusion in the limb. The small size of the canine limb relative to probe size led to differences among animals in the observed responses for measurement modalities. Another factor that affected results and led to variability was the differences in limb flow with iliac artery occlusion. The Rhesus monkey data was, on the other hand, less variable, consistent among animals, and consistent with a compartment representation for each type of limb measurement. The reflectance measurements were as consistent as $tcPO_2$, faster to respond than $tcPO_2$ and wound oxygen measurements, and showed less artefact than laser Doppler measurements.

Analysis of the data, particularly from the Rhesus monkey studies, shows consistency with a compartmental representation for the system, thereby provide the basis for gaining insight into the behavior of the reflectance method under conditions of restricted limb flow. The data also provided information on the way in which the reflectance measurements relate to other previously used methods for measuring limb oxygen in experimental and clinical settings. The advantage of the reflectance measurements is the noninvasive and continuous nature of the readings. The theoretical basis of the method suggests that the measurements in part demonstrate oxygen levels well below the surface of the skin. The data are currently being assembled into a paper for publication.

FUTURE PLANS—The clinical studies are in the process of being completed. The relationship between monitored and recorded measurements from the clinical study will be compared with the results of the arterial occlusion in the animal studies. The monitored data will be examined for consistency with other clinical parameters.

[219] MEASUREMENT OF PLANTAR FOOT SOFT TISSUE PROPERTIES OF PATIENTS WITH DIABETIC NEUROPATHY FOR PREDICTION OF PLANTAR FOOT PRESSURES AND ASSESSMENT OF PLANTAR ULCERATION RISK

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—This project involves the determination of soft tissue properties of the foot plantar surface, to be used in biomechanical and statistical modeling for predicting plantar foot pressures. Soft tissue properties of the foot plantar surface will be computed from measured data for load and displacement at the foot plantar surface. The properties of specific interest in this project are compliance and resistance. Successful development of appropriate means for obtaining soft tissue compliance and resistance at the foot plantar surface must account for inherent non-linearity of these properties, and dependence upon deformation and deformation rate. Collection of compliance and resistance data for the foot plantar surface also should be highly repeatable and relatively simple to perform. This project involves the following objectives: evaluate different means for collecting soft tissue property data from the foot plantar surface; quantify the depen-

dence of foot plantar pressure predictions on compliance and resistance values obtains by various means; evaluate plantar foot soft tissue properties obtained by various means, with respect to predicting plantar foot/orthotic insert interface pressure, individual plantar pressure tolerance, and plantar ulceration risk; and assess the value of different plantar pressure parameters and other clinical values.

METHODOLOGY—Our initial design concept for this instrument has undergone considerable evolution. Initially we had conceived of a device which imposed sinusoidally oscillating displacement of a given amplitude, via a shaft with a disk at its end. The device then would record this displacement (as measured by an LVDT) and the resulting soft tissue load (as measured by an axial load cell incorporated into the shaft) in a simultaneous and synchronous manner.

In the course of our efforts, however, we have decided that an instrument for soft tissue property measurement should have control of the load imposed, rather than the amplitude of the displacement imposed. Our determination of this requirement was based upon two primary concerns. First, the preliminary design required that the magnitude of the displacement of the plunger (i.e., compression of the soft tissue) would be present with sufficient uncertainty regarding the load on the soft tissue that would result from the tissue compression. Consequently, dangerous load levels potentially could result. Second, the oscillation of soft tissue compression might not permit appropriate reperfusion of soft tissue (as would be expected during walking).

RESULTS—We subsequently, however, have turned our attention to a progression of alternative design concepts that appear to demonstrate much more desirable attributes. As in the initial design concept, soft tissue will be compressed by a disk at the end of a shaft. In our alternative design concepts, however, the shaft will be driven pneumatically to permit us to control the load on shaft (which is transmitted to the soft tissue) rather than its displacement. A priori knowledge of safe input loading can be estimated from knowledge of typical plantar foot pressures experienced during walking. Additionally, this design concept involves a step load input which will simplify computation of soft tissue compliance and resistance from measured output soft tissue load and displacement. Following a soft tissue loading, the shaft can be retracted for a sufficient period of time to allow reperfusion prior to next loading trial.

[220] MEASURING THE EFFECTS OF VESTIBULAR STIMULATION ON CHILDREN WITH CEREBRAL PALSY

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PURPOSE—The vestibular stimulation project seeks a correlation between whole body vertical oscillations and the reduction of spasticity in those with cerebral palsy (CP). Over the past 2 years this project has taken on two distinct directions. The clinical aspect of the project has taken the form of a small pilot study. This study consisted of 10 subjects with spastic CP. Each subject was tested before and after a 15 min regime of controlled vertical motion, using the well-known leg drop pendulum test. Data from these tests were analyzed and 17 mathematical attributes identified. These attributes could all be related to the degree of spasticity of the limb. Comparison of the attributes before and after vertical stimulation showed that at least one of the 17 changed toward a more reduced level of spasticity in 9 of the 10 subjects. In the subject showing the greatest improvement, 16 of the 17 attributes were changed toward lesser spasticity.

The second aspect of the project concerns itself with more of the theoretical nature of the research. Quite by accident, two of the subjects involved in the pilot study were part of a set of triplets. The third triplet was without disability and was tested as a control. Further investigation with the triplet's data lead to the construction of progressively more complex models of the leg drop pendulum test of these three subjects.

METHODOLOGY—Starting with strictly passive models, we have shown that a nonlinear, second order system, employing exponential springs and dampers, is quite adequate in modeling the nondisabled subject's leg drop test, but is quite inadequate when attempting to model the limb of the subjects with spasticity. Model identification techniques involved the use of optimization algorithms to find model parameters. In the case of the passive models, many of these parameters took on negative values. Negative values of stiffness and dampening coefficients suggest the addition of energy to the model. In addition to the negative model parameters, optimization of the passive models clearly demonstrated the reduction of stiffness parameters when the spastic limb models were compared between the before-and-after stimulation outcomes.

The negative values of optimized model parameters lead us to suspect that a better model could be obtained with the use of active force input in conjunction with a physiologically sound passive model. Investigation along these lines has led to some very interesting results. The addition of active forces to the model result first and foremost in a better fit between model and actual data. In addition, active forces allowed for the elimination of the nonphysiological exponential damper. Of even greater importance, models optimized with active force inputs could be constructed for all three triplets (disabled and nondisabled alike) using the same set of passive parameters; the only differences being in the timing and amplitude of the active forces. In general, the forces required for the models of spastic limb were much greater in amplitude than those required for normal limb. With regard to comparisons before and after vertical whole body stimulation, forces were smaller in amplitude after stimulation but they were also longer in duration. The need for smaller amplitude of active forces is consistent with the reduction of spasticity; however, the increase in amplitude remains a puzzle. Further investigation with these models is ongoing.

PROGRESS—Presently we are investigating the use of velocity feedback. This has proven to result in models with the best fits to the actual data of all those investigated so far. Addition of velocity feedback has allowed the removal of a second nonphysiological element, a coulomb friction element was introduced into the models early in the investigation in order to dampen out unwanted oscillations at the end of the movement. This element has proven to be unnecessary in the models with velocity feedback. Comparisons of the feedback forces have not been completed at this time.

RECENT PUBLICATIONS FROM THIS RESEARCH

Leg drop pendulum test in spastic cerebral palsy: a passive, nonlinear, second order model. Fee Jr J. In: Proceedings of the Thirteenth Southern Biomedical Engineering Conference; 1994:923-26.

Measuring leg motion changes following vertical vestibular stimulation: a case study. Samworth KT, Fee Jr J. In: Proceedings of RESNA International '94; 1994 June, Nashville, TN. Washington, DC: RESNA Press: 161-3.

X. Oncology

[221] THE STRENGTH OF HUMAN CORTICAL BONE WITH SIMULATED METASTATIC DEFECTS

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PURPOSE—The objective of this study is to establish a technique for predicting the strength of bones with metastatic tumors. The underlying hypothesis of this study is that the risk of fracture is related to the strength of bone with its defect, and that this strength is a function of three-dimensional geometry and the distribution of mechanical properties. This study will take advantage of CT scan data to generate three-dimensional patient-specific finite element models—models that would demonstrate stress distributions in the bone surrounding the defect and predict the load at which the bone would fail.

METHODOLOGY—The proposed research contains both an experimental and a theoretical component. The experiment requires 15 matched pairs of human femoral shafts to be subjected to four-point bending. One of each pair will be left intact, and its failure load will represent whole bone strength; the other will have a spherical defect (6, 12, or 18 mm in diameter), and its failure load will represent the strength of a bone with a simulated metastatic tumor. CT scans will be taken of all the bones prior to mechanical testing and will be used for the generation of finite element models. The theoretical component of this research involves the generation of the models and calculating failure loads based on model predictions. A cylindrical model will be generated by using the CT scan data solely to ascertain periosteal and endosteal diameters; modulus and strength are set to constant values found in the literature. A second model will utilize CT scan data to generate geometries more representative of the true bone geometry.

A third model will use the CT scan data both to characterize the true geometry and allow variation in material properties. All three of these models will predict strengths that are to be correlated to the failure strengths of the experimental bones, and thus test our overall hypothesis that the use of CT data can improve the prediction of bone strength.

PROGRESS—The design and development of the finite element modeling technique and mechanical testing protocol have been accomplished. Modeling and mechancal testing of bone is well underway.

RESULTS—Early findings have demonstrated that assumptions of cylindrical geometry and homogeneous material properties greatly affect the finite element modeling predictions. Geometry especially seems to be a critical determinant in the distribution and magnitude of stresses of a modeled bone.

FUTURE PLANS—The technology developed in this study can potentially be used to identify patients at risk of fracture from metastic defects in the femur.

XI. Orthopedics

A. General

[222] MECHANICAL REGULATION OF SKELETAL TISSUE IN NORMAL AND PROSTHETIC JOINTS

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PURPOSE—The purpose of this study is an examination of the influence of mechanical stress histories in the development, maintenance, and adaptation of skeletal tissues. Investigations in the rapidly developing field of mechanobiology will play a critical role in the better understanding of a variety of orthopedic issues including: fracture healing; cartilage repair and regeneration; initial implant fixation; and long-term bone remodeling after joint arthroplasty.

In this study we are developing theoretical and computational models that can be used to emulate skeletal development, maintenance, and adaptation using a multiple loading, stress history approach. The end product of this work will be a consistent framework of theories and models that can be used to predict the biological events associated with the initial fixation and the subsequent bone remodeling around prosthetically replaced joints. This work will have a direct benefit for the aging and infirm veteran requiring total joint replacement.

METHODOLOGY—In this study we will use both theoretical and computational (nonlinear optimizations and finite element modeling) approaches to examine the role of mechanical loading histories in skeletal tissue biology. Our computational models will include linear and nonlinear, 2- and 3-D models. Simulations using these models will be validated by comparison with both existing and new histomorphological studies. These simulations will involve both simple model systems having idealized geometries, as well as highly complex systems and geometries such as the proximal femur, knee, vertebra, and calcaneus.

RESULTS—A significant outcome of this study has been the development of a quantitative theory relating skeletal tissue to the imposed mechanical stimuli. This theory has been integrated into a computer algorithm we are using to examine initial skeletal development (morphogenesis), growth, maintenance, adaptation, and aging. This algorithm shows great promise for better understanding skeletal pathologies as well as the nature of bone remodeling caused by the presence of orthopaedic implants (e.g., total joint replacements, fracture fixation devices).

During the previous year we have made significant advances in two areas: nodal-based bone remodeling and the determination of bone and joint loads from bone density distributions. The nodal-based remodeling approach has lead to a significant reduction in the amount of computer time required for each simulation. These advances are described in the publications that follow.

FUTURE PLANS—We have recently incorporated anisotropy into the bone remodeling algorithm using a approach that permits a determination of the bone

density and orientation, using a novel approach that does not depend upon the introduction of additional morphological parameters.

RECENT PUBLICATIONS FROM THIS RESEARCH

Cell response lag times affect bone adaptation simulations. Levenston ME, Beaupre GS, Jacobs CR, Carter DR. Trans Orthop Res Soc 1994:19:566.

Fading memory of recent loading enhances short-term bone adaptation simulations. Levenston ME, Beaupre GS, Jacobs CR, Carter DR. In: Proceedings of the Second World Congress of Biomechanics; 1994:II:55a.

General approach for adaptive bone remodeling incorporating simultaneous density and anisotropy considerations. Jacobs CR, Simo JC, Beaupre GS, Carter DR. In: Proceedings of the Second World Congress of Biomechanics; 1994:II:56a.

Influence of femoral component collar or taper on stress transfer and micromotion. Mandell JA, Beaupre GS, Goodman SB, Carter DR. Trans Orthop Res Soc 1994:19:224.

Modeling diaphyseal changes during growth and adaptation. van der Meulen MCH, Beaupre GS, Morey-Holton ER, Carter DR. In: Proceedings of the Second World Congress of Biomechanics; 1994:II:58b.

Role of loading memory in bone adaptation simulations. Levenston ME, Beaupre GS, Jacobs CR, Carter DR. Bone 1994:15:177-86.

[223] HIP FRACTURE RISK ASSESSMENT USING AUTOMATED 3-D FINITE ELEMENT MODELING

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A371-3RA)*

PURPOSE—The purpose of this project is to establish a technique for assessing the risk of proximal femoral (intertrochanteric and femoral neck) fracture in elderly patients.

In this study, finite element (FE) modeling and mechanical testing will be used to predict and measure the strength of cadaveric femora. The ultimate goal of this project is to develop a fracture risk index. Values of this index for an individual patient would be derived from patient-specific three-dimensional (3-D) FE models.

METHODOLOGY—Forty cadaveric femora from subjects over 50 years of age will be used in this study. Twenty of the femora will be examined under loading conditions simulating the stance phase of gait. The remaining 20 will be studied under conditions simulating a fall. A patient-specific 3-D FE model of each femur will be automatically generated from CT scan data. The mechanical properties of the elements of these models will be derived from the CT scan data, thereby enabling the inhomogeneity of the femur to be represented. Based on the FE model and CT scan data, the strength of each bone will be estimated and the location of fracture will be predicted. The FE models will be verified by mechanically testing the femora to failure.

PROGRESS—Our existing automated FE modeling software has been modified for operation on a workstation. A graphical interface that enables rapid preprocessing of CT scan data and postprocessing of FE analysis data has been written. This software will be useful for the current study as well as for future applications in the clinical setting. FE analysis and mechanical testing of femora are underway.

RESULTS—The fracture locations predicted by the FE models have tended to agree with the actual fracture locations obtained during mechanical testing. It appears that the FE models may consistently overestimate bone strength, but that the correlations between predicted and measured strength may be quite high.

FUTURE PLANS—We anticipate that the technology being developed in the present study will allow us to identify patients who are at great risk for hip fracture so that preventative measures can be taken. Our new software will enable analysis of a patient's femur to be performed by a technician in a few hours, thereby making such analyses economically feasible.

RECENT PUBLICATIONS FROM THIS RESEARCH

Validation of an automated method of three-dimensional finite element modelling of bone. Keyak JH, Fourkas MG, Meagher JM, Skinner HB. J Biomed Eng 1993:15:505-9.

Correlations between orthogonal mechanical properties and density of trabecular bone: use of different densitometric measures. Keyak JH, Lee IY, Skinner HB. J Biomed Mat Res 1994:28:1329-36.

Post-failure compressive behavior of trabecular bone in three anatomic directions. Keyak JH, Lee IY, Nath DS, Skinner HB. Trans Orthop Res Soc 1994:19:430.

Three-dimensional finite element modeling of a cervical vertebra: an investigation of burst fracture mechanism. Bozic KJ, Keyak JH, Skinner HB, Bueff HU, Bradford DS. J Spinal Disorders 1994:7(2):102-10.

[224] BIOCHEMISTRY OF CARTILAGE IN A MODEL OF DISUSE AND DIFFERENT TYPES OF RECOVERY: A PILOT STUDY

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PURPOSE—The purpose of this project is to explore critical variables governing recovery of cartilage from disuse atrophy. Pathological reduction of cartilage volume during disuse is an important finding after fractures and other injuries, where immobilization of the limb is necessary. In disuse atrophy, the accepted dogma is that most or all of the disturbed cartilage metabolism represents an effect on chondrocytes of reduced physical forces and secondary decreased synthesis of matrix components. However, the evidence in several studies, including recent data from our laboratory, of accelerated breakdown of proteoglycan (PG) and abnormal loss of PG aggregates as signs of accelerated proteolysis, has been overlooked. We believe that the loss of proteoglycans, because of failure of synthesis, may quickly lead to noxious stimulation of chondrocytes and a secondary enhancement of proteolysis and cartilage damage. Remobilization with a walking exercise program will result in reversal of these metabolic events and repair of the articular cartilage. In contrast, in rehabilitation with running, we hypothesize that changes in the metabolic activities of the chondrocytes will mimic changes seen in early osteoarthritis, resulting in severe degenerative changes in the matrix.

METHODOLOGY—Canine subjects include: 2 groups of control animals studied at 4 and 7 weeks, 1 group of immobilized weight-bearing for 4 weeks, and another group for 7 weeks. Two additional groups, after 4 weeks of disuse atrophy, undergo respectively conservative recovery walking or treadmill exercise for 2 weeks. The samples of cartilage taken after sacrifice are assayed in respect to histology and biochemistry. Metalloprotease MMP-1, 2, and 3, and the tissue inhibitor of metalloproteases (TIMP) are measured. Proteoglycan aggregation disrupted by these proteases is measured by transport ultracentriguation.

PROGRESS—We have described the first data showing that stromelysin and 72kDa gelatinase are elevated and TIMP are reduced at 4 and 7 weeks of disuse atrophy in canine knee joints. Collagenase levels are normal. Most of the results at 4 weeks were completed last year and 7 weeks of atrophy this year.

RESULTS—In addition, there has been completed and published a collaborative study on biomechanics on proteoglycan profiles in disuse atrophy in comparison to osteoarthritis. We have found that the link protein poor proteoglycan aggregates are reduced in the top third of the cartilage in contrast to osteoarthritis where the link protein rich aggregates are lost mostly from the middle and bottom thirds. In atrophy, the collagen network (coll II) is well protected in terms of tensile modules and so forth, but is badly damaged in even mild osteoarthritis.

FUTURE PLANS—Next year we are to study the genetic types of collagen on the surface of Type II collagen, collagen IX, and XI for likely degradation in disuse atrophy, as a result of the elevation of the

above proteases. We will study the effect of recovery with exercise on the protease levels. We will also study the kinetics of IL-1 25 albumin disappearance from the joints in disuse compared to normals. A hypothetical protein clearance in disuse might explain elevation of enzymes and degradation products in disuse synovial fluid.

RECENT PUBLICATIONS FROM THIS RESEARCH

Centrifugal and biochemical comparison of proteoglycan aggregates from articular cartilage in experimental joint disuse and joint instability. Muller FJ, Setton LA, Manicourt DH, Mow VC, Howell DS, Pita JC. J Orthop Res 1994:12:498-508.

Cartilage metalloproteases in disuse atrophy. Grumbles RM, Howell DS, Howard GA, et al. J Rheumatol. In press.

[225] PREDISPOSING FACTORS IN DISC PROLAPSE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A627-RA)*

No report was received for this issue.

[226] PULSED LASER DEPOSITED HYDROXYAPATITE COATING FOR PROSTHESIS-BONE BONDING

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A714-RA)*

No report was received for this issue.

[227] DIAGNOSIS OF CARTILAGE DEGENERATION: QUANTITATIVE SURFACE SPECTROSCOPY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A656-RA)*

No report was received for this issue.

[228] COMPARISON OF EVENTS IN BONE HEALING INFLUENCED BY CCEF AND PEMF SIGNALS

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PURPOSE—Questions regarding the efficacy and duration of application of exogenous electricity for fracture healing and the predictability of outcome remain to be answered. The purpose of this project is to identify critical events in bone repair influenced by two signals presently in clinical use: capacitively coupled electric field (CCEF) and the electric field component of pulsed electromagnetic field (PEMF/EF).

METHODOLOGY—The project was designed to test the following hypothesis: CCEF and PEMF/EF signals stimulate new bone formation in delayed-healing fractures by inducing proliferation of osteogenic cells and the subsequent synthesis of an ossifiable matrix. A corollary hypothesis is that these signals have no direct effect on the process of mineralization. If this hypothesis is proven, the duration of treatment, which currently lasts several months, can be reduced significantly. These hypotheses were tested by evaluating the repair response in segmental defects in canine ulna, without and with stimulation by the electrical signal for 3 weeks and 6 weeks. The response was evaluated by determining the effects of the signal on healing of a 6 mm defect as measured in terms of mineralization and mechanical rigidity at 12 weeks after osteotomy, and on proliferation of osteogenic cells and synthesis of bone-matrix proteins in a 10 mm segmental defect at various early time-points.

In addition, an *in vivo* segmental defect model in the rat fibula and an *in vitro* model that used explants of canine fracture callus in tissue culture medium were used to obtain supplementary data for interpretation of results from the *in vivo* canine studies.

RESULTS—The time-average of the electric field was calculated from weekly measurements in the canine models and designated as electric field dose. With three-point bending rigidity as the response, the dose-response for the CCEF signal in the 6 mm defect model showed a peak at 257 mV/cm, having a peak rigidity (experiment/intact ratio) of 1.7 and a width at half-maximum of 46 mV/cm. In addition, the data also suggest that stimulation for 6 weeks does not have any advantage over a 3-week stimulation. Biochemical analysis of repair tissue from the 10 mm defect model on days 5, 8, 11, and 22 showed the following results: total DNA and alkaline phosphatase activity were increased on days 5 and 8, but not on days 11 and 22, by CCEF stimulation; total protein was unchanged on day 5, but markedly increased by day 8; and CCEF also increased both collagen types I and II at all four time points. From measurements of pH of the repair tissue *in vivo* in the rat model and calcium content of the same tissue after sacrifice, we found that the phase of rapid calcification of the repair tissue (2–3 weeks) is associated with a rapid increase of pH from acidic to alkaline values. In the callus-explant culture model, the proximal, middle and distal segments of the repair tissue were investigated separately. The stimulatory effect of CCEF was mostly in the middle segment: total DNA and protein both increased on day 3, but there was no change in alkaline phosphatase activity. In nonhealing skeletal defects, the middle part is usually mostly fibrocartilaginous tissue. These results suggest that in our *in vivo* canine model, CCEF acted during the first three weeks to stimulate osteogenesis in the middle of the skeletal defect.

IMPLICATIONS—The results of this study have provided a scientific basis to attempt a shorter duration of treatment of fractures with the CCEF and PEMF signals in clinical trials.

[229] NEW STRATEGIES FOR LONG-TERM PERFORMANCE OF FEMORAL PROSTHESIS

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PURPOSE—In hip arthroplasty with noncemented, porous-surfaced femoral prostheses, it is important to develop procedures that would allow prostheses to remain functional for several years in active, older people as well as in younger people, so that repeated revisions can be avoided. The purpose of this project is to develop new strategies to enhance long-term performance of femoral prostheses by adjuvant treatments with selected therapeutic agents applied locally during hip arthroplasty in an experimental model.

METHODOLOGY—The main experimental model is a canine femoral prosthesis implanted in the right femur of the dog. Dogs implanted with the femoral component of the canine hip prosthesis are sacrificed at 6 weeks and 6 months for evaluation of short- and long-term performance, respectively. The femur with the implant is sectioned transversely and adjacent sections are used for push-out tests, histology, and scanning electron microscopy in the backscattered electron mode (SEM/BSE). Osseous and soft tissue formation within the pores of the prosthesis and around it and remodeling changes in the femur are quantified from SEM/BSE and histology using a computer-aided morphometry system. Standard statistical methods are used to determine correlations between mechanical and morphological data from adjacent transverse sections. Statistical comparisons between groups are done by paired analysis of transverse sections obtained from a given anatomical site.

PROGRESS—The canine prostheses were supplied to us by Zimmer, Inc. We also developed two supplementary models: a rat "medullary chamber model" and a canine bone marrow cell culture model. In the rat model, the medullary canal of the femur is reamed to mimic the procedure in the canine model. In the culture model, marrow cells from the proximal medullary canal of the canine femur are maintained in culture medium. These models are used mainly for two purposes. First, both models may be used to screen potential therapeutic agents and carriers for osteogenic efficiency. Second, studies of osteogenic differentiation of marrow cell culture on solid titanium and titanium fiber-mesh surfaces provide supplementary information on the nature and extent of early osteogenic response of the host tissues after the prosthesis is implanted in the *in vivo* model. Pilot studies using the rat model involved the use of chitosan preparations, hydroxyapatite, TGFbeta, and PDGF in the medullary chamber with and without a thin (0.3 mm dia) titanium wire.

RESULTS—Preliminary results suggested that PDGF may stimulate medullary osteogenesis. However, due to large variability in this model, we concluded it would not be useful as a screening system. Canine marrow cultures were grown on Ti-Al-V alloy, Co-Cr alloy and plastic discs for up to 2 weeks. These cultures demonstrated the beginning of osteogenic differentiation of a subset of cells starting on day 7 of culture. In the experiments using the *in vivo* canine model, push-out data at 6 weeks (from transverse sections of the femur-prosthesis composite) were analyzed for a preliminary group of six dogs (three saline controls, two chitosan-treated and one hydroxyapatite-treated) and more stringent selection criteria were adopted to further reduce variability in the data. Since then, 33 more dogs (27 for 6 week study; 6 for 6 month study) were entered into the protocol. The 6-week dogs were in three groups of nine each; hydroxyapatite-treated, chitosan-treated and saline-treated (controls). All except four of the 6-week dogs and all of the 6-month dogs were sacrificed and push-out strengths (two samples per dog) were determined. Morphometric measurements from histological sections and SEM/BSE images are in progress.

IMPLICATIONS—Results expected from this project on the effectiveness of various adjuvant treatment agents in the canine model can be directly applied to enhance functional performance in human hip arthroplasty.

[230] FACTORS AFFECTING STREAMING POTENTIALS IN HEALING AND REMODELING BONE

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PURPOSE—The processes of bone repair/remodeling are central to the welfare of VA patients after fractures or bone surgery, as well as conditions affecting the homeostasis of bone, ranging from spinal cord injury (SCI) to osteoporosis. While bone repair/remodeling is thought to be influenced by mechanical forces, the transducing signal that controls bone cell activity remains undefined. Circumstantial evidence points to mechanically induced fluid flow in bone, with concomitant production of streaming potentials. For the aging veteran, streaming potentials may have considerable relevance in relation to fractures and internal prosthesis, where loosening or osteoporotic changes at the bone implant interface are major factors affecting patient mobility. Also, knowledge of the role of streaming potentials in disuse atrophy is important post fracture in the aging veteran, patients afflicted with osteoporosis, and in SCI patients.

Specifically, the aim of this research is to identify a new mechanism of action for agents affecting bone healing to achieve increased therapeutic control over healing and remodeling process. If streaming potentials prove to be a controlling factor in bone homeostasis and prove to be modifiable by external biochemical or mechanical intervention, then a new treatment modality may be added to the VA's armamentarium.

The goal of this study is to determine whether or not certain pharmacological agents, or circulatory conditions which affect bone healing, regeneration, or remodeling may act in part by altering the magnitude or frequency characteristics of the streaming potentials produced by bone in response to a standard mechanical loading regime. If so, then similar techniques might be used clinically to strengthen streaming potential signal and enhance bone formation clinically.

METHODOLOGY—In our experimental studies, a modified drill hole model is used to study the characteristics of streaming potentials produced by healing of this defect with new bone. Factors that may affect the magnitude or frequency dependence of streaming potentials such as circulation (increased and decreased blood flow), agents promoting bone formation/remodeling, and agents inhibiting bone formation/remodeling are being studied using our model in living canine tibia. In this model, pharmacologic agents are introduced via the femoral artery where streaming potentials are generated by a servo-hydraulic device coupled to the bone by a 4 mm pin at each end of the diaphysis.

PROGRESS—We have demonstrated that both Guanidine HCl and Protamine Sulphate will reduce the magnitude of load generated streaming potentials in bone, and that sympathectomy, with associated changes in circulation, will increase the magnitude of pulse-generated streaming potentials in canine tibia.

RESULTS—The project ended Year I on schedule with the first series of six animals completed, including tests of the best configuration and time interval of healing to meet the project needs (5 mm diam, 8 wk healing). It was found that covering the hole with a delrin plate until used for measurement procedures provided the best test bed with a smooth new bone surface. Under these conditions, the drill hole healed with a flat cortical surface and a porosity of 20-40 percent. At the beginning of Year II, measurements on animals undergoing sympathectomy were begun, and are continuing with the assistance of Dr. Lee; a total of six animals have been tested to date. In addition, we have shown so far that Guanidine HCl reduces the magnitude of streaming potentials in living bone. This reinforces our prior work showing a similar effect of protamine and brings us one step closer to the goal of finding an agent that will increase streaming potentials and provide a new treatment modality for aging VA patients. So far, NaF, bisphosphonates and calcitonin have not affected streaming potentials.

FUTURE PLANS—Work will be completed on changes in streaming potential magnitude in response to sympathectomy as well as to additional biochemical

agents that affect bone including, prostaglandins, and indocin. Long term, we aim to identify a pharmacologic agent that will increase the magnitude of streaming potentials and possibly lead to enhanced bone repair.

[231] BIOCHEMICAL ANALYSIS OF SYNOVIAL ACTIVATION IN JOINT DYSFUNCTION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A052-7RA)*

No report was received for this issue.

[232] ORIGIN AND CHARACTER OF REGENERATE BONE

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No report was received for this issue.

[233] IN VIVO MEASUREMENT OF VERTEBRAL DISPLACEMENT AFTER LUMBAR FUSION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A738-RA)*

PURPOSE—Posterior spinal fusion is performed for a large variety of clinical problems, including spinal trauma with spinal cord injury, degenerative changes of the lumbar spine, tumors, and scoliosis. Spinal instrumentation systems have increased the fusion success rate. However, this increased rate comes attendant with higher risks of device-related osteoporosis, as well as accelerated degeneration of adjacent vertebral levels near a stiff fusion segment. To date, there are no data on the absolute mechanical environment that leads to fusion and/or non-union of the spine. In this study, we propose to characterize and quantify the biomechanical environment in which a lumbar spine fusion occurs in a goat model.

METHODOLOGY—An implantable transducer system to measure intervertebral motion has been developed. Motion will be measured *in vivo* and compared in normal, injured, and surgically fused spines. Fusion using bone graft alone and bone graft augmented by rigid or semi-rigid spinal instrumentation will be compared. The mechanical data will be correlated with radiographic and histologic evaluation of fusion quality and vertebral body density. In Phase 1, cadaveric

goat spine specimens were tested *ex vivo* to determine displacement across L4-5 using a new transducer system based on Hall-effect devices. The transducers were calibrated by simultaneous measurement of displacement with extensometers. In Phase 2, Hall-effect transducers were implanted across the normal and destabilized L4-5 disc space of live goats. The output of the transducers was measured periodically in a variety of postures, exercises, and manipulated positions for 6 to 12 weeks. The animals were then sacrificed, and the transducer systems recalibrated by testing the excised spine on the MTS machine. In Phase 3, three experimental treatment groups are similarly studied. Surgery includes laminotomy, resection of the facet capsule and the ligamentum flavum, and transducer implantation in all groups. A posterolateral bone graft fusion across L4-5 was performed in Group I. Group II will have the fusion augmented with a semi-rigid pedicle screw device. In Group III, a rigid pedicle screw system is being implanted.

PROGRESS—Phases 1 and 2 have been completed. Phase 3 surgeries are ongoing, with some goats having completed the *in vivo* portion of the study. Data has been used to quantify the surgical artifact of the sensor implantation surgery. The passive range of motion of a spinal segment, controlled by osteo-ligamentous structures, has been found to be 2 to 4 times greater than the range allowed under normal muscular control in the spine. Destabilizing injury to posterior ligaments increased these ratios by 30 to 100 percent. While the passive characteristics of spinal motion, including neutral zone and range of motion, are controlled by osteo-ligamentous limits, functional motion occurs in a portion of that range that is determined by muscular response to neural systems, or the active subsystem of the spinal column.

RECENT PUBLICATIONS FROM THIS RESEARCH

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In vivo measurement of intervertebral motion in the lumbar spine. Kunz DN, Zdeblick TA, McCabe RP, Vanderby R. In: Proceedings of the International Society for the Study of the Lumbar Spine; June 1994, Seattle, WA.

In vivo comparison of the effect of muscle activity on the mobility of the normal and injured lumbar spine. Kunz DN, Zdeblick TA, McCabe RP, Vanderby R. In: Proceedings of the ASME Summer Bioengineering Conference; July 1995, Beaver Creek, CO.

[234] PREDICTION OF BONE ADAPTATION BASED ON DAMAGE AND REPAIR IN BONE

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Sponsor: *Health Research Board, Ireland; Italian Government; Commission of the European Communities*

PURPOSE—The work reported here forms an ongoing study, begun in 1988, into the fundamentals of bone remodeling. Our research aims to measure bone remodeling *in vivo,* both in animals and in human patients following orthopedic surgery, and to make predictions using computer modeling via the finite element (FE) method.

METHODOLOGY—Animal studies have been carried out using 36 sheep; one third were subjected to ulnar osteotomy, and in one third the ulna was reinforced using a metal pin. Remodeling after 3, 6, and 12 months was measured and compared to a control group. Methods included: bone sectioning for measurement of area and calculation of second-moment (I) values; histology; flourochrome marking; and a method of strain measurement on the forelimb *in vitro* after sacrifice, which provides a test of the structural stiffness of the bone system.

Numerical studies modeled the above animal tests and also total hip arthroplasty in humans, using various prosthesis options. FE analysis combined with damage mechanics was used to predict both the initial tendency to remodeling and the time-course of bone deposition/resorption.

More detailed studies were conducted on complex FE models made of individual features of the bone microstructure (osteons, cement lines) with the

aim of quantifying the effect of microdamage (cracking) on local strain.

PROGRESS—Initial results are promising though further analysis is ongoing. Animal experiments showed that remodeling can be detected and quantified using all of the above methods. Increases and decreases in the mass of the radius were detected following osteotomy/pinning respectively. At 3 months postoperative, these effects are masked by a trauma reaction, which always causes a mass increase, but by 9 months the expected remodeling effect were clear.

RESULTS—FE analysis combined with damage-accumulation theory is a useful method of predicting the tendency toward remodeling; initial predictions are supported by results from animal studies and by measurements of calcar resorption in patients. On a fundamental level the mechanics of cracking and its relation to damage accumulation and remodeling has been studied and definite links established.

RECENT PUBLICATIONS FROM THIS RESEARCH

Experimental and numerical pre-clinical evaluation relating to total hip arthroplasty. McNamara BP, Toni A, Taylor D. In: Proceedings of the 2nd International Conference on Computer Methods in Biomechanics, Swansea, UK 1994.

Prediction of bone adaptation using damage accumulation. Prendergast PJ, Taylor D. J Biomech 1994:27:69-72.

Prediction of bone remodelling around hip prosthesis stems based on altered microdamage accumulation in bone tissue. McNamara BP, Prendergast PJ, Taylor D, Toni A. In: Proceedings of the 41st Spring Meeting ORS; Orlando, FL 1995:544.

[235] THREE-DIMENSIONAL RECONSTRUCTION OF SCOLIOTIC DEFORMITIES AND EVALUATION OF TREATMENTS

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Sponsor: *National Science and Engineering Council of Canada; Medical Research Council of Canada; National Health Research and Development Programme; Formacion d'Chercheurs à la Recherche*

PURPOSE—The purpose of this research program is to provide to clinicians 3-D tools to evaluate scoliotic deformities as well as the effect of orthopedic treatments such as orthoses or surgery.

METHODOLOGY—Three-dimensional reconstruction of the spine, rib cage, and pelvis is obtained by X-raying scoliotic patients in a positioning apparatus. Postero-anterior (PA), lateral, and PA numerical radiographs at a 20° downward angle are taken inside a calibrated volume. Rib midlines are reconstructed in 3-D by digitizing 11 points per rib. Reconstruction of the spine, using the DLT method, involved the digitization of 6 landmarks per vertebra: center of endplates and tips of both pedicles. New developments allow 3-D reconstruction of vertebral bodies as well as spinous processes and intervertebral articular facet joints. By digitizing the image extremities of the vertebral body, it is possible to represent each endplate by an ellipse of accurate dimensions and orientations in space, allowing measurement of vertebral wedging. Articular facet reconstructions are obtained by digitizing points forming a volume of interest around articular processes and by adding one CT slice per vertebral anatomical level. Maximum errors on facet joint positions and orientations were found to be less than 2 mm and 3.5°, respectively. On these 3-D reconstructions, reference vertebral models of each anatomical level (obtained by serial CT slices on a spinal cadaveric specimen) are mathematically deformed in order to fit as well as possible vertebral reconstructed landmarks and to give to clinician realistic, personalized, and accurate representations of scoliotic deformities.

PROGRESS—Using such methods, clinical studies were done on two scoliotic patient groups to evaluate both the immediate effect of the Boston brace treatment and the geometrical changes produced by the surgical Cotrel-Dubousset instrumentations (CDI).

RESULTS—Results concerning the immediate effect of the Boston brace revealed that there were almost no

correction of the rib hump, vertebral rotation, and orientation of the plane of maximum deformity. There was also a flattening of the back even if correction was achieved in the frontal plane. In brief, there were almost no 3-D correction produced by the Boston brace, explaining why prevention of progression is the best clinical result to be expected by this treatment. On the other hand, evaluation of the CDI revealed that this surgical procedure modifies "en bloc" the geometrical aspect of the spine by recreating the sagittal profile and correcting the scoliotic curve, but produces hardly any derotation of the apical vertebra at all. To complete this last study, a project involving per-operative measurements during surgery is in progress.

RECENT PUBLICATIONS FROM THIS RESEARCH

Application des techniques d'imagerie, de reconstruction, de modelisation et d'analyse 3D des deformations scoliotiques a l'etude de l'effet immediat des corsets de Boston. Dansereau J, Labelle H, De Guise J, Bellefleur C, Andre B, Beauchamp A. J Minerva Ortoped Trauma 1993:44:549-53.

Optimized vertical stereoradiographic setups for the clinical three-dimensional reconstruction of the scoliotic spine. Andre B, Dansereau J, Labelle H. J Biomech 1994:27:1023-35.

Comparison between pre and postoperative 3-d reconstructions of idiopathic scoliosis with the c-d procedure. Labelle H, Dansereau J, Bellefleur C, Poitras B, Rivard C-H, Stokes IAF. Spine. In press.

3-D Effect of the Boston Brace on the Thoracic Spine and Rib Cage. Labelle H, Dansereau J, Bellefleur C, Poitras B. Spine. In press.

[236] THE EFFECT OF A PLASTER CAST ON LUMBOSACRAL JOINT MOTION

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Sponsor: *St. Maartenskliniek*

PURPOSE—External lumbar supports are widely used in the treatment of low back pain. Besides conservative treatment, they are also applied to ascertain the effect of immobilization preoperatively, when spinal fusion is being considered, and to support the spine postoperatively until fusion has occurred. The most important effect expected from the support is the restriction of lumbosacral movements. Adding unilateral hip immobilization to the lumbar support should provide maximal stabilization of the lumbosacral joint. The purpose of this study was to assess the effect of a plaster cast on the mobility of the lumbosacral joint.

METHODOLOGY—Ten patients with intractable low back pain volunteered for this study. All patients were suspected of having instability of the lower lumbar spine and had been admitted for a temporary, percutaneous, transpedicular fixation test. Two Schanz screws (5 mm diameter) were inserted into the fourth (4 patients) or fifth (6 patients) lumbar vertebra, and two screws were inserted into the sacrum. By external fixation of the screw ends, the effect of immobilization of the lumbosacral spine can be analyzed. In the present study the external fixation was removed, permitting free mobility of the vertebrae involved. A set of reflective markers was mounted on the transpedicular screws. The movement of the markers was measured with a 3D-motion analysis system (PRIMAS). In this way, the translations (accuracy ±1 mm) and rotations in the frontal, sagittal, and transversal planes (accuracy ±0.5°) could be measured. The movements of the vertebrae were measured with the patient in neutral erect position, with maximal spinal flexion, with maximal spinal extension, with maximal pelvic tilt, and while walking. The same sequence was repeated twice with the patient wearing a plaster cast with, and once without, unilateral hip fixation. For all exercises, the total range of motion for the rotations and translations in the three planes were calculated. By means of a repeated measurement two-way analysis of variance (ANOVA), the values of these ranges in the condition without support (control condition) and in both cast conditions were compared.

RESULTS—The measured translations were of the order of 1 mm, which was considered too small compared to the accuracy of the system; therefore, they

were excluded from further analysis. Noteworthy rotations (over 1.0°) were only found in the sagittal plane. In the condition without support as well as in both cast conditions, inter-individual differences were considerable and the stabilizing effect was not predictable for any patient. In all three exercises, there was no significant difference in the sagittal rotations.

IMPLICATIONS—In this study no significant immobilization effect of the plaster casts with or without unilateral hip immobilization on the sagittal rotations of the lumbosacral joint was found.

As far as this study is concerned, the decrease in pain experienced by patients with chronic low back pain wearing a plaster cast cannot be explained by the immobilization of the lumbosacral joint. On the basis of this study, the use of this type of cast as a simulation of a spinal fusion of the lumbosacral joint is not recommended.

[237] FINITE ELEMENT MODELS GENERATED FROM MAGNETIC RESONANCE IMAGES

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Sponsor: *Engineering Foundation*

PURPOSE—The long-term goal of this project is to develop an IGES-like (Initial Graphics Exchange Specification) link between Magnetic Resonance Imaging (MRI) data and finite element model geometry. IGES allows a nearly transparent transformation from a CAD drawing to a finite element model; current methods for creating a finite element model from MRI data are quite tedious. In the initial stage of the project, the goal has been to generate a three-dimensional finite element model of a tibia from thirty transverse serial images spaced 12 mm apart.

The use of MRI data would allow the generation of a finite element model which matches a specific individual. There are numerous applications where the existence of an individual model is important, particularly for studies related to the disabled since their anthropometrics can vary widely from the general population.

METHODOLOGY—Visual Basic has been used on an IBM-compatible 486 computer to take advantage of the graphical nature of the images. A natural cubic spline parametric representation of the cross section of the body segment is created from the MRI data. Nodal point locations can be interpolated from the parametric functions. Another parametric representation will be created in the transverse direction, and three-dimensional geometry can be reconstructed by "stacking" the geometries of adjacent transverse sections.

PROGRESS—A prototype program shell with a graphic interface has been developed. Functions of local zoom, scroll, point selection, cubic spline fit, and centroid calculation have been developed and incorporated into the prototype. The parametric formulation of a single MRI image is complete.

FUTURE PLANS—The next step is to create the parametric representation in the transverse direction leading to the three-dimensional model. Then the translation of the model data to a finite element input file representation will be performed. Neural network algorithms are being examined as a possible means to improve the edge detection of the magnetic resonance image. Once the interface has been created, plans exist to generate finite element models for osteoporosis studies.

B. Hip Implants

[238] SUITABILITY OF TITANIUM ALLOY AS A JOINT REPLACEMENT BEARING SURFACE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A625-2RA)*

PURPOSE—This study was designed to evaluate the long-term wear resistance of surface-treated titanium alloy when used as a bearing surface in total hip joint replacement surgery.

METHODOLOGY—An eight-channel hip joint simulator is used to replicate the motion of the hip joint during the walking cycle. Treated titanium alloy balls (32 mm diameter) articulate against polyethylene acetabular cups with or without surface treatments. Components are run for the equivalent of 10 years worth of use (10 million cycles). Bovine calf serum is used for lubrication. Polyethylene wear is determined by weight loss at 250,000 cycle intervals. Surface wear is assessed by macro- and microscopic observation. Thickness of the surface treatment coating is assessed by metallurgical techniques.

RESULTS—The task of simulating the "runaway" wear process observed clinically with titanium alloy on polyethylene bearing surfaces has been completed. Particles were generated from bulk polymethylmethacrylate bone cement by shaking the material in a SPEX mill for periods of 30 sec, 1 min, or 2 min. The resulting powder was graded coarse to fine, respectively. The original proposal called for initiating the "runaway" wear process within 10,000 cycles. Rather, a gradual increase in the concentration of the powder was used and the specimens maintained for 1 million cycles at each concentration level. The initial series employed four untreated and four nitrogen ion-implanted titanium balls articulating against standard polyethylene. Initial wear rates were established under clean conditions. At 800,000 cycles the first contaminating dose of powder (50 mg/500 ml of 2-min powder) was added to the serum. Fresh serum with the same concentration of powder was added for the next interval. At the end of 1.4×10^6 cycles only minor burnishing and scratching of the components was observed. No change in the wear rate was observed. Gross blackening of the serum in all chambers was observed with 100 mg powder/500 ml of serum without a change in wear rates. Ion-implanted specimens demonstrated an improved wear rate over the untreated alloy with values of 4.4±7.1 mg/E06 cycles and 5.8±5.8 mg/E06 cycles, respectively.

Two coatings are currently available, nitrogen ion implanted components, and an oxygen diffusion hardened (ODH) coating. Under clean conditions the nitrogen ion implanted components showed excessive femoral ball wear (with obvious removal of the ion impregnated layer) in as little as 3 million cycles. Current tests have just been completed with the ODH treatment demonstrating pristine surfaces through 10 million cycles. The surfaces await detailed analysis.

Due to the scarcity of titanium balls, the program has been expanded to include the generation of polyethylene wear debris from the interface of the polyethylene liner and metal shell. Five components of each of five contemporary acetabular designs were subjected to sinusoidal loading for 10 million cycles. Extrusion of the polyethylene was observed in every design with the amount of extrusion inversely proportional to the number of holes. Surface wear was visualized through inspection of the damage to a thin coating of gold applied to the surface prior to cycling. The amount of abrasion that was evident was directly related to the type of component design (manufacturer).

This portion of the study has been expanded to include a single design of polyethylene and metal shell combination with variables of material (titanium alloy vs. cobalt chrome) and surface finish of the metal shell (polished vs. unpolished). These components are subjected to testing in the wear simulator.

Four unpolished titanium alloy components have completed 10 million cycles and await evaluation.

FUTURE PLANS—Tests are continuing with surface treatments and the metal-backed acetabular designs.

[239] THE EFFECT OF FEMORAL COLLAR GEOMETRY IN HIP REPLACEMENT

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A652-RA)*

PURPOSE—In this study we are examining the design of the collar region of the femoral stem component in hip replacements. The collar region is critical since load transfer between prosthesis and bone is influenced greatly by the presence or absence of a collar. Inappropriate load transfer is known to lead to adverse bone remodeling and implant loosening, which in turn can necessitate surgical revision. The maintenance of adequate levels of stress and strain in the calcar region is considered essential for the long-term success of total hip replacements in the aging veteran population. Without better designs, the longevity of hip replacements in the active or overweight patient will remain limited.

METHODOLOGY—In the present study we are using three approaches to study the effect of collar design on the performance of total hip replacements. These approaches include: computational modeling; *in vitro* testing; and *in vivo* implantation. The computer modeling is based upon the finite element technique. The *in vitro* laboratory testing includes strain gage studies using different collar geometries in synthetic femora and bone analogues. The *in vivo* implantation was conducted in sheep.

PROGRESS—We have used the finite element technique to analyze a series of two- and three-dimensional models. We have used these models to compare four uncemented prosthesis collar designs: flat collar (0 degree collar angle), conical collar (30 and 60 degrees), and near-collarless (80 degrees). We have also analyzed a subset of three-dimensional models. One significant observation from the computational modeling is the sensitivity of the results on the conformity or geometric mismatch of the bone-prosthesis interface. This may have important implications for all total joint arthroplasties, not only hip replacements.

Laboratory testing has been completed on a series of simplified prostheses. These prostheses have been implanted in bone analogues (paper-based phenolic). Subsequent to these tests, results from the computational models have indicated the necessity for additional levels of strain gages. The additional gages have been attached, and testing is currently underway. Pressure sensitive film has been used to record the distribution and extent of collar-bone contact. Implantation of prostheses in synthetic human femora has begun. Strain gage analysis comparing different collar geometries is underway.

Twenty-five sheep received a hemi-arthroplasties of the left hip. Twenty-one sheep survived the initial postoperative period. Two sheep were lost prior to the end of the study. Sacrifice of the remaining 19 sheep took place 1 year post arthroplasty. Histological processing of the retrieved femora is in process.

RESULTS—The results to date have provided new insights into the influence of collar design and load transfer in total hip arthroplasty. This should lead to a direct improvement in the quality of life of not only the aging and infirm veteran, but also any individual requiring total hip replacement.

FUTURE PLANS—By correlating the results of the histological analysis with surgical and design variables, we will be able to identify the parameters which most affect implant longevity.

RECENT PUBLICATIONS FROM THIS RESEARCH

Influence of femoral component collar or taper on stress transfer and micromotion. Mandell JA, Beaupre GS, Goodman SB, Carter DR. Trans Orthop Res Soc 1994:19:224.

[240] WEAR DEBRIS GENERATION IN HIP MODULAR HEAD AND NECK COMPONENTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A672-RA)*

PURPOSE—Because of widespread use of modular components, the concerns over the possibility for corrosion and wear at this interface and the disparate reports as to whether these phenomenon do occur *in vivo,* we examined a large number of retrieved uncemented femoral stems with modular heads. In addition, in an effort to quantify the amount of wear debris potentially generated at these interfaces, mechanical testing and electrozone particle analysis were used to evaluate titanium and cobalt-chromium alloy femoral tapers mated to cobalt-chromium alloy and ceramic femoral head materials.

PROGRESS—One hundred eight uncemented femoral stems with modular heads, retrieved for reasons other than loosening, were examined for interface corrosion. In addition, in an effort to quantify the amount of wear debris generated at modular interfaces due to cyclic loading, mechanical testing and electrozone particle analysis were used to study various surface, material, and design combinations.

METHODOLOGY—*Clinical Retrievals.* A total of 108 porous-coated uncemented femoral stems were examined. All had been inserted without cement and none were loose at the time of retrieval. Implants that were obviously loose, clinically or radiographically, at the time of removal were excluded from the study. Clinical information available in all cases included the manufacturer, metallic composition of the head and stem, patient age, time *in situ,* and reason for removal. All components were ultrasonically cleaned, and a stereomicroscope (to 70 magnification) was used to identify the extent and distribution of corrosion within each modular head and around the neck of each femoral stem. Wear and corrosion were graded on a scale of 0 to 3 with 0 = no abnormality; 1 = superficial scratches, burnishing, or localized pitting; 2 = larger regions of superficial pitting or significant abrasion or galling covering less than 25 percent of the interface; and 3 = extensive areas of pitting or surface degradation involving more than 25 percent of the interface.

Mechanical Testing. Mechanical testing of the modular head-neck interface was performed to evaluate wear particle generation during cyclic loading. Test specimens of the femoral taper were fabricated from both titanium (ASTM F-136) and cobalt-chromium (ASTM F-75) alloys. The specimens had a nominal diameter of 14.05 mm and a taper angle of 5.655±0.045°. Femoral tapers were studied with both a smooth as machined surface (<20 μin) and a roughened (>100 μin) surface. A nitrogen ion implanted smooth surface was also studied.

Mating femoral heads were fabricated from wrought cobalt-chromium alloy (ASTM F-799) and zirconium oxide (Yttrium stabilized). The metal and ceramic femoral heads had a 28 mm diameter and a standard neck length. Additionally, wrought cobalt-chromium alloy heads which resulted an additional 10 mm of neck length were fabricated.

The head-taper combinations were cleaned, assembled, and the interface sealed in Tygon tubing. Three ml of filtered (0.2 micron filter) physiologic saline was then injected into the tube with a syringe. Mechanical testing was performed on an MTS test system. An inverted haversine load with a range of 225 to 2250 N was applied at 10 Hz for a total of 10 million cycles. The load was applied to the femoral

head at an angle of 45° to the long axis of the taper component.

After 1, 5, and 10 million load cycles, the saline contained within the tube was removed for analysis of particle generation. The collected saline was analyzed for the number of particles and the size distribution using electrozone particle analysis.

RESULTS—*Clinical Retrievals.* Bony ingrowth was confirmed histologically in 87 of the 108 cases (81 percent). The average time *in situ* was 20.1 months (range 2 to 84 months). In 91 (84 percent) cases there was no evidence of surface corrosion. In 17 (16 percent) cases there was evidence of corrosion, 14 of which were rated as mild (grade 1) and 3 of which were graded as moderate (grade 2). There were no cases of severe wear or corrosion.

There were 76 cases in which a cobalt-chromium alloy head was mated with a cobalt-chromium alloy stem. In only 5 of the 76 (7 percent) was there any evidence of corrosion that was graded mild (grade 1) in every case. Twenty-nine components mated a cobalt-chromium alloy head on a titanium alloy stem. In 19 cases there was no evidence of wear or corrosion (66 percent). In 7 cases the surface damage was graded as mild (grade 1) and in 3 cases as moderate (grade 2) occurring at an average *in situ* time of 25.5 months (range 8 to 41 months). There were 3 specimens that combined a titanium alloy head with a titanium alloy stem. The average time *in situ* was 16.3 months (range 8 to 32 months). Two of the 3 stems had grade 1 corrosion. No correlation was seen between presence of corrosion and time *in situ*. The average time *in situ* for all components was 20.1 months, which did not differ significantly for the average time *in situ* of 25.4 months for corroded components. There was also no correlation seen between reason for removal and presence of corrosion. Corrosion was significantly more common in mixed alloy systems: 10 of 29 (34.5 percent) exhibited some degree of surface damage, whereas only 5 of 76 (7 percent) of all cobalt-chrome systems exhibited any corrosion or surface wear.

Mechanical Testing. The saline from the mechanically tested specimens revealed that a significant number of particles were generated by all test combinations. The number of particles generated far exceeded the number of particles determined in the stock saline solution or untested assembled test specimens. The wear debris generated was relatively uniform in size with over 99 percent of the particles in the range of 0.255 to 2.306 microns. All combinations generated a significant number of particles, the generation of which was greatest during the first 1 million cycles. The number of particles generated was found to decline per million cycles thereafter. There was no significant difference in the number of particles generated for the different femoral head materials. The roughened and nitrogen implanted surfaces generally reduced the number of particles generated, while the addition of 10 mm of neck length tended to increase particle generation. In general, cobalt-chromium alloy tapers were found to result in a greater number of particles generated regardless of surface finish or head material.

The number of particles generated was found to be related to the dimensional mismatch between taper and head. It should be noted that all components were within design and manufacture specification; however, the number of particles generated generally increased with increased dimensional mismatch, particularly at the 1 million cycle test interval. The effect of dimensional mismatch appeared to be more significant for cobalt-chromium alloy tapers.

FUTURE PLANS—Wear and corrosion do occur *in vivo* in some modular uncemented femoral stems. The mixed alloy combination of a cobalt-chrome head on a titanium alloy stem accounted for the majority of cases. It is apparent that manufacturing methods to minimize corrosion and wear at the head-neck interface should be pursued. Current studies both analytical and *in vivo* are determining the optimal modular taper angle. This data, in conjunction with the determined data related to particle generation and surface and material combinations, is being used to develop a modular conjunction with minimal generation of particulate debris.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Wear and corrosion of modular interfaces in total hip replacements. Cook SD, Barrack RL, Baffes GC, Clemow AJ, Serekian P, Kester MA. Clin Orthop Rel Res 1994:298:80-8.

[241] CHANGES IN BONE BLOOD FLOW ASSOCIATED WITH INTRAMEDULLARY NAILING

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PURPOSE—The purpose of this study is to measure *in vivo* changes in tibial blood flow associated with intramedullary reaming and nailing in a canine model. The changes are being monitored with the use of small implantable blood flow probes placed on the dog's tibial nutrient artery. Baseline measurements are made, after which the tibial intramedullary canals are either reamed, reamed and nailed, or nailed without reaming. Measurements are made for periods of up to 6 weeks. This study will determine the optimal use of nails for tibia fractures.

METHODOLOGY—Fifteen adult male mongrel dogs have been used in this study to date. The probes were attached to the tibial nutrient artery, and the probe exit cable was tunneled subcutaneously along the leg and to the middle of the back, where the probe was allowed to exit the skin for data collection. The dogs are then fitted with jackets to prevent them from damaging the probes. Blood flow probes were implanted bilaterally. A silicone sheet was sutured around the flow probe to secure it into place. Blood flow was measured weekly for seven dogs and daily for the remaining dogs in the study. Measurements have been made as long as 6 weeks postoperative. Two dogs had canals reamed and nailed unilaterally after baseline measurements were made. One dog received a nail with no reaming on the left and a nail with a reamed intramedullary canal on the right. Another dog received a nail with no reaming on the left leg and a reamed right intramedullary canal. Finally, a dog had his left tibia reamed while the other side was reamed and nailed.

Seven mm diameter nails were used in all animals. The probes collect the data and send it to the flowmeter that analyzes it and sends it to a computer to be displayed and recorded. Blood flow is measured at the time the probes are implanted for all dogs as a baseline measurement. For the dogs whose tibias were reamed and/or nailed, readings were taken prior to, and immediately after, the procedure. Readings are then recorded on a daily basis.

PROGRESS—Techniques have been developed to implant and chronically measure blood flow in the canine tibial nutrient artery. Chronic baseline measurements have been developed that do not change with time *in situ*. Measurements are now being taken after the intramedullary procedures.

PRELIMINARY RESULTS—Blood flow intraoperatively measured averaged 1.41±1.03 ml/min. Following probe placement, chronic baseline blood flow averaged 1.82±0.42 ml/min through 3 weeks post implantation. Nailing and reaming significantly reduced post operative blood flow, and the flow rate continued to decrease through 3 weeks post operative for nailed tibia. The average flow rate after reaming and nailing was measured at 0.52±0.22 ml/min a rate described by the linearly decreasing equation $Y=-0.0185\times X+0.738$ with $p<0.005$, where X is days and Y is ml/min. Following tibial reaming without placement of a nail, blood flow logarithmically increased back to normal levels within 2 weeks. The log of the curve was fitted to the equation $Y=0.9972\times X-0.973$, with $p<0.001$. Limited results for unreamed nailed canals did not allow for statistical analysis, but the flow rate and trend reflected that of canals that had been reamed and nailed.

IMPLICATIONS—This study shows that reaming alone does not permanently destroy tibial bone vasculature. Two weeks post implantation data shows that reamed tibias had re-established normal levels of blood flow. Canals that were both reamed and nailed showed a significant decrease in blood flow post operative and continued to decrease through 3 weeks. Nailing alone and reaming with nailing produced similar results. These results do not support theories that intramedullary reaming irreparably destroys tibial

bone vasculature. Blood flow to the tibia was found to re-establish normal levels within 2 weeks after reaming. Tibial nailing, whether reamed or unreamed, has not demonstrated that blood flow ever returns to normal levels, but continues to decrease through 3 weeks.

FUTURE PLANS—We will continue to take data and define the techniques for chronic blood flow measurement. The current amount of baseline data that has been recorded is satisfactory, but more data on reamed, nailed, and reamed and nailed tibias will be obtained. In the future, we plan to evaluate the blood flow rates of the fractured tibia, relative to the normal tibia.

