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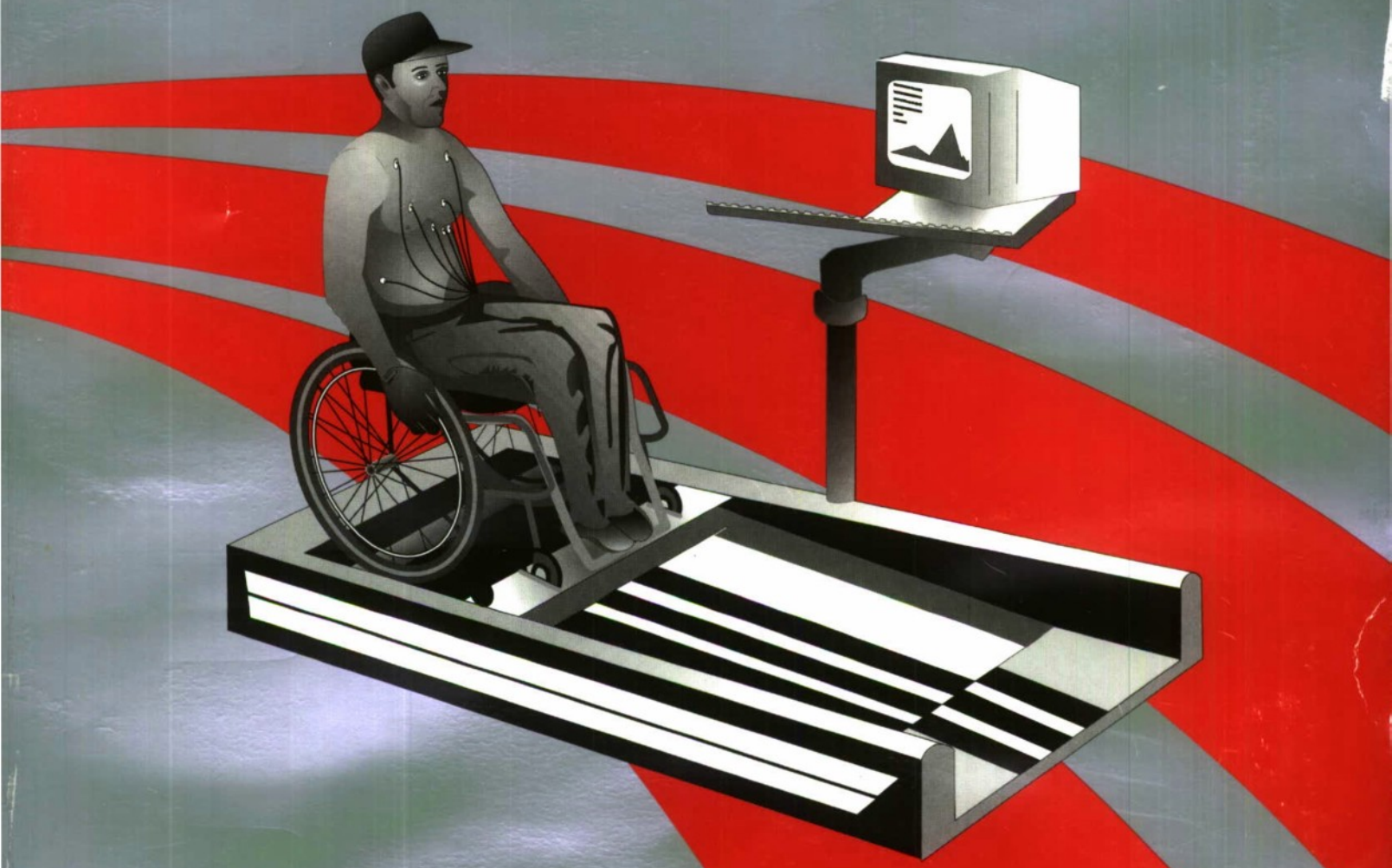
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Department of Veterans Affairs

Rehabilitation R&D Progress Reports



Vol 34, May 1997
Veterans Health Administration
Rehabilitation Researchand Development Service

1996

ON THE COVER

The Wheelchair Aerobic Fitness Trainer (WAFT) is a computer-controlled wheelchair ergometer used for the evaluation, rehabilitation, and development of cardiorespiratory fitness for persons with lower limb disabilities. The design uses electronic particle braking incorporated in the ergometer to provide a reliable method of creating variable power output for graded excercise testing and aerobic conditioning. The WAFT is a wheelchair exercise device designed to accommodate the user's own wheelchair. The WAFT user backs onto the inclined frame where the wheelchair is secured on computer-controlled rollers. Computer-controlled brakes produce resistance when the user pushes the wheelchair wheel during the workout. Wheelchair push speed is measured and physical work determined for each exercise stage. Data are recorded and stored by a computer with customized software. The WAFT is the result of research and development (R&D) under the sponsorship of the Department of Veterans Affairs (VA), Rehabilitation (Rehab) R&D Service, Baltimore MD, John W. Goldschmidt, MD, Director.

THE EDITOR

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

Department of
Veterans Affairs

Rehabilitation R&D Progress Reports

1996

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Rehabilitation Research and Development Service
Scientific and Technical Publications Section (122)
103 South Gay Street
Baltimore, MD 21202-4051

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Rehabilitation R&D Progress Reports

1996

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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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PURPOSE—This project was intended to develop a device and methodology for the automated production of sockets for artificial limbs. The device is to be used in conjunction with the computer-aided design (CAD) of sockets and represents a means for computer-aided manufacturing (CAM) of such sockets. The technology used in this application is inspired by recent advances in industrial prototyping in which additive fabrication principles are used to construct prototypes designed with CAD. Sockets for artificial limbs bear resemblance to prototypes in that they are one-of-a-kind geometric objects intended to be fabricated in single-unit quantities.

METHODOLOGY—The methodology is divided into three parts: 1) the method of operation of the socket fabricating device; 2) the method of preclinical evaluation of fabrication results; and 3) the method of clinical evaluation of fabricated sockets.

The device uses a technique of plastic deposition to fabricate sockets. Plastic material is melted and extruded through a shape-forming die to produce a a 5 mm wide ribbon of melted plastic 0.75 mm high. A computer-controlled manipulator directs the flow of the melted plastic so that multiple layers representative of cross-sectional contours through the socket are deposited successively, one upon another.

Tensile specimens are cut from pseudo-sockets fabricated using the device with regular, geometric shapes, which allow the specimens to conform to ASTM standards. These specimens are tested for ultimate tensile strength and fatigue life, and compared to similar values obtained from more traditional fabrication techniques and from factory-delivered extruded plate.

Clinical trials involve the fitting of sockets to persons with amputation and evaluating their mechanical performance over time. Participants in the study are provided with limbs incorporating sockets made using the device and are asked to use those limbs in unrestricted activity. Periodic follow-ups are made in which the sockets are evaluated for signs of mechanical degradation.

PROGRESS—The device is able to fabricate sockets during unattended operation. A 23-cm (9-in) long transtibial socket requires the deposition of 300 layers and takes between 50 and 60 min. Tensile and fatigue tests have been completed for two materials; polypropylene homopolymer and polypropylene copolymer. Clinical tests are underway and on-going. Methods of PELITE® liner production are being evaluated which utilize a technique for blow-molding. Additional materials are being investigated for future use.

RESULTS—Tensile and fatigue tests have indicated that polypropylene homopolymer is suitable for socket fabrication using the device and for unrestricted use of the fabricated sockets.

To date, a single subject has been using a transtibial socket made with the device for a period of 20 months, and two additional subjects have been using sockets for 3 months each. The first socket was recently evaluated and shows no visual signs of mechanical degradation. The active subject with transtibial amputation has used the

socket exclusively for the entire time without restriction in activity.

Attempts have been made to produce PE-LITE liners for sockets fabricated using the device. A blow-molding technique shows promise for this application as well as for fabrication of replacement liners for any socket. A PE-LITE preform is heated in an oven, inserted into the socket, and pressure-formed to the shape of the socket by expansion of an internal bladder. Heat and pressure parameters are being determined for satisfactory results.

FUTURE PLANS—We plan to construct three prototype fabricating devices for placement and evaluation in a clinical setting. The evaluation phase will be used to recommend modifications and enhancements to the device prior to commercial development and marketing.

[2] DOD 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 veterans with transtibial amputation.

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 pre-selected, anatomical features from optical digitizer camera output intensity measurements;
3. Investigate ultrasonic digitization of the residual limb skeletal, tendonous, and ligamentous tissue morphology;
4. Develop software for integration of residual limb optically digitized surface measurements and ultrasonically digitized subsurface measurements;
5. Develop measurement instrumentation and mathematical models characterizing the nonlinear, nonstationary, nonhomogeneous, anisotropic, viscoelastic behavior of residual limb soft tissues for prediction and analysis of residual limb stress-strain distributions arising from static and dynamic surface loads.

PROGRESS—A "P-Scan" transducer with 1360 force-varying-resistive elements has been designed and fabricated for measurement of normal and gradient shear socket/residual limb interface stresses. A pneumatic, uniform force, servo-actuated test fixture has been designed and constructed, and associated software written, for testing, equilibration, and calibration of P-Scan transducers. A position controlled, stepper-motor-driven test fixture, with a linear servo-actuated, strain-gauge-instrumented force probe has also been designed and constructed, for precise measurement and testing of the output response of P-Scan transducer elements and element subarrays. Comprehensive laboratory testing of the P-Scan transducer measurement system is being conducted with these test fixtures. Software for analysis and visualization of P-Scan measurement data is also being developed. In addition, clinical testing of the P-Scan system with two subjects with transtibial amputation and a nonimpaired control subject has been performed.

A neural network algorithm and software for automated detection of preselected anatomical landmarks from optical digitizer camera output intensity measurements has been developed. The algorithm has been successfully tested with data from scans of 20 subjects. A database of the relative spatial locations of the 18 fiduciary landmarks most commonly utilized by prosthetists in PTB and PTS socket designs has been compiled from a sample of 57 persons with transtibial amputation. A

maximum likelihood identification and registration algorithm and software have also been developed for identification and registration of the detected fiduciary landmarks in the optical digitizer measurements.

Laboratory tests have been conducted with the NY VA Medical Center Radiology and Cardiology Services' clinical diagnostic ultrasound systems. A prototype stepper-motor-driven seanning fixture has been fabricated, and numerous scans of the residual limbs of four subjeets with transtibial amputation and the lower limb segments of five nonimpaired controls have been performed. From these tests, faetors adversely affecting the signal-to-noise ratio, resolution, accuraey, and precision of the received interrogating aeoustic signal have been identified. Potential remedies for these problems have been investigated. Unfortunately, many of the factors have been found to be conflicting, so only limited success has been achieved.

A prototype, servo-actuated, strain-gauge-instrumented, indentor has been designed and constructed for measurement of the mechanical properties of residual limb tissues. Tests measuring the uniaxial, compressive, mechanical creep response of residual limb/limb segment tissues of 15 subjects have been performed. In addition, multisite tests, mapping the mechanical response at nine locations over the residual limbs/limb segments of two subjects have been performed. A second order, nonlinear Odgen model has been fit to the steady state, elastic response measurement data, and a seeond order generalized nonlinear Kelvin model has been used to charaeterize the transient, viscoelastic component of the measurement data. The resulting "bulk soft tissue" models have been used in a nonlinear finite element analysis to predict residual limb tissue stress and strain distributions associated with various prosthetic socket modifications and design.

FUTURE PLANS—Refinement and enhancement of the projeet P-Sean transdueer and stress measurement system shall continue. Development of new, improved, biomeehanically based CAD socket modifications and designs is planned, utilizing the knowledge obtained in the tissue meehanical property measurement and modeling studies, and in the static and dynamic loading studies eondueted in the project. Firmware for CAD system utilization of quantitative feedback of socket/residual limb interface stresses resulting from given socket design geometries and materials shall be developed.

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.

B. Upper Limb: General

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

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PURPOSE—To achieve significant improvement in the function of eleetric-powered upper-limb prostheses, we feel it is necessary to develop better control interfaees with inherent sensory feedback. Small tunnel cineplasties, or other surgieal procedures which externalize the force and excursion of the musele, could potentially provide this superior control. Connecting the muscle to a prosthetic component via a controller that embodies the

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. It is possible to envision multiple miniature tunnel cineplasties, each with an epp controller, providing independent multifinger control of hand prostheses. At higher levels 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.

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. Subjects performed pursuit tracking experiments to quantify the dynamic control capabilities of the cineplasties, which capability was compared with other control methods: 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 the tunnel cineplasty of each subject were recorded for isometric and isotonic muscle contractions. We have also developed a prototype epp electric hand prosthesis for a 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.

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. The mechanical properties of the cineplastized muscle of each subject were obtained. The measurements included the isometric length-tension curve and the isotonic load-excursion and force-velocity relationships. These relationships are valuable for prosthesis design and give an indication of the condition of the cinplastized muscle.

IMPLICATIONS—Previous work done in our laboratory showed the superiority of position control over velocity control in pursuit tracking tasks. By inference this implies that control by tunnel cineplasty should be superior to velocity-control techniques. In addition, tunnel cineplasty offers a number of advantages over control conventional harness arrangements. Tunnel cineplasties 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

FUTURE PLANS—The next phase of this project involves the development of a new microprocessor-based epp controller that can be fine tuned to better match the characteristics of the controlling joint or muscle/tendon. These new controllers will then be used by a number of upper-limb amputees with pre-existing cineplasties to control test prostheses by way of direct muscle attachment.

RECENT PUBLICATIONS FROM THIS RESEARCH

Direct muscle attachment as a control input for a position servo prosthesis controller (dissertation). Weir RF*ff*. Evanston, IL: Northwestern University, 1995.

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

[4] UPPER LIMB AMPUTEE SERVICES: THE VA APPROACH AS A MODEL SERVICE SYSTEM

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PURPOSE—To date, no quality of care standards have been developed to address the rehabilitative and ongoing support needs of persons with upper limb loss. The lack of such standards for them may be contributing to less than optimal outcomes for these individuals, who require diagnostic, therapeutic, and prosthetic services in order to function with maximal independence in the home, job, and other settings. The VA system, with its decades of service to such persons, may offer a model for quality of care that could be replicated in whole or in part by addressing the needs of people currently served through other systems. At present, there is no objective, systematic approach to documenting the strengths and weaknesses of the VA's service program, nor for determining its appropriateness as a model that might be adopted in meeting the needs of other populations currently unserved by the VA.

METHODOLOGY—This project is designed to employ an expert approach, similar to the national consensus approach employed by the Center for Accreditation of Rehabilitation Facilities (CARF), to develop and test quality of care standards, which approach can then be used to assess the efficacy of replicating the VA's service approach in other settings. The Amputee Services Assessment Inventory (ASAI) will be developed and will include quality-of-care standards and indicators as well as a protocol for self-assessment. Also, this project is designed to increase the representation of VA-served patients in the National Upper Limb Amputee Database (NULAD) developed by The Institute for Rehabilitation and Research (TIRR).

PROGRESS—The six member ASAI Expert Advisory Board has met and developed a preliminary, 25-page questionaire to be used for pilot testing at the Houston VA Medical Center and at TIRR.

FUTURE PLANS—The preliminary ASAI will be modified as needed and tested at four additional VA, and four additional private, rehabilitation facilities. Site visits will be made at each of these facilities. The ASAI will ultimately be a tool for rehabilitation facilities to use in ongoing monitoring and improvement of services. An additional goal is to increase the representation in the NULAD of VA-served individuals, whose data will be compared to that of those served by other systems, to determine whether there are special needs or service issues in the VA population.

[5] THE WILMER COSMETIC PROSTHETIC PREHENSOR FOR CHILDREN

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PURPOSE—The standard split hook prosthesis is, despite its functionality, most often rejected by parents of a child with an upper limb defect because of the very poor and deterring outward appearance. The objective of this project is to develop a new prosthetic prehensor for these children that combines the functionality of the standard

split hook prosthesis with an improved and appealing outward appearance.

METHODOLOGY—A shape study was performed to determine the outline of the new prehensor. The resulting outline is derived from the contour of a hand of a 4–6 year old child. The length of the fingertips and the position of the rotating finger are approximately similar to a healthy hand. The connection to the forearm is harmonic and smooth. All mechanical parts, including the operating cable, can be placed out of sight in the interior of the prehensor. A rather simple mechanism was designed and constructed that converts the actions of the control cable into movements of the rotating finger of the prehensor. Due to the construction of the mechanism the pinching force is almost a constant throughout the opening width. All mechanical parts are placed into a frame. Integrated into the frame is a light weight friction wrist prosthesis. Also the frame is the pillar to the cosmetic cover made out of flexible polyurethane resin. This way several unique features were obtained:

1. the outside of the prehensor is rugged and easy to maintain;
2. the cover can be easily removed to access the mechanism;
3. the cover can be coloured. Giving the cover a bright primary colour emphasizes the toy-like nature of the prehensor, thus advancing the acceptance and use of the prehensor by the child. It is even possible to supply several covers in different colours, which can be exchanged by the child according to daily moods.

RESULTS—In collaboration with our clinical partners of the rehabilitation centers *De Hoogstraat en Sint Maartenskliniek,* the new cosmetic prosthetic prehensor was clinically tested by 10 children. They all highly appreciate their new device. It has not caused any negative reactions or strange associations. The children are delighted by the bright colored appearance of the prehensor. Because of the smooth outline of the prehensor and the integration of the control cable, wear of clothing is reduced considerably. The mechanism of the prehensor proved to be reliable but is rather cumbersome to assemble.

FUTURE PLANS—In order to facilitate easy assembly of the prehensor, a new mechanism will be designed and constructed. Once this mechanism has proven to be reliable as well, the cosmetic prosthetic prehensor will be commercialized.

[6] 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 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 Lighter-weight Electric Prehensor 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°/s with a 6-volt battery (65°/s 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—Testing of our prototype units revealed that the commercial backlock mechanism, which prevents the fingers from being back-driven during gripping, was less efficient than had been estimated. As a consequence, the prototypes operated at considerably reduced performance from that predicted by our calculations. By changing the motor and gear ratio, we were able to partially compensate for the inefficiency of the backlock and achieve a maximum grip force of 32 N (7.2 lb-force) with a 6-volt battery or 46 N (10.4 lb-force) with a 9-volt battery. The speed of finger movement is 33.3°/s with a 6-volt battery (49.3°/s with a 9-volt battery).

Although these values are less than we had specified, further increase in force and speed would require significant weight-adding changes to the design. Given that the measured prehension force is still at least twice what can generally be achieved with a body-powered split hook at the transhumeral amputation level, we believe (pending user evaluation) that it is more important to keep the weight reduced rather than increase the performance through a new, heavier design.

FUTURE PLANS—We are preparing for a field evaluation of the current design. The evaluation period will be 3 months. The next phase of the project will depend on the outcome of this first evaluation.

[7] CLINICAL COLLABORATION TO IMPROVE HIGHER-LEVEL UPPER-LIMB PROSTHETIC FITTINGS

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PURPOSE—Persons with higher level arm amputations (through or proximal to the elbow) and with bilateral arm amputations represent a relatively small proportion of persons with amputations. Consequently, there is not the opportunity for developing a broad empirical foundation to guide clinical practice. Without guidelines, based on documented success in restoring function, it is difficult, at best, for clinicians to develop fittings with any degree of confidence in the outcome.

