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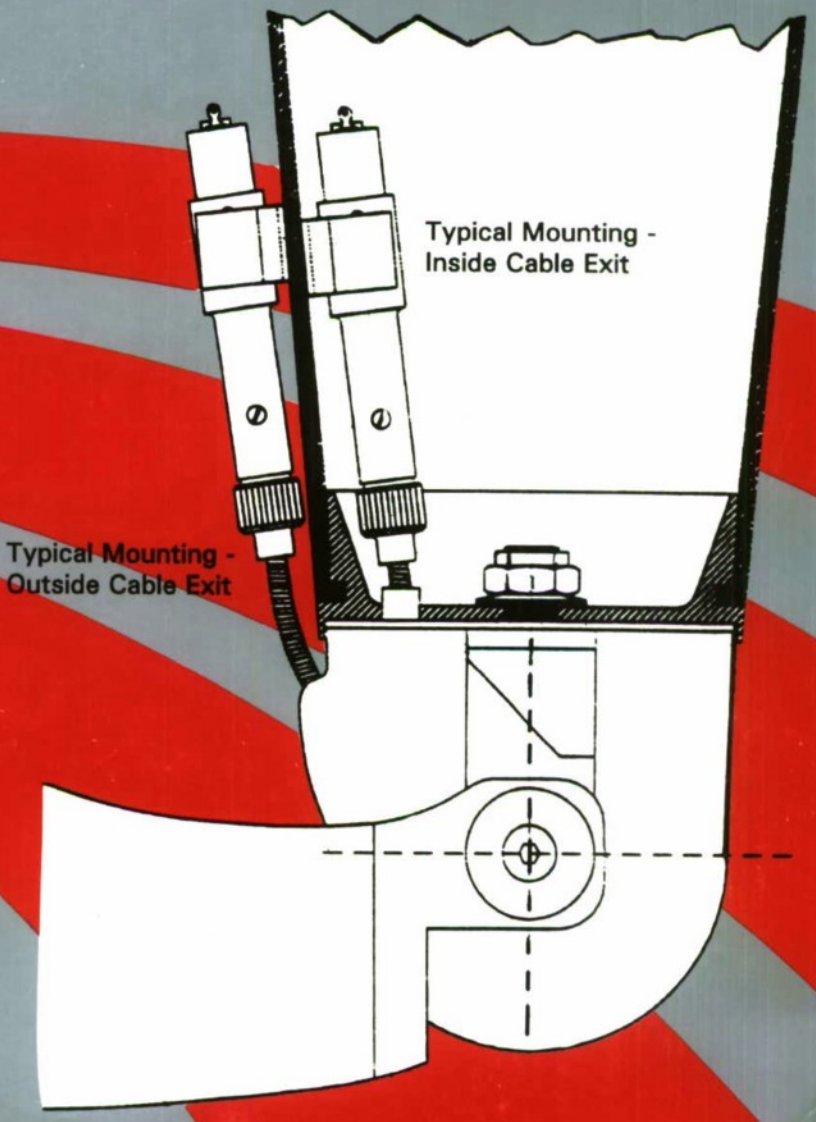
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BIT-96-004

Department of Veterans Affairs

Rehabilitation R&D Progress Reports





Vol 33, June 1996
Veterans Health Administration
Rehabilitation Research and Development Service

1995

ON THE COVER

The Modular Electromechanical Lock Actuator (MELA) is a simple, modular, electrically powered lock actuator designed to be used in conjunction with existing cable-locking elbow and wrist components. The electromechanical lock actuator and the electronic circuit are powered by a single 9-volt rechargeable battery. The overall weight is 26 g and does not contribute significantly to the total weight of the prosthesis. The actuator cycles from locked to unlocked and unlocked to locked. A momentary switch contact is all that is necessary to operate the system through the electronic circuit.

The MELA is the result of research and development (R&D) conducted under the direction of Dudley S. Childress, PhD, at the Northwestern University Prosthetics Research Laboratory (NUPRL), Chicago, Illinois. This work was funded by the Department of Veterans Affairs (VA), Rehabilitation (Rehab) R&D Service. With wide experience with prostheses for persons with high-level, above-elbow amputations, the NUPRL developed the MELA to assist those amputees experiencing difficulty operating existing manual elbows whether with a conventional harness, nudge control, excursion amplifier, or other arrangement.

THE EDITOR

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

Department of
Veterans Affairs

Rehabilitation R&D Progress Reports

1995

Rehabilitation R&D Progress Reports
is a publication of
The Department of Veterans Affairs
Veterans Health Administration

VA Rehabilitation Research and Development Service
Scientific and Technical Publications Section (122)
103 South Gay Street
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20100311129

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Department of Veterans Affairs

Rehabilitation R&D Progress Reports

1995

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I. Amputations and Limb Prostheses

A. General

[1] AN 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—Computer-aided design/computer-aided manufacture (CAD/CAM) in prosthetics has gained wide acceptance in the recent years. Our laboratory has been active in prosthetics CAD/CAM research since its advent. Over the past 3 years, our laboratory has developed a new rapid prototyping method based on additive fabrication. The system, referred to as SQUIRT Shape, fabricates sockets by extruding a continuous bead of molten plastic and laying it down in the desired socket form. This technique eliminates intermediary steps (e.g., fabrication of plaster blanks and carving of socket positives) used in contemporary CAD/CAM of prosthetics, and enables the socket to be fabricated in a single operation.

METHODOLOGY—The extrusion tool is mounted on a computer-controlled manipulator that positions the nozzle in space. As the extruded bead cools, the plastic solidifies, forming a layer of socket wall 0.7 mm in height and 5.0 mm in width. The socket is built by addition of multiple, layered cross-sections. The system uses clinically acceptable plastics (i.e., polypropylene homopolymer) and is capable of fabricating sockets in clinically practical times of 60 to 90 minutes.

PROGRESS—Testing to determine the material strength of sockets fabricated from the SQUIRT system has been completed. Standard ASTM tensile testing was used. Results show that tensile strengths of samples produced using the SQUIRT system were within the range of published values for polypropylene homopolymer (PPH) and polypropylene copolymer (PPC). Specimens were also tested in fatigue-failure studies. Results show that failure was generally not at laminar boundaries and that fatigue life was comparable with normal material. In general, the tests indicate that sockets fabricated using the SQUIRT system are comparable in strength and fatigue life with sockets fabricated using traditional methods. In fact, we suspect actual sockets made by extrusion method are stronger because vacuum forming seldom results in an even thickness of socket walls, which weakens the socket. Also, it is known that vacuum forming often incorporates stresses in the material. Sockets made with the SQUIRT system have a uniform wall thickness and low built-in stresses.

Laboratory trials have been carried out with several trans-tibial amputees, and one active user has been wearing the socket daily for more than 9 months without problems.

RESULTS—The sockets are fitted by first making a plaster impression of the subject's limb using an Ice-Cast pressure casting device. The shapes are digitized with a mechanical digitizer. Rectifications are carried out by a certified prosthetist using ShapeMaker CAD software. The socket is then fabricated using the SQUIRT system. The material used thus far is polypropylene homopolymer, although it is possible to use other plastics. A typical socket, 270 mm in length, contains about 360 layers. An IceRoss silicone suspension liner is used. Off-the-shelf prosthetics hardware

was selected to enable attachment of the socket to endoskeletal components of the artificial limb. A software program is used to form a hardware attachment structure on the distal aspect of the socket.

FUTURE PLANS—Our goal now is to fit a large number of trial subjects with the sockets in order to gain wide clinical experience. Field testing results do not always correspond to laboratory tests of materials. We are working on ways to make standard soft inserts for these sockets, possibly using blow-molding techniques.

[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 equipment and software enabling effective and efficient computer-aided design and manufacture (CAD/CAM) of more intimately fitting, comfortable, and functional prosthetic sockets for US veteran below-knee (BK) amputees.

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

1. Develop transducers, instrumentation, and software for measurement of socket/residual limb interface stresses
2. Develop software for automated detection, identification, and registration of premarked, anatomical features from optical digitizer camera output intensity measurements
3. Investigate ultrasonic digitization of BK 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 measurement instrumentation and mathematical models characterizing the nonlinear, nonstationary, nonhomogeneous, anisotropic, viscoelastic behavior of soft tissues for analysis and prediction of stress distributions in residual limb tissues.

PROGRESS—A force-varying-resistive P-Scan transducer with 1360 elements has been designed and fabricated for measurement of socket/residual limb interface normal and gradient shear stresses. A stepper motor position controlled test fixture, with a linear, servo-actuated, strain-gauge-instrumented, force probe, has also been designed and constructed for transducer testing and calibration. Comprehensive laboratory testing of the P-Scan transducers and measurement system is being conducted. In addition, a servo-actuated, uniform pressure, pneumatic bladder system for accurate, expeditious, clinical calibration of P-Scan transducers is being constructed. Clinical testing of the P-Scan system with two BK amputee test subjects has been conducted. Software for visualization and analysis of the resulting measurement data is being developed.

An algorithm for automated detection of selected, premarked, anatomical fiduciary landmarks from optical digitizer camera output intensity measurements has been developed. To date the algorithm has been successfully tested with optical scan data from 10 subjects. In addition, an algorithm for automated maximum likeli-

hood identification and registration of detected landmarks has been developed. The algorithm currently has been implemented for the 18 fiduciary landmarks most commonly utilized by prosthetists in PTB and PTS socket design.

Laboratory tests have been conducted with the NY VAMC Radiology and Cardiology Services' clinical diagnostic ultrasound units. A prototype stepper motor driven scanning fixture has been fabricated, and numerous scans of two BK subjects' residual limbs and five nonamputee control subjects' lower limb segments have been performed with a variety of ultrasonic transducers. From these tests, requirements for a prosthetics ultrasonic transducer have been formulated that should limit signal intensity and frequency content variations that degrade resulting residual limb acoustic images.

A nonlinear, biphasic viscoelastic model for characterization of the nonlinear, nonstationary, nonhomogeneous, anisotropic, viscoelastic mechanical properties of bulk, soft tissues is being investigated. A prototype servo-actuated, strain gauge instrumented indentor for measurement of the mechanical properties of soft tissue has been constructed, and is being utilized in tests to validate the results predicted by the project nonlinear, biphasic viscoelastic model.

FUTURE PLANS—Refinement and enhancement of the project P-Scan transducer and stress measurement system shall continue. Firmware for CAD system quantitative feedback of socket/residual limb interface stresses resulting from given socket design geometry and material shall be developed. Construction and testing of a prototype prosthetics ultrasonic digitizer is planned. In addition, development of new, improved, biomechanically based CAD socket designs is planned utilizing 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.

RECENT PUBLICATIONS FROM THIS RESEARCH

Automatic detection, identification, and registration of anatomical landmarks from 3-D laser digitizer body segment scans. Geisen GR, Mason CP, Houston VL, et al. In: Proceedings of the 17th Annual Conference of IEEE EMBS; 1995, Montreal, Canada. In press.

[3] POWERED PROSTHETIC HAND FUNCTION: DESIGN ISSUES AND VISUAL FEEDBACK

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Sponsor: *Natural Sciences and Engineering Research Council of Canada*

PURPOSE—There are several documented benefits of powered upper extremity prosthetic hands. Powered prostheses users, lacking tactile and proprioceptive feedback in their prosthetic hands, rely heavily on visual cues when aligning and maintaining objects within their grasp. A detailed investigation using a design method called Quality Function Deployment was used to identify visual feedback as an important design parameter to benefit the functional performance of the prosthesis. There has been little previous research into this important parameter.

PROGRESS—An experimental set-up was devised to relate what areas of the prosthesis the user could see, to the elemental time required to grasp the object. This was accomplished using a miniature head-mounted CCD camera while the prosthesis user was performing a grasping task developed for the test. The elemental time

required to grasp the object was determined using an industrial engineering technique called Methods-Time Measurement. Data were collected for a number of subjects with natural hands as well as several amputees using a variety of prosthetic hands.

Analysis of the collected data showed that the developed grasping task provided adequate variability in both grasping time and visibility. There were no substantial problems regarding the mechanics of collecting and processing these data. Visual feedback of several segments was correlated with grasping time for persons grasping cylinders using their natural hands. When a prosthetic hand was used, correlations were identified between visual feedback and grasping time only when the data were separated by orientation of the test cylinders. The results suggest that the compensatory postures necessary to achieve the desired visual feedback may have an important influence upon the grasping performance of users of electromechanical prosthetic hands.

FUTURE PLANS—The original goal of this research was to provide a measure of performance of prosthetic hands based solely on visual feedback. The lack of correlation between performance and visual feedback for a range of object grasps does not permit optimizing the prosthesis based solely on this parameter. Further investigation into factors such as compensatory postures are suggested in order to obtain a more general understanding of hand configuration and grasping performance.

RECENT PUBLICATIONS FROM THIS RESEARCH

Application of quality function deployment in rehabilitation engineering. Jacques G, Ryan S, Naumann S, Milner M, Cleghorn W. IEEE Trans Rehabil Eng 1994:2(3):158-64.

[4] COMPUTERIZED METHODS IN PROSTHETICS AND ORTHOTICS

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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.

PROGRESS—Work on final calibration of our CODA scanners was 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 is now routinely being collected and processed with these scanners.

Configuration of our multimedia workstation is complete. This platform will serve as both the host for our FEA analysis software, more than doubling our computational power, and as the host for creating the three-dimensional, colored renderings of prosthetic stress distributions.

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 col-

ored pressure/stress wave moving across the limb/socket.

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 monitor pressure during ambulation using sensors that provide many areas of pressure measurement across the surface of the prosthesis.

RECENT PUBLICATIONS FROM THIS RESEARCH

Analysis of trans-tibial prosthetics gait using the finite element technique. Steege JW, Childress DS. In: Proceedings of the Twenty-first Annual Meeting of the American Academy of Orthotists and Prosthetists; 1995 March 21-25; New Orleans, LA, 13-4.

Finite element analysis of below-knee prosthetic gait. Steege JW, Childress DS. In: Proceedings of the 1995 International Mechanical Engineering Congress and Exposition: ASME Winter Annual Meeting; 1995 November 12-17; San Francisco, CA. In press.

[5] MEASURES OF FUNCTIONAL AND PSYCHOSOCIAL OUTCOMES ASSOCIATED WITH THE PRESCRIPTION AND USE OF UPPER EXTREMITY PROSTHESES

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Sponsor: *Ontario Rehabilitation Technology Consortium funded by the Ontario Ministry of Health*

PURPOSE—The goal of the project is to determine what factors predict the long-term, functional use, and user satisfaction with upper extremity prosthetic devices. The work plan calls for a pilot study of the feasibility of collecting the required information, and housing it in a computer database.

PROGRESS—To date, the project team has been working to determine the nature and scope of research that would be required to address the goal described above. With the assistance of two University of Toronto rehabilitation students, the team has done the following: 1) reviewed the literature on outcomes assessment for prosthetic devices to confirm the need for this kind of project and to map out the interplay of relevant factors; 2) begun work to adapt existing data capture tools (e.g., questionnaires completed by clinicians and users), which have been used recently in large-scale studies, to accommodate potentially useful measures of predictors and outcome variables, for use with children as well as adults; 3) outlined a plan for a pilot study to determine the usefulness and validity of the adapted data capture tool; and 4) assuming that the pilot will be successful, identified an appropriate external agency to apply to for

funding for a large-scale, multicentered collaborative project to develop a database and to determine the predictors of good outcomes for users of upper extremity prosthetic devices.

FUTURE PLANS—By spring 1996, we expect to have achieve the following milestones: 1) completion of feasibility study of outcome measures database for upper extremity prostheses, and 2) commencement of work on an externally funded, multicenter collaborative project to partner in database development and sharing, and to determine the predictors of good outcomes for users of upper extremity prosthetic devices.

B. Upper Limb: General

[6] 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 #A306-4DA)*

PURPOSE—We believe it is necessary to develop better control interfaces with inherent sensory feedback if significant improvement in the function of electric-powered upper-limb prostheses is to be achieved. Small tunnel cineplasties, or other surgical procedures, such as the tendon exteriorization cineplasty developed by Robert W. Beasley, MD, which externalize the force and excursion of the muscle, could potentially provide this superior control. Connecting the muscle to a prosthetic component via a controller that embodies concept of extended physiologic proprioception (epp) enables the physiological sensory feedback inherent in the skin, muscle, and other tissues of the cineplasty to inform the user of the state of the prosthesis. 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 multifunctional 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.

METHODOLOGY—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 attempted 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 with 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.

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 these experiments.

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 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. The blind positioning experiments showed similar results. Work done earlier in our laboratory 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 be superior to velocity-control techniques. In addition, tunnel cineplasty offers a number of advantages over control using glenohumeral flexion and conventional harness arrangements.

IMPLICATIONS—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; eliminate the need for proximal harnessing and consequent encumbrance of an otherwise intact physiological joint for certain prosthetic configurations; provide an additional control source to supplement other, more conventional control sources in the fitting of total arm prostheses; and make possible the direct control of individual fingers in prostheses for persons with wrist disarticulation or long transradial amputations.

RECENT PUBLICATIONS FROM THIS RESEARCH

Direct muscle attachment as a control input for a position servo prosthesis controller (PhD Dissertation). Weir, RFff. Evanston, IL: Department of Biomedical Engineering, Northwestern University, 1995.

Quantitative assessment of direct muscle attachment to act as a control input for externally powered prostheses. Childress DS, Weir RFff. In: Proceedings of the 8th World Congress of the International Society of Prosthetists and Orthotists, ISPO; 1995, Melbourne, Australia; 1995:101.

[7] TACTILE SENSING FOR PROSTHETIC HANDS

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Sponsor: *Natural Sciences and Engineering Research Council of Canada; Aastra Aerospace Incorporated*

PURPOSE—Tactile sensing, in the context of this project, describes the ability of a synthetic hand to perceive the objects with which it comes into contact as if it were a real hand. The purpose of this study is to determine if a prosthetic hand can be equipped with tactile sensing using piezoelectric ceramics (PZTs) to detect slippage of an object. If slippage can be detected, a variable force control system can be designed into a child's prosthesis.

PROGRESS—Under slip conditions, PZTs generate electrical signals which can be monitored and interpreted. PZTs have therefore been installed in the fingertips of a VASI 5-9 hand. To interface to the environment, steel has been used as an overlay. Presently, the researchers are also investigating the possibility of placing a backing material behind the piezoceramic, such as rubber, to dampen any vibrations originating in the arm which may be interpreted by the

piezoceramic as a slip signal. However, it has not yet been implemented.

The signals generated by the PZTs are amplified and filtercd to achieve an appreciable signal level, and to isolate the appropriate frcquency spectrum, respectively. Once the signal passes this section, it is sent through an analog-to-digital converter to a PC which performs the slip detection and controls the motor torque to compensate. This would be converted to discrete circuitry in the final design. Also changed for ease of preliminary testing was the motor. The existing prosthesis uses a small, highly geared design to exert a large amount of force upon closure. This makes for a difficult control scheme for modifying the force. For prototyping, a large, high torque design was used since it provides a linear relationship between the grip force and the control voltage. Thus far, there have been some excellent results in the testing. The hand can grasp both heavy and fragile objects with a minimum amount of forcc. If the object is about to slide, the fingers incrcase their grasping force to hold more tightly.

FUTURE PLANS—The next stage will be to implement a force control scheme using the small, highly geared motor design. With a gearbox, the force cannot be reduced simply by reducing the voltage to the motor. The motor must be backdriven to achieve the correct force. This will require a closed-loop force control scheme. Another problem which will have to be solved is that of isolating the PZTs from vibrations occurring in the arm. The rubber backing may aid in this, but another possible solution may be to have a ceramic on the back of the hand which detects arm vibrations and subtracts this from the signal at the fingertips. This is a somewhat simplistic way of viewing the problem, and the concept needs further development.

RECENT PUBLICATIONS FROM THIS RESEARCH

Tactile sensing for prosthetic hands. D'Souza W, O'Beirne H, Naumann S, Uffen D. In: Proceedings of RESNA International '95; 1995 Vancouver, BC; Arlington, VA: RESNA Press, 1995:728-30.

[8] IMPROVING PROSTHETIC PREHENSION

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PURPOSE—The purpose of this research is to improve both body-powered and externally powered prehensors. Projects include:

Vector prehensor: 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 prehensor: 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: Improvements to prehension applicable to any type of prehensor, including anthropomorphic fingers with non-linearly compliant structure and variable hardness finger materials.

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

RESULTS—Several prototypes were designed, fabricated and evaluated, including a Variable Mechanical Advantage (VMA) prehensor and several models of Vector prehensors, one with split hook fingers and the other resembling a TRS Grip III device. The VMA prehensor met its performance specifications, but testing revealed a shortcoming that may limit its utility. When resistance is encountered, the prehensor "shifts gears" into a high force, low excursion mode of operation. However, if the object being grasped is compliant, there is not enough excursion left to continue compressing the object.

The vector prehensors performed well enough in limited amputee testing to warrant further development.

Two areas of development were explored. In the first, a significant cost analysis and redesign effort was undertaken to reduce the manufacturing cost. Using casting techniques, it appears that it will be feasible to produce these devices. The major area of work remaining is to perfect an elastomeric power module which can develop adequate power and provide acceptable fatigue life. Several prototypes have been tested which meet the power specification but not the fatigue life.

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. Further research and development of an elastic power module with longer fatigue life is the next area to focus on.

RECENT PUBLICATIONS FROM THIS RESEARCH

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

Vector prehensors: adjustable voluntary-opening gripping. Carlson, LE, Frey DD, Ramaswamy V, Radocy R. In: Journal of Proceedings, American Academy of Orthotists and Prosthetists 21st Annual Meeting and Scientific Symposium, 1995:50-1.

Efficiency of prosthetic cable and housing. Carlson LE, Veatch BD, Frey DD. J Prosthet Orthot 1995:7(3):96-9.

[9] THE DEVELOPMENT OF A SELF-ADAPTIVE DIGITAL PROCESSOR FOR PROSTHESIS CONTROL

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Sponsor: *Ontario Rehabilitation Technology Consortium funded by the Ontario Ministry of Health*

PURPOSE—The purpose of this project is to develop a microprocessor-based myoelectric controller for powered prosthetics. The digital controller will calibrate itself automatically to the user's myoelectric signals and have the programmability to allow a broad range of control strategies. In addition to allowing amputees to try out a variety of options without the need for calibration, the autocalibrating controller will accommodate changes in the amputee's inputs over the short and long term.

PROGRESS—An autocalibrating controller based on Motorola's 6805 processor family has been developed and tested with two above-elbow amputees. The microcontroller can accept up to four analog inputs (such as myoelectric input or pressure-sensitive transducers) and six digital inputs (such as switches). With this microcontroller, an amputee can control up to six prosthetic functions (three joints in two directions). The system calibrates itself to the level of the user's inputs regardless of the input device being used and the strength of the user's inputs. Software that allows a user to customize the microcontroller for individual use has been developed for an MS-DOS based microcomputer. Together with some serial interface hardware developed in this project, the microcontroller can be programmed and reprogrammed as the amputee and prosthetist try out a variety of strategies. For future versions of the microcontroller, a Windows-based graphical user interface has been developed to allow prosthetists to easily define and change controller configurations.

FUTURE PLANS—The system that has been developed is intended for use by above-elbow amputees but is too large to fit in most below-elbow prostheses. A smaller version of the microcontroller that will fit inside a child-sized prosthetic hand is currently under development.

[10] SIMULATION OF THE DYNAMICS OF THE HUMAN AMPUTATED ARM

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Sponsors: *The Segal Foundation; the Walter and Sandra Kaye Fund*

PURPOSE—The purpose of this study is to develop a model by which the dynamics of the human amputated arm can be simulated.

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. Amputation parameters are represented by the modified anthropometry as well as the modes of reinsertion of the residual muscles and possible flapping of the muscle around the residual limb. Data on the elbow kinematics, muscle tension histories, muscle length-tension, and velocity-tension relationships and joint forces are produced for different activation modes of the muscles.

RESULTS—Preliminary 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 extend the methodology developed to study the effect of muscle reinsertion in cases of upper limb amputation. Factors such as muscle flapping around the residual limband variations in anthropometric data due to amputation will be included in the model.

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.

[11] DESIGN OF A NEW PROSTHETIC HAND WITH TWO DEGREES OF FREEDOM IN THUMB MOVEMENT

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Sponsor: *None listed*

PURPOSE—The purpose of the present research is to improve the quality of grasping performance for child prosthetic users by developing a new prosthetic hand with two degrees of freedom in thumb movement. Currently, there are several commercial options available for prosthetic hands; however, none

of them has the function of two degrees of freedom in thumb movement for children. The new design is expected to improve overall grasping performance.

PROGRESS—After detailed study, we generated two possible solutions to achieve two degrees of freedom in thumb movement: 1) motorized control in which the movement of thumb is controlled by a micro motor installed near the thumb, and 2) mechanical control in which the movement of the thumb is achieved by pushing the thumb to the desired position. A focus group of therapists, prosthetists, engineers, and technologists with recognized experience working with children and powered upper-limb prostheses concluded that a prosthetic hand with mechanical control was more likely to be the first choice for a child user. This is because the size and weight of prostheses are very important design considerations, and easy training and learning are also major considerations. A computer software package is being used to develop a three-dimensional model to verify design solutions. A preliminary analysis is ongoing in order to synthesize the best design solution and to avoid further unnecessary cost.

FUTURE PLANS—After a concept design is developed and implemented, function will be compared using the currently available prostheses and the new design in the aspect of grasping abilities, functional characteristics, and overall performance.

B. Upper Limb: Above Elbow

[12] ELECTRIC HUMERAL ROTATOR

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PURPOSE—It is recognized in prosthetics practice that humeral rotation—inward and outward rotation of the forearm along the axis of the humeral section—is 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 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 facility 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 (20 pound-inches). A high-friction coupling pro-

vides 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 (72 pound-inches).

The rotator design is intended for use with either body powered 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—Following evaluation of a laboratory test set-up, a prototype rotator has been constructed in a size and shape appropriate for 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.

FUTURE PLANS—If tests confirm that the performance of the humeral rotator meets the design criteria, we will proceed with development of a second, lighter 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.

[13] DEVELOPMENT OF A MULTIFUNCTION MYOELECTRIC CONTROL SYSTEM

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Sponsor: *The Whitaker Foundation*

PURPOSE—Our goal is to investigate myoelectric signal characteristics as they affect pattern classification based multifunction control systems.

METHODOLOGY—Myoelectric prostheses are well accepted by below-elbow amputees but less well by those with higher level amputations. The primary limitation at present lies in the control system.

A new control strategy has recently been developed which promises to give all amputees greater functionality in their replacement limbs. The new strategy is based on the recognition of patterns in the myoelectric signal. Although excellent results have been achieved in the laboratory, much work is necessary to optimize a control system for clinical use based on this approach.

The objective of the proposcd research is to investigate myoelectric signal characteristics as they affect pattern classification based multifunction control systems. Specifically it is proposed:

1. To develop a method of predicting acceptable system performance by analyzing the myoelectric signal acquired from normally limbed and amputee subjects to determine the effects of elcctrode position, electrode separation, and contraction type on the observed myoelectric pattern features
2. To determine the performance of myoelectric pattern classifiers based on supervised and unsupervised learning
3. To design and develop an improved multifunction myoelectric control system based on the results obtained from 1 and 2 and evaluate several prototypes on amputees at our prosthetic fitting centre.

A key element of the research is an investigation into methods of training the amputee to use the new control system. The training approach will depend upon the age of the amputee. The control system for young children will be based on a recognition scheme that allows the designer to assign a prosthetic function to a specific myoelectric pattern produced by the child. A study will be developed to determine if the child can then learn the association between a particular muscle contraction and the corresponding artificial limb movement.

The results will provide valuable guidance to designers of pattern-based myoelectric control systems and to the clinical staff who fit these systems.

B. Upper Limb: Below Elbow

[14] LIGHTER WEIGHT ELECTRIC PREHENSOR

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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 effectiveness of this configuration is attributed to two principal characteristics. First, the cable linking the elbow to the movement of the physiological shoulder provides control of the elbow's position, speed and acceleration, as well as perception of those quantities through the shoulder's proprioception. Second, the electric-powered prehension device produces grip forces three to four times greater than is possible with a cable-actuated split hook and allows maintenance of low forces (for delicate handling) without physiological effort to sustain the gripping force.

In spite of its advantages, the hybrid configuration is typically not appropriate for persons with short residual limbs due to the weight of the electric prehension device. Flexing the mechanical elbow against the weight of the prehensor and forearm requires high operating forces generally not achievable by these persons. Furthermore, the prehensor's weight and its distal concentration of mass can significantly reduce the range of space in which the user can position the entire prosthesis using movement of the shoulder joint.

Although it is possible to utilize a mechanical elbow with a mechanism to counter-balance the weight of the electric prehensor and forearm or to use an electric elbow and thus greatly reduce the operating forces associated with flexing the elbow, these configurations only increase the overall weight of the prosthesis. Any increase in total prosthesis weight generally further compromises the range of space in which the user can position the prosthesis.

As an alternative, we have proposed to develop a lighter electric prehensor for use by adults. By reducing the weight of the prehensor, we believe it will be possible to fit the hybrid configuration to a broader range of persons with upper-limb amputations, especially persons with short transhumeral limbs, and without significantly compromising their ability to position the prosthesis in space.

METHODOLOGY—The Lighter-weight Electric Prehensor (LEP) is based on the design of our laboratory's Intermediate-size Electric Prehensor (ISEP), which, in turn, was derived from the design of our Synergetic Prehensor. The ISEP was intended for older children and adolescents. It had lower performance characteristics in comparison to the Synergetic Prehensor, so as to achieve a smaller package and simpler mechanical arrangement.

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 (10 lb-force) 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. Clinical observations suggest that slower finger closing speed may be an acceptable tradeoff for higher grip force.

With the #5 size hook fingers, we expect the LEP to weigh 230 gm (0.5 lb), two-thirds the weight of the Steeper Powered Gripper or Centri Ultralite Hand.

PROGRESS—A preliminary design for the Lighter-weight Electric Prehensor 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.

Two prototype units have been fabricated. These are undergoing tests to verify that they meet the design criteria.

FUTURE PLANS—We expect to have one of the two prototypes available for field evaluation. Our first test subject had been an evaluator of the earlier Intermediate-size Electric Prehensor 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.

[15] BIOMECHANICAL STUDY TO IMPROVE GRIP IN CHILDREN'S TERMINAL DEVICES

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Sponsor: *National Institute on Disability and Rehabilitation Research, Washington, DC 20202*

PURPOSE—Clinicians know that young children have difficulty getting a good grip with body-powered terminal devices, and this problem is especially acute in the toddlers and preschoolers. Before attempting new designs or recommending changes in prescription criteria, the investigators are gathering objective measures of children's strength and the mechanical work requirements for operating terminal devices. Results of this study should point to new directions for research and development for the investigators and others.

PROGRESS—Work accomplished during this project has verified that:

Children aged 5 years and older generally have sufficient strength to operate body-powered prehensors, but children aged 4 years and younger do not. As a result, younger children have insufficient grip force to hold objects and perform daily activities.

Today, parents of very young upper-limb deficient children want hands rather than hooks or other non-hand prehensors. Parents want a hand that is smooth in appearance and soft in feel. Present mechanical hands are hard in feel and have efficiencies of only 25-27 percent.

After quantifying the amount of work that children generate and the amount of work required to operate a prehensor, it was clear that we needed to develop a toddler hand which is more efficient than those currently available. The present focus of this project is to design and develop a child-size, mechanical, body-powered hand which meets established criteria and which is acceptable and useful to young children and their families.

To achieve the desired goal of having a smooth and soft hand, an endoskeletal design is being explored. The endoskeletal structure currently being investigated uses hollow plastic tubes for the fingers. The tubes are notched to provide joints. Plastic cable runs through the tubes so that pulling on the cables flexes the fingers.

Two concepts are being investigated to cover the endoskeleton. The two approaches under consideration are:

An endoskeletal hand covered with foam and replaceable fabric glove. There are newly available "Gore-Tex" types of fabrics with membranes that are stretchable and waterproof and would make good covers for mechanical hands. These fabrics come in different colors and textures suitable for gloves.

An endoskeletal hand covered with self-skinning foam. Polyurethane is likely the foam of choice. The concept is to "pot" or encase the endoskeletal structure in foam with a "built-in" skin so that no glove is required. The result would be a lightweight, sturdy, and soft hand that would be inexpensive and replaced when necessary rather than repaired.

RECENT PUBLICATIONS FROM THIS RESEARCH

Myoelectrics versus body power: is body power operation of upper-limb prostheses feasible for young limb-deficient children? LeBlanc M, Shaperman J, Setoguchi Y. In: Proceedings of the 20th Annual Symposium of the American Academy of Orthotists and Prosthetists; 1994; Nashville, TN, 1994:46-7.

Prehensor grip for children: a survey of the literature. Shaperman J, LeBlanc MA. J Prosthet Orthot 1995:7(2):61-4.

[16] DEVELOPMENT OF THE OMNI PASSIVE WRIST UNIT

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Sponsor: *Variety—The Children's Charity*

PURPOSE—It is obvious that hand function would be improved markedly by the introduction of a wrist unit that could provide passive flexion and extension, in addition to its current feature of pronation and supination. It would also be desirable to have the resistance of the above movements readily adjustable to suit individual user needs.

PROGRESS—A compact design was completed to meet the above requirements. The new arrangement can provide flexion and extension totalling 60° in all directions. A preproduction unit was fitted to a client and assessed by the clinical team. The feedback was positive. The product was released to VASI for production and is now available commercially. While the OMNI wrist prototype was shown at a conference in Europe, it was suggested that we integrate it with the current VASI powered wrist unit. This combination will offer more function, in particular to the high level amputee. In response to this, we designed and built three prototypes of this configuration to verify the arrangement. This spin-off product is also available from VASI.

C. Lower Limb: General

[17] 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 #A092-7RA)*

PURPOSE—Our goal is to advance research and development on prevention of limb loss, wound healing, amputation surgery, rehabilitation, prosthetic devices, and functional outcomes measurement.

METHODOLOGY—Engaging in fundamental prosthetics research, clinically implementing new technologies, and providing education through the following specific projects: 1) Automated Fabrication of Mobility

Aids (AFMA) system for fabricating and aligning prosthetic sockets and cosmesis; 2) revising current post-operative protocols; 3) conducting basic research in prosthetic kinematics; 4) creating an computer interactive gait training tool; 5) developing an automated custom insole fabrication process and designing and testing prototype shoes for patients with diabetes and neuropathy; 6) designing functional outcomes evaluation tools; and 7) developing a gait activity monitor for clinical use.

PROGRESS—PRS developed the AFMA training program to facilitate transfer of the AFMA technology to VA clinical service. An intensive 5-day course trained 46 VA prosthetists, followed by a 3–5 day site visit by a PRS staff member to provide technical assistance to each participating VA clinical facility. PRS staff members continue to provide needed technical support. During the past 18 months, 36 VAMC sites have incorporated AFMA into their routine patient care, resulting in significant annual cost savings to the Prosthetic and Sensory Aids Service.

The 1969 PRS VA Amputee Management Text has been edited for publication and release in CD-ROM format. A new text incorporating current practice is now being written for publication in both traditional print and CD-ROM formats.

PRS conducted preliminary artificial limb shank material and response tests to help develop prosthetic standards for the International Standards Organization (ISO), which will be used in the future design and fabrication of artificial limbs.

PRS developed an interactive computer gait simulator for use as a teaching tool by orthopaedists and prosthetists. A CD-ROM version of this video is now available for both Windows and Macintosh platforms to help clinicians gain mastery of amputee gait and prosthetic alignment. PRS staff also completed computer-based education kiosks for patients with arthritis and diabetes, using technology applicable to any database. The patient and professional resource contains easily accessible information on symptoms, self-care, and complications.

After extensive evaluation of commercially available digitizing devices, PRS developed a non-contact laser digitizer. Combined with PRS-authored software, PRS-generated templates, and an off-the-shelf milling machine, PRS extended the AFMA system to the foot by creating an automated custom insole fabrication process. These insoles fit the internal contour of our PRS-developed prototype extra-depth shoe for patients with diabetes and neuropathy. Shoes based on the final of several last iterations are currently being constructed to be used in a small trial designed to test the revisions. Upon completion of a pilot test of the original prototype shoes, worn alone or in combination with either cork or polyurethane insoles, we will propose a 3-year clinical trial.

A self-administered prosthetic evaluation questionnaire (using visual analog format) has been developed to evaluate the impact of artificial limbs on patient's functional status and satisfaction. Repeated measures validation testing of this tool in a prospective group of 120 stable, unilateral below-knee amputees will be conducted by PRS in conjunction with the Seattle VAMC.

PRS staff designed a Gait Activity Monitor (U.S. Patent Pending) to measure gait in nonlaboratory settings. Once engineering enhancements in the sensor design are complete, we will build up to 20 prototype units and begin a reliability and validity study to compare self-reported and interviewer-obtained levels of activity with the Gait Activity Monitor data.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Device for objectively evaluating the functional outcome of prosthetic, orthotic or medical treatment. ColemaNesset KC, Smith DG, Joseph AW, Borchers RE, Boone DA, Macomber G. In: Abstracts of the International Society for Prosthetics and Orthotics 8th World Congress. Melbourne, Australia 1995:74.

Independent contributions of diabetic neuropathy and vasculopathy in foot ulceration: how great are the risks? McNeely M, Boyko EJ, Ahroni JH, et al. Diabetes Care 1995:18(2):216-9.

Numerical comparison of 3-D shapes: application to the insensate foot. Borchers RE, Boone DA, Joseph AW, Smith DG, Reiber GE. J Prosthet Orthot 1995:7(1):29-34.

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 1995:38(1):44-7.

PRS above-knee prosthetic socket design for CAD/CAM. Boone DA, Mathews D, Burgess EM, Smith DG. In: Journal of Proceedings American Academy of Orthotists & Prosthetists 21st Annual Meeting & Scientific Symposium; New Orleans, LA 1995:61-2.

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

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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 initial 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 fifteen different prosthetic foot types in several orientations of contact.

A single unilateral trans-tibial amputee 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 15 prosthetic foot types has been completed for 4 foot/ground contact orientations: heel contact (−15° shank angle), heel off (0° shank angle), forefoot (+15° shank angle), and terminal double support (+30° shank angle). Data acquisition and analysis has been completed on the initial amputee walking trials.

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. The data for each of the 15 feet shows an increase in deflection and a shift of the center of pressure toward the toe when shank angles are increased. In this way, the feet have characteristics similar to a cantilever beam. The parameters of a cantilever beam model were fit to the measured foot data, in order to unify the relatively disparate data for each foot at several different testing orientations. The data from the amputee walking trials correlate well with the mechanical characterization of the feet in terms of both deflection and center of pressure location at the specific testing orientations. The effective shape that is created by the foot during walking trials is mapped in the sagittal plane as a function of the shank orientation and the center of pressure location. The preliminary results indicate that the SACH foot creates a relatively flat shape during single limb stance, where the center of pressure migrates quickly to the mid-forefoot area (analogous to the MTP area in humans) and remains there until opposite heel contact. In contrast the Flex Foot creates a noticeably more curved foot shape, where the center of pressure progresses slowly and consistently toward the toe throughout stance phase.

FUTURE PLANS—The amputee walking study will continue with other amputees.

RECENT PUBLICATIONS FROM THIS RESEARCH

Do shoes influence the forefoot mechanics of prosthetic feet? (Abstract). Childress DS, Sandifer A, Knox EH. In: Proceedings of the 8th World Congress of the International Society for Prosthetics and Orthotics; April 1995, Melbourne, Australia, 1-7.

[19] IDENTIFYING UNDERLYING BONE STRUCTURE, SURFACE CONTOUR, AND PRESSURES IN THE TRANSTIBIAL AMPUTEE

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PURPOSE—The purpose of this investigation is to study the relationships between surface contour, underlying bony contour, and surface pressures generated inside the socket during ambulation in the transtibial amputee. This information will improve CAD/CAM strategies to minimize surface pressures, thereby increasing the chances of a successful fit with the first CAD/CAM socket.

METHODOLOGY—There were six transtibial amputee subjects in this study (five unilateral and one bilateral). All participants had been ambulating for at least 6 months with mature, well-formed residual limbs. A CT-scan was performed of the residual limb to look at bony contour, and surface contour was studied by the San Antonio Laser Imager. A CAD/CAM socket was then manufactured, and the amputee walked wearing the socket with an in-socket force sensor to measure socket-residual limb interface forces.

PROGRESS—All data have been collected and data analysis is under way. Preliminary subject data analysis shows highest pressure over the distal anterior tibia, lowest pressure over the posterior residual limb muscles, and intermediate pressures over the mediolateral pressure points. We are still analyzing skin surface and bony radius of curvature, as well as in-socket pressures during gait to determine if areas of small radius of curvature on the skin surface correspond to areas of small bony radius of curvature, and also to areas of high pressure inside the socket.

C. Lower Limb: Above Knee

[20] TO DEVELOP A BIOMECHANICAL MODEL OF THE INTERFACE BETWEEN THE RESIDUAL LIMB AND THE PROSTHESIS FOR TRANS-FEMORAL AMPUTEES

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Sponsor: *Engineering Physical Science Research Council*

PURPOSE—The program of the research will be directed toward the generation of a finite element (FE) model of an amputee's residual limb, which model is 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 would allow a reduction of fitting errors and hence improved delivery of service to the physically disabled population.

METHODOLOGY—Several areas of research have been identified and attempted which will lead to the

creation of an accurate 3-dimensional model of the residual limb. These areas include tissue mechanical properties studies, magnetic resonance imaging (MRI), 2-D FE modelling, amputee gait analysis, and interface pressure measurement.

The mechanical properties of biological soft tissue (porcine skin, muscle, and liver) were tested using an Instron machine. FE models were created to outline the procedures and methods in modelling soft tissue.

We have collaborated with the Institute of Neurological Sciences (Glasgow University Department) of the Southern General Hospital in Glasgow to obtain geometrical detail of the residual limb using MRI techniques, providing geometrical details for the creation of FE models.

2-D FE modelling of the transverse section of the residual limb was attempted to understand the behavior of muscles in terms of movement and mechanical properties.

Amputee gait was studied using a VICON motion analysis system, providing realistic loading and boundary conditions for the FE model. The model predictions will be validated by measuring the interface pressure between the socket and the residual limb.

Commercial FE codes (Ansys, Abaqus and Patran) will be utilized.

PROGRESS—MRI scans, gait analysis, and interface pressure measurement are currently being performed.

RESULTS—The potential of using FE method to model soft tissue has been shown in porcine tissue studies which have been carried out. The 2-D model of the residual limb has highlighted the complication involving modelling the complete limb with musculature detail. The model was able to show significant movement in the musculature introduced by prosthetic socket loading.

RECENT PUBLICATIONS FROM THIS RESEARCH

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

Magnetic resonance imaging of the trans-femoral residual limb. Lee PVS, Solomonidis SE, Spence WD, Condon B, Hadley D. In: Proceedings of the 8th World Congress of ISPO; 1995, Melbourne, Australia. 1995:127.

Study of the biomechanics of residual limb / prosthesis interface in trans-femoral amputees. Lee PVS, Solomonidis SE, Spence WD. In: Proceedings of the 8th World Congress of ISPO; 1995, Melbourne, Australia. 1995:79.

[21] DESIGN MODIFICATION OF THE VAN NES PROSTHESIS: A STUDY OF ANATOMICAL AND PROSTHETIC JOINT MOVEMENT

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PURPOSE—The purpose of this research project is to improve the functional capabilities of a person with a Van Nes prosthesis. This is accomplished by redesigning the prosthetic knee joint to better harness the motion of the Van Nes rotated ankle joint, as well as allowing for a greater range of motion at this joint. The following objectives have been set in order to reach this main goal: to measure motion of the affected ankle joint, to model the motion of this anatomical joint and the prosthetic joint, to develop a parametric prosthetic joint design and location technique, and to verify the model.

PROGRESS—The study group consisted of people who have had the Van Nes or rotationplasty surgery to treat proximal femoral focal deficiency (PFFD), which is often accompanied by associated deficiencies of the lower limb. The study involved gathering three-dimensional motion data for plantar- and dorsi-flexion of the rotated ankle-foot outside the prosthesis, first with no load, and then with increasing loads.

Displacement data were collected with the VICON system and used to create a computer model of the rotated ankle joint on which the modified design of the

mechanical prosthetic knee joints could be based. The biomechanical analysis revealed that subjects used two types of motion: a hinge-like motion similar to that of the prosthetic knee joint, and a twisting motion at about 45° to the joint axis. It was found that by moving the center of rotation of the prosthetic hinge joint relative to the malleoli during stance and swing, moment and range could be increased, respectively.

FUTURE PLANS—It is anticipated that the design improvement, when implemented, will contribute to the overall performance benefits of this still somewhat controversial surgical procedure, which offers a functional alternative to PFFD management by Syme's amputation (right at the ankle) and knee arthrodesis.

RECENT PUBLICATIONS FROM THIS RESEARCH

Van Nes anatomical and prosthetic joint motion and co-function: towards design modification of the Van Nes prosthesis. Carson MC, Naumann S, Cleghorn W, Milner M. In: Proceedings of RESNA International '95; 1995 Vancouver, BC; Arlington, VA: RESNA Press, 1995:183-5.

[22] FEMORAL DISPLACEMENT IN ABOVE-KNEE SOCKETS

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PURPOSE—The purpose of this work is to produce an ultrasonic device that will enable the measurement of the location of bony structures within the body with respect to prosthetic/orthotic structures while a prosthesis or orthosis is being used. The goal is to develop portable ultrasonic devices that amputees or orthosis users can wear during ambulation. For example, transducers of this kind could be used to track the movement of the femur with respect to an above-knee amputee's socket during walking.

PROGRESS—A functioning prototype has been developed. The signal-to-noise ratio is around 20 dB and distances from the skin surface to the humerus in the arm and to the femur in the leg have been measured. Work is now centered on the issue of portability. The large current requirements of the ultrasonic transducer made it necessary to use D-cell batteries as the power source; ways to reduce this requirement are being sought.

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 pulse is made to correspond linearly to an output voltage between zero and ten volts. Knowing the speed of sound in tissue (~1540 m/sec), the output voltage can be used to establish the distance measurement.

FUTURE PLANS—Future work includes testing the device for accuracy using the reflected signal from the other side of the leg and the testing of the system on amputee subjects during ambulation.

[23] DEVELOPMENT OF A PAEDIATRIC ABOVE-KNEE ENDOSKELETAL RUNNING PROSTHESIS

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PURPOSE—The purpose of this research project is to develop a running prosthesis that will enable smooth and efficient gait for children between the ages of 5 and 12 with an above-knee amputation.

PROGRESS—Two primary areas of work have been undertaken: 1) the development of a three-dimensional computer simulation of nondisabled and prosthetic gait, and 2) the design and development of a multicomponent above-knee prosthesis to be used in running and other intense physical activities. Completed during an engineering master's thesis, the computerised gait simulation was developed on mechanical engineering software using a three-dimensional forward dynamic method integrating acquired nondisabled gait data with a biomechanical model of the lower body.

Following successful simulation of nondisabled movement, the biomechanical model was modified to approximate prosthetic gait. Various components were specified as a result of earlier analytical work, such as a polycentric knee linkage (stability), knee damping (stability/velocity control), and a shank/shock absorber (support control). Computer simulation of nondisabled and above-knee amputee gait has been successfully completed for both walking and running, where simulation of nondisabled gait yielded biomechanical gait characteristics comparable to experimental data.

Simulation of the prototype prosthetic gait demonstrated an improvement in the body's center-of-mass trajectory and control of knee flexion during the swing phase of gait. These results demonstrated sufficient promise to embark on development of a prototype. Manufacture of prototype components has been completed, resulting in a lightweight unit with a knee-to-foot length of approximately 13-14 inches, suitable for children of this age group. In order to ensure satisfactory strength of the components for testing on Centre clients, development of a cyclic testing device to meet International Standards Organization test standards for lower-limb prosthetics has been completed. An electropneumatic testing device was developed to cycle the knee unit over 1 million times to ensure design integrity.

FUTURE PLANS—Prototype evaluation is the next step of this product's development. Mechanical testing of the prototype will be completed to ensure design integrity, then field testing of a suitable client of the Centre will follow. A suitable client will be provided with a prototype to wear for an appropriate duration. Thereafter both subjective testing of the client's impression of the device and objective testing through gait analysis will be performed. Following this preliminary evaluation, any identifiable design changes will be made, and a second round of testing will be carried out on a number of client's in centers across the province. The conclusion of the research and development phase of this project will be followed by commercial manufacture and distribution of the product.

C. Lower Limb: Below Knee

[24] PROSTHETIC FOOT DESIGN FOR THE DYSVASCULAR BELOW-KNEE AMPUTEE

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PURPOSE—Diabetes mellitus or peripheral vascular disease contributes to nearly 70 percent of lower-limb amputations. Fifty-five percent of amputations occur at the trans-tibial level, causing significant alterations in gait mechanics. Despite new prosthetic designs, energy cost of walking among persons with a below-knee amputation is nearly 40 percent greater than normal. Strong individuals can overcome many prosthetic limitations by selective posturing and increased muscular activity. However, among persons with a dysvascular amputation, lower extremity strength may be insufficient, resulting in decreased walking ability.

This project's goal is to facilitate the design of a new prosthetic foot which provides knee stability while preserving energy for the individual with dysvascular amputation.

PROGRESS—Individuals participating in the study of strength and stride characteristics now number 25, and the hip extensors have emerged as a more significant muscle group during walking than was previously identified. The effects of heel compression and hindfoot pistoning were evaluated using three different motion marker systems to compare barefoot and shod walking. Eight subjects have completed gait testing wearing each of the three different prosthetic feet. Data from three of these individuals has been comprehensively analyzed.

RESULTS—*Foot-Coordinate Systems.* Three combinations of anatomical markers (i.e., foot-coordinate systems, FCS) were used to measure foot/ankle motion during gait. Barefoot ankle motion showed excellent agreement between the three FCSs. The hindfoot FCS, consisting of the lateral, dorsal, and hindfoot markers, proved to be the most sensitive in measuring heel compression. A comparison between the hindfoot FCS and the forefoot FCS (comprised of lateral malleolus, dorsal, and lateral foot markers) demonstrated that the traditional hindfoot FCS measurement included heel compression and overestimated plantarflexion during loading response. A 3.0° difference in peak terminal stance dorsiflexion between the hindfoot and forefoot FCS was also identified. During stance both the forefoot and dorsal FCS (made up of lateral and dorsal foot markers) recorded lower dorsiflexion values, while the hindfoot FCS showed a pattern similar to barefoot walking.

Comprehensive Gait Analysis. The first three participants to complete testing on all three prosthetic foot designs represented some of the most able walkers in this group. Of the three feet tested, average gait velocity was fastest for the Flex-foot (74 m/min) and slowest for the Single axis (67.5 m/min). All three designs provided inadequate plantarflexion during loading response (Seattle-lite exhibiting 1°, Flex-foot 5°, and Single axis 8° of plantarflexion). Use of the forefoot FCS revealed that 60–90 percent of previously recorded apparent plantarflexion was the result of heel compression. Limb stability, dependent on the transition from initial heel contact to foot-flat, was reduced by prolonged heel only contact for each of the three feet. Foot-flat occurred at 26 percent of the gait cycle for the Seattle-lite, 22.5 percent for the Flex-foot, and 18 percent for the Single axis foot (compared to normal at 10 percent).

Center of pressure normally progresses at a uniform rate during loading and stance. Of the three prosthetic feet tested, only the Flex-foot shows a similar progression to normal. It had no reversals in progression and two changes in rate during loading and stance. The

Seattle-lite foot also had no reversals but three to four rate changes in progression. By contrast, the Single axis foot demonstrated both reversals of direction and four to five changes in the rate of progression, indicating stance phase instability.

IMPLICATIONS—Although the Single axis foot produced the earliest foot-flat posture, its irregular rate of progression results in the highest degree of stance instability. The specific consequences of this instability have yet to been discerned.

RECENT PUBLICATIONS FROM THIS RESEARCH

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

Energy expenditures during ambulation in dysvascular and traumatic below-knee amputees: a comparison of five prosthetic feet. Torburn L, Powers CM, Guiterrez R, Perry J. J Rehabil Res Dev 1995:32:111-9.

Measurement of ankle motion while walking in shoes. Rao S, Bontrager E, Fontaine C, Perry J. Gait Posture 1995:3:80.

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

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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/residual limb. Additionally, we intend to develop computer design guidelines based upon the prosthesis/limb mechanics during gait as well as incorporate new techniques for determining complete below-the-knee limb geometry, techniques which do not rely on CT imaging.

METHODOLOGY— Our work to date on contact analysis has consisted of applying the procedure to a physical model of the residual limb/prosthetic socket system. A three dimensional finite element model of a generic, approximate residual limb was created. The surface geometry of the limb was approximated as a tapered elliptical cone, for simplicity. The internal geometry of the limb was generated from digitization of an anatomically accurate model of the joint capsule of a below-knee residual limb. These geometries were then mapped onto a pre-existing finite element mesh of a hollow, capped end cylinder. The resulting mesh is a layer of elements with an outer surface described by the tapered ellipse, and an inner surface described by our digitized model. The external surface data was then exported to a CAD/CAM socket program, Shapemaker, and a standard PTB rectification template applied to the limb surface data. This was then defined as a non-uniform rational B-spline surface (NURBS) to be used in our model as an analytical description of the socket surface. The socket was then defined as a rigid body described by the NURBS geometry and merged with the finite element model of the limb. This rigid surface was then slowly moved onto the limb to simulate the actual donning process.

The physical model was generated from the same data used in development of the finite element model. Shapemaker software was used to generate CAD/CAM carver files to allow carving of positive molds of the internal shape geometry, unrectified surface geometry, and rectified socket geometry. Two polypropylene sockets were pulled from the rectified and unrectified surface molds. The internal surface model was suspended within the unrectified socket and a silicone gel was poured into the socket and allowed to cure. After curing, the silicone encased internal surface model was removed from the socket/mold. This served as the physical model of the limb. Kulite pressure transducers were then mounted in the wall of the rectified socket to allow measurement of the interface pressures.

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. We also believe that this procedure can be used to model the donning of the prosthetic socket for quantification of the tissue pre-stresses generated before weight bearing.

Our work on investigating socket donning to date has consisted of design and fabrication of a generic physical model to approximate the residual limb/prosthetic socket system geometry and stiffness, and the development of FEA models to describe this physical model. The measurement of stresses generated by the pushing of the physical socket model onto the limb model will serve as validation of the accuracy of our FEA contact models.

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 these scans includes both bone and tissue boundaries and is thus well suited for finite element model generation They have provided us with their first and second scans of amputees 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.

RESULTS—The initial results have shown contact analysis to be very slow process; however, once the proper parameters are defined for the problem, analysis speeds up noticeably. We have been able to generate near complete modeling of the donning process. The results of these models are currently being compiled and converted to digital animation, to allow viewing of the development of stresses within the limb as the socket is donned. A partial animation is currently displayed on this laboratory's World Wide Web page. A complete animation is being developed and will be displayed as well. We are also in the process of acquiring the data from the physical model for comparison with our FEA results.

FUTURE PLANS—The next step in our contact investigation is to look at the effect of changing surface friction on the donning process. The donning analysis will be re-run with different interface friction coefficients. This will be compared with our current frictionless donning model, and also to a model where simple fixed displacements are applied to the surface to deform the limb to the socket shape. We also intend to apply the principles of contact modeling to our existing static and quasi-static FEA models, to examine relative motion of the socket to the skin during gait.

We will continue collaboration with the Wright State group with the intent of developing a system to create finite element models directly from ultrasound image data.

[26] SOFT TISSUE BEHAVIOR AND SENSATION OF LOWER EXTREMITY RESIDUAL LIMBS

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PURPOSE—The objectives of this research are: to complete sensory exams to evaluate light touch, deep pressure, and vibration for below-knee (BK) amputees to test the hypothesis that the sensation of the soft tissues of residual limbs of lower extremity amputees is impaired; and to develop a tissue tester to perform rate controlled *in vivo* indentor studies of the soft tissues of lower extremity residual limbs that do not exhibit impaired sensation to pressure. The goals of these objectives are to identify lower extremity amputees at risk of developing pressure sores, further the development of residual limb models to investigate residual

limb/prosthetic socket biomechanics, and aid the development of new socket designs to maximize amputee comfort and tissue viability.

METHODOLOGY—Clinical exams of the residual limbs of BK amputees are being conducted to determine the veteran's ability to discern pressure, light touch, and vibration.

PROGRESS—To date, sensory exams have been conducted on 2 BK amputees; an additional 20 subjects (unilateral BK amputees with healthy residual limbs, no prior history of dermatological problems, and sufficient strength, stamina, and stability to stand, with an assistive device, for approximately 45 minutes without tiring) have been identified for possible inclusion in this study. These exams serve to define the presence and extent of impairments, and the influence of age and vascular disease. The results of these sensory exams will be analyzed as a function of: incision site and bony prominences, residual versus contralateral limb tissue sensation, cause of amputation, and age.

A tissue tester is being developed to enable rate-controlled *in vivo* indentor studies of the BK residual limb tissues. This indentor will be threaded (0.95 mm hole, 16 turns per inch) into individual ports in the socket wall of an experimental prosthesis, fixing it with respect to the internal bony geometry of the residual limb. The 8 mm dia tip accommodates curvatures typically present in lower extremity prosthetic sockets. The linear actuator accommodates displacement rates ranging from 0–10 mm/s, has a maximum stepping rate of 14 mm/s, and can accommodate forces of 71 N. A compression load cell (maximum range of 45 N) was incorporated into the indentor to measure the corresponding reaction force. Aluminum and plastic were used to fabricate the indentor housing to minimize the weight of the device; the total mass and length of the indentor are 860 grams and 19 cm, respectively.

Minimum and maximum indentor excursion are software controlled. A manual override, controlled by the amputee, has been incorporated to prevent pain/damage. Additional safety features include plastic discs built into the indentor to act as mechanical stops.

In vivo bulk soft tissue indentor studies will be conducted on the residual limbs of seven below-knee amputees upon completion of the indentor. No clinical trials will be conducted until the safety of the indentor has been thoroughly verified. The results of these tissue tests will be force-displacement and force-time/displacement-time curves which will be used to determine whether the bulk soft tissues of the residual limb are viscoelastic.

[27] EFFICIENCY OF GAIT IN PERSONS WITH BELOW-KNEE AMPUTATION: EFFECT OF PROSTHESIS MASS AND MASS DISTRIBUTION

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PURPOSE—The purpose is to determine the influence of mass and mass distribution (CG location) of below-knee (BK) prosthetic limbs on the metabolic and biomechanical aspects of gait in unilateral BK amputees.

METHODOLOGY—Patellar tendon bearing (PTB) BK prostheses are constructed using standard techniques (i.e., using a laminated PTB socket featuring a pylon with a foot). The prosthesis is made of lightweight components: nonadjustable aluminum pylon and Seattle LightFoot. Lead weights are attached to the prosthesis to vary the mass properties. A neoprene sleeve suspension system is employed for all subjects. The prosthesis is optimally aligned by a certified and experienced prosthetist.

Using an ultra-lightweight prosthesis, a weight (including residual limb) of approximately 40 percent of the normal limb is feasible. The CG location is maintained in the "as manufactured" location. Stump mass is included in the lightweight condition. In the second configuration, weight is added such that the lightweight prosthesis plus the residual limb weighs 60 percent of a normal limb, while maintaining the CG location at the "as manufactured" location. In the third configuration, more weight is added to the prosthesis to produce a weight of the entire lower leg (residual limb plus prosthesis) equal to 70 percent of an intact limb. The CG of this prosthesis is maintained at the as manufactured location. Finally, in the fourth and fifth configurations, the weight distributions are varied for both weighted prostheses. The CG locations are moved distally to a location at 60 percent of the distance from the femoral condyle to the prosthetic equivalent of the medial malleolus. The radius of gyration of the prosthesis is measured (using a torsional pendulum method). For statistical analyses, the following dependent variables are derived for the five prosthesis configurations: self-selected walking speed (SSWS); metabolic efficiency at the SSWS and 120 m/min; symmetry of gait kinematics composed of a composite score of the ratio of amputated-to-intact-limb stance and swing phase durations and step length at SSWS and 120 m/min.

Metabolic rates are measured using a computerized metabolic cart. During ambulation, subjects inhale ambient air of a known composition. The quantity of oxygen and carbon dioxide in the exhaled gas sample is determined electronically. The metabolic efficiency is computed from the metabolic expenditure over a fixed walking distance. Expired gas collections are performed in stages:

1. two 1-minute collections during quiet rest
2. one 1-minute collection during metabolic "build-up"
3. three 1-minute collections
4. six 1-minute collections during recovery.

The total energy consumption during Stages 2, 3, and 4 is determined and divided by the total distance walked to compute overall metabolic efficiency. Gait kinematics are quantified using a computerized motion analysis system with a force platform and gait event detection system. Measurements are performed bilaterally with six trials per condition at the subject's SSWS and at 120 m/min.

Study subjects are unilateral BK amputatees, 18 to 65 years old who can walk at 120 m/min. for at least 3 minutes. Persons with excessively short residual limbs or those requiring suspension systems other than the neoprene sleeve are excluded, as are Syme's amputees. Prosthesis configurations are presented randomly.

PRELIMINARY RESULTS—Preliminary results suggest that it is highly unlikely that ultra-light prostheses allow their users to ambulate more quickly and efficiently. They also suggest that the mass and mass distribution of a prosthesis can be manipulated to increase the efficiency of the user's ambulation. Data from additional subjects is being acquired to substantiate these conclusions and permit the description of the underlying mechanism.

[28] VERTICAL SHOCK PYLONS

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PURPOSE—Many prosthetic components are beginning to add compliance, or "spring," without a clear understanding of the biomechanical advantage. The purpose of this work was to try and determine the effects of a vertical shock pylon in a new below-knee prosthesis (the Re-Flex VSP). In addition to the cantilever leaf spring forefoot (fiber composite or plastic) often associated with Dynamic Elastic Response

feet, this prosthetic foot also has a vertically mounted spring-loaded telescoping pylon. The advantage of this design is to add compliance to the limb during activities in which the plantarflexors normally aid in shock absorption, such as going down stairs and running.

PROGRESS—Mechanical testing was performed to determine the mechanical characteristics (stiffness and damping) of the vertical compliance pylon alone and of the entire prosthetic system. Subject testing was also performed on two subjects using the prosthesis. In order to isolate the effects of the vertical shock pylon, trials were performed with the vertical compliance pylon immobilized and were then repeated with the pylon active.

METHODOLOGY—Mechanical testing was conducted using a specially designed foot testing apparatus. The pylon and forefoot were modeled as a combination of linear masses, springs, and dampers. For subject testing, two trans-tibial amputees were fitted with the vertical compliance feet. Biomechanical parameters were recorded during walking, jogging in place, and curb descent trials. Ground reaction forces, vertical trunk motion, event timing, and pylon compression were observed. To isolate the effects of the pylon compression, it was immobilized for the first set of trials. The pylon was then released and trials were repeated the following week with the vertical compliance feature.

RESULTS—Overall, few biomechanical differences were seen when comparing trials with and without vertical compliance for freely selected walking. Significant differences in vertical trunk motion and timing were seen between the physiological limb and the prosthetic limb, as expected. Increased compliance caused the most differences during fast walking and jogging. Increased cadences, higher forces, and greater vertical motion of the trunk were observed when jogging. Few differences were seen for curb descent trials because of the controlled strategy for single curb descent adopted by the two subjects. For all activities, subjects preferred the prosthesis with the vertical compliance pylon active. Mechanical testing results compared well to values found by other investigators for the physiological limb. The pylon stiffness and net stiffness, respectively, are 49.4 kN/m and 31.9 kN/m for the subject weighing 600N and 91.4 kN/m and 37.8 kN/m for the subject weighing 800N.

FUTURE PLANS—Values calculated for the spring and damping of this new prosthesis fit well within the range of those reported for the physiological limb. The subjective preference, along with the fact that the system matched physiological measurements, indicates that the role of compliance in prosthetics has a reasonable foundation and should be investigated more fully. In addition to replacing the lost plantarflexor action for a below-knee system, the use of a compliant components in above-knee prosthetic systems has the advantage of helping to simulate stance phase knee motion and ankle motion. For further studies it would be interesting to compare components that add compliance as a vertical shock pylon with those that add compliance at the knee through a torsion spring.

RECENT PUBLICATIONS FROM THIS RESEARCH

Vertical compliance in prosthetic feet: a preliminary investigation (abstract). Miller LA, Childress DS. In: Proceedings of the 8th World Congress of the International Society for Prosthetics and Orthotics; April 1995, Melbourne, Australia, 1-8.

II. Biomechanics

A. Bone and Joint Studies

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

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PURPOSE—Many surgical procedures of the lumbar spine, like laminectomy and discectomy, require removal of tissue from the motion segment. 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 motion segment is fused the adjacent segments receive increased stress, placing these segments at risk of future injury. The purpose of this research is to quantify the segmental instability resulting from the commonly used surgical techniques of facet and disc resection through a combination of experimental and analytical techniques.

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 compression, flexion-extension, 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 facet removal and disc denucleation. 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. 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.

PROGRESS—We have fabricated and tested the spinal loading device, and verified the accuracy of the method to measure the three-dimensional load-displacement behavior of lumbar motion segments. Using these methods, we have tested four spine specimens to date as described above. The preliminary data are being analyzed, and more cadaveric tests are planned.

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 model

geometry and material properties. Based on these initial studies we have developed an improved model of the facet contact to conduct modeling studies of the effect of graded unilateral facetectomy on the flexibility of the lumbar motion segment.

FUTURE PLANS/IMPLICATIONS—During the next 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. The information generated in this study will be used as a basis for developing recommendations concerning when to fuse and when not to fuse.

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

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

No report was received for this issue.

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

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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 which 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 potentially 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) three times weekly for 6 weeks. Wheelchair tests are repeated at the end of the training program to determine changes in stresses.

PROGRESS—Since transfer of the program to Baltimore VAMC in November, all testing and training equipment has been reassembled and calibrated. Data from the original eight subjects is being processed and analyzed. Nine additional subjects have been recruited and have undergone pre-testing. Recruitment of new subjects is continuing. Dual Energy X-ray Absorptiometry (DEXA) has been added to the pre- and post-testing to enable a more accurate estimate of body composition changes resulting from the training intervention.

PRELIMINARY RESULTS—Results for the first eight subjects (age 47±14 yrs; weight 78±24 kg; spinal cord lesion level T3-L5; six male, two female, wheelchair users for 19±12 yrs) show a reduction in mean maximum handrim forces and moments in both right and left in all three directions with fatigue. The new group of subjects (age 42±9 yrs; weight 84±12 kg, one female, eight males, wheelchair users for 15±10 yrs) include five with spinal cord lesions (T4-L1), two with lower limb amputations, one with an artificial hip, and one with traumatic head injury. Mean percent body fat based on DEXA scans is 34±7 percent. Isokinetic strength testing shows no right-left differences except in eccentric shoulder flexors and concentric shoulder extensors.

FUTURE PLANS/IMPLICATIONS—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 is expected to provide the necessary foundation for improving wheelchair function.

RECENT PUBLICATIONS FROM THIS RESEARCH

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

[32] THE ORIGIN AND CHARACTER OF REGENERATE BONE

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PURPOSE—A canine model of distraction osteogenesis (DO) using a mobile-transport segment and monolateral frame was utilized to examine the biomechanical and histological properties of regenerate bone. Contrary to our expectations, endochondral bone formation was found to be the major ossification mechanism.

METHODOLOGY—Fifteen adult mongrel dogs underwent unilateral radial osteotomies with creation of a

2.5 cm diaphyseal defect and 2.0 cm proximal transport segment. Monolateral external fixator/transport frames were applied, and, after a latency period of 5 days, transport of the segment was initiated at a rate of approximately 1.0 mm once daily. One week after distal docking of the transport segment, the animals underwent an ipsilateral ulnar osteotomy (UO) to induce control callous formation for histological comparison to the regenerate bone. Regenerate bone and ulnar control fracture were analyzed by mineralized and demineralized histology and immunohistochemical staining (IHC). Intermediate and long-term regenerate segments also underwent biomechanical testing. Biomechanical evaluation consisted of torsion testing to failure of the regenerate segment only with determination of maximum torque, total energy, rigidity, and stiffness.

RESULTS—The surgical procedure was well tolerated and reproducible in the dog model. Excellent formation of regenerate bone was achieved in all animals with no nonunions in the regenerate segment. Only 9 of 16 had stable unions at the distal docking site at the time of sacrifice (80 percent after 6 weeks). Regenerate bone was evident radiographically at the time of the mid-transport radiograph and was well calcified by docking. Biomechanical values were normalized to the contralateral intact radius with mean values ranging from 18 to 41 percent of control. There was no significant change from 6 to 9 weeks after UO.

Histologic analysis revealed a consistent pattern of endochondral ossification within the regenerate segment. This was characterized by a V-shaped zone (zone of ossification, ZO) located in the distal third of the regenerate segment in the early group. In these specimens, the ZO appeared analogous to an open physis with up to 90 percent of its cells cartilaginous in nature and ossification extending both proximally and distally from it. At the periphery of the ZO in the vicinity of the periosteum, evidence of intramembranous ossification was present.

The middle third of the regenerate segment was characterized by large amounts of new bone with thick trabeculae aligned along the axis of transport and high levels of osteoid production. The proximal third revealed active remodelling with numerous osteoclasts and thinning of the trabecular pattern. No cartilage was seen in this zone.

Intermediate specimens displayed a more transversely oriented ZO with loss of the V-shape described above. No more than 20 percent of the cells were frankly cartilaginous at this time point, although a population of recently converted osteocytes could be identified. The appearance of the ZO in older specimens was consistent with a physis undergoing closure. The presence of isolated chondrocytes was confirmed by IHC. The ulnar fracture controls healed by common endochondral ossification with an exuberant fracture callus.

IMPLICATIONS—These findings contrast with those of direct intramembranous bone formation induced by DO in the canine tibia of Aronson, et al. Their methodology differed in that they used a circular-wire frame, did not create a segmental defect, and made a metaphyseal corticotomy. The latency, rate, and transfer techniques were similar. They predicted delayed or nonunion of the regenerate bone when endochondral ossification occurs. However, we observed no radiographic, histologic, or biomechanical nonunions in regenerate segments which uniformly contained extensive evidence of endochondral ossification.

The mechanism of osteogenesis in DO is technique and species dependent. It is interesting that a long bone retains its capacity to regenerate itself by a mechanism similar to that by which it was formed.

[33] SUBTALAR AND TRANSVERSE TARSAL JOINT MECHANICS

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PURPOSE—Stroke, head injury, and spinal cord injury often result in disordered movement in the lower limb. Most treatment is empiric because we lack the basic understanding of the normal function of the small tarsal joints. The goal of this study was to delineate the basic movements of the triple joint complex.

METHODOLOGY—Magnetic sensors were fixed to the tibia, talus, and calcaneus of nine cadaveric feet. The foot was circumducted while the applied forces and torques were monitored using a vector force and torque transducer. To validate the apparatus and the analysis software, a phantom ankle was constructed out of wood, with fixed miter joint hinges oriented as per Inman. The motions of this model were measured in a manner identical to the cadaveric feet. We then extended these methods to the talonavicular and calcaneocuboid articulations. Six additional fresh cadaver feet with tibiae attached were fixed to a plexiglas rod by bolts through the tibia, and the tibia, talus, calcaneus, navicular, and cuboid were instrumented. Two loading conditions were applied: circumduction of the hindfoot as with the first nine specimens and vertical compression of the foot with an applied force of 150 Newtons, coupled with internal/external rotatory torques sufficient to elicit a full range of inversion/eversion. Measurements were then repeated with the calcaneocuboid articulation fixed.

During numerical analysis the fitted tibiotalar rotational axis was fixed to the tibia, the fitted subtalar and talonavicular rotational axes were comoving with the talus, and the calcaneocuboid axis was comoving with the calcaneus. Numerical implementation of a the least-mean-squares fit to uniaxial motion was straightforward.

PROGRESS—The measurements have been completed in the loaded and unloaded state and with the calcaneocuboid joint fixed as if fused. In addition, the calcaneocuboid joint was blocked open to simulate lateral column lengthening and shortened to simulate excessive bone resection.

RESULTS—The measured angular motion of all four hindfoot articulations was uniaxial to a good approximation. Circumduction of the foot yielded a characteristic hysteretic loop in a plots of angular variables. By an appropriate choice of rotation axes, the tibiotalar motion could be fit by a purely uniaxial angular motion to within an average standard deviation of 4.5°, the subtalar articulation within 1.4°, the talo-navicular within 2.2°, and the calcaneo-cuboid within 0.7°. The kinematically determined orientation of the hindfoot axes agreed closely with Inman's anatomy-based measurements to within 3° of angulation. Standard deviations and extremal values of angular orientation also were similar to the values reported by Inman. Inman's conclusions were originally derived from goniometric measurements: these are the first quantitative kinematic check of Inman's conclusions.

Talonavicular and calcaneocuboid axes have not previously been reported in the literature. These axes are approximately aligned with the subtalar axis. The physical reason for this is that the overall orientation of the plantar surface of the foot can change by 60° and more as the foot is circumducted. The near-parallelism of the hindfoot rotation axes helps balance motion and stability. Calcaneocuboid fusion had little effect on the angular axes and range of motion of the other three hindfoot articulations. The main effect was a loss of 10° of talonavicular motion, which was observed during both loaded and unloaded motions of the foot.

FUTURE PLANS/IMPLICATIONS—Similar testing conditions will be applied to with the talonavicular and subtalar joints stabilized. The next phase will be to simulate peritalar subluxation and cavovarus, the two most common acquired hindfoot defromities affecting the VA population.

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[34] A NON-INVASIVE THREE-DIMENSIONAL IN VIVO MOTION ANALYSIS OF THE CERVICAL SPINE: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #A93-591AP)*

PURPOSE—Segmental instability may manifest with an increased range of motion or an abnormal pattern of movement. Current techniques used to assess instability have inherent limitations. For example, dynamic radiographs provide only a two-dimensional (2-D) view of the actual three-dimensional (3-D) motion. Roentgen stereophotogrammetry can be used to describe 3-D motion, but the implantation of radiopaque markers is an invasive procedure. The purpose of this project is to develop a non-invasive *in vivo* method of 3-D motion analysis for better diagnosis and understanding of segmental instability.

METHODOLOGY—Magnetic resonance (MR) and computer tomography (CT) images of the cervical spine are obtained in various rotated and translated positions. These images are then analyzed using commercial software which calculates the coordinates of the geometrical center (GC), area, and moments and product of inertia for each 2-D image. This will eliminate the need for manual digitization procedures used in previous studies and will increase repeatability. Custom software uses the 2-D data to calculate the 3-D volume and moments of inertia tensor for each vertebra. Once the moment of inertia tensor is determined, a subroutine is used to calculate the principal moments and the orientation of the principal axes at the geometrical center of each vertebra. Translational and rotational motions of each vertebra are described by the translations of the GC and orientation changes of the principal axes.

PROGRESS—A workstation will be used with commercial software for image analysis. Software has been developed to calculate the principal moments and orientation of the principal axes. CT scans of an isolated cervical vertebra have been obtained with 1 mm slice thickness. These images were reconstructed and sliced again at 0.1 mm offsets to produce a 0.1 mm slice thickness. This provides increased accuracy by increasing the number of data points.

PRELIMINARY RESULTS—CT scans have been taken of a cervical vertebra in two positions and analyzed to provide data of areas, geometric centers, and moments and products of inertia. Various checks were made to determine if the volume was accurately reproduced and what the benefit was of using smaller scans. Based on continuum mechanics theories, it is known that a rigid body should maintain a constant volume, eigenvalues (principal moments of inertia), and trace of moment of inertia tensor. Using a 1.0 mm scan thickness there was a 0.9 percent change in volume compared to a 0.4 percent difference when using the 0.1 mm scan thickness. There was maximum change in eigenvalue of 5.1 percent using the 1.0 mm scan versus a 2.6 percent change using the 0.1 mm scan. Finally, there was a 2.0 percent change in the trace of the moment of inertia tensor with 1.0 mm scans versus a 0.2 percent change with 0.1 mm scans. This showed that the volume was being accurately reproduced and that the accuracy increased with more scans.

Software has been tested with data from simple geometrical objects with known inertial properties in various positions. The program has been able to accurately calculate the rotation based on this data, confirming that the algorithm is valid.

FUTURE PLANS—A device is being designed to test the accuracy of the system. An isolated cervical vertebra will be scanned in various known positions and the system will calculate the change in position. Once this has been completed, various positions of an intact cervical spine will be determined using a three-dimensional motion analysis system. These positions will be compared to values calculated by this new method to determine the accuracy for a multisegment system.

This will be the only method capable of a three-dimensional non-invasive *in vivo* motion analysis of the spine.

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

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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 dynamic 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 loads in static and 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 will be 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 will be measured. The degeneration grade of each disc will be quantified using T2-weighted images of sagittal section MRI scans. Data will be analyzed using repeated measures ANOVA.

RESULTS—Eleven lumbar disc specimens have been tested and the data analyzed as described above. The stress relaxation and relaxation time constant, static and dynamic stiffness, and hysteresis were smaller in shear than in compression. Combined loading reduced both the shear stress relaxation behavior and the compressive stress relaxation behavior. In contrast, combined loading increased the static and dynamic shear stiffness but reduced the static and dynamic compressive stiffness. Increasing disc degeneration (grade 1 vs. 3) was associated with significantly decreased relaxation time constant and increased stress relaxation behavior, decreased static and dynamic stiffness, and increased hysteresis of lumbar discs in shear, compression, and combined 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 large shear at the L4-5 and

L5-S1 discs may explain the increased incidence of disc injuries at these levels.

FUTURE PLANS/IMPLICATIONS—Further studies are planned to investigate the effects of different shear/compression ratios, and to correlate disc responses to disc structure and composition. Understanding the combined effects of prolonged loading and low-frequency vibrations on the response of lumbar segments may help identify potentially harmful working environments and suggest ways to minimize detrimental effects to the spine and reduce the incidence of back pain.

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[36] FUNCTIONAL ADAPTATION IN COMPACT BONE

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Sponsors: *The Health Research Board of Ireland, Royal College of Surgeons in Ireland*

PURPOSE—Bone adapts to mechanical stimuli causing net formation when loading is increased and resorption when it is decreased. In total hip arthroplasty, such resorption contributes to loosening of the femoral stem requiring revision procedures in 11 percent of patients after 15 years. This study sought to characterize bone adaptation in terms of surface strain, cross-sectional area, and bone mineral density, and to quantify the process using fluorochrome labels. Fatigue damage has been proposed as the stimulus for adaptation and evidence of this, in the form of microcracks, was sought.

METHODOLOGY—Based on gait analysis in the sheep, an *in vitro* test rig was developed and surface strains on the cranial and caudal surfaces of the radius measured under load. Ulnar osteotomy caused cranial tensile strain to increase ×1.7 and caudal compressive strain ×4. Ulnar pinning halved cranial strain and put the caudal cortex into tension. Having established these methods for load alteration, they were then applied *in vivo* to elicit an adaptive response. Thirty-four sheep were randomly assigned to three groups for a sham procedure (controls), ulnar osteotomy, or ulnar pinning under general anaesthesia. Post-operatively the animals were given intravenous fluorochrome labels at known intervals and allowed to walk freely before sacrifice at 3, 6, 12, or 24 weeks.

PROGRESS—Post-mortem, the adaptation of bone to altered load was assessed by measurement of surface strain, cross-sectional area, and bone mineral density. Evidence of microdamage was sought and tissue kinetic parameters measured.

RESULTS—Post-mortem strain measurement showed that cranial and caudal strains in osteotomies were quadruple those of controls at 6 weeks but had returned to control levels by 24 weeks, indicating that equilibrium had been restored. In pinned specimens, cranial and surface strains were of the same magnitude as controls, but the caudal cortex was in tension, and neither changed over time. Cross-sectional area was adjusted by a scaling factor to account for differences in mass between animals. In all three categories a regional acceleratory phenomenon (RAP) was noted at 6 weeks, but this subsided in controls and pins. The increase in area was larger in osteotomies (20 percent) and was

sustained to 24 weeks, thus restoring the area of the excised ulna. The new bone formed was initially of low mineral density, and thus low strength, but this increased to control levels by 24 weeks. Hence the restoration of normal strain patterns was dependent on both the structural and material properties of the bone.

Fluorochrome labels revealed two adaptive processes: formation of woven bone *de novo* on the endosteal and periosteal surfaces or modelling, and resorption and intracortical formation of secondary Haversian systems or remodelling. A new method of crack detection was developed utilising the green epifluorescence of fuchsin stain. Using this, crack counts were found to be maximal at 6 weeks, coinciding with a peak in the number of resorption spaces in the osteotomies. Formation of secondary osteons peaked at 10 weeks and a formation Sigma of 7.5 weeks was calculated. The spatial and temporal associations of cracks, resorption cavities, and refilling osteons suggest that microdamage is a stimulus for bone remodelling.

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Functionally adaptive bone remodelling. McMahon GT, Noelke L, Mulville JP, Lee TC. Clin Anat. In press.

[37] 3-D KINEMATIC ASSESSMENT OF FOOT-ANKLE COMPLEX

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PURPOSE—The *in-vivo* quantification of 3-D motion in the main foot joints by noninvasive techniques under dynamic conditions is very useful in the clinical evaluation of foot diseases, but it has proven to be a complicated procedure. Specimen studies of the foot would therefore not be indicated for the above-mentioned techniques, nor would methods based on instrumented linkage system, due to the impossibility of data acquisition during human walking. Many authors have proposed different approaches for the *in-vivo* studies of foot 3-D kinematics based on high speed video systems and video motion analyzers, but often with a limited number of foot landmarks and segments, and by lack of rigorous anatomical axes calibration. In this study, a five-segment rigid body model is proposed in order to investigate foot and ankle kinematics.

METHODOLOGY—The foot and ankle were modelled as five rigid body segments: shank, calcaneus, mid-foot, I metatarsal bone, and proximal phalanx of great toe. The shank and foot functonal evaluation during walking was assessed using the stereo photogrammetric ELITE system, with a force platform and two CCD cameras. We used a dedicated TV configuration and markers that allow a calibrated field of view of 840 mm. With this configuration the precision and accuracy in row data marker position reconstruction during dynamic tests was estimated to be respectively 0.2 and 0.35 mm. Five rigid plates, with four retroreflective markers were strapped to each model bony segment using glue and surgical tape. The number of markers and their trapezium geometry facilitate the array visibility and the manual tracking procedure. The redundant number of markers may also be used to reduce photogrammetric error effects. In order to obtain more clinically useful anatomical information, the calibrated anatomical system technique (CAST) was applied; for each segment of the foot model, at least three anatomically palpable landmarks were located and calibrated in relation to the relevant technical array.

PROGRESS—Kinematic analysis was performed on one asymptomatic subject during a number of sessions in order to evaluate the intra-subject reproducibility, and on five nondisabled and one pathological subject (with a flat foot) in order to assess the ability of the technique to discriminate different motion patterns.

PRELIMINARY RESULTS—An experimental protocol for kinematic analysis of foot during walking was presented. The acquisition protocol is simple and fast to perform and noninvasive. Moreover, the location of anatomical landmarks using a stick tip is usually more practical than single marker placing, expecially when the anatomical landmark is in an awkward position. The results of reliability tests, calculating the segment and joint rotation characteristics in the relevant anatomical axes, seem to suggest that the stereophotogrammetric system configuration and the patient set-up enable the detection of small angles, and the preliminary choice of anatomical frames proposed are close to the human joint axes. In the field of clinical application, the most useful benefit from this protocol is the possibility to obtain the 3-D rotation angles of the selected segments and joints.

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[38] HIP CENTRE LOCATION BY USING DIFFERENT TECHNIQUES

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PURPOSE—The present study aims at estimating the accuracy associated with two classes of techniques for the 3-D location of the hip joint centre (HC) in a pelvic frame: 1) the functional approach. The HC is assumed to be the center of a sphere described by markers located in the thigh with respect to a pelvis frame during flexion-extension followed by abduction of the hip. 2) The prediction approach. This locates the HC by use of regression equations based on statistical information acquired in a given population of subjects. The accuracies of these techniques were evaluated by comparing their results with those obtained using the Roentgen Stereophotogrammetric Analysis (RSA), which was considered to be more accurate than either of the above-mentioned methods.

METHODOLOGY—Presently, eight healthy adult male volunteers have participated in the investigation. HC location was estimated through three different methods. RSA (considered to provide the actual HC location): four tantalum balls (0.8 mm) were stuck on the skin above the two anterior (ASIS) and posterior (PSIS) superior iliac spines. Two Roentgen tubes simultaneously exposed the subjects who stood in such a way that calibration cage markers, the four skin markers, and the femural head contours were visible in both films. Reconstruction of the 3D position of the markers was calculated mathematically. The image coordinates of the HC on each film were estimated as the centroids of the digitized femoral head image contours.

The functional approach. The ELITE stereophotogrammetric system was used. Two rigid plates, mounting four retroreflective markers, were strapped to the pelvis and thigh respectively, using velcro fasteners. The location of the four superior iliac spines (where the tantalum balls were placed during the RSA experiment) was obtained through an antomical landmark calibration technique (CAST). A series of hip flexion-extension exercises followed by abduction were recorded.

Prediction approach. The regression equations proposed by Bell and Davis were implemented.

PROGRESS—The distance between the HC location, as estimated using RSA and the other two methods under analysis, was considered to be a good measure of method accuracy. The functional approach has provided better results in all subjects evaluated compared to those obtained through the prediction techniques.

RESULTS—The RSA technique has proved to be suitable and accurate in obtaining 3-D HC location from a large population of subjects; this should be particularly useful for updating regression parameters in different consistent populations of nondisabled subjects. The functional method seems to be better than the prediction method. If care is taken in maximizing the amplitude of hip rotation and minimizing skin movement artifact, the approach can provide local HC coordinates within a maximum error of 2 cm. The functional method may prove inappropriate or even impossible to use in patients with limited hip mobility. In this case even the other two methods do not seem to be definitely outstanding.

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[39] KINEMATIC AND DYNAMIC ANALYSIS OF THE SHOULDER MECHANISM

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Sponsor: *Netherlands Organisation for Research, Foundation of Medical Sciences*

PURPOSE—The goal of the research team is to gain insight in the functioning of the shoulder mechanism (i.e., its muscles, ligaments, bones, and so forth) in order to improve the diagnosis, treatment and prevention of shoulder complaints. Specific clinical applications are the development of a glenohumeral endoprosthesis and the treatment of habitual subluxation. Ergonomic applications focus on manual wheelchair propulsion and steelmill bricklayers.

METHODOLOGY—A wide variety of biomechanical methods are combined. The research is centered around a three-dimensional biomechanical model of the shoulder, and includes morphological studies (cadaver experiments and MRI), motion recording (spatial digitizers, X-ray, video and electomagnetic devices), and EMG. By means of computer simulations (inverse and forward) the function of muscles, ligaments, and propriocepsis is assessed. Finite element models of the scapula are used to calculate the stress distribution in the cortical and cancellous bone. Experiments focus on deriving the principal action of muscles, and on perturbation experiments evoking reflexes around the glenohumeral joint in order to excite the stabilizing mechanism.

RESULTS—A cadaver is carefully dissected and muscle attachments have been measured for 104 muscle lines of action. Sarcomere length has been measured using laser diffractioning, and optimum length has been assessed. Results are compared with a MRI recording of the same cadaver. Muscle and bone contours have been derived using semi-automatic algorithms. Preliminary results show good agreement. Muscle principal action is assessed using EMG for load conditions perpendicular to the humerus and in the plane of the humerus. They show very good agreement with computer model predictions using the shoulder model. Muscle action for stabilizing the glenohumeral joint have been evoked by pulse-like perturbations to the humerus. Reflex activity show stretch reflex bursts, accompanied by pattern-like activities of agonists and antogonist to resist the

perturbation. Extensive computer simulations including muscle dynamics and proprioceptive dynamics have led to theories explaining the results. Proprioceptive information is likely to be used in the learning of movements. Simulations with neural networks show the importance of several sources of proprioceptive information, and how to excite them. The biomechanical shoulder model has been applied to analyse design and surgical technique parameters of a total shoulder arthroplasty, and also to analyse the wheelchair propulsion stroke.

FUTURE PLANS—The sensitivity of different morphologies will be tested using the biomechanical model. Muscle principal action will be assessed for the entire working range of the shoulder. The stability of the upper extremity will be recorded for various tasks using a robotic manipulator.

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Use of a musculoskeletal model of the shoulder mechanism in wheelchair propulsion. Van der Helm FCT, Veeger HEJ. J Biomech. In press.

[40] PERFORMANCE ANALYSIS OF UPPER LIMB MOTOR FUNCTION IN CHILDREN WITH DISABILITIES

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PURPOSE—The purpose of this project is to evaluate and quantify the performance of children with motor disabilities in the use of different control devices. Different performance measures will be extracted from the data obtained from two interface devices, which will then be used to identify the functional differences in children with different levels of motor disabilities and a control group.

METHODOLOGY—Test subjects were of pre-school age between 4 and 5 years old. Two input devices were used in this experiment, the force or isometric joystick, and the position joystick. The force joystick, instrumented with strain gages, provides signals in X and Y directions, and is connected to the computer via strain gage amplifier. The signals so obtained control the movement of cursor on the screen, which is initially located in the center corresponding to zero force. The subjects were asked to move the cursor onto the fixed target appearing at different locations and at different distances from the center of the screen. Various measures such as movement time, movement patterns and path distance were compared in children with different motor disabilities and between control group.