[242] BONE CEMENT COLLAR (BCC) FOR SEALING THE FEMORAL CANAL AROUND NON-CEMENTED PROSTHESES: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #A92-513AP)*

No report was received for this issue.

[243] OPTIMIZED SURFACE BONDING AND STIFFNESS OF FEMORAL ENDOPROSTHESES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A498-2RA)*

No report was received for this issue.

[244] NEW METHODS TO TREAT IMPAIRED FRACTURE HEALING USING GROWTH FACTORS

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PURPOSE—The goal of the proposed research is to develop new, more effective methods to treat fractures that do not respond to normal fracture treatment with the best available methods. These have been termed "biological fracture failures" in the literature. Research during the past decade suggests that several local and systemic growth factors and other local mediator mechanisms may be involved in the endogenous regulation of fracture healing.

METHODOLOGY—Based on this evidence, we propose the following hypothesis: biological failures of

fracture healing are associated with abnormal (low or high) gene expression and/or synthesis of one or more molecular factors during specific early stages of healing. If exogenous agents can be applied to correct these aberrations at the molecular level, normal fracture healing will be restored. The specific objectives of this proposed study are: 1) to determine whether each of the four growth factors TGF, PDGF, IGF-I, and IGF-II applied exogenously can restore normal healing in an *in vivo* rat model of impaired fracture healing; 2) to determine the time-dependent changes in selected indices of osteogenesis in the fracture callus (i.e., the repair tissue in the skeletal defect in the rat model); and 3) to determine the time-dependent changes in both the mRNA and the amounts of growth factors TGF, PDGF, IGF-I, IGF-II, aFGF, and bFGF in the fracture callus in the rat model.

We will use surgically created skeletal defects in rat fibula grafted with an acid-demineralized bone matrix (DBM) cylinder made from femora of allogeneic animals, as experimental models for fracture healing. A 2 mm defect represents a normal healing fracture and 4 mm defect is the model for a delayed healing fracture in this project. The DBM-grafted skeletal defect provides a well-defined fracture site for evaluating the effectiveness of therapeutic agents proposed for stimulation of fracture healing. The experiments have been designed in a normal impaired-restored healing sequence. The first specific objective will be achieved by measuring bending rigidity and mineral content weekly for 8 weeks, to determine the progress and final status of healing of the fibulae.

For the second specific objective, DNA synthesis, alkaline phosphatase activity, total protein, steady-state levels of mRNA encoding bone-matrix proteins (osteocalcin, collagen types I, II, and X), and the amounts of these proteins in the fracture callus excised weekly during 8 weeks will be measured to determine indices of osteogenic response. For the third specific objective, mRNA and amounts of the six growth factors in the fracture callus will be measured at the same 8 time-points when the osteogenic indices are measured. The temporal patterns of the indices of osteogenic response in the skeletal defect and factors that may regulate it (mRNA encoding the six growth factors and the amounts of these peptides) are determined from measurements in these fracture callus specimens. Each of four growth factors (TGF, PDGF, IGF-I, and IGF-II) will be applied to the defect at the time of surgery and callus excised and assayed as above to determine which growth factor stimulates osteogenic response the most. The data will be analyzed to gain insight into the roles of endogenously expressed growth factors in regulating this response.

PROGRESS—Experiment involving the normal healing model is in progress.

RESULTS—This is an initial report; results are not yet available.

IMPLICATIONS—The results of this project may lead to new treatment methods based on an understanding of the cellular and molecular mechanisms involved in stimulation of osteogenic response by growth factors.

[245] CONTINUATION OF THE CENTER FOR THE EXAMINATION OF RETRIEVED, ORTHOPEDIC PROSTHESES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A473-2DA)*

No report was received for this issue.

[246] HIP JOINT BIOMECHANICS: THE EFFECTS OF FEMORAL HEAD ENDOPROSTHETIC REPLACEMENTS

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Sponsor: *National Institutes of Health*

PURPOSE—The implantation of two pressure-instrumented, femoral head prostheses (8 years of data) and the subsequent recovery of one of the prostheses provided a unique opportunity for the study, both *in vivo* and *in vitro* of the human hip joint.

METHODOLOGY—Comparison of the data from the subjects, different in both morphology and gender, provides information on the effects of small size mismatches, less than 1 mm, in prosthetic fit and illuminates the changes cartilage undergoes when in contact with the prosthetic femoral head for extended periods of time *in vivo*. The total of 8 years of pressure data from the two subjects also provides information on the magnitude and location of maximum stresses in the hip joint and on the timing of pressure changes during different maneuvers. The data demonstrate the presence of muscle co-contraction during some movements and quantify the effects of rehabilitation exercises.

The acetabular locations of high pressure regions in general supports Wulff's law connecting bone response to loading history: the higher stress locations on the pelvis corresponded to the most dense bone. The location differences in the regions over which high stresses were measured can be attributed to the slightly oversized and slightly undersized fit of the two prostheses. Regions of high pressure were more localized for the undersized prosthesis in analogy to Hertz stresses. Retrieval of the first prosthesis after 5 years of data acquisition provided the opportunity for recalibration. Although the pressures reported in life were higher than the original calibration, the transducers and data-processing systems proved quite competent to accurately report the higher pressures. We have now retrieved the endoprosthesis from the second subject and will undertake a similar recalibration procedure.

RESULTS—When pressure measurements from the two subjects were normalized by the ratio of body weight over height squared, pressure was found to change over the implantation period in a similar manner for both subjects for the first postoperative year. Maximum normalized pressures were usually found to be slightly higher for the slightly undersized prosthesis, while the maximum normalized pressures covered a similar range for the two subjects despite significant differences in their sex, morphology, mobility, and coordination. The movements for which the highest normalized pressures were measured were different for the two subjects. Rising from a chair resulted in the highest pressure measure for the first subject, while climbing and descending stairs produced higher measurements for the second subject. The highest pressures measured for the second subject were during jumping off a step, a movement not performed by the first subject. The normalized maximum pressures during gait are in the range of 20 to 25 MPA (weight/height) for both subjects during the first year post-operative.

RECENT PUBLICATIONS FROM THIS RESEARCH

In vivo hip pressures: a comparison in two patients. Hodge WA, Krebs DE, Carlson KL, Riley PO, Mann RW. In: Proceedings of the 39th Annual Meeting of the Orthopedics Research Society, San Francisco, CA, February, 1993.

C. Arthritis

[247] INDIVIDUAL ADAPTABILITY AND ITS RELATION TO RECOVERY AFTER THERAPEUTICAL INTERVENTIONS IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Sponsor: *St. Maartenskliniek*

PURPOSE—Individual differences in sensorimotor skills after injury and after therapeutical interventions are evident. In the areas of rehabilitation, orthopedics, and rheumatology, one is often confronted with these differences. Why, for example, does a patient with rheumatoid arthritis (RA) with serious deformities of the hands show a reasonable manual dexterity, while another patient with less serious deformities has great difficulty performing everyday life activities with his/her hands? These differences often can not be satisfactorily explained by differences in technical and clinical aspects of the injury and/or intervention. This project focuses on individual differences in recovery of patients with RA with disease of the lower extremities after therapeutical interventions.

This project is performed in accordance with a theory of recovery of motor control. The main premise of this theory is that RA patients, in order to maintain satisfactory control of posture and gait, are constantly forced to adapt to the peripheral changes of the disease, to pain, and to destruction of the joints of the lower extremities. Therapeutic interventions, such as the prescription of orthopedic shoes and implantation of prostheses, will also tax the adaptive capacity of the nervous system. An investigation will be carried out to determine whether a relation between the ability to adapt to external/peripheral perturbations and the rate of recovery after therapeutical interventions exists. Individual differences in this adaptability are presumed to be an important explanatory factor for individual differences in motor skill recovery.

METHODOLOGY—A group of well-described patients with RA will be studied before and after a number of therapeutical interventions (orthopedic shoes, total knee prosthesis, surgery of foot and ankle). Disease variables such as Erythrocyte Sedimentation Rate (ESR) and Ritchie Articular Index (RAI), and indices of impairment of the lower extremities such as joint mobility, RAI of the lower extremities, and scores of foot deformity will be measured. Health status and a (psychological) coping list will be completed. A series of balance and gait tasks will be performed to ascertain the ability of patients and healthy controls to adapt to external/peripheral perturbations.

PROGRESS—This project is in the process of being implemented. Pilot studies are being conducted to test different task sets on their suitability and applicability for the purpose of the project and for the specific limitations of the RA population.

FUTURE PLANS—After the implementation and the pilot phase, a large group of patients with disease of the lower extremities will be followed for at least 1 year as well as patients scheduled for a therapeutical intervention. The relation between impairment variables, psychological coping, and the balance and gait tasks will be studied.

XII. Orthotics

[248] FES-AIDED PARAPLEGIC GAIT USING A CONTROLLED-BRAKE ORTHOSIS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B579-RA)*

PURPOSE—Restoration of gait to paraplegics using functional electrical stimulation (FES) is a challenging problem. One difficulty is controlling the FES system for stability and smooth gait. It is possible to improve walking function using surface stimulation by adding a mechanical orthosis in combination with the FES. Based on preliminary work of our group, we have developed such a hybrid system for functional FES-aided gait. The orthosis contains controllable friction brakes at the joints. The purpose of the brakes is to shift the burden from having to control the stimulated muscles and spastic reflexes to controlling the brake, a well-behaved mechanical element. To evaluate brake designs and performance, we are testing and comparing the ability of SCI paraplegics to achieve FES-aided gait both with and without the orthosis. The assessment includes kinematic, dynamic, and metabolic variables.

PROGRESS—We have designed and constructed a wearable orthosis that can apply controlled braking loads to the knee and hips. The orthosis structure is fabricated from machined aluminum and chromoly tubing. Braking loads are applied by magnetic particle brakes coupled to the joints through an Evoloid gear transmission. Joint position and torque are measured by sensors. The entire system is controlled by a PC connected to the brace with a long umbilical cable.

The orthosis has been tested on two paraplegic subjects (one extensively) at the West Roxbury VA Medical Center, and one paraplegic subject at the Minneapolis VA Medical Center. Quantitative results from one of the subjects demonstrate gait for longer distances, reduced heart rate, and improved joint trajectory control when compared to FES gait without the brace.

FUTURE PLANS—We are continuing to test the system on additional SCI subjects, building a second generation orthosis incorporating small DC motors at the hips to aid in hip flexion, and developing a product design process for producing commercial versions of the brace. Investigative trials take place at the VA Medical Center in Minneapolis, MN and the West Roxbury VA Medical Center in Boston, MA. Contacts have been initiated with industrial partners to develop the commercial version.

RECENT PUBLICATIONS FROM THIS RESEARCH

Control of standing and gait using electrical stimulation: influence of muscle model complexity on control strategy. Durfee W. Prog Brain Res 1993:97:369-81.

Design of a wearable orthosis for applying controlled dissipative loads to the lower limbs. Durfee W, Goldfarb M. In: Proceedings of the Winter Annual Meeting of the American Society of Mechanical Engineers, 1993.

Preliminary evaluation of a controlled-brake orthosis for regulating FES-aided gait. Durfee W, Goldfarb M, Wiegner A, Walsh N. In: Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 1993.

Verification of musculoskeletal models for FES applications. Durfee W. In: Proceedings of the IFAC Symposium on Modeling and Control in Biomedical Systems, 1994.

Controlled-brake orthosis for FES-aided gait (Thesis). Goldfarb M. Cambridge, MA: Department of Mechanical Engineering, Massachusetts Institute of Technology, 1994.

[249] DEVELOPMENTAL ENHANCEMENT AND APPLICATION OF THE VA-CYBERWARE PROSTHETICS-ORTHOTICS OPTICAL LASER DIGITIZER

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A514-RA)*

PURPOSE—The objectives of this project are: 1) to continue developmental enhancement of the VA-Cyberware Prosthetics-Orthotics Optical Laser Digitizer; and 2) to conduct primary application studies with the optical digitizer to test and demonstrate its capabilities, effectiveness, and efficiency in quantitatively characterizing the spatial geometry and surface topography of lower residual limbs and the limb segments of orthotics patients.

METHODOLOGY—To achieve these objectives, the following research protocol has been established:
1) Develop specifications for, procure, and test a new optical laser digitizer prototype of a more advanced design, in which the deficits identified in the first prototype digitizer are corrected, its capabilities enhanced, and its performance improved.
2) Enhance, optimize, and integrate into a single, user-friendly, menu-driven program, the control, data acquisition, image generation, image processing, and image measurement and analysis software modules developed with the original digitizer prototype.
3) Continue development of computer-aided socket design (CASD) templates for use with optically digitized residual limb measurement models, and refine and optimize the control, tool path clearance, and the surface contour interpolation and smoothing software developed for use with the VA-HMO Five Degree-of-Freedom Prosthetics-Orthotics CNC milling machine for CAM of the resulting CASD socket models.
4) Develop CAD templates for design of ankle-foot orthoses (AFOs) and knee-ankle-foot orthoses (KAFOs) from optically digitized limb segment measurements.
5) Continue investigations with the optical digitizer in estimation of limb segment effective joint center trajectories for application in orthotics CAD and biomechanics research.

PROGRESS—Since the project began in October 1994, specifications for a new, more advanced design, prosthetics-orthotics optical laser digitizer have been formulated, and a new prototype is being constructed. Work on enhancing, optimizing, and integrating the control, data acquisition, image generation, image processing, and image measurement and analysis software modules developed for the original optical digitizer prototype into a single, user-friendly, menu-driven program for clinical prosthetics-orthotics use has begun. Work has also commenced on enhancement and optimization of the control, tool path clearance, and the surface contour interpolation and smoothing software developed for use with the VA-HMO Five Degree-of-Freedom Prosthetics-Orthotics CAM milling machine. Clinical scans and fittings of amputee and orthotics test subjects for CAD system socket and orthosis design development for use with optically digitized residual limb/limb segment measurements shall be performed on a limited basis until construction and testing of the new optical digitizer prototype is completed. Similarly, investigations using the optical digitizer in estimation of patient limb segment joint center trajectories shall remain restricted to relatively small subjects, until construction and testing of the new prototype digitizer with a significantly increased scannable spatial envelope is completed.

FUTURE PLANS—Refinement and enhancement of the optical laser digitizer shall continue. When development of the new, enhanced digitizer prototype is completed, expanded application studies with the optical digitizer shall be conducted. Future studies shall include: compilation of a consistent, quantitative prosthetics and orthotics patient database of residual limb/limb segment geometries, measurements, and histories for use in developing improved prosthetic socket and orthosis designs; compilation of a database of patient limb segment contours, areas, and volumes for correlation with and quantitative assessment of the efficacy of medical treatment and rehabilitation regimens; use as an instructional visualization aid for enhancement of prosthetics and orthotics education.

RECENT PUBLICATIONS FROM THIS RESEARCH

VA-Cyberware lower limb prosthetics-orthotics optical laser digitizer. Houston VL, Mason CP, Beattie AC, et al. J Rehabil Res Dev 1995:32(1):68-84.

[250] COMPUTER-AIDED DESIGN AND COMPUTER-AIDED MANUFACTURING OF ORTHOPEDIC FOOTWEAR

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PURPOSE—The objective of this project is to develop a clinically effective and efficient pedorthic computer-aided design and computer-aided manufacturing (CAD/CAM) system that will quantify, automate, and expedite the design and manufacture of custom orthopedic footwear for US veteran pedorthic patients.

METHODOLOGY—To achieve this objective, the following research protocol has been established:
1) Sample 250 representative patients from the 10,000 pedorthic patients whose lasts, patterns, and medical/podiatric records are on file in the NY VAMC Prosthetic Treatment Center Orthopedic Shoe Service (OSS). Digitize the lasts, shoe patterns, (and when available, foot casts), of the 250 sampled patients, together with the stock, library lasts from which their custom orthopedic lasts were constructed. Compile the data thus obtained with the information available on the patients' medical, podiatric, biomechanical, and orthotics-pedorthics conditions and characteristics in a computerized relational database.
2) Develop an intuitive, user-friendly, functional, clinically effective, and efficient pedorthic CAD/CAM system satisfying OSS needs.
3) Analyze the data compiled in task 1 to establish last, inlay, and shoe structural component design principles, and to derive parametric statistical means for the most common modifications and design features identified among the sampled patients for use in developing CAD system design templates.
4) Conduct limited clinical tests of the pedorthic CAD/CAM system developed to identify those areas/features that are successful and those that require further research and development.

PROGRESS—The custom orthopedic lasts, stock library lasts from which they were derived, and the orthopedic shoe upper patterns for 289 patients have been optically digitized and compiled in the project computerized database. The medical, podiatric, biomechanical, and orthotics-pedorthics information available in OSS files for these patients has also been compiled in the project database. Statistical analysis of the data is being performed to codify pedorthic design principles, and establish parametric statistical distributions and means for use in development of CAD last design templates.

The Vorum Research Lastfit;tm CAD system, and the Tekscan, Inc. F-Scan plantar pressure measurement system have been procured and thoroughly tested. Adaptation and enhancement of these systems to meet OSS needs is being performed. Testing of the project's pedorthic CAD system developments with five veteran research subjects has begun.

FUTURE PLANS—Refinement and enhancement of the project pedorthic CAD system shall continue. Research in CAD design, engineering, and styling of orthopedic shoe upper patterns and soles is planned. In addition, utilization of the results and knowledge obtained in this project, together with results obtained by the investigators in their other research in tissue mechanical property characterization, measurement of static and dynamic loading, and foot/ankle biomechanics, is planned for development of new, improved, biomechanically based orthopedic footwear designs.

[251] GAIT ANALYSIS OF PARAPLEGIC PATIENTS WALKING WITH MECHANICAL ORTHOSES AND FES

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Sponsor: *Italian Ministry for University and Scientific Research, Italian National Research Council, European Community*

PURPOSE—This project seeks to develop and apply a biomechanical evaluation protocol to analyze the locomotor pattern of paraplegic patients walking with pure mechanical orthoses and with hybrid systems (orthoses + FES). The aim is to obtain a tool for optimizing the external walking device to each patient, taking into consideration both the mechanical adjustment and the electrical stimulation pattern.

METHODOLOGY—A multifactorial gait analysis system has been adopted to collect simultaneously all significant data about assisted walking. It consists of an ELITE system for kinematic analysis, a force platform for ground reaction force detection, an eight-channel electromyograph to record myoelectric activity of supralesional muscles, and a personal computer with suitable software to store, process, and graphically represent all collected data.

PROGRESS—A devoted kinematic acquisition protocol in terms of particular markers displacement with technical reference points (used to calibrate and reconstruct anatomical landmarks covered during movement) has been developed and implemented. A set of interesting variables has been individuated, ranging from general spatiotemporal gait parameters to time course of upper and lower limb joint angles, center of gravity displacements, joint torque and power, and GRF impulses. Taking into account the complexity of considered movement and the severity of locomotor disability, we had to minimize the number of trials and the acquisition times, guaranteeing data consistency and significance. Gait analyses are performed both with and without FES assistance, in order to quantify the improvement on walking pattern produced by electrical stimulation. Attention is devoted also to the improvement provided by the addition of horizontal rotation to the orthosis hip joint.

RESULTS—The acquisition protocol development, the validation of the methodology, and the application on first patients have been performed previously with good results. In particular acquisition with ORLAU-hip guidance orthosis (HGO) and with LSU-RGO (reciprocating gait orthosis) were performed on several paraplegic patients. Data comparison showed interesting differences in locomotor strategy strictly correlated with the different mechanisms involved in the two orthoses. More recently, study on the addition of FES to LSU-RGO orthosis has been performed on two patients, showing the improvement provided by the electrical stimulation on walking pattern. Concerning the analysis of modifications provided to the LSU-RGO orthosis by adding horizontal rotation to the hip joint, results show an improvement on pelvis rotation, in accordance with stride phases, and the possibility to identify the best sagittal-horizontal rotation ratio.

FUTURE PLANS—Acquisitions on patients using RGO with and without FES will be repeated after 6 months of functional use of the orthosis. A set of trials with modified stimulation patterns is planned, in order to find the optimal one for each patient. Finally experiments toward the optimization of hip joint rotations are foreseen.

RECENT PUBLICATIONS FROM THIS RESEARCH

Biomechanical assessment of paraplegic locomotion with hip guidance orthosis (HGO). Ferrarin M, Pedotti A, Boccardi S, Palmieri R, Clin Rehabil 1993:7(4):303-8.

Gait analysis in paraplegics walking with RGO orthosis. Ferrarin M, Rabuffetti M, Pedotti A, Lusvardi M. In: Book of abstracts of Biomechanics XIV ISB Congress; Parigi, July 4-8, 1993:402-3.

Biomechanical analysis of paraplegic gait assisted by hybrid orthosis. Ferrarin M, Rabuffetti M, Pedotti A. In: Book of Abstracts of the World Congress on Medical Physics and Biomedical Engineering; August 21-26 Rio de Janeiro, Brasil, 1994:867.

[252] CRITERIA FOR INTERFACING AND CONTROL OF A POWERED UPPER EXTREMITY ORTHOSIS

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Sponsor: *National Institute on Disability and Rehabilitation Research; Nemours Research Programs, A.I. duPont Institute*

PURPOSE—This project is concerned with the development of an upper limb orthosis intended primarily for individuals with muscular dystrophy (MD). What characterizes this etiology is a progressive loss of muscle function where the distal musculature is the last to be affected. When a person retains sensory and partial muscular control, it is possible to augment his abilities with the aid of the appropriate technology. This project explores ways of using powered orthoses that can support a person's arms against gravity and provide a broad range of arm movement.

The objective of the project is to create the engineering knowledge that will allow the development of a powered orthotic mechanism. A prototype system, able to support and assist the function of a partially or fully impaired arm, is currently being constructed. An important element of this project is the involvement of consumer groups in all aspects of the work. This ensures proper response to consumer needs and is expected to expedite the dissemination of the knowledge buildup and the transfer of technology.

METHODOLOGY—The general assumption is that if some residual force is available and proprioception is unimpaired, then a powered orthosis can operate as an extender by amplifying the person's residual strength or by using signals obtained from other body sites. On the other hand, if there is little or no muscle function at all, then auxiliary signals, derived from other body sites or electrodes, can be used to drive the actuators, enhancing the person's strength. Residual hand function of potential users and the possibility of using supplementary end effectors will also be investigated.

Work in progress has two phases: the first is generating the information needed to specify the design criteria for a powered orthosis; the second phase will assess the functionality of possible designs and develop usable prototypes.

During the first phase, the range motions of such a device are specified by identifying and prioritizing the tasks that users wish to perform. In addition, methods of controlling such a devices are identified and further studied and developed, to facilitate the design of a suitable mechanism. This investigation relates both to traditional design issues such as kinematics, power consumption, and impedance and to the human interface issues such as the force that can be exerted by and on a person who would benefit from such a system.

The goals of the second phase are to develop a series of prototypes that will lead toward a marketable device. Consumers and their families are to be involved at all stages in this work.

PROGRESS—Programmed focus group meetings were held on two occasions when families and children with SMA and MD were invited together to look at how technology could assist with problems encountered in daily life. A set of tasks were identified and several new points emerged, for example, the use of the orthosis to assist with posture shift.

Several configurations of antigravity mechanisms have been designed and are being constructed, with the objective of passively biasing the orthosis to support the arm of the subject against gravity. At the present time a modified prototype version is being constructed for field testing and evaluations with subjects. Concurrently, several control schemes have been tested on RT100 robot test bed. The subject's residual force is being monitored and used as input to control the orthosis. Several relationships have been evaluated such as relating force to position, velocity, and acceleration, and relating impulse to velocity.

RESULTS—A set of tasks needed by the target population has been identified. A passive orthotic system has been designed that enables the affected individual to place an arm anywhere in 3-D space within the limitations of the arm and the orthosis with a minimal demand on his muscular system. Several alternative control schemes, which could be used in the final design, have been evaluated.

[253] DESIGN AND EVALUATION OF A TRICEPS ORTHOSIS FOR C5/C6 QUADRIPLEGICS

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Sponsor: *Paralyzed Veterans of America Spinal Cord Research Foundation*

PURPOSE—Persons with spinal cord injury at the C5/C6 cervical level typically have relatively well preserved biceps function, but minimal or no voluntary control of triceps. Our previous work has showed that this results in deficiencies in speed and accuracy of elbow movements, as well as a reduction in the reachable workspace, and that these deficiencies can be corrected by the addition of constant extensor torque and damping at the elbow. The overall goal of this project is to develop and implement a triceps orthosis, composed of only passive mechanical elements, to improve arm movements of such individuals.

PROGRESS—The significant challenge of the current year is to design an orthosis which is likely to be acceptable to users. Last year's two-hinge prototype orthosis, although functionally successful, was somewhat inconvenient from the user's point of view because the medial hinge (on the inside of the elbow) could interfere with daily activities such as propelling a manual wheelchair. The primary goal of this year is to provide a lighter prototype with a single, lateral hinge.

A new hinge mechanism has been designed, with a light-weight spring cage provided to hold a prestressed power spring which provides near-constant torque over the full range of motion. Hinge arms are made of stainless steel tubes 7 mm in diameter, all thickness 0.11 mm. The forearm rod incorporates a coiled spring to facilitate pronation. The four cuffs are fabricated of carbon fiber lamination braid and lined with T-foam™. Damping can be provided by an adjustable linear air damper.

Part of the challenge of the design of a one-hinge orthosis is to properly balance the various torques, so that the orthosis will not tend to change position on the arm. The current design allows for cuff rotations along the axis of the hinge arm (roll) and perpendicular to it (pitch). Translation (sliding) of the cuffs along the hinge axis is also possible. Part of our continuing evaluation is determining which of these degrees of freedom are necessary and which need to be restricted in order to provide the best stability and fit.

RESULTS—Based on our progress to date, we know that this orthosis "works" in the sense that it allows more rapid, better controlled arm flexions and expands the user's accessible workspace. Three subjects wearing the orthosis showed increased ability to reach targets above shoulder level both in front and to the side. There was improvement in back-and-forth movements mimicking feeding and in movement speed of elbow flexions to a target. Evaluation procedures also include the ability of subjects to draw ellipses in the air in front of themselves, to test improved gross motor coordination in a gravity field.

IMPLICATIONS—Basic research in neuromuscular motor control has recently led to recognition of deficits in control of arm movements of C5 tetraplegic subjects, even in the absence of biceps spasticity or flexion contractures. This suggests that the applicability of elbow extension orthoses to the C5 tetraplegic population may be wider than previously appreciated.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Mechanical compensation for weak triceps in C5/C6 tetraplegia. Wiegner AW, Wierzbicka MM. IEEE Trans Rehab Eng 1993:1:72-8.

Functional assessment of a triceps orthosis for C5/C6 tetraplegia. In: Proceedings of the 17th Annual RESNA Conference. Washington, DC: RESNA Press, 1994:164-66.

[254] ORTHOTIC FOOT APPLIANCES FOR LEPROSY PATIENTS: A STUDY BASED ON PODIATRIC PRINCIPLES

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Sponsor: *Poona District Leprosy Committee (PDLC)*

PURPOSE—Treating plantar ulcers in a neuropathic foot of leprosy and preventing their recurrence has always been a challenge. The resulting loss of protective sensations, muscular paralysis, and autonomic disturbance as a consequence of peripheral nerve involvement makes the neuropathic foot vulnerable to injury. Management of plantar ulcers by plaster casts and conventional modified microcellular rubber footwear and other appliances is well known.

It was decided to look at the foot and its biomechanics from the principles of podiatry. The purpose of this study was mainly to consider the influence of rear-foot function on the fore-foot and to study the effect of external orthoses for prevention of recurrence of plantar ulcers in leprosy.

The pathological foot needs alignment by external supports in such a way that the phasic motions of the sub-talar joint can be maintained to reduce the abnormal forces occuring on the neuropathic fore-foot, the site of maximum ulcers. In this context, understanding the sequence of motion at the sub-talar joint, the key joint during the gait cycle, is essential. Pronation is required during the first half of stance between heel strike and foot flat and supination in the latter part between heel lift and toe-off. Failure to pronate produces a hard jarring gait and pressure lesions. Failure to supinate (abnormal pronation or pronation that continues beyond midstance) produces hypermobility, friction, and deformity.

METHODOLOGY—Eighty patients of the Dr. Bandorawalla Leprosy Hospital who had plantar anesthesia and uncomplicated ulcers were studied. Subjects having foot drop and tarsal disintegration were excluded from the study. Foot examination included sensory motor assessments, and longitudinal and horizontal dimensions of ulcers and their morphology.

Several varieties of orthotic devices were incorporated in the tailor-made microcellular rubber footwear: the plantar metatarsal pad (PMP) for redistribution of weight from a pressure point to all other metatarsal heads and shafts; the valgus dome to increase weight-bearing area in the medial arch and to stop arch flattening; the cobra pad modification to prevent excessive pronation; the Shaf pad for lesions at interphalangeal joints (IPJ), to remove weight from metatarsal head to metatarsal shaft or from the first IPJ backwards on the metatarsal head and shaft; and other varieties, including the filler pad, metatarsal bar, and rocker.

PROGRESS—The subjects were evaluated at a period of 3 months interval and preliminary findings show that ulcers larger than 2 cm in diameter do not benefit from orthoses as a first line approach. After responding to plaster cast as a primary intervention, orthoses supplement the approach by restricting recurrence. We also found that the reduction of the longitudinal dimension of ulceration is faster than a reduction in horizontal dimension. This was observed in almost 50 percent of the cases. In all cases, the efficacy of the device depends directly on the condition of the footwear.

The subjects will be followed up for a period of 1 year from the time the orthoses are issued.

IMPLICATIONS—Evaluating the effects of podiatric orthoses has not been the subject of investigation previously. The study should contribute toward a wider understanding in the management of plantar ulceration (especially recurrence) occuring in the neuropathic foot of leprosy.

XIII. Psychological and Psychosocial Disorders

[255] EFFECTS OF EXPECTATION, REWARD, AND ACTIVITY ON SUBTYPES OF SCHIZOPHRENIA: STATUS REPORT

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #D515-2DA)*

PURPOSE—This research investigates the benefits of productive activity in the rehabilitation of patients with diagnoses of schizophrenia. The key questions are: a) Does pay act as a reward for schizophrenic patients in a work program leading to greater productivity? b) Does greater expectation for productive activity lead to more productivity? c) Does greater productivity lead to better rehabilitation and clinical outcomes? d) Does greater expectation increase the likelihood of relapse and rehospitalization? e) Are subtypes of schizophrenia based on psychological and neurobehavioral measures useful predictors of rehabilitation outcome? f) What are the enduring effects of a time-limited work therapy intervention?

METHODOLOGY—One hundred fifty patients with DSM-III-R diagnoses of schizophrenia have been recruited, stratified by prior work function and negative symptoms, and randomly assigned to one of three levels of expectation for work: 20 hours (''High Expectation'' N=60), 10 hours (''Low Expectation'' N=60), or no minimum hours (''Self-regulation'' control condition, N=30) of work required per week. Subjects were offered duties similar to those of regular employees at the medical center and attended weekly groups where support is provided, level of expectation reinforced, and information on productivity and clinical status are obtained. Research staff evaluated work performance through on-site monitoring and supervisor interview.

Half of the subjects were paid ($3.40 per hour for 6 months) and half were not. Clinical status, productivity, and other measures were evaluated at baseline and re-evaluated at 6, 12, and 36 months.

PROGRESS—We have randomized 150 subjects, conducted 520 group meetings, developed a comprehensive manual of group procedures, achieved good-to-excellent reliabilities on measures used, conducted over 2,300 weekly individual symptom evaluations and over 950 biweekly work evaluations of an excess of 26,000 work hours, and completed 96 percent of 5-month follow-up interviews, 93 percent of 1-year follow-up, and 100 percent of 3-year follow-up.

RESULTS—Paid subjects were more likely than unpaid to begin and sustain productive activity; they demonstrated a decrease in total symptom severity and emotional discomfort symptoms (42 percent experienced at least a 20 percent reduction in emotional discomfort); they worked more hours and had a significantly lower rate of rehospitalization both during the intervention and the following 6 months.

Subjects in the high expectation group worked more 20-hour work weeks than other subjects; however, these subjects did not work more hours or weeks over the course of the 6-month work program: subjects in the self-regulation condition worked more weeks than the other subjects. Findings indicate that subjects had their greatest impairments in social skills, although these deficits improve over time. Concurrent symptomatology predicts work performance accounting for more than 27 percent of the variance on some measures. Neuropsychological deficits were associated with impairments in work performance.

We have examined methods of subtyping schizophrenia using premorbid history, negative symptoms, and insight level. We found that insight predicted

poorer work performance and that negative symptoms predicted poorer performance also, but not decreased levels of participation. We have replicated factor analyses suggesting that symptomatology of schizophrenia can be described using five components: positive, negative, cognitive disorder, hostility, and emotional discomfort.

Findings indicate that receiving pay and participation in the work program were not associated with greater amount of productivity over the 2.5 years following the intervention. A trend in the data, however, suggested that most paid subjects sustained their clinical improvements in emotional discomfort.

Analyses revealed that for every dollar spent on paid work activity the VA saved $5.69 in hospitalization costs over three years. In total dollars, the VA saved $416,360 by providing the 6-month paid work activity program.

IMPLICATIONS—Findings indicate that pay increases participation in work activity and greater work activity is associated with greater clinical improvements, including symptom improvement and fewer relapses. We will shortly be conducting a cost-benefit analyses to determine whether the costs of paid work program were offset by saving in reduced rehospitalization rates.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Work capacity in schizophrenia. Lysaker PH, Bell MD, Milstein RM, Bryson GJ, Shestopal AS, Goulet JG. Hosp Com Psychiatr 1993:44:278-80.

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Insight and psychosocial treatment compliance in schizophrenia. Lysaker PH, Bell MD, Milstein RM, Bryson GJ, Goulet JG. Psychiatr. 1994:57:289-97.

Relationship of positive and negative symptoms to cocaine abuse in schizophrenia. Lysaker PH, Bell MD, Milstein RM, Goulet JG. J Nerv Ment Dis 1994:182:109-12.

Work rehabilitation and improvements in insight in schizophrenia. Lysaker PH, Bell MD. J Nerv Ment Dis 1995:183:103-7.

Changes in work performance over time for patients with schizophrenia. Lysaker PH, Bell MD. Psychsoc Rehabil J. In press.

Cognitive deficits in schizophrenia: prediction of symptom change for participators in work rehabilitation. Lysaker PH, Bell MD, Bioty SM. J Nerv Ment Dis. In press.

Relationship of psychiatric symptoms to work performance for persons with severe mental disorders. Bell MD, Lysaker PH. Hosp Com Psychiatr. In press.

Wisconsin card sorting test and work performance in schizophrenia. Lysaker PH, Bell MD, Goulet JG. Psychiatr Res. In press.

[256] SEXUALITY ISSUES AMONG WOMEN WITH PHYSICAL DISABILITIES

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—Research has been conducted on the physiological aspects of sexuality in women with physical disabilities; however little has been done to examine the psychosocial influence that physical disability has on the development of intimate relationships and the abilities of women with various physical disabilities to pursue behaviors typically taken for granted by women without disabilities, including dating, physical intimacy, marriage, and parenting.

Funded by NIH for 3 years, this project is designed to examine the broad spectrum of sexuality issues among women with a variety of physical disabilities. The three primary research hypotheses are: 1) there are significant differences in sociosexual behaviors of women with physical disabilities as compared to women without disabilities; 2) the sexual functioning of women with disabilities is significantly related to age at onset of disability; and 3) psycholog-

ical factors (including perceived control, self-esteem, and prior sexual exploitation) explain more of the variance in the sexual functioning of women with physical disabilities than do disability factors, social factors, or environmental factors.

PROGRESS—The first phase of this research project was a qualitative study using a semistructured interview format with 31 women having physical disabilities. The 2-hour interviews were conducted in the participants' homes by three project staff who are also women with disabilities, including the principal investigator. Interviews were transcribed, analyzed in terms of wellness, and used to generate a 300-item questionnaire, which was pilot tested on 60 women with disabilities and 60 women without disabilities. These data were then used to further refine the questionnaire, which was sent to 1200 women with disabilities and 1200 women without disabilities. Questionnaires were received from more than 900 women, and these data are currently being entered into computer storage. Data have been analyzed on the first 200 women with disabilities and matched with 200 women without disabilities.

RESULTS—Analysis of qualitative data revealed 200 themes related to sense of self, sexuality information, relationships, environmental and social barriers, emotional, physical, and sexual abuse, and health and physical sexual functioning.

In the first quantitative study of 400 subjects, disabling conditions reported, from most-to-least frequent, were: spinal cord injury, polio, joint and connective tissue disorders, muscular dystrophy, cerebral palsy, multiple sclerosis, skeletal abnormalities, traumatic brain injury, amputation, stroke, and spina bifida. The majority of women described their race as Caucasian, although African Americans, Hispanics, Native Americans, Asians, and biracial backgrounds were also represented. Age ranged from 23 to 63, with a median age of 41.7 among disabled women and 38.5 among nondisabled women. Education level tended to be higher overall than in the general population, with only 2 percent of disabled and 3 percent of nondisabled women not completing high school; 25 percent of disabled women held postgraduate degrees. Although employment rates tend to be low among disabled women in the general population, 61 percent of our sample were engaged in paid employment, while the remainder volunteered in the community.

Analysis of sexual functioning data on these 400 subjects dispelled the common belief that women with disabilities are neither interested in sexuality nor sexually active. Although disabled women reported being kissed, touched, and hugged as frequently as nondisabled women, they had sexual intercourse significantly less frequently. Disabled women were as likely to be married as their able-bodied counterparts. Prevalence of sexually transmitted disease was 23 percent among disabled compared to 31 percent of nondisabled women, which also provides evidence of sexual activity. Nearly half of disabled women had natural, adopted, or stepchildren living in their home, compared to 77 percent of able-bodied women.

The majority of both disabled and nondisabled women had seen a primary care physician in private practice for health care services in the past 12 months. More disabled than nondisabled women had received a mammogram in the past 2 years, possibly because disabled women have more frequent contact with the health care system. White disabled and nondisabled, as well as minority nondisabled, women were about equally likely to have an annual pelvic exam; disabled minority women were the least likely group to have regular exams ($p=0.014$). Hysterectomy rates were significantly higher among women with disabilities compared to women without disabilities (23.1 percent vs. 13.9 percent; $p=0.005$). This substantiates claims by several of the women interviewed that a physician had tried to persuade them to get a hysterectomy for birth control or convenience reasons.

FUTURE PLANS—Data from the survey will continue to be analyzed and disseminated. The results of this study will be used in developing and modifying educational and counseling programs for assisting women with physical disabilities in pursuing a full range of life options.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Sexual abuse of women with physical disabilities: findings from a qualitative study. Nosek MA. In: Monga TN, ed. Sexuality and disability. Philadelphia: Hanley and Belfus. In press.

Wellness models and sexuality among women with physical disabilities. Nosek MA, Howland CA, Young ME, et al. J Appl Rehabil Couns. In press.

[257] THE DEVELOPMENT AND EVALUATION OF A TREATMENT PROGRAM DIRECTED AT THE IMPROVEMENT OF PSYCHOSOCIAL BEHAVIOR FOLLOWING STROKE

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Sponsor: *Prevention Fund*

PURPOSE—Stroke is an unpredictable and often disabling condition, with an extensive impact on both its victims and their family. Until now, the majority of stroke patients are treated neurologically in a general hospital, whereas only a small percentage receive a rehabilitation program primarily aimed at functional recovery. Emotional and behavioral consequences receive much less attention, if any at all. However, in the stages following the acute phase, psychosocial consequences become increasingly important and can form a severe hindrance for a successful return to family, friends, and work. The main goal of the project is to answer the question whether it is possible to improve psychosocial functioning following stroke by means of a special treatment program. Furthermore it is attempted to distill predictors for psychosocial dysfunctioning from the early post-stroke measurements.

METHODOLOGY—Stroke patients between 18 and 70 years old are followed from admission to a general hospital until 2 years after. As soon as possible, patients are neuropsychologically assessed. After 9 months, both patients and relatives are interviewed, and a number of questionnaires (focused on social and emotional functioning, and coping style) are completed. The Sickness Impact Profile (SIP), and particularly its psychosocial score (SIPps), is being used as a criterion for classifying patients into one of four groups of 34 persons each. There are three groups with a SIPps score of 18 or more (group I, experimental group; group II, placebo group; group III, control group), and 1 group with a SIPps-score less than 18. A SIPps score of 18 or more is seen as an indication of psychosocial dysfunctioning.

The experimental group receives a treatment program of 20 sessions. Elements of this program are information, relaxation, fear reduction, social skills training, development of coping skills, and changing behavior patterns, for both patients and proxies. Twenty-four months after the stroke, patients and proxies of all groups are requested again to fill out the questionnaires.

It is predicted that patients from the experimental group will function better than those of the groups II and III. This will be reflected in a decline of the SIPps score, improvement on the questionnaires, attainment of therapeutical goals, and the patient/partner satisfaction with the whole program.

PROGRESS—In a cross-sectional study of 166 patients and proxies, the degree of physical and psychosocial dysfunction over time has been established by using the SIP, along with the extent to which problems were felt to be a handicap. Results are presented in an article. Until now 165 patients have been neuropsychologically assessed, 73 patients and proxies have been assessed at 9 months after stroke, and 8 at 24 months after stroke. Two pilot-therapy groups and two therapy groups for the experimental group have started. Reactions are positive, but it is still too early in the study to draw any conclusions.

FUTURE PLANS—We intend to continue subject recruitment and testing, start five more therapy groups, improve the therapy and materials used, and analyze the data. Manuscripts will be written about the psychosocial problems following stroke, about the neuropsychological aspects of stroke supported by data, about the intervention program and its results, and about possible predictors for dysfunctionality.

XIV. Sensory, Cognitive, and Communication Aids

A. Hearing Impairment

[258] SIGNAL PROCESSING AND HEARING AID DESIGN

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C432-3RA)*

PURPOSE—The long-range purpose of this project is to evaluate the relative merits of selected nonlinear signal processing strategies (especially compression amplification) for use in hearing aid design. The goal of the first experiment is to compare the relative effects of speech quality and intelligibility on output compression limiting and peak clipping systems.

METHODOLOGY—Subjects with hearing-impairment are tested using the Revised Speech Intelligibility Rating Test under conditions of symmetrical output compression and peak clipping. A digital master hearing aid system is used to process the speech signals, and the assessment includes both measurements of speech intelligibility and speech quality. Speech quality is assessed using paired-comparison methods to obtain preference judgments and categorical scaling methods to measure overall impressions of sound quality and satisfaction. The study will be accomplished in conditions of background speech and "in quiet," with assessments made at signal input levels below and above the thresholds of compression and clip levels.

PROGRESS—The digital master aid system and associated software has been completed and testing of subjects is ongoing.

PRELIMINARY RESULTS—While speech intelligibility is only modestly affected by either peak-clipping or compression limiting (10:1 compression ratio), speech quality is affected by both nonlinear limiters relative to linear-processed speech. The quality of clipped-processed speech is, however, judged to be progressively poorer in regard to the compression systems as speech input levels increase above their respective thresholds.

FUTURE PLANS—The current studies of clipping versus compression limiters will be completed. These investigations will be followed by comparisons between a linear system with output compression limiting and selected input compression systems.

RECENT PUBLICATIONS FROM THIS RESEARCH

Comparison of probe insertion methods on estimation of ear canal SPL. Dirks D, Ahlstrom J, Eisenberg L. J Rehabil Res Dev. In press.

Speech intelligibility of normal and hearing impaired listeners in fluctuating noise. Eisenberg L, Dirks D, Bell T. J Speech Hear Res 1995:38(1):48-54.

[259] OPTOKINETIC TESTING FOR DIAGNOSIS AND REHABILITATION OF BALANCE DISORDERS

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PURPOSE—The goals of this research are to develop binocular and monocular testing of horizontal and vertical vestibulo-ocular (optokinetic nystagmus) and vestibulospinal reflexes (postural sway), thereby improving the diagnosis and rehabilitation of vestibular disorders.

METHODOLOGY—Horizontal optokinetic motion stimuli are presented binocularly and monocularly (right and then left eye). Optokinetic nystagmus (OKN) is recorded at stimulus velocities 10 to 100/s in 10 increments to the right and then to the left (randomized presentation). In procedure 1, OKN is recorded while the subject is seated 1 m from the screen. In procedure 2, subjects stand on a platform that records postural sway during visual stimulation.

RESULTS—For procedure 1, 70 nondisabled subjects, ages 8 to 74 years, have been evaluated. All subjects have similar response patterns, producing OKN at speeds consistent with stimulus condition velocities up to 50 to 60/s. At velocities greater than 60/s, most subjects are unable to maintain velocities of greater than 60/s and response gain decreases. There is no significant regression with age and no gender effects. Stimulus direction is significant (higher gain when the stimulus is moved to the right as compared to the left) for all viewing conditions.

Six hemilabyrinthectomized subjects presented an abnormal response pattern. Before surgery, OKN was asymmetrical; gain was low when the stimulus moved away from the side of the compensated lesion as compared to normal values when the stimulus moved ipsilaterally. During the acute postoperative period (<30 days), the ipsilateral and contralateral gain of horizontal OKN was low and symmetrical. In the intermediate period of postoperative recovery (30–60 days), the OKN became asymmetrical with an improvement in ipsilateral gain. During the chronic phase of recovery (>2 months), 3 of the 6 hemilabyrinthectomized subjects revealed OKN gain that was symmetrical and within normal limits. Monocular optokinetic stimuli produced similar pre- and postoperative effects. These data suggest that monocular and binocular optokinetic testing can be used to monitor the vestibular compensation of subjects following vestibular nerve section.

Ongoing data collection for procedure 2 presently includes findings from 54 normal subjects. The data indicate that lateral and forward-backward sway amplitudes are significantly higher when subjects view a horizontal optokinetic pattern than when they view a stationary pattern or have their eyes closed. The directionality of the postural sway induced by horizontal optokinetic patterns was highly variable. Destabilization of posture by horizontal optokinetic stimulation was only minimally dependent on the stimulus velocity. The average forward-backward sway amplitude was significantly greater than the lateral sway amplitude. Sway amplitude was not correlated significantly with age in the eyes open condition, but sway amplitude in the forward-backward direction was correlated with age for the eyes closed condition. There was a significant correlation between increasing sway amplitude and age when the optokinetic stimulus was present.

In addition, 3 subjects with an acoustic neuroma were evaluated. A pre- and post-surgical subject, both with symptoms of dizziness, exhibited postural sway in the direction of the site of lesion. The third subject, 2.5 years post-surgical with no complaints of dizziness, exhibited responses similar to those seen in the control group.

FUTURE PLANS—These results suggest that evaluation of postural sway could be used for diagnostics as well as post-surgical monitoring of vestibular compensation and treatment (i.e., physical therapy). Data collection to increase the number in the experimental and normal groups is ongoing.

RECENT PUBLICATIONS FROM THIS RESEARCH

Monocular and binocular testing to improve the diagnostic value of horizontal optokinetic nystagmus. Fowler CG, Zizz CA, Blanks RHI. Am J Audiol 1993:3:44-47.

[260] EVOKED OTOACOUSTIC EMISSIONS FOR OTOTOXIC MONITORING IN ADULTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C696-RA)*

PURPOSE—Evoked otoacoustic emissions (EOAE) provide an objective measure of cochlear function that is linked to the activity of the outer hair cells. EOAE are being used widely as an auditory screening tool for infants and children, since they tend to extinguish in the presence of hearing loss in excess of 30–40 dB HL. Applications for older adult populations have lagged, since early data suggested that emissions declined with age as well as hearing impairment. Our study is designed to establish normative data of EOAE for older adults with some pre-existing hearing loss, and to apply the test as a monitoring protocol for the ototoxic drug CIS Plat. We proposed to measure EOAE on 50 control subjects drawn from our clinic caseload, to establish normative data, and verify the salience of EOAE in our older population with pre-existing hearing loss. Second, we proposed to provide serial measures on 20 patients receiving cisplatin treatment and determine whether this new protocol could be used in auditory monitoring applications with our population.

METHODOLOGY—Our original plan was to employ two pure tone signals to elicit the cubic difference tone, a technique known as distortion production otoacoustic emissions (DPOAE). Delays in the availability of DPOAE instrumentation and software would have led to a delay in data collection, so we modified our original plan, and to begin data collection using a somewhat simpler click stimuli to elicit transiently evoked otoacoustic emission (TEOAE). Access to new analysis software has allowed us to extract frequency specific data in one-sixth Octave bands from TEOAE, so our original objective of focusing attention on the more vulnerable high frequency region of hearing was not seriously impeded by this change.

PROGRESS—We have collected TEOAE data on 110 patients ranging in age from 40 to 81 years. This exceeded our estimated normative data goal. We have also collected complete serial TEOAE control data on 20 nonmedicated patients and on 5 cisplatin patients. The development of a reliable serial monitoring protocol turned out to be more complicated than originally estimated, and this along with a move from Seattle, WA to Iowa City, IA mid-study has delayed recruitment of cisplatin patients and publication goals.

RESULTS—Results for the normative data portion of our study, based on 110 patients, revealed the following results: 1) for those frequencies where hearing was better than 40 dB HL over 85 percent of our patients revealed reliable TEOAE, independent of age; 2) for those frequencies where thresholds were greater than 40 dB HL, less than 20 percent of our patients demonstrated reliable TEOAE; 3) there was no correlation between age and the absence of expected TEOAE; and 4) there was no measurable correlation between age and magnitude of TEOAE.

Results for the cisplatin portion of our study are not yet complete. Based on the 20 control subjects, we have evaluated five different parameters of the basic TEOAE response for their stability as serial monitors. An FFT performed on the cross-correlation between baseline and re-test is the most promising monitor. One confounding result was the presence of greater

than normal test-retest audiometric variability for our five cisplatin patients, which has made it difficult to draw conclusions from our TEOAE data.

FUTURE PLANS/IMPLICATIONS—We are still developing a cisplatin referral base at Iowa City VAMC, and hope to have additional cisplatin data before the conclusion of the project. The salience of EOAE in our elderly population has been established, but sensitivity of this measure for serial monitoring is still to be verified. We feel that additional data will confirm this application, and lead to additional objective serial monitoring applications to include other ototoxins and noise exposure.

[261] EFFECT OF PRESENCE VERSUS ABSENCE OF PROLONGED AMPLIFICATION ON AUDITION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C578-2R)*

PURPOSE—This longitudinal study investigates the effect of presence versus absence of amplification on various measures of audition in monaurally aided (MA) and binaurally aided (BA) adults with bilateral, sensorineural hearing impairment (BSHI).

METHODOLOGY—BA and MA experimental subjects (Ss) and control, normal-hearing Ss have been evaluated annually for the last 5 years. Measures included pure-tone thresholds, speech-recognition threshold, W-22 suprathreshold speech-recognition score (SSRS), nonsense syllable test (NST) score, acoustic admittance, brainstem auditory evoked potentials, and middle latency responses.

RESULTS—Of the 103 experimental Ss with BSNHI who were seen in year 1, 42 (15 MA and 19 BA and 8 subjects whose status was changed from monaural to binaural were seen in year 4 thus far).

In the aided ears of the BA and MA Ss, there was no significant difference in the mean W-22 suprathreshold speech-recognition score (SSRS) between year 1 and year 4. There was significant difference in the W-22 (SSRS) between year 1 and year 4 ($p=0.0002$) in the unaided ear of the monaurally aided subject.

There was no significant difference in the mean NST score for the aided ears of the MA Ss between year 1 and year 4. There was a significant decline between year 1 and year 4 in the unaided ear of the MA subject in the NST. Surprisingly, there was also a significant difference between year 1 and year 4 in the NST in the aided ear of the monaurally aided subject; however, the magnitude of change in the unaided ear as it compares with the aided ear was remarkable 0.079 aided versus 0.137 unaided ($p=0.0053$ and $p=0.0012$, aided and unaided respectively). As for the BA, there was no significant change in left ear between year 1 and year 4, but a slight but significant decline in the right ear. The reduction of the NST in the aided ears of the BA and the aided ear of the MA most likely are related to age. However, the small sample size may have contributed to the disparity between the R and L ears. A better picture will be drawn when the data of more subjects have been evaluated.

The lack of sufficient data on the normal control group at this time did not permit us to make a final statistical analysis. Such analysis will be made as soon as more subjects have been seen. No significant changes were obtained for the other measures.

FUTURE PLANS—Further evaluation of the experimental and control Ss will continue over years 5 and 6 to further define and quantify the auditory-deprivation effects.

RECENT PUBLICATIONS FROM THIS RESEARCH

Effects of prolonged lack of amplification on speech-recognition performance: preliminary findings. Silman S, Silverman CA, Emmer MB, Gelfand SA. J Rehabil Res Dev 1993:30(3):326-32.

[262] EFFECT OF LACK OF AMPLIFICATION ON PERSONS WITH UNILATERAL HEARING LOSS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C578-2RA)*

PURPOSE—This study investigates the effect of presence versus absence of amplification on various measures of audition in aided and unaided adults with unilateral, sensorineural hearing impairment.

METHODOLOGY—Aided and unaided subjects (Ss) between 25 and 75 years of age with unilateral, sensorineural hearing impairment have been evaluated for the last 3 years. Measures included pure-tone thresholds, speech-recognition threshold, W-22 suprathreshold speech-recognition score (SSRS), nonsense syllable test (NST) score, acoustic admittance, brainstem auditory evoked potentials, and middle latency responses.

RESULTS—Of the 80 Ss (38 aided and 42 unaided) who were seen in year 1, 52 (19 aided and 33 unaided) have been seen in year 2, and 12 (5 aided and 7 unaided) have been seen so far in year 3. Statistical analysis was made only in the first 2 years between the aided ears of the unilaterally aided and the unaided ear of unilaterally unaided. In the unaided ears, the mean W-22 SSRS declined significantly from Y1 to Y2 ($p=0.002$). In contrast, in the aided ears, the mean W-22 SSRS did not show significant difference between year 1 and 2. For the NST, there was a significant decline in the unaided ear between year 1 and 2. There was no significant difference between the aided ear over year 1 and 2.

No significant changes from year 1 and 2 were observed for the other measures in the aided and unaided unilaterally sensorineural hearing-impaired Ss.

The unaided ears in this unilateral study demonstrated an auditory-deprivation effect in the second year of investigation. The auditory-deprivation effect occurred earlier in this unilateral investigation than in our study of subjects with bilaterally symmetrical sensorineural hearing impairment. In the latter investigation, an auditory-deprivation effect did not become evident until the third or fourth year following the introduction of monaural amplification. The findings of an earlier significant deprivation effect in the unilaterally unaided Ss as compared with subjects with bilateral symmetrical sensorineural hearing loss who were fitted monaurally, suggest that the interaural asymetry as well as lack of amplification are the possible reasons for earlier deprivation in the former than the latter group of subjects.

FUTURE PLANS—Further evaluation of the aided and unaided unilaterally sensorineural hearing impaired Ss will continue through year 3 to further define and quantify the auditory-deprivation and apparent pure-tone asymmetry effects on audition in adults.

RECENT PUBLICATIONS FROM THIS RESEARCH

Auditory deprivation and recovery in adults with asymmetric sensorineural hearing impairment. Silverman CA, Emmer MB. J Am Acad Audiol 1993:4:338-46.

[263] PROGRAMMABLE HEARING AIDS: EVALUATION AND PREDICTION OF BENEFIT

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C664-RA)*

PURPOSE—Many models of programmable hearing aids now exist. They incorporate features that conventional hearing aids do not: multiple memories for storage of different frequency responses, wide-dynamic range compression, and precise frequency shaping. Manufacturers also claim that programmable hearing aids have superior sound quality. However, programmable hearing aids cost considerably more than conventional hearing aids and take more time to fit. One aim of this study is to determine whether programmable hearing aids are sufficiently superior to conventional hearing aids as to justify the additional costs to the VA if it were to dispense them. In addition, no one has determined which of the many features of programmable hearing aids is more or less important than others.

We seek to determine whether individuals prefer and/or perform better with four accessible frequency responses instead of one, with high fidelity circuitry instead of conventional circuitry, with a wide frequency response instead of a conventional range, and with wide dynamic range compression instead of peak clipping. Since research has shown that hearing aid benefit and satisfaction are only partly explained by actual hearing loss, a further aim is to investigate some of the personality, attitude, cognitive, and psychoacoustic factors that might influence the benefit an individual receives from a hearing aid. We hope to develop a predictive protocol for clinical use prior to hearing aid dispensing.

METHODOLOGY—Seventy-two males aged from 55 to 75 with mild-to-moderate sensorineural hearing loss took part. Each subject wore three hearing aids (two programmable, one conventional) with total of six settings. Each setting was worn for 3 months: subjects were in the study for 18 months each. At the start, all subjects underwent psychoacoustic, cognitive, and personality tests. They then completed subjective evaluations of each hearing aid on a monthly basis and carried out tests of speech-in-quiet and speech-in-noise at the start and end of each 3-month period. Real-ear aided gain was measured for each hearing aid setting.

PROGRESS—Forty-nine subjects have completed the study, 16 will end within 3 months and the remainder within 9 months. Analyses have been carried out on several aspects of the data where the experimental design permits. A new technique for analyzing subjective ratings is currently being developed.

RESULTS—The relationship between subjective evaluations of the six hearing aid settings and performance has been analyzed using ranked data. One programmable hearing aid is highly preferred over the other two hearing aids; the second programmable aid is the least favored hearing aid. Individuals perform best on the speech-in-noise test with the preferred aid and best on the speech-in-quiet tests with the least favored aid, suggesting speech-in-noise measures are better predictors of preference than are speech-in-quiet measures. Multiple regression analyses show that personality and attitudes to hearing loss/aids are the main predictors of reported hearing handicap and disability, audiological measures play a minimal role. The data lend some support to the concept of perceptual acclimatization. However, another factor, possibly motivation, seems to enhance performance on the day of initial dispensing.

FUTURE PLANS—Data collection from the remaining subjects will continue and final statistical analyses will be carried out. The test battery for predicting hearing aid benefit prior to dispensing will be developed once all data has been collected. Its validity and reliability will then be assessed.

[264] ASSESSMENT OF NONAUDITORY FACTORS IN HEARING

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C570-RC)*

PURPOSE—The goals of this study were to determine how several nonauditory factors affect the use of hearing aids in an elderly veteran population. The factors identified for investigation from the pilot study were mental status, visual acuity, fine motor coordination, motivation, and social support. A secondary question was to determine if a change in the Hearing Handicapped Inventory for the Elderly (HHIE), resulting from the benefit of amplification, related to a change in the Sickness Impact Profile (SIP), a self-assessment of general well-being.

METHODOLOGY—The nonauditory factors listed above, as well as several auditory factors, were evaluated in a group of elderly, outpatient veterans (age ≥60 yrs) who were to receive hearing aids through the VA. Subjects either had never worn hearing aids before or had not worn hearing aids for at least 2 years.

Each veteran had an initial evaluation including pure-tone air and bone conduction thresholds, spondee thresholds, and performance intensity functions for recordings of the Maryland CNC word recognition lists. Additional audiological assessment included measures of MCL and UCL for speech stimuli, unaided and aided sound field measures of word recognition in quiet and in noise, and acoustic immittance tests including tympanometry, and acoustic reflex thresholds. The initial assessment also included completion of the HHIE and the SIP, and a hearing aid evaluation. Subjects were reevaluated on all outcome and predictor variables after a minimum of 4 months of hearing aid fitting. Additionally, it was decided to include a self-assessment, the Hearing Aid Satisfaction Questionnaire (HAS), of hearing aid satisfaction, which neither the HHIE nor the SIP address.