Our goal is to promote and develop principles and guidelines for improved higher-level and bilateral upper-limb prosthetic fittings. Toward that goal, we are using

our research and development capabilities in direct collaboration with a clinical service program in prosthetics, the Prosthetic/Orthotic Clinical Services Department of the Rehabilitation Institute of Chicago (RIC). The RIC Amputee Program has a national and international reputation and, consequently, receives referrals of persons with high-level amputations from across the United States and abroad.

METHODOLOGY—Over the past 10 years, we have collaborated in the treatment of 36 persons with bilateral arm amputations. Of these, 23 had sustained high-level bilateral limb loss. To maximize manipulative capability and provide complementary function, we have developed prosthetic designs that incorporate multiple actively positioned components in a hybrid configuration (combining body-powered and electric-powered components). In general, the dominant prosthesis of this bilateral pair is configured with all mechanical, cable-actuated components while the nondominant side incorporates either all electric or hybrid componentry.

PROGRESS—During the past year, we have been assessing the outcomes of these fittings and now have a high degree of confidence in this approach. We are especially convinced of the utility of the all mechanical, cable-actuated four-function control system used on the dominant side at the transhumeral and shoulder disarticulation levels. In this configuration, a mechanical elbow, a wrist rotation unit, a wrist flexion unit, and a voluntary-opening split hook prehension device are arranged so that a single control cable can be used to position any one of the four components. The single control cable and associated harness provide close coupling of the user and the prosthesis. Body movements and forces are transferred directly to the prosthetic components and the response of the components (their position, velocity, acceleration, and forces acting on them) are perceived through the intact proprioception of the user. We believe, with the support of users' comments, that the extension of the user's physiological proprioception via the control cable reduces the mental effort required in positioning and using the prosthesis.

FUTURE PLANS—During the next year we will complete a manual for prosthetists describing the design and implementation of the four-function control system. In addition, we will continue our cooperative efforts to identify unresolved clinical problems.

[8] IMPROVING PROSTHETIC PREHENSION

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

Vector Prehensor: a voluntary opening prehensor with grip force that 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 cable excursion coupled with large grip force generation).

General Prehension Research: improvements to prehension applicable to any type of prehensor, including anthropomorphic fingers with nonlinearly compliant structure and variable hardness finger materials.

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

PROGRESS—A comprehensive laboratory testing program was undertaken to quantify the mechanical performance of typical prosthetic cable and housing systems. Four different cable materials and two different housing liners were tested over a range of bend angles and weights in order to deduce the determinants of prosthetic

efficiency. It was found that prosthetic cable/housing systems follow the classical Coulomb friction model and the efficiency is therefore a function of only coefficient of friction and angle of bend. This allows practitioners in the field to estimate mechanical efficiency for any body-powered prosthetic system with a simple calculation.

The Vector Prehensors reported earlier are functional prototypes that have performed well in limited testing on persons with upper-limb amputation. However, we have not been able to produce the elastic power bands that provide the adjustable grip force with long enough fatigue lives to be practical for commercial use.

Finite-element modeling of the elastic bands, using ABAQUS and Patran3, is underway to analyze the bands that are failing and to design suitable bands. Preliminary results are encouraging. New band geometries have been modeled that have significantly lower stresses at comparable levels of load and deflection compared to the experimental bands that have inadequate fatigue performance. Presumably, lower stress will result in improved fatigue life.

FUTURE PLANS—We are currently completing the modeling of a variety of candidate bands. Fabrication of test power bands is underway. When we receive them, we will subject them to static and fatigue testing to determine if their actual performance matches that predicted by finite element modeling.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[9] BODY-POWERED TODDLER HAND

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PURPOSE—The goal of this research is to develop an improved body-powered hand for toddlers 1 to 4 years of age. Primary goals are for an affordable hand of acceptable cosmesis to provide useful grasp for children in their play activities, while requiring minimal harness force and excursion.

METHODOLOGY—We shall explore several hand design strategies and methods of harnessing the child's energies, addressing the needs of the toddlers and the desires of their parents. Prototypes will be field-tested and evaluated for mechanical performance, reliability, and cosmetic acceptability. Designs will evolve based on this feedback.

PROGRESS—Beginning November 1995, staff have met with researchers and manufacturers having expertise in hand design and use, and also reviewed studies on new materials and children's prehensors.

Exploring Designs: Initially, a wide spectrum of approaches is under investigation. Models, sometimes as modifications of commercial units, have been built to embody various principles and features, including:

1. Prehensors able to grasp objects of 2.5 in (6.35 cm) span with under 1 in (2.5 cm) harness cable excursion.
2. Mechanisms utilizing diverse power sources from the child, e.g., the energy developed by the sound hand as it places objects into the prehensor. Some devices do not require a conventional harness and cable.
3. Development of hand geometries, activating mechanisms and compliant materials to provide "form closure grasp" wherein objects are restrained by secure capture rather than high pinch forces.
4. Harness and control modules utilizing bidirectional scapular rotation to provide dual power and command inputs to a prehensor while minimizing discomfort and restriction of motion. Efficiency of op-

eration and perhaps proprioceptive feel is enhanced by dual-aetion eontrol.
5. Abrasion-resistant "skins" and foams for eontoured, high-frietion grasp.
6. Preliminary investigation of praetieal hydraulie transmission and actuation componentry.

Focusing Design Goals and Evaluating Performance: Films of normal toddlers in a loeal presehool doeumented how they typically hold and use objects. Comparison to videos of ehildren with unilateral below-elbow prostheses elarified differenees in grasp patterns helpful in setting design goals. The observations, coupled with literature on child development and prosthesis performance tests, also helped in developing a list of objeets to use for testing prehensor function. Laboratory measures of gripper performanee have been developed to simulate real-world use and so help prediet the effect of design changes. The study protoeol ineorporates the objeets and grasp patterns identified in the videotapes, and provides a standardized proeedure for measuring forces required to remove or dislodge objects from prehensors. As the design proeess continues, tradeoffs between form, funetion, and complexity are manifested in different ways. Ultimately, it is the parents who will evaluate these tradeoffs. To investigate whieh balanee points are desirable between eosmesis and grip funetion, parents will participate in a hands-on survey involving "test drives" of various grippers. This study is in cooperation with the Child Amputee Prostheties Program at Shriners Hospital in Los Angeles.

PRELIMINARY RESULTS—Observation of toddlers suggests the need for foeus on aehieving stable spherical and eylindrical grasp patterns, with some fine-tip prehension. Grasping tests eonfirm the effeetiveness of various combinations of grasp geometries, foams, and skins. Modifieations of a CAPP II gripper for bidireetional eontrol reduees input cable exeursion requirement by 50 pereent while doubling the foree output. A eable-free deviee provides easy objeet insertion for grasp, while a hand equipped with nonbinding elutch mechanism provides seeure capture.

FUTURE PLANS—Continued field testing and design iteration are needed to both refine and investigate new strategies. A test will be developed to evaluate the grasp characteristics of different combinations of foam and skin. Further collaboration with industrial partners will be sought.

[10] DEVELOPMENT OF A MULTIFUNCTION MYOELECTRIC CONTROL SYSTEM

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PURPOSE—The purpose of this projeet is to develop a myoelectrie control system that is easy to operate yet provides eontrol of many independent prosthetie limb functions.

Myoelectric prostheses are well aeeepted by persons with transradial amputations but less aecepted by those with higher level ones. The primary limitation at present lies in the eontrol system. Although these systems have been sueeessful for single deviee eontrol (hand or elbow), the extension to the eontrol of more than one deviee (either simultaneously or sequentially) has been difficult. It is the eontrol systems that now limits the performance and, at times, the aeeeptanee of the prosthetic fitting. For the person with transhumeral or higher amputation and espeeially for those with bilateral amputations, the need for improved control systems for multifunction prostheses is eritieal.

METHODOLOGY—The projeet was divided into two stages. The first, undertaken primarily during the initial 24 months of the projeet, determined the specifies of a new control strategy based on the recognition of patterns in the myoeleetric signal. This work involved eomputer simulations of eontrol schemes, using various waveform features to determine whieh provided the most information to the artificial neural network classifier. The results indicated that a eontrol scheme that used information

from two myoelectric channels provided a richer feature set and improved system performance at the expense of increased system complexity over the original single channel system. As well, the additional myoelectric channel gives the system the ability to operate as a degree-of-freedom (DOF) controller as opposed to the more restrictive state controller of the original design.

PROGRESS—The control scheme developed during this phase of the project uses information collected from the patient to train a pattern classifier in the control system to recognize his or her specific contraction patterns. The classifier uses features extracted from the first 200 ms of myoelectric activity following the initiation of a contraction to determine intent, then matches this feature set with the features sets obtained during the initial system calibration. The closest match is used to select which device (hand/elbow/wrist) is to be controlled. Control of this device continues until the signal level returns to a predetermined low level.

Pattern classifiers based on alternate neural network structures were also investigated to determine the feasibility of implementing a classifier based on continuous data. In particular, a dynamic feed forward network which incorporates memory in the form of an FIR filter structure for each network weight has been shown to be appropriate for these transient myoelectric signals.

Work is continuing with the goal of finding alternate feature representations and neural network structures that give continuous recognition of the raw myoelectric signal. The advantage of such a scheme is that system delay is reduced compared to the present scheme which uses features from time-averaged data.

During the second or current stage of the project, a microprocessor-based multifunction control system has been designed that incorporates results from this project as well as the latest advances in electronic hardware. The current prototype is the result of several design iterations which have reduced the size and power consumption of the control system. The current device uses surface mount technology on multilayer circuit boards to achieve an approximate size of 1.5×2.5×0.5 in (3.80×6.35×1.27 cm) and can be built into the prosthetic arm. The device operates on standard 6 volt NiCad batteries, drawing approximately 40 mA.

FUTURE PLANS—Clinical trials with this control system have begun at our fitting center in Fredericton. Arrangements have also been made with Hugh Steeper Ltd. (UK) to do test fittings on several of their current clients in their Rochampton and Birmingham clinics. This activity will be the focus for the remainder of the grant.

The results of this research will provide valuable guidance to designers of pattern-based myoelectric control systems and to the clinical staff who fit these systems. The new control system will yield a prosthetic limb that is more functional and easier to control.

B. Upper Limb: Transhumeral

[11] 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 transhumeral amputation 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 transhumeral 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 provides a safety "breakaway," allowing the forearm to rotate if external forces, such as from falling on the prosthesis, are greater than 8.1 N-m (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—Our tests of the first prototype have produced conflicting results related to the action of the locking motor when the drive motors are positioning the rotator. During positioning, the locking motor is powered so that the worm and worm gear are able to turn and free the drive mechanism. The voltage to the locking motor is adjusted so that it is neither turning too fast, leading the drive motors and pushing the rotator mechanism, nor turning too slowly, lagging the drive motors and retarding the rotation. The parameters for this adjustment have been different under different test conditions. We are reexamining our test procedures to determine the source of the difference. Possible causes include variance in motor parameters or mechanical inefficiencies that may have developed over the course of testing.

FUTURE PLANS—Once the conflict in the prototype's performance has been resolved, we will design and build a second, lighter prototype for field evaluation.

[12] MECHANICAL HUMERAL ROTATOR LOCKING MECHANISM

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PURPOSE—The purpose of this project is to develop a mechanical humeral rotator locking mechanism for persons with transhumeral amputations. The device will allow the user to rotate the forearm section freely about the humeral axis when it is unlocked. This positioning is currently provided by a friction turntable that resists rotation with a preset constant friction. The unit can be locked in any position.

METHODOLOGY—The design goals for this project were determined by studying other types of humeral rotators and considering the needs and abilities of persons with bilateral transhumeral amputation. It was decided that the device should have an infinite number of locking positions and to hold against a minimum torque of 72 lbf-in, which is twice the recommended friction setting for a standard turntable. A two-position actuator was chosen over a momentary actuator because it would be easier for the user to operate. Cable travel of less than 0.5 inches with an actuating force of less than 7.2 lbf was a goal based on the capabilities of Northwestern University's Modular Electromechanical Lock Actuator. By meeting this goal, the device could be actuated by the electromechanical actuator or any manual method.

Various designs were evaluated with respect to these mechanical specifications and user needs. A multiple disk brake design was selected as the prototype locking mech-

anism. It was judged to resist the target torque with low actuating force, with a low height profile. This kind of design would be fairly easy to fabricate using standard machining methods. A ratcheted face cam was selected as the actuator. This design was easily fabricated and had a low profile.

PROGRESS—Several different disk materials have been tested. A prototype of the humeral rotator has been fabricated that meets the actuating force and cable excursion goals.

RESULTS—The prototype is capable of locking against a torque of approximately 78 lbf-in with an actuating force of 6.8 lbf at an excursion of 0.43 in.

FUTURE PLANS—An adapter plate will be made to allow this device to be mounted to the Hosmer E400 body-powered elbow. The device will be tested by an amputee user.

B. Upper Limb: Transradial

[13] VOLUNTARY CLOSING HAND PROSTHESIS

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PURPOSE—The objective of this project is the design of a useful body-powered hand prosthesis. This implies that not only motoric function will be regarded, but cosmesis, wearing comfort, and ease of operation as well. The project focuses on a device for persons with unilateral transradial amputation.

METHODOLOGY—In voluntary closing devices, operating force corresponds to pinching. To make full use of the feedback potential of this working principle, the operating mechanisms should transfer the actual pinching force to the operating member as purely as possible. Therefore, friction should be absent, and the counteraction by the cosmetic covering should be compensated for. Among the practical problems to overcome, the opened resting position, which is generally not acceptable for cosmetic as well as practical reasons, seems to be the most important one.

PROGRESS—This research is divided into several projects.

1. *Assessment of glove characteristics.* This project has resulted in general recommendations for the design of prostheses incorporating cosmetic coverings.
2. *Compensation of glove forces.* The elastic component of the glove counteraction may be statically balanced by a compensatory spring mechanism. A project was started to systematically investigate the possibilities of designing purely mechanical devices to eliminate the glove's influence on prosthesis operation.
3. *Reduction of friction.* An alternative solution for slide bearings (high friction) and ball bearings (low resistance to water and sand) is being investigated. Rolling link mechanisms (RLMs) are created by having members directly roll on one another, thus eliminating sliding friction.
4. *Optimal feedback.* Psychophysical measurements are conducted to assess the sensitivity function of the upper arm, where the operating force in elbow control is applied. Normal pincing forces should be obtained with operating forces in the highest sensitivity range, yet not be uncomfortably high.

5. *Operating pattern.* A control scheme is thought of which combines the voluntary closing principle and the wish for a closed resting position of the hand. Currently a prototype is under development which is to be evaluated in close collaboration with Dutch rehabilitation teams.

PRELIMINARY RESULTS—The general rules of fist in glove characteristics prove to be of much practical value. Counteraction is considerably reduced, which facilitates the compensation of glove forces. A theory on the realization of exact solutions for simplified situations has been formulated and approximation methods for practical circumstances are under development. Several prototypes of prosthesis mechanisms incorporating RLMs with significantly improved efficiency have been made.

Normal operating forces seem to be in the range of high upper arm sensitivity. The mechanical advantage of the prosthesis operating mechanism is therefore chosen to be unity as a starting point.

[14] 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 service team. The feedback from the clinicians and user 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 person with high level amputation. In response to this, we designed and built three prototypes of this configuration to prove the arrangement. This spin-off product is now available from VASI.

[15] VASI 2-6 PROSTHETIC HAND ENHANCEMENTS: COSMETICS AND FUNCTION

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PURPOSE—The aim of this project is to improve the cosmetic appearance and function of the VASI 2-6 hand (for children 2 to 6 years of age) by acting on the following three recommendations: a) reduce the bulk in the palm area, b) make the ring finger and baby finger of the glove move with the other fingers when the hand closes, and c) incorporate pliable tips to the fingers and thumb.

PROGRESS—In response to these recommendations, we have made and are making the appropriate modifications. With the introduction of a smaller electronics package, we were able to redesign the hand cover and made it thinner in the palm area, hence more cosmetically appealing. The fingers and thumb were redesigned to improve the shape and orientation of the thumb. A wire type ring finger and baby finger were designed to couple to the middle finger. Movement of the smaller fingers are now driven by the middle finger. These changes were prototyped and evaluated by clinical team members. Concepts incorporating pliable material into the inferior surface of the fingers has begun.

FUTURE PLANS—It was decided that, prior to production, we fabricate four hand units with the above changes. This way we could have the new arrangement evaluated by VASI's representatives in North America and Europe prior to committing to production tooling. To help us in this effort, we contracted the Industrial Research and Development Institute (IRDI) to recommend more cost effective tooling technologies for the VASI 2-6 hand.

C. Lower Limb: General

[16] 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—Prosthetics Research Study (PRS) is completing an integrated program of eight research and development projects which address the continuum of care of the amputee from prevention of amputation to objective measurement of functional outcomes.

PROGRESS—The status of the eight programs is as follows:

AFMA Technology Transfer Training Development PRS developed the Automated Fabrication of Mobility Aids (AFMA) training program to facilitate transfer of the AFMA CAD/CAM technology to VA clinical service. In all, 46 VA prosthetists from 36 sites have incorporated AFMA into their routine patient care, resulting in significant annual cost savings to the Prosthetic and Sensory Aids Service. Over 1,847 AFMA

prostheses have been made for Veterans by the trainees of this program.

AFMA Lower Extremity Alignment A method of computer-aided alignment of the lower extremity prosthesis has been created. ANSI C software has been completed that imports VA/Seattle ShapeMaker CAD/CAM socket files for interactive graphical and numeric manipulation of a simulated alignment fixture distal to the socket. Alignment measurements are made relative to the surface position of the two-point landmark of the long bone being contained in the socket (femur or tibia). This alignment can be modified in adduction or abduction angle, flexion/extension angle as well as translation in the A-P or M-L planes. The methods have been transferred to ShapeMaker software version 4.0.

AFMA Lower Extremity Cosmesis This project is ongoing and is expected to be completed by October 1996. Software has been written to facilitate carving of foam formed directly over the endoskeletal components rather than the mandrel, in order to minimize distortion of the contralateral shape. The AFMA cosmesis process also lends itself to the central fabrication methods used in the VA prosthetics clinics.

Prosthetic Alignment and Gait Evaluation Simulator To improve the teaching and understanding of gait and prosthetic alignment of persons with amputation, we have completed the multimedia CD-ROM "Visual Interactive Prosthetics" gait simulator. The user can adjust alignment of a prosthesis on the computer screen and instantly see pre-recorded video of the patient walking with the specified alignment change. PRS has provided the CD-ROM to approximately 30 universities and 30 medical clinics on six continents. The American Board for Certification in Prosthetics awards users of this program four continuing education credits.