PROGRESS—We have collected data from four children without disabilities and two children with cerebral palsy. The experiment included standard protocol in data collection with three different gain settings for the joystick. That is, the range of movement of the cursor on the screen for the applied force is changed through software. The performance reflects their target-reaching ability with force joystick under different gain settings.

PRELIMINARY RESULTS—The results obtained are being evaluated in terms of movement time, movement distance, and the pattern of reaching ability. The preliminary results show that there are several distinguishing features in the movement pattern of children with disabilities and those without disabilities, and also, there are several differences in the performance of the target reaching ability among children with disabilities.

The effect of changing the gain of the joystick on their performance is evident in terms of their reaching ability which in tum reflects the amount of force and the time needed to reach the target. This gives us a good indication for finding the optimum setting of joystick parameters to get maximum performance.

FUTURE PLANS—Additional subjects will be tested on the force joystick. Data will also be collected from the position joystick. Complete analysis of the experimental data obtained from these two devices will give us an insight into the performance measure among subjects with disabilities and those without disabilities.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Quantitative evaluation of upper limb motor function in children with physical disabilities. Rao RS, Sudarsan S, Seliktar R, Benvenuto P. In: Proceedings of the RESNA '95 Annual Conference; 1995 June 9-14; Vancouver, BC. Washington, DC: RESNA Press, 1995:159-61.

[41] BIOMECHANICAL STUDY OF THE SUBTALAR JOINT OF THE FOOT

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PURPOSE—The purpose of this project is to perform a quantitative analysis of internal foot mechanics in the subtalar joint and determine its relationship to external observations. This method will then be applied to: 1) examine, compare and improve the current surgical techniques available for the treatment of subtalar joint instability, and 2) develop an evaluation program for quantitative analysis of foot function, particular that of the subtalar joint. Two hypotheses to be tested are that properly selected soft tissue reconstruction based on predefined objective will have better surgical results, and that the joint contact area and pressure of the subtalar joint, as well as ligamentous deformation, can be estimated and interpreted based on the kinematic measurement of skin markers and pressure measurements of in-shoe pressure transducers.

METHODOLOGY—This study involves two phases. First, *in vitro* cadaveric foot specimens are studied on a specially designed loading apparatus to determine the kinematics, contact areas, and pressures of the subtalar and adjacent joints, in order to establish the statistical correlation between the external measurement and internal biomechanical parameters. This apparatus simulates the body weight and muscle forces, and tests the foot at different positions. Bony motion of the talus, calcaneus, and navicular is monitored, and the geometry of articular surfaces of ankle, subtalar and talonavicular joints, ligamentous attachment sites, and one landmark on each measured tarsal bone are digitized after testing for the joint contact area calculation, ligament elongation and local bony coordinate formulation. The joint contact area is estimated based on the concept of proximity of articulating surfaces. To statistically correlate joint contact patterns to external measurements, a few parameters characterizing the contact patterns are used, including the contact area size, centroid, and resultant pressure. The elongation of ligaments are approximately represented from the displacements of the attachment sites by assuming the ligament pathways as straight lines. An

optoelectronic motion analysis system used in the *in vivo* foot functional evaluation is calibrated *in vitro*. The kinematic data are compared with that from the motion monitor. The magnitude and location of the maximum pressure and the centroid of the pressure distribution on the foot are determined by an F-Scan sensor to statistically correlate to the internal parameters.

Secondly, the specimens are predissected in order to identify and prepare the three structures, deltoid ligament, interosseous talocalcaneal ligament and medial talocalcaneal ligament, for sectioning based on standard anatomic description. The standard posterior tibial tendon reconstruction, subtalar fusion, and proposed soft tissue reconstruction are performed and tested.

PROGRESS—To date, most studies in the first phase have been finished. Results include analysis of the kinematic and subtalar joint contact variations before and after loading the six muscle structures, intact foot kinematic responses to the various loadings, contact patterns of the subtalar and ankle joint in intact and unstable feet, and elongations of nine major ligamentous structures surrounding the hindfoot under different physiologic loading conditions.

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Validation of F-scan pressure sensitive system. Luo ZP, Berglund L, Westreich A, Growney E, An KN. In: Proceedings of the 19th Annual Meeting of the American Society of Biomechanics; Stanford, CA, 1995.

[42] FUNCTIONAL ADAPTATION IN BONE: EXPERIMENTAL MEASUREMENT AND THEORETICAL PREDICTION

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Sponsor: *None listed*

PURPOSE—Bone adaptation phenomena, such as calcar resorption following hip arthroplasty, are a major cause of failure of orthopedic implants. Research in this area has developed very slowly in recent years, partly due to a lack of understanding of the underlying mechanisms of the process, and partly due to a lack of quantitative experimental data. Ongoing work in this department aims to develop and test a theory of adaptation which proposes that the underlying mechanism is bone's ability to detect, and to react to, damage in the form of microcracks.

METHODOLOGY—Adaptation was generated experimentally in sheep by performing ulnar osteotomy to encourage growth of the radius and by stiffening the ulna using a plate to reduce stress on the radius. After 6 months, remodeling was assessed by measuring: bone cross-section, bone mineral density, structural stiffness (using strain gauges), and density of microcracks. Adaptation in human patients following cementless hip arthroplasty was monitored over a 5-year period in collaboration with the Rizzoli Institute in Bolonga, Italy. Both situations were modelled using finite element (FE) analysis linked to predictions based on external remodelling driven by rates of damage accumulation (i.e., the rates of fatigue crack growth). Bone deposition was assumed to occur in regions where crack growth outstripped the rate of normal repair mechanisms. Resorption was assumed to occur in the opposite situation, where crack growth rates dropped below the rates of normal repair.

PROGRESS—The theoretical development of the subject has proceeded by including a more realistic model of crack growth, which benefits from improved understanding of fatigue cracking in engineering materials. Nonlinear behavior is evident when crack growth rates are modelled, taking into account the effect of crack length and stress. This has given us a better understanding of the interaction between cracks and microstructural features such as osteons and cement lines. Improved theoretical models correlate more accurately with experimental data, both for the sheep experiments and for the human subjects.

RESULTS—Growth of the radius following ulnar osteotomy was well characterized by the various methods used. Adaptation is complicated by the short-term proliferation of bone following the operation (which occurs even in controls), but when this is factored out, the changes in strain, cross-section area, and microcrack density correlate well. Adaptation has not been completed after 6 months; studies of 1-year data are planned. FE analysis accurately predicts the time course of deposition. Results following the ulnar plating were less satisfactory: instead of reducing stresses on the ulna, the plate reversed the stress pattern with little change in magnitude. FE analysis was used to predict the initial propensity for calcar resorption in human THR patients, and this was found to correlate very well with 5-year follow-up studies. Further work is needed in order to predict the time course in this situation. There are considerable consequences for the design of artificial hip joints.

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Functional adaptation in compact bone (PhD thesis). Lee TC. Dublin, Ireland: University of Dublin, 1995.

B. Human Locomotion and Gait Training

[43] GAIT PATTERN ABNORMALITIES IN EARLY STAGE MS

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PURPOSE—In the clinical management of multiple sclerosis (MS) patients, the monitoring of movement disorders and the assessment of functional parameters usually take place as soon as the threshold of clinical evidence has been crossed. This time point seldom corresponds to the very beginning of motor drive involvement, and many abnormalities and rearrangements therefore go unobserved, judging by the rather stable level of performance. The paraclinical evidence of this type of subclinical involvement could help the clinician by giving a better starting point for functional monitoring protocols, and early information for prognostic purposes. Dealing with gait, the paraclinical evidence of early disorders (subclinical or borderline) is supposed to be achievable by means of movement analysis (MA) techniques. The aim of this work was to evaluate whether the MA technique can really supply some paraclinical evidence of minimal involvement of the gait functional system, in a group of MS patients showing no functional limitations.

METHODOLOGY—Seven patients, five females and two males, mean age 34 years, suffering from MS were evaluated. The Kurtzke Expanded Disability Status Scale (EDSS) score ranged between 0 and 2. Data obtained from patients was compared with data obtained from a control population of 10 nondisabled subjects of matching age and sex. Gait analysis was assessed by an

ELITE System (BTS) for kinematics, a Kistler platform for GRF and a TELEMG (BTS) for surface EMG. Both calculate 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.

PRELIMINARY RESULTS—We found abnormalities in time-distance parameters in all patients, mainly due to stride length and velocity reduction. Alterations found in GRF were common to all patients, particularly concerning the decreased fore-aft component during push-off phase. The most severe abnormalities were found at the ankle joint in almost all the patients: increased plantarflexion at heel strike, increased dorsiflexion at toe off, and a reduced plantarflexion during the swing. As far as EMG is concerned, five patients showed an abnormal muscular activity pattern. The main finding seems to be the altered recruitment of triceps and tibialis anterior during the stance phase of gait.

IMPLICATIONS—Almost all the patients assessed, regardless of the EDSS score, show abnormalities in gait pattern. Such abnormalities are related mainly to time-distance parameters, and to the ankle kinematic and muscular function, even in patients with no neurological signs or clinical evidence of gait disturbance. Gait analysis seems therefore able to supply the clinician with paraclinical evidence of motor abnormalities long before any functional involvement could be observed by a trained physician.

RECENT PUBLICATIONS FROM THIS RESEARCH

Benedetti MG, et al. Functional evaluation of gait in patients with multiple sclerosis: preliminary results. In: Roessingh Research and Development B.V., eds. Functional evaluation protocols for Europe-wide network of clinical centres. Enschede, The Netherlands: C.E.C. Programme AIM-CAMARC II, 1994:130-5.

[44] INERTIA PROPERTIES OF BODY SEGMENTS FROM MRI DATA

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PURPOSE—One of the variables in the equations of human motion is the moment of inertia of body segments. In addition to the moment of inertia, volume and center of gravity of segments must be determined. Collectively these are known as inertia properties.

Traditionally, investigators have estimated inertia properties from regression equations based on experimental data collected from a sample of elderly Caucasian male cadavers. There are many body types: females, children, members of other races, and the disabled, whose inertia properties are not well represented by these regression formulae.

The purpose of this project is to use data from magnetic resonance imaging (MRI) to determine the centers of mass and mass moments of inertia of body segments *in situ* so that the inertia properties can be determined for specific individuals.

METHODOLOGY—Fifty-nine transverse serial MRI images from the right lower extremity of a 38 year old white female subject weighing 128 lbs (58 kg) and 66 inches (167.6 cm) in height have been used in this study. It is well known that inertia properties of structures with complex geometry can be determined by breaking them down into simpler pieces. By dividing each tissue type in a given image into a finite number of triangles and rectangles and extruding these shapes into triangular and rectangular prisms, inertia properties of body segments can be determined.

PROGRESS—In the initial stages of this study, the dissection and measurement of the images were completed manually with only the final calculations performed in a spreadsheet. Currently the process is being automated. Software is being written with Visual

BASIC® for a 486 computer to take advantage of the graphic nature of the images. After zooming in on a region of interest in an image, points on the boundary of a section of tissue can be selected. Tissue regions are enclosed by cubic spline functions calculated from the chosen points. Using Simpson's 3/8 Rule, appropriate integrals corresponding to area, first moment, and moment of inertia are calculated for each tissue area of interest.

RESULTS—Centers of gravity and mass moments of inertia of the subject's shank and thigh have been calculated manually. Results have been compared with those from the regression formulae and simple geometric approximations of the extremities.

FUTURE PLANS—Properties of segments calculated with varying tissue densities will be compared with properties calculated with a homogeneous segment density. When the software is completed, the properties calculated by the automated system will be compared with those calculated manually.

To complete the software, an algorithm will be written to extrude the area integrals to calculate the volumetric properties of tissue prisms. Properties from each slice will be combined appropriately to determine the inertia properties of each body segment. It is planned that this software will be used with MRI data for a number of studies.

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Mass moments of inertia of right triangular prisms. Todd BA, Dorough DR. 24th Midwestern Mechanics Conference; Ames, IA. In press.

[45] GAIT ANALYSIS IN CHILDREN WITH FLAT FOOT

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PURPOSE—Flat foot represents a common disease in young people. According to a modern approach to this problem, flat foot diagnosis can not be confined to a morphological examination but must be based on an accurate clinical and radiographic examination, as well as functional and instrumental analysis. Movement analysis techniques have been largely used as a support in clinical practice to quantify biomechanical alterations. The aim of the present work is to verify the presence of an abnormal gait pattern in children and correlate it with clinical assessment and X-ray measurements.

METHODOLOGY—Fifty young patients with symptomatic bilateral essential or idiopathic flat foot were studied. Gait analysis was assessed by an ELITE System (BTS) for kinematics, a Kistler Platform for GRF, and a TELEMG (BTS) for surface EMG. Both calculate 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. Six free speed barefoot walks were recorded for the right and six for the left side. Clinical assessment was performed calculating the heel valgus angle and the footprint grading according to Viladot. X-ray measurements consisted of evaluating the talo-calcaneal angle and the Costa-Bertani angle.

PROGRESS—Foot-ground reaction forces data obtained from the first 20 examined children were

evaluated according to the parametric analysis introduced by Chao. We identified eighteen parameters (F1–F9, T1–T9) describing the fore-aft, mid-lat and vertical component in amplitude and time. Flat foot data were compared to a control population by statistical analysis.

PRELIMINARY RESULTS—Results showed that all the analyzed forces were significantly altered, but some parameters depended on velocity as the flat foot group walked faster than normal. In particular, we found three key parameters: the significant absence in some cases of F4 in the fore-aft component and/or F7 in the mid-lat component, the increasing of F8 and F9, and the decreasing of F3, not related to velocity. Moreover, a significant abnormal sequence of GRF parameters was found in the terminal stance phase: the time in which the maximum mid-lat force (F9) occurs in fact is postponed compared to the maximum time in the vertical component (F3). There was generally a good correlation between GRF parameters and clinical radiographic measurement.

IMPLICATIONS—The gait analysis of children with flat foot seems to be very important in defining some of the key parameters able to describe impaired function in this pathology. This evaluation enables us to identify an excessive eversion gait pattern in order to differentiate a simple morphological flat foot and a functional, or true, flat foot. Only the last one, in fact, needs treatment to prevent future pain due to overloading, degenerative arthritis, and forefoot deformities.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[46] THE 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 have developed an economical direct ultrasound ranging system (DURS) for the quantitative evaluation of ambulation. 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.

PROGRESS—A prototype DURS has been completed. This prototype is interfaced with a personal computer via the parallel port. Calibration for the speed of sound is achieved by measuring a known distance and adjusting the hardware until this distance registers. The velocity is found using a three point differentiator, implemented in software, on the distance samples obtained by the device. A time averager was also used 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 compared well with veloc-

ity profiles obtained from a CODA 3 system in our Human Mechanics Measurement Laboratory.

RESULTS—The velocity profiles 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 with 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—The next stage of the DURS development involves the modification of the first prototype to improve its operation. The first modification will be to improve the transmission and reception of the infrared light through the use of a strobe, since the limited receptive field of this particular signal limits the overall performance and hence usefulness of the device.

A second modification, to have the computer measure the time difference between the arrivals of the infrared and ultrasound signals at the receiver unit, will be attempted. 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 laptop computer to increase its portability.

[47] DEVELOPMENT OF A GAIT INTERPRETATION, INSTRUCTION, AND REPORT GENERATION SYSTEM

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PURPOSE—Both health care and rehabilitation for orthopaedic patients may be improved by taking advantage of the increasingly sophisticated quantitative measures now available for gait analysis. To ensure the effective use of these measures, this project's goal is to develop a computer-based tutoring and report-generation system. This system can be used to help orthopedic residents and physical therapists gain experience and skill in analyzing various gait dysfunctions, and to develop more informative patient reports for referring physicians.

METHODOLOGY—The GAIT (Gait Analysis Instructional Tool) tutor and report generation system is currently being developed on a Macintosh computer environment using the C programming language. This environment allows users to easily manipulate multimedia elements such as sound, video, animation, illustrations, and graphical representations. Providing data in these formats will support both the instruction of individuals interested in acquiring the skills of gait analysis and the production of detailed patient reports for those who manage and provide patient care.

PROGRESS—A fully functional prototype of the GAIT system has been developed for the Macintosh environment. This system is being subjected to preliminary formative evaluations using orthopedic residents and physical therapists. This system will also be ported to an IBM environment as evaluation results are compiled and the preliminary system design is refined.

The system allows users to enter, review, and annotate data from actual patient cases. This annotated data and accompanying text segments can be incorporated into a detailed report about a patient's progress. Preliminary interviews with orthopaedic surgeons revealed that in addition to providing a tutoring system for residents, the ability to maintain and manage patient information is an important additional function from the vantage of those who provide patient care.

FUTURE PLANS—Following the completion of the current formative evaluation, a formal evaluation study is planned. Following this evaluation, the GAIT system will be distributed for general use as both a case-based interactive learning environment and a patient evaluation and care management tool. Further evaluations will accompany this distribution.

RECENT PUBLICATIONS FROM THIS RESEARCH

Advanced technologies for educational tools in science. Kumar D, Smith PJ, Helgeson S, White A. In: Thomas D, ed. Scientific visualization in mathematics and science teaching. Charlottesville, VA: Association for the Advancement of Computers in Education, 1994.

[48] REFINEMENT, EVALUATION, AND DISSEMINATION OF A DIAGNOSTIC AND TREATMENT ASSESSMENT EXPERT SYSTEM FOR THE INTERPRETATION OF WALKING DISORDERS LEADING TO DISABILITY

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PURPOSE—Over the past decade, research efforts have been developing tools to assess human gait performance objectively. This has resulted in the establishment of gait analysis laboratories that are currently proving to be of significant clinical value. However, the analysis of information derived from such laboratories is left to the clinician, and this can be a major obstacle to the clinically widespread use of such systems, since there are few experts and new techniques are constantly being discovered and applied. To assist clinicians, computational methods in analyzing gait could ensure a standardized, high quality level of analysis, decrease the time involved in doing an analysis, provide updates for new techniques, and be part of a tool for instruction regarding gait analysis.

METHODOLOGY—We have been working with a prototype expert system called QUAWDS (Qualitative Analysis of Walking DisorderS) for diagnosing cerebral palsy gait disorders from the multiple sources of raw data that are used by the gait analysis expert. QUAWDS was built using generic task theory (from artificial intelligence) to identify and define the subtasks involved in gait analysis. The major subtasks for gait analysis include: motion deviation identification, muscle fault generation, muscle fault rating, explanatory coverage determination, and determination of overall interpretation. These modules use a combination of associational knowledge (rule-like) and a qualitative model of the physical system.

For this project, we are in the process of isolating the various subtasks in QUAWDS and embedding them as cognitive tools within a user-friendly cooperative problem solving interface so that a gait analysis expert can easily use any or all submodules of QUAWDS for gait analysis. We are also evaluating QUAWDS performance against human experts to refine QUAWDS to achieve expert level performance.

PROGRESS—We have nearly completed the transfer of knowledge from QUAWDS to cognitive tools to be embedded in a user-friendly system. Currently, there is a tool for identifying significant findings with respect to

joint angle graphs, range of motion, time and distance data, and EMGs. Another tool for determining likely causes for a finding will soon be completely integrated in the interface. Refinement to the joint angle finding detection has been made to keep up with current trends in the field. Finally, we have begun preliminary field testing of the current tools and interface.

RESULTS—As preliminary field testing has just begun, there are no concrete results to report. However, response to the system has been quite positive whenever it has been demonstrated to potential users.

FUTURE PLANS—As the system develops, we intend to identify which cognitive tools are useful, what modifications are necessary to the tools for better accuracy and/or usability, and whether more tools would aid gait analysis further. One such tool we are already investigating is the addition of a treatment assessment module. Other research in our lab about the assessment and quantification of performance will be incorporated into a module that will indicate the amount of improvement a particular treatment will give under particular patient conditions.

RECENT PUBLICATIONS FROM THIS RESEARCH

Applications of intelligent multi-media technology in human motion analysis. Simon SR, Smith PJ, Smith JW, et al. In: Harris GF, Smith PA, eds. Human motion analysis: current applications and future directions. Piscataway, NJ: IEEE Press. In press.

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

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PURPOSE—This project is intended to study 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—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 prosthetic femoral stem (very problematic). We have speculated that duringh single limb stance phase (i.e., from opposite foot off, OFO, to opposite foot contact, OFC) 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 movement versus transverse hip rotation. Due to difficulties in validating some of the previous results we have reprocessed all of our raw data from these subjects using recently acquired software.

Another study looked at the relation between power and improvements in motion and velocity parameters.

PROGRESS—Following our reprocessing of this data, the plots of dynamic rotational joint stiffness suggest

that limbs with loose prosthetic stems will tend to exhibit differences in either the magnitudes of the peaks in stiffness or in the "smoothness" of the stiffness trajectories. Conversely, involved limb and uninvolved limb stiffness trajectories appeared very similar when prosthetic loosening was not present.

In the power study, it was found that in patients who showed an improvement in motion parameters and velocity, more energy was used at the hip than at the ankle.

[50] WALKING: FROM STANDING TO NORMAL SPEEDS

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PURPOSE—Many researchers argue that gait deviations in the pathological gait of the elderly and amputees are a result of their specific pathology. However, gait parameters in able-bodied individuals are lacking at walking speeds comparable to the walking speeds of these groups. We propose that many of these supposed deviations are primarily a function of the velocity rather than a function of the pathology itself. The long-term goal of this project will be to characterize gait parameters of able-bodied individuals walking at speeds ranging from 0 to 1 m/s, emphasizing changes in walking strategies as speed increases.

PROGRESS—A preliminary report on this project is near completion. The pilot study includes seven able-bodied ambulators with a mean age of 25. During this stage, we have characterized many of the parameters that are also well documented for normal speeds of walking. Our current focus is on the medial-lateral displacement of the body center of mass, step width, the harmonics associated with the vertical position of the anterior iliac crests and the body center of mass, and vertical ground reaction force minimums, all with respect to walking speed.

METHODOLOGY—Kinematic data is collected with the CODA-3 Movement Monitoring Instrument which uses optical scanning devices to scan retroreflective markers. The markers are placed on the left and right anterior iliac crest. Six degree of freedom force plate measurements are recorded, and step width, defined as the distance between the center of the left heel and the center of the right heel of one step, is measured directly. Two protocols are used to obtain an evenly distributed range of velocities between 0 and 1 m/s. In the first, the subject is instructed to walk at an initial step length of approximately 2 inches. The subject is then instructed to take steps "a little larger than in the previous trial" until a freely selected step length is achieved; cadence and step width are freely selected. In the second protocol, the subject begins by walking at a freely selected pace and is then instructed to decrease their speed gradually until a speed of less than 0.1 m/s is achieved. The strategy used to decrease the speed is independently selected by the subject, and no other instruction is given. In both protocols, the subject practices walking at the specified step length until they feel that their gait is comfortable and can be reproduced. Data is collected for three trials at each step length; the sampling period is dependent upon the time needed to cross both force plates, however, at least four gait cycles are recorded for each trial.

RESULTS—Both quantitative and qualitative examination of the data indicates that many of the gait parameters studied are influenced strongly by walking speed. An example is that as speed is decreased, the second vertical peak of ground reaction force, associated with the toe-off portion of a gait cycle, begins to diminish in strength. This characteristic is also noted in many pathological gaits. At the slowest speeds, the ground reaction force is only a single peak; this characteristic is also documented for elderly with Parkinson's disease. In addition to these findings, we

have also noted differing strategies used at transitional speeds of walking. Every subject alters their walking strategy during these transitional speeds.

FUTURE PLANS—We plan to increase the number of healthy ambulators used in the study, and to then analyze the gait of elderly with Parkinson's disease as well as trans-femoral amputees in order to differentiate between gait deviations that are due to walking speed and those that are due to the pathology. In addition, we will examine the transitional regions more closely.

[51] ASSESSMENT OF VARIABILITY IN HUMAN WALKING

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Sponsor: *Natural Science and Engineering Research Council of Canada*

PURPOSE—Our goal is to expand on existing variability models in gait analysis.

METHODOLOGY—This project continues to investigate the variability inherent in human movement. The objective has been to develop techniques which will allow quantification of the variability in gait data, and then allow the normal variations to be used to identify pathological conditions.

PROGRESS—The basic algorithms of the processing of data have been altered recently to make them more readily used on personal computers rather than on large computers. This development has been in FORTRAN, but present work includes development of equivalent algorithms in other more commonly used computer languages.

The techniques developed under this project are becoming widely distributed in the clinical gait analysis field and have been used in a variety of applications, other than direct processing of movement data.

The local application of the techniques has been to analyze individuals who have had total knee replacements to try to identity differences between types of replacements. To do this, movement force and EMG data have all been processed using similar analytical tools.

[52] COORDINATION OF MUSCLES IN GAIT

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PURPOSE—We are studying the coordination of lower limb muscles in explosive movements of the lower limb. Rules for coordination of bi-articular leg muscles have been formulated and tested in movements and in simulation studies. Recently the work has been extended to arm functioning. Neuronal network modelling is used for studying learning aspects of coordination.

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

PROGRESS/RESULTS—Bi-articular 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 modelling. In gait, bi-articular hamstring and rectus femoris muscles are active in early stance. They co-contract with mono-articular 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.

Simulation proved most of the above-mentioned concepts. A sensitivity analysis, concentrating on length of moment-arms of bi-articular 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 programme in nearly optimal performance. From the study of running it appeared that bi-articular muscles distribute net moments in ballistic leg extensions. Optimal coordination is regulated with the aim of efficiency of expenditure of mechanical energy by mono-articular and bi-articular muscles. Arm movements are studied in which direction of force application and movement is not identical.

FUTURE PLANS—We would like to learn the optimal stimulation pattern by conducting simulations of mechanical nature and simulations of neural networks. Wheelchair propulsion will be analyzed.

[53] GAIT CHARACTERISTICS IN THE EVALUATION OF FUNCTION FOR PATIENTS WITH RHEUMATOID ARTHRITIS

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PURPOSE—This work was preparatory for a longitudinal study which aimed to evaluate second line drug intervention in patients with newly diagnosed rheumatoid arthritis (RA).

The initial objective was to identify a series of measures that could be used to create a biomechanical profile of gait characteristics applicable to the proposed population. It was identified that the instrumentation and protocol utilized must not be invasive nor fatiguing and must have acceptable test-retest repeatability. The parameters under investigation must be of a sensitivity to detect change, reflect both kinetic and kinematic function, and have acceptable levels of intra-subject variance.

Secondly, the parameters and protocol identified were used to compare the gait characteristics of a population with RA to an age- and sex-matched control group. This served as a pilot study to evaluate the methodology in detecting change between groups prior to the proposed longitudinal study to monitor the rheumatoid population over time.

METHODOLOGY—Temporal and spatial characteristics were measured using an instrumented walkway, with software developed in-house specifically for the study. A force platform was used to collect kinetic data.

Repeatability trials were undertaken on both instruments to identify parameters with acceptable test and retest variance. From these results, 11 parameters were identified that fulfilled the criteria for the study. From the walkway, stride length, single support phase time, velocity, relative velocity, and cadence were selected.

From the force plate, suitable kinetic gait characteristics were: stance phase duration, time to midstance, peak vertical force during breaking and thrusting periods of stance, and the time taken to reach these points of maximal force.

Potential subjects were medically and radiologically assessed, and those fulfilling selection criteria set by the consultant rheumatologist were invited to participate. A normative database under development at the Clinical Research Centre provided control data. Gait assessment was performed before and after a trial period of drug therapy.

PROGRESS—To date, 16 RA subjects with forefoot involvement have been tested prior to commencing second line drug therapy. Three have completed their 6-month drug trial and have undergone final gait assessment.

In order to evaluate the methodology, six RA subjects were compared with an age- and sex-matched control group using a matched paired t-test (two-tailed).

RESULTS—Significant differences ($p<0.05$) between the RA and control groups were found in all five temporal and spatial parameters measured from the walkway. From the force plate, the peak vertical thrusting force ($p<0.05$) and the time taken to reach this point in stance ($p<0.01$) were significantly different between groups.

IMPLICATIONS—The initial results would tend to suggest that the methodology utilized and the parameters tested were both repeatable and capable of detecting differences between the gait of RA subjects and a control. Furthermore it is suggested that the differences in terminal stance kinetics may provide a valuable indicator of disease or measure of therapeutic intervention for RA subjects with forefoot involvement.

The findings of the preparatory work indicate that progression onto the proposed longitudinal study is appropriate. A patent application is pending for the walkway which is currently being lengthened to provide a more representative sample of the subjects gait for future studies.

[54] LOW COST GAIT ANALYSIS SYSTEM MEASUREMENT OF PRECISION AND ACCURACY

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Sponsor: *None listed*

PURPOSE—We aim to measure precision and accuracy of a low cost 2-dimensional infrared gait analysis system developed at the San Antonio VA. We also plan to analyze 20 nondisabled subjects during treadmill walking. Developmental cost of our real-time, infrared gait analysis system was under $5,000.

METHODOLOGY—Precision is the position-dependent random error (standard deviation) along each axis of N samples at one marker position. Accuracy is the position-independent systematic error (standard deviation) along each axis of M sampled markers equally distributed over the whole measuring area. A square grid was engineered to cover a 1.2 m × 1.2 m viewing area of our gait analysis system at 1.7 m distance. The infrared camera was set perpendicular to the grid at a distance of 1.7 m. Each of 4 infrared markers was placed at the intersection of each 0.2 meter equidistant gridline. Precision was measured for 20 samples at each of 49 gridline intersections, and accuracy was measured for all 49 gridline intersections.

PROGRESS—Twenty nondisabled subjects were recruited to walk on the treadmill. Infrared markers were placed on the greater trochanter, lateral femoral condyle, lateral ankle malleolus, and lateral fifth metatarsal head.

PRELIMINARY RESULTS—The mean precision over the viewing area was 1.2 percent horizontally and 0.8 percent vertically based on 20 samples at 49 marker locations. Uncorrected accuracy over the viewing area was 13 percent horizontally and 6 percent vertically based 1 sample at each of 49 locations. We have begun testing a calibration grid correction overlay to correct for nonlinearities in order to improve accuracy, and preliminary results show a corrected accuracy of less than 3 percent in both horizontal and vertical axes. The data on 20 nondisabled subjects walking on a treadmill are still being analyzed.

C. Other

[55] HOLTER SYSTEM DEVELOPMENT FOR RECORDING PLANTAR PRESSURES

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PURPOSE—The purpose of this study was to develop and evaluate a portable, Holter type, in-shoe, plantar pressure monitoring system capable of recording up to 16 hours of continuous pressure data. Clinically, this system is to be used to study plantar pressures during unrestrained daily activity.

METHODOLOGY—A Holter type, microprocessor-based plantar pressure data acquisition system was built using existing, proven technology, based on our previous work. The system is programmed to sample 14 analog channels of pressure data at sampling rates of either 20, 40, or 120 Hz. Data is stored in 16-MB of pseudo-static RAM. Insoles are instrumented with thin profile, Interlink, force-sensing resistors (FSRs), to measure pressure at seven predetermined loading sites per foot. The transducer sites include the first, second, fourth, and fifth metatarsal heads, anterior and posterior heel, and the great toe.

The response of the FSRs is non-linear. To account for this non-linearity, the FSRs are dynamically calibrated using a compression lever and 440 N load cell. A linearization look-up table is created and down-loaded to the microprocessor unit for real time linearization. Data compression routines using the Lemel-Ziv-Welch algorithm have been implemented to maximize memory usage. After collection, data are uploaded to a 486-PC using the parallel printer port.

PROGRESS—System development is now complete. Bench testing has been completed to verify the analog system response, A/D conversion routines, memory systems, and microprocessor timing. Testing with 10 nondisabled subjects (5 males and 5 females) has validated the system's durability, reliability, and accuracy to measure plantar pressures during unrestricted activity. Preview software has been written to view and segment the large data files that are collected. To automate the preparation of the data for statistical analysis software to detect peak pressures, and to calculate contact durations and pressure time, integrals were created.

RESULTS—The Holter type, plantar pressure data acquisition system has been developed and proven through clinical testing. This system has also been used in a study to evaluate the effectiveness of metatarsal pads in the treatment of metatarsalgia and in a pilot study to compare three types of rocker sole treatments.

FUTURE PLANS—Results from our clinical validation series support clinical implementation of the

system. Studies of stair climbing and descent, total contact casting, and pneumatic walking brace characteristics are planned.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Multistep measurement of plantar pressure alterations using metatarsal pads. Chang A, Abu-Faraj Z, Harris GF, Nery J, Shereff MJ. Foot Ankle Int 1994:15(12):654-60.

[56] BIOMECHANICAL MODEL OF INDEX FINGER DYNAMICS

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Sponsor: *The Fund for Promotion of Research at the Technion; the Segal Foundation; the Walter and Sandra Kaye Fund*

PURPOSE—The purpose of this study is to develop a dynamic model of the index finger for flexion-extension and abduction-adduction motion.

METHODOLOGY—The model takes into account all the tendons in the finger and relates to their varying moment arms during motion. A new set of moment arm coefficients and elongation equations is derived based on experimental measurements of previous studies. Constraint equations using variable coefficients are introduced into an optimization approach used to obtain the tendon forces for any given motion and external force.

RESULTS—The model and optimization approach are tested with data from a rapid punch experiment as well as a hypothetical disc rotation. Good correlation has been obtained with respect to electromyographic data in the literature. Time histories of the angular position of the joints and of the tendon forces during these simulated motions were obtained.

RECENT PUBLICATIONS FROM THIS RESEARCH

Biomechanical model of index finger dynamics. Brook N, Mizrahi J, Shoham M, Dayan J. J Med Eng Phys 1995:17:54-63.

[57] ESTIMATION OF CENTER OF GRAVITY TRAJECTORY IN STANDING SWAY FROM BILATERAL REACTIVE FORCE MEASUREMENTS

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PURPOSE—We seek to develop an iterative algorithm to evaluate the center of gravity (CG) trajectory from bilateral forceplate measurements in standing sway.

METHODOLOGY—A three-dimensional, four-joint, five-segment model of the human body is used to describe standing sway dynamics. An iterative algorithm was developed to evaluate the rate of change of the angular momentum of the body about the CG. The model is based on the reactive forces and centers of pressures as measured bilaterally, that is, from two force platforms. This method is illustrated on a group of 11 able-bodied subjects and 2 subjects with musculoskeletal pathologies.

RESULTS—The results obtained indicate that the contribution of the rate of change of the angular momentum to the estimation of the CG trajectory is negligibly low. A spectral analysis of the estimated and approximate CG trajectory shows that for the mediolateral direction, the frequency of the principal harmonic is three-fold higher in the approximate trajectory as compared to the estimated one. The differences between the first and second iterations are small and become negligible between the second and third iterations. The average position of the CG trajectories of able-bodied subjects is shown to fall around the separation line between the two forceplates. In pathological subjects, however, the average position of the CG trajectory is shifted toward the direction of the sound leg. A good correlation is found between this shift and weight-bearing imbalance between the legs.

FUTURE PLANS—It is planned to use the model developed for the prediction of the joint torques, and the power transmitted through the joints in standing sway.

RECENT PUBLICATIONS FROM THIS RESEARCH

Iterative model for estimation of the trajectory of center of gravity from bilateral reactive force measurements in standing sway. Levin O, Mizrahi J. Posture Gait. In press.

[58] POSTURAL SWAY DYNAMICS IN LOW BIRTHWEIGHT, PRETERM INFANTS

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

PURPOSE—The aim of this study is to monitor the forces below the knee in low birthweight infants, determination of the bilateral pattern of their oscillation, and possible correlation with neurodevelopmental outcome.

METHODOLOGY—Monitoring of the forces is made by means of force sensoring resistor (FSR) transducers, connected through an amplifier to a PC. Processing of the data is both in the temporal and frequency domains, using methods previously developed. Additionally, pa-

rameters related to the relative sequence between the forces obtained from both knees and asymmetry are being determined. Normal and abnormal patterns are characterized and correlated to the neurodevelopmental outcome of the infants.

RESULTS—Preliminary results indicate that contact forces below the knees of preterm infants vary periodically due to the continuous swaying motion of the infants. It is believed that the measurement of the forces below the knees and the determination of parameters such as symmetry, period, and sequence of oscillations, can shed light on their skeletal joint loading and their motor behavior.

FUTURE PLANS—It is planned to extend the measurements to include in this stage 10 infants. It is expected that knowledge of the normal and abnormal bilateral reaction force patterns will assist in the early diagnosis of abnormal neurodevelopment.

[59] PLANTAR PRESSURE ALTERATIONS WITH METATARSAL AND SCAPHOID PADS

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Sponsor: *Department of Orthopaedic Surgery, Medical College of Wisconsin*

PURPOSE—This work was designed to quantify changes in plantar pressures with metatarsal and scaphoid pad usage. This article addresses results obtained from a study of a group of 10 normal adult male subjects. Subjects were evaluated during a set of 400-step trials during which the pads were used. Data were gathered from eight plantar locations at the right hindfoot, midfoot, and forefoot regions.

METHODOLOGY—A Holter type, microprocessor-based, portable, in-shoe data-acquisition system was used in this study to monitor pressure data from eight plantar locations at the right heel (H), medial longitudinal arch (MLA), metatarsal shaft region (MSR), metatarsal heads (1M, 2M, 3/4M, and 5M), and hallux (Hx). The system provided long-term recording capability (up to 2 hours at 40 Hz) from up to 14 discrete sensor locations. It utilized an 8-bit microprocessor, was battery operated, and weighed 350 g. Subjects carried the unit in a beltpack during unrestricted gait. Upon test completion, recorded pressure data were uploaded into a 486 computer for further processing, analysis, and display. The Interlink circular FSR (15 mm active sensing diameter) was used to record the plantar pressure history. A compression lever, a precalibrated 440 N load cell, and preamplifier were used to dynamically calibrate the FSRs. Clinical examination and recorded foot impressions from an Apex foot imprinter were used to determine precise sensor locations. Sensors were embedded within the insole material. The pads used in this study were made of a rubber material and were affixed to the base of the insoles. Each subject's instrumented insole and pad were inserted in a pair of athletic shoes.

RESULTS—Ten nondisabled male rearfoot strikers were selected for the study. The subjects were asked to walk at a freely selected cadence on an 80 m concrete walkway. Acclimation to the experimental shoes and establishment of a constant temperature shoe environment was provided during a 30 min pretest period. Three (400 step) data gathering sessions were then conducted. Subjects were first tested without pads. Subsequently, subjects were tested with the metatarsal and scaphoid pads, respectively. A 10-min rest period was allowed in between sessions. Peak plantar pressures, pressure-time integrals, and sensor contact durations were determined for each of the insole sensors during the multistep trials. With metatarsal pad use, pressure redistribution was characterized with peak load increases ($p \leq 0.05$) to the normally unloaded metatarsal shaft region (MSR) of the foot, and peak load decreases to the peripheral pad areas, particularly under the metatarsal prominences. This redistribution is support-

ive of the postulate that decreasing the metatarsal prominence loads (peripheral pad areas) is effective in reducing pain associated with metatarsalgia and Morton's neuroma. On the other hand, scaphoid pad use resulted in peak load increases at the lateral foot and peak load decreases at the medial and calcaneal regions of the foot. This redistribution in pressure metrics came at a cost of a significant increase in pressure in the normally unloaded medial longitudinal arch (MLA) region of the foot ($p \leq 0.05$).

RECENT PUBLICATIONS FROM THIS RESEARCH

Multistep measurement of plantar pressure alterations with the use of metatarsal pads. Chang AH, Abu-Faraj ZU, Harris GF, Shereff MJ, Nery J. Foot Ankle Int 1994:15(12):654-60.

Plantar pressure distribution with the use of metatarsal pads: a quantitative study (Abstract). Abu-Faraj Z, Harris GF, Chang AH, Shereff MJ, Nery J. Gait Posture 1994:2(1):62.

Quantitative evaluation of plantar pressure alterations with metatarsal and scaphoid pads. Abu-Faraj Z, Harris GF, Chang AH, Shereff MJ, Nery J. In: Harris GF, Smith PA, eds. Human motion analysis: current applications and emerging horizons, 1st ed. Piscataway, NJ: IEEE Press, 1995.

[60] QUANTITATIVE FUNCTIONAL ANATOMY OF THE UPPER EXTREMITY

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

PURPOSE—We are making a collection of 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 cannot be studied directly, but needs the application of a three-dimensional (3-D) biomechanical model. In addition, the 3-D nature of upper extremity motion and the covert motions of the scapula, require a highly sophisticated 3-D movement analysis.

Quantitative data on the morphology of shoulder and arm are needed as a basis for the 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; the analysis of the outcome of shoulder arthrodeses; and the interpretation of *in-vivo* human palpation data.

PROGRESS—To date, morphological parameters have been collected on the shoulder mechanism as well as the arm. These data comprise 3-D insertion sites of upper extremity muscles, the 3-D orientations of axes of rotation for elbow flexion/extension and pro/supination, and the rotation center of the glenohumeral joint. Also collected were data on muscle morphology such as muscle mass, the physiological cross sectional area, and the biomechanical model of the shoulder. With the use of the model it is possible to calculate muscle forces, tensions in ligaments, and reaction forces in joints of the shoulder. We are in the process of adding the morphological information of the arm to the model. Parallel to the model development, 3-D techniques for the measurement of upper extremity kinematics have been developed. 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

Finite element musculoskeletal model of the shoulder mechanism. Van der Helm FCT. J Biomech 1994:27(5):503-27.

Quasi-statie analysis of musele forees in the shoulder mechanism during wheelehair propulsion. Van der Helm FCT, Veeger HEJ. J Biomech. In press.

[61] QUANTITATIVE EVALUATION OF PRE- AND POST-OPERATIVE PLANTAR PRESSURE DISTRIBUTION IN CHILDREN WITH CEREBRAL PALSY

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Sponsor: *Shriners Hospitals for Crippled Children*

PURPOSE—This study was designed to quantitatively characterize the biomechanics of the planovalgus foot and the effectiveness of intervention in the correction and rehabilitative treatment of this disorder. A Holter type, microprocessor based, portable, in-shoe, data-acquisition system was used for the multistep evaluation of the plantar pressure distribution in hemiplegic and diplegic children and adolescents with cerebral palsy. A group of children with planovalgus foot deformity secondary to spastic cerebral palsy were evaluated pre-operatively and following subtalar fusion for correction of the foot deformity.

METHODOLOGY—A multichannel, portable data acquisition system has been used to record continuous plantar pressure data from the pediatric population. The microprocessor-based system is designed to be light-weight (350 grams with batteries) and portable (no umbilicus) in order to minimize encumbrances to gait patterns. The system allows real time recording of both pressure and gait parameters for up to 2 hours at a sampling rate of 40 Hz. The system consists of 16 analog amplifiers, a 12-bit A/D converter, an 8-bit microprocessor, 4M bytes of PSRAM, and serial and parallel I/O interfaces. Twelve of the available 16 channels were used for data acquisition in this study. Recorded plantar pressure data and calibration data are uploaded into a 486 computer for further processing, analysis, and display. The sensor used in this study was the Interlink FSR with an 11 mm active sensing diameter. The APEX foot imprinter was used in this study to determine sensor locations within the insole. Sensors were located at each of six preselected bilateral plantar locations under the calcaneus, medial and lateral midfoot, medial and lateral metatarsal heads, and hallux.

Sensors were embedded within the insole material. The instrumented insoles were fitted into a pair of standard canvas tennis shoes. A dynamic force application unit consisting of a compression lever, 440 N strain gage load cell, and preamplifier was used to dynamically calibrate the FSRs.

RESULTS—Twelve children and adolescents (eight males and four females) with planovalgus foot deformity secondary to spastic cerebral palsy participated in this study. The subjects were evaluated just prior to surgery, and at 6 and 12 months following subtalar fusion for correction of the foot deformity. During testing, the instrumented subjects walked continuously at their respective freely selected natural cadences on a smooth 21 m concrete walkway. Acclimation to the experimental shoes and establishment of a constant temperature shoe environment was provided during a 30-min pretest stabilization period. Several data gathering sessions were conducted for each subject with a 10-min rest period in between. From the recorded raw pressure-time data of each trial, the following parameters were processed and obtained: peak pressures,

foot-to-floor contact durations, and pressure-time integrals. Comparing pre- and post-operative results, the Holter-type data acquisition system has been successful in showing quantifiable differences in loading of the foot after surgery. At the midfoot the peak pressures, contact durations, and pressure-time integrals were diminished medially and increased laterally. The same three metrics were also diminished at the first metatarsal head with increases at the more lateral metatarsal heads.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[62] THE KINEMATICS AND KINETICS OF THE LOWER EXTREMITIES IN STAIRCLIMBING

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Sponsor: *None listed*

PURPOSE—As the beginning of a series of studies on the biomechanics of the lower extremity in patients with different lower extremity disorders, the purpose of this study was to evaluate the reproducibility of the kinematics and kinetics of the lower extremity in stairclimbing and the effects of steps in stairclimbing on the reproducibility of the kinematics and kinetics of the lower extremity in this locomotion.

METHODOLOGY—Six adults (three males and three females) without any previous history of lower extremity disorders, were recruited as the subjects for this study. Four video cameras and three force plates were used to record the subject's motion and ground reaction force at a sampling frequency of 60 Hz. A specially designed staircase was made which allows a four-step staircase to be attached to two of the three force plates for measuring ground reaction forces during stairclimbing. The video and force plate data were collected for the transition step from level walking to ascending (A0), the first two ascending steps (A1 and A2), the last two descending steps (D2 and D1), the transition step from descending to level walking (D0) in descending trials, and two consecutive steps (L and R) in level walking. Each subject had at least three trials in which he or she placed his or her feet on the force plates or stairs as required for each of ascending, descending, and level walking conditions. The three-dimensional joint angles and resultant moments of the ankle, knee, and hip joints were calculated for each step. The coefficient of multiple correlation (CMC) was used to determine the intra-subject reproducibility of each of the abduction/adduction, flexion/extension, and internal/external rotation angles and moments at different joints for different steps. An analysis of variance with repeated measures was conducted to test the effect of walking condition on the CMC of each kinematic or kinetic variable. The 0.05 level of confidence was chosen to indicate statistical significance for each analysis of variance.

RESULTS—It was found that the magnitudes of the CMCs for most of the joint angles were generally above 0.8, and that the magnitudes of the CMCs for the joint resultant moments were generally above 0.9. The results suggest that these kinematics and kinetics of the lower extremity in stairclimbing are reproducible. The magnitudes of the CMCs for the flexion/extension angles and moments were greater than those for the abduction/adduction and internal/external rotation angles and moments. These results suggest that the kinematics and kinetics of the flexion/extension are more reproducible than those for abduction/adduction and internal/external rotations. The magnitudes of the CMCs for joint resultant moments were generally greater than those for joint angles. These results suggest that joint resultant moments are more reproducible than joint angles in

stairclimbing, and that kinetic analysis should be emphasized in the clinical applications of the biomechanics analysis of stairclimbing. It was also found that the CMCs of the joint angles and moments in the transition steps were lower than those in the other steps. This result suggests that joint angles and moments are less reproducible in the transition steps than in the other steps, and that the transition steps should be considered cautiously in the clinical applications of kinematic and kinetic analysis of stairclimbing.

FUTURE PLANS—The kinematics and kinetics of stairclimbing will be compared to those in level walking to have a basic understanding of the biomechanics of the stairclimbing. Patients with different lower extremity disorders will be tested pre and post-operatively to explore the possible applications of biomechanics analysis of stairclimbing for different patient populations.

III. Functional Assessment

[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 sueeessfully transfcr from a seated position in a chair to a stable standing position is eritieally important for maintaining functional indepen-dencc and mobility. Elderly persons and persons with arthritis or Parkinson's disease oftcn have difficulty completing the sit-to-stand transfcr. The purpose of this pilot projeet is to develop and validate a system to eharaeterize the fundamental differenees between sue-eessful and unsuccessful performanee of the sit-to-stand motion. This pilot projeet will advanee our understand-ing of the sit-to-stand motion, and lead to improvements in rehabilitation treatments, intervention strategies, and chair design.

METHODOLOGY—An adjustable instrumented ehair has been designed and fabricated to measure the reaction forces on thc seat and armrests during the sit-to-stand motion. The chair will be used with existing systems that measure three-dimensional kinematics and ground reaetion forees to eharacterize the sit-to-stand motion. We will collect data during the sit-to-stand motion for 10 persons with Parkinson's disease and 10 age-matched healthy subjects.

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 differenees between the persons with Parkinson's disease and the healthy age-matched sub-jects, and between unsuccessful and sueeessful trials of the persons with Parkinson's disease.

PROGRESS—We have designed and fabrieated 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 indepen-dently measure the vertical and horizontal reaction forces on the seat and eaeh of the armrests. Strain gage-based triaxial force transdueers were designed and fabricated for the ehair seat and armrests. Signal eonditioning eireuits were designed and fabrieated for these foree transdueers.

The height of the seat, the height and spacing of the armrests, and the anterior-posterior position and height of the baek support are independently adjustable. All of these adjustments can be made while a subjeet is seated in the ehair. The seat and armrest surfaees will aeeommodate a variety of padding and grip materials.

We are eurrently ealibrating the force transducers and data acquisition system. We have collaborated with the Physical Medieine and Rehabilitation Service to establish the subjeet testing protocol, and with the Neurology Serviee to identify prospective patients with Parkinson's disease for partieipation in this study.

FUTURE PLANS—We will finish calibrating the instrumented chair, and then use this ehair to evaluate the sit-to-stand motion in persons with Parkinson's Disease and healthy age-matched subjects. The chair will be used in conjunction with existing systems for measuring three-dimensional kinematics and ground reaction forces. We expect to identify specific perfor-mance differences betwcen the patients with Parkin-

son's Disease and the healthy age-matched subjects, as well as between successful and unsuccessful trials in the persons with Parkinson's disease.

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 independence in veterans with impaired functional abilities.

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

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PURPOSE—The Americans with Disabilities Act (ADA) of 1990 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 the ADA prohibits employment discrimination against people with disabilities who are qualified to perform the essential functions of a job.

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 in light of 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 with documentation of subjects' functional capabilities to prescribe job-specific rehabilitation programs and/or assistive devices, that would enable individuals to perform the essential functions of the job.

METHODOLOGY—Healthy subjects performed a variety of lifting tasks in order to quantify what joint motion and strength capabilities are needed in order to complete the tasks. Subjects were tested while the speed of lift, lifting style, weight of lift, and duration of task were varied for lifts occurring in the sagittal plane. Video kinematic analysis and biomechanical modeling 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—The validation of the testing protocol, using the state-of-the-art lift simulator, was completed. The lifting protocol was expanded to incorporate the dimension of endurance, which is an important aspect of the task demand that has been neglected in ergonomics evaluation until recently. Furthermore, novel testing protocols were developed to examine how trunk motor performance changes during fatiguing tasks.

RESULTS—Functional equivalence was shown between tasks performed with the lift simulator and with a free weight box. The effect of fatigue on the performance of a repetitive lifting task indicated that subjects had greater trunk flexion and less postural stability in the fatigued conditon. Subjects also demonstrated decreased trunk performance by failing to maintain a set trunk extension torque, as an isometric endurance test progressed. Altered patterns of muscle recruitment quantified by the emg in an EMG-assisted model indicated that there may be increased spinal loading as one fatigues. The dimension of endurance is as critical to ergonomic evaluation as are the traditional aspects,

such as weight of lift, speed of lift, and lifting posture. This research expands the tools available for quantification of task and provides methods for further examination of trunk motor performance during fatiguing activities.

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[65] ASSESSMENT OF AMBULATION MOTION PARAMETERS FOR CLINICAL EVALUATION

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PURPOSE—This project is directed toward development and assessment of 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 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.

Efforts have been directed 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 been working on developing data processing techniques for identification of thresholds at which dynamic spasticity becomes present in young children with CP. Other recent work within the scope of this project has involved utilizing basic gait parameters to determine whether CP surgery outcomes are improved when recommendations from gait evaluation are followed versus when such recommendations are superseded. Yet another project compares the pre- and post-derotational osteotomy laboratory values for evidence of success or failure or predictability of pre-op values.

METHODOLOGY—To estimate threshold levels for dynamic spasticity onset, we 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. In order to utilize the biomechanical simulation software that has been obtained for this project, we have been developing techniques to process raw EMG data in order to generate smooth, continuous, positive EMG trajectories suitable for determining muscle activation levels.

To assess CP surgery outcomes based upon whether gait evaluation recommendations are followed,

we have identified patients at least two intervals between gait evaluations. One interval must include surgery and one must include no surgery. In this manner, we will be able to track the progress of basic gait parameters over each interval and associate such progress with whether the recommendations of evaluation at the beginning of the interval were followed.

For the evaluation of gait parameters pre- and post-op, a study was performed on 14 patients who each had a distal femoral osteotomy. Before and after surgery, each patient had CT scans to determine the femoral anteversion, and gait studies to determine internal/external rotation and velocity, cadence, and stride length measures.

PROGRESS—Presently, we have been able to process EMG data as to eliminate background noise and produce smooth, positive EMG trajectories. Additionally, thresholding techniques have been applied to generate zero level EMG during periods of no activity. To date, we do not have results from the outcome assessment portion of our work. The derotational osteotomy study showed little correlation between pre- and post-operative values. There was some correlation between the change in anteversion and the change in internal rotation. A lack of velocity improvement could be due to many patients already performing pre-operatively at more than 90 percent of normal.

[66] DEVELOPMENT OF PROTOCOLS AND MODELS USED TO QUANTIFY FUNCTIONAL CAPABILITIES OF PERSONS IN RESPONSE TO THE AMERICANS WITH DISABILITIES ACT

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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 the quantification of job demand profiles have become crucial in the industry.

The objective of this project has been to develop a series of models that could predict the functional capabilities (i.e., joint velocity, torque, and power generation capabilities) of an individual that can be contrasted with the job demands for the purposes the employment and rehabilitation processes of injured workers in light of the ADA.

METHODOLOGY—Twenty subjects (10 males and 10 females) were assessed with a muscle testing and training system. 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 were used to predict the joint torque generation capability for any combination of angle and velocity within the range of experimental values.

PROGRESS—Testing and data analysis have been fully completed. Dynamic surface responses were constructed of the various joint torques as a function of joint position and velocity for all the subjects. Each of these regressions represents the functional capacity profile for the specific joint for that subject and can be used with the previously determined task parameters to determine the individual's utilization ratio (strength capacity relative to the task demands). The utilization ratio provides a unified scalar of joint stress since it represents the task demand normalized by one's maximum capability. A biomechanical simulation program is currently being developed for various lifting tasks. In

addition to providing a time- and cost-effective tool, the simulation would provide means by which one can answer "what if" type of questions. Optimization techniques are being used to find the feasibility of a given task performance given the existing impairment and limitations on functional capacity such as: range of motion, strength, and speed. It also has potential use as a biofeedback tool for training injured workers to lift safely.

RESULTS—In an attempt to answer the question of how to best assess strength, 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 than traditional use of single value of strength without consideration of length-tension and velocity-tension relationship. These profiles were combined with the quantified task demand parameters previously determined in order to provide appropriate task assignment based on an individual's capabilities. In addition, a computer simulation of various lifting tasks is currently being developed. In the light of the ADA, this would be of great value in predicting the consequences of task modifications and/or worksation alterations without subjecting an injured worker or a disabled individual to unnecessary testing.

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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 1994 Annual Meeting, 1994:59-60.

[67] MEASURING ENABLING/HANDICAPPING ENVIRONMENTS: THE INFLUENCES OF DESIGNED ENVIRONMENTS ON FUNCTIONAL PERFORMANCE

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Sponsor: *U.S. Department of Education, National Institute for Disability and Rehabilitation Research, Washington, DC 20202*

PURPOSE—This research is designed to extend the usefulness of the Functional Independence Measure (FIM) instrument by linking it to environmental variables and developing additional, complementary assessment methods that address environment and its influences on functional performance in more detail. Specifically, this project is developing assessment instruments that provide quantitative measurements of the "goodness of fit" between environment and individual functional ability.

METHODOLOGY—Four assessment instruments have been developed and are now being tested.

The first instrument is a Usability Rating (UR) scale that has been developed to provide quantitative measures of a person's perceived difficulty completing an activity or task in a particular environment. This rating scale can be used for preliminary assessment of specific environments' general influences on the performance of selected activities.

The second instrument is a version of the FIM called the Functional Independence in the Environment Measure (FIEM). This instrument has been developed to measure actual functional ability of individuals within any environment.

A third instrument known as the Function Performance Measure (FPM) has been developed to assess a person's performance of discrete tasks associated with accomplishment of selected activities. This instrument makes it possible to identify empirically the specific

design features which either contribute to or undermine an individual's functional task performance.

The final instrument examines a standard set of observable and quantifiable Performance Indicators (PI) for accomplishment of certain tasks that can be used to measure observed behavioral capabilities of an individual for use as predictors of that person's subsequent task performance in specific environments.

PROGRESS—In recent months, multiple rounds of studies have been undertaken to establish the reliability and validity of each of these four assessment instruments. After each round, refinements have been made in measurement and rating techniques, and additional training procedures have been developed to further enhance the reliability and validity of each instrument. A final round of studies assessing the reliability and validity of the fully developed instrumcnts are now underway. Formal training programs, documenting these four instruments and designed to facilitate their reliable and valid application, are now being developed.

RESULTS—The coordinated, sequential application of these four instruments in selected environmcnts has already demonstrated their collective abilities not only to measure those environments' enabling and handicapping influences on the functional performance of persons with various types of mobility impairments but also to identify the corrective design action(s) required to further enhance the functional performance of such persons.

FUTURE PLANS/IMPLICATIONS—These four assessment instruments will assist rehabilitation practitioners and environmental designers not only in prescribing environments or environmental modifications with greater predictive utility but also in evaluating proposed environmental designs' impact on functional performance more easily. These assessment instruments will also significantly increase the reliability and validity of research on accessibility, particularly for measuring the severity of architectural barriers, determining priorities for barrier removal, and improving accessibility standards.

Armed with such empirical evidence, existing priorities for barrier removal can then be reviewed and, if warranted, revised. These instruments will also be used to validate and improve both existing and proposed accessibility standards by documenting the degree of benefit to functional performance provided by adherence to specific standards.

[68] 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 the 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 prcliminary studies have illustrated the motor and cognitive recovery attained by patients undergoing comprehensive medical rehabilitation and also 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—Patients with stroke, with traumatic brain dysfunction, and with spinal cord dysfunction will be included in this study. These groups are among the largest populations served by inpatient rehabilitation programs. Seven inpatient rehabilitation programs, all of them subscribers to the Uniform Data System for Medical Rehabilitation, will collect patient data. A sample of 100 patients per impairment group (a minimum of 700 total) will be collected; each hospital will provide data on 100 patients. 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 then convened 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 began March 1995, and will continue through January 1997.

PRELIMINARY RESULTS—Pilot data has helped us to revise forms and procedures. Formal data collection awaits accrual of sufficient number of patients.

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[69] COMPUTER SOFTWARE TO ASSESS HIGHER VISUAL FUNCTIONS

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Sponsor: *Ontario Rehabilitation Technology Consortium, funded by the Ontario Ministry of Health, and the Easter Seal Research Institute of Ontario (Summer Studentship Program)*

PURPOSE—We have developed a software program called the Componential Assessment of Visual Perception (CAVP), for the precise assessment of abilities and strategies used by people with disabilities when performing visual tasks. The CAVP runs in a Windows environment.

PROGRESS—We are pursuing a licence agreement for this product with a computer software company, which includes a royalty arrangement. More than 25 clinical centers in Metro Toronto are participating in prototype evaluation of it with pediatric, adult, and elderly populations with head injury, stroke, neuromuscular,

and other disabling conditions. A subset of these centers have confirmed that they will collaborate with us in multi-center validation studies.

FUTURE PLANS—By spring 1996, we expect to have completed a precommercial version of CAVP software and manual, in preparation for commercial release in 1996, and the first phase of validation and normative data gathering on the CAVP project.

RECENT PUBLICATIONS FROM THIS RESEARCH

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IV. Functional Electrical Stimulation

A. General

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

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B658-2RA)*

PURPOSE—Implanted electrodes have gained widespread acceptance for functional neuromuscular stimulation (FNS). Currently, FNS is used in the treatment of many neurological disorders, including bladder dysfunction, respiratory pacing, and limb paralysis. Stainless steel (316LVM) electrodes are often used for FNS applications requiring mechanical strength and fatigue resistance. However, this electrode material may be susceptible to pitting corrosion. A maximum current density of 20–40 $\mu C/cm^2$ has been recommended for avoiding corrosion, and with balanced stimulating waveforms, lower charge injection densities are required for anodic-first pulsing than cathodic-first pulsing. The primary problem with these low charge injection density electrodes is that large surface area electrodes have to be used to avoid corrosion. To develop high charge injection density electrodes, we have investigated activated Ir Oxide Films (AIROF) on stainless steel electrodes.

METHODOLOGY—Wire electrodes of 316LVM stainless steel were coated with Ir metal by DC magnetron sputtering at EIC Laboratories under the direction of Dr. Stuart Cogan. A thin film of Ti was sputtered onto the 316LVM as an adhesion layer prior to Ir deposition. In order to promote uniform coating, the wire electrodes were positioned parallel to the target surface at a distance of 9 cm and rotated at 14 rpm. The sputtering was accomplished with an Ar plasma at a pressure of 10 millitorr for the Ti deposition and 22 millitorr for the Ir deposition. The sputtering was done at an average current density of 7.5 mA/cm^2 over 3 cm length targets.

PROGRESS—AIROF coatings have shown good adherence and remarkable resistance to high charge injection protocols. The coated electrodes appear suitable for bipolar pulsing protocols. There is little tissue reaction to chronically implanted AIROF coated electrodes.

RESULTS—Scanning electron microscopy of the Ir film showed evidence of smooth layers with some nodular growth morphology. *In vitro* and *in vivo* analysis of the AIROF coated electrodes were performed at Hines VA Center. *In vitro* scratch tests showed good adherence of the films to the electrodes. Implantation of the electrode in the hind leg of a cat for 7 weeks did not reveal any disruptions in the AIROF film. Tissue reaction was minimal. Studies during 240 hours of pulsing at 60 pulses per second revealed no corrosion up to 320 $\mu C/cm^2$ for anodic-first pulsing and higher charge injection densities for cathodic-first pulsing (no corrsion was evident at 620 $\mu C/cm^2$ and higher densities are being tested). Electrical transients were small and decreased during the stimulation protocol indicating both low resistance of the film and activation of the film during pulsing. Thus, much higher charge injection densities can be obtained without the high electrical transients associated with the irreversible oxidation/reduction reactions and the hydrolysis of water. In addition, this coating will allow for much

smaller surface area electrodes, which could have applications for many neuroprosthetic implant devices.

FUTURE PLANS—We plan to finish our detailed 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. Ann Biomed Eng 1994:22:202.

[71] REHABILITATION OF RESPIRATORY PARALYSIS: ACCESSORY MUSCLE STIMULATION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B806-RA)*

PURPOSE—Activation of the diaphragm via phrenic nerve stimulation has been used for respiratory management of chronic ventilatory insufficiency for over 25 years. However, even with recent improvements in electrode technology, the lack of coordinated contractions from accessory support muscles has severely limited the usefulness of this technique in many cases. Lack of accessory thoracic muscle stimulation causes a collapse of the chest wall during inspiration, which decreases the efficiency of breathing and contributes toward diaphragm fatigue and failure. Electrical activation of the chest wall inspiratory muscles would assist the diaphragm and increase the efficiency of diaphragm pacing. Further, activation of expiratory muscles would provide additional support and demonstrate the feasibility of inducing an electrically generated cough. The purpose of this project is to determine if intramuscular electrodes in the chest wall can selectively activate intercostal and parasternal muscles that assist chest expansion and promote inspiration.

METHODOLOGY—In high level spinal cord injured (SCI) subjects, bilateral pairs of intramuscular needle electrodes were inserted into upper intercostal regions. During electrode stimulation, thoracic expansion was measured using a respiratory belt, and lung volume changes were monitored using a spirometer.

PROGRESS—We have demonstrated in high level SCI subjects that intramuscular electrodes are capable of stimulating thoracic muscles which support inspiration. Currently, studies are underway to provide the best thoracic locations for electrode placement and the optimal stimulating parameters for diaphragm assistance.

RESULTS—Electrode stimulation in a relaxed state caused thoracic expansion and a modest tidal volume. Electrode stimulation during inspiration reversed a collapsing chest into chest expansion and enlarged tidal volumes. A greater response was found for electrodes in the third than in the fifth or sixth interspaces.

FUTURE PLANS—Experiments will continue to refine stimulation parameters and determine the electrode locations that best support the diaphragm during inspiration.

RECENT PUBLICATIONS FROM THIS RESEARCH

Diaphragm and accessory respiratory muscle stimulation using intramuscular electrodes. Dunn RB, Walter JS, Walsh J. Arch Phys Med Rehabil 1995:76(3):266-71.

[72] REHABILITATION OF THE COLON AFTER SPINAL CORD INJURY: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #B92-511AP)*

PURPOSE—The objectives of this study include: 1) establishing baseline parameters of normal colonic responses in an animal (cat) model; 2) evaluating direct colonic stimulation using implanted electrodes; and 3) comparing direct colonic stimulation with stimulation of the sacral nerves for managing constipation and fecal impaction.

METHODOLOGY—Male cats with spinal cord injury (SCI) at the T-4 level are used to study the effects of direct colon stimulation on bowel responses. Previously, we developed a suture style electrode for direct stimulation of the bladder wall. Electrodes consist of 316LVM multistranded stainless steel wire. This type of electrode is implanted semi-circularly around the colon at 5 and 25 cm from the anus. This method of implantation allows complete expansion of the colonic walls without obstructing the movement of the feces. Two additional electrodes are implanted longitudinally approximately 10 and 20 cm, respectively, from the anus to determine the effects of longitudinal stimulation on colon function. Stimulating parameters that induced affective defecation were a 1 ms pulse, a repetition rate of 40 pps, and an effective current sweep from 5–35 mA.

PROGRESS—We have continued to developed instrumentation for direct colon stimulation and chronic monitoring of colon function. Baseline parameters of normal colon function before SCI have been established. Manometry and transit studies are being used to compare the effects of SCI and/or stimulation on normal colon function.

RESULTS—Following preliminary observations previously reported, the most significant preliminary finding is that direct colon stimulation is capable of promoting defecation and colon pressure changes similar to those observed in a spontaneously active animal. Stimulation has successfully induced defecation in both the pre-SCI and post-SCI animal. For both of these animal models, abdominal straining was observed. The electrodes most effective at promoting defecation were either both located semi-circularly in the descending segment or longitudinally with one electrode in the descending segment and the other in the transverse segment of the colon.

FUTURE PLANS—To date, the majority of the studies have focused on developing the instrumented, pre-SCI animal model and then characterizing normal colon function both before and after stimulation. In the final 3 months, we plan to assess the effects of SCI and stimulation on a T4 SCI animal. 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 continue to be monitored with a videotaped fluoroscopy of the movements of radio-opaque makers injected into the ileocecal junction through an implanted tube. Gastrocolic responses will be monitored by observing the effects of eating on segmental transit times.

[73] 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 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 spinal cord injury (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—Three paraplegic and three quadriplegic subjects have received these implants, the first of this type in the United States. Recruitment has been extended to non-veterans, and the first non-veteran has received an implant.

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 catheterisation, and those with good hand function no longer use leg bags. Five have found that regular use of the stimulator reduces constipation and four 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 non-veterans, and may be extended to other centers in the USA. 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 which activates bladder and rectum without activation of the sphincters.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[74] ELECTRICAL ACTIVATION OF THE DIAPHRAGM FOR VENTILATORY ASSIST

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B634-3RA)*

PURPOSE—The objective of this project is to develop a diaphragm pacing system for clinical applications.

METHODOLOGY—We propose to: 1) develop endoscopic methods to place stimulating electrodes on or in the diaphragm muscle using an abdominal approach to access the diaphragm muscle, and 2) evaluate the suitability of the methods and devices for clinical applications.

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.

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. This involves mapping each hemidiaphragm in order to locate the optimal placement site in the least number of trials and thus, the shortest amount of time. 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.

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, and 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 over come with the intramuscular electrode is placement in the diaphragm without entering the thorax. A tool has been developed to place intramuscular electrodes in the diaphragm through an abdominal approach. Preliminary tests on dogs suggest that this is a viable technique for electrode placement. Although some problems still exist with the device, modifications to the implant tool and intramuscular electrode have shown promise. Further experiments are needed to evaluate the efficacy of these modifications.

FUTURE PLANS AND IMPLICATIONS—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. Also, the mapping paradigm will be modified to facilitate optimal electrode placement. 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.

[75] 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 to: 1) 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) to assess potential benefits and risks of these therapies to persons with SCI; 2) 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) design more progressive FES exercise training protocols to optimize adaptations of the muscles utilized and of 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) under FES of their paralyzed lower-limb muscles 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. A questionnaire is used to assess changes in medical problems during participation in FES exercise programs.

PROGRESS—From our findings, we have implemented several changes to the original FES parameters to significantly improve LCE performance and magnitudes of metabolic and cardiopulmonary responses. It appears that these modifications can elicit accelerated and greater physiologic training adaptations. In contrast to the original Therapeutic Alliances Incorporated model ERGYS I FES parameters, we presently: 1) limit maximal current output to 300 mA (vs. 140 mA), which increases muscle fiber recruitment; 2) set firing angles to 120° (vs. about 70°), which increases contraction duration to 0.40 sec (vs. 0.23 sec); and 3) add the tibialis anterior and gastroc-soleus muscles to the already used quadriceps, hamstrings, and gluteus maximus muscles. A specially constructed multichannel amplifier, and modified ERGYS I ROM chip were used to accomplish these FES parameter changes.

Furthermore, we have designed more aggressive exercise testing and training protocols that present greater and more continuous "overload" of the subjects. To enable this, we designed and constructed an electronic circuit to permit adjustment of LCE load resistance during pedaling (without the necessity of stopping and reprogramming) so that power output could be varied up or down in the desired increments (e.g., 1.5–3 watt rather than 6 watt) to better match the power output to the pedaling capability of the subjects. The LCE testing protocol now incorporates continuous exercise with power output being incrementally increased every 2 minutes until fatigue. This system also facilitates implementation of interval training programs, rather than being limited to continuous/endurance training programs as with the original ERGYS I. Prior to and following exercise training, we are evaluating performance of each muscle group on our KinCom isokinetic dynamometer by incorporating a specially designed and constructed electrical stimulator and a repetitive isometric contraction protocol.

FUTURE PLANS/IMPLICATIONS—We are currently conducting our final FES-LCE training for this

program to enable comparison of physiologic results between the original and modified FES parameters. A newly designed interval training program protocol is being used. 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 patients with SCI should derive important 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

Biomechanical comparison of functional electrical stimulation-induced and active knee extension exercise. Rodgers MM, Glaser RM. In: Conference Proceedings of the American Society of Biomechics 1994:217-8.

Effects of electrical stimulation of shank musculature during ES-leg cycle ergometry. Figoni SF, Rodgers MM, Glaser RM. Med Sci Sports Exerc 1994:26(5):S77.

Effects of increased maximum current during electrical stimulation leg cycle ergometry. Glaser RM, Figoni SF, Couch WP, Collins SR, Shively RA. Med Sci Sports Exerc 1994:26(5):S111.

Functional neuromuscular stimulation: exercise conditioning of spinal cord injured patients. Glaser RM. Int J Sports Med 1994:15(3):142-8.

Psychological changes resulting from electrical stimulation training of spinal cord injured individuals. Aaronson AL, Rodgers MM, Glaser RM, Figoni SF. In: Proceedings of the American Psychological Association Annual Meeting, 1994:44-6.

Tibial bone density loss in spinal cord injured patients: effects of FES exercise. Hangartner TN, Rodgers MM, Glaser RM, Barre PS. J Rehabil Res Dev 1994:31(1):50-61.

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

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PURPOSE—The primary objective is to determine if electrical stimulation, with surface electrodes applied adjacent to the anal sphincter, can significantly reduce urge symptoms and incontinence in adults and elderly and subjects with hyperreflexic bladders. The secondary objectives include: 1) the evaluation and assessment of patient perception of treatment and outcome; 2) the assessment of long-term effects of treatment with follow-up; 3) the assessment of whether there are subgroups that can be correlated with the outcome based on characteristics such as patient history, weight, age, and so forth; and 4) the determination of the percentage of patients who come under incontinence control during each part of the study, and assess other aspects for the feasibility of a long-term study. These aspects will include: a) adequacy of patient accrual, b) patient acceptance of therapy arms, c) 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: 1) It is a small device that can fit into the patient's pocket or clip to the belt. 2) It has an on-off switch for continuous stimulation and a light source to indicate that the stimulation is on. 3) Frequency and pulse duration are custom set for optimum stimulation effect with a minimum of pain. 4) It has a single dial with friction resistance which will allow the user to turn the stimulator on and off easily 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 electrical stimulation will be kept below a level that creates an uncomfortable sensation for the patient. As the patient becomes used to the current, he/she may be able to increase the current. Safe use of the stimulator, and thus painful stimulation, will be avoided.

PROGRESS—Subjects are being enrolled.

[77] REHABILITATION OF URINARY INCONTINENCE USING STIMULATED MUSCLE FLAPS

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PURPOSE—This study will evaluate the effectiveness of stimulated skeletal muscle flaps in elevating urethral closure pressure in a male dog model. Urethral ischemia and stricture formation are known complications of urethral wrap procedures, and these complications will be evaluted. 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 gracilis muscle neosphincter. Group 2 will be composed of animals that will undergo alternating stimulation of two independent and separate gracilis 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. Acute studies have been conducted with an implantable stimulator applied to a skeletal muscle flap on the urethra.

PROGRESS—The feasibility of stimulated skeletal muscle flap was evaluted in acute studies using a single muscle wrap around the bulbous urethra in the perineum. High urethral closure pressure was obtained with low stimulation parameters. The surgical procedures were easy to perform.

RESULTS—Acute studies have been conducted in one anesthetized dog with an implantable stimulator applied to a skeletal muscle flap on the urethra. The gracilis muscle was loosely wrapped around the urethra to avoid the potential for stricture formation. Stimulation at 10 pulses per second produced a current response curve with induced pressures from 10 to 150 cm H_2O. At this low stimulation frequency, contraction could be obtained without fatigue for a 10 minute protocol indicating that conditioning of the muscle might not be necessary.

[78] MANAGEMENT OF URINARY DISORDERS IN SCI

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PURPOSE—This project has two overall goals: 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 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. Five animals received an upper motor neuron lesion, and four animals received 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 near the ureters in the trigone area. One electrode was implanted in some of the animals for impedance monitoring of bladder volume. 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—Prolonged bladder contractions and voiding to direct bladder stimulation have been shown before and after SCI. For maximal voiding rates, a urethral resistance measure showed that urethral resistance was not increased by direct bladder stimulation. However, voiding responses to stimulation were less effective at small bladder volumes.

RESULTS—The feasibility of direct bladder stimulation has been evaluted in nine male cats. We have developed suitable tethering procedures and effective stimulation has been shown. 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 second 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_2O. 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 the 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_2O. Repeated stimulation completely emptied the bladder in 3 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: 1) the pudendal nerve in the pelvic floor may not be directly stimulated; 2) the large surface area woven eye electrode may be an improvement in electrode design; and 3) we are currently developing a suture electrode that can be sutured into the serosa of the bladder wall. However, problems related to clinical trials of direct bladder stimulation include: 1) SCI patients must be continent and their high urethral resistance must be managed; 2) acute evaluation procedures must be

developed that will show which patients will benefit from direct bladder stimulation. If these problems, the subject of our current research, can be addressed, direct bladder stimulation may become more widely available to the SCI patient.

FUTURE PLANS—Future 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 evaluation of sexual function.

RECENT PUBLICATIONS FROM THIS RESEARCH

Walter JS, Zaszczurynski P, Cai W, et al. Direct bladder stimulation with percutaneous electrodes and impedance monitoring of volume in a SCI animal model. J Spinal Cord Med. In press.

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

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PURPOSE—Functional Electrical Stimulation (FES) is a technique that can maximize health and function in persons with spinal cord injury (SCI) or 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 MS 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 SC disease need specialized information about FES to build a knowledge base that permits them to understand, identify, and pursue appropriate FES treatment options which will maximize their independence, function, and health.

The objectives of this project are: 1) to increase the knowledge base of persons with spinal cord injury/disease on the use of FES; 2) to increase access for persons with spinal cord injury/disease to FES providers; and 3) to increase the decision-making ability of persons with spinal cord injury/disease to make informed decisions regarding the appropriateness of FES interventions.

To accomplish these objectives, in cooperation with the National Spinal Cord Injury Association and ABLEDATA, we will develop and disseminate to the spinal cord injury/disease community, a resource guide on functional electrical stimulation.

METHODOLOGY—The guide will serve as a "one-stop-shop" for persons with SCI and disease seeking information about FES options. The guide will include a tutorial section covering: 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 proportion 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 and 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 is under revision after review by a committee of experts in the field. The data collection survey is underway, with approximately 100 stimulation programs described thus far.

FUTURE PLANS—The FES resource guide is expected to be available at the end of 1995.

[80] FATIGUE AND RECOVERY OF ACTIVATED PARALYZED MUSCLES BY INTERRUPTED STIMULATION

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

METHODOLOGY—The lower limb of a paraplegic patient can be analyzed as a dynamically determinate system, since the muscles there are isolated from voluntary control. Hence, under conditions of zero or low spasticity, when activated by functional electrical stimulation (FES), the only non-zero 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. Anthropometric parameters of the muscle are monitored by using MRI. 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, after rest periods of prescribed durations.

A musculo-tendon model for fatigue and recovery has been developed and incorporated in the dynamic model of the activated limb. The variables in this model are anatomical, mechanical, anthropometric, myoelectric, metabolic, electrolytic, and history-dependency.

RESULTS—The results obtained reveal a correlation between muscle force and EMG during fatigue. This correlation was found to be independent of the state of training. Intracellular pH was shown to indicate muscle force in primary fatigue. In recovery, however, the force was found to recover faster than pH, indicating that force-pH relations in fatigue and recovery are different from each other.

FUTURE PLANS—The force and EMG parameters demonstrated substantial recovery with the first 3 min of rest. This suggests that metabolic factors alone are not sufficient to describe fatigue and recovery. The role of electrolytic factors in governing the dynamics of fatigue and recovery will thus be studied in the next stage.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[81] REHABILITATION OF PARALYZED MUSCLES BY TRANSCUTANEOUS FES

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Sponsor: *The Segal Foundation; the Walter and Sandra Kaye Fund; the 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 the aim. In the CP populations, the feasibility of FES for strengthening muscles and control of spasticity is examined. Proper evaluation techniques are developed.

METHODOLOGY—A microprocessor 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 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 videotaped prior to and following 4 weeks and 3 months of home treatment. Data on the muscle during training, such as cross section area, tendon length, and overall length are monitored using MRI techniques.

RESULTS—Three paraplegic patients were treated in the past year, one complete and two incompletes. The complete and one of the incomplete subjects achieved standing and stepping while using an instrumented walker. In the other incomplete subject, sensation in the lower limbs thwarted use of the high intensity stimulation, as required for standing and stepping. The subjects were regularly monitored for recruitment, spasticity, fatigue, and recruitment, using muscle force, EMG, and MRI.

FUTURE PLANS—It is planned to continue to develop evaluation methods, to miniaturize the apparatus, and to improve the stimulator device for implementation on more patients.

RECENT PUBLICATIONS FROM THIS RESEARCH

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

Myoelectric and force characteristics in transcutaneous isometric FES. Mizrahi J, Isakov E, Susak Z. Basic Appl Myol 1994:4(2):147-54.

Aspects of artificial activation of human actuators (muscles) in paralyzed subjects. Mizrahi J, Aviram A, Seelenfreund D, Isakov E, Susak Z. In: Proceedings of the 3rd French-Israeli Symposium on Roboties; Herzlia, Israel, 1995:17-21.

B. Upper Limb Applications

[82] RESTORATION OF FOREARM AND ELBOW FUNCTION BY FNS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B835-RA)*

PURPOSE—The purpose of this project is to integrate restoration of forearm and elbow control with hand grasp neuroprostheses for people with cervical level spinal cord injury (SCI). Our objective is to increase the range and type of upper extremity functions the patients can perform, by electrically stimulating paralyzed pronator quadratus and triceps in addition to the muscles providing hand grasp and release. We hypothesize that augmenting the hand grasp neuroprosthesis will give individuals with C5 and C6 SCI the ability to grasp and move objects over a greater range of spatial locations and orientations, and will improve movement quality.

METHODOLOGY—The triceps muscle is stimulated electrically to provide elbow extension when the arm is in an orientation where active elbow extension is desirable. The stimulation is adjusted to overcome the effects of gravity and loads in the hand, and is controlled by an accelerometer mounted on the arm, which measures the arm's orientation in the gravitational field. Elbow angle is controlled in a natural manner by the subject voluntarily contracting the biceps to counteract the elbow extension torque. Forearm rotation is provided in a similar manner, by stimulating the pronator quadratus at a constant level whenever the hand grasp neuroprosthesis is active. Supination/pronation angle is controlled by the subject voluntarily supinating to counteract the pronation torque. Thus, the additional functions do not require additional command signals unrelated to the desired function. Elbow and forearm stimulation is integrated with the VA/CWRU hand grasp neuroprosthesis.

The forearm and elbow functions are evaluated in terms of the basic mechanical capabilities (force, moment, dynamic stiffness), the ability of the patients to use the restored function to achieve stable postures and produce smooth movements, and the improvement in the ability to perform common activities of daily living that require picking up and placing objects over a wide range of locations and orientations.

PROGRESS—This is the first year of this project. One neuroprosthesis has been constructed and is currently being used at home by one person to provide hand grasp and elbow extension. The triceps is stimulated via percutaneous intramuscular electrodes, and elbow extension is controlled by an accelerometer mounted on the lateral side of the upper arm, just distal to the shoulder. At this time, the individual has used the system for 3 months.

We designed a series of functional tests to evaluate the upper extremity workspace. The person is instructed to pick up an object at one location, move the object, and place it in another location. Object orientation (e.g., horizontal or vertical) is also specified at both locations. Success or failure is recorded at both the starting and ending location, and the 3D kinematics of the arm and the object are recorded throughout the task. Object contact and force data, and the control signals to the stimulated muscles, are also recorded. Four evaluations have been conducted to date.

RESULTS—The data from the kinematic evaluation are not yet analyzed, but in general, elbow extension is of greatest benefit when the objects are located high on the opposite side of the body, and are oriented horizontally. This is consistent with the need for elbow extension to counteract gravity. Objects on the opposite side of the body and with a horizontal orientation require internal arm rotation, which increases the need for active elbow extension.

FUTURE PLANS—Neuroprostheses with elbow and forearm control will be implemented in four individuals. Additional evaluations will include assessment of single and multiple joint movements, and measurements of the dynamic stiffness of the arm to characterize and improve the FNS control.

RECENT PUBLICATIONS FROM THIS RESEARCH

Biomechanical factors determining postural stability at the elbow joint. Lin CC, Crago PE. In: Proceedings of the 16th Annual International Conference IEEE Engineering in Medicine and Biology Society; 1994 November; Baltimore, MD.

Techniques for characterizing elbow and shoulder mechanics and neural control in normal and disabled subjects. Kirsch RF, Acosta AM. In: Proceedings of the 17th Annual International Conference IEEE Engineering in Medicine and Biology Society; 1995 September; Montreal, Ontario.

Restoration of pronosupination control by FNS in tetraplegia: experimental and biomechanical evaluation of feasibility. Lemay MA, Crago PE. J Biomech. In press.

[83] FUNCTIONAL NEUROMUSCULAR SYSTEMS FOR UPPER EXTREMITY CONTROL

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

METHODOLOGY—Implantable neuroprostheses, in conjunction with augmentative surgical procedures, have been used to provide grasp and release for C5 and C6 quadriplegic individuals. Eight-channel implant receiver stimulators have been in human use for over 9 years. A more advanced 10-channel implantable stimulator/telemeter, with an implanted joint angle transducer, is now undergoing animal trials in preparation for implantation in humans. The new device has the capability to transmit data from the body and provides additional stimulus channels that will be used to activate the finger intrinsic muscles for improved grasp opening. The implantable joint angle transducer, utilizing a magnet and a Hall-effect sensor enclosed in a titanium capsule, will be placed in the wrist, allowing voluntary wrist motion to be used to control grasp opening and closing. A single transmitting/receiving coil will be placed externally on the patient.

Patient funetion is evaluated using a variety of assessments designed to measure impairment, disability, handieap, quality of life, and device utility. Assessments are performed pre-surgery, during an intense training session post-surgery, and 1 year after the training period.

PROGRESS—A complete 10-channel implantable stimulator-telemeter, including an implantable joint angle transducer, has been operational in an animal for 10 months. Additional animals will be implanted with a transducer redesigned to allow easier surgical placement. Multicenter clinical trials, which have been transferred to industry, have continued with the 8-channel device and a total of 29 subjects have received implant stimulators at seven cooperating sites. In Cleveland, 14 subjects have received implant stimulators (11 males, 3 females; 8 are C5 subjects and 6 are C6). Thirteen subjects have completed the majority of the training and functional evaluations. The remaining subject is currently undergoing post-operative exercise.

RESULTS—Patients generate lateral and palmar pinch strengths with the neuroprosthesis in the range of 2.5 to

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

FUTURE PLANS—Human studies for the 8-channel hand neuroprosthesis will continue through 1995. Human studies with the 10-channel implant will begin in 1996, and human implantation of the joint angle transducer will commence at the completion of animal trials in late 1996.

RECENT PUBLICATIONS FROM THIS RESEARCH

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.

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

Data transmission from an implanted biotelemeter by load-shift keying using circuit configuration modulator. Tang Z, Smith B, Schild JH, Peckham PH, IEEE Trans Biomed Eng 1995:5:524-8.

Tendon transfers and functional electrical stimulation for restoration of hand function in spinal cord injury. Keith MW, Kilgore KL, Peckham PH, Wuolle KS, Creasey G, Lemay M. J Hand Surg. In press.

[84] THIN-FILM PERIPHERAL NERVE ELECTRODE

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PURPOSE—Complex hand movements might be obtained with direct median nerve stimulation through an implanted multielectrode nerve cuff. Repeatable hand responses should be obtained with no injury to the nerve. The purpose of this study is to evaluate a multielectrode circumneural thin-film 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 are curretly available on this electrode. A standard 12-electrode cuff, using small platinum disk electrodes on a silastic cuff, has also been procured for comparison to the thin-film cuff. Studies are conducted on an anesthetized raccoon. Forearm and paw movements are observed with intramuscular electrodes and the implanted cuff electrodes. In addition, five forearm muscles were isolated and their tendons connected to force transducers. Current response studies were conducted for each electrode arrangement.

PROGRESS—Forearm and paw movements have been obtained through selective stimulation with both percutaneous electrodes inserted directly into forearm muscles and with the multielectrode cuffs. Cuff electrodes were also used with direct recording from the tendons of five forearm muscles. These results showed

selective recruitment curves that were enhanced by longitudinal and steering currents. Comparison of our new thin-film cuff to the standard cuff constructed of silastic with platinum electrodes showed nearly identical recruitment curves.

RESULTS—Four raccoons have been evaluated under anesthesia with the 12-electrode (standard) cuff. A variety of paw movements could be obtained with different electrode arrangements, including forearm pronation, wrist flexion, and digit flexion. Selective activation of the thumb was obtained in one animal. The movements were similar to those elicited with electrodes implanted directly in the muscles. Direct recording from the tendons of five forearm muscles showed selective recruitment curves with the cuff electrodes that were enhanced by longitudinal and steering currents. Comparison of our new thin-film cuff to this standard cuff showed nearly identical recruitment curves. Thus, the thin-film cuff is suitable for further testing.

FUTURE PLANS—A new thin-film cuff with 12 electrode sites is being developed for chronic implantation. Connections to a 16-channel RF coupled stimulator have been developed and will be evaluated over a 4-month implantation period in the raccoon.

[85] CLOSED-LOOP CONTROL OF FUNCTIONAL NEUROMUSCULAR STIMULATION: METHODS OF PROVIDING SENSORY FEEDBACK

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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, 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. The goal of this project is to investigate methods of providing sensory feedback to users of a hand neuroprosthesis using electrocutaneous stimulation of sensate skin to represent kinesthetic information measured external, implanted, or natural sensors.

METHODOLOGY—In the past year, experiments have focused on measuring interactions between simultaneous modulations of stimulus amplitude and stimulus frequency. Since these two physical dimensions are chosen most often for providing information via sensory feedback, it is important to understand whether their corresponding psychological dimensions of loudness (perceived intensity) and pitch, respectively, are independent or interact with each other. Two paradigms have been used to investigate two forms of interaction: 1) cognitive delays in processing simultaneous changes in loudness and pitch (i.e., Garner interference) were measured using speeded-classification tasks in which subjects identified one of two to four stimuli with different combinations of two pitches and loudnesses. 2) Bekesy tracking was used to measure isoloudness contours to investigate distortion, i.e., the effects of stimulus frequency on perceived stimulus intensity.

PROGRESS—The speeded-classification experiment is complete, and the measurement of isoloudness contours is in progress. Complementary measurements of isopitch contours are under development.