PROGRESS—To date, 158 subjects have been entered into the study; 89 at Portland and 69 at Albuquerque. Outcome data are available on 78 of these individuals. The mean age of all subjects was 68.99 years, with a standard deviation of 5.73 years. The average audiogram for these subjects is a sloping, symmetrical hearing loss. Maximum speech recognition scores were 79.7 and 79.2 percent in the right and left ears respectively. Unpaired t-tests of these variables showed no significant difference between subject samples in Albuquerque and Portland.

Paired t-tests were performed on pure-tone average, speech discrimination, vision, fine motor coordination, mental status, and social support auditory and nonauditory factors to ensure that these measures did not change between initial and follow-up visits. Only two of the measures showed significant differences between initial and follow-up visits, mean hearing aid insertion time and mental status. The first was to be expected as subjects gained experience with their hearing aids; for the second, it is unlikely that subjects' cognitive function improved over time. It is possible that with normal subjects there is somewhat of a learning effect with this instrument. It is our conclusion that any change in outcome measures between initial and follow-up visits would be the result of hearing aid use.

RESULTS—It was expected that if a subject benefited from hearing aid use, this would result in a significant change in the scores of the functional outcome measures, (HHIE, SIP). Both were analyzed between entry and follow-up using repeated t-tests. The data indicate a significant improvement in the HHIE total and subscale scores but not the SIP scores.

A stepwise linear regression of the variables with the highest correlations to the HHIE difference scores and the HAS show that three of the eight variables correlating most highly with change in the HHIE are nonauditory factors. Six of the eight variables correlating most highly with the HAS are nonauditory factors. These variables are able to predict approximately 20 percent of the variance of the HHIE difference scores, and 28 percent of the variance of the HAS scores. These preliminary analyses suggest that nonauditory factors are important to consider when attempting to maximize hearing aid benefit in the elderly.

IMPLICATIONS—Results to date are encouraging in that they demonstrate the contribution of nonauditory factors to changes in perceived benefit and satisfaction from hearing aid use. The data analyzed thus far have shown small, but statistically significant correlations between nonauditory factors and change in the HHIE. One possible explanation for the low correlations is that the sample evaluated thus far has been predominantly healthy outpatient subjects below the age of 75. Scores on many of the tests of nonauditory function have been skewed in the direction of normal, therefore restricting the variability of the data. With older and sicker patients we anticipate a greater range of scores on the predictor variables.

[265] EVALUATION OF A NEW NUCLEUS COCHLEAR IMPLANT SPEECH PROCESSOR: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #C93-616AP)*

PURPOSE—Multichannel cochlear implants have been proven to be safe and efficacious for the restoration of some degree of auditory ability in profoundly hearing-impared indivduals. Technological improvements have been made to the external portion, the speech processor, of the Nucleus multichannel cochlear implant. The purpose of this study is to evaluate the effectiveness of this new processing strategy (SPEAK). The system consists of 20 filters from 250 to 10,000 Hz, extracting the highest 6 spectral peaks per stimulation.

METHODOLOGY—Twenty-two original CSP #304 Nucleus users have been fit with the SPEAK processor at the VA center of their original implantation. Testing was conducted immediately following the initial stimulation with the new device and after 3 months usage, the study end-point. Data analysis will commence following the completion of data collection on all patients. SPEAK test results obtained at each of the time intervals will be compared to results obtained with the old coding strategy and to each other.

PROGRESS—All patients have been fit with the new processors, and data collection is progressing. No adverse reactions have occured.

[266] EARLY DETECTION OF HEARING LOSS FROM OTOTOXIC AGENTS BY HIGH-FREQUENCY AUDITORY EVALUATION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project ##C227-RA)*

PURPOSE—A four-site continuation study was designed to determine whether loss of hearing sensitivity due to ototoxicity is detectable in the high-frequency (9-20 kHz) range prior to the conventional frequency (0.25-8 kHz) range. Additional objectives for this study relate to the ototoxic process (progression, direction, and recovery of threshold change) and to individual patient baseline variables (e.g., age, disease state, pre-existing hearing loss). In earlier data analyses, a limited high-frequency range consisting of five consecutively tested frequencies with threshold for the highest frequency no greater than 100 dB SPL, was

found to be sensitive to initial ototoxicity. This range is specified by each individual's hearing threshold configuration and was added as another study objective which may prove to maintain the integrity of early detection of ototoxicity while shortening the time required to conduct monitoring tests.

METHODOLOGY—A computer-based audiometer and immittance system is being utilized by all sites for data collection. This audiometer was shown to provide valid and reliable intra- and inter-session pure-tone threshold results in both conventional and high-frequency ranges with normal-hearing individuals. The geographic distances of the remote-sites from the central-site, and the extensive data management requirements of a multisite research protocol, required the inclusion of computer technology in the study. A computer software program managing the total research project was custom-designed with three main functions: 1) to facilitate remote-site data management; 2) to provide electronic transfer of remote-site to the central-site database; and 3) to consolidate and categorize all data at the central-site for analyses.

Patients treated with ;me4 days of aminoglycoside antibiotics (AMG): amikacin, gentamicin or tobramycin and/or ;mel dose of the chemotherapeutic agent cisplatin (CDDP) are being monitored for hearing sensitivity prior to, during, and following treatment. Control subject data were also obtained. The hearing threshold criteria for the peripheral-sites included baseline thresholds ≤100 dB SPL at 10 and 11.2 kHz in at least one ear. At the central-site, a lower frequency criteria of ≤100 dB SPL at 9 kHz was chosen for further analyses of the target frequency range. Also, younger patients from two additional sites were added as subjects to provide a broader-based population sample.

PRELIMINARY RESULTS—Currently, 337 patients (674 ears) have met criteria and completed ≥3 tests. Data analyses were conducted on the 334 AMG, 193 CDDP, and 75 control-treated ears. Negative (poorer) hearing threshold changes were demonstrated in 30 percent (N=101) of those receiving AMG and 74 percent (N=143) CDDP. Of those ears showing hearing changes, initial changes occurred in the high frequencies (≥8 kHz) or in both the high and low frequencies, in 87 percent (N=212) of the individuals who showed changes. CDDP patients revealed more significant hearing threshold changes across the frequency range. Control subjects revealed minimal change in the hearing thresholds throughout testing. Data analyses of the individualized high-frequency range of hearing demonstrated that if only the target range would have been monitored, 91 percent of initial hearing changes (AMG and CDDP combined) would have been detected.

FUTURE PLANS/IMPLICATIONS—Data from this project have resulted in the development of national guidelines for ototoxicity monitoring. Final analyses of the individualized range data is currently being conducted. Additionally, the development of a miniaturized hearing monitoring device that will flag the target range and electronically report any significant changes in hearing thresholds is in progress. When accomplished, this device will shorten test time and increase patient accessibility without compromising the sensitivity of the monitoring program. The ultimate goal of this research is to prevent communicatively handicapping hearing losses in patients at risk from potentially ototoxic agents.

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[267] EFFICACY OF AN AUDITORY REHABILITATION PROGRAM: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #C92-479AP)*

PURPOSE—The efficacy of a patient-education auditory rehabilitation program, a "Living with Hearing Loss" class (LHL), is being evaluated in a 1-year pilot project. Two research questions are being addressed: 1) Do veterans who participate in LHL report using more effective communication strategies, as measured by the Communication Profile for the Hearing Impaired (CPHI) than veterans who do not participate? 2) Are the changes or lack of changes in the use of coping strategies reported by veterans socially validated by their wives when they are requested to respond to CPHI items as they observe their husbands' behavior?

METHODOLOGY—LHL is an ongoing part of hearing loss management at OETVC and ASOPC. Couples in the treatment group attend six 2-hour classes, receiving information on coping strategies, assistive devices, and rules for improved communication. They participate in group discussions, view and discuss videotapes, and complete and discuss problem-solving homework assignments.

Subjects of this study are retired, first-time hearing aid users, aged 55–75, who were motivated to participate in the LHL and whose wives would also participate. Participation began 3 months after hearing aid fitting. Subjects and their wives are assigned either to treatment or to deferred treatment groups. The CPHI was administered to veterans and their wives on four occasions: week 1, week 5, week 12, and week 24. Couples in the treatment group attended LHL from week 6 to week 11.

PROGRESS—Group data on the sum of the three Communication Strategies subscales of the CPHI are being compiled and will be used for analysis.

Question 1 will be addressed by applying a repeated measures analysis of variance to test differences in mean scores between the two veteran groups at the four points in time. If treatment is effective, it is predicted that the groups will be similar at weeks 1 and 5, but will differ significantly at weeks 12 and 24. Contrasts to be analyzed are Week 1 versus Week 5 (for time changes unrelated to treatment); the average of Weeks 1 and 5 (pretreatment) versus Week 12 (for immediate changes related to treatment); and the average of Weeks 1 and 5 versus Week 24 (for longer term changes related to treatment). Question 2 will be addressed in exactly the same way using the wives' responses. In addition, the correlation between the veterans' and their wives' responses will be evaluated at each time period.

PROGRESS—Data has been collected on 12 subject couples to date. A change in clinic demographics (decrease in the number of first-time hearing aid users requesting services) has resulted in fewer than anticipated subjects being recruited into the study. Data collection will continue until data on the required 30 subjects has been collected. Analysis will not be done until data collection is completed.

RESULTS—Statistical analysis of self-reported performance of two groups of veterans on the CPHI will not be conducted until data collection is complete.

FUTURE PLANS—Data collection is ongoing at two sites: Olin E. Teague Veterans' Center (OETVC) and Austin Satellite Outpatient Clinic (ASOPC).

[268] HEARING AID RESEARCH: IMPROVING THE SELECTION, FITTING, AND EVALUATION PROCESS

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Sponsor: *AudioScan/Etymonic Design Incorporated; Health Canada; Natural Sciences and Engineering Research Council of Canada; Ontario Ministry of Health; Starkey Canada*

PURPOSE—The global objective of this work is to increase the benefit received by hearing aid users. Components of the project include: 1) improving procedures for characterizing the electroacoustic performance of new and existing hearing aids and associated assistive devices such as FM systems; 2) improving procedures for assessing the residual auditory abilities of candidates for a hearing aid; 3) improving procedures for selecting hearing aids for individual hearing-impaired persons; 4) identifying and controlling sources of error in the process of selecting and fitting a hearing aid for a user; and 5) improving procedures for measuring the benefit that a given hearing aid provides to a given user. A particular emphasis is placed on those methods that best characterize the ''real-world'' performance of hearing aids in everyday use and on methods that are clinically feasible.

PROGRESS—We have developed a systematic approach to selecting and fitting linear hearing aids, the desired sensation level approach (DSL). A software system for IBM/PC-compatible systems has been developed and distributed to more than 200 clinics throughout the world. A generalization of this method to guide the selection of compression hearing aids, DSL[i/o], has also been developed. A component of this project has been to develop and validate an innovative clinical protocol for the purpose of predicting real-ear hearing aid performance in infants and children. A computer-based hearing aid test system (HATS) permitting the evaluation of advanced, signal processing hearing aids has been developed. Results relating to the use of this system with noise-based testing, maximum length sequence (MLS) testing, signal-biased testing, and MLS-based coherence have been published. A PC-based system for assessing hearing aid candidacy and the benefit provided by a hearing aid has been developed and some aspects of this test system published.

RESULTS—The DSL approach to hearing aid selection is widely used internationally, with both children and adults. DSL[i/o] is a generalization of the DSL approach that is suitable for hearing aids with compression circuits, as well for as linear aids. Our HATS system completes MLS-based hearing aid tests approximately three times faster than the noise-based measurements (for equivalent frequency responses), and permits both signal-biased testing to evaluate devices in their various operating modes and distortion measurement using MLS-based coherence testing.

FUTURE PLANS—We are continuing to investigate and evaluate the relation between the amplification provided to an individual and the benefit received by the individual. The results from this research will be applied to our system for selecting amplification characteristics. We are studying alternative measures of hearing aid distortion and examining the effects of hearing aid processing on speech sounds, using the computerized speech research environment (CSRE) system. Much of our current work focuses on the application of these approaches to compression and completely-in-canal (CIC) hearing aids.

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Maximum-length-sequence-based coherence measures of hearing aid distortion. Schneider AT, Jamieson DG. J Acous Soc Am. In press.

[269] SHOWSOUNDS AND SOUNDSENTRY: ACCESS TO COMPUTERS AND INFORMATION SYSTEMS FOR PEOPLE WHO ARE DEAF OR HARD-OF-HEARING

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—In the past, people with hearing impairments or deafness have not had much difficulty in operating computers or information systems. The use of sound was usually minimal and usually either decorative or redundant. With the advent of more sophisticated sound systems and multimedia, however, sound is being used in much more diverse fashions. Speech and sophisticated sounds are now being used to convey information which is not otherwise available to the user. As this change in the design of systems occurs, individuals with hearing impairments and deafness are finding themselves at a distinct disadvantage.

METHODOLOGY—To address this issue, the Trace Center has developed a strategy called "ShowSounds." This involves the implementation of a system-level flag or switch which can be turned on by the user. In a computer, this switch would appear in the same place one might adjust the keyboard, mouse parameters, volume of the speaker, and so forth. If a user were unable to hear sounds effectively (due to either a hearing impairment or environmental noise), the person could turn the ShowSounds switch on. Application software which was ShowSounds compatible would automatically check the status of the switch whenever important information was being displayed auditorially. If the ShowSounds switch were turned on, the application software would provide a visual presentation of the information along with the auditory presentation. If speech were being used, then some presentation of the text on the screen would be provided.

A subset of the ShowSounds concept is the SoundSentry, a function that monitors speaker activity and provides an indication of any sound activity occurring at the speaker. The SoundSentry is a fallback function, and would be used with software that is not ShowSounds-compatible.

PROGRESS—The ShowSounds concept has been described in the guideline document "Making Software More Accessible for People with Disabilities," produced by the Trace Center. The Center is in the process of assisting makers of computers and operating systems in implementing versions of ShowSounds in their products.

RESULTS—Preliminary forms of ShowSounds (SoundSentry) are already available from IBM and Microsoft via AccessDOS (for DOS) and the Access Pack (for Microsoft Windows). In addition, Microsoft has endorsed a much fuller implementation of the ShowSounds concept, and has encouraged developers in its Windows NT environment to have their software check for a ShowSounds flag and behave accordingly. Microsoft has also incorporated both ShowSounds and SoundSentry features in to the beta version of Windows 95.

FUTURE PLANS—The Trace Center will be providing assistance to other computer makers who wish to incorporate ShowSounds. Plans also call for the development of a logo to indicate software which is "ShowSounds-compatible." A concept similar to ShowSounds will also be developed for information systems, and included in information system design guidelines published by the Trace Center.

B. Speech Impairment

[270] EVALUATION OF WORD-RECOGNITION PERFORMANCE WITH SENTENCE MATERIAL

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C690-RA)*

PURPOSE—The purpose of this project is to develop a valid and reliable speech test in a sentence format that is useful for diagnostic and assessment of receptive speech communication problems. The following concepts underlie the the speech test developed: 1) a sentence format that can be used adaptively; 2) the use of words in sentence forms that provide either no or neutral contextual cues; 3) test words that are differentiated on the basis of phonologic and psycholinguistic characteristics (viz., frequency of usage and phonetic similarities); and 4) use of the Articulation Index to normalize recognition performance among the various audiometric configurations. In contrast to previous sentence materials, the target words vary with respect to word frequency, confusibility, and linguistic context. The sentences, which are spoken by a female, are representative of everyday speech and easy to repeat.

METHODOLOGY—Selection criteria for target words was based on the number and nature of the component phonemes, syntactic use, and linguistic properties of the words. Initially, more than 1000 mono- and bi-syllabic words representative of everyday speech (nouns, verbs, adjectives, adverbs, and pronouns) were selected from a lexicon of 19,000 words and were sorted sequentially with respect to word frequency and to an index based on the phonetic similarity to other words. The words are divided into the following four groups: high- and low-frequency of usage and high- and low-phonetic distinctiveness. Within each of these four categories, two or three target words were selected for each phonemic content that is representative of language usage. With this sentence format, the task of the subject is to repeat the sentence that is presented. Scoring (correct or incorrect) is restricted to the whole word responses to the target words.

PROGRESS—The initial four studies in this series determined the normal characteristics of the sentence materials for individuals with normal hearing and individuals with hearing loss.

RESULTS—In the most recent study of this ongoing project, the learning effects associated with repeated presentation of sentence materials were investigated. Ten subjects in each of three age groups (<30 years, 40–60 years, and 65–80 years) were studied in 5 sessions over 5 to 10 days. The seven to nine syllable sentences had three target words. Lists of 25 sentences were formed for each of four sentence categories that were based on word-usage frequency and word confusibility. Randomly for each subject, lists of sentences were designated as "control" or "experimental." Adaptive thresholds were obtained for the control lists in each of the five sessions and for the experimental lists in Sessions 1 and 5. Thus, the experimental lists were withdrawn in Sessions 2, 3, and 4.

The following general results were obtained: 1) the mean thresholds for the three groups of subjects were significantly different; 2) the thresholds for the experimental conditions and the control conditions were not significantly different; and 3) the thresholds obtained in Session 5 were significantly lower than the thresholds obtained in Session 1. By receiving practice on the control conditions, the subjects' word-recognition performance improved across sessions. Similarly, the recognition performance of the subjects improved on the experimental materials on which little practice was received. The implication is that the subjects learned the test procedure, including the lis-

tening task and test environment, and did not learn the test words/sentences.

FUTURE PLANS—Our future plans are to incorporate the sentence materials into a test employing fluctuating noise backgrounds typical of everyday listening environments. The test in noise should be capable of reliably identifying individuals with speech communication problems, particularly in noisy listening situations representing a continuum of signal-to-noise ratios typical of everyday listening environments.

[271] COMPUTER-ASSISTED SPEECH EVALUATION EXPERT SYSTEM

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C468-3RA)*

PURPOSE—Diagnostic evaluation of speech requires analysis of speech deviance and speech-related physiological performance. Transfer of laboratory technologies to clinical environments has been slow. Traditional methods are subjective and highly variable. A software/hardware system has been developed for computer-assisted speech evaluation (CASPER). Measures are made of acoustic, aerodynamic, and physiologic signals collected during connected speech, specific diagnostic maneuvers, and user-specified tasks. Performance profiles are obtained and automatically compared to stored normative data.

METHODOLOGY—Programs are written in the C language using algorithms developed and tested in our labs. Studies of normal and speech disordered subjects have assisted in testing reliability and validity of the protocols under development. Field users of the software continue to provide valuable suggestions for refinement.

PROGRESS—During the last year we completed work on additions and refinements to the software. New hardware specifications have been developed and modular CASPER work station is now available. Patient demographic data and clinician comments are stored with the results in a database. Statistical summary data can be requested for a patient or for a group of patients based on user-specified criteria for group label, gender, age, and protocol. Users may enter and edit normative values and critical limits that are used to flag deviant speech or physiological function. The user-specified protocol has been refined to support nearly any custom-designed protocol that results in up to four channels of analog voltage produced by a microphone or physiologic transducers. Full support for calibration allows the user to enter the unit-name of the measured quantity, and voltage levels for both quiescent and reference levels of transducer excitation. Statistics are then reported in calibrated units rather than raw voltages. The analytical tools now include FIR filtering and FFT.

RESULTS—CASPER systems have been installed in 23 VA medical centers and 14 private-sector laboratories, clinics, and universities.

FUTURE PLANS—Dissemination of a windows-compatible version of CASPER in early 1995 will mark the end of active development of the diagnostic system. All current users of CASPER will receive this upgrade. Collaborative work among existing CASPER sites will assist in identifying VA system-wide standard speech assessment protocols. We plan to extend the impact of the existing technology by creating a system for real-time biofeedback that can be used during behavioral treatment of speech disorders.

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[272] USING SELF-MONITORING TO IMPROVE COMMUNICATIVE EFFICIENCY IN APHASIA

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C693-RA)*

PURPOSE—Our objectives are to determine the efficacy of self-monitoring treatment for subjects with mild and moderate aphasia, to determine the social validity of treatment (that is, how unsophisticated listeners rate the effects of treatment), and to determine the influence of speech, language, cognitive, and demographic variables on treatment effectiveness.

METHODOLOGY— The project uses a multiple-baseline design across subjects and across behaviors. Thirty subjects will be selected, 10 in each of the 3 severity groups, according to proportion of disfluencies and communicative efficiency criteria. They will also be assessed with measures to provide additional information about speech production, word-retrieval, and nonverbal cognitive function: variables that may influence treatment effectiveness. Data will be analyzed for effect of self-monitoring on disfluencies and communicative efficiency, for the influence of speech, language, and cognitive variables on treatment effectiveness, and for the social validity of treatment effect. Each subject will be exposed to four conditions: baseline, training, independent self-monitoring, and follow-up. Proportion of disfluencies in the treatment condition and two generalization conditions will constitute the data points for each session. Effectiveness of self-monitoring treatment will be shown by the consistent replication of a treatment effect (the reduction in proportion of disfluencies) each time treatment is applied, across subjects and across behaviors (disfluencies) in each subject.

PROGRESS—Although no treatment data have been collected to date, several aphasic subjects have been pretested and three selected to begin the treatment program January 1995. All speech pathology programs in Dade and Broward Counties were contacted during the summer to assist in recruiting subjects; key personnel in those facilities have provided information about several potential subjects. We plan to enter two to three subjects into treatment at a time, for multiple baseline comparisons. Treatment is estimated to take a minimum of 2, a maximum of 10 weeks per subject. Data from the initial group of subjects, however, will provide information necessary for logistic changes (e.g., actual treatment time, scheduling, and data analysis time). During November and December nearly all the control data was collected on 28/30 subjects, and analysis has begun on this data.

RESULTS—As expected, preliminary analysis shows that normal speakers are substantially more efficient communicators (fewer revisions, repetitions) when compared with even mildly impaired aphasic subjects. Also as expected, the use of a language analysis program (SALT) has dramatically reduced analysis time for discourse samples; however, learning the program required more time than was anticipated and has delayed the start of data collection.

FUTURE PLANS—It is anticipated that all of the aphasic subject data will be collected in the next year. If the self-monitoring treatment program is effective in improving the communicative efficiency of these aphasic subjects, it will provide a simple and quick treatment tool for clinical application in any aphasia rehabilitation setting appropriate for patients at any stage of recovery. In addition, analysis of relation-

ships among several variables and treatment effect will enhance the ability of the clinician to better predict those patients for whom the treatment program is indicated.

[273] CHARACTERISTICS OF CONNECTED SPEECH IN APHASIC ADULTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C817-RA)*

PURPOSE—The overall objective of the research is to determine which characteristics of aphasic adults' connected speech are likely to have the strongest effects on their communicative success in daily life. Specific objectives are: 1) to develop reliable measures of disruptive speech behaviors in the connected speech of aphasic adults; 2) to quantify the frequency and nature of disruptive speech behaviors exhibited by aphasic adults and by non-brain-damaged adults, and to assess how aphasic adults and non-brain-damaged adults differ with regard to these behaviors; and 3) to evaluate the extent to which normal listeners' judgments of the quality and adequacy of aphasic and non-brain-damaged adults' connected speech are related to objectively measured characteristics of the connected speech such as macrostructural integrity, communicative efficiency, and the presence of disruptive speech behaviors.

METHODOLOGY—Connected speech samples from non-brain-damaged adults and adults with aphasia have been transcribed and scored for the presence of several specific behaviors, in addition to the samples' overall communicative efficiency and informativeness. Audiotape recordings of non-brain-damaged or brain-damaged speakers are then played to nondisabled judges, who make subjective judgments about the communicative success of the speakers and the degree to which the speaker's speech characteristics cause various subjective reactions in the listeners.

RESULTS—Speech transcripts from 40 non-brain-damaged adults and 20 adults with aphasia (10 with fluent aphasia and 10 with nonfluent aphasia) have been collected and scored for the presence of nine categories of disruptive speech behaviors (inaccurate words, false starts, unnecessary exact repetition, nonspecific or vague words, filler, the word "and" used as filler, off-task or irrelevant words, part-words or unintelligible words, and nonword fillers). Both groups of aphasic speakers produced significantly greater overall proportions of disruptive speech behaviors than the non-brain-damaged group (approximately one-third of the words produced by the aphasic speakers were classified as disruptive speech behaviors), while only 14 percent of the words produced by the non-brain-damaged speakers were so classified. Aphasic speakers produced significantly more inaccurate words, false starts, and part-words and unintelligible words than non-brain-damaged speakers. The only measure which significantly differed between fluent and nonfluent aphasic speakers was the percentage of nonword filler produced. We have also completed a pilot study of the relationships between various objective measures of communicative informativeness, communicative efficiency, and disruptive speech behaviors and listeners' subjective reactions to aphasic and non-brain-damaged speakers. Preliminary results suggest that normal listeners do not react negatively to the presence of filler, unnecessary repetition, and nonspecific or vague words within the ranges produced by the majority of our aphasic speakers, but are strongly affected by the presence of inaccurate words. In addition, speakers who elaborate on the basic information of narratives are considered more positively than those who provide only the key concepts or main ideas.

IMPLICATIONS—The results of this research promise to affect clinical management of aphasic patients. Sensitive and reliable methods for quantifying the disruptive speech behaviors of aphasic adults will provide for databased decisions about the effectiveness of specific treatment approaches, and enable clinicians to formulate treatment procedures and objectives based upon reliable measures of communicative

anomalies. Knowledge of which disruptive speech behaviors have the greatest effects on normal listeners' subjective judgments of communicative success will enable clinicians to focus treatment on aspects of connected speech that have the greatest potential for improving daily-life communication.

RECENT PUBLICATIONS FROM THIS RESEARCH

System for quantifying the informativeness and efficiency of the connected speech of adults with aphasia. Nicholas LE, Brookshire RH. J Speech Hear Res 1993:36:338-50.

Speech sample size and test-retest stability of connected speech measures for adults with aphasia. Brookshire RH, Nicholas LE. J Speech Hear Res 1994:37:399-407.

Test-retest stability of measures of connected speech in aphasia. Brookshire RH, Nicholas LE. Clin Aphasiol 1994:22:119-34.

[274] APHASIC NAMING DEFICITS: EFFECTS OF DEEP- AND SURFACE-LEVEL TREATMENTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C789-RA)*

PURPOSE—This project is comparing the long-term naming accuracy of aphasic (APH) and non-brain-damaged (NBD) subjects who are being taught the names of complex visual stimuli via a phonologically based or semantically based training procedure. The goal of this study is to develop personalized cueing, the semantically based training procedure, into a treatment for the word-finding deficits associated with aphasia, perhaps as a method of teaching a core vocabulary to moderately and severely aphasic individuals.

METHODOLOGY—Forty APH and 40 NBD subjects will participate in the study. These subjects are being randomly assigned to one of two experimental training conditions. The first training condition is personalized cueing, a cued recall training task where the subjects are asked to create their own training cues. The other condition is first phoneme cueing, a well-known procedure in aphasia therapy that has been used to treat word-finding deficits. Utilizing one of these two training procedures, the subjects are being taught the names of unfamiliar dogs and birds, three times a week for 4 weeks. Some stimulus items, however, are not directly trained by the examiner; rather, they are used as nontrained control items, with the examiner merely saying the target name and not providing any cues. Follow-up probes to assess long-term naming accuracy are conducted 1 week, 1 month, and 6 months after the completion of training.

PROGRESS—Thus far, the project has shown that aphasic subjects are able to create personalized cues for realistic, visually complex stimuli. In addition, all personalized-cue subjects have shown treatment effects out to 1 and 6 months post training.

PRELIMINARY RESULTS—One preliminary analysis of the data compared the naming accuracy of the APH and NBD personalized-cue subjects. Not surprisingly, it revealed that the NBD subjects performed better than the APH subjects. A more interesting finding is the stability of the probe scores out to 1 and 6 months, especially for the APH subjects who often demonstrate rapid declines in naming accuracy over time. Most importantly, paired two-tailed t-tests revealed that the APH subjects' scores for the trained stimuli on the labeling probes were significantly higher ($p<0.05$) than those for the control stimuli, an indication that the APH subjects were assisted by the personalized cue training. In contrast, there were no significant differences between the NBD subject probe scores for the stimuli sets, showing that the NBD subjects accurately learned the names regardless of whether or not they were given any cues.

FUTURE PLANS—Data collection will continue as planned.

RECENT PUBLICATIONS FROM THIS RESEARCH

Labeling of novel stimuli by aphasic adults: effects of phonological and self-cueing procedures. Marshall RC, Freed DB, Phillips D. Clin Aphasiol 1994:22:335-43.

Comparison of personalized cueing and provided cueing on the facilitation of verbal labeling by aphasic subjects. Freed DB, Marshall RC. J Speech Hear Res. In press.

Effects of cue origin on the facilitation of aphasic subjects' verbal labeling. Freed DB, Marshall RC. Clin Aphasiol. In press.

[275] AN ANALYSIS OF A TREATMENT FOR APRAXIA OF SPEECH IN ADULTS WITH APHASIA

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C692-RA)*

PURPOSE—The primary objective of this project is to conduct an experimental analysis of the effects of a treatment designed to promote improved sound productions in apraxic\aphasic speakers. Specifically, the effects of training three different sounds sequentially are being examined in terms of 1) acquisition of trained sounds; 2) response generalization (i.e., to untrained exemplars of treated sounds and to untreated sounds); 3) stimulus generalization (i.e., production of treated sounds in oral reading and phrase/sentence repetition); and 4) maintenance of correct sound production.

A secondary objective of this project is to determine if there are significant differences over time among apraxic speakers and non-brain-damaged speakers on the following aspects of speech production: 1) voice onset time, 2) fricative noise duration, 3) vowel duration, 4) articulatory dynamics, and 5) total word and sentence durations.

METHODOLOGY—A combination of single-subject and group design is being used to accomplish the preceding project objectives. A series of single-case experimental analyses is being conducted and comparative data are being obtained from normal speakers.

Specific sound errors are identified during pretreatment assessment, and three consistent error patterns are targeted for treatment for each apraxic subject. Treatment is applied to each subject individually and in a manner consistent with a multiple baseline design across behaviors and subjects. Treatment consists of a combination of minimal pair contrast and traditional therapy methods. Baseline, treatment, and maintenance probes are conducted for each individual subject to evaluate production of specific sounds.

In addition to continuous measures, pre- and post-test measures have been obtained from the treatment subjects and from nondisabled subjects to further evaluate treatment effects and reliability of measures, respectively. These measures include temporal and spectral analyses of 400 words and 25 phrases/sentences, elicited twice from each subject.

RESULTS—Findings, to date, have indicated that treatment is effective in improving target sound production in treated words; treatment is effective in promoting response generalization to target sounds in untreated words; stimulus generalization to phrase level productions may be limited or lacking for some subjects; and measurement of stimulus generalization to oral reading may be confounded by aphasic deficits.

Acoustic analyses involving non-brain-damaged speakers have been completed. These findings revealed VOT to be a stable measure across sampling times. However, measures of total duration (e.g., word and sentence durations) were variable over time in these nondisabled speakers. Additional acoustic analyses of our normative sample and pre- and post-treatment samples of apraxic speech are currently being completed. Although these analyses are ongoing, it appears that most of the treatment subjects did evidence timing and coordination difficulties. It also ap-

pears that the rather general acoustic measures (e.g., VOT, vowel duration, etc.) were not always reflective of changes effected in treatment. That is, sound specific measures may be a better indication of treatment changes than general acoustic measures.

FUTURE PLANS—Our findings suggest that our future treatment efforts should be directed toward promoting additional, stronger stimulus generalization effects, possibly by modifying and extending treatment to additional stimulus conditions. To advance our understanding of stimulus generalization, speech production will be measured in numerous contexts external to the treatment situation. In order to better understand the nature of our apraxlc\aphasic subjects' sound errors, future research will include simultaneous acoustic and physiologic examination of correct and incorrect sound productions. Perceptual evaluations will continue to be an important part of determining treatment effects.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Minimal contrast treatment for apraxia of speech. Wambaugh JL, Doyle PJ, Kalinyak MM, West JW. Clin Aphas. In press.

Review of acoustic analyses of aphasic and/or apraxic speech. Wambaugh JL, Doyle PJ, Kalinyak MM, West JW. Clin Aphas. In press.

[276] CONVERSATIONAL SKILLS TRAINING FOR APHASIC SUBJECTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C330-RA)*

PURPOSE—The objectives of the program are to 1) evaluate the effects of Conversational Skills Training (CST) on the informativeness of aphasic subjects narrative and conversational discourse; 2) determine the extent to which objective measures of informativeness obtained under structured discourse conditions predict subjects' performance on those measures under conversational discourse conditions; and 3) describe the relationship between objective measures and subjective ratings (i.e., direct magnitude estimates) of the informativeness of aphasic subjects' discourse.

METHODOLOLOGY—Single-subject experimental designs are being utilized to examine the effects of CST on several objective measures of informativeness across a variety of sampling conditions. Descriptive correlational designs were employed to examine the relations between measures of informativeness under conversational and structured sampling conditions, and between objective measures and direct magnitude estimates of informativeness.

RESULTS—Preliminary results of single subject data indicate that the effects of CST on the informativeness of aphasic subjects connected discourse are equivocal as measured by correct information units, and accurate and complete main concepts. Clearer effects have been demonstrated for some subjects on measures of informative minimal discourse units obtained under conversational sampling conditions. Post hoc analyses of conversational interactions reveal that much of the uncontroled variability in subject performance may be attributed to characteristics of the conversational partner, with some partners serving as better conversational facilitators than others.

Comparisons of subject performance under conversational and structured discourse conditions (n=20) revealed that subjects produced significantly greater percentages of correct information units under conversational discourse conditions, but that the percentage of correct information units produced during structured discourse tasks could be used to predict performance under conversational conditions with a high degree of accuracy. Correlational analysis of objective measures and direct magnitude estimates of aphasic subjects' informativeness (n=25) indicated that objective measures were strongly correlated with perceived informativeness, and that overall severity of aphasia did not fully account for the perceptions of the raters.

RECENT PUBLICATIONS FROM THIS RESEARCH

Effects of setting variables on conversational discourse in normal and aphasic adults. Doyle PJ, Thompson CK, Oleyar KS, Wambaugh JL, Jackson AV. Clin Aphas 1994:22:135-44.

Relation between objective measures and listeners' judgments of the communicative informativeness of aphasic adults' connected discourse. Doyle PJ, Tsironas D, Goda AJ, Kalinyak M. Clin Aphas. In press.

[277] MEASUREMENT AND PREDICTION OF BENEFIT FROM AMPLIFICATION

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PURPOSE—The goals of this project are to elucidate underlying mechanisms that determine the amount of benefit received from hearing aids in everyday life and to develop methods of quantifying and predicting hearing aid benefit for elderly listeners.

METHODOLOGY—Two major avenues of investigation have been pursued in the past year: the study of the relationship between certain cognitive variables and hearing aid benefit, and the development and evaluation of methods for selecting and fitting nonlinear hearing aids so that these types of instruments can be included with linear hearing aids in studies of benefit prediction.

To assess the contributions of cognitive variables to hearing aid benefit, experienced hearing aid wearers provide data on tests of working memory, speed of mental processing, use of auditory context, and mental flexibility. Other variables thought to be related to benefit are also measured (audibility change, *in-situ* distortion, and auditory resolution). The dependent variable, hearing aid benefit, is quantified in terms of improvement in speech understanding resulting from amplification. Multiple regression techniques are used to address the research questions.

Nonimpaired and hearing-impaired subjects provide data that are used to develop a clinically practical approach to hearing aid selection and fitting that can include nonlinear as well as linear amplification.

PROGRESS—Data collection has been completed for 18 hearing aid wearers in the study of cognitive variables. Data collection is continuing on this project. In addition to using established procedures for measurement of cognitive function, we have developed a new test to quantify the use of auditory context, called the Word In Context Intelligibility Test (WICIT).

Three clinical test instruments are under development to facilitate fitting nonlinear amplification: 1) The Contour test determines the level of pulsed warble tones that corresponds to each of seven loudness categories from "very soft" to "uncomfortably loud." 2) Results of the Contour test are used by the Visual Input/Output Locator Algorithm (VIOLA), a DOS-based software program developed in our laboratory, to determine amplification targets necessary to normalize loudness relationships among typical speech input levels. VIOLA is also used to evaluate the ability of various hearing aids to amplify speech to match the target levels. These results are used as the basis for selection of an appropriate instrument. The concept of the VIOLA approach to selecting amplification has undergone preliminary evaluation. An investigation of the accuracy of hearing aid selection based on input/output functions is underway. 3) The Abbreviated Profile of Hearing Aid Benefit (APHAB) was developed based on data from 128 hearing aid wearers. The APHAB is a self-assessment inventory that quantifies disability resulting from a hearing loss. It is used pre- and post-fitting to document benefit from the hearing aid.

RESULTS—No results are available as yet in the study of cognitive variables.

Norms for the Contour test have been determined based on responses of 45 normal-hearing listeners. Test-retest differences for hearing-impaired subjects are typically less than 10 dB. Preliminary norms for the APHAB have been developed based on responses from successful wearers of linear hearing aids. Cur-

rent versions of the Contour Test and the APHAB are in use in several clinical sites as well as in our research laboratory.

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On the evaluation of a new generation of hearing aids. Cox RM. J Rehabil Res Dev 1994:30:297-304.

Prediction of hearing aid benefit: the role of preferred listening level. Cox RM, Alexander GC. Ear Hear 1994:15:22-9.

Relationship between in-situ distortion and hearing aid benefit. Cox RM, Taylor IM. J. Am Acad Audiol 1994:5:317-24.

Abbreviated profile of hearing aid benefit (APHAB). Cox RM, Alexander GC. Ear Hear. In press.

[278] RESTORATION OF ORAL FUNCTION WITH MAXILLARY BONE GRAFTS AND IMPLANTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A649-RA)*

PURPOSE—Dental implants can greatly improve oral function. However, many candidates for implants have resorbed too much bone to support maxillary implants. This study was designed to demonstrate that autologous corticocancellous bone grafts from the ilium to the maxillary sinuses will mature (consolidate) and support titanium cylindrical implants, which will in turn support a fixed prosthesis that will withstand the masticatory forces of a similar prosthesis in the mandible. It is expected that subjects' biting force, mastication, deglutition, dietary intake, nutritional knowledge/attitudes, and reported self-esteem will improve subsequent to implant therapy and nutritional education, while speech articulation and acceptability will remain unaffected. The current patient population of the VA can benefit greatly from these procedures.

METHODOLOGY—After pretherapy evaluation of bite force, speech, deglutition, mastication, dietary intake, nutritional knowledge/attitudes, and reported self-esteem, subjects undergo the following: 1) bone transplant from the ilium to the maxillary sinus, and placement of five titanium cylindrical implants into the anterior mandible; 2) a soft tissue procedure on the mandible 2 months following bone augmentation and implant placement, if necessary; 3) 2 months later, placement of abutments through the soft tissue and attachment to the mandibular implants; 4) construction and placement of a fixed bridge to the mandibular implants and construction of a new maxillary conventional denture; 5) bone grafting placement of 6-8 implants in the bony maxilla, 4 of which are in the bone grafts 5.5 months later; 6) placement of abutments through the maxillary soft tissue and attachment of abutments to implants 6 months later; and 7) implant-supported maxillary fixed bridge construction. Computerized axial radiographs are used to determine the status of osseointegration. Post-testing is performed 1 month and 1 year after step 7.

PROGRESS—Autologous corticocancellous bone grafts from the ilium to the maxillary sinuses have matured and supported titanium cylindrical implants in all 20 subjects selected for this study. More than 75 percent of these subjects who have completed the treatment protocol have an implant supported maxillary fixed bridge successfully opposing an implant supported mandibular fixed bridge.

RESULTS—Thirteen out of 20 subjects have completed the treatment protocol. Twelve of these subjects have undergone post-testing at 1 month. Two of them have undergone post-testing at 1 year. Bite force testing results at 1 month indicate significant differences in both maximum average bite force ($F=37.87$, $df=1/7, p<0.0005$), and peak bite force ($F=41.52$, $df=1/7$, $p<0.0004$). The bite forces have been maintained at the 1 year follow-up. In some cases, bite

force has increased by a factor of 10. Masticatory performance tests conducted at 1 month have shown significant differences in masticatory effectiveness ($M=52.81$, $SE=9.01$, $p<0.05$) and a trend toward improvement in masticatory efficiency.

FUTURE PLANS—We will continue to pursue objectives and conduct 1 year post-testing of this therapeutic approach. We will seek future grants to extend current experimentation by using other sources for bone grafting, including freeze-dried bone.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Nutritional intake, knowledge and attitudes of geriatric long-term denture wearers. Mobley C, Chamberlain C, Saunders M. In: Proceedings of the 47th Annual Convention of the Gerontological Society of America, Atlanta, GA, November 1994.

[279] TREATMENT OF DYSPHAGIA IN AGE-RELATED DISEASE: STROKE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E728-GA)*

No report was received for this issue.

[280] CRICOPHARYNGEAL MYOTOMY STUDY

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Sponsor: *National Cancer Institute, National Institutes of Health*

PURPOSE—This study will attempt to answer on a prospective basis whether performance of a cricopharyngeal myotomy improves swallowing. This surgical procedure has been purported to improve dysphagia from a variety of illnesses.

PROGRESS—This multi-institutional, multiyear trial has been closed to case accrual. The subjects for this trial were patients with squamous cell carcinoma involving the supraglottic larynx and the base of tongue. This population is anticipated to suffer with dysphagia following standard therapy. The randomization of the study is between performance of a cricopharyngeal myotomy versus no myotomy. The primary methodologic tool was videofluoroscopic examination with a central review. The study has recently been unblinded and the data is being correlated for publication.

C. Vision Impairment

[281] DESIGN AND TESTING OF AN ELECTRONIC TRAVEL AID FOR BLIND PERSONS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C637-RA)*

No report was received for this issue.

[282] EVALUATING THE EFFICACY OF A PERIPHERAL VISION EXPANDER SYSTEM: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #C92-466AP)*

No report was received for this issue.

[283] DESIGN AND EVALUATION OF LIQUID CRYSTAL (LC) DARK-ADAPTING EYEGLASSES FOR PERSONS WITH LOW VISION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C776-RA)*

No report was received for this issue.

[284] NATIONAL SURVEY OF IMPACT OF LOW VISION AID USE AMONG VETERANS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C639-RA)*

No report was received for this issue.

[285] ENVIRONMENTAL INFORMATION NEEDS FOR WAYFINDING BY SPECIAL POPULATIONS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E561-RA)*

No report was received for this issue.

[286] DEVELOPMENT OF A PREDICTIVE MODEL OF DRIVING PERFORMANCE IN STROKE PATIENTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C754-RA)*

PURPOSE—The overall aim of our studies is to determine the visual and cognitive factors predictive of automobile driving performance in patients who have suffered cerebral vascular accidents (CVAs) or strokes affecting primarily the occipital cortex resulting in hemianopsia, or hemifield loss.

METHODOLOGY—We are currently collecting data from stroke patients over the age of 65, and from an age-similar control group. These data include the results of visual tests, including contrast sensitivity, visual fields, color vision, and visual acuity. In addition, we are collecting information from a battery of neuropsychological tests including subtests from the Wechsler Adult Intelligence Scale-Revised, the Wechsler Memory Scale-Revised, and test of visual from discrimination. The neuropsychological tests are designed to establish the level of cognitive deficit as a result of the stroke. The driving abilities of the subjects are evaluated through the use of an interactive driving simulator and an on-road test. The stroke patients also undergo a neurological screening.

PROGRESS—To date, we have tested a large group of older control subjects, a group of CVA patients (approximately equivalent numbers of left and right visual field loss), and a sample of younger control subjects (age range, 21 to 64 years).

PRELIMINARY RESULTS—On the simulator, the stroke patients are having more incidents where they cross over the boundaries of the driving lanes, more accidents, delayed response time to stop signs, more abrupt braking patterns, and are driving at slower speeds compared to the older control subjects. On-road, the stroke patients have lower overall scores and lower scores on subareas of the test such as intersection observance, backing-up, attention, lane observance, and merging. The stroke patients also tend to drive at slower speeds on the road test.

We are finding some strong relationships between vision and driving performance. On the simulator, better visual acuity appears to be correlated with higher speeds, shorter braking response time and fewer lane boundary crossings; additionally, better contrast sensitivity has shown to be related to higher speeds, fewer lane boundary crossings, and fewer accidents. On the road test, better visual acuity also appears to be positively correlated with higher overall scores, and specific subindexes include maintaining proper lane position while merging and maintaining appropriate speed. Likewise, higher contrast sensitivity also seems to be positively correlated with higher scores on specific subindexes, including maintaining proper lane position, maintaining proper lane position while making turns, and driving at appropriate speeds.

Higher cognitive abilities also show a relationship to driving performance. Lower scores on the test of visual form discrimination have been found to be

significantly related to higher slopes of the braking response curve. This may reflect a tendency for those who have difficulty discriminating a sign to brake more abruptly. The overall score on the road test has been shown to be related to digit span subtest scores (a test of visual attention) and the judgment-of-line orientation scores (a test of visual perception).

Simulator performance seems to be correlated with on-road test performance especially in the areas of lane boundary observance, speed, and merging behaviors. A subgroup of the stroke patients has been identified with more horizontal eye scanning movements than the control group, reflecting an attempt to expand their perceptual/visual field space in order to compensate for visual field losses. Future research will be aimed at identifying characteristics indicative of these compensation strategies in the stroke patients.

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[287] STIMULATION OF RETINAL PHOTORECEPTOR FUNCTION WITH ARRAYED SUBRETINAL MICROPHOTODIODE IMPLANTS: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #C93-569AP)*

PURPOSE—Many blinding conditions affect selectively the photoreceptors, the cells that transduce photic energy into a neural signal. The purpose of this project was to assess whether a semiconductor-based microphotodiode array might provide the basis for the development of a prosthetic device that could be used in such patients. The current generation of the array consists of a series of microphotodiodes (each 20 μm^2) arranged in a silicon disc substrate (1100 microphotodiodes/mm^2). Each element of the array responds to light (from 500 to 1100 nm) with a graded electrical current.

METHODOLOGY—In the first step, semiconductor microphotodiode arrays (SMAs) were implanted into adult cats under isoflurane anesthesia (0.8 percent) using sterile surgical techniques. An incision made in the temporal sclera was used to provide access to the vitreous chamber and the retina. Different degrees of vitrectomy were used to assess the ease with which the implant could be passed through the vitreous body. A small amount of saline was injected subretinally and an incision made at the side of the bleb that was formed. The SMA was carried through the vitreous and inserted under the retina. The scleral incision was then closed and the cat awakened.

At later dates, the status of the SMA under the retina was assessed by ophthalmoscopy. In addition, responses were recorded from the retina (electroretinograms or ERGs) and the cortex (visual evoked potential or VEPs) in response to infrared (IR) stimulation. Since the visual system of the cat is not sensitive to IR wavelengths, IR stimulation was used to isolate SMA-mediated activity. Electrophysiological responses were recorded after the cat was sedated with ketamine (11 mg/kg) and xylazine (2 mg/kg). A corneal contact lens electrode was used to pick up the ERG; a sterile needle electrode inserted over the visual cortex was used to record the VEP. An electrode placed in the mouth served as the reference while a second needle electrode placed in the skin of the lower back served as ground.

PROGRESS—SMAs were reliably placed under the retina. The vitrectomy is a critical determinant of the surgical success. While a degree of vitrectomy is necessary to allow the SMA to be passed through the vitreous body, a complete vitrectomy invariably re-

sults in a complete retinal detachment. In comparison, a partial vitrectomy that opens a channel to the implant site appears to be ideal. In fact, one SMA has remained in a stable position for over 8 months using a partial vitrectomy technique.

RESULTS—After successful surgeries, the SMA responded to IR light with an implant spike of several hundred μVs. Small ERG signals have been recorded that can be attributed reliably to SMA activity. SMA-driven cortical signals have not been seen to date.

FUTURE PLANS—These results attest to the appropriateness of the present approach toward developing a retinal prosthetic device. Nevertheless, many questions remain. We plan to follow animals with successfully implanted SMAs, to characterize the long-term stability of the SMA position and tolerance for the subretinal space. Eyes with implants will be prepared for histological evaluation. Since the relatively large size of the implant appears to make it unsuitable for human application, smaller devices are being designed. These smaller devices may interfere less with nutrient supply to the inner retina overlying the solid implant, a factor which may be responsible for the lack of cortical activity observed in the present studies. Future generation devices will be tested as they become available to determine whether this approach can be optimized in terms of function and long-term stability for use in patients with retinal disorders.

[288] TOUCHSCREEN ACCESS FOR INDIVIDUALS WHO ARE BLIND: "TALKING FINGERTIP" STRATEGY

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—One of the most rapidly proliferating types of public information system is the touchscreen kiosk. These self-serve devices provide information in a wide variety of settings, including shopping centers, airports, and government offices. The touchscreen (often combined with color graphics, sound, and video) makes the system easy to use and attractive for many users. The touchscreen has also become common in the design of automated transaction machines (ATMs).

As more and more information systems use the touchscreen as an input device, access by people who are blind, who have low vision, or who have reading problems must be addressed. Because public information systems cannot be modified for the needs of individual users, any accessibility strategy must be built into the original design and must work equally well for sighted users.

METHODOLOGY—Using a combination of haptic and audio strategies, a "talking fingertip" technique is being explored. Users can locate on-screen objects (such as menu lists, buttons, on-screen keypads, and fields of text) by moving a fingertip across the touchscreen. When an on-screen object is encountered, audio output provides the text to correspond to that object. Auditory cues are also provided to indicate areas which are not active. Once the user has located a chosen selection, he or she can select it. Several strategies for selecting are being considered, including: removing the fingertip from the screen, touching the chosen area a second time, or increasing pressure on the chosen area.

PROGRESS—An initial prototype has been created, based on a commercially available kiosk software package. Informal testing and user feedback have resulted in several changes to the design.

RESULTS—The goal of testing the technique is to determine if it, or some modified version, could be used in commercially available information systems. If the technique produces successful performance and is acceptable to users, it could provide access to a type of information system interface which is currently inaccessible to many people with disabilities.

FUTURE PLANS—The current Talking Fingertip prototype is being modified to accept increased finger pressure as a selection technique. Two different selection strategies (removing the finger and increased pressure with the finger) will be compared for effectiveness and user preference. The system will also be laboratory tested for performance issues. A test implementation will be done on a commercial kiosk system to test the practicality and applicability across a wide range of screen layouts and controls.

[289]IDENTIFICATION OF SKILLS AND KNOWLEDGE NECESSARY FOR PEOPLE WITH VISUAL IMPAIRMENTS BEGINNING JOBS AFTER GRADUATING FROM POSTSECONDARY INSTITUTIONS

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Sponsor: *National Institute on Disability and Rehabilitation Research; Mississippi State University*

PURPOSE—The purpose of this project is to identify skills and knowledge necessary for people with visual impairments to make the transition from college to the workplace. This project builds on work completed in a previous project on transition from high school to college.

METHODOLOGY—Researchers wrote state directors of vocational rehabilitation programs and college administrators to obtain names of recently employed college graduates with visual impairments. An employee questionnaire was written and administered to 55 employees. We secured permission from some of the employees to contact their employers, designed and tested interview forms, and completed interviews with 26 employers. Data from the employee survey have been entered into the computer and analysis is ongoing.

PRELIMINARY RESULTS—Employees stated that the following were the most important in obtaining a job: making a career choice, developing a resume, locating transportation, communicating with others about the type of job desired, communicating with employers about accommodation needs, practicing being interviewed, visiting job sites, and making housing arrangements. The most common problems experienced by employees at work included the following: having enough money; locating transportation; being discriminated against because of the visual impairment; assessing books, written materials, diagrams, and charts; being lonely; and managing time. Employer data has not yet been analyzed.

FUTURE PLANS—Analysis of employee data will be completed and employer data will be analyzed. Particular attention will be paid to the qualitative portion of the analysis. Reports will be written and disseminated during late 1995. Results from this study and a related study on transition from high school to college will be used to write a brochure identifying the skills, knowledge, and steps necessary for students with visual impairments to successfully make the transition from high school to college and from college to the workplace. These materials will be disseminated to high school students, counselors, and parents, as well as to college students, advisors, and rehabilitation personnel to help increase the number of students with visual impairments completing college and beginning work.

[290] IDENTIFICATION OF SKILLS, KNOWLEDGE, AND STEPS NECESSARY FOR STUDENTS WITH VISUAL IMPAIRMENTS ENTERING POSTSECONDARY INSTITUTIONS

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PURPOSE—The purpose of this project was to identify skills, knowledge, and steps necessary for students with visual impairments to make the transition from high school to college for the purpose of advanced training in order to successfully compete in the job market.

METHODOLOGY—Telephone interviews were conducted with 102 college students, and mail survey instruments were completed by 65 college administrators. Questionnaire responses were analyzed using frequency analysis, correlation analysis, and factor analysis. A separate qualitative analysis of students' responses to two open-ended questions was also conducted.

RESULTS—Students with visual impairments can successfully attend college with their sighted peers if support services are available. In order to successfully compete at the college level, students with visual impairments must: 1) have a good academic background, 2) possess a repertoire of study skills, notetaking skills, and test-taking skills, 3) be able to keep up with reading assignments, 4) be able to ask for appropriate assistance, and 5) have adequate financial resources. The biggest problems encountered by students were managing their time; accessing diagrams, charts, books, and written materials; having enough money; and overcoming difficult classes or assignments.

FUTURE PLANS—The project is complete. However, results from this study will be used in a related project which identifies skills and knowledge necessary for people with visual impairments beginning jobs after graduating from college. A Transition Activity Calendar was developed from this study, which will be used to help high school students prepare for college.

RECENT PUBLICATIONS FROM THIS RESEARCH

The transition to college for students with visual impairments: technical report. McBroom LW, Sikka A, Bartlett LJ. Mississippi State, MS: Mississippi State University, Rehabilitation Research and Training Center on Blindness and Low Vision. 151 pages. 1994.

[291] THE HEAD READER—A DISPLAY FOR SENSORY IMPAIRED BOWLERS

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Sponsor: *Royal Society for the Blind, Gilles Plains, South Australia*

PURPOSE—Lawn bowls is a popular sport for the visually impaired (VI) sportsperson as it requires a great deal of skill without the fast reflexes and physical exertion inherent in most sports. This project commenced in 1991 with a grant to build an audio-tactile display for VI lawn bowlers, known as "The Head Reader," which would assist the bowler in interpreting the current status of the bowls in play. This would lead to greater control and independence in the match play for the VI bowler. A device based around a personal computer which translated an image from an overhead camera into an audio-tactile and enlarged visual display was installed on indoor rinks at the Royal Society for the Blind and on an outdoor rink at the headquarters of the Blind Bowling Association during 1992.

PROGRESS—During installation, and since, there has been resistance from senior bowlers to the Head Reader which has been seen as threatening the special relationship between the VI bowler and the assistant who currently helps the bowler throughout the game. A more favorable response was obtained by bowlers with residual vision who could examine the enlarged visual display.

FUTURE PLANS—Further evaluation will concentrate on younger VI bowlers who may adapt more readily to the Head Reader. The Head Reader is currently being installed at the new Lend-A-Hand Centre on covered outdoor rinks. This Centre aims to provide facilities for bowlers with many types of handicaps. The Head Reader will be evaluated by these different groups and already appears to be popular amongst non-VI bowlers with an impaired vision of the rink, including wheelchair bowlers and brain injured bowlers.

XV. Spinal Cord Injury and Related Neurological Disorders

A. General

[292] MULTIMODALITY IMAGE REGISTRATION OF THE CERVICAL SPINE

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PURPOSE—Computed tomography (CT) provides excellent contrast for the vertebrae of the cervical spine, but its contrast for intervertebral discs, nerves, and muscles is poor. On the other hand, magnetic resonance imaging (MRI) provides excellent contrast for intervertebral discs, nerves, and muscles. Due to the above complementary characteristics, both CT and MRI are often acquired when treating certain spine disorders. A surgeon must mentally register these images to reconstruct a three-dimensional model of the cervical spine, a difficult task for the most experienced surgeon. This subjective practice is prone to error and does not provide quantitative means of registration or intuitive means of visualization. The goal of this project is to register CT and MRI images of the cervical spine and provide a set of tools for visualizing and manipulating these images.

METHODOLOGY—MRI images suffer from significant geometric distortion, which we correct using our patented algorithm. We then segment the CT and MRI images to isolate individual vertebra of the cervical spine. Two sets of image-features are extracted from each subvolume: the surfaces corresponding to the vertebrae, and the "boneness" in CT and lack of "boneness" in MRI. Features from CT and MRI images are then matched to find the rigid body transformations (RBT) between the CT and MRI, thus completing registration. Two matching methods are used: surface matching-based registration (SMBR) and image correlation-based registration (ICBR). We assume a piece-wise RBT between CT and MRI images of each vertebra, since patient posture is different in CT and MRI images. CT-space is then mapped to the MRI-space, producing a composite image set.

PROGRESS—We have developed a spiral CT and a 3D fast GRE (gradient recalled echo) MRI protocol (with distortion correction) to highlight the image-features. Automatic and semiautomatic tools to localize vertebrae in CT and MRI for matching have been developed. Our SMBR uses contour detection followed by triangulation to generate the surfaces, which are then matched using a nonlinear optimization algorithm. For ICBR, we have developed a set of filters optimized for the imaging protocols to generate feature images. These feature images are then matched using a multiresolution pyramidal search algorithm. We have also created three tools to visualize the composite images: flood fill, window in/window out, 3-D surface rendering.

RESULTS—Fusion accuracy of the order of 1 mm has been achieved in cadaver brain models. Preliminary demonstrations of nine patients to physicians have resulted in enthusiastic positive responses. The

physicians were able to visualize the spinal organization of individual patients significantly better by using our tools compared to the traditional light-box-based mental visualization.

FUTURE PLANS—New imaging protocols (with MRI distortion correction) to highlight vertebral structure and particular spinal pathologies will be developed. With this, a sizable population of patients can potentially benefit from the system. Surface localization and registration accuracy will be further improved by incorporating new algorithms for SMBR. The semiautomatic segmentation will be made automatic or more user-friendly. A set of experiments will be performed using phantoms, cadavers, and VA patients to quantify CT/MRI registration accuracy of the cervical spine.

RECENT PUBLICATIONS FROM THIS RESEARCH

MR geometric distortion correction for improved frame-based stereotaxic target localization accuracy. Sumanaweera T, Glover G, Hemler PF, Martin D, Adler J, Napel S. Magn Reson Med. In press.

[293] WHEELCHAIR EXERCISE AND DIGITAL ECHOCARDIOGRAPHY FOR THE DETECTION OF HEART DISEASE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B716-RA)*

PURPOSE—This investigation will compare the sensitivity, specificity, and predictive value of wheelchair (WC) ergometry with and without exercise digital two-dimensional echocardiography (ECHO) for the detection of myocardial ischemia. The purpose of this research is to establish a cost effective and clinically useful noninvasive diagnostic procedure for detection of coronary artery disease (CAD) in persons with lower limb disabilities.