Custom Insoles For Diabetics Veterans with diabetes mellitus with peripheral neuropathy are at increased risk for foot ulcers and amputations. Improper footwear precipitates many diabetic foot ulcers. A 6-month crossover trial of 24 diabetic male veterans has been completed. There were no breaks in the cutaneous barrier of the foot with use of either computerized cork insoles or a specially designed polyurethane insole combined with the study shoe designed by PRS and NIKE. A proposed 3-year clinical trial has been approved by VA merit review.

Amputee Management and Post-Amputation Protocols We have completed a new edition of the PRS VA Amputee Management Text which was last printed in 1969. This document has been published in HTML format on the World Wide Web at http://weber.u.washington.edu/~prs. A CD-ROM of the PRS amputation and rehabilitation protocols is scheduled to be completed in September 1996. In addition, during the past year we have completed three book chapters on this topic.

Prosthetic Evaluation The Prosthesis Force Transducer (PFT) has been developed at PRS for the remote monitoring of the axial force and A/P and M/L moments during the ambulation of persons with amputation. In its current design, the transducer is 3.25 in square by 0.78 in thick, weighs 13 ounces, and mounts to the standard 2 in bolt circle used by most endoskeletal prostheses. Electronics which fit into a small "fanny pack" amplify the output from each load cell, convert it to a digital signal, and transmit it to a remote computer via wireless modem, allowing the subject to be untethered and to perform any activity within transmission range (~500 ft) of the laptop computer. Output can be displayed in real time and saved to disk for further analysis. By allowing the researcher to examine forces and moments over many steps and to examine conditions other than level walking, the PFT will provide invaluable data about the real world use of prosthetic components and real axial loads and bending moments. The next generation design is expected to be lighter, smaller, and able to provide higher data sampling rates (currently 380 Hz for four channels).

Measurement of Functional Outcomes The goal of the Prosthetic Evaluation Questionnaire (PEQ) is to complete the development of a validated, easy to administer, questionnaire for comparing groups of prosthetic patients. After two pilot surveys using the questionnaire, we finalized the item pool and prototype questions, which use a linear analog scale format. We then recruited 114 persons who use a lower limb prosthesis; 92 of these subjects returned the baseline questionnaires, and all are being used to test correlation of questions within scales. Of the 92, 81 then completed a re-test between 2 and 6 weeks following the baseline test. Twenty-one of these 81 subjects had a major event that altered their prosthesis, residual limb, or health between the two test dates. The remaining 60 subjects are being used to check the temporal stability of the questions and scales. The analysis of correlation and temporal reliability is currently being completed.

This year we used the PRS Gait Activity Monitor to investigate the levels and patterns of gait activity of 62 subjects with mobility impairment: 45 diabetics with peripheral neuropathy and 17 patients with dysvascular amputation. Each patient wore the monitor for 2 consecutive weeks, and kept an activity log for a portion of that time for the purposes of validation. Before and after each monitoring period, an accuracy trial involving indoor and

outdoor walking as well as stair climbing and descent was performed to verify the performance of the monitor. In addition, the monitor itself was tested to verify the calibration. Data collection has been completed. Data analysis is in progress. The device has proven robust and highly accurate (99.69 percent), and patients reported no discomfort or difficulty with wearing the monitor.

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[17] PROSTHETIC FITTING SYSTEMS RESEARCH PROJECT: PHASE 2

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Sponsor: *National Institutes of Health/National Institute of Child Health and Human Development (NICHD), National Center for Medical Rehabilitation Research (NCMRR), Bethesda, MD 20892*

PURPOSE—We seek to provide validated clinical instruments to the Orthotocs and Prosthetics profession and industry which provide quantifiable parameters for objective assessment of prosthesis fit, and capable of providing quantifiable measures necessary to achieve the "ideal" socket shape. There is a significant need, given a certain residual limb, for better means of predicting the quality of fit, specifying the optimal socket shape, and objectively evaluating the quality of fit *in situ*. An image-based method to evaluate *in situ* lower limb prostheses, focused on the socket/residuum interface and interrelationship to underlying supporting skeleton, can aid socket design, serve as a quality control method, and improve the assessment of residual limb function.

Geometric effects of poor fit and interface limitations are amenable to evaluation with spiral CT methods. This project employs nonlinear computational mechanics theory and p-version finite element analysis to conduct a thorough and systematic investigation of factors that govern the quality of fit. Experiments are performed to examine and predict the relationships among socket shape, static limb remnant geometry, and soft tissue envelope composition on responses to, as well as judgments of, lower limb prosthesis fit quality. Knowledge gained from these studies will contribute to understanding how the interaction of socket geometry and the residual limb influence the prosthesis function. The process by which prosthetists might improve results will be explained. The overall goal of our prosthetics research is to provide comprehensive 3-D static evaluation of lower limb prosthesis fit and residuum characteristics.

METHODOLOGY—An axial loading device was designed and built which allowed axial loading of the *in situ* prostheses during SXCT scanning to assess tissue shape change under static loading conditions.

For comparison of tissue deformation between a well- and poorly fitting prosthesis the two CT scans must

be oriented within a common reference frame. Segmentation of the bony structure facilitates the registration process. The bone surface was extracted from both volumes and used to estimate the transformation matrix, which is used along with volumetric resampling to transform a target data set into the same coordinate space as the source data set (Analyze™ software).

Cylindrical maps are used to represent residuum trunk morphology, while the distal end is represented in polar coordinates. These maps display surface data, soft tissue thickness over bone, displacements between residuum scanned in air and with prosthesis *in situ*, and measurement of reference markers.

Boolean operations allow isolation and quantification of positive and negative change (local and global) in residuum morphology relative to a baseline scan. Errors due to registration and resampling have been shown to be small compared to volume shape differences.

Surface (optical) and volumetric (CT) data of transtibial (TT) residua were used to generate solid models and specify socket shape in SDRC I-DEAS™ CAD software. Contour extraction methods were developed, rational and nonrational B-spline representations used for solid modeling.

We studied state-of-the-art imaging systems, solid modeling, and other software tools to determine the associated errors in mass property estimation by spiral CT, 3-D MR, and optical surface scanning using phantoms and cadaver parts.

PEGASYS™ p-version finite element analysis software was used to create 2-D finite element models of the TT residuum. Models were created of bone, skin and socket from contour information extracted from SXCT volumetric data using Analyze software. A 3-D model has recently been created. The 2-D model has been validated by comparison of FEA displacements to measured displacements from CT data obtained with the prosthesis in situ under known static load. The 3-D model is currently undergoing refinements and validation.

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Mapping of residual limb changes by spiral/helical computed tomography. Vannier MW, Commean PK, Smith KE. In: Proceedings of Computer Assisted Radiology (CAR); 1996, Paris, France. In Press.

C. Lower Limb: Transfemoral

[18] DEVELOPMENT OF A BIOMECHANICAL MODEL OF THE INTERFACE BETWEEN THE STUMP AND THE PROSTHESIS FOR TRANSFEMORAL AMPUTEES

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Sponsor: *Engineering Physics Science Research Council (EPSRC)*

PURPOSE—This investigation is directed toward the generation of a Finite Element (FE) model of the residual limb of a person with transfemoral amputation (TFA). The model is capable of predicting the pressure distribu-

tion at the patient/prosthesis interface. This would lead to a better understanding of the biomechanics at the residual limb/socket interface.

METHODOLOGY—Prior to the creation of an accurate FE model, the mechanical properties of the tissues, geometrical details of the stump, and the loading and constraints the amputee undergoes during standing and during gait have to be determined. To validate the FE models created, stump/socket interface pressures were measured and compared with those predicted. In addition, the study also attempts to obtain a better understanding of the biomechanical characteristics at the stump/socket interface using interface pressure measurement and magnetic resonance imaging (MRI) techniques. The ongoing controversy regarding the quadrilateral (quad) and the ischial containment (IC) sockets also provided a suitable case study for the project.

PROGRESS—Two- and three-dimensional (2-D, 3-D) FE models of the TFA residual limb were attempted. Residual limb/socket interface pressure was measured for four TFA patients prescribed with both quad and IC sockets. Geometrical details of the lower limbs of five of five TFA patients were acquired using magnetic resonance imaging (MRI) techniques. Three sets of scans were taken for each subject in a supine position for the following situations: a) wearing a plaster cast which maintained the residual limb in a natural or undeformed state, b) wearing a quadrilateral socket, and c) wearing an ischial containment socket.

RESULTS—The 3-D FE models were able to predict interface pressures during various phases of the gait cycle and during standing. The predicted stress distribution pattern matches that of the measured pressure. The 2-D model, which included geometry of the musculature obtained from MRI, was able to show significant movement in the musculature due to prosthetic socket loading. High stresses were also predicted at regions where muscles are attached to bone.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Stump/socket interface pressure as an aid to socket design in prostheses for trans-femoral amputees: a preliminary study. VSP Lee, WD Spence, SE Solomonidis. Proc Instn Mech Engrs, Part H. In press.

[19] INVESTIGATION OF 4-BAR LINKAGE KNEES AS AN AID TO FLOOR CLEARANCE DURING PROSTHETIC SWING

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PURPOSE—The advantages of 4-bar linkage knees include stance-phase stability during gait and cosmesis for the person with a long transfemoral amputation. However, another distinct advantage is that the 4-bar knee is able to provide greater floor clearance during the swing phase of walking than a single axis knee. Four-bar knees may be especially beneficial for persons with transfemoral and hip-disarticulation amputations who have trouble with floor clearance during gait. We investigated the ability of commercially available 4-bar linkage knees to provide swing-phase foot clearance, and compared the results with a single-axis knee in order to demonstrate the distinct advantage these mechanisms provide.

METHODOLOGY—We investigated 4-bar linkage knees by simulating knee kinematics with a computer. Knees included in our study were subject to the following criteria: they had to have been adult endoskeletal units,

commercially available during 1994-95, and to have rigid-linkages throughout knee flexion range.

The following knee units were evaluated in the course of our research: Hosmer VC4, Hosmer Ultra-RoeLite, Ohio Willow Wood Pendulum Senior, Otto Bock 3R23, 3R36, 3R60, and 3R70, and the USMC OHC.

We developed a computer model of a transtibial prosthesis into which the representation of a particular 4-bar knee could be inserted for evaluation. Leg parameters, such as the hip-toe distance and floor clearance, were calculated as the hip and knee joints were rotated systematically through their full ranges of motion. These results were compared with those obtained from a computer simulation of the prosthesis model incorporating a single-axis knee.

RESULTS—A plot of the simulated hip-toe distances versus the knee flexion angle for all of the knees clearly demonstrated the ability of the 4-bar linkage knees to shorten the prosthesis to a greater extent than the single-axis knee. We found that 4-bar knees have an apparent ankle dorsiflexion that allows them to effectively lift the toe of the prosthesis during swing to increase toe clearance. Contour plots were created to show the first 5 cm of toe clearance as a function of the hip and knee flexion angles for all of the knees analyzed. Some of the knees provided as much toe clearance at 30° as the single-axis knee had at 50°. The 4-bar knees increased floor clearance by 0.9–3.2 cm beyond that of the single-axis knee at a knee flexion angle of 49° and a hip flexion angle of 23°, which are the approximate swing leg joint angles at the time of minimum toe clearance.

FUTURE PLANS—We plan to measure the swing-phase hip and knee joint angles on the prosthetic side of above-knee amputees walking with different commercially available 4-bar knees. Curves of hip angle versus knee angle can be corrected for hip elevation, then overlaid onto the appropriate knee contour plot to show the amount of prosthetic toe clearance throughout swing. We may also use our computer model to determine what effect different prosthetic alignments have on the hip-toe distance and toe clearance for the 4-bar and single-axis knees.

RECENT PUBLICATIONS FROM THIS RESEARCH

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An investigation of 4-bar linkage knees as an aid to floor clearance during swing. Childress DS, Gard SA, Uellendahl JE. In: Proceedings of the 8th World Congress of the International Society for Prosthetics and Orthotics (ISPO); 1995, Melbourne, Australia.

The influence of four-bar linkage knees on prosthetic swing-phase floor clearance. Gard SA, Childress DS, Uellendahl JE. JPO: J Prosthet Orthot 1996:8(2):34–40.

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

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Sponsor: *Variety Ability Systems Inc.; The National Research Council; Ontario Rehabilitation Technology Consortium funded by the Ontario Ministry of Health*

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 a transfemoral amputation.

PROGRESS—Since the inception of this project, progress has been made through: 1) development of a three-dimensional computer simulation of nondisabled and prosthetic gait; 2) design and manufacture of a prototype multicomponent above-knee prosthesis to be used in running and other intense physical activities, and 3) current field testing of the prototype prosthesis on clients of the Centre. Computerized simulation of walking and running gait was completed during an engineering master's thesis; the simulation was carried out on Dynamic Analysis and Design of Systems (DADS) mechanical engineering software using a 3-D forward dynamic method integrating acquired nondisabled gait data

with a biomechanical model of the lower body. These results demonstrated sufficient promise to embark on development of a prototype. Following successful simulation of nondisabled movement, the biomechanical model was modified to approximate transfemoral prosthetic gait. Simulation of the prototype prosthetic gait demonstrated an improvement in the body's centre-of-mass trajectory and control of knee flexion during the swing and stance phases. As a result of this and other analytical work, various components were specified such as a polycentric knee linkage (stability), knee damping (stability/velocity control), and a shank-shock absorber (support control).

Thus far, development has been steady. Manufacture of prototype was completed in the Bloorview MacMillan Centre Machine Shop, 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, cyclic testing of the device was carried out to meet International Standards Organisation test standards for lower-limb prosthetics. An electro-pneumatic testing device was developed to fatigue the knee unit over 6 million cycles to ensure design integrity. The knee was successful in exceeding these testing standards. Presently client testing of the device has been undertaken.

FUTURE PLANS—A suitable client of BMC's Prosthetics Department will test the knee unit for a 6-week period. The client will undergo quantitative gait analyses in BMC's Human Movement Laboratory, and metabolic (oxygen consumption) tests at Variety Village Recreation Centre to objectively determine whether his/her pattern of walking has changed and is more efficient from that with his/her conventional prosthesis. 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 clients in centres across the province. The conclusion of the research and development phase of this project will be proceeded by commercial manufacture and distribution of the product.

C. Lower Limb: Transtibial

[21] PROSTHETIC DESIGN FOR THE PATIENT WITH DYSVASCULAR BELOW-KNEE AMPUTATION

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PURPOSE—It has been assumed that with the advent of the dynamic elastic response feet to enhance push off, significant energy cost would be saved by those with transtibial amputations. However, this has not occurred. Major inefficiencies at both the hip and knee during the loading phase of walking continue to be found. The problem seems to be related to the mechanics of the prosthetic hind-foot. Current designs cause knee instability, requiring postural and muscular stabilization at the knee and hip, a demand that the already weak dysvascular patient has difficulty meeting. The purpose of this research was to quantitatively define by comprehensive gait analysis muscle activity and motion patterns of those wearing three prosthetic feet.

METHODOLOGY—Ten persons with dysvascular transtibial amputation were tested on separate occasions wearing three prosthetic feet: single-axis foot (SA), Seattle Litefoot (SL), and Flex Foot (FF). Comparisons were made with 10 nonimpaired controls. Dynamic electromyography (EMG) recorded the timing and intensity of the vastus lateralis, biceps femoris long head, semi-

membranosus, and lower gluteus maximus. To permit comparison of EMG intensity between subjects and muscles, all EMG data were normalized to a maximal isometric effort. Mean onset and cessation times were calculated and stretched or shrunk to 62 percent of the gait cycle (GC). All EMG onsets and cessations were reported as a percentage of the gait cycle. Dunnett's test was used to compare the control group with amputee performance. Repeated measures ANOVA determined the significant of differences between each foot type.

RESULTS—Although no significant difference in EMG intensity or onset timing was found between the three prosthetic feet or versus nonimpaired, a pattern of prolonged muscle activation was noted. Consistently, when wearing the SA foot, EMG cessation times were later than normal. This was most evident for the vastus lateralis, with those wearing the SA foot demonstrating quadriceps action until 40 percent GC (NC=21%GC, $p<0.01$). Similarly, the SL foot also had prolonged knee extensor action until 34 percent GC ($p<0.05$), while the FF was a more normal 26 percent GC. Quadriceps action when wearing the SA foot was significantly later in its cessation time from the other prosthetic foot designs ($p<0.05$).

Increased muscular activity also was evident in the hip extensors. Biceps femoris long head activity was prolonged for all three prosthetic foot designs when compared to normal (NC=13.6%GC, SA=42%GC, SL=41%GC, FF=41%GC, $p<0.01$). Similarly, the semimembranosus also was prolonged for both the SL and FF (SL=42%GC, FF=49%GC) when compared to nonimpaired (24%GC, $p<0.05$). Semimembranosus cessation for the SA occurred at 36 percent GC. Finally, lower gluteus maximus was significantly long in its action for the SA (33%GC, $p<0.01$) and FF (29%GC, $p<0.05$) when compared to nonimpaired (12%GC). The SL (26%GC) did not differ statistically from nonimpaired.

Two distinct patterns of motion were evident in the prosthetic ankle during loading response. The SA foot demonstrated the largest amount of plantar flexion, 8.9°, due to its mobile ankle design. Both the SL and FF, had much less plantar flexion ability during loading (SL=1.9° and FF=4.2°). This difference was not statistically significant. Peak plantar flexion occurred later than normal for the SL and FF.

Likewise, peak knee flexion during loading was diminished from normal for all prosthetic feet. Due to large amounts of variability, however, this was not significantly different. The timing of peak knee flexion was significantly later for the SA (23%GC, $p<0.01$) and SL (22%GC, $p<0.01$) from nonimpaired (13%GC). Loading response knee flexion normally results from the heel rocker. Disruption and prolongation of this shock absorbing mechanism is one likely contributor to prolonged vastii action. As heel rocker mechanics were inadequate, (occurring fast and uncontrolled for the SA foot, and late in both the SL and FF designs), the vastii must work harder despite the reduced knee flexion range to control tibial advancement.

While hip motion did not differ from normal there were marked amounts of anterior pelvic tilt throughout the gait cycle. In an effort to reduce the demands on the knee extensors and augment progression each amputee group demonstrated significantly greater forward trunk leans during loading (NC=0.91, SA=3.72, SL=3.75, FF=3.70°; $p<0.01$). By maintaining center of mass forward longer, (22%GC amputation, 10%CG nonimpaired; $p<0.05$), individuals with transtibial amputation decreased the demands on the quadriceps. This is a characteristic compromise used to protect weak quadriceps while maintaining advancement over the prosthetic foot.

FUTURE PLANS—Data analysis continues, focusing on integrating findings to improve prosthetic foot and ankle design criteria. Prosthetic foot designers will be encouraged to participate in the development of less demanding feet.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Prosthetic ankle joint stiffness during weight acceptance in trans-tibial amputees. Rao S, Bontrager E, Boyd L, Powers C, Gronley J, Perry J. Gait Posture 1996:4:187.

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

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

PURPOSE—This work intends to continue refinements in the application of the finite element analysis (FEA) technique to the design of transtibial 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 which do not rely on CT imaging.