RESULTS—The results from the speeded classification experiment show that the perceptual dimensions of pitch and loudness exhibit Garner interference, just as in vibrotaction and audition. That is, identification of changes along one dimension are delayed by approximately 20 ms (on average) for identifications made between two loudnesses or two pitches if the stimuli

also changes at random along the other dimension. After subtraction of the minimum reaction time, the delay accounts for an average decrease of 0.4 bits per second in the information transfer rate. In contrast, if both dimensions are changed in a correlated fashion, information transfer rates are improved by 0.7 bits/sec. The Bekesy tracking paradigm yielded stable isoloudness contours within and across sessions for frequencies from 4–64 Hz, and stimulus amplitudes between 3–12 dB SL. The contours measured to date vary across subjects, but the shape of the contour is constant within a subject at different loudness levels (i.e., the isoloudness contours are all parallel within a subject).

FUTURE PLANS—The speeded classification task was constrained to identification of only two pitches or loudnesses, which fails to capture the variations expected in a real feedback application. More realistic simulations of a real system are needed. The isoloudness contours measurements need to be completed, and complemented by similar measurements of isopitch contours. The contours, then, may be used to compensate for distortion by co-varying amplitude and frequency to produce the desired orthogonal changes in loudness and pitch.

RECENT PUBLICATIONS FROM THIS RESEARCH

Independence of pitch and loudness of an electrocutaneous stimulus for sensory feedback. Menia LL, Van Doren CL. IEEE Trans Rehabil Eng 1994:2(4):197-206.

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

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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 this procedure 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 and other rehabilitation methods 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.

METHODOLOGY—The ability of individuals with spinal cord injury and subsequent tendon transfer surgery to perform arm movements is being examined in several ways. The mechanical success of the transfer is quantified by measuring the torque generated by the donor muscle at the joint producing the restored function, while any deficits in the original function of the donor muscle introduced by the surgery is examined by measuring the torque capability at the donor's original joint. The ability of the nervous system to adapt to the new mechanical situation and use the donor muscle appropriately is being examined by obtaining electromyographic (EMG) recordings of the donor muscle and other muscles throughout the limb. In particular, the ability to voluntarily activate the donor muscle independently of its original synergists is being examined, as are the development of muscle co-activation patterns throughout the limb appropriate to compensate for undesirable actions of the donor. The endpoint stiffness of the arm is also being characterized, since this quantity directly reflects the stability of a postural configuration or a movement trajectory and is useful in localizing the sources of any significant performance deficits. A specialized robotic manipulator

has been developed for this purpose and is used both to generate constant forces, which must be resisted by the subjects to maintain a specified hand position, and to impose small force perturbations needed for the stiffness estimates.

PROGRESS—Manipulator performance has been significantly improved by new controller hardware and modifications to the control software. A multi-input, multi-output system identification procedure has been developed to estimate endpoint stiffness and has been extensively tested by computer simulations. This identification procedure was found to work very well under conditions (force bandwidth, perturbation force dependence, measurement noise) similar to those provided by the current manipulator. Stiffness measurement in nondisabled subjects has been initiated, and the recruitment of tendon transfer patients has begun.

RESULTS—Manipulator performance has been significantly improved. A multi-input, multi-output system identification technique needed for accurate endpoint stiffness characterization has been developed and validated.

FUTURE PLANS—In the next year, extensive experimentation with neurologically intact subjects will be performed to characterize nondisabled endpoint stiffness and muscle EMG properties during a variety of postural tasks. Spinal cord injured patients with posterior deltoid-to-triceps muscle tendon transfers will be examined both before and after their surgeries; the pre-surgery measurements will focus on potential deficits in shoulder function introduced by the surgery, while post-recovery measurements will also examine movement performance relative to normal. Potential improvements in the surgical procedure and possible enhancements such as functional neuromuscular stimulation of other muscles in the limb will be examined.

RECENT PUBLICATIONS FROM THIS RESEARCH

Techniques for characterizing elbow and shoulder mechanics and neural control in nondisabled and disabled subjects. Kirsch RF, Acosta AM. In: Proceedings of the 17th Annual International Conference IEEE Engineering in Medicine and Biology Society. In press.

C. Lower Limb Applications

[87] 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 lower extremity cycling (FESILEC) for SCI patients are enhanced functional capabilities, improved cardiovascular fitness, decreased blood cholesterol levels, decreased 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 FESILEC 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. A total of 36 subjects were screened, of which 24 (3 quadriplegics and 21 paraplegics) were admitted to the study. In addition, 17 nondisabled subjects were studied as controls for the muscle blood flow studies and 10 nondisabled and 6 flaccid SCI subjects were studied as controls for the spasticity studies.

RESULTS—*Muscle Tone (Spasticity):* The time course effect of FESILEC on the spasticity of 7 spastic patients immediately after, 2 hours after, and the next day following FESILEC suggests only immediate decreases in muscle tone, not lasting more than 2 hours. Using a discriminant analysis technique, 5 out of 7 subjects were classified to a single cluster closer to the nondisabled and flaccid group means. Following the CONTROL condition, the results were more variable. Subjective evaluation of spasticity by the subjects demonstrated that all 7 subjects believed that their spasticity decreased immediately after riding the REGYS bicycle. Three of the 7 subjects perceived this decrease to remain for less than 2 hours, while 4 subjects believed the decrease lasted up to 6 hours. All subjects felt that they had fewer spasms per day, transfers were easier, and that their legs felt looser. Six of the 7 perceived a greater range of motion in their legs. Three subjects found that the strength of their spasms increased following the 9-month exercise training.

Bone Density: Dual Energy X-ray Absorptiometry (DEXA) studies have been completed to assess bone density before and after training (average 68±14 sessions over 34±8 weeks). Significant training effects have been found only in the lumbar spine region. Continued training (additional 37±15 sessions over 25±9 weeks) indicated no further change.

Metabolic Studies:—VO_2 kinetics results during arm ergometry and FESILEC were compared in 9 subjects during a 10-minute session of FESILEC before and after leg training showed that VO_2 time constant is significantly slower for leg exercise than arm exercise both before and after training. FESILEC training significantly improved VO_2 kinetics for legs, but not for arms. While exercise VO_2 was the same, slower leg kinetics were accompanied by an attenuated increase in heart rate and a greater blood lactate response. These improvements in leg, but not in arm exercise suggest peripheral adaptations only in the contracting leg muscles with FES leg training.

Muscle Blood Flow: Muscle blood flow (MBF) to the anterior compartment of the thigh at rest and after exercise using $H_2{}^{15}O$ uptake measured with positron emission tomography (PET) has been studied in 4 SCI and 5 nondisabled subjects. Preliminary analysis in one SCI subject showed that MBF at rest was 0.6 mml $min^{-1}100\ g^{-1}$, immediately after exercise of one leg was 118 mml $min^{-1}100\ g^{-1}$, and 20 minutes after exercise was 3.2 mml $min^{-1}100\ g^{-1}$. MBF on the non-stimulated leg remained essentially constant throughout the experiment.

FUTURE PLANS—Plans to complete work in the areas of muscle blood flow, hybrid leg-arm exercise, metabolic studies, calf muscle mass, and FESILEC effects on spasticity using H-reflex measurements.

RECENT PUBLICATIONS FROM THIS RESEARCH

Peak and submaximal physiologic responses following functional electrical stimulation indueed cyele ergometer training. Hooker SP, Scremin AME, Mutton DL, Kunkel CF, Cagle TG. J Rehabil Res Dev. In press.

Gas exchange kinetics during functional electrical stimulation in spinal cord injured subjects. Barstow TJ, Seremin AME, Mutton DL, Kunkel CF, Cagle TG, Whipp BJ. Med Sci Sports Exerc. In press.

Quantifying muscle tone in spinal cord injury patients using isokinetie dynamometrie teehniques. Perell KL, Seremin AME, Seremin OU, Kunkel CF. Paraplegia. In press.

Effeets of funetional eleetrieal stimulation (FES) indueed lower exttremity cycling on bone density of spinal cord injured. BeDell K, Seremin AME, Perell KL, Kunkel CF. Am J Phys Med Rehabil. In press.

Measurement of resting and activated skeletal musele blood flow by $H_2{}^{15}O$ positron emission tomography. Cuevas-Trisan RL, Scremin AME, Scremin OU, Brown C, Mandelkern M. In: Proceedings of the American Academy of Physical Medicine and Rehabilitation Annual Meeting, 1995.

Determination of the effect of functional electrical stimulation induced ergometry on musele tone in spinal eord injury subjects. Seremin AME, Perell KL, Seremin OU. Paraplegia. In press.

[88] 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 of controlling a gait trajectory 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 which 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 by 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. A second system is under construction to enable simultaneous subject testing at the two VA sites.

FUTURE PLANS—We are continuing to test the system on additional SCI subjects; we are also building a second generation orthosis which incorporates small DC motors at the hips to aid in hip flexion. Additionally, we are developing a product design process for producing commercial versions of the brace. Contacts have been initiated with industrial partners to develop the commercial version.

RECENT PUBLICATIONS FROM THE RESEARCH

Controlled-brake orthosis for FES-aided gait (Thesis). Goldfarb M. Cambridge, MA: Department of Mechanical Engineering, Massachusetts Institute of Technology, 1994.

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Reducing muscle fatigue in FES: applications by stimulating with n-let pulse trains. Karu Z, Durfee W, Barzilai A. IEEE Trans Biomed Eng. In Press.

[89] FES MOBILITY IN PARAPLEGIA: RF-CONTROLLED IMPLANTED SYSTEM

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B681-2RA)*

PURPOSE—The overriding goal of this research effort is to develop options to enhance the personal mobility of individuals with complete thoracic level spinal cord injuries. Functional Electrical Stimulation (FES) systems employing implantable technology will be refined and employed to provide stable standing, slow walking, and other maneuvers with a minimum of bracing and personal assistance. The 3-year effort will be directed toward establishing the clinical and technical components and implementation procedures required to introduce implantable FES systems into the home and community environments safely and effectively. The results of the project are anticipated to yield the information necessary to define the scope and content of wider scale clinical trials of the technology.

METHODOLOGY—Sixteen-channel implanted FES walking systems will be developed using two eight-channel CWRU/VA receiver/stimulators. These will activate electrodes of the closed double helix intramuscular type (as well as others depending on the particular muscle). New surgical techniques will be developed to enable the electrodes and implantable stimulator to be implanted in a few sessions within a few weeks time. A new external control unit (ECU) will be redesigned that can generate radio frequency signals to synchronize the actions of both implantable stimulators and coordinate the activation patterns for up to 16 muscles. This design effort will result in reliable and manufacturable technology that is suitable for transfer to other clinical sites or commercial manufacturers. Software to provide an easy-to-use clinical interface for specifying and modifying stimulus patterns will also result from the technical development. Current subjects who use percutaneous FES systems with up to 48 channels of stimulation will be converted to systems utilizing only 16 channels. These subjects will allow us to complete studies to gain data on muscle choice, to help establish rehabilitation and training protocols, and to adapt existing or develop new evaluation tools to quantify and document the clinical utility of the 16 channel implantable systems.

RESULTS—Subjects who previously used percutaneous FES systems with more channels have been reprogrammed for function with 16 channels. Initial data indicate that individuals can walk up to 0.4 m/s with the help of a rolling walker. New surgical approaches using open techniques have been mapped for the posterior adductors, gluteal, tensor fascie latae, hamstrings, quadriceps, sartorius, gastrocnemius and tibialis anterior muscles. Arrangements for manufacture and delivery of cuff and epimysial electrodes have been accomplished. The ECU hardware and software to synchronize the two implants and coordinate muscle activation patterns have been designed, tested, and are working.

FUTURE PLANS—The early portion of the second year of the project will be dedicated to refining the surgical plan and finalizing the technical components in preparation for the first human implant. Major effort is being directed into further testing for interference between the two implants, developing reliable and miniaturized packaging of the ECU, and developing a friendly user-device interface. Four volunteers will be implanted with a 16-channel system throughout the next 2 years. At least 1-year follow-up in the home and workplace is anticipated for the first implant volunteer. The last subject to be implanted will be followed for at least 3 months by the end of year 3. In addition to completing the implantation and follow up schedule, the primary goals of year 3 will be to re-evaluate the technical components, streamline the implementation protocols, document the system, and prepare staff training materials for multicenter testing.

RECENT PUBLICATIONS FROM THIS RESEARCH

Creating operating space for the endoscopic implantation of cuff electrodes on the hamstring branches of the sciatic nerve: a new technique. Osman SG, Marsolais EB. In: Proceedings of the 41st Annual Orthopaedic Research Society Conference; 1995 February 13-16; Orlando, FL.

Status of paraplegic FNS assisted walking. Marsolais EB, Kobetic R, Polando G. In: Proceedings of the 41st Annual Orthopaedic Research Society Conference; 1995 February 13-16; Orlando, FL.

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

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B743-RA)*

PURPOSE—This project was designed to investigate the feasibility of applying an implanted eight-channel functional neuromuscular stimulation (FNS) system to provide standing and transfer function to individuals with incomplete tetraplegia. Tetraplegia compromises the ability to stand and transfer, increasing dependence on families, caregivers, or assistants and compounds the risk of contractures and pressure sores. Conventional transfers are problematic for individuals with elderly spouses or caregivers who lack the strength to assist with the lifting phases of the maneuvers. The objective was to install and evaluate implantable FNS systems to provide individuals with low tetraplegia with the ability to stand independently and to facilitate standing transfers by eliminating the need for heavy lifting by the caregiver.

METHODOLOGY—A staged implementation strategy was employed in which subjects progressed from temporary systems with helically coiled percutaneous electrodes, through the introduction of the eight-channel CWRU/VA implant. Chronically indwelling percutaneous intramuscular electrodes were used to exercise the hip, knee, and trunk extensors. When sufficient strength and endurance were achieved, stimulation patterns were developed to coordinate their actions and provide standing and standing transfer functions. The temporary systems were replaced with eight silicone-enclosed intramuscular electrodes suitable for eventual use with the implant. Subcutaneous in-line connectors to percutaneous leads allowed continued standing and transfer training with an external stimulator until a stable electrode system could be obtained. The percutaneous portions were then removed and the implantable receiver/stimulator was installed surgically for long-term use.

PROGRESS—Four volunteers between the ages of 21 and 55 years (mean=34) participated in the study. All subjects exhibited neurological levels between C5 and C7, were more than 1 year post-injury, wheelchair dependent, and unable to stand or perform standing transfers at the time of admission. One subject completed the initial percutaneous development phases and has received the implanted receiver/stimulator. Two are still in the process of having their percutaneous systems replaced in preparation for the implant. The fourth volunteer completed the initial percutaneous trial but has left the program for personal reasons.

FINAL RESULTS—With FNS, every volunteer was able to exercise, stand, and sit independently or with minimal assistance. Although they still required assistance with the pivot phase of the standing transfer maneuver, all were able to raise and lower their body weight under their own power with FNS. Users generally preferred to rely on others to help with donning/doffing or to activate the stimulator, suggesting that the system may be best suited for facilitating an

assisted transfer. Few subjects were able to assume or maintain a stable upright "C" posture due to activation of the rectus femoris or inadequate hip extension. Movement of intramuscular electrodes in both percutaneous and implanted systems degraded standing performance and required frequent reimplantation, especially in the hip extensor muscles, and delayed final installation of the CWRU/VA implant. The implantable receiver/stimulator itself remains operational at 3 years follow-up, verifying its reliability.

IMPLICATIONS—It is feasible to use FNS to provide standing function to individuals with incomplete tetraplegia. FNS facilitated standing transfers by eliminating the heavy lifting usually required of the caregiver. The difficulties experienced with percutaneous electrodes can be largely circumvented by implantable technology, which can be safely and effectively applied to this population. Efficient implementation procedures still need to be developed before such systems can be considered clinical options for wider scale deployment. Surgical implantation of all system components in a single procedure is indicated.

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FNS assisted standing pivot transfers for individuals with incomplete tetraplegia. Triolo RJ, Marsolais EB, Polando G, Kobetic R. In: Proceedings of the RESNA '95 Annual Conference; 1995 June 9-14; Vancouver, BC. Washington, DC: RESNA Press, 1995:390-2.

[91] RESTORATION OF GAIT FOR THE STROKE PATIENT

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B679-RA)*

PURPOSE—We are testing a new technology, a 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 carry-over 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 functional 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—Eight subjects have been admitted into the study. All have completed conventional physical therapy treatment. Preliminary analysis indicates that following conventional physical therapy, three subjects improved in either walking speed, muscle strength, or gait pattern; two subjects showed no change in either gait pattern or muscle strength following conventional rehabilitation.

Five subjects have had three to five intramuscular electrodes implanted in the involved lower extremity. Following FNS treatment intervention using implanted electrodes, one subject demonstrated improved voluntary gait (i.e., with the FNS not active). The specific gait components which were improved included: stance knee control, stance weight shift, and swing phase limb

flexion. A second subject demonstrated that following treatment with FNS, the gait pattern was superior with the FNS pattern activated than when the FNS pattern was not activated. Sufficient data on three subjects are not yet available.

IMPLICATIONS—Results of this study have the potential to provide the following clinically applicable information:

1. Efficacy of FNS exercise/gait training as compared with conventional neurorehabilitation techniques and as compared with no treatment.
2. Suitability of an array of FNS stimulator subject command controls for use during rehabilitation procedures and home use.
3. Preliminary predictive criteria established regarding suitability of stroke patients for the implanted FNS orthotic system.

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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; 1994 May; Case Western Reserve University, Cleveland, OH.

[92] 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 complete paraplegic subjects. 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 human gait (both nondisabled and paraplegic) with 23 degrees-of-freedom has been developed. It is driven with biomechanical data from laboratory experiments and simulates the complete gait cycle, including foot-to-floor contact. The results of this study show that stable, repeatable gait is possible for FNS-induced gait in paraplegics (at 0.2 m/s), whose range of muscle torque generation is limited by their implanted electrodes. This model and computer simulation is being extended to simulate stair climbing and descent and walking on level and sloping surfaces.

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, five phases of gait for walking paraplegic subjects have 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. Work is now proceeding toward finding the set of sensors that provides the most information about gait while being cosmetically acceptable and easily donned and doffed by the paraplegic subject.

Hardware and software for a microprocessor-based stimulation parameter controller has been developed. This unit is based upon a Pentium PC which acquires and processes up to 64 channels of analog signals. It communicates with the existing portable microprocessor-controlled 48-channel external stimulator, using a high-speed digital interface.

FUTURE PLANS—Within the follow-on project, we will focus on the implementation of this automatic gait adjustment methodology for 16-channel systems (initially using 16 percutaneously connected electrodes, but then graduating to 16 channels driven by two 8-channel implanted stimulators). Our goal is to achieve devices that are ready for use in multi-center trials by 1997. During the next year, sensors and feedback controlled stimulation adjustment for specific gait anomalies resulting from errors in timing and muscle fatigue will be implemented and evaluated.

RECENT PUBLICATIONS FROM THIS RESEARCH

Effect of joint stiffness on simulation of the complete gait cycle. Scheiner A, Ferencz DC, Chizeck HJ. In: Proceedings of the Annual Conference of the IEEE EMBS, 1994.

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

[93] PARAPLEGIC WALKING MADE PRACTICAL WITH FNS AND ORTHOSES

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Sponsor: *National Institute of Child Health and Human Development and the National Institute on Neurological Disorders and Stroke, National Institutes of Health, Bethesda, MD*

PURPOSE—The purpose of the proposed research is to determine whether the combination of eight channels of implanted functional neuromuscular stimulation (FNS) and a proposed functionally activated trunk hip knee ankle foot orthosis can result in a practical mobility aid for use by the complete paraplegic individual. The target population consists of persons with an impairment to lower extremity motor function due to upper motor neuron lesion in the T4 to T11 range.

METHODOLOGY—We employ a combination of the existing Case Western Reserve University (CWRU)/VA 8-channel radio frequency (RF) controlled and powered implantable stimulator with a to-be-designed programmable orthosis. CWRU/VA investigators have demonstrated the capability of generation of strong, fatigue resistant, reproducible muscle forces in both upper and lower extremity using implantable FNS. This technique will be combined with expertise in electro-mechanical 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 new subjects have begun receiving electrodes which can be connected to the implantable stimulator system (a total of three subjects are in this track). The initial laboratory-designed reciprocating gait orthosis has been delivered, and our first subject is working in it on functional tasks (walking, opening doors, ramps, steps, and so forth). Two additional subjects, not immediately scheduled to receive the implantable stimulator, are assisting in the identification of functional tasks achievable in a hybrid orthosis. Open

loop control strategies for the system are progressing while utilizing the greater ROM available with the new brace. All subjects are focusing on crutch-assisted walking.

FUTURE PLANS—The primary focus of this work is to provide sufficient control to the existing FNS capability to allow meaningful functions such 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.

V. Geriatrics

[94] BALANCE TRAINING IN ELDERLY FALLERS AND NONFALLERS

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PURPOSE—The purpose of the study was to determine if a sensory balance training program utilizing biofeedback could improve postural stability in elderly fallers and nonfallers. The biofeedback training included visual and/auditory feedback of center of gravity vertical force location during various dynamic activities under differing sensory conditions.

METHODOLOGY—The balance training included static posturography (Balance Master®) activities in the following sensory conditions in all combinations: firm and foam support surface, eyes open and eyes closed, and head neutral and head extended. The training consisted of eight 1-hour sessions, two times per week for 4 weeks. The participants were 85 healthy older adults (age 65–99, x=80.57) recruited from four independent living centers. They were classified as fallers and nonfallers from their history of falls in the last year and from the number of falls during dynamic posturography testing (EquiTest®). The volunteers were randomly assigned to a training (n=37) and nontraining group (n=28). Postural stability was measured by the following tests: dynamic posturography, timed up and go, and stand on one leg. These tests were repeated at 6 weeks and at 4 months post training.

PROGRESS—The research is completed and the data analyzed.

RESULTS—ANOVA revealed no significant difference ($p<0.05$) between the training and nontraining groups on the repeated measures of postural stability. There was a significant difference ($p<0.05$) within both groups on repeated measures of dynamic posturography. Both the training and the nontraining groups improved on the both of the repeated measures test. For posturography, there was no significant difference in the fallers and nonfallers as classifies by history of falls on the postural stability measures. In summary, all of these older adults improved in dynamic repeated measures regardless of their history of falls or of their experience with sensory balance training.

FUTURE PLANS—All older adults in this study improved in dynamic balance repeated measures but the variable/variables that are responsible need further investigation. The improvements in balance were not only present post test but additional improvements were present 4 months post test. This research has produced an additional investigation of correlation's of falls classification by history of falls and by the number of falls on dynamic posturography with six commonly used balance tests for determining risk for falls.

[95] UPPER BODY MOTION ANALYSIS FOR AMELIORATION OF FALLS IN THE ELDERLY

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No report was received for this issue.

[96] AGE-RELATED CHANGES IN THE TRICEPS SURAE STRETCH REFLEX AND POSTURAL CONTROL

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No report was received for this issue.

[97] EFFECTS OF STRENGTH CHANGES ON FUNCTIONAL ABILITY IN OLDER ADULTS

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PURPOSE—A decline in muscle strength associated with the resorption of bone and the diminishing integrity of muscle and connective tissue is a common characteristic of aging that threatens the independence of elderly persons. This 2-year study was designed to evaluate the effects of strength training and flexibility exercises on muscle strength, muscle morphology, and functional ability in older adults. An additional aspect of this project was the investigation of the effects of reduced or no strength training on changes in strength and functional ability in older adults following a 4-month training intervention.

This research will assist health care professionals in establishing guidelines for strength training and flexibility exercises to improve functional ability and independence in older adults.

METHODOLOGY—This study was designed to evaluate the impact of a 4-month strength training and flexibility exercise intervention on the muscular fitness and functional independence of 43 elderly participants training 3 days a week, for 1 hour a day. A control group of 43 individuals received the same treatment as the experimental group, except for the training interven-

tion. A repeated measures experimental design where both the experimental and control groups received pre- and post-testing for muscle strength, endurance, flexibility, balance, and functional ability was employed in this study. Morphological changes within the muscle was assessed with Magnetic Resonance Imaging and selected anthropometric measurements. Balance was measured by a Neurocom Equitest Dynamic Posturography machine. Selected functional ability tests were also measured. The obtained data were evaluated to determine the effects of strength training on strength, flexibility, and functional independence.

The effects of reduced or no training on strength and functional ability in older adults was evaluated as the experimental subjects were reevaluated for strength and functional ability 6 to 24 months after the 4-month strength training intervention. The data from this aspect of the study was compared with results from the training intervention to determine the effects of reduced or no training on strength and functional ability.

PROGRESS—Data collection has been completed for the study. The investigators have complete data sets on 43 experimental subjects and 43 control subjects.

RESULTS—Preliminary analyses showed that overall body strength increased an average of 45 percent for the experimental subjects after the intervention. In this group, no change was observed in muscle morphology as measured by MRI assessment, although moderately high correlations (0.60 to 0.73) were observed between muscle morphology and strength (one repetition maximum; 1RM). Improvement in strength without an increase in muscle mass is consistent with reports in the literature and appear to reflect the initial muscle fitness status of the subjects. When the functional test items were evaluated individually, little improvement was observed. The functional assessments were then grouped in a manner consistent with tasks involved in daily living, functional balance (standing on one foot, toes, and heels), and coordination (placing a book above head on a shelf, picking up a penny from the floor, and getting up from the floor). Improvements were shown in functional balance and coordination in the experimental group after the intervention. These changes were observed even though the mean values of the experimental subjects were in the acceptable range for most functional assessments on the pre-test. The latency period (time necessary to adjust muscles to maintain balance) was improved following training. The preliminary results for the detraining phase showed that the subjects 6–30 months after the training intervention have strength and functional task values greater than the pre-training values but less than the post-training values.

IMPLICATIONS—The preliminary results of this study indicate that in healthy older adults, certain aspects of functional independence improved due to the strength training intervention. These preliminary results indicated that functional status changes in a pattern consistent with strength. Evaluation of changes in functional status following the training intervention will be included in the final report.

While these results detail the effects of a short training intervention (4 months) on functional tasks and strength in older adults, these data provide no information on the effects of long-term training (2 years or longer) on older adults. There is a need for such a study, especially with different samples (frail, diabetic, and so forth) of older adults.

[98] EVALUATION OF INTERVENTIONS TO PREVENT ELOPEMENT AMONG NURSING HOME PATIENTS

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PURPOSE—This 2-year study evaluates the effectiveness and appropriateness of widely used environmental interventions to control elopement or exiting among dementia patients in long-term care settings. The two

interventions under study are an electronic alarm system and a secure outdoor space. Specific objectives of the study are to determine: the difference in the average time that elapses between an elopement incident and staff response with alarms with conventional and a less aversive signal; whether a less aversive alarm signal affects the frequency of subjects' elopement incidents; whether access to a secure outdoor space reduces amount of time spent in close proximity to exit doors; and whether a less aversive alarm system signal and access to a secure outdoor space impact resident mood and behavior (e.g., decrease in motor agitation and socially inappropriate/disruptive behaviors) and staff ratings of job stress.

METHODOLOGY—A multiple baseline methodology will be used to collect baseline data, followed by staggered implementation of the interventions at all three sites. During the baseline a wanderer alarm with conventional (loud and aversive) signal will be installed. Intervention 1 will entail modifying the wanderer alarm system signal used to alert staff to a less aversive sound (e.g., verbal message); Intervention 2 will be a secure outdoor space adjacent to the unit. Observational data will be obtained with video recording technology. Staff stress and ratings of resident mood and behavior will be obtained with standardized instruments. During the baseline, video taping will continue from 6AM to 8PM in order to obtain information on which to base post-intervention time sampling plans. The frequency and degree of target behaviors, pre-intervention, will be established during the baseline. Intervention 2 will not be implemented until after the frequency of target behaviors have stabilized following Intervention 1. Video tapes will be viewed and coded to identify target behavior incidents. Interrater reliability for incident identification and coding will be established by having an independent observer repeat the tape screening for 25 percent of the tapes, and coding of target behavior occurrence for 25 percent of the incidents on composite tapes. Data on the frequency of actual and attempted elopements, and the duration of elopement incidents prior to detection by staff will be collected during baseline and during each intervention phase. Staff stress and resident mood and behavior will be assessed during baseline and following each intervention. A minimum of three residents at risk of elopement at each site will be the subjects.

PROGRESS—Installation of wander alarm and video recording equipment is in process. Baseline data collection is scheduled to begin upon completion of installation of the alarm system and video-taping system. The design of the secure outdoor spaces is being developed in collaboration with participating sites.

[99] EFFECTS OF AGE AND RESISTANCE TRAINING ON SKELETAL MUSCLE METABOLISM

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Programs, Washington, DC 20420 (Project #E724-RA)*

No report was received for this issue.

[100] QUANTITATIVE POSTUROGRAPHY: AGE-RELATED CHANGES IN POSTURAL STABILITY

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No report was received for this issue.

[101] EFFECTS OF AGING ON MOTOR UNIT FIRING BEHAVIOR

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No report was received for this issue.

[102] EFFECT OF CHAIR DESIGN ON CHAIR RISE PERFORMANCE IN DISABLED OLD ADULTS

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No report was received for this issue.

[103] BEHAVIORAL TREATMENT OF URINARY INCONTINENCE

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PURPOSE—This study is attempting to validate prompted voiding as a technique for treating urinary incontinence among male patients on a VA intermediate care unit. We are also identifying the characteristics of male intermediate care patients who are successful in a program of prompted voiding training and rehabilitation, and assessing the implications of participation in such a program for patient mental health status.

PROGRESS—This project has completed baseline data collection, the prompted voiding intervention, post intervention assessments, and a 3-month follow-up measurement on two treatment groups. Baseline, post intervention, and follow-up information were also gathered on control subjects. Seventy-eight patients were recruited for the study (attrition: 3), and necessary urological assessments were made. Nursing staff on the intermediate care ward were trained in the prompted voiding procedure and data gathering. Pre and post intervention measures of the Dementia Rating Scale (DRS), Indepcndent Toileting Assessment (ITA), Hamilton Anxiety Scale (HAS), and incontinence procedures for experimental and control subjects were also successfully implemented.

METHODOLOGY—During the 21-day interventions, assistants checked each patient every hour for wetness or dryness. They then prompted the patient and toileted him only if he rcsponded affirmativcly to the prompt. Social approval was delivered for dry checks and for requests for toileting assistance. Mild social disapproval has becn delivered for wet checks. The proposed elemcnts of prompted voiding have been followcd. Thesc clements include:

1. Contacting the patient on an hourly basis
2. Asking the patient if he is wet or dry
3. Physically checking the patient and providing feedback on the accuracy of his response
4. Delivering social approval if dry and corrective feedback if wet
5. Prompting the patient to request toileting assistance
6. Providing toileting assistance if requested
7. Redelivery social approval for appropriate toileting (minimum of 1 minute of pleasant social interaction)
8. Offer water, make sure call light is within reach, and tell the patient when he can expect the next visit.

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 significance at 0.05). The average number of requests for toileting assistance for experimental patients increased from an averagc of 0.38 per day per patient to a treatmcnt average of 2.3 (Chi-square significance at 0.05). Control group patients did not show such significant changes on either measure: Baseline average wet=35.4 percent, treatment period requests=0.40 per day per patient. Furthermore, there was a 36 percent increase in corrcct toileting (Chi-square significance at 0.05) between baseline and treatment for the experimental group. Correct toileting was defined as voiding in a bedpan, urinal, or toilet. The control group did not show such substantial change with a 3 percent decrease in correct toileting.

The variables that were the best predictors of how wet patients were at the end of the prompted voiding trcatment were: 1) whether or not the patients rcsponded to a prompt for toileting on the first day of treatment; 2) a staff assessment of thc patient's ability to function; 3) level of cognition as measured by the DRS; 4) normal bladder capacity; and 5) age. For the treatment group there were significant declines in depression (as measured by the CESD) between baseline and post intervention measures, but no significant changes in the lcvel of cognition (as measured by the DRS).

In summary, there is significant evidence that male VA intermediate care paticnts 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 were observed for the trainees from pre to post treatment.

Analysis of 3-month follow-up information shows a tendency for patients to regress to pretreatment levels of incontinence and correct toileting. There were significant increases in wet checks and declines in correct toileting for the experimental group. These findings suggest the importance of hourly prompts to the maintenance of improved continence.

[104] SWALLOWING PHYSIOLOGY RELATED TO NORMAL AGING

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Programs, Washington, DC 20420 (Project #E727-2RA)*

No report was received for this issue.

[105] 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 healthy elderly subjects and fallers. Performance measures in healthy subjects 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; 4) biomechanical and neurophysiologic changes become risk factors for falls in the elderly; and 5) compensatory mechanisms are used to cope with deficits.

METHODOLOGY—We evaluate performance measures in healthy elders and fallers from the VA Nursing Home and the community, using the neurological exam, objective measures of reflexes, joint compliance, voluntary reaction times, SSEPs, 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; significantly limited exercise tolerance.

RESULTS—We have tested 27 fallers and 102 healthy elderly subjects (45 years and older); 66 subjects are 65–75 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 healthy elderly subjects (65–75 years) are unremarkable in 60 percent 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 healthy elderly subjects (65–87 years) demonstrates: 1) slowed kinematic measures with increasing age: increased gait cycle duration and percentage stance time; decreased stride length and velocity by approximately 27 percent; 2) shorter stride lengths and lower velocities in females than males up to 75 years; 3) 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: 1) significant age-related changes in time- and frequency-based measures; 2) 45 percent decrease in mean velocity of sway in healthy elderly subjects; 3) more age-related changes with EC than with EO; and 4) many significant measures are non-collinear and non-correlated, 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° target.

SSEPs: In 58 subjects, onset latency of the SSEP is significantly prolonged. Latencies are even more prolonged with vibratory/proprioceptive deficits.

Healthy Aging 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. Relationships among performance deficits that differentiate healthy elders and fallers are used to identify "predictive markers" of risk factors for falls. This will guide therapeutic interventions to minimize fall risk.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[106] A 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, U.S. Department of Education*

PURPOSE—In 1993 the Policies for Aging with Disabilities (PAD) project at the University of Southern California was funded by NIDRR to investigate current policies and practices that affect the use of and access to assistive technologies that support employment and maintain community-based living among adults with disabilities. This project is part of the RRTC on Aging with Disability and Aging with Spinal Cord Injury, located at Rancho Los Amigos Medical Center. The joint mission of the RRTCs is to develop a coordinated program of research, training, and clinical service that advances our understanding of the "natural" course of aging with physical disability

The objectives of the PAD project include: 1) describing current patterns of utilization and recent changes in patterns of utilization related to type of assistive technology; 2) examining the impact of assistive technology use on health status and on quality of life issues; 3) identifying the barriers, both attitudinal and financial, which may limit use; 4) investigating the adequacy of current policies on assistive technology; and 5) identifying the need, if any, for policy changes.

METHODOLOGY—Data are being collected and analyzed at three levels through: 1) a consumer survey, 2) a national survey of state agencies, and 3) case studies involving consumer and national state agency respondents.

The consumer survey will focus on issues such as information-seeking related to acquisition; use and abandonment of devices; funding patterns; changing needs over time, and unmet needs for assistive technology. The sample includes 4 groups: rheumatoid arthritis, cerebral palsy, post-polio, and Stroke.

Our policy research efforts include: 1)identifying all of the current federal and state policies concerning assistive technology and adults with disability; 2) reviewing existing research and reports on assistive technology and home modifications; and 3) interviewing key informants to identify differences in policies, programs, and services across states.

PROGRESS—Our policy research on federal and state policies affecting assistive technology has allowed us to identify what we know and what we need to know to develop better policies concerning assistive technology. In Spring 1996, we will field a national survey to state agencies that will identify the extent to which state agencies are collaborating and developing linkages across systems to facilitate access to assistive technology for middle aged and older adults.

Our analyses of the consumer survey on assistive technology use will examine the relative impact of assistive technology 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. Data collection began in fall 1995.

RESULTS—Existing reports on assistive technology policy have focused heavily on federal policy. Little is known about how state policies on assistive technology differ and what the implications of such variability mean for adults with disability. Our policy report on assistive technologies, available in fall 1995, synthesizes the literature on state policy and identifies the gaps which remain in our understanding.

RECENT PUBLICATIONS FROM THIS RESEARCH

Report on policies affecting assistive technology for persons aging with disability. Liebig PS, Sheets DJ, Mueller L. Los Angeles: University of Southern California, 1995.

Incorporating consumer expertise in applied social research on aging with disability. Campbell ML, Sheets DJ, Mitchell J, McNeal D. eds. In: Participatory Action Research. Towson, MD: Brooke Publishers. In press.

[107] HEALTH BEHAVIORS IN THE ELDERLY: EFFECTS OF AGE, GENDER, AND PSYCHOSOCIAL FACTORS

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PURPOSE—Empirical evidence shows that psychosocial factors may influence health outcomes by way of intervening health-related behaviors. However, little data is available to determine whether associations between psychosocial factors and health behaviors hold for the elderly and whether gender may also be an important determinant.

METHODOLOGY—Relationships between personality, social support, health locus of control, and health behaviors were studied with 135 elderly, generally healthy persons (61 male, 74 female, mean age=75.6). Behaviors included average daily cigarettes smoked, average daily alcohol intake, and average score on a physical activity scale.

RESULTS—Age was significantly correlated with lower levels in both Activity ($r=-0.26$, $p<0.01$) and Alcohol consumption ($r=-0.2298$, $p<0.01$). Males smoked more ($t=3.39$, $p<0.001$), consumed more alcohol ($t=2.39$, $p<0.019$), and were more physically active than females ($t=3.01$, $p<0.003$). When all variables were analyzed by MANOVA, further associations were found between higher levels of Alcohol consumption and Independence ($B=0.427$, $t=2.66$, $p=0.01$) and between greater physical Activity and the presence of Confiding Relationships ($B=0.381$, $t=2.34$, $p=0.02$). In summary, results show meaningful relationships between age, gender, psychosocial factors, and health-related behaviors in an elderly sample. These relationships may be particularly significant in elderly populations where health is significantly compromised, such as in very old or disabled groups.

PROGRESS—Additional data have been obtained for the sample, which includes daily diet records and supplementary vitamin intake. The full data set is currently being analyzed.

[108] REHABILITATION RESEARCH AND TRAINING CENTER ON AGING AND DISABILITY: OVERVIEW OF RESEARCH PROJECTS

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PURPOSE—The Rehabilitation Research and Training Center on Aging with Disability (RRTC), located at Rancho Los Amigos Medical Center, was established in 1993 to respond to an emerging public health issue of persons aging with early onset of physical disability, as well as those who become disabled with age. The mission of this RRTC is to develop a coordinated program of research, training, and clinical service that advances our understanding of the "natural" course of aging with physical disability, and identifies opportunities for intervention aimed at maintaining independence, productivity and community integration, and preventing secondary disability and premature institutionalization.

RESEARCH PROJECTS—The six research projects associated with this RRTC can be divided into two components. The larger component focuses primarily on working-age study populations of individuals aging with

cerebral palsy, polio, rheumatoid arthritis, spinal cord injury or mid-life onset of stroke. Consistent with the life course perspective guiding the research program, these five conditions were selected to reflect variations in the stage of the life cycle when both acute onset of disability and potential "later-life effects" occur. The objectives of the first component are to: 1) document cross-disability variations in the frequency of age-related changes in health and functioning; 2) examine the effects of socio-demographic characteristics, lifestyle practices, cultural beliefs, and access to social and environmental resources on quality of life indicators; and 3) assess patterns of utilization and changing needs for health-related services, such as assistive technology, personal attendant services, and work-site accommodations. The second research component is more gerontological and focuses on the community based long-term care needs of older adults with severe functional limitations who are aging into disability rather than aging with disability.

Our six research projects are: 1) variations in secondary conditions, risk factors, and health care needs for four groups of people aging with physical disability; 2) preventing and treating late life complications of disability through quantified identification of muscle weakness, with post polio as the model; 3) use of technology services to maintain employment among people aging with disability; 4) policy barriers that impede utilization of technology to maintain independence and employment among individuals aging with disability; 5) assessment of residential care facilities as a community alternative for disabled older adults; and 6) utilization of paid in-home support by Hispanic and Anglo older adults, and model development to enhance utilization.

RECENT PUBLICATIONS FROM THIS RESEARCH

Incorporating consumer expertise in applied social research on aging with disability. Campbell ML, Sheets DJ, Mitchell J, McNeal D. eds. In: Participatory Action Research. Towson, MD: Brooke Publishers. In press.

[109] REHABILITATION RESEARCH AND TRAINING CENTER ON AGING WITH SPINAL CORD INJURY

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Sponsor: *None listed*

CENTER RESEARCH PURPOSE—The establishment of this RTC in 1993 is associated with the fact that people with spinal cord injury (SCI) are aging in substantial numbers for the first time in history. As they age, many people with SCI are developing new health, functional, support, and psychological problems, some of which seem premature from an aging perspective. Early-onset cardiac disease, diabetes, osteoporosis, joint pain, fatigue, job loss, needs for personal assistance, and difficulty coping with these changes are all research topics under consideration. The primary purpose the Center's research is to separate the effects of age, number of years since onset, and the historical period of injury and rehabilitation associated with these topics.

RESEARCH PROJECTS—Answering questions regarding cause of later life problems for people with SCI requires sophisticated research designs and an adequate database of people for investigations. All projects conducted by the Center utilized cross-sequential designs and a large database of people with SCI representative of the diversity of ethnic groups in America as a common sampling frame. The database contains a minimum data set on nearly 2,300 people with SCI who range in age from 16 to 82 and who have been injured from 1 to 60 years. Moreover, this sample contains about 40 percent minority members, especially Hispanics and African-Americans. While projects employ the database as a sampling frame, a portion of the research effort is directed at expanding the database itself.

The research projects address medical, functional, health maintenance, employment, social support, and coping issues, including: changes in physiologic and health status; depression in people aging with SCI; assessment of social support, lifestyle factors, and cultural beliefs in moderating the natural course of aging with SCI; use of job accommodation services to maintain employment among people aging with SCI; and analysis of policy barriers to accessing technology services for individuals aging with SCI. Within each, comparisons and contrasts among and across ethnic groups are central themes. There is strong emphasis on prospective versus retrospective collection of data.

PROGRESS—While this Center's activities began only 2 years ago, prospective data on 358 cases ranging in age from 18 to 75, and from 1 to 56 years since onset, have been gathered for cross-sequential comparisons.

[110] AN INVESTIGATION OF FALLS IN THE ELDERLY

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Sponsor: *None listed*

PURPOSE—The population of elderly people in the United Kingdom, as well as many other countries, is increasing; the most dramatic increases are predicted in those over 85 years old. These elderly people place great demands on health care systems. Falls have been identified as one of the major problems experienced by elderly people, with an estimated 3 million falls occurring each year in Britain. The consequences of falling can be physically and psychologically devastating. Many factors have been identified which may contribute to a fall, such as physiological changes with advancing age, pathological conditions, external hazards, and drug interactions. Many of these elderly fallers are referred to physiotherapy departments with a nonspecific diagnosis of "Falls," leaving the potentially complex assessment to the physiotherapist. By more accurately identifying and assessing the possible factors leading to a fall, more specific and thus effective rehabilitation programmes may be implemented.

METHODOLOGY—In this study, the experimental group consisted of 30 subjects admitted to a geriatric assessment unit due to falling. Thirty control subjects were admitted to the same unit for some other reason such as anaemia. A database was completed for each subject, including information on age, reason for admission, drug history, and past medical history to exclude the presence of neurological or severe orthopaedic conditions. Diagnosed reason for the fall, on admission, was also recorded for the experimental group. Each subject completed a semistructured interview covering mobility, wearing of spectacles, and social support. The fallers reported the number of falls and any subsequent change in lifestyle. The postural sway of all 60 subjects was assessed on the Chattecx Balance System under four testing conditions: eyes opened platform stable, eyes closed platform stable, and both eyes opened and eyes closed with the platform moving linearly. In addition, dominant hand grip strength, as a measure of general muscle strength, was assessed for the total sample by the best of three hand dynamometer readings.

FINAL RESULTS—Nonparametric statistical tests were used to compare the age, postural sway, hand grip, and number of drugs taken between the fallers and controls. Descriptive methods were employed to compare the psychosocial variables between the two groups, and discriminant analysis was performed to identify the influence each measurement had in classifying subjects as fallers or nonfallers. No relationship was found between age and postural sway, but under all four testing conditions the postural stability of the fallers was significantly poorer than that of the controls. Similarly the dominant hand grip strength of the fallers was significantly less, and fallers were found to have higher input from social services, be less mobile, have less contact with friends, and be taking particular medications, notably benzodiazepines, than were controls.

IMPLICATIONS—Many factors, physical and psychosocial, were identified which together or in isolation could contribute to elderly people falling. An appreciation of all these risk factors is needed to ensure effective assessment and treatment of these individuals. Additional assessment of other reported risk factors such as cognitive impairment and change in vibration sense may provide a more holistic view of the problem of falls affecting the elderly population.

VI. Head Trauma and Stroke

[111] A NEW TECHNIQUE FOR IMPROVING REHABILITATION OF MOVEMENT AFTER STROKE: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #B93-692AP)*

PURPOSE—The purpose of this project was to further develop and test a new type of physical therapy, Constraint-Induced Facilitation (CIF), that preliminary evidence suggested can substantially reduce the incapacitating motor deficit of many chronic stroke patients and increase their functional independence. The techniques of CIF include prolonged constraint of movement of the unaffected upper extremity and training of the affected upper extremity.

METHODOLOGY—Fifteen subjects have been given CIF therapy to the present. The subjects were chronic stroke patients, defined as patients whose stroke occurred more than 1 year earlier. The main inclusion criteria were ability to extend against gravity at least 20° at the wrist and 10° at the fingers, while at the same time exhibiting greatly reduced use of the extremity in the activities of daily living. These criteria identify approximately 20 percent of the chronic stroke population with motor deficit. The results of these 15 subjects were compared to 5 subjects given an attention-control procedure.

PROGRESS—The work to date has served to confirm our preliminary findings and indicates that CIF techniques can significantly improve patients whose functional independence has been significantly compromised by motor deficits resulting from a stroke.

RESULTS—Each of the 15 patients given CIF treatment improved very substantially as documented by the motor activity log in amount of use of the affected upper extremity in the activities of daily life, and they did so to the same extent as patients in the earlier work (ANOVA; p's ranging from <0.05 to <0.0001). The five attention-control subjects did not improve significantly. They were given a set of procedures that were therapeutically neutral but that were designed to focus attention on the affected extremity, as occurs as a result of the experimental intervention. The group difference between the CIF and control subjects was significant beyond the 0.0001 level (ANCOVA with pretreatment values as the covariate). The CIF subjects also improved significantly in range of motion, especially active range of motion, though the change in this area was not as impressive as for amount of use of the affected limb. The control subjects did not exhibit any range of motion changes.

FUTURE PLANS—Two limitations of the present study are that the currently employed CIF techniques are intensive in terms of expensive therapist time, and have been applied only to chronic stroke patients with relatively moderate upper extremity motor deficit. We propose to develop a less therapist time-intensive procedure and working with patients that are more impaired than previously.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[112] 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, that is, neglect, hemispatial neglect to left space. Previously, we demonstrated the effectiveness of using our computer-assisted training program to teach subjects to compensate for neglect-related problems during simulated, high accident risk activities like wheelchair propulsion, and thus to reduce patients' accident proneness. Presently, we are analyzing data comparing LCD projected image training versus CRT image training. If the results of CRT training are as good as LCD training, computer training could be conducted more cheaply and conveniently.

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 6×8 ft (1.83×2.44 m) screen. Training was initiated within the first week of admission to the acute rehabilitation service.

PROGRESS—We have screened 40 subjects for the study, and training has been completed with 24 subjects who met criteria for participation. We have completed a training manual and continue to revise the computer programs to make them easier to use by professional staff.

RESULTS—Twelve subjects completed training in each of the described conditions. Preliminary results from our Wheelchair Obstacle Course suggests that the LCD-projection systems produced better performance than did training with the CRT. Moreover, both groups avoided obstacles and/or detected objects in left hemispace better than the non-trained group. However, the CRT trained group tended to make more errors in right hemispace than did the LCD trained subjects. It is possible that training using the larger image generated by the LCD projector fostered better broad scanning of the entire frontal environment. Group differences for fall rates and OT and PT evaluations have not been analyzed yet.

FUTURE PLANS—We are currently training the last of our subjects in Study 1. We are preparing to begin training OTs in the use of the system. Finally, we are closely evaluating treatment failures to better understand the limitation of this training.

RECENT PUBLICATIONS FROM THIS RESEARCH

Digit span performance and unilateral neglect. Rapport LJ, Webster JS, Dutra R. Neuropsychologia 1994;32:517-25.

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Rightward orienting bias, wheelchair maneuvering, and fall risk. Webster JS, Roades LA, Morrill B, et al. Arch Phys Med Rehabil 1995;76:924-8.

[113] THE ROLE OF IMAGERY IN AUDITORY COMPREHENSION IN BRAIN DAMAGED ADULTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C818-RA)*

PURPOSE—The purpose of this project is to examine the contribution of imagery as an aid to auditory comprehension of connected language in aphasic and right hemisphere lesioned individuals. Specifically, the following questions are being asked: Do imagery laden verbal passages enhance accuracy of comprehension on verbal tasks? And do imagery laden verbal passages increase inter and intrahemispheric differences in right- and left-brain damaged patients as measured by probe auditory evoked potentials (AEP)?

METHODOLOGY—Moderated by a computer signal averaging program, a probe evoked potential technique, in which a task-irrelevant sensory stimulus is superimposed on ongoing complex tasks, is used to measure intra/interhemispheric response to the task. The paradigm includes a baseline or non-differentiating task and two language or left-hemisphere tasks. The baseline task provides a comparative measurement of processing a task that has never been shown to differentially bias one hemisphere over the other. The two language tasks include passages rated as high imagery and passages rated as low imagery by nondisabled subjects. In addition, multiple choice questions are asked following each language passage. These questions are used as measures of the subject's comprehension of the material as well as an indicator of his or her involvement in the task. The questions require both literal and interpretive conclusions to be made about the material. Aphasic patients whose PICA Overall severity levels fall between 55th–85th percentile are included as subjects. Right hemisphere damaged patients whose overall scores on the PICA fall between 55th–85th percentile serve as pathological comparisons. In addition, a non-brain damaged control group is included. Each subject undergoes two sessions of electrophysiological testing resulting in evoked potential measures of hemispheric responsivity and test/re-test data.

PROGRESS—To date, all of the equipment has been ordered and received. Language passages have been selected and rated as hi/low imagery. The baseline and language stimuli have been tape recorded. Literal and interpretive multiple choice questions have been prepared.

FUTURE PLANS—Pilot subjects will begin participating in the project in the next month. Following the pilot period, actual running of study subjects will begin.

[114] ASSESSING LIMB APRAXIA AND ITS RELATIONSHIP TO FUNCTIONAL SKILLS

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PURPOSE—Brain damage from stroke often produces limb apraxia which impairs skilled movements independently of weakness, sensory loss, language comprehension deficits, or general intellectual deterioration. Pre-

liminary work suggests that limb apraxia may be one of the best predictors of impairment in functional independence after brain damage. Traditionally, limb apraxia has been assessed by examining a patient's ability to perform a single gesture to verbal command, imitation, and/or with object use. Some have also examined the performance of sequences of gestures. However, none of the current limb apraxia assessments are reliable, valid, easy to use, and have normative data. Moreover, the reasons for apraxia are not always clear from traditional assessments.

The primary goal of this project is to develop a valid, reliable, and normed limb apraxia assessment protocol that can be used easily by clinicians. Our protocol includes a comprehensive examination of related cognitive abilities (e.g., visual perception, object agnosia, memory, serial ordering) in order to identify the different reasons for the disorder. We also will examine the relationship between limb apraxia and functional skills (i.e., activities of daily living, functional independence) to identify the kinds of deficits in everyday activities that can be diminished with different types of apraxia.

METHODOLOGY—A limb apraxia battery was pilot tested in a normal control group and in individuals who have survived a stroke to the left and/or right hemisphere of the brain. Individuals were videotaped as they: 1) Imitated meaningless gestures (e.g., hand under chin), intransitive gestures which do not incorporate an object (e.g., snap fingers), and transitive gestures which involve the use of an object (e.g., brush teeth); 2) pantomimed transitive gestures with and without sequencing requirements; and 3) performed transitive gestures with and without sequencing requirements using the actual object. Language, visual perception, serial ordering, and memory also were evaluated. Functional abilities were evaluated by examining skilled activities (e.g., make a sandwich) and a questionnaire that assesses functional independence in a broad range of activities of daily living (e.g., cooking, managing money).

PROGRESS—During the first year we developed an apraxia battery and tests of related cognitive abilities. To date, we have tested 16 individuals with left-hemisphere damage, 17 with right-hemisphere damage, 6 with damage to both hemispheres, and 31 age and education matched control subjects.

PRELIMINARY RESULTS—Interrater reliability of the apraxia assessment was excellent (r=0.90)1111. Preliminary analyses of the apraxia protocol and the functional assessments will be conducted when we have identified 15 apraxics. In addition, we plan to test individuals who have suffered a head injury since there is evidence that many of these patients have difficulties performing familiar, everyday tasks. Some of these difficulties may be due to apraxia, which has not been well documented in head-injury patients.

IMPLICATIONS—Assessment of cognitive abilities is the first step toward designing rehabilitation programs that address the patient's deficits and strengths. Before this can be done reliably, the assessment of apraxia needs to better specify which cognitive factors produce apraxia and how they relate to functional skills. Clinicians do not routinely assess limb apraxia, despite its prevalence in stroke populations, largely because of the problems with currently available tests. Our apraxia assessment protocol will confront these shortcomings and should increase the systematic assessment of limb apraxia in clinical settings. This is vital because it will allow clinicians to make suggestions to patients and families about living arrangements and environmental support, and it will alert therapists to the specific reasons for a patient's apraxia so that they can design more focused therapies.

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Representations of actions in ideomotor limb apraxia: clues from motor programming and control. In: Gonzalez Rothi LJ, Heilman KM, eds. Apraxia. In press.

[115] N-ACETYLASPARTATE: A PREDICTOR OF OUTCOME IN NEUROREHABILITATION

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PURPOSE—Little is known about the mechanisms of recovery after coma. Accordingly, it is difficult to predict outcomes and advise families with any degree of certainty, particularly in patients with traumatic brain injury. Consequently, significant resources are expended in attempts to rehabilitate patients with head injury, even when there may be little chance for recovery for some patients. Thus, a better understanding of the reversible and irreversible changes that occur during coma would be of great benefit to guide rehabilitation of head-injured patients and, perhaps, provide insight into potential therapies.

A large part of the uncertainty regarding the potential for recovery after traumatic coma may be due to the insensitivity of conventional imaging techniques in detecting neuronal loss. MRI and CT are primarily measures of brain water. Although neurons constitute about 30-35 percent of the volume of brain, selective neuronal loss is poorly visualized on MRI and CT. Conventional scans reveal structural lesions such as contusions and hematomas in many cases of head trauma, but many patients have diffuse head injuries without such mass lesions. The pathology in these cases reveals diffuse axonal injury due to shear injury and/or diffuse neuronal cell body loss due to hypoxia. Macroscopic evidence of axonal injury may be detected by MRI, but MRI does not reveal the full microscopic extent of these changes, nor is it definitive in predicting outcome.

N-acetylaspartate (NAA) has been shown to be produced only by neurons and not by glia or other non-neuronal elements of mature brain. The distribution of NAA may be determined noninvasively by magnetic resonance spectroscopy (MRS). Therefore, MRS may be used to regionally estimate the population of viable neurons in the brain.

It is hypothesized that MRS imaging of total brain NAA of head-injured patients at the time of entry into neurorehabilitation predicts functional and neurobehavioral outcome after 1 year.

The specific objectives are: 1) to determine if MRS measurements of total brain NAA in head-injured patients at time of entry into neurorehabilitation predict functional independence and neurobehavioral performance at 1 year after entry into rehabilitation; 2) to determine if gray or white matter NAA predicts outcome more accurately than total brain NAA; and 3) to determine if there are changes in NAA that occur during recovery. Do these changes correlate with the degree of improvement?

METHODOLOGY—MRS NAA measurements will be obtained in patients entering rehabilitation after coma due to closed head injury. MRS will be used to determine NAA in gray and white matter in cortex. The Functional Independence Measure (FIM) at 1 year after entry into rehabilitation will be used as the primary outcome measure. Neurobehavioral dysfunction will be measured by a battery of neuropsychological tests sensitive to the executive, organizational, attentional, and memory deficits prevalent in head injury. In half of the patients studied, a second MRS study will be performed at this time.

PROGRESS—Previous work in animals and man has shown that NAA measured by MRS is decreased in some diseases where neurons are selectively injured, such as hypoxic-ischemic encephalopathy and status epilepticus. Human studies demonstrate that NAA is decreased in other diseases where neurons are lost, such as Alzheimer's disease, epilepsy, and stroke. Our preliminary results have shown that MRS NAA is decreased in patients with hypoxic-ischemic encephalopathy and head trauma.

RESULTS—MRS studies have been completed on 18 patients and controls in the first 6 months. Because these patients have not reached the 1-year follow-up, outcome data are not yet available.

[116] PROTON MAGNETIC RESONANCE SPECTROSCOPY IN TRAUMATIC BRAIN INJURY

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Sponsors: *Department of Neurological Surgery, Seattle, WA 98195; National Institutes of Health, Washington, DC 20892*

PURPOSE—This pilot study was carried out to examine the use of proton magnetic resonance spectroscopy (1H-MRS) in evaluating the brain metabolic profile of persons in a vegetative state from severe traumatic brain injury (TBI). We compared spectra from five neurologically nondisabled persons to those of six persons with severe TBI and collected data on neurological and functional outcome on TBI patients to explore the potential for prediction of outcome using metabolic data. Two areas of the brain that are involved in the maintenance of arousal and attention were studied, the upper pons and the thalamus.

METHODOLOGY—Six patients with initial GCS scores of six or less and five neurologically nondisabled controls were studied with 1H-MRS. Each patient was studied between 35 and 70 days after initial injury. Each subject was evaluated at admission and at 4–12 months using the Coma Recovery Scale, the Disability Rating Scale and the Glasgow Outcome Scale. A standard MRI study, using a 1.5 Tesla magnetic resonance imager, was obtained of each subject and control to allow localization of the thalamus (in three subjects) and the pons (in six subjects). For the 1H-MRS study, a single voxel (size about 4 cc) was obtained of the thalamus and pons using an optimized volume-localized technique called point resolved spectroscopy (PRESS). Spectra were studied for N-acetylaspartate (NAA, thought to be a neuronal marker), choline (Cho), and lactate (Lac). The spectra were processed, determining the peak areas using integration, resulting in a numerical representation that was referenced to creatine to compare metabolite levels.

RESULTS—Analysis of the data using a t-test design demonstrated a significant difference between subjects with TBI and controls for NAA/Cr ratio in both the pons and thalamus ($p<0.03$ in the pons, $p<0.01$ in the thalamus). No difference was identified for Cho/Cr ratio. Lac/Cr was insignificant for all subjects. No correlation of ratios with outcome on the GOS or DRS was attempted with this small group, but two-thirds of the subjects with the lowest NAA/Cr ratio had the worst outcomes (persistent vegetative state or severe disability), while two-thirds of the subjects with the highest NAA/Cr ratio had the best outcomes (discharge to the community with at least partial independence).

FUTURE PLANS/IMPLICATIONS—Even with this small group of subjects, differences were measurable for NAA between TBI subjects and controls. A larger group of subjects will be needed for statistically significant correlation with outcome. Our plans for future study include adding the frontal cortical region to the analysis using a multiple-voxel technique, to determine the area yielding maximal information on outcome for recovery from vegetative state and functional recovery. In addition, subjects will be studied at different periods of time from injury to identify the most appropriate time to perform MRS. It is likely that combining MRS with other clinical factors will result in the best overall prediction of recovery.

[117] EVALUATION OF AN ADJUNCTIVE MUSICAL ATTENTION TRAINING PROGRAMME WITH BRAIN-INJURED ADOLESCENTS

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Sponsor: *Easter Seal Research Institute and Police Association of Ontario*

PURPOSE—The goal of this project is to investigate whether improvements of attention in brain-injured adolescents, trained through the adjunctive mode of electroacoustic music, are: 1) clinically significant, 2) specific to auditory information processing, 3) long lasting, and 4) dissociable from motivational/emotional factors.

PROGRESS—Brain-injured adolescents are randomly assigned to two treatment groups: an experimental group (n=9) receiving 10 weeks of musical attention training, and a control group (n=9) on a similar schedule working with electronic music technology in an unstructured context. The musical attention training consists of two task modules addressing progressively higher attention levels. The first task module involves percussion sound identification and is modelled on similar attention process training activities employing letters, words, and numbers. The second task module requires that the subject respond to a melodic motive or pair of motives and, in some cases, track a musical metre.

Software has been developed to be used in administering the tasks and recording data. Two validated tests administered weekly record baseline and outcome measures of information processing: the Paced Auditory Serial Addition Task and the Continuous Performance Test. A test battery is also given for comparison before and after the treatment period, to distinguish changes in attentional processing from changes in other cognitive domains. For this study, the data-gathering software was rewritten from the original MS-DOS to Windows format, and an additional task administration module was added. A further upgrade has been produced based on knowledge gained from the pilot study. Activities including improvisation and song-playing have been developed for the control group. Task administration and testing are completed; data analysis is in progress.

[118] PREVENTION OF THROMBOEMBOLISM IN STROKE REHABILITATION PATIENTS

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Sponsor: *Department of Education, National Institute on Disability and Rehabilitation Research, Washington, DC 20202*

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 vulnerability to thromboembolism, which has been shown to affect 60–75 percent of elderly stroke patients. This is a study to compare 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 thrombus, as defined by venous flow studies, venography, positive V/Q scan, or pulmonary angiography. Also, 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 >2g).

PROGRESS—Currently, 30 subjects have been enrolled in the study and subject recruitment is continuing. Both the compression boots and the low molecular weight heparin appear to be safe and effective anti-thrombotic interventions, but too few patients have been studied to determine which intervention would be preferred.

[119] IMPROVING VOCATIONAL OUTCOMES OF INDIVIDUALS WHO HAVE SUSTAINED A STROKE

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Sponsor: *Department of Education, National Institute on Disability and Rehabilitation Research, Washington, DC 20202*

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 is significantly less than individuals with other disabling conditions. It is strongly felt that there currently exists a lack of a focused, succinct assessment to assist the Vocational Rehabilitation 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:

1. The Functional Assessment Inventory (FAI) will be investigated and evaluated for its suitability for application to the stroke population.
2. Based on results of objective 1, identify appropriate areas of the FAI which require modifications to improve the assessment tool for the stroke population.

PROGRESS—By the end of 1994, the data collection for the 110 control cases had been completed. The only remaining data to be collected for the control group are the units of vocational services provided. This has been obtained for 1 year out of the 2 year time period. To date, a total of 43 cases have had the modified FAI completed for the experimental group.

[120] THE EFFECTIVENESS OF A TELEPHONE SUPPORT GROUP FOR STROKE CAREGIVERS

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Sponsor: *Department of Education, National Institute on Disability and Rehabilitation Research, Washington, DC 20202*

PURPOSE—This study explores the effectiveness of a unique intervention for the stress of caring for a stroke survivor. 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. All participants will be assessed upon recruitment, after the group intervention, and at 6 months. It is hypothesized that the treatment group will

show less depression, loneliness, and burden, as well as increased health behavior and increased competence.

PROGRESS—In this first year, approximately 470 people have been solicited to participate in the study by these strategies: 66 have been recruited and 57 have been fully enrolled and assigned to study groups. The leading reasons for people declining participation are: stroke patient is deceased, spouse is not interested, spouse is too busy, or spouse is ill.

RESULTS—Of the 56 subjects with complete data, the average age is 70 years. Seventy-seven percent of the sample are women and 71 percent are white. They have been married on average for 41 years to the stroke survivor (range 4–64 years) and have an average of 14.25 years of education. Twenty-one percent of the sample work full or part-time. Twenty-one percent of the sample rate their health as fair to poor. In the sample, the median number of years caregiving is 3.15 with a range of 0.08–15 years.

[121] EFFECTS OF AEROBIC EXERCISE ON YOUNG PERSONS POST-STROKE

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Sponsor: *Department of Education, National Institute on Disability and Rehabilitation Research, Washington, DC 20202*

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 after they responded to a survey assessing outcomes after discharge from a rehabilitation hospital. 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/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—Groups one, two, and three have completed the entire protocol. Recruitment is underway for the fourth and final group. Preliminary analysis on the data from the first three groups has begun.

[122] A CONTROLLED STUDY OF THE EFFECTS OF EMG FEEDBACK AND ELECTRICAL STIMULATION ON MOTOR RECOVERY IN ACUTE STROKE PATIENTS

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Sponsor: *Department of Education, National Institute on Disability and Rehabilitation Research, Washington, DC 20202*

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 eight patients with low motor function have been randomized. Most of these patients have completed 18 to 20 treatment sessions. Pre- and post-evaluation data is currently being analyzed.

[123] THE PREDICTIVE VALUE OF COGNITIVE/BEHAVIORAL MEASURES IN PATIENTS AFTER STROKE IN ASSESSING FUNCTIONAL OUTCOME

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Sponsor: *Department of Education, National Institute on Disability and Rehabilitation Research, Washington, DC 20202*

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. Some of the major methodological strengths of this study are the following.

PROGRESS—Approximately 15 subjects were pilot-tested with some or all of the neuropsychological tests. The final set of tests include: Rivermead Behavioral Memory Battery; Benton Facial Recognition; Sensory Imperception Test; Trailmaking Test; Executive Interview Test; Boston Diagnostic Aphasia Examination Commands; Ravens Matrices, Standard; Line and Symbol Cancellation; Boston Diagnostic Aphasia Examination, Sentence Repetition; Tower of Toronto; Weschler Adult Intelligence Scale-Revised, Vocabulary; Ross Comprehension Questions; Repeatable Battery for the Assessment of Dementia; and the Geriatric Depression Scale.

Subject recruitment is underway. Eighteen subjects have undergone the initial testing. Following testing will begin in the next few months. It is still too early to draw any conclusions.

[124] REDUCING MOTOR DISABILITY IN HEMIPARETIC STROKE BY MANIPULATION OF SENSORY INPUT FROM THE PARETIC UPPER LIMB: A QUANTITATIVE EVALUATION

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Sponsor: *Department of Education, National Institute on Disability and Rehabilitation Research, Washington, DC 20202*

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 both activities of daily living and in the workplace. 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 toward 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 the 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) has not been examined yet.

To determine 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 six hemiparetic subjects. Currently, experimental data has been collected during 12 experimental sessions from these six subjects. Prestimulation torque responses of the impaired upper limbs were measured during slow ramp perturbations of the elbow 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.

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 sec on, 2.5 sec 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 prestimulatory 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.

To study the effect of sensory manipulation on arm movements, we are gathering additional control data from nondisabled and hemiparetic stroke subjects. To date, eight stroke subjects have been studied. Four of the subjects, with mild to moderate motor deficits, showed abnormal movement trajectories in reaching and

retrieval directions where intersegmental coupling torques are most significant. The remaining four subjects, with moderate to severe 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 attenuations of spasticity in elbow muscles do 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.

[125] COURSE OF RECOVERY OF COGNITIVE-COMMUNICATIVE PROBLEMS IN RIGHT-BRAIN DAMAGED INDIVIDUALS

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Sponsor: *Department of Education, National Institute on Disability and Rehabilitation Research, Washington, DC 20202*

PURPOSE—Historically, it was assumed that only left hemisphere (LH) damage resulted in language deficits while right hemisphere (RH) damage had no important effect on communication. However, recent evidence suggests that the RH makes an important contribution to language processing, and it is now widely acknowledged that RH stroke also results in impairments in communication. RH communication impairments are believed to result from underlying deficits in attention, memory, 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 RH damage. Increased knowledge about the rate, amount, and patterns of recovery of communication problems in RH stroke patients is needed to facilitate the selection of more effective rehabilitation interventions.

PROGRESS—Subject recruitment has been progressing steadily. The charts of all consecutive admissions to RIC with unilateral RH stroke are reviewed weekly. During this period of time, 20 patients have met the criteria for the project, and a total of 16 subjects have been recruited. All subjects 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 1 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.

[126] 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.

PROGRESS—Data have been collected on all patients admitted to the inpatient stroke rehabilitation service since December 1993. There have been 567 new stroke admissions through mid-April 1995. Demographic, stroke, medical comorbidity, and other information has been collected on 425 patients and entered into the database. Laboratory results and data on secondary complications have been reviewed for 300 of those patients. Impairment disability measures have also been collected on these same 300 patients. Although it is too early to detect any trends or to draw any conclusions, preliminary data show that in our stroke population the most common pre-existing complications are hypertension, a history of smoking, and diabetes. The most frequent complications developed during acute hospitalization are urinary tract infection, pneumonia, and congestive heart failure.

RESULTS—In addition to comorbidity and complications, data on types and site of stroke lesions are collected. The majority of strokes were infarcts (62 percent), whereas 38 percent of stroke admissions had a bleed. Stroke subtypes included intracerebral hemorrhage (27 percent), subarachnoid hemorrhage (11 percent), thrombotic (39 percent) and embolic (22 percent). A little more than a third (36 percent) had multiple sites on CAT scan. Twenty-three percent had had a previous clinical stroke.

[127] NONINVASIVE MEASUREMENT AND CLASSIFICATION OF DYSPHAGIA, AND COMPUTER AIDED BIOFEEDBACK THERAPY

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PURPOSE—Dysphagia is a disorder of swallowing and presents a major problem in the rehabilitation of stroke and head injury patients. In the current clinical practice, the diagnosis of swallowing disorders is qualitatively based on bedside clinical evaluation or videofluorography examination. Recently, we have identified and developed techniques for noninvasive measurement of several biomechanical parameters that characterize the oral and pharyngeal phases of swallowing. The oral phase measurements included lateral and forward tongue thrust and lip pulling force. We have found significant differences in these parameters measured in normal and dysphagic patients. To quantify the pharyngeal phase, we have placed an ultraminiature

aeeelerometer on the throat and simultaneously measured the swallow suetion pressure with a eatheter plaeed in the oral cavity. The question arises if these measurements ean be used elinieally to elassify the dysphagie patient so as to identify the patient at risk of aspiration. Another question arises if these measurements ean be used for biofeedbaek therapy. The purpose of the present investigation is to address these questions.

PROGRESS—We have made a elinieal eorrelation of the biomeehanieal measurements with videofluorographie findings. Also, we have developed and elinieally evaluated an expert system to elassify the patient into four eategories using the set of measurements obtained from eaeh patient. We have developed and elinieally evaluated a set of neural network models to elassify the dysphagie patients using the biomeehanieal measurements. Also, a fuzzy deeision system was developed to elassify the pharyngeal dysphagia into four eategories using the set of biomeehanieal measurements.

Sinee the aeeeleration signal provides a measure of the mechanical events (rate of laryngeal elevation), we have eorrelated the aeeeleration signal with eleetrieal events during the pharyngeal phase of swallowing by simultaneously measuring aeeeleration and EMG signals in normal individuals during dry and wet swallowing.

We have developed biofeedbaek deviees that provide audiovisual feedbaek of tongue thrust and lip pulling foree. The visual feedback is in terms of inereasing number of LEDs lighted with inereased amount of foree exerted by the tongue or the lips. The system ean be used both for self training and therapy. In order to provide improved motivation, we have developed a eomputerized Tongue Musie System in whieh the patient ean play various keys on the eomputer with different levels of foree exerted on the tongue or lip transdueer, and thus can aid in the therapy.

For phrayngeal stage biofeedbaek therapy, we have developed a eomputerized biofeedbaek system whieh provides a visual display of the aeeeleration signal during swallowing.

RESULTS—We have found signifieant differenees in the magnitudes, mean power, and mean frequeneies of aeeeleration during swallowing between nondisabled subjeets and dysphagie patients. The mean power and mean frequeney of aeeeleration signals during eoughing were signifieantly larger than those obtained during swallowing. The surfaee EMG eorrelated well with the throat aeeeleration (eorrelation eoeffieient 0.8). The aeeeleration patterns were signifieantly different in dry swallowing when eompared to wet swallowing.

In a double blind study, the biomeehanieal elassifieation eompletely agreed with elinieal elassifieation based on videofluorography examination in 58 percent of subjeets, overestimated by one eategory in 31 pereent and underestimated by one eategory in 11 pereent.

The neural network model results were in eomplete agreement with clinieian elassifieation in 92 pereent of patients for the oral and 88 pereent of patients for the pharyngeal phase. The oral models overestimated the severity by one eategory in 4 pereent and underestimated by one eategory in 4 pereent of the eases. The pharyngeal models results over estimated by one eategory in 12 pereent of eases. The fuzzy deeision system eompletely agreed with elinieian in 88 pereent of the eases, overestimated by half a eategory in 6 pereent and under estimated by half a eategory in 6 pereent of the cases.

Evaluation with a limited number of subjeets has shown that biofeedbaek therapy was effeetive in the rehabilitation of dysphagie subjeets.

IMPLICATIONS—The noninvasive biomeehanieal measurements (aeceleration at the throat, tongue thrust, surface EMG, ete.) together with neural network and fuzzy deeision systems, ean be used to assess the risk of aspiration to compliment the videofluorography examination, and ean aid the physieian in continuing patient assessment on a daily basis. The biofeedbaek systems can be used in treating the oral dysphagia as well as pharyngeal phase dysphagia.

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Surface EMG measurement during pharyngeal phase of swallowing. Gupta V, Reddy NP, Canilang EP. Dysphagia. In Press.

[128] COST-EFFECTIVENESS OF ROUTINE SCREENING FOR PROXIMAL DEEP VENOUS THROMBOSIS IN ACQUIRED BRAIN INJURY PATIENTS ADMITTED TO REHABILITATION

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Sponsor: *University of Alabama at Birmingham Southeastern Regional Head Injury Center; U.S. Department of Education*

PURPOSE—The goal is to determine the prevalence of proximal deep venous thrombosis (DVT) among acquired brain injury patients on admission to rehabilitation, and to assess cost-effectiveness of routine ultrasound screening for proximal DVT in those patients.

METHODOLOGY—One hundred and sixteen traumatic brain injury patients (TBI) and 48 nontraumatic brain injury patients were admitted to our brain injury (BI) unit over a 21-month period and screened for a DVT on admission to rehabilitation utilizing real time, spectral doppler, and color doppler ultrasound. Patients with a previous clinically recognized and treated DVT were excluded. No patients had been treated with prophylactic anticoagulation or intermittent anticoagulation since their BI and all patients were within 4 months of original injury.

PROGRESS—Fourteen patients in total (8.5 percent) were found to have a DVT in the thigh or popliteal area: 9 of the 116 patient TBI group (7.8 percent), and 5 of the 48 patient nontraumatic BI group (10.4 percent). Statistically there was no significant difference in the total number of detected proximal lower extremity DVTs between the TBI and the nontraumatic BI groups (Fisher's exact test). In the TBI group, 22 patients had associated lower extremity or pelvic fractures, but this factor appeared not to be significant, as only 1 of the 22 patients was discovered to have a DVT. The average admission Glascow Coma Score (GCS) of the TBI group was 8.6, but there was no correlation with the GCS and the prevalence of DVT. The additional cost of screening for and treating the additional DVTs utilizing color doppler ultrasound is conservatively estimated to be $674.84 per patient admitted to the BI rehabilitation unit. It can be estimated the cost of saving one life is $129,527.83.

FUTURE PLANS—Comparisons will be made with other screening methods.

RECENT PUBLICATIONS FROM THIS RESEARCH

Use of intrathecal baclofen in brain injury patients. Meythaler JM. Arch Phys Med Rehabil 1994;75:1036.

[129] PROSPECTIVE STUDY ON THE USE OF BOLUS INTRATHECAL BACLOFEN FOR SPASTIC HYPERTONIA DUE TO ACQUIRED BRAIN INJURY

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Sponsor: *U.S. Department of Health and Human Services, Centers for Disease Control and Prevention*

PURPOSE—The research goal 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 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.

PROGRESS—Patients were randomized in a double blind, placebo-controlled crossover study to receive a bolus injection of either intrathecal normal saline or 50 micrograms 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. Eleven patients, more than 1 year out from their brain injury with disabling lower extremity spastic hypertonia, took part in the study.

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. A continuous infusion trial similar to those used in patients with in spinal related causes of spastic hypertonia is underway.

RECENT PUBLICATIONS FROM THIS RESEARCH

Use of intrathecal baclofen in brain injury patients. Meythaler JM. Arch Phys Med Rehabil 1994;75:1036.

VII. Independent Living Aids

A. General

[130] DESIGN OF NEW TOILET PROTOTYPES FOR ELDERLY AND DISABLED VETERANS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E666-RA)*

PURPOSE—This study is one in a series of projects concerned with improving the ability of older veterans and those with disabilities to carry out routine activities independently and safely. 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. As a result, 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—Full scale mockups of prototype designs were based on an analysis of previous research and anthropometric data. 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 over 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 as well as a standard accessible toilet were installed and tested in a portable bathroom testing facility. Sixty-eight subjects (7 females and 61 males) ranging in age from 20 to 102 years (mean=58.1 years) were tested in Atlanta and Milwaukee. Subjects 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. Subjects who could ambulate (n=35) were tested on the three inserts; whereas those who required a wheelchair (n=33) were tested on the straddle toilet and the inserts with recessed and side handles. All subjects were tested on the accessible toilet.

RESULTS—Self report data indicate that the insert with vertical handles for the ambulatory group and straddle toilet for the nonambulatory group provided safer and less difficult transfers than the existing accessible toilet. Videotape data also indicate that the insert with vertical handles and the straddle toilet were significantly easier and took less time to transfer onto than the other prototypes and the standard accessible toilet. Although both of these prototypes required more time for the particular test group to transfer off, getting off of the insert with vertical handles was significantly easier than getting off of the standard accessible toilet

for the ambulatory group and not significantly different from the level of difficulty with the standard toilet for the nonambulatory group.

FUTURE PLANS—Based on the data analysis, it appears that at least two of the prototypes, as well as some of the specific features of the other two, show promise. Modifications to the prototypes will be assessed and working models will be constructed and evaluated in-use at the VA Research and Evaluation Unit.

RECENT PUBLICATIONS FROM THIS RESEARCH

Design and development of new toilet prototypes to meet the needs of disabled and elderly people. Malassigne P, Cors M, Hoehn T. In: Proceedings of the RESNA '95 Annual Conference; Vancouver, BC. Washington, DC: RESNA Press, 1995:14:603-5.

[131] DESIGN OF A NEW BOWEL CARE/SHOWER CHAIR FOR SCI VETERANS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B768-RA)*

PURPOSE—The purpose of this 2-year project is to design new bowel care/shower chairs that can be safely and efficiently used by both patients and caregivers for the bowel program of SCI and other disabled users who cannot transfer to the toilet.

Because bowel care procedures can take several hours, proper seating posture and comfort is necessary in order to prevent pressure ulcers, a serious threat in standard bowel care chairs. Several features of existing models of bowel care chairs have been found during a previous pilot study to be less than optimal: space opening for digital stimulation, seat design and cushioning, armrests, footrests, backrest, brakes, and the size of the wheels.

METHODOLOGY—The overall procedure used by the investigators includes the following three phases: 1) design development and fabrication of two new bowel care/shower chair prototypes; 2) testing of the prototypes according to the ANSI/RESNA wheelchair standards; and 3) evaluation of the new bowel care/shower chair prototypes with patients and caregivers in the SCI Centers at the Milwaukee and Tampa VAMC.

PROGRESS—*Wheelchair frame development:* Full-size frame solutions have been designed to provide a proper seating position and hand access for digital stimulation without interference from the frame and the wheels. These frames were fabricated into full-size prototypes and tested for static stability. A minimum of 15° was set for tipping forward and rearward in frame development. Finally the prototypes are being evaluated by volunteers from the participating VA hospitals.

Seat development: A C-shaped series of seats were designed to provide multipositioning on the frame allowing hand access in four positions (front, sides, and back). Various foam densities for the seats were evaluated with the Force Sensing Array to determine an ideal density. The appropriate density evenly distributes the pressure created by the buttocks and the legs on the seat.

Hand-ring diameter development: A preference study, with volunteers at the Milwaukee VAMC, with three hand-ring diameters (27, 34, and 42 mm) led to the selection of the 34 mm as the preferred diameter for grasping. This new size will be compared to the largest commercially available hand ring: the Duracush of 25 mm in diameter. In addition, coated surfaces are used on the hand rings to provide better grasping under wet conditions.

Footrest development: Design of safer footrests was the prime consideration. Larger support area for the feet and an overall contoured shape for comfort and positioning

is being used for the prototypes. In addition a foot-lift to ease cleaning of legs and feet is being explored and will be tested in the production prototypes.

FUTURE PLANS—During the second year of the project, the production prototypes will be evaluated with volunteer participants at the Milwaukee and Tampa VAMCs. This evaluation will involve the use of videotaping and answering questionnaires to collect the opinions of caregivers and participants. Following this, final design adjustments will be made to the chairs. In addition they will be tested according to the ANSI/ RESNA wheelchair standards. From this phase, final production considerations will be addressed with Ortho-Kinetics, the collaborating manufacturer.

RECENT PUBLICATIONS FROM THIS RESEARCH

Comparison of seating pressures on three bowel care/shower chairs in SCI: results of a pilot study. Nelson A, Malassigne P, Murray J. SCI Nursing: 1994:11(4):104-6.

Determination of static stability of bowel care/shower chairs in SCI. Malassigne P, Amerson T, Nelson A. In: Proceedings of RESNA International '94; Nashville, TN. Washington, DC: RESNA Press, 1994:318-20.

[132] THE 'SPREAD BOARD®': A SAFE DEVICE TO ENABLE HEMIPLEGIC PEOPLE TO PUT SPREADS ON BREAD

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Sponsor: *Action Research, Vincent House, North Parade, Horsham, West Sussex RH12 2DP, UK*

PURPOSE—The Brunel Institute for Bioengineering has investigated the expressed needs of many elderly or disabled people. One request, particularly from people with a hemiplegic condition, was for a safe means of putting spreads on bread. Many people with this condition, and others who lack a strong grasp, find cooking difficult, and so have one or two noncooked meals a day, often based on bread and butter or other spreads. Spike boards, for securing items for a one-handed operation, have been available for many years. However, the concept of having vertical spikes on a working surface is not acceptable to some disabled people. They feel it would be too easy to impale their hands on such spikes, when reaching out to prevent falling or when just needing extra support for their upper body.

METHODOLOGY—A fresh approach to the problem was taken, concluding in the design of a lightweight plastic board with two adjacent raised edges to hold the slice of bread. This board has a larger lip, turned downward, that secures it against the edge of the table or working surface. The twin edges that hold the bread on the board are molded at 90° to each other and at 45° to the lip that secures the board itself, so the user can easily spread the bread directly away from his/her body, ensuring a relatively clean operation.

PROGRESS—The Spread Board® has developed from a laboratory model, through a production prototype, to a consumer tested product. The Mark 1 board was fabricated from 'Foamex®' to allow a low capital cost method of testing the market. This Foamex® model has now been superseded by the injection molded Mark 2 version. This model had a considerable tooling cost for manufacture of the injection-molding master, but has a much lower unit cost for each Spread Board®.

RESULTS—The injection molded Spread Board® is now commercially available through disability equipment stores and mail-order catalogues. This version is dishwasher proof, and so hygienic cleaning is easy.

[133] THE 'PLUG PULL®': A SIMPLE ADD-ON HANDLE FOR ELECTRICAL POWER PLUGS

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PURPOSE—The Brunel Institute for Bioengineering has investigated the expressed needs of many elderly or disabled people. One frequent request, particularly from the majority of pensioners with arthritic hands, was for help in using the 3 pin electric power plugs that are fitted in the UK. Such plugs require a considerable pinching force to grip them when being pulled out of a power socket, and this action is very painful for some arthritic people. There are several special plugs on the market that have loop handles, within which a user is supposed to be able to place his or her fingers, but the shapes of the loops sometimes leave a lot to be desired, and any new plug will involve rewiring. Such rewiring may be beyond the dexterity capability of the very people who could need such plugs, and so a further labor expense may have to be incurred.

METHODOLOGY—It was decided to eliminate the rewiring problems by designing a specially shaped open handle that would be stuck to the flat back of an existing plug with an integral strip of double sided adhesive. A set of handles was initially designed using anthropometric data. This was followed by practical evaluation of these handle shapes using a group of people aged between 65 and 85 with a variety of hand problems. These older people found that one particular shape of open handle was the easiest to use, the major reason being that it gave the most choices of how many fingers were used to do the pulling. There are two distinct advantages of the adhesive method for fixing the handle. Firstly, no re-wiring of the plug is needed, and so the disabled person is more likely to be able to adapt the plugs themselves as and when it is needed. Secondly, it allows the handle to be attached at an angle and not just vertically or horizontally: some arthritic people found the handle much easier to grasp when fixed at a 45° angle. Care needs to be taken to carefully de-grease the back of the plug before applying the Plug Pull®.

PROGRESS—The Plug Pull® has progressed from a laboratory model, through a production prototype, to the consumer tested product.

RESULTS—The injection molded Plug Pull® is now commercially available through disability equipment stores and mail-order catalogues.

[134] THE 'SWITCH STICK®': AN ELECTRICAL SWITCH EXTENSION FOR DISABLED PEOPLE WITH LIMITED DEXTERITY

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PURPOSE—The Brunel Institute for Bioengineering has investigated the expressed needs of many elderly or disabled people. One frequent request, especially from older and stiffer people, was for help in using domestic electrical fittings, particularly light and power switches. Such switches are frequently in the form of small rocker

switches that can require a level of dexterity to locate the switch, and a fair amount of pressure to operate it. A particular problem exists for most power switches in the UK, as such switches usually are mounted on skirting boards an inch or so off the floor. This position is very hard to reach for the many people with arthritis, for people in wheelchairs, and for people with other mobility conditions. The Switch Stick® also gives a clearer and more positive indication of the on/off status of the switch for visually disabled people.

METHODOLOGY—A simple angled switch extension has been designed to solve this problem. It is formed of plastic and fitted with a patch of double-sided adhesive. To apply the unit, the rocker switch itself is first carefully degreased. The protective covering over the adhesive, on the shorter 0.75 in (1.9 cm) part of the unit, is then removed and the adhesive pad pressed against the cleaned rocker switch. After allowing an overnight curing period, the switch is ready for use. The 2.5 in (6.35 cm) lever, angled at 150° to the adhesive section, makes the operation of the switch very easy. If the switch is not within arm's length, a walking stick, or a reacher, can be used to operate the switch; either is quite satisfactory.

PROGRESS—The Switch Stick® has progressed from a laboratory model, through a production prototype, to a consumer-tested product.

RESULTS—An injection molded Switch Stick® is now commercially available through disability equipment stores and mail-order catalogues.

[135] COMPUTER ACCESS SELECTOR

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Sponsor: *Commonwealth Department of Human Services and Health*

PURPOSE—The selection of computer access products for an individual with a disability involves a compromise of many different parameters. Professional assessment is generally required to determine the needs and abilities of a person with a disability who wishes to access a computer. Even when their capabilities are understood, selection of specific products is not necessarily straightforward due to the large number of products available. Computer Access Selector narrows down the large number of products for Macintosh and IBM compatible computers based on feature selections made by the user.

In addition, multiple products are often used together to form a complete access solution. For example, an alternative keyboard may be used together with a word prediction software package to gain the optimal typing speed for an individual with motor control difficulties. This cascading of multiple products complicates the selection of the specific products. The Computer Access Selector addresses this by suggesting combinations of products that are known by experienced computer access professionals to work together under most circumstances.

METHODOLOGY—The software, which runs under Microsoft Windows, gives the user an opportunity to specify the requirements of the computer access system they are looking for by selecting from a series of parameters. Computer Access Selector uses expert knowledge to suggest potentially suitable products. The suggestions are dynamically adjusted as user selections are changed. This provides a means for the user to explore different possibilities.

With one click of the mouse, the user is able to view details about a product of their choice and see a picture of it on-screen. Supplier and manufacturer contact information is provided in the product details. The software can be instructed to generate a report of the user's findings for printing or inclusion in a word processing document.

PROGRESS—A working version of the software has been completed and is now being demonstrated in Australian capital cities. Evaluation copies of the software are soon to be distributed to disability professionals around Australia.

RESULTS—Initial feedback and responses to the software have been sought via a survey questionnaire completed by partieipants of the demonstrations in the eapital eities. Responses have been positive, with most people indieating their belief that the software will have wide signifieance to oeeupational therapists and professionals working with computer aceess teehnology.

FUTURE PLANS—The antieipated release date for Computer Aecess Seleetor version 1.0 is October 1995. The produet information eontained in software is expeeted to be updated annually.

RECENT PUBLICATIONS FROM THIS RESEARCH

Computer aceess seleetor: a tool to assist in the seleetion of computer aecess deviees. Stapleton D, Garrett R, Stewart H, Seeger B. In: Proceedings of the 2nd Australian Conferenee on Teehnology for People with Disabilities. Kilkenny, Australia: Regency Park Centre, 1995:128-30.

[136] 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, Washington, DC 20202*

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 physieal disabilities.

PROGRESS—To date, 100 persons aged 18 to 65, living independently in the community, who use at least 1 hour of personal assistance daily, have completed weekly checklists for 1 year recording any ehanges in their personal assistanee or health status, visits to hospitals, emergeney rooms, or physieians, and, when health ineidents occur, effeets on productivity and levels of distress. Special efforts were made to oversample persons from minority ethnic backgrounds. Subjeets were given a ehoiee of reporting by written checklist, telephone, or eomputer to aecommodate disability-related limits in eommunication method. All survey instruments have been developed and pilot tested on 10 subjects, and distributed to 100 subjects. Data analysis has been completed on the initial PAS and Health Study questionnaire, and hypothesis testing is ongoing.