METHODOLOGY—Data from patients who have had angiography within ±6 months of WC+ECHO will be used to evaluate sensitivity and specificity. Patients who complete the WC exercise but do not undergo angiography will be followed for 9 months to establish predictive value of a positive or negative test. Cardiologists blinded to patient status will independently review WC+ECHO studies, electrocardiograms (ECG), and angiographic films. The WC exercise test protocol utilizes 2-min stages with 30-sec pauses between stages for blood pressure measurements. Exercise will begin at 6 W with 6 W increases in subsequent stages. We have designed and constructed a new prototype imaging table that will permit us to begin echocardiographic imaging with the lower limb disabled patient in the left lateral reclined position within 20 sec of the end of exercise. Information that will be collected for analysis includes subjects' medical history and demographic data (prior to testing and 9 months after testing), metabolic measurements, blood pressure, ECG, rating of perceived exertion, exercise induced symptoms, and resting and peak exercise echocardiographs.

PROGRESS—One hundred seventy-nine maximal WC exercise tests with ECHO (WC+ECHO) have been completed. Additionally, 47 subjects finished the WC exercise test without ECHO. Fifty-seven patients underwent coronary angiographic procedures. Follow-up interviews have been completed on 82 subjects.

RESULTS—The peak metabolic and hemodynamic measures (mean ± one standard deviation) for the 179 subjects who completed WC+ECHO were heart rate (133±23), systolic (169±26) and diastolic (84±15) blood pressure, rate pressure product (22432±5279), percentage of age predicted maximal heart rate (85±14), and metabolic equivalents (4.6±1.4). We cannot report sensitivity, specificity, or prognostic value of WC+ECHO at this time because the data analysis is in progress.

Consistency of echocardiogram interpretation (i.e., intra- and inter-rater reliability) is important. In this study, for the first time, we have begun examining inter-rater reliability for WC+ECHO on a small subset of the sample (n=13). The interpretation of the echocardiograms (normal, abnormal, and non-diagnostic) by two cardiologists working independently were in complete agreement. In 100 percent of the cases they agreed on the affected distribution of coronary blood flow at peak exercise, and had 60 percent agreement in the resting condition. There was a strong relationship ($p<0.002$) between the cardiologists' evaluation of segmental wall motion changes, the wall motion score index (WMSI), and percent normal muscle score (%NMS).

The procedures developed by Bland and Altman to assess agreement between clinical measurements was also applied to the WMSI and %NMS. As the average WMSI and %NMS given by the cardiologists increased, the differences in the WMSI and %NMS increased. This pattern tended to widen the 95 percent confidence interval for the lower and upper limits of agreement. The small number of subjects used in the analysis could explain this finding. However, the participating cardiologists found this information to be useful and recommended that these analysis be expanded to include all 179 echocardiograms.

FUTURE PLANS/IMPLICATIONS—We believe the final data analysis will demonstrate that the sensitivity and specificity of WC+ECHO for the detection of CAD in patients with lower limb disabilities is markedly improved with the addition of echocardiography. The feasibility of expanding this research to include a minimum of two additional VA Medical Centers is being explored.

RECENT PUBLICATIONS FROM THIS RESEARCH

Initial clinical evaluation of a wheelchair ergometer for diagnostic exercise testing. Langbein WE, Maki KC, Edwards LC, Hwang MH, Sibley P, Fehr L. J Rehabil Res Dev 1994:31:317-25.

[294] EFFECT OF SUPPORTED STANDING AND UPPER BODY EXERCISE ON LOWER EXTREMITY SPASTICITY IN PERSONS WITH SPINAL CORD INJURY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B811-RA)*

PURPOSE—The purpose of this research is threefold: 1) demonstrate that supported standing and/or aerobic upper body exercise (AUBX) significantly alters signs of the upper motor neuron syndrome (UMNS), particularly lower extremity tone and reflexes, in patients with spinal cord injury (SCI); 2) analyze neurophysiological measures indicative of altered motor neuron pool excitability and/or presynaptic inhibition and define the relationship between these measures and changes in signs of UMNS following AUBX or standing; 3) use electrophysiological measurements to explain the pathophysiology of specific aspects of UMNS.

METHODOLOGY—In the full experimental protocol, subjects complete three procedures: 1) to test the effect of moderate intensity AUBX on signs of UMNS, subjects perform 20 min of submaximal wheelchair ergometry (WCE) exercise; 2) to examine the effect of low intensity activity, subjects complete 30 min of supported standing; 3) a timeout (control condition) is included to isolate effects of low and moderate intensity physical activity on tone and reflexes from changes occurring during quiet rest and testing procedures.

Tone at the knee is assessed by pendulum drop test (PDT) via computer-sampled electrogoniometers and R2n, the normalized relaxation index (ratio of bidirectional angular deflections of the limb from final resting position). To assess tone at the ankle, perturbations are applied to the foot via a motor; the stiffness coefficient is estimated from measured displacement, acceleration, and torque. The tibial nerve is stimulated and H/M ratios and F-waves used to assess motoneuron pool excitability. Suppressive effects of vibration on H reflexes are measured.

Baseline measurements of tone and reflexes are followed immediately by one of the experimental conditions. To examine the temporal pattern of changes in tone and reflexes following the experimental condition, all measurements are repeated immediately following activity or timeout and at 90-min intervals for 3 hours.

PROGRESS—In a pilot investigation, the above protocol, excluding the supported standing condition, was applied to three SCI and two neurologically intact subjects. Subsequently, a modified protocol was formulated using maximal AUBX and measurements of only pre- and post-exercise reflexes and tone at the knee. This protocol was applied to a group of 12 participants of the 1994 Golden Age Games (ages 62 to 83 years) having a variety of lower limb disabilities including SCI, arthritis, peripheral neuropathy, amputation, fracture, knee replacement, cerebral vascular accident, and multiple sclerosis.

RESULTS—Pilot study results suggested that 20-min submaximal AUBX is associated with decreased lower limb tone and physiological changes at the segmental spinal cord level, which can last at least 3 hours. Conversely, among 12 subjects completing maximal AUBX, no significant differences were found between pre- and post-exercise measures of tone and reflexes including R2n, H/M ratio, percent vibratory suppression of H reflexes, F/M ratio, and F-wave persistence. Hence, reductions in reflexes and tone observed following longer duration, moderate-intensity exercise (50 percent peak oxygen uptake) were not seen following short-duration (<9 min), maximal exercise. Further, although changes in neurophysiological recordings following maximal AUBX were not statistically significant, changes in H/M ratios were found to be significantly correlated with indicators of exercise intensity, specifically, oxygen consumption and exercise duration. It is important to emphasize that only immediate effects (30 min post) of stressful maximal exercise on tone and reflexes were investigated. Whether a tranquilizing effect appears 1–3 hours following a maximal effort is left to future research.

FUTURE PLANS—Twenty-five subjects with SCI will participate in a 2-year project beginning January 1995, utilizing the full protocol with submaximal AUBX.

[295] THE CORTICOSPINAL SYSTEM

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B389-3RA)*

PURPOSE—Classically, a single region of the cerebral cortex, the primary motor cortex, has been viewed as the major source of descending commands for the generation and control of limb movement. Other cortical and subcortical regions of the brain were thought to influence motor output largely by gaining access to the motor cortex. The results of our recent studies have led us to challenge this view.

METHODOLOGY—We have recently examined the topographic organization of corticospinal neurons in the premotor areas. In one set of experiments, we injected one fluorescent tracer (fast blue or diamidino yellow) into lower cervical segments and another fluorescent tracer into lower lumbar segments. We then mapped the distribution of cortical neurons labeled by retrograde transport of the two tracers. This experiment enabled us to determine the location of 'arm' and 'leg' representations in the motor areas that project to the spinal cord. In a second set of experiments, we injected one fluorescent tracer into upper cervical segments (C2-C4) and another fluorescent tracer was injected into lower cervical segments (C7-T1). This experiment enabled us to determine the location of 'proximal' and 'distal' arm representations in the motor areas.

PROGRESS—We found that, like the primary motor cortex, each premotor area contains an arm and a leg representation. In addition, we have evidence that the

arm representation in five of the six premotor areas contains a well-defined region concerned with the control of hand movements. In most instances, the size of the distal arm representation is the same as the that of the proximal arm representation. However, the premotor area that is located on the dorsal bank of the cingulate sulcus contains a larger distal representation than proximal.

RESULTS—We have found that the primary motor cortex receives input from at least six distinct premotor areas in the frontal lobe. These areas are located in diverse cytoarchitectonic regions including subfields of areas 6, 23, and 24. Each premotor area receives a unique pattern of inputs from the parietal lobe and from subcortical motor nuclei like the cerebellum and basal ganglia. Perhaps more importantly, each of the six premotor areas projects directly to the spinal cord. In fact, the number of corticospinal neurons in the premotor areas equals or exceeds the number in the primary motor cortex. Thus, each premotor area has the potential to influence the control of movement not only at the level of the primary motor cortex, but also more directly at the level of the spinal cord.

IMPLICATIONS—These findings raise serious questions about the utility of viewing the primary motor cortex as the sole "final common pathway" for the central control of movement. Instead, it may now be useful to view each premotor area and the primary motor cortex as separate sources of central command signals. If this view is correct, then it challenges us to determine the specific contribution each motor area makes to the generation and control of voluntary motor behavior. Furthermore, these results suggest that the premotor areas in the frontal lobe could provide an important part of the neural substrate responsible for the restitution of motor function that follows damage to the primary motor cortex or its spinal projections.

RECENT PUBLICATIONS FROM THIS RESEARCH

Cingulate motor areas. Dum RP, Strick PL. In: Vogt BA, Gabriel M, eds. The neurobiology of cingulate cortex and limbic thalamus. Boston: Birkhauser, 1993:415-41.

Corticospinal terminations in two new world primates: further evidence that cortico-motoneuronal connections provide part of the neural substrate for manual dexterity. Bortoff GA, Strick PL. J Neurosci 1993:13:5105-18.

Topographic organization of corticospinal projections from the frontal lobe: motor areas on the lateral surface of the hemisphere. He, S-Q, Dum RP, Strick PL. J Neurosci 1993:13:952-80.

Topographic organization of corticospinal projections from the frontal lobe: motor areas on the medial wall of the hemisphere. He S-Q, Dum RP, Strick PL. J Neurosci. In press.

[296] CARBOHYDRATE METABOLISM AND CARDIOVASCULAR RISK FACTORS IN PERSONS WITH SPINAL CORD INJURY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Core funds)*

PURPOSE—Several investigators have reported that persons with spinal cord injury (SCI) often have disturbances of glucose and lipid metabolism that may increase their risk of developing atherosclerotic cardiovascular disease (CVD) and non-insulin-dependent diabetes mellitus (NIDDM). The specific goal of the study is to determine whether a group of persons with SCI displays abnormalities of carbohydrate and lipid metabolism in comparison with age and sex-matched group of nondisabled men. Expanded fat mass has an important influence on several CVD and NIDDM risk factors. However, this condition is often masked in persons with SCI due to the loss of lean body mass resulting in low relative weight. Therefore, the potential confounding influence of adiposity will be controlled statistically by analysis of covariance using supine abdominal circumference as the covariate (a proxy for total and abdominal fat mass).

METHODOLOGY—The intravenous glucose clearance rate and its physiologic determinants (insulin sensitivity, insulin secretion, and insulin-independent

glucose disposal) will be evaluated using mathematical modeling of the insulin and glucose curves during a 3-hour intravenous glucose tolerance test. In addition, fasting lipoproteins and uric acid will be measured and habitual physical activity will be estimated by questionnaire.

PROGRESS—Data analysis has been completed for 11 men with SCI and 16 age- and sex-matched nondisabled controls.

RESULTS—Intravenous glucose tolerance was found to be normal in both groups. A trend was noted for depression of insulin sensitivity (corrected mean ~25 percent lower) in the men with SCI. However, insulin-independent glucose disposal was ~25 percent greater in the SCI group, which may represent a compensatory mechanism by which glucose tolerance is maintained in the presence of insulin resistance. The insulin response to glucose was similar in the two groups. A significant negative relationship was noted between abdominal circumference and insulin sensitivity (SCI: $r=-0.73$, non-SCI: $r=-0.62$, both $P<0.05$). The intercept of the regression line was 30 percent lower among the men with SCI, but the slopes of the lines were not different between groups. Insulin sensitivity was associated with high density lipoprotein cholesterol concentration ($r = 0.53$, $P = 0.01$), total cholesterol/high density lipoprotein cholesterol ratio ($r = -0.51$, $P = 0.01$), and uric acid concentration ($r = -0.50$, $P = 0.01$).

No evidence was found for significant noncoincidence of the regression lines for the two groups. Total and low density lipoprotein were significantly lower in the men with SCI, while other lipoproteins were not different. Thus, our preliminary data are consistent with the hypothesis that increased adiposity plays an important role in the depression of insulin sensitivity observed in men with SCI. In addition, insulin sensitivity is associated with serum lipoproteins and uric acid concentration among men with and without SCI.

RECENT PUBLICATIONS FROM THIS RESEARCH

Comparison between bioelectrical impedance and near infrared interactance for assessing body composition in persons with spinal cord injury (abstr). Maki KC, Briones ER, Langbein WE, et al. J Am Coll Nutr 1993:12:616.

Insulin sensitivity and serum lipids in lean men with SCI (abstr). Maki KC, Sam M, Nemchausky BA, Langbein WE, Orebaugh C. J Am Paraplegia Soc 1994:17:203.

[297] EFFECT OF QUADRUGBY ON PHYSICAL CAPACITY AND PHYSICAL STRAIN AMONG A GROUP OF SUBJECTS WITH A CERVICAL SPINAL CORD INJURY

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Sponsor: *Dutch Prevention Fund*

PURPOSE—To study the effect of quadrugby on work capacity and physical strain, three groups of subjects with quadriplegia were followed for a 6-month period. A group of trained quadrugby players, a novice group and a nonsporting control group, were selected to participate in a series of standardized wheelchair exercise tests.

METHODOLOGY—Exercise tests were performed on a wheelchair ergometer and daily wheelchair tasks were evaluated during standardised wheelchair-related ADL tasks. Heart rate was monitored during the ADL with a Sporttester PE3000, and thus percentage heart rate reserve (%HRR) was determined. Apart from maximum isometric force of different muscle groups, work capacity was determined in both an arm crank and wheelchair exercise test. Additionally, cardiovascular risk factors were determined.

RESULTS—Preliminary results indicate that the training effects are relatively marginal. The untrained group showed a negative trend in physical strain during ADL, a somewhat higher isometric force but no significant increase in other performance parameters over time. There was indeed a significant difference between the trained and untrained subjects, but this

may partly be explained by differences in lesion characteristics and previous training activity.

FUTURE PLANS—A follow-up study will focus upon a more systematic intervention of training intensity, frequency, and form among subjects with quadriplegia.

RECENT PUBLICATIONS FROM THIS RESEARCH

Effect of quadrugby training on exercise capacities of individuals with quadriplegia. Hopman MTE, Woude LHV van der, Dallmeijer AJ. In: Proceedings of the XIIth World Congress of IFMPR, Sydney, 1995, In press.

Effect of quadrugby training on physical performance capacity and physical strain during standardized ADL-tasks in persons with spinal cord injury. Dallmeijer AJ, Hopman MTE, Woude LHV van der. In: Proceedings of the European Congress on Adapted Physical Activity and Sports, Leuven, 19-20 December 1994, In press.

[298] CAUSES AND COSTS OF UNPLANNED REHOSPITALIZATIONS AMONG PERSONS WITH SPINAL CORD INJURY

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—There have been several published studies of rehospitalization rates, risk factors for rehospitalization, and associated costs among persons with spinal cord injuries (SCI). However, only limited baseline data on the long-term incidence of a few secondary medical complications such as renal and bladder stones have been published, and the relationship between the occurrence of these secondary complications and subsequent rehospitalizations has not been determined. Moreover, the National Spinal Cord Injury Statistical Center (NSCISC) data set cannot be used for this purpose because there is no established linkage in that data set between reported occurrences of secondary complications and rehospitalizations.

The purpose of this study is to provide baseline data documenting the leading causes of unplanned rehospitalizations among person with SCI, and the average costs associated with each cause so that frequent and costly complications can be given higher priority for further study, and the effectiveness of techniques to reduce the incidence of complications and hospitalizations can be assessed using rigorous cost-benefit analyses. The objectives of this study are to: 1) identify the most frequent causes of unplanned rehospitalizations; 2) to determine the average length of stay and cost for each cause of unplanned rehospitalization; and 3) to describe, epidemiologically, the causes and costs of unplanned rehospitalization among persons with SCI.

METHODOLOGY—The basic study design is cross-sectional with a 2-year prospective data collection period. All persons with traumatic SCI who are currently being followed at the University of Alabama at Birmingham Spinal Cord Injury Care System (UAB-SCISC) are eligible for this study, regardless of how long ago their injury occurred.

Hospital admission sheets are scanned daily to identify rehospitalizations of these persons. Those returning for clinic visits and outpatient annual evaluations are asked whether they have been rehospitalized at another facility since their last contact with us.

When appropriate rehospitalization is identified, medical record and billing information is obtained. Diagnosis codes are used to document the primary cause of rehospitalization. Other complications that may have contributed to the need for rehospitalization are documented as secondary causes.

The percentage of rehospitalizations, average length of stay, and charges due to each type of secondary complication will be determined. Mean length of stay and charges of each cause of rehospitalization will be compared by using Student's t test. The distribution of causes of rehospitalization will be characterized epidemiologically. The chi-square test will be used to compare the percentages of rehospitalizations due to each cause by time post injury, age group, gender, race, education level, neurologic level of injury, degree of injury completeness, urban/rural hospi-

tal location, marital status, and presence of insurance coverage. When sample sizes for individual causes of rehospitalization permit, multiple linear regression analysis will be conducted to determine the effect of these predictor variables on length of stay and charges for rehospitalizations resulting from that cause.

PRELIMINARY RESULTS—Prior to conducting this study, we completed a study of rehospitalization frequency and risk factors using the NSCISC's database. The project began October 1, 1994. During the first 2 months, 21 persons were identified as rehospitalized. We have begun the process of obtaining medical records for those hospitalizations.

FUTURE PLANS—We shall continue data collection and begin analysis when the sample size is sufficient.

RECENT PUBLICATIONS FROM THIS RESEARCH

Predicting unplanned rehospitalizations in persons with spinal cord injury. Ivie CS III, DeVivo MJ. Arch Phys Med Rehabil 1994:75:1182-8.

[299] IMMUNE RESPONSES TO PNEUMOCOCCAL VACCINE IN SPINAL CORD INJURY

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—Pulmonary complications, with pneumonia being the most frequent, are a major cause of both morbidity and mortality in persons with spinal cord injury (SCI). Both bacterial and viral immunizations have been recommended to prevent infectious pulmonary complications in patients with neuromuscular disorders producing mechanical dysfunctions of the respiratory system. Although patients with SCI, particularly those with tetraplegia and high paraplegia, have been shown to be at increased risk for the development of serious pulmonary complications, including pneumonia, we are unaware of any studies documenting the efficacy of either bacterial or viral immunizations to reduce the incidence of pulmonary complications in this population.

Objectives of this study are to document changes in immunologically related laboratory values of patients vaccinated at varying intervals after spinal cord injury, and to compare the incidence of pulmonary complications in unimmunized patients with SCI with the incidence in a series of patients with SCI vaccinated at varying times following injury.

METHODOLOGY—This study entails random assignment of SCI patients into one of four groups following their entry into the University of Alabama at Birmingham (UAB) Hospital care system. Groups 1 and 2 will receive the vaccine or placebo at 17 days (±24 hours) of injury. Groups 3 and 4 will receive the pneumococcal vaccine or placebo at 4 to 6 months post injury. The groups for which a patient is eligible to be randomized as a subject (to receive vaccine) or control (to receive placebo) are determined according to the time at which the patient is admitted to the hospital or rehabilitation center. Following enrollment, four blood samples are collected: the first at the time of vaccination or administration of placebo, the second 1 month later, the third 2 months later, and the fourth at 1 year following enrollment.

Laboratory tests performed at each blood sampling interval include: antipneumococcal antibody titers to four major representative serotypes, quantitative immunoglobulins, complete blood count with differential leukocyte count, liver profile, total serum protein and albumin. Subjects and controls are monitored during their initial hospitalization for the occurrence of respiratory or other systemic complications of pneumococcal disease. Appropriate microbiological and/or immunological diagnostic procedures are implemented whenever possible to determine whether or not such complications are indeed due to infection with Streptococcus pneumoniae.

PROGRESS—*Changes in Plan.* Recent developments in the acute care of persons with SCI have made it necessary to alter the study design and eliminate the group immunized immediately post injury because of the high dose of methylprednisolone often given within 8 hours of injury. Steroid presence negates the immunogenicity of the pneumococcal vaccine unless at least 2 weeks elapse prior to immunization. Therefore, no groups will be vaccinated at 72 hours. Groups 1 and 2 will receive vaccine/placebo at 17 days and Groups 3 and 4 will receive vaccine/placebo at 6 months post injury.

Preliminary Data. Data collection instruments and accompanying syllabus have been completed and are in use. Subject identification, enrollment, administration of vaccine or placebo, follow-up and collection of blood samples are underway. As of December 1994, 128 eligible persons have been asked to participate. Of these, 80 have been enrolled and 48 refused to participate.

FUTURE PLANS—Plans are to continue enrollment until December 1995. Follow-up data will be collected through December 1996. Antibody levels will be determined in batches with all four samples from each person assayed at the same time after collection of the 12-month specimen. All laboratory data and pulmonary complications are being recorded and entered into the computer database. Preliminary antibody determinations and analysis of laboratory and clinical data will be conducted after 50 persons have completed the study to discern whether significant trends are present or whether protocol changes are necessary.

[300] ADJUSTMENT AFTER SPINAL CORD INJURY: THE 20-YEAR MINNESOTA LONGITUDINAL STUDY

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Sponsor: *National Center for Medical Rehabilitation Research, National Institutes for Health*

PURPOSE—The purpose of this research is to identify how chronologic age, time since injury, and environmental change impact life adjustment after spinal cord injury (SCI).

METHODOLOGY—*Participants.* Three study samples have participated over the 20-year period. The first sample began participation during the first stage of this study in 1974 (n=256). The second sample was added during the second stage in 1985 (n=193). Although no new participants were added in 1989, a third sample was added for the current data collection (n=199). There were three screening criteria for inclusion to the study: a traumatic SCI, the injury was suffered at least two years prior to inclusion, and all participants were at least 18 years of age.

Procedures. The Life Situation Questionnaire (LSQ) was sent to participants during each stage of this study (1974, 1985, 1989, 1993). Responses to the Multi-dimensional Personality Questionnaire (MPQ) were also obtained in 1989. The Reciprocal Social Support Scale (RSSS) has been added for the current stage. Participants have been offered stipends during each stage. Follow-up phone calls and second mailings have routinely been implemented with nonrespondants. The primary sources of attrition over time have been mortality and geographic mobility, not refusal to participate.

Instruments. The LSQ was developed in 1974 to measure mostly objective information on a broad range of areas relevant to persons with SCI and was revised in both 1985 and 1989. The MPQ measures 3 higher-order dimensions, 11 primary personality dimensions, and 6 validity indicators, and was developed for use with nonpsychiatric populations. The RSSS was designed to measure support received, as well as opportunities to give support to others.

PROGRESS—The fourth stage of this longitudinal study is just being completed. A total of 383 participants have responded to date, approximately half of whom have participated during at least two previous study stages. Data analysis and dissemination are ongoing.

RESULTS—Some of the more prominent results include the relationship of employment history with adjustment and biographic status; the stability of adjustment over 11-year and 15-year periods; and the positive impact of the environment on adjustment.

IMPLICATIONS—This research has been instrumental in validating the need for a comprehensive rehabilitation program by identifying relationships between nonmedical and medical outcomes (including survival), and between employment and adjustment.

FUTURE PLANS—Consolidation of the 20-year data is currently underway in preparation of publication.

RECENT PUBLICATIONS FROM THIS RESEARCH

Social support and health status in spinal cord injury. Anson CA, Stanwyck KJ, Krause JS. Int J Paraplegia 1993:31:632-8.

[301] PREDICTION OF MORTALITY AFTER SPINAL CORD INJURY: A 20-YEAR PROSPECTIVE STUDY

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Sponsor: *National Center for Medical Rehabilitation Research, National Institutes of Health*

PURPOSE—The purpose of this research is to investigate the relationship between several aspects of life adjustment (psychosocial, vocational, and medical) and mortality after spinal cord injury (SCI). The most important aspect of this study is the utilization of prospective data obtained in 1974, 1985, and 1989 to predict current mortality status.

METHODOLOGY—*Participants.* All participants were identified from case files of former recipients of urologic services at a large midwestern university hospital clinic prior to 1985. There were three screening criteria for inclusion to the study: a traumatic SCI, the injury was suffered at least 2 years prior to inclusion, and all participants were at least 18 years of age. Two study samples and three sets of prospective data have been utilized. Sample 1 began participating in 1974 (stage 1; n=256) and Sample 2 was added in 1985 (stage 2; n=193), for a total of 449 participants.

Procedures. Responses to the Life Situation Questionnaire (LSQ) were obtained from sample 1 in 1974, 1985 (n=154), and 1989 (n=135); and from sample 2 in 1985 and 1989 (n=151). Responses to the Multi-dimensional Personality Questionnaire (MPQ) were also obtained in 1989. All former participants are being contacted to identify their current survival status. To date, a total of 90 of the 449 former participants are known to be deceased. Prospective data from 1974, 1985, and 1989 will be used to compare the life adjustment of participants known to be deceased in 1994 with those who are now deceased.

Instruments. The LSQ was developed in 1974 to measure mostly objective information on a broad range of areas relevant to persons with SCI and was revised in both 1985 and 1989. The MPQ measures 3 higher-order dimensions, 11 primary personality dimensions, and 6 validity indicators and was developed for use with nonpsychiatric populations.

PROGRESS—Prospective data on life adjustment has been collected over the 15-year period from 1974 to 1989, with three stages of data collection completed thus far (1974, 1985, 1989). At the present time, participants are being contacted to identify their current survival status. Death certificates are being obtained on all deceased participants.

RESULTS—Consistent relationships have been identified between psychosocial and vocational adjustment with mortality. Recent medical history has not proven to be as highly correlated with mortality.

IMPLICATIONS—This research has been instrumental in validating the need for a comprehensive rehabilitation program by identifying relationships between nonmedical and medical outcomes including survival.

FUTURE PLANS—The current study will extend previous 4-year, 11-year, and 15-year findings to a 20-year period.

RECENT PUBLICATIONS FROM THIS RESEARCH

Social support and health status in spinal cord injury. Anson CA, Stanwyck KJ, Krause JS. Int J Paraplegia 1993:31:632-8.

[302] SECONDARY CONDITIONS AFTER SPINAL CORD INJURY: RELATIONSHIP TO LIFE ADJUSTMENT

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Sponsor: *Shepherd Spinal Center*

PURPOSE—The purpose of this study is threefold: to identify the prevalence of secondary conditions after spinal cord injury (SCI), to correlate secondary conditions with life adjustment, and to identify the extent to which gender and race moderate the relationship between secondary conditions and life adjustment.

METHODOLOGY—*Participants.* A stratified sample of 587 cases has been identified from outpatient files of a large southeastern rehabilitation hospital. There were three screening criteria for inclusion to the study: a traumatic SCI, the injury was suffered at least two years prior to inclusion, and all participants were at least 18 years of age. The three stratification criteria were gender, race, and age.

Procedures. The Life Situation Questionnaire (LSQ) and Secondary Conditions Questionnaire (SCQ) were sent to each potential participant. After a follow-up call, a second set of materials is being sent to all initial nonrespondants. Participants are being offered $20 and a copy of study results as inducements to participate.

Instruments. The LSQ was designed to measure information on a broad range of life areas. It includes employment, recent medical history, adjustment, life satisfaction, and problems. The SCQ has been developed specifically for this study. It includes 50 items, each reflecting a different secondary condition. Participants are asked to identify whether they have had the condition (not since SCI; yes, more than 1 year ago; or yes, within last year) and how often the condition has disrupted their lives (never; sometimes; often; or always).

PROGRESS—The first stage of this study has just been initiated within the past 6 months. To date, a total of 309 individuals have participated in this study, with a goal of 500. The first mailing and follow-up phone calls have just been completed.

RESULTS—None available at present.

IMPLICATIONS—The results of this research will help identify: the prevalence of various secondary conditions after SCI; the relationship of secondary conditions to life adjustment; and the role of gender, race, and age in long-term SCI outcomes.

FUTURE PLANS—Completion of data collection will occur over the next 6 months, followed by data entry and data analysis.

RECENT PUBLICATIONS FROM THIS RESEARCH

Social support and health status in spinal cord injury. Anson CA, Stanwyck KJ, Krause JS. Int J Paraplegia 1993:31:632-8.

[303] PERFORMANCE CAPACITY AND PHYSICAL STRAIN IN SUBJECTS WITH A SPINAL CORD INJURY

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Sponsor: *None listed*

PURPOSE—The performance capacity and physical strain of activities of daily living (ADL) in spinal cord injured (SCI) wheelchair confined subjects are evaluated with systematic and repeated standardized wheelchair exercise and ADL tests to study the evolution in physical capacity and physical strain over time. Also during the process of rehabilitation and during systematic interventions, measurements are conducted. Thus, the long-term consequences of a wheelchair confined lifestyle on the cardiorespiratory as well as the musculoskeletal systems are systematically studied.

METHODOLOGY—Both subjects with a recent acquired spinal injury (and intramurally treated) as well as those with long-standing SCI are studied in a cross-sectional and a longitudinal research design. In each session, maximum performance capacity is determined on a computer controlled wheelchair ergometer. Maximum aerobic capacity, anaerobic sprint performance, and isometric strength are individually determined. The strain of standardized ADL is evaluated in different wheelchair-related ADL tasks with Percentage Heart Rate Reserve (HRR) with a simple SportTester PE3000. Risk factors for cardiovascular disease (blood pressure, cholesterol levels, etc.) are determined. Different physical and personal characteristics are inventoried with questionnaires.

RESULTS—The results on extramurally treated subjects with long-standing SCI indicate a close inverse association between physical strain in ADL wheelchair tasks and indicators of maximum performance capacity both cross-sectionally as well as longitudinally. This was found among a group 44 male subjects with SCI. The indicators for maximum performance capacity appeared positively associated. The expected reduction in performance capacity over a period of 3 years was not found. Even a slight tendency to improvement of performance was seen in maximum power output.

Also in subjects involved in the process of rehabilitation, significant inverse associations between performance capacity and the physical strain during standardized ADL was found. Effects of quadrugby training among a group of trained and novice athletes with a cervical spinal cord lesion was also evaluated in a 6-month intervention study. There were significant differences between groups, but a strong overall training effect could not be substantiated.

FUTURE PLANS—Systematic intervention on the role of sports and physical activity among quadrugby players will proceed, as will continued analysis of physical capacity and physical strain among subjects with a spinal cord injury during rehabilitation.

RECENT PUBLICATIONS FROM THIS RESEARCH

Isometric strength, sprint power and aerobic power in spinal cord injured subjects. Janssen TWJ, Oers CAJM van, Hollander AP, Veeger HEJ, Woude LHV van der. Med Sci Sport Exerc 1993:25(7)863-70.

Maximal wheelchair exercise responses in spinal cord injured subjects: comparison of a discontinuous and continuous protocol. Rasche W, Hollander AP, Janssen TWJ, Oers CAJM van, Woude LHV van der. Eur J Appl Phys 1993:66:328-331.

Physical strain in daily life of wheelchairs with spinal cord injuries. Janssen TWJ, Oers CAJM van, Woude LHV van der, Hollander AP. Med Sci Sports Exerc 1994:26:661-70.

Physical stress and strain in active wheelchair propulsion: overview of a research programme. Woude LHV van der, Janssen TWJ, Meijs PJM, Veeger HEJ, Rozendal RHJ. Rehabil Sci 1994:7:18-25.

Anaerobic Power output and propulsion technique in spinal cord injured subjects during wheelchair ergometry. Dallmeijer A, Kappe Y, Veeger HEJ, Woude LHV van der. J Rehabil Res Dev. In press.

Coronary heart disease risk profile, aerobic power, and physical activity in Dutch men with spinal cord injuries, Janssen TWJ, Oers CAJM van, Kesselaar CP, et al. Arch Phys Med Rehabil. In press.

Relationship between physical capacity and physical strain during standardized ADL in men with spinal cord injuries. Janssen TWJ, Oers CAJM van, Woude LHV van der, Hollander AP. Paraplegia. In press.

[304] EMPLOYMENT STATUS AMONG PERSONS WITH SPINAL CORD INJURY: ASSOCIATIONS WITH NEED TO WORK, CREATIVITY, AND NEED FOR STIMULATION

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Sponsor: *None listed*

PURPOSE—This present study measured creativity, boredom susceptibility, and perceived need to work in spinal cord injured (SCI) populations of differing employment status. The immediate purpose was to explore associations between these variables and employment history. The ultimate end of these studies was to contribute to the increase of employment among persons with SCI.

METHODOLOGY—Seventy-six persons participated; half had paraplegia and half quadriplegia. Subjects were classified into three groups on the basis of employment: Group A: employed for 2 years, Group B: intermittently employed for 2 years, and Group C: unemployed for 2 years. Participants were tested using three instruments: a *Need to Work Scale* (NWS) developed for this study, the *Lifetime Creativity Scales* (LCS) developed by Richards, as a measure of creativity, and the *Sensation Seeking Scale* (SSS V), as a measure of need for stimulation/susceptibility to boredom.

Descriptive statistics were produced for all variables in the study. The influence of variables that may influence employment status (i.e., age, income, education, marital status) was explored. Analysis of variance/covariance was performed to test for differences. A direct discriminant function analysis was performed using 12 variables as predictors of membership in the three groups.

RESULTS—There was no significant difference between the three groups on the NWS, although there were differences in reasons cited. Five of the LCS (all except the avocational scales) showed significant differences between the three groups, with employed persons scoring higher. On the SSS V, the Boredom Susceptibility subscale showed significant differences between the groups. Employed persons had higher scores than the unemployed or intermittently employed.

Two significant discriminant functions were calculated. The first maximally separates employed and unemployed individuals. The second function separates the intermittently employed from the other two groups. Correlations suggested the best variables for distinguishing between employed and unemployed to be: peak-vocational, peak-summary, and education.

Variables which loaded moderately were: extent-vocational, peak-avocational, extent-summary, overall, race, and Boredom Susceptibility. On average, employed individuals scored higher on the five LCS than unemployed, had higher levels of education, and a lower percentage of African Americans than the unemployed group. Membership in the intermittently employed group is not as easily predicted. The best predictors were suggested to be sex and age, with the intermittently employed group being younger and including proportionately more females.

The discriminant functions correctly classified 72.71 of the cases. It classified 391 of the individuals as employed, 301 as unemployed, and 31.21 as intermittently employed. There were actually 33.8 percent employed, 33.8 percent unemployed, 32.5 percent intermittently employed. Of the total population, 33 percent should be correct by chance alone. The classification procedure correctly classified substantially more than that: 72.7 percent.

These findings suggest a difference between employed and unemployed based on creative ability/effort and on need for stimulation. Causality cannot be addressed, of course, since we do not know which came first, the creativity or the employment. Are persons unemployed because they can tolerate boredom, or do they learn to tolerate boredom after remaining unemployed for a lengthy period of time? Some of the variables of interest were not significant in the analysis of this sample. Some of these findings are surprising; for example, findings in the literature lead one to expect age to be significant. This may be accounted for by factors peculiar to this particular participant sample.

IMPLICATIONS—This research has implications for future research and for vocational services. Do personal characteristics contribute to, or result from, employment status? If personal characteristics precede employment status, ways can be found to leverage this clinically. Secondly, who are the intermittently employed? This group may represent those for whom services are most crucial.

[305] A STUDY OF EMPLOYERS: EXPERIENCES AND ATTITUDES OF UPPER MANAGEMENT AND ITS RELATIONSHIP TO THE HIRING OF PERSONS WITH MOBILITY IMPAIRMENTS

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Sponsor: *None listed*

PURPOSE—This study explores the experiences and attitudes of management toward hiring persons with spinal cord injury (SCI). The study looks particularly at the relationship between the position of the employer respondent, the existence (or absence) of employees with SCI in the respondent's company, and what we have termed the "hassle factor," those factors that have to do with the applicant and which imply inconvenience and/or possible problems for the employer. The long-range purpose of this study is to enable us and others to prepare our clients better and influence employers more effectively in order to increase hiring of persons with severe mobility impairments.

METHODOLOGY—Questionnaires were designed to include vignettes describing 13 hypothetical applicants with SCI. Respondents were asked to indicate on a scale of 1-5 their likeliness to hire each applicant. Questionnaires were mailed to a random selection of 600 employers in the southeast. After two mailings, 51 questionnaires had been returned. To increase the size of the sample, researchers attempted to reach a random selection of 75 employers by telephone. The final study sample was comprised of 64. Because the study sample and the original 600 employers have virtually identical characteristics, the completed questionnaires were analyzed together.

PROGRESS—This study has been completed.

RESULTS—The majority of respondents were male executives with college and postgraduate degrees, an average age of 47, and more than 17 years experience in supervision and hiring. Smaller companies were less likely to have existing employees with SCI. A majority (55.6 percent) of companies with +250 employees reported persons with SCI on payroll. One important question that this research sought to answer was: "Is there a relationship between the responses of upper management and actual hirings of persons with SCI?" There was no multivariate relationship between these two variables. Age and length of time in supervisory/hiring activities have a low significant correlation to likeliness to hire certain individuals with SCI.

Each applicant was assigned a total hassle score. An "easy" factor was also assigned. Finally, the total hassle score was determined. Categories of individuals were created. Those applicants with a hassle factor of 1 were a group, those with a score of 2 another group, etc. This procedure was repeated for easy scores, and again for total hassle scores, creating 12 groups. A mean composite likeliness-to-hire score for each respondent was then determined. For each group of respondents, as the hassle factors go up, the mean likeliness-to-hire scores go down. As the number of easy factors increases, the mean likeliness-to-hire score goes up. As the total hassle score increases, the likeliness-to-hire score goes down.

IMPLICATIONS—The hassle factor may be the variable with the greatest impact on the hiring of individuals with SCI. It can do no harm, and may be extremely important, to make it a priority to reduce the perception of hassles for potential employers by such means as anticipatory problem solving.

[306] MODIFICATION OF TROMBONE TRIGGER ALLOWS PERFORMANCE ON THE TROMBONE BY PERSONS WITH SPINAL CORD INJURIES

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Sponsor: *None listed*

PURPOSE—Striving to attain usual activities in spite of disability imposed by spinal cord injury (SCI) is an important goal, which has been met in occupational and recreational endeavors by adaptive devices. Aside from the use of computer-generated music, little literature can be found describing modifications of musical instruments which would benefit persons with limited hand function. The trombone appears to be ideally suited to allow the use of proximal muscle strength to provide the necessary variance in the instrument, so that a scale can be performed. The drawback to present trombone design is that isolated function of the thumb is important to use the trigger. This report, therefore, describes modifications which reverse the means by which the trigger of the trombone is opened.

METHODOLOGY—Instead of the usual trigger operated by the thumb, this has been replaced by a ring. The ring allows inherent stability with the performer looping his thumb into the ring, a movement not requiring significant fine motor control. The long finger flexors, even if only partially intact, are sufficient to operate the trigger. The thumb loop was positioned through trial and error to allow optimum control of the trigger. Gravity assisted in the movement of the slide outward, with movement inward easily done with more proximally intact segments of C5 and C6.

RESULTS—Following the modifications, a gentleman with a Frankel A C7 SCI was able to successfully perform. Other positive therapeutic changes have occurred with practice. Previous hand contractures, which had resulted following a prior tenodesis, have improved over the years of playing, with the only obvious intervention being the musical instrument. Similarly, improved sitting balance and endurance occurred in association with the increased concentration on appropriate posture for musical performance. The success in achieving a high level of musical performance despite SCI demonstrates the usefulness of adapting musical instruments, as well as the importance of individual motivation. Given the ability to use the larger muscles of the upper extremities for control of the trombone slide, modifying the trombone appears to be appropriate for individuals with decreased fine hand dexterity.

B. Treatment and Rehabilitation

[307] NONINVASIVE URODYNAMIC EVALUATION OF VESICOURETHRAL FUNCTION: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #B92-519AP)*

PURPOSE—Our objective is to use digital image processing techniques to extract clinically important information from ultrasound imaging of the bladder and urethra. The central focus of this approach is to improve the diagnosis of voiding dysfunction sphincter dyssynergia in the spinal cord injured (SCI) patient

and to define the status of urethral function in a more quantitative and less invasive way.

METHODOLOGY—The current clinical standard of diagnosis of SCI patients necessitates the combined invasive use of urodynamics and imaging of the bladder and urethra. The advantages of urodynamics is that it provides quantitative and functional information. This advantage is at the cost of inducing confounding artifacts such as urethral and bladder irritation and catheter induced hypeffeflexia. Transrectal ultrasound imaging yields morphologic and functional evaluation and provides a record of bladder and urethral activity.

We seek to quantify ultrasound imaging and extract useful information of the regional contractibility of the bladder neck and the posterior aspects of the urethra. To define the status of the bladder and urethra, urodynamic and imaging methods are routinely used. Both of which are invasive since a catheter has to be placed in the urethra for these studies. Transrectal sonography is noninvasive to the bladder, therefore least irritating to the bladder and urethra.

We will improve the ultrasound image by averaging and edge enhancement. Voiding sequences will be serially recorded, stored, and analyzed by outlining the shape of the urethra. Consecutive sequences will be overlaid to establish which part of the urethra is contracting due to dyssynergia and which is opening due to bladder contraction. The shape of the urethra/bladder neck will be quantified and the data from such observations will be obtained and correlated with urodynamic studies to develop algorithms characterizing bladder outlet obstruction.

PROGRESS—We have successfully digitized and analyzed ultrasound images. From these images, we obtained a clearer view of the vesicourethral structures and made measurements of the localized compliance of the prostate.

RESULTS—A total of 66 new patients were scanned and information about the urethral/bladder/neck was archived on the computer. Among these patients, only 16 were able to void under ultrasound imaging.

Completion of this research, using this type of technology, will provide a framework for improved diagnosis of dyssynergia, a better means of measuring the outcome and effectiveness of therapy, and reduced invasion of the patient by reducing the need for frequent invasive urodynamic investigations.

FUTURE PLANS—This study has shown that quantitative evaluation of vesicourethral dynamics can be successfully applied in a clinical setting without interferring with the urodynamic procedures. We, however, consider that the field of view of the existing ultrasound linear array is too small to encompass the entire bladder-urethra-prostate in a single frame. This methodology could be greatly enhanced in the future if an ultrasound system is used that encompasses all the structures of interest. Such a system is becoming available in the imaging technology field.

[308] FUNCTIONAL RESTORATION OF GRASP: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #B93-612AP)*

PURPOSE—The objective of this pilot project is to develop a computer model of the index finger that includes all muscles and their associated tendons (musculotendons). The model will estimate the maximum finger tip forces biomechanically possible, including the musculotendons involved in their generation, and how musculotendon properties affect finger force generation. Index finger tip forces exerted during common grasping tasks (i.e., thumb-index key and tip pinch) will be emphasized. The insight gained will

lead to hand therapy and rehabilitation surgery that has grasp quality as an objective goal, which will enhance the self reliance and independence of persons with cervical spinal cord injuries.

METHODOLOGY—A 3-D computer biomechanical model of the index finger is being developed. The index finger is modeled as a metacarpal and three phalanges articulated by pin joints, two at the metacarpophalangeal and one at each interphalangeal joint. All index finger musculotendons are included. Force generation of a muscle is assumed to depend on its excitation level (to be determined by the model) and on experimentally obtained musculotendon architectural parameters. The moment arm of each tendon at each spanned joint, as a function of joint angle, was found from a fresh cadaver. Engineering tools are used to find the maximum static index finger tip force biomechanically possible at any finger posture, the muscle excitations generating the force (called the muscle excitation pattern), and the sensitivity of force production to musculotendon parameters and the muscle excitation pattern.

PROGRESS—We have obtained predictions for maximum index finger tip forces in key and tip pinch and the unique muscle excitation patterns producing them. Because of the complex biomechanics of the multijointed finger, all muscles simultaneously contribute to the task, which is to generate maximum force in a specific direction while maintaining finger posture. At times, small changes in one musculoskeletal parameter can disrupt the delicate balance of muscle excitations required to produce the maximum force, as well as disproportionately affect the magnitude of the finger tip force being generated.

FUTURE PLANS—We propose to test these predictions and further develop the model by measuring finger tip forces while recording intramuscular electromyographical (EMG) signals. Our ability to interpret finger tip force and muscle excitation pattern measurements within the context of a musculoskeletal model will allow us to better understand the complex biomechanical and neural interactions that make grasping possible.

[309] MANAGEMENT OF MUSCULOSKELETAL COMPLICATIONS OF SPINAL CORD INJURY

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PURPOSE—The specific purpose of this research is the development of clinical assessment procedures that can be used in the diagnosis and management of the musculoskeletal complications of patients with spinal cord (SC) disease and injury. The goal of the project is to provide a panel of biochemical and immunochemical tests that can be applied along with other modalities such as bone densitometry to the clinical evaluation of the SC patient. This project is designed to develop and apply newly discovered, bone cell-specific serum markers and new densitometry/imaging procedures for the skeleton to clinical studies of musculoskeletal assessment in patients with trauma and illness involving the SC.

METHODOLOGY—We have recently obtained a bone densitometer and have applied it to our studies of bone markers. The bone markers we have developed and used are immunochemically based. They are classical and novel immunoassays for the respective bone proteins under study. Thus, in addition to standard immunoassays, they also include new immunoassay formats that allow the precise identification in serum of the bone proteins under study, such as bone alkaline phosphatase (BAP), and new skeletal markers, such as Gla protein (BGP, osteocalcin) and its derived peptides.

PROGRESS—We have developed new procedures for the measurements of bone alkaline phosphatase

and bone gla protein, and we have made substantial progress toward the development of procedures for the measurement of bone acid phosphatase. We also have established assays for the calcemic hormones. In addition, we have implemented our protocols in clinical studies of SC patients, and we have initiated studies in 32 patients and a control population.

FUTURE PLANS—Our future plans are to apply our new procedures to clinical studies of patients with SC injury and disease in order to improve the care of patients with these disorders.

RECENT PUBLICATIONS FROM THIS RESEARCH

Associations and disassociations between gla protein (BGP) and alkaline phosphatase (AP) in skeletal metabolism. Parthemore JG, Burton DW, Deftos LJ. J Ortho Res 1993:11:671-6.

Markers of bone turnover in primary hyperparathryoidism. Deftos LJ. In: Bilezikian JP, Levine MA, Marcus R, eds. The parathyroids. New York: Raven Press Ltd. 1994:485-92.

[310] VERTEBRAL FUSION BY NEW OSTEOGENIC AGENTS TO ACCELERATE REHABILITATION

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PURPOSE—The purpose of this study is to accelerate vertebral fusion leading to elimination of pain and early rehabilitation. Vertebral trauma is often associated with spinal cord and nerve injuries that may result in serious disabilities. Our hypothesis is that pain relief and vertebral stability, allowing early rehabilitation, depend on a solid fusion that can be effected or significantly stimulated by the use of newly developed osteogenic agents delivered to the fusion site via an appropriate carrier.

METHODOLOGY—Our rabbit vertebral fusion model utilizes a surgical procedure that minimizes the animal versus human anatomical differences. It involves T11-12 and L1-2 discectomies, creation of a 4 mm diameter and 5 mm deep cylindrical defect and application of autologous bone (control) or an osteogenic agent (DBM, BMP, $rTGF_{\beta 1}$ and their composites with a microcrystalline hydroxyapatite (HA) carrier by open grafting or percutaneous injection 3 days post-surgically. Fusions at 3, 6, and 12 weeks post-grafting is evaluated radiographically, biomechanically, histologically and immunohistochemically; and by alkaline phosphatase, osteocalcin, ash, and calcium analyses of grafted tissue compared to controls.

PROGRESS—During the first 6 months of the first year of this project, osteogenic agents and composites were prepared and the osteogenic activity of DBM, BMP and $rTGF_{\beta 1}$ alone or after adsorption on microcrystals of HA, was tested in our intramuscular rabbit bioassay system. Subsequently, a total of 13 rabbits were grafted with autologous bone chips or powder (13×2=26 grafts) and sacrificed: 5 at 3 wks, 4 at 6 wks and 4 at 12 wks. Two additional animals served as nongrafted controls.

RESULTS—Roentgenographic, histological, and biochemical evaluations have been completed. Biomechanical testing has been performed on the spine of 7 rabbits. On the basis of the data obtained to date, it appears that: 1) at 12 weeks post-grafting with autologous bone fusion is radiographically, histologically, and biochemically complete; 2) at 6 weeks post-grafting, fusion is incomplete but of considerable magnitude by all four evaluation criteria when using powdered bone rather than bone chips; and 3) at 3 weeks post-grafting, some osteogenesis was observed radiographically and histologically, but there was no fusion biomechanically.

FUTURE PLANS—In the course of the coming year, we will continue to bioassay and graft materials for

osteogenic activity and proceed with the grafting of each osteogenic agent by open surgery and percutaneously. Results will be compared to the autologous bone (AB) control and to demineralized bone matrix (DBM).

IMPLICATIONS—This research is expected to contribute to the decrease of the risk associated with autologous bone grafting and allograft associated HIV infection. It has the potential of substantially increasing the effectiveness of the presently costly osteogenic agents, through the use of an appropriate delivery system, and allowing for speedier recovery and reduced duration of hospitalization leading to earlier rehabilitation.

RECENT PUBLICATIONS FROM THIS RESEARCH

Contribution of osteoinductive and osteoconductive properties of demineralized bone matrix to skeletal repair. Strates BS, Tiedeman JF, Eur J Exp Musculoskel Res 1993:2:61-7.

Mineralization and pH relationships in healing skeletal defects grafted with demineralized bone matrix. Chakkalakal DA, Mashoof AA, Novak J, Strates BS, McGuire MH. J Biomed Mat Res 1994:28:1439-43.

[311] SPINAL CORD INJURY-INDUCED BONE LOSS

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PURPOSE—Both the central and peripheral nervous systems are altered after spinal trauma; thus we hypothesize that changes in neuropeptides, neurotransmitters, and cytokines found in nerves supplying bone are involved in the osteopenia which develops following spinal cord injury (SCI). We propose to gain an understanding of how these alterations affect bone metabolism after SCI, since a considerable number of veterans suffer SCI, are paralyzed, and are treated in the VA system annually. The significance of the research lies in the potential for discovering the neural mechanism(s) involved in the osteopenia which develops following SCI. These results could lead to a therapy to prevent the pathogenic loss of bone in newly injured veterans, or aid in the recovery of bone in chronic SCI veterans. Such treatment would result in enhanced rehabilitation, and potentially increased independence and productivity in many veterans with SCI.

METHODOLOGY—The studies are being done using a rat model in which the animals are well maintained, and in which the bone loss is both dramatic and progressive over time. Histomorphometry, mechanical testing, radioimmunoassays, and molecular biology techniques are being used to characterize bone loss following SCI. This will allow us to determine changes in neuropeptide distribution and levels in bone and periosteum over time. Specifically we have focused on calcitonin gene-related peptide (CGRP), substance P (SP), vasoactive intestinal peptide (VIP), neuropeptide Y (NPY), and interleukin-1 (IL-1), since these substances are known to be contained in nerve fibers in bone and are implicated *in vitro* as modulators of bone metabolism. Immunohistochemistry, receptor binding assays, and autoradiographic methods will be used to evaluate receptor changes.

PROGRESS—We have defined the model and as such have histomorphometrically evaluated the effects of SCI on the bone at various times post lesion, as the animals age. We have developed methods to isolate bone cells for *in vitro* evaluation from the bones of lesioned animals. Methods have been developed to evaluate the neuropeptide content and their respective mRNAs in bone and periosteum. We have established a bone cell model in which to evaluate the effect of various neuropeptides on mRNA levels of proteins involved in cell-cell communication via gap junctions which we have shown to be present and functionally regulated in bone cells.

RESULTS—Characterization of the effects of SCI on bone metabolism at the histomorphometric level indicated that as the animals aged, they lost approximately 60 percent of their trabecular bone compared to nonlesioned animals. This bone loss resulted in considerable loss of mechanical strength in the femurs of lesioned animals. Immunohistochemical and retrograde tracing studies of nerves associated with bone demonstrated that sensory nerves containing the neuropeptides CGRP, VIP, and NPY, which affect bone cell metabolism, are particularly dense in the periosteum and penetrate the bone surface. VIP, but not SP, is capable of acutely up-regulating the mRNA for the predominant gap junction protein (connexin 43) in osteoblasts. VIP also regulates functional cell-cell communication in osteoblasts as shown by single cell injections. CGRP is capable of regulating osteoblast function via modulation of potassium channels, and intra-cellular calcium. Preliminary results indicate a part of the regulatory role of CGRP in osteoblast is via nitric oxide.

FUTURE PLANS—We will continue our comparative studies with periosteal bone cells of lesioned and nonlesioned animals for the effects of neuropeptides on mRNA levels and functional status of cell-cell communication and gap junctions. We are beginning studies to identify any post-SCI changes in bone cell receptors for these neuropeptides. We will also continue our studies to understand the mechanism of CGRP modulation of osteoblast functions.

RECENT PUBLICATIONS FROM THIS RESEARCH

Calcitonin gene-related peptide opposes parathyroid hormone effects on osteoblastic gene regulation via potassium channel activation. Burns DM, Kawase T, Howard GA, Roos BA. J Bone Min Res 1993:8(Suppl 1):S173.

Calcitonin gene-related peptide rapidly activates multiple signaling pathways in UMR 106 osteoblast-like cells. Kawase T, Howard GA, Roos BA, Burns DM. In: Abstracts, 75th Annual Meeting, The Endocrine Society 1993:401.

Nitric oxide stimulation of mineralization in osteoblastic cell cultures. Kawase T, Howard GA, Roos BA, Burns DM. J Bone Min Res 1993:8(Suppl 1):S372.

Similar regulation of bone cell communication by parathyroid hormone and the neuropeptide vasoactive intestinal peptide. Howard GA, Schiller PC, Bendix M, Mehta PP, Roos BA. In: Abstracts, The Endocrine Society 75th Annual Meeting 1993:325.

Transcriptional stimulation of connexin 43 gene expression by parathyroid hormone in osteoblastic cells. Schiller PC, Mehta PP, Roos BA, Howard GA. J Bone Min Res 1993:8(Suppl 1):S161.

Altered neuroendocrine and growth factor responses during aging reflect changes in inter- and intracellular channels and junctions. Howard GA, Schiller P, Mehta P, et al. Gerontologist 1994:34(Special Issue I):55.

[312] REHABILITATION OF THE COLON AFTER SPINAL CORD INJURY: A PILOT STUDY

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PURPOSE—The objectives of this study include: establishing baseline parameters of normal colonic responses in an animal (cat) model; evaluating direct colonic stimulation using implanted electrodes; and comparing direct colonic stimulation with stimulation of the sacral nerves for managing constipation and fecal impaction.

METHODS—Male cats with T-1 spinal cord injury (SCI) will be used to study the effects of sacral anterior root, sacral spinal cord, direct colon, and anal sphincter stimulation on bowel responses.

Previously, we developed a "suture" style electrode for direct stimulation of the bladder wall. This type of electrode will be implanted semi-circularly around the colon at 5, 15, and 25 cm from the anus. This method of implantation will allow complete expansion of the colonic walls without obstructing the movement of the feces. Two additional electrodes will be implanted longitudinally approximately 10 and 20 cm, respectively, from the anus to determine the effects of longitudinal stimulation on colon function. An electrode will also be inserted into the sacral canal through a small hole drilled through the superior as-

pect of the sacrum. These electrodes consist of 316LVM multistranded stainless steel wire. Stimulating parameters that induced affective defecation included a 6 ms pulse, a repetition rate of 40 pps, and a current sweep from 1–35 mA.

PROGRESS—We have continued to develop instrumentation for direct colon stimulation and chronic monitoring of colon function. Animals are on site to initiate these studies.

RESULTS—Following preliminary observations reported last year, the most significant preliminary finding is that direct colon stimulation alone may promote defecation and colon pressure changes similar to those observed in a spontaneously active animal. Sacral nerve stimulation alone appears to produce increased abdominal pressure but less colon activity.

FUTURE PLANS—In the next 10 months, we plan to fully instrument and evaluate direct colonic stimulation in eight SCI cats. Measurements of transit times, gastrocolic reflexes, as well as colon and abdominal pressures will be used to define colon function. Transit times and segmental movements will be monitored with a videotaped fluoroscopy of the movements of radio-opaque makers injected into the ileum through an implanted tube. Gastrocolic responses will be monitored by observing the effects of eating on segmental transit times.

We plan to continue evaluating the various stimulation tactics (intermittent, high-energy stimulation, and continuous low energy) in order to optimize their effects on increasing colonic motility. In addition, we plan to determine if a combined stimulation approach may be the most effective treatment of colonic dysfunctions such as impaction.

[313] ADVANCED TECHNOLOGY NEURAL INFORMATION SENSORS FOR PROSTHETIC CONTROL BY QUADRIPLEGICS

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PURPOSE—The objective is to develop clinical implant technology useful for long-term sensing of neural information from the cortex. This sensor must be bioresistant, biocompatible, and mechanically stable. The research plan consists of three categories: 1) physical assessment of implant geometry includes fabrication of CNS implants of varying geometry including tip shape, shaft size, and surface roughness; 2) development of nontethered implant technology involves developing optical power and data communications with an implanted sensor chip; and 3) the stability of neural signals from tethered and nontethered implants in rabbit cortex will be evaluated using the optimal geometry and optical communication techniques developed during the program. Intrinsic signal variability and drift of signals due to relative changes in the electrode-neuron relationship will be studied. Bioresistance is being studied under a separate contract.

METHODOLOGY—Devices are being fabricated using CMOS compatible process technology. Sharpening and final shaping of the tips of the devices is being accomplished by chemical-mechanical polishing techniques. Sharpening by ion milling is also being investigated. New Zealand White Rabbits will be implanted with the devices in the visual cortex to allow ease of testing. Comparative quantitative histological analysis will be used to determine the extents of damage ('kill zones') about the various shaft types. Results will be used to determine the best design for future work.

Circuit development will use rapid prototype foundries. Initial circuits will not be implantable, but will serve to test various ideas on the optimal circuit approaches. Analysis of the noise characteristics of the transistors is in progress. Initial implants will be accomplished by assembling hybrid circuits consisting of power supply circuit, sensing and encoding circuit, and data transmission circuit.

Stability of the neuron-signal relationship will be studied by observing the statistics of the recordings over time. By varying electrode spacings, and using triangulation techniques, it may be possible to detect neuron movement.