METHODOLOGY—Our latest analyses of sockets has consisted of applying the contact algorithm to a physical model of the limb-socket system. A three-dimensional model of a generic, approximate residual limb was created and analyzed, using internal geometry generated from digitization of an anatomically accurate model of the joint capsule of a transtibial residual limb. These geometries were then mapped onto a pre-existing finite element mesh of a hollow capped end cylinder, resulting in a layer of elements whose outer surface is described by the tapered ellipse, and an inner surface described by the 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 geometry was then used to define a rigid nonuniform, rational, B-spline surface (NURBS) to be used in our model as an analytical description of the socket surface. This surface was then slowly moved onto the limb to simulate socket donning.

Using the same data as the FE model, we generated a physical model consisting of a polyester resin replication of the joint capsule geometry encased within silicone gel in the shape of a tapered ellipse, in order to simulate the soft tissues of the residual limb. The rectified socket geometry created in ShapeMaker was used to carve a positive mold for socket manufacture over which a polypropylene socket was vacuum-formed. Kulite pressure transducers were then mounted in the wall of the rectified socket at six locations for interface pressure measurement.

PROGRESS—An approximation made previously in our FE modeling was that the limb-socket interface was fixed, where no slippage or loss of contact may occur. We have begun work to more accurately model this interface using a contact analysis (CA) algorithm. We have completed an initial analysis of socket donning using CA and compared the results with both our previous method of modeling and measured data.

RESULTS—At all six transducer locations where stresses were measured on the physical model, CA results predicted slightly lower stresses than those measured, while the traditional FE models (applied radial displacements) predicted much higher stresses. Additionally, comparison of FEA generated plots of pressure versus time at each of the transducer locations are very similar to experimentally measured pressure/time plots, showing that contact analysis is capable of simulating the dynamic interface conditions arising during gait. A digital animation demonstrating this capability is displayed on our Web page (http://www.repoc.nwu.edu/).

FUTURE PLANS—The next step in our work is to integrate FE modeling with gait analysis techniques to create an improved methodology for socket design. We intend to use our contact methods to analyze the residual socket/limb system under simulated gait loads to investigate the effect of socket shape changes on overall socket fit. Our modeling procedure will enable us to quantify motions of the socket relative to the limb during gait, as a measure of socket stability, as well as quantifying tissue stresses as a measure of adequate support. Clinical assessment of sockets designed with varying quantitative parameter values will determine what are acceptable ranges for these parameter values. Finally, an optimization scheme will be developed to create socket shapes with optimal stability and support characteristics.

RECENT PUBLICATIONS FROM THIS RESEARCH

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A review of prosthetic interface stress investigations. Silver-Thorne MB, Steege JW, Childress DS. J Rehabil Res Dev 1996:33(3):253–66.

[23] SOFT TISSUE BEHAVIOR AND SENSATION OF LOWER EXTREMITY RESIDUAL LIMBS: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #A93-673PA); National Science Foundation, Bioengineering and Aiding the Disabled Program, Arlington, VA 22230*

PURPOSE—The goal of this study was to increase our understanding of the soft tissues of the residual limb in individuals with transtibial amputation. Such knowledge will augment prosthetic socket design and the evaluation of prosthetic fit. Two specific aims of the project were: to describe the sensory changes in the person with transtibial amputation because any loss of sensation may have significant impact in the successful use of a prosthesis, and to quantify the response of the residual limb bulk soft tissues to load.

METHODOLOGY—Sensory modalities of light touch, deep pressure, vibration, and superficial pain (pin prick) were examined on the residual and contralateral limbs of 16 veterans with transtibial amputation. In addition, *in vivo* rate-controlled (2, 5 and 8 mm/s) indentor tests were conducted on the residual limb tissues of 4 individuals who exhibited intact sensation of the residual and contralateral limbs using an indentor designed specifically for this project. Stress relaxation tests were also conducted. For these trials, indentation at 2 mm/s was applied until the desired displacement was achieved; the corresponding reaction force was monitored for 300 s.

PROGRESS—Six of the 16 subjects demonstrated normal sensation of the contralateral limb and impaired sensation of superficial pain, vibration, and/or light touch of the residual limb. Superficial pain was the most frequently impaired sensation, and vibration and superficial pain sensation appeared to be age dependent, with increased impairment observed in the elderly subjects. Deep pressure sensation was intact in all subjects. These preliminary data suggest that although neither the amputation nor the prosthetic rehabilitation resulted in impaired deep pressure sensation, these factors contributed to minimal impairment of light touch and vibration, and significant impairment of the superficial pain sensation.

RESULTS—The *in vivo* indentation tests indicated that the bulk soft tissue response to compressive load is nonlinear, and for the indentation rates tested, nearly independent of the loading rate. Significant inter- and intra-subject stiffness variations were observed. The stress relaxation studies indicated that approximately 80 percent relaxation may occur; the relaxation time constants generally ranged from 150 to 300 s.

FUTURE PLANS—Nonlinear numerical models (finite element analyses) simulating the tissue indentation trials are underway to develop constitutive equations for human bulk soft tissue. Additional subject trials are also being conducted.

RECENT PUBLICATIONS FROM THIS RESEARCH

Design of a rate-controlled indentor for in vivo analysis of residual limb tissues. Pathak A, Silver-Thorn MB. IEEE Trans Rehabil Eng. In press.

[24] PROSTHETIC FITTING SYSTEMS RESEARCH PROJECT: PHASE 1

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PURPOSE—Computer Aided Design/Computer Aided Manufacturing (CAD/CAM) methods are increasingly used in the design and manufacture of prosthetic componentry including the socket itself. These methods offer potential for objective assessment of prosthesis fit quality. The measurements which drive the CAD/CAM process may come from a variety of sources. Before these measurements can be reliably used in the design/manufacturing process they must first be subject to scientific and statistical evaluation and compared to a previously accepted form of measurement or "gold standard." The overall goal of this research project was to establish the precision and repeatability of new 3-D imaging devices for accurate assessment of lower limb residua. We tested the ability of an optical surface scanner (OSS), a clinical spiral x-ray CT scanner (SXCT), and an electromagnetic point digitizer to repeatably and precisely measure residua in transtibial volunteers. Linear and volumetric measurements were obtained and compared to caliper and hydrostatic weighing methods respectively.

METHODOLOGY—An optical surface scanner was designed and built to facilitate lower limb residuum scanning. Four camera/projector sensors were configured to view the residual limb or plaster cast surface in overlapping segments. Utilization of multiple sensors allowed 360° coverage of residua including the distal end. A rigid mechanical structure was designed and built to which the sensors were mounted. The scanner design principle was based on triangulation between a projector and camera.

Spiral CT scanning was also evaluated for residua imaging. A spiral CT scanner (SOMATOM Plus S, Siemens Medical Systems, Inc., Iselin, NJ) with slip-ring technology that allows continuous 1 s/revolution rotation of the X-ray source and detectors was used to obtain raw X-ray projection data. This scanner can acquire and store contiguous data sets obtained over a 32-s period with successive spiral turns of 1 mm with 1 mm collimation. Two advantages of spiral CT over conventional CT are a considerable reduction in radiation dosage and scan time, and improved definitive representation of soft tissue.

A 3Space™ electromagnetic point digitizer (Kaiser Aerospace and Electronics, Colchester, VT) consisting of a hand-held wand used to capture information with six degrees of freedom was also evaluated. The stylus of the wand is tracked in a calibrated feature space and the location digitized when a foot pedal is pressed.

RESULTS—Work on this project has demonstrated that measurements of surface geometry by manual, optical, and x-ray CT methods are accurate and reproducible and that volumetric images reconstructed from spiral x-ray CT provides accurate volumetric measurement of the limb remnant soft tissue envelope. Surface and volumetric residua data from the OSS and SXCT respectively were used to construct accurate 3-D solid models. The results demonstrate that the 3Space, OSS, and SXCT precision and repeatability are sufficient for quantitative studies and found substantial equivalence of these methods.

IMPLICATIONS—Any of these methods can be reliably used to acquire measurement data for input to a CAD/CAM package. For the more ardent task of prosthesis fit, evaluation spiral X-ray CT seems most appropriate. SXCT not only yields an accurate high resolution representation of surface morphology, but was also shown to yield high delineation of internal residuum morphology. This device was the only one of those examined capable of soft tissue morphology with a prosthesis *in situ*. Optical surface scanning would be well suited for diurnal evaluation (short-term) of residua when internal information is not required.

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II. Biomechanics

A. Bone and Joint Studies

[25] EFFECT OF THE BANKART LESION ON ANTERIOR JOINT STABILITY GLENOHUMERAL MUSCLE FORCES

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PURPOSE—The objective of this project is to biomechanically assess the contribution of two common shoulder injuries to glenohumeral instability: tear of the origin of the inferior glenohumeral ligament (the Bankart lesion) and joint effusion.

METHODOLOGY—To study the effect of the Bankart lesion and joint effusion on glenohumeral joint kinematics and kinetics requires a building of a custom shoulder loading apparatus that utilizes a six-axes load cell, six degrees of freedom (DOF) electromagnetic tracking device, four differential variable reluctance transducers (DVRT) and a video digitizing system (VDS). Using this device, we will simulate the shoulder muscles and static joint restraints in the joint position of instability to measure: the joint compression force, the position of the humeral head on the glenoid, and the strain in the inferior glenohumeral ligament.

PROGRESS—The shoulder testing apparatus has been designed and built. This device permits the application of each individual muscle forces in the shoulder while permitting simultaneous measurement of the glenohumeral joint compression force and kinematics. The joint compression force is measured with the six-axes load cell and the glenohumeral joint kinematics is measured with the magnetic tracking device. In addition, the strain distribution in the inferior glenohumeral ligament (IGHL) has also been determined.

PRELIMINARY RESULTS—Thirteen fresh frozen cadaveric glenohumeral joints were used to determine the strain distribution in the IGHL. Two were positioned at 60° of abduction, externally rotated, and then frozen for histological analyses. The remaining 11 joints were used for biomechanical testing of the IGHL with the humerus abducted 60° and then externally rotated. The histology results showed that the anterior band of the IGHL has two attachments at the glenoid insertion site: the labrum and, the anterior glenoid neck. The results from the biomechanical testing showed that eight (73 percent) of the b-l-l-b complexes failed at the glenoid insertion site (representing the Bankart lesion), one (9 percent) at the humeral insertion site, and two (18 percent) at the anterior band midsubstance. The results also demonstrated that most of the strain occurs at the insertion sites, with failure occurring most often at the glenoid insertion.

FUTURE PLANS—Fresh frozen full upper limb specimens will be mounted by rigidly attaching the scapula on the shoulder testing apparatus. The muscles simulated are those active in abduction of the joint: deltoid (middle and upper portions), supraspinatus, subscapularis, and the infraspinatus/teres minor. The scapula will be positioned in 30° of abduction and muscle force will be applied to the tendons of the simulated muscles until the shoulder joint reaches 90° of abduction. The force in the infraspinatus/teres minor muscles will then be increased for maximum external rotation. Glenohumeral joint motion will be measured with a six DOF magnetic tracking device. Three DVRTs and continuous VDS will be used to

determine *in-situ* strain in the IGHL. The IGHL will then be tested in tension to determine the *in-situ* stress. For the measurement of the resultant glenohumeral joint compression force, a six-axes load cell will be used. The intracapsular pressure in the joint will then be increased and the test repeated, then a Bankart lesion will be surgically created and the test repeated again. At the completion of joint motion each glenohumeral joint will be dissected and the center of curvatures for the humeral head and the glenoid will be determined.

[26] BIOMECHANICS OF THE PATELLOFEMORAL JOINT AND PERIPATELLAR RETINACULUM

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PURPOSE—The purpose of this study is to quantify the structural and mechanical properties as well as *in-situ* stress and forces in the peripatellar retinaculum. This study is designed to quantitatively assess the functional role of the peripatellar retinaculum in addition to determining the effects of lateral patellar retinaculum release, tibial torsion, and complete transverse patellar fracture.

METHODOLOGY—Fresh frozen human cadaver knees will be used with an Instron machine and a custom patellofemoral joint loading jig that permits the measurement of strain in the peripatellar retinaculum while controlling the knee flexion angle, degree of tibial torsion and tension in the quadriceps muscles (rectus femoris/vastus intermedius as well as vastus medialis and vastus lateralis). The mean strain in the peripatellar retinaculum will be measured using six differential variable reluctance transducers (DVRT), and the surface strain will be measured using the video digitizing system (VDS). To determine the *in-situ* stress and forces in the peripatellar retinaculum, the *in-situ* strain is first measured in intact knees. The peripatellar retinaculum is then isolated for tensile testing to determine both the structural and mechanical properties. The results will then be correlated to compute *in-situ* stress and forces in peripatellar retinaculum.

PROGRESS—The patellofemoral joint (PFJ) loading jig has been built. This jig allows 5 degrees of freedom (DOF) at the femur and 3 DOF at the tibia. Muscle loading can be accomplished through stainless steel clamps, an adjustable pulley system and lead weights. This custom jig permits independent application of all knee extensor muscle (rectus femoris/vastus intermedius, vastus lateralis, vastus medius, iliotibial band) forces in its anatomic/physiologic orientation at any knee flexion angle. This jig also permits simultaneous measurement of the patellofemoral joint contact pressures and kinematics using Fuji pressure sensitive film and a three-dimensional magnetic tracking device, respectively. We have also determined the anatomic/physiologic loading conditions for the *in-vitro* testing of the patellofemoral joint.

PRELIMINARY RESULTS—We have quantified the PFJ kinematics and contact pressures while considering physiologic/anatomic muscle loading parameters. These loading configurations will be used for the quantification of the *in-situ* stress in the peripatellar retinaculum. The physiologic/anatomic loading conditions using the individual extensor muscles resulted in a significantly greater peak PFJ contact pressure at 0° of knee flexion and significantly less peak contact pressure at 90° of flexion as compared to the resultant quadriceps tendon loading. Significantly greater joint contact area was observed with the physiologic/anatomic loading condition at 30° of knee flexion. Kinematic differences between the two loading conditions was evident in patella rotation with the physiologic/anatomic loading condition demonstrating increased medial rotation from 0 to 75° of knee flexion. In addition, the resultant quadriceps tendon loading condition resulted in greater patella flexion from 0 to 45° and greater lateral patellar shift at 15° of knee flexion.

FUTURE PLANS—We plan to determine the tissue strain and stress in the peripatellar. This will be accomplished by quantifying the biomechanical properties as well as the *in situ* forces in the peripatellar retinaculum. We will also quantitatively assess the effects of lateral patellar retinaculum release, tibial torsion, and complete transverse patellar fracture.

[27] THE EFFECT OF HYDROSTATIC PRESSURE ON INTERVERTEBRAL DISC METABOLISM

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PURPOSE—This 3-year study tests the hypothesis that hydrostatic pressure directly affects the synthesis of collagen and aggrecan (the cartilage specific proteoglycan) by the intervertebral disc cells.

METHODOLOGY—Chondrocytes maintained in a 3-dimensional configuration suspended in an alginate gel will serve as our *in vitro* biological assay system. Using this culture system and three pressure chambers, our research plan is designed as follows:

1. Establish the time of steady-state for collagen and aggrecan metabolism at atmospheric pressure. Measure the effect of different levels of hydrostatic pressure on collagen and aggrecan synthesis by assaying the incorporation of proline and sulfate per μg DNA, respectively (Experiment 1).
2. Based on the results from Experiment 1, we will focus only on the most effective pressures to differentiate between quantitative or qualitative changes in the biosynthetic activity of the cells subjected to these pressures. We will use indirect immunoprecipitation, SDS-polyacrylamide gel electrophoresis, and HPLC methodologies (Experiment 2).
3. Determine by Northern Blot analyses the effect of hydrostatic pressure on mRNA levels for aggrecan core protein and collagen types I and II (Experiment 3). On the basis of the data from Experiment 1, we obtained the experimental pressure value(s). On the basis of the data from Experiment 2, we will determine which collagens are affected and whether the aggrecan core protein is also affected. This experiment will determine whether the change in the collagen and aggrecan are related to changes in their respective mRNAs.

PROGRESS—Our experimental system works and the cartilage cells are affected as anticipated. The progress to date is as follows: 12 separate experiments have been completed. The endpoint for each experiment was the amount of radioactive proline and sulfate incorporated into collagen and sulfated proteoglycans (CSPG) respectively in canine intervertebral disc cells cultured under a pressure of 150 lb/in^2 compared to cells cultured at atmospheric pressure. For each experiment, the annulus and nucleus were isolated separately from lumbar discs, and their cells were enzymatically released. Cell number was expanded by culturing in 25 cm T-flasks for 8 days followed by a subsequent subculturing of 8 days in a 75 cm T-flask. The cells in the confluent cultures were resuspended in alginate gel at a concentration of 3×10^6 cells/ml before encapsulation into gelatinous beads. Equal aliquots of beads were transferred to 5 cc syringes containing complete culture medium sealed with a cap at one end and a plunger at the other end. The syringes were placed in a holding device and lowered into a pressure tank. The tank was pressurized at 150 lb/in^2 and placed in a 37 °C humidified incubator for 9 days. In some cases the pressure was not applied until day 8 of incubation. For all experiments, radioactive incorporation was carried out for 24 hours between day 8 and day 9 of incubation. After each experiment, the cells were released from the alginate gel, collected and assayed for collagen, CSPG, and DNA. Greater than 98 percent of the radioactive label remained with the extracellular matrix which surrounds the cells.

PRELIMINARY RESULTS—The data showed a significant increase in both proline and sulfate incorporation caused by pressure applied for either the entire 9 days or for only the last 24 hours of the 9-day incubation period. The values (DPM/μg DNA) ranged between 100 and 500 percent above control levels.

FUTURE PLANS—We have completed year 1 of our project. We will now proceed with Experiment 2.

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

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PURPOSE—Many surgical procedures of the lumbar spine require removal of tissue from the motion segment, for example laminectomy and discectomy. When large amounts of tissue are removed, the stiffness of the motion segment is reduced to a degree that there is an abnormal response to an applied load. To compensate for this decrease in stiffness which, in addition to creating pain, may present a risk to neurological structures, fusion surgery is sometimes performed. At the present time, there is a clinical controversy about when a fusion should or should not be performed. The question of whether to fuse or not is important since the fusion procedure increases the morbidity from spinal surgery. Further, when one 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—Based on the results of our preliminary tests, we have completed final modifications to the experimental set up for testing multisegment human cadaveric lumbar specimens. We are conducting experiments to determine the effects of different surgical procedures on the load-displacement behavior of lumbar motion segments as outlined above.

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. In addition, a three-dimensional finite element model of an L4-5 disc-body unit has been developed using serial CT scans. The model predictions for different loading conditions agreed well with the experimental data in the literature. We are now combining the disc-body model with the facet model to develop a model of the complete motion segment which will be used in the final phase of the study.

FUTURE PLANS/IMPLICATIONS—During the next year we will complete remaining experiments on fresh human cadaveric lumbar spines. The validated finite element model will be used to conduct a detailed parametric study of the effects of surgical procedures on the change in stiffness of the lumbar motion segments. The information generated in this study will be used as a basis for developing recommendations concerning when to fuse and when not to fuse.