METHODOLOGY—Survey packets were mailed to 120 subjeets with the objeetive of having at least 100 complete the study, allowing for attrition. Data eolleeted will be used to construct a profile on each participant and his/her health serviee use and health eonditions over a 12-month period. These profiles will be used to identify differences between partieipants divided into four categories based upon whether the disability was aequired in ehildhood or adulthood and whether personal assistanee services are provided exelusively by family members or by nonproviders alone or supplementing family assistanee.

In year 2, open-ended, qualitative interviews were conducted with 20 participants who represented two subsets of the original sample: 5 participants whose scores on the Personal Assistanee Satisfaetion Index (PASI) fall into the top quartile and 5 in the bottom quartile, and 5 partieipants whose total number of negative health incidents fall into the top and 5 in the bottom quartile. The sample for this segment of the study was strietly limited to 20 partieipants to allow in-depth exploration of PAS and health issues.

RESULTS—Disabling conditions requiring PAS included spinal cord injury, polio, museular dystrophy,

cerebral palsy, multiple sclerosis, traumatic brain injury, stroke, and amputation. Many subjects also had other pre-existing major medical conditions which could further decrease functional capacity, the most prevalent being hypertension, osteoporosis, kidney stones, major depression, degenerative joint disease, diabetes, restrictive lung disease, seizure disorder, rheumatoid arthritis, and heart disease. Mean age was 42 years, with 25 percent being at least 50. Personal care was provided by hired attendants only for 50 percent, family only for 17.1 percent, and a combination for 32.9 percent.

This sample tended to have many years of experience using personal assistance, with paid assistants used for a mean of 13.53 years and unpaid for 14.54 years, which could account for their relatively high level of satisfaction with their PAS. The only aspects of PAS that received low ratings were the amount of money available to pay for the hours of help needed and availability of people to be personal assistants. It's believed that satisfaction may be overrated due to the tendency for people with less stable assistance to be unavailable to participate in research studies and due to concerns about ending up with no assistance. Sixty percent had trained their attendants themselves, while 23 percent were trained by an agency, 11 percent by a rehabilitation hospital, and 6 percent by relatives. The majority of participants received training in managing attendants by a rehabilitation hospital (57.1 percent), followed by an independent living center (23.8 percent). The main source of payment for assistance was personal funds followed by a personal assistance agency, state grant, insurance company, and Department of Human Services. The main source for finding assistants was a private home health agency followed by friends. The majority of participants perceived themselves to have low susceptibility to getting sick. Health maintenance activities that had lowest compliance were eating three regular, balanced meals a day and exercising, even passively. The majority felt happy and content and believed that their lives have purpose.

[137] 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, Washington, DC 20202*

PURPOSE—The preponderance of available studies indicates 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.

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.

[138] 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 were 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 has been established, 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. 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 10 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 is 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 $p<0.00001$.

[139] 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. We have categorized AT use as depending upon characteristics within four major areas: 1) the particular technology (e.g., design, service delivery), 2) the person's abilities and personality (e.g., aptitudes, outlook, expectations), 3) the nature of the disability (e.g., type, severity), and 4) 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 nonuse (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. One side of the form consists of questions about the consumer on temperament and psychosocial resources, and inquires into individuals' subjective satisfaction with current functioning in many areas and where the person wants the most improvement to occur. The other side contains 10 questions about technology: their views of it and their expectations. Companion professional forms are similarly constructed and allow the assessment of shared perspectives between consumer and professional.

PROGRESS—A study was conducted with persons discharged from an inpatient rehabilitation unit between March and October, 1994. They were administered the ATD PA consumer form at time of discharge and at the 3-month follow-up. Their occupational and physical therapists completed the professional form of the ATD PA. Chi-square comparisons of consumer- and therapist-completed forms on walkers, wheelchairs, reachers, tub seats, etc. show: 1) patients view some ATs more positively than others, the least positive in this study being walkers; 2) patients and therapists have different views of the benefits of an AT; and 3) the adaptations required for use of an AT are not well recognized by patients.

Other research efforts used the ATD PA to study consumer perspectives of hand grasp systems. Results confirmed the importance of consumer perceptions and

personality on decisions regarding adoption of a hand grasp system.

Individuals precategorized into five groups according to level of hearing loss are being asked to complete the ATD PA. The outcome will profile individuals who choose to wear (or not wear) hearing aids and will give psychosocial markers associated with awareness of and adaptation to hearing loss.

Studies of the reliability (primarily inter-rater) are ongoing. Case examples of individuals being matched with an AT (consisting of narrative case histories, the consumers' responses on the ATD PA, 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 consistently show the instrument to be reliable.

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 matching of persons with technology and enhanced consumer AT use and training for use.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Psychological assessment in medical rehabilitation. Cushman LA, Scherer MJ, eds. Washington, DC: APA Books, 1995.

Technology and disability. Scherer MJ. In: Dell Orto A, Marinelli RP, eds. Encyclopedia of disability and rehabilitation. New York: Macmillan, 1995.

[140] DEVELOPMENT OF AN ADAPTIVE TOILETING SYSTEM FOR YOUNG CHILDREN

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Sponsor: *Ontario Rehabilitation Technology Consortium, funded by the Ontario Ministry of Health*

PURPOSE—An area of concern for parents, daycare providers, and school staff is toileting young children with physical disabilities. Unless appropriate postural support is provided on a secure base, this event can be frightening for the young child and disconcerting for the attendant. Many commercially available devices are inadequate because they are production units that do not offer postural support and are inherently unstable when mounted on a standard toilet seat. A few products do have features that can be adapted to seat the child with a physical disability. However, these devices are cumbersome to store, prohibitive in cost, and do not effectively position the child for this activity. This project is designed to identify and incorporate desirable features identified by consumers into a commercially viable product.

PROGRESS—A review of the commercially available options for children with special postural needs was initiated through the Department of Occupational Therapy at the University of Western Ontario in London. Of the 21 manufacturers and distributors identified as offering adaptive toilet seats, we found that there are only a few devices that offer any degree of postural support. While these models have their merits, they have common limitations. These devices are typically bulky, difficult to clean, not portable, and costly. In particular, existing commercial toilet seats lack the versatility to adapt to the postural needs of young children with physical disabilities. We conducted a preliminary investigation of 13 integrated daycare centers in the Metropolitan Toronto area. Results of this survey suggest that staff at these facilities generally do not understand the importance of properly positioning children who have problems using commercial toilets. However, those interviewed agreed that for a toileting program to be effective for a child, both the parents and daycare provider should be consistent in their ap-

proaches. To obtain the perspectives of consumers before proceeding with the development of the product, we organized two focus groups with consumers to understand the specific problems with existing products and techniques they use when managing young children in the bathroom. We also wanted to understand the relative importance of consumer needs for the new toileting system.

FUTURE PLANS—We will develop a functional model which shows the basic operation of the device. We will meet with consumers and clinicians to critique this model. Following this, we expect to have enough information to develop a functional prototype ready for field testing. Once the prototype is created, site trials will be organized. Following family trials, we will review the results and make recommendations to help our industry partner (yet to be determined) to develop preproduction prototypes and appropriate marketing strategies. We will participate in the commercialization process to ensure that important features identified by consumers are not compromised.

[141] LOW-COST UNIVERSAL TRANSFER DEVICE

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PURPOSE—The purpose of this engineering research program is to develop a universal transfer device (UTD) that can be used in health care facilities, nursing, and private homes. The device will provide mobility impaired persons with safer and more efficient transfers. The device is operated by an attendant to perform transfers between a bed, wheelchair, shower, toilet, floor, and an automobile.

It is a further purpose to develop a low-cost UTD that provides greater functionality than existing commercial products. Specific design objectives include seating comfort, safety, ease of operation, lightweight, maneuverability, compactness, easy storage, reliability, robustness, and appearance.

The UTD concept has been developed to eliminate the need to physically lift a person to effect a transfer, thereby minimizing risk of injury. Currently, no commercial product is able to perform the transfers listed above in both care facilities and the rigid confines of a private home. The UTD concept will have this capability. The UTD will be designed for low cost and additional savings might be achieved such as eliminating the need to modify a vehicle for transfers. Unique features such as these make the UTD a strong candidate for commercial development.

METHODOLOGY—Surveys conducted at health care facilities indicate a strong need for a device of this type to replace existing commercial products with less functionality. Existing devices were studied, and innovative ideas created to overcome their limitations. Moreover, spatial constraints in both commercial facilities and private homes were studied to determine the needed geometry of a UTD to be fully maneuverable and practical.

Two innovative UTD prototypes have been designed and fabricated. Both concepts employ the use of a thin, unobtrusive "transfer seat" compatible with all wheelchairs, car seats, toilets, and so forth. The transfer seat carrying the occupant is coupled with a mobile transfer unit and moved between transfer sites. Such transfers occur throughout the day with the occupant remaining in the seat. Thus, instead of lifting a person each time a transfer is needed—which requires a trained, strong attendant—the transfer seat is moved easily by any attendant.

Both prototypes will be evaluated to assess the success of meeting all design objectives and commercial potential.

PROGRESS—The UTD prototypes are in the process of being evaluated technically. Both prototypes appear to have the capability to perform the desired transfers; however, cost performance will govern the final design selection.

FUTURE PLANS—The UTD prototypes will be evaluated by the staff at the Rehabilitation Hospital of the Pacific. The findings of the evaluators will be used to make improvements to the designs, and the design attributes that show the greatest potential will be selected for commercial development.

IMPLICATIONS—No current commercial products satisfy all of the above-stated design objectives. It is expected that the UTD prototypes being designed and manufactured in this research program will help persons become less dependent on professional care givers and provide for a fuller, more productive life.

[142] 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 significant disabilities can be enhanced by appropriate applications of technology. 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; to demonstrate 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; to 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; to increase the community's capacity to respond to technology needs of individuals with severe disabilities through exposing to assistive technology students in engineering and related fields, community volunteers with technical expertise, and high school students with technical interests; and to develop a replicable 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 staff from several local supported employment and supported living agencies. The project has targeted transition-aged students (18 to 22 years) and young adults who, with suitable individualized assistive technology, can become more active participants in school, work, and community settings. Resources have been utilized to build up the technical capabilities of local schools and service agencies, expand the network of rehabilitation and assistive technology professionals, and reduce possible duplication.

One key component of the project has been the use of multidisciplinary Tech Teams, individually organized to the specific needs of the consumer. The Tech Teams have included 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 in designing and fabricating a customized assistive device, the seminar fosters diverse exchanges of ideas and viewpoints. 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 24 months include: 1) more efficient collaboration with the school district, supported employment, and supported living agencies through better utilization of each others' assistive technology resources and expertise; 2) expanding key intra-state and inter-state linkages; 3) designing, building, and delivering over 45 customized technical adaptations; 4) documenting individualized adaptations with photographs, videotape, technical drawings, and case study descriptions; 5) making over 48 presentations at the local, state, and national levels; 6) evaluating the completed projects in terms of the reasons for success or failure through periodic follow-up.

Examples of recently completed adaptations include: a residential automatic door that is remotely controlled by a person seated in a wheelchair; a customized work station (i.e., desktops, drawers, shelves, sliders, etc.) that increases the ability of a person with limited reach, stamina, and mobility to independently use a computer, print, edit videotapes, and make phone calls; modified trousers that permit independent toileting; a custom made jacket harness that allows a student to use his electronic communication device while moving across environments; a single switch operated staple remover and single switch operated automatic ticket hole puncher; a modified throttle control for a jet ski; a customized laptray to support a computer on a Permobile® chair; and a self-transportable wheelchair ladder to facilitate independent egress and ingress.

RECENT PUBLICATIONS FROM THIS RESEARCH

Consumer-driven tech teams: creating customized adaptations. Sax CL, Kozole K. In: Proceedings of the 9th Annual International Conference of Technology and Persons with Disabilities, 1994. 24-29.

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Change of life. Sax CL. TeamRehab Report 1995:6(5):16-20.

Jet skiing for fun and (non)-profit: adaptations for recreation and small business development. Sax CL. In: Proceedings of the RESNA International; 1995, Vancouver, BC. Washington, DC: RESNA Press. In press.

[143] 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 fundamentally is a transdisciplinary project that establishes 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 are being 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 is being developed.

METHODOLOGY—Because students entering this program 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, students seeking a "Certificate in Assistive Technology" 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 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 local agencies.

PROGRESS—During the initial 10 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 the project staff's lectures.

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: 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; a special merchandise security tag dispenser that permits single handed operation; a mounting system that can fit different wheelchairs of an individual without adjustments; an automatic electrically powered leg rest that elevates the left leg of a woman having limited strength and reach in her upper limbs; and a modified tricycle used by a 7 year old with cerebral palsy to move around the campus and playground with her classmates.

FUTURE PLANS—During the next 12 months, TRANS-TRAIN will submit a certificate program in Assistive Technology for review by the Department of Special Education and Rehabilitation, College of Education, and the University. TRANS-TRAIN will offer an advanced version of the transdisciplinary seminar in assistive technology, set-up initial internships at local agencies with appropriate experts, and offer a course in engineering on electronic devices for rehabilitation.

RECENT PUBLICATIONS FROM THIS RESEARCH

Consumer-driven tech teams: creating customized adaptations. Sax CL, Kozole K. In: Proceedings of the 9th Annual International Conference of Technology and Persons with Disabilities, 1994. 24-29.

Change of life. Sax CL. TeamRehab Report 1995:6(5):16-20.

Processing speed for electrotactile signals: evidence for tactonic storage. Szeto AYJ, Lin D. IEEE Trans Rehabil Eng. In press.

B. Robotics

[144] THREE-DIMENSIONAL POINTING SYSTEM FOR CONTROL OF A REHABILITATION ROBOT

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PURPOSE—Interfaces customarily used to control robotic arms, such as keypads and joysticks, are inaccessible to individuals with high level spinal cord injuries and other types of disabilities characterized by severe motor impairments. Alternative interfacing solutions using residual function of such individuals are needed. This project explores the use of a head pointing device as the means for controlling a robot arm. The

interface is based on an active computer vision system, whose role it is to process the information in the surrounding area and to interpret the pointing action. The action itself is performed with a head-mountable laser pointer.

PROGRESS—The prototype system will be realized in the Vision Laboratory, at the Department of Computer Science, University of Toronto. It will be comprised of an active stereo vision head, a monochrome digitizer, image processing software implemented on a workstation, and the robotic arm, controlled, via TCP/IP protocol link, by a DOS computer. An algorithm has been implemented as a feature extracting agent. The feature to be extracted from the image is the laser spot. Two pairs of images of the same scene are taken, without and with the spot marking the object of interest. Relevant pixel intensity changes between the two consecutive views of the same camera are searched for. If the search is successful, the position of the spot on the images is determined. Preliminary results show that the spot detection is significantly influenced by illumination of the scene, color and texture of the object, and its orientation with respect to the cameras' optical axes. Procedures for active camera control have been developed. The means for deducing the exact 3D spot location in the Cartesian world from its convergent binocular view are being examined.

FUTURE PLANS—The project is currently focused on the implementation of computer vision principles in the interface design. Upon the integration of all hardware and software parts, the interface reliability and technical performance will be assessed.

[145] MULTIMODAL CONTROL OF A REHABILITATION ROBOT

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PURPOSE—The rehabilitation robotics research literature describes many demonstrations of the use of robotic devices by individuals with disabilities. In general, the existing interface strategies have not met the desires of the disabled community. The conventional prototype interfaces have taken two approaches to achieving effective use by individuals with disabilities: many have commands which are issued by the user and activate the robot to perform pre-programmed tasks, while others have sought to give the user control of the manipulator's motions. In this project, a new hybrid interface strategy is designed, one that 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 strengths of 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 user's world 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 which are in the immediate environment, and an object-oriented knowledge base and planning system which superimposes information about common objects in the three-dimensional world. The effectiveness of this approach can be demonstrated in the following example: an individual with a disability uses an electric wheelchair and a portable robot arm. The user wishes to move the pen, which is on the desk,

to the box. The user (in this example using a head laser pointer), points to the pen and says, move. The user then points to the box, and says, there. The combination of the initial pointing accompanied by the command, move, tells the robot to pick up an object at a specific location. The combination of the subsequent pointing and the command, there, tells the robot where to move the object.

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, a 3D stereo vision system, a voice command system, a manipulator, and a 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 has been 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. Experimental trials in coordinating the vision system, voice command system, and robot manipulator through the command (voice) interface and the control interface (pointing) have been made in the past to test and evaluate the designed software and the communication links. The system shows a robust performance of locating the light spot directed by the user in the three dimensional robot space.

RECENT PUBLICATIONS FROM THIS RESEARCH

Multi-modal direction of a robot by individuals with a significant disability. Chen S, Foulds R, Kazi Z, Chester D. Proceedings of ICORR '94; Wilmington, DE, 1994:55-64.

[146] 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 develop a functional, stand-alone, educational robotic system for children with severe physical disabilities, 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 The 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 robotic manipulation abilities into a complete science laboratory environment. This setting will eventually enable young learners who have 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 by using simple object manipulation activities. The second phase of the curricular design involves the development of science education activities that follow 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 is 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, including the selected student in the ASEL pilot project. The students include both disabled and nondisabled students who will be working in research teams at the field site in the schools.

PROGRESS—For the second year of this project, the design team has concentrated its efforts on the development of the educational curriculum and strategies. 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. These activities are also designed to increase student's observational skills, which are a necessary prerequisite for their involvement in science education lessons which follow.

A set of studies has been performed at the RERC to examine subjects on their accuracy of scientific concepts of exploring, observing, thinking, finding out, and recording. These studies were achieved by using the senses of touch, hearing, sight, and smell via a robot to transfer the objects to and from the subject.

Students have also been introduced to the robotic setup by performing fun tasks such as painting and playing basketball to become familiar with the input devices and the robot itself. The George Reed Middle School, of New Castle, DE, has been identified as a school site to take part in the protocol.

RESULTS—Data gathering is ongoing and the preliminary tests show scientific aptitude. The team is ready to engage in complete prototype field testing including the revised hardware/software configuration, the science curriculum, and related strategies.

RECENT PUBLICATIONS FROM THIS RESEARCH

Design of an integrated interface to an educational robotic system. Beitler MT, Stanger CA, Howell RD. In: Proceedings of RESNA International'94; Nashville, TN. Washington, DC: RESNA Press, 1994:448-50.

Robotically-Aided Science Education for Children with Disabilities. Howell R, Stanger C, Chipman C. In: Proceedings of the Fourth International Conference on Rehabilitation Robotics, 1994:165-168.

Interface specification for children with severe physical disabilities using robotics or other assistive technology. Stanger CA, Howell RD. In: Langton A, ed. Proceedings of RESNA International'95; Vancouver, BC. Washington, DC: RESNA Press, 1995:202-4.

[147] 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 which allows 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: because it is in intimate contact with the user's mouth, which is rich in tactile and proprioceptive sensing ability, and because the mouth-stick itself is lightweight and very stiff, and therefore conveys 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 user head-neck mobility and strength limitations. 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 virtual head-stick to 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 six degree-of-freedom 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 six-degree of freedom contacting force sensible light industrial robot. The system is modeled using both analytical techniques 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. 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 trial version mechanical safety mechanism has been constructed which will prevent excessive feedback forces from being applied to the user. More complete safety break-away mechanical design is currently under investigation, starting with conducting a survey of safety devices that are widely used and available on the market. The system has been tested by nondisabled subjects in performing activities of daily living such as key inserting and light switch flipping. Initial results show that they have been able to successfully turn on a wall-mounted flip switch and complete a high tolerance key insertion. It was noticed that when one subject was tested with force feedback deactivated, it was impossible for him to complete the task relying solely on visual information. We anticipate more evaluations by consumers in terms of user acceptability of the system, quantitative psychophysical measurement (e.g., minimum detectable forces), and ergonomic and task effectiveness of the system.

RECENT PUBLICATIONS FROM THIS RESEARCH

Rehabilitation robot control with enhanced sensory feedback. Rahman T, Harwin W, Chen S, et al. In: Proceedings of ICORR '94, Wilmington, DE. 1994:43-8.

[148] REHABILITATION ROBOTICS INFORMATION PROGRAM

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PURPOSE—The information program in rehabilitation robotics will collect information, organize and/or synthesize it, and disseminate it to professionals, consumers and their families, manufacturers, and other researchers in rehabilitation robotics.

METHODOLOGY—This program will produce technical reports, book chapters, journal articles, and conference and symposium presentations that describe the research, development, and evaluation work underway within ASEL. The project will also produce a number of resource materials to be used by the constituents it serves, including 1) a videotape comparing features of robotic devices; 2) The Sourcebook on Control, Environmental Control, and Robotics to be included in the Assistive Technology Sourcebook series published by RESNA Press; 3) a chapter on rehabilitation robotics to be included in the Atlas of Prosthetics and orthotics published by the Academy of Orthopedic Surgeons; 4) a white paper on funding for robotic devices and services; 5) the quarterly Rehabilitation Robotics Newsletter; 6) a comprehensive bibliography of robotics-related publication to be transferred to existing databases such as NARIC/ABLEDATA, ERIC, and COMPENDEX; and 7) the annual list of commercially available rehabilitation robotics products. Annual workshops on current robotics topics will also be sponsored by this program.

PROGRESS—Robotics research staff have produced 15 publications that will be disseminated through the program. Inquiries for informational materials and technical assistance have been personally answered. The annual compilation of commercially-available robotics devices and their features has been disseminated. Surveys and questionnaires are being developed and distributed in preparation for writing the book for the Assistive Technology Resource Series and the Atlas of Prosthetics and Orthotics. The Rehabilitation Robotics Newsletter continues to be mailed quarterly. Cataloging and database creation of AAC literature and books continues in an effort to forward ASEL holdings to national databases.

[149] EYE POSITION INTERFACE FOR THE MANUS MANIPULATOR

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Sponsor: *Ontario Ministry of Health, the Natural Sciences and Engineering Research Council and the Hospital for Sick Children Foundation*

PURPOSE—This project investigates the feasibility of using eye position information to control the MANUS manipulator arm.

PROGRESS—An interface has been developed between the BioMuse, which uses electrooculography (EOG) to record eye position information, and the MANUS manipulator, a wheelchair-mounted robotic arm. The interface divides the user's field of view into zones which correspond to MANUS command. The zones function as virtual pointing device buttons, which the user presses by gazing at the zone. The computer

software maps eye positions (up, down, left, right) to the corresponding MANUS commands. A computer exercise is used to train users and to gather information about performance. Speed and error rates are analyzed. The interface will also be used to control the MANUS manipulator to perform tasks of various level of difficulty to evaluate the user's ability to relate the eye positions to MANUS commands. The interface will be compared to two other interfaces suitable for users with limited or no hand function: the Ninteno Hands-Free Controller, a chin-operated joystick, and the Spaceball, an isometric joystick.

RESULTS—Data collection is still in progress, but results to date indicate that the eyes can successfully be used to target the command zones in the field of view. Errors rates have been higher when targeting the vertical command zones. This may be attributable to the difficulties inherent in measuring vertical eye movements using EOG.

FUTURE PLANS—It is hoped that the data collected in this study will aid in the future refinement of an eye position robotic interface.

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[150] AN ALTERNATIVE JOYSTICK CONTROLLER FOR THE MANUS MANIPULATOR

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Sponsor: *Ontario Rehabilitation Technology Consortium*

PURPOSE—The purpose of this project is to proportionally control the MANUS robotic manipulator's position and orientation using the Spaceball controller. Spaceball is a six-degree-of-freedom isometric joystick. It has previously been used as a pointing device in CAD and other virtual environments for three-dimensional positioning and orientation. Joysticks are typically of the two-axis variety. When used to control devices with more than two degrees of freedom such as MANUS, mode switching becomes a necessity. As a robotic manipulator, MANUS is positioned and oriented using x, y, z, roll, pitch, and yaw. A two-axis joystick can only control two out of the six necessary parameters at any one time. In addition, the input-output mapping is such that the MANUS' z, roll, pitch, and yaw responses have to mapped onto either one of the joystick's x or y control directions. Therefore, using a two-axis joystick to control MANUS is both cumbersome and non-intuitive. The Spaceball controller senses forces and torques in three dimensions; as such, this allows a direct Spaceball {x, y, z, roll, pitch, yaw} to MANUS {x, y, z, roll, pitch, yaw} input-output mapping scheme. Thus, control of MANUS via Spaceball is rendered easily and intuitively.

PROGRESS—The first task involves configuring MANUS to accept the proposed control scheme. An analog signal is needed for each degree of freedom. ADAPTICOL is the MANUS Control software. This software allows MANUS to be controlled by six analog signals. The MANUS controller's interface card was also modified to allow MANUS to accept six analog inputs instead of the original two. Preliminary testing has allowed three-dimensional proportional control of MANUS with six simultaneous analog inputs. The second task involves designing and building the Spaceball interface. The interface converts the packets of data output by Spaceball into analog signals for

MANUS. The interface has been designed and is presently being built and debugged.

FUTURE PLANS—The third task is concerned with the issue of modular control. This involves the Multiple-Master Multiple Slave (M3S) protocol, a proposed rehabilitation communications standard; Spaceball and MANUS will be made M3S compatible. This will allow Spaceball to control any M3S effector and MANUS to be controlled by any M3S controller. Furthermore, a proposal to The National Strategy for the Integration of Persons with Disabilities, Industry Canada, has been submitted and approved. The proposal addresses integration within the wheelchair environment using M3S, and will serve to complement the work done in this project.

RECENT PUBLICATIONS FROM THIS RESEARCH

Development of an interface between the Spaceball GDOF isometric joystick and the MANUS rehabilitation robot. Wisaksana A, Verburg G, Naumann S. In: Proceedings of RESNA International '95; 1995, Vancouver, BC; Arlington, VA: RESNA Press, 1995:478-80.

[151] A "DOCKING" SYSTEM FOR A WHEELCHAIR-MOUNTED ROBOT MANIPULATOR

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Sponsor: *None listed*

PURPOSE—A current client of The Hugh MacMillan Rehabilitation Centre has been a partner in the testing of a wheelchair-mounted manipulator (RoboArm/MYQUAD) with an interface that gives him direct control of the arm. Using the manipulator, the client is able to perform ad hoc tasks such as feeding himself, retrieving printer or fax output, and performing other functions for which he previously relied on the assistance of an attendant. Unfortunately, the current controlling method was found to be very slow and cumbersome, even for the simplest of tasks. Ideally, the user would like to drive up to a workstation, request a predefined task, and have the manipulator automatically execute it. This way, the user is relieved of the burden of controlling the manipulator himself for regular tasks. The goal of this project is to develop a system that provides the means for a wheelchair to "dock" at a specific workstation so that the wheelchair-mounted manipulator has a known, fixed environment in which it can perform pre-defined or user-defined actions. Specifically, the system must determine the precise location, both coordinates and orientation, of the manipulator with respect to the known workstation.

PROGRESS—The first stage of the project involved researching the fields of Mobile Robots and Automatic Guided Vehicles (AGV's) to determine what approaches have been attempted to solve this problem. An evaluation of these approaches was made and a general approach was selected. Essentially, the method chosen is equivalent to the "3-Point Problem" of land surveying. Three or more distinguishable landmarks in the environment are used and are viewed from the robot to determine the robot's location and orientation uniquely. Due to a lack of time for complete prototype development, efforts were focused on determining the best algorithm for the mathematical solution. Based on results of literature evaluations, an algorithm was chosen (Geometric Circle Intersection), and software was developed for implementation. Currently, the algorithm is being tested for speed, accuracy, and sensitivity to errors.

FUTURE PLANS—Future plans involve development of a prototype including system hardware and software and appropriate interfaces. Several systems have been proposed as potential models. One such system uses a

rotating laser to illuminate reflective targets mounted in the workstation area. The light reflected by the target is detected by a photodiode and the angular position is measured. Another system uses a rotating optical receiving system to provide the angular measurements between the landmarks, which, in this case, are infrared diodes. The ultimate goal of this project is to provide an easier, more efficient way for disabled persons to perform regular tasks in their environment, thus further enhancing their independence.

C. Communication Methods and Systems

[152] AN INTERACTIVE VIDEO SYSTEM TO TEST AND TREAT NONLITERAL LANGAUGE DISORDERS

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PURPOSE—The goal was to develop a computer workstation for testing and training patients with selected communicative deficits. This workstation is innovative in two ways: it uses interactive video administered by computer, and it presents nonliteral, familiar expressions, which have a special theoretical status in communication disorders. Our goal is to test a large cohort of patients with left and right hemisphere damage, as well as nondisabled control subjects, using this workstation. Familiar nonliteral expressions (speech formulas, idioms, and proverbs) were selected because they are commonly used in daily conversation and they are often retained in aphasia. In addition, there is evidence that nonliteral familiar expressions are stored and processed differently from literal sentences; these expressions may be retained in aphasic speakers and disturbed in right hemisphere damage. Materials for evaluating and rehabilitating patients in these kinds of expressions are lacking or inadequate. Nonliteral expressions have complex meanings, requiring dynamic visual materials to depict their meanings; thus, nonliteral expressions are particularly suited for use with movie scenes presented in the interactive video format.

METHODOLOGY—The workstation consists of a test module and a training module. Stimuli for the test component are dynamic videotaped scenes depicting the meanings of 120 target expressions. The task of the subject is to determine whether the expression matches the scene in meaning. The 120 target expressions consist of 30 speech formulas, 30 idioms, 30 proverbs, and 30 matched literal expressions. An enacted scene depicting the meanings was captured on videotape for each expression. In addition, three wrong expressions (foils) are paired with each scene, resulting in 480 test presentations. The foils were chosen to investigate questions about nonliteral language structure and its processing by nondisabled and brain-damaged individuals. Patients respond nonverbally, by pointing to a touchscreen on a computer monitor, and scoring is objective and automatic. The training component offers 540 presentations of 90 expressions, each randomly presented with two correct scenes and one incorrect scene. In this case, the scenes presented in the interactive video format are taken from a commercial movie on laserdisc. Patients work at their own pace, matching the expression presented in written and spoken form to each 15-second scene.

PROGRESS—Two workstations are operational, and 10 stroke patients and 10 nondisabled control subjects were pilot-tested. Revisions in the design of the

workstation were made as a result of the pilot work. The training component of the nonliteral language workstation was expanded considerably. The format of the study has been changed to include testing throughout the training experience. Tests of social validity have been added by including functional communication questionnaires and a videotaped interview.

PRELIMINARY RESULTS—The revised workstation is fully operational and has been found to be practical and user-friendly for patients, including those with paralyzed limbs or other physical handicaps affecting hand-eye coordination. The workstation materials in both test and training modules are effective in obtaining data on patient and nondisabled performance and enjoyable for subjects to use.

FUTURE PLANS—Current plans are to evaluate 120 patients in a randomized treatment/nontreatment protocol, testing and training 60 persons with left hemisphere or right hemisphere damage, as well as 30 nondisabled control subjects. Sixty nontreatment patients will receive testing only. Results will provide information about processing of nonliteral language in the brain, the ability of interactive video materials to evaluate these communication disorders, the efficacy of training nonliteral language, and the effects of brain damage on abilities to comprehend idioms, proverbs, and speech formulas.

[153] THE DEVELOPMENT OF TALKSBAC, A COMPUTER-BASED COMMUNICATION SYSTEM

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PURPOSE—TalksBac (Talking and Language Knowledge System for Better Aphasic Communication) was a 2-year collaborative research project involving the University of Dundee and the Dundee Speech and Language Therapy Service. The projeet investigated the use of this computer-based communication system with four nonfluent Broca-type dysphasic adults and was staffed by two full-time researchers and a part-time speech and language therapist. The broad aims of the project were to develop the TalksBac system for dysphasic adults and to evaluate the system's effectiveness in facilitating communication between client and partners.

METHODOLOGY—The first phase focused on the development of the software, while the second investigated the implementation of this software with four dysphasic adults. TalksBac uses predictive retrieval techniques to anticipate sentences and narratives which the dysphasic client may wish to use in conversation. Written in C++, the program runs on a Macintosh PowerBook with an internal speech synthesizer.

The second phase involved four clients using the system for a period of 6 months. In order to measure the effeetiveness of TalksBac, two types of evaluations were conducted. The first focused on the clients' comprehension and communicative abilities before and after the introduction of TalksBac. This involved administering a battery of formal tests on each client at the beginning and end of the project. The second evaluation analyzed the difference between aided and unaided communication (with and without TalksBac) using conversational profiles and analyzing videotaped conversations.

PROGRESS—Conversational information, collected from clients with help from their caregivers at the beginning of the project, was used to create small individual TalksBac knowledge bases. The clients and their caregivers were introduced to the computer and

were supported in learning to use both the computer and the TalksBac program.

Group meetings were held where the clients and caregivers could meet each other, providing an opportunity for clients to use TalksBac in a supportive group setting. The researchers visited the clients regularly to develop individual systems, monitor progress, and provide encouragement. Feedback from clients and caregivers, along with observations by the researchers, contributed to an iterative software development cycle.

RESULTS—Results from tests related to comprehension abilities indicated that all clients' formal communicative and cognitive skills had remained stable over the intervention period. Conversations between each client and two conversational partners, one familiar and one unfamiliar, were videotaped. This was repeated using TalksBac with the same familiar partner and a different unfamiliar partner. Conversational analysis and a formal profile of functional communication showed a difference between conversations for two of the four clients.

TalksBac was found to be useful with clients who had conversational intent but who had not developed effective strategies to overcome their communication difficulties. Perseveration was found to have an adverse effect when using TalksBac in its present form as repeated trackball button presses results in unwanted selections being processed by the software.

The results and conclusions indicate that our nonfluent dysphasic clients benefited from a computer-based communication system developed specifically for this group and individually tailored to meet their communication needs.

FUTURE PLANS—We plan to work on improving the efficiency of the software. Techniques will be developed to facilitate the caregivers ability to generate conversational information for the system.

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[154] LANGUAGE FACILITATION THROUGH GRAPHICS AND GRAPHICAL ANIMATION

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PURPOSE—There are many products on the market intended to enhance the communicative effectiveness of individuals with severe communication limitations. Many of these use pictures as the means for transferring meaning, and we are beginning to see the emergence of animation capabilities in a subset of these products. Although it is hypothesized that animation will enhance the recognizability of picture-based language representations, particularly those for action words, we currently have no empirically derived information supporting this

contention. However, we can rely on what we know about language acquisition and language behavior to provide the alternative and augmentative communication field with a scaffold for exploration of the picture issue.

This project is investigating the representation of actions in two-dimensional forms. It is examining the relative efficacy of a number of approaches for representing movement, including static pictures, video, and animated pictures. The results will provide guidance to those selecting and customizing augmentative communication systems, as well as to manufacturers who are trying to make their products maximally responsive to the needs of people who rely on picture-based systems.

PROGRESS—Our investigators have developed a system capable of generating animations and incorporating them into an assessment protocol. The system supports the simultaneous presentation of a number of video clips, static graphics, or animated graphics. We will use it to evaluate the relative efficacy of various approaches to representing movement, including static pictures, video, and animated pictures. Subjects will be asked to select a target image corresponding to a spoken prompt. They will make their selection from four options, all equivalent in terms of the level of representation (static line drawing, animated line drawing, or video). For example, they might hear, "Show me throwing," and see video clips representing throwing, bouncing, catching, and kicking. The computer system incorporates a touch screen, requiring subjects simply to indicate their selecting by pointing on the screen.

Each subject will receive a number of trials with video stimuli, animated line drawing stimuli, and two different types of static line drawing stimuli. The computer will record all response data automatically. We will analyze the data to determine if responses differ as a function of subject characteristics or stimulus characteristics.

[155] DEVELOPMENT OF AAC SYSTEMS BASED ON PERSONAL COMPUTERS

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PURPOSE—This project focuses on the development of new augmentative communication systems based on personal and portable computers. In addition, results from other REC research efforts are incorporated into systems through this project. Finally, this project serves to develop systems for experimental evaluation of research techniques.

METHODOLOGY—The primary goal is to research and develop techniques to increase an individual's communication rate. This project focuses on enhancing a user's input process, particularly multimodal input, and increasing a user's vocabulary selection rate through a variety of prediction strategies and abbreviation expansion techniques.

PROGRESS—Development of a software-based communication system named Meta4 has been completed and the pakage has been successfully transfered to a manufacturer for commercialization. The Meta4 package consists of a main program, which turns any PC into a dedicated augmentative communication device, and three supporting utilities that make Meta4 easier to set up and maintain. Progress in the last year has centered around the completion of all parts of the package in preparation for transfer. Meta4 is designed for users with severe speech impairments in addition to physical disabilities. It is also designed for the user with visual and/or perceptual difficulties. With this in mind, much of the emphasis in developing the system has been on flexibility of system configurations and screen

displays. This flexibility allows Meta4 to be set up, or eonfigured, for eaeh individual and ehanged to follow that individual's needs.

Work eontinues on another prototype eommunication system called Grapheom. Grapheom uses gray-scale images to display the eontents of a voeabulary set. Images are eaptured by a small, inexpensive camera and put into the voeabulary set in a designated loeation. New images ean be imported at any time. The vocabulary set is eomprised of pages of images arranged in rows and eolumns. A VGA monitor displays one page of the vocabulary set at a time, and the user construets a message by seleeting one or more images from the set. This system is designed for individuals who have diffieulty dealing with abstraet symbol sets but work well with more life-like images. At this point, the system has been developed as a demonstration program; therefore, the only input method is by mouse and only minimal eontrol over the arrangement of thc voeabulary set is possible. Version 1.5 of Graphcom has been completed and an advaneed prototype named ZapCom is underway.

ZapCom will be a Windows applieation running on a laptop eomputer. ZapCom will integrate both vidco eapture and voice recording eapabilities. It will also provide more enhaneed input and output control, ineluding support for a printer and speech synthesizer. Another feature of ZapCom will be the ability to support more pietures. Grapheom eurrently supports a fixed number of pictures that can be loaded into memory during system initialization. ZapCom will allow pictures to be loaded dynamically.

FUTURE PLANS—Once development of ZapCom is eomplete, it will be transfered to the evaluation projeet for user testing. This projeet may investigate eommunication applications for hand held, pen-baseel computers and tcleeommunication applieations.

[156] EVALUATION OF HUMAN-SYSTEMS INTERACTION IN AAC

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PURPOSE—The challenge in technology development is the creation of innovative teehniques that both maximize function and minimize the demands on the user. Realizing that eaeh user of augmentative and alternative eommunieation brings a different set of skills to thc eommunieative process, we must be careful about relying on unsubstantiated assumptions about the effeetiveness of teehnology. Instead, we must begin to understand the efficacy of teehniques in terms of thc eontext in whieh the technology will be used and in terms of the eapabilities that the user brings to thc proeess. The goal of the Evaluation Project is to conduct in-depth evaluations of the relationship between teehnologieal eapability and funetional use by individuals using AAC deviees. The topic that is eurrently being addressed is that of aeeeleration techniques, employed to improve the effieieney of communieation. Efficieney in this sense refers not only to rate but also to the easc with which messages are generated.

METHODOLOGY—We know that eurrent aeeeleration teehniques ean be effeetive but do exact a eost from the user in regard to allocation of eognitive resources. Building on teehnologieal developments to date, two novel aeeeleration teehniques that eombine thc best of what exists with teehniques designed to minimize known drawbacks have been developed. The first, a scanning Letter Predietion system, was ereatcd as an alternative to existing word predietion systems that require the user to monitor both the selection area and the predietion menu. The second, a Flexiblc Abbreviation Expansion (FAE) system, was designed to reduee the profound memory load placed on users as a result of having to remember eodes for each available expansion.

To determine the efficacy of these new approaches, the Evaluation Project will subject the systems to rigorous evaluation with both typical communicators and those with significant communication limitations. Subjects will be asked to generate standard texts with and without the use of an acceleration technique. As part of the objectives, the effects of familiarity of the material and communicative context on generation will be investigated. It is expected that the results from the clinical evaluations will identify keystroke savings, the influence of various contextual factors, and the comparative performance of individuals with and without severe communication limitations. It is also expected that results from these studies will indicate whether the acceleration technique offers more efficient text generation capability than the systems being used by daily users of AAC devices. The results from the clinical testing will be analyzed and recorded and shared with the community of AAC professionals.

PROGRESS—The Evaluation Project subjected the Letter Prediction system to rigorous evaluation with two individuals with significant communication limitations. Both subjects were asked to generate standard texts via scanning with and without the use of letter prediction. The results from the clinical evaluations indicated that both subjects required fewer switch presses using letter prediction software. The results further showed that the letter prediction software did not increase the communication rate of either user. The results of this study will be assembled into a case study report and distributed within the AAC community. There has also been evidence to support alternative applications for using the technique, including the possibility of using letter prediction as a writing tool or a spelling tutor. FAE, although is early in its evaluation phase, has been evaluated on a case study basis by an augmentative communication device user. Preliminary results show that combining FAE with current communication strategies used by this individual can enhance overall communication rate. This case study has also provided us with valuable feedback regarding the functionality of the program. This feedback can be used to make FAE a more robust communication tool for individuals with significant communication limitations.

FUTURE PLANS—Following analysis of data collected from this case study, we will evaluate FAE relative to other word prediction techniques as well as to other abbreviation techniques. Clinical testing will be performed using both typical communicators and those with significant communication limitations. Similar to the evaluations performed using letter prediction, the FAE evaluations will compare results between generating text with and without the FAE implemented as well as results implementing FAE with and without generated prediction lists. Technology transfer will also become a priority for the Letter Prediction System as well as the Flexible Abbreviation Expansion Technique program in the upcoming year.

In addition to the two acceleration techniques described above, the Evaluation Project is also testing two alternative input technologies to improve the access capabilities of people with disabilities. The first device is the Headmaster Plus, a head mounted mouse emulator. The HeadMaster is used with an on-screen keyboard software to enter text. People using the Headmaster Plus use a puff switch to access mouse button functions. The second device is DragonDicate for Windows. DragonDicate is a discrete speech recognition application used for entering text and controlling the mouse cursor. The first stage of this study will determine empirically the quantitative and qualitative advantages of each input technology and then assess whether a combination of the two technologies produces a speed advantage and/or a user preference over the original input system.

[157] HUMAN FACTORS STUDIES IN EYE MOVEMENTS RELATED TO AAC HEAD MOUNTED UNIT

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PURPOSE—In order to overcome the many human factors obstacles in using eye movements to control AAC devices, a head mounted unit is being developed that will compensate for many of the complications affecting the ultimate utility of an eye tracking AAC system. A small, commercially available head mounted display provides a convenient way to offer a computer display to an individual with disability. The unit is worn on a head band and presents the image of the computer screen in the field of view of the wearer. This form of "heads up" display presents information that is independent of head movement.

The primary goal of this project is to retrofit the unit with additional optics and optical sensors so that it becomes a small camera as well as being a display. The same software used to calculate the line of gaze in other eye tracking projects can be used to determine the line of gaze with respect to the display. This system is potentially a portable eye gaze communication system that allows face-to-face communication.

FUTURE PLANS—A prototype of the system will be constructed beginning in late-1994 and evaluated for its ability to accurately detect the gaze. Clinical studies using the entire system as a communication device will follow.

[158] HUMAN FACTORS STUDIES IN EYE MOVEMENTS RELATED TO AAC HEAD MOVEMENT STUDIES

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PURPOSE—The use of eye movements as a method of interaction in augmentative communication has been explored for many years with limited success. Significant data exists on the ability of individuals with severe disabilities to coordinate their oculo-motor function with sufficient accuracy to use the line of gaze as an indicator of selection of a target. Instrumentation has been constructed using a camera to detect reflections of infrared light from the surfaces of the eye. This information allows the calculation of the line-of-gaze. Such a system can be used as a line of gaze typewriter or communication device.

The difficulties in the use of these instruments have been the human factors considerations associated with severe disability. Head movement is often unstable in individuals with disabilities. This project includes the development of an instrument which incorporates a pair of motorized mirrors that are servo-controlled and can follow the movement of the head in order to maintain a camera view of the eye.

METHODOLOGY—The major portions of this project involve the calibration and programming of the two servo- controlled mirrors connected to a 386-PC. Once software libraries have been written to control the mirrors, these libraries can be integrated with other eye-tracking software routines to control the mirrors to compensate for head movement during the line-of-gaze calculations.

PROGRESS—The servo-controlled motorized mirrors have been successfully programmed to follow the movements of the head and makes the system considerably more appropriate for individuals with cerebral palsy and other disabling conditions.

FUTURE PLANS—Work is now underway to develop improved calibration techniques that will accommodate the movement of the head and allow for accurate calculation of the line of gaze.

[159] THE APPLICATION OF NATURAL LANGUAGE PROCESSING TO AAC

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PURPOSE—The goal of this project is to investigate the application of natural language processing (NLP), a branch of artificial intelligence, to the development of more effective augmentative communication systems. This work is based on the underlying concepts and model of communicative competence that describes augmentative communication system use on linguistic, operational, strategic, and social levels. NLP provides the computational techniques necessary to give communication systems the capability to reason about lexical, syntactic, semantic, and pragmatic knowledge.

METHODOLOGY—The project is conducting studies of language use in augmentative communication systems using conversational analysis techniques. The data are contributing to the development of a conceptual model describing how the processing components of an intelligent system can best work together. It builds upon our previous research on applications of syntax and semantics by considering the incorporation pragmatic knowledge and the development of user models that will facilitate system learning. The model is being tested in the implementation of several prototype intelligent systems. This project also focuses on the transfer of previous research results into the commercial marketplace via collaboration with corporate partners.

PROGRESS—We have been conducting studies involving the transcription of videotaped conversations between augmentative communication users and their conversational partners. Analysis has revealed a number of interesting interactional patterns that occurred as sentences were cooperatively constructed. This sentence co-construction involved word finding (strategies used when a vocabulary item is unknown or unavailable), conversational repair (feedback, inferencing, correction), and confirmation. Supportive verbal feedback from the listener varied in its level of incremental repetition and interpretation.

In addition, linguistic observations of the interpretations of the augmentative communication user's selections have provided evidence the validity of the Compansion technique (which interprets telegraphic input) and have suggested areas of improvement as well. These enhancements are being implemented in an expanded Compansion-based prototype that relies on an

individual user model for better interpretation of a user's input. Technology transfer of a simpler Companion prototype has also been a priority.

Additional work focuses on integrating pragmatic knowledge into a system based on conversational schemata. This powerful tool captures common language experiences and situations that can be accessed quickly to communicate effectively. Also, we are developing an extensive object-oriented language database that will provide the detailed information necessary for each natural language processing technique. Evaluation of all of these project tasks is, of course, an ongoing effort.

RESULTS—The anticipated results include: 1) a better understanding of the language and interaction capabilities that should be incorporated into future intelligent communication aids; 2) unique contributions to our understanding of how artificial intelligence can be applied to AAC technology development; 3) the development of new research prototypes that demonstrate the use of NLP and surpass existing efforts in terms of their ability to adapt to the user's language capabilities; and 4) the commercialization of the Companion and flexible abbreviation expansion techniques that have been previously developed.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[160] SPATIALIZATION AND SPATIAL METAPHOR IN AAC

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PURPOSE—In this project, we are interested in exploring new methods for the organization and access of language, based on principles of spatialization and spatial metaphor that have emerged from the field of human-computer interaction. The predominant approaches to language organization that currently exist (e.g., levels) are largely based in the physical constraints of current AAC hardware such as screen size. Language is often organized to "fit" into the display or keyboard of the device. As a consequence, many users who have manual communication boards with hundreds of words are forced into the use of spelling, multiple levels, coding, and/or predictive systems. As an alternative approach, we would like to consider technology that supports expanded information spaces as a means to provide more natural communication for individuals with severe communication impairments. The primary objectives of this project are to: 1) investigate the comparative usage of large manual word boards versus electronic systems by the same user; 2) develop a theoretical framework for describing new spatial metaphors in AAC; and 3) develop and evaluate prototypes of new systems that offer large language spaces that can be accessed in a multimodal fashion. We will utilize the technology available from the emerging field of virtual reality (VR) to create systems consisting of head-

mounted displays that provide the user with a view of the information space, a tracking system that will adjust the view based on head position, and a selection interface based on hand and/or eye pointing. In addition, the VR approach will be balanced with the design of systems that use conventional computer screens. The anticipated outcomes of this project are the contribution of a novel model of language organization and the demonstration, evaluation, and commercialization of systems that exploit this model.

PROGRESS—An application of the virtual word concept is under development. VAL (Virtual Access to the Lexicon), is intended to support spatial equivalence between manual and electronic systems. It also supports evolutionary changes in the word board structure by allowing the user to access a large lexical database that stores words and their relationships to other words. A second prototype called VISOR (Visual Information Seeking of Reusable-Conversation) has also been developed. It provides a virtual environment for the storage and retrieval of narratives that are spatially indexed.

[161] SPEECH SYNTHESIS PROGRAM

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PURPOSE—The purpose of this program is to develop the software for the production of high quality, highly intelligible synthesized speech with an unlimited vocabulary. Areas of research in the program include the creation of a rule system for converting text into synthesized speech, the development of a method for changing the pitch and the duration of utterances, the development of a graphical user interface for the text-to-speech system, and the development of an automatic diphone extractor that allows for the customization of voices for each individual.

METHODOLOGY—The work in this program is based on diphone speech synthesis. Diphones are speech segments that run from the steady state of one phoneme through the transition between phonemes to the steady state of another phoneme. Diphones are obtained by recording someone saying words with the desired transitions in them, and then extracting the transitions from the recorded words and storing them. Diphones can be appended together to create any word or phrase. Thus, a limited number diphones can be used to create a natural sounding voice with an unlimited vocabulary.

PROGRESS—Methods for creating diphone libraries have previously been developed and refined. This process has resulted in two synthesized voices: a male and a child's voice. More recently, the focus of the program has been on improving the quality of the system that converts text to synthesized speech. This system converts written text into a phonemic representation of the text. It also syllabifies and determines the stress patterns of the text. Using these stress patterns, along with syntactic information and punctuation, duration patterns and pitch patterns are determined. These patterns can then be implemented using a method developed in this program.

In order to facilitate the use of the text-to-speech system, a graphical user interface was developed for the system. The interface was developed for Windows 3.1. This greatly enhanced the program's ability to transfer technology. This program has also developed a method for automatically extracting diphones from recorded speech. The automatic extractor takes a set of recorded words and automatically determines the best instance of each diphone in those carrier words and then extracts and stores the diphone. The automatic extractor greatly reduces the amount of time and manpower needed to create a new set of diphones and thus a new synthesized voice.

RESULTS—The text-to-speech system is nearing completion. The rules for converting text to its corresponding phonemic representation, along with syllabification and stress patterns, have been completed. The rules for duration and pitch patterns, along with the rules for generating syntactic information, have been implemented and are currently being evaluated. The graphical user interface has been implemented at a beta level, but still needs to be refined. The automatic extractor was used on the same carrier words used in the manual development of the synthesized male voice, and the results were encouraging. In formal tests comparing the results of the automatic extractor and the manually extracted diphones, speech synthesized from automatically extracted diphones was consistently close in intelligibility and consistently rated as more natural sounding than the speech synthesized from the manually extracted diphones.

FUTURE PLANS—Future plans include thorough testing and refining of the text-to-speech system, incorporating the method for changing pitch and duration into the text-to-speech system, thoroughly testing and refining the graphical user interface, testing and improving the efficiency of the automatic diphone extractor, and determining methods for conveying emotions in the synthesized speech.

[162] AUGMENTATIVE AND ALTERNATIVE COMMUNICATION TECHNICAL ASSISTANCE AND OUTREACH PROGRAM

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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 augmentative communication. 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 augmentative and alternative communication.

PROGRESS—The researchers in augmentative communication 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 information 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 scheduled for completion by fall 1995. Fifteen of the augmentative communication research staff traveled throughout Pennsylvania and Ohio visiting several AAC device manufacturers to discuss practical issues of device 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, October 1996 in Philadelphia. Plans for this major scientific conference are well underway.

[163] RESEARCH IN INTERFACE METHODOLOGIES FOR AAC

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PURPOSE—To explore innovative methods for human interaction with 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 is taken from the gloves, and sensors are 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 factors parameters related to eye gaze. Latter 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.

[164] REHABILITATION ENGINEERING RESEARCH CENTER ON UNIVERSAL TELECOMMUNICATIONS ACCESS

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Sponsor: *National Institute on Disability and Rehabilitation Research, U.S. Department of Education*

PURPOSE—Over a 4-year period, this new Rehabilitation Engineering Research Center will conduct research and engineering activities with the overall goal of improving the accessibility of emerging telecommunication systems and products. The RERC will analyze major telecommunications trends and predict opportuni-

ties and barriers for people with disabilities, collect or develop accessible/universal design principles, document them in design guidelines, and, where necessary, conduct research to identify principles where these are unknown. It will work within the culture of the industry to improve accessibility of products and educate consumers so that they can locate and identify the most accessible telecommunications products and services, understand how to best access and use telecommunications technologies, and contribute more effectively to the design of future telecommunications technologies.

METHODOLOGY—The program areas of the RERC are: systems engineering analyses; telecommunications access research (focusing on needs assessment and development of design solutions); universal design specification and review (aimed at developers of products and services); development of telecommunications standards that include accessible features; telecommunications applications for increased independence; and knowledge utilization and dissemination.

PROGRESS—The RERC is scheduled to begin operations in the fall of 1995.

[165] USER PERFORMANCE WITH COMPUTER ACCESS AND ALTERNATIVE COMMUNICATION SYSTEMS: MEASUREMENTS AND MODELS

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PURPOSE—This project explores the application of engineering modeling techniques to improve understanding of the user interface of augmentative communication (AAC) systems. There are two prongs to this work. The first is empirical, involving the observation of behavior and measurement of performance during use of AAC systems. The second is analytical, involving the development of quantitative models that accurately represent these observations. The goal of the modeling process is to provide developers and clinicians with a framework that can improve the design and delivery of AAC systems. If we are successful, the models will be capable of quantitatively predicting user performance with these systems and simulating the effects of varying user and system characteristics. The modeling process also offers a valuable qualitative analysis, since it provides the opportunity to analyze the interaction between the user and an AAC system under a wide range of conditions.

PROGRESS—Modeling techniques used in the field of human-computer interaction continue to be the foundation of the models developed in this project. Models have been developed to estimate quantitative performance measures (e.g., text generation rate) for direct selection interfaces with and without word prediction. Empirical studies have been performed in order to validate the models and gain more understanding about user performance with AAC systems. These include traditional group studies in an experimental setting as well as studies employing single case design to evaluate specific clinical interventions.

RESULTS—*Group Study 1.* Fourteen subjects transcribed text with and without a word prediction feature for seven test sessions. Eight subjects were nondisabled and used mouthstick typing, while six subjects had high-level spinal cord injuries (SCI) and used their usual method of keyboard access. Subjects were specifically taught to use one of two search strategies with word prediction. Use of word prediction significantly decreased text generation rate for the SCI subjects and only modestly enhanced it for the controls. Performance was analyzed in more detail by deriving subjects' times for keypress and list search actions during word prediction use. All subjects had slower keypress times during word prediction use as compared to letters-only typing, and SCI subjects had much slower list search

times than controls. These results demonstrate that there can be a substantial time cost associated with the cognitive processes during use of a word prediction system.

Three model implementations were developed and validated against the empirical data. Models 1A and 1B shared a structure which represented performance as a combination of two user parameters, keypress and list search time, while Model 2 used a revised model for list search time. For Model 1A, user parameter values were determined independently, while Models 1B and 2 used parameter values derived from subjects' data. The average errors for Models 1A, 1B, and 2 in simulating subjects' word entry times were 27, 16, and 14 percent, respectively.

Group Study 2. Four additional nondisabled subjects followed the same protocol used for Group Study 1, except that they were given no rules about when to search the word list, beyond the guideline of "when they thought it would be helpful." Preliminary results suggest that relative to the subjects in *Group Study 1,* there was more variation in these subjects' performance, but overall, the freedom to use their own strategy did not significantly enhance performance with word prediction or reduce cognitive load. These data will be further analyzed to determine what sort of search rules, if any, subjects employed under these conditions.

FUTURE PLANS—Ultimately we hope to determine guidelines for the efficacy of word prediction, as well as validate general modeling techniques that support the development of guidelines for other AAC systems. An additional goal is to integrate human performance research with clinical practice through the use of single case designs.

RECENT PUBLICATIONS FROM THIS RESEARCH

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User performance with augmentative communication systems: measurements and models (dissertation). Koester HH. Ann Arbor, MI: Graduate Bioengineering Program, University of Michigan, 1994.

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[166] ENGAGING, RECRUITING, AND RETAINING STUDENTS WITH DISABILITIES IN SCIENCE, ENGINEERING, AND MATH

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PURPOSE—Individuals with disabilities are currently under-represented in science, engineering, and math (SEM) academic programs and professions. While this under-representation is due to many factors, several impediments are clear: attitudinal, physical, and curriculum 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 curriculum 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, who 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.

PROGRESS—Several existing SEM programs that are collaborating on this project have been identified and students with disabilities have been enrolled in these programs. This summer, several deaf students were enrolled in the Delaware AeroSpace Academy, and additional students are being sought for enrollment in other collaborating programs. The summer programs focus on actively engaging middle school students. The SEM program involves high school students in an Internet mentoring program. This program has four current student participants and this number is expected to increase significantly in the fall. To address the problems effecting teachers, counselors, and families, the project sponsors a workshop and video conference series focussing on assistive technology, education, and college transition. These programs focus on physical and learning disabilities. The virtual laboratory is being constructed and research into alternative interfaces, such as audio and tactile, for the use in science experiments is being conducted. Interested parties are encouraged to send email to sem-info@asel.udel.edu or examine the project World Wide Web page (http://www.asel.udel.edu/sem/) for more information.

[167] EEG INTERFACE PROGRAM

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PURPOSE—The object of this project is to explore the potential use of the P300 event related potential as a control signal in a computer interface for locked-in patients. There exists a significant population who, due to disease or injury, are totally paralyzed but have normal or near-normal brain function. In such cases, called Locked-in-Syndrome, the individual is aware of his or her surroundings, but has no way of communicating with the outside world. In cases where the person has even a slight degree of voluntary movement (e.g., eyebrow motion), it is possible to use that movement as a switch for controlling a computer. Likewise, when the person has good eye control, he or she can be fitted with an eye-tracking device to control cursor movement on a computer screen. In many cases, however, the individual may have no reliable voluntary motion to which a switch may be attached, and eye-movement may not be precise enough to use with an eye-tracking device. In such cases, the only possible method of communication would be to use electrical signals produced by the brain itself as a switching device for computer interaction. In order to achieve this, a reliable, detectable brain signal must be found.

Because of its robustness, we believe that an evoked electrical potential, called P300, may serve as a good candidate for an EEG-based computer interface. The P300 is a late positive wave that occurs between 250 and 800 milliseconds after the onset of a meaningful stimulus. In this project, we will explore the possibility of using P300s to control cursor movement

on a computer screen by presenting simultaneous visual target-detection tasks and measuring peak P300 amplitudes to targets occurring at each of four compass locations (N, E, S, W). Peak amplitudes are expected to be greatest for P300s in response to the direction to which the subject is attending.

METHODOLOGY—Subjects will be seated in a sound-attenuated chamber facing a monochrome monitor 18 inches away. The central fixation point on the screen will be a cross. There will be four target arms (compass positions N, E, S, W) with a target (a cross) at the end of each arm and one centimeter away from the central fixation point. Each stimulus will be presented for 250 msec with an interstimulus interval of either 750 or 1,000 msec. There are two different stimulus sets: in the first, each of the four target crosses will be replaced by an asterisk one at a time and in random order; in the second, a null-stimulus will be included, in which no asterisk appears. The subject will be instructed to fixate the central point and count the number of times one particular cross (N, E, S, or W) is replaced by an asterisk. The order of asterisk substitution will be random without replacement within each set of four (asterisk always appearing) or five (null included) stimuli. The target stimulus will occur with a probability of 0.25 in the first case, and 0.2 in the second. When a blink is detected (any signal beyond a preset threshold on the EOG channel), that stimulus trial will be discarded, and presented again later in the set. No set will be complete until at least one good (non-blink) trial is recorded for each target position. Thus, each set will consist of at least four or five trials (more if the subject blinks). Sessions will consist of 50 complete sets.

Data Acquisition: Grass silver-silver chloride electrodes will be placed according to the international 10-20 system at Fz, Cz, and Pz and referenced to bilateral (joined) earlobe electrodes. The EOG will be recorded from an electrode as SO2 (inferior and lateral to the right eye) also referenced to bilateral earlobes. The three EEG channels and single EOG channel will be amplified 50,000 times, bandpass filtered between 0.15 Hz and 150 Hz, and digitized (12-bit resolution) at a 300 Hz sampling rate on a 486 computer with an 8-channel DSP card. Data recording for each trial will begin 50 msec before presentation of the target stimulus and continue for a total of 650 msec. Thus, 600 msec of EEG data will be recorded for each channel following target onset. These data will be saved for subsequent analysis.

Data Analysis: Off-line analysis of collected data will model a real-time process in which the computer estimates the direction the subject wishes to move the cursor, moves the cursor one step in the estimated direction, obtains another estimate of the desired direction, and so forth. It is in the nature of the task that each estimate must be independent of the last estimate since the subject must be free to change cursor direction at will. The estimated direction will be based on comparing P300 levels for targets on each arm of the cursor and selecting the largest P300 level as the most likely direction for cursor motion. This comparison can be made as soon as a single set (i.e., four target positions) has been obtained, or EEG activity for each target location can be summed over a series of sets to obtain a more stable P300 estimate.

RESULTS—Preliminary results showed that, overall, cursor movement based on P300 detection was correct about 50 percent of the time based on comparisons among peak levels within a single set of trials (chance is 25 percent). Overall average performance for our slowest subject was 0.13 bits per second (44.27 percent correct) and our fastest subject was 0.18 bits per second (51.92 percent correct). However, considering only the task in which target frequency was 0.2 for these two subjects, bit rates were 0.15 and 0.27 respectively. Accuracy increased when successive sets of trials were summed before comparing P300 levels, but this gain in accuracy was accompanied by an increase in the amount of time to make a decision. In no data examined to date have we observed an instance in which the trade-off between accuracy of P300 detection and time would result in advantages for summing trials; the cost in time far exceeds the benefits of accuracy in this task.

FUTURE PLANS—Averaging over trials in the present task does not appear to be a productive way to improve bit rate. However, varying other task variables like target frequency and presentation rate may lead to moderate improvements in the accuracy with which P300 events are detected. In future studies we will continue to explore these and other task variables to find conditions which lead to optimum performance. As a signal for control of communication devices and interfaces, the P300 has several limitations. The most serious of these is the relatively low bit rate associated with its use. However, for some potential users, this low bit rate may still exceed the rates available via other

communication channels, and at present, communication rates associated with P300 detection seem equivalent to those associated with the detection of other brain events or states.

[168] INFRASTRUCTURE AND USER SUPPORT FOR COMPUTER-MEDIATED COMMUNICATION (CMC)

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PURPOSE—The potential for computer-mediated communication (CMC) to enhance the effective participation by people with physical and sensory disabilities in the research and development of assistive technologies is enormous. Our research team, called the Psychosocial Evaluation Team (PSET) has arranged for virtually unlimited access to CMC for members of the Ontario Rehabilitation Technology Consortium (ORTC) at a comparatively inexpensive annual fee. Also, we have developed user-friendly orientation and resource publications for CMC users. PSET is coordinating efforts to bring ORTC researchers and consumers on-line, according to a plan and schedule. A key component of the plan is a pilot study with the Vision Team and its Consumer Advisory Panel to conduct an in-depth evaluation of the usefulness of CMC in enhancing consumer contributions to the productivity of an ORTC research team.

By 1996, we will have completed the process of getting the relevant participants equipped and oriented to CMC, and have completed a negotiation of the goals, objectives, and terms of reference for evaluation with the Vision Team and Panel. In the meantime, other teams, such as the Mobility Team, are coming on-line. While some components of the evaluation framework proposed for the Vision Team will generalize across research teams, others may not. Consequently, we have been trying to identify desired outcomes and deliverables for CMC for each team individually as it comes on-line.

PROGRESS—The ORTC Secretariat is being equipped and trained in how to use CMC to transmit more of the Consortium's business electronically, rather than on paper. We expect by the end of next year to have data on how consumer-friendly and cost-effective it will be for the Consortium's administrative operations.

FUTURE PLANS—By spring 1996, we expect to have achieved the following milestones: 1) all ORTC research team and advisory panel members will be equipped and oriented for active exchange of ideas, information, and contributions via the ORTC's CMC system, and 2) completion of the evaluation study of CMC impact on productivity of the Vision Team, including publication and review of results.

[169] DATABASE OF COMMUNICATION AID USERS AND FACILITATORS WILLING TO PARTICIPATE IN PRODUCT RESEARCH AND DEVELOPMENT

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Sponsor: *Ontario Rehabilitation Technology Consortium, funded by the Ontario Ministry of Health*

PURPOSE—This project arose from the Consortium's Communication Team's need for an easier way to involve consumers in its research and development efforts. The team has difficulty involving sufficient numbers of consumers because of the efforts required to identify and recruit individuals from among people who are not all members of consumer organizations. The project has begun as a pilot effort to establish a database containing information about adults with cerebral palsy, who do not speak, or are unable to speak successfully, in at least some situations important to them. If successful, the database should help researchers interested in improving the communication devices of nonspeaking individuals to call upon those individuals to: help determine what research and development needs to be done; participate in the design and administration of projects; and/or cooperate in interpreting the data gathered during projects. We expect that the results of this project will provide a useful model for the ORTC in general.

PROGRESS—We first designed a preliminary draft of a questionnaire to be used in gathering information for the database. Next, a research assistant was hired and trained. The research assistant held key informant interviews with a group of augmentative/alternative communication (AAC) users and a group of individuals who act as facilitators for AAC users. The participants provided their insights into what information should be included in the questionnaire, how the information should be presented, and the best ways to recruit individuals for inclusion in the database. The information from these meetings has been quantified, and the investigators have modified the questionnaire to incorporate the suggestions provided.

FUTURE PLANS—By spring 1996, we expect to have completed the evaluation of pilot database of communication aid users, and publication of results and completed a plan for ORTC maintenance and cost-recovery on the communication database.

[170] DEVELOPMENT AND FIELD TESTING OF ACCESSIBLE SOFTWARE MODULES FOR A MULTIMEDIA DESKTOP SYSTEM

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PURPOSE—Three of the most popular technologies of persons with physical disabilities (phone, video, and computer) are being combined in single multimedia telecommunications products. This project selected one such product to start the development of universal access features for these products which will make the information highway accessible for persons of all ages and of all physical and sensory abilities. This new telecommunications technology based on the integration of the computer and telephone system has tremendous

potential to allow people to attend meetings, telecommute, and operate devices remotely. This system could offer alternative or supporting channels of communication to people with physical, communication, and/or sensory impairments.

PROGRESS—A group of Canadian adaptive software developers and rehabilitation technology experts are working with a large international telecommunication company, Northern Telecom (NT), to develop adaptive software for VISIT, NT's multimedia desktop system. Seven rehabilitation technology partners are collaborating with NT in this project. The three principal Canadian adaptive software development companies, two partners with expertise in vision enhancement technology and two clinical sites are reviewing, developing, and testing the prototypes. The director and staff of NT's Multimedia Small Business Unit (SBU) were actively involved in the development work. Each of the three software developers (MAP, Madenta, and Biolink) had their own suite of access software products and the VISIT modules were based on these products. The Centre for Sight Enhancement comprised the most comprehensive laboratories with sight enhancement technologies in Canada with broad experience in clinical testing and prescription. The team reviewed the VISIT, developed access prototypes for people with physical and visual impairments, and drafted universal access guidelines for the next generation VISIT system.

RECENT PUBLICATIONS FROM THIS RESEARCH

Designing adaptive software for and via multimedia telecommunications. Verburg G, Shein F, Prada D. In: Proceedings of the 2nd TIDE Congress, 1995. In press.

[171] KTCODE: A NEW COMPUTER ACCESS TECHNIQUE FOR SWITCH USERS

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PURPOSE—The purpose of KTCode is to provide individuals who cannot access a keyboard or a pointing device with an efficient means to access a computer using 1–3 switches.

PROGRESS—Two efficient techniques for accessing words in a stored vocabulary have been developed. A U.S. patent is pending for both these techniques. The first technique involves creating a binary tree of the user's vocabulary. Words are placed in the tree vertically in order of their frequency of use. Horizontal placement of the words is done according to alphabetical order. To navigate through the tree, the user activates 1–3 switches, similar to the switching required for Morse Code entry. In the second technique, each letter of the alphabet is assigned a 1-bit code (a dot or a dash). The user enters the code for a word and pauses. The computer then presents the user with all the possible words that fit the pattern that has been entered. The user is then required to select the desired word from the list using scanning or some other appropriate technique.

KTCode, a Windows application currently under development, uses the two techniques in combination with a single user interface. As in Morse Code, KTCode uses a variable length binary code to access a predefined set of tokens. KTCode fundamentally differs from Morse Code in that whole words from a vocabulary list are encoded instead of letters. Since the vast majority of letter combinations are not used in most vocabularies, a much smaller binary code is needed for word-based codes as compared with letter-based codes. For added efficiency the combined technique described above takes advantage of the variable length of the hash code to limit the search to words of a particular length and the frequency of use information that is used in the organization of the binary tree.

FUTURE PLANS—Several factors will have to be considered in the design of a practical system based on the techniques described here. The usability of the system will partially depend on the design of the user interface. Representation of the vocabulary to the user during binary searching remains a significant challenge, especially when the vocabulary subset that is being searched is large. What auditory feedback should be used during input keying to augment the visual feedback during hashing and binary searching? Allowing the user to back up if an error is made during keying will also be an important factor in the usability of the system. In addition, the system will need to provide the user with a means to enter words that are not in the vocabulary. This would likely be done by switching to a scanning or Morse Code input mode. Providing this functionality with a limited number of switches, however, may compromise the ease of use of the system.

RECENT PUBLICATIONS FROM THIS RESEARCH

New computer access techniques for switch users. Kurtz I, Farr S, Treviranus J, Shein F. In: Proceedings of CSUN'95. In press.

[172] KEYREP: WIVIK/KEYBOARD RATE ENHANCEMENT

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PURPOSE—The purpose of KeyREP rate enhancement software is to increase typing efficiency in Windows. Typing is relatively slow when using a single finger or stylus to type on a keyboard or when using WiViK. Two versions of software had previously been developed featuring word prediction and abbreviation/expansion: KeyREP (keyboard rate enhancement package) and WiViK 2 REP. However, there was consumer confusion between products and high costs associated with maintaining two similar but separate products. Therefore, the software has been merged into one package.

PROGRESS—New KeyREP rate enhancement software has been developed that works with WiViK and standalone. It also provides support for new access methods such the KTCode encoding method. When used with WiViK, predicted words are displayed within the WiViK window. When used standalone, predicted words are displayed in a floating window and selected by typing a number key. Word prediction completes words that the user begins typing. Its frequency-of-use dictionary adapts to the user's writing style. Separate custom dictionaries are easily created by reading in the user's own files or from other sources such as Internet and CompuServe—a great help when writing about specific topics. This also allows the creation of foreign language dictionaries. Dictionaries may be viewed or edited at any time. Punctuation is handled intelligently. Spaces are automatically added after predicted words. Punctuation characters are positioned correctly and a space is automatically added when appropriate. In addition, following a period, question mark, or exclamation mark, the next letter typed is capitalized. Abbreviation-expansion saves time by allowing frequently used words, phrases, sentences, or other sequences to be replaced with abbreviations. Typed abbreviations are instantly converted into their corresponding, user preprogrammed expansion. All characters and functions of the standard keyboard may be used when creating expansions. Several sets of abbreviation/expansions may be created.

FUTURE PLANS—KeyREP will be ported to Windows 95 and released at the same time as WiViK 3. WiViK 3 users who use KeyREP will get both on-screen and physical keyboard functionality. For users

who do not need WiViK, KeyREP will be available on its own. Planned additional functions within KeyREP include: auditory prompting of predicted words, next word prediction, and spell checking.

[173] WIVIK 2 SCAN: 1–5 SWITCH SCANNING ACCESS

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Sponsor: *The Ontario Rehabilitation Technology Consortium, funded by the Ontario Ministry of Health; IBM Canada Ltd.; IBM Corporation; University Research Incentive Fund of the Ontario Ministry of Colleges and Universities; National Research Council Canada*

PURPOSE—WiViK 2 Scan is a module that adds switch-based scanning capabilities to WiViK 2 on-screen keyboard software. This enables individuals who cannot use a keyboard or any pointing device to access a computer. Scanning involves the successive highlighting of items and selection by the activation of a switch when a desired item is highlighted.

PROGRESS—Three basic scanning methods are available using one to five switches: automatic, inverse, and directed. When automatic scan is selected, a highlight moves sequentially across successively smaller groups of items until the desired key is highlighted for selection. With inverse scanning, the highlight is moved manually by repeated or maintained switch activation. Directed scanning uses separate switches for each direction. Automatic and inverse scanning supports several patterns of movement. The function of each switch is individually adjustable in all methods along with timing of the moving highlight to match the abilities of the user. Several keyboard layouts specifically designed for the various scan methods are available. WiViK 2 Scan solves a particularly difficult problem of controlling Windows which is usually done with a pointing device such as a mouse. A typical solution is to emulate the mouse with a scanning mouse cursor. However, this is an additional task for the user. Our approach is to apply the scanning directly to the objects typically manipulated with the mouse. Thus, windows, menus, scroll bars and other objects usually manipulated with a mouse scan themselves. Menu choices are highlighted or scanned in succession. Similarly, the text cursor scans for easy editing. Since many of these scanning approaches are new, efforts are underway to educate clinicans to the benefits through workshops, presentations, and publications.

FUTURE PLANS—It is recognized that scanning systems have a limited potential in terms of speed of access and overall productivity. Therefore, future work will emphasize approaches that provide greater direct control and accommodate of the users' skills, such as the degree of imprecision in pointing. In the near future, education efforts will continue in teaching clinicians and users the benefits that can be gained by exploring some of the advanced scanning capabilities contained within WiViK 2 Scan. An updated scanning module will be released along with WiViK 3 in the fall of 1995.

RECENT PUBLICATIONS FROM THIS RESEARCH

Scanning the Windows desktop without mouse emulation. Shein F, Galvin R, Hamann G. In: Proceedings of RESNA International '94; 1994, Nashville, TN; Washington, DC: RESNA Press, 1994:391-3.

[174] WIVIK 2 ON-SCREEN KEYBOARD

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Sponsor: *The Ontario Rehabilitation Technology Consortium, funded by the Ontario Ministry of Health; IBM Canada Ltd.; IBM Corporation; University Research Incentive Fund of the Ontario Ministry of Colleges and Universities; National Research Council Canada*

PURPOSE—WiViK 2 enables people with physical disabilities to have complete access to any Windows application by creating an on-screen image of the familiar standard keyboard. WiViK 2 can be controlled by any pointing device that works like the standard mouse. Simply clicking or dwelling on the desired key's image activates that key's function. WiViK goes beyond simple keystrokes; it is essentially a graphic holder of information that can be displayed in flexible arrangements and easily accessed. Information that WiViK can contain includes: keystrokes, words, phrases, application commands, sounds, underlying Windows messages, and external device commands.

PROGRESS—WiViK has been designed in a modular fashion. A basic module supports the display of keyboards and selection with pointing devices. An additional module provides rate enhancement including word prediction and abbreviation-expansion. By reducing the number of key selections, user efficiency is increased. A third module provides scanning access with 1 to 5 switches. In 1994-95 WiViK increased its sales in North America, Europe, and Australia: much effort had gone into ensuring that WiViK is fully compatible with international languages to support such wide distribution. Commercial partners in Germany and Spain are translating WiViK menus, dialogs, manuals, and on-line help into German and Spanish. An OS/2 version of WiViK has been completed; however, marketing arrangements are not yet finalized. Although WiViK software has not changed significantly in the past year, it has been updated incrementally. Updates take into consideration feedback from users and plans for future expansion in its use as a framework for a comprehensive computer-based communication system.

FUTURE PLANS—A major update, WiViK 3, and its associated modules is planned for the fall of 1995. This version will be compatible with the new Microsoft Windows 95 operating system. Additional functionality will be added to increase its usefulness for communication including enhanced graphics display, auditory feedback, and strategies for phrase retrieval. OLE (Object Linking and Embedding) automation will be supported allowing control of external applications within WiViK.

RECENT PUBLICATIONS FROM THIS RESEARCH

Predictive selection technique for single-digit typists. Nantais T, Shein F, Treviranus J. IEEE Trans Rehabil Eng 1994;2(3)130-6.

Usability considerations for on-screen keyboards. Shein F, Hamann G, Treviranus J, Nantais T, Galvin R, Milner M. In: Proceedings of the 12th Triennial Congress of the International Ergonomics Association. 1994:284-6.

D. Private and Public Programs

[175] 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, Washington, DC 20202*

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 post-discharge period. Independent living centers (ILCs) can provide vital services in facilitating transition of the individual with a recently incurred spinal cord injury (SCI) 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 ILCs 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 ILC for facilitating the post-hospitalization life adjustment of persons with recently incurred, ventilator-dependent SCI.

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 SCI 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 to which the Houston ILC assisted them with that process. Data from the interviews will be analyzed and the results will be used to create a coordinated, comprehensive discharge program between TIRR and the Houston ILC, incorporating factors that persons with SCI found to be the most useful in re-entering the community with severe disability.

FUTURE PLANS—Measures of community integration will be examined quantitatively from three databases: 1) ventilator user database; 2) national database of 450 women with disabilities, containing 120 women with SCI and 500 controls without disability; and 3) database of people with severe disabilities who use at least 1 hour of personal assistance daily. Variables to be examined include disability type, severity, and age at onset; assistive devices and equipment used; productivity; personal assistance services; living arrangement; mobility in the community and social integration, as measured by the CHART; marital status and romantic relationships; health status and maintenance; and life satisfaction. Using analysis of variance, extent of community integration will be compared among three groups: 1) persons with SCI; 2) persons with other disabilities such as cerebral palsy, polio, and muscular dystrophy; and 3) persons with no disability.

RECENT PUBLICATIONS FROM THIS RESEARCH

Personal assistance services: the hub of the policy wheel for community integration of people with severe disabilities. Nosek MA, Howland CA. Policy Stud J 1994:21(4):789-800.

[176] INCREASING THE ABILITY OF INDEPENDENT LIVING CENTERS TO SERVE THE POPULATION OF AFRICAN AMERICANS WITH DISABILITIES

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PURPOSE—This project is intended to 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 student 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—African-American students with disabilities have been recruited at TSU and interviewed on issues of personal care skills, interpersonal skills, and consumer skills such as managing personal assistance, advocacy, and participation in support groups. Concepts of independent living have been presented to a home economics class 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; and integrate independent living concepts into existing courses into the human services and consumer sciences curriculum.

[177] DEMONSTRATING A MODEL APPROACH TO INDEPENDENT LIVING CENTER-BASED ASSISTIVE TECHNOLOGY SERVICES

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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 is 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 irreparable to appropriate service providers or vendors who can assist them in obtaining new equipment; and 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 supervise the clinics and conduct 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.

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 1995;7(1):48-54.

[178] THE EVOLUTION OF INDEPENDENT LIVING PROGRAMS: A LONGITUDINAL STUDY

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PURPOSE—The purpose of this project is to maintain a database on the status of independent living programs (ILPs) nationally, and to identify trends in the development of ILPs, the emergence of issues encountered in the delivery of their 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 1994, a revised and updated survey instrument was mailed to 296 independent living centers and 62 independent living programs listed in the ILRU Directory of ILPs. 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 197 programs (67 percent response rate) were received and are currently undergoing data analysis.

RESULTS—Preliminary results are available regarding funding. ILC survey respondents reported that 55 percent received federal funds, 72 percent received state funds, 43 percent received local government support, 35 percent reported receiving funds from foundations, 74 percent received private donations, and 40 percent have for-profit business income. The 1994 survey revealed a dramatic decrease in federal funding available compared to 1992 funding. Between 1992 and 1994, there was an overall 42 percent decrease in federal, a 13 percent decrease in state funding, and a 20 percent decrease in funding from United Way and not-for-profit fees for service, with no substantial increase in foundation or private sources of funding. However, there was a substantial increase in income from for-profit business ventures.

FUTURE PLANS—The Directory of ILPs 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. Of particular interest is changes in funding patterns, which will be compared to results from the 1988 and 1992 surveys.

VIII. Muscles, Ligaments, and Tendons

A. Muscles

[179] THREE-DIMENSIONAL ARM STRENGTH MODEL

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PURPOSE—The objective of this research is to develop and validate a three-dimensional computer model of the upper extremity. There are two distinct versions of the model: one predicts isometric arm strength (maximum hand force) and the other predicts internal muscle forces from submaximal external loadings on the arm.

A secondary goal of this research is to develop a method to account for population variability in the model. Using average parameter values in biomechanical models does not provide information about the distribution of predicted values that could be found within a population. This severely limits the applicability of many biomechanical models to the intended target populations, because often the groups of interest in rehabilitation and medicine are not well represented by the average person.

METHODOLOGY—A three-dimensional static model of the arm is developed to calculate the net reaction moments and forces at the wrist, elbow, and glenohumeral joints. Muscle moment arms and physiological cross-sectional areas are taken from the published literature or measured on cadaveric specimens. Numerical optimization is used to solve for the maximum hand force that satisfies the moment equilibrium conditions at all the joints and keeps the muscle stresses below the specific tension of muscle. Muscle forces are predicted from external loadings on the hand by assuming the central nervous system minimizes the sum of cubed muscle stresses such that the moment equilibrium conditions are satisfied at all the joints.

Variability in model parameters (such as muscle moment arms) is dealt with by modelling the input parameters as random variables. The Monte Carlo simulation is used to determine the distribution of model predictions once the statistical distribution of input parameters has been determined. The quality of the simulations were assessed by comparing the results (means and standard deviations of muscle forces) to an analysis of a complete analysis of each individual cadaveric specimen in the specimen.

The two versions of the model will be validated differently. The version for predicting maximal hand forces will be compared to published and measured maximum arm strengths (push, pull, lift, and so forth). An experiment will be performed to measure hand force exertion capabilities at three locations in the reach envelope. Maximum force in six directions will be measured using a six DOF load cell. The version of the model for predicting internal muscle forces will be tested by comparing model predictions to published EMG data and EMG data collected in this laboratory. Future plans include comparing the predicted muscle forces to forces determined using an EMG-driven muscle force prediction model.

PROGRESS—Moment arms of muscles crossing the glenohumeral joint have been measured using cadaveric specimens. Additionally, muscle moment arms have been measured for simulated repairs of rotator cuff tendon defects. The mathematical model has been formulated and implemented on a workstation. The model has been used to conduct a Monte Carlo

simulation of planar arm abduction and analyze three-dimensional maximal abduction and external rotation arm exertions.

PRELIMINARY RESULTS—The most important result of this project to date is the demonstration that Monte Carlo techniques are a convenient way to generate the distribution of model predictions arising from variability in model inputs. Moreover, use of average parameter values gives large errors in some cases when compared to an analysis of all specimens separately. Monte Carlo simulation gives estimates of mean predicted values that agree well with the analysis of the whole specimen sample.

FUTURE PLANS—The primary emphasis on future work will be on model validation. Model simulations of surgical procedures will also be performed. Specifically, the effect on arm strength of resection of portions of the abduction mechanism during osteoarticular allograft surgery will be analyzed. Analyses of methods for repairing massive rotator cuff tears will also be performed.

RECENT PUBLICATIONS FROM THIS RESEARCH

Monte Carlo simulation model of the glenohumeral joint. Hughes RE, An, K-N. In: XVth Congress of the International Society of Biomechanics Book of Abstracts. Jyvaskyla, Finland, 1995.

[180] 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 timing of the loss in cytoskeletal desmin that was previously observed. Since cytoskeletal loss can result in myofibrillar disruption, we felt that understanding its timing would provide insights into the damage mechanism.

METHODOLOGY—Rabbit extensor digitorum longus (EDL) and tibialis anterior (TA) muscles were examined 5 min or 15 min after eccentric exercise and 1 hour or 1 day after 30 min of an eccentric exercise protocol (n=16 rabbits). Muscles were cyclically activated at 40 Hz for 400 ms (approximately 50 percent Po) and allowed to relax for 600 ms over the treatment period. This stimulation frequency (40 Hz) was chosen based on motor unit studies which demonstrated that, at this frequency, force decline was due to fatigue of the muscle fibers themselves and not the neuromuscular junction or motor nerve, and to produce the force level observed during moderate intensity exercise.

RESULTS—The earliest change noted was a significant loss of desmin labeling in 2.5 ± 0.63 percent of the rabbit extensor digitorum longus muscle (EDL) muscle fibers ($p<0.005$) 5 min after initiation of eccentric exercise. Some loss of tibialis anterior (TA) fiber desmin was also apparent at this time period (0.24 ± 0.19 percent), but the magnitude was not significantly different from zero ($p>0.2$). Fifteen minutes after initiation of exercise, desmin loss was more pronounced, increasing to 7.4 ± 1.4 percent and 4.6 ± 1.0 percent in the EDL and TA, respectively ($p<0.005$). Finally, 1 day after 30 min of eccentric exercise, the percentage of fibers without desmin staining rose to 23.4 ± 3.7 percent and 7.7 ± 2.4 percent in the EDL and TA, respectively ($p<0.001$). Loss of desmin staining occurred in the absence of contractile or metabolic protein disruption. Increased staining intensity of the intrasarcomeric cytoskeletal protein titin and an inability to exclude plasma fibronectin was also observed in most but not all fibers which had lost desmin staining. Desmin disruption thus

represents a very early structural manifestation of muscle injury during eccentric contraction. Cytoskeletal disruption may predispose the contractile apparatus to previously reported structural damage.

RECENT PUBLICATIONS FROM THIS RESEARCH

Biomechanical basis of muscle cellular damage. Lieber RL, Friden J. Basic Appl Myol 1994:4:25-34.

Contractile and cellular remodeling in rabbit skeletal muscle after cyclic eccentric contractions. Lieber RL, Schmitz MC, Mishra DK, Friden J. J Appl Physiol 1994:77:1926-34.

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.

Muscle cytoskeletal disruption occurs within the first 15 minutes of cyclic eccentric contractions. Lieber RL, Thornell L-E, Friden J. J Appl Physiol. In press.

[181] ADAPTIVE BIOLOGICAL SIGNAL PROCESSING

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Sponsor: *Natural Science and Engineering Research Council of Canada*

PURPOSE—Our research goal is to investigate the performance of adaptive matched filters, and adaptive noise cancellation filters in evoked potential estimation.

METHODOLOGY—In order to obtain useful somatosensory evoked potentials, signal enhancement methods must be applied in order to increase the signal-to-noise ratio (SNR). To date an adaptive matched filter has been investigated, and a SNR gain of 6dB has been found while tracking slowly varying changes in the signal. In order to reduce the effects of large interfering myoelectric signals, adaptive noise cancellation filters are being studied.

PROGRESS—To date the performance equations have been derived, and the initial experimental work is encouraging.

[182] SKELETAL MUSCLE LENGTH FORCE CHARACTERISTICS DURING MAXIMAL AND SUBMAXIMAL ACTIVATION

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Sponsor: *Netherlands Organization for Research, Foundation for Biological Sciences*

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 muscles that are rarely characterized by maximal activation. For that purpose several conditions of submaximal activation will be imposed on *in situ* muscles 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 filament length parameters were determined. Submaximal activity of was induced in two ways. In fully recruited muscle we changed stimulation frequencies, imposing stimulation frequencies between 100 and 15 Hz. This was performed for both a constant frequency and a decreasing frequencies protocol. In partially recruited muscle, we simultaneously stimulated 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). We also lowered stimulation current to a bipolar electrode on the nerve, noting that only a part of the motor units remained 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, 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

Decreasing stimulation frequency dependent length-force characteristics of rat muscle. Roszek B, Baan GC, Huijing PA. J Appl Physiol 1994:77:2115-24.

Effects of distribution of fiber length on active length force characteristics of rat GM.Ettema GJC, Huijing PA. Anat Rec 1994:239:414-20.

Hip joint position and architecture on rat semimembranosus: implications for length force characteristics. Willems MET, Huijing PA. Acta Anat 1995:152:56-65.

Important experimental factors for skeletal muscle modelling: non-linear changers of muscle length force characteristics as a function of degree of activity. Huijing PA. Eur J Morph. In press.

Parameter interdependence and success of skeletal muscle modelling. Huijing PA. Hum Mov Sci. In press.

[183] 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—We studied the effects of 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), we studied number of sarcomeres in series within fibers, and filament length parameters.

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 the muscle length 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, Kronnie G te, Huijing PA. Eur J Appl Physiol 1995:70:49-57.

[184] EFFECTS OF MUSCULAR FATIGUE ON THE MES AND A MULTIFUNCTIONAL MYOELECTRIC CONTROL SYSTEM

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Sponsor: *New Brunswick Medical Research Fund and UNB Research Fund*

PURPOSE—Our goal is to assess the effects of various types of muscular fatigue on the myoelectric signal as well as upon a multifunctional myoelectric control system.

METHODOLOGY—The project will study the effects which neuromuscular fatigue (induced by different, controlled muscular exercise protocols) may have on the spectral characteristics of, and any deterministic pattern within, the myoelectric signal. If fatigue is found to alter selected spectral characteristics or the deterministic pattern, this will provide important insight into the functioning and refinement of the new multifunctional myoelectric control system.