RESULTS—Using instrumentation developed for this project, noise and device characteristics have been measured for CMOS transistors with a variety of geometries. Noise measurements are being used to determine the appropriate device areas consistent with this application. Once the area of a device is determined, the width-to-length ratio of the device can be set such that the device will operate in the subthreshold region. The subthreshold region of operation is determined by measuring transconductance versus drain current and determining the linear region. Once this information is complete, an optimized low power integrated circuit amplifier with automatic offset cancellation will be designed. Bonded wafers are being used to fabricate optical power supplies using dielectrically isolated photodiode arrays. A prototype power supply with an area of 4 mm^2 was fabricated and tested using an 820 nm laser at 2.5 mW/mm^2. The power supply produced 7 volts open circuit and 300 μA short circuit. An 8-channel CMOS preamplifier and data acquisition system was implemented using commercial devices. The system exhibits 5 μVRMS noise for an 8 kHz bandwidth. It has been used to record from a chronically implanted animal and to map the evoked potential response of the visual cortex for future implants. A silicon probe sharpening system using a quartz mandrel has been developed and is being used to sharpen test structures to study the insertability of the silicon devices. Instrumentation for measuring force during insertion is being completed.

FUTURE PLANS—Future work will focus on gathering data for evaluation of the insertability, fabrication of an implantable integrated circuit that is optically powered, and evaluation of the recording properites of implanted electrode arrays.

[314] DEVICE FOR TREATMENT OF PERIPHERAL NERVE INJURY

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PURPOSE—The primary focus of experimental methods attempting to promote and improve peripheral nerve regeneration has been the guidance of the axonal growth cone to the distal stump. These efforts have centered on entubating the proximal and distal nerve ends. A substrate in the tube may improve regeneration further by providing more specific directional orientation for the axons. Previous research in this lab indicated that a collagen-glycosaminoglycan (GAG) copolymer matrix inside a silicone tube greatly enhanced regeneration compared to a saline-filled tube implanted *in vivo* in a gap in the sciatic nerve of rats.

The goal of this project was to develop a nerve prosthesis including the collagen-GAG matrix using a biodegradable collagen tube. These prostheses and controls were implanted in a 10 mm gap in the rat sciatic nerve model and the regeneration assessed histologically after six weeks.

METHODOLOGY—A collagen-GAG slurry prepared by blending acid dispersed bovine-hide collagen with chondroitin-6-sulfate was injected into plugged silicone tubes. The filled tubes were frozen under controlled conditions to yield axially oriented pores in the collagen matrix with an average diameter of 5 mm. The tubes were freeze-dried and de-hydro thermally crosslinked. The cylinders of collagen-GAG copolymer were removed from the silicone tube in which they were synthesized and inserted into the experimental collagen tubes. Six types of prostheses were made: empty silicone tubes (designated Se), silicone with matrix (Sm), empty porous collagen (PCe), porous collagen with matrix (PCm), empty non-porous

collagen (NPCe), and non-porous collagen with matrix (NPCm). The finished prostheses were 20 mm long, with an internal diameter of 1.5 mm (the mean diameter of the rat sciatic nerve is approximately 1.1 mm).

The prostheses were implanted into the sciatic nerves of 37 adult female Sprague-Dawley rats by transecting the nerve at the mid-femoral level, inserting the cut ends 5 mm into the prosthesis and suturing them into place.

At six weeks, the animals were cardiac perfused with a solution of glutaraldehyde and formaldehyde and the sciatic nerve was excised. Intact contralateral nerves (designated Norm) were obtained as controls from seven animals. The nerves were cut into sections and samples were divided into groups for a) epon embedding, stained with osmium tetroxide for analysis of axonal development and b) paraffin embedding, stained with Hemotoxylin and Eosin for gross cellular response and with Masson's Trichrome, for connective tissue.

Light microscopy images of the epon sections were digitized. Image analysis was performed on a Macintosh using the public domain NIH Image program. Size histograms of the axons were generated and compared using three nerves per prosthetic group.

PROGRESS—The normal nerve had very little intrafascicular collagen, a thin, fibrous epineurium, and some surrounding connective tissue. All of the regenerated nerves showed a substantial increase in intrafascicular collagen, as well as a thick, cellular layer bordering the tubes on both sides. The regenerated tissue contained some acute inflammatory cells, but not enough to indicate an adverse reaction to the prostheses. Macrophages and giant cells could occasionally be seen engulfing particles that appeared to be collagen tube remnants, indicating a likelihood of phagocyte participation in the breakdown of the tubes.

RESULTS—The density of axons in the regenerated nerves was slightly higher than the intact nerve in the section proximal to the gap, then decreased to numbers approximately comparable to normal in the gap region and distal to it. The regenerated nerves all had smaller axons than the normal nerve and thinner myelin sheaths (likely due to immaturity of the axons). The distribution of axonal sizes for regenerated nerves peaked at 3 to 4 mm, while the axons in normal nerve were nearly evenly distributed over the size range of 3 to 12 mm. The average axon density for all axons was 7.29×10^3 $\pm8.79\times10^3$ axons/mm^2 for PCm, 1.08×10^4 $\pm5.58\times10^3$ axons/mm^2 for NPCm, 2.44×10^4 $\pm8.93\times10^3$ axons/mm^2 for Sm, and 1.02×10^4 $\pm5.57\times10^3$ axons/mm^2 for Norm. Although the axonal density was somewhat higher for the Sm group than the PCm and NPCm, the nerves regenerated through silicone tubes tended to have much smaller tissue area than those regenerated through the collagen tubes. There was no significant difference between the two collagen tube groups.

Axonal regrowth occurred through prostheses of collagen-GAG matrix in collagen tubes in this study at a rate comparable with that through matrix in silicone tubes. The results showed that the two collagen tubes performed approximately comparably with the silicone tube, and did not appear to elicit adverse reactions.

IMPLICATIONS—The matrix-filled collagen tubes appear to be approximately comparable with the matrix-filled silicone tubes in promoting axonal regrowth. Further analysis must be done to better determine the overall condition of the regenerated nerve and compare the different groups. This study does not permit conclusions regarding the long-term results of the regrowth. Other studies have shown that although the number of apparent axons is elevated during early regeneration (axons may sprout off multiple processes from a single nerve body), branches that do not reconnect with an end-organ die off over time. The resulting decrease over time in axonal numbers is particularly an issue with nerves regenerated through silicone tubes, which undergo degenerative changes after several months of entubation.

[315] PROKINETIC AGENTS FOR CONSTIPATION IN SPINAL CORD PATIENTS: A PILOT STUDY

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PURPOSE—The purpose of this project is to better understand constipation in spinal cord injured (SCI) patients by testing the efficacy of cisapride and erythromycin in improving chronic constipation.

METHODOLOGY—Both SCI inpatients and outpatients were interviewed at the Jefferson Barracks VA Medical Center in St. Louis, Missouri. Patients who reported chronic constipation, and who had significant paresis as the result of SCI were invited to participate in this study. After explanation of the study, 22 patients agreed to participate. Fifteen of 22 have taken cisapride and were tested. Ten of 22 have withdrawn. Fifteen patients remain in the study.

Patients began participation at the earliest opportunity. Patients swallowed a Sitz-Marker tablet containing 24 radiopaque markers. Subsequently, serial abdominal x-ray films were obtained to determine marker progression through the gastrointestinal tract. Physiological evaluation consisted of anorectal manometry. Patients were placed in the left lateral decubitus position, the perineum was inspected, and gentle digital examination performed. Manometry was performed using a flexible, polyethylene, 8-channel, water-perfused catheter with a radial head design connected to an 8-channel, hydraulic, microcapillary perfusion pump, and using a station pull-through technique beginning at 7.5 cm from the anal verge. Measurements for resting pressure and maximum voluntary contraction were obtained at each half centimeter interval. The presence of the anorectal inhibitory reflex was also tested.

After establishing baseline function, intestinal transit, and pelvic floor studies, participants received 20 mg of cisapride three times each day orally for 1 month. At the end of 1 month, function results were recorded and colonic transit and anorectal manometry repeated.

PROGRESS—Since January 1994, 15 male patients have participated. Twelve of 15 (80 percent) are quadriplegics, and the remaining 3 are paraplegics. All patients reported normal bowel function previous to their injuries. Twelve of the 15 patients had initial baseline colonic transit and pelvic floor studies. Only 23 percent of patients passed colonic transit markers by day five and 57 percent by day seven. Baseline anal manometry revealed variable results. In summary, resting and squeeze pressures within the anal canal were poor.

All 12 patients have had 3 months or more of treatment with cisapride, 20 mg po t.i.d. Only 1 patient reported abdominal cramps, which subsided after the first week of treatment. Six of the 12 (50 percent) subjectively felt that the progression of stool movement increased and symptoms of constipation improved. Nine of 12 (75 percent) patients have remarked that the amount of time needed to accomplish a bowel movement has decreased.

All 12 have had their first set of follow-up colonic transit studies and pelvic floor studies while on the medication. Since the initiation of cisapride, 33 percent of patients passed colonic transit markers by day five and 71 percent by day seven. Anal manometry results following initiation of cisapride shows that 6 of 12 (50 percent) demonstrated a 10 percent or more increase in maximum resting anal canal pressure. Similar results were obtained for maximum average squeeze pressure. All of the squeeze pressure values following initiation of cisapride were increased. The remaining 6 patients reported no noticeable improvement and demonstrated the same in colonic transit and anal manometry tests.

FUTURE PLANS—The investigators plan to test the efficacy of erythromycin, in the same, or similar group of patients. Additionally, a regional outcome

study is currently under review and, as it is proposed, will involve VA Spinal Cord Units in Cleveland, Milwaukee, and Chicago.

[316] EXERCISE TESTING AND TRAINING OF MULTIPLE SCLEROSIS PATIENTS

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PURPOSE—The purpose of this project was to provide a basis for objective exercise testing and training, as well as to provide a better understanding regarding expected rehabilitation outcomes in persons with MS. Specific objectives were: to develop stress testing techniques to accurately document arm/leg exercise muscle performance and cardiopulmonary fitness in MS patients; and to evaluate the efficacy of an aerobic exercise training program in improving exercise performance and other functional and psychological parameters.

METHODOLOGY—All subjects performed a multistage leg cycling test on a recumbent ergometer designed and developed by these investigators in order to evaluate pre-, mid-, and post-training aerobic power. Upper and lower extremity muscle performance was also evaluated using a isokinetic dynamometer. Gait characteristics were studied using both kinematics and force plate measurements. Psychological status (i.e., affect, mood, and cognition) was measured pre- and post-training using appropriate, validated tests for each (e.g., SCL-90-R, 16 PF, CES-D, SADS, Q-LES-Q, Wechsler Memory Scale-Revised, Aphasia Screening Test, Shipley Institute for Living Scale).

PROGRESS—Upon completion of this 2-year project, 11 ambulatory (MS1) patients, 8 semi-/non-ambulatory (MS2), 4 non-exercising MS patients (MS3), and 11 non-MS controls (non-MS) have completed all pre-training testing, 3 months of training and post-training testing. Seven patients who were enrolled at the beginning of the project have since terminated participation at various stages of the protocol.

RESULTS—*Preliminary Testing.* All subjects were able to successfully perform the exercise stress testing protocol without any adverse reaction. This test was also successfully repeated at the 3- and 6-month training points. Acute physiologic responses from baseline, pre-training measurements indicated that the MS1 and MS2 groups had significantly lower maximal aerobic power (VO_{2max}) than non-MS controls. These data were accompanied by a significantly lower minute ventilation, respiratory exchange ratio, blood lactate, heart rate, and systolic blood pressure during maximal effort aerobic leg cycling. Evaluation of gait showed that individuals with MS had a significantly slower stride velocity, stride length, and stride rate. Preliminary analysis of mood state revealed that both groups of MS patients were significantly more depressed. Baseline levels of fatigue were significantly higher for the two MS groups than the non-MS group. Perceived quality of life was significantly lower for the MS2 group, but not for the less-impaired MS1 group.

Post-Training (6 months) Most individuals in all groups showed some improvement in VO_{2max}. Maximal power output improved by 9.2 percent and 11.2 percent for the MS1 and non-MS groups, respectively, and declined 8.5 percent and 11.9 percent for the MS2 and MS3 groups, respectively. Gait analysis for a small sample revealed an increased range of motion for the left ankle at foot contact and increased knee extension at toe off. Psychological testing showed that depressive symptoms were significantly reduced for the MS1 group, but not in the more severely impaired MS2 group. The MS1 group also had an overall reduction in the number of psychological symptoms and intensity of distress. Indicators of cognitive flexibility and efficiency of cognitive processing also improved

for the MS1 group following 6 months of exercise training.

FUTURE PLANS/IMPLICATIONS—Further research should evaluate other modes of exercise for testing and training, more aggressive protocols, and the efficacy of body cooling upon acute and chronic physiological, psychological, and functional outcomes following aerobic exercise training.

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[317] IMPROVING EXERCISE PERFORMANCE OF QUADRIPLEGICS

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PURPOSE—The purpose of this project was to develop and evaluate an arm+leg (hybrid) exercise system for spinal cord injured (SCI) quadriplegics. Phase III aimed to determine the changes in fitness gained in the reclined posture, over and above those gained in the upright posture. The data derived from this project should contribute toward optimizing methods for exercise testing and testing of quadriplegics so they can achieve substantially higher cardiopulmonary fitness levels.

METHODOLOGY—Phase I involved modification of a prototype voluntary-arm+ES-leg cycle ergometer to permit operation in either the upright sitting or reclined/recumbent posture. Phase II consisted of evaluation of acute physiologic responses of subjects during maximal exercise testing using voluntary arm cranking, ES-leg cycling, and hybrid exercise in each posture. Phase III involved evaluating the chronic physiologic training responses of subjects during two consecutive hybrid exercise training programs (target for each training program: 15 weeks × 3 sessions/week). The first hybrid exercise training program was conducted with subjects exercising in the upright sitting posture. The second hybrid exercise training program was conducted with subjects in the reclined (legs elevated) posture.

PROGRESS—All phases of the project have been completed.

RESULTS—*Phase I.* The hybrid exercise system was developed and constructed, and exercise testing protocols were devised for SCI quadriplegic subjects.

Phase II. Fourteen subjects underwent assessment of acute physiologic responses during graded exercise testing in upright and reclined postures with voluntary arm cranking alone, ES-leg cycling alone, and hybrid exercise. The results demonstrated that, compared with voluntary arm or ES-leg cycling performed separately, hybrid exercise induced significantly higher peak levels of metabolic and central cardiopulmonary variables. Compared with the upright sitting posture, each exercise mode in the reclined posture elicited a significantly higher peak cardiac output. The results also documented chronic exercise hypotension in quadriplegics, especially during and after arm and hybrid exercise without application of protective compressive garments or vascular supports.

Phase III. A. Upright Hybrid Training. Fourteen subjects completed the 45-session upright hybrid training program. Training produced significant (18 to 34 percent) increases in peak metabolic and respiratory parameters with no changes peak central cardiovascular parameters. Therefore, these data suggest that this training protocol induced primarily peripheral training effects in exercising skeletal muscles of quadriplegics with no marked effects on central circulation.

B. Reclined Hybrid Training. Seven subjects completed the 45-session reclined hybrid training program (target: 15 weeks × 3 sessions/week). Compared with the changes previously induced by upright hybrid exercise training, reclined training produced a significant (9 percent) increase in mean peak arm crank power output and a significant (13 to 18 percent) increases only in peak oxygen uptake in each posture, accounted for by 8 to 13 percent increases in arteriovenous oxygen difference. Therefore, these data suggest that this training protocol induced further peripheral training effects in exercising arm skeletal muscles of quadriplegics. Overall, following reclined hybrid exercise training, peak levels of central cardiopulmonary function were maintained during maximal exercise testing with arm, leg, and hybrid exercise in each posture.

FUTURE PLANS—Research is needed to improve exercise tolerance and exercise compliance of SCI quadriplegic subjects, so they can benefit maximally from extended training programs. Mechanical or pharmacologic methods may be necessary to maintain and regulate arterial blood pressure to prevent hypotension.

RECENT PUBLICATIONS FROM THIS RESEARCH

Exercise responses and quadriplegia. Figoni SF. Med Sci Sports Exerc 1993:25:433-41.

[318] OBJECTIVE ASSESSMENT OF SPASTICITY IN SPINAL CORD INJURY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B705-RA)*

PURPOSE—There are no widely accepted, objective, and comprehensive measures of spasticity and other components of upper motor neuron (UMN) dysfunction currently available to the clinician. Such measures, if available, would promote the development and application of more appropriate intervention measures. At present, studies depend on subjective, clinical evaluations, leading to many difficulties in interpreting the results. We propose to develop methods for quantitative measurement of spasticity in lower limbs of SCI subjects, comparing those results with results of conventional clinical assessment. This measurement is based upon the amount of surface EMG activity recorded during various maneuvers, along with recording the amount and timing of stimulation and the movements themselves.

METHODOLOGY—The study will compare clinical and neurophysiological methods of evaluation of the SCI subjects. SCI subjects will be recruited from the general clinic population of the SCI Unit of the VA Medical Center, Houston. The study will include a comprehensive, systematic clinical evaluation and a 1-hour neurophysiological examination. Studies will be repeated to demonstrate the stability of the procedure. Additional studies will be conducted when changes in spasticity are observed. Subjective scores will be used as the clinical measures (e.g., Ashworth, tendon taps), whereas the amount of EMG activity in response to each maneuver, along with transducers quantitating the maneuvers and movements, will serve to document the neurophysiological tests. Principal component analyses and canonical correlation techniques will be used to identify important, reliable measures of spasticity, in all of its manifestations, to compare clinical and neurophysiological measures, and to identify specific neurophysiologic parameters related to various manifestations of spasticity.

PROGRESS—Initial operational status of the laboratory was verified through a total of five studies on nondisabled subjects, followed by pilot studies while the laboratory was completed. A regular schedule of studies has continued weekly since September 1993. The pilot phase of data collection continued until November 1993 when final installation of the transducer processing electronics was completed. A total of 183 studies had been completed by January 1995. The subjects have been relatively evenly distributed across the categories of spasticity.

The data collection algorithms have been streamlined through incorporation into a large database. The efforts to refine the data processing are continuing. Alternative methods of segmenting the data are being evaluated.

RESULTS—Preliminary analysis of the data collected to date subdivided according to category of event (passive movement, tendon taps, plantar stimulation, etc.) indicates a strong correlation between electrophysiological and clinical measures as anticipated (0.6–0.7). This strong correlation was present even without any sort of transformation of the data. Efforts have begun to collect additional information to permit transformation and scaling of the electrophysiological data to improve its validity and to make possible valid comparisons across subjects. This additional information includes limb temperature and dimensions and skin and subcutaneuos tissue thickness overlying the recorded muscles.

The systematic utilization of the clinical scales employed led to the realization that there was a need for a refinement of these scales, for example, clonus evaluation or self-report of severity versus frequency of spasms. An effort is underway to refine these scales in order to provide better clinical information.

As a result of the initiation of this work, we have begun collaborative studies with other investigators on the effects of electroejaculation on spasticity. To date, we have made detailed recordings in five subjects, two with pronounced, short-term effects of such stimulation.

Finally, we have begun development of a report form which summarizes the salient points from clinical and electrophysiological studies in one page.

RECENT PUBLICATIONS FROM THIS RESEARCH

Assessment of spasticity in spinal cord injury: a comparison of clinical and neurophysiological measures. Sherwood AM, Priebe MM, Markowski J, Kharas NF, Ambatipudi R. In: Proceedings of the 16th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, November 1994, Baltimore, MD, 1994:16:463.

EMG as a measure of motor control in man: toward a basis for quantification. Sherwood AM, Eaton WJ, McKay WB, Kharas NF. In: Shiavi R, Wolfe S, eds. Abstracts of the 10th International Congress of the International Society for Electrophysiology and Kinesiology, June 1994, Charleston, SC, 30.

[319] MINIMIZING HYPERTONUS TO IMPROVE RECOVERY AFTER SPINAL CORD INJURY

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PURPOSE—Spasticity and other types of muscle hypertonus commonly develop as voluntary strength recovers after spinal cord injury (SCI). This hypertonus may interfere with mechanisms such as denervation supersensitivity and reactive synaptogenesis that may mediate recovery of voluntary movements. The purpose of this preliminary research was to determine whether the rate of motor recovery declines as hypertonus develops after SCI; such an observation would then suggest that optimal motor recovery may not be achieved with traditional rehabilitation and that early interventions might be needed to prevent the development of hypertonus to allow optimal recovery of voluntary movements. A secondary aspect of the study was to use high doses of oral baclofen medication to attempt to prevent the develop-

ment of muscle hypertonus and thereby improve recovery of voluntary movements.

METHODOLOGY—We serially measured the recovery of voluntary motor strength and the development of spasticity in patients with acute SCI. Electromechanical and electrophysiologic measures of voluntary strength and muscle hypertonus were measured biweekly over the first 6 months after SCI.

RESULTS—We observed a decline in the rate of voluntary motor recovery as hypertonus developed in two patients with acute cervical cord injuries. These observations support the hypothesis that developing muscle hypertonus interferes with the neural mechanisms mediating recovery of voluntary movements. In three subjects, we were unable to suppress muscle hypertonus in acute SCI subjects, despite high oral doses of baclofen.

In other SCI patients we have identified additional factors that interfere with recovery of voluntary movements during acute rehabilitation. In two subjects, post-traumatic syrinxes developed during acute rehabilitation; in both cases, shunting of the syrinx led to partial relief of pain and in one case, it led to marked improvement in upper limb motor strength and function. In other subjects, we observed incomplete motor recovery due to inadequate decompression of the spinal cord and to peripheral nerve entrapments.

IMPLICATIONS—Recovery of voluntary movements after SCI may be compromised by the appearance of muscle hypertonus. To achieve optimal recovery of function may require new spasmolytic treatments that selectively prevent the development of hypertonus but which enhance recovery of voluntary movements.

RECENT PUBLICATIONS FROM THIS RESEARCH

Electrodiagnosis in spinal cord injury. Little JW, Stiens SA. Phys Med Clin N Am 1994:5:571-93.

Electrodiagnosis of upper extremity weakness in acute quadriplegia. Little JW, Powers RK, Micklesen P, Moore D, Robinson LR, Goldstein B. Am J Phys Med Rehabil 1994:73:15-22.

M/RMS: an EMG method for quantifying upper motoneuron and functional weakness. Haughton JF, Little JW, Powers RK, Robinson LR, Goldstein B. Muscle Nerve 1994:17:936-42.

[320] HIGH-FREQUENCY MAGNETIC STIMULATION OF THE BLADDER AND BOWEL: A PILOT STUDY

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PURPOSE—The purpose of this study was to determine the effects of high-frequency magnetic stimulation (HFMS) of the sacral nerves on bladder and rectal pressures (BP and RP) in spinal cord injured (SCI) patients, and to determine the type of neurogenic bladder or bowel that may be most benefited by HFMS of the sacral nerves.

METHODOLOGY—Experiments were performed in eight chronic SCI, C3-T7. Each subject received a screening history and physical examination, as well as a full urodynamic study before the stimulation protocol, and a set of laboratory studies, including Chem 20, CBC with differential, PT, PTT, UA, and urine culture both before and after the experiment. This was followed initially by placing a multilumen urinary catheter into the bladder and inserting an anorectal monitor catheter into the rectum. Functional magnetic stimulation of the bladder and bowel was then performed using a Cadwell high-frequency magnetic stimulator, with the 9-cm magnetic coil placed near the L2-L4 vertebrae. The frequency and power were set at 30 Hz and 70 percent of maximum power (225 Joules/pulse, pulse width=0.2 ms), respectively. Vital signs were monitored every 3 minutes by a Paramed Blood Pressure Monitor for evidence of autonomic dysreflexia.

PROGRESS—We have demonstrated that: HFMS of the bladder and bowel is effective in elevating the

bladder and rectal pressures; SCI patients without lower motor neuron lesions may be most benefited by HFMS of the bladder and bowel; and HFMS of the bladder and bowel is safe in our subjects.

RESULTS—Two high cervical SCI patients (one C3, and one C4) demonstrated small hyperreflexic bladders; their BP increased from 6 to 19, and 28 to 48 (cm H_2O) respectively; similarly, their RP increased from 41 to 53, and 42 to 60, respectively. Two C6, and one T2 subjects demonstrated small reflexic bladders: their BP increased from 12 to 56, 4 to 33, and 5 to 59, respectively; and their RP increased from 30 to 54, 20 to 34, and 26 to 72, respectively. One out of two T7 subjects demonstrated a small reflexic bladder, and the second demonstrated a large hyporeflexic bladder; their BP increased from 20 to 82 and 32 to 77, respectively; and their RP increased from 46 to 104 and 23 to 48, respectively. One L2 subject demonstrated lower motor neuron lesion with a hyporeflexic bladder; while his BP increased from 6 to 12, RP showed no change.

FUTURE PLANS—We plan to 1) identify the mechanisms involved in magnetic stimulation in generating a bladder and bowel contraction by simultaneously monitoring the pressures and electrophysiological reflexes with urodynamics; 2) optimize the magnetic stimulation characteristics and anatomical approach to produce the desired physiological effects with the least magnetic stimulation; 3) critically evaluate the relative response of HFMS data to existing information using the electrical field stimulation methodology; 4) determine whether bowel motility is modified by HFMS by evaluating colonic transit time; 5) develop criteria that will be used to predict which SCI patients are optimally suitable for HFMS; and 6) establish comprehensive electrodiagnostic criteria that will reflect the safety and effectiveness of structures associated with the bladder and bowel that are exposed to the electromagnetic field.

RECENT PUBLICATIONS FROM THIS RESEARCH

High-frequency magnetic stimulation of the bowel in man: a pilot study. Lin VWH, Frost FS, Lee SB, Cadwell J. Muscle Nerve 1994:17(9):1098.

High frequency magnetic stimulation of the sacral nerves in spinal cord injured patients. Lin VWH, Frost FS, Lee SB, Perkash I. Arch Phys Med Rehabil 1994:75(9):1033.

[321] BACLOFEN PUMP: FUNCTIONAL AND NEUROPSYCHOLOGICAL IMPACT

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—The development of severe upper motor neuron spasticity is among the most common secondary medical complications for persons with spinal cord injury (SCI). This spasticity is often severe enough to affect the ability to perform routine activities of daily living, thereby causing many individuals to remain homebound, in acute care hospitals, or in nursing facilities. Oral baclofen (Lioresal) has proven to be a relatively effective agent for treating upper motor neuron spasticity due to spinal pathology. Unfortunately, the oral dosage of baclofen is limited by systemic toxicity and cognitive side effects such as drowsiness and lethargy. Moreover, because of baclofen's incomplete penetration across the blood-brain barrier, the concentration of drug at the site of action within the nervous system is typically low. As a result, 25 percent of persons with SCI do not receive adequate therapy.

Recent research has focused on the administration of baclofen intrathecally by means of a subcutaneously placed pump with a drug reservoir. This delivery system bypasses the blood-brain barrier and delivers baclofen directly into the cerebrospinal fluid surrounding the spinal cord. The objectives of this study are: 1) to determine the degree to which spasticity is reduced following administration of intrathecal baclofen; 2) to determine whether intrathecal baclofen administration significantly improves the ability of individuals to function independently in activities of daily living, mobility transfers, and bowel and bladder

care; 3) to determine whether the level of cognitive awareness changes after administration of intrathecal baclofen; 4) to assess the cost-effectiveness of intrathecal baclofen administration; and 5) to document systemic side effects that occur secondary to intrathecal baclofen administration.

METHODOLOGY—This time series experiment will collect baseline data on 35 persons with SCI, followed by an experimental intervention (intrathecal baclofen administration), and subsequent data collection to assess any changes as a result of the intervention. Participants will receive a bolus dosage intrathecally of 50 μg of baclofen to determine the response to the medication and observe any adverse effects. Those not responding adequately (average drop of two points on their muscle tone and reflex scores) or having any significant adverse effects will be ineligible for further study. Those who respond adequately to the bolus dose, baseline data will be collected during a routine clinic visit. Data will include demographics, measures of injury and spasticity severity, muscle strength, functional independence, cognition and economics. Follow-up data will be collected at months 1, 3, 6, 9 and 1 year after pump implantation, and annually thereafter.

It is expected that at least 10 persons will be enrolled in the study during each of the first 3 project years with an additional 5 persons enrolled during the first 6 months of the 4th project year. Data will be analyzed by paired comparisons within subjects pre- and postimplantation.

RESULTS—Between December 1993 and December 1994 we have implanted seven Baclofen pumps after screening eight patients. Of the seven patients, six have continued to be followed-up for data and one moved to the Oklahoma area.

FUTURE PLANS—We shall continue following enrolled subjects described in protocol for data collections and continue to implant 5–7 patients per year with pumps.

RECENT PUBLICATIONS FROM THIS RESEARCH

Intrathecal baclofen for intractable spasticity of spinal origin: results of a long-term multicenter study. Coffey RV, Cahill D, Steero W, Park TX, Ordia J, Meythaler J. J Neurosurg 1993:78:226-32.

[322] LONGITUDINAL ANALYSIS OF WELL-BEING IN PERSONS WITH SPINAL CORD INJURY AND THEIR CAREGIVERS

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PURPOSE—Much of the research in spinal cord injury (SCI) has been focused on acute medical aspects of SCI, with relatively little emphasis being placed on follow-up concerns, particularly quality of life issues. Recent work has suggested that there is a strong relationship between both physical health and emotional well-being of the person with SCI and the existence of an effective social support system. There is very little information, however, on the impact of care demands on the caregiver who also, most typically, is the major source of social support. The purpose of this project is to investigate on a longitudinal basis, the relationship between the physical and emotional care needs of the person with SCI and the physical and emotional health of the caregiver at several intervals post injury.

Objectives for this project are to: 1) examine the relationship between factors of well-being in persons with SCI and their caregivers, measured at preselected times postinjury; 2) determine the association between physical and psychosocial characteristics of the person with SCI and feelings-of-burden variables in caregiver(s) at preselected times during postinjury; 3) determine the interrelationships between feelings of well-being of the person with SCI and his caregiver(s) in different cohorts over time; and 4) determine the interrelationships between physical and psychosocial

characteristics of the person with SCI and the feeling of burden in the caregiver over time.

METHODOLOGY—This is a longitudinal study consisting of four waves of data. A sample size of 100 SCI/caregiver pairs has been targeted. Individuals who identify themselves as most likely to be the primary caregiver are approached regarding participation in the study. The caregivers are administered four structured interviews: one in person during the rehabilitation phase prior to discharge, and three by mail at 1 month, 6 months, and 1 year postdischarge. The predischarge interview serves as a baseline of the caregiver's mental and physical health, as well as an indicator of anticipated burden of care.

To date, 49 caregivers have been enrolled in the project. Nine of those 49 missed the in-hospital (T_0) questionnaire, and 45, 37, and 32 individuals have completed T_2 through T_4 respectively. To date, 31 caregivers have completed all 4 phases; 36 other caregivers, in addition to the 49 listed above, were approached about participating in the project but were inappropriate and/or refused participation.

PRELIMINARY RESULTS—Eighty-nine percent of the caregiving sample is female, 66 percent have a high school education or better, and 51 percent were employed outside the home at the time of injury. With regard to relationship to the person with SCI, 57 percent are spouses, 37 percent are parents, and 5 percent are children. Of the persons with SCI, 95 percent are male and 57 percent have a high school education or greater. Fifty-two percent of the persons with SCI have a cervical injury, while the remaining 48 percent have paraplegia.

Preliminary analysis of data reveals the caregivers are experiencing increasing negative affect secondary to caregiving over the first year postdischarge. Decreasing instrumental support is also apparent over the first year postdischarge.

FUTURE PLANS—Subjects will continued to be enrolled through May 1995 with follow-up completed by the end of May 1996. Preliminary analysis will be descriptive and correlational. Longitudinal/causal analyses will not be possible until the project is completed.

RECENT PUBLICATIONS FROM THIS RESEARCH

Caregivers of persons with SCI: a longitudinal investigation. Richards JS, Shewchuk RM, Elliott RT, Bullard J. (Abstract) Arch Phys Med Rehabil 1994:75:725-6.

Outcomes for caregivers of persons with SCI: a longitudinal investigation. Richards JS, Shewchuk RM, Elliott RT. (Abstract) J Amer Paraplegia Soc 1994:17(2):103.

[323] ULTRASOUND FOR URINARY TRACT SURVEILLANCE OF PERSONS WITH SPINAL CORD INJURY

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—Patients with SCI require long-term surveillance to detect and treat urinary tract dysfunction. Because such dysfunction is often asymptomatic, continued screening of patients who appear to be doing well is important. Screening of the urinary tract requires an examination that is sensitive, specific, easily performed, well-tolerated by the patient, and cost effective. The renal ultrasound examination (RUSE) is less invasive than either excretory urography (EXU) or comprehensive renal scintigraphy (CRSP) and, therefore, might further increase the likelihood of patients returning for routine annual evaluations. The RUSE eliminates the risk of ionizing radiation, can be performed in considerably less time than CRSP, and costs substantially less to perform.

Objectives of this project are: 1) to determine the sensitivity and specificity of the RUSE compared to CRSP for detecting upper urinary tract abnormalities of persons with SCI; 2) to determine the sensitivity and specificity of the RUSE compared to EXU for

detecting upper urinary tract abnormalities of persons with SCI; and 3) to determine the role of the RUSE in the long-term urologic follow-up of persons with SCI.

METHODOLOGY—Standardized data collection instruments and a syllabus have been developed. At this Center, CRSP is routinely performed on all patients with SCI who have neurogenic bladders prior to first definitive discharge and annually thereafter.

The RUSE will be performed on a random sample of 10 percent of patients scheduled for routine CRSP. The RUSE will be performed using an ACCUSAN 128 Real Time ultrasound scanner utilizing 3.5 and 5.0 Mhz transducers. Renal size, parenchymal thickness, presence, size, and location of calculi; presence, size, location, and character of renal masses; presence and severity of hydronephrosis; size of ureters (normal or enlarged); bladder volume and anterior wall thickness; presence of other abnormalities; and the overall quality of the examination will be recorded. Overall, at least 100 patients will receive both the RUSE and CRSP within 4 weeks of each other during the 5-year project time frame. Most will receive both the RUSE and CRSP within 2 weeks of each other.

EXU is routinely performed only once per person, just prior to the first definitive discharge from the rehabilitation hospital. The RUSE will be performed on a random sample of 25 percent of persons scheduled for EXU. Overall, at least 100 persons will receive both the RUSE and EXU within 2 weeks of each other during the 5-year project time frame. Most will receive the RUSE and EXU on the same day.

PROGRESS—A total of 58 patients has been entered into the study. Thirty-one patients have received CRSP, RUSE and EXU, all within a 2-week period. Nine patients have had RUSE and EXU within 2 weeks but had CRSP greater than 4 weeks prior to EXU and RUSE. Eleven patients had RUSE and EXU within a 2-week period and had CRSP within 4 weeks of EXU. Six patients had only RUSE and CRSP done. One patient had only EXU and RUSE. A preliminary investigation of findings on 48 patients that have had CRSP, EXU, and RUSE within 2–4 weeks time has been completed. Scheduling is still difficult but data collection is continuing.

Change in Plans. Initially, most RUSE and EXU tests were performed on the same day, while the CRSP was typically performed some time earlier. Because this resulted in occasional scheduling difficulties, the current policy is to schedule the CRSP and RUSE on the same day. EXU is then scheduled for a return visit.

FUTURE PLANS—Data collections will continue for 1 year and formal reviews will be done at the conclusion of the project.

[324] NATURAL HISTORY AND CLINICAL COURSE OF URINARY TRACT COMPLICATIONS IN PATIENTS WITH SPINAL CORD DYSFUNCTION

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PURPOSE—Analyzing a spectrum of urologic data acquired from a large number of persons with spinal cord injury (SCI) will help clinicians understand the natural history of the urinary tract and its complications following SCI, thus helping clinicians select those prevention and management methods capable of assuring the most positive prognosis.

The objectives of this study include: 1) documenting the natural history and clinical course of urinary tract complications among persons with SCI who utilize various methods of neurogenic bladder management; 2) answering a series of important clinical research questions that can impact future urologic management and improve the medical care and well-being of persons with SCI; and 3) encouraging the utilization of the UAB-SCI Urologic Database by other institutions which could provide a much larger cohort of persons with SCI for future collaborative studies.

METHODOLOGY—Data are collected prospectively for each patient admitted to the UAB-Spinal Cord Injury Care System (UAB-SCOTCHES) at admission, discharge, and annually thereafter. In addition, data have been collected retrospectively from chart reviews on 596 patients between January 1970 and April 1979. Since 1979, persons who were enrolled retrospectively have been followed prospectively, along with the more recently injured persons. Persons constituting the prospective study group (n=1493) were injured and admitted between May 1979 and December 1993. The latter group will continue to grow in size as the project continues. Overall, 2,089 persons have been entered into the project database, although not every record has been retained. Data from 269 persons in the retrospective study group and 258 persons in the prospective study group have been purged from the database because of inadequate follow-up information. Nonetheless, complete data have been collected on 327 persons from the retrospective study group and 1,235 persons from the prospective group, yielding a total of 1,562 persons with usable data in the database.

PRELIMINARY RESULTS—The database is used to identify appropriate subjects for other clinical studies as well as supplement the knowledge of urologic care for person with SCI. The project has led to the publication of 1 book, 10 book chapters, 10 peer-reviewed journal articles, 3 publications in Proceedings, and 11 abstracts in leading medical journals. Twenty-four presentations were made at scientific meetings of professional societies and organizations.

The database is now available on computer software with quality control computer programs that crosscheck the data for out-of-range entries and internal consistency. This increases opportunities to compare data among users since variable definitions and collection method will be uniform.

During this project period, work has continued relating to renal calculi. Our study showed persons with SCI who were living in states with the highest general population renal stone incidence rates were most likely to have a history of renal stones during SCI acute care and rehabilitation. This was not correlated with higher risk locations for the general populations, even after controlling for differences in age, gender, race, level and extent of injury, previous history of renal stones, and method of bladder management.

FUTURE PLANS—New patients with SCI are continually added to the study population and followup data on the large population followed in our clinics are continually added to the database. Some patients have been followed for as long as 24 years. Further investigation and analysis of data will continue during the next four years.

RECENT PUBLICATIONS FROM THIS RESEARCH

Long-term follow-up of neurogenic bladder. Lloyd LK. In: Stover S, Lloyd LK, eds. Neurogenic bladder. Phys Med Rehabil Clinics North Am 1993:391-409.

Neurogenic bladder. Stover S, Lloyd LK, eds. Phys Med Rehabil Clinics of North America. Vol. 4. Philadelphia: WB Saunders Co., 1993.

Spinal cord injury: knowns and unknowns. 1993 Donald Murro memorial lecture of the American Paraplegia Society. Stover SL. J Amer Paraplegic Soc 1994:17:1-6.

[325] MOTOR COMPLETE SPINAL CORD INJURY: PROGNOSIS FOR AMBULATION

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PURPOSE—Research has suggested a relationship exists between preservation of pin sensation after a motor complete spinal cord injury (SCI) and recovery of motor function with eventual ambulation. Therefore, it is important to be able to determine at what point the presence of pin and touch post SCI is a positive prognostic factor for future ambulation. This would enable clinicians to accurately predict ambulation soon after SCI. This study is designed to determine: 1) at what point post spinal cord injury is the

presence of pin and touch sensation a predictor for future ambulation; 2) to what degree do these patients become ambulatory; and 3) if there is a difference in prognosis between patients with sensation limited to light touch and those with pin and touch.

METHODOLOGY—Quadriplegic and paraplegic subjects who are admitted to the Regional Spinal Cord Injury Center of Delaware Valley within 1 week of injury will be enrolled in the study if they are medically stable, motor complete but sensory incomplete (Frankel B), and have an upper motor neuron type injury. Therefore, levels of injury will be restricted from C4 to T10. Subjects will be tested on admission, at 72 hours post-injury, once a week for 1 month, and at 2, 3, 6, 12, and 24 months post SCI.

The sensory exam will be done with a safety pin to access pin appreciation and by the finger to access touch appreciation, using a 3-point scale of absent, decreased, or normal. Sensory exams will be performed on the lateral aspect of the thigh, medial aspect of the knee, medial malleolus of the tibia, dorsal aspect of the proximal phalanax of the third and little toes, the penis or clitoris and the perianal area. The subject's level of ambulation will be evaluated as appropriate at the same intervals as the sensory examination and will be defined as a reciprocal gait. Three categories of ambulation will be identified: exercise, household, and community.

FUTURE PLANS/IMPLICATIONS—Thirty-four subjects have been enrolled. Data will be analyzed to determine when sensation best predicts future ambulation and if light touch appreciation alone is sufficient to predict ambulation.

[326] RECOVERY OF UPPER EXTREMITY MUSCLES FOLLOWING CERVICAL SPINAL CORD INJURY

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PURPOSE—Research has shown that a relationship exists between muscle strength and function following spinal cord injury. Therefore it is important to be able to determine the course and extent of motor recovery following spinal cord injury. Normative data on both the degree of recovery at time intervals post injury and the time required to reach maximum strength after the onset of injury has not been presented in the literature. These data would enable clinicians to predict the degree of motor recovery in cervical spinal cord injured patients and to identify the effects of pharmacological, surgical, and rehabilitative interventions on the course of recovery. A major multicenter, multiyear study is needed to obtain the data necessary to determine normative recovery rate and extent. Further, a multicenter study would enable the results to be generalized beyond one center and its associated modes of treatment. This study is a collaborative initiative of the Regional Spinal Cord Injury Systems in New York, Birmhingham, Downey, and Philadelphia. This study will expand on a recent multicenter project which investigated biceps and wrist recovery.

METHODOLOGY—Patients with spinal cord injury, C4-C8, Frankel A-D who are between the ages of 15 and 70, in each of the collaborating model spinal cord injury system centers, will have sequential motor strength examinations if possible, immediately post injury, 72 hours, 1, 2, 3, 4 weeks, and 2, 6 12, 18 and 24 months post injury. A modified manual muscle test (MMT) will be performed on the biceps, extensor carpi radialis, triceps, and flexor digitorum profundus. Inter-rater and intra-rater reliability will be determined to insure that all centers are consistently and properly performing the MMT.

Data will be analyzed for the extent of recovery at specific time intervals and the percentage of individuals at each neurological level of injury and Frankel grade who achieve that extent of recovery. Normative data relative to the recovery of muscle

strength will be established to serve as a basis for future analysis of therapeutic interventions.

PRELIMINARY RESULTS—One hundred and ninety-four subjects from three centers have been enrolled. Data analysis is being conducted to determine the time to reach maximal strength and the degree of recovery obtained.

FUTURE PLANS/IMPLICATIONS—Information from this study will allow clinicians to better predict recovery from spinal cord injury and to determine when to best initiate therapeutic interventions.

[327] VASOPRESSIN AND BLOOD PRESSURE CONTROL IN SPINAL CORD INJURY PATIENTS

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Sponsor: *Spinal Cord Research Foundation, Paralyzed Veterans of America*

PURPOSE—These studies were performed to assess the role of vasopressin, a potent vasoactive peptide, in the maintenance and/or stabilization of arterial pressure in patients with quadriplegia due to cervical spinal cord injury during and following the development of orthostatic hypotension.

METHODOLOGY—These studies include observations in 12 quadriplegic subjects who were tilted head-up on a tilt-table to a degree at which mean arterial pressure (MAP) was approximately 20 percent lower than pre-tilt MAP in supine posture. The subjects were then held at this degree of tilt for 60 minutes, during which MAP and heart rate (HR) were measured and recorded every 2 minutes and blood samples were obtained at 10-minute intervals for determinations of plasma arginine vasopressin (Pavp), plasma renin activity (PRA), and plasma atrial natriuretic peptide concentrations (Panp). To assess the effect of vasopressin on the maintenance of arterial pressure during the period of sustained head-up tilt, comparable studies were performed on the same quadriplegic subjects on a separate day following administration of a selective vasopressin V1 receptor antagonist [$d(CH_2)_5$ Tyr(Me) AVP]. Hemodynamic parameters were measured and blood samples were obtained for determinations of PRA and Panp as in the studies performed without administration of the V1 receptor antagonist. Plasma arginine vasopressin concentrations could not be determined in these studies because of cross-reactivity of the V1 receptor antagonist with the antibody used in the radioimmunoassay for vasopressin.

We have also performed studies in eight quadriplegic subjects who were tilted head-up in increments of 150 at 10-minute intervals to a maximum inclination of 600. These studies were also performed in the presence as well as in the absence of V1 receptor blockade. Mean arterial pressure and HR were measued every 2 minutes and blood samples were obtained during a 75-minute period prior to tilting, at each degree of tilt, and 10-15 minutes after return to a horizontal position for determinations of PRA in all studies, and for determinations of Pavp in the absence of V1 receptor antagonist administration.

PROGRESS—The studies in this project have yielded results that have been analyzed and assembled for publication.

RESULTS—We have concluded from these studies that vasopressin may contribute to the maintenance of arterial pressure during periods of prolonged postural stress even though Pavp is only moderately increased, but is clearly within the range of changes induced by non-osmotic stimulation of vasopressin release. The degree of postural stress associated with 20 percent reduction in MAP in the sustained tilt studies was comparable to that experienced by quadriplegic subjects sitting upright in a wheelchair for an extended period of time. However, vasopressin does not prevent the development of orthostatic hypotension during pe-

riods of acute postural stress, as shown by similar reductions in MAP during incremental head-up tilting to maximally tolerated tilt in the absence and in the presence of V1 receptor blockade. Plasma vasopressin concentrations increase exponentially under these conditions, but do not increase to high levels until a threshold level of reduced MAP (approximately 60 mmHg) is exceeded. The possibility that stimulation of vasopressin release at this reduced level of MAP may play a role in the stabilization or recovery of arterial pressure is suggested by the observation that MAP immediately following acute head-up tilting is lower in the presence of V1 receptor blockade than in its absence.

RECENT PUBLICATIONS FROM THIS RESEARCH

The role of AVP in blood pressure control during postural stress in quadriplegic subjects. Huch KM, Wall BM, Mangold T, Bobal MA, Gavras H, and Cooke CR. Clin Res 1994:41:793A.

Characteristics of vasopressin release during controlled reduction in arterial pressure. Wall BM, Runyan KR, Williams HH, Bobal MA, Crofton JT, Share L, and Cooke CR. J Lab Clin Med 1994:124:554-63.

Hemodynamic response to vasopressin during V1-receptor antagonism in baroreflex-deficient subjects. Huch KM, Runyan KR, Wall BM, Gavras H, and Cooke CR. Am J Physiol. In press.

[328] BACTERIURIA IN PATIENTS WITH NEUROGENIC BLADDER TREATED WITH INTERMITTENT CATHETERIZATION

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Sponsor: *Spinal Cord Research Foundation*

PURPOSE—The long-term goal of this research project is to prevent deterioration of kidney function caused by bacterial infection of the urinary tract in patients with neurogenic bladder. As a first step we followed patients on intermittent catheterization (IC) to determine the frequency of bacteriuria over time and to examine whether bacteriuria led to subsequent infection and/or deterioration of the upper urinary tract.

METHODOLOGY—Weekly home visits were made during 6 months of surveillance of 14 patients (2–18 yrs of age) with neurogenic bladder, a normal upper urinary tract (renal ultrasound, serum creatinine concentration) on IC and no antibiotics. During visits a sample of bladder urine was obtained by IC for culture and urinalysis; signs and symptoms of urinary tract infection (fever, abdominal pain, change in color/odor of urine) and all medications were recorded. The surveillance urine cultures were not part of the patient's care and the results were not available to the investigator or the patient's physician. All patients continued to receive care from their physician and no therapies were withheld or altered. At the end of 6 months renal ultrasound and serum creatinine were repeated.

A positive urine culture or bacteriuria was defined as $\geq 10^4$ cfu bacterial/ml urine obtained by bladder catheterization. Symptomatic infection was defined as a positive urine culture with fever, abdominal pain, change in continence pattern, or change in color/odor of urine (guidelines developed at the October 1990 Meeting of the American Academy for Cerebral Palsy and Developmental Medicine).

RESULTS—Fourteen patients were observed over 323 weeks of observation. Seventy percent (172/244) of the urine cultures grew $\geq 10^4$ cfu/ml, 152 (88 percent) for pathogens and 20 (12 percent) for commensal bacteria. Bacteriuria was associated with pyuria two-thirds of the time regardless of bacterial species. Carriage of the same pathogen for 4 weeks or longer, with associated pyuria was common during surveillance. Despite frequent episodes of bacteriuria with associated pyuria, there were only 5 symptomatic infections during the 323 patient weeks. Patients remained clinically well and their upper tract did not deteriorate.

IMPLICATIONS—Bacteriuria persists for weeks in asymptomatic patients being treated with IC for neurogenic bladder and normal upper urinary tract. Be-

fore attempts are made to eradicate bacteriuria, treatment should be proven to be beneficial to this population.

RECENT PUBLICATIONS FROM THIS RESEARCH:

Bacteriuria in children with neurogenic bladder on intermittent catheterization\Mnatural history. Schlager T, Dilks S, Trudell J, Whittam T, Hendley JO: J Pediatr. In press.

[329] EFFECTS OF SURGICAL DECOMPRESSION ON IMPAIRMENT AND DISABILITY PARAMETERS IN CERVICAL SPONDYLOTIC MYELOPATHY

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Sponsor: *St. Maartenskliniek*

PURPOSE—The purpose of this project is to investigate the effects of decompressive surgery on impairment and disability parameters in patients with Cervical Spondylotic Myelopathy (CSM). Disability is evaluated by a global compound score, European Myelopathy Score (EMS), and by a disability-oriented task set for fine motor control and for postural control. These task sets are designed in accordance with a theory of recovery of motor control. The main premise of the study is that a progressive disorder of the spinal cord is accompanied by a reorganization of motor control, resulting in an increase in a visual compensatory strategy and in a cognitive compensatory strategy.

METHODOLOGY—Patients with the diagnosis CSM are pre-operatively and post-operatively (1, 3, 6, and 12 months) tested. A number of clinical parameters (spasticity parameters, grip strength, sensibility) and a global compound score, EMS, are used. Static balance is measured in three trials of 30 seconds for each of three conditions: with eyes open, with eyes closed and while performing a secondary arithmetic task. The root mean squares (RMS) of the velocity of center of pressure (CP) in fore-aft and lateral direction are used as dependent parameters. In the dynamic balance task, the CP position is displayed on-line on a monitor. Patients are instructed to shift their weight by moving their CP position between two stationary goals presented on the monitor. The number of weight shifts and a measure of fluency are used as dependent parameters.

In addition, patients are asked to perform a number of fine motor control tasks on a digitizer with a specially devised electronic pen, which enables registration of the kinematic aspects of the movements. These tasks are performed under a normal and visually deprived condition and while performing a secondary arithmetic task. Mean and standard deviation of movement velocity as well as a measure of dysfluency are analyzed.

PROGRESS—Six patients have been investigated pre-operatively and post-operatively. The disability-oriented task sets seem to be sensitive to pre-operative problems and to post-operative changes in motor control which could not be demonstrated so clearly by the clinical parameters and global myelopathy score.

FUTURE PLANS—This project will be continued with a larger number of patients with CSM. The sensitivity of the different tasks will be investigated and new tasks aimed at subtle changes in postural control will be developed. A pilot study combining the disability-oriented task sets and neurological parameters (MEP and SSEP) is planned. Results will be compared with those of healthy controls.

[330] COMPLICATIONS OF ANTERIOR CERVICAL FUSION WITH PLATE AND SCREW FIXATION

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Sponsor: *None listed*

PURPOSE—Between June 1988 and July 1993, 70 Shepherd Spinal Center patients with cervical spine fractures received anterior fusion with plate and screw fixation. This procedure is regarded as safe and effective when properly performed, but it is technically challenging and has not yet been widely embraced by orthopedic surgeons. Due to the relative obscurity of anterior plating, information regarding the complications sometimes encountered during or following this procedure has been somewhat scarce in the literature. The purpose of this study is to contribute to the advancement of anterior cervical plating by analyzing data from this series of patients, with an emphasis on describing the complications encountered and attempting to identify any factors related to incidence of complications.

METHODOLOGY—Patient data, including demographics, injury level, neurological status, type of fracture, type of instrumentation used (Caspar plating or AO H-plates with titanium screws), outcomes, and complications encountered, were collected respectively by reviewing the patients' medical files and by examination of postoperative and follow-up radiographs by the primary author. Factor analysis and analysis of variance will be employed to try to identify factors related to complications and unsuccessful outcomes.

PROGRESS—All data have been collected and a literature review has been conducted. Analysis of the data is currently underway. After the results have been obtained, they will be incorporated (along with several case reports of complication-fraught patients and the literature review) into an article for publication.

PRELIMINARY RESULTS—Although the results of the statistical analyses have not yet been obtained, some subjective observations can be made concerning the patient data. Although the rate of serious complications appears to be acceptably low and comparable with that of other published series of anterior cervical plating patients, there may be some cause for concern regarding a relatively high number of suboptimally placed screws (over- or underpenetration of the vertebral body, or insertion into the disk space). Screw malplacement led to screw and/or plate loosening to an extent that impacted the patient's course in only a very few cases, but each of these cases of significant hardware migration did result from a malplaced screw. This underscores the critical importance of intraoperative radiographic visualization to ensure proper screw placement and the necessity of repositioning any malplaced screw at the time of initial surgery. One case report is of a 51-year-old man who received a technically faulty anterior cervical plating procedure at another institution. His neurological impairment was minimal and he was discharged home to convalesce. Five weeks postoperatively, however, he developed a persistent cough and then coughed up a screw, and the next day he noticed progressive weakness in his arm. The patient was reoperated on, and upon waking he was a complete C7 tetraplegic. The exact cause of this tragic outcome remains mysterious, but the case dramatically illustrates that anterior cervical plating should only be performed by experienced spine surgeons with extensive training in this technique.

C. Spinal Cord Regeneration

[331] APPLICATION OF ELECTRIC FIELDS TO ENHANCE RECOVERY FOLLOWING SPINAL CORD INJURY: BEHAVIORAL STUDIES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #423-2RA)*

PURPOSE—The purpose of this study was to evaluate whether the application of small direct electric currents (DC) would enhance functional recovery after severe contusion injury to the spinal cord in cats. Recent studies have suggested that the application of electric fields to the injured spinal cord may result in long-term improvements. It is essential to further evaluate the effect of applied electric fields under controlled parameters of injury and stimulation. Beneficial effects of electrical stimulation could have great clinical potential.

METHODOLOGY—Eighteen cats were used in this study. The cats were anesthetized, and a laminectomy was performed at the T8-T9 level. An impact force of 90 N was delivered to the spinal cords using a trauma device developed in our laboratory. This force was found to produce a severe contusion injury. Of the 18 cats, 6 received long-term (6-month) stimulation using newly perfected, implantable stimulators; 6 received short-term (2-month) stimulation; and 6 served as surgical controls. The animals received daily care in accord with AAALAC guidelines. Behavioral tests were performed biweekly over the 6-month period using the following tests: Open Field: the animals were observed on a flat barrier-free environment for spontaneous activity of the hind limbs, and rated on a scale from 0-5. Placing: the animals were observed for a placing response after stimulation of the skin of the front of the hind limb, and rated on a scale from 0-2. Tail Pinch: the response to a mild tail pinch was recorded on a scale from 0-3. Withdrawal Response: the response to withdrawal of the hind limb to pain, pressure, or extension was rated on a scale from 0-3.

PROGRESS—The first phase of the study, in which we compared severe contusion injury and moderate contusion injury, has been completed. The second phase, which involves evaluating newly designed electrical stimulators on cats that sustained severe contusion injuries, is in progress. Behavioral analysis has indicated that the animals that received 6 months of electrical stimulation after severe contusion injury were capable of weight bearing and minimal ambulation.

RESULTS—The results of the Open Field test showed that at the end of 6 months, the cats receiving the new improved implantable stimulators and stimulated for 6 months, demonstrated positive postural changes, some weight bearing, and even minimal ambulation (Score: 3.0). The results of the Placing test showed that these cats also exhibited favorable placing responses (Score: 1.9). The Tail Pinch test demonstrated that these cats showed vigorous stepping and some vocalization after mildly pinching the tail (Score: 2.5). The Withdrawal Response was also favorable in these cats, as compared to the cats in the other two groups. The overall health of the animals receiving the improved implantable stimulators was excellent, and muscle atrophy in the hind limbs was not as excessive as compared to the other groups.

FUTURE PLANS—We will continue to implant the newly perfected stimulators into additional animals, in order to refine parameters that bring about optimum recovery. In addition, we will begin studies centered around the effects of implanting stimulators following a chronic spinal cord lesion. If promising results materialize in future studies, the benefit to disabled veterans will be significant.

RECENT PUBLICATIONS FROM THIS RESEARCH

Electric field distribution within the injured cat spinal cord: Injury potentials & field distribution. Khan T, Myklebust JB, Swiontek T, Sayers S, Dauzvardis M. J Neurotrauma 1994:11:699-710.

Electric field distribution within normal cat spinal cord. Khan T, Myklebust JB, Swiontek T, Sayers S. J Neurotrauma 1994:11:563-72.

[332] APPLICATION OF ELECTRIC FIELDS TO ENHANCE RECOVERY FOLLOWING SPINAL CORD INJURY: ELECTROPHYSIOLOGICAL STUDIES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #423-2RA)*

PURPOSE—The purpose of this study was to evaluate the functional benefit of electrical stimulation of the spinal cord, as measured by electrophysiological techniques, using a severe contusion model of spinal cord injury.

METHODOLOGY—Twelve cats were anesthetized, and sustained a severe contusion injury to their spinal cord. The animals were divided into two groups: in one group six cats received newly perfected, implantable stimulators; and in the other group six cats served as surgical controls. The animals received daily care in accord with AAALAC guidelines. Electrophysiological tests were performed on all animals. Somatosensory evoked potentials (SSEPs) and motor evoked potentials (MEPs) were recorded before injury, and then bimonthly after contusion injury, throughout the duration of the 6-month experimental period.

To record SSEPs, the sciatic nerve was stimulated using needle electrodes. A square wave stimulus pulse of 100 μsec duration and 10 μsec delay was delivered at a repetition rate of 5 pulses per second. The SSEPs were recorded at three locations: the motor cortex, the upper thoracic level (above the lesion site), and at the lower lumbar level (below the lesion site).

To record MEPs, the motor cortical area was stimulated using a magnetic stimulator with a 5 cm focal point pediatric coil. The evoked potentials were recorded from both the right and left tibialis anterior muscles using needle electrodes.

RESULTS—Preliminary results obtained from the cats that received the new model implantable stimulators, after severe contusion injury, have been very encouraging. Various degrees of electrophysiological recovery have been observed in these animals. The peak latencies recorded from the thoracic spinal cord, and from the cortex (above the injury), from the contusion injury group were significantly delayed. Electrical stimulation of the spinal cord after contusion injury resulted in a shortening of the thoracic and cortical peak latencies toward preinjury values. In addition, the amplitudes of the peaks recorded from the thoracic spinal cord, and from the cortex of the contusion injury group, were significantly reduced. The SSEPs recorded 5 months postsurgery, in the contusion injury plus implantable stimulator group, exhibited an increase in amplitude of the thoracic and cortical values toward normal. The MEPs were recorded across the injury site in four out of the six animals that received implantable stimulators.