[29] CONTACT CHARACTERISTICS OF THE SUBTALAR JOINT AFTER LATERAL COLUMN LENGTHENING THROUGH THE ANTERIOR CALCANEUS AND THE CALCANEOCUBOID JOINT

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PURPOSE—Lengthening the lateral column of the foot is used to restore the medial longitudinal arch. Dillwyn-Evans advocated lengthening the calcaneus by insertion of a bone graft between the anterior and medial facets, within the talocalcaneal joint. An alternative technique, which places the bone graft at the calcaneocuboid joint is also done. This study was designed to compare the joint contact properties after restoration by either method.

METHODOLOGY—Ten feet were selected after screening. A posterior approach was made into the posterior facet. The entry site for the middle and anterior facet transducer was made medially. The approach to the talonavicular joint consisted of retracting the extensor digitorum longus (EDL) and hallucis longus (EHL) tendons, and cutting the joint capsule superiorly, while preserving the dorsal talonavicular ligament. The soft tissues were otherwise left intact. Pressure film transducers were made of pressure sensitive film, 0.305 mm thick, inserted between the joint surfaces, and imaged along with a set of calibration prints. The imaged films were analyzed for total contact area (>0.5 MPa) and mean pressure. Intramedullary rods were placed into the tibial and fibular shafts. Axial load was applied by a pneumatic cylinder acting through a shaft with a bearing on its end, against a plate connected to the tibial shaft. Fifteen percent of the applied axial load was transmitted into the fibula. Tendon clamps and cables connected 7 tendons of the foot to pneumatic cylinders. The three positions for testing were: **heel strike** with 6° of plantarflexion, axial force, 68 percent body weight (BW: 700 N); **stance** with 7° of dorsiflexion, axial force of 82 percent BW, and respective muscle forces; and **heel rise** with 10° dorsiflexion, axial force of 110 percent BW. Muscle force values were calculated from physiological cross-sectional areas, reported peak forces, and normalized EMG values.

Each foot was tested first in normal state, then after sectioning the spring ligament and cyclic axial loading to create a radiographically documented flatfoot deformity. Five feet were reconstructed by placing a 1 cm thick tricortical bone graft between the cuboid and calcaneus, while the other five were reconstructed by placing the bone graft into a calcaneal osteotomy between the anterior and medial facets, followed by retesting. An ANOVA was used to determine differences between normal, flatfoot, and the two reconstruction techniques.

RESULTS—The contact area of the talonavicular joint decreased significantly with flatfoot (from 410 mm^2 intact to 336 mm^2) and was not restored by either reconstruction method. In addition, the area of the anteromedial facet of the talocalcaneal joint decreased with the Dillwyn-Evans reconstruction (from 340 mm^2 to 248 mm^2). The only significant difference was an increase in pressure in the posterior facet with the Dillwyn-Evans procedure (from 2.22 MPa to 2.53 MPa), although there was a trend to higher pressure in the anteromedial facet (from 1.49 MPa to 1.87 MPa).

CONCLUSIONS—Flatfoot decreases talonavicular joint area, which is not restored by either reconstruction. The Dillwyn-Evans procedure decreases anteromedial facet contact area and increases posterior facet pressure. Therefore, lengthening through the calcaneocuboid joint has less effect upon hindfoot joint contact characteristics.

[30] THE EFFECT OF FOOT POSITION ON LOAD DISTRIBUTION BETWEEN THE TALOCALCANEAL AND TALONAVICULAR JOINTS

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PURPOSE—During gait, load is transmitted from the tibia into the talus, where it is transferred to both the hindfoot and midfoot. Previous study has determined the relative load distribution between the posterior and anterior facets of the talocalcaneal joint; however, the role of the talonavicular joint as part of this mechanism is not known. This information is necessary when determining the effects of foot deformity or fracture on foot function. We tested the hypothesis that load transmission between the calcaneus and navicular, measured by contact pressure and area, would change with foot position.

METHODOLOGY—Ten feet were used. A posterior approach was made into the posterior facet and a medial entry site for the middle and anterior facet. A superior approach was used for the talonavicular joint. Pressure sensitive film transducers, 0.305 mm thick, were made from Superlow and Low Prescale film. After insertion of the film between the joint surfaces and loading, the pressure film was imaged along with a set of calibration prints. The imaged films were analyzed for total contact area (>0.5 MPa), mean pressure, and total force. Axial load was applied by a pneumatic cylinder to intra-medullary rods placed into the tibial and fibular shafts. This allowed axial force to be transmitted with the tibial shaft at an angle to the vertical for each position. Ten percent of the applied axial load was transmitted into the fibula. Tendon clamps and cables connected 7 tendons of the foot to pneumatic cylinders. Muscle forces were calculated from physiological cross-sectional areas, reported peak forces, and normalized EMG values. For stability, one-third of the calculated forces were applied. The scaled forces are listed below.

The three positions for testing were: **heel strike** (at 5 percent of the gait cycle), with 6° of plantarflexion, axial force of 159 N, achilles 80 N, tibialis anterior 54 N, EHL 8 N, EDL 20 N, and tibialis posterior 32 N loaded over 35 s; **stance** (at 30 percent gait cycle) with 7° of dorsiflexion, axial force of 191 N, and respective muscle forces, 329 N, 18 N, 0 N, 0 N, 24 N, as well as the peroneus longus 16 N, the flexor hallucis longus 10 N, and the flexor digitorum longus 8 N loaded over 48 s; and **heelrise** (at 45 percent gait cycle) with 10° dorsiflexion, axial force of 257 N, and muscle forces of 564 N, 10 N, 0 N, 0 N, 92 N, 36 N, 62 N, and 30 N loaded over 80 s. The Kruskal-Wallis test was used to determine significant differences between total talocalcaneal and talonavicular joint force for the three selected positions.

RESULTS—Posterior facet talocalcaneal joint: contact area increased between heel strike and stance as did contact pressure so total force was significantly increased from 685 βN to 932 N. The changes were even larger for stance (932 N) to heelrise (1492 N; $p<0.001$). Anterior and middle facets talocalcaneal joint: load was unchanged in this joint in different foot positions. Talonavicular joint: joint pressure and force increased between stance (655N) and heelrise (887N; $p=0.019$).

IMPLICATIONS—The increases in joint load between heel strike and heelrise were more likely due to differences in total load applied than due to differences in orientation of the talus since differences in joint angle were small (10° dorsiflexion for heelrise compared with 6° of plantarflexion for heelstrike). High forces in heelrise were due primarily to a combination of higher axial load and larger Achilles force required to create thrust.

[31] THE EFFECT OF RELEASE OF THE POSTERIOR TIBIAL TENDON ON THE KINEMATICS OF THE HIND FOOT

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PURPOSE—Acquired flatfoot deformity has been attributed to the loss of the tibialis posterior (TP) tendon. However, there has been no study of the effect of TP rupture on hind foot kinematics. This study documents the effect of releasing the tibialis posterior tendon (simulating rupture) on the kinematic positions of the hind foot bones.

METHODOLOGY—The soft tissue was stripped from the tibial shaft of 8 human cadaver specimens exposing the remaining tendons down to the hind foot level. Motion sensors were attached to carbon fiber pins in the calcaneus, talus, navicular, and cuboid. An acrylic rod was inserted into the intramedullary canal to allow for axial loading of the foot.

Simulated axial compressive and tendon loads were applied to each specimen in three different loading positions: **heel strike** (at 5 percent of gait cycle), **stance** (at 30 percent of gait cycle), and **heel rise** (at 45 percent of gait cycle). Nylon cables with tendon clamps were used to connect the tendons to regulated pneumatic cylinders. For this study, this initial unloaded position of the foot was considered to be the "neutral" position.

The basic test protocol for each specimen entailed the collection of the bone position (motion) data in each of three conditions: neutral position (unloaded); loaded (either in heel strike, stance, or heel rise with all tendons loaded); and finally loaded, but with the TP tendon released. The three different foot positions were achieved by applying various axial compressive and tendon loads in appropriate ratios while positioning each foot on an inclined surface. The degree of incline selected for each position included 6° of plantar flexion for heel strike, 7° of dorsiflexion for stance, and 10° of plantarflexion for heel rise. All of the loads applied in this study were scaled to one fourth body weight, which was a limitation imposed as a result using a plastic loading frame.

Data were reported relative to the neutral position. A nonparametric, Wilcoxon Signed Rank paired analysis was used to statistically compare the angular positions of the four bones.

RESULTS—Statistically significant changes in the angular position of the four-bone complex were observed when the TP tendon was released (as compared to all tendons loaded) for all three loading conditions. These changes, however, were generally small in magnitude (less than 1 or 2°), particularly during stance and heel strike simulation. The greatest changes in angular position resulting from unloading of the TP tendon were seen during heel rise. This was not surprising, since the TP tendon is most actively recruited during this phase of the gait cycle. Mean talar ($3.6°\pm1.5$, $p=0.011$) and calcaneal ($2.4°\pm0.7$, $p=0.011$) internal rotation together with talar plantar flexion ($1.0°\pm0.8$, $p=0.011$) was observed when the TP tendon was released. Eversion of the navicular ($3.8°\pm1.8$, $p=0.011$), cuboid ($2.4°\pm1.1$, $p=0.011$), and calcaneus ($1.9°\pm0.8$, $p=0.011$) was also observed at heel rise.

Although directional changes in the hind foot bones associated with TP tendon release were largely consistent with acquired flatfoot deformity, the magnitudes of these changes were much smaller. This suggests that the intact osteo-ligamentous structure of the hind foot is at least initially sufficient to maintain normal alignment following TP tendon rupture. Subsequent cyclical loading (e.g., normal gait) without TP tendon function may, however, progress toward an acquired flatfoot condition. This is consistent with the clinical presentation in which the hindfoot subluxation is delayed by 6 months to 1 year following the rupture. The fact that the most change occurred in heel rise may explain the lack of success of bracing in some patients.

FUTURE PLANS—Future work will attempt to better clarify the position afer repeated cycling without posterior tibial tendon support.

[32] THE EFFECTS OF CALCANEAL LENGTH AND FUSION POSITION ON THE KINEMATICS OF THE HINDFOOT WITH LATERAL COLUMN LENGTHENING AND CALCANEOCUBOID FUSION FOR SYMPTOMATIC FLATFOOT

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PURPOSE—Surgical treatment of symptomatic flatfoot may include calcaneal lengthening through the calcaneocuboid joint, which restores the shape of the foot. However, the effect of the procedure on hindfoot kinematics is unknown. Therefore, the kinematics of the hindfoot were measured first in normal cadaveric feet, then measured after simulated lateral column lengthening and fusion in different positions.

METHODOLOGY—An acrylic shaft was placed into the intramedullary canal of the tibia to support the transmitter of an electromagnetic motion transducer and transmit load to the specimen. A carbon fiber pin was placed into holes drilled in the calcaneus, talus, navicular, and cuboid that had been filled with Methacrylate cement. An acrylic mount with a receiver of the motion tracking system was fixed to the pin. The motion tracking system consists of a transmitter defining the global axis system, which is located on the tibial shaft, and a set of receivers. Verification of sensor measurement accuracy ranged from 0.944 to 1.006 in rotation, and 0.996 to 1.045 in translation. Crosstalk (ratio of output in any other direction to known input) ranged from 0.000 to 0.083.

Each foot was moved manually while holding the tibial shaft stationary, into maximum plantar flexion/inversion and dorsiflexion/eversion. Moments were measured by a six axis load cell. After three repetitions, the foot was placed on the floor, the tibia and shaft were oriented vertically, a 150 N axial load applied manually, and the tibia was internally and externally rotated. After testing intact, fusion was performed across the calcaneocuboid joint using one screw with 1) placement of a 10 mm thick tricortical iliac crest bone graft lengthening the lateral column, with the foot in neutral position, 2) with bone graft and the foot in plantar-flexion/inversion, 3) with bone graft and the foot in dorsi-flexion/eversion, 4) without bone graft and the foot in neutral position, and 5) after removal of a 5 mm thick bone section at the calcaneo-cuboid articulation to obtain congruent fusion surfaces, thereby shortening the lateral column, with the foot in neutral position. Data analysis Kinematics after fusion were compared to intact using a repeated measures ANOVA and Fisher's PLSD post hoc statistics, with significance established at $p<0.05$). In this scheme, each foot acted as its own control.

RESULTS—Kinematics of the hindfoot joints were unaffected by simulated fusion of the calcaneocuboid joint with the foot in neutral position and the lateral column lengthened. When the joint was fused with the foot in plantarflexion/inversion or dorsiflexion/eversion, motion of the talo-calcaneal was significantly affected. For example, when the foot was fused in plantarflexion/inversion, in/eversion decreased from 15.7° (sd=9.5°) intact to 4.7° (SD=6.2°) after fusion, while dorsi/plantar flexion decreased from 9.0° to 3.1° and rotation decreased from 7.0° to 1.4° ($p<0.01$). Similarly, talo-navicular motion decreased in flexion from 17.3° (SD=10.4°) to 3.4° (SD=6.0°), in version from 34.3° to 9.2°, and in rotation from 27.6° to 7.6°, ($p<0.01$). There were no significant effects of calcaneal length on any recorded joint motions.

IMPLICATIONS—Calcaneo-cuboid fusion with the calcaneus lengthened and the foot in neutral position has no effect on hindfoot kinematics. However, fusing the foot in other orientations limits talocalcaneal and talonavicular joint motion. When performing arthrodesis, care should be taken to preserve the neutral position of the joint.

[33] ALTERATIONS IN TALAR MORPHOLOGY ASSOCIATED WITH ADULT ACQUIRED FLATFOOT

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PURPOSE—Talar morphology is complex due to its unique role in coupling the mechanics of the leg and the foot. In acquired adult flatfoot (AAF), there is uncertainty whether the shape of the bone differs or whether joint subluxation is responsible. We compared the talar morphology of 10 control lower extremities without deformity with the tali from 10 patients with AAF using a computerized 3-D reconstruction format to determine whether the talar bone morphology is different in patients with AAF when compared to feet with a "normal" arch.

METHODOLOGY—CT scans with 1.5 mm cuts through the hind foot were made and the scan data containing the tali downloaded by digital tape and processed using computer-aided design (CAD) software to generate 3-D models; these could be rotated to any view and their dimensions measured by software tools that allowed instantaneous readout of the distance between two points. Measurements of talar length, talar width, talar height, and talar head length and width were taken on each model. In order to assess the accuracy of the dimensions taken from the models, a disarticulated cadaver talus was measured directly using dial calipers with a resolution of 0.01 mm and compared to multiple measurements on the CAD model. Statistical analysis using the unpaired t-test was performed.

PROGRESS—The 3-D CAD models built from CT data had an average difference of 3.2 percent compared to direct physical measurements. There were significant differences between control tali and flatfoot tali in talar width ($p=0.005$), talar height ($p=0.001$), and head width ($p=0.001$). Although flatfoot tali tended to be of greater overall length than the control tali, this difference was not statistically significant. The tali from the flatfoot group were narrower in width and shorter in height when compared to overall length, and had heads that were more oval shaped (i.e., less spherical).

IMPLICATIONS/FUTURE PLANS—The shape of the talus is important to hind foot function and is known to be altered in pathological disorders such as clubfoot. The role of bone morphology in acquired adult disorders is less clear. Our results show that talar morphology is different in patients who have an AAF. Whether these patients develop flatfect as a result of their altered bone morphology or the bone changes in the flatfoot condition occur as a result of stress remodeling is unclear and will require future investigation. The alteration in talar head dimensions may make axis measurements unreliable. Thus, surgical procedures designed to correct AAF should be evaluated based on the shape of the foot, not on radiographic parameters.

[34] DETECTION AND ACCUMULATION OF MICRODAMAGE IN BONE

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PURPOSE—Fatigue damage is a stimulus for bone remodeling. However, if it accumulates too rapidly and the capacity for repair is exceeded, stress fractures result. If the repair mechanism is deficient, as in old age, damage also accumulates and contributes to fragility fractures. To better understand the fatigue behavior of bone *in vivo*, we

must first understand it *in vitro*. The purpose of this study is to develop methods for detecting microcracks and use them to demonstrate microcrack initiation, propagation, and coalescence during fatigue testing in compression.

METHODOLOGY—The right sixth rib was excised from 10 human subjects from the Harvard Anatomical Gifts Program and cut into six 0.5 cm sections. Each section was randomly assigned to one of six stains: alizarin complexone, calcein, calcein blue, oxytetracycline, xylenol orange, and the accepted standard, basic fuchsin. Using fluorescence microscopy, the number, density, and length of microcracks labeled by each stain was recorded. No significant difference was found between the six stains for any parameter (ANOVA, $\alpha=0.05$), indicating that they are all equally effective at detecting microcracks. These stains were then used to differentiate between pre-existing microcracks, those sustained *in vivo* or during preparation, and microcracks caused by fatigue testing in compression. Pairs of waisted trabecular bone specimens were prepared and stained with oxytetracycline for 16 hours at 20 psi pressure to label pre-existing damage. They were then fatigue tested in compression under load control until a 10 percent decrease in initial elastic modulus was achieved. One from each pair was then randomly assigned to a second staining in xylenol orange. The specimens were embedded in methylmethacrylate, longitudinally sectioned, examined using fluorescence microscopy, and microcrack counts made.

PROGRESS—Five pairs of waisted trabecular bone specimens have been tested to date. In addition two pairs were subjected to a three stain procedure: oxytetracycline prior to testing, calcein blue for the first 75 percent of the test, and xylenol orange for the final 25 percent of the test.

PRELIMINARY RESULTS—Preliminary staining with oxytetracycline revealed that pre-existing damage was present in all specimens and was not confined to the machined edges. In the double stain specimens, microcracks were labeled by oxytetracycline, indicating that they existed prior to the test, by xylenol orange, indicating that they were incurred during the test, and by both, indicating crack growth during testing. The density of labeled microcracks was significantly greater in double stain as compared with single stain specimens (paired t-test, $p=0.011$). Triple staining suggests that microcracks are incurred during the first 75 percent of the test and well as in the final quarter.

FUTURE PLANS—These results indicate that double labeling can be used to differentiate pre-existing microcracks from those incurred by a mechanical test. We plan to use this technique in monotonic testing of bone. The triple stain data suggest that, used in sequence, these fluorescent stains can label crack growth. We plan to use this tool to study microcrack propagation and coalescence in both trabecular and compact bone.

[35] VALGUS-VARUS MOTION OF THE KNEE IN STAIR CLIMBING AND LEVEL WALKING

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PURPOSE—Osteoarthritis is one of the most common knee disorders. Proximal tibial osteotomy is a commonly used intervention for treatment of osteoarthritic knees. Previous studies indicated that the abduction-adduction (A-A) moment at the knee in gait might be an important parameter for patient selection when using the proximal tibial osteotomy in treating knee deformity due to osteoarthritis. Stair climbing is an important functional activity of daily living and may be a more informative evaluation procedure for patients with osteoarthritic knees. The purposes of this study are to determine (a) the maximum A-A moments and the corresponding angles of the knee, (b) the factors contributing to the variations of the knee A-A moments, (c) the range of valgus-varus (V-V) motion of the knee, and (d) the factors influencing the V-V motion of the knee in stair climbing and level walking.