PROGRESS—The second phase of the project (dynamic fatigue protocols) has been completed. In summary, selected dynamic fatigue protocols produced different physiological environments within selected contracting muscles (biceps and triceps). Induced muscle fatigue significantly altered the spectral characteristics and thus neural network classifier values which represent the distinct myoelectric signal patterns.

[185] MYOELECTRIC DATA COMPRESSION USING ADPCM

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Sponsor: *UNB Research Fund*

PURPOSE—Our goal is to determine whether adaptive differential pulse code modulation (ADPCM) can be employed to compress myoelectric data.

METHODOLOGY—The myoelectric signal, obtained either by surface or needle electrodes, is used in many areas of clinical research and diagnostics. The conventional method of storing such information is in digitized form on a computer. However, the bandwidth of the signal and the required resolution results in large memory requirements. In this work, adaptive differential pulse code modulation (ADPCM) has been investigated as a method of reducing the memory requirements for myoelectric data storage.

Differential PCM is a technique whereby the difference between successive samples is coded, thus reducing the required dynamic range of the coder. The disadvantage of such a scheme is that slope overload can result if the input signal amplitude changes suddenly. ADPCM overcomes this drawback by using a predictive algorithm to modify the quantization width of the coder. Thus the resolution of the coding scheme varies due to the statistics of the data.

PROGRESS—A system based on this principle has been designed and fabricated that compresses 12-bit data to 4-bits, thus reducing the memory requirements by a factor of 3. In reality, this compression ratio is closer to 4:1 due to the fact that the width of most memories are organized as multiples of eight bits. Dedicated hardware was designed around the MSM5218 Speech Analysis/Synthesis integrated circuit from Oki Semiconductor. This device is available in a 24-pin plastic package at a cost of $6.75, and provides all the required ADPCM digital signal processing.

This system has been evaluated in real time using both sinusoidal and myoelectric data. The myoelectric data, obtained using surface electrodes, was the result of a steady state isometric contraction of the wrist flexors. Comparisons in the time domain were made between the original signal and a compressed/expanded signal.

FUTURE PLANS—Future work in this area is needed to assess this technique for dynamic myoelectric signals, in which the contraction level is time variant. This may pose a problem for ADPCM due to the predictive nature in which the quantization width is set. In addition, more extensive studies into the nature of the error introduced by ADPCM is warranted to determine any trends or biases. These aspects are currently under investigation.

[186] THE STRETCH REFLEX RESPONSE IN THE NORMAL AND SPASTIC ANKLE: EFFECT OF ANKLE POSITION

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Sponsor: *None listed*

PURPOSE—A spasticity measurement system (SMS) to quantitatively measure ankle spasticity has been developed. Apparently the stretch reflex in spasticity depends on ankle angle. The purpose of this study was to determine how the spastic stretch reflex changes over the ankle positions used in our SMS measurements, thus

showing which ankle position maximizes the response. This knowledge is also valuable for intervention studies when the range of motion (ROM) changes during the intervention. Subjects with and without spasticity were compared.

METHODOLOGY—Sixteen subjects with self reported and clinically evident ankle spasticity, as a result of stroke (n=3 subjects), spinal cord injury (n=4), or multiple sclerosis (n=9) were studied. Eight subjects were taking anti-spasticity medication. Ages ranged from 25 to 82 years (mean 47, SD 16), with 9 males and 7 females. The control group consisted of 16 nondisabled subjects, aged 19 to 71 years (mean 41, SD 16), 10 males and 6 females. All could achieve at least 7.5° of dorsiflexion. Informed consent was obtained from each subject.

The SMS quantifies stretch reflex activity, producing sinusoidal oscillations of the ankle joint over a range of 5°. The frequency is varied from 3 to 12 Hz in 1 Hz increments. The axis of the angular rotation of the device is fixed to coincide with the ankle joint axis. The bias angle of the ankle (i.e., the midpoint of oscillation) is varied from 10° of plantarflexion (PF) to 5° of dorsiflexion (DF). Torque resistance resulting from the angular perturbations and the angular displacement itself are acquired by a computer system sampling at a rate of 500 Hz. Surface EMG data from both gastrocnemius and tibialis anterior are collected by an electromyograph. After eliminating friction and inertially induced torques, the resultant total stiffness is calculated, as are viscous and elastic stiffness components. Variations in the total and elastic stiffnesses with frequency are calculated and reported as total and elastic path lengths, respectively; presence of reflex responses increases both path length values.

The variable amount of stretch of the gastrocnemius-soleus muscle was achieved by placing the ankle joint in five different bias angles: 5° of DF (D5), 2.5° of DF (D2), neutral (0), 5° of PF (P5) and 10° of PF (P10). The order in which the positions were applied was randomized. Differences between the normal and spastic group were statistically tested by a Mann-Whitney-U-Test. First, a comparison between the two groups was made by taking the overall average value across the five positions. After that, comparisons were made for each ankle position separately, using the Bonferroni correction for multiple comparison. Orthogonal comparisons for both linear and quadratic trends were used to find patterns in the reflex behavior throughout the ROM, using techniques modified for non-parametric comparisons. Significance level was 0.05.

PROGRESS—The study has been completed.

RESULTS—Total and elastic path lengths increased with increasing bias angle for both groups. Using the orthogonal comparisons, increasing trends were significant ($p \leq 0.002$ for the spastic group and $p \leq 0.0005$ for the normal group), with greater increase in the spastic group. In the spastic group the maximal value was at D2. Average values over the five positions for both path length measures were significantly higher in the spastic group.

IMPLICATIONS—It must be considered that the amount of stretch reflex activity varies with the ankle angle when performing spasticity tests subsequent to an intervention changing available ROM and when comparing subjects measured at different ankle positions.

B. Ligaments and Tendons

[187] PHYSIOLOGICAL BASIS OF STRENGTH FOLLOWING SURGICAL TENDON TRANSFER

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PURPOSE—The purpose of this project is to understand the biomechanical design of the human wrist. Having defined biomechanical properties of muscles and tendons, wrist joint moment arms were determined. This enabled prediction of sarcomere length operating ranges and modeling of common tendon transfers.

METHODOLOGY—Instantaneous moment arms were calculated by differentiating tendon excursion with respect to joint rotation. Maximum isometric tension of each wrist muscle-tendon unit was predicted based on muscle physiological cross-sectional area. Muscle forces were subsequently adjusted for sarcomere length changes resulting from joint rotation and tendon strain. Torque profiles were then calculated for each prime wrist motor (i.e., muscle-tendon unit operating through the corresponding moment arm). Influences of moment arm, muscle force, and tendon compliance on the torque profile of each motor were quantified.

PROGRESS—Wrist extensor motor torque production varied considerably throughout the range of motion. The contours of the extensor torque profiles were determined primarily by the moment arm-joint angle relations. In contrast, wrist flexor motors produced near-maximal torque over the entire range of motion. Flexor torque profiles were less influenced by moment arm and more dependent on muscle force variations with wrist rotation and with tendon strain.

RESULTS—These data indicate that interactions between the joint, muscle, and tendon yield a unique torque profile for each wrist motor. The flexors increase joint moment with extension by increasing sarcomere length "up" the ascending limb of the length-tension curve and decreasing joint moment. The extensors also increase joint moment with extension by decreasing sarcomere length "up" the descending limb of the length-tension curve and increasing moment arm. This represents a design where wrist joint stiffness increases with extension but remains balanced between flexion and extension.

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.

Biomechanical determinants of wrist joint strength. Loren GJ, Shoemaker SD, Burkholder TJ, Jacobson MD, Friden J, Lieber RL. Trans Orthop Res Soc 1995:20:20-5.

Tendon biomechanical properties enhance human wrist muscle specialization. Loren GJ, Lieber RL. J Biomech 1995:28:791-9.

Influences of human wrist motor design on joint torque. Loren GJ, Shoemaker SD, Burkholder TJ, Jacobson MD, Friden J, Lieber RL. J Biomech. In press.

Stepwise regression is an alternative to splines for analysing noisy data. Burkholder TJ, Lieber RL. J Biomech. In press.

[188] SARCOMERE LENGTH CHANGES AFTER TENDON TRANSFER

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B591-RA)*

PURPOSE—The purpose of this project is to understand the biomechanical design of the human wrist. We are using intraoperative sarcomere length measurements to not only validate and refine the experimental model, but to provide concrete guidelines for surgeons performing such procedures.

METHODOLOGY—Sarcomere length was measured intraoperatively on patients undergoing tendon transfer of the flexor carpi ulnaris (FCU) to the extensor digitorum communis (EDC) for radial nerve palsy. Following insufflation of a pneumatic tourniquet and administration of intravenous regional anesthesia, an electrogoniometer was placed on the palmar surface of the subject's wrist and hand. The illuminating prism of the laser device was inserted beneath the fiber bundle and approximated into the normal plane of the muscle. We made every effort to measure sarcomere length in the *in vivo* position of the fibers and not to elongate them artificially by elevation of the fiber bundle.

PROGRESS—Sarcomere length was measured with the wrist placed in each of three positions: full flexion, neutral, and full extension. The actual angular value corresponding to each position was noted from the electrogoniometer's digital display.

RESULTS—The most significant result was that the absolute sarcomere length and sarcomere length operating range of the FCU increased significantly after transfer into the EDC complex. Preoperatively, with the wrist fully extended, FCU sarcomere length was 4.22±24 fm and decreased to 3.19±05 fm as the wrist was fully flexed. This represented an overall sarcomere length range of 1.03 fm. After the tendon transfer, all sarcomere lengths were significantly longer ($p<0.001$). Specifically, sarcomeres were 1.05±34 fm longer with the muscle in its fully lengthened position (4.96±43 fm) and 0.60±14 fm longer with the FCU in the fully shortened position (3.50±06 fm). Mathematical modeling of this relationship revealed that the nature of torque generation at the wrist was altered significantly by the increase in sarcomere length.

These data demonstrate that small number of sarcomeres in the FCU render it unsuitable to function as both a multiarticular wrist and finger extensor and instead relies on the tenodesis effect to perform both of these functions.

RECENT PUBLICATIONS FROM THIS RESEARCH

In vivo measurement of human wrist extensor muscle sarcomere length changes. Lieber RL, Loren GJ, Friden J. J Neurophysiol 1994:71:874-81.

Physiological consequences of surgical lengthening of extensor carpi radialis brevis muscle-tendon junction for tennis elbow. Friden J, Lieber RL. J Hand Surg 1994:19A:269-74.

Sarcomere length changes after flexor carpi ulnaris-to-extensor digitorum communis tendon transfer. Lieber RL, Ponten E, Friden J. J Hand Surg. In press.

[189] COMBINED FUNCTIONAL LOADING AND LASER PHOTO STIMULATION OF REGENERATING TENDONS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Programs, Washington, DC 20420 (Project #A534-2RA)*

No report was received for this issue.

IX. Neurological and Vascular Disorders

A. General

[190] EFFECT OF ADCON ON PERIPHERAL NERVE RESPONSES TO INJURY: A PILOT STUDY

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PURPOSE—Following peripheral nerve trauma, transected axons may demonstrate disorganized growth resulting in a bulbous scarred mass called a neuroma. Neuroma formation often leads to the generation of abnormal electrical activity that can be perceived as intensely painful. In addition, scar formation following surgical or other types of trauma can produce adhesions and constrictions involving peripheral nerves that can compromise their function. We have previously shown that a carbohydrate gel device, ADCON, can significantly reduce extraneural scar formation. In addition, preliminary results indicated that neuromatous hyperactivity could be reduced by the application of ADCON to the cut end of a sciatic nerve in a plastic tubular device. However, the tube itself was found to produce a proximal neuroma generating hyperactivity at the point of nerve entry. Our current study was, therefore, designed to assess the effect of direct extraneural application of ADCON without a tubular device on important intraneural responses following sciatic nerve injury in the adult rat.

METHODOLOGY—In one set of experiments, 16 rats underwent unilateral transection of the sciatic nerve followed by local application of either ADCON or nothing. Four animals in each group were then sacrificed after 1 and 4 weeks and their sciatic nerves examined histologically. In a second set of experiments, 36 rats underwent surgical manipulation of their sciatic nerves: 9 underwent bilateral simple external neurolysis with splitting of the tibial and peroneal divisions, 10 were subjected to an additional abrasive injury applied bilaterally to the nerve and surrounding muscle, 8 underwent unilateral crush of the nerve, and 9 underwent unilateral transection and suture repair of the nerve. Rats undergoing neurolysis or abrasion of the nerve were sacrificed at 4 weeks while rats undergoing crush or cut of the nerve were sacrificed at 6 weeks. Animals received either ADCON, control gel, or no gel placed around their sciatic nerves.

PROGRESS—We characterized the effects of ADCON on several important peripheral nerve responses following various types of trauma.

RESULTS—In the first set of experiments, both light and electron microscopic observations failed to detect a difference in the amount of axonal regeneration seen at 1 and 4 weeks following sciatic nerve transection and local application of either ADCON or nothing. In the second set of experiments, analysis demonstrated no evidence for a toxic effect of ADCON on sciatic nerve as assessed by counts of degenerating axons and measurement of nerve conduction velocity in the simple neurolysis and abrasion injury groups of rats. The intraneural macrophage response and expression of low affinity Nerve Growth Factor receptor was not altered by the extraneural application of ADCON. Counts of

regenerating axons at both the light and electron microscopic level in cut and suture repaired nerves did not differ in control and ADCON treated animals.

IMPLICATIONS—Our results indicate that ADCON is both safe and effective in reducing extraneural scarring. They demonstrate that ADCON does not alter important intraneural responses to nerve injury during both its degenerative and regenerative phases. Direct application of ADCON was found not to be effective in suppressing neuroma formation following nerve transection.

FUTURE PLANS—Approval has been obtained from the FDA to initiate a clinical trial employing ADCON to treat patients suffering from recurrent carpal tunnel syndrome and enrollment has begun. In the laboratory, we have initiated studies to investigate factors that interfere with the capacity of a peripheral nerve to recover following trauma. We are interested in how repetitive stretch and compression trauma, as occurs in common clinical entrapment syndromes such as carpal tunnel, can over time produce significant intraneural pathology with profound functional deficits.

RECENT PUBLICATIONS FROM THIS RESEARCH

Spatial and temporal response of macrophages in the mammalian peripheral and central nervous system following axonal injury. Avellino AM, Dailey A, Hart D, MacKinnon M, Ellegala D, Kliot M. Exp Neurol. In press.

[191] 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-minute regime of controlled vertical motion, using the leg drop pendulum test. Data from these tests was analyzed and 17 mathematical attributes were 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, the author has shown that a nonlinear, second order system, employing exponential springs and dampers, is quite adequate in modelling 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 the author to suspect that a better model could bc obtained with the use of active force input in conjunction with a physiologically sound passive model. Investigation along these lines has lead to some very interesting results. The addition of active forces to the model result first and foremost in a bettcr 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, with 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 rcquired for nondisabled 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 the author is 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 indicate that gains around the loops are higher in the models of spasticity and that these gains are reduced after whole body vertical oscillations.

RECENT PUBLICATIONS FROM THIS RESEARCH

Active, non-linear model of the leg drop pendulum test: assessing changes in spastic CP. Fee J. In: Proceedings of the 1995 IEEE Annual Northeast Bioengineering Conference 1995:25-7.

Passive leg motion changes in CP children after whole body vertical accelerations. Fee J, Samworth K. IEEE Trans Rehab Engr 1995:3(2):228-32.

B. Low Back Pain

[192] DEVELOPMENT OF A CLINICAL DATABASE FOR THE BACK ANALYSIS SYSTEM

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Programs, Washington, DC 20420 (Project #B748-RA)*

No rcport was received for this issue.

[193] 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 Programs, Washington, DC 20420 (Project #B749-RA)*

No report was received for this issue.

[194] DESIGN AND CLINICAL APPLICATION OF A WIRELESS TENS (TRANSCUTANEOUS ELECTRIC NERVE STIMULATOR) IN PAIN MANAGEMENT: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #B93-620AP)*

PURPOSE—The purpose of this pilot study is to determine whether traditional TENS devices can be replaced by a wireless version of these types of stimulators utilized in pain therapy. The elimination of the wires makes the new TENS device more acceptable by the patients and would have increased reliability and reduced electric power requirements. After developing three prototypes of the wireless version of this device, it was found that the new electric field patterns generated affect patients in a different manner from the traditional TENS units. The objectives then become the identification of which etiologies afflicted by pain may benefit from the new device developed from this study. The types of patients presently being treated include those suffering pain due to recent surgery, lower back pain due to prior accidents, arthritis, post polio syndrome, and a number of other afflictions.

METHODOLOGY—Over 40 patients with chronic pain have been tested with both the traditional TENS device and a wireless version. At the start of each data run, the subjects are given a McGill-Melzack Pain Questionnaire to identify the site and type of pain being experienced that day. Each data run then consists of a comparison of just noticeable differences (JND) of stimulation threshold at both the pain site and another body location with a similar anatomical structure. The JNDs are tested in random order with a Latin Square design to preclude any ordering effects. The patients are blind to which stimulator is being applied. After the JNDs are determined, the pain site is administered 20 minutes of an electric field generated by the wireless device. This field differs from the stimulation produced by the traditional TENS, because it has both space varying properties as well as the normal time varying properties of the traditional TENS. Measurements are also made of the electric power required for stimulation (for equivalent pain relief) for the traditional TENS versus the new wireless TENS device, which is being patented with all rights assigned to the US Government. Measurements are also recorded of any accommodation (pain returns with stimulator on) and extinction (the time when the pain returns after the stimulator is turned off). Both devices are being compared in terms of accommodation and extinction.

PRELIMINARY RESULTS—The new wireless device produces an electric field which changes both in a spatial pattern as well as in time. This can be contrasted with the traditional TENS device which only allows the

generation of the electric fields with time variations. The results of this new technology on patients within the VA system has shown that certain etiologies show benefits but others may not. The testing continues to identify which types of patients are benefited. Patients tested prefer the new, wireless, device since it is free of lengthy wires and the associated problems caused by these wires.

FUTURE PLANS—Traditional TENS units do not work on at least 50 percent of the present population of VA patients who suffer from pain. At least one subject in our pilot study has received 100 percent pain relief with the wireless device, but received substantially less pain relief from the traditional device. Other patients have reacted differently, but their pain relief is apparently a function of their specific etiologies that cause the pain. Our testing continues on which groups benefit the most. We also continue to monitor the electric power consumed by both devices in comparing how the wireless device can mitigate equivalent or greater amount of pain for the same source of external power. A Phase II study is being designed to include a remote control device to make the system more user friendly for the physician and the patient alike, as well as to investigate which types of patients benefit most from this new technology.

RECENT PUBLICATIONS FROM THIS RESEARCH

Wireless TENS (transcutaneous electric nerve stimulator). Ho CC, Repperger DW, Johnson DC. US Government Invention, Disclosure Number 23,201, Patent in Progress.

[195] VERMONT REHABILITATION ENGINEERING RESEARCH CENTER FOR LOW BACK PAIN

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Sponsor: *National Institute on Disability and Rehabilitation Research, U.S. Department of Education, Washington, DC 20202-2305*

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—Engineering Design and Development

Project 1. 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.

Project 2. 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.

Project 3. 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.

Project 4. 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.

Project 5. 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.

Clinical and Workplace Intervention *Project 6. A 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.

Project 7. 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.

Project 8. A 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, a rehabilitation engineering intervention program.

Project 9. 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.

Information Services Division The Center's Information Services Division comprises 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 at 1-800-527-7320 (voice/TDD).

RECENT PUBLICATIONS FROM THIS RESEARCH

Workers' compensation and return-to-work in low back pain. Gallagher RM, Williams RA, Skelly J, et al. Pain 1995:61:229-307.

[196] QUANTIFICATION OF MOTION CHARACTERISTICS IN LOW BACK DISORDERS

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PURPOSE—This study quantified three dimensional trunk motion characteristics as a function of asymmetric tasks for nonaffected and specific low back disorder groups. The goal was to determine whether or not different low back disorder categories had distinguishable motion characteristic.

METHODOLOGY—Subjects were classified as nondisabled or in one of nine disease categories. Nondisabled subjects were defined as those without previous history of low back pain. Disease categories were based on either diagnosis or symptom categories from the Quebec Task Force Study. The nine disease categories contained four diagnostic categories, including: 1) herniated disc with pain greater than three; 2) herniated disc with pain less than three; 3) spondylolisthesis; and 4) stenosis; and four symptom categories, including: 5) Quebec 1, 6) Quebec 2, 7) Quebec 3, and 8) Quebec 9.2. The ninth category consisted of patients who exhibited signs of non-organic pain syndrome during examination.

An experiment was developed to investigate the manner in which three dimensional trunk motion characteristics change as the trunk is flexed and

extended repeatedly in symmetric and asymmetric postures. The lumbar motion monitored was used to measure the three dimensional trunk motion characteristics. A display was shown to the subjects which indicated the amount of trunk twist and a target twisting posture. Subjects were instructed to control their twisting position, while flexing and extending their trunk as fast as comfortably possible.

There were five asymmetric trunk positions evaluated in this study, including: 1) zero (symmetric), 2) 15° twist to the right, 3) 15° twist to the left, 4) 30° twist to the right, and 5) 30° twist to the left. Subjects performed the symmetric task first followed by the 15° conditions and then the 30° conditions.

Key dependent variables include an indicator variable as to whether or not the subject performed the task at each asymmetric task and total twisting range (maximum—minimum). Additional key dependent trunk motion characteristics included : 1) sagittal range of motion, 2) sagittal flexion velocity, 3) sagittal extension velocity, 4) sagittal flexion acceleration, 5) sagittal extension acceleration, 6) lateral range of motion, 7) lateral right velocity, 8) lateral left velocity, 9) lateral right acceleration, and 10) lateral left acceleration.

PROGRESS—There are currently 350 nondisabled and 325 patients in the 9 disease categories with at least 20 subjects in each category. This sample sizes allows the data to be split into two data sets, training and test.

RESULTS—Discriminant function analysis has been performed on all subjects. A five variable model was developed which included: 1) sum of ability on all five test conditions, 2) twisting range of motion, 3) sagittal extension velocity at zero, 4) sagittal extension acceleration at zero, and 5) lateral range of motion at zero. The results showed that both the training and test set error rate were 9 percent. The test set sensitivity was 93 percent and 88 percent for nondisabled and low back pain patients, respectively.

Additional discriminant function models were developed to distinguish between specific patient categories and all other patients. The test set error rates ranged from 19 percent to 40 percent, depending upon disorder category. The test set sensitivities for the nine disease group test sets varied from 50 percent to 93 percent.

FUTURE PLANS/IMPLICATIONS—These results show that the lumbar motion monitor may be used as a diagnostic tool in distinguishing low back patients from nondisabled persons as well as among different disease categories. Our long-term goal is to determine when someone is ready to return to work, based on functional performance as well as their job demands.

C. Swallowing Disorders

[197] THE EFFECTS OF HEAD POSITIONING ON PRESSURE GENERATION IN THE PHARYNX DURING NORMAL SWALLOWING: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #C91-221AP)*

PURPOSE—We seek to compare forces generated in the pharynx and applied to the bolus during normal swallows with various clinically used altered head positions and compare these data to previously obtained data on normals without altered head positions. We shall then use these comparisons to establish a normative database regarding forces on the bolus for later studies evaluating dysphagic patients. Along with this,

we are working to develop and perfect the operations of a Manofluorographic Laboratory at the Atlanta VA Medical Center.

The prototype instrumentation used to obtain force measurements in this investigation adds a new quantitative dimension to the traditional evaluation and treatment of dysphagia. After completing this study and the follow-up study on dysphagic patients, the swallowing clinician will have a more accurate basis for selecting particular head positions for specific types of dysphagia.

METHODOLOGY—Fifteen subjects, between the ages of 20 and 65 and with no history of swallowing problems, underwent the simultaneous recording of manometry and fluoroscopy (manofluorography). Each subject was seated and a four-sensor, solid-state pressure catheter was positioned. Four 10 cc swallows were accomplished in each of four head positions (turning, tilting, forward and back). Radiation times were limited to 2 minutes to avoid overexposure. Six bolus forces will be determined for each swallow in addition to transit times and bolus velocities. These data will be analyzed by a Repeated Measures Analysis of Variance. Results will be compared to previously obtained with upright head positioning.

PROGRESS—The Manofluorographic Laboratory has been established and is used for patient evaluation as well as for research. The protocol for its use is in place. All 15 subjects have been run and data collected. Preliminary data analysis is complete. Thorough review of relevant literature had been accomplished.

RESULTS—Preliminary results reveal the noteworthy phenomenon of aspiration in three of the normal subjects. Two extra subjects were included to allow for subject attrition if the procedure was not completed within the radiation time limits. This event did not occur. Subject attrition did occur, however, due to repeated unforeseen equipment failures.

FUTURE PLANS—Immediate future plans are to complete the data analysis and prepare the results for publication. We are proposing to study the effects of head positioning on pressure generation in the pharynx during the swallowing of dysphagics: with the data to be obtained in this study, we expect to contribute substantially to the knowledge regarding the use of head positions as a clinical tool in dysphagia management.

[198] 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 consisted of 43 medically stable hospitalized, dysphagic stroke patients drawn from 10 VA hospitals. All patients had a stroke-caused dysphagia with onset between 1 and 12 weeks prior to enrollment in the study. Each subject was

randomly assigned to one of four treatment groups. Group I (n=12) received 150 trials; Group II (n=10) received 300 trials; Group III (n=10) received 450 trials; and Group IV (n=11) received 600 trials.

A trial consisted of three rubs of TTA on each of the faucial pillars and one swallow. Videofluoroscopic examinations were conducted at intake, at the end of the first treatment week, and at the end of the second treatment week.

Each exam consisted of five 3-ml thin liquid boluses and five 10-ml thin liquid boluses. The initial videofluoroscopic exam showed evidence of dysphagia characterized by abnormally long duration of stage transition (DST) measures and abnormal penetration-aspiration measures on at least one swallow, unless it was the first swallow, in which case it must have been present on at least one of the next nine swallows. Treatment was conducted on at least 3 of the 5 days of each treatment week. No treatment was conducted for at least 2 hours prior to the videofluoroscopic swallowing exam conducted on the fifth day of each week.

RESULTS—The first finding to emerge from this study was that 600 trials per week are impossible for clinical speech pathologists to provide because of the time involved. In addition, patients responded significantly to 1 week of 600 trials, but their performance deteriorated during the second week. The second finding was that there is no clear trend for the relative efficacy of the other three treatment intensities.

The third finding was that even more rigid enrollment criteria than those used in the present study should be applied to enroll patients into a treatment trial of TTA. A single delay in DST and a single instance of penetration or aspiration were not rigid enough criteria to identify those dysplagia patients in need of treatment. The fourth finding was that TTA does appear efficacious for individual patients.

Among the remaining clinical challenges is the requirement to identify more efficiently those individuals who are likely to profit from different treatment intensities.

FUTURE PLANS—A manuscript is being prepared for publication. A randomized group efficacy study is being designed.

RECENT PUBLICATIONS FROM THIS RESEARCH

Penetration aspiration scale. Rosenbek, JC, Robbins J, Roecker E, Coyle J, Wood J. Dysphagia. In press.
Efficacy in dysphagia. Rosenbek JC. Dysphagia. In press.

D. Vascular Disorders

[199] NONINVASIVE MEASUREMENT OF CHANGES IN MUSCLE OXYGEN WITH CLAUDICATION

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PURPOSE—Different quantitative tests have been used to assess claudication, but these tests do not directly measure oxygen in the affected ischemic tissue regions. The current technique utilizes a small diameter light beam at the surface of the skin. The differential light reflectance on the skin surface at dual source-detector separations and at dual wavelengths provides information on oxygen saturation at greater depths into limb

tissue than has been previously available in the clinical environment. The goals are to determine if noninvasive measurement of oxygen within the tissue provides a sensitive and specific indicator of claudication leading to possibilities for better evaluation of available therapies.

METHODOLOGY—The laboratory portion of the study consisted of transcutaneous oxygen ($tcPO_2$) and differential light reflectance spectrography (DLRS) measurements from the limb on 4 rhesus monkeys following a canine study with arterial occlusion in 10 animals. In the primate study, a 3 in wide cuff was placed to restrict limb blood flow. Reflectance and $tcPO_2$ sensors were placed distal to the flow restriction. The reflectance was examined for red (660 nm) and infrared (880 nm) light. Reflectance and $tcPO_2$ data was recorded before, during, and immediately following the flow restriction.

For the clinical study, reflectance and $tcPO_2$ probes are placed at the lateral mid-thigh, the lateral mid-calf, and at the dorsum of the foot. The measurements are taken after a rest period in the supine position and then while standing and walking. The patient is asked to indicate when any pain is experienced and the exercise is terminated when the patient reaches absolute claudication.

PROGRESS—The laboratory phase of the study is complete and the clinical portion is in progress. Clinical data has been obtained from the lateral calf on subjects with varying degrees of claudication.

RESULTS—For the DLRS technique, infrared reflectance decreases with increasing blood concentrations within the tissue and shows much less sensitivity to oxygen change when compared with red reflectance. The red reflectance responds to changes in both oxygen saturation and tissue fractional blood volume. The DLRS technique includes measurement of photons which have reached the venous plexus within the subcutaneous tissue while the $tcPO_2$ technique measures transcutaneous diffusion of oxygen at more shallow depths from superficial dilated capillaries. The flow restriction in the laboratory studies produced an oxygen deficit in the presence of continuing metabolic demand. The red reflectance and $tcPO_2$ information received from the rhesus monkeys showed pronounced changes after application of the tourniquet. The results indicate that the $tcPO_2$ readings reached their lower limits rapidly, while the DLRS readings for red reflectance continued to resolve the deteriorating oxygen content within the tissues and their vasculature.

For the clinical trials, preliminary data show that subjects described as severe claudicants show behavior similar to that seen in the primate tourniquet studies. In these patients, the red reflectance measured at light source-detector separations of 2 and 3 cm sharply decreases during exercise. The decrease in reflectance corresponds with ischemic pain reported by the patients and indicates a flow limited condition. Data from patients described as mild claudicants showed little change in red and infrared reflectance during exercise.

FUTURE PLANS—Clinical trials will continue with the addition of the $tcPO_2$ probes and reflectance probes located on the lateral mid thigh and the dorsum of the foot. The preliminary clinical trials demonstrate that the DLRS technique appears to effectively detect a flow limited condition found in claudicants, while the laboratory studies reveal that the DLRS technique is more sensitive to graduated changes in oxygen when compared with $tcPO_2$.

RECENT PUBLICATIONS FROM THIS RESEARCH

Oxygen measurement during limb blood flow restriction in primates. Muller MR, Santoro D, Chang HY, Lee BY, Ostrander LE. In: Proceedings of the 17th Annual International Conference of the IEEE Engineering in Medicine and Biology Society; 1995, Montreal Canada. In press.

[200] 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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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, as well as the development and evaluation of new plantar loading parameters. Soft tissue properties of the foot plantar surface will be computed from measured data for load and displacement at the foot plantar surface. This project involves the following objectives: evaluate different means for collecting soft tissue property data from the foot plantar surface; quantify the dependence 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; determine the efficacy of treatments for plantar pressure relief; and assess the value of different plantar pressure parameters and other clinical values.

In addition, we are studying Charcot Arthropathy in two contexts: the factors that may contribute to its onset and an evaluation of treatment methods.

METHODOLOGY—The present evolution of a device that we have been developing for measuring plantar surface tissue properties involves a closed cylindrical air chamber with a flexible diaphragm at one end. A shaft connected to that diaphragm is fitted with a load cell at the other end that imparts load, onto soft tissue of interest, that is proportional to the air pressure in the cylinder. By measuring the imposed compression of soft tissue and the concurrent load on the tissue, we will be able to compute our desired soft tissue material properties (i.e., compliance and resistance).

In another aspect of this project we have computed plantar surface pressure gradients as well as peak pressures for persons walking with orthotic inserts filled with silicone gel, in order to evaluate the potential efficiency of these orthotics. Walking trials with these insoles have included walking with and without insoles and barefoot, and also variations of cadence, as a means of varying stance time.

For Charcot arthropathy, two studies were performed. The first compared the clinical outcome of salvage versus amputation. The second examined the relationship between onset of Charcot arthropathy and organ transplantation and rejection episodes.

PROGRESS—We have recently completed construction of our prototype soft tissue property tester, and are beginning testing with the device. Our preliminary assessment of silicone gel filled insoles on 13 subjects has demonstrated that these insoles show a statistically significant average decrease in pressures as compared to shoes without the insoles. Additionally, the subjects wearing their own shoes without gel insoles showed a statistically significant decrease in pressure over the barefoot condition. We are presently expanding our evaluation of these orthotics to include greater numbers of subjects and more walking condition variations.

The first Charcot arthropathy study showed that salvage demonstrated a statistically significant improvement in gait functionality as measured by velocity parameters. However, this did not translate into improvement of activities of daily living. The transplantation study showed a significant increase in the development of Charcot arthropathy after transplantation, especially after rejection episodes in which steroids were administered.

RECENT PUBLICATIONS FROM THIS RESEARCH

Frequency content of normal and diabetic plantar pressure profiles: implications for the selection of transducer sizes. Davis BL, Cothren RM, Quesada PM, Hanson SB, Perry JE. J Biomech. In press.

[201] A RETROSPECTIVE STUDY OF CASES OPERATED FOR FOOT DROP IN LEPROSY

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PURPOSE—In leprosy, involvement of Lateral Popliteal (Common Peroneal) nerve at the neck of the fibula results in paralysis of dorsiflexors and evertors of the ankle. This causes muscular imbalance both in the sagittal and frontal plane. The foot assumes a posture of equino-varus due to unopposed action of tibialis posterior and gastro-soleus muscles. If left untreated, fixed equino-varus deformity develops, leading to marked instability.

Absence of heel strike during stance and dorsiflexion during midswing phase of gait leads to the typical "high step gait," resulting in overloading of pressures underneath the lateral border and forefoot (in the presence of pre-existing intrinsic paralysis following involvement of posterior tibial nerve at the medial malleolus).

Such a neuropathic foot is vulnerable for developing plantar ulcers, due to repetitive trauma occuring during the gait cycle following concentration of pressures at specific sites. Redistribution of plantar pressures is therefore essential and is achieved by substituting the function of paralysed dorsiflexors by using tibialis posterior which is spared in leprosy.

METHODOLOGY—Thirty feet having footdrop and operated during the last 10 years were studied. All of them underwent the circumtibial route tibialis posterior transfer. Tibialis posterior was inserted by two slips: a medial one into the tendons of tibialis anterior and extensor hallucis longus, and a lateral one into the tendons of extensor digitorum. Tendo-achilles lengthening was done in 21 feet. All cases were given sufficient pre-operative motor isolation and strengthening exercises. After 6 weeks of immobilization in a below-knee plaster cast, post-operative non-weight bearing re-education was started. Three weeks later graded weight bearing was instituted with emphasis on the re-education pattern (phasic contraction of motor muscle) and gait training.

Range of motion, effect of tendo-achilles lengthening gait, plantar pressures, and incidence of plantar ulcers was studied. Plantar pressures were studied using "Harris Mats." Static and dynamic pressures on plain ground and micro-cellular rubber were studied.

RESULTS—In both groups (i.e., tendo-achilles lengthening versus no tendo-achilles lengthening), the majority of cases achieved 10° of active dorsiflexion post-operatively and no high step gait was seen. However, higher values of dorsiflexion (range 10–25°) were seen more predominantly in the group who underwent tendo-achilles lengthening.

A total of six feet developed plantar ulcers (five in forefoot and one in heel). Three patients having persistent high step gait post-operatively developed forefoot ulcers. Three had recurrence and three had occurrence for the first time.

Three patients who showed post-operative varus tendency had a more prominent medial slip action. These patients had total paralysis of peronei muscles. Two patients having intact peronei pre-operatively showed a marked eversion tendency post-operatively, with lateral slip action being prominent.

In the study of plantar pressures, patients having 5° of dorsiflexion showed forefoot overloading. These

cases also had recurrence of forefoot ulcers. Patients with predominant lateral slip overaction or having a tendency for excessive eversion showed loading on the medial border and no weightbearing on the lateral border at all.

FUTURE PLANS—Further studies include studying the influence of the other foot on the operated foot during gait, plantar pressures, and gait in bilateral operated feet, and the co-relation between tendo-achilles lengthening, range of motion, plantar pressures, and incidence of plantar ulcers.

X. Oncology

[202] THE STRENGTH OF HUMAN CORTICAL BONE WITH SIMULATED METASTATIC LESIONS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A741-RA)*

PURPOSE—The objective of this study is to establish a technique for predicting the strength of bones with metastatic tumors. The underlying hypothesis 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 takes advantage of CT scan data to generate three-dimensional, patient-specific, finite element (FE) 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 involves matched pairs of human femoral shafts that are subjected to four-point bending. One of each pair is left whole, and its failure load represents whole bone strength; the other has a spherical defect (6, 12, or 18 mm in diameter), and its failure load represents the strength of a bone with a simulated metastatic tumor. CT scans are taken of all the bones prior to mechanical testing and are used for the generation of the FE models.

The theoretical component of this research involves the generation of the models and calculating failure loads based on model predictions. A cylindrical model is 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 utilizes CT scan data to generate geometries more representative of true bone geometry. A third model uses 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 can be correlated to the failure strengths of the experimental bones, and thus test the overall hypothesis that the use of CT data can improve the prediction of bone strength.

PROGRESS—Six pairs of femoral shafts have undergone the procedure described above. Correlations between measured and predicted strengths have been completed for all three models, demonstrating coefficients of 0.86, 0.95, and 0.98 for the first, second, and third model types.

RESULTS—This study demonstrated that the use of CT scan data in the FE modeling of bone improved the quality of model predictions. Moreover, the heterogeneous, true-geometry models of this study were the first to accurately predict the strengths of bones with and without defects, marking a significant step toward clinical fracture prediction.

FUTURE PLANS—This methodology will be extended to an experiment involving the torsional failure of femoral shafts with defects.

XI. Orthopedics

A. General

[203] HIP FRACTURE RISK ASSESSMENT USING AUTOMATED 3-D FINITE ELEMENT MODELING

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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 Silicon Graphics 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 analyses and mechanical testing have been performed for over half of the femora, and we expect to complete these experiments by fall 1995.

PRELIMINARY RESULTS—For the specimens tested to date, significant correlations were found between measured strength and FE-computed strength for both loading conditions. The correlation for the fall loading condition ($r=0.91$, $p<0.001$) appears to be stronger than that for the stance loading condition ($r=0.74$, $p=0.02$). In comparison with densitometry measures obtained for these same bones, the FE correlations were stronger. The fracture locations predicted by the FE models have generally agreed with the actual fracture locations obtained during mechanical testing.

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

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.

Prediction of femoral fracture load and location using CT scan-derived finite element models. Keyak JH, Lee IY, Rossi SA, Skinner HB. Trans Orthop Res Soc 1995:20:457.

[204] IMPROVED BONE CEMENT FATIGUE RESISTANCE VIA CONTROLLED STRENGTH INTERFACES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Programs, Washington, DC 20420 (Project #A796-RA)*

No report was received for this issue.

[205] BIOCHEMISTRY OF CARTILAGE IN A MODEL OF DISUSE AND DIFFERENT TYPES OF RECOVERY: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Programs, Washington, DC 20420 (Project #A739-RA)*

No report was received for this issue.

[206] DIAGNOSIS OF CARTILAGE DEGENERATION: QUANTITATIVE SURFACE SPECTROSCOPY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Programs, Washington, DC 20420 (Project #A656-RA)*

No report was received for this issue.

[207] AN IMPLANT TO FACILITATE ARTICULAR CARTILAGE REGENERATION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Programs, Washington, DC 20420 (Project #A424-2RA)*

No report was received for this issue.

[208] IMMUNOLOGICAL RESPONSES TO IMPLANT BIOMATERIALS FOLLOWING ARTHROPLASTY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A797-RA)*

PURPOSE—Aseptic loosening, loss of support by the surrounding bony architecture due to osteolysis, is the single most common complication of total joint replacement. Until recently, aseptic loosening has been theorized to be the result of surgical technique and prosthetic design. Since the biological responses to plastics and metals are poorly understood, a reaction against the implanted materials has not been seriously examined as a possible cause of prosthetic loosening. We are examining the hypothesis that implanted biomaterials elicit an inflammatory immune reaction, which may lead to osteolysis with eventual failure of the prosthesis.

METHODOLOGY—Immunological techniques are used to assess both the serological and cellular responses directed against biomaterials in the patient with aseptic loosening. We are examining failed prosthetic implants for the presence of antibodies bound to the implant surface, or reactive with proteins bound to the implant. Polyethylene implants recovered during surgical revision procedures are washed extensively, and bound proteins extracted from the surface. Electrophoresis (SDS-PAGE) is performed to determine the number and molecular weight of the proteins in the extracts. Specific proteins in the extracts are analyzed by immunoblot and Western blot techniques. Celluar responses to biomaterials are measured in peripheral blood mononuclear cells (PBMC) from patients with painful or loosened total joint prostheses, and preoperative patients qualified for total joint replacement. Cells are cultured *in vitro* with polymethylmethacrylate (PMMA) cement, ultra high molecular weight polyethylene (UHMWPE), cobalt-chrome alloy (Co-Cr), and titanium (Ti) particles for seven days at 37° C. Cell proliferation is assayed during the final 16 hours using an MTT conversion assay, and the responses to each biomaterial are calculated.

PROGRESS—Extracts from 26 failed prosthesis have been evaluated for bound proteins. Sera from 24 patients drawn at the time of the surgical revision have been evaluated for autoantibody reactivity to the implant bound proteins. Cellular responses to biomaterials in particulate form have been evaluated in 79 patients. Changes in the responses 1 year after the implantation have been assessed in 28 patients.

RESULTS—Analysis of the implant bound proteins by SDS-PAGE indicated a minimum of one protein band and a maximum of 19 protein bands. Molecular weights of the proteins varied from 129kD–13kD. Immunoblot-

ting revealed the presence of Type I collagen, aggrecan proteoglycans, and immunoglobulin in the extracts. Antibodies reactive against extracted proteins were assessed by Western blot techniques. Serum antibodies from 20/24 implant recipients bound to autologous extracted proteins. The number of reactive bands varied from 1–11, with strong binding against high molecular weight proteins. The data support the hypothesis that immunoglobulin complexed with implant-bound protein may fix complement, and in turn attract inflammatory cells to prosthesis surface. Cellular responses to PMMA in the preoperative patients and the postoperative patients were both high, while responses to UHMWPE were universally low. The response to cobalt-chrome particles was significantly elevated ($p<0.05$) in the postoperative group compared with the preoperative group. Although proliferation responses to Ti were higher in postoperative patients than the preoperative group, it was observed that this difference was due to Ti-related toxicity in cell cultures from preoperative patients (stimulation index <1). These results suggest that all patients respond to stimulation with PMMA particles, but the development of a painful or loosened total joint prostheses may be associated with the response to Co-Cr particles.

RECENT PUBLICATIONS FROM THIS RESEARCH

Antibodies reactive with polethylene bound proteins: a role in aseptic loosening? Wooley PH, Nasser S, Whalen JD, Fitzgerald RH. Arthritis Rheum 1994:37:S186.

Cellular responses to biomaterial particles in patients with aseptic loosening. Wooley PH, Sud S, Song Z, Petersen S, Nasser S, Fitzgerald RH. Arthritis Rheum 1994:37:S186.

Cellular proliferation and cytokine responses to polymethylmethacrylate particles in patients with a cemented total joint arthroplasty. Chadha HS, Wooley PH, Sud S, Fitzgerald RH. Inflammation Res 1995:44:145-51.

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

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A623-2RA)*

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

METHODOLOGY—This project is designed to test 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 are measured over the fracture site within 24 to 48 hours after initial treatment. These measurements are 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, are compared for groups of patients in whom the fractures have been clinically judged to be normally healing or delayed healing at 4 months after fracture. Thus, we will determine if these early electrical measurements can predict whether or not the fracture will heal normally.

Only patients with single fractures of arms or legs treated at the Omaha VAMC, Creighton University Medical Center, and the University of Nebraska Medical Center will be included in the study. Instrumentation and procedure for bioelectric measurements are as described previously for the canine study using EKG-type miniature Ag/AgCl electrodes. Based on X-ray, stress fluoroscopy and pain assessment, Dr. Garvin or Dr. McGuire will classify fractures at 4 months into normal healing (NH) and delayed healing (DH) groups for each class of fractures. This is repeated, if needed, at 2-month intervals until "healing time" (T), when the

fracture is determined to be healed. The temporal patterns of voltages will be described in terms of rate parameters (i.e., rate of decay of the initial potential), magnitude parameters, and time parameters, as indicated above. The relationship between these parameters and T will be analyzed to develop indices that represent electrical signatures for NH and DH groups.

PROGRESS—So far, 15 patients have been enrolled in the study, with fractures of the tibia (7), femur (6), radius (1) and humerus (1).

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

FUTURE PLANS—Additional patients are being enrolled at Creighton University Medical Center and University of Nebraska Medical Center. 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.

[210] NEW METHODS TO TREAT IMPAIRED FRACTURE HEALING USING GROWTH FACTORS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A833-RA)*

PURPOSE—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. 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. Our approach is to identify and correct deficiencies in local mediator mechanisms to stimulate fracture healing.

The specific objectives of the 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 a model of impaired fracture healing, and 2) to determine time-dependent changes in selected osteogenic indices and growth factors, associated with the restoration of normal healing.

METHODOLOGY—The project is designed to test the following hypothesis: biological failures of fracture healing are associated with abnormal (low or high) gene expression and/or synthesis of one or more regulatory 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.

We use surgically created skeletal defects in rat fibula grafted with a DBM cylinder (DBM=acid-demineralized bone matrix) made from femora of allogeneic animals, as experimental models for fracture healing. A 2 mm defect represents a normal healing fracture and a 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 growth factors are applied immediately after the skeletal defects are created. The methodology includes measurement of (a) bending rigidity of the fibula and mineral content of the repair tissue, (b) DNA synthesis, alkaline phosphatase activity, collagen types I, II and X and osteocalcin, and (c) growth factors TGFβ, PDGF, IGF-I, and IGF-II. The steady-state mRNA levels and the amounts of the bone-matrix proteins and growth factors will be measured.

PROGRESS—To determine the characteristics of normal healing, the 2 mm defect model was created bilaterally in rat fibula. Animals were sacrificed at weekly intervals during weeks 1 through 8 and rigidity and mineral content were measured. Measurements (b)

and (c) are in progress. The roles of osteoconductive and osteoinductive processes in the repair of the 4 mm defect grafted with a 7 mm DBM cylinder were investigated in a series of experiments using DBM cylinders subjected to treatments with trypsin (tDBM), guanidine hydrochloride (gDBM), or both (gtDBM). The use of growth factor TGFβ to stimulate healing of this defect was also investigated.

RESULTS—Comparison of results of a standard bioassay for osteoinductive activity (bone induction in rat muscle) and repair of skeletal defect suggests that the bioassay is not a valid predictor of the ability of a biomaterial to promote repair of a skeletal defect. By filling the defect with DBM powder, healing was restored to normal. But a DBM cylinder loaded with 100, 50, 10, 5, or 1 ng of TGFβ did not promote healing.

IMPLICATIONS—The results of this project may lead to new treatments for difficult fracture healing problems without surgery. Growth factors that are found to be effective in this study could be injected into the fracture site. The new treatments will be based on a better understanding of cellular and molecular mechanisms involved in the regulation of fracture healing by growth factors.

[211] FACTORS AFFECTING STREAMING POTENTIALS IN HEALING AND REMODELING BONE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A160-4RA)*

PURPOSE—The processes of bone repair/remodeling are central to the welfare of patients after fractures and/or bone surgery and conditions which affect the homeostasis of bone, ranging from spinal cord injury 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, which may affect bone cells directly or indirectly by stimulation of biochemical intermediaries such as growth factors.

The aim of this research was to identify a previously unrecognized mechanism of action for agents affecting bone, and thus to achieve increased therapeutic control over healing and remodeling process. This study was designed to determine whether or not certain pharmacological agents (or circulatory conditions) known to affect bone healing, regeneration, and/or remodeling may act in part by altering the magnitude or frequency characteristics of the streaming potentials produced by bone in response to a set mechanical loading regime.

METHODOLOGY—A 5mm drill hole in canine tibia was the model used to study changes in streaming potentials produced by new bone in this defect and/or by adjacent cortical bone. The factors studied included blood flow, biochemical agents promoting bone formation/remodeling and agents inhibiting bone formation/remodeling. Eight weeks after surgical creation of the drill holes at the mid/distal third of the bone bilaterally, the animal was anesthetized and 4 mm pins were placed through each tibial metaphysis. Then silver chloride electrodes were placed on the drill hole surface and adjacent cortical bone sites. Streaming potentials were measured differentially between the surface electrodes and an intramedullary electrode during bending loading (4 Hz sinewave) of the pins by a custom-built, servo-hydraulic system. Signals were recorded via preamps and a digital oscilloscope before, during, and after direct injection of the test agent via the femoral artery.

PROGRESS—Final tests were completed on protamine sulphate and guanidine. Screening tests were completed on nine other agents and on eight animals following femoral vein occlusion and/or prior sympathectomy (3 days).

FINAL RESULTS—The first series of six animals included tests of the drill hole configuration and time interval of healing (5mm, 8 wks). Covering the drill hole with a delrin plate during healing until needed for measurement proeedures provided an excellent test bed as the drill hole healed with a flat eortical surfaee and a porosity of 20–40 percent. Final tests showed that Guanidine HC1 reduced the magnitude of streaming potentials in living bone. This reinforced our earlier work on protamine sulfate and brought us one step eloser to the goal of finding an agent that would increase the magnitude of streaming potentials. Unfortunately, it was not possible to identify other agents that produce inereases or decreases in magnitude of streaming potentials when given on an *acute* basis.

While definitive work was not aeeomplished in terms of animals tested, no ehange in streaming potentials was noted on two or more oeeasions in assoeiation with administration of the following agents via the femoral and nutrient artery of the tibia in therapeutie doses: didronyl (bis-phosphonate), NaF, hydrocortisone, argenine (charged amino acid component of protomine), ealcitonin, PGE-2, EDTA, estradiol. Indomethacin was not given due to solubility problems. Furthermore, no eonsistent effect was found in response to lumbar sympathectomy, venous occlusion or administration of papaverine to the hind limb.

IMPLICATIONS—This projeet has a potentially high significance for the aging veteran population with referenee to surgical procedures, wound healing, and bony fixation of internal joints prostheses wherein loosening and/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 and in patients afflicted with osteoporosis or in spinal eord injury. If streaming potentials prove to be modifiable by external intervention, then a new treatment modality will be added to the VA armamentarium.

FUTURE PLANS—Protamine and guanidine reduee the magnitude of streaming potentials, but other agents affecting them on an *acute* basis eould not be identified. Aecordingly, this projeet has been terminated without using additional animals to confirm negative results. To investigate effeets on streaming potentials further, it is reeommended that future work should be aeeomplished on animals given the test agents on a ehronie basis for periods of 2–12 weeks before streaming potential measurements, with results eompared to a control group. Unfortunately, this work was beyond the seope of this project.

RECENT PUBLICATIONS FROM THIS RESEARCH

Intraarterial administration of guanidine HCl reduees streaming potentials in living eanine tibiae. Coehran GVB, Otter MW, Wu DD, Bieber WA. In: Proeeedings of the 14th Annual Meeting of the Society for Physieal Regulation in Biology and Medieine, 1994:29.

Guanidine HCl reduees the magnitude of streaming potentials in living bone. Coehran GVB, Otter MW, Wu DD. Orthop Trans. In press.

[212] BIOCHEMICAL ANALYSIS OF SYNOVIAL ACTIVATION IN JOINT DYSFUNCTION

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PURPOSE—Previous results have indieated that inhibiting interleukin-1 (IL-1) not only blocks synovial responses to IL-1, as expeeted, but also to particulate stimuli of the type implicated in the aseptic loosening of prosthetic joints. This suggests that inhibitors of IL-1, such as the IL-1 reeeptor antagonist (IL-1ra), may be useful agents with whieh to inhibit aseptie loosening. The purpose of this project is to determine whether IL-1ra

inhibits the osteolysis that occurs around particulate materials implanted in rabbit femurs and if so, whether IL-1ra can be delivered by gene transfer technology.

METHODOLOGY—The past year has been devoted to developing a retroviral vector with which to deliver the IL-1ra gene. This has been achieved by cloning a cDNA encoding human IL-1ra into a derivative of the Moloney Murine Leukemia virus known as "MFG." The resulting vector, MFG-IRAP generated with a producer line known as ϑ-CRIP, infects rabbit fibroblasts, leading to the production of large amounts of hIL-1ra. To test the effectiveness of this system in blocking responses to IL-1, a rabbit synovial cell line, HIG-82, was infected with MFG-IRAP and was shown to have a blunted response to IL-1.

PROGRESS—A retroviral vector has been produced with the required biological properties. It has been shown to infect rabbit synovial fibroblasts, leading to the production of IL-1ra in quantities sufficient to protect the cells from IL-1 mediated responses.

RESULTS—The producer line generates the vector at a titer of approximately 10^6 particles/ml. Infection of rabbit synovial fibroblasts with supernatants containing this virus leads to stable transduction of fibroblasts, resulting in the production of up to 150 ng hIL-1ra per day per million cells. Addition of human, recombinant IL-1β to uninfected cells provokes the production of prostaglandin E_2, the matrix metalloproteinase collagenase, gelatinase and stromelysin, and the free radical nitric oxide. Addition of the same amount of hIL-1β to cells infected with MFG-IRAP results in reductions of up to 90 percent in the production of each of these mediators.

[213] IN VIVO MEASUREMENT OF VERTEBRAL DISPLACEMENT AFTER LUMBAR FUSION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Programs, Washington, DC 20420 (Project #A738-RA)*

No report was received for this issue.

[214] FINITE ELEMENT MODELS GENERATED FROM MAGNETIC RESONANCE IMAGES

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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 CAD (Computer Aided Design) 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 30 transverse serial images spaced 12 mm apart.

METHODOLOGY—Visual BASIC® has been used on a 486 computer to take advantage of the graphic 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. Linear interpolation is used in the axial direction, and three-dimensional geometry is reconstructed by stacking the geometries of adjacent transverse sections.

PROGRESS—A prototype program shell with a graphical user interface interface has been developed. Routines include: zoom in, zoom out, scroll up, scroll down (also scroll left, scroll right), point selection and modification, cubic spline fit, 2D mesh generation, 3D mesh generation, 3D fine mesh generation, 3D mesh display, removal of the hidden lines of 3D mesh, view angle selection, and output file of nodal coordinates and element node connectivity. The generation of 3D mesh from MRI data of a tibia is finished.

FUTURE PLANS—The program output will be formatted as a standard input data file for a commercial finite element program. A model of a femur will be generated from MRI data to determine if any modifications to the software will be necessary for other long bones. Once the interface has been created, plans exist to generate finite element models for osteoporosis studies with forces applied at locations of muscle insertion and origin.

RECENT PUBLICATIONS FROM THIS RESEARCH

Pre-processing for generation of finite element models from magnetic resonance images. Wang H, Todd BA. In: Proceedings of the American Society of Mechanical Engineers Region XI Graduate Student Technical Conference; Tampa, FL, 1995. Tampa: USF, 1995:77-9.

Conversion of magnetic resonance images to finite element models. Todd BA, Wang H. In: Proceedings of the 1995 ASME Winter Annual Meeting; San Francisco, CA, 1995. In press.

B. Hip Implants

[215] SUITABILITY OF TITANIUM ALLOY AS A JOINT REPLACEMENT BEARING MATERIAL

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A625-2RA)*

PURPOSE—The purpose of this program is to identify coatings and treatments for titanium alloy that may be used to improve the wear characteristics of this material when used as a bearing surface in total joint replacement arthroplasty.

METHODOLOGY—The initial task involved simulation of the "runaway" wear process observed clinically with titanium alloy on polyethylene bearing surfaces. This is manifested by blackening of the lubricant in association with extensive scratching of the surfaces of both materials. Particles were generated from bulk polymethylmethacrylate bone cement by shaking the material in a SPEX mill for periods of 30 seconds, 1 minute, or 2 minutes. The resulting powder was graded coarse to fine, respectively. The original proposal called for initiating the runaway wear process within 10,000 cycles. Upon initiation of the project and after some

initial experience was developed with the simulator, it was decided that this was too aggressive an approach since even the best of surfaces may be susceptible to excessive wear. Rather, a gradual increase in the concentration of the powder was used and the specimens maintained for 1 million cycles at each concentration level.

An initial run using an untreated polyethylene and titanium alloy bearing combination was conducted to verify that the runaway wear process would not be demonstrated under clean conditions. The runaway wear process could not be established under clean conditions up to 2.5 million cycles. Progressively greater amounts and coarser powder was used with 60 ml of serum lubrication. The test was halted when the serum became black or when 10,000 cycles was reached, whichever came first. Runaway wear was observed in three of four chambers by 3,000 cycles with 10 mg of 2 minute powder.

PROGRESS—Two coatings have been evaluated to date: nitrogen ion implanted components, and an oxygen diffusion hardened (ODH) coating. Under clean conditions the nitrogen ion implanted components showed excessive femoral ball wear in only 3 million cycles. This series of tests was discontinued at that time. In a second series of tests with the ODH treatment, pristine surfaces were maintained at up to 10 million cycles. In a related study, the generation of polyethylene wear debris from the interface of the polyethylene liner and metal shell was studied. Five components of each of five contemporary acetabular designs were subjected to sinusoidal loading for 10 million cycles.

RESULTS—The femoral balls are currently undergoing detailed analysis to determine the residual coating thickness and any micro damage that may have been imparted to the surfaces. The wear rate of the polyethylene averaged $33.4 \pm 3.2 mm^3$/million cycles which compares favorably to the value of $31.6 mm^3$/million cycles reported by McKellop, et al for CoCr heads against conventional polyethylene. With the modular components 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.

FUTURE PLANS—Currently modular components are being evaluated to assess the influence of material (titanium versus cobalt chrome) and surface finish (polished versus unpolished) on the wear of polyethylene at the shell/liner interface under wear simulation conditions. An additional series of wear simulator tests will be conducted using nitrided surfaces.

RECENT PUBLICATIONS FROM THIS RESEARCH

Wear of the polyethylene liner-metallic shell interface in modular acetabular components: an in vitro analysis. Lieberman JR, Kay RM, Hamlet WP, Park S-H, Kabo JM. J Arthroplasty. In press.

[216] CHANGES IN BONE BLOOD FLOW ASSOCIATED WITH INTRAMEDULLARY NAILING

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Programs, Washington, DC 20420 (Project #A708-RA)*

No report was received for this issue.

[217] OPTIMIZED SURFACE BONDING AND STIFFNESS OF FEMORAL ENDOPROSTHESES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Programs, Washington, DC 20420 (Project #A498-2RA)*

No report was reeeived for this issue.

[218] PULSED LASER DEPOSITED HYDROXYAPATITE COATING FOR PROSTHESIS-BONE BONDING

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Programs, Washington, DC 20420 (Project #A714-RA)*

No report was received for this issue.

[219] NEW STRATEGIES FOR LONG-TERM PERFORMANCE OF FEMORAL PROSTHESIS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A667-RA)*

PURPOSE—In hip arthroplasty with noncemented, porous-surfaeed, 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 performanee of femoral prostheses by adjuvant treatments with seleeted therapeutic agents applied loeally during hip arthroplasty in an experimental model.

METHODOLOGY—The experimental model is a canine femoral prosthesis implanted in the right femur of the dog. Before implantation, the prosthesis is treated with either chitosan (CH) or hydroxyapatite (HA). Coating with chitosan solution is done under vacuum at room temperature. Hydroxyapatite coating is also applied at room temperature by an electrolytic proeess. Prostheses eoated with physiologieal saline under vaeuum are used as eontrols. Dogs implanted with the femoral component of the canine hip prosthesis are

sacrifieed at 6 weeks and 6 months for evaluation of short- and long-term performanee, respeetively.

The femur with the implant is seetioned transversely, and adjacent seetions are used for push-out tests, histology and seanning eleetron mieroseopy in the baekseattered eleetron mode (SEM/BSE). Osseous and soft tissue formation within the pores of the prosthesis and around it and remodeling ehanges in the femur are quantified from SEM/BSE and histology using a eomputer-aided morphometry system. Standard statistieal methods are used to determine eorrelations between meehanieal and morphologieal data from adjaeent transverse seetions. Statistieal eomparisons between groups (untreated eontrols, treated groups) are done by paired analysis of transverse seetions obtained from a given anatomieal site.

PROGRESS—A total of 32 dogs were implanted with the prosthesis (26 for 6-week study; 6 for 6-month study). The 6-week study eonsisted of 8 dogs treated with ehitosan, 9 with hydroxyapatite and 9 eontrols. The 6-month study had 2 dogs in eaeh group. Two samples from eaeh dog were used for push-out tests and up to four seetions adjaeent to these were used for histomorphometry and SEM/BSE morphometry. Measurements of depth and area of ingrowth of bone and soft tissue into the prostheses are in progress.

RESULTS—In several of the dogs, a periprosthetie membrane was observed at 6 weeks, whieh was assoeiated with lower bonding strengths in the push-out tests. The average strengths for the three groups did not show any statistieally signifieant differenees. The mean values were nearly the same for CH and eontrol, but the mean value was approximately 20 pereent higher for the HA group. When the dogs with the periprosthetie membrane were exeluded from the analysis, the CH group had approximately 40 pereent greater average bonding strength eompared to eontrol ($p<0.03$), whereas the HA had only slightly (12 pereent) higher strength. Partial results from SEM/BSE morphometry eorrelated with these results. Chitosan group had a 40 pereent inerease in depth of bone ingrowth ($p<0.03$). The bone:soft tissue ratio of the area of tissue ingrowth for the CH group was nearly 2.5 times that of the eontrol ($p<0.01$). The slight inereases in these variables for the HA group were not statistieally signifieant. Histomorphometry data showed that the remodeling ehanges in the three groups were nearly the same.

IMPLICATIONS—Chitosan treatment appears to enhanee funetional performance of the prosthesis. It may be eonsidered for elinieal use, provided the safety of chitosan as a therapeutic agent for human use can be established through standard toxieity studies.

[220] THE EXAMINATION OF EXPLANTED, UNCEMENTED ORTHOPAEDIC PROSTHESES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A473-2DA)*

PURPOSE—The objective of this study is to assess the long-term feasibility of porous eoating as a meehanism for fixing orthopedie prostheses to bone. Additionally, the influenee of design and material on the performanee of these prostheses is being determined through this analysis.

METHODOLOGY—Examination of elinieally retrieved hip and knee prostheses allows the assessment of material, design, and porous eoating, and their impaet on the prosthesis/bone interfaee. The study addresses issues of stress shielding, ion release, and wear debris formation, and elarifies eausal relationships with prosthesis parameters. Retrieved prostheses are fixed in formalin, examined macroscopieally, and graded for wear, eorrosion, fretting, and tissue adherenee. Metal eomponents are mapped for tissue apposition, embedded, seetioned for histology, and stained. Post-mortem

specimens permit assessment of bone resorption and stress shielding. Polyethylene bearing surfaces are macroscopically graded for damage and defects, while consolidation, oxidation level, and mechanical properties are determined using microtomed sections.

PROGRESS—The major focus this year has been investigating sources of failure of polyethylene acetabular and tibial bearings. Our previous examinations have revealed that the early failure of polyethylene bearings is relatively independent of patient and implantation variables, and implant design. This led to the detailed examination of hundreds of microtomed sections of polyethylene, including bar stock, virgin components, and retrieved prostheses.

RESULTS—Microtome sections of many polyethylene components revealed a white band following the contour of the components approximately one millimeter below the surface. Analysis showed a startling correlation between the presence of the white band and the wear modes of cracking and delamination: 100 percent of polyethylene components with cracking, and more than 90 percent of components with delamination, revealed the white band upon sectioning. Chemical analysis using FTIR revealed that the white band was an area of high oxidation which occurred subsurface in the samples. Investigation of identical components with different service histories has allowed us to eliminate *in vivo* environment and stress as sources of the band, and to establish that gamma sterilization in an air environment is a critical factor in the development of the white band. Retrieval studies showed that the white band may not appear until nearly 3 years post sterilization.

A novel technique was developed in which thin sections from hip and knee components were produced and tested for mechanical properties. The tests revealed that components with the white band were significantly weaker and less ductile than components without the white band. Further testing of the individual zones in the components revealed that while the surface of the prosthesis maintained original material properties, the white band region had severely reduced ductility and strength.

IMPLICATIONS—This study has shown that one of the major causes of delamination and cracking in knees and hips is the sterilization method of gamma irradiation in air, which has been a standard industry technique for the past 10 to 15 years. In light of these results, most device manufacturers are re-evaluating their sterilization practices. Several companies are currently in the process of changing to a method other than gamma sterilization in air.

To evaluate these alternative techniques, we have developed a protocol for accelerated "aging" of polyethylene bearing material. The focus of our work now is to incorporate our clinical retrieval results with laboratory testing to investigate ways to increase the *in vivo* service life of prosthetic implants.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Impact of gamma sterilization on clinical performance of polyethylene in the hip. Suiula LC, et al. Clin Orthop Rel Res 1995. In press.

C. Arthritis

[221] AN IN VIVO MODEL FOR CARTILAGE REGENERATION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A799-RA)*

PURPOSE—The object of this work is to produce a neocartilage covering over subchondral bone in a load-bearing joint after the normal hyaline cartilage has been removed. It is our hypothesis that an environment can be created in a load-bearing joint where the mechanical effects of compression and abrasion are temporarily suspended. During the time when the mechanical effects of compression and abrasion are not damaging the joint surface, which has been denuded of all articular cartilage, some new tissue, perhaps neocartilage, will grow.

METHODOLOGY—The model for producing a site in a load-bearing joint where mechanical compression and abrasion are not allowed to interfere with new tissue growth was designed. First, we selected a load-bearing joint with a large enough contact surface to provide material for study which would include biochemical, biomechanical, and histologic evaluation.

We chose the dog patella because it provided an adequate amount of tissue for study. In addition, the dog patella comes reasonably close to simulating the human patella in that it is under a very large compression load. The model is created by removing all of the hyaline cartilage from the experimental patella. This process extends to a point where there is raw bone with punctate bleeding on its surface. Thus, we have a source of progenitor cells. The next step in the creation of the model is to insert a high density polyethylene spacer into the proximal and distal poles of the patella. The stems of the spacers are threaded so that they can be inserted into drilled and tapped holes in the subchondral bone, and the external surface is dome-shaped. The dome has been designed to conform to the femoral groove on the contralateral surface of the dog patello-femoral joint.

PROGRESS—The first goal for this project in the first year was to create a model for shielding a site in a load-bearing joint in which new tissue growth could take place.

The second objective in the first year of the study was to design the spacers so they would do minimal damage to the normal, gliding surface; that is, the femoral side of the patello-femoral joint. The final design of spacer successfully separated the moving joint surfaces allowing tissue to grow, and at the same time, the spacers caused minimal damage to the normal articular cartilage left intact on the femoral side of the patello-femoral joint.

RESULTS—Histologic sections taken 6 weeks after surgery through the distal femur showed that the normal hyaline cartilage was thinned minimally to only 70 to 80 percent of normal height or thickness. Further, histologic examination showed that there was no reactive change in the normal cartilage or subchondral bone. The animals walked with little or no inhibition within 3 or 4 days after the operation. Thus, we have successfully completed the first phase of this research project.

FUTURE PLANS—The project now moves to a phase in which the new tissue growing in the shielded environment will be subjected to analysis. The next step is to determine when the new tissue has reached a mature stage. When that question has been resolved, the spacers will be removed, and normal joint stresses will be reintroduced. The final phase of this study is designed to answer the question: how well and how long will the new tissue perform once the normal joint stresses have been reintroduced.

IMPLICATIONS—Injury to articular cartilage or degenerative arthritis in weight-bearing joints is a major problem in rehabilitative medicine and constitutes the main cause of joint impairment. Once damage has been initiated, arthritis of the joint is an inevitable conclusion. Such problems are frequently treated symptomatically with physical therapy and medication, and ultimately, by joint replacement or joint fusion. These are not attractive solutions, especially for patients who are younger and whose lifestyle demands upon implants often exceed their functional capabilities.

Alternatives to artificial arthroplasty are under intense study. One such alternative is the application of biological resurfacing techniques. The model described above can and may well provide another practical method of creating a biologic resurfacing in load-bearing joints.

XII. Orthotics

[222] COMPLIANCE MONITOR TO MEASURE PATIENT WEARING-TIME FOR SPINAL ORTHOSES

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PURPOSE—Spinal orthoses play an important role in the treatment of spinal injuries, low back pain, and spinal deformities. Whether or not a patient complies with the prescribed orthosis wearing hours is considered to greatly influence the clinical outcome of orthotic treatment. At the present time a reliable and objective method of measuring orthosis wearing-time is lacking. Current estimates are based on self-reported compliance and estimated wear and tear of the orthosis itself. As a result, there are no objective data to evaluate whether a correlation exists between the orthosis wearing-time and outcome of treatment for a given disorder. Further, there is no rational basis to determine the minimum number of wearing hours necessary to achieve good outcome for a given condition and type of orthosis.

In the proposed study we intend to refine the existing design of the compliance monitor that has been developed in our laboratory, and assess its accuracy and reliability in measuring wearing-time for spinal orthoses under a variety of clinically relevant conditions.

METHODOLOGY—The study will be carried out in four stages. In the first stage, we will refine the existing design of the compliance monitor that has been developed in our laboratory. This step will involve refinements in the current design of the data recorder unit and software. Next, we will assess the effects of temperature, humidity, and wear duration on the accuracy and reliability of the refined compliance monitor in the laboratory over a period of up to 3 months. Laboratory testing will allow us to precisely control the temperature and humidity conditions with the use of an environmental chamber and the number of hours an orthosis is worn per day. The orthoses, instrumented with compliance monitors, will be tested on plaster casts under four environmental conditions and five wearing durations for up to 3 months. In the third stage, we will validate the ability of the compliance monitor to make accurate measurements of orthosis wearing time during activities of daily living using volunteer subjects. Although preliminary studies indicated satisfactory function of the sensors and the recording unit, these tests were limited in the duration of wear time and the number of subjects. In the proposed study, 10 volunteers will be tested over a 1-week period, with up to 23 hours/day of orthosis wear time. Finally, we will evaluate the effect of long-term exposure to activities of daily living on the durability and accuracy of the compliance monitor. Twenty patients will participate in this phase of the study with informed consent. The patients will be tested for up to 3 months, thus providing long-term data on the performance of the device.

RESULTS—This is an initial report.

FUTURE PLANS/IMPLICATIONS—Availability of an accurate and reliable technique to measure how long a patient wears a prescribed spinal orthosis will allow clinicians to objectively study the relationship between patient compliance and outcome of orthotic treatment, and arrive at rational guidelines for prescribing orthosis wearing hours.

[223] DEVELOPMENTAL ENHANCEMENT AND APPLICATION OF THE VA-CYBERWARE PROSTHETICS-ORTHOTICS OPTICAL LASER DIGITIZER

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PURPOSE—The objectives of this project are to continue refinement and developmental enhancement of the VA-Cyberware Prosthetics-Orthotics Optical Laser Digitizer and 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 limb amputees' residual limbs and orthotics patients' limb segments.

METHODOLOGY—To achieve these objectives, the following research protocol has been established:

1. Refine the specifications for, procure, and test a new, more advanced design, optical digitizer prototype, which corrects the deficits identified in the initial digitizer prototype, and further enhances its capabilities and performance
2. Enhance and optimize the control, data acquisition, image generation, image processing, measurement and analysis software modules, developed with the initial prototype digitizer, and integrate them into a composite, user-friendly, menu-driven program for use by clinicians
3. Continue development of design templates based on optically digitized measurements for use in prosthetics computer-aided socket design (CASD)
4. Refine and optimize the control, tool path clearance, and the surface contour interpolation and smoothing software for the VA-HMO Five Degree-of-Freedom Prosthetics-Orthotics CAM CNC milling machine 5. Develop CAD templates for design of ankle-foot orthoses (AFOs) and knee-ankle-foot orthoses (KAFOs) from optically digitized limb segment measurements
6. Continue investigations with the optical digitizer in estimation of limb segment effective joint center trajectories for application in orthotics CAD and biomechanics research.

PROGRESS—Specifications for a new, more advanced design, prosthetics-orthotics optical digitizer have been developed that correct the deficits identified in the initial prototype, and that further enhance its capabilities and performance. A new prototype based on these specifications is under construction. Work on enhancing and optimizing the code for the control, data acquisition, image generation, image processing, and image measurement and analysis software modules developed for the original optical digitizer prototype is progressing. Work has also begun on integrating these modules into a single, composite, user-friendly, menu-driven program for use by prosthetics-orthotics clinicians. A new automated method of testing and calibration, enabling correction of optical nonlinearities optimizing the digitizer's field of view, has been developed. Work on enhancement and optimization of the control, tool path clearance, and the surface contour interpolation and smoothing software for the VA-HMO Five Degree-of-Freedom Prosthetics-Orthotics CAM milling machine is underway. Scans and fittings of amputee and orthotics test subjects for CAD system socket and orthosis design from optically digitized residual limb/limb segment measurements is being conducted with five test subjects. Similarly, investigations using the optical digitizer in estimation of patient limb segment joint center trajectories is proceeding on a limited basis until construction and testing of the new digitizer prototype 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: 1) 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; 2) 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; and 3) application as an instructional aid for direct visual presentation of concepts and principles in prosthetics and orthotics education.

RECENT PUBLICATIONS FROM THIS RESEARCH

VA-Cyberware lower limb prostheties-orthoties optical laser digitizer. Houston VL, Mason CP, Beattie AC, et al. J Rehabil Res Dev 1995:32(1):55-73.

[224] 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 computer-aided design and computer-aided manufacturing (CAD/CAM) system to quantify and automate the design and manufacture of better fitting, more comfortable, and more functional orthopedic footwear for US veteran pedorthic patients.

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

1. Identify VA Orthopedic Shoe Service (OSS) orthopedic footwear design and manufacturing requirements, and develop an intuitive, user-friendly, functional, clinically effective, and efficient pedorthic CAD/CAM system meeting these requirements
2. From the 10,000 pedorthic patients served by, and whose medical/podiatric/pedorthic records, and custom orthopedic lasts, and shoe patterns are on file in the NY VAMC Prosthetic Treatment Center Orthopedic Shoe Service, sample 250 representative patients, compiling pertinent information in a computerized relational database on their medical/podiatric/pedorthic conditions and footwear prescriptions, and digitized records of their lasts and shoe patterns (and when available, casts of their feet), together with digitized records of the stock library lasts from which their custom orthopedic lasts were constructed
3. Analyze the data compiled in the project database to establish last, inlay, and shoe pattern quantitative design principles, and derive statistical average values for the most common types of modifications and design features per each category of patient, for use in developing respective pedorthic CAD system design templates
4. Conduct limited clinical tests to identify those areas/features of the pedorthic CAD/CAM system developed that are successful and those that require further research and development.

PROGRESS—A pedorthic CAD/CAM system incorporating the VA-Cyberware optical laser digitizer, the Tekscan F-Scan in shoe stress measurement system, the Vorum Research Lastfit CAD last design system, the Gerber Garment Technologies FDS CAD shoe upper pattern design system, the VA-HMO CAM milling machine, and an Hewlett Packard Draft Pro (pattern) plotter/cutter has been developed. The constituent systems have been interfaced and various enhancements introduced to satisfy VA OSS design and manufacturing requirements. Additional adjunct software modules have also been developed enabling optical scan model variable reference center selection, last regional bound-

ary identification and registration, model surface smoothing, accurate stress transducer calibration, and data incorporation for insole design.

Two hundred eighty-nine subjects from the VA OSS pedorthic patient population have been sampled, their pertinent medical/podiatric/pedorthic information recorded in the project database, and their custom orthopedic shoe lasts, the stock library lasts from which they were derived, and their orthopedic shoe upper patterns have been optically digitized and compiled in the project database. Statistical analysis of the data is being performed to establish parametric statistical distributions and means for use in development of CAD last and shoe upper pattern design templates.

CAM toolpath correction, clearance, and surface smoothing software for last manufacture has been written and tested. Clinical trials of the project's pedorthic CAD/CAM system with four control subjects and five US veteran pedorthic patients are being conducted.

FUTURE PLANS—Refinement and enhancement of the project pedorthic CAD/CAM system shall continue. Utilization of the results and knowledge obtained in this project, together with results obtained by the investigators in their other research in tissue biomechanical characterization, measurement of static and dynamic loading, and foot/ankle biomechanics, is planned for development of new, improved, biomechanically based orthopedic footwear designs.

[225] ASSESSMENT OF THE EFFECTIVENESS OF FABRICATED INSOLES: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #A94-832AP)*

PURPOSE—We seek to assess the feasibility and safety of fabricating custom cork insoles and to test standard polyurethane insoles and custom cork insoles together with our prototype study shoe in 24 diabetic men with foot insensitivity over a 6-month interval.

METHODOLOGY—We began this pilot cross-over clinical study to demonstrate the feasibility of fabricating a cork insole for use with our custom therapeutic footwear. Patients were assigned to either a) cork or b) standard polyurethane molded insoles to be used in a casual walking shoe we designed specifically for this study. Patients wore one type of insole for 4 weeks and then crossed-over to the opposite type insole for the next 4 weeks. They then were asked to wear the insole of their choice with the special prototype shoe for the next 4 months. We are now collecting data for the patients' 6-month study visit.

PROGRESS—Study patients were older (mean age 66 years old), predominately white (92 percent), and fairly well educated. More than half of the patients reported a clinical duration of diagnosis of diabetes of less than 10 years. Sixty percent were found to be clinically neuropathic in one or both feet at baseline, and 40 percent presented with at least one mild foot deformity.

More than two-thirds of patients were using off-the-shelf insoles (36 percent) or custom insoles (32 percent), and one patient (4 percent) was currently using extra-depth shoes. These patients reported good foot self-care, washing their feet an average of 5 times a week and examining their feet for sores or irritations an average of six times a week. However, nearly half reported that they did not break in new shoes by wearing them for short periods of time.

There were no breaks in the cutaneous barrier in either standard or cork insoles, though six patients were determined to be at risk of skin ulceration while wearing standard insoles. These insoles were modified to relieve pressure off the dorsal surfaces of the toes. No modifications to cork insoles were clinically required.

[226] ANALYSIS AND DESIGN MODIFICATION OF A PAEDIATRIC ANKLE-FOOT ORTHOSIS

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PURPOSE—Approximately 100,000 ankle-foot orthoses (AFOs) are prescribed annually in North America for children and adolescents with neuromuscular disorders, such as spina bifida and cerebral palsy, in order to limit unwanted movement and maximize functional activities. The current AFO fabrication process is a lengthy and labor intensive process, and requires at least two client visits. There is a need for the development of an AFO that can be prescribed in a single visit at a lower cost. Through finite element analysis, new materials and design, modifications of orthotic devices can be investigated in order to decrease their cost and time of fabrication. To accurately model these complex systems a knowledge of the loads that an orthosis undergoes during functional activities is required.

PROGRESS—The first stage of the research is to determine the interface pressures between the subject's limb and AFO during gait in order to obtain the stress distribution for use with finite element modelling. Areas of interest include the plantar surface and ankle malleoli regions of the AFO which are believed to contribute to the majority of the loading of the AFO. A data acquisition system has been developed to obtain the interface pressures between a subject's limb and the AFO. Uniforce sensors were chosen to measure the interface pressures because of their thin sensor design, durability, overloading capability, and relative low cost. A preliminary trial was performed with an adult able-bodied subject with thin pressure sensors mounted on the plantar surface, medial and lateral ankle malleoli regions, and upper cuff of the AFO.

FUTURE PLANS—The final stage of this research is to determine the required thickness of the AFO and effects of alteration of the orthosis trimlines with proposed new material combinations using the finite element method. Interface pressures measured during gait analysis will be applied to a digitized computer model of the AFO and a dynamic analysis will be performed. A case study will be conducted with a paediatric subject with spina bifida. This research will further our understanding of the mechanical characteristics of the AFO and should also provide some idea on interface pressures that may be useful clinically.

RECENT PUBLICATIONS FROM THIS RESEARCH

Pilot study on ankle-foot orthosis loading during gait to determine the stress distribution for finite element modelling. Parker KZ, Naumann S, Cleghorn WL. In: Proceedings of RESNA International '95; 1995, Vancouver, BC; Arlington, VA: RESNA Press, 1995:189-91.

[227] CRITERIA FOR INTERFACING AND CONTROL OF A POWERED UPPER EXTREMITY ORTHOSIS

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Sponsor: *National Institute on Disability and Rehabilitation Research, U.S. Department of Education, Washington, DC 20202; Nemours Research Programs, A.I. duPont Institute, Wilmington, DE 19899*

PURPOSE—This project is concerned with the development of an upper limb orthosis, intended primarily for individuals with muscular dystrophy. What characterizes this etiology is the 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 attitude is superior to a total substitution of his manipulative function with a robot. This project explores ways of doing this 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 build-up 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 of motion of such a device is 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 also 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—A series of prototypes have been designed and evaluated. Promising technologies include a novel mechanism for mechanically countering gravity, bowden cables to transfer forces to the base frame of the unit, and utilizing nonlinear springs to control the effective impedance of a joint.

A powered test bed has shown that a force amplification scheme is viable and has also illustrated possibilities for utilizing other control sites. Several force amplification schemes have been evaluated and a force to velocity relationship found to be the most intuitive.

RESULTS—A set of tasks needed by the target population has been identified. An active test-bed and several passive orthotic prototypes have been designed, enabling the affected individual to place an arm anywhere in 3-D space within the limitations of the arm. Active and passive systems allow the orthosis to be moved with a minimal demand on his muscular system, although eventually the system must have the capacity for active control of the person's arm.

[228] LIGHTWEIGHT, COSMETIC, ARTICULATING ANKLE-FOOT ORTHOSIS

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Sponsor: *National Institute on Disability and Rehabilitation Research, Washington, DC 20202*

PURPOSE—The purpose of this project is to develop a lightweight, cosmetic, articulating ankle-foot-orthosis (AFO) that restrains dorsiflexion but permits unencumbered plantarflexion. Allowing free plantarflexion from neutral accommodates the loading response and permits a smooth transition from swing to stance without the knee flexion thrust that accompanies a rigid system. Currently there is no acceptable AFO design that meets the needs of children whose calf strength is below normal while anterior compartment strength and proprioception are within normative range. Practitioners must provide either a conventional metal AFO with dual adjustable ankle joints or a totally rigid or totally flexible plastic AFO. Each of these choices presents objectionable qualities.

PROGRESS—One rigid and three articulating AFOs were selected for clinical study. These are the Gillette with a posterior restraining strap, the Gaffney with a limited motion stop, and the Rancho with an adjustable plantar/dorsiflexion stop. Instrumented gait analysis has been performed on six subjects with flaccid paralysis of the plantarflexors, but strong dorsiflexors. Subjects ranged in age from 5 to 12 years with diagnosis of either incomplete cauda equina lesion or Guillian-Barré.

Motion analysis revealed that the rigid AFO was more capable than all of the articulating AFOs at restraining excessive terminal stance dorsiflexion. Mean dorsiflexion at terminal stance for the rigid AFO was 13° versus 17, 15, and 15.5° for the Gaffney, Gillette and Rancho designs respectively. Stride characteristics recorded during walking were similar for all four brace conditions. Velocity with all AFOs was measured between 55 and 61 m/min (approximately 72 percent of normal). Mean stride length for the four brace conditions was also very similar, measuring from 0.935 to 0.942 meters.

Knee joint torque recorded from the ground reaction forces showed less knee flexion torque during loading response for the rigid AFO compared to the articulating AFOs. This was unexpected as it was thought that an articulating AFO would permit a more normal transition from swing to stance by avoiding the knee flexion thrust caused by a rigid AFO. Investigation of EMG data showed that quadriceps activity was increased during terminal swing and loading with a rigid AFO. This produced more knee extension prior to heel strike, thereby reducing knee flexion thrust, though at a penalty as evidenced by the increased EMG.

Three patients were tested to document the effects of setting the dorsiflexion stop in one of three positions: 10° of dorsiflexion, neutral, and 10° of plantarflexion. Preliminary data indicates that changing the position of the dorsiflexion restraint did alter the mechanics of the ankle and knee. Specifically, all subjects had progressively less dorsiflexion in terminal stance as the brace stop was adjusted from a position of dorsiflexion to plantarflexion. Peak terminal stance dorsiflexion was reduced by 22 to 43 percent when restrained in a position of more plantarflexion. Additionally, peak knee flexion position in loading response was changed in two subjects, providing progressively less knee flexion as the stop was moved into plantarflexion. Finally, the one subject who was unable to fully extend the knee in stance with the stop set in dorsiflexion or neutral was able to achieve an extended posture during the plantarflexed condition.

RECENT PUBLICATIONS FROM THIS RESEARCH

Viscoelastic properties of plastic pediatric AFOs. Lunsford TR, Ramm T, Miller JA. J Prosthet Orthot 1994:6(1):3-9.

[229] DEVELOPMENT OF A MODULAR-DESIGN CUSTOM-FIT ANKLE-FOOT ORTHOSIS

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Sponsors: *Ontario Rehabilitation Technology Consortium funded by the Ontario Ministry of Health; The Hospital for Sick Children Foundation*

PURPOSE—The current method of producing custom ankle-foot orthoses involves taking a negative plaster cast of the shank-foot, forming a plaster positive mold, and vacuum-forming a high-temperature thermoplastic sheet over the mold. This method is labor intensive, resulting in at least two client visits before orthosis delivery and leading to high costs. The aim of this project is to develop a modular ankle-foot-orthosis which can be fit to a client in a single 2-3 hour visit at a lower cost than the present design. A material which can be formed as a prefabricated blank in the general form of an orthosis and custom formed directly on the client's limb will be developed.

PROGRESS—Shank-foot molds are currently being digitized to provide shape information for the prefabricated blanks. Material strains and ground reaction forces have been measured in gait trials of subjects wearing conventional orthoses instrumented with strain gauges. A fatigue testing system based on the measured orthosis deformation and loading is being set up for mechanical testing of prototypes. New materials have been developed to be formable and have similar mechanical properties to polypropylene. Mechanical testing has been carried out on numerous samples. Several full orthosis test prototypes have been fabricated.

FUTURE PLANS—Prototypes made using the new material will be subjected to mechanical testing. Clinical testing to optimize fitting procedures will then take place followed by clinical evaluation to assess the effect of the new orthosis on ambulation.

RECENT PUBLICATIONS FROM THIS RESEARCH

Strain and deformation in ankle-foot orthoses during gait. Kofman J, Sheil E, Slack M, et al. In: Proceedings of the Second World Congress of Biomechanics, Amsterdam, 1994.

[230] DETERMINATION OF THE EFFECT OF RANGE OF MOTION CHANGES IN AN ARTICULATED ANKLE FOOT ORTHOSIS ON LOWER EXTREMITY MUSCLE DEMANDS

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Sponsor: *Post Polio Clinic of the Albert Einstein Medical Center Philadelphia, PA; Calhoun Fellowship Endowment of Drexel University, Philadelphia, PA.*

PURPOSE—In a continuing project to utilize EMG signals to assist in the orthotic alignment procedure, the effect of range of motion restrictions in an articulated ankle foot orthosis on muscle demands in a Post Polio

Syndrome (PPS) population is being studied. Prior work had indicated that statistical analysis of integrated linear enveloped stride EMG signals from differing physical restrictions (test conditions) allowed comparison of muscle activity corresponding to these conditions. The initial and post accommodation responses to new alignment conditions were assessed.

METHODOLOGY—Subjects walked with their own orthotics in several different range of motion restrictions. Surface EMG signals from tibialis anterior, soleus, rectus femoris, vastus medialis, vastus lateralis, and biceps femoris (long head) were recorded. Data were collected immediately after administering the change in range of motion to the orthosis and again after the subjects had used the orthosis in the new alignment for a period of 1 to several months. Linear enveloped and integrated stride EMG data from different conditions were statistically compared. Ensemble averaged (visual) profiles were also compared to the numerical data.

PROGRESS—PPS subjects were used to gage whether a population with neuromuscular deficiencies responded in a way similar to that of nondisabled subjects. Heart rate (as an indicator of overall energy expenditure), joint moment data, and subject opinions were measured to corroborate the statistical findings in EMG data.

PRELIMINARY RESULTS—Muscle response was well defined and consistent in the PPS subjects. The processing method used facilitated the statistical comparison which showed highly significant changes between test conditions. Statistical comparison seemed to provide a higher resolution than the more common visual analysis of ensemble averaged EMG profiles. Heart rate did not show any significant changes, most likely due to the small amount of time the subjects had to walk in each condition. A heart rate plateau was not reached. Joint moment date was incomplete since it was chosen not to ask subjects to actively target force plates which would constrain their gait and influence the EMG data. Nonetheless, there was a modest correlation between the moment and EMG data. Trends in the EMG data suggested that the initial response to any new condition may be an extreme one where there was either maximal or minimal muscle activity.

FUTURE PLANS—Further work includes testing additional subjects as well as developing a biomechanical model to predict the effect of range of motion constraints, due to an orthosis, on muscle demands.