FUTURE PLANS—We will continue to implant the newly perfected stimulators into additional animals in order to evaluate and refine the parameters that bring about optimum recovery.

[333] ENHANCED CARBON FILAMENT PROSTHESES AS SUBSTRATES FOR REGROWTH OF INJURED SPINAL CORD: RECOVERY OF FUNCTION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B742-RA)*

PURPOSE—Fetal tissue grafts have been investigated as a means of attaining functional recovery after spinal cord injury. Most studies have suggested fetal grafts exert some trophic influence on the damaged spinal cord tissue, thereby reducing the damaging consequences of the lesion, and facilitating axonal sprouting and regeneration. However, successful regeneration requires not only trophic influences, but also elongation and guidance of the regrowing lesioned fibers toward their target tissues. The purpose of this project was to determine whether culturing fetal spinal cord explants on carbon filaments, and then subsequently implanting these filaments into the injured spinal cord, would enhance axonal regrowth and promote functional recovery.

METHODOLOGY—Fetal spinal cords from 14/15-day-old rat embryos were removed and the meninges and dorsal root ganglia were carefully detached. Small segments (0.5–1.0 mm) of the thoracolumbar spinal cord were placed on carbon filaments attached to the bottoms of tissue culture dishes. After culturing for 24 hours, the filaments were implanted into the lesion site of contused rat spinal cord. All animals were cared for according to AAALAC guidelines.

The assessment of neurological function was made by different behavioral measures: open field walking, toe spread, withdrawal responses to pain and pressure, placing response and spasticity. At the end of the 10-week survival period, antegrade and retrograde neuronal labeling was performed by injection of WGA-HRP into the motor cortex or lumbar spinal cord, respectively.

RESULTS—The results of the open field walking test showed that after 10 weeks, all the animals receiving cultured implants exhibited weight bearing with minimal ambulation. Animals receiving uncultured carbon filament implants, or no implants, showed frequent movement of the hind limbs with minimal weight bearing. The withdrawal reflexes to pain and pressure were found to be normal in the animals that received cultured implants, as compared to animals that received uncultured, or no, implants, in which case the withdrawal reflexes were hypertensive. The placing and toe spread responses were also greatly improved in the animals that received cultured implants as compared to the other groups. In addition, much less spasticity was observed in the animals receiving the cultured implants.

At the end of the 10-week survival period, the injection of WGA-HRP in the motor cortex, or lumbar spinal cord, resulted in antegrade and retrograde labeling across the lesion site in the animals receiving the cultured implants.

The results of this study suggest that the combination of fetal spinal cord tissue (supplying neurotrophic and neurogenic properties) with carbon filaments (providing a favorable substrate with polarizing and scaffolding effects) may prove useful in the repair of descending motor pathways.

FUTURE PLANS—We are currently in the process of further evaluating the use of these implants for the repair of the damaged spinal cord after injury.

RECENT PUBLICATIONS FROM THIS RESEARCH

Recovery of function after spinal cord injury using co-implants of carbon filaments and fetal tissue. Khan T, Dauzvardis MF, Trausch C, Sayers S. J Am Paraplegia Soc 1994:40:8.

[334] ENHANCED CARBON FILAMENT PROSTHESES AS SUBSTRATES FOR REGROWTH OF INJURED SPINAL CORD: ELECTROPHYSIOLOGICAL RECOVERY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B742-RA)*

PURPOSE—The work from a number of laboratories has shown that fetal spinal cord transplants placed into the site of spinal cord injury in adult animals can support axonal regrowth of the host. Embryonic spinal cord explants may contribute to functional recovery by acting as a relay between host spinal cord neurons, thereby restoring interrupted neuronal circuits, by secreting neurotrophic factors, and by acting as a bridge to traverse the site of injury. Recent studies have also suggested that regeneration can be encouraged in the injured spinal cord by the introduction of substrates that provide a favorable attachment surface, and also directionality to regrowing axons. The purpose of the present study was to determine whether the coimplantation of carbon filaments and fetal spinal cord tissue could promote functional recovery following spinal cord injury as determined by somatosensory-evoked potentials (SSS) and motor-evoked potentials (MPS).

METHODOLOGY—Fetal spinal cords from 14/15-day-old rat embryos were removed and small segments (0.5–1.0 mm) of the thoracolumbar spinal cord were placed on carbon filaments and cultured for 24 hours. Adult rats sustained a severe contusion injury to their spinal cord, and were divided into four groups: Group 1 received carbon filament implants cultured with fetal tissue; Group 2 received carbon filament implants; Group 3 received fetal tissue implants; and Group 4 served as an injury control. All animals were cared for according to ALC guidelines.

Electrophysiological recovery was assessed at the end of the 8-week survival period by recording SSS and MPS. The SSS and MPS were also recorded before injury to obtain a preinjury baseline for comparison. For SSS, the sciatic nerve was stimulated, and SSS were recorded at the lumbar spinal cord (below the lesion), and at the thoracic spinal cord and cortex (above the lesion). For MPS, the motor cortex was electromagnetically stimulated, and the MPS were recorded in both tibialis anterior muscles.

RESULTS—When SSS were recorded across the lesion site from the thoracic spinal cord and from the cortex, potentials were present in 50 percent of the rats from Group 4, in 50 percent of the rats from Group 2, in 75 percent of the rats from Group 3, and in 80 percent of the rats from Group 1. When the SSS were present, the latencies from the thoracic and cortical potentials were significantly delayed in groups 2 and 4, whereas the latencies in groups 1 and 3 were the same as preinjury levels. The amplitudes of the SSS responses were reduced in all groups as compared to preinjury levels.

When MPS were recorded across the lesion site, the MPS responses were present in all groups, although the latencies and amplitudes varied. The latencies of the MPS recorded from Groups 1 and 3 were the same as preinjury levels. However, the amplitude of the peaks were slightly reduced in Group 1, moderately reduced in Group 3, and considerably reduced in Groups 2 and 4, as compared to normal values.

This study demonstrates that electrophysiological recovery after spinal cord injury, as measured by SSS and MPS, was the most dramatic in Group 1, the group of animals receiving carbon filament implants cultured with fetal spinal cord tissue, suggesting that this combination plays an important role in promoting spinal cord functional recovery after injury.

FUTURE PLANS—e are currently in the progress of further evaluating the use of these implants for the repair of the damaged spinal cord after injury.

[335] ELECTRIC FIELD EFFECTS ON CNS AXONAL TRANSPORT IN SCI: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #B92-446AP)*

PURPOSE—Axons of peripheral nerves often regrow and reinnervate their targets if the severed nerve is carefully anastomosed. However, for as yet unknown reasons, injured axons of the adult spinal cord seldom undergo a functional regeneration. Numerous approaches are being tried in order to coax central axons to regrow. Recent studies have shown that a direct current field at the injury site enhances neurite outgrowth, and stimulates directed neurite growth. Spinal cord injury (SCI) temporarily increases the level of slow axonal transport, which contains cytoskeletal proteins needed for axonal elongation, in adult rats to the higher level normally seen in young developing rats. The present study was designed to test the hypothesis that electrical stimulation increases neurite regrowth by enhancing the period of increased slow axonal transport following SCI. Parameters may then be identified to optimize changes in axonal transport, which will maximize regrowth of injured CNS axons.

METHODOLOGY—Adult rats received a dorsal spinal cord hemisection at the T8 level. Miniature stimulators were implanted at the time of surgery with platinum disk electrodes placed extradurally proximal (anode) and distal (cathode) to the injury. Electrodes were spaced 1 cm apart. The stimulators provided a constant 15 μA of DC current.

Axonal transport in the corticospinal tract was labeled with 35S-methionine 1 week, 5 weeks, or 14 weeks after injury by injecting 200 μCi of radioisotope unilaterally into the sensorimotor cortex. One day (fast transport) or 3 weeks (slow transport) after the isotope injection the animals were perfused with 10 percent formalin, the entire spinal cord was dissected, and the radioactivity in each 5 mm segment of the spinal cord determined by scintillation counting.

The distribution of radiolabel among the slow transport polypeptides was analyzed using the Laemmli buffer system on 6–17.5 percent polyacrylamide gradients with a 4 percent stacking gel. Fresh-frozen samples of brain or spinal cord containing the corticospinal tract were delipidated and dissolved in a SDS containing sample buffer. Total protein in the gel bands was detected by staining with Coomassie blue. Radioactive bands were detected by fluorography on X-ray film. Intensity of the radiographic pattern of each lane was normalized to the protein content in the segment containing the corticospinal tract decussation using the NIH Image 1.54 program.

PROGRESS—We have obtained data indicating that a local DC field applied at the site of a dorsal, spinal cord hemisection, enhances and prolongs the injury-induced increase in slow axonal transport within the corticospinal tract.

RESULTS—In agreement with others, we found that 1 week after SCI the corticospinal tract contained twice the amount of radiolabel as the tract from a control rat. Adding a stimulator at the injury site increased the amount of label in the tract above that measured in animals with sham stimulators. The increase was statistically significant after 14 weeks of treatment.

Polyacrylamide gel analyses of the radiolabeled corticospinal tract polypeptides suggest that the injury increases synthesis/transport of the SCb component of slow axonal transport more than the SCa component. Yet, the DC field appears to have greater impact on the synthesis/transport of the SCa component polypeptides.

The amount of radiolabel carried by fast axonal transport was not altered by the DC electric field at any time point.

FUTURE PLANS—A continuation project will examine the following questions: 1) does the DC field affect expression of cytoskeletal protein genes? 2) what electric field parameters produce maximal increases in cytoskeletal gene expression? and 3) can increased neurite sprouting at the site of spinal cord injury be correlated with electric field treatment?

RECENT PUBLICATIONS FROM THIS RESEARCH

Electrical stimulation enhances slow axonal transport in the corticospinal tract after spinal cord injury. McLane JA, Khan T. Soc Neurosci Abst 1993:19:1874.

Electric field effects on axonal transport in the corticospinal tract following spinal cord injury. McLane JA, Cobb T, Khan T. Soc Neurosci Abst 1994:20:1324.

[336] TUBULAR PROSTHESES TO ENHANCE AND DIRECT NEURONAL REGROWTH IN SCI

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Core Funds)*

PURPOSE—Although it has been shown that CNS neurons are capable of vigorous regeneration, functional regeneration is seldom successful because of the formation of a dense scar and the presence of inhibitor factors. There are few exceptions to date in experimental models. Peripheral nerve autografts have been shown to enhance regenerative processes within the optic nerve. Autografts have also supported regrowth of other injured CNS axons. Apparently, it is the Schwann cells within the grafts that enhance the regeneration. However, the supply of peripheral nerve to use as autografts is limited. Therefore, tubular prostheses seeded with cultured Schwann cells should be investigated as a means of enhancing and directing regeneration of neurites in the corticospinal tract of the spinal cord following injury. We hypothesize that the regenerative potential of corticospinal neurons is increased by providing channels for the growing axons that supply a permissive environment while protecting them from inhibitory factors associated with the glial scar. The long-term goal of this program is to develop a bridging prosthesis that will enhance and direct the regrowth of injured long-tract axons to sites of potential functional synapse formation.

METHODOLOGY—The corticospinal tract of rats was cut in the midthoracic region of the spinal cord. At the time of injury, one end of an artificial nerve containing either a purified extracellular matrix or the matrix containing cultured, isogeneic Schwann cells was implanted at the injury site. The other end of the tube was implanted deep into the spinal cord to approximate the ventral horn at a site caudal to the initial injury. Regeneration of axons within these tubes will be compared to regeneration of axons within a similarly grafted segment of predegenerated, isogeneic peripheral nerve. Comparisons will be based upon immunocytochemical and morphometric evaluations.

PROGRESS—We have isolated and expanded Schwann cell cultures from Fisher 344 rats and tested their *in vitro* labeling with Fluoro-Ruby. A set of grafts were implanted into experimental rats for a 2-week period. Morphologic analysis of the grafts is not yet completed.

RESULTS—Schwann cells were harvested from adult sciatic nerve following an extended period of *in vitro* Wallerian degeneration, during which time most of the potentially contaminating fibroblasts migrated out onto the culture dish. The remaining cells were released from explants by protease treatment. More than 95 percent of the cells obtained possessed the spindle or triangular shape characteristic of Schwann cells. The cultures were expanded through numerous passages using mitogenic medium (forskolin and pituitary extract) to stimulate cell division. Immunocytochemical staining with antibodies to S-100 protein and fibronectin demonstrated that the cultures were >95 percent Schwann cells, with fibroblasts the most common contaminant.

Schwann cells were cultured overnight in medium containing 1 percent Fluoro-Ruby (tetramethylrhodamine conjugated to 10,000 MW dextran). The fluorescent label was readily taken up by the cells, staining the entire cytoplasmic contents. In order to determine whether the treated cells were still viable

and whether the fluorescent label was stable, the labeled cultures were trypsinized and replated at low density. After 5 days the Schwann cells had proliferated extensively, yet retained a strong fluorescent labeling. This experiment suggests Fluoro-Ruby may be an effective prelabel for subsequent identification of the Schwann cells introduced into tubular prostheses.

FUTURE PLANS—We should next compare the ability of tubular prostheses containing a fibrous collagen matrix with or without Schwann cells and predegenerated peripheral nerve grafts to attract regrowing corticospinal tract axons; and second, determine the maximal distance that regrowing axons can traverse within tubular prostheses.

[337] NEURON-GLIA INTERACTION AND CNS REGENERATION

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Sponsor: *National Plan of Research and Development; the Madrid Autonomous Community; Europharma (Boehringer Ingelheim Spain) S.A.*

PURPOSE—We believe that neural plasticity is the result of glia-neuron interactions. Understanding these interactions will permit functional repair of damaged CNS.

PROGRESS—Two brain mitogen inhibitors have been purified to homogeneity. Their 500 MHz nuclear magnetic resonance spectra indicate that one of the inhibitors is a glycolipid and the other a peptide. The determination of the precise structure of these compounds is in progress.

Based on the immunological properties of the natural inhibitor, we have synthetized, in collaboration with Drs. Fernández-Mayoralas and Martín-Lomas of the Instituto de Química Orgánica of the CSIC, oligosaccharides with antimitotic activity against normal and tranformed cells of neural lineage. The most active tetrasaccharide exhibits selective cytotoxicity and antitumoral activity against malign neuroblastomas and gliomas transplanted in the rat brain.

In collaboration with Dr. T. Díaz García-Mauriño, of the Instituto Rocasolano of the CSIC, we have purified, using affinity chromatography, receptors for the tetrasaccharide and have prepared antibodies against them. A study of the number, affinity, and localization of these receptors is in progress.

Distinct temporal patterns of glial reactivity were observed in astrocytes and microglia after anisomorphic (stab wound) and isomorphic (intraventricular kainic acid) injuries. Isomorphic gliotic tissue contained the greatest neurite outgrowth inhibitory activity. With the help of an *in vitro* glial scar model, the inhibitory molecules were partially purified and characterized. They are heparan-sulfate/chondroitin-sulfate proteoglycans, of molecular weight about 250 kD and core protein of 48 kD, probably located in reactive microglial cells. Definitive studies on their cellular location and function depend on the preparation, now in progress, of specific monoclonal antibodies against them.

Olfactory axons, the only fibers capable of navigating toward their targets in an adult CNS environment, may do so with the help of ensheathing glia, a type of macroglia unique to the bulb. Ensheathing glia were cultured from adult olfactory bulb, immunopurified, and transplanted in the rhizotomized rat spinal cord. Transplantation made possible the ingrowth and navigation in the cord of regenerating sensory axons. We are now exploring the possible generalization of this intervention to help regeneration of pure central axons, such as optic nerve or corticospinal fibers.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Differential activation of microglia and astrocytes in aniso- and iso-morphic gliotic tissue. Fernaud-Espinosa I, Nieto-Sampedro M, Bovolenta P. Glia 1993:8:277-91.

Neurite outgrowth inhibitors associated with glial cells and glial cell lines. Bovolenta P, Wandosell F, Nieto-Sampedro M. NeuroReport 1993:5:345-8.

Active microglia, sick astroglia and Alzheimer's type dementias. Nieto-Sampedro M, Mora F. NeuroReport 1994:5:375-80.

Differential effects of glycosaminoglycans on neurite outgrowth from hippocampal and thalamic neurones. Fernaud-Espinosa I, Nieto-Sampedro M, Bovolenta P. J Cell Sci 1994:107:1437-48.

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XVI. Wheelchairs and Powered Vehicles

A. General

[338] CLINICAL WORKSTATION FOR REDUCING WHEELCHAIR PROPULSION INJURIES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B686-RA)*

PURPOSE—The purpose of this research was to test a system for measuring the kinematics and dynamics of wheelchair propulsion, and to develop clinically relevant techniques for analyzing wheelchair propulsion. The system tested and the techniques developed through this research should lead to a better understanding of the mechanisms related to upper extremity pain among wheelchair users. Armed with this new information, we should be able to reduce the incidence of upper extremity pain, and develop better treatment strategies.

METHODOLOGY—Subjects are asked to complete a medical history and fitness questionnaire. Each subject is given an upper extremity physical examination by a physician. Upon completion of these tasks, upper extremity clinical electromyograms are taken for each subject's upper extremities (both radial and ulnar nerve). Body segment parameters are recorded and used with a modified Hanavan's mode. The SMART^{wheel} is placed on the subject's own wheelchair or one of the test wheelchairs depending upon the experiment being conducted. The SMART^{wheel} calibration is verified. The wheelchair and subject are placed upon a computer-controlled wheelchair dynamometer. Subjects are asked to propel their wheelchairs forward at two speeds (2 mph and 4 mph) at two workloads (5 W and 10 W). Subjects are also requested to propel in reverse at 2 mph, and to perform right and left spins. The kinetic data are analyzed in real time, while kinematic data are processed later.

PROGRESS—The kinematic and kinetic analysis system has been developed, calibrated, and validated. Kinematic data are collected via a video-based commercial motion analysis system and the SMART^{wheel} developed by this group. Mechanical and electronic hardware were developed to synchronize and integrate kinematic and kinetic analysis systems. Software was also written for data acquisition and analysis. The analysis software is capable of animation in synchrony with line charts and tables. The software generates pushrim forces and moments, not body joint forces and moments and body angles.

Data have been collected on about 30 subjects who range from sedentary to marathon racers. Data have been analyzed and shown to be capable of distinguishing active wheelchair users from wheelchair users with and without upper extremity injuries.

RESULTS—We have been able to identify differences between wheelchair users and non-wheelchair users as well as between wheelchair users with and without upper extremity injury. Subjects with and without injury are classified based upon the upper extremity physical examination and through electro-

myography. We have begun to develop a set of clinical indices that classify the severity of injuries and risk for injury among wheelchair users.

FUTURE PLANS—We intend to follow a group of patients through rehabilitation to 5 years postinjury to investigate factors related to the development of upper extremity pain among wheelchair users. We also intend to investigate the precise mechanisms of orthopedic and neurological injury among wheelchair users. We hypothesize that most wheelchair injuries can be prevented through the proper selection and configuration of the wheelchair. Proper selection of the wheelchair will require training of clinicians and wheelchair users. For this research to be successful, the clinical workstation must yield useful research and clinical results that can be presented to clinicians in a clear and precise manner.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Clinical workstation interface for the analysis of wheelchair propulsion. Ensminger GJ, Cooper RA, and Robertson RN. In: Proceedings of the 16th Annual IEEE/EMBS International Conference; 1994 Baltimore, MD, 1994:16:494-5.

Upper extremity net joint forces and moments during wheelchair propulsion. Robertson RN, Cooper RA, Ensminger GJ, and Stewart KJ. In: Proceedings of RESNA International '94; June 1994, Nashville, TN. Washington, DC: RESNA Press, 1994:155-7.

Wheelchairs and seating. Cooper RA, Brienza D, Brubaker CE. Curr Opin Orthop 1994:5(6)101-7.

[339] ELECTRICAL CONTROL OF BLADDER AND BOWEL FOLLOWING SPINAL CORD INJURY

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PURPOSE—The purpose of this research is to evaluate bladder, bowel, and sexual function in patients with spinal cord injury (SCI) before and after implantation of an electrical stimulator for activation of the sacral anterior nerve roots. The goal of the research is reduction of bladder and bowel complications and increased independence following SCI.

METHODOLOGY—Subjects with complete SCI and complications of bladder, bowel, and sexual function are being implanted with an electrical stimulator intended to reduce these complications. This device consists of electrodes implanted surgically on the sacral anterior nerve roots at the base of the spine, and connected by fully implanted wires to a stimulator implanted surgically under the skin of the front of the chest. This stimulator is powered and controlled by transmission of radio waves from a battery-powered portable controller outside the body, operated by the subject.

Subjects are being evaluated before and after operation with regard to bladder, bowel, and sexual function, using clinical examination and investigation, including urodynamics and colorectal manometry.

PROGRESS—Two patients with paraplegia and three with quadriplegia have received these implants, the first of this type in the United States, at the VA Medical Center in Cleveland, OH. Approval has been obtained to extend recruitment to nonveterans in order to include a greater number of female subjects.

PRELIMINARY RESULTS—All the subjects are using the stimulator routinely at home for emptying the bladder. Residual volumes are low and infection rates have been reduced. All subjects have discontinued routine use of indwelling or intermittent catheterization, and those with good hand function no longer use leg bags. Four have found that regular use of the stimulator reduces constipation and three use it to produce defecation. In three of the four males, the stimulator also produces penile erection.

FUTURE PLANS—Recruitment and follow-up of subjects will continue among veterans and will be extended to nonveterans. A smaller, lighter external controller capable of being programmed by computer will be introduced. New techniques will also be tested to improve bladder and bowel control by the use of more selective electrical stimulation that activates bladder and rectum without activation of the sphincters.

RECENT PUBLICATIONS FROM THIS RESEARCH

Management of the neurogenic bowel in patients with spinal cord injury Banwell JG, Creasey GH, Aggarwal AM, Bodner DR, Mortimer JT. Urol Clin North Am 1993:20(3)517-26

Sacral root electrical stimulation for micturition after spinal cord injury Creasey GH. Urol Clin North Am 1993:20(3):505-15.

Effect of anterior sacral root electrical stimulation on bladder management of spinal cord injured patients. Creasey GH, Bodner DR, Hoffman D, Banwell JG, Fenstermaker RA. In: Proceedings of the American Paraplegia Society, Las Vegas, NV; September 1994.

Review of electrical stimulation in the management of the neurogenic bladder. Creasey GH, Bodner DR. Neurorehabil 1994:4(4):266-74.

[340] DESIGN AND SELECTION GUIDELINES FOR WHEELCHAIR RIDE COMFORT

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B805-RA)*

PURPOSE—Many wheelchair breakdowns occur each year. Although the exact number is not known, a recent survey of wheelchair users indicated that even one breakdown per year is unacceptable. The consensus among those actively testing wheelchairs is that a chair should withstand 200,000 cycles on an International Standards Organization (ISO) Double Drum Tester and a corresponding 6,600 drops on an ISO Curb Drop Tester. After several years of independent wheelchair testing, we have observed a large number of premature failures. Moreover, consumers have reported problems with both active use and traditional design wheelchairs.

METHODOLOGY—We are dynamically measuring and recording the three-dimensional forces, accelerations, and strains at several points on wheelchairs (representative of those commercially available) during actual use and during ISO fatigue testing. These measures will be related to each other. We plan to develop FEM for both actual use and test modes of operation and to illustrate the practical application of advanced design methods to wheelchairs. Independent collection of data ensures its availability to all manufacturers, clinicians, and interested consumers.

PROGRESS—We have developed an ISO/ANSI and VA wheelchair test facility at Highland VAMC in Pittsburgh. As a part of this facility, we have designed and built an ANSI/ISO Double Drum Tester and ANSI/ISO Curb Drop Tester. Both machines are closed-loop computer controlled and exceed specifications. Construction of the equipment and development of several of the standards are crucial to the success of this project.

Accelerometer data have been collected and analyzed in both two and three dimensions. From this data, dynamic load and stress distributions have been

calculated and used as inputs into a finite element package (ALGOR). One prototype carbon fiber wheelchair design was optimized using this data and then constructed. The use of accelerometers for load analysis has become practical by the recent reduction in their price, and this analysis of loads is based on rigid body kinetics. A body must be much stiffer than the load bearing surface. The segments of the ISO/RESNA test dummy satisfy this requirement.

Accelerometry has greater validity than simply applying a factor of safety to static loads. The factor of safety is often about 3 and many times as low as 1.5. Realistic dynamic loading is more complicated than simply a scaled version of the static loads. Our experience has shown that wheelchairs experience accelerations in excess of the 3 Gs used by many wheelchair manufacturers.

RESULTS—We are in the process of dynamically measuring true road loads and perceived ride comfort of manual wheelchair users during the performance of selected activities of daily living. In our laboratories, we have conducted ≈ 50 wheelchair ANSI/RESNA standard tests. Much to the dismay of the manufacturers, a substantial number of wheelchairs experience premature failures during fatigue testing. Consumers have reported that wheelchairs are expensive, often uncomfortable, and require frequent repair. We believe that this problem can be reconciled. The use of ANSI/RESNA wheelchair standards as selection/prescription criteria may be helpful. However, ride comfort and other ergonomic considerations cannot be overlooked.

FUTURE PLANS—This project will lead to: a) the development of methods for collecting road load data; b) clarification of the relationships between road loads and ISO fatigue test methods; c) suggestions for improvement of the ISO tests; and d) guidelines for applying FEM to wheelchair design which balances ride comfort and durability.

RECENT PUBLICATIONS FROM THIS RESEARCH

Evaluation of methods for determining rearward static stability of manual wheelchairs. Cooper RA, Stewart KJ, VanSickle DP. J Rehabil Res Dev, 1994:31(2):144-7.

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Wheelchairs and seating. Cooper RA, Brienza DM, Brubaker CE. Cur Opin Orthop, 1994:5(6)101-7.

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Whole Body Dampening Properties of a Wheelchair Rider. VanSickle DP, Cooper RA, Albright SJ. In: Proceedings of the 16th Annual IEEE/EMBS International Conference, Baltimore, MD, 1994:16(1):498-9.

Power wheelchair range testing and energy consumption during fatigue testing. Cooper RA, VanSickle DP, Albright SJ, Stewart KJ, Flannery M, Robertson RN. J Rehabil Res Dev. In press.

[341] TOWARD THE DESIGN OF A NEW PRONE CART: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #B92-522AP)*

PURPOSE—One segment of the SCI population has no adequate equipment designed for its use: patients who live on a prone cart, either long or short term. Prone carts are used by patients bedridden for weeks, months, or years at a time because of pressure sores that prevent their use of a wheelchair. SCI patients are at high risk for developing pressure ulcers due to decreased mobility, impaired circulation, and sensory deficits. Sacral and ischial ulcers are most common area for pressure ulcers. If ulcers are located in these areas, SCI patients cannot sit during the healing process and must use a prone cart lying on their stomach for mobility. However, prone carts in the form available now often exacerbate or promote development of ulcers, and are also associated with scoliosis, back problems, and increased pain. In addition prone carts

are not adaptable enough to permit many activities that wheelchair users take for granted: socializing, working, shopping, doing household chores, and participating in recreational activities.

METHODOLOGY—We conducted a clinical evaluation of the E&J (a flat/horizontal cart of which the height is not adjustable by its user) the Gendron (essentially the same as the E&J prone cart, differing only by providing a protective metal strip with a rubber molding around its periphery and a chin support cushion), and the new MIAD/PVA prone cart designed at the Milwaukee Institute of Art & Design in collaboration with a VA patient and clinicians. This prone cart enables the user to lie at an angle rather than laying flat as in the others. This position has been found to relieve back pressure. With an hydraulic system, the user can adjust both the front and rear angles of the matt to achieve desired comfort. In addition, a front deck provides an eating and working area. This prone cart was manufactured with sponsorship from EPVA, PVA, and Ortho-Kinetics Inc.

We evaluated these devices by using photography of patients employing the prone carts in a variety of ADL settings; administering questionnaires to caregivers and patients regarding usage and effectiveness of the prone carts. In addition we sought their opinion as to the features that an ideal prone cart should have, and designing an experimental prone cart mock-up for the purpose of establishing functional characteristics of new prone cart designs.

RESULTS—E&J and Gendron prone carts: both patients and caregivers commented that the lack of user-accessible angle adjustability was a major problem, as well as the lack of a chest support area, storage and a eating/working surface.

MIAD/PVA prone cart: both patients and caregivers had positive impressions about its unique features: front and rear angle adjustability, chest support area, shelf for eating/reading or writing. Suggested improvements were made as well: incorporate a retractable front deck to provide closer access to a bed/table; relocate the storage drawer under the front deck; design a sectional mat with removable areas to provide space for colostomy bags; and modify the geometry of the cart for improved weight distribution and develop a motorized version.

FUTURE PLANS—This study resulted in research-based information and criteria for the design of new prone carts. Findings of this pilot study will be incorporated in a proposal for the design of a new manual and motorized prone cart.

[342] AARP ELECTRIC SCOOTER STUDY

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Sponsor: *American Assocation of Retired Persons*

PURPOSE—The purpose of this study is to evaluate features and specific models of scooters using a group of individuals who are candidates for a scooter and who are at least 55 years of age. The goal is to identify strengths and limitations of specific features as they relate to the static and dynamic anthropometric characteristics of the scooter users. A total of 15 scooters from 15 manufacturers were evaluated.

METHODOLOGY—The study consists of three separate components: manufacturer's input, scooter user input, and a field experiment to evaluate scooters in indoor and outdoor activities frequently undertaken by the scooter user.

Manufacturer's Input: Manufacturers of the scooters were invited to attend a meeting and to complete a short written survey instrument about their product, information they would like to obtain from the study, and recommendations for the parameters investigated. Information obtained was included in the technical report and used to develop and/or modify the evaulation protocol.

Scooter User Input: Scooter users were asked to provide information about their experiences in pur-

chasing and using their scooter. ProMatura analyzed the letters using a template to assign the letter writer's comments to specific categories. Data was analyzed to identify trends and statistically significant differences among subgroups of letters. All of the letter writers were also sent a 12-page questionnaire to document their experiences and perceptions of their scooter's usefulness and usability.

Field Experiment: A usage trials assessment of the scooters was completed. Each of the 25 subjects used the scooters in a specified series of tasks. The tasks were used to determine the subject's ability to perform the task with each particular scooter, their level of competence, their sense of stability, and their evaluation of the scooter feature, ease-of-use, comfort, and so forth. The data were collected through objective (time, number of errors, ability or inability to complete) and subjective measures (rating scales and paired comparisons).

PROGRESS—Manufacturer and scooter user input has been gathered and the field experiment has been completed. A technical report of the findings will be submitted to AARP so that a consumer product report can be released.

RESULTS—AARP will release the results in a consumer product report.

[343] SHOULDER KINEMATICS DURING PROPULSION OF DIFFERENT WHEELCHAIR TYPES

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Sponsor: *National Institutes of Health*

PURPOSE—The goal of this study was to develop a three-dimensional kinematic measurement protocol of shoulder motion during wheelchair propulsion. Using two different wheelchair types, the impact of wheelchair design features on shoulder kinematics and temporal parameters of the propulsion task were investigated.

METHODOLOGY—Motion of the left upper extremity and trunk was measured on 10 nondisabled adult males during propulsion of two different wheelchairs: a standard, nonconfigurable ''Traveler'' (Everest & Jennings, Inc., Camarillo, CA); and a lightweight, ''sport'' use, adjustable ''Quickie 2'' (Sunrise Medical, Fresno, CA). Each chair was propelled three times by each subject on a stationary roller system. Reflective, spherical markers placed on the wheelchair, left arm, and trunk were tracked using a four-camera Expert Vision;tm system (Motion Analysis Corp., Santa Rosa, CA) at 60 frames/sec. Marker data were used to measure wheel angular velocity, duration of propulsion and recovery phases of the propulsion task, three-dimensional kinematics of the shoulder complex, and trunk lean. Statistically significant differences in these parameters between the two chair types were assessed.

RESULTS—A segmental model for describing triaxial motion of the shoulder was developed and successfully used in describing shoulder motion during the wheelchair propulsion task. Wheelchair design features such as lower seat position and more forward location of the rear wheel axle of the ''sports'' chair compared to the standard chair required significantly greater shoulder abduction during the recovery phase while providing a significantly greater propulsion arc and a significantly longer propulsion phase. Additionally, significantly greater degrees of shoulder internal rotation were required for propulsion of the ''sports'' chair.

IMPLICATIONS—Subsequent studies to examine spinal cord injured wheelchair users must account for the differences in wheelchair design in order to standardize results for comparison between subjects. Currently, experimental design considerations are for using one, fully configurable chair that can be adjusted to fit a large variety of body sizes and types

using a set of anthropometric measurements as standardization guides.

FUTURE PLANS—Three-dimensional kinematics of the shoulder will be measured on a series of 10 male and 10 female spinal cord injured subjects propelling a wheelchair during level and variable gradient ramp ascent tasks. An instrumented handrim will allow simultaneous measurement of loads applied to the hand and will provide the data necessary for net resultant load calculations for the wrist, elbow, and shoulder.

[344] DESIGN AND DEVELOPMENT OF A WHEELCHAIR FOR ENHANCED ACCESS

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Sponsor: *Paralyzed Veterans of America, Spinal Cord Research Foundation*

PURPOSE—As recently as a decade ago, the functionality of wheelchairs was still a major issue. While all the questions have not been answered, it is clear that much has been accomplished to make wheelchairs more functional for a variety of applications, yet there continues to be a need for greater reliability, lower cost, and more versatility. While the most obvious effort of this project focuses on enhanced accessibility and compatibility for travel, the project was conceived to address all these issues. It should be noted that such considerations as manufacturability, reliability, alternative materials, and others have been initiated with this project and will be pursued well beyond its conclusion as part of the University of Pittsburgh Rehabilitation Engineering Research Center activities.

A particular goal of this project is to develop a wheelchair that can meet all the requirements of a general purpose/active use wheelchair and also provide for enhanced access that is frequently needed (e.g., for travel). A design has been developed and analyzed for a chair that folds easily to a very compact size and shape. The individual can, while seated in the chair, readily achieve a configuration that permits very narrow access, limited only by his or her own width. Other elements of the design are the use of molded parts and glass filled polyester material to result in an inexpensive, manufacturable design.

METHODOLOGY—The conceptual design is complete. A computer database containing the geometry of the preliminary design was used to created a solid computer model with added detail. Once the design is fully detailed, we can begin to verify its performance by computer analysis. This process increases the probability that when the expensive process of building a prototype is complete, the chair will not fail. At a minimum, fewer design revisions will be needed. While the analysis is under way, manufacturers will quote the parts and may recommend changes to reduce tooling and production costs. A customer review meeting was conducted to allow users to review the design and suggest changes and improvements. This approach keeps the engineering up front and allows quick, low-cost design iterations. Finally, parts are produced, delivered, and assembled.

PROGRESS—Detailed design work is continuing. Structural analysis was used to verify the seat design and the die cast fastener/hinge assembly. A wheelchair user review was held to solicit their responses to the current design. Their comments will be incorporated into the design if possible.

FUTURE PLANS—We expect to build two prototype chairs using inexpensive temporary molds during year 2 of this project. At least one chair will be tested at the University of Pittsburgh wheelchair testing facility. Once this chair demonstrates that structural components of inexpensive, glass filled polyester are feasible, we envision an entire line of wheelchairs built on the same tooling. The cheapest materials are heaviest but a wide range of more expensive, lighter and stronger materials are available. By using a range of compression molded materials, the weight and cost of the chair can be varied to meet a wide variety of consumer needs.

[345] ERGONOMICS OF MANUAL WHEELCHAIR PROPULSION

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Sponsor: *None listed*

PURPOSE—Manual wheelchair propulsion is studied from a combined physiological and biomechanical experimental perspective. The general aim is to improve the mobility of wheelchair users, as far as the wheelchair-user combination is concerned. Important areas of research are currently on factors influencing the wheelchair-user interaction in terms of functional load and mechanical efficiency, and on factors influencing the work capacity and power output (among others: functionality and propulsion technique) of the wheelchair user as the 'motor' in wheelchair mobility.

METHODOLOGY—Wheelchair propulsion is being studied during standardized aerobic wheelchair exercise and sprint tests on a motor driven treadmill and during simulated conditions on a computer-controlled wheelchair ergometer. During the treadmill tests (which are used in studies on prototype-evaluation, performance capacity, and propulsion technique), physiological measures are combined with 3-D kinematics and electromyography. On the wheelchair ergometer an additional 3-D reconstruction of the movement pattern of arms and trunk is combined with measures of force and power production, electromyography of upper arm and trunk muscles, and overall physiology. An inverse dynamics segment model of the upper extremity and shoulder region is used to interpret cardiorespiratory phenomena and measures of efficiency from a biomechanical and anatomical perspective. A model of the shoulder complex allows simulation of static and dynamic activity of shoulder muscles during wheelchair propulsion. The model also allows the calculation of joint forces and muscle forces and torque, which helps in explaining the high prevalence of repetitive strain injuries (RSI) in the shoulder (and hand-wrist) among wheelchair users.

PROGRESS—Apart from detailed studies on wheelchair propulsion technique, analysis of lever propulsion is proceeding as well as the analysis of the hubcrank. Both are much more efficient propulsion mechanisms than the conventional handrim. A seat-height study among a group of spinal cord injured subjects revealed a significant trend, which could not be explained by variations in technique parameters. They seemed associated with variation in lesion level and thus overall functionality.

FUTURE PLANS—Fitting quidelines will be further refined for groups of disabled subjects, also during the process of rehabilitation. This entails, among others, a more detailed study of seat height in a repetitive measures design among a small group of well classified spinally injured subjects.

Detailed analysis of wheelchair arm work during handrim and hubcrank propulsion must contribute to a better understanding of the mechanisms and risks of RSI and possible preventive measures in terms of wheelchair design or propulsion technique.

RECENT PUBLICATIONS FROM THIS RESEARCH

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B. Powered Controllers

[346] THE NAVCHAIR CONTROL SYSTEM FOR AUTOMATIC ASSISTIVE WHEELCHAIR NAVIGATION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B630-DA)*

PURPOSE—The NavChair control system is designed to assist a user with marginal or insufficient ability to operate a power chair safely and effectively. In operation, commands from the user joystick or other control interface go first to the onboard NavChair computer where they are evaluated in terms of what the system knows about surrounding obstacles and the mode of operation (obstacle avoidance, wall following, and so forth). Control commands from the user which will not cause the chair to collide with nearby objects and are within the scope of the current mode are passed on to the wheelchair drive controller unchanged. Commands which do cause conflict are modified in real time to avoid the obstacles and/or maintain the mode function. This includes both alteration of steering direction and reduction of forward speed.

METHODOLOGY—The NavChair prototype is based on a standard powered wheelchair and consists of three units: 1) a 33 MHz 80486-based computer, 2) an array of 12 ultrasonic transducers mounted on the front of a standard wheelchair lap tray, and 3) an interface module which provides the necessary interface circuits for the system. During operation the NavChair intercepts the unprocessed joystick position and uses them in combination with sonar and wheel position sensor readings to determine the control signals sent to the power module.

The original navigation software for the NavChair, called the VFH method, was derived from work in autonomous mobile robotics. A modified version of this routine, called Minimal VHF (MVFH), was developed to allow a variable distribution of control between the user and the Navchair control system, as well as to provide smoother and more intuitive control for the user. As part of these changes the wheelchair is treated as a rectangular object instead of a circular source. Operational modes for closely approaching objects or passing through narrow doorways in addition to those for wall following and obstacle avoidance were implemented using the MVFH navigation routine.

A new approach for automatic mode selection was developed for the NavChair system. It is based on a novel method called "stimulus-response" modeling (SRM), which models human behavior based on a response to a known stimulus. SRM uses auto-regressive modeling techniques to classify user behavior and intention, and then determine the most appropriate mode of operation.

RESULTS—The NavChair project has been very successful in meeting the work plan as proposed. Results with the MVFH navigation routine demonstrated improvements over the previous methods in open environment and hallways as measured by speed and smoothness and in door passage as measured by success in passing through significantly narrower doors than was previously possible. Testing with the SRM technique demonstrated an ability to differentiate between driving in an open room versus a hallway with 80 to 94 percent accuracy. This accuracy approached 100 percent as data was accumulated over time. Obstacle avoidance performance was not significantly affected by implementation of automatic mode selection using SRM methods. In door passage tests automatic mode selection using SRM performed correctly in every test with mode selection occurring an average of almost 3 sec before the NavChair entered the doorway. No significant effect on door passage success rate was noted with automatic mode selection.

FUTURE PLANS—The NavChair is an excellent test platform for both the investigation of improved "shared control" methods (allowing a human and machine to interactively control a task) and the development of enhanced methods for wheelchair navigation assistance. In the area of shared control, ongoing work is focused on the integration of environmental sensor information together with results of human modeling using SRM in order to create a more robust system that can predict user intention and appropriately modify system performance. Continuing work is also aimed at the development of NavChair operational modes with increased autonomy in order to meet the needs of potential users with no means for maneuvering a chair.

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C. Seating Systems

[347] DESIGN OF A VIDEOFLUOROSCOPY CHAIR FOR SCI AND OTHER DISABLED PATIENTS: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #B92-419 AP)*

PURPOSE—This study involved the clinical evaluation of two Hausted video-fluoroscopic imaging chairs (VIC) at the Atlanta and Milwaukee VAMC for a period of 12 months. A VIC Chair is used in conjunction with a fluoro x-ray table for the evaluation of dysphagia (swallowing disorder), using the modified barium swallow roentgenography procedure.

The evaluation of the VIC was necessary to determine if its actual performance corresponds to the established criteria developed by the investigators for the design of a new videofluoroscopy chair.

METHODOLOGY—The clinical evaluation of the chairs was undertaken at the two VAMC's with radiologists and speech pathologists. The performance of the chairs was evaluated in the following activities: transferring the patient from bed, cart, or wheelchair into the chair; positioning and attaching patient in the

chair; positioning of the chair in the fluoro x-ray machine; performing the modified barium swallow roentgenography procedure; and transfering the patient back to bed, cart, or wheelchair.

Patients exhibiting a wide range of illnesses and disabilities: SCI (paraplegics and quadriplegics), cerebrovascular accidents (CVA's) right and left, multiple sclerosis or neurological diseases (i.e., Parkinson's), and multiple medical problems, participated in this evaluation.

In addition to the clinical evaluation, the investigators developed a questionnaire to assess the various features and usage of the Hausted chair in comparison with other chairs commonly used for swallowing studies, such as Rehab Tech, Vess, Mama, Escort. Questions concerning transfer, transportation and use of the chair, and its various features were included. The questionnaire was sent to the 1025 members of the Dysphegia Special Interest Group of the American Speech Language Hearing Association and to the 180 VA Audiology and Speech Pathology Services. From these questionnaires, 280 responses were received or a 23 percent return rate. Final results and data analysis of these questionnaires will be published at a later date.

PROGRESS—The overall findings resulting from this evaluation is that the Hausted VIC chair is the best videofluoroscopy chair available to perform swallowing studies. It is also the chair of which the performance most closely meets the list of criterion established for the design of a new videofluoroscopy chair.

However, the evaluation has showed that there were several areas of the Hausted VIC chair needing improvement or modifications. The investigators believe that these improvements will enhance the performance of the chair, for the Speech Pathologists and Radiology technicians who perform the swallowing studies as well as the patients undertaking the procedure.

[348] EFFECTS OF SEATING TYPE AND DISABILITY LEVEL ON STABILITY DURING DRIVING

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Sponsor: *Center for Automotive Research, The Ohio State University; Federal Transit Administration; Transportation Research Board*

PURPOSE—The aim of this research is to begin to examine body dynamics in drivers with disabilities to address questions relating to the type of seating to recommend for these individuals. In particular, their stability while in the vehicle is of interest. Inherent in this study is the goal of developing controlled, repeatable, and easily accessible techniques for analyzing subject response to driving maneuvers.

METHODOLOGY—The experimental protocol calls for an evaluation of four different groups of occupants: quadriplegics, paraplegics, those with no disabilities, and test dummies. The stability of each subject in an OEM seat, a captain's chair from a Ford Econoline van, and in a manual wheelchair with and without lateral supports is to be tested.

Stability is to be determined by observing the movement of the subject's center of gravity relative to the wheelchair. This is accomplished by mounting the four corners of the seating type to load cells anchored to the floor. This rigid attachment of the chair to the floor eliminates the confounding variable on stability of the securement of the wheelchair. The wheels of the wheelchair are removed, though the chair's normal height is maintained. Video recordings of the individual's movements are to be made to correlate with the motion of the center of gravity.

Test subjects are to experience specific, controlled driving maneuvers in a van while seated in the described OEM seat or wheelchair. Vehicle and occupant accelerations are to be measured with linear accelerometers during the maneuvers.

This acceleration data is to be used to simulate driving maneuvers with a servo-controlled tilt table. The laboratory simulator would provide a more controlled and more easily accessible experimental environment than is possible to attain with a moving vehicle. The table is to be tilted in such a manner that the

components of the centripetal and gravitational forces parallel to the table match the vehicle acceleration profiles recorded during the controlled driving maneuvers. The response of a subject seated atop the table is then to be correlated with that of the subject in the van. Effects of disability level and seating type on stability during travel can then be tested using the highly repeatable acceleration input supplied by the tilt table.

PROGRESS—The accelerometers and corresponding signal conditioning have been constructed and tested, along with the video camera arrangement, in controlled driving conditions in a city bus. The accelerometer data was analyzed to determine which driving maneuvers would be performed during the remainder of the testing. The load cells, signal conditioning, and corresponding software to calculate the center of gravity have been created and tested using the tilt table in a static manner. The servo-controlled tilt table has been designed and the necessary motors and other equipment ordered.

PRELIMINARY RESULTS—Pilot studies testing equipment performance, methodology, and ranges of acceleration profiles were conducted in a bus undergoing controlled driving maneuvers. A Hybrid II test dummy was restrained with a lap and shoulder belt in either a wheelchair or scooter secured to the vehicle. The vehicle acceleration profiles for all maneuvers were found to be repeatable within 10 percent for a given maneuver and within the range of those that can be simulated with the motorized tilt table.

FUTURE PLANS—The testing outlined in the Methodology section involving the van and the simulator will be conducted. Possible correlations between responses obtained with the dynamic tilt table and those obtained during driving with the van will be examined. Based on the results, a recommended test protocol and suggestions for seating systems will be formulated.

[349] A PROCEDURE FOR SEAT CUSHION ANALYSIS ON WHEELCHAIR USERS

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Sponsor: *Italian Ministry for University and Scientific Research*

PURPOSE—This project seeks to develop and apply an evaluation protocol to compare different types of seat cushions for wheelchairs. The aim is to define and measure some parameters (physical measurements, postural parameters, functional parameters, and so forth) useful for evaluating and comparing the performances of the different analyzed cushions.

METHODOLOGY—The instrumentation is an integrated device for measuring interface pressure that consists of a thin matrix (42 rows and 48 column) of 1 cm^2 pressure sensors in a pad connected with a personal computer with a particular software that allows to store and to represent all collected data. Dedicated software with the goal of finding more parameters and making it easier to process the acquired data is under development. The individuated variables are maximum peaks and mean pressures in particular areas under the buttocks. The most involved areas under the bony prominences are: the ischial tuberosities, great trochanters, sacrum, and coccyx. We also use the same acquisitions to evaluate some postural parameters as the asymmetry of load distribution, position of pressure centers in respect to an anatomical reference system, and seat contour characteristics.

The study will consider patients with different types of pathologies (spinal cord injured, multiple sclerosis, and so forth) and elderly persons with walking problems. The cushions considered in the study are done with different types of materials: the first is a contoured firm foam base covered by a gel pad, the second is composed of rows of air-filled rubber balloons connected by narrow air channels in a flat rubber base, and the last is formed by gel-filled rubber balloons with a foam base.

A subjective evaluation (comfort, stability, and so forth) taken from a dedicated questionnaire will

also be considered and correlated with the measured parameters.

PRELIMINARY RESULTS—Preliminary acquisitions have been performed with all considered types of cushions both on nondisabled and paraplegic patients, in order to validate the acquisition procedure. These preliminary results showed the reliability of the procedure, while data analysis provided some interesting differences between the different types of cushion.

FUTURE PLANS—The developed procedure will be applied on a statistically significant number of patients, looking at the pattern of pressure distribution present in the different class of pathologies. The modification in time during long-term sitting and trials in dynamic conditions during wheelchair locomotion activity will also be considered.

In the long term, a new protocol will be developed to study particular variables that allow changes of some cushion parameters (thickness, gel distribution, gel amount, for example) in order to adapt to individual patient characteristics. The aim is to change in the best way the shape of the cushion to reduce pressure peaks and to improve patient comfort.

[350] CUSTOM CAR SEATS FOR SCHOOL-AGED CHILDREN

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Sponsor: *Rotary Club of Toronto; The Ontario Rehabilitation Technology Consortium funded by the Ontario Ministry of Health; Special Health Systems Limited*

PURPOSE—Many children with disabilities are being transported in their wheelchair seating systems while traveling in the family car. We have shown that transporting children in this manner is not safe. Parents usually have no alternative because commercial car seats do not offer the postural support that their children need. The aim of this project is to develop a transportation system that will allow children weighing from 40 to 75 pounds to use their custom seats in a car safely. We are also developing a device that will aid parents in transferring their child into and out of the family vehicle.

PROGRESS—We interviewed parents who live in various regions of Ontario, Canada to understand their concerns about transferring their children into and transporting them in the family car. Parents who responded to the survey thought that there were better ways to manage their children when traveling in their vehicles, but the methods suggested were often out of reach financially.

A detailed workshop manual was prepared and distributed to ten North American clinics, along with a restraint system developed for younger children to gauge the ability and willingness of seating clinics to adapt their construction techniques to meet motor vehicle safety standards. Subsequently, a new restraint system prototype was constructed, taking into account the input of seating clinics and parents. In parallel, we tested upholstery fabrics and seating foams for compliance with various standards, in particular as they applied to use in motor vehicles.

After receiving parents' comments and suggestions on two very different prototypes of low-cost transfer devices we developed, a third prototype model was constructed. Parents were given the opportunity to try both the transfer device prototype and the new restraint system prototype in actual hands-on demonstrations. Both systems were positively received. The transfer device is currently undergoing modifications to make it even easier to use before the next prototype is constructed.

FUTURE PLANS—Restraint system preproduction units will be crash tested in early 1995. A new transfer device prototype will be constructed in 1995. Plans

for developing a comprehensive education program for parents and seating clinicians are underway. We hope to bring both products to market in 1995.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Understanding flammability standards: guidelines for classifying materials used to construct seating systems. Rigby P, Ryan S. In: Proceedings of the Canadian Seating and Mobility Conference, Toronto, ON, 1993.

[351] CONSUMER INVOLVEMENT IN CHILDREN'S SEATING DESIGN

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Sponsor: *Rotary Club of Toronto; The Ontario Rehabilitation Technology Consortium funded by the Ontario Ministry of Health; Special Health Systems Limited*

PURPOSE—The aim of this project is to develop and evaluate the performance of an adjustable, contoured wheelchair seat. The seat design proposed is unique because it can be easily fitted by a seating clinic, adjusted by the parent, and later altered to accommodate for the child's growth. It is being specifically developed for children with cerebral palsy between 6 and 12 years of age.

PROGRESS—The design criteria for the new seat were developed through extensive interactions with consumers: parents, clinicians, and children. Initially we polled 33 seating therapists from across Canada and the United States to learn what they thought of existing seats that were commercially available. We also asked them to tell us what features they thought should be included in a new seating system. We also had 81 parents respond to a mailout survey to obtain their thoughts on seating systems.

Two unique sessions were organized for children who use seating systems so that they could also comment on various aspects of seating system design. We presented the children with concrete examples of shapes, colors, styles, cushions, upholstery, and belts to evaluate.

We held focus groups with parents and clinicians to generate and then further define what characteristics they expected the new seating system to have. We asked a number of these consumers to later evaluate three general design concepts.

We constructed a number of prototypes and models for evaluation in collaboration with Special Health Systems Limited (Aurora, Ontario, Canada) as our industrial partner. Clinicians and parents were given opportunities to critique these prototypes and suggest design changes. We are now constructing the final prototype before clinical testing begins.

In parallel, we have designed and constructed three test rigs and modified life testing procedures based on the ANSI/RESNA WC/08 standard. These rigs will be used to predict the long-term performance of the prototypes.

FUTURE PLANS—Clinical trials will complete the preproduction development phase for the new seating system. Special Health Systems Limited expects a market release of the commercial product in 1995.

RECENT PUBLICATIONS FROM THIS RESEARCH

Clinical views of modular seating systems. Rigby P, Ryan S. In: Proceedings of the Canadian Seating and Mobility Conference, Toronto, ON, 1993.

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Using focus groups to guide the design of a new seating system. Rigby P, Thompson D, From W, Ryan S. In: Proceedings of the Canadian Seating and Mobility Conference, Toronto, ON, 1994.

[352] TESTING OF CUSHIONING FOAMS TO DETERMINE THEIR MATERIAL RESPONSE

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Sponsor: *University of Alabama Jordan Fund*

PURPOSE—Decubitus ulcers, or pressure sores, are a serious problem for the disabled and elderly who may be confined to a wheelchair for as many as 12 to 16 hours per day. A significant contributing factor to the formation of decubitus ulcers is inadequate pressure relief between the wheelchair cushion and the buttocks. In the development of new seating systems, the material response of the cushioning foam must be understood. In this project, samples of cushioning foams have been tested. Results of the tests are being analyzed to gain knowledge related to several issues, such as the effect of coating a foam and the viscoelastic nature of the material.

METHODOLOGY—Thirty-four samples of six different cushioning foams were compressed according to the American Society for Testing Materials Standard ASTM D 3574-86, "Standard Methods of Testing Flexible Cellular Materials-Slab, Bonded, and Molded Urethane Foams," Tests B1 and B2. The compression tests were performed on five types of foam, both coated and uncoated. The five types of foam are: fire resistant (FR) polyurethane (PU), #6 PU, PU beige, and vinyl/nitrile copolymer (tradename UL Spongee), and Gel Foam. Samples of the first four types of foam were either coated or uncoated. The Gel Foam samples were coated on one side and uncoated on the other side. Additionally, a pressure relief pad, a prototype composite cushion, was tested. An Instron Universal Testing Machine was used to perform the compression test. During the tests, the Instron Machine plots the force vs. deflection curves. The test was repeated six times for each specimen. The data from the six tests were averaged and used to generate the force vs. deflection, stress vs. strain, and modulus of elasticity vs. strain curves. The support factor (SF), the ratio of the force at 65 percent deflection to the force at 25 percent deflection, was calculated for each material. According to the standard, "seating foams with low support factors will usually bottom out and give inferior performance."

PROGRESS/RESULTS—Experimental data are still being analyzed. All materials have both a linear and a nonlinear region. In some materials, the linear region exists up to 50 percent strain. Results from the compression tests also show that a coating can have a significant effect on the material properties of the foam. The addition of a coating increased the modulus of elasticity and decreased the support factors. The SFs for the FR, PU, and PU beige coated foams could not be calculated. The coated foams did not fully recover after the preflex and had an initial deformation greater than 25 percent. In other words, there was an initial deformation or residual strain in the material with no load being applied.

FUTURE PLANS—For the previous results, the modulus of elasticity was calculated using the linear portion of the curve. The analysis of the nonlinear portion of the curve has yet to be performed. Also, the data from the six tests were averaged and used to generate the data. However, the modulus of elasticity decreased as the tests were repeated. Future plans include calculating the change in material properties over time. To better understand the meaning of the data, further investigation of the viscoelastic behavior of the material is required. After the data is studied in more detail, the material properties of the foam can be combined with the finite element model of the human buttocks to determine which cushion provides the maximum pressure relief.

XVII. Wound and Fracture Healing

[353] IN VITRO TEST OF AN ARTIFICIAL/CELLULAR GRAFT FOR PRESSURE SORE REPAIR: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #B92-476AP)*

PURPOSE—Severe pressure sores are commonly repaired by a myocutaneous flap rotated from an adjacent unaffected site. This project is a pilot investigation of a graft constructed of natural or synthetic biomaterials inoculated with autologous cells. This technique is a further development of a concept explored by others for skin grafts for burn treatment, and by us for peripheral nerve grafts. In comparison to traumatic wounds, pressure sores have impaired vascular supply due to soft tissue compression. The proposed solution is to perfuse the graft via an artificial capillary bed: a branching network of permeable tubes similar to the straight tubes used for artificial nerve grafts.

The composite artificial matrix/autologous cell graft has advantages over both reconstructive surgery and inert dressings. The composite graft may be useful for cases that have progressed past the point at which dressings are effective, but surgery is not yet indicated. Morbidity, prolonged healing time, and loss of function associated with myocutaneous flap surgery may be avoided. The artificial graft results in immediate restoration of tissue-equivalent mechanical properties, thus protecting the regenerating vascular network.

METHODOLOGY—There are six variables under investigation; all have been applied previously in the clinic, but not simultaneously:

Subcutaneous matrix: Type I collagen, with cell attachment factors and noncollagen components (hyaluronic acid, glycosaminoglycans, etc.) added as needed.

Synthetic skin: A membrane that prevents moisture loss and bacterial ingress; published formulations are being adapted.

Synthetic capillary network: Methods for producing branched tubes are not as well developed as straight tubes. Capillary walls must be permeable to large molecules but not to cells, and must eventually biodegrade as function is taken over by the host vasculature.

Donor cells: For clinical use, cells will be obtained from the patient's tissues remote from the injury; for *in vitro* testing, specimens are taken from neonatal and adult rats.

Perfusion system: Includes: peristaltic pumps, oxygenators, heaters, pH, pO_2 and pressure sensors, media reservoirs and connecting tubing.

Surgical protocol: This comprises the preparation of the graft, attachment to surrounding tissues, and maintenance of the graft once it is in place.

RESULTS—*Subcutaneous matrix:* The matrix that best mimics mechanical and geometric properties of intact tissue is an interdigitated composite of collagen and hyaluronic acid, with the collagen cross-linked using ultraviolet light to avoid toxic chemicals.

Synthetic capillary network: Fabrication of porous branched tubes from resorbable materials having the requisite lifetime has been the most difficult part of the project. Since resorption is a surface phenomenon, porosity reduces durability of the tubes, resulting in premature fragmentation. Connections of the capillary network to the perfusion tubing are also potential sites of early failure. In order to proceed with *in vitro* testing, nonresorbable porous tubing connected to a silicone manifold is being used.

Donor cells: Enzymatic, selective adhesion, and density gradient techniques are used to separate

keratinocytes, dermal cells, fibroblasts, adipocytes, and myoblasts.

Perfusion system: This system has been assembled and is now being tested to demonstrate fibroblast viability and growth.

FUTURE PLANS—Because of the difficulty of producing resorbable artificial capillaries, a pilot proposal is being submitted to explore revascularization by means of microsugically fabricated arterio-venous pedicles. Upon demonstration of feasibility of the semisynthetic graft with either artificial capillaries or microsurgical vascular loop, a proposal will be submitted for expanded animal trials.