METHODOLOGY—An Expert Vision™ system (Motion Analysis Corp., Santa Rosa, CA) with four video cameras was used to collect kinematic data at a sampling frequency of 60 Hz. A specially designed staircase with four stairs was attached to two of three force plates for measuring ground reaction forces for two of four steps in stair climbing.

Three-dimensional angles and resultant moments of the knee were calculated using the OrthoTrak II System (Motion Analysis Corp.). Analyses of variance with repeated measures were conducted to compare the maximal A-A moments and V-V angles of the knee between ascending, descending, and level walking. Multiple regression analyses were conducted to identify the factors influencing the A-A moment and V-V motion of the knee in stair climbing and level walking. The 0.05 level of confidence was chosen to indicate statistical significance.

PROGRESS—Ten nonimpaired subjects (five males and five females) without any history of lower extremity disorders have been tested. There was generally an abduction moment at the knee during the stance phases of stair climbing and level walking for all subjects. There was no evidence that the maximum abduction moment at the knee in stair climbing was different from that in level walking. The within-subject variation of the knee abduction moment was mainly affected by the variation in the vertical ground reaction force in descending and level walking, and by the variation in the medial-lateral ground reaction force in ascending. The knee V-V angle was a major contributor to the between-subject variation of the knee abduction moment, especially in stair climbing. The maximal V-V angle of the knee was significantly increased in stair climbing in comparison to level walking. The range of knee V-V motion could be over 10°. The V-V angle of the knee essentially was a function of knee flexion angle. Ground reaction forces had little effect on the knee V-V motion. There seemed to be a coupling between knee flexion-extension motion and V-V motion.

FUTURE PLANS—The relationship between the knee abduction moment and the V-V angle and the coupling between knee flexion-extension and V-V motions are the most important findings of this research project to date. These findings support the use of the biomechanical analysis of stair climbing as a clinical evaluation tool for patients with knee osteoarthritis and warrant further studies on the biomechanics of stair climbing and its clinical applications. Different devices will be used to measure the knee flexion-extension and V-V angles to confirm the relationship between knee flexion-extension and V-V motions and the cause of the coupling between these two motions of the knee. Patients with knee osteoarthritis will be tested and compared to the normal data base. The dynamic load on the knee and the knee V-V motion in different functional activities will be compared. A knee model will be developed to estimate the force distribution across the knee in different functional activities.

RECENT PUBLICATIONS FROM THIS RESEARCH

Abduction-adduction moment at the knee in stair climbing and level walking. Yu B, Growney ES, Hansen DK, Johnson ME, An K-N. In: Proceedings of the 1st Annual North American Society of Gait and Clinical Movement Analysis Conference, 1996.

Abduction-adduction motion of the knee in stair climbing and level walking. Yu B, Growney ES, Hansen DK, Johnson ME, An K-N. In: Proceedings of the 20th Annual American Society of Biomechanics Conference, 1996.

[36] COORDINATION OF MOVEMENTS WITH MULTIPLE DEGREES OF FREEDOM

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PURPOSE—The voluntary control of human movement is a complex task involving tens of skeletal joints and hundreds of muscles. In any task, the brain must devise a command to coordinate many muscles, the consequences of which are the activation of motor units, the development of muscle force, and the evolution of movement. This all takes place within several reflex loops that feed back measures of motion and force to many levels of the

central nervous system from the spinal cord through the cerebral cortex. How is this complex coordination of so many degrees of freedom achieved?

METHODOLOGY—Our experiments involve asking normal subjects to stand and point on command to a stationary object, located in the same plane as their right arm. Using a motion analysis system, we record the motions of the limb segments and the electromyographic (EMG) patterns of muscle acting about the shoulder and elbow. From these data we can solve the inverse dynamic equations to compute the net muscle torques about both joints. We can then examine the relations between torques, EMGs, and motions. We can also examine the relations of these variables across joints.

PRELIMINARY RESULTS—We have found that examination of the individual joints during a multijoint movement reveals patterns of activation that are very much like those of a single joint movement. This reveals, not that single joint strategies are used for much more complex multijoint movements but rather the reverse, multijoint strategies are conserved and used for simpler, single joint movements because they are sufficient for the task. We have recently proposed that for many of the reaching movements we can perform, there is a simple rule for coordinating the actions of the elbow and shoulder. It is remarkably simple. The central nervous system activates the muscles of the two joints to produce biphasic pulses of torque that are approximately proportional to each other throughout most of the movement.

RECENT PUBLICATIONS FROM THIS RESEARCH

Organizing principles for voluntary movement: extending single joint rules. Almeida GL, Hong D, Corcos DM, Gottlieb GL. J Neurophysiol 1995:74:1,374–81.

[37] MECHANISMS UNDERLYING COMPLIANT BEHAVIOR OF THE LIMBS

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

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

PRELIMINARY RESULTS—Experiments show that during sudden perturbations and during rapid movement, limb compliance is primarily due to the velocity sensitive (i.e., viscous) force, producing mechanisms of the muscle's contractile mechanism. During postural maintenance, length sensitive mechanisms are important and presumably are responsible for achieving end point accuracy in spite of the variability in kinematics. These intrinsic muscle mechanisms are supported by rapidly acting reflex mechanisms that can alter the activity of the muscles to oppose the effects of the perturbations. Neither is sufficient, however, to prevent limbs from being displaced by external perturbations. The motor system relies on the corrective actions of higher centers, including conscious ones, to provide a complete and adequate response.

We have also attempted to demonstrate the adaptability of reflex mechanisms that have hitherto been regarded as highly stereotyped in their behavior. We asked subjects to make movements in which they knew that the load might change without warning. After they became

used to this condition, we altered the nature of the unpredictable load and we compared the responses. As we had previously shown, subjects react to unpredicted loads with a combination of reflex and preprogrammed reactions. What we found that was new was that the nature of these reflex and preprogrammed reactions depends, not only on the properties of the unexpected load but also on the subject's recent experience with unexpected loads. We interpret this as evidence that not only is voluntary movement a process of planned muscle activation patterns, but it also involves adjustment of reflex mechanisms to better adapt to possible, but not predictable, perturbations.

RECENT PUBLICATIONS FROM THIS RESEARCH

On the voluntary movement of compliant (Inertial-Visco-Elastic) loads by parcellated control mechanisms. Gottlieb GL. J Neurophysiol. In press.

[38] EVALUATION OF HIP STABILITY FOLLOWING SIMULATED TRANSVERSE ACETABULAR FRACTURES

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Sponsor: *Orthopaedic Trauma Association*

PURPOSE—One of the major goals in managing acetabular fractures is to prevent post-traumatic arthritis. Unreduced fractures involving the weight-bearing portion of the acetabulum lead to post-traumatic arthritis, while fractures outside the weight-bearing area have a better prognosis. However, the portion of the acetabulum which is necessary for normal weight-bearing is not well-defined. Little previous work has examined hip stability following either actual or simulated acetabular fractures. The purpose of this study was to distinguish between fractures requiring open reduction, those treatable with traction, and those requiring even less aggressive treatment to prevent post-traumatic arthritis.

METHODOLOGY—An *in vitro* cadaveric model simulating transverse acetabular fractures was developed. Custom guides were designed to create precisely reproducible cuts simulating transverse acetabular fractures at 0, 30, 60, and 90° relative to the roof-arc angle. Each proximal femur was potted in a cylindrical fixture, mounted onto an instrumented x-y displacement table and secured to the load cell of a mechanical testing machine. Steinmann pins were inserted into the posterior-superior acetabulum to provide a reference to the sagittal, coronal and transverse planes. Each acetabulum was potted and mounted to the test machine actuator using an articulated fixture which allowed variable flexion and abduction/adduction. The specimens were loaded in compression to 800 N (at 200 N/s in load control).

Simultaneous recordings were made of the applied load, displacement and x-y translation of the femur. Specimens were tested intact and after simulating the fractures in neutral, 10° abduction, and 10° adduction; in turn, each of these positions was tested in fixed angles of 0, 20, 40, 60, and 80°. A specimen was considered stable if no dislocation occurred during the loading to 800 N. To evaluate contact stresses in the hip joint, pressure sensitive film was placed in the joint, and the resulting pattern of loading was correlated with the fracture type and position of the hip joint.

RESULTS—The results demonstrated that transverse fractures into a roof-arc angle of 90° do not affect the weight-bearing position of the acetabulum. Fractures with a roof-arc angle of 60° began to infringe on the weight-bearing area, and those with roof-arc angles of less than 60° are clearly in the weight-bearing region. Hip stability was significantly affected by the roof-arc angle and by the interaction of the roof-arc angle and the angle of hip abduction or adduction.

FUTURE PLANS—Another series of experiments examining different ranges of both flexion angles and roof-arc angles is currently underway to better define the true weight-bearing portions of the acetabulum.

RECENT PUBLICATIONS FROM THIS RESEARCH

In vitro stability and contact stresses of the hip following simulated acetabular fractures. Thomas KA, Noble JW, Vrahas MA, Reid JS, Bearden CM, Guzman MA. In: Transactions of the Orthopaedic Research Society; 1995 February, Orlando FL.

[39] BIOMECHANICAL ANALYSIS OF NONREAMED TIBIAL INTRAMEDULLARY NAILING AFTER SIMULATED TRANSVERSE FRACTURE AND FIBULECTOMY

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Sponsor: *None listed*

PURPOSE—As a continuation of a previous study on the effect of fibulectomy on loading of the tibia, a model was developed to simulate transverse tibial shaft fractures. The model was used to evaluate the patterns of loading across a diaphyseal fracture under various conditions, including the changes in loading after fracture fixation with an intramedullary (IM) nail and the changes due to partial fibulectomy.

METHODOLOGY—Cadaveric lower extremities were instrumented with three pairs of strain gauges on the anteromedial, arterolateral, and posterior aspect of the tibia at about the middle of the tibial shaft. Each pair of strain gauges was separated by approximately 20 mm to allow the simulated fracture to pass between the strain gauges. Using a servo-hydraulic testing machine, loading was applied through the proximal tibia with the ankle and subtalar joints held in neutral flexion-extension and neutral inversion-eversion. Each specimen was tested under six conditions: intact tibia, intact tibia with IM nail, fractured tibia without IM nail and intact fibula, fractured tibia with IM nail and intact fibula, fractured tibia with IM nail after fibulectomy, and fractured tibia without IM nail after fibulectomy.

RESULTS—Creation of the fracture was found to cause significant decrease in the loading across the anterolateral and anteromedial tibia. Placing the IM nail was shown to counter these changes, with an increase in loading across the anterior aspects of the tibia. With an IM nail in place, the effect of fibulectomy was minimal. In the fractured tibia without an IM nail, the effect of a fibulectomy was to increase the loading of the anterior tibia, as was demonstrated in the previous study. The results of this study demonstrate the redistribution of the applied loading after an IM nail is placed across a simulated transverse fracture and explains how the nail can promote healing across the fracture site. There was no benefit to performing a fibulectomy in the presence of an IM nail.

RECENT PUBLICATIONS FROM THIS RESEARCH

Biomechanieal analysis of nonreamed tibial intramedullary nailing after simulated transverse fraeture and fibulectomy. Thomas KA, Bearden CM, Gallagher DJ, Hinton MA, Harris MB. Orthopedics. In press.

[40] QUANTITATIVE FUNCTIONAL ANATOMY OF THE UPPER LIMB

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Sponsor: *None listed*

PURPOSE—We are collecting musculoskeletal parameters for the shoulder and arm for biomechanical modelling of the upper limb. Many 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 directly studied, but needs the application of a 3-D biomechanical model. In addition, the 3-D nature of upper limb motion and the covert motions of the scapula require a highly sophisticated 3-D analysis. Quantitative data on the morphology of shoulder and arm are needed as a basis for analysis of the load on the shoulder and arm, based on arm movement registration in wheelchair propulsion, activities of daily living and vocational activities; analysis of the outcome of shoulder arthrodeses; and 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 centre of the glenohumeral joint. Also collected were data on muscle morphology such as muscle mass, in a physiological cross sectional area, for 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 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. Morphological data on previous research are now available at http://www-mr.wbmt.tudelft.nl/schouder/dsg/dsg.info.html.

RECENT PUBLICATIONS FROM THIS RESEARCH

Quasi-static analysis of muscle forces in the shoulder mechanism during wheelchair propulsion. Van der Helm FCT, HEJ Veeger. J Biomech 1996:29(1):39–52.

Geometry parameters for musculoskeletal modelling of the arm. Veeger HEJ, Yu B, An KN, Rozendal RH. J Biomech. In press.

B: Human Locomotion and Gait Training

[41] GAIT MECHANICS OF THE PARTIAL FOOT AMPUTEE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A861-RA)*

No report was received for this issue.

[42] QUANTITATIVE POSTUROGRAPHY: OPEN-LOOP AND CLOSED-LOOP POSTURAL CONTROL MECHANISMS IN PARKINSON'S DISEASE, INCREASED MEDIOLATERAL ACTIVITY DURING QUIET STANDING

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PURPOSE—Idiopathic Parkinson's Disease (IPD) is a common neurodegenerative disease of later life. The clinical hallmark of advanced IPD is postural instability, which can result in significant morbidity due to falls, associated injury, and functional impairment. Despite the morbid consequences of this problem, the postural dyscontrol associated with IPD remains a poorly understood phenomenon. The objective of this study was to use stabilogram-diffusion analysis to gain an increased understanding of these postural impairments.

METHODOLOGY—We obtained clinical data from 22 subjects with IPD and 24 nonimpaired elderly subjects. The two groups were matched for age and gender. The postural stability of each individual was evaluated by using a force platform to measure the movements of the center of pressure (COP) under their feet. The individuals were tested under eyes-open conditions for multiple 30 s trials. The COP trajectories were parameterized according to stabilogram-diffusion analysis. Standard statistical analyses were used to compare the results from the IPD subjects with those from the nonimpaired.

PRELIMINARY RESULTS—We found that the postural control mechanisms in the IPD subjects, compared to the nonimpaired elderly, were characterized by an increase in the effective stochastic activity in the mediolateral direction. We also found that the mediolateral posturographic measures were associated with a history of falls and poor performance on clinical measures of balance. We hypothesize that the increase in mediolateral activity in subjects with IPD may reflect an attempt to maintain potentially stabilizing movements during quiet standing in the face of impaired movement in the anteroposterior direction. This study supports the notion that mediolateral instability is an important posturographic marker of functional balance impairment in the elderly.

RECENT PUBLICATIONS FROM THIS RESEARCH

Open-loop and closed-loop control mechanisms in Parkinson's Disease: increased mediolateral activity during quiet standing. Mitchell SL, Collins JJ, De Luca CJ, Burrows A, Lipsitz LA. Neurosci Let 1995:197:133–6.

[43] QUANTITATIVE POSTUROGRAPHY: A PINNED POLYMER MODEL OF POSTURE CONTROL

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PURPOSE—The objective of this project was to use techniques of nonequilibrium statistical mechanics to study the time-varying displacements of the center of pressure (COP) under the feet of quietly standing subjects. It had been previously shown by our group that the two-point correlation function (stabilogram-diffusion plot) of the COP trajectory

exhibits three distinct scaling regions. A theoretical model which explained these regions was developed.

METHODOLOGY—Guided by the posturographic data and the biomechanical constraints of the human body, a stochastically driven equation to model posture control was derived. This equation considered the upright body to be a stochastically forced "pinned polymer" (i.e., a flexible string under tension). The pinning represents the neuromuscular forces needed to keep the body upright. The stochastic forcing represents the inherent noisiness of the system. The resulting equation is completely solvable analytically.

PRELIMINARY RESULTS—The model reproduces the two-point correlation function of the experimental data. In particular, the scaling exponents and break points between the scaling regions were determined. The model provides a starting-off point for future theoretical analysis of the posture control system, including the connection between static and dynamic posture control.

RECENT PUBLICATIONS FROM THIS RESEARCH

Pinned polymer model of posture control. Chow CC, Collins JJ. Phys Rev E 1995:52:907–12.

[44] QUANTITATIVE POSTUROGRAPHY: A QUANTITATIVE ANALYSIS OF STATICS AND DYNAMIC POSTURE CONTROL

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PURPOSE—The bulk of recent research in posture control at the NeuroMuscular Research Center has concentrated on static posture control. However, many falls are a result of an external perturbation and thus, understanding dynamic posture control could be important. We hypothesize that the two modes of posture control are inherently connected. The objective of this study was to test this hypothesis.

METHODOLOGY—The pinned polymer model provides a theoretical model to analyze posture control. The dynamic response to perturbations can be computed explicitly from the model. The parameters of static posture control obtained from the two-point center of pressure (COP) correlation function (stabilogram-diffusion plot) can be related to the properties of the dynamic response function, which gives the essential information about dynamic posture control. The response function can be obtained by experimentally measuring the COP motion immediately following a perturbation.

PRELIMINARY RESULTS—The shape of the response function calculated from the pinned polymer model is fully determined by the parameters of the two-point COP correlation function. This connection is a result of the Fluctuation-Dissipation Theorem of statistical mechanics. Both quantities can be experimentally measured independently and then compared to the theoretical predictions. Preliminary experimental data support the hypothesis that static and dynamic posture control are fundamentally linked.

[45] CHARACTERIZING POSTURAL STABILITY IN RELATION TO AGE AND SUSCEPTIBILITY TO FALLING

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PURPOSE—Older adults exhibit problems in posture and balance. These disorders predispose the elderly to falls, which are their most common cause of trauma and the largest single cause of accidental death. Despite the severity and frequency of this problem, postural instability in the elderly remains a poorly understood phenomenon. The objective of this study was to evaluate the ability of the multisegmental posturographic technique to identify age-related changes in posture control.

METHODOLOGY—We examined 20 nonimpaired young subjects (21–30 years) and 20 nonimpaired elderly subjects (71–80 years). Each subject was instructed to stand in a standardized position on a force platform, which measured the displacements of the center of pressure under the feet. Simultaneously, an ELITE motion analysis system and linear variable differential transformers measured the movements of body segments, and electromyographic (EMG) signals were recorded from five lower-limb muscles. Multiple 60-s trials were conducted on each subject.

PRELIMINARY RESULTS—We found that there were no significant differences between the two groups for the quiet-standing fluctuations at the ankle, knee, and hip. However, we found that the elderly subjects exhibited significantly larger fluctuations at the head and shoulders during quiet standing. In addition, we found that the correlated structure of the organizational strategy utilized by the quasi-static postural control system was diminished in the elderly subjects. Finally, we found that the elderly subjects exhibited significantly greater lower-limb muscle activity during quiet standing. These findings clearly indicate that the multisegmental posturographic technique can be used to quantify the physiological effects of aging on the mechanisms involved in regulating quiet-standing balance.

[46] SYNTHESIS OF A SIMPLE BALLISTIC WALKING MOVEMENT WITH PUSH-OFF

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Sponsor: *Delft University of Technology*

PURPOSE—In this project ballistic walking is considered to be the most fundamental, and therefore the most revealing, approach to bipedal walking. Ballistic walking also brings practical advantages, like energy saving properties and simple mechanical realization. These are primary aspects for successful applications in rehabilitation technology. The goal of this research is to obtain a method of synthesis with which a desired three dimensional bipedal walking movement can be constructed. This is to result in an autonomous prototype biped, which is to be robust for small disturbances. Also, concepts for a renewing hip orthosis are to be developed.