XIII. Psychological and Psychosocial Disorders

[231] 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 #D828-RA)*

PURPOSE—This research investigates the benefits of produetive activity in the rehabilitation of patients with diagnoses of schizophrenia. The key questions are: a) Does pay increase participation in a therapeutic work placement and lead to higher rates of work placement in the community? b) Do high intensity services yield better elinical and rehabilitation outcomes than standard services? c) Is productive aetivity assoeiated with better clinical and rehabilitation outcomes for patients with schizophrenia. d) Is community placement associated with better rehabilitation and clinical outcomes? e) Is performance on psychological, neurobehavioral, and work performanee measures a useful predictor of rehabilitation outcomes? This study continues a program of previously funded researeh whieh has found signifieant clinical benefits and cost of care saving associated with work rehabilitation.

METHODOLOGY—One hundred twenty subjeets with DSM-IV diagnoses of schizophrenia will be recruited, stratified by prior work funetion and randomly assigned to one of two pay situations: Pay ($3.40 per hour for up to 20 hours of work a week) and No pay (work for no monetary remuneration); and to one of two levels of service intensity: High (regularly scheduled individual and group eounseling and work performanee feedback) and Standard intensity (individual eounseling as needed). Clinieal status, produetivity, and other measures were evaluated at baseline and re-evaluated at 5 and 12 months.

PROGRESS—Projected goals have been met: a) all instruments and materials have been gathered and organized; b) intake and weekly data bases have been created and data entry is up to date; c) forty-one subjects have entered the study and been randomized in the first six month. This represent recruitment of the first third of subjects and is well ahead of the projected rate of recruitment of 25 percent; d) randomization has been uniform to all conditions as follows: 21 subjects to the Pay and 20 subjeets to the No-pay condition and 21 subjects to the High intensity 20 subjects to the low intensity condition. e) services have been created and are being delivered as described in the protocol e) twelve subjects have completed the six month intervention and follow-up evaluation.

RESULTS—Although analysis of main effects would be premature, the data suggest that pay continues to be a robust predictor of partieipation in work services. Of the 21 subjeets randomized to the Pay eondition all accepted a work plaeement and only two diseontinued participation during the first month. Of the 20 subjects randomized to the No-pay condition 11 (55 percent) accepted a work placement and of those, two discontinued their participation in the first month of the intervention.

FUTURE PLANS—These preliminary results suggest that pay is a erucial variable which should be eonsidered in the guidelines for programs of rehabilitation of veterans with schizophrenia. We will shortly be able to begin analyses exploring issues such as the effects of intensity of services delivered and the effects of community plaeement. We also plan to study the variability of work capacity in sehizhphrenia and its neuropsychological and psyehosocial correlates The technologies being

developed in this study should be easily transferred to other settings and used as clinical tools in rehabilitation of veteran's with schizophrenia. These include the Work Behavior Inventory, an improved work behavior rating scale, a group counseling manual and recommendations for accommodations in the work place.

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The Relationship of psychiatric symptoms to work performance for persons with severe mental disorders. Bell MD, Lysaker PH. Psychiatr Serv 1995:46:508-11.

Paid work activity in schizophrenia: Program costs offset by costs of rehospitalization. Bell MD, Lysaker PH. Psychosoc Rehabil J. In press.

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Prominent negative symptoms and work impairment in schizophrenia. Lysaker PH, Bell MD. Acta Psychiatr Scand 1995:91:205-8.

[232] SEXUALITY ISSUES AMONG WOMEN WITH PHYSICAL DISABILITIES

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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.

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.
3. Psychological 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 women with disabilities on the project staff. Interviews were transcribed, analyzed in terms of wellness, and used to generate a 300-item questionnaire, which was pilot tested on 60 women with, and 60 women without, disabilities. These data were then used to further refine the questionnaire, which was sent to 1,200 women with, and 1,200 women without, disabilities. Questionnaires were received from 950 women. Data have been analyzed on dating, sexual functioning, and barriers to reproductive health maintenance.

RESULTS—Significantly more women with disabilities reported having chronic urinary tract infections, osteoporosis, major depression, hypertension, restrictive

lung disorders, inflammatory bowel disorders, and heart disease than the able-bodied comparison group. These women reported having sexually transmitted diseases at about the same rate as women without disabilities, but had a higher rate of hysterectomy, and were significantly less likely to receive regular pelvic exams. Some women with physical disabilities lack basic knowledge about their reproductive health. For 60 percent of such women, health insurance coverage was inadequate to cover necessary medical services, resulting in the rapid exacerbation of serious health problems when health care was delayed or unavailable and often requiring emergency treatment. Many women with disabilities reported sexual and emotional abuse in medical facilities, particularly during childhood. Of the 45 women reporting abuse by health care providers, 22 listed emotional abuse, 9 physical abuse, and 25 sexual abuse.

Some medical facilities operated under policies that exclude women with physical disabilities from receiving services. Some prohibited staff from lifting patients onto inaccessible exam tables. Some women covered by managed care plans experienced increased health problems when not allowed to access specialists for health conditions related to their disability. More than half of women with spinal cord injury (SCI) reproted that the hospital could not accommodate their disability during childbirth, and 23 percent reported that available mammography equipment could not be positioned for them. Twenty-nine percent of women with disabilities, and 33 percent of women with SCI, reported that a physician had refused to see them for reproductive health care. Thirty-eight percent of women with disabilities reported that the physician does not speak directly to them if someone else is accompanying them. Thirty-seven percent of women with disabilities believed that their physicians were not well-informed about the effect of their disability on reproductive health, and 30 percent believed that they had been given inaccurate information about birth control by their physicians.

Women with disabilities also reported having less control over dating experiences, more constraints on attracting dating partners, more physical barriers to dating, and more social barriers to dating than women without disabilities. The two groups of women reported similar amounts of communication problems and saw themselves as equally approachable for dates.

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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Wellness models and sexuality among women with physical disabilities. Nosek MA, Howland CA, Young ME, et al. J Appl Rehabil Couns 1994:25:50-8.

Barriers to reproductive health maintenance among women with physical disabilities. Nosek MA, Young ME, Rintala DH, Howland CA, Foley CC, Bennett JL. J Women's Health. In press.

Sexual functioning among women with physical disabilities. Nosek MA, Rintala DH, Young ME, Howland CA, Foley CC, Rossi CD, Chanpong G. Arch Phys Med Rehabil. In press.

[233] SCALES TO ASSESS THE PSYCHOSOCIAL IMPACT OF ASSISTIVE DEVICES

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Sponsor: *Ontario Rehabilitation Technology Consortium funded by the Ontario Ministry of Health*

PURPOSE—Assistive devices (ADs) are frequently abandoned for psychosocial rather than mechanical reasons. Users may adopt an AD with expectations of improvement in the quality of their lives but discover

that the device has failed to improve them and, in fact, may have had negative consequences. Furthermore, the choice among alternative ADs is often made by the user in anticipation of psychosocial improvements rather than physical utility. During the past year we began work to develop a Psychosocial Impact of Assistive Devices Scale (PIADS), an outcome measure designed to assess the impact of rehabilitation and/or device interventions.

PROGRESS—We collaborated with a group of disabled people to create questionnaire items appropriate for this kind of measure. Preliminary determinations of the scale's reliability and sensitivity were made in studies of eyeglass and contact lens wearers. We are working on the development of a version of PIADS which can be used as a pre-/post- intervention or repeated measure of psychosocial status. Three more projects involving clinical populations have been initiated this year, with clinical and industrial partnerships, as follows: 1) comparison of constant, intermittent, and task-specific eyeglass wearers and non-wearers; 2) psychosocial factors associated with contact lens, and other eyewear, use, non-use, and abandonment; and 3) assessment of functional vision and psychosocial status of pre- and post-operative cataract patients. Related PSET activities have been concerned with psychosocial factors in the abandonment of assistive devices by people with visual impairment. We are collaborating with other investigators to explore factors affecting the utilization and/or abandonment of high technology visual aids.

FUTURE PLANS—At present, we are working to achieve the following milestones: 1) publication of report on development of PIADS, 2) completion of clinical validation studies for PIADS scale for populations with visual disabilities, and 3) impact and status versions of PIADS under licence for commercial distribution.

XIV. Sensory, Cognitive, and Communication Aids

A. Hearing Impairment

[234] COMPUTERIZED ADAPTIVE METHODS FOR SELECTING HEARING AIDS

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PURPOSE—The long-range purpose of this project is to evaluate the relative merits of selected non-linear signal processing strategies (especially compression amplification) for use in hearing aid design.

METHODOLOGY—Subjects with hearing-impairment were tested using the Revised Speech Intelligibility Rating Test under conditions of symmetrical output compression and peak clipping. A digital master hearing aid system was used to process the speech signals and the assessment included both measurements of speech intelligibility and speech quality. Speech quality was assessed using paired-comparison methods to obtain preference judgments and categorical scaling methods to measure overall impressions of sound quality and satisfaction. The study was accomplished in conditions of background babble and "in quiet." The speech was processed at four equivalent input levels (−12, 0, +12, and +18 dB) re the thresholds of clipping and/or compression. As a reference, results were obtained for unprocessed speech (linear condition) at previously described input levels.

PROGRESS—The goal of the experiments conducted during the past year was to compare the effects of peak clipping and output compression on speech intelligibility and quality among individuals with moderate hearing loss using a digital master hearing aid. Each investigation included the experimental conditions; 1) linear amplification, 2) symmetrical peak clipping, and 3) output compression (compression ratio 10:1).

RESULTS—In the first experiment, the results showed no differences in intelligibility between the linear and compression conditions and modest but significant reductions in intelligibility when the signal was clipped at a level 18 dB above the clipping threshold. Results from the second experiment also indicated that intelligibility in background babble, in general, was virtually unaffected for the compression system. Speech intelligibility was progressively reduced for the clipping once the threshold for the clipping was exceeded. Results from both experiments of the paired-comparison and rating methods demonstrated progressive reductions in perceived quality as clipping levels increased. Compression and linear processing produced similar high quality judgments except for the condition where the input signal was compressed 12 dB above compression threshold. The results suggest that output compression appears to be the more effective strategy for limiting the hearing aid output of linear amplification systems.

FUTURE PLANS—Studies are planned to compare results between hearing aid systems with linear amplification and output compression limiting and those with wide band single or multichannel input compression systems with low compression thresholds.

RECENT PUBLICATIONS FROM THIS RESEARCH

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.

Comparison of probe insertion methods on estimation of ear canal SPL. Dirks D, Ahlstrom J, Eisenberg L. J Am Acad Audiol. In press.

[235] OPTOKINETIC TESTING FOR DIAGNOSIS AND REHABILITATION OF BALANCE DISORDERS

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PURPOSE—The purpose of this study is to develop binocular testing of horizontal vestibulo-ocular (optokinetic nystagmus) and vestibulospinal reflexes (postural sway) to gain information about the normal interaction between visual, vestibular, and proprioceptive centers as well as improve the diagnosis and rehabilitation of vestibular disorders.

METHODOLOGY—Horizontal optokinetic motion stimuli, randomized 2×4 in (5×10 cm) light bars, are presented via an overhead projection system onto a 180° circular screen located 1 m from the subject, producing a strong sensation of motion. Subjects stand on a stationary platform which records postural sway in the presence of stimulus velocities of 20–100°/s in 20° increments to the right and then to the left (randomized presentation). In addition, an eyes open (EO) and eyes closed (EC) condition in the absence of moving visual stimulation is recorded. Postural sway data are collected for 30 sec for each condition in the study protocol. Subjects wear a parachute harness with straps attached to safety bars as a precaution in the unlikely event of a fall. The above described protocol requires approximately 20 min to complete.

PROGRESS—Ongoing data collection presently includes findings from 70 nondisabled subjects. In addition, 3 subjects with an acoustic neuroma were evaluated. One pre-surgical subject and one post-surgical subject, both with symptoms of dizziness, and one 2.5 years post-surgery with no complaints of dizziness.

RESULTS—The data indicate that lateral and forward-backward sway amplitudes are significantly higher when nondisabled subjects view a horizontal optokinetic pattern than when they view a stationary pattern or have EC. 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 EO condition, but sway amplitude in the forward-backward direction was correlated with age for the EC condition. There was a significant correlation between increasing sway amplitude and age when the optokinetic stimulus was present.

The subjects with acoustic neuroma and dizziness exhibited an increase in postural sway when the stimulus was moving in the direction of their site of lesion (i.e., greater postural sway to the right for the subject with a right acoustic neuroma). The third subject 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). Studies to evaluate the effect of physical therapy on sway amplitude in older subjects are being planned to determine the effect of therapy/exercise on reducing the propensity

for falling in this high-risk group. Data collection to increase the number in the experimental and non-disabled groups is ongoing.

RECENT PUBLICATIONS FROM THIS RESEARCH

Postural adjustments produced by moving visual (horizontal optokinetic) patterns. Blanks RHI, Fowler CG, Zizz CA, Williams KE. J Am Acad Audiol. In press.

[236] IS THERE AN "ACCLIMATIZATION EFFECT" WITH HEARING AIDS?

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PURPOSE—In 1992, Gatehouse coined the term "acclimatization effect" to refer to the improvement in speech recognition scores over time he saw in a small sample of hearing-aid users following the fitting of hearing aids. He believed that the improvement was due to the subjects learning to use amplified speech cues now available to them, rather than simply stimulation of auditorily deprived ears. Since that time, however, there have been conflicting reports regarding the existence of such a phenomenon. The present study will examine the acclimatization effect in new hearing-aid users with a carefully designed study which controls for test-retest variability of the speech recognition tasks, evaluates the role of changes in preferred volume wheel setting over time, and uses both linear and nonlinear amplifiers.

METHODOLOGY—Data will be obtained on 30 adults with bilaterally symmetrical sensorineural hearing loss, who have not previously used amplification. Following probe-microphone fitting of binaural linear or nonlinear hearing aids using NAL-r prescribed gain for a 60 dB SPL input signal, aided speech recognition will be evaluated using the adaptive Hearing-In-Noise-Test to determine signal-to-noise ratio (SNR) for 50 percent correct sentence intelligibility and with high-frequency weighted monsyllables in multitalker babble at a fixed SNR. A unique aspect of this study is that each subject will serve as his/her own control. There will be multiple, repeat sessions measuring binaural-aided speech recognition during a 2-week period prior to the subjects taking the hearing aids home, in order to assess across-session test/retest reliability. Subsequently, repeat measurements will be made over a 4-month period, during which the subjects will wear the hearing aids on a daily basis. At each session, testing will be accomplished both with the volume wheel at user-preferred setting and at the original prescribed gain setting. Questionnaire data also will be collected to examine any changes over time in hearing aid satisfaction. Also evaluated will be 10 additional subjects with bilaterally symmetrical hearing loss, but who have been wearing monaural amplification for a number of years. The unaided ear of these subjects will be fitted with a hearing aid and aided speech recognition will be measured monaurally over time for each ear with the opposite ear plugged during testing.

PROGRESS—The research laboratory has now been equipped and subject recruitment is underway. There are no preliminary data at this time.

IMPLICATIONS—Determination of the existence of an acclimatization effect with hearing aids is crucial because such an effect would have significant implications for both clinical practice and research protocols. If there is a period of acclimatization to new amplification, longer trial periods will be necessary prior to decision making regarding changes in electroacoustic parameters and measurement of user benefit.

[237] PROGRAMMABLE HEARING AIDS: EVALUATION AND PREDICTION OF BENEFIT

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PURPOSE—We aim to determine whether programmable hearing aids are superior to conventional hearing aids in terms of benefit and satisfaction; and if so, which particular features underlie this. We will examine whether individuals prefer and/or perform better with: four accessible frequency responses versus one, high fidelity circuitry versus conventional circuitry, a wide frequency response versus a conventional one, and wide dynamic range compression versus peak clipping.

Hearing aid benefit and satisfaction is only partly explained by audiometric measures. We aim to learn what personality, attitude, cognitive, and psychoacoustic factors influence hearing aid benefit. From this we hope to develop a predictive protocol for clinical use prior to hearing aid dispensing.

METHODOLOGY—Subjects were 72 males aged between 55 and 75, with mild-to-moderate sensorineural hearing loss. Each wore one conventional and two programmable hearing aids, with a total of six settings. Each setting was worn for 3 months, thus each subject took part for 18 months. Subjects carried out psychoacoustic, cognitive, and personality tests. They also made subjective evaluations of each hearing aid on a monthly basis and did tests of speech-in-quiet using W-22 spondees and the nonsense syllable test (NST) and speech-in-noise (HINT test) at the start and end of each 3-month period. Real-ear aided responses (REAR) were measured for all conditions.

PROGRESS—Sixty-four subjects have completed the study, the remaining will finish within 6 months. Analyses have been carried out on several aspects of the data.

RESULTS—Comparisons between the hearing aids showed significant differences on all three performance measures. Subjects performed best with Programmable Aid 1 on the HINT test, and with Programmable Aid 2 on the other measures. Performance with the conventional aid was midway between the other two aids on all tests. Thus, programmable hearing aids do not appear to be superior to conventional hearing aids. However, preference ratings provide a different picture. Patients reported least disability and handicap with Programmable Aid 1, and 87 percent of subjects chose it as being their favorite hearing aid. Thirty-nine percent of these patients used two of the four available programs, while 45.4 percent used three or four. It is concluded that: 1) speech-in-noise performance is a better predictor of preference than speech-in-quiet; 2) high frequency gain is not liked; 3) patients do not necessarily prefer the amplification that leads to best performance; and 4) Most subjects find two accessible frequency responses sufficient, three or more are probably unnecessary.

An Attitude to Hearing Questionnaire has been developed. Factor analysis extracted five reliable subscales. The questionnaire has good test-retest reliability. Multiple regression analyses showed that the attitudes subscales are the main predictors of reported hearing handicap and disability-audiological measures played a minimal role. Articulation indices, calculated from REARs, were significantly correlated with W-22 and HINT performance, but not with NST scores nor with subjective ratings. This suggests that audiologists must take into account other psychoacoustic and cognitive abilities if this is to be a useful predictor of hearing aid satisfaction and benefit.

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. The Attitude to Hearing Questionnaire will be further investigated as a potential tool for assessing the effectiveness of counselling and rehabilitation.

[238] 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 #C655-RA)*

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 were evaluated annually in years 1 and 2 (Y1,Y2). 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 Y1, 39 (14 aided and 25 unaided) have been seen in Y3. Comparisons were made between the aided ears of the aided, unilaterally sensorineural hearing-impaired Ss and the unaided, hearing-impaired ears of the unilaterally sensorineural hearing-impaired Ss. Thus, "aided ears" refers to the aided, hearing-impaired ears of the aided group, and "unaided ears" refers to the hearing-impaired ears of the unaided group.

In the unaided ears, the mean W-22 SSRS declined significantly from Y1 to Y2 ($p=0.005$). In contrast, in the aided ears, the mean W-22 SSRS improved significantly from Y1 to Y2 ($p=0.01$). For the NST, there was no significant change from Y1 to Y3 in either the unaided or aided ears.

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 investigation on subjects with bilaterally symmetrical sensorineural hearing impairment; in the latter investigation, an auditory-deprivation effect in the unaided unilateral Ss together with, in the bilateral investigation, a later-occurring deprivation effect in the monaurally aided Ss with bilaterally symmetrical sensorineural hearing impairment suggest the following: interaural asymmetry as well a prolonged lack of amplification is associated with decline in speech recognition.

The significant improvement in the aided ears of the unilateral Ss after only 1 year of amplification together with a nonsignificant trend toward improvement in the monaurally aided ears of the bilaterally symmetrical, sensorineural hearing-impaired Ss in the bilateral investigation indicates that recovery with amplification is more striking in unilateral than bilaterally symmetrical, sensorineural hearing-impaired Ss.

No significant changes from Y1 to Y3 were observed for the other measures in the aided and unaided unilaterally sensorineural hearing-impaired Ss.

FUTURE PLANS: Further evaluation of the aided and unaided unilaterally sensorineural hearing impaired Ss will continue through Y3 to further define and quantify the auditory-deprivation and apparent pure-tone asymmetry effects on audition in adults.

[239] 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 #C578-2RA)*

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, sensorincural hearing impairment (BSHI). These measures have been evaluated annually for the last 4 to 6 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.

PROGRESS—Because of the increase in the attrition rate over time, and because many subjects changed their status from monaural to binaural, analysis of variance does not seem to be practical. Instead of analysis of variance, the upper limits (UL) and the lower limits (LL) of the 95 percent critical differences limits (CDL) were used for the W22. As for the NST, the UL and LL of the 95 percent CDL were established for each individual NST score based on a list of 56 items. The retest NST score was compared with the UL and LL to determine if the retest NST score differs significantly from initial score.

Up to the end of the 5th year and beginning of the 6th year we were able to analyze the data of total 70 subjects, 38 binaurally aided and 32 monaurally aided.

RESULTS—The following results were compiled: in the monaurally unaided ears, 16 ears out of 32 (50 percent) fell outside the LL. As for aided ears, 4 ears (12.5 percent) fell outside the LL. The results of the NST indicated 8 ears (25 percent) of the unaided ears fell outside the LL, and none of the aided ears.

Eight subjects changed status from monaural to binaural and are being followed up. 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.

[240] EVALUATION OF NONAUDITORY FACTORS WHICH AFFECT HEARING AID USE IN ELDERLY VETERANS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C570-2RA)*

PURPOSE—The purpose of this study was to determine how several nonauditory factors affect the use of hearing aids in an elderly veteran population. The factors identified for investigation were mental status, visual acuity, fine motor coordination, motivation, and social support. The outcome measures used to determine hearing aid benefit were the Hearing Handicap Inventory-Elderly (HHIE), and the Sickness Impact Profile (SIP).

METHODOLOGY—The nonauditory factors described above, as well as several auditory factors, were evaluated in a group of elderly outpatient veterans (aged 60 and older) 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, acoustic immittance tests including tympanometry, and acoustic reflex thresholds. The initial assessment also included the nonauditory factors described above, completion of the HHIE, and the SIP. Subjects were reevaluated on all outcome and predictor variables after a minimum of 4 months of hearing aid use. A self-assessment of hearing aid satisfaction (HAS) was also included.

RESULTS—It was expected that if a subject benefitted from hearing aid use, this would result in a significant change in the scores of the outcome measures. The HHIE and the SIP were measured at entry into the study and at follow-up. Both the HHIE and SIP scales were analyzed between entry and follow-up using repeated t-tests. The data indicate a significant improvement in the HHIE total and sub-scale 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 HAS scores.

FUTURE PLANS—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 of many of the tests on 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. We plan to continue to enroll subjects meeting the criteria for inclusion.

Additionally, we plan on evaluating a sample of patients in institutionalized settings such as nursing homes. There is much anecdotal evidence indicating that nursing home residents derive less benefit from hearing aids than noninstitutionalized patients. However, there is no known investigation of the relationship between the nonauditory factors used in this study and outcome with hearing aid use in this group.

[241] DEVELOPMENT OF AN AUTOMATED TECHNIQUE FOR CLINICAL TINNITUS EVALUATION: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #C93-693AP)*

PURPOSE—Subjective tinnitus is the perception of sound that has no environmental source. Tinnitus as a pathological condition is severe for at least 10 million Americans, and veterans are particularly affected. The VAMC system, however, has few options with regard to clinical management of tinnitus, and many veterans are inadequately treated for the condition. Additionally, veterans' claims of tinnitus for compensation purposes are difficult to validate or refute, resulting in the processing of claims that are unsubstantiated. The VA pays approximately $90,000,000 per year in compensation benefits to over 80,000 veterans who are service-

connected for tinnitus. This laboratory has concerned itself with addressing the need for standardization of tinnitus management procedures, beginning with clinical measurement of the phenomenon. The purpose of this pilot study was to develop a prototype system for computer-automated evaluation of tinnitus, and to demonstrate test-retest reliability of the measures.

METHODOLOGY—A PC-controlled psychoacoustical system was assembled and programmed to automatically obtain tinnitus loudness and pitch, using the tone-matching method. The system generates test stimuli and simultaneously controls a video monitor, placed in the sound booth in front of the patient, that displays instructions for responding. The subject initiates response choices by pointing to response boxes with a pen device, and the system acquires and stores the responses. Subjects with stable tinnitus were recruited and evaluated with the automated technique. To assess reliability of the measures, each measurement was obtained multiple times within each session, and two sessions were required. Reliability, as it pertains to clinical testing, implies consistency of within-subjects measurements both within- and across-sessions as well as between examiners. The subjects were divided into two groups, each consisting of half of the subjects, and each group was evaluated by a separate examiner.

PROGRESS—This work has demonstrated the feasibility of using a computer-automated system to obtain reliable measurements of tinnitus loudness and pitch. Preliminary results show consistency of within-subject measurements over time, which is essential for quantification of the disorder and subsequent rehabilitative strategies for remediation.

RESULTS—To date, a system has been developed to conduct the procedure in an automated fashion, and 20 patients with tinnitus have each been evaluated with the system over two sessions. Statistical analyses were conducted using one-way repeated measures Analysis of Variance (ANOVA) and Pearson's product-moment correlations. Results of these analyses indicated reliability of responses within-subject, within-session; within-subject, across-session; and between-examiner (between groups).

FUTURE PLANS—This research endeavor is working toward standardization of measurement techniques and rehabilitative procedures associated with the treatment of tinnitus. Future research is designed to: 1) refine the prototype system to optimize test reliability and sensitivity, and minimize testing time; 2) demonstrate that the automated system can achieve test reliability comparable to results obtained when the same testing is conducted manually by trained examiners; and 3) demonstrate between-examiner uniformity of test results in a large group of subjects. Development of an automated system for tinnitus evaluation has the potential to significantly impact the clinical management of veterans, with application beyond the VA health care system. With successful completion of the current project, an automated technique will be fully documented for the clinical assessment of tinnitus. This accomplishment will result in a technique that will minimize between-examiner variability and promote uniformity between clinics. The new methodolgy can thus facilitate the standardization of tinnitus measurement, provide a means for validating tinnitus claims, and make a substantial contribution to tinnitus management and rehabilitation.

RECENT PUBLICATIONS FROM THIS RESEARCH

Automated technique for tinnitus evaluation. Henry JA, Fausti SA, Mitchell CR, Flick CL, Helt WJ. In: Vernon JA, ed. Proceedings of the 5th International Tinnitus Seminar. In press.

[242] EARLY DETECTION OF HEARING LOSS DUE TO 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 #C227-2RA)*

PURPOSE—Patients receiving treatment with drugs that have ototoxic potential are at risk for loss of hearing. Early detection of ototoxicity allows implementation of intervention strategies that can prevent hearing loss from becoming communicatively disabling. When intervention is not possible, early detection allows time to prepare the patient and/or family for hearing loss and to introduce rehabilitation strategies. A four-site study was designed to determine whether loss of hearing sensitivity due to ototoxicity is detectable in the high-frequency (9–20 kHz) range of hearing prior to the conventional-frequency (0.25–8 kHz) range.

METHODOLOGY—Patients are monitored for hearing sensitivity prior to, during and following treatment for ≥4 days with the aminoglycoside antibiotics (AMG) amikacin, gentamicin or tobramycin and/or ≥1 dose of the chemotherapeutic agent cisplatin (CDDP). Hearing threshold criteria for study inclusion was ≤100 dB SPL at 10 and 11.2 kHz. Ototoxic change criteria are those suggested by the American Speech-Language-Hearing Association.

PROGRESS—Three hundred sixteen subjects (198 AMG and 188 CDDP) have completed this study to date, with 182 of these subjects demonstrating threshold change in one or both ears. Fifty-five percent of the AMG-treated subjects revealed bilateral hearing losses (45 percent unilateral), while 88 percent of CDDP-treated subjects revealed bilateral losses (12 percent unilateral).

All further results are presented in relation to ears rather than subjects. Change was seen in 289 ears. Results from these ears were analyzed to determine exactly where changes were initially detected (high-frequency, conventional-frequency, or concurrently in both frequency ranges). In the AMG-treated ears, 64.3 percent of initial changes occurred in the high frequencies, 12.2 percent in the conventional frequencies and 23.5 in both frequency ranges concurrently. In the CDDP-treated ears, 60.3 percent of initial changes occurred in the high frequencies, 5.7 percent in the conventional frequencies, and 33.9 percent in both frequency ranges concurrently.

Preliminary analyses indicated that thresholds greater than 100 dB SPL showed little or no change throughout treatment, and that initial change seemed to appear within just a few frequencies in most cases. More thorough analyses revealed a five-frequency range, with the highest frequency ≤100 dB SPL and including the next four lower frequencies, within which 90 percent of all ototoxic hearing changes would have been initially detected. This Five-Frequency Range (FFR) is specific to each individual's threshold-of-hearing configuration. All the frequencies above this range accounted for only 1.5 percent of change, while all frequencies below this range accounted for 8.5 percent of change. Six percent of changes occurred within five lower adjacent frequencies to the FFR.

IMPLICATIONS/FUTURE PLANS—Data from this project have resulted in the development of national guidelines for ototoxicity monitoring. Identification of a FFR that is highly sensitive to initial ototoxic hearing change has implications for testing of ill patients who are capable of giving reliable responses for short periods of time, but are unable to withstand the rigor of behavioral threshold testing at all frequencies. A modified software program is being developed that flags each patient's FFR and automatically reports any significant changes in hearing thresholds. This program will be supported by a miniaturized testing system. When completed, this system will reduce testing time and increase patient accessibility without compromising the sensitivity of the monitoring plan. Additionally, we plan to explore objective means of monitoring hearing (ABR; OAE) in order to include all types of hospital patients (responsive, limited responsive, and unresponsive) in ototoxicity monitoring programs.

RECENT PUBLICATIONS FROM THIS RESEARCH

High-frequency audiometric monitoring strategies for early detection of ototoxicity. Fausti SA, Larson VD, Noffsinger PD, Wilson RH, Phillips DS, Fowler CG. Ear Hear 1994:15:232-9.

Ototoxicity. Fausti SA, Henry JA, Olson DJ, Frey RH. In: Northern JL, ed. Hearing Disorders. In press.

[243] MEASUREMENT AND PREDICTION OF BENEFIT FROM AMPLIFICATION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C344-4RA)*

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—In the past half-year, work has continued on an investigation of the relationship between certain cognitive variables and hearing aid benefit. To assess the contributions of cognitive variables, 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.

An evaluation of the Visual Input/Output Locator Algorithm (VIOLA) method for selecting and fitting non-linear hearing aids is in progress. In this study, linear and non-linear hearing aids are worn by a manikin and subjected to speech inputs at various levels. Sound levels developed at the eardrum are compared to levels predicted by the VIOLA method.

Relationship between several psychological variables and self-assessed hearing aid benefit has been explored. For this investigation, hearing aid wearers provide data on the Abbreviated Profile of Hearing Aid Benefit (APHAB) inventory as well as on measures of extraversion, anxiety, and locus of control.

Work has begun on development of two additional clinically useful inventories: the Hearing Instrument Satisfaction Score (HISS) and the Reality of Expectations of Hearing Aid Benefit (REHAB) Index. These will be developed using the traditional protocol of item development, analysis, and testing.

PROGRESS—Data collection has been initiated for 40 hearing aid wearers in the study of cognitive variables. Data collection and analysis is continuing on this project.

To evaluate the VIOLA fitting strategy, data have been collected using a set of behind-the-ear hearing aids fitted to a KEMAR manikin. The instruments include commercially available linear and compression devices.

Eighty elderly hearing aid wearers have provided data on self-assessed hearing aid benefit and the three psychological variables. This group includes successful and unsuccessful hearing aid wearers.

Item development for the HISS and REHAB Index is underway. Structured interviews with hearing aid owners are in progress and the results will serve as a major source for these items.

RESULTS—No results are available as yet in the study of cognitive variables.

Preliminary comparisons of amplified speech at the eardrum with predicted levels based on the VIOLA method suggest that eardrum levels are generally lower

than predicted for soft, average, and loud speech inputs. Analyses are continuing and adjustments will be made to the procedure as necessary.

Preliminary analyses of data suggest that the three psychological variables tested do not have a large direct influence on self-assessed hearing aid benefit. However, there appear to be moderate relationships between locus of control and anxiety and some aspects of self-assessed hearing disability, both with and without amplification. Analysis is continuing.

RECENT PUBLICATIONS FROM THIS RESEARCH

Prediction of hearing aid benefit: the role of preferred listening level. Cox RM, Alexander GC. Ear Hear 1994:15(1):22-9.

Relationship between in-situ distortion and hearing aid benefit. Cox RM, Taylor IM. J Am Acad Audiol 1994:5(5):317-24.

Abbreviated profile of hearing aid benefit (APHAB). Cox RM, Alexander GC. Ear Hear 1995:16(2):176-86.

Using loudness data for hearing aid selection: the IHAFF approach. Cox RM. Hear J 1995:48(2):10,39-44.

[244] SIGN PS: THE DEVELOPMENT OF AN INTERACTIVE PRINTING SYSTEM FOR SIGN LANGUAGES

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PURPOSE—In 1994, the University of Dundee MicroCentre, as part of a collaborative venture of five European partners, began the investigation of the development of a printing system for sign languages. Specifically, we are working on both computer recognition of sign gestures using glove technology and also the development of a prediction system to aid sign input. Both methods will form part of a natural and efficient computer interface for the creation of documents written in sign language. The entire system will form a computer software package that will perform the recognition and render two-dimensional graphical representations of signs.

METHODOLOGY—Specialized recognition devices for glove and video input will be investigated to allow the user to perform sign language in a natural manner and input signs into the system. A standard device for mouse and on-screen display input will also be developed.

As information about sign input is supplied, it will be passed on to a Prediction and Completion System which, using knowledge of how parts of signs can be combined, what signs already exist in any databases being used, and how often any signs have been used, will attempt to improve the performance of the input devices and reduce user effort.

Completed signs will be passed on to a Document Editor that will represent them in a specially developed graphical font and allow the user to change and create the graphical representation of any sign.

PROGRESS—Users have been approached for involvement in data collection and the development of the characteristics of the font. A prototype of the system has been developed.

RESULTS —Preliminary results at recognizing small sets of handshape information supplied by glove hardware have been positive.

RECENT PUBLICATIONS FROM THIS RESEARCH

SignPS: the development of a sign language printing system. Cairns AY, Cracknell JF, Gregor P, Pyfers, Ramsay CD, Ricketts IW. In: Proceedings of the RESNA '95 Annual Conference; Vancouver, BC. Washington, DC: RESNA Press, 1995:443-5.

[245] REMOTE TEXT TRANSCRIPTION SERVICES FOR USE IN WORKSITES

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Sponsor: *U.S. Department of Education, National Institute on Disability and Rehabilitation Research, Washington, DC 20202*

PURPOSE—Computer-assisted notetaking (CAN) and computer-aided real-time transcription (CART) are popular techniques for displaying text to provide people with hearing problems visual access to the spoken word. To date, however, remote services delivered by telephone have not been made widely available. Tools and demonstration studies are needed.

METHODOLOGY—Off-the-shelf products, along with software developed as part of the project, are integrated into a system for remote transcription. Further refinement is proceeding with feedback from field sites.

PROGRESS—Software was developed for the application. The software provides user-friendly data communications as well as display characteristics that can be altered by the viewer during use. Automatic save and error checking are also included. An analog simultaneous voice and data (ASVD) modem was used for handling both voice and transcription on the single telephone line. A speakerphone at the meeting site also was used. All components are widely available through commercial outlets. During the past year, the system has been pilot tested at a worksite, with promising preliminary results.

RESULTS—One deaf and five hearing persons participated in meetings transcribed by Gallaudet staff at a remote location. The system was rated "very useful" eight times and "somewhat useful" three times. Testing of the system will continue at at least one other worksite in 1996. The software is available for downloading from the department's Web page: http://fshb41.gallaudet.edu.

[246] INTERNATIONAL TELECOMMUNICATIONS STANDARDS FOR TEXT TELEPHONY

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PURPOSE—Text telephone devices used in the U.S. are based on Baudot, a five-level code transmitted in a carrierless mode. Baudot is incompatible with ASCII communication protocols. In Europe, at least six different text telephone codes are used in different regions. All are incompatible. The purpose of this work is to end the problem of incompatibility of text telephones of the world.

METHODOLOGY—The RERC participated in the development of ITU-T Recommendation V.18, a telecommunications standard for interworking between the world's text telephones and conventional modems. Annual meetings of domestic text telephone representatives and other stakeholders, such as vendors of telephone relay services, were held during the development of V.18. On-line discussions have been an ongoing instrument for information exchange and standards development.

PROGRESS—The ITU-T passed Recommendation V.18 in September 1994. This significant event marked

the first teleeommunications standard that recognized the existence of the text telephone network. The approval of the standard is the beginning of a process through which it is hoped the text telephone network will migrate to updated and compatible teehnology.

To achieve that end, extensive testing of the logic and implementation of V.18 will be necessary. During 1994 a manufacturer indicated an intention to build a V.18 modem, and collaborative work began; but the eompany's dccision was reversed midway through 1995. Thus, to date, no manufacturer has deliverecl a V.18 modem to market. Work continues on sceking a major manufacturcr.

RECENT PUBLICATIONS FROM THIS RESEARCH

ITU-T recommendation V.18: the first communications standard for the deaf. Brandt RP. Technol Disabil 1994:3(3):199-202.

[247] COMPUTER-BASED TEXT TELEPHONY FOR DEAF PEOPLE WITH LOW VISION AND BLINDNESS

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PURPOSE—Deaf people with low vision are limited in their options for using the text telephone, particularly as vision deelines to a severe level. The purpose of this projeet is to provide new tools for telephone access for this population.

METHODOLOGY—In-depth interviews with nine deaf people who have low vision formed the basis for the development of a funetional speeifieation for a teleeommunications workstation. The first priority in workstation development has been the development of text-telephone software that will work with popular screen enlarging software packages.

PROGRESS—A eombination text telephone/fax/data modem was evaluated and selected for use as the text telephone deviee in the system. The speeifieation has been written and initial software dcvelopment has begun. The DOS-based software is being built around truncated menu structures (few ehoiees per menu and short eommands for eaeh menu) to minimize the need for panning when the text is magnified. Features to be ineluded are direetory funetions for automatie dialing, auto-redial, save features, time and date stamp, answering maehine functions, and macros for giving speeifie instructions to telephone relay serviee operators. Completion of the software and preliminary testing by users are seheduled for eompletion in 1996.

B. Speech Impairment

[248] COMPUTER-ASSISTED SPEECH REHABILITATION SYSTEM

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PURPOSE—This project is to develop, test, and refine a clinical hardware/software system to assist in behavioral training and analysis of speech production. The objective is to provide a flexible set of easy-to-use software tools for routine use by speech clinicians with a variety of patients. Ten specific protocols are being developed to assist self-directed and clinician-directed training in the control of breathing, voice, prosody, and velopharyngeal valving during speech. Acoustic, aerodynamic, nasal accelerometric, and electroglottographic signals will be monitored, depending on the protocols selected. The software will be compatible with the more than 40 existing work stations developed for Computer Assisted Speech Evaluation and Rehabilitation (CASPER).

METHODOLOGY—Programs are written in Delphi-Pascal and the C language by professional programmers under our supervision, with algorithms developed and tested by the principal investigator and a biomedical engineer.

PROGRESS—During this past year we have completed design and implementation of the user interface and developed and tested new algorithms for measurement of speech rate and fundamental frequency. We are now working on the real-time graphics required to implement the feedback.

The user interface has been implemented in the Windows environment using a tabbed notebook metaphor which allows the user to: 1) select among protocols, 2) enter or edit subject demographic information, 3) design the stimulus, response, and feedback particulars, or 4) request a summary report of performance. Relational databases store subject information, teaching paradigm parameters, and subject performance. The session designer allows the professional user flexibility in programming the nature of the teaching paradigm. The clinician may select and schedule audio-visual alerting signals, cues, and models to be used as part of stimulation prior to a response. Responses may include one or more tokens. Feedback screens can be varied from a simple binary hit/miss indicator to more complex near real-time display of raw and derived data. The time intervals between all stimulus events, the data-collection sweep, feedback events, and restimulation are also programmed by the clinician.

FUTURE PLANS—Studies of speech disordered subjects using the biofeedback tool with a professional speech clinician will be undertaken. Careful monitoring of this work will allow ongoing refinement of the system. We expect beta-site users of the software to provide additional valuable suggestions for refinement.

RECENT PUBLICATIONS FROM THIS RESEARCH

Accelerometric difference index for normal and hypernasal speakers. Till JA, Jafari M, Law-Till C. In: Till J, Yorkston K, Beukelman D, eds. Motor speech disorders: advances in assessment and treatment. Baltimore, MD: Paul H. Brookes, 1994:119-33.

Aerodynamic and temporal effects of laryngeal insufficiency. Till JA, Crumley RL, Jafari M, Law-Till C. Arch Otolaryngol 1994:120:317-25.

Effects of inspiratory airway impairment on continuous speech. Till JA, Jafari M, Law-Till C. In: Robin D, Yorkston KM, Beukelman DR, eds. Disorders of Motor Speech. Baltimore, MD: Paul H. Brookes. In press.

[249] EVALUATION OF WORD RECOGNITION PERFORMANCE WITH SENTENCE MATERIALS

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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 assessment of receptive speech communication problems. Sentences were developed that can be used adaptively to obtain thresholds. In contrast to previous sentence materials, this project involves target words that vary with respect to word frequency, confusibility, and linguistic content. The sentences have seven to nine syllables and three target words. They are grouped into one of the following categories based on the word category of the target words: 1) HH: high usage with high confusibility, 2) HL: high usage with low confusibility, 3) LH: low usage with high confusibility, and 4) LL: low usage with low confusibility. Six lists of 25 sentences were compiled. The sentences are representative of everyday speech and are easy to repeat. The end product will be sets of test materials useful for multipurpose applications recorded on audio compact disc.

METHODOLOGY—With this sentence format, the task of the subject is to repeat the sentence that is presented. Scoring is restricted to the whole word responses to the target words. If two or three of the target words are recognized, then the level of the subsequent sentence is decreased 2 dB; if fewer than two of the target words are recognized, then the level of the subsequent sentence is increased 2 dB. The threshold search is terminated after 12 reversals and threshold calculated from the midpoints of the last 9 reversals. The sentences were reproduced from digital audio tape, fed through an audiometer, and presented to the subjects through TDH-59P earphones encased in a P/N 510C017-1 cushion. All testing was done in a double-walled sound booth.

PROGRESS—The sentences have been shown to be homogenous with respect to psychometric slope, range, and midpoint. Thresholds obtained on the six lists are not statistically different when used with subject having normal hearing or no greater than mild hearing losses with sloping configurations.

RESULTS—The sentences have been evaluated on subjects with normal hearing under different band pass filter conditions. Findings revealed that the homogeneity of the sentences was maintained across filter conditions: that is, filtering had no impact on the variability within each list or differences in thresholds between lists. Evaluation of these sentences on a hearing-impaired population is in the initial stages and suggests that, in most cases, the lists of sentences are homogeneous. In subjects with very poor word recognition ability the excursion rates are wider.

FUTURE PLANS—The sample size, at present, is too small to describe the usefulness of these sentences on individuals with varying degrees and configurations of hearing loss. Future research will focus the efficacy of obtaining thresholds with these sentences in noise with a variety of subjects with hearing impairment.

[250] 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—The objectives are: 1) to determine the efficacy of self-monitoring treatment for subjects with mild and moderate aphasia; 2) to determine the social validity of treatment, that is, how unsophisticated listeners rate the effects of treatment; and 3) 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, according to proportion of disfluencies and communicative efficiency criteria, 10 each representing mild, mild-moderate, and moderate aphasia. Subjects will also be assessed with measures to provide information about motor 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 (reduction in proportion of disfluencies) each time treatment is applied, across subjects and across behaviors (disfluencies) in each subject.

PROGRESS—Four aphasic subjects have entered the treatment program. All four completed the baseline phase; contrary to the expectation that aphasic speakers would have good days and bad days, when disfluencies would vary widely, all patients reached stable baselines in 5–6 sessions. Two have completed training and independent self-monitoring on their most frequent, and most distracting, (target) disfluency. Beginning with the first training session, both showed lower disfluency levels for the target disfluency. During independent self-monitoring, however, it was apparent that levels of the nontarget disfluencies remained high. Thus, both patients are now being trained to self-monitor another disfluency, with noticeable improvement in communicative efficiency. Both patients and family members report that subjectively speech is better. The other two subjects have completed baseline and are in training on the first target disfluency. Additional subjects are being recruited from local stroke support groups and with the cooperation of Miami area speech pathologists. Data from 25 nondisabled subjects have been analyzed; as expected, these subjects show lower disfluency levels, and virtually no overlap with aphasic subjects. Experience with the treatment subjects seen to date have allowed for streamlining of the treatment program to decrease total number of sessions and increase overall efficiency of the program.

FUTURE PLANS—All of the aphasic subject data will be collected and analyzed in the next 8 months. The social validation rating scale will be prepared in the next 2 months and the social validation ratings will be completed in the next 10 months. All data analysis will be completed in the final 2 months, and the report will be completed. If self-monitoring treatment is effective in improving communicative efficiency for these aphasic subjects, it will be a simple, quick treatment tool for clinical application in any aphasia rehabilitation setting, appropriate for patients at any stage of recovery. In addition, analysis of relationships among several variables and treatment effect will enhance clinicians' ability to predict the patients for whom the treatment program is indicated.

[251] CONNECTED SPEECH DEVIATIONS OF APHASIC AND NON-BRAIN-DAMAGED 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 proposed 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 (NBD) adults, and to assess how aphasic and NBD adults differ with regard to these behaviors; and 3) to evaluate the extent to which nondisabled listeners' judgments of the quality and adequacy of aphasic and NBD 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 NBD adults and adults with aphasia have been transcribed and scored for the presence of several specific behaviors, as well as for the samples' overall communicative efficiency and informativeness. Audiotape recordings of NBD 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 NBD adults and 20 adults with aphasia (10 with fluent aphasia and 10 with nonfluent aphasia) have been 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 filler). Both groups of aphasic speakers produced significantly greater proportions of inaccurate words, false starts, part-words, and unintelligible words than NBD speakers. The only measure which significantly differed between fluent and nonfluent aphasic speakers was the percentage of nonword filler. Individual-subject performance was consistent with the group results for all measures.

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 NBD speakers. Preliminary results suggest that nondisabled 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.

In another pilot study, we are evaluating changes in two aphasic adults' disruptive speech behaviors over time, to determine the sensitivity of various measures of such speech behaviors to the recovery process, and to evaluate potential relationships between the presence of disruptive speech behaviors and nondisabled listeners' subjective judgments of informativeness and ease of comprehension. At this time we have determined that nondisabled listeners' judgments of informativeness and ease of comprehension appear to have acceptable reliability.

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 data-based 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 nondisabled 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

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Test-retest stability of measures of connected speech in aphasia. Brookshire RH, Nicholas LE. Clin Aphasiol 1994:22:119-34.

Comprehension of spoken narrative discourse by adults with aphasia, right-hemisphere brain damage, or traumatic brain injury. Nicholas LE, Brookshire RH. Am J Speech-Lang Pathol 1995:4:82-94.

Presence, completeness, and accuracy of main concepts in the connected speech of NBD adults and adults with aphasia. Nicholas LE, Brookshire RH. J Speech Hear Res 1995:38:145-56.

[252] 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 study seeks to verify the advantage of a deep-level treatment (personalized cueing) over a surface-level method (phonologicallybased cueing) as a facilitator of aphasic subjects' long-term naming recall. Prior research has shown that deep-level methods that activate semantic representations of naming targets result in significantly better long-term recall than surface-level training procedures which provide phonological information about the target.

METHODOLOGY—Forty aphasic (APH) and 40 non-brain-damaged (NBD) adults will be randomly assigned to two training conditions, personalized and phonological cueing. Personalized cueing is a cued recall task where subjects create their own training cues (e.g., Egyptian king dog) for specific breeds of dogs (e.g., Pharaoh hound). In the phonological cueing condition the subject is provided phonological information about the target (e.g. Pharaoh hound) in the form of the first phoneme (/f/), a well-known method for treating aphasic naming deficits. These procedures are to cue subjects to produce and learn the names of unfamiliar dogs (e.g., Saluki, Kuvaz) three times per week for 4 weeks. Independent sets of unfamiliar dogs and birds (e.g. Tufted Puffin) serve as untreated-related and untreated-unrelated control items. Follow up probes to assess long-term naming accuracy and generalization are conduced 1 week, 1 month, and 6 months after training.

PROGRESS—Over 30 APH and NBD subjects have been enrolled in the study to date. APH subjects have been able to create personalized cues for realistic, visually complex stimuli. The value of personalized cueing as a long-term facilitator of naming accuracy has clearly been evident in results to date. Findings support those of prior studies that used non-iconic symbols as experimental stimuli.

RESULTS—One early study has compared the naming accuracy of 10 APH and 10 NBD subjects assigned to the personalized cueing condition. NBD subjects were found to perform significantly better than the APH subjects. Stability of probe scores out to 1 month were stable for both groups, however. This is an encouraging result given the previously demonstrated declines in naming accuracy for APH subjects over time. In addition, APH subject's labeling probe scores for trained stimuli were significantly higher ($p<0.05$) than those for the control stimuli, suggesting that they were aided by personalized cue training. Conversely, there

were no differences in the labeling probe scores for NBD subjects for trained and untrained sets of items.

FUTURE PLANS—We expect to develop three-to-four manuscripts from the final data set. These will involve: 1) analysis of the training data and its relation to probe performance; 2) a comparison of groups on the probe across treated, untreated-related, and untreated-unrelated stimuli; 3) a correlational study of the factors related to long-term naming accuracy; 4) examination of personalized cue forms and long-term recall; and 5) comparison of a subset of demented subjects' performance on the personalized cueing task with APH and NBD groups.

RECENT PUBLICATIONS FROM THIS RESEARCH

Labeling of novel stimuli by aphasic adults: effects of phonological and self-cueing procedures. Marshall RC, Freed DB, Phillips DS. Clin Aphasiol 1994:22:335-43.

Effects of cue origin on the facilitation of aphasic subjects' verbal labeling. Freed DB, Marshall RC. Clin Aphasiol 1995:23:227-36.

Comparison of personalized cueing and provided cueing on the facilitation of verbal labeling by aphasic subjects. Freed DB, Marshall RC, Nippold MA. J Speech Hear Res. In press.

[253] 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 purpose of this project was to conduct an experimental analysis of the effects of a treatment designed to promote improved sound productions in apraxic speakers. Specifically, the effects of training sounds sequentially were examined in terms of: 1) acquisition of trained sounds; 2) response generalization; 3) stimulus generalization; and 4) maintenance of correct sound production.

A secondary objective was to determine whether there were significant differences in various acoustic measures of speech production, over time, among groups of apraxic and normal speakers.

METHODOLOGY—A combination of single-subject and group design was employed and entailed conducting a series of single-case experimental analyses and obtaining comparative data from a group of nondisabled speakers. Treatment was applied to each treatment subject individually and in a manner consistent with a multiple baseline design across behaviors and subjects. Treatment consisted of a combination of minimal pairs contrast and traditional therapy methods. Baseline, treatment, and maintenance probes were conducted for each treatment subject to evaluate production of specific sounds. Additionally, pre- and post-treatment measures were obtained from the treatment subjects for comparison to the same measures obtained from the normal subjects.

FINAL RESULTS—Eleven chronic apraxic-aphasic subjects received treatment as part of our program. These subjects were males, ranging in age from 52 years to 70 years, with a mean of 60.5 years. Education levels ranged from 6 years to 22 years, with a mean of 12.8 years.

Treatment was effective in promoting improved sound production of treated sounds in trained and untrained words for all subjects. Effects were specific to sounds under treatment, in that generalization effects across sounds were not noted. Stimulus generalization effects were absent or limited for most subjects. Positive maintenance effects were observed for all of the subjects, with levels of maintenance varying across subjects and sounds.

Speech samples were obtained from 12 non-brain-damaged speakers to serve as a basis of comparison for apraxic/aphasic speech samples and to examine the stability of acoustic measures across sampling times.

Results were as follows: repeated measures ANOVAs revealed that: (a) there were no significant differences in VOT values across times; (b) subjects produced appropriate and significant contrasts in vowels preceding voiced and voiceless stops at both sampling times; (c) there were no significant differences across times for four of the five intrinsic vowel duration words; (d) there were no significant differences in total sentence durations across sampling times; and (e) there were no significant differences across time for five of the six total word duration items. Fricative durations were not statistically analyzed for two reasons: adequate measurement reliability values could not be obtained, and the majority of subjects demonstrated difficulty in repeating these stimuli.

In comparing the speech samples from our apraxic/aphasic subjects to those of our normative group, we found statistically significant differences among groups for all measures. However, in examining individual subject data, we found that not all subjects deviated from normal across all measures.

In order to determine whether individualized, error-sound-specific acoustic analyses had potential in accurately portraying our subjects' speech, we conducted two studies in which subjects' sound errors were examined in detail. The first, a VOT analysis, revealed that the subject's erroneous productions were not phoneme selection errors. The second, spectral analysis, indicated that one subject's productions were more accurately characterized as distortions, whereas the remaining subject's productions appeared to be indicative of sound selection errors.

FUTURE PLANS—Future research will focus on facilitating stimulus generalization effects of sound production treatment and acoustically examining individual sound errors in persons with apraxia of speech.

RECENT PUBLICATIONS FROM THIS RESEARCH

Treatment for acquired apraxia of speech: a review of efficacy reports. Wambaugh JL, Doyle PJ. In: Lemme ML, ed. Clin Aphasiol 1994:231-43.

Minimal contrast treatment for apraxia of speech. Wambaugh JL, Doyle PJ, Kalinyak MM, West JE. Clin Aphasiol. In press.

Review of acoustic analyses of aphasic and/or apraxic speech. Wambaugh JL, Doyle PJ, Kalinyak MM, West JE. Clin Aphasiol. In press.

Spectral analysis of sound errors in persons with aphasia and apraxia of speech. Wambaugh JL, Doyle PJ, West JE, Kalinyak MM. Am J Speech-Lang Pathol. In press.

[254] PROMOTING GENERALIZED LANGUAGE USE: AN ANALYSIS OF TREATMENT VARIABLES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C330-4RA)*

PURPOSE—The purposes of this project were to examine the effects of Conversational Skills Training (CST) on the informativeness of aphasic subjects narrative and conversational discourse, to determine the extent to which objective measures of informativeness obtained under structured discourse conditions predict subjects' performance on measures of informativeness under conversational discourse conditions, and to describe the relationship between objective measures and listener's judgments of the informativeness of aphasic subjects' discourse.

METHODOLOGY—Single-subject experimental designs were used to examine the effects of CST on the number and percentage of correct information units, percentage of accurate/complete main concepts, and percentage of informative minimal discourse units produced by aphasic subjects under structured and conversational discourse sampling conditions. Analysis

of variance procedures were used to examine differences in subject performance under structured and conversational sampling conditions. Correlations were computed to examine the strength of the relationship between subject performance across sampling conditions and unfamiliar listeners' direct magnitude estimates of informativeness.

FINAL RESULTS—The results of these studies indicate that the effects of CST on the informativeness of aphasic subjects' connected discourse was limited to the training context. Measures of correct information units, accurate and complete main concepts, and informative minimal discourse units under novel sampling conditions were variable across subjects with several subjects showing limited generalization effects. Post hoc analyses of conversational interactions reveal that much of the uncontrolled variability in subject performance could be attributed to characteristics of the conversational partner with some partners serving as better facilitators than others. Comparisons of subject performance across conversational and structured discourse conditions 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 (R^2=0.82). Correlational analysis of objective measures and direct magnitude estimates of aphasic subjects' informativeness indicated that objective measures were strongly correlated with perceived informativeness, and that overall severity of aphasia did not fully account for rater perceptions.

IMPLICATIONS—There are several implications of this research for practicing clinicians. First, CST alone may not result in generalized improvement of conversational skills across a variety of natural contexts without additional generalization programming. Second, the informativeness of aphasic subjects' conversational discourse may be predicted on the basis of their performance under structured sampling conditions. Third, the extent to which aphasic subjects' discourse will be perceived as informative by normal listeners may be accurately predicted from the objective measures used in these studies.

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 Aphasiol 1994:22:135-44.

Communicative informativeness of aphasic adults' connected discourse under structured and conversational sampling conditions. Doyle PJ, Goda AJ, Spencer KA. Am J Speech Lang Pathol. In press.

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 Aphasiol. In press.

[255] AUDITORY EVOKED RESPONSES, SEVERITY, AND PROGNOSIS IN APHASIA: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project C94-761AP)*

PURPOSE—The purpose of this pilot study is to test the precision of auditory evoked responses (AERs) to provide a prognosis for improvement in aphasia subsequent to a left hemisphere thromboembolic infarct. The primary research question is: Do AERs to semantic, syntactic, and phonologic stimuli predict improvement in the language performance of aphasic patients? A secondary research question is: Are AERs to semantic, syntactic, and phonologic stimuli significantly related to severity of aphasia?

METHODOLOGY—Phonologic, semantic, and syntactic language tasks will be used to elicit AERs, including the MMN, P300, N400, and P600. Nondisabled AERs will be established on 10 young, nondisabled subjects. Then, 10 mildly aphasic subjects, 10 moderately aphasic subjects, 10 severely aphasic subjects, and 10 nondisabled subjects (selected to reflect the age, education, and gender of the aphasic subjects) will be tested. All aphasic subjects and controls will be evaluated with the AER test battery and three language tests: the Western Aphasia Battery (WAB), Porch Index of Communicative Ability (PICA), and the Token Test (TT) from the Neurosensory Center Comprehensive Examination for Aphasia. All tests will be repeated in 1 to 2 months, after the aphasic subjects have received approximately 20 treatment sessions. The presence, latency, and amplitude of the AER waveform components will be examined. Analyses of variance will be used to determine whether the aphasic subjects have made significant improvement between the pre- and post-treatment evaluations, and a multiple regression technique will be used to determine whether the AER measures are good predictors of severity of aphasia and improvement in aphasia.

PROGRESS—Instrumentation has been ordered for integration with existing resources. Programs for presenting the AER stimuli and analyzing AERs are being written. Study patients have been identified and are being evaluated.

FUTURE PLANS—Depending on the results obtained in this pilot study, a more comprehensive proposal that includes larger samples will be developed. This may include testing the prognostic value of an additional measure, functional MRI, for predicting improvement in and severity of aphasia.

[256] COMMUNICATIVE PARTNERS: INTEGRATING APHASIC ADULTS BACK INTO SOCIETY

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PURPOSE—Adults with aphasia often return home with minimal use of communicative gains acquired in clinical settings. Restricted use of communication in natural settings is likely due to many factors. One may of these be the handicap of having become aphasic, that is, the psychosocial well-being of the person afflicted. Perhaps adults with aphasia fail to communicate outside the clinic, 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 project was to evaluate a novel treatment plan that incorporates issues of psychosocial well-being, while permitting that therapy to occur at home or in the community.

METHODOLOGY—Ten adults with aphasia (AWA) were paired with adult volunteers from their communities, serving as Communication Partners (CP). AWAs were at least 1 year post-onset and possessed sufficient communicative abilities to exchange simple descriptive content with a trained speech/language pathologist. All AWAs were required to have a caregiver (C), someone with whom they resided or had frequent and ongoing contact.

Repetitions of a multiple baseline design containing three treatment formats A, B, and C were used. Incoming triads consisting of AWA, C, and CP were randomly assigned to one of these treatment formats. All treatment formats included a minimum of two treatment phases and four assessment periods. Format A contained a maintenance condition; Format B had an extended second phase treatment condition, and Format C had an initial no treatment or control condition. All treatment formats extended over 8.5 months.

Phase One of treatment consisted of teaching AWA/CP pairs how to share informational content effectively (two 1-hour sessions weekly at a VA hospital over a duration of 6 weeks). Phase Two of treatment involved selecting, planning, and undertaking AWA activities of choice in the community with the assistance of the CP (a 1-hour planning session at the hospital and a 2-hour session in the community weekly over a duration of 14 weeks). Planned activities in the community were idiosyncratic to the desires of the AWA, and might consist of volunteering as a gardener at a local botanical gardens or relearning to play a musical instrument. With each chosen activity, the CP served as facilitator until the activity was established or discarded out of choice. The prime emphasis of this program was on restoring participation in life while attempting to encourage and establish optimal function and independence.

Standardized and nonstandardized measures were systematically administered at all four assessment periods. Standardized measures included the Boston Diagnostic Aphasia Examination for language, the Communicative Abilities of Daily Living for communication, and Affect Balance Scale for psychosocial well-being. Nonstandardized measures included two investigator-constructed questionnaires. One of these was an index of communication readiness and use (CRUI) and the other was an index of psychosocial well-being (PWI).

RESULTS—A nonparametric Wilcoxan ANOVA failed to yield any statistical levels of significance ($p<0.05$) on pre-, post-treatment differences from standardized measures. Nonstandardized measures showed significant differences on both the CRUI and PWI. Other informal measures obtained post hoc suggest that further modifications are needed to strengthen the efficacy of nonstandardized measures and treatment protocols. Results support Communication Partners as an effective treatment technique when attempting to integrate issues of well-being and communication into natural settings.

FUTURE PLANS—As an alternative to providing services in a rapidly changing healthcare system, Communication Partners offers a promising method for moving treatment from clinical to natural or residential settings.

[257] ALADIN: ADVANCED LANGUAGE DEVICE FOR INTERACTION

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Sponsor: *Commission of the European Communities, Technology Initiative for Disabled and Elderly People, B-1049 Brussels, Belgium*

PURPOSE—The ALADIN project is developing a novel, linguistically based software system which will enable a non-vocal, physically impaired person to hold effective conversation.

METHODOLOGY—The software will run on a wide range of commercially available hardware platforms (computer plus speech synthesizer). The system will include a model of conversational interaction which will provide the user with appropriate conversational material, prompts, and predicted utterances. An innovative interface is being developed that will help the user to navigate through a conversation with minimal attention on the interface and maximum attention on the other speaker. The users of this system will be people who are non-vocal from birth (e.g., through cerebral palsy) and also people who have permanently lost the ability to speak through degenerative conditions or accidents.

RECENT PUBLICATIONS FROM THIS RESEARCH

ALADIN: advanced language device for interaction. Alm N, Dye R, Harper G. In: Proceedings of the Third European Conference on the Advancement of Rehabilitation Technology; 1995, Lisbon, Portugal.

Communication system based on scripts, plans and goals for enabling non-speaking people to conduct telephone conversations. Alm N, Morrison A, Arnott JL. In: Proceedings of IEEE Systems Man and Cybernetics Conference; 1995, Vancouver, BC.

[258] USING ADVANCED INFORMATION RETRIEVAL TECHNIQUES IN A COMMUNICATION SYSTEM FOR NON-SPEAKERS

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Sponsor: *Commission of the European Communities, Human Capital and Mobility Programme, 1040 Brussels, Belgium*

PURPOSE—The aim is to develop a highly efficient interface by which a physically disabled non-speaker can use a computer to communicate reusable conversational material.

METHODOLOGY—Users can potentially communicate faster by selecting whole pre-stored utterances, rather than by constructing every message character by character. However, current sytems impose a high cognitive load on the user who must remember access codes. The project will tackle this problem using text retrieval methods.

PROGRESS—We begin work on this project November 1995.

[259] HAMLET: SIMULATING EMOTION IN SYNTHETIC SPEECH

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Sponsor: *Engineering and Physical Sciences Research Council, Swindon SN2 1ET, UK*

PURPOSE—This project aims to derive a set of rules to include vocal emotion effects in synthetic speech produced by rule.

PROGRESS—A basic set of rules were derived from the existing literature on human vocal emotion, to produce a prototype system (HAMLET). Later analysis of actor recordings were used to enhance and extend the system.

RECENT PUBLICATIONS FROM THIS RESEARCH

Implementation and testing of a system for producing emotion by rule in synthetic speech. Murray IR, Arnott JL. Speech Commun. In press.

[260] FURTHER DEVELOPMENT OF TALKSBAC

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Sponsor: *The Leverhulme Trust, London EC4A 1NR UK*

PURPOSE—We are working to improve the quality of conversational data stored within the TalksBac System, to improve its predictive technique, to refine the training of support necessary for a dysphasic user, and to evaluate the revised system of training and support in terms of clients' communication interaction.

METHODOLOGY—We have implemented a spell-checker, a thesaurus, a morphological module, and a reduced semantic network in the TalksBac software. We are investigating the roles of user and caregiver over the augmentative conversational diad.

PROGRESS—The new features have been installed in the software. The improved system is in clinical trials.

[261] SPEECH PROCESSING PROGRAM

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Sponsor: *Nemours Research Programs, A.I. duPont Institute, Wilmington, DE 19899; National Institute on Disability and Rehabilitation Research, U.S. Department of Education, Washington, DC 20202*

PURPOSE—The purpose of this project is to integrate computer hardware and software that will implement speech enhancement algorithms developed for dysarthric speech as a real-time prototype speech prosthesis. The device will accept speech produced by a person with a speech disorder, process the speech to make it more natural sounding, and then replay the processed speech on command. The prototype under development is to serve as a test bed for implementing new speech processing algorithms and for studying how users will interact with such a device.

METHODOLOGY—This program is based on ongoing work in the Speech Processing Laboratory to develop signal processing techniques capable of improving the intelligibility and naturalness of disordered speech. These techniques involve adjusting the timing of the speech as well as adjusting its spectral properties. Timing adjustments are performed by simply cutting out unwanted portions of the speech, or lengthening (by repeating) sections of speech that are too short. This form of signal processing is computationally simple and fast and therefore attractive from a practical standpoint.

More complex rule-based systems are also being developed that will require recognition of general acoustic speech patterns to determine how segments should be shortened or lengthened. These systems will be able to automatically decide which parts of the original speech are important to keep and which parts can be safely discarded without losing important information. Once optimal timing has been accomplished, spectral characteristics of the speech can be adjusted to further enhance intelligibility.

PROGRESS—We are currently working on an implementation of an interface for the speech prosthesis between a PC and DSP card. Perceptual experiments have been performed to test the intelligibility of the

disordered speech both before and after speech processing. In a typical experiment, normal-hearing subjects listened to samples of original and processed speech in a sound-attenuated chamber. In tests of segmental intelligibility, subjects listened to short nonsense sentences and chose the words they thought they heard from a closed response set differing on a single phoneme. These experiments helped to identify which speech production errors are common for specific disordered talkers, as well as which type of articulations were helped (or hindered) by speech processing.

RESULTS—From the first set of studies we concluded that time-adjustment leads to significantly better sounding speech and small but significant improvements in intelligibility for some phonemes. However, improvements in intelligibility were sometimes offset by artifacts of the signal processing techniques used for timing adjustment. A new version of the software for timing adjustment has been developed which minimizes such processing artifacts and at the same time incorporates a simple heuristic for determining which segments to alter in adjusting the timing of the signal.

C. Vision Impairment

[262] VISUAL CORRELATES OF MOBILITY IN THE VISUALLY IMPAIRED

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C775-RA)*

PURPOSE—The purpose of this project is to investigate relationships between different aspects of visual function and independent ambulation (mobility performance) in individuals with mild to severe visual impairments.

METHODOLOGY—Subjects are visually impaired veterans with varying degrees of vision loss from mild to severe; these are divided by type of vision loss into three groups: acuity loss (primarily age-related macular degeneration and glaucoma); field restriction (primarily retinitis pigmentosa); combination acuity loss and field restriction. Each subject is administered a mobility behaviors questionnaire and the following vision tests: high and low contrast letter acuity, glare sensitivity, Pelli-Robson contrast sensitivity, color confusion (d-15), stereopsis, scanning reaction time, figure-ground, motion sensitivity, spatial contrast sensitivity, and Goldmann visual field. In an indoor experiment, a high-density obstacle course and an open hallway course are completed under high and low illumination conditions. In an outdoor experiment, the obstacle course and a four-block outdoor mobility route are completed under the two illumination levels.

PROGRESS—The indoor experiment is nearly complete, with 92 subjects tested. Seventeen subjects in the field restriction and combination loss groups remain to be tested. The outdoor study has begun with testing of subjects in the acuity loss group.

RESULTS—Preliminary results for a subset of the acuity loss subjects in the indoor study indicate: 1) reducing light level significantly increased errors and times spent on the mobility courses (p's<0.003); 2) under high illumination, visual field extent and motion sensitivity at mid-frequency drift rates (3.5 and 7.0 Hertz) were significantly correlated with mobility performance (multiple R's range 0.45-0.73, p's<0.05); and 3) under low illumination few significant correlations between visual functioning and performance were found. Data is currently being processed for all of the acuity loss subjects in the indoor study.

FUTURE PLANS—Data collection on the indoor study should be completed in the next month. The outdoor study is currently ongoing and should be completed by the end of next summer. We also plan to start an experiment in which mobility performance of normal adults wearing simulators is compared to that of persons with similar vision losses. The purpose is to test the fidelity of various low vision simulators. These devices may be useful in future studies of mobility as the exact nature of the vision loss can be strictly controlled.

RECENT PUBLICATIONS FROM THIS RESEARCH

Visual processing and mobility performance in adults with central vision loss. Kuyk TK, Elliott JL, Biehl J, Fuhr PW. Invest Ophthalmol Vis Sci 1995:36:s533.

[263] DIRECTIONS BY PHONE—AUTOMATED WAYFINDING ASSISTANCE: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #C93-543AP)*

PURPOSE—The goal of this one-year project was to formulate systematic guidelines for giving directions to a visually impaired traveler by telephone using an automated system and to demonstrate this system's technical feasibility. In addition, we intended to develop suitable evaluation instruments for such a system and to estimate the demand for it within the VA.

METHODOLOGY—Two studies were conducted to develop the guidelines. Seven orientation and mobility instructors were asked to compose directions for travel routes within a given building. First, they were given a floor plan and asked to compose directions for three routes. Later, they physically traveled the routes and were asked to modify their descriptions as needed. Four blind subjects were given an orientation to the same routes while walking through them with an instructor. Then they composed a verbal description of the route as if giving directions to another blind traveler. The route descriptions were rated by two investigators for common elements of content, structure, and language.

A telephone Interactive Voice Response (IVR) application was developed using Cypress Research PhonePro on the Apple Macintosh. A set of directions was composed using the draft guidelines; it was tested and revised in a read-through protocol, and resulting scripts were programmed into the IVR system, along with menu selection, help, and supplemental message features. The system was put on-line with a dedicated phone extension at VA Palo Alto for preliminary evaluation. Instruments and procedures were developed for evaluating both the wayfinding information and the telephone interaction.

To estimate the demand for the technology, a market survey was conducted. Blind veterans participated in conference call focus groups to develop an interview questionnaire. This questionnaire was then given to 83 blind veterans nationwide. Subjects were given a description of the proposed system and asked questions to elicit an estimation of their demand. A transformation used in market research yielded an estimate of the percentage of respondents who would actually use the system. Pearson's correlation coefficient was used to identify the statistical relationship between the intent question scale values, the scale values of the benefits being sought, and the system features preferred.

PROGRESS—We have compiled a useful set of guidelines for giving directions to a visually impaired traveler and demonstrated the technical feasibility of delivering them through an an automated system. Evaluation instruments have been formulated, and a demand estimation study is complete.

RESULTS—The guidelines for giving directions describe the elements of content, structure, and language that may be most useful in route descriptions, including overview, hazard, and landmark descriptions, as well as their terminology and syntax. The technical demonstration provided a functional test bed for evaluating route descriptions and gave wide access to an example interactive wayfinding information system. It is now in formative evaluation with both blind and sighted users. The evaluation instruments remain to be tested, though overall system performance criteria have been identified, namely, route completion, travel time, maintenance of orientation, and degree of certainty.

The market study showed that if the technology were available, 3,066 end users and 11,192 end uses could be expected in the first year at 55 VA outpatient clinics. The three features perceived to be the most important were the following: skip between menu items; control of playback; and simple and easy to use.

FUTURE PLANS—The results of the study indicate that there is a demand for automated wayfinding information and that the technology is available to provide it. We are exploring application of this content area to emerging voice interactive information systems.

RECENT PUBLICATIONS FROM THIS RESEARCH

Designing automated wayfinding information systems for blind and visually impaired travelers: a review. Curtis GE, Apple LE, McKinley JL, Martin EG. J Vis Impair Blind. In press.

[264] 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)*

PURPOSE—The purpose of this project is to develop and evaluate liquid crystal (LC) light/dark-adapting eyewear for individuals with low vision. Many persons with low vision function best only within a very limited range of ambient lighting. We seek first to develop LC sunglasses that very quickly and precisely control the amount of illumination reaching the user's eyes, and second, to test the usefulness and practicality of these LC sunglasses in actual use by persons with low vision.

METHODOLOGY—First, potential LC materials (those with a wide light to dark range) were evaluated for optical quality (transmission range, spectral characteristics, and optical distortion). The two LC materials with the best optical quality and widest light/dark range were chosen for use in the first prototypes. These first prototypes were tested by a small, diverse, population of 44 persons with low vision. The purpose of this was to insure that the stated design objectives and resultant prototypes would optimally suit the diverse needs of the population. Required changes in design indicated by these results have been incorporated into a design revision that is currently being constructed in four prototypes.

A final, and more rigorous, subject testing and analysis will begin in 1996. This final testing will be conducted with 104 subjects, including 1) persons with central vision loss from age-related macular degeneration, 2) persons with cloudy ocular media, 3) persons with retinitis pigmentosa, and 4) persons with rod/cone dystrophy. Analysis of quantitative elements will be descriptively presented through measures of central tendency and dispersion. Tabulation and graphic representations will be employed when appropriate. The objective data (visual acuities, visual fields, contrast sensitivity function (CSF), travel time, productive walking index (PWI), stride length, and unwanted contacts) will be evaluated with multiple paired t-tests or repeated

measures ANOVA to identify main effects and interactions of condition by device. Subjective data will form the basis for specific case studies which will complement the objective findings, identifying specific examples of advantages and disadvantages of the LC eyewear system. These results will then be published and made available to manufacturers.

PROGRESS—Investigators have completed an initial subject testing of first-design prototypes, and have revised the LC sunwear design based on the results of these tests. New prototypes are under construction and subject testing will begin in 1996.

RESULTS—The light/dark range of initial prototypes was much less than that expected by the investigators, who had desired an 80 percent to 1 percent dynamic range for the prototypes. However, no noticeable visual distortion was evidenced in either case, and ultraviolet and infrared transmissions were attenuated by more than an order of magnitude at the highest transmission levels and by as much as three orders of magnitude at the lowest transmissions levels. Subject comments have complained most of the limited dynamic range, the weight of the prototypes, and the visual effect that occurs when the glasses darken in which it appears as if a window shade is moving up or down each time they lighten or darken.

FUTURE PLANS—A new prototypes that address the above three concerns have been designed. These will be tested thoroughly by subjects in 1996.

[265] AN ADAPTIVE CANE FOR SPECIAL ADULT GROUPS: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #C92-482AP)*

PURPOSE—The purpose of this project was to develop an alternative mobility device (AMD) for visually impaired adults who are unable to use the long cane and have multiple impairments or are elderly. Many of these individuals are unable to use the traditional long cane because it requires strength, coordination, and cognitive abilities they lack. Unlike the long cane, an AMD requires minimal instruction: the user has only to push the device in the direction of travel. The design of the new AMD is based upon devices that have been designed and built by orientation and mobility (O&M) specialists to meet the needs of specific clients. The goals of this project were to: determine the preferred and non-preferred features of AMDs being used in the O&M profession, evaluate AMD design features such as materials, shape, and grips; design a new AMD to meet the needs of older adults and multiply-impaired adults; build prototypes for field testing; and field test the prototype.

METHODOLOGY—A telephone survey, designed to determine the benefits and drawbacks of existing AMDs, was developed by the principal investigators in consultation with O&M specialists who had worked with clients who used AMDs or had done research on the use of AMDs. Twenty-six O&M specialists who have previously provided AMDs to their clients were interviewed. These interviewees felt that previous AMDs were bulky, conspicuous, and had a homemade appearance that was socially unacceptable. Devices that rolled on wheels tended to lead the student away from the intended path of travel and were noisy to the point of distraction when used indoors. Devices that had runners or skids and were used outside had to be repaired frequently.

The information obtained from the survey was used to develop the prototype AMD, designed specifically for older adults and multiply-impaired adults. The prototype is constructed from aluminum tube. It is

lightweight, has a sleek, professionally made appearance, and interchangeable runners and caster wheels.

O&M specialists participating in the field testing were required to spend at least 1 hour per week for 5 weeks instructing and observing each client participating. They were instructed to begin by teaching the clients to walk along a quiet hallway and proceed to more difficult tasks, such as ascending stairs and traveling in unfamiliar environments, as time permitted. At the end of the 5-week testing period, the specialists completed a questionnaire designed by the principal investigators in consultation by other O&M Specialists in practice and in research, to determine the effectiveness of the AMD prototype. Topics covered in the questionnaire included the client's functional abilities, ability of the AMD to detect obstacles, performance of the runners, performance of the wheels, performance of the AMD on stairs, and its appearance.

PROGRESS—We received 83 completed questionnaires on the 100 prototype AMDs constructed and distributed. The clients were distributed as follows: 18 elderly adults (aged 65 and over) who were also visually impaired, 28 adults (under age 65) who were multiply-impaired and visually impaired, and 37 individuals of any age who had previously used an AMD. Each participating individual was working with an O&M specialist and was unable to use a long cane as a primary mobility device, as determined by the specialist. The results of the field testing are being compiled and analyzed.

[266] ADJUSTABLE POWER LIQUID CRYSTAL LENSES TO ASSIST PERSONS WITH LOW VISION: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420*
(Pilot Project #C93-608AP)

PURPOSE—The purpose of this pilot project was to develop and evaluate Adjustable Power Liquid Crystal Lenses (APLCLs) for use as adjustable-power magnifiers for persons with low vision. The intent was to develop a single lens whose magnification range could be continuously varied from 2.5× to 4× or greater via the application of a variable voltage.

METHODOLOGY—First, potential LC lens materials, those with large refractive ranges, were evaluated for optical quality (optical clarity, media "bubbles," cloudiness, and visual distortion). The material with the best optical quality, as observed in three-ply samples, was chosen as the one to develop. In an attempt to maximize refractive range, the viscosity of the material was increased. Lenses of varying magnification power, from −1 diopter to +2.5 diopter were constructed. This was done by sandwiching the LC material between a plano lens and lenses of 1×, 3×, and 5× power. The resulting lens combinations were then evaluated for optical clarity and power range. Two "back-to-back" lenses were also constructed to see whether a wider power range could be achieved in this fashion. Finally, an expert panel comprised of two low vision experts, two low vision device consumers, and a low vision device manufacturer was convened to evaluate investigator findings.

RESULTS—The best optical quality was exhibited by an anti-parallel LC material arrangement of viscosity 40 C Stokes. By increasing the viscosity of this material to 80 C Stokes, a refractive index range of 0.28 was obtained. Five lenses of varying power and range were constructed of this material. The maximum range obtained was 5.5 diopters (from +4.75 to 10.25 diopters). A larger range was not attempted because of an observed increase in media cloudiness with greater lens curvatures. Prior to this discovery, investigators had observed cloudiness in plano LC lenses that was proportional to material thickness in the lens, and had

made design decisions based on these measured values. However, the cloudiness added by lens curvature increased the cloudiness of the resultant lenses to four times that predicted. Application of an electric field reduced this cloudiness; however, maximum clarity only occurred when maximum voltage (producing maximum magnification) was employed.

Prototypes employing a double-lens structure were constructed in a fashion that was to eliminate the double image produced by single lenses. Unfortunately, this strategy did not work, and instead these lenses produced a multiplicity of images.

The expert panel reviewed the results and agreed that the concept of an adjustable power device had merit and should have significant appeal to low vision consumers. Numerous examples of potential applications in retrofitting existing devices and developing new devices were offered. The limitation of optical cloudiness was viewed by the panel as the most significant issue to resolve. The panel felt that additional work with this concept should be pursued to emphasize: 1) clinical trials to include testing of the current prototypes' effect on contrast sensitivity, illumination, and color; 2) additional engineering to develop a means of reducing media cloudiness via the application of constantly applied differential voltages; and 3) developing prototypes representing a wider variety of applications. Areas of additional research and development were recommended through this undertaking.

[267] FOUNDATIONS OF ORIENTATION AND MOBILITY

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

PURPOSE—This is a 1-year project to prepare a revised edition of the textbook *Foundations of Orientation and Mobility*. The first version was edited by Richard L. Welsh and Bruce B. Blasch and published in 1980. Developed in an effort to create a comprehensive textbook of information for the orientation and mobility (O&M) professionals and students, this book is and continues to be the only text of its type used in university programs to train mobility specialists for individuals who are visually impaired. It is used worldwide in English-speaking countries and has been translated into Japanese, Spanish and German.

The first edition is now fourteen years old and needs revision to include the many changes and additions that have occurred in the field of orientation and mobility over the past decade.

METHODOLOGY—A questionnaire was sent to the instructors of the various 0&M programs around the nation. The feedback received gave critical insight into what is currently being taught in the field of visual impairment and blindness. Using the information from the questionaire, the editors Drs. Blasch, Wiener, and Welsh have designed the new outline for the second edition, assigned chapter topics to individual authors, and examined outlines of the chapters submitted by the various authors.

Each author has been assigned to work closely with either Dr. Blasch or Dr. Wiener, the editor serving as consultant and supervisor to the author during the writing of the chapter. The editors meet to review the drafts of each chapter, assuring a thorough review and discussion of the text materials in their entirety. This procedure will also permit greater consistency of quality among chapters.

The manuscript of the entire textbook will be given to the American Foundation for the Blind (AFB) for publication.

PROGRESS—There are now 6 chapters completed and more are being finished; publication is scheduled for 1996.

[268] DEVELOPMENT OF A PREDICTIVE MODEL OF DRIVING PERFORMANCE IN STROKE PATIENTS

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PURPOSE—The overall aim of our studies is to develop predietive models of automobile driving performance in patients who have suffered eerebral vascular aeeidents (CVAs) or strokes affeeting primarily the oeeipital eortex, resulting in hemianopsia or hemifield vision loss. These models are eompared to those being developed for a group of age-similar patients with central vision loss due to Age-Related Maeular Degeneration (ARMD), and an age-similar eontrol group of normally sighted subjeets. The findings from the CVA patients are being eompared to the findings from the ARMD patients in an attempt to determine the relative effects of peripheral versus eentral visual field loss in older individuals.

METHODOLOGY—The test battery has tests of visual function, ineluding eontrast sensitivity, visual fields, color vision, and visual acuity and neuropsyehologieal tests, including subtests from the Weehsler Adult Intelligenee Scale-Revised, the Weehsler Memory Seale-Revised, and tests of visual form diserimination. The subjeets' driving abilities are evaluated through the use of an interactive driving simulator system and an on-road test administered by a state-licensed kinesiotherapist. The stroke patients also undergo a neurologieal sereening.

PROGRESS—To date, the study groups are charaeterized by the following numbers and age distributions: 1) CVA: N=20, mean age±SD=68.2±7.9; 2) ARMD: N=10, mean age±SD=76.7±4.1 years; and 3) eontrol: N=26, mean age±SD=67.1±8.2 years. The three groups did not differ in the number of miles driven per year (CVA, mean±SD=10.2±10.5 thousands of miles; ARMD, mean±SD=6.7±4.0 thousands of miles; control, mean±SD=9.5±8.1 thousands of miles. H (2 degrees of freedom) =0.187, p=0.91) There were no significant differences in performance between the groups on any of the neuropsyehological tests.

RESULTS—Analysis of varianee proeedures were used to analyze for differences in the driving performance between the three groups. Post hoc multiple comparison procedures revealed that any significant differenees between the three groups eould be accounted for primarily by the disparities between the CVA group and the control group.

The differences were the most pronounced for the road test indexes. There was a signifieant main effeet for group in the overall score ($F(2,28)=3.91$, $p=0.032$), with the following means and standard deviations for the three groups: CVA, -66.3 ± 26.4; ARMD, -62.5 ± 17.3; eontrol, -38.7 ± 26.7. Though the CVA and the ARMD groups both performed more poorly than eontrol group, pairwise multiple eomparison post hoc procedures showed that the main effect for group was due to the difference between the performanee of the CVA and the control group ($p<0.05$). A similar pattern of findings was observed for the road test indexes including speed-too-slow ($H(2)=7.50$, $p=0.024$), the eomposite seore for merging ($H(2)=9.25$, $p=0.01$), and proper use of a signal while merging, ($H(2)=7.52$, $p=0.023$). Both the CVA and the ARMD groups performed more poorly than the eontrol group on these indexes, though post hoc procedures showed that the main effeet for group was due primarily to the difference between the CVA and the control group ($p<0.05$). For the road test index lane observanee, there was also a signifieant group effeet ($H(2)=9.69$, $p<0.008$), with both the CVA group and the ARMD group performing significantly more poorly than the eontrol group ($p<0.05$).

There were also signifieant differences between the groups for the simulator indexes. Though both the CVA and the ARMD groups had more lane boundary crossings than the control group, and a significant main effect was found for group ($H(2)=8.75$, $p=0.013$), post hoc procedures did not isolate the source of the main effeet. Similarly, both the CVA and the ARMD groups

had longer braking response times compared to the control group, and a significant main effect also was found for group ($H(2)=6.27$, $p=0.044$), post hoc procedures did not isolate the source of the main effect. Both the CVA (16.6 ± 8.00 mph) and the ARMD (18.9 ± 6.42 mph) groups drove more slowly on the simulator than the control group (24.1 ± 6.81 mph), and a significant main effect was found for group, $F(2,53)=6.43$, $p=0.003$. Post hoc comparisons revealed that the main effect was due to the differences in the speeds of the CVA and the control group ($p<0.05$).

These findings suggest that the CVA patients with hemifield loss have more difficulty with driving-related tasks than patients with central vision loss due to ARMD. The results are consistent with the findings from a previous study done in our laboratory with younger patients. This prior study demonstrated that patients with peripheral vision loss had more difficulty compensating for this loss while driving than patients with central vision loss.

FUTURE PLANS—We plan to determine the effectiveness of visual rehabilitation in patients with central versus peripheral vision loss. The effectiveness will be measured using objective tests of visual and functional performance.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[269] LOW VISION ENHANCEMENT SYSTEM MULTICENTER CLINICAL EVALUATION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C638-2DA)*

PURPOSE—The purpose of this 3-year project is to clinically evaluate the Low Vision Enhancement System (LVES) in the visually impaired veteran. The intent is to develop a head-worn, closed-circuit television system with electronic enhancement of the image that will serve as a future platform for real-time image processing.

METHODOLOGY—Patients are recruited from inpatient and outpatient veterans undergoing rehabilitation for visual impairment. Visual impairment must be at least 20/100 in the better eye and no worse than 20/1000. Specific areas of VA research with the current headset include: distance visual acuity, contrast sensitivity, reading speed, eye-hand coordination, motor coordination, postural assessment, and training techniques.

PROGRESS—Approximately 120 patient encounters with the LVES have been conducted so far across the VA system. As of August 1995, 56 patients have participated in formal training, dispensing, and testing of LVES units. Patient reports indicate that average usage is approximately 2 hrs per day initially, with a gradual decrease over time to approximately 1 to 1.5 hours per day. Overall, visual acuity improved significantly in all except one case. Up to 10-fold improvement in visual acuity was noted using the highest or

best patient selected magnification. Some patients were able to achieve 20/20 acuity from vision as low as 20/200 to 20/400 initially.

Very early results also show that all patients had improvement in contrast sensitivity, some by several log units. Preliminary results using non-autofocus LVES units indicate that reading speed is decreased in most cases. Abilities to perform physical tasks are similarly decreased. Observations for this include the patients inability to maintain adequate focus while reading and doing other tasks and patient discomfort with the headset. It is felt that autofocus capabilities would significantly decrease both training time, and enhance performance in these areas. Overall patients appear to be motivated despite limitations of the system.

FUTURE PLANS—Currently, the VA has four preproduction autofocus units. Preliminary testing is underway using both new patients without prior LVES experience and old patients who have had previous experience with manual focus units. Data from these patients will be used for full production version of the headset with autofocus capability built in. Testing on image remapping is expected to begin this year.

[270] INCLUSION OF WOMEN IN THE RANDOLPH-SHEPPARD PROGRAM: A NATIONAL STUDY

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Sponsor: *National Institute on Disability and Rehabilitation Research, Washington, DC 20202*

PURPOSE—There is a need for more qualified facility managers in the Randolph-Sheppard Program for the blind. The recruitment of additional women could be one solution to this ongoing problem. However, recruitment success will depend upon the evaluation of existing barriers to the participation of women in the Business Enterprise Program (BEP). Building on previous research conducted at our Center, the present research will address those barriers and identify strategies for overcoming them.

METHODOLOGY—BEP directors in 51 states and territories will be surveyed regarding a wide array of issues pertaining to the program in their individual states. They will also be asked to identify women who are successful operators, and women who have been unable to complete the program or become licensed operators. They will also be asked to offer recruitment suggestions and strategies with regard to recruiting more women for the BEP Program. They will also be asked to identify barriers to female participation in the program and to enumerate incentives or program practices that would encourage the participation of women in the program.

PROGRESS—A written survey instrument/questionnaire has been mailed to all 51 directors. A total of 36 responses have been received thus far.

RESULTS—Data are in the process of being analyzed.

[271] IDENTIFICATION OF SKILLS AND KNOWLEDGE NECESSARY FOR PEOPLE WITH VISUAL IMPAIRMENTS BEGINNING JOBS AFTER GRADUATING FROM POSTSECONDARY INSTITUTIONS

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PURPOSE—The purpose of this project is to identify skills and knowledge necessary for people with visual impairments to successfully 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—Using contacts with colleges and state vocational rehabilitation agencies, telephone interviews were completed with 55 employees and 29 employers. Frequency analysis, correlation analysis, and limited factor analysis were used to analyze the quantitative portion of the surveys. Qualitative analysis was also conducted using responses from several open-ended questions. The project is now complete.