RECENT PUBLICATIONS FROM THIS RESEARCH

Collagen/hyaluronic acid matrices for connective tissue repair. Sabelman EE, Koran P, Diep N, Lineweaver W. In: Proceedings of the Materials Research Society, Symposium on Polymers in Medicine and Pharmacy; San Francisco, 1995.

[354] SKIN COMPOSITION IN SPINAL CORD INJURY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B688-RA)*

PURPOSE—The aim of this research project is to test the following hypothesis: the increased susceptibility among the spinal cord injury (SCI) population to the development of pressure ulcers is due in part to defective collagen biosynthesis below the level of injury. The defect in collagen biosynthesis produces skin collagen that is structurally weak and therefore more susceptible to damage due to pressure or shear forces.

METHODOLOGY—Skin punch biopsies from non-weight bearing parts of the body above and below the level of injury were obtained from SCI subjects who have had pressure ulcers and also from some who have not had pressure ulcers. Skin biopsies were also obtained from nondisabled men with a 4 mm disposable punch biopsy; they were analyzed for content of four amino acids characteristic of collagen (proline, hydroxyproline, lysine, and hydroxylysine). Relative proportions of type I and III collagen were determined. Activity of two important collagen biosynthesis enzymes (prolyl hydroxylase and lysine hydroxylase) was measured. Comparison was made between skin composition above and below the level of injury among the SCI subjects who have or have not had pressure ulcers and between the SCI subjects and nondisabled controls.

Amino acid analysis was done using precolumn derivatization with dansyl chloride and high pressure liquid chromatography. Gel electrophoresis was used to determine the type of collagen present in the skin biopsy and the ratio of type I to type III. Radioactive ligands and a scintillation counter will measure enzyme activity. All the methods used are well established and reliable. If the hypothesis is true, it is expected that the skin composition above and below the level of injury among the subjects that have not had pressure ulcers will be similar, while persons with pressure ulcers will have distinct differences in the skin composition below the level of injury compared to the skin above the level of injury.

PROGRESS—Biopsies were obtained from 30 nondisabled subjects, 21 SCI patients that had never had a pressure ulcer, and 18 SCI patients with a history of pressure ulcers. Biopsies were assayed for amino acid content and collagen type or for lysyl and prolyl hydroxylase enzyme activity.

FINAL RESULTS—Results demonstrated a trend toward decreasing content of lysine and hydroxylysine in biopsies from below the level of injury of subjects with a history of pressure ulcers compared to subjects with no history of pressure ulcers. The ratio of type I to type III collagen was much lower in the biopsies from below the level of injury in subjects who had had previous pressure ulcers compared to subjects who had never had pressure ulcers. There was a negative correlation between the ratio of type I to type III collagen and years since injury in subjects that had had pressure ulcers. Prolyl and lysyl hydroxylase en-

zyme activity was decreased in biopsies below the level of injury in subjects who had had pressure ulcers compared to enzyme activity above the level of injury in the same subjects and compared to nondisabled and to subjects who had never had a pressure ulcer.

FUTURE PLANS/IMPLICATIONS—The above findings are an indication that skin collagen structure and composition in persons who develop pressure ulcers is defective. These deficiencies might be amenable to pharmacological treatment and this possibility should be the basis for further research.

[355] A PROSPECTIVE STUDY OF RISK FACTORS FOR DIABETIC FOOT ULCER

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A318-3RA)*

PURPOSE—We are conducting a prospective study that is designed to identify risk factors for foot ulceration and lower extremity amputation associated with diabetes. We are examining the independent contributions of foot deformity, macrovascular and microvascular disease, peripheral neuropathy, and behavioral factors on the risk of developing a full thickness diabetic foot ulcer.

METHODOLOGY—We invite subjects enrolled in the General Internal Medicine Clinic, who meet the criteria for diabetes mellitus by physician diagnosis or treatment with a hypoglycemic medication or insulin, to attend a Diabetic Foot Clinic where we perform examinations to assess the presence of suspected risk factors, grouped into four categories: circulation, neuropathy, foot deformity, and self care behaviors. Circulation factors include standard segmental lower extremity Doppler blood pressures, toe blood pressures, transcutaneous oximetry at five lower extremity sites, laser Doppler flowmetry at the dorsal foot, arterial pulse palpation, venous filling time, and capillary refill time. Neuropathy measures in the lower extremities include monofilament testing, bioesthesiometry, deep tendon reflexes, measures of intrinsic muscle atrophy, and cardiovascular reflexes that reflect autonomic neuropathy. Foot deformity measures include clinical examinations, posture and gait assessments, joint ankle measurements, and Harris mat testing for abnormal pressure points. Behavioral factors assessed include type of foot wear, diabetes history and control, foot self-care practices, and visual acuity.

We conducted baseline examinations on all study subjects between 1990 and 1993. To assess development of the outcome of interest, all subjects receive yearly repeat examinations and a mailed questionnaire on a quarterly basis, asking them to report occurrence of the target condition. We compare rates of outcome occurrence (incidence) by exposures of interest to determine which particular factors are related to risk of diabetic foot ulcer and lower extremity amputation.

PROGRESS—To date we have enrolled 778 diabetic subjects from the Seattle VAMC general internal medicine outpatient clinic. We perform annual screening examinations on all subjects to determine presence of possible risk factors for diabetic lower extremity complications.

PRELIMINARY RESULTS—As of November 1994, we observed 88 foot ulcers and 20 lower extremity amputations occurring over a cumulative 1,375 person years of follow-up. A case-control analysis of 46 patients with diabetic foot ulcer and 322 controls revealed that 3 factors independently predicted higher risk of foot ulcer: insensate to the 5.07 monofilament (odds ratio [OR]=18.42, absent Achilles tendon reflexes (OR=6.48), and transcutaneous dorsal foot O_2<30 mm Hg (OR=57.87). We recently reported an increased relative risk of death of 2.55 (95 percent confidence interval 1.21 to 4.89) in subjects who developed a foot ulcer during the follow-up period that was independent of other co-morbid conditions associated with mortality. Another recent preliminary analysis found that the risk of lower extremity amputation was highest among diabetic subjects with a past history of foot ulcer (relative risk=7.9, p=0.001). Results of a preliminary analysis on the diagnostic utility of

many commonly used history and physical examination findings for the detection of peripheral vascular disease in 1,369 lower extremities from 687 diabetic subjects showed that 3 findings independently determined the probability of peripheral vascular disease: the subject's age, history of peripheral vascular disease, and examination of the peripheral pulses by palpation.

FUTURE PLANS/IMPLICATIONS—It is premature to conclude which risk factors are related to diabetic foot ulcer development at this stage of the study since the person years of follow-up will increase substantially by the end of the study, which will enhance the power to detect associations of small magnitude. It does appear from preliminary data that structural factors and neuropathy will be important in the pathogenesis of diabetic foot ulcers. Final analysis, when completed in 1996, should provide additional interesting information concerning the risk factors for diabetic foot ulcer and potential means for prevention.

RECENT PUBLICATIONS FROM THIS RESEARCH

Diabetic foot ulcer healing: extrinsic versus intrinsic factors. Ahroni JH, Boyko EJ, Pecoraro RE. Wounds 1993:5:245-55.

Teaching foot care creatively and successfully. Ahroni JH. Diabetes Educ 1993:19(4):320-5.

Health and functional status of veterans with diabetes mellitus. Ahroni JH, Davignon D, Boyko EJ. Diabetes Care 1994:17:318-21.

Independent contributions of diabetic neuropathy and vasculopathy in foot ulceration: how great are the risks? McNeely MJ, Boyko EJ, Ahroni JH, et al. Diabetes Care. In press.

Lower extremity foot ulcers and amputations in persons with diabetes. Reiber GE, Boyko EJ. In: Harris MI, ed. Diabetes in America. Bethesda, MD: NIH Publications, 1995.

[356] HOLTER SYSTEM DEVELOPMENT FOR RECORDING PLANTAR PRESSURES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A624-2RA)*

No report was received for this issue.

[357] THE USE OF GROWTH FACTORS IN PRESSURE ULCER HEALING

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—In order to develop optimal active treatment protocols for pressure ulcers, basic wound-healing research is essential. Speeding up the rate of regenerative healing would reduce both the likelihood and impact of other secondary complications.

METHODOLOGY—The objectives of this study are: to develop two nonporous biodegradable fibrin matrices (that degrade in 1 and 2 weeks, respectively) for delivery over time of acidic fibroblast growth factor (FGF-I); to develop a porous biodegradable fibrin matrix for delivery of FGF-I; and to evaluate clinically the pressure ulcer healing efficacy of FGF-I in porous biodegradable fibrin matrices. The matrices will be developed during the first 18 to 24 months of the project. Clinical trials will then be conducted with 3 treatment groups of 10 patients each: Group 1 will have standard clinical treatment (saline wet to dry gauze dressings); Group 2 will receive the porous biodegradable fibrin matrix; and Group 3 will receive the porous biodegradable fibrin matrix with FGF-I at 8 μg/ml.

Persons will be recruited for clinical trials from those seen in the Pressure Ulcer Clinic at SRC-UAB.

Only one ulcer per person will be included in the study. The first 15 persons will be randomly divided into the 3 groups. This will allow preliminary data analysis to occur halfway through the study. The trial will be stopped if a clear and distinct advantage is identified for one of the treatment groups.

PRELIMINARY RESULTS—The *in vivo* phase was extended until the end of the second year of this study. Because of the results from animal studies, the clinical study was modified to include only 3 groups.

Progress during the first year included the following results. The porous system enhanced the angiogenic and healing response in the rabbit ear mode. The *in vivo* studies using the growth factor have also shown an increase in healing response in the ear model. The full-thickness dorsal skin model study allowed comparison to topical FGF-1. From the results so far, it is anticipated that this arm of the clinical trial will be dropped and the 3 groups will parallel the dermal model (porous fibrin, porous fibrin/FGF-1, and control).

FUTURE PLANS—The *in vivo* studies will be completed during the remainder of the second year and clinical studies will begin by the end of year two. During this year the data for the *in vivo* studies will be analyzed and prepared for manuscripts and presentations.

RECENT PUBLICATIONS FROM THIS RESEARCH

Acidic fibroblast growth factor delivery through a fibrin matrix without exogenous heparin. Wilson D, Feldman D, Thompson J. In: Transactions of the Society for Biomaterials 1994:30:255.

Effect of a porous degradable fibrin scaffold on would healing. Pandit A, Feldman D. In: Transactions of the Society for Biomaterials 1994:30:34.

Effect of oxygen permeability on full-thickness skin defects. Pandit A, Feldman D. Wound Heal Regeneration 1994:2:130-7.

Histomorphometric analysis of biomaterial enhanced regeneration. Osborne S, Pandit A, Feldman D, Patterson B. In: Transactions of the Annual Alabama Materials Research Conference 1994:8:33.

Wound healing: a technological approach. Dixon J, Pandit A, Feldman D. In: Transactions of the Annual Alabama Materials Research Conference 1994:8:27.

Wound healing: a technological approach. Dixon J, Feldman D. In: Transactions of the National Conference on Diversity in the Scientific and Technological Workforce Conference 1994:3:25.

[358] PROBLEM-SOLVING SKILLS TRAINING IN THE TREATMENT OF PRESSURE ULCERS IN PERSONS WITH SPINAL CORD INJURY

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—People with spinal cord injuries (SCI) may experience a variety of psychosocial problems following injury. It has yet to be determined such persons can learn effective problem-solving skills, and use these skills to improve their rehabilitation outcomes. In this project, a problem-solving intervention will be developed to reduce the incidence of repeat pressure ulcers in those who have already undergone surgery for pressure ulcer repair. The project will employ an intervention that helps individuals acquire effective problem-solving skills and goal-setting techniques by teaching them to anticipate, plan, choose, execute, and monitor effective problem-solving efforts.

The objectives of this study are to test the effectiveness of a problem solving skills training intervention for pressure ulcer prevention on the following criteria: the degree of self-perceived responsibility for health care and maintenance, the degree of psychosocial impairment secondary to disability, the general problem-solving skill, the demonstrated ability to solve problems specific to skin care and maintenance, the demonstrated compliance with pressure relief maneuvers, and the prevalence of skin re-breakdown following discharge.

METHODOLOGY—Potential participants will be randomly assigned to one of two groups: a problem-

solving skills training group (treatment) or a no treatment group (control). Randomization will be stratified by neurologic level of injury (paraplegia/tetraplegia) to ensure comparability of the two groups. After randomization, potential study subjects will be approached regarding participation in the study. Those who consent and are assigned to the intervention group, will be administered an initial battery of measures prior to the intervention. The treatment group will complete this battery again (posttest) to assess possible changes in outcome as a function of participating in the intervention. Those assigned to the control group will be given the pretest battery and, 2 weeks later, the posttest battery. Both treatment and control groups will be further evaluated at 6 weeks post-discharge and during their next annual follow-up visit.

Those who participate in the intervention will engage in focused, psychoeducational sessions that will meet every other day for a total of eight sessions. Data will be collected on six dimensions: 1) personal responsibility for health care and maintenance, 2) psychosocial impairment secondary to SCI, 3) personal appraisal of problem solving skills, 4) demonstrated abilities in solving a problem specific to skin care, 5) demonstrated compliance with therapeutic regimen to conduct periodic pressure reliefs, and 6) prevalence of skin breakdown.

It is anticipated that a total of 68 persons (34 per treatment group) will participate in this study. This is a larger sample size than other published studies of problem solving interventions have used.

PROGRESS—A total of 23 patients have been interviewed for the study. Sixteen were successfully interviewed within the 10-day pre-post window; 9 participants were then seen at the 6-week appointment; and 2 have had interviews at their annual evaluations.

RESULTS—This is a newly funded project and no data have as yet been analyzed.

FUTURE PLANS—Patients will continue to be enrolled. Participants will continue to be followed, as outlined. Problem-solving training with new participants will begin in January 1995. It is the intent of the project to deliver the intervention as outlined to all new participants as soon as possible in the upcoming year.

[359] SPERMATOGENESIS FOLLOWING SPINAL CORD INJURY: QUANTITATIVE AND DYNAMIC ASSESSMENT IN THE RAT MODEL

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Sponsor: *Paralyzed Veterans of America, Spinal Cord Research Foundation*

PURPOSE—Rehabilitation of male fertility potential following SCI has been successfully accomplished in various centers during the past decade. Most of the outcomes research has focused on semen parameters and pregnancy rates in couples entering reproductive rehabilitation programs utilizing stimulated semen recovery methods. Most men with SCI demonstrate semen parameters consistent with poor sperm motility and fertilizability. Moreover, review of the literature studying spermatogenesis in SCI men shows abnormal testis biopsies and sperm production in >60 percent. Thus far spermatogenesis has not been systematically studied in the setting of SCI, and the degree and onset of spermatogenic defect is, as yet, unknown. Using the model of experimental SCI developed at the A.I. du Pont Institute and the expertise in quantitative assessment of spermatogenesis of the South Dakota State University, we studied the dynamics of spermatogenesis in the rodent undergoing controlled impact experimental SCI.

METHODOLOGY—Sexually mature male Sprague-Dawley rats underwent controlled impact SCI by exposure of the thoracic spine, T-10 laminectomy, and directing a a 50 gm-cm force onto an impounder resting upon the dura. Experimental SCI was verified by intraoperative ablation of SEP and postoperative neurologic evaluation utilizing the modified hindlimb Tarlov scale 2 weeks after injury. In a control group a sham operation was performed by exposure of the

dura without weight drop. Using dual parameter DNA flow cytometry analysis of the testicular homogenates, spermatogenesis was objectively quantitated in each group by determination of the mean percentage of haploid cells indicative of normal spermatogenesis. Additionally, a determination was made of the relative percentage of early, middle, and mature spermatids in an expanded analysis of the haploid cell population. Testis homogenates were recovered from subjects sacrificed at 2, 4, 6, 8, 12, 16, and 20 weeks following experimental SCI. Statistical analysis was performed comparing the total haploid percentages between experimental and control groups at each time point using exact Kruskal-Wallis methods.

PROGRESS—We conclude from this controlled prospective study that rodent spermatogenesis following experimental SCI shows no significant deterioration with time. Extrapolating these data to humans and having recently observed the relatively favorable spermatogenic parameters in contemporary studies, we may attribute these findings to the current advances in rehabilitation medicine and urologic management of SCI men. This study is among the first to systematically investigate the reproductive sequelae of SCI in an experimental model and indicates that the primary reproductive insult after SCI is most likely localized at the post-testicular level (i.e., epididymis or distal genital tract).

RESULTS—Statistical analysis revealed no significant difference between groups of experimentally injured subjects and sham-operated controls relative to the total haploid content or the relative percentage of haploid cell subtypes. Importantly, subjects showed no significant time trend differences between the groups analyzed. During weeks 2–20 experimentally injured subjects showed a haploid cell percentage ranging from 54.9 percent to 77.2 percent. Analysis of the various spermatid subtypes also showed no intergroup variation with duration of injury.

FUTURE PLANS—Future clinical and basic scientific investigations in the areas of male reproductive rehabilitation should therefore be most appropriately directed at delineating specific mechanisms of epididymal dysfunction and methods of epididymal preservation following SCI.

XVIII. Miscellaneous

[360] PROMPTED VOIDING IN THE TREATMENT OF URINARY INCONTINENCE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E725-RA)*

PURPOSE—This study validated prompted voiding as a technique for treating urinary incontinence among male patients in a VA intermediate care unit. We also identified characteristics of male intermediate care patients who were successful in a program of prompted voiding training and rehabilitation, and assessed implications of participation in such a program for patient mental health status.

METHODOLOGY—This project completed baseline data collection, a prompted voiding intervention, post-intervention assessments and a 3-month follow-up measurement on two treatment groups. Baseline, post-intervention, and follow-up information was also gathered on control subjects.

PROGRESS—Seventy-eight patients were recruited for the study (with an attrition of 3) and necessary urological assessments were made. Nursing staff on the intermediate care ward were trained in prompted voiding procedure and data gathering. Pre- and post-intervention measures of the Demential Rating Scale (DRS), Independent Toileting Assessment (ITA), Hamilton Anxiety Scale (HAS), and the Hamilton Depression Rating Scale (HDRS) were taken. Seven-day baseline incontinence procedures for experimental and control subjects were also successfully implemented.

RESULTS—Our results show that the percentage of checks that all experimental patients were assessed wet declined from an average of 42 percent during the baseline to 17 percent during treatment conditions (Chi square sig. at 0.05). The average number of requests for toileting assistance for experimental patients increased from an average of 0.38 per day per patient to a treatment average of 2.3 (Chi-square sig. at 0.05). Control group patients did not show such significant changes on either measure.

IMPLICATIONS—There is significant evidence that male VA intermediate care patients become more continent and are more likely to engage in correct toileting as a result of participation in a prompted voiding program. Furthermore, significant declines in depressive symptoms, which were observed for the trainees from pre- to post-treatment, appear to be a secondary benefit of this incontinence rehabilitation intervention.

[361] DETERMINANTS OF GLUCOSE TOLERANCE IN PERSONS WITH HYPERTENSION: EFFECTS OF MODERATE INTENSITY EXERCISE TRAINING

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Core Funds)*

PURPOSE—Several epidemiologic investigations have reported that the presence of hypertension (HTN) confers an increased risk for the development of impaired glucose tolerance and non-insulin-dependent diabetes mellitus (NIDDM). Recent observations have suggested that, as a group, lean and obese per-

sons with HTN display abnormalities of carbohydrate metabolism, principally impaired insulin action (insulin resistance), when compared to normotensive controls matched for age and adiposity. Resistance to the insulin's glucoregulatory effects typically leads to compensatory insulin hypersecretion, which is necessary for maintenance of normal glucose tolerance. In predisposed individuals, this may eventually lead to pancreatic beta-cell exhaustion with decompensation to NIDDM. Therefore, efforts toward reducing the degree of insulin resistance in HTN hold promise for preventing or delaying the onset of NIDDM in these patients. In addition, the growth promoting properties of insulin may not be impaired, despite resistance to its effects on glucose metabolism. Thus, compensatory hyperinsulinemia may contribute to vascular and cardiac dysfunction by promoting smooth and cardiac muscle hypertrophy.

The objectives of this investigation are to: 1) compare the determinants of glucose tolerance (pancreatic insulin secretion, hepatic insulin extraction, insulin sensitivity, and glucose effectiveness) between persons with established HTN and a matched group of normotensive subjects; 2) assess the relationships between left ventricular mass, insulin resistance, and the insulin response to an intravenous glucose load in normotensive and hypertensive subjects (after statistically controlling for resting blood pressure); and 3) assess the effects of 12 weeks of moderate intensity exercise training on the determinants of glucose tolerance in a subgroup of sedentary hypertensive subjects while on standardized antihypertensive therapy with diltiazem.

METHODOLOGY—Three hour intravenous glucose tolerance tests will be administered. Plasma glucose, insulin, and c-peptide concentrations will be measured prior to glucose injection and at 18 postinjection time points. Bergman and colleagues' minimal model of glucose disappearance and combined minimal models of C-peptide and insulin kinetics will be used to evaluate carbohydrate metabolism. Echocardiography will be used to assess left ventricular mass. Maximal and submaximal graded exercise tests will be performed with indirect calorimetry in order to evaluate aerobic power.

PROGRESS—Subject screening and recruitment is underway.

[362] HEALTH BEHAVIOR IN SCHOOL-AGED CHILDREN WITH PHYSICAL DISABILITIES

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Sponsor: *Bloorview Childrens Hospital Foundation*

PURPOSE—Health promotion strategies for children with physical disabilities constitute a major void and offer a significant challenge to health professionals, educators, community workers, and families. In order to develop health promotion programs, a database of the health behaviors of children with physical disabilities was needed. Thus, we conducted a survey to determine the wellness and health risk factors for children living with physical disabilities.

METHODOLOGY—Participants were 101 children with physical disabilities who lived in Metropolitan Toronto. They completed the World Health Organization Survey Questionnaire on the Health Behaviors of School-Aged Children. The survey is a major international effort and was administered to 11 to 16 year old children in 26 countries, including Canada, in 1993-94. The survey captured information about important health-related variables such as smoking habits, alcohol consumption, diet, fitness, leisure activities, physical symptoms, and psychosocial factors including self-esteem, peer relationships, and attitudes toward school and family life.

RESULTS—Results indicated that in comparison with the Canadian national sample of children who completed the same survey, children with physical disabilities had poorer diets, more sedentary leisure

activities and socialized less with friends after school and in the evenings. However, children with physical disabilities were less likely to smoke, consume alcohol, and use marijuana—a pattern which, according to the adult literature, will not persist into adulthood. Areas of strength for children with physical disabilities included close relationships with parents and positive attitudes toward school, teachers, and fellow students.

Health promotion strategies for children with physical disabilities must take into account these special health needs. The children's close relationships within their families and schools suggest that both should be actively involved in health promotion efforts.

FUTURE PLANS—Our primary future goal is to create a Centre for Disability and Wellness with three primary objectives: 1) to develop an interagency network which will increase intersectoral collaboration, and have significant participation from children and adults with physical disabilities; 2) to identify health behaviors that predispose children with physical disabilities to secondary or additional disabilities; and 3) to develop effective health promotion initiatives targeted at children with physical disabilities.

[363] DEVELOPMENT OF A MODEL PROCESS FOR DETERMINING ADA PARATRANSIT ELIGIBILITY

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Sponsor: *Project ACTION of the National Easter Seals Society*

PURPOSE—The Americans with Disabilities Act (ADA) requires transit authorities to provide paratransit service to qualifying individuals until transit facilities are made fully accessible. This stipulation has prompted the need to develop an unambiguous method for determining who is eligible for paratransit in accordance with the ADA. The purpose of this research is to develop and test a "model process" for determining paratransit eligibility. The Cleveland Clinic, in collaboration with KRW, Inc., the Association for Retarded Citizens, and the American Federation for the Blind, is developing comprehensive paratransit eligibility guidelines which match the functional ability of a person with a disability with the functions necessary to navigate a fixed route trip.

METHODOLOGY—An innovative approach will be used to determine paratransit eligibility. Fixed route service will be divided into individual trip segments, and the functions required to negotiate each trip segment will be determined. The project staff will classify physical disabilities into groups. Nonphysical disability groupings will be considered by the collaborating agencies. Each disability will be categorized by medical diagnosis, and the functional ability of each category will be determined. The functions necessary to negotiate each trip segment will be matched to the abilities of the members of each disability category. Recommendations for paratransit eligibility can then be made.

PROGRESS—Each fixed route trip has been broken down into five segments. Transportation barriers, or accessibility factors, present for each trip segment have been identified based on the ADA requirements for transit facilities. Eight categories for physical disabilities have been determined. The category divisions are based on the individual's method of mobility and function in each limb. The ability of members of each category to negotiate the accessibility factors presented by each trip segment were then evaluated, and recommendations for paratransit eligibility have been made for each category based on the assumption that all accessibility factors are present. Finally, questions have been formulated which allow simple classification of each individual based on ability to perform simple tasks.

PRELIMINARY RESULTS—Preliminary testing with paratransit providers has begun to determine the correlation between paratransit eligibility determined by the model and eligibility determined by current

methods. The transit authority evaluated paratransit applications using their current methods and our model. The project staff independently evaluated the same applications. Classification of the applicant was judged to be a relatively simple task. Generally, agreement existed between the eligibility recommendations determined by each method. Differences resulted when evaluating applicants with sensory or cognitive limitations, in addition to physical limitations. Other differences occurred when the applicant listed two different mobility aids on the application. Familiarity with the applicant allowed the transit facility to make one classification, while the project staff had to assume which mobility aid was used in travel, resulting in a different classification.

FUTURE PLANS—This work shows that using broad classifications based on functional ability may by used to determine paratransit eligibility. Further testing of the model is necessary to show this to be the case. If testing shows this model to be feasible, future work will develop expert systems software to expedite the model.

[364] CAREER DEVELOPMENT OF WOMEN WITH PHYSICAL DISABILITIES

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—There has been a dearth of research relating to the career development and advancement of persons with disabilities. In fact, career development research for people without disabilities is at a relatively early stage. Prior research deals primarily with entry-level employment. The current study was designed to explore this gap in knowledge for women with disabilities. Therefore, the purpose of this project is to discover, and describe relationships among, variables that relate to career development and advancement of people with disabilities, including persons who are members of racial and ethnic minority groups.

PROGRESS—This project focuses on identifying factors that contribute to successful career development among women with physical disabilities. This study uses ethnographic techniques and grounded theory methodology to address: 1) how the disability affects career development and advancement; 2) how ethnicity affects career development and advancement of women with disabilities; and 3) how cultural, language, gender, ethnicity, and educational factors mediate career development and advancement.

Eleven women were selected for participation who represent a diversity of physical disabilities, ages at onset, chronological age, and ethnic backgrounds. Three of the women were employed, three were unemployed and not looking for work, four were unemployed and seeking work, and one was a student. Disabilities included amputation, SCI, polio, spina bifida, CP, MD, and MS. One subject had two disabilities. Subject ages ranged from 27 to 52, with a mean age of 37. Ages of onset ranged from birth to adult. Four had high school diplomas, four had college degrees, and two had master's degrees.

The participants were interviewed regarding their career development and advancement. All interviews have been transcribed and are in the process of being analyzed using a variety of qualitative techniques, including an ethnographic approach and grounded theory analysis. Analysis will be directed at understanding the critical factors for career development and advancement from the frame of reference of the participants. Specific codes and categories of analysis will emerge throughout the inquiry. Participants will be enlisted to review analyses to assure accuracy of recording and interpretation. A monograph presenting the results of this study and other materials on career development will be produced by the end of the project.

RESULTS—Preliminary results are available at this time. Two of the eight women not working retired for health reasons related to their disabilities. One had been fired from her job because of her disability, one

had quit after being discriminated against because of her disability, and a third quit after her employer refused to make an accommodation to her disability and because she felt it placed an unfair burden on the other employees. It is interesting to note that the first two women mentioned had adult onset disabilites that began while they were employed. Six of the women felt their disabilities played an important role in their being hired. Most (9) of those who were or are employed required little or no accommodations for their disabilites by their employer.

FUTURE PLANS—The information gathered from this study will be used to provide information to people with disabilities themselves, as well as assist education and rehabilitation professionals in counseling people with disabilities regarding successful career development and advancement.

[365] COMPUTERIZED METHODS IN PROSTHETICS AND ORTHOTICS

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Sponsor: *National Institute on Disability and Rehabilitation Research*

PURPOSE—Finite element analysis (FEA) computer models and computer graphics will be used to expand and enhance the original biomechanical work which Radcliffe and others applied to prosthetics and orthotics. Technological advancements permit the development of realistic, three-dimensional, colored renderings that reveal stress distributions during various dynamic and static aspects of prosthesis usage. The results will be suitable for usage in prosthetic manuals, for slide and video presentations, and for computer-aided demonstrations and interactive instructional programs.

METHODOLOGY—Dynamic load information for trans-tibial amputees was applied to our existing CT-scan-based computer models in a quasi-static fashion. The stance phase was taken to be 65 percent of the entire gait cycle. In all, there were 21 load steps for this analysis.

For visualization purposes, rotations were imposed upon the models to simulate limb angle during the gait cycle. The incrementally calculated stresses in tissue, socket, and pylon were then displayed on a monitor in an animated fashion resulting in a colored pressure/stress wave moving across the limb/socket.

PROGRESS—Work on final calibration of our CODA scanners has been completed. These are the position measurement devices used in our laboratory and are essential tools for the acquisition of the data required. Gait data of amputees are now routinely collected and processed with these scanners.

We have made many of our results available on the information superhighway via the World Wide Web (http://www.repoc.nwu.edu/). This provides the ability for anyone in the world with Internet access and minimal system configuration to access and view our results.

RESULTS—It should be remembered that these results are based upon a mixture of data from different sources. Pressures between the socket and tissue ranged from 0 to 200 Kpa and were maximum beneath the patella and over the fibular head at 23 and 50 percent of the entire gait cycle. Socket stress levels were seen to be highest (61 MPa) at a point along the socket-pylon junction during the 50 percent point of the gait cycle.

FEA runs were made for the three load cases extracted from the literature. In these separate analyses, stiffness values for socket and bone were varied to examine their effect on the results. For lower stiffness values of the socket (1 MPa) a large amount of deformation was noted. As would be expected, for very high socket stiffness (2100 MPa), little deformation occurred. Also, when bone was modeled as cancellous (10 MPa), animation revealed a large amount of bone deformation. Bone stiffness was then switched to cortical (1500 MPa), greatly reducing the amount of bone flexion.

FUTURE PLANS—We will perform analysis of amputee gait for multiple alignments of their prosthesis. As the amputee traverses the walkway, measurements of lower limb kinematics, ground reaction forces, heel contact, toe off, and socket/limb pressures will be made. Digital movies will be taken of the ambulation. FEA of these trials will then be conducted and results examined and animated.

We plan to purchase a TEKSCAN unit and integrate it into our work over the upcoming funding periods. These sensors provide many areas of pressure measurement across the surface of the prosthesis and will be integrated into the project.

RECENT PUBLICATIONS FROM THIS RESEARCH

Analysis of trans-tibial prosthetics gait using the finite element technique. Childress DS, Steege J. In: Proceedings of the Twenty-first Annual Meeting of the American Academy of Orthotists and Prosthetists; New Orleans, LA, March 1995. In press.

[366] MEASUREMENT OF BURDEN OF CARE WITH PARENTS OF CHILDREN WITH CEREBRAL PALSY: A PILOT STUDY

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Sponsor: *Neurodevelopmental Clinical Research Unit, Faculty of Health Sciences, Chedoke-McMaster Hospitals*

PURPOSE—Few studies in pediatrics have examined the concept of burden of care as it relates to either attitudes toward the caregiving experience or change in various aspects of the caregiver's life. There appears to be no published research focusing on how caregiving attitudes or behaviors of parents are affected by improved or decreased physical functioning of their child. One study did measure the burden of care of adult caregivers of cognitively impaired partners. This questionnaire was examined and adapted for this study.

The intent of the study was to investigate the applicability of this adapted burden-of-care questionnaire (BOCQ) to parents of children with cerebral palsy. We hypothesized that increased functional and physical abilities will be reflected by lower burden of care scores.

METHODOLOGY—A sample of families from a dorsal rhizotomy study already in progress was accessed. It is acknowledged that this was a select population and not a representative sample.

The BOCQ, the Paediatric Evaluation of Disability Inventory (PEDI), and the Gross Motor Functional Measurement (GMFM) were the instruments used for this study. They were administered during three designated assessment periods already scheduled for the Rhizotomy Study (baseline, 6 months, and 12 months). Eleven of 16 families approached agreed to the study from the control group (n=3) and rhizotomy group (n=8).

RESULTS—The direction and extent of change from baseline to 6 and 12 months were evaluated for each child for the BOCQ, PEDI, GMFM.

The Rhizotomy group's BOCQ scores at baseline and 12 months appeared essentially unchanged with median scores of 60.50 at baseline and 59.00 at 12 months. The control group's BOCQ scores indicated a shift in the direction of increased burden over the 12 months with median scores of 51.00 at baseline and 52.00 at 12 months. Due to the small sample size of control group, these scores were influenced by one large change in score of one parent during this period.

There was small improvement in PEDI and GMFM scores over the same period. The estimated correlations for the rhizotomy and control groups combined for BOCQ versus PEDI and BOCQ versus GMFM scores met or exceeded the hypothesized levels. Unlike BOCQ scores which did not change over time, the rhizotomy group, the GMFM, and PEDI scores demonstrated clinically important gains post-rhizotomy over the 1 year follow-up. The BOCQ's relationship to the GMFM and PEDI indicates trends in the appropriate direction, that is, lower burden scores are reflective of high GMFM and PEDI scores.

FUTURE PLANS—The adapted BOCQ shows initial promise in terms of construct validity in pediatric populations with cerebral palsy. It is clear that in order to develop better understanding of its validity, larger numbers of subjects will need to be used. In addition, the extent of caregiver burden should ultimately be included with more detailed psychosocial assessments of families/parents of children with physical disabilities to provide a broader base for understanding of the factors that contribute to the adjustment to their caring.

[367] ASSESSING THE TEAM APPROACH IN REHABILITATION ENGINEERING

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Department of Physical Sciences, Royal Brisbane Hospital; Department of Mechanical Engineering, University of Queensland

Sponsor: *Royal Brisbane Hospital*

PURPOSE—We are examining the utilization by a cross-discipline team working in a rehabilitation engineering center of information that emerges during assessment of a disabled client for wheelchair seating. The study is researching the manner in which information is gained, exchanged, and lost by the team and how this impacts on the quality of the equipment (design and manufacture) and on the outcome for the client.

METHODOLOGY—Video tapes were made of client assessment and subsequent team-only discussions of assessment-derived information. Video tapes were viewed and a transcript made of what was said and who said what. The transcript elements were separated into categories of the physical components of equipment such as seat, backrest, headrest, etc. The elements in each category were examined to ascertain the information conveyed that had a bearing on the design and manufacture of the physical item and the quality of the item to meeting the client's requirements. The categorized information was checked against details of assessment and recommendation, design and manufacture in the client's file and against the finished product supplied to the client. Discrepancies in the use of information, interpretation of information, and loss of the information were noted and referenced back to the transcript or video to see what may have caused this incident.

PROGRESS—Video tapes of assessment and discussion for four clients have been reviewed during 1994 and transcripts made. The visual information content of client assessment and the use of mimicry by team members and clients is an important source of information which is not possible to appreciate in transcript form. A database using Claris Hypercard was developed as an alternative way of handling the transcript of the audio information on the video tape, coding the information for easier retrieval and referencing visual data also. Importing video clips of the important visual data to view during the analysis by control of the VCR through the computer database is highly desirable. (This can be done using current software but not Claris Hypercard.)

RESULTS—Analysis to date of video tapes revealed considerable vagueness in the team's coming to terms with actual detail and design specifications of the client's equipment requirements. Engineering information involving dimensions, shapes, and positions of components does not seem to originate at the assessment/discussion sessions. The occupational therapist or physiotherapist often took the lead in assessment sessions. Positioning and function of the client was emphasized without considering how these would be achieved by design and manufacture.

Examination of client notes demonstrated that a proforma to guide the taking of client notes elicited specific client information but failed to capture general and detailed information that was discussed. The extent of information recorded seemed dependent on who was the scribe during assessment and discussion. Written note-taking did not seem an effective way to capture the wealth of oral and visual information passed between parties at assessment. The examination of the equipment developed for the clients revealed a high correspondence between requirements

that were intimated at assessment and features appearing in the client's customized wheelchair seating. The compliance of equipment with requirements does not seem to depend on the assessment process and the assessment-derived information but the concurrent engineering technique utilized for seating manufacture.

FUTURE PLANS—Further video tapes will be made and analyzed. They will be extended to the manufacturing activity to acquire more data and insight into the source and use of information in the complete process of providing customized seating.

RECENT PUBLICATIONS FROM THIS RESEARCH

Considering quality in a cross-discipline rehabilitation engineering service. Logan GD, Radcliffe DF. In: Proceedings of the 17th Anual RESNA Conference, 1994, Nashville, TN. Washington: RESNA Press, 1994:37-9.

Section II
Sponsor Index
with Selected Program Summaries

Part A: Department of Veterans Affairs

Rehabilitation Research and Development Service
810 Vermont Avenue, N.W.
Washington, DC 20420
John W. Goldschmidt, MD, Director, Rehabilitation Research and Development Service, Department of Veterans Affairs, Washington, DC

The mission of the Rehabilitation Research and Development Service Program is to support an Intramural Research and Development Program for improving the quality of life of impaired and disabled veterans. This is accomplished by conducting a comprehensive program of research, development, and evaluation of existing and emerging rehabilitation technology (devices, techniques, and concepts of rehabilitation). This provides for rapid transfer of Rehabilitation R&D technology and dissemination of information into the VA medical care system, allowing for greater functional independence in the activities of daily living of disabled veterans, and contributes to the nation's knowledge about diseases, disability, and rehabilitation.

Areas of special emphasis include aging, physical fitness, and psychosocial rehabilitation (e.g., dementia, schizophrenia, Alzheimer's disease, etc.).

In areas of prosthetics, amputation, and orthotics, VA-sponsored researchers are continuing to test new materials and use computer technology such as CAD/CAM to develop a new generation of artificial limbs. For spinal cord injuries, the use of robotics continues to be studied, as does the possibility that computer-controlled electrical stimulation can be used to restore function to paralyzed limbs. Research projects in the area of sensory aids include the continuing development of advanced mobility aids for visually impaired people, digital hearing aids for those with hearing impairment, and various studies on treatment strategies and communication systems for aphasic individuals.

The Department of Veterans Affairs Rehabilitation Research and Development Service (Rehab R&D) sponsors a national program to review proposals submitted by researchers in the field of rehabilitation. The Scientific Review and Evaluation Board for Rehabilitation Research and Evaluation for Research and Development, and ad hoc members assess proposals for their scientific and technical merit, budgetary needs, and time requirements.

The VA Rehab R&D Service has a working arm located at 103 South Gay Street, Baltimore, MD 21202, which consists of the following three programmatic sections:

Program Analysis and Review Section
Frank Marchione, Acting Program Manager

The Program Analysis and Review Section (PARS) coordinates the administration of the semi-annual Scientific and Evaluation Peer Review Program.

Rehab R&D Service does not issue "grants." The program is primarily intramural and is conducted at VA medical centers (VAMCs) where VA facilities and staff solve problems relevant to the veteran. Rehab R&D Service conducts a comprehensive program of research, development, and evaluation of existing and emerging rehabilitation technology (devices, techniques, and concepts of rehabilitation).

The VA Rehab R&D program accepts research and development proposals from non-VA facilities under the following conditions:

1. The proposal is submitted through a local VAMC.
2. The proposal is reviewed and approved by the R&D Committee and its Subcommittee for Human Studies, or Subcommittee for Animal Studies, as applicable.
3. A VA physician or scientist must be co-principal investigator.
4. VA patients should be involved in the clinical trials.
5. The non-VA facility must meet the eligibility requirements for contractors as specified in the Federal Procurement Regulations.

The Associate Chief of Staff for Research and Development (ACOS/R&D) in the local VAMC coordinates the submissions for the medical center Director. These proposal submissions should follow the prescribed VA format which is available from the ACOS/R&D. In this manner, all proposals are reviewed and coordinated at the local VAMC, whether from an intramural or non-VA source.

Rehab R&D Service has two proposal submission dates per year: April 15 and October 15. A Letter of Intent (LOI) must precede all proposals prior to the submission period. Pilot proposals may be submitted at any time.

Proposals are reviewed by the Scientific and Evaluation Peer Review Program for Rehab R&D, which consists of nationally recognized independent experts in these areas. The Review Board recommends approval only for the most meritorious proposals. The funding decision is made by the Rehab R&D Service Director based on the recommendation of the Board, available resources, and the immediate needs of the VA.

Technology Transfer Section
Saleem J. Sheredos, Program Manager

The Technology Transfer Section (TTS) is responsible for the evaluation of prototypes and new techniques developed under the Rehab R&D program to provide the prompt transfer of promising devices into commercial production and clinical use.

The goals of TTS are to 1) screen ongoing rehabilitation research and development sponsored by the Department of Veterans Affairs Rehab R&D Service and thereby identify products or techniques that are ready for transfer from research and development to clinical application; 2) coordinate clinical application studies away from the R&D arena on the selected products and techniques to affirm their application in treatment programs; and 3) foster the commercial availability of successful products by helping to overcome the barriers faced by potential manufacturers.

When a development (technique or device) is identified as completed, a Request for Evaluation (RFE) is prepared in accordance with VA Circular 10-87-32 and forwarded to the Program Manager, TTS. The RFE must be sent over the signatures of the R&D principal investigator (PI), the ACOS/R&D, and the Director of the VA Medical Center funded for that R&D effort.

When the RFE is received, it is nominally reviewed by three experts on the readiness and current value for clinical application, which leads to recommendations for a field study, or the need for further development, or project termination.

TTS coordinates the evaluation, collects the data, performs data analysis, issues progress reports, and prepares the final report with special recommendations.

Scientific and Technical Publications Section
Jon S. Peters, Acting Program Manager

The Scientific and Technical Publications Section (STPS) disseminates the results of VA and non-VA scientific and engineering projects among researchers, engineers, clinicians, and consumers in the United States and throughout the world. The offices disperses research, development and clinical information through print and electronic media. STPS publishes the *Journal of Rehabilitation and Development (JRRD), Rehabilitation R&D Progress Reports,* and clinical supplements to *JRRD.*

Rehab R&D Service has a Research and Development Center in each of the following locations:

The Rehabilitation Research and Development Center, Edward Hines Jr. Hospital, Department of Veterans Affairs, Hines, IL 60141
Joseph B. Green, MD, Director

1994 was a productive year for the VA Hines Rehabilitation Research and Development Center. The Rehabilitation R&D and clinical staff have been developing pilot studies with local funds to generate pilot data for full merit review applications to be prepared and submitted. Nine such studies have been supported.

Efforts have been underway to increase the number of funded projects. Since January 1994, 11 Letters of Intent were submitted to Rehab R&D Service with 81% encouragement to submit a full proposal. In 1994, four merit review proposals and two pilot proposals were approved and funded. In October, two merit review proposals were submitted for review in January 1995.

The Rehabilitative Neuroscience Research Section has made excellent progress, especially in the areas of neural regeneration and restoration of autonomic functions. One new area that the Rehabilitation R&D Center has begun studying is the role of neural transplantation in stroke. Since there is no treatment for stroke at this time, we have begun to investigate the possible role of fetal neuronal transplantation in functional recovery after stroke. Research is also being done to help patients with retinal disorders. So far our studies have focused on whether a semiconductor-based microphototiode array might provide the basis for the development of a retinal prosthetic device. Our work on restoration of autonomic function has attracted the attention of clinicians and medical equipment manufacturers who are eager to see our research results put to clinical use. For respiratory studies, clinical trials are beginning using percutaneous wires to stimulate paralyzed respiratory muscles in the chest and abdomen. For bladder function research, both surface and percutaneous electrodes are entering clinical trials for

bladder emptying and urinary incontinence management. For colon studies, an animal model has been developed for direct colon stimulation to investigate treatments of fecal impaction and incontinence. Our studies on spinal cord regeneration have lead to an improved understanding of the requirements for neuronal regeneration within the central nervous system. Considerable progress on spinal cord regeneration has been made through the use of advanced devices, biocompatible materials, and genetic engineering.

The Preventive and Rehabilitative Exercise Science Section has made great strides in the development and transfer of techniques and devices or promotion of the cardiorespiratory fitness and independent mobility of lower limb disabled veterans of all ages. Studies have focused on new methods for the diagnosis of coronary artery disease, treatment of spasticity through health-promoting behaviors, and identification of physiological factors and behaviors that positively and negatively influence cardiovascular and respiratory health.

The Musculoskeletal Disorders Research Section has made excellent progress in developing concepts and techniques to improve the diagnosis, treatment, and prevention of spinal disorders. These include characterizing the response of the lumbar spine in prolonged and dynamic loading environments which are potential risk factors for low-back disorders, development of techniques to measure patient compliance in wearing spinal orthoses, analyzing a diagnostic test used for neck pain patients, and characterizing the long-term response of the lumbar spine to fusion surgery.

Investigators in the Center have been collaborating with other medical centers and government agencies, including VA medical centers in Milwaukee (Clement J. Zablocki), Palo Alto, and Seattle; Rush Presbyterian-St. Luke's Medical Center, and the Wright Patterson Air Force Base; several universities including the University of Illinois at Chicago, University of Rochester School of Medicine, Northern Illinois University, California State University at Sacramento, University of Pittsburgh, University of Notre Dame, and the Departments of Pharmacology, Physiology, Urology, Medicine, and Orthopaedics at Loyola University Medical Center; other colleges including the Research Department at the National Chiropractic College and the Medical College of Wisconsin; and several companies including Life-Tech, Inc., EIC Laboratories, Packer Engineering, Inc., and Wynn Institute for Metabolic Research (London, England).

In summary, the Rehabilitation R&D Center at VA Hines Hospital continues to be a significant resource for research on disability related problems and the development and commercialization of enabling technologies.

Atlanta Rehabilitation Research and Development Center, Department of Veterans Affairs Medical Center, 1670 Clairmont Road, Decatur, GA, 30033
William R. De l'Aune, PhD, Acting Director

The mission of the Rehabilitation Research and Development Center on Aging is to enhance the quality of life of aging veterans through applied, multidisciplinary research and development. To achieve this mission, the Center conducts a broad range of research programs to identify and respond to the needs of older veterans experiencing age-related and chronic disability as well as those who are healthy.

Because the process of aging is complex, issues are explored in a multidimensional and interdisciplinary manner. Research, development, dissemination, and training are structured around four primary interdisciplinary research programs: environment, vision, behavior, and engineering and computer science. The *Environmental Research Section* is devoted to the study of design-related problems that affect the quality of life of older people, including least restrictive environments, falls, and independence and safety. The staff members have diverse backgrounds and expertise in architecture, environment and behavior research, housing research, and product design. *The Vision Research Section* conducts studies and develops technologies that ultimately will improve the quality of life of older individuals with low vision and blindness. The Section's researchers are trained in education, rehabilitation counseling, optometry, psychology, and blind rehabilitation. Much of their effort in recent years has focused on electronic travel aids, orientation and mobility, low vision, and rehabilitation outcome measurement for older persons with visual impairment. The Center's *Behavioral Section* places an emphasis on understanding the neurological and physiological changes that accompany aging and behavioral problems. Members of this group are known for their work in social and behavioral problems as well as prescriptive rehabilitation strategies, including exercise and frailty. The mission of the *Engineering and Computer Science Section* is to develop and apply new technologies to the design of assistive devices and software. A variety of prototype devices, including prosthetic and orthotic designs, specialized surgical instruments, and electromechanical human evaluation systems are produced in the fully equipped fabrication facility. Biomechanics studies are conducted using an Instron biaxial materials testing system and a gait analysis system.

The Center received 21 Merit Review funded projects in FY 1992, 93, and 94. Additional funding includes subcontracts from projects funded by the National Institute on Disability and Rehabilitation Research (NIDRR) and private agencies. Research of the Center staff has been disseminated through a variety of mechanisms. Staff published 79 articles, 73 abstracts, 19 book chapters, and 3 books. Of these, 20

refereed articles, 13 book chapters, and 19 other publications represented center-related activities. In addition, Center staff provided 229 conference presentations at national and international meetings.

Center research focuses on rehabilitation issues and functional problems that threaten the health, safety, or quality of life of older veterans. The Center's development activities focus on strategies and devices to maintain and improve veterans' everyday functioning.

Rehabilitation Research and Development Center, Department of Veterans Affairs Medical Center, 3801 Miranda Avenue, Palo Alto, CA 94304
Felix E. Zajac, PhD, Director

The Rehabilitation Research and Development Center (Rehab R&D) is dedicated to bringing science and technology to the problems faced by physically impaired veterans in their pursuit of independent living. Specific goals are as follows:

1. Define concepts, products, and processes which address issues of relevance to the rehabilitation of physically disabled veterans.
2. Perform research needed to apply concepts, define mechanisms, and validate new theories in order to advance the scientific basis of rehabilitative techniques.
3. Demonstrate feasibility of new devices, evaluation tools, and treatments.
4. Develop and clinically test the devices and treatments in preparation for transfer to the private sector or clinics.
5. Expose engineering and medical students to the exciting challenges of a career in rehabilitation.

The Rehab R&D Center is staffed by engineers and scientists dedicated to building an intellectual foundation in rehabilitation based on state-of-the-art engineering, medical science, and technology. Under the leadership of the Engineering/Scientific and Medical Directors, three scientific sections—the Human-Machine Integration, Orthopaedic Biomechanics, and Neuromuscular Systems Sections—share responsibility for developing this foundation and defining the rehabilitation problems on which to focus. Fields of expertise among Center investigators include biomechanics, biocontrols, and biodynamics, computer modeling, kinesiology, mechanical design, signal processing, microcomputers, smart products, and robotics. As principal investigators, they are responsible for obtaining funds to perform the specific research needed to solve the rehabilitation problems and fulfill the objective above. Three support sections—Administration, Technical Support, and Technology Transfer—contribute to this effort by assuring efficient Center operation, including the timely transfer of products and techniques to veterans, clinics, and the disabled community.

The Human/Machine Integration (HMI) Section is charged with fulfilling the assistive device design mandate of the Palo Alto Rehab R&D Center. The ideal HMI project marries rapidly evolving high technology with well-defined needs of caregivers and individuals with disabilities, to generate new tools for diagnosis, therapy, and daily living. Most HMI projects are involved with 1) manipulation (e.g., tactile sensors to replace lost sense of touch); 2) ambulation (e.g., walking aids for patients transitioning from wheelchairs to independent walking); 3) living aids (e.g., computer-assisted wayfinding for individuals with disabilities who are traveling in public places); and 4) spinal cord injury (e.g., vocational manipulators for workers with quadriplegia). HMI often sponsors engineering student design projects at Stanford, San Jose State, and Sacramento State Universities. The prototypes made by student design teams are then tested at Palo Alto VAMC, and often serve as starting points for further research.

During 1994, the Neuromuscular Systems (NMS) Section performed research related to the basic understanding, assessment, diagnosis, and treatment of movement and movement disorders. Earlier work in computer modeling of multijoint, multimuscle motor control mechanisms influenced the design of new research. Theoretical studies of intramuscular coordination during pedaling and during standing posture, development and evaluation of a new exercise device for restoring lower limb function in stroke patients with hemiplegia, and study of the biomechanics of pedaling in stroke and non-stroke patients, seek to objectively assess neuromuscular control of upper and lower limb function. In the future, the NMS Section plans to continue focusing on stroke rehabilitation and electrodiagnosis. They intend to perform experiments and computer simulations that will better characterize the biomechanical and motor-control factors that contribute to movement deficits in hemiplegia, and to apply the knowledge obtained to develop better therapeutic treatments.

A new Center theme developed in 1994 focuses on the use of mechanical stimuli to restore function to the neuromusculoskeletal system. This focus builds upon the Orthopaedic Biomechanics (OBM) Section's prestigious history of scientific investigations in several critical areas in the fields of orthopaedic rehabilitation, in conjunction with prior achievements of the NMS Section. OBM investigators developed a theory on how mechanical forces modulate skeletal tissue growth, repair, and regeneration. Based upon this theory, new methods have been developed to 1) reduce the extent of bone loss (osteoporosis) in patients with spinal cord injury and in the elderly, 2) to promote cartilage repair in damaged (e.g., arthritic) joints, and 3) decrease the failure rate of endoprostheses (e.g., hip and knee replacements).

It is anticipated that future work within the Center will continue to build upon its prior research. The focus areas of mechanical loading to promote musculoskeletal repair and regeneration, and of mechanical manipulation to promote rehabilitation of patients with stroke, are expected to bring a convergence of efforts and expertise among the three scientific sections. The

initiation of new endeavors within these area should further enhance the process of rehabilitation, and promote the dissemination of techniques, treatments, and tools to the clinical community and the end-user.

Rehab R&D Service has established the following Center of Excellence:

VA Center of Excellence in Functional Electrical Stimulation, Department of Veterans Affairs Medical Center, 10701 East Boulevard, Cleveland, OH 44106
P. Hunter Peckham, PhD, Director

The mission of the Functional Electrical Stimulation (FES) Center is to improve the quality of life of veterans with disabilities through the introduction of advanced technology employing FES, and to advance scientific knowledge in FES in order to generate new knowledge and promote additional development of clinical application. Specific objectives are to 1) transfer FES technology into clinical practice, 2) coordinate the development of new FES technology, and 3) perform advanced research in FES to advance the knowledge base and clinical applicability of FES.

Technology transfer is the broadest and most complex programmatic area of the FES Center. Activities of the FES Center include technology transfer to industry of FES technology through the use of conventional technology transfer mechanisms, and technology transfer to other clinical centers through the establishment of FDA-monitored clinical studies. Technology transfer techniques have been established whereby technology with a proven clinical feasibility is refined for manufacture, and relationships with industrial manufacturers are established to transfer the fabrication of clinical systems to them.

Transfer to clinical sites is accomplished by establishing multicenter research collaborations in which VA medical centers jointly work to develop and test FES technology. Multicenter clinical studies focusing on the safety and effectiveness of the technology are carried out by identifying suitable VA sites for collaboration, conducting workshops and site visits to jointly develop procedures and teach technique, and carefully coordinating and monitoring the actual study and associated data collection.

Coordination of technology development has been accomplished by establishing a central Core Engineering Laboratory and coordinating the development of advanced FES technology through this laboratory. Advanced research is carried out by facilitating and coordinating the research and development activities of clinical and scientific researchers working on FES.

Of the various FES research programs in Cleveland, the application of FES to restore hand function in individuals with high-level spinal cord injury is the most mature in terms of clinical application and readiness for transfer. An implantable FES hand system has been the focus of the initial technology transfer project. Fabrication of implantable and external components has been transferred to two contract manufacturers, with the latter transfer being accomplished during the past year. A multicenter research study is underway at four VA medical centers (Baltimore, Cleveland, Palo Alto, and West Roxbury) at which a total of 15 subjects have received the implantable FES hand system with eight of them joining the study during the past year. Of the 22 subjects that have received the device, one died due to causes unrelated to the device, and another had the device removed during part year because of infection. The management of this study has been transferred to a private company during the past year.

The establishment of the Core Engineering Laboratory has been completed; it is now in use for advanced technology development and is being upgraded with new equipment as appropriate. Coordination of research activities has focused on maintaining management procedures that were instituted to insure focused activity and productivity in accordance with project projections. Management occurs within individual projects and across projects. Regular review is performed to insure productivity. Scientific overview is achieved through review of internal reports and presentations as well as through peer-reviewed publications. An interinstitutional FES Council oversees the management of the FES Center.

Future research will focus on technology transfer of a lower limb FES system and technical development of a new generation implantable stimulator having additional stimulation channels and an implantable command/control transducer.