METHODOLOGY—Theory and practice support one another in order to form a firm basis of insight. Bifurcation theory gives insight in the influence of system para-

meters on the dynamics of the mechanical oscillating bipedal system, and stability can be quantified. This analysis is to be performed with the aid of numerical computer force. Experimental setups provide reliable information of all effects of parameter variation with respect to periodicity and stability. This mutual pollination of a theoretical and practical approach provide information which would not be found if both approaches were handled individually.

PROGRESS—A mathematical model of a simple bipedal walking movement is built gradually. Each effect of a model extension is to be studied in order to expose its effect on system behaviour. Simultaneously experiments are performed to verify theoretical validity. These actions build a toolbox which is to result in a method for synthesis of a desired ballistic walking movement.

PRELIMINARY RESULTS—A working prototype biped already has been constructed and is capable of stable three dimensional walking on a horizontal surface. The ballistic walking motion is actuated solely by a periodic push-off, which is active for only one-forth of a step cycle. This makes the specific energy consumption per unit time 6.5 W/kg. Because of the present small step width 3.5 mm, the specific energy per unit distance amounts to 100 W/kg.m. Improvements on step width as well as on robustness for external disturbances are currently in development.

[47] DEVELOPMENT OF A SYSTEM TO AID ORTHOPAEDIC SURGICAL DECISION-MAKING IN CHILDREN WITH CEREBRAL PALSY THROUGH PREDICTION OF POST-SURGICAL GAIT PATTERNS

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Sponsor: *The Easter Seal Research Institute*

PURPOSE—Cerebral palsy (CP) is a nonprogressive neurological disorder that has many effects, including a resulting difficulty in walking due to improper control of muscle activity via the central nervous system. Individuals with this disorder tend to have spastic or hypertonic activity of some muscles, improper sequencing of muscle activation, reduced range of joint motion, walking patterns which are more variable than nondisabled persons, and higher energy requirements for walking. In order to compensate for the effects of CP, orthopaedic surgery is used to modify the lengths and/or position of lower-limb muscles and tendons to reduce the exaggerated muscle activity in the hope of uncovering the normal sequence of muscle activity.

In order for the best possible outcome of surgery to be realized, there is a need for physicians to have objective criteria by which to analyze walking patterns and decide on the type of intervention for individual patients. The purpose of this project is to develop a computer software tool that would be used to assist surgeons in planning orthopaedic surgery specific to CP. The software tool will give surgeons the ability to predict the results of their surgery by seeing hypothetical walking patterns from hypothetical surgical decisions.

METHODOLOGY—It is hypothesised that there exist relationships between the presurgical walking patterns, postsurgical walking patterns, and surgical intervention. Identification of these relationships will allow for the prediction of surgical outcomes in the form of a predicted postsurgical walking pattern. Through the use of a combination of quantitative motion analysis, engineering mechanics, electromyography, numerical optimization techniques, simulation of mechanical systems, and computerized artificial neural networks, the development of a system to identify and utilize the relationships should be possible.

Such a system is required to predict the mechanical affects of either lengthening and/or transfer of muscle by a developing a detailed dynamic musculo-skeletal simu-

lation model of walking, and to predict the change in muscle activity patterns that would result due to surgery by developing a computerized model to relate presurgical muscle activation patterns, postsurgical muscle activation patterns and surgical intervention variables. To dynamically simulate walking, a biomechanical model will be developed to include rigid-bodies, 3-DOF linkages, and multiple 1-DOF muscle actuators; this will provide a framework to input muscle activation patterns which drive the system. The second model to predict changes in muscle activation patterns will be developed through a database of individuals with cerebral palsy and electromyography (muscle activation) records of both pre- and postsurgery. A model will be developed based on the use of computational technique known as artificial neural networks; the technique will enable convergence to a model that relates the multitude of variables between surgery and presurgery electromyography (input) and postsurgery electromyography (output).

PROGRESS—The project is just getting under way.

[48] EFFECT OF AN INDUCED LEG LENGTH DISCREPANCY ON GAIT BIOMECHANICS

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PURPOSE—We seek to better understand the physiologic factors involved in the compensation for the inequality of lower limb lengths, and we are working to document at what levels of leg length inequality does compensation at the hip occur, and what overall changes occur in the mechanics of gait. With this information, pathologic changes that occur in the hips, lower back, and lower limbs due to compensation for leg length inequality may be better understood. This may facilitate inferences on effective treatment options.

METHODOLOGY—Six to 10 nonimpaired subjects with documented normal leg length (using both the ASIS to floor method and ASIS to medial malleolus methods to assure no structural or functional pre-existing pathology) will be tested by completion of the study. Many have studied the clinical assessment of degree of leg length discrepancy, and we choose the ASIS to medial malleolus because it seems to be the most rigorously tested; although some claim that ASIS to lateral malleolus can detect functional leg length inequalities, this technique has not been as well proven in the literature. Two mechanisms of leg length discrepancy are used: 1) a tapered heel (variable thickness with maximum thickness of 1/2 inch at the heel) lift is placed in one shoe, and 2) a full shoe, constant thickness of 1/2 inch lift is placed under the shoe. Each subject is given a chance to accommodate to the test condition before data is recorded. The subject is tested without any orthotic as well. Temporo-spatial foot fall parameters (such as stride lengths and times, stance/swing lengths and times, step lengths, and walking velocity) as well as ipsilateral hip, knee, and ankle kinematics and kinetics are recorded. Upon completion of the test session, the subject is given the partial lift to wear during all activities for 2 to 3 weeks. Each subject is then retested as outlined above in just the heel lift and no lift conditions.

PROGRESS—This is the first year of the study. Several subjects have been tested to date; testing is ongoing.

PRELIMINARY RESULTS—There appear to be statistically significant differences in lower limb kinematics and kinetics of the longer limb. Differences are noted between the lifted limb and same limb when no orthotic is used to induce a leg length discrepancy, as well as between the lifted limb before and after the accommodation period. An insufficient number of subjects has been tested so far to be able to speculate about trends in the methods of compensation.

FUTURE PLANS—The following questions need to be answered: What are, if any, the differences between short

term changes and long term changes in the biomechanics of gait in compensation of leg length discrepancy? What is it about leg length discrepancy that leads to pathologic changes in the hip and back? What is the clinical end point for treatment: clinical symptoms, a fixed length discrepancy, or both depending on activity level of patient, or documented changes in biomechanics of the spine or hip?

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

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PURPOSE—Following the idea that more may be obtained from less, we have developed an economical single marker direct ultrasound ranging system (DURS) for the quantitative evaluation of ambulation.

METHODOLOGY—The DURS operates by emitting an infrared pulse at a frequency of 22 Hz from a base unit to a transponder worn by the subject. This transponder is triggered by the infrared pulse and emits an ultrasound pulse back to the base unit. The time of flight of light over these distances is essentially instantaneous but the speed of sound is not. The base unit measures the time difference between the emitting of the infrared pulse and the arrival at the base unit of the ultrasound pulse. By calibrating for the speed of sound in air, this time difference is then converted into a measurement of the distance between the base and transponder units. These distance samples are then stored in a computer and processed through a differentiation algorithm to obtain an estimate of the horizontal velocity, in the plane of progression, 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—The prototype DURS completed last year has been extensively modified to further simplify its operation and reduce the number of components required. This new prototype is interfaced with a laptop computer via the serial port. Calibration for the speed of sound is achieved by measuring the air temperature and known distance and adjusting the hardware until this distance registers. The velocity is computed from the distance data using a three-point differentiator, implemented in software. A time averager is also used to smooth the velocity data as the process of differentiation tends to enhance discontinuities and sharp edges.

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 D.U.R.S. was consistently within 3 percent of the gait speed determined from the CODA 3 system. The new prototype can accurately measure distance out to 13 meters with a mean error over that range of about 1 mm. The distance limitation is now no longer due to hardware and signal strength limitations but rather due to the distance sound can travel within the designated sample interval.

FUTURE PLANS—The software will be improved to incorporate the algorithms for single marker gait being developed at our laboratory by Dr. Richmond Chan. Changes will also be made in the software to further simplify the devices set-up, calibration, and operation.

RECENT PUBLICATIONS FROM THIS RESEARCH

The development of a direct ultrasound ranging system for quantification of human ambulation (thesis). Licameli J. Evanston, IL: Northwestern University, 1995.

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

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PURPOSE—This project evaluates the value of using lower limb joint torque, energy, and power for diagnosing primary motion disorders, making clinical intervention decisions, estimating long-term prognoses, and assessing disability levels. A related measure is musculotendon length. Knowing the behavior of muscle length can help to model the torques, energies, and powers observed.

METHODOLOGY—We first examined the clinical utility of determining mechanical energy during gait analysis studies in subjects with cerebral palsy (CP). Secondly, we launched an investigation into the behavior of muscle length and tension of the lower limbs and how various surgical and bracing treatments affect this behavior, as well as how musculotendon length could be used in the modeling of joint torque, moment, and power.

PROGRESS—To evaluate the clinical usefulness of quantifying lower extremity mechanical energy in determining efficacy of orthopedic interventions in CP, we conducted a retrospective study comparing pre- and posttreatment quantitative gait analysis in subjects with gait abnormalities residing in the sagittal or transverse planes. The pre- and posttreatment studies of each patient were compared to determine treatment efficacy. Joint powers and energies were calculated as described by Winter. These data were evaluated and compared to the other gait data to assess whether complementary or redundant information was being provided.

Using a software package that includes a model of the lower limb and following appropriate modeling of the kinematics of each of the joints of the lower limb, we have determined the kinematic and kinetic information with respect to the musculotendon units of interest at different joint positions. We have assessed the effects of all the input and output parameters of the software package with a variety of experimentation schemes to evaluate the response of the program and identify its limitations. Our sensitivity analysis indicates that the length and force outputs determined for each individual musculotendon unit are the most acceptable variables to be investigated.

We have also been able to modify the kinematic output of our standard laboratory motion data to achieve compatibility with this software package. Such modifications have allowed us to use our already existing database as well as information collected from recent studies in an effort to combine presurgery and postsurgery data to investigate the effects of musculotendon unit lengthening.

RESULTS—When a change in velocity was compared with the change in energy, three groupings emerged: 1) a large change in velocity with a small change in energy, 2) a moderate change in both velocity and energy, and 3) a small change in velocity with a large change in energy. These patient groupings were based on the initial position of the lower limb at heel strike and ability to compensate for abnormal positioning during stance based on examination of motion and EMG data. We found that mechanical energy analysis calculated from routine gait study measurements is complementary to other gait data and useful for determining the efficacy of orthopedic interventions.

We are currently proceeding with the incorporation of motion data from gait evaluations from patients with CP who have decided to undergo different treatment procedures to determine the effects of these treatments also. We currently combine the output of the program to investigate the changes in strength of the affected musculotendon units. Our initial results indicate that surgery, and in particular musculotendon lengthening, has the most dramatic effects. Future efforts are focused on validating this finding with more studies.

[51] 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—This project involves the continuing development of a diagnostic and treatment expert system for the interpretation of walking disorders leading to disability. Over the past decade, research efforts have been developing tools to objectively assess human gait performance. 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 a generic task theory from artificial intelligence to identify and define the subtasks involved in gait analysis: 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 are tools for identifying significant findings with respect to joint angle graphs, range of motion, time and distance data, and EMGs. We have programmed additional functions that can be used to pull information from the AI decision support tools into a report. We have also written code to determine the muscle faults associated with a particular deviation, and we are currently developing the interface to integrate this function into the interface. There are also some smaller related tasks that are being added such as the ability to sort findings according to importance where that importance is based on several factors such as magnitude of deviation, length of time that the deviation occurred, and qualitative factors concerning the finding's relation to other findings detected.

RESULTS—Providing a single place for data to reside for gait analysis is proving to be quite a useful concept for both teaching gait analysis and facilitating clinical report generation. The decision-aid tools that have been provided up to this point seem to be useful and fairly accurate. Another benefit to this line of research is the ability to easily explore other methods of accomplishing subtasks of gait analysis and comparing the results (as we are currently investigating in the case of motion deviation determination). This eventually leads to a better method for performing gait analysis as well as better support for the people currently doing (or learning to do) gait analysis.

FUTURE PLANS—We are working to add new functionality to the system based on other research into the clinical significance of data analysis types for gait analysis. As we determine new categories of findings based on our research into torques, powers, moments, time/distance parameters, and the like, decision-aid tools will be developed and added to the system. These tools will improve both the functioning of the system as well as our understanding of the process of gait analysis.

RECENT PUBLICATIONS FROM THIS RESEARCH

Applications of intelligent multi-media technology in human motion analysis to appear in human motion analysis. Simon SR, Smith PJ, Smith JW et al. In: Harris GF, Smith PA, eds. Current applications and future directions. New York: IEEE Press. In press.

Gait III: a system for gait analysis. Johnson K, Denning R, Smith PJ, Smith JW, Simon SR. In: Proceedings of the 19th Annual RESNA Conference; 1996, Salt Lake City, UT. Washington, DC: RESNA Press. In press.

Gait III: a multimedia system for gait analysis. Johnson K, Denning R, Smith PJ, Smith JW, Simon SR. Gait Posture 1996:4:195–6.

[52] 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, the goal of this project is to develop a computer-based tutoring and report-generation system. This system can be used to help orthopaedic 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 Analysis Instructional Tool (GAIT) 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. This system is being subjected to preliminary formative evaluations using orthopaedic residents and physical therapists and 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 on patient 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.

The system uses data directly from the gait analysis laboratory. The data that can be viewed on-line includes: medical history, physical exam, time/distance data, joint angle graphs, moment graphs, power graphs, force plate graphs, EMGs, Quicktime video, and animated stick figures.

Each screen of data may be annotated in a manner appropriate to the type of data. Text screens provide the capability to change the typeface and color of the text. The colors that are made available have been chosen for saturation and depth so that they are distinctly identifiable when printed on a grayscale printer.

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

Applications of intelligent multi-media technology in human motion analysis to appear in human motion analysis. Simon SR, Smith PJ, Smith JW et al. In: Harris GF, Smith PA, eds. Current applications and future directions. New York: IEEE Press. In press.

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Gait III: a multimedia system for gait analysis. Johnson K, Denning R, Smith PJ, Smith JW, Simon SR. Gait Posture 1996:4:195–6.

[53] CENTRAL MECHANISMS FOR MOMENTUM GENERATION DURING GAIT INITIATION AND THEIR DEGRADATION WITH NONIMPAIRED AGING

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PURPOSE—During gait initiation, the center of pressure (COP) under the feet moves backward and toward the foot which is to be lifted first, before any appreciable movement of the body's center of mass. Although this movement has been shown to be controlled by centrally programmed motor commands, its functional significance has remained unclear. The objective of this project was to determine the functional significance of the initial shift of the COP and to study how the motor control and biomechanical factors involved in gait initiation change with aging. The information derived from this study could eventually be utilized in the development of a clinical technique for evaluating and characterizing posture and movement disorders.

METHODOLOGY—We examined 20 nonimpaired young subjects (18–29 years) and 20 nonimpaired elderly subjects (64–80 years). Subjects initiated walking under three different speed conditions (slow, normal, fast) from a force platform, which measured the ground reaction forces and displacements of the COP under their feet. Simultaneously, an ELITE motion analysis system measured the movements of the body segments, and electromyographic (EMG) signals were recorded from three lower-limb muscles.

PRELIMINARY RESULTS—We found that the functional significance of the initial COP shift is to generate, in a stable manner, the momentum needed for gait initiation. We also found that in nonimpaired older adults, the gait-initiation motor program is expressed less frequently and the momentum-generating capacity of the COP-shift mechanism is significantly diminished. These findings suggest that the central nervous system employs stable, efficient mechanisms for dealing with the inherent instability of upright bipedalism and that the integrity of these mechanisms degrades with aging.

[54] ASSESSMENT OF VARIABILITY IN HUMAN WALKING

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PURPOSE—The purpose of this project is to expand on existing variability models in gait analysis.

METHODOLOGY—This project has had its primary activity in modeling human walking. During 1994-95, this activity was also applied to other activities. Some of the data were gathered in the Forest Machine Simulator project, and the technology was also applied to upper limb motions during the time the principal investigator was on sabbatical.

The core activity is to develop general purpose "bootstrap" and error estimation models that can be applied to many different types of data. The general purpose bootstrap routines now existing in their original form in FORTRAN and in MATLAB, allow assessment of prediction regions for time series data without resorting to any particular type of analytical model. Bootstrap methods work by taking an original data sample and resampling it to improve the estimate of various sorts of statistical measures. The technique involves taking a group of time series that are to be modeled as the mean and a prediction region around it. The only constraint is that the vectors must be of consistent length. Processing is then done on a time slice basis. The output of the model is a mean value for the group of time series and a boundary around the mean that can be set to enclose any desired fraction of new time series which may come into the study. This has had particular application in gait analysis where the patterns of motion for walking are well defined and an individual being tested can be compared to "normal."

PROGRESS—The new applications in the past year involve applying the same sort of techniques to movements of the upper limb.

Related to this project is a joint effort with the Children's Rehabilitation Centre in St. John's Newfoundland, which will use the bootstrap information along with a modified version of the San Diego Children's Hospital Gait Analysis software to analyze walking data for children.

FUTURE PLANS—The laboratory is currently in the midst of acquiring a VICON Motion Analysis System and will use it in both upper limb and gait studies. The initial objectives are to characterize amputee movement patterns while doing desktop tasks, to assess joystick use in heavy equipment applications, and to assess gait in low tone children undergoing bracing.

[55] MEASUREMENT OF GROUND-FOOT REACTION FORCE TO DETERMINE GAIT ASSYMMETRY USING A COMPUTER-BASED TELEMETRY SYSTEM

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PURPOSE—The objectives of this research are: to develop a computer-based data acquisition telemetry system for the continuous monitoring of ground foot forces (GFF) to test this system on nondisabled subjects and on those with pathologic gait and to assess the reliability of the system for clinical use.

METHODOLOGY—The telemetry system is comprised of a mobile and a stationary component.

The Mobile Assembly consists of a pair of instrumented shoes, a force signal processing unit, and an FM transmitter. The instrumented shoes are flat-soled canvas, with force sensors attached to the metatarsal and heel of each sole. The force sensors form part of bridge/amplifier circuits, and their corresponding output sensor is amplified and multiplexed by time: division pulse: width: modulator (PWM). The PWM multiplexed signal is applied to the modulating input of the FM transmitter.

The Stationary Assembly is made up of an FM receiver, signal conditioning unit, frame synchronization and edge detector unit, pulse-width to digit converter, an intermediate memory storage, an RS 232C serial interface, a microcomputer, an analogue processing unit, and a strip chart recorder. The received output is applied to the signal conditioning unit where the pulses corresponding to the transmitted signal is recovered. This PWM multiplexed signal is converted directly to digital output by the pulse-width-to-digit converter. The purpose of the frame synchronization and edge detector unit is to synchronize the receiving end and transmitting end multiplexed signal and for channel identification.