FINAL 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 jobs, communicating with employers about accommodation, practicing being interviewed, visiting job sites, and making housing arrangements. The most common problems experienced by employees at work included having enough money; locating transportation; being discriminated against; accessing books, written materials, diagrams, and charts; being lonely; and managing time. Employees encouraged younger students to pursue their dreams in spite of their visual limitations; to understand their visual limitations and make informed decisions about their abilities; to prepare for work through study, networking, and skill development; to obtain appropriate accommodations; and to be on guard against discrimination.

Employers wanted early notification of the visual impairment, preferred direct contact by the job applicant, expressed ambivalent feelings toward sighted guides (as long as they were not present during the interview), favored dog guide users, and preferred eye contact. Employers advised potential workers to not expect special consideration for an impairment, to obtain skills needed to perform the job, to emphasize abilities and assets during job interviews, to select the job that matches abilities and skills, to discuss accommodations and provide information about obtaining accommodations, and to educate employers and coworkers about the impairment.

FUTURE PLANS—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, parents, college students, advisors, and rehabilitation personnel to help increase the number of students with visual impairments completing college and beginning work.

[272] TACTILE AND HAPTIC INTERFACE PROJECT

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PURPOSE—Individuals with visual disabilities face tremendous challenges that can be insurmountable in interfacing with the ever more prevalent graphical computer interface environments. Not surprisingly, these individuals are underrepresented in science, engineering, and math (SEM) academic programs and professions, which often rely on the latest computer technology. As a part of the SEM Project to recruit and retain students, the Tactile and Haptic Interface Project addresses the needs of the visually impaired person through basic human factors research and display system design and development. Our research investigates and quantifies viable methods for the rendering of traditionally visual information such as photographs, graphs of mathematical functions, physics and chemistry experiments, and other images in a tactual or haptic fashion which can subsequently be understood by the student. Development of a number of software and hardware systems is underway, and includes using devices for the tactile and haptic display of such visual information, and combining various existing technologies in new ways to achieve the goal of tactile accessibility.

METHODOLOGY—Understanding the human factors involved in the basic human ability to recognize physically represented visual information is the first goal of our research. Through measurement of factors including the tactile resolution of the fingertip under various real world constraints, tactile image discernment tasks, such as distinguishing various tactile shapes from each other, and abilities of blind and deaf-blind persons to comprehend tactile and haptic information, we will gain insight into how the mind perceives what the human tactile and haptic systems sense. Concurrently with this basic research, and subsequently relying on its results, will be the development of a number of software and hardware systems to provide blind computer users access to visual information. Using combinations of products and devices such as capsule paper, the Optacon, the PHANToM, screen reading software, touch screen technology, and others, together with the appropriate software, either commercial or custom written, we will create tactile and haptic access systems. While some of this research will involve the use of new and somewhat expensive technology, most of it will emphasize the use of affordable equipment and software to ensure that the end product will be as widely available as possible to help the greatest number of visually impaired individuals.

PROGRESS—A great deal of preliminary research into the current state of tactile and haptic information representation has already been performed by our staff. A number of tactile and haptic devices have been purchased, including an Optacon, a PHANToM, a capsule paper developer, and a touch screen device. A preliminary system which haptically displays mathematical equations has been completed, and will soon be extended for general use in representing science experiments. A general purpose software system for handling display of science experiments on haptic display devices is under development. Materials for conducting basic two-point and point-line tactile experiments have been produced using isotropically etched glass slides, and these will be supplemented with more complex shapes portrayed on capsule paper in experimentation into the human factors of the sense of touch. An image processing system for simplifying and generating a tactile representation of photographs, drawings, and other images is in the early stages of development.

FUTURE PLANS—The coming year promises to be one of rapid discovery and development. Tactile studies will be conducted and will be extended to the haptic sense system. The image simplifcation system will be completed, and so will systems that make use of touch screen technology and tactile overlays. Finally, a Virtual Laboratory will be developed using the PHANToM to haptically display science experiments, making them accessible to blind and deaf-blind persons.

[273] WIVOX: VOICE OUTPUT FOR WINDOWS

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Sponsor: *The Ontario Rehabilitation Technology Consortium, funded by the Ontario Ministry of Health; IBM Canada Ltd.; IBM Corporation; University Research Incentive Fund of the Ontario Ministry of Colleges and Universities; National Research Council Canada*

PURPOSE—The purpose of WiVox is to provide auditory feedback of typing when using any Windows application. As a separate product, it is intended to augment the standard visual presentation and enhance interaction by users who are learning to read or who have slight visual impairments. WiVox can also be used with WiViK and KeyREP as a means to communicate through a computer. It is not a screen reading package.

PROGRESS—WiVox currently works with any external speech synthesizer. During this past year, support for software text-to-speech output through standard sound cards has been added in English, French, Spanish and German. WiVox provides a small on-screen window to turn speech on or off as required. When turned on, WiVox speaks the typed text. Choices may be made for speaking letters, words, partial words (up to the current character), complete sentences, or menus. WiVox also speaks text highlighted in any window. A simple on-screen menu is provided for specifying the synthesizer and its settings. Default settings for several common synthesizers are included. A word exceptions editor is included to allow the user to specify correct pronunciation of unusual or proper names. WiVox has also been updated to provide direct support of speech feedback from WiViK and KeyREP for auditory prompting.

FUTURE PLANS—WiVox will become closely integrated with WiViK and KeyREP as part of solutions-based packaging. Example solution packages include: a writing aids package for users learning to read and write; an auditory scanning access package; and an augmentative communication package. Additional functions will be necessary to support these packages including auditory review of text for writing, and a pop-up window to quickly retrieve and output communication phrases.

XV. Spinal Cord Injury and Related Neurological Disorders

A. General

[274] 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—The purpose is to establish a cost effeetive and clinically useful noninvasive diagnostic procedure for deteetion of eoronary artery disease (CAD) in persons with lower limb disabilities. The investigation compares the scnsitivity, specificity, and predictive value of wheelchair (WCE) ergometry with and without exereise digital two-dimensional echocardiography (ECHO) for the detection of myoeardial ischemia.

METHODOLOGY—Patients complete a symptom limited maximal WCE test using an intermittent proto-eol of 2 min stages with a 30 sec pause between stages. The initial workload is 6 W with increases of 6 W per stage. The ergometer eomputer automatieally sets the braking resistance and target wheeling speed. Supine pre- and post-exercise ECHO images are obtained on a speeially designed imaging table adjoining the WCE. An abnormal exereise eleetroeardiogram (ECG) is defined as 1 mm horizontal or down sloping ST segment depression occurring 80 msec after thc J point. An ECHO study is abnormal whcn a stress induced wall motion abnormality or worsening of a resting wall motion abnormality is present. A blind review of the ECHO studies, ECGs, and angiograms is conducted by indepcndent investigators. A wall motion score index (WMSI) is used to quantify the presence, location, and severity of myoeardial abnormalities, and a pereent normal musele seore (%NMS) quantifies the percentage of normally funetioning myocardium. Correlations be-tween wall motion abnormalities and coronary circula-tion are determined using a two-region distribution model.

PROGRESS—One hundred ninety-two maximal WCE exercise tests with ECHO have been completed. Ninety-two patients (48 percent) underwent coronary angio-graphic procedures. Follow-up interviews have been completed on 109 subjects.

RESULTS—The focus of Analysis One is inter-rater reliability and Analysis Two is sensitivity, specifieity, and predictive value of WCE+ECHO testing. Subjects in Analysis One did not undergo coronary angiography, while subjects in Analysis Two underwent ANGIO within 6 months of the WCE+ECHO test.

Analysis One: The average rate pressure product was >20,000 and subjccts were positioned for imaging in <30 sec. Thirteen subjects completed WCE+ECHO testing. One subjeet's resting and post-exereise echocardiogram were interpreted as nondiagnostie. Five resting echocardiograms wcre interpreted as abnormal and seven normal. Six post-exercise echocardiograms were interpreted as abnormal and six normal. There was 100 pereent agreement for rest and post-exercise ECHO

interpretations (normal, abnormal, or nondiagnostic) between the cardiologist (MD-I) who acquired the resting and post-exercise echocardiograms and cardiologist (MD-II) who was blinded to the interpretation of MD-I. There was a significant ($\leq$0.002) relationship (Rho$\geq$0.91) between cardiologists' WMSI and also %NMS at rest and post exercise. Differences between the rest WMSI and %NMS given by MD-1 and MD-II were significant (P=0.04; Wilcoxon Signed Rank). This was not true for the post-exercise WMSI and %NMS (P>0.05). There was complete agreement between MD-I and MD-II regarding the affected distribution of coronary blood flow post exercise. Inter-rater reliability will be studied further by applying procedures designed to assess agreement between clinical measurements to all of the 192 WCE+ECHO tests.

Analysis Two: Fifteen subjects completed WCE+ECHO testing and elective angiography. WCE+ECHO had a sensitivity of 75 percent and specificity of 100 percent. The predictive value of a positive test and negative test was 100 and 78 percent, respectively. In these 15 WCE tests diagnostic accuracy was 87 percent. Based on these few cases when WCE+ECHO test interpretations were compared to WCE with ECG, WCE+ECHO was superior in detecting the presence or absence of CAD. An analysis of the sensitivity, specificity, and prognostic value of WCE+ECHO for 92 patients who underwent coronary angiography is being conducted.

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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.

Wheelchair exercise and digital echocardiography for the moninvasive assessment of cardiac function in active wheelchair users 55 years of age and older. Edwards LC, Langbein WE, Louie EK, Oregaugh C, Maki KC. In: Langbein WE, Wyman DJ, ed. National Veterans Golden Age Games Research Monograph: Health-Related Physical Activity, Hines, IL: Hines VA Hospital 1994:20-29

[275] MULTIMODALITY IMAGE REGISTRATION OF THE CERVICAL SPINE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Programs, Washington, DC 20420 (Project #B762-RA)*

No report was received for this issue.

[276] EFFECT OF SUPPORTED STANDING AND UPPER BODY EXERCISE ON LOWER EXTREMITY SPASTICITY IN PERSONS WITH SPINAL CORD INJURY

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PURPOSE—The purpose of this research is threefold: 1) demonstrate that supported standing and/or aerobic upper body exercise (AUBX) significantly alter 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 minutes of submaximal wheelchair ergometry (WCE) exercise; 2) to examine the effect of low-intensity activity, subjects complete 30 minutes 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 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-minute 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 having a variety of lower-limb disabilities. Substantial progress has been made toward the design and construction of a miniaturized ankle compliance measurement device suitable for future integration into a clinical environment; electrophysiological recording equipment has been purchased. Subject recruitment efforts were begun in summer 1995. Two subjects have been screened for participation in the study and have completed maximal exercise tests.

RESULTS—Pilot study results suggested that 20-minute 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 minutes), maximal exercise. Similarly, among subjects completing maximal AUBX pursuant to the merit review project (n=2), one exhibited only a 2 percent decrease in tone while the

other demonstrated a 10 percent increase in tone following maximal exercise.

FUTURE PLANS—Twenty-five subjects with SCI will complete the full protocol with submaximal AUBX.

[277] PERIPHERAL NERVE REPAIR: MOTOR AND SENSORY FASCICLE ORIENTATION: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Programs, Washington, DC 20420 (Pilot Project #B93-681AP)*

No report was received for this issue.

[278] THE CORTICOSPINAL SYSTEM

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PROGRESS—A remarkable recovery of motor function can follow lesions of the primary motor cortex or its projections to the spinal cord. The goal of our studies is to define the cortical systems that are responsible for this restitution of function. Several studies have suggested that recovery may depend on the integrity of descending pathways from the premotor areas in the frontal lobe.

METHODOLOGY—Our studies have demonstrated that the frontal lobe contains at least six premotor areas which project directly to the primary motor cortex and to the spinal cord. These premotor areas are located in subfields of cytoarchitectonic areas 6, 23, and 24. They include the supplementary motor area and cingulate motor areas on the medial wall of the hemisphere, and two premotor areas on the lateral surface of the hemisphere. Furthermore, we have recently found that some of the premotor areas project to the same regions of the spinal cord as the primary motor cortex, including terminations around motoneurons in the ventral horn that innervate hand muscles. As a consequence, our results indicate that 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 spinal cord motoneurons and interneurons. Thus, we believe that the corticospinal projections originating from the premotor areas could play an important role in the restitution of motor function that follows lesions of the primary motor cortex.

PROGRESS—In the last year, we have shifted the emphasis of our research to investigate the actual processes responsible for functional recovery. As a first step, we have examined the effects of motor cortex lesions on wrist movements in trained monkeys. Initially, animals with large lesions are unable to make simple step-tracking movements of the wrist. However, after extensive retraining, we have found that the

recovery of wrist function displayed by these animals is remarkable. Although several lasting deficits remain, lesioned animals are capable of making well-defined wrist movements in multiple directions. We have also begun experiments using metabolic imaging in trained primates (i.e., the 2-deoxy-glucose technique) to define the pattern of cortical activation associated with the performance of arm movements in normal trained monkeys. Surprisingly, in normal trained monkeys, the metabolic activation of some premotor areas on the medial wall of the hemisphere is greater than that in the arm area of the primary motor cortex. These preliminary experiments will form the basis of similar studies performed in monkeys that have received large ablations of the primary motor cortex.

IMPLICATIONS—The outcome of our research could have an important impact on the methods used to evaluate and treat stroke patients. Our results should lead to a clearer definition of the short- and long-term deficits that are caused by a lesion of the primary motor cortex. In addition, our data should enable clinicians to make more accurate predictions about the potential for functional recovery and its time course. Specifically, our studies may indicate which cortical areas are essential to the recovery of wrist movement following damage to the primary motor cortex. If these areas are involved in the initial disease process, the potential for recovery may be limited. This information could be critical to attempts to rehabilitate stroke patients.

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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 1995:15:3284-306.

Effects of a primary motor cortex lesion on step-tracking movements of the wrist. Hoffman DS, Strick PL J Neurophysiol 1995:73:891-5.

Corticospinal system: a structural framework for the central control of movement. Dum RP, Strick PL. In: Rowell LB, Shepard JT, eds. Handbook of exercise physiology: integration of motor, circulatory, respiratory and metabolic control during exercise, section A: neural control of movement. New York: Oxford University Press. In press.

[279] RECURRENCE OF BACTERIURIA AND PROGRESS TO SYMPTOMATIC URINARY TRACT INFECTION IN SPINAL CORD-INJURED PATIENTS

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PURPOSE—The four objectives of this project were to: 1) analyze the effect of treating asymptomatic episodes of urinary tract infection (UTI) on the progression to symptomatic UTI in spinal cord-injured (SCI) patients who undergo sterile intermittent bladder catheterization; 2) explore the potential relationship between the *in-vitro* adherence of *Klebsiella pneumoniae* organisms and recurrence of bacteriuria in these patients; 3) localize the site(s) adjacent to bladder where bacteria may continue to reside despite eradication of bacteriuria by antibiotic therapy; and 4) differentiate between relapse of UTI by same bacterial strain vs reinfection by a different bacterial strain.

METHODOLOGY—Eligible hospitalized patients were randomized to receive either a 1-week course of antibiotic therapy for asymptomatic episodes of UTI ($\geq 10^5$ cfu of bacteria/ml of urine and $\geq 10^4$ WBC/ml of urine) or no antibiotic treatment and were monitored for the development of the primary outcome of symptomatic UTI. The *in-vitro* adherence of recovered *K. pneumoniae* organisms to human uroepithelial, HEp-2 and buccal cells was correlated to the likelihood of particular bacterial strains to cause recurrence of UTI despite antibiotic therapy. Cultures of potential reservoir sites, including prostate, urethra, perineum, and rectum, were simultaneously obtained with urine cultures from patients

randomized to the treatment group. Among those with recurrent UTI, DNA typing of bacterial isolates was done using the polymerase chain reaction (PCR) technique.

PROGRESS—The practicality of this study was proven in 31 evaluable patients so far.

RESULTS—The progression to symptomatic UTI was significantly lower among patients randomized to the treatment (3/16=19 percent) versus the non-treatment group (10/15=67 percent; p=0.007). The adherence of *K. pneumoniae* to human cells was mediated by type 1 fimbria and correlated with the likelihood of recurrent UTI. Preliminary results suggest that sites adjacent to the bladder, such as prostate, urethra, perineum and rectum, may contribute to recurrence of UTI by acting as potential reservoir sites from which bacteria may migrate again into the bladder following eradication of bacteuiria with appropriate antibiotics. Molecular analysis by PCR showed that the majority of instances of recurrent UTI were due to relapse by the same bacterial strain.

FUTURE PLANS—Patient enrollment will continue to a maximum of 60 evaluable patients. A cost-benefit analysis of the treatment of asymptomatic episodes of UTI in these SCI patients will be done. The findings of this study should also help guide health care providers as to which SCI patients are likely to experience progression from asymptomatic to symptomatic UTI and, therefore, perhaps administer antibiotic therapy for asymptomatic UTI in only those at high risk of progression. If the role of potential reservoir sites is confirmed, it should have an impact on the type and duration of antibiotic therapy for UTI in this population.

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Type 1 fimbriae of *Klebsiella pneumoniae* mediate adherence to human uroepithelial cells. In: Proceedings of the 57th Annual Assembly of the American Academy of Physical Medicine and Rehabilitation, Orlando, FL, 1995.

[280] 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—Three groups of 10 subjects with tetraplegia were followed for a 6-month period to study the effect of quadrugby participation on work capacity, physical strain in standardized ADL tasks, and risk factors for cardio-vascular disease. A group of trained quadrugby players (TG), a novice group of starting quadrugby players (NG) and a non-sporting control group (CG) were selected for this purpose and participated on a voluntary basis.

METHODOLOGY—In a longitudinal design maximum exercise tests were performed on a computer-controlled wheelchair ergometer on three occasions: at 0, 3, and 6 months of quadrugby training. Standardized daily wheelchair tasks were evaluated on heart rate response. Heart rate was monitored during the ADL, and percentage heart rate reserve was determined. Apart from maximum isometric force of different muscle groups, physical work capacity was determined in both an arm crank and wheelchair exercise test. Also personal characteristics, blood samples, and sport participation and training intensity were determined. Ventilatory capacity and cardiac characteristics were determined in comparison with a able-bodied control group in a cross-sectional design.

PROGRESS—The experimental setup suffered from a loss of subjects over the 6-month period, generally due

to illness. This substantially hampered the outcome of the study. Also, differences in lesion level between groups, which could not be matched, led to a loss of statistical power.

RESULTS—Results indicate that the training effects are relatively marginal. UG showed a negative trend in physical strain during ADL, a somewhat higher isometric force but no significant increase in other performance parameters over time as a consequence of partieipating in quadrugby. The intensity of training seemed to be sufficient aeeording to the guidelines of the American College of Sports Medicine, but the frequeney is too low, whereas much care should be taken to aeeomodate training intensity to the interindividual differences in performance capacity.

Performanee capacity appeared inversely related to the strain during the training and sports events and the ADL tasks, indicating that those with a higher VO_2-peak showed lower levels of strain, and vice versa. Overall, the TG appeared to have a significantly higher perfomance capacity than the UG and CG when studying the data eross-seetionally.

Cardiac characteristics and ventilation parameters were clearly redueed in comparison to non-wheelchair users. Blood samples did not indicate an increased risk for cardiovascular disease.

FUTURE PLANS—A follow-up study should address a more systematic intervention of training intensity, frequency, and training form among subjects with tetraplegia. Special attention should be focussed upon training of remaining ventilatory museles.

RECENT PUBLICATIONS FROM THIS RESEARCH

Effeets of quadrugby training on physieal performanee in persons with quadriplegia. Dallmeijer AJ, Hopman MTE, Woude LHV van der. Med Sei Sports Exere (Suppl) 1995:27:5:S138.

Physieal eapaeity and physieal strain in persons with quadriplegia. Dallmeijer AJ, Hopman MTE, Woude LHV van der. RESNA REcreability Proceedings. Vaneouver, BC 1995:752-4.

Effeet of quadrugby training on exereise eapaeities of individuals with quadriplegia (abstraet). Hopman MTE, Woude LHV van der, Dallmeijer AJ. In: Proceedings of the XIIth World Congress of IFMPR, Sydney, 1995.

[281] ADJUSTMENT AFTER SPINAL CORD INJURY: THE 20-YEAR MINNESOTA LONGITUDINAL STUDY

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PURPOSE—The purpose of this research is to identify how life adjustment changes over time after spinal cord injury (SCI), along with the relative impaets of chronologic age, time since injury, and environmental change upon adjustment.

METHODOLOGY—Three study samples have partieipated over the 20-year period. The first sample began participation during the first stage of this study in 1974 (n=256). The second sample (n=193) was added in 1985, and a third (n=205) in 1994. There were three screening criteria for inclusion to the study: a traumatic SCI, the injury was at least 2 years duration, and at least 18 years of age at the time of the study.

The Life Situation Questionnaire (LSQ) has been 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 Seale (RSSS) has been added for the current stage The primary sourees of attrition over time have been mortality and geographie mobility, not refusal to partieipate.

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 both support received and opportunities to give support to others.

PROGRESS—The fourth stage of this longitudinal study has just been completed. A total of 441 participants has responded to date, 236 of whom have participated during at least two previous study stages. Data analysis and dissemination are currently underway.

RESULTS—Whereas adjustment appears to be highly stable over the first 15 years of this longitudinal study, the current findings have identified declines in adjustment over the past 9-year period. Furthermore, it appears that the positive impact of environment change on adjustment found during the second study stage may have been reversed.

IMPLICATIONS—This research has been instrumental in identifying the impact of aging and environmental change on adjustment and quality of life after SCI.

FUTURE PLANSA fifth follow-up study is planned for 1997.

[282] MOTOR COMPLETE SPINAL CORD INJURY: PROGNOSIS FOR AMBULATION

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Sponsor: *National Institute on Disability and Rehabilitation Research, Washington, DC 20202*

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) whether 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.

PRELIMINARY RESULTS—Data for 32 subjects with definitive ambulation outcome were analyzed. The analysis suggests that consistent pin appreciation in the S4-5 dermatome is predictive of recovery of ambulation.

FUTURE PLANS/IMPLICATIONS—Data will be further analyzed to determine when sensation best predicts future ambulation and if light touch apprecia-

tion alone is sufficient to predict ambulation. Information from this study will allow clinicians to better predict recovery of ambulation after SCI and to determine when best to initiate therapeutic interventions.

[283] 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 its acute medical aspects, 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 postinjury.

Objectives for this project include: 1) examining the relationship between factors of well-being in persons with SCI and their caregivers, measured at preselected times postinjury; 2) determining the association between physical and psychosocial characteristics of the person with SCI and feelings-of-burden variables in caregiver(s) at preselected times postinjury; 3) determining the interrelationships between feelings of well-being of the person with SCI and his caregiver(s) in different cohorts over time; and 4) determining 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 caregiver mental and physical health, as well as an indicator of anticipated burden of care.

To date, 58 caregivers have been enrolled in the project, and 52, 39, and 35 individuals have completed T2 through T4 respectively. To date 35 caregivers have completed all four phases. Thirty-six other caregivers in addition to the 58 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 1996, with follow-up completed

by the end of May 1997. Preliminary analysis will be descriptive and correlational. Longitudinal/causal analyses will not be feasible until the project is completed.

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Outcomes for caregivers of persons with SCI: a longitudinal investigation (abstract). Richards JS, Shewchuk RM, Elliott RT. J Amer Paraplegia Soc 1994:17(2):103.

[284] 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 are to: 1) document the natural history and clinical course of urinary tract complications among persons with SCI who utilize various methods of neurogenic bladder management; 2) answer 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) encourage 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=1,544) were injured and admitted between May 1979 and July 1995. The latter group will continue to grow in size as the project continues. Overall, 2,141 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 267 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 1,277 persons from the prospective group, yielding a total of 1,604 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 one book, 10 book chapters, 10 peer-reviewed journal articles, 3 publications in Proceedings, and 14 abstracts in leading medical journals. There were 27 presentations made at scientific meetings of professional societies and organizations.

The database is now available on computer software with quality control computer programs that cross-check 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 and urinary tract infections. 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 follow-up data on the large population followed in our clinics are continually added to the database. Some patients have follow-up data for as long as 26 years. Further investigation and analysis of data will continue during the next 3 years. Employers of the research will focus on long-term renal function outcome resulting from various methods of bladder management.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Endemic renal stones in persons with spinal cord injury (abstract). Huang CT, DeVivo MJ, Stover SL. J Spinal Cord Med 1995:18:159.

Predicting compliance with annual urologic examinations in persons with spinal cord injury (abstract). Canupp KC, Waites KB, DeVivo MJ, Richards JS. J Spinal Cord Med 1995:18:150.

Predictors of compliance with annual evaluations in persons with spinal cord injury (abstract). Canupp KC, Waites KB, DeVivo MJ, Richards JS. J Alabama Academy of Sci. 1995:66.

[285] IMMUNE RESPONSES TO PNEUMOCOCCAL VACCINE IN SPINAL CORD INJURY

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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 SCI, 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 4–6 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. 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: anti-pneumococcal antibody titers to four major representative serotypes, quantitative immunoglobulins, complete blood count with differential leukocyte count, liver profile, and 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 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 RESULTS—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 June 1995, 147 eligible persons have been asked to participate. Of these, 95 have been enrolled and 52 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.

[286] CAUSES AND COSTS OF UNPLANNED REHOSPITALIZATIONS AMONG PERSONS WITH SPINAL CORD INJURY

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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 it has no established linkage 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 persons 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

among persons with SCI; 2) determine the average length of stay and cost for each cause of unplanned rehospitalization among persons with SCI; and 3) 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.

Admission sheets for University Hospital are scanned daily to identify rehospitalizations among persons with SCI. Persons 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 are obtained. ICD9CM 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 hospital 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—As a precursor to conducting this study, we recently completed a study of rehospitalization frequency and risk factors using the NSCISC's database. The project then began in 1994. During the first 9 months, 117 persons were identified as rehospitalized. We have begun the process of obtaining medical records for those hospitalizations and now have completed data collection forms for 32 cases.

FUTURE PLANS—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.

[287] ULTRASOUND FOR URINARY TRACT SURVEILLANCE OF PERSONS WITH SPINAL CORD INJURY

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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 to determine: 1) the sensitivity and specificity of the RUSE compared to CRSP for detecting upper urinary tract abnormalities of persons with SCI, 2) the sensitivity and specificity of the RUSE compared to EXU for detecting upper urinary tract abnormalities of persons with SCI, and 3) 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 RRTC, 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—Sixty-five patients have been entered into the study. Thirty-four patients have received CRSP, RUSE, and EXU all within a 2-week period. Twelve 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. Seven 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.

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.

Due to increasing difficulty scheduling outpatients for RUSE and EXU within 4 weeks of CRSP, patients are being entered into the project with EXU and RUSE as soon as possible after completion of CRSP. EXU is not routinely performed on inpatients prior to first definitive discharge from the rehabilitation center. Therefore, special attention is given to obtaining consent from attending physicians to order EXU.

FUTURE PLANS—Data collections will continue until the end of this year and formal reviews will be done at the conclusion of the project.

[288] PREDICTION OF MORTALITY AFTER SPINAL CORD INJURY: A 20-YEAR PROSPECTIVE STUDY

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PURPOSE—The purpose of this research is to identify the relationship of several aspects of life adjustment (psychosocial, vocational, and medical adjustment) with length of survival 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—All participants were identified from case files of former recipients of urologic services at a large Midwestern university hospital clinic prior to 1994. There were three screening criteria for inclusion to the study: a traumatic SCI, the injury was at least 2 years duration, and at least 18 years of age at the time of the study. Three study samples and four sets of prospective data have been utilized. Sample 1 began participating in 1974; sample 2 was added in 1985; and sample 3 in 1994. A total of 654 individuals have participated (sample 1=256; sample 2=193; sample 3=205).

Responses to the Life Situation Questionnaire (LSQ) were obtained from sample 1 in 1974 (n=256), 1985 (n=154), 1989 (n=135), and 1994 (n = 114); from sample 2 in 1985 (n=193), 1989 (n=151), and 1994 (n=122); and from sample 3 in 1994 (n=205). Responses to the Multi-dimensional Personality Questionnaire (MPQ) were also obtained in 1989 and the Reciprocal Social Support Scale in 1994. All former participants from samples 1 and 2 are being contacted to identify their current survival status. To date, a total of 92 of the 449 former participants from samples 1 and 2 are known to be deceased.

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 a 20-year period from 1974 to 1994, with four stages of data collection completed (1974, 1985, 1989, 1994). Survival status is currently being ascertained by obtaining death certificates on all deceased participants.

RESULTS—Consistent relationships have been identified between psychosocial and vocational adjustment 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 (particularly survival).

FUTURE PLANS—The focus of the previous studies was to compare prospective adjustment scores taken at one point in time (e.g., 1974) between groups of participants classified according to survival status at a later point in time (e.g., 1985). However, current efforts will focus on predicting length of survival among deceased participants and predicting years of life gained or lost based on adjustment profiles.

[289] SECONDARY CONDITIONS AFTER SPINAL CORD INJURY: RELATIONSHIP TO LIFE ADJUSTMENT

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PURPOSE—We seek 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—A stratified sample of approximately 850 cases has been identified from outpatient files of a large Southeastern rehabilitation hospital. Three screening criteria for inclusion to the study included traumatic SCI, at least 2 years post-injury, and at least 18 years of age at the time of the study. The three stratification criteria were gender, race, and age.

The Life Situation Questionnaire (LSQ) and Secondary Conditions Questionnaire (SCQ) were sent to each potential participant. A follow-up call and mailing of a second set of materials are being mailed to all initial nonrespondants. Participants are being offered $20 and a copy of study results as inducements to participate.

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 ("yes, right now"; "yes, within last year"; "yes, more than 1 year ago"; "no, never since SCI") and how often the condition has disrupted their lives ("none"; "sometimes"; "often"; "always").

PROGRESS—The first stage of this study was initiated within the past year. To date, a total of 585 individuals have participated: our goal is 650.

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. Plans are underway to integrate this study with the Minnesota Longitudinal Study by obtaining responses to the SCQ from the Minnesota sample.

[290] RACE, GENDER, AGE, AND ADJUSTMENT AFTER SPINAL CORD INJURY: THE SOUTHEASTERN LONGITUDINAL STUDY

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PURPOSE—The purpose of this research is to identify how life adjustment and quality of life after spinal cord injury (SCI) differ as a function of gender, race, and age.

METHODOLOGY—All participants were selected from outpatient files of a Southeastern rehabilitation hospital. Three selection criteria were used: traumatic onset of SCI, a minimum of 18 years of age at the time of the study, and the injury occurred at least 2 years prior to the time of the study. A stratified sample was selected based on three stratification criteria, race, gender, and age at injury onset.

Racial status had two categories: Caucasian and minority (mostly African-American). Age at onset was broken down into four categories. A total of 362 individuals participated in the study (63 percent response rate). Overall, 57 percent of the participants were male and 65 percent were Caucasian.

All participants were mailed the Multidimensional Adjustment Profile (MAP). A random subsample (approximately one-third) were also sent the Acceptance of Disability Scale (ADS) in order to help establish the validity of the MAP. Participants were offered $5 as well as descriptive study results as inducements to participate in the study.

The MAP was developed specifically for this study and is an updated version of the Life Situation Questionnaire. It contains six sections including: biographic and injury-related status, vocational and avocational activities, educational history, psychological adjustment, problems, and health and medical status. Ten scales have been developed from the MAP, nine of which were based on factor analysis of life satisfaction and problems scales.

PROGRESS—The first stage of this study has been completed. Current efforts are focusing on analysis and dissemination of the study results.

RESULTS—Gender and race differences in employment outcomes were identified. Race differences were also obtained in subjective outcomes.

IMPLICATIONS—This research has been helpful in identifying the roles of gender and race in adaptation after SCI.

FUTURE PLANS—A longitudinal follow-up is planned within the next 2 years.

[291] ENDEMIC RENAL STONES IN PERSONS WITH SPINAL CORD INJURY

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Sponsor: *None listed*

PURPOSE—The incidence of renal stones in the United States general population varies substantially in different geographic regions. Areas with the highest incidence rates, such as the Southeast, have become known as "endemic stone belts." The purpose of this study was to assess the influence of living in such belts on the incidence of renal stones among persons with spinal cord injury (SCI).

METHODOLOGY—A study was conducted to assess the geographic association between renal stone occurence in the general United States population and the SCI population. Previous history and occurence of renal stones was documented between 1986 and 1993 for 4,921 persons with SCI treated at 17 model systems in 13 states and compared to previous published general population renal stone incidence rates using Spearman's rank correlation coefficient. All patients included in the study were enrolled in the National SCI statistical center database.

RESULTS—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 ($r=0.50$, $p=0.09$). However, occurence of renal stones after spinal cord injury was not correlated with high-risk locations for the general population. Therefore, personal and injury characteristics as well as treatment practices at each model system appear to be more important determinants of renal stone risk for persons with SCI than environmental factors associated with geographic location.

RECENT PUBLICATIONS FROM THIS RESEARCH

Endemic renal stones in persons with spinal cord injury (abstract). Huang CT, DeVivo MJ, Stover SL. J Spinal Cord Med 1995:18:159.

B. Treatment and Rehabilitation

[292] FUNCTIONAL RESTORATION OF GRASP: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Programs, Washington, DC 20420 (Pilot Project #B93-612AP)*

No report was received for this issue.

[293] HIGH-FREQUENCY MAGNETIC STIMULATION OF THE BLADDER AND BOWEL

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B803-RA)*

PURPOSE—The purpose of this research 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 optimize the magnetic stimulation parameters to obtain functional micturition and defecation.

METHODOLOGY—Experiments were performed in eight chronic SCI patients, C3–T7. Each subject received a screeing history and physical examination, as well as a full urodynamic study before the stimulation protocol, and a set of chem 20, CBC with differentials, PT, PTT, UA and urine culture both before and after the experiment. This was followed by placing the multilumen urinary catheter into the bladder and inserting the 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 percent power output was fixed at 30 Hz and 70% of maximum (225 Joules/pulse, fixed pulse width of 0.2 ms). Vital signs were monitored every three minutes by Paramed Blood Pressure Monitor for evidence of autonomic dysreflexia.

PROGRESS—We have demonstrated that: (1) HFMS of the bladder and bowel was effective in clevating the bladder and rectal pressures; (2) SCI patients without lower motor neuron lesions may be most benefited by HFMS of the bladder and bowel; and (3) HFMS of the bladder and bowel was safe in our subjects.

RESULTS—Two high cervical subjects (one C3, and one C4) demonstrated small hyperreflexic bladders; their BP increased from 6 to 19, and 28 to 48 (cm H2O) respectively; similarly, their RP increased from 41 to 53, and 42 to 60. Two C6, and one T2 subjects demonstrated small reflexic bladders: their BP increased from 12 to 56, 4 to 33, and 5 to 59; and their RP increased from 30 to 54, 20 to 34 and 26 to 72. 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, 32 to 77; and their RP increased from 46 to 104 and 23 to 48. One L2 subject demonstrated lower motor neuron

lesion, with a hyporeflexic bladder, his BP increased from 6 to 12, and 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 the criteria that will be used to predict which SCI patients are optimally suitable for HFMS; (6) establish a comprehensive electrodiagnostic set of 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-frequeney magnetie stimulation of the bowel in man: a pilot study. Lin VWH, Frost FS, Lee SB, Cadwell J. Musele Nerve 1994:17(9):1098.

High frequeney magnetie stimulation of the saeral nerves in spinal cord injured patients. Lin VWH, Frost FS, Lee SB, Perkash I. Areh Phys Med Rehabil 1994:75(9):1033.

[294] TREATMENT OF MUSCLE SPASTICITY USING PHENOL NERVE BLOCKS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B740-RA)*

PURPOSE—Stroke and traumatic brain injuries often lead to spasticity or related disorders in the extremities. Clinically, peripheral nerve blocks are often used to produce a sustained but temporary motor nerve block that decreases spastic muscle tone and reduces clonus over a period of weeks or months. The amount of denervation produced and the ability of the neuromuscular system to fully recover from the damage produced by phenol has been poorly evaluated. The purpose of this study was to study the time course of muscle recovery following application of phenol to the rat sciatic nerve. Two methods of application and two concentrations of phenol were used to produce the peripheral nerve block.

METHODOLOGY—Seventy-two female Sprague-Dawley rats were assigned to one of four 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. Two concentrations of phenol, low (3 percent) and high (7 percent), were used for each application technique. The effects of the phenol-induced nerve block were examined at three time periods: 1, 2, and 4 weeks. Six animals per group were studied. The groups were intraneural low (IL), intraneural high (IH), bath low (BL), and bath high (BH). At each time point the sciatic nerve was stimulated proximal to the lesion and the presence or absence of contraction of the lower limb was noted. If a contraction could be elicited, the conduction velocity of the sciatic nerve and the isometric contractile properties of the solcus muscle were measured. The sciatic nerve, soleus muscle, and tibialis anterior muscle were removed at the end of each testing session.

PROGRESS—We have completed this series of experiments and are collecting additional data at 4 weeks because of the high degree of variabilty observed at this time point. At a low phenol concentration, the muscles

distal to the block were reinnervated by 4 weeks. The time course of recovery did not depend on the application method used. At the high phenol concentration, reinnervation was variable and dependent on the application technique used. Histological analyses of the muscle and neural tissues are in progress.

RESULTS—Application of phenol to the sciatic nerve caused denervation of the lower limb muscles in all cases. At 2 weeks, contractions were detectable in the soleus muscle in only 3 of 48 cases. At 4 weeks, contractions were detectable in all muscles tested in the IL and BL groups. In the high concentration groups, the amount of reinnervation at 4 weeks was dependent on the application technique used. In the IH group, 50 percent of the animals tested at 4 weeks showed detectable contractions in the soleus. In the BH group, only 1 of 6 animals tested at 4 weeks had detectable contractions in the soleus. At 4 weeks, the soleus and tibialis anterior muscles were significantly smaller than control. In the IH and BH groups, the soleus was 55 percent and 45 percent of control, respectively. In general, the tibialis anterior was more atrophied than the soleus. The tibialis anterior in the IH and BH groups was 30 percent and 25 percent of control, respectively.

IMPLICATIONS—These data suggest that phenol produces an injury that damages the endoneurial connective tissue resulting in more extensive damage than previously expected. The primary mechanism of damage following phenol application is generally thought to be protein degradation leading to Wallarian degeneration. Another potential mechanism, however, is axon demyelination produced by ischemia. Bathing of the nerve in phenol may cause damage to epineurial vessels leading to ischemia and axonal demyelination. We have observed extensive damage to blood vessels within the nerve and are investigating the potential role of ischemia in producing the damage observed following phenol application. Future studies will also examine long-term muscle recovery and the specificity of reinnervation following phenol induced nerve blocks.

RECENT PUBLICATIONS FROM THIS RESEARCH

Muscle recovery following phenol induced peripheral nerve block. Davey JP, Botte MJ, Bodine-Fowler SC. Trans Orthop Res Soc 1995:20:606.

Time course of muscle atrophy and recovery following a phenol-induced nerve block. Bodine-Fowler SC, Allsing S, Botte MJ. Muscle Nerve. In press.

[295] MANAGEMENT OF MUSCULOSKELETAL COMPLICATIONS OF SPINAL CORD INJURY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B576-2RA)*

PURPOSE—Musculoskeletal complications are common clinical events in the patient with spinal cord injury and disease. Therefore, the purpose of this research is to develop clinical assessment procedures that can used in the diagnosis and management of the musculoskeletal complications of patients with spinal cord disease and injury. The goal 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 spinal cord patient. More specifically, this project is designed to develop and apply newly discovered, bone cell-specific serum markers and new densitometry/imaging procedures for the skeleton to clincial studies of musculoskeletal assessment in patients with trauma and illness involving the spinal cord.

METHODOLOGY—The bone markers we have developed and use 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. We have applied these immunoassays along with bone densitometry studies to access skeletal changes in our patients.

PROGRESS—Since this project was reinstituted in 1994, we have achieved our goals or made substantial progress toward them. 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 have also established assays for the calcemic hormones. In addition, we have implemented our protocols in clinical studies of spinal cord patients, and we have extended our studies to include 240 patients and 46 controls.

RESULTS—We have developed and applied to clinical studies assays for bone alkaline phosphatase (BAP) and bone Gla protein (BGP), and we have developed key reagents for other measurements such as parathyroid hormone (PTH) and calcitonin (CT). In addition, we have initiated studies with our bone densitometer. Thus, we have achieved the essential goals of the first phase of our project and are in the middle of clinical studies. Our preliminary results indicate that: 1) both BAP and CT levels of acutely injured (less than 1 year) patients are greater than control levels, 2) PTH levels are lower, and 3) BGP levels are unaffected. As the time after injury increases, 1) BAP levels continue to increase until approximately 6–9 years post injury, decreases to control levels over the next 10 years, and then plateaus at this level; 2) BGP levels never change; 3) PTH levels gradually increase to above control levels; and 4) after the initial rise in CT levels there is a plateau that is maintained for the next 20–30 years and then decreases to control levels. These results coincide with our densitometry studies that show a significant decrease in bone density in the femoral region but not in the lumbar region of our patients.

FUTURE PLANS—Our future plans are to continue following our acutely and chronically injured patients throughout their rehabilitation and/or treatments using our new procedures to document changes/improvements in the care of spinal cord injury patients. These data will also be used to prevent osteoporosis/fractures following spinal cord injury.

RECENT PUBLICATIONS FROM THIS RESEARCH

Markers of bone turnover in primary hyperparathyroidism. Deftos LJ. In: JP Bilezikian, Levine MA, Marcus R, eds. The Parathyroids. New York: Raven Press Ltd., 1994:485-92.

[296] VERTEBRAL FUSION BY NEW OSTEOGENIC AGENTS TO ACCELERATE REHABILITATION

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PURPOSE—The purpose of this project is to stimulate vertebral fusion leading to elimination of pain and early rehabilitation. Our hypothesis is that pain relief and vertebral stability, allowing early rehabilitation, depend on a solid fusion which can be significantly stimulated by the use of osteogenic agents appropriately delivered to the fusion site.

METHODOLOGY—Our rabbit vertebral fusion model utilizes a surgical procedure that minimizes the animal

versus human anatomical differences. It involves T11–12 and T12–L1 discectomies, creation of a cylindrical defect and application of autologous bone (AB) comparative control or an osteogenic agent (DBM: demineralized bone matrix; BMP: bone morphogenetic protein or $TGF_{\beta 1}$: transforming growth factor β1) and their composites with an organoapatite carrier. Fusion at 3, 6, and 12 weeks post-grafting is evaluated radiographically (digitized densitometry), biomechanically (3-point bending), histologically and immunohistochemically, and by alkaline phosphatase, osteocalcin, ash, and calcium analyses of grafted tissue and comparison with controls.

PROGRESS—We have tested the feasibility of: (a) using a anterolateral surgical technique, similar to that employed in our clinic, for spinal fusion in the rabbit; (b) adapting to the animal model a digitized imaging method for quantitating radiographic density of grafted discs; and (c) stimulating fusion with AB powder, prepared intraoperatively, and comparing it to morselized AB.

RESULTS—Initially, the bone inductive activity of each osteogenic agent and its composite with our organoapatite was determined in an intramuscular rabbit bioassay model. Subsequently, a total of 24 adult NZW rabbits were grafted intradiscally with AB using a novel anterolateral approach. Measured amounts of AB, morselized or powdered intraoperatively in liquid N_2, were packed in each surgically tunneled disc using a dental applicator. Animals were sacrificed at 3, 6, and 12 weeks post-surgery, spines cleaned of soft tissues, sawed bilaterally into two halves and x-rayed with high resolution mammography film.

Fusion rates were: 25 percent at 6 weeks and 38 percent at 12 weeks post-grafting with morselized AB; 50 percent at 6 weeks and 67 percent at 12 weeks after grafting with powdered AB. Radiographic density was then quantitated by digitized imaging adapted to our spinal fusion model. Little or no bone was formed at 3 weeks post-grafting. At 6 weeks post-surgery, average radiographic density of discs grafted with morselized AB was higher compared to non-operated controls and significantly lower than that of discs grafted with AB powder ($p<0.01$). At 12 weeks post-surgery, mean density values of grafted discs were not significantly different. Histologically, formation of cartilage and bone was seen 6 weeks after grafting of powdered AB with considerable consolidation to the vertebral bone, whereas unresorbed AB chips with comparatively small amounts of new bone and some consolidation were evident in grafts of morselized AB. At 12 weeks post-grafting, there was new bone associated with consolidation in all grafted sites.

IMPLICATIONS—Autologous bone (AB) powder, prepared at surgery and grafted intradiscally, stimulates healing 6 and 12 weeks after grafting, presumably because of faster graft resorption and replacement with new bone compared to the all-time standard of morselized AB. Because of its apparent effectiveness and the relatively easy intraoperative preparation and application, powdered AB has the potential of becoming a useful osteogenic agent for stimulation of bone formation and early spinal fusion.

RECENT PUBLICATIONS FROM THIS RESEARCH

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.

[297] 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 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 SCI veterans.

METHODOLOGY—The studies utilize a rat model in which the bone loss is both dramatic and progressive over time. Histomorphometry, radioimmunoassays, and molecular biology techniques are being used to characterize bone loss following SCI, as well as to determine changes in neuropeptide distribution and levels in bone and periosteum over time. We have focused on calcitonin gene-related peptide (CGRP), substance P (SP), vasoactive intestinal peptide (VIP), neuropeptide Y (NPY), and interleukin-1 (IL-1), all substances are known to be in nerve fibers in bone and implicated *in vitro* as modulators of bone metabolism. Immunohistochemistry, receptor binding assays, and auto-radiographic methods are used to evaluate receptor changes.

PROGRESS—We have defined the model and 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, as well as to evaluate the neuropeptide content and respective neuropeptide mRNAs in bone and periosteum. We have established a bone cell model to evaluate the effect of 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 by systemic and local factors (e.g., neuropeptides).

RESULTS—Characterization of the effects of SCI on bone metabolism at the histomorphometric level indicate that as the animals age, they lose approximately 60 percent of their trabecular bone compared to non-lesioned animals. This bone loss results in considerable loss of mechanical strength in the femurs of lesioned animals. Immunohistochemical and retrograde tracing studies of nerves associated with bone showed that sensory nerves containing the neuropeptides CGRP, VIP, and NPY 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. Analysis is underway to determine whether the protein (connexin 43) is also upregulated by VIP. CGRP is capable of regulating osteoblast function via modulation of potassium channels and intra-cellular calcium, but with only moderate increases in cAMP production, suggesting other second messenger pathway(s) for CGRP actions.

FUTURE PLANS—We will continue our studies with bone cells of lesioned and non-lesioned 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. Work is continuing toward cloning the gene which encodes the CGRP receptor to allow assessment of receptor function in osteoblasts in a manner similar to the VIP receptor work.

RECENT PUBLICATIONS FROM THIS RESEARCH

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.

Diverse actions of calcitonin gene-related peptide on intracellular free Ca^{2+} concentrations in UMR 106 osteoblastic cells. Kawase T, Howard GA, Roos BA, Burns DM. Bone 1995:16:379S-84S.

Increase in gap junctions precedes the increase in mineralization during maturation of MC3T3-E1 osteoblastic cells in culture. Schiller PC, Roos BA, Howard GA. J Bone Min Res 1995:10(Suppl 1):S415.

Calcitonin gene-related peptide in the developing mouse limb: ontogeny and effect on cAMP production. Bidegain M, Roos BA, Hill EL, Howard GA, Balkan W. Endocr Res. In press.

[298] EMPLOYMENT OF IBM SPEECH RECOGNITION IN USER-BASED REMOTE CONTROL: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #C94-712AP)*

PURPOSE—The overall purpose of this 1-year pilot study is to improve the quality of life of veterans with Spinal Cord Injury (SCI) through the development of a device that gives them the ability to verbally control their environment wherever they may choose to go—around the home, in their van, to their office, to friends' homes, public buildings and on public streets. The specific objective is to evaluate the feasibility of making such a device available to veterans. The outcome of this work is to be a prototype for User-based Voice Interactive Control of the Environment (U-VOICE). It is to have universal control capabilities, be battery-powered and travel easily with the user as a user-based (as opposed to a home-based) device.

PROGRESS—Hardware design of the U-VOICE is complete and two prototypes are under construction. Initial voice-recognition testing has been performed, and software development for control of voice recognition functions has been outlined and basic routines defined. Outdoor X-10 receivers for vans have been designed and are under construction.

METHODOLOGY—The U-VOICE device is developed around four hardware components: 1) a speech recognition board that also has speech synthesis capability; (2) an embedded 8088 controller card with standard DOS on ROM, a flash RAM "hard drive" and standard parallel and serial ports; 3) an infrared transceiver circuit capable of communicating with TV's, VCR's, stereos, other computers, modems, and printers; and 4) an X-10 transmitter circuit capable of controlling home automation devices. Investigators are adapting X-10 receivers for use in modified vans for control of lifts and accessories, for use in activating pedestrian crosswalk buttons and elevator call buttons. Investigators also are contacting elevator companies to implement infrared control of elevator functions.

U-VOICE software is being developed by the investigators based on the Value Oriented Design (VOD) model for interactive systems. VOD is a user-friendly control interface that uses the interactive nature of voice interfaces to impart a sense of mutual respect, open communication, and a cooperative sense of excellence. It is to provide voice assistance with positive feedback during all aspects of device training and use.

Once the design is completed, the investigators will conduct engineering tests to determine the reliability of the Speech Recognition Board and of the infrared and X-10 transmitters under varying indoor and outdoor conditions and the utility of the VOD control interface during all aspects of operation, indoors and outdoors.

RESULTS—Single-user voice recognition is very good, with about 98 percent accuracy on all vocabulary

tested. A means of implementing a limited subset of the VOD model that is capable of running in the limited space of the U-VOICE controller environment has been determined.

FUTURE PLANS—Investigators expect the prototypes to be completed by fall 1994; software development and environmental testing is to begin with 1996.

[299] ADVANCED TECHNOLOGY NEURAL INFORMATION SENSORS FOR PROSTHETIC CONTROL BY QUADRIPLEGICS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Programs, Washington, DC 20420 (Project #B706-RA)*

No report was received for this issue.

[300] EXERCISE TESTING AND TRAINING OF MULTIPLE SCLEROSIS PATIENTS

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PURPOSE—The purpose of this 3-year study is to: 1) further document metabolic and cardiopulmonary responses to leg and arm/leg exercise in order to standardize training norms for MS patients; 2) examine physiologic adaptations to both continuous and discontinuous exercise training protocols and at a greater-than-moderate level of intensity and duration; 3) evaluate the efficacy of a cooling garment to reduce thermal stress and its adverse affect upon exercise performance; and 4) determine the effects of these interventions upon independent and assisted ambulation, psychological status, and general health parameters. The stress testing protocols will be used to obtain baseline measurements of physical capabilities/limitations, as well as to indicate changes in fitness as a result of exercise training.

METHODOLOGY—All 30 subjects with MS (15 ambulatory, 15 non-ambulatory) will perform several pretraining tests to measure baseline body composition, joint range of motion, ambulation, serum cholesterol, psychological status, maximal aerobic power, and aerobic endurance. Gait characteristics will be studied using both kinematics and force plate measurements. Psychological status (i.e., affect, mood, and cognition) will be measured pre- and post-training using appropriate, validated tests for each (e.g., BDI, MDI, NIS, Trails A & B, FSS, Q-LES-Q, Wechsler Memory Scale-Revised, Aphasia Screening Test, Neuropsych Interview).

We have recruited 17 individuals with MS. Of these, 13 have received a preliminary neurological examination; 9 have finished body composition testing,

resting ECG, and medieal history; and 8 have completed gait analysis. Six water flow and volume eontrol deviees have been completed and ealibrated to keep water temperature and flow volume preeise. All units are paired with an exereise bicyele for the training session. Three of the six body cooling suits have been finished and tested several times to insure that they are working properly. The computer program neeessary to run the maximal aerobie tests has been completed, and all the equipment needed for the max testing has been installed. As for the psyehologieal testing, nearly all of the neeessary testing forms have been reeeived and psychological testing will begin soon.

FUTURE PLANS—Further research should evaluate other modes of exercise for testing and training cooling devices upon aeute and ehronic physiologieal, psychological, and functional outcomes following aerobic exereise training.

RECENT PUBLICATIONS FROM THIS RESEARCH

Maximal aerobic exercise of individuals with multiple sclerosis using three modes of ergometry. Ponichtera-Mulcare JA, Mathews T, Glaser RM, et al. Clin Kinesiol 1995:49(1):4-12.

Maximal acrobic exercise of persons with multiple sclerosis following a 6-month endurance training program. Ponichtera-Mulcare JA, Mathews T, Barrett PJ, et al. Med Sci Sports 1995:27(5):Sup 81.

Quality of life, fatigue, depression and maximal aerobic capacity in ambulatory and semi-ambulatory patients with multiple sclerosis. Harrell KB, Glaus KO, Ponichtera-Mulcare JA. Med Sci Sports 1995:27(5):Sup 81.

Disease severity in multiple sclerosis and its effect on gait. King DL, Rodgers MM, Ponichtera-Mulcare JA. Gait Posture 1994:2(1):60.

[301] OBJECTIVE ASSESSMENT OF SPASTICITY IN SPINAL CORD INJURY

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PURPOSE—We propose to develop methods for quantitative measurement of spasticity in lower limbs of SCI subjeets. This measurement is based upon the amount of activity generated during various maneuvers recorded eleetromyographically, in comparison with elinieally used seales of spastieity (tendon reflex, plantar reflex, clonus, Ashworth and Penn spasm frequency scales).

METHODOLOGY—Surfaee eleetromyographie (EMG) eleetrodes are placed over major muscle groups of the lower limbs bilaterally. Standardized maneuvers, including reinforeement and voluntary efforts, passive limb movement, and reflex elicitation, are undertaken with eontinuous digitization of amplified EMG, position, and event mark data. The envelope of aetivity is calculated from the full bandwidth data using an RMS algorithm, and the average EMG (aEMG) ealculated for eaeh maneuver. Clinical and aEMG results are stored in a database for subsequent analysis.

PROGRESS—Data acquisition is nearly completed, and data processing underway. To date, more than 240 data sets on more than 90 SCI subjects and 5 nondisabled subjects have been collected. The subjects ineluded a balaneed eross-section of ASIA Impairment Seores from A to D, relatively uniformly distributed in tone as estimated by the Ashworth seore, with the exception of relatively few with a score of 4 (on a scale of 0 to 4). Pairs of studies under (presumably) identical eonditions have been carried out in 49 subjeets.

We have also recorded 6 subjects pre- and post-treatment with reetal stimulation, which was done to induee ejaculation, but whieh also has been shown to reduce spasticity. We found that the electrophysiologieal results were able to doeument ehanges in spasticity, that those ehanges eorrelated with the clinical findings, but had a higher resolution, and furthermore, were able to independently traek changes in hypertonia independently of ehanges in phasie stretch reflexes. Reeently,

we began a study of the effects of Neurontin on spasticity in SCI, employing the protocol to evaluate patient responses in the double-blind crossover study; results are not yet available because the study has not been completed.

We are developing a new approach to the quantitative analysis of this data, based upon first subtracting the background noise, then forming a ratio of the greater of the RMS voltage averaged over the maneuver or a threshold value calculated for the second study over the same calculation for the first study: one ratio formed for each muscle and each maneuver. Development of appropriate methods of combining the various scores continues.

RESULTS—We have correlated the quantitative values from the BMCA with clinical findings. Examination of the various cross correlations formed revealed that the voluntary component calculated as the simple average of activity in the various phases did not correlate well with any clinical measures of spasticity, and thus was not included in the overall index. The data collected to date clearly demonstrate the importance of a multifaceted approach to the assessment of altered motor control and spasticity in spinal cord injured subjects. Analysis of the scores from the physician's examination of the patient and the patient's self-reports of the spasticity revealed a very low correlation for these measures, demonstrating that the aspects of altered motor control assessed by the typical clinical scales do not well represent the patient's own perspective of spasticity.

The recordings clearly identify features of spastic paresis not customarily accounted for in any existing scales, clinical or neurophysiological. Anectodal reports from the subjects suggest that these "extra-protocol" events, which are nevertheless documented in the continuous recording, may be more important and relevant to the subjects than features more customarily indexed, such as hypertonia, or exaggerated tendon reflexes.

RECENT PUBLICATIONS FROM THIS RESEARCH

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; 1994, Charleston, SC; 1994:30-1.

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: Sheppard NF, Eden M, Kantor G, eds. Engineering Advances: New Opportunities for Biomedical Engineers 1994:16:462-3.

[302] CATHETER CLEANING FOR RE-USE IN INTERMITTENT CATHETERIZATION

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Sponsor: *American Association of Spinal Cord Injury Nurses*

PURPOSE—Clean intermittent catheterization is a common method of urinary elimination for people with spinal cord injuries and other neurological impairments. The numerous methods of catheter cleaning for re-use currently recommended, however, have by and large not been validated by research studies. Can urinary catheters be safely and effectively cleaned for re-use? How is this to be done exactly? Our goal was to find a research-based method that is simple, uses products widely available at low cost, is safe, and feasible anywhere quickly. In short, a method that people would use.

METHODOLOGY—The ability of hydrogen peroxide (3 percent USP), vinegar (5 percent acetic acid), dishwashing detergent, and lukewarm running water alone, to reduce *Pseudomonas aeruginosa* 10^7 and *Escherichia coli* 10^7 from plastic urinary catheters was

measured in an experimental design. As well, the effect of four precleaning conditions; rinsing, drying, rinsing and drying, and no rinsing or drying, was examined. The effect of storage in paper or plastic bags after cleaning was also of interest. The number of colony forming units as well as the log reduction from contamination values was measured. A minimum of three log (or tenfold) reductions was defined as clinically significant. Data was analyzed using a one-way or two-way ANOVA where appropriate, with SPSSTM statistical software.

PROGRESS—Three pilot studies were completed (n=56, n=16, n=32) to confirm laboratory methods. Three related research studies (n=342, n=72, n=426) were conducted in 1993. A follow-up study (n=40) completed the laboratory research phase.

RESULTS—Final results indicated that rinsing and drying catheters immediately after use was most effective at reducing bacteria to very near zero. Rinsing and drying significantly reduced bacteria by 5 logs ($p<0.001$), 5.3 logs ($p<0.001$), and 7.5 logs ($p<0.001$), leaving very near zero bacteria on catheters, and was significantly better than rinsing only, drying only, and no rinsing or drying ($p<0.05$). Drying only was found better than rinsing only ($p<0.001$), acheiving near 3 log reductions. None of the cleaning agents on their own achieved 3 log reductions. The effect of storage in paper or plastic bags after cleaning was not significant when catheters were previously rinsed and dried.

FUTURE PLANS—A second phase research study, catheter cleaning for re-use; a rinse and dry procedure, is being conducted to verify laboratory findings under naturalistic conditions. A rinse and dry procedure was developed with input from users of intermittent catheterization. Control and experimental catheters, collected from clients with a yet untreated urinary tract infection, will be processed and bacterial colony count as well as log reduction from contamination values measured. A third phase study is planned where the final rinse and dry procedure would be implemented and various clinical outcomes measured.

RECENT PUBLICATIONS FROM THIS RESEARCH

Catheter cleaning for re-use in intermittent catheterization: new light on an old problem. Lavallee DJ, Lapierre NM, Henwood PK, et al. SCI Nurs 1995:12(1):10-2.

[303] PERFORMANCE CAPACITY AND PHYSICAL STRAIN IN SUBJECTS WITH A SPINAL CORD INJURY

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Sponsor: *Dutch Prevention Fund*

PURPOSE—To study the evolution in physical capacity and physical strain over time, parameters of performance capacity and physical strain in ADL are evaluated with repeated standardized wheelchair exercise tests and ADL tests in a group of spinal cord injured subjects (SCI). This involves both subjects with a long-term SCI as well as those in the course of rehabilitation. Thus the effects of wheelchair use on cardio-respiratory and musculo-skeletal parameters are evaluated.

METHODOLOGY—Currently different subject groups are studied in both cross-sectional as well as longitudinal research designs in the course of the rehabilitation process. Maximum aerobic capacity, anaerobic sprint performance and isometric strength are individually determined at fixed times during and after rehabilitation. The physical strain of daily life in rehabilitation, and more specifically in the therapy sessions, are evaluated with the Percentage Heart Rate Reserve (%HRR). Risk factors for cardio-vascular

disease(blood pressure, cholesterol, etc.) are repeatedly determined. Questionnaires are used to study different physical and personal characteristics and their possible influence upon the performance parameters.

RESULTS—The results on intramurally treated SCI indicate an inverse association between physical strain in standardized ADL wheelchair tasks and indicators of maximum performance capacity, which is similar to results previously found in a group of male long-standing SCI subjects.

Initial results on the physical strain of wheelchair-specific therapy sessions and physical and vocational therapy showed a strong interindividual (lesion level dependent) variance as well as a strong inter-therapy variance. Physical therapy appears the most straining and therefore the most effective in terms of training stimulus for the cardio-respiratory system. However, physical strain during rehabilitation does not seem to meet criteria for training as formulated by the American College of Sports Medicine. Also, intensity should be tuned more carefully to the individual.

FUTURE PLANS—A further analysis of the rehabilitation process and its effects upon spinally injured subjects will be conducted in a longitudinal perspective. The effects of therapy sessions and daily life in rehabilitation will be documented on a larger subject group.

RECENT PUBLICATIONS FROM THIS RESEARCH

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 1994:31:2:120-9.

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.

Relationship between physical strain and physical capacity during standardized ADL in men with spinal cord injuries. Janssen TWJ, Oers CAJM van, Woude LHV van der, Hollander AP. Paraplegia 1994:32:844-59.

Reliability of heart rate responses to non-steady state activities in daily living in men with spinal cord injuries. Janssen TWJ, Oers CAJM van, Woude LHV van der, Hollander AP. Scan J Rehabil Med 1994:26:71-81.

Effects of quadrugby training on physical performance in persons with quadriplegia. Dallmeijer AJ, Hopman MTE, Woude LHV van der. Med Sci Sports Exerc (Suppl) 1995:27(5)S138.

Lipoprotein profile, aerobic power and physical activity in men with spinal cord injuries. Janssen TWJ, Hollander AP, Woude LHV van der. Med Sci Sport Exerc (Suppl) 1995:27:5:S208.

Physical capacity and physical strain in persons with quadriplegia. Dallmeijer AJ, Hopman MTE, Woude LHV van der. RESNA REcreability Proceedings, Vancouver, 1995:752-4.

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.

[304] RECOVERY OF UPPER EXTREMITY MUSCLES FOLLOWING CERVICAL SPINAL CORD INJURY

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Sponsor: *National Institute on Disability and Rehabilitation Research, Washington, DC 20202*

PURPOSE—Research has shown that a relationship exists between muscle strength and function following spinal cord injury (SCI). Therefore it is important to be able to determine the course and extent of motor recovery following SCI. 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 SCI 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 Jersey, Alabama, and Philadelphia. This study will expand on a recent multicenter project which investigated biceps and wrist recovery.

METHODOLOGY—Patients with SCI, C4-C8, Frankel A-D, between the ages of 15 and 70, in each of the collaborating model SCI system centers will have sequential motor strength examinations if possible, immediately post injury, 72 hours, 1, 2, 3, and 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.

[305] BACOLFEN PUMP: FUNCTIONAL AND NEUROPSYCHOLOGICAL IMPACT

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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 independently 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, 25-35 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 purpose of this study is to examine the effects of intrathecal baclofen on cognition and the ability to conduct routine activities of daily living independently. Incidence of any medical complications will also be determined. The cost-effectiveness of treating spasticity with intrathecal baclofen will also be addressed.

The objectives of this study are to: 1) determine the degree to which spasticity is reduced following administration of intrathecal baclofen; 2) 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) determine whether the level of cognitive awareness changes after administration of intrathecal baclofen; 4) assess the cost-effectiveness of intrathecal baclofen administration; and

5) 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 micrograms of baclofen to determine the response to the medication and observe any adverse effects. For 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 post-implantation.

PROGRESS—Between December 1993 and June 1995, 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 collectionsand continue to implant 5 to 7 patients per year with pumps.

[306] BACTERIURIA IN CHILDREN WITH NEUROGENIC BLADDER TREATED WITH INTERMITTENT CATHETERIZATION: NATURAL HISTORY

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PURPOSE—To determine whether bacteriuria unassociated with symptoms in patients with neurogenic bladder will lead to symptomatic infection and/or deterioration of the upper urinary tract if left untreated, we examined whether bacteriuria persisted in bladder urine of children with neurogenic bladder treated with clean intermittent catheterization and whether persistence of bacteria led to symptomatic infection or deterioration of the upper urinary tract.

METHODOLOGY—Weekly home visits were made during 6 months of surveillance of 14 children on the intermittent catheterization regimen with a normal upper urinary tract and no reflux (as determined by renal ultrasonography, voiding cystourethrography, and serum creatinine measurement). During visits a sample of bladder urine was obtained by intermittent catheterization, and signs and symptoms of urinary tract infection and all medications were recorded.

PROGRESS—Fourteen children were observed for 323 weeks. Cultures of 70 percent (172/244) of the urine samples collected were positive for organisms ($\geq 10^4$ colony-forming units per milliliter urine), 152 (88 percent) for the usually pathogens (Enterobacteriaceae) and 20 (12 percent) for commensal organisms (coagulase-negative staphylococci). 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 five

symptomatic infections during the 323 patient-weeks. Children remained clinically well during the study period, and their upper urinary tract did not deteriorate.

IMPLICATIONS/CONCLUSION—Bacteriuria persists for weeks in symptom-free children being treated with clean intermittent catheterization for neurogenic bladder associated with a normal upper urinary tract. Before attempts are made to eradicate bacteriuria, treatment should be proved to be beneficial to this population.

FUTURE PLANS—The question of whether antimicrobial prophylaxis prevents urinary tract infection in children with neurogenic bladder has not been adequately studied. We will conduct a double blind, placebo-controlled trial on the effect of antimicrobial prophylaxis in children with neurogenic bladder on intermittent catheterization. We will examine the following hypothesis: There will be no significant difference in the frequency of urinary tract infection during the months when a child with neurogenic bladder is on antimicrobial prophylaxis compared to when the same child is on placebo. The upper urinary tract will remain normal by diagnostic imaging 5 years post completion of study. If we find that there is no significant difference in the frequency of urinary tract infection during the months when a child is on prophylaxis compared to when the same child is on placebo, the routine use of antimicrobial prophylaxis may not be necessary for patients with neurogenic bladder and a structurally normal upper tract.

RECENT PUBLICATIONS FROM THIS RESEARCH

Bacteriuria in children with neurogenic bladder on intermittent catheterization: natural history. Sehlager T, Dilks S, Trudell J, Whittam T, Hendley JO. J Pediatr 1995;126:490-6.

[307] ENVIRONMENTAL AND PSYCHOSOCIAL FACTORS RELATED TO DYSESTHETIC PAIN

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Sponsor: *Shepherd Center, Atlanta, Georgia 30309*

PURPOSE—Dysesthetic pain syndrome (DPS), a little-understood phenomenon characterized by diffuse burning, stabbing, and/or tingling sensations in the otherwise anesthetized areas below the level of a spinal cord injury (SCI), affects 50 to 94 percent of persons with SCI. DPS is often severe enough to have a substantial negative impact on a variety of psychosocial domains, such as social interactions and employment, frequently causing more dysfunction than the original injury. In response to this problem, a study was conducted to gather information about DPS from the patient perspective.

METHODOLOGY—A random sample of 120 participants who, according to case records, reported pain below the level of injury were selected; the sample was stratified on the basis of gender and race. An initial pilot of in-depth interviews guided the construction of an interview instrument that included medical and demographic information, descriptions of the pain, types of treatments used and their effectiveness, and environmental, social, and behavioral factors perceived to influence the onset and nature of pain. This instrument, along with the short form of the McGill Pain Questionnaire, was administered by telephone.

PROGRESS—Ninty-two patients agreed to participate in the survey and completed the interview.

RESULTS—When asked to rate the intensity of their pain on a scale from 0 to 10, 50 percent gave their pain a rating of 6 or higher. Moreover, 53 percent of the participants stated that they experienced the pain often or constantly and that it lasted for hours. Pain severity in this sample had a significant impact on issues related to community reintegration, social relationships, and productivity. When asked about the effect of pain on

their life activities, participants responded that it was difficult to go to work at their jobs (45 percent), to participate in recreational activities (56 percent), and to "keep their spirits up" (24 percent) when in pain. A high percentage of individuals (69 percent) reported that pain made it difficult to fall asleep and nearly as many (62 percent) reported that the pain was intense enough to wake them after falling asleep. The individuals in the study identified environmental and behavioral factors that were associated with increases or decreases in pain (intensity, frequency, and duration). For instance, 44 percent of those interviewed reported that exercise decreased their pain, and 49 percent used distraction to alleviate painful sensations. A significant majority (63 percent) noticed that being over-tired contributed to pain onset and intensity, and subsequently modified their behavior to manage this phenomenon.

The survey described was unique in that individuals with chronic pain were interviewed in-depth to determine their perspectives on environmental, social, and behavioral correlates of the pain experience. This perspective provides significant implications for psychological treatment interventions.

[308] RISK PROFILE OF ELITE WHEELCHAIR ATHLETES, RECREATIONAL ATHLETES, AND NON-ATHLETE CONTROLS

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Sponsors: *Shepherd Center, Atlanta, GA 30309; The Centers for Disease Control and Prevention, Atlanta, GA 30341-3704*

PURPOSE—The purpose of this research is to examine the relationships among physical activity, physical health, other health risk behaviors, and psychosocial characteristics among persons with spinal cord injury who use wheelchairs as their primary mode of ambulation. This study will provide data about the risks and benefits of different types and amounts of physical activity in this group.

METHODOLOGY—Participants in this study will reside in North America or Russia and use a wheelchair as the primary mode of ambulation. Potential subjects who engage in high intensity physical activities will be drawn from the North American and Russian Paralympic participant lists (United States and Canada, n=200). A sample of recreationally active athletes will be drawn from the membership lists of Wheelchair Sports USA; this sample will be matched by age, sex, and race/ethnicity to the sample of paralympic athletes. A third age, sex, and race/ethnicity matched sample of non-athlete controls will be selected from membership lists of wheelchair users advocacy groups and other organizations. Each potential participant will be contacted and provided with a letter requesting their participation in the study, a consent form, a parental consent form for participants under age 18, and a questionnaire to be self-administered.

Respondents will be asked a standard set of questions concerning sociodemographics, current level of physical activity (training and participation), selected health risk behaviors (e.g., smoking, alcohol use, dietary patterns), psychosocial characteristics, social support, activity-related injuries sustained during the past year, and health problems experienced during the same period.

PROGRESS—Instruments are being refined and will be used in pilot testing fall 1995. Data from the entire sample will be collected in late 1995 and early 1996.

RESULTS—Currently there is a paucity of information about the risks and benefits of physical activities among persons with mobility impairments. This research will identify the correlates of successful participation in regular physical activity and sports, significant determinants of activity-associated injury, and the relationship between health and activity levels. Furthermore, the data will provide sufficient information to generate hypotheses about potential research strategies for the prevention of injury and maintenance of good health among persons who use wheelchairs.

C. Spinal Cord Regeneration

[309] ELECTRIC FIELDS AND CARBON FIBERS IN THE TREATMENT OF SPINAL CORD INJURY: GAIT ANALYSIS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B423-3RA)*

PURPOSE—The spinal cord pathways of cats can be studied by analyzing a single step cycle and the four-legged interlimb sequence of movement. Studies have shown that descending pathways of the spinal cord are not essential for triggering or organizing the basic locomotor pattern. However, these pathways are essential for modulation of the locomotion pattern. Some reports indicate that, if they are trained regularly, cats are able to walk with planter digitigrade placing following complete transection of the spinal cord. The purpose of this study was to evaluate the functional benefit of electrical stimulation of the spinal cord, as measured by gait pattern, using a severe contusion model of spinal cord injury.

METHODOLOGY—There were five groups of animals that were analyzed in this study: severe contusion injury to the spinal cord, severe contusion injury plus electrical stimulation of the spinal cord, severe contusion injury plus guanphylline administration, severe contusion injury with carbon filament implants and electrical stimulation of the spinal cord, and normal uninjured animals. Cat gait analysis was accomplished using Motion Analysis software. Retroreflective markers were placed at the hip, knee, ankle, and toe; the animals were then suspended in a sling and positioned with the top of their paws touching the treadmill. Stepping responses were produced by the moving treadmill and video taped. The movements of retroreflective markers were digitized, and the angular excursions of the joints were calculated. Standard kinematics and joint angle time series were obtained. Based upon this data, the gait cycle duration and the angular velocity of the hip were computed.

RESULTS—The normal values of uninjured cats for the gait cycle duration ranged from 0.6–0.9 second and the average hip angular velocity ranged from 25–40°/second. The group which received severe contusion injury showed an increase in gait cycle duration and a decrease in angular velocity of the hip as compared to the normal uninjured group.

All three treated groups showed a significant reduction in the gait cycle duration ($p<0.05$) and a significant increase in average angular velocity of the hip, bringing the respective values closer to those of normal cats in all three groups.

FUTURE PLANS—Future plans include identification of characteristics of the cat gait pattern, which are altered by incomplete and complete spinal cord injury, and the identification of the parameters of treatment which modify these characteristics.

[310] ENHANCED CARBON FILAMENT PROSTHESES AS SUBSTRATES FOR REGROWTH OF INJURED SPINAL CORD: ELECTROPHYSIOLOGICAL RECOVERY

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PURPOSE—Evoked potential monitoring provides an objective means for assessing the functional integrity of the spinal cord after injury (SCI). In rats, somatosensory evoked potentials (SSEPs) are dependent on conduction through ascending sensory fibers in the dorsal column, while motor evoked potentials (MEPs) are propagated through descending motor fibers. Therefore, recording of SSEPs and MEPs provides assessment of both ascending and descending pathways in the spinal cord. In the present study, the electrophysiological integrity of the rat spinal cord was assessed after the animals sustained a severe contusion injury to the spinal cord and received either carbon filament cultured with fetal spinal cord tissue implants, fetal tissue implants, or carbon filaments alone.

METHODOLOGY—Adult rats were anesthetized, and subjected to a severe contusion injury at the T8 level. The rats were divided into five groups. The normal group (N) consisted of rats that received no injury. A second group (C+CF+FT) consisted of rats that sustained a severe SCI and the lesion cavity was subsequently filled with a bundle of approximately 10,000 carbon filaments of 5 μm in diameter, that were cultured with fetal spinal cord explants. A third group (C+FT) consisted of rats that received fetal spinal cord tissue implants after severe SCI. A fourth group (C+CF) consisted of rats that received carbon filament implants after SCI. The last group (C) consisted of rats that were not treated after SCI. The SSEPs were elicited by stimulating the left sciatic nerve and were recorded simultaneously at the lumbar level, the lower cervical level, and at the cortex. Motor evoked potentials were elicited using an electromagnetic stimulator. Coil intensities of 20, 30, and 50 percent of the peak magnetic flux were used to stimulate the lumbar, thoracic, and motor cortex, respectively. The MEPs were recorded from both the left and right tibialis anterior muscles. Both SSEPs and MEPs were recorded 8 weeks after injury.

RESULTS—At the end of the 8-week survival period, the latencies and amplitudes of the SSEPs at the lumbar level (below the lesion) in all experimental groups were not significantly different from those of the normal control group. In the cervical and cortical recording points (above the lesion), SSEPs were clearly present in 4 out of 5 of the animals from the C+CF+FT group, but the amplitudes were reduced. In the other three groups, the presence of SSEP peaks in the cervical and cortical recording points could not be clearly determined, although some of the animals from the C+FT group showed the presence of a slow potential at both levels.

The latencies of the MEPs at the lumbar level (below the lesion) in all experimental groups were not significantly different from those of the normal uninjured group. When the thoracic spinal cord and the cortex were stimulated (above the lesion), the MEP latencies were prolonged in the C+CF and C groups, as compared to the N group. However, the implantation of carbon filaments cultured with fetal spinal cord tissue (C+CF+FT group), or the implantation of fetal spinal cord tissue alone (C+FT) after severe contusion injury, reduced the MEP latencies to those of normal animals.

FUTURE PLANS—The most significant electrophysiological recovery, as determined by SSEPs and MEPs, was seen in the group of animals that received carbon filament implants cultured with fetal spinal cord tissue. These results of our preliminary study suggest that the transplantation of the combination of carbon filaments and fetal spinal cord tissue play an important role in promoting spinal cord functional recovery after injury, as demonstrated by increased axonal conduction of the motor and somatosensory tracts in the injured host spinal cord. We are currently in the progress of further evaluating the use of these implants for the repair of the spinal cord after injury.

[311] MOLECULAR MECHANISMS UNDERLYING REHABILITATION AFTER NEURONAL INJURY: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #B94-743AP)*

PURPOSE—Damage to the nervous system, either through trauma or disease, often results in extensive neurological disabilities which severely compromise the quality of life for the affected person and his/her family. While many rehabilitation approaches exist for improving outcomes, these approaches generally depend upon stimulating uninjured brain regions to provide alternate routes for recovery. However, in order to obtain full recovery and complete rehabilitation from neurological disorders, including spinal cord injury, promoting survival and regrowth of directly damaged brain and spinal cord cells must ultimately be accomplished. Elucidating the molecular mechanisms underlying nervous system damage is therefore important in identifying and implementing rehabilitation strategies designed to promote full functional recovery. The purpose of the experiments in this proposal is to establish a new technological approach for determining the molecular basis for successful regeneration in the nervous system.

METHODOLOGY—The overall research plan that is being followed is: obtain tissue punches of injured and normal brain tissue, isolate and tag messenger RNA that is contained in these punches, and then hybridize the RNA to various DNAs encoding genes known to be important for regeneration. In this way, immediate early events that occur within damaged neurons can be identified and the sequence of changes important to successful regeneration established.

PROGRESS—Work on this project was just initiated. The procedures to isolate and tag RNA from injured brain tissue have been accomplished.

RESULTS—Validation experiments have been completed. The isolated RNA hybridizes to established genes that are known to be altered with injury.

[312] INJURED BLOOD-SPINAL BARRIER PERMEABILITY TO THE NEUROTROPHIN EBIRATIDE: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #B94-783AP)*

PURPOSE—The aim of this pilot project was to evaluate ebiratide as a therapeutic neurotrophin in spinal cord lesions by determining if it can cross the blood-brain barrier (BBB) of the spinal cord. ACTH, non-corticotrophic fragments of ACTH, and analogs of those fragments have been shown to have important neurotrophic activity. In particular, the $ACTH_{4-9}$ analog Org 2766 has been shown to stimulate peripheral nervous system axonal regeneration and to significantly enhance axonal sprouting of injured brain and spinal cord neurons in *in vitro* and *in vivo* studies. Unfortunately, the clinical use of Org 2766 is impractical because of its poor penetration of the BBB. However, a substituted analog of Org 2766, ebiratide, has been shown to easily cross the BBB of the brain because of the presence of a saturable transport system. This raises

the possibility that ebiratide might be transported across the BBB of the spinal cord. If ebiratide is transported at the injured spinal cord, then it might be of therapeutic benefit in spinal cord injury. Our goal was to determine if ebiratide was transported across the injured and normal spinal cord.

METHODOLOGY—Radioactively labeled ebiratide was given by intravenous injection into mice with normal and severed spinal cords. Ebiratide was radioactively labeled with ^{125}I (I-Eb) by the chloramine T-method. The spinal cord was severed between L2 and L3 and the uptake of I-Eb at brain, at cervical and thoracic spinal cord, and at the lumbar cord both distal and proximal to injury assessed. To appropriately interpret these studies, we measured the disruption in the BBB that can occur with lesioning by including serum albumin radioactively labeled with ^{99m}Tc (T-Alb) in the IV injection. This allowed us to distinguish entry due to BBB disruption from the specific uptake of ebiratide.

PROGRESS—Current results are very promising. I-Eb was found to rapidly enter the spinal cord of the normal mouse at rates similar to those previously reported for brain. With spinal cord injury, the uptake of I-Eb was not altered in any region. The increased uptake of T-Alb in lumbar regions, reflecting disruption of the BBB, was small compared to the uptake of I-Eb. These studies were extended to include the measurement of spinal cord uptake of radioactively labeled sucrose. Sucrose is also used as a marker of BBB integrity, but has a molecular weight similar to that of I-Eb. Its smaller size makes it more sensitive to the measurement of partial disruptions of the BBB. The results with sucrose more clearly showed impaired function of the BBB, but these alterations were still unable to account for the rapid uptake of I-Eb in either normal or lesioned mice.

RESULTS—We conclude that ebiratide is able to rapidly enter both the normal and injured BBB by a selective mechanism. The mechanism is not impaired with spinal cord injury. The results suggest that ebiratide may be a unique therapeutic agent, combining the neurotrophic action of this class of peptide with a high permeability to the BBB. We now hope to extend these studies by investigating the therapeutic potential and mechanism of action of ebiratide in a rodent model of spinal cord injury.

[313] DEVICE FOR TREATMENT OF PERIPHERAL NERVE INJURY

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PURPOSE—The purpose of this project is to develop a prosthesis that will enhance nerve regeneration in the event of a nerve transection. Previous experiments have shown that an analog of the extracellular matrix, ensheathed in a silicone tube, promotes regeneration across a 15 mm gap in the rat sciatic nerve. The current effort is to replace the inert silicone tube with a biodegradable collagen tube.

METHODOLOGY—Collagen-glycosaminoglycan (CG) matrices, with axial pores 5–10 microns in diameter, were prepared following an established laboratory protocol. Ten mm lengths of CG matrix were inserted into 20 mm segments of either a porous collagen, nonporous collagen, or silicone tube. Empty tubes of each type and a sciatic nerve autograft were used as controls.

The sciatic nerve of adult female rats was transected at the mid-femoral level. The nerve ends were inserted 5 mm into the prosthesis, leaving a 10 mm gap, and secured in place. For the autograft, a 10 mm section of the sciatic nerve was removed, realigned in its original position and secured.

At 6 weeks, the tissue was prepared for embedding in either paraffin or Epon. The paraffin sections were analyzed qualitatively using hematoxylin and eosin, Masson's trichrome, and α-smooth muscle actin stains. The Epon sections were fixed in osmium tetroxide and analyzed quantitatively using digitized images.

A standardized gait analysis is presently being used as a functional analysis technique. The rat's footprints are measured for print length, toe spread and intermediate toe spread on both the normal and experimental foot.

PROGRESS—The initial experiment with the collagen tubes was a full histological study of the regeneration after 6 weeks. A second study is in progress which involves the long-term (30 week) evaluation of regeneration both functionally and histologically.

RESULTS—The density of axons in the regenerated nerves was higher than intact nerve, probably due to the sprouting of many axons from one nerve body after injury. The regenerated axons were much smaller in diameter and had thinner myelin sheaths compared to normal nerve. The diameter of regenerated axons peaked at 3–4 microns, while the normal axons were evenly distributed in the range from 3–12 microns. Each prosthesis group was evaluated with n=3. Normal nerve had a total of 6371±942 axons/nerve. The number of axons per nerve in each of the prosthesis groups is as follows: autograft, 12963±2313, silicone with matrix, 4670±2617, porous collagen with matrix, 3441±2980, non-porous collagen with matrix, 7030±10968, silicone empty, 0±0, porous collagen empty, 547±928, and non-porous collagen empty, 3424±1821. There was no significant difference between any of the tube groups filled with the collagen-GAG matrix. This indicates that the collagen tubes with matrix performed comparably to the silicone tube with matrix.

Immunohistochemical staining for α-smooth muscle actin has shown that myofibroblasts are present in the healing nerve. In an ongoing study, we are investigating the role of these cells in the peripheral nerve healing process. In addition, studies are in progress to measure the concentration of certain cytokines and cerebroglycan in wound fluid.

Early results from the gait analysis indicate that function is completely eliminated immediately following surgical transection and implantation in all of the animals. This work is currently in progress.

FUTURE PLANS—The completion of the current study will produce important functional and morphological information on the long-term effectiveness of each prosthesis type. This data will be useful in planning a protocol for a clinical study of the most promising prothesis. In addition, preliminary investigations into the effect of collagen matrices on the cytokine concentrations in wound fluid will help develop a molecular probe into the process of regeneration.

[314] SCHWANN CELL COATED CARBON FILAMENTS STIMULATE CNS AXONAL GROWTH

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

PURPOSE—Regrowth of axons in the central nervous system (CNS) occurs to a limited extent due to the nature of the environment. We have previously utilized small diameter (5 μm) carbon filaments as an adjuvant to stimulate directed regrowth of transected axons in the CNS. In order to enhance the regrowth of severed CNS axons, we co-cultured Schwann cells with carbon filaments in the absence and presence of 14-day-old fetal rat spinal cord tissue.

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 48 hours, Schwann cells were added to the culture dishes. The Schwann cell line (NF-1T) utilized in these experiments was a human Schwann cell line derived from a patient diagnosed with neurofibromatosis. These cells show the expected immunoreactivity to antigens known to be present on Schwann cells. In culture, these cells demonstrate the typical spindle-shaped bipolar morphology and align themselves in fascicles.

After culturing for an additional 96 hours, the cultures were fixed and processed for scanning electron microscopy. The cultures were osmicated, dehydrated, critical point dried, sputter coated with gold, mounted on specimen stubs, and then observed under an ISI scanning electron microscope.

RESULTS—Scanning electron microscopy revealed that the NF-1T cells interacted with the surface of the carbon filaments aligning themselves with their long axis parallel to the long axis of the carbon filaments. The surface of the NF-1T cells was covered with numerous filopodia which appeared to aid in the stabilization of these cells on the carbon filaments. The NF-1T cells aligned in this way on the carbon filaments appeared to extend filopodia perpendicular to the axis of the cell. These processes appear to wrap around the surface of the carbon filament and aid in the adherence of the NF-1T cells to the filament. The presence of the Schwann cells in the co-culture with fetal spinal cord explants induced extensive neuritic outgrowth from the explants.

FUTURE PLANS—Experiments are being designed to manipulate the NF-1T-carbon filament culture conditions so that the majority of the surface of the carbon filaments will be completely covered with NF-1T cells. In turn, these Schwann cell-coated carbon filaments should act as an effective stimulator of axonal regrowth *in vivo*.

[315] GENETICALLY ENGINEERED NEUROTROPHIN SECRETING SCHWANN CELLS FOR THE TREATMENT OF SPINAL CORD INJURY

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

PURPOSE—Neurotrophins are proteins essential for the survival, target innervation, and function of different populations of neurons. Nerve growth factor (NGF), brain derived neurotrophic factor (BDNF), neurotrophin-3 (NT-3), and neurotrophin 4/5 (NT-4/5) all belong to the same family. The neurotrophins have great potential as pharmacological agents. However, the use of neurotrophins for the treatment of spinal cord injury (SCI) has not been evaluated at present.

Studies have suggested that regeneration can be encouraged in the damaged mammalian spinal cord by providing trophic factors, and by introducing substrates which provide a favorable attachment surface and provide directionality to regrowing axons. Recent studies have shown that many populations of central nervous system neurons are responsive to BDNF and NT-3, providing a rationale for the use of BDNF and NT-3 for encouraging the regrowth of motor and sensory fibers after SCI.

Recently, through the use of genetic engineering technology, we have infected Schwann cells with a retrovirus-based vector containing the cDNA for either BDNF or NT-3. Once infected, these cells act as biological pumps which continuously secrete either BDNF or NT-3. These BDNF or NT-3 secreting Schwann cells, if implanted into the injured spinal cord, could then continuously deliver these growth factors and maintain an enriched environment for the injured spinal cord axons to regenerate. The primary purpose of the present study was to infect Schwann cells with a replicative incompetent retrovirus-based vector into which the cDNA for BDNF or NT-3 has been inserted.

METHODOLOGY—The cDNA for BDNF and NT-3 were each inserted into retroviral vectors, and the orientation of the cDNA with respect to the promoter was determined by restriction enzyme digestion and agrose gel electrophoresis. Retroviruses were generated from the plasmid forms of the retroviral vectors by transient transfection of PA 317 amphotropic retroviral packaging cells. The resulting BDNF and NT-3 retroviruses were used for infecting Schwann cells. Stable BDNF- and NT-3-secreting colonies were selected. Total RNA was prepared from the BDNF and NT-3 secreting Schwann cells, and mRNA was isolated from the total RNA. The mRNA levels for these two neurotrophic factors will be evaluated by slot and Northern blots. Levels of BDNF and NT-3 secreted by the Schwann cells will be measured by Western blotting using BDNF and NT-3 standards and anti-BDNF and anti-NT-3 antibodies.

PROGRESS—At the present time, both the BDNF and NT-3 retroviral vectors have been constructed. Amphotropic retrovirus packaging cells have been transfected with BDNF and NT-3 retroviral vectors, and BDNF and NT-3 retrovirus have been harvested. Schwann cells have been infected with the BDNF and NT-3 retroviruses and stable BDNF- and NT-3-secreting colonies have been selected. The BDNF- and NT-3-secreting Schwann cells are currently being evaluated for mRNA levels of these two neurotrophins by slot and Northern blots. In addition, levels of BDNF and NT-3 secreted by the Schwann cells are being measured by Western blotting.

FUTURE PLANS—The Schwann cells will be evaluated *in vitro* for the production of these two neurotrophins, and subsequent studies will involve culturing these cells on carbon filaments and implanting them into the lesion sites of spinal cord contused rats to determine their effect on the regrowth of injured spinal cord axons.

The use of genetically modified cells that secrete BDNF or NT-3 has great potential as a means of gene therapy for the treatment of SCI. This technology, once evaluated in an animal model, can be directly applied to the treatment of human SCI.