The following VA Medical Centers have reported projects sponsored fully or in part by the Department of Veterans Affairs Rehabilitation Research and Development Service. *(Note: VA Centers are listed alphabetically by state.)*

Long Beach VA Medical Center
5901 E. Seventh St., Long Beach, CA 90822

	Page
Prosthetic Design for Dysvascular Below-Knee Amputees	19
Computer-Assisted Treatment of Hemi-Inattention in R-CVA Patients	114
Optokinetic Testing for Diagnosis and Rehabilitation of Balance Disorders	226
Early Detection of Hearing Loss from Ototoxic Agents by High-Frequency Auditory Evaluation	232
Evaluation of Word-Recognition Performance with Sentence Material	237
Computer-Assisted Speech Evaluation Expert System	238

Palo Alto VA Medical Center
3801 Miranda Ave., Palo Alto, CA 94304

Page

Skeletal Changes after Spinal Cord Injury and Cast Immobilization . . . 27
Upper Body Motion Analysis for Amelioration of Falls in the Elderly . . . 97
Bicycle Ergometry to Improve Ambulation in Hemiplegic Stroke Patients . . . 115
Vocational Training Facility . . . 136
Artificial Nerve Graft: Union of Cellular and Noncellular Components . . . 167
Mechanical Regulation of Skeletal Tissue in Normal and Prosthetic Joints . . . 193
Effect of Femoral Collar Geometry in Hip Replacement . . . 206
Multimodality Image Registration of the Cervical Spine . . . 254
Noninvasive Urodynamic Evaluation of Vesicourethral Function: A Pilot Study . . . 268
Functional Restoration of Gasp: A Pilot Study . . . 269
In Vitro Test of an Artificial/Cellular Graft for Pressure Sore Repair . . . 316

San Diego VA Medical Center
3350 La Jolla Village Dr., San Diego, CA 92161

Page

Muscle Denervation and Recovery following Phenol-Induced Peripheral Nerve Block . . . 116
Physiological Basis of Strength following Surgical Tendon Transfer . . . 156
Management of Musculoskeletal Complications of Spinal Cord Injury . . . 270

San Francisco VA Medical Center
4150 Clement St., San Francisco, CA 94121

Page

Strength of Human Cortical Bone with Simulated Metastatic Defects . . . 192
Hip Fracture Risk Assessment Using Automated 3-D Finite Element Modeling . . . 194

West Los Angeles VA Medical Center
Brentwood Division, Wilshire and Sawtelle Blvd., West Los Angeles, CA 90073

Page

Functional Electrical Stimulation of Spinal Cord Injury Patients . . . 26
Suitability of Titanium Alloy as a Joint Replacement Bearing Surface . . . 205
Signal Processing and Hearing Aid Design . . . 225
Early Detection of Hearing Loss from Ototoxic Agents by High-Frequency Auditory Evaluation . . . 232

West Haven VA Medical Center
950 Campbell Ave., West Haven, CT 06516

Page

Effects of Expectation, Reward, and Activity on Subtypes of Schizophrenia: Status Report . . . 221

Gainesville VA Medical Center
1601 S.W. Archer Rd., Gainesville, FL 32608-1197

Page

Vertebral Fusion by New Osteogenic Agents to Accelerate Rehabilitation . . . 271

Miami VA Medical Center
1201 Northwest 16th St., Miami, FL 33125

Page

Biochemistry of Cartilage in a Model of Disuse and Different Types of Recovery: A Pilot Study . . . 195
Using Self-Monitoring to Improve Communicative Efficiency in Aphasia . . . 239
Spinal Cord Injury-Induced Bone Loss . . . 272

James A. Haley Veterans' Hospital
13000 Bruce B. Downs Blvd., Tampa, FL 33612

Page

Toward the Design of a New Prone Cart: A Pilot Study . . . 304

Augusta VA Medical Center
One Freedom Way, Augusta, GA 30904-6285

Page

Early Detection of Hearing Loss from Ototoxic Agents by High-Frequency Auditory Evaluation . . . 232

Atlanta VA Medical Center
1670 Clairmont Rd., Decatur, GA 30033

Page

Applicability of Accessibility Codes to Meet the Needs of Elderly People . . . 98
Balance Training in Elderly Fallers and Nonfallers . . . 98
Effects of Strength Training on Functional Ability of Older Adults . . . 98
Age-Related Changes in the Triceps Surae Stretch Reflex and Postural Control . . . 99
Design of New Toilet Prototypes for Elderly and Disabled Veterans . . . 128
Predisposing Factors in Disc Prolapse . . . 196
Design and Evaluation of Liquid Crystal (LC) Dark-Adapting Eyeglasses for Persons with Low Vision . . . 247
Design and Testing of an Electronic Travel Aid for Blind Persons . . . 247
Evaluating the Efficacy of a Peripheral Vision Expander System: A Pilot Study . . . 247
National Survey of Impact of Low Vision Aid Use among Veterans . . . 247
Environmental Information Needs for Wayfinding by Special Populations . . . 248
Design of a Videofluoroscopy Chair for SCI and Other Disabled Patients: A Pilot Study . . . 310

VA Medical Center
Highway 6 West, Iowa City, IA 52240

Page

Evoked Otoacoustic Emissions for Ototoxic Monitoring in Adults . . . 227

Chicago VA Medical Center (Lakeside)
333 E. Huron St., Chicago, IL 60611

Page

Additive Fabrication Technique for the CAM of Prosthetic Sockets . . . 1
Direct Muscle Attachment: Multifunctional Control of Hands and Arms . . . 6
Practical Applications of New CAD and CAE Techniques to Socket Design . . . 20

Chicago VA Medical Center (West Side)
820 S. Damen Ave., Chicago, IL 60612

Page

Aged Muscle Metabolic Adaptations to Resistance Exercise . . . 99
Development of a Predictive Model of Driving Performance in Stroke Patients . . . 248

Danville VA Medical Center
1900 E. Main St., Danville, IL 61832

Page

Feasibility of a Dynamic Dermofluorometer to Monitor Skin Fluorescence: A Pilot Study . . . 187

Edward Hines Jr. VA Hospital
5th Ave. and Roosevelt Rd., Hines, IL 60141

Page

Biomechanics of Cervical Diagnostic Maneuvers: A Pilot Study . . . 28
Effects of Spinal Fusion with Instrumentation on the Stabilized Spine: A Pilot Study . . . 29
Effect of Surgical Procedures on the Stability of the Lumbar Motion Segment . . . 30
High Charge Density, Bipolar Electrodes for Chronic FNS . . . 72
Rehabilitation of Respiratory Paralysis: Accessory Muscle Stimulation . . . 73
Recognition of Hand Gestures by People with Motor Impairments: A Pilot Study . . . 141
Stimulation of Retinal Photoreceptor Function with Arrayed Subretinal Microphotodiode Implants: A Pilot Study . . . 249
Wheelchair Exercise and Digital Echocardiography for the Detection of Heart Disease . . . 255
Effect of Supported Standing and Upper Body Exercise on Lower Extremity Spasticity in Persons with Spinal Cord Injury . . . 256
Rehabilitation of the Colon after Spinal Cord Injury: A Pilot Study . . . 273
Application of Electric Fields to Enhance Recovery following Spinal Cord Injury: Behavioral Studies . . . 293
Application of Electric Fields to Enhance Recovery following Spinal Cord Injury: Electrophysiological Studies 294
Enhanced Carbon Filament Prostheses as Substrates for Regrowth of Injured Spinal Cord: Recovery of Function . 295
Enhanced Carbon filament Prostheses as Substrates for Regrowth of Injured Spinal Cord: Electrophysiological Recovery . . . 296
Electric Field Effects on CNS Axonal Transport in SCI: A Pilot Study . . . 297
Clinical Workstation for Reducing Wheelchair Propulsion Injuries . . . 301

New Orleans VA Medical Center
1601 Perdido St., New Orleans, LA 70146

Page

Wear Debris Generation in Hip Modular Head and Neck Components . . . 207
Changes in Bone Blood Flow Associated with Intramedullary Nailing . . . 209

VA Outpatient Clinic
21 Causeway St., Boston, MA 02114

Page

Pinned Polymer Model of Posture Control . . . 36
Common Drive of Motor Units: In Numero Experiments . . . 55
Ranked-Ordered Regulation of Motor Units . . . 55
Effects of Hand Dominance on Motor Unit Firing Behavior . . . 56
Firing Patterns, Firing Rate Behavior, and Force Generation of Motor Units . . . 57
Age-Related Changes in Open-Loop and Closed-Loop Postural Control Mechanisms . . . 100
Vestibular System Dysfunction and Quiet-Standing Postural Control . . . 101
Biochemical and Myoelectric Events during Fatigue . . . 157
Effects of Muscle Fiber Size on Surface EMG Parameters . . . 157
Muscle Adaptation following Limb Unloading and Its Influence on EMG Parameters . . . 158
Development of a Clinical Database for the Back Analysis System . . . 173
Development of Test Protocols to Assess the Behavior of Back Muscles . . . 174
Back Analysis System Update . . . 175
EMG Spectral Parameters as a Treatment Outcome Measure for Low Back Pain . . . 175
Muscle Performance in the Back Analysis System Compared to Lifting Tasks . . . 176
Spectral Parameters of Lumbar Back Muscle Electromyography at Different Contraction Levels . . . 177

Brockton/West Roxbury VA Medical Center
940 Belmont St., Brockton, MA 02401

Page

Diagnosis of Cartilage Degeneration: Quantitative Surface Spectroscopy . . . 196
Pulsed Laser Deposited Hydroxyapatite Coating for Prosthesis-Bone Bonding . . . 196
Bone Cement Collar (BCC) for Sealing the Femoral Canal around Non-Cemented Prostheses: A Pilot Study . . . 210
Optimized Surface Bonding and Stiffness of Femoral Endoprostheses . . . 210
Advanced Technology Neural Information Sensors for Prosthetic Control by Quadriplegics . . . 274
Device for Treatment of Peripheral Nerve Injury . . . 275

VA Medical Center
1400 Veterans of Foreign Wars Pkwy., West Roxbury, MA 02132

Page

FES-Aided Paraplegic Gait Using a Controlled-Brake Orthosis 214

Ann Arbor VA Medical Center
2215 Fuller Rd., Ann Arbor, MI 48105

Page

Does Leg Strength Influence Rising from a Chair in Older Adults? 101
Effects of Muscle Strength on Balance during Movement in the Elderly 101
Navchair Control System for Automatic Assistive Wheelchair Navigation 309

Minneapolis VA Medical Center
One Veterans Drive, Minneapolis, MN 55417

Page

FES-Aided Paraplegic Gait Using a Controlled-Brake Orthosis 214
Characteristics of Connected Speech in Aphasic Adults 240

Kansas City VA Medical Center
4801 Linwood Blvd., Kansas City, MO 64128

Page

Combined Functional Loading and Laser Photostimulation of Regenerating Tendons 166

St. Louis VA Medical Center
915 N. Grand Blvd., St. Louis, MO 63106

Page

Prokinetic Agents for Constipation in Spinal Cord Patients: A Pilot Study 277

Durham VA Medical Center
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Page

Do Changes in Strength Influence Measures of Balance and Function in Elderly Men and Women? 103

Omaha VA Medical Center
4101 Woolworth Ave., Omaha, NE 68105

Page

New Bioelectric Method for Early Diagnosis of Delayed Fracture Healing 74
Comparison of Events in Bone Healing Influenced by CCEF and PEMF Signals 197
New Strategies for Long-Term Performance of Femoral Prosthesis 198
New Methods to Treat Impaired Fracture Healing Using Growth Factors 210

East Orange VA Medical Center
385 Tremont Ave., East Orange, NJ 07018

Page

Effect of Presence versus Absence of Prolonged Amplification on Audition 228
Effect of Lack of Amplification on Persons with Unilateral Hearing Loss 229
Programmable Hearing Aids: Evaluation and Prediction of Benefit 230

Albuquerque VA Medical Center
2100 Ridgecrest Dr., SE, Albuquerque, NM 87108

Page

Assessment of Nonauditory Factors in Hearing 231

Castle Point VA Medical Center
Castle Point, NY 12511

Page

Noninvasive Measurement of Changes in Muscle Oxygen with Claudication 188
Factors Affecting Streaming Potentials in Healing and Remodeling Bone 199

New York VA Medical Center
423 E. 23rd St., New York, NY 10010

Page

Software and Equipment Development for Improved Computer-Aided Prosthetic Socket Design 2
Developmental Enhancement and Application of the VA-Cyberware Prosthetics-Orthotics Optical Laser Digitizer 215
Computer-Aided Design and Computer-Aided Manufacturing of Orthopedic Footwear 216
Evaluation of a New Nucleus Cochlear Implant Speech Processor: A Pilot Study 232

Syracuse VA Medical Center
800 Irving Ave., Syracuse, NY 13210

Page

Corticospinal System 257

Cleveland VA Medical Center
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Page

Neuroprosthetic Control of Bladder and Bowel in Spinal Injury Patients 75
Electrical Activation of Diaphragm for Ventilatory Assist . . . 76
Functional Neuromuscular Systems for Upper Extremity Control 86
Restoration of Standing Pivot Transfer for Quadriplegic Patients Using a Totally Implanted FNS System 89
Functional Paraplegic Walking with Electrical Stimulation . . 90
Restoration of Sit-to-Stand Function in Elderly Patients Using FNS 91
Restoration of Gait for the Stroke Patient 92
Development of an On-Line Correction Capability for FNS Locomotion 93
Electrical Control of Bladder and Bowel following Spinal Cord Injury 302

Dayton VA Medical Center
4100 West 3rd St., Dayton, OH 45428

	Page
Wheelchair Propulsion Performance in Young, Middle-Aged, and Elderly	51
Evaluation and Optimization of FES Techniques for Exercise	77
Exercise Testing and Training of Multiple Sclerosis Patients	278
Improving Exercise Performance of Quadriplegics	279

Portland VA Medical Center
3710 Southwest U.S. Veterans Hospital Rd., Portland, OR 97207

	Page
Early Detection of Hearing Loss from Ototoxic Agents by High-Frequency Auditory Evaluation	232
Aphasic Naming Deficits: Effects of Deep- and Surface-Level Treatments	241

Pittsburgh VA Medical Center (Highland Dr.)
Highland Drive, Pittsburgh, PA 15206-1297

	Page
Demonstrating the Efficacy of Memory Training	104
Manipulating Joint Compliances and Ground Reaction Forces to Predict Falling Potential: A Pilot Study	104
Analysis of a Treatment for Apraxia of Speech in Adults with Aphasia	242
Conversational Skills Training for Aphasic Subjects	243
Design and Selection Guidelines for Wheelchair Ride Comfort	303

Pittsburgh VA Medical Center (University Dr.)
University Drive C, Pittsburgh, PA 15240

	Page
Biochemical Analysis of Synovial Activation in Joint Dysfunction	200

Memphis VA Medical Center
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	Page
Measurement and Prediction of Benefit from Amplification	244

Alvin C. York VA Medical Center
3400 Lebanon Rd., Murfreesboro, TN 37130

	Page
Prompted Voiding in the Treatment of Urinary Incontinence	323

Nashville VA Medical Center
1310 24th Ave., South, Nashville, TN 37212-2637

	Page
Origin and Character of Regenerate Bone	200

Houston VA Medical Center
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	Page
Objective Assessment of Spasticity in Spinal Cord Injury	280
Skin Composition in Spinal Cord Injury	317

Audie L. Murphy Memorial Veterans Hospital
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	Page
Restoration of Oral Function with Maxillary Bone Grafts and Implants	245

Olin E. Teague Veterans' Center
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	Page
Efficacy of an Auditory Rehabilitation Program: A Pilot Study	234

White River Junction VAM&ROC
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	Page
Artificial Nerve Graft: Union of Cellular and Noncellular Components	167
Continuation of the Center for the Examination of Retrieved, Orthopedic Prostheses	211

Seattle VA Medical Center
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	Page
Clinical and Laboratory Study of Amputation Surgery and Rehabilitation	10
Subtalar and Transverse Tarsal Joint Mechanics	31
Minimizing Hypertonus to Improve Recovery after Spinal Cord Injury	281
Prospective Study of Risk Factors for Diabetic Foot Ulcer	318

William S. Middleton Memorial Veterans Hospital
2500 Overlook Terrace, Madison, WI 53705

	Page
Swallowing Dysfunction in Elderly Head and Neck Cancer Patients	104
Effects of Age on Oropharyngeal Swallowing	106
Communicative Partners: Integrating Aphasic Adults Back into Society	117
Determining Response Curve for Tactile-Thermal Application: A Pilot Study	182
In Vivo Measurement of Vertebral Displacement after Lumbar Fusion	200
Treatment of Dysphagia in Age-Related Disease: Stroke	246

Clement J. Zablocki VA Medical Center
5000 West National Ave., Milwaukee, WI 53295

	Page
Biomechanical Analysis of the Sit-to-Stand Motion: A Pilot Study	57
Age-Related Changes in Sensory-Motor Performance	107
Design of New Toilet Prototypes for Elderly and Disabled Veterans	128
Application of Electric Fields to Enhance Recovery following Spinal Cord Injury: Behavioral Studies	293
Application of Electric Fields to Enhance Recovery following Spinal Cord Injury: Electrophysiological Studies	294
Toward the Design of a New Prone Cart: A Pilot Study	304

Design of a Videofluoroscopy Chair for SCI and Other Disabled Patients: A Pilot Study 310

Holter System Development for Recording Plantar Pressures 319

Part B. Non-VA Sponsoring Organizations

A.I. duPont Institute
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Page
Improving the Functional Utility of Rehabilitation Robotics through Enhanced Sensory Feedback: The Virtual Headstick 137
Developing a Robotically Aided Science Education Laboratory for Students with Severe Physical Disabilities . 138
Rehabilitation Robotics Technical Assistance and Outreach . 138
Multimodal Control of a Rehabilitation Robot 139
Engaging, Recruiting, and Retaining Students with Disabilities in Science, Engineering, and Math 142
Augmentative and Alternative Communication Technical Assistance and Outreach Program 147
Research in Interface Methodologies for AAC 147
Criteria for Interfacing and Control of a Powered Upper Extremity Orthosis 218

American Association of Retired Persons
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Page
AARP Evaluation of Assistive Devices for the Bathroom . . . 108
AARP Electric Scooter Study 305

Apple Computer, Inc.
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Page
Development of Extensions for Standard Computers and Operating Systems to Allow Access by Users with Motor Impairments 145

AudioScan/Etymonic Design Inc.
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Page
Hearing Aid Research: Improving the Selection, Fitting, and Evaluation Process 235

Bloorview Children's Hospital Foundation
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Page
Health Behavior in School-Aged Children with Physical Disabilities 324

Boston University
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Page
Postural Control in Parkinson's Disease 38
Development of Test Protocols to Assess the Behavior of Back Muscles 174
Back Analysis System Update 175
Muscle Performance in the Back Analysis System Compared to Lifting Tasks 176
Spectral Parameters of Lumbar Back Muscle Electromyography at Different Contraction Levels 177

Camera di Commercio di Torino
Torino, Italy

Page
Modeling of EMG Signals: The Effect of Layered Media . . 160

C.E.C. Program AIM—CAMARC
Roma, Italy

Page
Anatomical Frame Definition, Determination, and Exchange in Movement Analysis 36
Experimental Artifacts in Movement Analysis 37
Integrated, Computer-Managed System for Clinical Motor (DIS)Ability Assessment 61

Center for Automotive Research
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Page
Effects of Seating Type and Disability Level on Stability during Driving 311

Commission of the European Communities—TIDE
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Page
Integrated, Computer-Managed System for Clinical Motor (DIS)Ability Assessment 61
Restoration of Muscle Activity through FES and Associated Technology: The Raft Project, A Concerted Action 80
Prediction of Bone Adaptation Based on Damage and Repair in Bone 201

Del Harder Rehabilitation Fund
No address listed.

Page
Development of an Adult Clinical Version of the Tufts Assessment of Motor Performance (TAMP) 59

Dutch Prevention Fund
Amsterdam, The Netherlands

Page
Development and Evaluation of a Treatment Program Directed at the Improvement of Psychosocial Behavior following Stroke 224
Effect of Quadrugby on Physical Capacity and Physical Strain among a Group of Subjects with Cervical Spinal Cord Injury 259

Edward Hines Jr. VA Hospital
5th Ave. and Roosevelt Rd, Hines, IL 60141

Page

Dynamic Response of Spinal Segments: Experimental and Analytical Studies . . . 32
Perineum Stimulation for Control of Urge Incontinence and Frequency . . . 78
Rehabilitation of Urinary Incontinence Using Stimulated Muscle Flaps . . . 79
Thin-Film Peripheral Nerve Electrode . . . 87
Fetal Transplants and Repair of Stroke in Adult and Aged Rats . . . 118
Influence of Resistance Exercise Training on the Determinants of Glucose Tolerance . . . 158
Effects of 2 Weeks of Oral Albuterol on Insulin Sensitivity and Lipoprotein Lipids in Healthy Men . . . 159
Carbohydrate Metabolism and Cardiovascular Risk Factors in Persons with Spinal Cord Injury . . . 258
Tubular Prostheses to Enhance and Direct Neuronal Regrowth in SCI . . . 298
Determinants of Glucose Tolerance in Persons with Hypertension: Effects of Moderate Intensity Exercise Training . . . 323

Engineering and Physical Sciences Research Council
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Page

Developing a Biomechanical Model of the Interface between the Residual Limb and the Prosthesis for Trans-Femoral Amputees . . . 11

Fonds de la Recherche en Sante du Quebec
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Page

Quantification of Upper Limb Synkinesis in Hemiparetic Subjects . . . 118

Formacion d' Chercheurs a la Recherche
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Page

Three-Dimensional Reconstruction of Scoliotic Deformities and Evaluation of Treatments . . . 202

The Fund for the Promotion of Research at the Technion
Technion, Israel Institute of Technology, Haifa, Israel

Page

Characterization of Normal and Pathological Sway Dynamics . . . 52

Health and Welfare Canada
Program Development Section, Extramural Research Programs, Ottawa, K1A 1B4, Ontario Canada

Page

Quantification of Upper Limb Synkinesis in Hemiparetic Subjects . . . 118

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Page

Hearing Aid Research: Improving the Selection, Fitting, and Evaluation Process . . . 235

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Page

Prediction of Bone Adaptation Based on Damage and Repair in Bone . . . 201

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Page

Postural Control in Parkinson's Disease . . . 38

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Page

Assessment of the Reliability and Validity of the Pediatric Evaluation of Disability Inventory (PEDI) . . . 60

IBM Corporation
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Page

Development of Extensions for Standard Computers and Operating Systems to Allow Access by Users with Motor Impairments . . . 145

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Page

Integrated, Computer-Managed System for Clinical Motor (DIS)Ability Assessment . . . 61

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Page

Relationship Identification between Electrical and Muscle Stimulus Torque for FES Optimization in Paraplegic Patients . . . 94
Prediction of Bone Adaptation Based on Damage and Repair in Bone . . . 201
Gait Analysis of Paraplegic Patients Walking with Mechanical Orthoses and FES . . . 217
Procedure for Seat Cushion Analysis on Wheelchair Users . . . 312

Italian National Research Council
Roma, Italia

Page

Relationship Identification between Electrical and Muscle Stimulus Torque for FES Optimization in Paraplegic Patients . . . 94
Gait Analysis of Paraplegic Patients Walking with Mechanical Orthoses and FES . . . 217

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Page

Model of the Neuro-Musculo-Skeletal System for Human Posture and Gait 39

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Page

Biomechanical Evaluation of the Effects of Load Carrying on Dynamic Balance Control 40
Model for the Dynamic Postural Control System 40
Effects of Head Injury on Open-Loop and Closed-Loop Postural Control Mechanisms 41
Effects of Spaceflight on Open-Loop and Closed-Loop Postural Control Mechanisms 42
Common Drive of Motor Units: In Numero Experiments . . . 55
Ranked-Ordered Regulation of Motor Units 55
Effects of Hand Dominance on Motor Unit Firing Behavior . 56
Motor Unit Control Properties during Sustained Isotonic Isometric Contractions 62
Synchronous Behavior of Motor Unit Firings 62
Control of Muscle Fibers: How Does a Muscle Regulate Force? 63
Biochemical and Myoelectric Events during Fatigue 157
Effects of Spaceflight on Human Muscle Performance 160
Development of Test Protocols to Assess the Behavior of Back Muscles 174
Back Analysis System Update 175
Muscle Performance in the Back Analysis System Compared to Lifting Tasks 176
Alterations in EMG Characteristics Coinciding with Low Back Pain 177
EMG Parameters of Lumbar Back Muscles 178
Normative Database for Low Back Pain Evaluation in Blue Collar Workers 179
Predictability of the Susceptibility to Low Back Pain 179
Evaluation of Low Back Pain Treatment Outcome 180

L and L Richmond Research Fund
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Page

Rehabilitation of Paralyzed Muscles by Surface FES 96

Massachusetts Institute of Technology
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Page

Effects of Spaceflight on Human Muscle Performance 160
Advanced Technology Neural Information Sensors for Prosthetic Control by Quadriplegics 274

Medical Research Council of Canada
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Page

Three-Dimensional Reconstruction of Scoliotic Deformities and Evaluation of Treatments 202

Mississippi State University Rehabilitation Research
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Page

Identification of Skills and Knowledge Necessary for People with Visual Impairments Beginning Jobs after Graduating from Postsecondary Institution 251
Identification of Skills, Knowledge, and Steps Necessary for Students with Visual Impairments Entering Postsecondary Institutions 252

National Aeronautics and Space Administration
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Page

Development of a Control System for Robots 140

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Page

Biomechanical Effects of Tracheostomy Tubes 183
Comparison of Manofluorography, the Modified Barium Swallow, and Biomechanical Analysis in the Post-Surgical Pharynx 183
Biomechanics of Swallow After Head and Neck Cancer . . . 184
Effects of Surgical Reconstruction on Speech and Swallowing 185
Assessment of Performance Outcome in Laryngeal Cancer Patients 186
Cricopharyngeal Myotomy Study 246

National Center for Medical and Rehabilitation Research
NIH, Bethesda, MD 20892

Page

Improving Prosthetic Prehension 8
Adjustment after Spinal Cord Injury: The 20-Year Minnesota Longitudinal Study 262
Prediction of Mortality after Spinal Cord Injury: A 20-Year Prospective Study 263

National Easter Seal Society
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Page

Development of a Model Process for Determining ADA Paratransit Eligibility 325

National Health Research and Development Programme
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Page

Three-Dimensional Reconstruction of Scoliotic Deformities and Evaluation of Treatments 202

National Institute of Arthritis & Musculoskeletal Disorders
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Page

Muscle Fiber Damage Due to Eccentric Contractions 163

National Institute on Aging
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Page

Postural Control in Parkinson's Disease 38
Age-Related Changes in Open-Loop and Closed-Loop Postural Control Mechanisms 100
White Matter Hyperintensities 109

National Institute of Child Health & Human Development
National Institutes of Health, Bethesda, MD 20892

Page

Paraplegic Walking Made Practical with FNS and Orthoses . 95

National Institute on Disability and Rehabilitation Research
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Page

Lighter Weight Electric Prehensor 3
Electric Humeral Rotator 9
Dynamic Response Prosthetic Feet and Their Role in Human Ambulation 12
Femoral Displacement in Above-Knee Sockets 16
Investigation of 4-Bar Linkage Knees as an Aid to Floor Clearance 16
Development of a Direct Ultrasound Ranging System for the Quantification of Ambulation 42
Relation of Rehabilitation Intervention to Functional Outcome 64
Development of Protocols and Models Used to Quantify Functional Capabilities of Persons in Response to the American with Disabilities Act (1992) 65
Development of Mathematical Models to Quantify Joint Velocity, Torque, and Power during Lifting Tasks 66
Assessment of Ambulation Motion Parameters for Clinical Evaluation 67
Use of Joint Torque, Energy, and Power in Clinical Gait Evaluation 68
Use of Technology Services to Maintain Employment among People Aging with a Disability 109
Assessment of Residential Care Facilities as an Alternative Community Service Model for Disabled Older Adults . . 110
Role of Training to Enhance Utilization of In-Home Support: A Comparison between Older Hispanics and Anglos with a Disability 110
Variations in Secondary Conditions, Risk Factors, and Health Care Needs for Four Groups of Persons Aging with Physical Disability 111
Study of Policy Barriers Impeding Use of Assistive Technology by Persons Aging with Disabilities 112
Prospective Study on the Use of Bolus Intrathecal Baclofen for Spastic Hypertonia Due to Acquired Brain Injury . . . 119
Prevention of Thromboembolism in Stroke Rehabilitation Patients 120
Comorbidities and Complications in Stroke: Incidence, Risk Factors, and Effects on Outcomes 121
Course of Recovery of Cognitive-Communicative Problems in Right-Brain-Damaged Individuals 121
Predictive Value of Cognitive/Behavioral Measures in Patients after Stroke in Assessing Functional Outcome . . 122
Reducing Motor Disability in Hemiparetic Stroke by Manipulation of Sensory Input from the Paretic Upper Limb: A Quantitative Evaluation 123
Controlled Study of the Effects of EMG Feedback and Electrical Stimulation on Motor Recovery in Acute Stroke Patients 124
Effects of Aerobic Exercise on Young Persons Post-Stroke . 124
Effectiveness of a Telephone Support Group for Stroke Caregivers 125
Improving Vocational Outcomes of Individuals Who Have Sustained a Stroke 125
Assisting Community-Based Rural Independent Living Programs 129
Life Satisfaction of People with Physical Disabilities: Relationship to Personal Assistance, Disability Status, and Handicap 130
Use of Personal Assistance Services by Persons with Spinal Cord Injury 130
Improving the Functional Utility of Rehabilitation Robotics through Enhanced Sensory Feedback: The Virtual Headstick 137
Developing a Robotically Aided Science Education Laboratory for Students with Severe Physical Disabilities . 138
Rehabilitation Robotics Technical Assistance and Outreach . 138
Multimodal Control of a Rehabilitation Robot 139
Engaging, Recruiting, and Retaining Students with Disabilities in Science, Engineering, and Math 142
Selecting Items from Lists and Menus in Information Systems 143
Uni-Flex: A Universal-Flexible Human Interface Protocol . . 143
Development of Cross-Disability Access Techniques for Database Systems 144
Development of Extensions for Standard Computers and Operating Systems to Allow Access by Users with Motor Impairments 145
General Input Device Emulating Interface (GIDEI) Standard Version 2 146
Augmentative and Alternative Communication Technical Assistance and Outreach Program 147
Research in Interface Methodologies for AAC 147
Evolution of Independent Living Programs: A Longitudinal Study 148
Development of an Instrument to Measure Adequacy of Personal Assistance Services 149
Effect of Personal Assistance Services on the Long-Term Health of a Rehabilitation Hospital Population: Perceptions of Rehabilitation Professionals 150
Demonstrating a Model Approach to Independent Living Center-Based Assistive Technology Services 151
Collaboration between Medical Rehabilitation Programs and Independent Living Centers in Facilitating Independent Living by Persons with Recently Incurred Spinal Cord Injury 153
Increasing the Ability of Independent Living Centers to Serve the Population of African Americans with Disabilities 153
Relationships among Age at Onset, Adequacy of Personal Assistance, Negative Health Incidents, and Health Care Utilization for Persons with Physical Disabilities 154

Neuromuscular Function in Postpolio Subjects: A 5-Year Follow-Up Study . . . 169
Neuromuscular Function in Postpolio Subjects: A 5-Year Follow-Up Study . . . 169
Comparison of Symptoms between Swedish and American Postpolio Individuals and Assessment of Lower Limb Strength: A Four-Year Cohort Study . . . 170
Comparison of Symptoms between Swedish and American Postpolio Individuals and Assessment of Lower Limb Strength: A Four-Year Cohort Study . . . 170
Vermont Rehabilitation Engineering Research Center for Low Back Pain . . . 180
Measurement of Plantar Foot Soft Tissue Properties of Patients with Diabetic Neuropathy for Prediction of Plantar Foot Pressure and Assessment of Plantar Ulceration Risk . . . 189
Measuring the Effects of Vestibular Stimulation on Children with Cerebral Palsy . . . 190
Criteria for Interfacing and Control of a Powered Upper Extremity Orthosis . . . 218
Sexuality Issues among Women with Physical Disabilities . . 222
Showsounds and Soundsentry: Access to Computers and Information Systems for People Who Are Deaf or Hard-of-Hearing . . . 236
Touchscreen Access for Individuals Who Are Blind: "Talking Fingertip" Strategy . . . 250
Identification of Skills and Knowledge Necessary for People with Visual Impairments Beginning Jobs after Graduating from Postsecondary Institution . . . 251
Identification of Skills, Knowledge, and Steps Necessary for Students with Visual Impairments Entering Postsecondary Institutions . . . 252
Causes and Costs of Unplanned Rehospitalizations among Persons with Spinal Cord Injury . . . 260
Immune Responses to Pneumococcal Vaccine in Spinal Cord Injury . . . 261
Baclofen Pump: Functional and Neuropsychological Impact . 283
Longitudinal Analysis of Well-Being in Persons with Spinal Cord Injury and Their Caregivers . . . 284
Ultrasound for Urinary Tract Surveillance of Persons with Spinal Cord Injury . . . 285
Natural History and Clinical Course of Urinary Tract Complications in Patients with Spinal Cord Dysfunction . . 286
Motor Complete Spinal Cord Injury: Prognosis for Ambulation . . . 287
Recovery of Upper Extremity Muscles following Cervical Spinal Cord Injury . . . 288
Use of Growth Factors in Pressure Ulcer Healing . . . 319
Problem-Solving Skills Training in the Treatment of Pressure Ulcers in Persons with Spinal Cord Injury . . . 320
Career Development of Women with Physical Disabilities . . 326
Computerized Methods in Prosthetics and Orthotics . . . 327

National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD 20892

Page
Kinesthetic Perception in the Hand and Arm . . . 81
Paraplegic Walking Made Practical with FNS and Orthoses . 95

National Institutes of Health
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Page
Synovial Joint Biomechanics and the Pathogenesis of Osteoarthritis . . . 34
Central Nervous System Control Rules for Voluntary Movement . . . 69
Mechanisms Underlying Compliant Behavior of the Limbs . . 69
Kinesthetic Perception in the Hand and Arm . . . 81
Implantable Stimulation, Telemetry, and Transducer System for Neural Control . . . 82
Management of Urinary Disorders in SCI . . . 83
Paraplegic Walking Made Practical with FNS and Orthoses . . 95
Patient Management and Rehabilitation Protocols following Major Hip Surgery Based on Quantitative in Vivo Data . . 161
Quantifying Co-Contraction in Agonist/Antagonist Muscles: A Force Instrumented Endoprosthesis . . . 162
Biomechanical Effects of Tracheostomy Tubes . . . 183
Comparison of Manofluorography, the Modified Barium Swallow, and Biomechanical Analysis in the Post-Surgical Pharynx . . . 183
Biomechanics of Swallow After Head and Neck Cancer . . . 184
Effects of Surgical Reconstruction on Speech and Swallowing . . . 185
Assessment of Performance Outcome in Laryngeal Cancer Patients . . . 186
Hip Joint Biomechanics: The Effects of Femoral Head Endoprosthetic Replacements . . . 212
Cricopharyngeal Myotomy Study . . . 246
Adjustment after Spinal Cord Injury: The 20-Year Minnesota Longitudinal Study . . . 262
Prediction of Mortality after Spinal Cord Injury: A 20-Year Prospective Study . . . 263
Electrical Control of Bladder and Bowel following Spinal Cord Injury . . . 302
Shoulder Kinematics during Propulsion of Different Wheelchair Types . . . 306

National Science Foundation
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Page
Pinned Polymer Model of Posture Control . . . 36
Controlling Neuronal Noise Using Chaos Control . . . 43
Initiation of Human Walking . . . 44
Using Chaos Control to Control Non-Chaotic Systems . . . 44
Assessing Individuals' Predispositions to the Use, Avoidance, or Abandonment of Assistive Technologies . . . 70

National Welfare Grants Program—Human Resources Canada
No address listed.

Page
Variables Affecting Independent Living for Persons with Physical Disabilities . . . 131

NATO Science Fellowship
No address listed.

Page

Quantitative Functional Anatomy of the Upper Extremity . . . 53

Natural Sciences and Engineering Research Council of Canada
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Page

Three-Dimensional Reconstruction of Scoliotic Deformities and Evaluation of Treatments 202
Hearing Aid Research: Improving the Selection, Fitting, and Evaluation Process 235

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Page

Coordination of Muscles in Gait 53
Skeletal Muscle Reaction to Growth and Immobilization . . 164

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Page

Measurement of Burden of Care with Parents of Children with Cerebral Palsy: A Pilot Study 328

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Page

Evaluation of Carpal Tunnel Syndrome 71

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Page

Effects of Seating Type and Disability Level on Stability during Driving 311

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Page

Hearing Aid Research: Improving the Selection, Fitting, and Evaluation Process 235
Custom Car Seats for School-Aged Children 313
Consumer Involvement in Children's Seating Design 314

Paralyzed Veterans of America, Spinal Cord Research Foundation
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Page

Implantable Stimulation, Telemetry, and Transducer System for Neural Control 82
Development and Dissemination of a Resource Guide on Functional Electrical Stimulation (FES) for Persons with Spinal Cord Dysfunction 84
Design and Evaluation of a Triceps Orthosis for C5/C6 Quadriplegics 219
Vasopressin and Blood Pressure Control in Spinal Cord Injury Patients 289
Bacteriuria in Patients with Neurogenic Bladder Treated with Intermittent Catheterization 290
Electrical Control of Bladder and Bowel following Spinal Cord Injury 302
Design and Development of a Wheelchair for Enhanced Access 307
Spermatogenesis following Spinal Cord Injury: Quantitative and Dynamic Assessment in the Rat Model 321

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Page

Development of a Procedure for the Assessment of Motor Behavior in Young Children under Natural Conditions . . 171

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Page

Neuropathic Foot in Leprosy 21
New Grip Aid for Leprosy Patients 132
Podiatric Evaluation of the Neuropathic Foot in Leprosy . . . 171
Orthotic Foot Appliances for Leprosy Patients: A Study Based on Podiatric Principles 220

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Page

High-Frequency Magnetic Stimulation of the Bladder and Bowel: A Pilot Study 282

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Page

Development of an Adult Clinical Version of the Tufts Assessment of Motor Performance (TAMP) 59

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Page

Relation of Rehabilitation Intervention to Functional Outcome 64

Royal Brisbane Hospital
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Page

Assessing the Team Approach in Rehabiliation Engineering . 329

Rotary Club of Toronto
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Page

Custom Car Seats for School-Aged Children 313
Consumer Involvement in Children's Seating Design 314

Royal Society for the Blind
Gilles Plains, South Australia

Page
The Head Reader—A Display for Sensory Impaired Bowlers 252

San Antonio Area Foundation
San Antonio, TX 78284

Page
Computer-Aided Prosthetic Alignment System Using Neural Networks 22

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No address listed.

Page
Fatigue and Recovery of FES-Activated Paralyzed Muscles . 85
Rehabilitation of Paralyzed Muscles by Surface FES 96
Simulation of Distal Tendon Transfer of Arm and Forearm Muscles 166

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Page
Secondary Conditions after Spinal Cord Injury: Relationship to Life Adjustment 264

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Page
Neuron-Glia Interaction and CNS Regeneration 299

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Page
Custom Car Seats for School-Aged Children 313
Consumer Involvement in Children's Seating Design 314

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Page
Aftercare Program Focused on the Postconcussion Syndrome following Mild Traumatic Brain Injury 126

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Page
Stepping Over an Obstacle: A Comparison of New and Experienced Prosthesis Users 13
Stepping Over an Obstacle: Effect of Reduced Visual Field . 45
Effect of Reduced Optic Flow on Gait 46
Processing Spatial Information 127
Effect of a Plaster Cast on Lumbosacral Joint Motion 203
Individual Adaptability and Its Relation to Recovery after Therapeutical Interventions in Patients with Rheumatoid Arthritis 213
Effects of Surgical Decompression on Impairment and Disability Parameters in Cervical Spondylotic Myelopathy . 291

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Page
Development of a Control System for Robots 140

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Page
Development of a Control System for Robots 140

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Page
Effects of Seating Type and Disability Level on Stability during Driving 311

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Page
Finite Element Models Generated from Magnetic Resonance Images 204
Testing of Cushioning Foams to Determine Their Material Response 315

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Page
Special Projects and Demonstration: Applications of Technology to Enhance Quality of Life—A Community Model 133
Trans-Train: Transdisciplinary Training of Rehabilitation Personnel in Assistive Technology 134
Assessing the Capabilities of Independent Living Center Staff to Deliver ADA-Related Services 155
Causes and Costs of Unplanned Rehospitalizations among Persons with Spinal Cord Injury 260
Immune Responses to Pneumococcal Vaccine in Spinal Cord Injury 261
Problem-Solving Skills Training in the Treatment of Pressure Ulcers in Persons with Spinal Cord Injury 320

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Page
Fatigue and Recovery of FES-Activated Paralyzed Muscles . . 85
Rehabilitation of Paralyzed Muscles by Surface FES 96
Simulation of Distal Tendon Transfer of Arm and Forearm Muscles 166

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Page
Mechanical Effects of Muscle Tendon Transfer and Functional Neuromuscular Stimulation 88

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Page

Loads in a Prosthetic Pylon Using Strain Gauges 4
Assessment of the Accuracy and Reliability of Three Hand-Held Infrared Temperature Probes for Clinical Use . . 5
Skin Perfusion Pressure Response Monitor 6
Dynamic Diagnostic Socket/Skin Interface Monitoring Using a Prosthesis Mounted Video Camera 14
Finite Element Models to Assist Prosthetic Socket Design . . 15
Waterski for a Bilateral Above-Knee Amputee 17
Update on the Elastic Strain Energy Discus Leg 18
Artificial Limb Design: Assistant System Using Knowledge-Based Expert System 23
Trans Tibial Suspension Evaluation 23
Neural Network Models to Assist Medical Imaging Systems for Prosthetic Fabrication 24
Calculation of Knee Ligament Loads during Rehabilitation Exercises 35
Effects of Robotic-Assisted Weight Support on Gait and Energy Expenditure 47
Surface EMG Signal Analysis in Normal and Pathological Subjects during Gait by Means of a Novel Algorithm for On-Off Timing Detection 48
Optimal Rigid Body Degrees of Freedom Estimation in Movement Analysis 49
Gait Analysis in TKR Patients 50
Skeletal Muscle Length Force Characteristics during Maximal and Submaximal Activation 164
Kinematics of Human Tremor Using Stereophotogrammetry . 172
Performance Capacity and Physical Strain in Subjects with a Spinal Cord Injury 265
Employment Status among Persons with Spinal Cord Injury: Associations with Need to Work, Creativity, and Need for Stimulation 266
Study of Employers: Experiences and Attitudes of Upper Management and Its Relationship to the Hiring of Persons with Mobility Impairments 267
Modification of Trombone Trigger Allows Performance on the Trombone by Persons with Spinal Cord Injuries 268
Complications of Anterior Cervical Fusion with Plate and Screw Fixation 292
Ergonomics of Manual Wheelchair Propulsion 308

Section III
Author Index

Abadee P 114
Abello G 217, 312
Abrahamson J 234
Abraira C 323
Adam A 56
Adams TC 311, 325
Adler JR 254
Agarwal G 104
Agrawal S 73
Agre JC 169, 170
Ahern D 177
Ahroni JH 318
Albert D 57
Albright SJ 303
Alexander GC 244
Alexander M 218
Alexander NB 101
Almeyda JW 77, 279
Amerson TL 310
Amirouche F 32
An HS 29
An K-N 269
An KN 53, 306
Anderson PG 13, 45, 46
Andersson GBJ 30
Angenot E 265
Anzel S 19
Apple DF 292
Arsenault B 118
Ashton-Miller JA 101
Averbuch M 124
Avignone E 160
Ayyappa E 19

Baan GC 164
Bacon D 138, 147
Bading J 109
Banwell JG 75, 302
Barner K 142
Barstow T 26
Batra HP 62
Beaupre GS 27, 193, 206
Beitler M 139
Bell DA 309
Bell M 221
Bell RB 292
Benedetti MG 36, 37, 48, 50, 172
Bennett JL 222, 326
Bergman RN 323
Berman M 310
Bernards ATM 213
Biggar D 324
Billakanti SR 24
Binard J 304
Binford TO 254
Blackstone S 147
Blanks RHI 226
Blasch BB 247, 248
Bloebaum R 206
Bobbert MF 53
Bodine-Fowler S 116
Bodner D 75
Bodner DR 302
Boissy P 118
Bonato P 48
Bonifay R 304
Boninger ML 303
Boone DA 10
Borenstein J 309
Borowski SR 16
Bortolussi J 324, 328
Bosch P 164
Boschen KA 60, 131
Botte MJ 116
Bourbonnais D 118
Bovelenta P 299
Boyd L 19
Boyette LW 98
Boyko EJ 318
Branch M 101
Brandon JL 98
Brauner DJ 99
Breit G 27
Brienza DM 307
Brookshire RH 240
Brown DA 115

Brown DL 84
Brown TI 4
Brubaker CE 307
Brule N 118
Bruninga K 273
Bryant L 84
Buijs RJC 101, 175, 178
Bulgheroni M 61
Bunag J 32
Burgar CG 115
Burkholder TJ 156
Burrows A 100

Cai W 79, 83, 87
Campbell ML 111
Cappello A 49, 172
Cappozzo A 36, 37
Cariski DL 117
Carlson LE 8
Carter DR 193
Catani F 35, 36, 37, 48, 49, 50, 172
Chahande A 15, 22, 23, 24
Chakkalakal DA 74, 197, 198, 210
Chancellor MB 321
Chandler J 103
Chao EYS 47
Cheesman MF 235
Chen S 137, 139
Cherney LR 121
Chester D 139
Childress DS 1, 3, 6, 9, 12, 16, 20, 42, 327
Ching R 31
Chipman B 138
Chizeck HJ 93
Chow AY 249
Chow CC 36
Christakis P 209
Christini DJ 43, 44
Chui H 109
Churchward TJ 5, 6
Cienkowski K 230
Cochran GVB 199
Cogan S 87
Cogan SS 72
Cohen NL 232
Collier J 211
Collins JJ 36, 38, 39, 40, 41, 42, 43, 44, 55, 100, 101
Collins SR 77
Constantinou CE 268
Contoyannis B 14
Contoyannis C 17, 18, 23
Coogler C 98
Cook SD 207, 209
Cooke RC 289
Coombs F 310
Cooper RA 301, 303, 307
Corlew M 310
Cornelisee L 235
Cors M 128, 304
Cottell CM 196
Couch WP 77, 279
Cox RM 244
Coyle J 104
Coyne S 117
Crago PE 86, 88
Creasey G 75, 302
Cross H 220
Crown D 125
Crozier KS 287
Cumbo J 17, 18, 23

D'Alessio T 48
D'Arco S 230
Dallmeijer AJ 259, 265
Dansereau J 202
Dauzvardis M 293, 294, 295, 296
Davey JP 116
Davis JL 306
Dawicki A 209
de Guise J 202
Deftos LJ 270
Della Croce U 36, 37
DeLuca CJ 38, 40, 41, 42, 44, 55, 56, 62, 63, 71, 100, 101, 157, 158, 160, 173, 174, 175, 177, 178, 179, 180
Demasco P 147
Denison M 6
Devaney LP 274
DeVivo MJ 119, 260
Dewald J 123
Dey A 21, 171, 220
Dirks DD 225
Disler P 6
Ditunno JF 288
Dornay M 85
Dorrough K 267
Downing A 252
Doyle PJ 242, 243
Drace J 27, 254
Dum RP 257
Duncan P 103

Dunlap J 209
Dunn J 230
Dunn RB 73, 83
Durfee WK 214

Edell DJ 274
Edwards LC 158, 255, 323
Einarsson G 170
Eling PATM 126
Elliot TB 320
Emley MS 42, 160, 173, 175, 176, 177, 179, 180
Emmer MB 228, 229
Enwemeka C 166
Erenshteyn R 147
Erim Z 55, 62, 63, 71
Ershler WB 104
Espinosa IF 299
Etter BD 140
Evans C 200
Evenson DP 321
Ewers N 250

Faulkner V 22, 23
Fausti SA 232
Fee JW 190
Fehr LS 256
Feldman DS 319
Ferencz DC 93
Ferrarin M 94, 217, 312
Fields J 273
Figoni SF 51, 77, 279
Firoozbakhsh KK 26
Fischer K 193
Fisher MA 256
Foley C 222
Foley PJ 62
Ford C 104
Foulds R 138, 139, 142, 147
Fowler CG 226, 232
Franke TM 169, 170
Freed DB 241
Friden J 156, 163
Frieden L 155
Friedman J 101
Fritz J 142
From W 313, 314
Fuhrer MJ 130, 149

Galuska S 147
Gans BM 59
Garbarini M 2, 215, 216
Gard SA 16
Garvin KL 74, 197, 198, 210
Gavras H 289
Gayle GW 51
Geil M 68
Gelfand SA 228
Georgiou D 222
Gerhart KD 270
Gerken L 148
Geruschat D 247
Giacomozzi C 61
Giampaoli R 35
Giannini S 50
Giat Y 85, 166
Giddings VL 27, 206
Gilmore LD 157, 160, 175, 176
Giphart JE 174, 175, 177, 178
Given J 123
Glaser RM 51, 77, 278, 279
Glass R 137
Glaus KO 278
Goldish G 214
Goldstein B 281
Goldstein G 104
Goodman R 122
Goodman SB 193, 206
Gottlieb GL 69
Grafton S 109
Grahn EC 3, 6, 9
Gravel D 118
Green D 120
Gregor RJ 26
Grimby G 170
Grodzinsky A 196
Gronley JK 19
Gross M 101
Growney ES 306
Gudavalli MR 28
Gupta SC 51, 77, 278, 279

Haley S 59
Halper AS 121
Hamilton B 64
Hammonds-Smith M 153
Hangartner TN 77
Harari P 104
Harrington R 31
Harris GF 319
Hartke R 125

Harwell RM 231
Harwin W 137, 138, 218
Haskell GB 227
Havey R 28, 293, 294
Heckathorne CW 3, 6, 9
Heinemann A 64, 121
Helt J 216
Hemler PF 254
Hentz VR 269
Herndon TO 274
Heslinga HE 164
Hibler J 124
Hilyer K 266
Hinkens J 144, 145
Hirsch IH 321
Hochstenbach J 224
Hodges S 29
Hollander AP 259, 265
Hong JH 29
Hopman MTE 259, 265
Hopp JF 99
Houston VL 2, 215, 216
Howard GA 272
Howell DS 195
Howell R 138
Howland CA 129, 148, 154, 222
Hu F 15
Huang B 321
Huch KM 289
Huijing PA 164
Hunter JD 292
Hutton WC 196
Hwang MH 255

Isakov E 52, 85, 96

Jabre JF 57, 58, 168, 173
Jacobs CR 193
Jacobs JL 91, 92
Jacobs JR 246
Jamieson DG 235
Janssen TWJ 265
Jaros LA 309
Jayachandran V 137
Jessen JH 159
Johnson FE 277
Johnson MW 82
Johnston M 64
Joyce A 147
Ju Gu M 101
Jutai J 324

Kabo JM 205
Kaegi C 118
Kalnins I 324
Kamper DG 311
Kandarian S 157, 158
Karakostas T 67
Kazi Z 139
Keelor DR 26
Keisler L 117
Keith MW 86, 88
Kelso DP 144
Kemp B 111
Kennell T 106
Kerns JM 298
Kerrigan C 41, 44
Keshavarzian A 273
Keyak JH 192, 194
Khalaf K 65, 66
Khan T 293, 294, 295, 296, 297
Kheirallah S 235
Khouri M 62, 71
Kilgore KL 86
Kilgus DJ 205
Kilmartin DP 252
Kim J 187
King R 125
Kiratli BJ 27
Kirsch RF 88
Kirschner K 122
Knaflitz M 48
Knox EH 12
Kobetic R 90
Kochersberger G 103
Kofman J 313, 314
Koren Y 309
Krag M 180
Krause JS 262, 263, 264
Krebs DE 161
Krouskop T 151
Kulkarni VN 21, 132, 171, 220
Kumpula J 117
Kunkel C 26
Kunz DN 200
Kupa E 157, 158, 160
Kurta L 26

Labelle H 202
LaBlanc KP 2, 215, 216

Langbein WE 255, 256, 301
LaPalombara F 49
Larson BC 274
Larson VD 232
Lavender SA 30
Lawson L 323
Leardini A 35, 36, 37, 49, 50, 61, 172
Lee BY 188, 199
Lee C 201
Lee PVS 11
Lehneis HR 2, 215, 216
Levenston ME 193
Levin KA 77
Levine O 52
Levine R 106, 117
Levine SP 309
Levins J 173, 175, 177
Levitt H 230
Levy M 85
Licameli JN 42
Lieber RL 156, 163
Lieberman JR 205
Liebig PS 112
Liguori R 172
Lim TH 29
Limke J 58
Lin VW-H 282
Linden MA 311, 325
Lineweaver W 316
Linn JG 323
Lipsitz LA 38, 44, 100
List M 186
Little JW 281
Liu LS 296
Lloyd LK 285, 286
Loeb H 323
Logan GD 329
Logemann JA 183, 184, 185, 186, 246
Long RG 247, 248
Longo WE 277
Loren GJ 156
Lorenz M 32
Lorenze EJ 2, 215, 216
Louie EK 255
Lu TW 35
Ludlow L 59
Lutolf J 228, 229
Lyon JG 117
Lysaker P 221
Mace RL 98
Macellari V 61
MacMillan M 271
Magin RL 187
Mahoney R 137
Maiers B 59
Maimon Y 166
Maki KC 158, 159, 255, 258, 323
Malassigne P 128, 304, 310
Maloof P 175
Mancil GL 247
Mancil R 247
Mandell JA 206
Mann JR 274
Mann RW 34, 161, 162, 212
Marcacci M 50
Marcus R 27
Markowski J 280, 317
Marras W 65, 66
Marshall RC 241
Marsolais EB 89, 90, 91, 95
Martin E 270
Mason CP 2, 215, 216
Mathews T 77, 278
Matsumoto K 26
Matthes R 230
McAnear JT 245
McBroom LW 251, 252
McCaffrey M 87
McConnel F 183, 185
McEleney J 180
McGregor M 28
McGuire J 124
McGuire MH 74, 197, 198, 210
McKirgan LW 277
McLane JA 87, 297, 298
McMahon R 125
McNamara B 201
McNeal D 109
McNelis S 176
Meade KP 32
Megrew MB 128
Mehta JM 21, 132, 171, 220
Mehta PP 272
Mendenhall J 143, 250
Merfeld D 160
Merletti R 160
Messing L 147
Meythaler JM 119, 283
Miller GE 140

Millington PJ 57
Milner M 313, 314
Mineo B 147
Mineo K 55, 63
Mingrino A 94
Mishra DK 163
Mitchell JM 110
Mitchell SL 38
Mizrahi J 52, 85, 96, 166
Montanari P 50
Moodie S 235
Mortimer JT 76
Morton P 141
Mulder T 13, 45, 46, 61, 126, 171, 213, 224, 291
Muniz OE 195
Mussman M 216
Mutton DL 26
Myklebust BM 57, 107
Myklebust JB 57, 107, 293, 294

Nanna M 59
Napel S 27, 254
Natarajan RN 30
Nelson AL 304
Nemchausky BA 255, 258
Nicholas LE 240
Nienhuis B 13, 45, 46, 203, 213
Nieto-Sampedro M 299
Nitschke T 310
Noffsinger PD 232
Norris J 79
Nosek MA 129, 130, 148, 149, 150, 151, 153, 154, 155, 222, 326
Novak M 145, 146, 236
Nunn AK 5, 6

O'Connor 35
Oddsson L 174, 175, 176, 177, 178, 179
Orr TE 210
Oslakovic K 20
Ostrander LE 188

Pajak TF 246
Palmer G 177
Parker WD 51, 279
Parnianpour M 65, 66
Parthemore JG 270
Patwardhan AG 28, 29, 30, 32
Pavlik AE 40, 41, 42
Pavlov PW 203, 291
Peachey NS 249
Peckham PH 82, 86
Pedotti A 80, 94, 217, 312
Perell KL 26
Perkash I 27, 254, 268, 269, 282
Perry J 19
Phalangas A 138, 147
Piech R 138, 147
Pietro B 94
Pino D 137
Pizzimenti CE 248
Plowman SA 158
Polcyn AF 44
Polonsky K 323
Ponichtera-Mulcare JA 278
Potter CG 130
Potter PJ 268
Powers CM 19
Powers RK 281
Prendergast P 201
Priebe M 280
Prieto TE 57, 107
Pumpian IR 133, 134
Pusakulich KM 244

Quesada PM 67, 68, 189

Rabuffetti M 217
Radcliffe D 329
Rahman T 137, 138, 218
Rainville J 58
Rajterowski G 71
Ramanathan R 218
Ramji K 235
Rao S 19
Ratcliffe A 195
Redfern M 104
Reger SI 311, 325
Reiber GE 10
Reynolds NC 107
Richards JS 284
Richards L 148
Riedy L 72, 83, 273
Rigby P 313, 314
Riley LH 29
Rintala D 222
Robbins J 104, 106
Robertson RN 301, 303
Robinson C 87
Robinson C 104

Robinson LR 281
Rodgers MM 51, 77, 278, 279
Rodriguez GP 317
Rodriquez AA 169, 170
Roecker E 106
Rogriquez JA 299
Roland JT 232
Roninger ML 301
Rosen JM 167
Rosenbek JC 117, 182, 246
Ross DA 247
Rossi CD 153
Rossi SA 192
Roszek B 164
Roth E 121
Rovick JS 1
Roy SH 42, 157, 158, 160, 173, 174, 175, 176, 177, 178, 179, 180
Rozendal RH 53, 164, 259, 265, 308
Ruff RL 92
Runyan KR 289
Ryan S 313, 314
Ryff C 117

Sabelman EE 97, 167, 269, 316
Saghal V 311, 325
Salganicoff M 137, 139
Salkeld S 209
Salzman SK 321
Salzsieder B 57, 58
Sam M 258
Samworth K 190
Sandler M 147
Sandri G 160
Sane SB 21
Sanford JA 98, 128
Sangeorzan BJ 31
Sartori MJ 141
Saunders G 230
Saunders M 245
Sawyer FD 189
Sax CL 133, 134
Sayers S 293, 294, 295, 296
Scalzitti DA 99
Scarpine V 78, 87
Schauer JM 144, 145
Scheiner A 92, 93
Schenkman M 103
Scherer MJ 70
Schlager TA 290
Schneider AT 235
Schnurr E 304
Schultz AB 101
Schumeyer R 142
Schurman DJ 193
Schwartz HS 200
Scremin AME 26
Scremin OU 26
Seewald RC 235
Segal RL 99
Seliktar R 218
Sha BB 176
Sharon BF 98
Sharp C 138
Sheets DJ 112
Sherwood AM 280
Shoemaker SD 156
Sibert R 147
Sidles J 31
Sietsma M 203
Silman S 228, 229
Silverman CA 228, 229
Simon SR 65, 66, 67, 68, 189
Simoncini L 48
Simpson CD 266, 267
Sims G 27
Sinclair S 235
Skelly M 93
Skinner HB 192, 194
Skorodin MS 159
Smith C 245
Smith DG 10, 318
Smith SL 315
Smuts J 58
Solomonidis SE 11
Somerville N 109
Song G 315
Spagnoletti C 172
Sparto P 65, 66
Spector M 196, 210, 275
Spence WD 11
Stanger C 138
Steege JW 20, 327
Steele C 324
Stern G 147
Stevens E 324
Stewart MR 4, 14, 17, 18, 23
Stone JD 6, 14, 17, 18
Stover SL 286
Strates BS 271

Strick PL 257
Stroud S 218
Strysik JS 9
Studenski S 103
Suh CK 23
Sumanaweera TS 254
Suryaprasad AG 77, 279
Susak Z 52, 85, 96
Sutton C 304
Svanborg A 99
Szeto AYJ 133, 134
Szlyk JP 248
Szollar S 270

Taga G 39
Taylor D 201
Taylor H 179, 180
Taylor I 244
Teeter JO 84
Temkin A 266, 267
Tencer A 31
Thomas I 310
Thompson D 313, 314
Till JA 238
Tillotson GL 118
Tirosh E 96
Tjon A Hen SSK 213, 291
Todd BA 204, 315
Toleikis SC 249
Toutoungi DE 35
Trausch C 293, 294, 295, 296
Trefsger J 142
Triano JJ 28
Triolo RJ 89
Trockman B 79
Tromp EH 127
Trumbo L 59

Uellendahl JE 6, 16
Ulerich PL 307
Umehara S 32

Vaithianathan CT 4
Valero-Cuevas FJ 269
van As H 265
Van der Helm FCT 53
Van der Loos M 136
van der Meulen M 206
van der Schaaf DB 203
van der Woude LHV 259, 265, 308
van Ingen Schenau 53
van Lankveld WGJM 213
van't Pad Bosch P 213
Vanderby R 200
Vanderheiden GC 143, 144, 145, 146, 236, 250
VanDoren CL 81
Vannier MW 2
VanSickle DP 303
Veeger HEJ 53, 308
Venus C 245
Vernava AM 277
Virgo KS 277

Waites KB 261
Walden E 129, 155
Wall BM 289
Walsh JM 73
Walsh NE 24
Walter JS 72, 73, 78, 79, 83, 87, 273
Waltzman SB 232
Wambaugh JL 242
Wang H 204
Watson GR 247
Way T 142
Webster JS 114
Weir RF 6
Wertsch JJ 319
Westerman RA 6
Westzaan P 171
Whalen RT 27
Wheeler JS 78, 79, 83
Whipp BJ 26
Whitestone JJ 2
Whitney JL 239
Wiegner AW 214, 219, 274
Wierzbicka MM 219
Willems M 164
Willems PC 203
Williams HH 289
Willis L 109
Wilson DG 200
Wilson R 237
Winograd CH 97, 101
Winter LW 187
Wolf SL 98, 99
Wood JL 106
Woolsey RM 277
Wright FV 60, 328
Wu Y 6
Wurster RD 83

Wusteney E 101
Wylde MA 108, 305

Yannas IV 275
Yeh C-K 245
Yelamarti A 137
Young L 160
Young ME 222

Zafiriou T 14
Zajac FE 269
Zarow C 109
Zaszczurynski P 72, 78, 87
Zdeblick TA 200
Zindrick MR 29, 32
Zizz CA 226
Zwaard PLJM 126

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