[316] COMPARISON OF SYNTHETIC TUBES AND SCIATIC NERVE GRAFTS AS BRIDGES FOLLOWING SPINAL CORD INJURY

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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 a brief period of vigorous growth, functional regeneration is seldom successful because of the formation of a dense scar and the presence of inhibitor factors. Peripheral nerve autografts have been shown to enhance regenerative processes within the optic nerve. Autografts of peripheral nerves have also supported regrowth of other injured CNS axons. Apparently, it is endogenous factors within the grafts, perhaps released by the Schwann cells, which 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 will be increased by providing channels for the growing axons, channels which 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 consisting of a 1.2 mm i.d. polysulfone tube (Amicon) filled with 30 percent Matrigel 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 was compared to regeneration of neurites within a similarly grafted segment of predegenerated, isogeneic peripheral nerve. Comparisons were based upon immunocytochemical staining with anti-neurofilament protein and electron microscopic evaluations of the bridges 2 weeks after implantation.

PROGRESS—Bridges composed of polysulfone tube filled with Matrigel were found to support the development of a cable of cells, but to contain fewer neurites than bridges composed of a segment of predegenerated, isogeneic peripheral nerve.

PRELIMINARY RESULTS—Synthetic tubes were found to support the growth of a cable of organized cells when used to bridge over a spinal cord injury. This cable was composed of a mixture of cell types, including fibroblasts, glial cells, and a few bare or loosely ensheathed neurites. The cable was highly vascularized and wrapped by a layer of connective tissue. The control bridge, consisting of predegenerated, isogeneic peripheral nerve, contained many neurites ensheathed by either Schwann cells or compact myelin.

FUTURE PLANS—We will examine the following specific aims using another type of synthetic tube found to be effective in bridging peripheral nerves:

1. 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.
2. Determine the maximal distance that regrowing axons can traverse within tubular prostheses.

XVI. Wheelchairs and Powered Vehicles

A. General

[317] COMPUTER-AIDED WHEELCHAIR PRESCRIPTION SYSTEM (CAWPS)

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B685-DA)*

PURPOSE—Current wheelchair users and prescribers have a large and increasing selection of wheelchairs to choose from, each having a variety of accessories that tune the wheelchair to individual need. Thus users have the opportunity to select the wheelchair that is closest to being ideal for their needs. However opportunity does not always translate into reality due to three factors: 1) *Information overload:* a number of companies make wheelchairs in a variety of models with many configurable options for each; a huge quantity of information has to be searched in order to make the most appropriate selection; this information continually changes as new models, options and companies enter the scene; information between different manufacturers is often difficult to compare; and wheelchair standards information is not easily available. 2) *Incorrect prescription or purchase of wheelchairs:* this problem particularly affects inexperienced, first-time wheelchair users. 3) *Laborious Procedures:* time-consuming written reports and justifications are required to obtain funding for wheelchairs.

The purpose of the CAWPS project is to develop a computer program that provides an effective, easy to use, and affordable wheelchair prescription aid to assist the team normally associated with wheelchair prescription: the wheelchair user, the therapist, and the wheelchair vendor. The computer program will provide easy access to expert prescription methodologies and currently accurate and comparable wheelchair information based on the ANSI/RESNA wheelchair standards, as well as assistance with the preparation of written reports and justifications necessary to obtain funding.

METHODOLOGY—Developed to address these problems, the CAWPS project is based on information from: ANSI/RESNA wheelchair standards, experts in wheelchair prescription, expert wheelchair users, and information from manufacturers. The CAWPS will incorporate an interface that updates the system based on the availability of information on new wheelchair models that have been tested according to the ANSI/RESNA wheelchair standards.

PROGRESS—To date, we have defined and acquired appropriate software and hardware, collected and analyzed information on existing work and on commercially available software, and developed a preliminary GUI for demonstration to experts. We are presently in process of developing second version of the interface and have developed and distributed a questionnaire aimed at potential users. We are working on first prototype of rules of wheelchair prescription by means of telephone conferences; face-to-face meetings with the experts on the team have been held to critique the prototype software. We have developed ongoing collaborative links with related projects and resources.

PRELIMINARY RESULTS—Our completed analysis of the first 40 questionnaires shows a need for the project among wheelchair prescribers. The tools—both

hardware and software—exist to develop CAWPS, and the rules and information exist to develop CAWPS.

FUTURE PLANS—The system is being designed to enable the collection, recording, and analysis of information on wheelchair prescription practices over time, which could be used to provide input to educators, manufacturers, funding agencies, prescribers, and users.

[318] 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—The proper selection of a wheelchair requires making several critical decisions, not the least of which is what type of wheelchair is appropriate. The International Organization for Standards (ISO) continues to develop and refine wheelchair standards that allow the objective comparison of products from various sources, enabling the consumer or clinician to assess unfamiliar wheelchairs by comparing test results.

METHODOLOGY—This study consisted of three components: 1) the comparison of fatigue test results with the planar ANSI-RESNA test dummy to a contoured HERL test dummy; 2) the comparison of fatigue test results for common depot versus common rehabilitation manual wheelchairs; and 3) the comparison of fatigue test results for manual rehabilitation wheelchairs with solid 8-in casters versus pneumatic 8-in casters.

The depot wheelchairs were placed on a double-drum tester for 10,000 cycles and then moved to a curb-drop tester for 350 cycles. This process was repeated in sets of 10,000 and 350 until the wheelchair either broke or became permanently deformed. Similarly, the rehabilitation wheelchairs were placed on a double-drum tester for 100,000 cycles and 3,500 cycles for a curb-drop tester. Previous experience with these types of chairs led us to choose the number of cycles in each set, so that both types of chairs would experience about the same percentage of double-drum and curb-drop equivalent cycles during their lifetime. Testing was terminated after a class III failure or 2.05 million equivalent cycles.

PROGRESS—We tested 15 manual wheelchairs (6 depot wheelchairs and 9 rehabilitation wheelchairs with identical components), commonly purchased by the VA and other third party providers, using ANSI-RESNA Double-Drum and Curb-Drop testers. All of the wheelchairs were folding models.

RESULTS—The rehabilitation wheelchairs lasted on average 13.2 times longer than the depot wheelchairs. The three rehabilitation wheelchairs equipped with 8-in pneumatic casters lasted on average 3.2 times longer than the six rehabilitation wheelchairs equipped with solid 8-in casters. When evaluating wheelchairs, the initial purchase price can be misleading. Therefore, the suggested retail price for each wheelchair was divided by the total number of cycles until a Class III failure occured to yield the dollars per equivalent cycle. This gives a measure of how much it cost to operate a wheelchair until it needs to be replaced. The depot wheelchairs cost about 3.4 times as much to operate per cycle or per meter as did the rehabilitation wheelchairs. The six rehabilitation wheelchairs equipped with solid 8-in casters cost 3.2 times as much per cycle than the

three identical rehabilitation wheelchairs equipped with pneumatic 8-in casters.

FUTURE PLANS—This study did not examine clinical factors related to the two styles of wheelchairs (e.g., adjustability, postural support, maneuverability). Clinical factors are important and need to be addressed in future work. The ISO-ANSI/RESNA standards do provide useful information and can be used to assure a minimum quality level. It should be a goal of all people intimately involved with wheelchairs to understand and apply wheelchair standards and to work toward a quality standard. One step toward this process is to systematically investigate the effect of wheelchair components and design features on durability. Another step is to investigate user perceptions of rider comfort and how these perceptions are related to wheelchair design. Eventually, comprehensive selection guidelines could be developed which incorporate product evaluation information.

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[319] 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—Little published information is available on the joint kinetics during wheelchair propulsion. This is partially due to the lack of appropriate instrumentation and techniques. Wheelchair propulsion is accomplished by the bilateral simultaneous repetitive motion of the upper extremities. The pushrim is grasped or struck and pushed downward and forward, in turn, rotating the wheels. The most commonly reported site of musculoskeletal injury in manual wheelchair users is the shoulder. Surveys show the prevalence of shoulder pain to be between 73 and 31 percent. Elbow, wrist, and hand pain have been reported to exist among 16, 13, and 11 percent of manual wheelchair users, respectively. Biomechanical techniques can be developed to assist in the amelioration of upper extremity pain among wheelchair users.

METHODOLOGY—The complexity of developing a system for measuring pushrim forces is evidenced by the paucity of data in the literature on the kinetics of wheelchair propulsion. A number of researchers have attempted to develop a force sensing system with varying degrees of success. The wheelchair kinetic data reported in the literature can be divided into 3

categories: 1) static force measurements, 2) external devices for measuring forces and torques, and 3) measurement of force components at the pushrim, indirectly or directly. This study focuses on measurement of force components.

RESULTS—We have shown, utilizing the SMART^{wheel} (a force/torque sensing wheelchair wheel), differences in propulsion biomechanics between wheelchair users and non-wheelchair users. The results showed that experienced wheelchair users produced pushrim forces that were lower in magnitude, while maintaining lower peaks for longer periods of time. An impact spike was observed at hand contact, which indicated a rapid force loading at the beginning of the stroke. Tangential forces applied to the pushrim were also shown to be more optimally produced by wheelchair users. We have also shown that joint moments at the shoulder peaked approximately 75 percent of the way through the propulsion cycle, while considerable variability was observed across speeds and between subjects. This data showed that variable net joint forces and moments were observed across subjects and joints. All subjects exhibited large forces and moments at the shoulder, most notably a large vertical component. This produces a force at the shoulder which has a tendency to drive the humeral head into the acromial shelf, a possible mechanism traumatizing shoulder joint structures.

FUTURE PLANS—We intend to follow a group of patients through rehabilitation to 5 years post injury 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.

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[320] DEVELOPMENT OF A LABORATORY DEVICE FOR DYNAMIC SIMULATION OF DRIVING FORCES

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PURPOSE—Forces generated during normal driving conditions may prove destabilizing, fatiguing, and uncomfortable, especially for travellers with disabilities. Studies conducted in the vehicle on the effects of these forces on subject response are very laborious, time-intensive, and difficult to repeat precisely. Lack of repeatability may severely confound experimental results used to evaluate variables that affect disabled travellers, such as seat type or seat cover material.

Thus, to accurately model the inertial driving forces as a function of time while maintaining repeatability in a controlled, laboratory environment, a servomotor-driven tilt table was constructed and tested.

METHODOLOGY—The concept driving the development of the tilt table is the utilization of primarily gravitational forces parallel with the table to simulate the inertial forces experienced by the vehicle occupant during acceleration, braking, or turning. A sideways tilt (roll) simulates a turn while a frontwards tip (pitch) simulates a brake for the subject seated in a chair secured to the table. Since the inertial forces perpendicular to the long axis of the torso will generate the largest moments on the trunk, these forces are the ones matched by movement of the tilt table while the normal forces are allowed to differ between the two situations. Hence, the resultant force acting on the subject in the van will differ slightly from that acting on the subject on the table, but by less than 10 percent in magnitude and 10 percent in angle up to a 0.45 g acceleration.

The table is a 4×5 foot (1.22×1.52 m) wooden platform. Cables attached to the sides of the table are wrapped around take-up spools suspended directly above. A servomotor turns the spool, thereby winding or unwinding the cable and causing the corresponding side of the platform to be raised or lowered, in turn, to attain the desired acceleration. Servo control of the motors enables the matching of acceleration profiles as a function of time on the tilt table to those recorded in the vehicle.

PROGRESS—A device employing two servomotors was designed and built. Pitch and roll ranges are 0–30°. Fully-loaded peak rotation rates are approximately 17°/sec.

Tests comparing subject response in a 22 foot (6.71 m) van and on the tilt table were conducted for three able-bodied subjects at two different speeds of left turns. The acceleration profile recorded in the van for each trial was simulated on the tilt table. Videotapes of subject response were made for both settings. Digital images were created from the videotape using FrameGrabber software. Pelvic, sternoclavicular, and head displacements were measured from the images at the peak acceleration.

PRELIMINARY RESULTS—Paired t-tests between the two experimental environments failed to reject the null hypotheses that the responses were the same on the tilt table and in the vehicle for α=0.2 for the sternoclavicular and pelvic displacements and for α=0.1 for the head displacements. Differences in head displacements may be attributable to the lack of instructions to the subject on where to keep his gaze fixed in the van.

FUTURE PLANS—In upcoming experiments body response (movement of the center of gravity, body curvature, and pelvic tilt) in the van and on the tilt table will be compared for groups of quadriplegic, paraplegic, and able-bodied individuals for both turning and braking. If correlations are found, the table may then be used for examining the effects of seat and support type on stability.

[321] ERGONOMICS OF MANUAL WHEELCHAIR PROPULSION

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Sponsor: *Dutch Prevention Fund*

PURPOSE—We are undertaking an analysis of manual wheelchair propulsion from a combined biomechanical and physiogical perspective, eventually to improve the mobility of the wheelchair user combination. Our central areas of interest include both wheelchair design and the physical factors of wheelchair use.

Our study of wheelchair design characteristics looks at those elements that influence the wheelchair user interaction in terms of overall physiology (i.e., functional load and mechanical efficiency) and biomechanics (i.e., kinematics, kinetics, and the loading

of structures). This should lead to theoretically based guidelines for wheelchair design and wheelchair fitting.

Our study of factors influencing the work capacity and power output (including functionality and propulsion technique) of the wheelchair user, as the "motor" of the wheelchair-user combination, should lead to guidelines of wheelchair training in sports and rehabilitation, as well as to design and fitting guidelines.

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 kinematics (3-D) 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 extremity and trunk muscles, and overall physiology. An inverse dynamics segment model of the upper extremity and shoulder region is used to interprete cardio-respiratory phenomena and measures of efficiency from a biomechanical and anatomical perspective. A model of the shoulder complex allows calculation of the contribution of different muscles on power production during static and dynamic activity of shoulder in wheelchair arm work and other tasks. Thus the high prevalence of repetitive strain injuries (RSI) in the shoulder and hand-wrist complex among the wheelchair-user population may be understood more clearly.

PROGRESS—This past year, detailed studies were conducted on lever and (synchronic and asynchronic) crank propulsion in relation to different gear ratios. Results on crank propulsion indicated a significantly better performance using the synchronic mode. The levers showed a better performance when using a "high resistance-low speed" condition. The latter was contrary to the cranks, which seems associated with the different levels of power output at which the tests were performed and the linear hand velocity, associated with this.

A second analysis of the hubcrank propulsion mechanism was conducted supporting previous findings on the higher efficiency of this system. This clearly is associated with the more natural coupling of the hand to the hand grip, its continuous bi-modal motion and power transfer and a more effective power transfer. The more natural coupling also appears beneficial to the stresses upon the hand-wrist area, which tend to be high in handrim propulsion. The latter was further studied in a detailed 3D kinematic analysis of the hand/wrist during handrim propulsion.

This study indicated that large excursions are common around the flexion/extension axis and ulnar/radial deviation axis, indicating that this in itself may be a risk factor for RSI, obviously in combination with the large gripping forces and propulsion torque produced. A follow-up on the seat height experiments on three individuals with a spinal cord injury (13 seat height levels and 3 repetitions) indicated a statistical significant individual optimum in only one of the three subjects. For the other two there were tendencies but no significant effects. This seems associated with the limitations of the experimental techniques used, which are not developed for low level of physiological strain in submaximal arm work.

FUTURE PLANS—Fitting quidelines will be further refined for groups of disabled subjects, also during the process of rehabilitation.

Detailed analysis of wheelchair arm work during handrim and other propulsion mechanisms 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. Obviously, also the efficiency question will be further addressed.

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[322] EVALUATION OF MODIFIED VAN CRASH SAFETY

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Sponsor: *National Institute on Disability and Rehabilitation Research, US Department of Education, Washington, DC 20202-4725*

PURPOSE—The purpose of this project is to test the crash safety of a van modified to accommodate wheelchair occupants.

PROGRESS—The initial crash test of a 1992 Ford E150 van with a lowered floor took place on April 22, 1995 at the Insurance Institute of Highway safety in Ruckersville, Va. Problems were identified within the remounted fuel tank and wheelchair lift.

FUTURE PLANS—The next crash test will involve a similar van with its floor lowered via cutting and lowering the frame.

[323] THE DETERMINATION OF ENVIRONMENTAL ACCESSIBILITY AND WHEELCHAIR USER PROFICIENCY THROUGH VIRTUAL SIMULATION

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PURPOSE—This research involves the development of a tool for three groups of people: 1) for architects and designers, it provides structure previsualization and analysis that can both improve the handicapped accessibility of building designs and test a structure for ADA compliance; 2) for wheelchair users, it provides more appropriate device fitting and training with wheelchair control systems; and 3) for health care professionals, it helps evaluate wheelchair user proficiency.

METHODOLOGY—The system consists of an instrumented, joystick-driven power wheelchair connected to a high-performance graphics workstation that simulates the actual speed and maneuverability of the particular wheelchair within a virtual structure, specifically imported previsualized architecture. The system can generate 30 frames per second, with no latency from command execution to scene update. This provides the user with an excellent sense of causality.

PROGRESS—Currently the system allows the user to maneuver through a previsualized architectural data set. Collision detection between the virtual chair and the virtual environment allows for evaluation of architectural data sets for ADA compliance (specifically clearance), and it can be used by users to train and adjust newly appropriated equipment prior to actual use. The user is cued to collisions through visual feedback, such as scene jarring.

Current efforts include improved physical modeling of the environment, including various friction models for surfaces (carpet, tile, cement, and so forth), to assist in evaluating surfaces and ramps. Additional efforts include the ability to increase the level of realism in the environment while maintaining real-time performance. This includes pre-processing the architectural data through implementation of a visibility computational scheme for determining only visible surfaces, thus sending a subset of the data set to the renderer at any one time.

PRELIMINARY RESULTS—The current systems can be used for evaluating architectural data sets for ADA compliance. Current efforts include improving the realism of the environment and its interactions while maintaining real-time performance. Thus, the system can be used for training users who are being upgraded from a manual to a power chair. Results so far warrant further development for allowing a health care professional to track the user through the system, specifically tracking reaction times and number and areas of collisions, such as is evident in cases of side neglect. In addition, we are transferring the system to a more generic type of seating, to provide for evaluation of a broader range of individuals with disabilities.

[324] COGNITIVE READINESS FOR POWERED WHEELCHAIR MOBILITY

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Sponsor: *National Institute on Disability and Rehabilitation Research, Washington, DC 20202*

PURPOSE—Independent powered mobility allows young children with physical disabilities to participate more fully in play, educational, and community situations. However, few resources are available to therapists to assist in the decision to recommend a powered wheelchair to a young child. Information gained from this project will be used to assist professionals in determining cognitive readiness for powered wheelchair mobility, as well as to describe a program of mobility skills necessary for functional operation of a powered wheelchair. The project seeks to identify the cognitive developmental skills and temperament factors that influence readiness for powered wheelchair mobility in young children with physical disabilities from ages 18 to 36 months. All participants are children who have severely limited independent mobility, yet demonstrate age-appropriate cognitive abilities.

PROGRESS—To date, 23 children (17 males, 6 females) have participated in the project. In an attempt to minimize the influence of dynamic sensorimotor integration problems, only children with physical disabilities were selected (i.e., arthrogryposis, spinal cord injury, muscle disease). Fourteen had some form of prior mobility such as rolling, scooting, or walking. The average age of the children was 29 months (six=18 to 24 mo; eight=25 to 30 mo; nine=31 to 36 mo).

Cognitive developmental skills were evaluated using an assessment battery with 83 tasks grouped into 5 Piagetian-based scales, including cause-effect, object permanence, problem solving, spatial relations, and symbolic play. Because of the ordinal structure of the scales, the child's stage of developmental thinking within each cognitive scale was determined. This was to insure that specific scale scores, not a global average, was obtained. Tasks were individually modified to tap the child's cognitive, not physical, abilities.

Power mobility skills were introduced and evaluated through play in safe and unstructured environments. Thirty-four mobility tasks were evaluated, ranging from key basic skills to integration of these skills into more functional maneuvers and community skills. Each child spent six 1-hour sessions in the wheelchair, and the last session was videotaped and scored. The final score reflected the average amount of hands-on assistance or verbal cueing the child needed to maneuver the powered wheelchair safely through each skill.

Preliminary interrater agreement was high across the five scales for the cognitive assessment battery using the Kappa statistic. Kappa scores of 0.75 or above represent excellent interrater agreement above chance, and scores between 0.40 and 0.75 represent fair to good agreement above chance. Interrater agreement was also high on independently rated performance on the mobility program ($r=0.95$, $p<0.01$). It was interesting to note that preliminary data indicated there was no relationship between having had prior mobility and being able to functionally maneuver a powered wheelchair.

When 25 children have completed the project, the data from the developmental assessment battery will be

scaled and clustered using the Rasch model. Scores on these developmental clusters will be used in a regression analysis to predict scores in the powered mobility program.

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[325] SAFETY STANDARDS FOR WHEELCHAIRS USED AS SEATING SYSTEMS IN VEHICLES

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PURPOSE—The purpose of this project, in conjunction with the Subcommittee on Wheelchairs and transportation (SOWHAT) committee member organizations, is to develop test procedures for crash safety and wheelchair stability. For people with disabilities who are unable to transfer from their wheelchair when traveling in motor vehicles, the wheelchair must serve as the vehicle seat, and aftermarket equipment must be installed to secure the wheelchair and provide occupant restraint.

PROGRESS—A preliminary test procedure has been developed for frontal crash tests.

FUTURE PLANS—Finalization and validation of test procedures will be accomplished.

[326] TESTING PROTOCOLS FOR WHEELCHAIR SECUREMENT SYSTEMS IN NORMAL DRIVING CONDITIONS

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Sponsor: *Transportation Research Board, Federal Transit Administration*

PURPOSE—Testing of wheelchair securement devices has focused largely on performance during crashes; operation of the devices during normal driving conditions has received little attention. Yet, at these lower acceleration levels, not only can the securement system affect the comfort and functionality of the wheelchair user, but safety also because a considerable number of injuries occur without vehicle impact.

As part of a study to provide guidelines for the testing of wheelchair securement systems and to develop a model securement system that conforms to those guidelines, a number of methods for evaluating device operation in normal driving conditions were compared. The goal was to determine which of the modalities would prove best in terms of expense, ease of use, repeatability, and validity.

METHODOLOGY—The performance of the model securement system and commercial wheelchair securement systems were assessed during in-vehicle and laboratory test protocols. Manual, powerbase, and electrical wheelchairs and a scooter, loaded with a 50th-percentile Hybrid II anthropomorphic test dummy (ATD), were used for the evaluations with each testing modality.

Controlled driving maneuvers were conducted both in a public bus with a professional driver at a test track and in a 16-passenger van at a designated off-road location. The accelerating, braking, and turning maneuvers were based on recommendations in the 1986 UMTA Workshop for Bus-Wheelchair Accessibility. Vehicle acceleration data was recorded, and wheelchair movement was captured on videotape.

A tilt table in which the gravitational force parallel to the tilted platform simulates the inertial driving forces was utilized for testing the securement system. Servomotors were used to tilt the table with the wheelchair and ATD secured to various angles. Computer control of the motors provides dynamic control of the tilt table to precisely match the acceleration profiles recorded in the vehicles. The wheel location was marked on the floor prior to testing and under maximum load to determine the wheelchair motion.

Pull testing was also employed as a means of simulating driving forces. The load was applied manually via a turnbuckle and force gauge arrangement to the center of gravity of the wheelchair/dummy system. The wheelchair motion was again recorded before and after the load was applied.

PROGRESS—The testing described above has been completed, and the results tabulated and reported to the funding agency.

RESULTS—The vehicle accelerations were found to reproducible within 10 percent with the professional driver, and within 15 percent with an experienced driver in a van. Both the tilt-table and static pull testing closely simulated the conditions experienced in the vehicles. When testing with identical securement systems, slightly less motion occurred during the vehicle testing than during the laboratory conditions. This may have been caused by the difference in floor material or the static test conditions in the laboratory. In all tests, the wheelchair motion was less than the 2 inches allowed by the ADA.

FUTURE PLANS—To investigate the effect of the dynamic variables on the performance of wheelchair securement systems, the tilt-table will be used to dynamically duplicate the acceleration profiles measured in the vehicle. The results of these tests will be compared to the results obtained earlier under static conditions. The test protocols developed and validated through this work will allow for evaluating the wheelchair stability provided by securement systems in the laboratory without the inconvenience and expense of in-vehicle testing.

[327] UNIVERSAL WHEELCHAIR TIEDOWN/OCCUPANT RESTRAINT SYSTEM

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Sponsor: *Triangle Research and Development Corporation, Raleigh, NC 27612*

PURPOSE—The goal of this project is to develop a standard wheelchair-vehicle interface analogous to a trailer hitch. If universally employed, any wheelchair could be quickly and safely secured in a van or bus.

PROGRESS—An initial prototype has been fabricated and successfully crash tested with a standard manual and a powered wheelchair.

FUTURE PLANS—The prototype will be redesigned to accommodate other mobility aid configurations. Field trials of the final design will be conducted.

B. Powered Controllers

[328] DETERMINING THE APPROPRIATENESS OF INTEGRATED CONTROL OF ASSISTIVE DEVICES

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PURPOSE—Integrated controls (ICs) allow the user to control more than one assistive device through a single, "universal" input device. Typically, this is the device chosen to control the powered wheelchair. Since the technology providing the capability to integrate is relatively new, there is little information available to suggest when the use of integrated controls is appropriate. The purpose of this project is to identify the factors which support integrating control of multiple assistive devices and those which suggest that control be distributed across multiple input devices.

RESULTS—The purpose of the retrospective review was to identify the factors that were of primary importance in the decision to integrate control. Findings indicated that 15 percent of the individuals received recommendations for systems with IC. Situations in which IC was preferred include: 1) when the client has a single reliable access site, 2) when the best site and method of access for each assistive device (when evaluated independently) is the same, and 3) when the client prefers IC for personal reasons such as aesthetics or reduction in fatigue. Additionally, if an individual might require the use of additional assistive technology in the future (e.g., due to progressively deteriorating function or changes in personal assistance or living environment) consideration should be given to a system that can be upgraded to provide IC capabilities.

The remaining 85 percent received recommendations for systems with separate, distributed controls (DCs). Reasons for DC recommendations include: 1) severe performance trade-offs with the use of IC, 2) access desired from locations other than from the powered wheelchair (e.g., bed, manual wheelchair), 3) difficulties with IC systems due to functional limitations in cognition, vision, and physical control, and 4) other factors (e.g., lack of technical compatibility of assistive devices with ICs, high cost of ICs).

Seven performance case studies were conducted to follow-up the findings of the retrospective review. Participants' abilities to access more than one assistive device and to switch between devices were compared using systems with both IC and DC. Speed and accuracy of performance and subjective opinions were obtained and compared across subjects.

Four individuals preferred IC and three preferred DC. Three of the four who preferred IC did so primarily because they became less physically fatigued when using a single input device. Other reasons included a reduction in the number of input devices used, easier positioning of switches, and greater independence resulting from decreased reliance on others to set up equipment interfaces. The primary reason for preferring DC was performance-related (i.e., performance on at least one assistive device became severely degraded when using IC).

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Access to assistive technology: a comparison of integrated and distributed control. Guerette P, Nakai R. Technol Disabil. In press.

C. Seating Systems

[329] DEVELOPMENT OF BETTER ANTERIOR PELVIC STABILIZATION DEVICES

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PURPOSE—In our efforts to understand the concerns of consumers who use seating products, we have discovered that postural belts appear to be the source of greatest dissatisfaction. To address this, we initiated a project to focus our developments on these components. We will consider improving the functional design of the belting material, buckles, and attachments of postural belting systems with the help of consumers and service clinicians. Survey, focus group techniques, and lab testing will be used to evaluate current belting approaches to support the development and commercialization of innovative alternate designs.

PROGRESS—We have begun to understand more about the problems and frustrations consumers have experienced with belting arrangements. From the research we conducted with consumers during the development of a modular pediatric seating system, we have started to accumulate valuable information in support of this effort. Since this project began, we have sorted responses from over 100 parents and service clinicians received through our earlier self-report surveys. We are also reviewing our videotaped focus group sessions with parents, clinicians, and children to develop a clearer understanding of consumer needs. The data we have compiled are being organized into needs domains. We plan to use this information to guide the development of renderings and models of devices which address this issue.

FUTURE PLANS—We will organize three to four discussion groups with consumers and seating service professionals to further understand their concerns about postural belting systems. We will use commercial options and design concepts to investigate which aspects need to be improved. With this information, we will develop more sophisticated models and prototype systems. We will first focus on developing systems that are secured by the parent or attendant. We will, however, investigate other schemes for enabling users to manage belting systems. To test some ideas, we will be recruiting consumers to participate in the laboratory evaluations of various design options. The number of sessions will depend upon the number of features to be evaluated. However, we envisage 10–20 children, and similar numbers of parents, caregivers, attendants, and service providers being asked to independently evaluate each aspect of the design. This will ensure that valid and unbiased information will be collected through structured interviews and open-ended inquiry.

RECENT PUBLICATIONS FROM THIS RESEARCH

Pelvic stabilization for children with cerebral palsy: why?, how?, for whom?, what next? Reid DT, Rigby P, Lederer D, From W, Ryan S. In: Proceedings of the Canadian Seating and Mobility Conference, Toronto, September, 1995. In Press.

[330] DEVELOPMENT OF CUSTOM CAR SEATS FOR SCHOOL-AGED CHILDREN WITH PHYSICAL DISABILITIES

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Sponsor: *Rotary Club of Leaside (Toronto) Ontario Rehabilitation Technology Consortium, funded by the Ontario Ministry of Health*

PURPOSE—Many children with physical disabilities need custom-made seats to be comfortable and well-supported while in their wheelchairs. This poses a safety problem for parents wanting to transport their child in the family car. Commercially available car seats are not suitable because these children do not fit into them. As a result, parents use the custom-made insert from their child's wheelchair for this purpose. While the child may appear to be buckled in safely, this arrangement may not provide adequate occupant protection during a motor vehicle accident. The goal of this project is to develop a custom car seat for older children weighing from 40 to 75 pounds (about 5 to 12 years of age). In this way, they will be offered the same level of occupant protection as other passengers in a motor vehicle, yet be comfortable and well-supported. Another issue that concerns parents is how to transfer their child safely to and from the car without injuring their backs. To help them deal with this problem, the project includes the development of a portable lifting device that can be conveniently used for this purpose.

PROGRESS—We evaluated the willingness and ability of seating clinic workshops to construct custom car seats. Ten clinic workshops across North America agreed to participate in the study by constructing a custom car seat using the FRAME-IT system, a similar system we developed for younger children with disabilities. Results indicate that clinics can do this; however, we need to provide more detailed instructions and hardware templates to ease the construction. We met with parents through focus groups to evaluate various design models of both the lifting device and new restraint system. We modified our designs based upon the feedback we received and constructed full scale prototypes. With the assistance of eight parents, both devices were evaluated during hands-on trials. The parents who participated approved of the prototypes and made suggestions for how we could improve them.

FUTURE WORK—Over the next year, we will modify the designs to address the concerns expressed by consumers. We will conduct a marketing investigation to understand how these devices should be sold. We will prepare an educational package (written materials and video) to instruct clinics and parents on how to use these devices safely and effectively.

RECENT PUBLICATIONS FROM THIS RESEARCH

Evaluation of a program to teach seating clinics to build custom car seats, Ryan SE, From W, and Day K. In: Proceedings of RESNA International '95; 1995 Vancouver, BC; Arlington, VA: RESNA Press, 1995: 317-9.

[331] TESTING OF CUSHIONING FOAMS TO DETERMINE THEIR MATERIAL RESPONSE

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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. While an American Society for Testing Materials (ASTM) standard exists for testing the response of cushioning foams, cushions themselves do not usually come in the size specified by the standard. Thus, different investigators who are testing these materials have modified the test sample size in different ways, and it is not clear how these modifications affect the results of the test. In this project, foam samples will be tested in four different sizes. In particular the effect of hammocking forces, forces associated with the overhang of the cushion under the indentor, will be noted.

METHODOLOGY—Samples of four different cushioning foams will be compressed according to Standard ASTM D 3574-86, "Standard Methods of Testing Flexible Cellular materials-Slab, Bonded, and Molded Urethane Foams," Tests B_1 and B_2. The four types of foam are: Fire Resistant (FR) Polyurethane (PU), #6 PU, PU Beige, and Vinyl/Nitrile Copolymer (trade name UL Spongee). The standard states that samples be a minimum of 15 (38.1 cm) inches square and 1 inch (2.5 cm) thick. In the first phase of tests, the samples were tested as rectilinear slabs measuring 12 inches (30.5 cm) square and 4 inches (10.2 cm) thick except for the UL Spongee which was 11.75 inches (29.8 cm) square and 1.5 inches (3.8 cm) thick. In the second phase of tests, the samples are 4-inch thick disks with a radius of 4 inches. The cross section of these samples matches that of the disk-shaped indentor specified for the test. In the third phase of tests, the samples will be tested as 4 cm×4 cm×5 cm rectilinear slabs. In these phases of testing, all guidelines of the standard are being followed except for the sample size. In the fourth and final phase of testing, the samples of the same material will be tested in the standard 15-inch square size.

During the standard test and for the 12-inch square samples, there are portions of the rectilinear slabs which are not loaded. Thus a restoration force exists along the boundary of the deformed and undeformed portions of the sample. This is known as a hammocking force. In the second phase of tests, it is expected that no hammocking force will be present. In the third phase of tests, it is again expected that no hammocking forces will be present in the small rectilinear slabs. The sample sizes for the first three phases of the test were chosen based on published work by several investigators.

PROGRESS—Data is still being analyzed from the first phase of tests, but some initial results are available. The second phase of testing with the disk-shaped cushions is currently underway.

RESULTS—All material property curves have both linear and nonlinear regions. In some materials, the linear region exists up to 50 percent strain.

FUTURE PLANS—Current plans include the completion of phases two and three of the cushion testing as well as testing of samples which meet the ASTM standard. Analysis of the nonlinear portion of all of the data has yet to be performed. Future plans include further investigation of the viscoelastic behavior of the material.

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Mathematical model and analysis of physical characteristics of a linear visco-elastic material. Song G, Smith SL, Todd BA. In: Proceedings of the American Society of Mechanical Engineers Region XI Graduate Student Technical Conference, Tampa, FL, 1995. Tampa: USF, 1995:46-8.

Mechanical effects of coatings on cushioning foams. Smith SL, Song G, Todd BA. In: Langton A, ed. Proceedings of the RESNA '95 Annual Conference, Vancouver, BC, Canada. Arlington, VA: RESNA Press, 1995:294-6.

[332] THE BOBBLE WHEELCHAIR: A WHEELCHAIR SEAT CONTROL SYSTEM

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Sponsor: *None listed*

PURPOSE—This project examines the feasibility of a wheelchair designed as a therapeutic tool for cognitively impaired individuals of 6 to 18 months developmental age. One of the important developmental activities all children need is the ability to explore their environment in a normal, questioning manner. This wheelchair will provide the maximum amount of motion possible for the clients and the invaluable experience of examining the world at their will.

PROGRESS—This system has been designed for the Miniature Powered Vehicle (MPV) and is targeting clients 4 to 9 years chronological age. The controls have been placed in the seat of the wheelchair, and motion occurs in the direction that the user leans. It is believed that this motion will be instinctive as the child reaches for objects they desire. Movement occurs in only three directions: left, right, and forward. One direction will be added at a time as the child becomes comfortable with the given control. Each direction will be automatically set to a pressure level necessary to cause motion, based upon how the child is seated. Because it is necessary to avoid jerking starts and stops, this wheelchair will move and accelerate slowly. A therapist will be able to control speed. There is an adjustable time delay between wheelchair seat control activation and response, since each client will have differing levels of upper body control.

Force-sensitive bumpers that surround the chair provide added safety. A sound is heard when the force sensors are triggered. The wheelchair response is to either enter a waiting mode until the object that obstructs the path is removed, or to extricate the chair automatically. In the latter case the chair will automatically back up 50 cm and turn 90° to the left of the current direction of motion, after which the child can proceed. The response is selected by a switch in the control box.

This project is proceeding on schedule. The main concern is the difficulty in teaching the client the concepts of cause and effect. The analysis of this system will include an evaluation of the features of this wheelchair and an outline for teaching the client to use this chair.

XVII. Wound and Fracture Healing

[333] A PROSPECTIVE STUDY OF RISK FACTORS FOR DIABETIC FOOT ULCER

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PURPOSE—We are conducting prospective research designed to identify and quantify risk factors for foot ulceration 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—Eligible subjects, those who meet the criteria for diabetes mellitus by physician diagnosis or treatment with a hupoglycemic medication or insulin, are enrolled in a general medicine clinic. Subjects who participate attend a Diabetic Foot Clinic where we perform comprehensive 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 oxymetry ($TcPO_2$) 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 measurments, and Harris mat testing for abnormal pressure points. Behavioral factors assessed include type of footwear, diabetes history and control, foot self-care practices, and visual acuity.

We conducted baseline examinations on all study subjects between 1990 and 1994. 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 factors are related to risk of diabetic foot ulcer.

PROGRESS—To date we have enrolled 778 diabetic subjects from the Seattle VAMC general internal medicine outpatient clinic. We screen these subjects at yearly examinations for presence of possible risk factors for diabetic foot ulceration and for the occurrence of foot ulcer, lower extremity amputation, and death.

PRELIMINARY RESULTS—As of June 1995, we observed 99 foot ulcers occurring over a cumulative 1,651 person years. Subjects who develop a foot ulcer have an increased relative risk (RR) of death of 2.55 (95 percent confidence interval (CI) 1.21 to 4.89) independent of self-reported coronary heart disease and age.

We have examined 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 participating in this study. We can obtain the probability of peripheral vascular disease from knowledge of the subject's age, history of peripheral vascular disease, examination of the peripheral pulses by palpation, and venous filling time. Other purported findings such as cold feet have little diagnostic importance.

A preliminary analysis has revealed that foot ulcer risk is high in subjects with inonomic neuropathy (RR 3.0; 95 percent CI 1.3 to 7.1) and low $TcPO_2$ on the dorsal foot (RR 1.6; 95 percent CI 1.0 to 2.6).

FUTURE PLANS—The findings related to risk faetors for foot uleer should be viewed as preliminary. It does appear from eurrent data that sensory and autonomie neuropathy and skin oxygenation will be important in the pathogenesis of diabetie foot ulcers. Final analysis, when completed in 1996, should provide additional information eoneerning the risk faetors for diabetie foot ulcer and potential means for prevention.

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Health and functional status of veterans with diabetes mellitus. Ahroni JH, Boyko EJ, Davignon D, Pecoraro RE. Diabetes Care 1994:17(4):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 1995:18(2):216-9.

Lower extremity foot ulcers and amputations in persons with diabetes. Reiber GE, Boyko EJ. In: Harris MI, ed. Diabetes in America. In press.

Paradoxical transcutaneous oxygen response to cutaneous warming on the plantar foot surface: a caution for interpretation of plantar foot $TcPO_2$ measurements. Smith DG, Boyko EJ, Ahroni JH, Stensel VL, Pecoraro RE. Foot Ankle. In press.

[334] REDUCING THE PERIOD OF IMMOBILIZATION FOLLOWING PRESSURE SORE SURGERY: A PROSPECTIVE RANDOMIZED TRIAL

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PURPOSE —The cost of surgical care for a patient with pressure sores may exceed $50,000. One part of this expense results from the prolonged post-operative immobilization to further wound healing. Three weeks is our conventional period of immobilization following surgical closure of pressure sores. Published protocols from other medical centers report 3 to 8 weeks of immobilization routinely; however, there are no studies that establish longer periods of immobilization as superior to shorter periods. To justify our treatment, we conducted a prospeetive randomized trial comparing outcome of 2 versus 3 weeks of post-operative immobilization. Our hypothesis was that the eomplieation rate after 2 weeks of immobilization post-operatively was equivalent to 3 weeks.

METHODOLOGY—Patients seleeted for reeonstruetive surgery were managed on the Rehabilitation Medieine Service with Plastie Surgery as consultant. Eaeh patient was randomized pre-operatively to either 2 versus 3 weeks of post-operative immobilization. Patients who presented with multiple pressure sores or osteomyelitis were excluded from this study. These groups were compared for the ineidenee of short-term complications, delay in mobilization resulting from the complieations, and a delay in the time to aehieve sitting.

PROGRESS—A total of 42 patients with a diagnosis of paraplegia, quadriplegia, or multiple selerosis and a solitary pressure sore were enrolled in this study over 5 years: 23 into the 2-week group and 19 into the 3-week group.

RESULTS—Comparison of these two groups revealed no statistically significant differences for age, sex, size of ulcer, primary disease, or number of previous operations for uleers. The minor and major wound complication rates between the two groups (9/23 or 39 pereent for the 2-week group and 9/19 or 47 pereent for the 3-week group) were not statistieally different ($p<0.493$). One patient in the 2-week group required re-operation on post-operative day 35 to elose a eomplete dehiscence. Three patients in the 3-week group had a partial dehiscence of their wounds that did not require re-operation. Whereas the eomplication rates between these groups were equivalent, the time to

mobilization was significantly reduced in the 2-week group (16.1±6.1 days versus 22.9±4.9 days; $p<0.003$). There was a statistically significant reduction in time to sitting in the 2-week group (21.2 versus 28.9 days, $p<0.026$).

IMPLICATIONS—Decreasing the post-operative period of immobilization from 3 to 2 weeks did not increase our complication rate and did not increase our re-operation rate. The 2 weeks of immobilization shortened the time to begin mobilization and reduced the length of stay in the hospital. The reduced hospital stay without increased complications suggests that 2 weeks of post-operative immobilization is sufficient for patients with solitary uncomplicated pressure sores.

[335] THE USE OF GROWTH FACTORS IN PRESSURE ULCER HEALING

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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. The objectives of this study are to: 1) develop a nonporous biodegradable fibrin matrix for delivery of acidic fibroblast growth factor (FGF-I); 2) develop a porous biodegradable fibrin matrix for delivery of FGF-I; and 3) clinically evaluate the pressure ulcer healing efficacy of FGF-I in porous biodegradable fibrin matrices.

METHODOLOGY—The following phases are planned in this study. First, we seek to develop a nonporous biodegradable fibrin matrix that will degrade over 1 week and deliver FGF-I in a controlled manner over time. Then, we will develop a porous one that will degrade over 2 weeks with the same delivery characteristics. Finally, we will determine the clinical efficacy of FGF-I in biodegradable fibrin matrices on pressure ulcer healing.

Phases 1 and 2 will be conducted 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 recieve the 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 g/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. Randomization will be blocked such that the first 15 persons will be equally divided into the 3 groups. This will allow preliminary data analysis to occur half-way 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 three 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 three 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

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Effect of a porous degradable fibrin scaffold on wound healing. Pandit A, Feldman D. Trans Soc Biomat 1994:30:34.

Effect of oxygen permeability on full-thickness skin defects. Pandit A, Feldman D. Wound Heal Regener 1994:2:130-7.

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Use of FGF-1 delivered through a porous scaffold to enhance meshed skin graft healing in a rabbit model. Osborne S, Pandit A, Feldman D, Thompson JA. Trans Wound Heal Soc 1995:5:81.

[336] AN ULTRASOUND DEVICE FOR DISTORTION MEASUREMENT AND BIOMECHANICAL ANALYSIS OF IN VIVO LOAD-BEARING SOFT TISSUE

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PURPOSE—Pressure ulcers continue to be a common complication and costly clinical problem for, among other populations, people with spinal cord injuries (SCI). Interface pressure distributions between buttocks and seat support surfaces are used clinically to evaluate the efficacy of seat cushions relative to the risk of pressure ulcer development. Soft tissue distortion (internal strain) is a superior indicator of pressure ulcer risk, however, limitations of current clinical assessment technology render tissue distortion measurements inaccessible in the clinic.

As an alternative, interface pressure, a parameter that is clinically accessible, is used as an indicator for potentially harmful internal stresses and strains. This research will work toward validating or invalidating the use of external pressure as an indicator for harmful internal strain in soft tissues: muscle, skin, and fat.

METHODOLOGY—This research effort aims to develop an ultrasound sensor that may be used to study *in vivo* tissue distortion (i.e., soft tissue thickness changes) in response to external loading and then apply the sensor to investigate the relationship between resulting internal distortion and the applied external pressure on the weight-bearing human buttocks in seating. The work described is closely related to the research team's current research program (described separately in this issue) that has resulted in the development of a closed-loop automated seating system (CASS) with the ability to precisely control seat support surface shape while measuring externally applied pressure. The proposed project will augment this instrumentation with the ability to measure changes in soft tissue thickness thereby allowing the determination of the efficacy of using external pressure measurements to assess the risk of pressure ulcers. The CASS system is in use in the seating laboratory at the University of Pittsburgh, Rehabilitation Technology Program. Integration of A-mode ultrasound transducers into the pressure-sensing heads of the controllable seat support surface of the CASS allows the determination and modeling of soft tissue thickness changes resulting from changing external pressure and altered support surface shape. Such information is fundamental to the investigation seat support surfaces relative to risk of pressure ulcers.

PROGRESS—Preliminary work has been performed at the University of Pittsburgh Medical Center where B-mode ultrasound images were recorded to determine first the feasibility of using ultrasound to locate bone

and second to determine the frequency necessary to image the desired aspects of the test subject. Additional work has been performed using the proposed A-mode device technology. An initial prototype ultrasound transducer has been designed, constructed, and tested to determine the ability of such a device to detect the interface between skin and muscle; muscle and fat; fat and bone; and muscle and bone. Tests using fresh pork have indicated that each of these interfaces will be detectable with an oblique planer disk structured ultrasound transducer and signal processing system. In these preliminary tests, the echoes from both the muscle-to-bone interface and the fat-to-muscle interface are clearly distinguishable from the background noise and other reflections.

FUTURE PLANS—Two configurations of the ultrasound transducer are considered for this application: an oblique planar structure and a ring array structure. The CASS system is made up of 128 actuator/sensor elements. Integration of ultrasound transducers into a select group of actuator elements (probably 4 to 9 elements in the area around one ischial tuberosity) will allow for the detection of bony structures and measurement of soft tissue layer thickness between the seat interface and the bony structure. Furthermore, these determinations will be automated so that thickness changes can be tracked while the support surface shape is manipulated and interface pressures are measured.

XVIII. Miscellaneous

[337] RESTORATION OF ORAL FUNCTION WITH MAXILLARY BONE GRAFTS AND IMPLANTS

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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 cortico/cancellous 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 capable of withstanding 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 pre-therapy evaluation of bite force, speech, deglutition, mastication, dietary intake, nutritional knowledge/attitudes, and reported self-esteem, subjects undergo the following steps: 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) placement of abutments through the soft tissue and attachment to the mandibular implants 2 months later; 4) construction and placement of a fixed bridge to the mandibular implants and construction of a new maxillary conventional denture; 5) placement of 6 to 8 implants in the bony maxilla, 4 of which are in the bone grafts 5.5 months after bone grafting; 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—All 20 subjects have finished all surgical and prosthetics procedures.

RESULTS—All 20 subjects have completed the treatment protocol; 16 of these subjects have undergone post-testing at 1 month, and 8 of the 20 subjects 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 ($F=41.52$, $df=1/7$, $p<0.0004$). Subjects' bite forces have been maintained at the 1 year follow-up with a slight tendency for an increase in force. The bite force of some subjects 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 seek to extend current experimentation by using other sources for bone grafting, including freeze-dried bone. We propose following these implant subjects for a 5-year period to assess the dimensions and densities of the bone grafts in the sinuses with computed tomography and the endosseous implants with standardized intraoral radiography.

[338] COMMONWEALTH REHABILITATION SERVICE

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Sponsor: *Commonwealth Department of Human Services and Health of Australia*

PURPOSE—The Commonwealth Rehabilitation Service (CRS) is a subprogram of the Commonwealth (Federal) Department of Human Services and Health of Australia. CRS provides direct vocational and social rehabilitation services to Australians of working age through a nationwide network of 170 service locations. CRS programs assist people with disabilities to develop skills for employment and personal independence.

PROGRESS—CRS is undertaking a project to develop a classification system to provide information that will guide funding, provide for continuous quality improvement, assist research, describe outcomes, and provide for intra CRS comparisons as well as for those across the relevant components of the health continuum. We are very keen to keep abreast of other research projects being conducted in the rehabilitation area.

[339] DESIGN OF A HORSE SADDLE FOR A QUADRIPLEGIC

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PURPOSE—Due to advances in assistive technology, horseback riding is becoming more accessible to the disabled. United Cerebral Palsy has asked that a conventional horse saddle be modified to accommodate a client who is a high-level quadriplegic with extended legs. Although a specific client has been chosen to ride and the saddle will be constructed according to his needs, modifications could be made to the saddle structure in order to accommodate other disabled individuals.

METHODOLOGY—Presently, there are two design options, one in which the rider faces forward and the other in which the rider faces backwards. For the forward riding option, the rider must have the flexibility to position his legs on both sides of the horse. In the case that the rider cannot sit completely upright (i.e., legs are not in the traditional riding position), the legs may rest on either side of the horse's neck. The backward riding option seems more feasible for the situation in which a rider with extended legs simply rests the legs on the horse's back. For both design options, the horse will be led, and an attendant will walk on each side of the horse.

In choosing one of the design options, there are several issues that need to be investigated: attachment of seating to horse, cushioning and shock absorption for horse and rider, structural stability of the modified saddle, and materials for construction.

PROGRESS—Most of the research is to begin fall 1995. However, the issue of seat cushioning for the rider has been discussed, and a commercial sponsor has been acquired.

FUTURE PLANS—Following completion of the initial design, the saddle will be built and tested by a nondisabled individual of the client's size. After all possible safety precautions have been taken, the saddle will be evaluated by the client.

[340] THE EFFECT OF TEFRA LEGISLATION ON THE BEHAVIOR OF REHABILITATION HOSPITALS

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Sponsor: *Department of Rehabilitation Medicine, University of Washington, Seattle, WA 98195; Office of Health Care Studies, Seattle, WA 98121; Robert Wood Johnson Clinical Scholars Program*

PURPOSE—The goal of this project is to examine the behavior of new PPS-exempt rehabilitation hospitals before and after their Medicare reimbursement limits are set under The Tax Equity and Fiscal Responsibility Act (TEFRA). Using Medicare data, we are examining the incentives in the TEFRA payment system to see if they impact the case mix admitted to rehabilitation facilities, the type of treatment patients receive, and the quality of that treatment.

METHODOLOGY—Our study uses a retrospective cohort design. We have identified a cohort of new rehabilitation hospitals and have confirmed the dates their reimbursement limits were set through Medicare's fiscal intermediaries. Patient level data is being gathered from Medicare databases for each of these institutions. The data includes all Medicare discharges occurring at least 1 year before and at least 1 year after the reimbursement limit is set. Data gathered includes age, diagnosis, co-morbid conditions, length of stay, financial charges, disposition, and mortality.

Data analysis utilizes the generalized estimating equation (GEE) for correlated data. Temporal trends and covariates, such as age and severity of illness, are being controlled for using GEE's regression techniques.

PROGRESS—A cohort of 83 Rehabilitation Hospitals has been identified in 29 different states. Their average bed size is 69. A search strategy for the patient level data has been developed. This strategy has been successfully attempted on four rehabilitation hospitals.

RESULTS—Currently data collection is ongoing. It is still too early to draw any conclusions.

[341] CAREER DEVELOPMENT OF WOMEN WITH PHYSICAL DISABILITIES

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Sponsor: *National Institute on Disability and Rehabilitation Research, Washington, DC 20202*

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.

METHODOLOGY—This study uses ethnographic techniques and grounded theory methodology to address the following research questions:

1. How does disability affect career development and advancement?
2. How does ethnicity affect career development and advancement of women with disabilities?
3. How do cultural, language, gender, ethnicity, and educational factors mediate career development and advancement?

PROGRESS—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.

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 disabilities that began while they were employed. Six of the women felt their disabilities played an important role in their being hired. Nine of those who were or are employed required little or no accommodations for their disabilities 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.

[342] RESOURCE UNIT FOR INFORMATION AND EDUCATION

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PURPOSE—In the seven years since its inception, the Resource Unit for Information and Education (RU) has established itself as a major clearinghouse for information on prosthetics and orthotics. The RU is not a support group; however, it believes that information provides support. Free information is available to consumers, service providers, research professionals, manufacturers, and others. All publications created by the RU are available free. The RU collects information, disseminates information about research projects, and generates new information on prosthetics and orthotics. The Unit does not endorse or recommend any product, service, or clinician.

PROGRESS—Current RU information databases contain over 2,000 entries related to prosthetics, orthotics, and disabling conditions. These entries contain information on amputation and disability management; amputee support groups, state-of-the-art research; general disabilities; recreational resources; self-help groups;

prosthetic/orthotic schools and organizations; publications; and manufacturers. New information is added after review by RU staff. The NURERC & PRL *Prosthetic-Orthotic Resource Directory,* published in late 1992 by the RU and planned annually, is a direct result of information in the databases.

The RU is currently taking advantage of the information dissemination potential of the Internet by creating a page on the World Wide Web for Northwestern University Prosthetic and Orthotic research, professional education and clinical collaborations. The NU Prosthetics/Orthotics page allows visitors to the site to review progress on research and clinical projects through written reports and computer graphic presentations. This advanced method of communications makes possible interactive communication with consumers, professionals, manufacturers and other research facilities. The Web site is http://www.repoc.nwu.edu/

A Help-Line, available on (312) 908-6524 (voice) or (312) 908-6526 (FAX/TDD) disseminates information to callers. Additionally, the RU directs callers to other information clearinghouses or professionals that may be better able to service their request. Information requests are filled by sending clients printed information on topics in which they express interest.

Educational opportunities in prosthetics and orthotics are available through the Northwestern University Prosthetic-Orthotic Center (NUPOC). Various courses and NUPOC publications are coordinated by the Resource Unit. Close cooperation between research investigators and NUPOC faculty ensure that prosthetists and orthotists taking certification courses at Northwestern have the benefit of the findings of the research and clinical trials.

Consumer feedback is formally acquired through regular meetings of the Consumer Advisory Panel (CAP) of the Rehabilitation Engineering Program. The group meets annually. The Panel, which consists of consumer advocates and persons with disabilities, held a joint meeting on May 6, 1995, with members of the NURERC Technical Advisory Panel. Increased dissemination of information is resulting from recommendations made by the CAP.

PUBLICATIONS—The RU continues its regular publication of the quarterly prosthetic-orthotic newsletter *Capabilities;* informational brochures; information packets; and the *Prosthetic-Orthotic Resource Directory.*

RECENT PUBLICATIONS FROM THIS RESEARCH

Capabilities, a quarterly newsletter, ©1991-1995, Northwestern University Rehabilitation Engineering Research Program.

[343] DEVELOPING A CONSUMER'S GUIDE ON FUNDING ASSISTIVE TECHNOLOGY

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PURPOSE—The goals of this 3-year project are to develop a consumer-oriented guide for acquiring funding for assistive technology and to develop and implement a plan to disseminate the guide nationally. Contents of the guide will be based on results of a survey of disabled children and their families, consultation with funding experts and our editorial board, and a review of current literature.

RESULTS—A guide to assist parents of children with disabilities with the process of obtaining assistive technology, entitled "Tips on Breaking the Funding Barrier...How to Get Assistive Technology for Your Child," has been developed. Text, layout, and front cover design were completed by the end of 1994. Final proof of the guide has been completed and published copies are now available. This guide contains an introduction to the funding process and provides infor-

mation to parents of newly disabled children on access to assistive technology services. It is not a textbook on all the ins and outs of obtaining funding for assistive technology. However, parents of children with disabilities, some older children, and some rehabilitation professionals have felt, after their review, that it is important and helpful information for consumers to have. Over 100 pre-publication copies have been distributed locally to parents of children with disabilities to answer questions they posed regarding possible ways to obtain funding and sources for assistive technology services for their children.

During the development of this guide, meetings were held with key members of our advisory group and representatives from the consumer group Alliance for Technology Access to discuss ideas for national dissemination of the guide. Ideas included distribution by medical equipment suppliers, distribution by the RESNA Technical Assistance Project, and distribution by the local State Technical Assistance projects. A copy of the funding guide may be obtained by contacting Project Threshold at our medical center.

[344] GATHERING AND DISSEMINATING INFORMATION ON ASSISTIVE TECHNOLOGY FOR CHILDREN

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Sponsor: *National Institute on Disability and Rehabilitation Research, Washington, DC 20202*

PURPOSE—The focus of this project is to gather and disseminate information on assistive technology for children. The initial goals were to establish a resource library on assistive technology for children and to provide educational sessions at a local level on a variety of assistive technologies and issues. Dissemination of information on a broader scale has also been addressed.

PROGRESS—A resource library on assistive technology for children has been established, and educational sessions on a variety of assistive technologies and issues have been held on a yearly basis. Dissemination of information on a broader scale includes completing a packet of information on how to hold an Adapted Toy Fair and establishing a data base on resources dealing with toy and play adaptations and computers for children with disabilities. Once completed, plans are to include this data base on Co:Net, an integrated collection of information resources on disability on CD-ROM disk developed by the Trace Research and Development Center.

Educational sessions have been very successful and well received. Several agencies in the Los Angeles area that have Toy and Adapted Toy Lending Libraries are networking and forming coalitions as a direct result of information disseminated through educational sessions provided by this project. Additionally, a Toy Lending Library for Special Needs Children has been set up at Rancho Los Amigos Medical Center as a direct result of information obtained through educational sessions.

[345] ASSISTIVE TECHNOLOGY USAGE OUTCOME

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PURPOSE—The goal of this project is to collect and analyze outcome data in the area of assistive technology usage. A measurement protocol has been developed, and data are being collected at four time intervals up to 2 years after delivery of, and proper training on, all assistive technology equipment. It is anticipated that this project will provide professionals, reimbursing agencies, and consumers with objective information on outcomes that are related to the usage of assistive technology. This information should assist in addressing the issues of the appropriateness and the necessity of assistive technology.

PROGRESS—To date, the assistive technology usage outcomes database includes 123 subjects who are at various stages in the data collection process. The study has lost 11 subjects due to families moving out of the area. A collaborative agreement with California Children Services has proven to be successful in increasing the number of subjects in the project data pool and will continue throughout the course of this study. The current database encompasses a sex distribution of 51 percent male and 49 percent female. The age of the subjects at the point of initial data input ranges from 2 years, 11 months to 21 years, 9 months. The breakdown of types of equipment includes augmentative and alternative communication systems (61 percent), computer systems (27 percent), environmental control units (7 percent), and other types of assistive technology (5 percent).

Data collection will continue during the fifth and final year of the project. This will include obtaining the longitudinal data on existing subjects within the database as well as continuing to add new subjects into the study. Preliminary data analysis has begun and will continue through the term of this project. The data will be examined according to site placement in addition to the current method of examination. As additional longitudinal data are obtained, the relational data analysis will be conducted. Approximately 8 months into the year 5, subject inclusion into the database will terminate, and final analysis will be conducted.

RECENT PUBLICATIONS FROM THIS RESEARCH

Evaluating outcomes in assistive technology: do we understand the commitment? DeRuyter F. Assist Technol 1995:7(1):3-8.

[346] A COMPUTER-ASSISTED CRITICAL CARE DECISION SUPPORT SYSTEM

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Sponsor: *New Brunswick Medical Research Fund; University of New Brunswick Research Fund*

PURPOSE—We seek to enhance the existing medical model using computer and engineering methodologies and develop a clinical decision support system that will improve intensive care unit (ICU) patient care.

METHODOLOGY—We will follow standard statistical analysis techniques and will make use of substantial clinical trials to test the hypothesis that the application of the intelligent monitoring and engineering systems in

the hospital will improve patient outcome, as measured by mortality and length of stay; and provide more efficient utilization of scarce health care resources.

Our research utilizes a database of over 2000 past ICU patients to develop and test the clinical decision support system. Research will also be done to investigate whether the same or a similar method can be used with other databases, including a database of rheumatoid arthritis and one on coronary-artery bypass surgery patients. The project will also attempt to complete the integration of on-line patient data information into the system, and a novel approach is being pursued for visual display of on-line data and its incorporation into the clinical decision support system.

PROGRESS—The project is just beginning.

[347] EFFECT OF RESISTIVE EXERCISE ON PHYSICAL FUNCTION IN MULTIPLE SCLEROSIS

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Sponsor: *National Multiple Sclerosis Society, New York, NY 10017-3288*

PURPOSE—We seek to test the practical, patient-centered questions of: 1) whether resistive exercises can effectively strengthen major postural muscles and ultimately increase physical function and decrease disability; 2) how the effects of exercise noted in mild MS (Expanded Disability Status Scale, (EDSS) $\leq$3.0) can be extrapolated to more severe MS (EDSS$\geq$6.0), as the capacity to generate requisite intramuscular tension will vary markedly at different stages of MS; and 3) whether the possible benefits of such exercise are offset by resultant fatigue.

METHODOLOGY—In a pilot study we evaluated eight MS subjects (mild MS (M) n=4, EDSS$\leq$3.0; and severe MS (S) n=4, EDSS$\geq$6.0). All subjects were prescribed progressive resistive exercise (PRE) training sessions three times per week for 3 months at the University-based Exercise Performance Laboratory under the supervision of an exercise scientist. Subjects' knee and elbow extensors and flexors were trained using the highly effective and well-established method described by DeLorme and Watkins. Each 45-minute PRE session consisted of bilateral resistance training of the quadriceps, hamstrings, triceps, and biceps muscle groups.

Primary outcome measures to test intervention efficacy included both mobility performance variables (self-selected ambulation velocity: WALK; self-selected stair climbing: CLIMB; and 'up and go' agility test: CHAIR) and a self-reported disability scale, the Sickness Impact Profile (SIP).

PROGRESS—Both M and S groups showed improvement in all mobility performance measures: WALK (M=11 percent and S=2 percent); CLIMB (M=21 percent and S=26 percent); and CHAIR (M=17 percent and S=14 percent).

The S group had greater absolute improvements in CLIMB (M=1.39 sec, S=4.78 sec) and CHAIR (M=1.40 sec, S=2.10 sec) while the M group achieved greater, and significant ($p\leq0.05$) absolute changes in WALK (M=9.1 meters/minute ($t(3)=2.68$, $p\leq0.05$), S=1.1 meters/min). Consistent with these physical performance gains were significant ($p\leq0.05$) improvements in both M and S group self-reported disability as measured by: 1) the overall SIP (M: $t(3)=3.43$, $p\leq0.05$; S: $t(3)=3.17$, $p\leq0.05$); 2) the psycho social-dimension component (M: $t(3)=2.71$, $p\leq0.05$; S: $t(3)=2.74$, $p\leq0.05$); and 3) the physical-dimension component (M: $t(3)=2.80$, $p\leq0.05$; S: $t(3)=34.00$, $p\leq0.05$).

All subjects encountered typical acute fatigue which lessened within 24 to 48 hours after each training session. Collectively, they trained over 200 hours without any MS-related excacerbations. All subjects that began their resistance training programs completed the 12-week protocol.

IMPLICATIONS—We conclude that progressive resistance exercise training among MS persons improves ability to perform common daily activities (physical function), has a significantly positive impact on the psychosocial, physical, and overall well being in mildly- and severely-affected MS patients, and the risk of resistance training-induced adverse effects upon MS persons is minimal compared to the benefits gained.

FUTURE PLANS—We plan to examine the dose-response relationship of resistive training upon key antigravity and ambulatory muscles of MS persons and the optimization of medical management of MS persons, followed up by randomly prescribed, clinically controlled, therapeutic resistive exercise and/or acute cooling treatments.

[348] EFFECT OF RESISTIVE EXERCISE ON STRENGTH IN PATIENTS WITH MULTIPLE SCLEROSIS

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Sponsor: *National Multiple Sclerosis Society, New York, NY 10017-3288*

PURPOSE—Increasing muscle strength with resistive exercises requires the development of a certain level of intramuscular tension through a certain number of repetitions per unit time. Persons with muscles weakened by MS are impaired in their ability to generate intramuscular tension, due to defects in motor pathways above the level of the upper motor neuron (UMN). Thus MS patients are often unable to generate levels of intramuscular tension typically used for optimal strength training. This pilot study investigates skeletal muscle adaptive potential in MS subjects with mild (M) and severe (S) disease when engaged in a progressive-resistive exercise (PRE) program.

Specifically, we seek to determine whether enough resistance can be developed to increase strength, and whether any resultant increase in strength is greater in more mildly affected muscles not as impaired in their ability to generate intramuscular tension in these patients.

METHODOLOGY—Eight female subjects with no significant spasticity or ataxia were recruited with definite MS according to the criteria of Poser. All subjects had MS for at least 3 years and were divided into two groups: 4 M subjects (Expanded Disability Status Scale (EDSS) ≤ 3.0) and 4 S subjects (EDSS ≤ 6.0). Subjects were stable and remitted from MS-related exacerbations for at least 4 months.

Subjects trained 3 days per week for 3 months in the University-based performance laboratory. Subjects strength-trained their knee and elbow extensors and flexors. All repetitions are full range and isotonic (concentric and eccentric) contractions. Subjects were instructed to produce, at moderate speed, continuous contractions that were within their comfort and ability. Three sets of 10 repetitions were performed, separated by 60-second rest periods.

PROGRESS—In all four muscle groups, in both M and S subjects, strength increased as a result of a 12-week PRE program. In all cases, the absolute gain of strength was greater in the M subjects. In three of four muscle groups, the relative gain was greater in the M category. Statistically significant increases were observed in M subjects: quadriceps, $t(3)=3.78$, hamstrings, $t(3)=3.14$, biceps, $t(3)=2.50$, and triceps, $t(3)=5.00$, as well as S subjects: hamstrings, $t(3)=5.14$, biceps $t(3)=4.00$, and triceps, $t(3)=3.00$ (in all cases $p<0.05$).

IMPLICATIONS—We conclude that paretic muscles can be strengthened in MS patients with UMN weakness, and that our hypothesis that more mildly affected muscles respond better to exercise was not disproved.

FUTURE PLANS—We plan to examine the dose-response relationship of resistive training upon key

antigravity and ambulatory muscles of MS persons and the optimization of medical management of MS persons, followed up by randomly prescribed, clinically controlled, therapeutic resistive exercise and/or acute cooling treatments.

[349] REHABILITATION ENGINEERING CENTER, TEXAS A&M

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Sponsor: *NSF Bioengineering and Research to Aid the Disabled Program, Arlington, VA, 22230*

PURPOSE—This program provides rehabilitation engineering support and consultation at Texas state mental health and mental retardation facilities, the Texas Rehabilitation Commission, Shriners Hospitals, and the Cerebral Palsy Foundation. This program encompasses faculty and bioengineering students working in cooperation with physicians, therapists, nurses, and special education teachers to design and produce devices to aid the disabled. Projects are constructed to assist the disabled in physical therapy, speech therapy, occupational therapy, and in daily living.

PROGRESS—This is an ongoing program. Faculty meet with therapists and rehabilitation specialists to discuss the needs of the patients and clients and the types of projects that would best serve their needs. Faculty then meet with bioengineering students to discuss the design and construction of these devices. A wide array of electronic and mechanical devices have been designed and delivered under this program. In addition, design and electronics workshops have been conducted to enhance the technical skills of therapists and on-site rehabilitation personnel.

RESULTS—The direct result of this work is the delivery of new or modified adaptive equipment directly into the rehabilitation or special education settings. Examples of projects include a guitar which can be completely played with a single finger and a laser activated (hands-free) electronic keyboard, both for use in music therapy for disabled children; laser activated environmental controls; postural feedback systems including shadow switches and low force pressure switches; hippotherapy posture control devices which provide the therapist with feedback on the angle of the patient's head with respect to the body; and various wheelchair control switches for individuals with limited hand coordination.

FUTURE PLANS—This program provides important engineering support to a variety of medical and rehabilitation settings that would not be able to afford custom design and construction of devices otherwise. In addition, this program provides and important educational design experience for undergraduate bioengineering students. Future plans include expanding the program into more special education settings in Texas schools. Technology transfer will be expanded with additional short courses offered to teachers and therapists throughout the state.

RECENT PUBLICATIONS FROM THIS RESEARCH

Design in bioengineering capstone courses. Miller GE. In: Proceedings of the Biomedical Engineering Society Annual Meeting; 1994, Tempe, AZ.

Rehabilitation engineering design projects. Miller GE. In: Proceedings of the Biomedical Engineering Society Annual Meeting; 1994, Tempe, AZ.

[350] ONTARIO REHABILITATION TECHNOLOGY CONSORTIUM (ORTC)

Dayle Levine

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Sponsor: *Ontario Ministry of Health*

PURPOSE—Initiated in 1991, the Ontario Rehabilitation Technology Consortium (ORTC) is charged with developing innovative rehabilitation technology-based products and services that enhance the lives of persons with disabilities, their families, and their communities.

METHODOLOGY—The Consortium's organizational structure consists of an Advisory Board of consumers, industrial partners, and others who bring expertise in marketing and general business; a Management Committee of research team leaders, institutional partner representatives, and advisory panel consumer representatives; and Research Teams located throughout the Province of Ontario.

Researchers and developers in the Consortium are drawn from Queen's and York Universities, the Universities of Toronto, Western Ontario, and Waterloo, the Ontario Institute for Studies in Education, the Centre for Studies in Aging (Sunnybrook Health Science Centre, Toronto), The Hugh MacMillan Rehabilitation Centre (HMRC), West Park Hospital, and The Rehabilitation Centre, Ottawa. Areas of assistive technologies addressed by the Consortium include Communication, Hearing, Mobility, Prosthetics and Orthotics, Respiration, Seating, Telecommunication and Vision. There is also a Psychosocial Evaluation Team.

ORTC Research Teams work in cooperation with Advisory Panels consisting of consumers, clinicians, researchers, and industrial partners where appropriate.

GENERAL PROJECTS—The *Communication Team* is developing computer-based technology to help people who are non-speaking or who have other communication needs. This same technology can also help at school, work, and play. The *Hearing Team* is developing devices, systems, and procedures to overcome barriers to communication and daily living for people who are hard of hearing and deaf. The Team is working closely with a number of Ontario companies to maximize the impact of these activities. The *Mobility Team* focuses on developing technologies to enable elderly people and those with disabilities to continue to live at home. It has also brought several important products to market. The *Prosthetic Team* is developing new lower limb prosthetic components and upper limb electronic control systems. In Orthotics, new materials to facilitate rapid fitting of braces and rehabilitation applications for new injectable electrical stimulation systems are being explored. The *Psychosocial Evaluation Team* (PSET) consists of social scientists who support ORTC research teams in the areas of psychosocial evaluation and consumer research. Additionally, PSET is bringing to market new and useful assessment tools. The *Respiration Team* is continuing work on the design of an improved valve and hose system for home ventilators. The *Seating Team* is developing innovative positioning devices for young children with physical disabilities both in home and school environments. The *Telecommunication Team* focuses primarily on the accessibility of the information highway and participation of people with disabilities in the evolving knowledge service industry. The *Vision Team* is involved in initiatives intended to overcome the significant barriers encountered by people who are blind or visually impaired, particularly with respect to accessing information. The *Technology Transfer Unit* supports product commercialization within the ORTC.

[351] DEVELOPMENT OF A MODULAR PAEDIATRIC SEATING SYSTEM

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Sponsor: *Rotary Club of Leaside (Toronto); Ontario Rehabilitation Technology Consortium, funded by the Ontario Ministry of Health; Special Health Systems Limited, Aurora, Ontario*

PURPOSE—Modular or "off-the-shelf" seating systems are attractive to seating service providers because the components can be readily combined to produce a functional system for clients with minimal physical disability. Yet for the client who is constantly changing due to growth or changing medical condition, these systems do not easily adapt to change.

The purpose of this project is to develop and assist in the commercialization of a new generation of adjustable, contoured wheelchair seating. This new system is intended to serve children 6 to 12 years of age having neuromuscular disabilities with minimal orthopaedic deformity, mild to moderate muscle tone, and normal skin sensation. The system is to provide the degree of flexibility and adjustability requested by consumers and service clinicians.

PROGRESS—Since this project began in 1992, we have collaborated with over 300 consumers to understand how this system should be designed. In the present year, with our industry partner Special Health Systems (SHS) Limited, we developed a comprehensive design criteria document to convert what we learned from consumers into technical design specifications. We developed operational models and functional prototypes based on this information, and evaluated these systems with the help of parents, service clinicians, and other rehabilitation professionals. We created mechanical test rigs and modified international wheelchair test protocols to help us understand the safety and long-term reliability of the proposed seating system. We also tested over 75 different foams, upholsteries, and flame barriers to understand what materials and material combinations would enhance the safety of consumers.

FUTURE PLANS—Special Health Systems has taken on the project management role for this project. However, we are working with them and their manufacturing subcontractors to develop a preproduction version of the prototype that is within the production cost ceiling determined from SHS marketing research.

RECENT PUBLICATIONS FROM THIS RESEARCH

Development of a specialized seating system for children: obtaining input from children. Ryan S, Rigby P, From W, Walczak E, Jutai J. In: Proceedings of the Canadian Seating and Mobility Conference; Toronto, ON 1994:238-43.

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 1994:244-50.

Processes used to involve consumers in the development of an adaptive seating system for children. Ryan SE, Rigby P, From W. In: Proceedings of the Eleventh International Seating Symposium; Pittsburgh, PA, 1995:52-7.

Towards development of a new paediatric seating system: Understanding the perspectives of parents. From W, Ryan SE, Rigby P. In: Proceedings of the Canadian Seating and Mobility Conference, Toronto, September, 1995. In press.

[352] EVALUATION OF THE INJURY PREVENTION PROGRAM

Edmund N. Biden, DPhil; T. Hruczkowski, BSc, MScEE; Dennis F. Lovely, PhD, PEng; Bernard Hudgins, PhD, PEng; J. Rickards, DipEng, DipMang; K. Rush, BscN, MS; James R. Sexsmith, PhD; M. Tingley, PhD

Institute of Biomedical Engineering, University of New Brunswick, Fredericton, NB, E3B 5A3 Canada; email: biden@unb.ca

Sponsor: *Workers' Compensation Board of New Brunswick*

PURPOSE—The Workers' Compensation Board has implemented a pilot program in back injury prevention among nursing staff. To evaluate the program, the Institute was asked to develop an on-body monitor, which could monitor lifting activities, and to test it in the field in a pilot study that provided an objective assessment of whether or not a back injury prevention program altered the way in which a group of nurses actually worked.

METHODOLOGY—An eight-channel, data recording/digital signal processing system was developed. For these tests, the device recorded muscle electrical activity on both sides of the low back, and in the quadriceps muscles in the thighs. In addition, the angle of bending of the knees and the load under each foot was measured. The device was configured to record all variables once each second during a 4- to 5-hour test period.

Participants wore the device during three regular work shifts before they had been trained, and then repeated the three-shift sequence after training, and again after a 4-month period to see whether any changes persisted.

RESULTS—The findings were that there was a measurable training effect between the pre- and post-training tests. This effect had begun to drift back toward its original state after 4 months.

FUTURE PLANS—The recording device is being evaluated for commercialization and also for use in follow-up projects with the Workers' Compensation Board.

Section II
VA 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 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.

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 Rehabilitation Research and Development Service Scientific Merit Review Board and ad hoc members assess proposals for their scientific and technical merit, budgetary needs, and time requirements.

The VA Rehab R&D Program's scientific and technologic operation is located at 103 South Gay Street, Baltimore, MD 21202, which consists of the following three programmatic sections:

Program Analysis and Review Section
Jon S. Peters, 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 Service 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) evaluates potential products emerging from rehabilitation R&D, primarily sponsored by the VA. Requests involving non-VA funded development are also reviewed to identify products or techniques that may meet specific VA needs in one of the designated special emphasis areas: Prosthetics/Amputations/ Orthotics; Spinal Cord Injury; and Communication, Sensory, and Cognitive Aids, with aging and rehab outcomes crossing all three specialties.

The TTS is responsible for the design and management of a systematic process to validate proven rehab R&D findings and to transfer the successful outcomes into clinical use, product manufacture, and commercial availability. The ultimate goal is for timely transition of prototypes into commercially viable products and techniques that benefit veterans and non-veterans with disabilities. This process partners and coordinates the developer, a manufacturer, VA Headquarters, and clinical test sites.

Once the research idea/concept has moved into development, the outcome is usually a working prototype, which then completes laboratory and limited clinical trials prior to entering the technology transfer process.

The R&D principle investigator next submits a Request For Evaluation (RFE) to the TTS. The RFE elicits specific information that is used to review the appropriateness and readiness of the development as a TTS project. A RFE peer review then confirms VA's need, interest, and readiness of the developed product or technique for evaluation and clinical use. The following selection criteria are used for the review: 1) VA level of need/interest; 2)fitness for use; 3) manufacturable/precommercial; and 4) marketable.

Once the RFE peer review is complete and responses are positive, the TTS formulates and submits a recommended plan of action, including budget support, to the Director, Rehab R&D Service. Approval at this level commences the manufacture and evaluation phases, after which TTS prepares the final report with specific recommendations for commercial availability.

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. STPS distributes research, development, and clinical information through print and electronic media, including publication of the *Journal of Rehabilitation and Development (JRRD), Rehabilitation R&D Progress Reports,* and clinical supplements to JRRD. STPS also has an Information Resource Unit with a visual information specialist and a scientific and technical photographer.

Under the Office of Research and Development, Rehab R&D Service has a Research and Development Center or Unit in each of the following locations:

The Rehabilitation Research and Development Center, Edward Hines Jr. VA Hospital, 5th Avenue and Roosevelt Road, Hines, IL 60141
Joseph B. Green, MD, Director

The Research and Development Program currently has seven approved Merit Review projects and two Pilot projects funded through the Scientific and Evaluation Peer Review Program for the Rehabilitation Research and Development Service. The Center also receives funding for five other projects from other sources including the Technology Transfer Section of Rehabilitation Research and Development Service and The Cooperative Research and Development Agreements (CRADAs). These current projects have generated 21 recent publications and presentations. The Center's academic affiliations provide scientists from Chicago area universities the opportunity to actively participate in Center projects. The Center and its academic affiliates have recently submitted five new Merit Review proposals and two Pilot proposals and still others are pending.

The Rehabilitation Research and Development Center includes seven laboratories. These are the Neurorehabilitation Laboratory, the Neuroscience Laboratory, the Neuroregeneration Laboratory, the Neuroregulation Laboratory, the Preventive and Rehabilitation Exercise Science Laboratory, the Biomechanics Laboratory, and the Autonomic Dysfunction Laboratory.

The Neurorehabilitation Laboratory is studying cerebral reorganization of motor functions in stroke, traumatic brain injury, and spinal cord injury (SCI). Using High Resolution (128 electrodes) Electroencephalography and Co-registration with Magnetic Resonance Imaging, we are able to identify brain structures involved in generating movements and define their temporal relationships. The plasticity of the human brain following lesions of either the peripheral or central nervous systems

is reflected in a reorganization of motor networks and a demonstrable change in the representation of affected parts of the body in the cerebral cortex. Some of these changes may impede recovery and may be circumvented by rehabilitative therapies such as peripheral stimulation.

The Neuroscience, Neuroregeneration, and Neuroregulation Laboratories are primarily concerned with neural regeneration and regrowth. The Neuroscience Laboratory has examined the action of gonadal steroids as neurotropic agents. Specifically, it has been demonstrated that the sex hormone testosterone accelerates nerve regeneration following injury. The Neuroregeneration Laboratory focuses on promoting spinal cord regeneration by controlling factors known to govern the regrowth of nerve fibers and their formation of appropriate connections in target tissues. A variety of new techniques is used, including the application of electric current fields to spinal cord lesions and the implantation of fetal spinal cord tissue. In the Neuroregulation Laboratory, the level of slow axonal transport components has been found to be increased in SCI. Electric current applied to the site of SCI prolongs the increase of slow axonal transport which is necessary for neurite elongation. The goal is to eventually facilitate regeneration and regrowth of axons to restore motor function.

The Preventive and Rehabilitation Exercise Science Laboratory, in collaboration with Packer Engineering of Naperville, IL, has designed a prototype computer-controlled wheelchair ergometer, the Wheelchair Aerobic Fitness Trainer or "WAFT." Developed with funds provided by the Technology Transfer Section of Rehabilitation Research and Development Service, it is a very promising research tool. Clinical evaluations are underway for determining the effectiveness of the WAFT in improving the cardiorespiratory fitness of veterans with lower limb disabilities. The WAFT may also be combined with echocardiography to detect coronary artery disease in persons unable to undergo traditional treadmill stress tests. Other studies underway include measuring changes in lower limb spasticity following moderate upper-body exercise and evaluating rehabilitation and health maintenance strategies for wheelchair users.

The Biomechanics Laboratory has developed an electronic compliance monitor to determine the wearing time for spinal orthoses used in treating SCI. One of the major problems associated with orthotic treatment of SCI is ensuring sufficient patient wearing time. The new compliance monitor contains electronic sensors which can record wearing times over a period of days to help determine optimal wearing times and orthosis efficacy. The controversy surrounding spinal fusion procedures following laminectomy and discectomy is being addressed by determining the breakpoints for different spinal segments after tissue removal and the application of stress to the altered specimens. The Autonomic Dysfunction Laboratory conducts research into bladder control problems following SCI. An evaluation protocol for the home monitoring of bladder pressure has been devised to help reduce infections. The procedure uses a digital pressure gauge developed in cooperation with industry. Another project involves implantation of electrodes into the bladder wall stimulating voiding.

Atlanta Rehabilitation Research and Development Center, Department of Veterans Affairs Medical Center, 1670 Clairmont Road, Decatur, GA 30033
William R. De l'Aune, PhD, 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. Their efforts in recent years have focused on electronic travel aids, orientation and mobility, low vision, and rehabilitation outcome measurement for older persons with visual impairment.

The Center's Behavioral Sections place 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 eight new Merit Review funded projects and five funded pilot studies in FY 94–95. Additional funding includes subcontracts from projects funded by public and private agencies. Research of the center staff has been disseminated through a variety of

mechanisms. Staff published 16 articles, 7 abstracts, and 3 books, book chapters, or manuals. In addition, Center staff provided conference presentations at 27 regional and 27 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, III, PhD, Engineering/Scientific Director; Charles G. Burgar, MD, Medical Director

In 1995, Center investigators from the three scientific sections (Human Machine Integration, Nerve/Muscle Systems, Orthopaedic Biomechanics) forged collaborations and pooled expertise to focus on understanding how applied mechanical forces affect changes in form and function of the neuromusculoskeletal system. This understanding will allow the design and development of better rehabilitation methods and devices. Clinical issues addressed within this focus include hip and knee replacement failures; loss of bone strength in persons with spinal cord injury (SCI) and in the elderly; loss of cartilage in arthritic joints; arm and leg paresis following stroke; and hand and arm paralysis following SCI.

In 1900, only 4 percent of our nation's population were over 65. This age group will represent 13 percent of the US population by the year 2000, and 22 percent by 2030. World War II veterans now constitute the largest proportion of persons eligible for VA health care. Most of these veterans are over 65 years of age and are approaching the average age at which stroke occurs (71 years). In 1994, 50 percent of admissions to the Comprehensive Rehabilitation Program at VAPAHCS carried the diagnosis of stroke. Since the prevalence of arthritis and osteoporosis increase with age, this population is also at increased risk for orthopaedic injuries. As our population ages and more persons, including veterans, are faced with one or more of these physical impairments, their treatment costs are expected to become an increasing financial burden on our health care system. (Hip fracture alone is estimated to cost $9 billion per year.) The Rehab R&D Center is addressing the challenge to find more effective treatments and rehabilitation of such neuromuscular impairments. The goal is to improve the quality of life for patients and their families, and to improve the overall quality and effectiveness of our health care system.

The emphasis is on musculoskeletal and neurologic rehabilitation. We seek to understand biomechanical principles and develop new rehabilitation techniques, procedures, and devices; engineering methods (i.e., computer modeling, mechanics, robotics) are merged with experience achieved in clinical and laboratory studies.

Improvement of joint replacement addresses two of the most prevalent musculoskeletal conditions in our nation, arthritis and osteoporosis. In one study, investigators look at why the femur often becomes weaker after a total hip replacement. Through computer modeling and laboratory experiments, we have developed tools that explain how bones grow and maintain their strength. Weakening and fracture of the bone can result from changes in the pattern of mechanical forces transmitted to the bone through the new joint. This insight will lead to new designs for artificial implants that will function more like the joints they replace.

Improved rehabilitation of upper and lower limb movement, and restoration of ambulation are significant endeavors as well. Computer models helped develop a theoretical framework for diagnosis and rehabilitation of persons with neurological impairment of the lower limbs. These models allowed investigators to understand and assess the coordination of movement. Using these models we can discover the leg function that is essential in various motor tasks, such as the aspects of pedaling that are common with walking. This will enable us to design new therapy techniques for early treatment to restore leg coordination following stroke.

Other examples of Center research directed toward the restoration of limb function include: a biomechanical model of the index finger to predict outcomes of tendon-transfer surgeries; a walking aid for patients unable to bear full body weight; real-time computer diagnosis of gait and balance in individuals with Parkinson's disease; devices to enhance rapid recovery of upper limb motor patterns after stroke; and development of a mathematical model of the compound muscle action potential to improve accuracy of electrodiagnosis of neuromuscular disorders.

Cleveland Rehabilitation Research and Development Center, Functional Electrical Stimulation, Department of Veterans Affairs Medical Center, 10701 East Boulevard, Cleveland, OH 44106
P. Hunter Peckham, PhD, Director

The Cleveland FES Center is a consortium including the Cleveland VA Medical Center, Case Western Reserve University, MetroHealth Medical Center, and Edison Biotechnology Center.

The mission of the Center is to improve the quality of life of veterans with disabilities through the introduction of advanced technology employing functional electrical stimulation (FES), and to advance scientific knowledge in FES in order to generate new knowledge and promote additional development of clinical applications. 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 further the knowledge base and clinical applicability of FES.

Technology Transfer. The FES Center has completed the transfer to industry of an implantable hand grasp

neuroprosthesis. This device is now undergoing multicenter testing for FDA approval that may be obtained as early as 1997. Four VA Medical Centers are participating in the trials. Following the success of the hand grasp neuroprosthesis, the Center is now directing technology transfer resources to FES devices to provide standing and mobility.

Technology Development. The core Technology Development Laboratory is now fully operational and available as a resource to investigators. Investigators need not be affiliated with the FES Center to utilize the laboratory resources. The laboratory offers state of the art software and hardware design facilities for prototype development, as well as a Class 1000 cleanroom, suitable for fabricating implantable medical devices.

Advanced Research. Research projects in progress include 1) a new 10-channel implantable stimulator/telemeter and an implantable joint angle sensor that are now undergoing animal testing; 2) techniques to provide enhanced upper limb function through hand intrinsic muscle stimulation, elbow movement, and closed loop control; and 3) restructured standing and mobility projects focused on clinical outcomes in preparation for transfer to industry. These research activities are occurring in conjunction with existing Cleveland VA Merit Review projects.

Coordination of Research Activities. To facilitate the coordination of Cleveland research activities, the Center has initiated an external Scientific Advisory Committee to provide research project oversight. This committee will enhance the work of the FES Council, which provides institutional representation to FES Center project planning discussions. Internally, Center investigators meet weekly to share expertise, resources, and updates on project progress. An outreach program has been launched to disseminate information about Center programs, expertise, and opportunities for collaboration via print, video, and electronic media.

Rehabilitation Services Research and Development Unit, Department of Veterans Affairs Medical Center, 508 Fulton Street, Durham, NC 27705
Byron B. Hamilton, MD, PhD, Director

Established by the Rehabilitation Research and Development Service in 1994, the Rehabilitation Services Research and Development Unit (RSRDU) is located at the Durham VA Medical Center in Durham, NC, with access to all the Center's vital resources, including Health Services Research and Development, and the Quality Management Institute and Education Center. The mission of RSRDU is to evaluate and facilitate optimal delivery of rehabilitation care and care outcomes for disabled veterans. All 171 VA medical centers provide some rehabilitation services, and 72 centers support a physical medicine and rehabilitation bed service.

One of the Unit's important objectives is to build and maintain capacity for rehabilitation services research by identifying resource people from across the VA system, prioritizing research activities, and facilitating rehabilitation services research in the medical centers.

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.)*

Birmingham VA Medical Center
700 South 19th St., Birmingham, AL 35233

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West Los Angeles VA Medical Center, Brentwood Division
Wilshire and Sawtelle Blvd., West Los Angeles, CA 90073

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Los Angeles VA Outpatient Clinic
351 East Temple St., Los Angeles, CA 90012-3328

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Long Beach VA Medical Center
5901 E. Seventh St., Long Beach, CA 90822

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Palo Alto VA Medical Center
3801 Miranda Ave., Palo Alto, CA 94304

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VA Medical Center
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1201 Northwest 16th St., Miami, FL 33125

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820 S. Damen Ave., Chicago, IL 60612

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5th Ave. and Roosevelt Rd., Hines, IL 60141

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1601 Perdido St., New Orleans, LA 70146

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940 Belmont St., Brockton, MA 02401

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1400 Veterans of Foreign Wars Pkwy., West Roxbury, MA 02132

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10 N. Greene St., Baltimore, MD 21201

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9600 North Point Rd., Fort Howard, MD 21052

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Ann Arbor VA Medical Center
2215 Fuller Rd., Ann Arbor, MI 48105

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Allen Park VA Medical Center
Southfield & Outer Drive, Allen Park, MI 48101

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One Veterans Drive, Minneapolis, MN 55417

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4801 Linwood Blvd., Kansas City, MO 64128

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4101 Woolworth Ave., Omaha, NE 68105

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