The digital output is first stored in the intermediate storage memory before it is sent to the microcomputer for analysis. The output of the analogue processing unit is applied to the input of a chart recorder to obtain optional and alternative analogue display of the GFF data. This system works with any microcomputer with serial port.

RESULTS—The system has a maximum measurable groundfoot force of 100 kgf. The system has a range of 100 meters, while the bandwidth of each force signal extends beyond 50 Hz. The gait waveform obtained for normal subject was a true representation of well known patterns of GFF.

Pathological waveforms showed deviations from normal ones vis-a-vis the rate of loading and peak force normalized to body weight. In unilateral clinical condition, differences between the waveforms of the two lower limbs is indicative of gait assymetry.

FUTURE PLANS—The research project is ongoing. The next step is to incorporate a GPIB IEEE 488 parallel interface unit into the stationary assembly for faster data acquisition and simultaneous analogue display on the microcomputer during ambulation.

C. Other

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

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PURPOSE—The purpose of this 3-year continuation research program is twofold: 1) to investigate how wheelchair performance compares among three different age groups of disabled (lower-limb impaired) wheelchair users; and 2) to test a specific exercise intervention for its effectiveness in reducing potentially injury-producing biomechanical characteristics and excessive physiologic stresses.

METHODOLOGY—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 (stretching, strengthening, and aerobic training three times weekly for 6 weeks). Shoulder, elbow, and wrist joint kinetics (joint moments and joint reaction forces) are calculated from three dimensional motion and handrim force data. Changes with training are statistically tested using paired t-tests and a significance level of 0.05.

PROGRESS—A total of 15 subjects have now completed the study and 5 more have started initial testing; active recruitment of new subjects is continuing. Institutional Review Board approval for additional testing of nonimpaired subjects for database comparisons has been obtained.

PRELIMINARY RESULTS—Fifteen subjects (age 47±11 yrs; weight 80±19 kg; spinal cord lesion level T2–L5 and multitrauma; 12 male, 3 female; wheelchair users for 17±10 yrs) have completed the study. Biceps skinfolds increased (15.2 percent), yet no significant differences were evident in segment girths, body weight, body mass index, or total body fat as determined by a DEXA scan. Eccentric isokinetic strength increased for wrist flexors (54.0 percent), extensors (45.1 percent), and ulnar deviators (47.4 percent). Temporal changes were reflected in a decreased stroke frequency (6.6 percent) and increased contact time (17.7 percent). Kinematic changes included a 13.6 percent increase in elbow range of motion during the entire cycle, with more extension (8.0 percent unfatigued, 9.1 percent fatigued) and less flexion (5.5 percent unfatigued, 7.8 percent fatigued) during contact. The arm position at contact was in more elbow extension (8.4 percent). Maximum shoulder flexion during contact increased (44.3 percent unfatigued,

35.6 percent fatigued) and maximum shoulder adduction decreased (16.5 percent). Maximum trunk forward flexion during contact was increased by 9.9 percent in the fatigued condition. At release, the wrist was extended (3.8°) as opposed to flexed (9.6°); the elbow was more extended (8.1 percent unfatigued, 9.1 percent fatigued); the shoulder was more flexed (40 percent fatigued); and the trunk was more forward flexed (8.8 percent fatigued).

Kinetic changes included a change in the maximum vertical handrim force. Prior to training, vertical handrim force (69.4 N) was highest after fatigue. After training, the vertical force was lower with fatigue (64.8 N). The difference between fresh and fatigued vertical force decreased after training (−6.22 to 4.87 N). The tangential (effective) moment increased by 14.9 percent. Kinematic effects with training were greatest at the elbow, but also evident at the shoulder and trunk. Training induced improvements were evident in the increased contact time, decreased stroke frequency, increased effective moment, and decreased vertical handrim force.

FUTURE PLANS/IMPLICATIONS—Initial findings indicate that specific training for wheelchair users can improve wheelchair propulsion mechanics and decrease the probability of overuse injuries. Further investigation of joint stresses is continuing. Testing and exercise training will continue until the desired sample size is reached (n=60). Data from non-wheelchair users will be collected for comparison.

RECENT PUBLICATIONS FROM THIS RESEARCH

Wheelchair propulsion biomechanics. Rodgers MM. AAPT Announcer 1996:26(2):41.

[57] IN VIVO MEASUREMENT OF VERTEBRAL DISPLACEMENT AFTER LUMBAR FUSION

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PURPOSE—Posterior spinal fusion is performed for a large variety of clinical problems, including spinal trauma with spinal cord injury, degenerative changes of the lumbar spine, tumors, and scoliosis. Spinal instrumentation systems have increased the fusion success rate. However, this increased rate comes attendant with higher risks of device-related osteoporosis, as well as accelerated degeneration of adjacent vertebral levels near a stiff fusion segment. To date, there are no data on the absolute mechanical environment that leads to fusion and/or nonunion of the spine. In this study, we propose to characterize and quantify the biomechanical environment in which a lumbar spine fusion occurs in a goat model.

METHODOLOGY—An implantable transducer system to measure intervertebral motion has been developed. Motion will be measured *in vivo* and compared in normal, injured, and surgically fused spines. Fusion using bone graft alone and bone graft augmented by rigid or semirigid spinal instrumentation will be compared. The mechanical data will be correlated with radiographic and histologic evaluation of fusion quality and vertebral body density.

In Phase 1, cadaveric goat spine specimens were tested *ex vivo* to determine displacement across L4-5 using a new transducer system based on Hall-effect devices. The transducers were calibrated by simultaneous measurement of displacement with extensometers. In Phase 2, Hall-effect transducers were implanted across the normal and destabilized L4-5 disc space of live goats. The output of the transducers was measured periodically in a variety of postures, exercises, and manipulated positions for 6 to 12 weeks. The animals were then sacrificed, and the transducer systems recalibrated by testing the excised spine on the MTS machine.

In Phase 3, three experimental treatment groups were similarly studied. Surgery included laminotomy, resection of the facet capsule and the ligamentum flavum,

and transducer implantation in all groups. A posterolateral bone graft fusion across L4–5 was performed in Group I. Group II had the fusion augmented with a semirigid pedicle screw device. In Group III, a rigid pedicle screw system was implanted.

PROGRESS AND RESULTS—All 3 phases of the study have been completed. Data have been used to quantify the surgical artifact of the sensor implantation surgery. The passive range of motion of a spinal segment, controlled by osteo-ligamentous structures has been found to be 2 times greater than the motion under normal muscular control in the spine. Destabilizing injury to posterior ligaments increased these ratios by 30 to 100 percent. While the passive characteristics of spinal motion, including neutral zone and range of motion are controlled by osteo-ligamentous limits, functional motion occurs in a portion of that range that is determined by muscular response to neural systems, or the active subsystem of the spinal column. All of the animals with rigid fixation achieved boney arthrodesis, compared 83 percent of the animals in the semirigid group. The stiffness of the fused segments in the semirigid group, however, was greater in all modes of loading, than the fusion with rigid instrumentation. This indicates that rigid instruments improve the rate of fusion, but load stimulation of bone growth with semirigid implants is important to long-term stiffness and strength of the fusion. Muscular control limited intervertebral motion with semirigid implants to a level less than that observed with rigid implants during active exercises, while passive motion allowed by the semirigid system exceeded passive motion allowed by the rigid implants. Muscle action therefore is very important to spinal stability and healing in surgical treatment of the spine.

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

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

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

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

PRELIMINARY RESULTS—We examined 10 nonimpaired young subjects (21–30 years) using the above protocol. In this first set of experiments, each was tested under unloaded conditions. We found that in the anteroposterior and mediolateral directions, respectively, the size of the COP shift was highly correlated with the amount of momentum generated. We also found that the size of the backward COP shift was highly correlated with walking speed. We hypothesize that these relationships will change under loaded conditions, indicating that individuals utilize alternative strategies for dynamic balance control while carrying loads. This hypothesis will be tested in a future study.

[59] A MODEL FOR THE "DYNAMIC" POSTURAL CONTROL SYSTEM

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

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

PRELIMINARY RESULTS—We found that with the addition of low levels of noise, the values of active stiffness (arising from activated postural muscles) needed to stabilize the posture model could be reduced. Importantly, high levels of noise destabilized the model, causing it to fall. These findings suggest that physiological noise, under certain circumstances and in certain amounts, can play an important and beneficial role in the maintenance of quiet standing.

[60] SEATED AND RELATED POSTURAL DEVICES FOR ELEMENTARY SCHOOL ENVIRONMENTS

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

PURPOSE—The purpose of this project is to develop school furniture that uses universally accessible design features. We plan to identify consumer needs and the issues related to posture and school work to design and develop furniture that can be used by most children with or without physical disabilities.

PROGRESS—The first phase is underway and involves applying qualitative methodologies to acquire information regarding the product needs of consumers. The consumer groups include: teachers, teacher assistants, principals, occupational and physical therapists working in schools, educational consultants, parents, and children. We are also reviewing the relevant literature and conducting a comprehensive product search of ergonomically designed school furniture. We have identified two steps for this first phase. In step one, we are conducting nonstructured interviews with a small number of key informants, representing the various groups we have identified. We are exploring their views about school furniture and the needs of the students in relation to the priorities set by the schools and school boards. In step two, we will develop a survey protocol using the relevant variables identified by the key informants and issues discussed in the literature. We plan to create a self-report questionnaire that will be sent to over 200 consumers across Ontario. The survey findings will be analyzed to determine trends and to establish major consumer needs and issues.

FUTURE PLANS—In the second phase of this project, we will focus on developing and evaluating design concepts for two products. The survey findings will be used in two ways. First, they will be formulated into consumer objectives to guide the design process. Secondly, a consumer-based evaluation tool will be developed. We believe that this tool will help consumers to focus on key issues for school furniture design and assess the various features of the design. Consumers will be invited to participate in 3–4 regionally based focus groups to evaluate existing school furniture products using the evaluation tool. These sessions will include consumers from the groups identified above. The issues and opinions raised in the focus groups, combined with the consumer objectives, will be incorporated into preliminary design criteria for this project to provide directions for the development of furniture design concepts and presentation models. The outcomes of the focus groups will also help to examine the validity of the consumer objectives and the items included in the consumer-based evaluation tool. Design concepts and simple models will be taken to consumer focus groups for evaluation. By spring 1997, we will have developed and evaluated models for each of two new classroom products.

[61] ISOMETRIC LENGTH FORCE CHARACTERISTICS OF PENNATE MUSCLES DURING AND AFTER SHORTENING: EXPERIMENTAL AND MODELING RESULTS

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PURPOSE—The purpose of this project was to study effects of shortening history on isometric length force curves of pennate muscle and model muscle geometry and its functional effects.

METHODOLOGY—Variables of muscle geometry (i.e., fiber length, aponeurosis length, and fiber and aponeurosis angles) were determined during maximal activition. Isometric length-force curves were determined without previous shortening and after shortening over different length ranges at a number of shortening speeds. A Finite Element (FE) model was constructed that takes into account muscle fiber properties as well as aponeurosis and tendon properties and the mechanical interaction of these variables.

RESULTS—After previous shortening, length-force characteristics of maximally active rat medial gastrocnemius muscle differ very substantially from that determined in fully isometric contractions. Particularly at or over optimum length attained after low speed shortening, muscle force is decreased compared to the fully isometric case. Actual isometric length force properties can be constructed by connecting points of different curves according to shortening history. Negative length-force slopes found in the fully isometric condition are not present at lengths well over optimum length. FE modelling shows that a secondary distribution of fiber mean sarcomere length develops on activation through mechanical interaction of fibers and elastic components. FE modelling could not predict either fully isometric or shortening history influenced length force curves, due to a primary distribution of fiber mean sarcomere length.

IMPLICATIONS—Due to alterations of length-force curves it is not appropriate to consider actual force delivered by a muscle as a result of combination of a fully isometric length force curve and a force-velocity curve.

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[62] EVALUATION OF DUAL BAND GRAFTS FOR ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

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Sponsor: *None listed*

PURPOSE—The human anterior cruciate ligament (ACL) consists of at least two distinct bands. Techniques currently employed in ACL reconstruction do not attempt to recreate these two bands; instead, a single band of tissue is placed in an isometric position. These procedures do not emulate the natural ACL and restore normal knee kinematics, as evidenced by the degenerative arthritis experienced by some patients after reconstruction. The purpose of this study was to measure the changes in length of the anteromedial (AM) and posterolateral (PL) bands of the intact ACL and to compare these with six different techniques of ACL reconstruction.

METHODOLOGY—Fresh-frozen cadaveric knees were used in this study. To quantitate the changes in length of the bands of the ACL or grafts, miniature displacement transducers were placed in the tissues. Continuous recordings were made of the shortening or lengthening of the ligament or graft tissues, and of the angle of knee flexion over the range of 0–120°. The graft techniques evaluated were either single or double hamstrings or split bone-patellar tendon-bone (B-T-B) graft. Fixation of the graft was by interference screws for the B-T-B grafts and by post fixation for the hamstring grafts. Single or double tunnels for graft placement in the femur or tibia were used, with the tissues tensioned separately at 90° of flexion (AM band) and at 0° of flexion (PL band). The graft techniques included: (1) dual hamstrings with two femoral and two tibial insertions; (2) dual hamstrings with one tibial and two femoral insertions; (3) dual hamstrings with one femoral and two tibial insertions; (4) dual hamstrings with one femoral and one tibial insertion; (5) single hamstrings graft with one femoral and one tibial insertion; and (6) split B-T-B graft with one femoral and two tibial insertions.

RESULTS—Testing of the ACL reconstructions employing single tunnels at both ends all revealed lengthening of the AM and PL bands of the graft tissues from full extension to 120° of flexion. Similarly, grafts employing double tunnels at only one end also lengthened with knee flexion. The technique employing double femoral and double tibial tunnels most closely reproduced the behavior of the intact ACL. The double bundle, double tunnel technique of ACL reconstruction may be a step toward recreating the complex behavior of the natural ACL. This procedure may restore more normal knee kinematics without adding significant technical demands to the current ACL reconstruction procedures.

RECENT PUBLICATIONS FROM THIS RESEARCH

Evaluation of dual limb grafts for anterior cruciate ligament reconstruction. Guanche CA, Edwards TB, Petrie SG, Hairrell EN, Nguyen GT, Thomas KA. In: Transactions of the Orthopaedic Research Society; 1996 February, Atlanta, GA.

III. Functional Assessment

[63] A STUDY OF VA STROKE REHABILITATION SERVICES AND PATIENT OUTCOMES

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PURPOSE—The goal is to determine if there are differences in patterns of stroke rehabilitation services within the VHA and whether these differences correlate with differences in patient outcomes (functional outcomes, discharge destinations, readmission rates, 180-day mortality, lengths of stay). This study will identify important attributes of rehabilitation services, which will serve as a basic taxonomy for rehabilitation and help focus future research. Specifically, it will determine whether the domains of provider of care, setting of care, and system of care independently predict rehabilitation outcomes, whether stroke patients hospitalized in VAMCs with greater resources have better outcomes, and whether patients hospitalized in VAMCs with more structural characteristics favoring coordination of care have better outcomes.

METHODOLOGY—A national Physical Medicine and Rehabilitative Services (PM&RS) survey will describe rehabilitation settings, physical resources, and providers, and systemic factors affecting rehabilitation. A national VA survey of acute care resources for stroke patients has already been performed, as of December 1994: its response rate was 95.6 percent. These data will be linked to facility rehabilitation characteristics to provide a complete description of each VAMC. Centralized administrative and computer resources will provide data on patient outcomes, patient descriptors, personnel, special programs, and other facility descriptors. These data will be also used to cross-validate selected survey items from the PM&RS and Acute Care Surveys.

In the second and third years, we will perform descriptive statistics on all study variables. Selected survey items will be cross-validated using bivariate analyses. We will survey VISN Directors and PM&RS HQ to identify data elements of greatest importance to VA programmatic planning efforts. For those specific variables, we will perform simple correlational analysis with our outcomes measures. Variables will be retained for further analysis and final scale development based on statistical analyses, identified programmatic planning priorities, and clinical judgment. We will specify several different models using different scaling techniques (e.g., equal weighted, weighted, ordinal, etc.) to select the best fit for the data. Finally, we will group facilities into types (e.g., hospitals with limited resources), and examine outcomes within types.

PROGRESS—The first year was directed to survey development/mailing, and obtaining data from centralized sources. We completed alpha and beta testing of the PM&RS survey. Site visits at 3/8 pilot sites indicated 95 percent accuracy. Actions taken to maximize compliance with the survey included soliciting letters of support from the Chief Network Officer and all 14 Network Directors (these were enclosed with the surveys), and we informed PM&RS Service Chiefs about the study and survey during June and July PM&RS conference calls, at the National PACT Training, and on FORUM. We mailed 166 surveys on July 5, 1996, and as of 8/28/96 received 129 in return. We identified data sources for all variables from administrative and computerized data sources and identified and piloted methods for downloading data from these sources.

FUTURE PLANS—In preparation for the second year, based on feedback from the reviewers, we reassessed our analytic methods concerning potential for data loss from over-simplistic data reduction. To address this problem, we deemed it necessary to increase the statistical support

for the project. This resulted in the revised data analytic plan described above. We are currently using pilot data collected from VISN 6 to pilot our analytic methods and will be using this to provide a report to the VISN 6 Network Director. The second year will be directed toward data entry and data analysis.

[64] CHARACTERIZING MEASURES OF STROKE REHABILITATION OUTCOMES

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No report was received for this issue.

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

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PURPOSE—Left-hemisphere stroke often produces limb apraxia, which impairs skilled movements independent of weakness, sensory loss, language comprehension deficits, or general intellectual deterioration. Though preliminary work suggests that limb apraxia may be one of the best predictors of impairment in functional independence after brain damage, clinicians frequently do not assess it because valid tests with normative data have not been developed. The purpose of this research is to begin the development of a valid and easy-to-use limb apraxia battery and then investigate its relationship to activities of daily living.

METHODOLOGY—A limb apraxia battery was pilot-tested in a nonimpaired control group and in individuals who survived a stroke to the left 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. Related cognitive abilities (e.g., gesture perception and recognition, object agnosia, serial ordering) were assessed to identify the different reasons for the disorder. Functional abilities were evaluated using patient and caregiver reports of functional independence and a performance-based assessment of functional competency (meal preparation).

PROGRESS—To date, we have tested 34 individuals with left-hemisphere damage (LHD), 20 with right-hemi-

sphere damage (RHD), and two groups of control subjects who were matched in age and education (36 left-hand and 18 right-hand controls).

PRELIMINARY RESULTS—Interrater reliability was excellent across all nine subtests of the apraxia assessment ($r=0.90$ to $r=0.98$), and the incidence of the disorder was in agreement with other reports. The item analyses suggested that the battery could be shortened so that it would be easier to use clinically. Other analyses suggested that apraxia is primarily related to problems in gesture perception and/or recognition, but not serial ordering or object agnosia. Importantly, apraxia severity was strongly related to meal preparation competency ($r=0.64$) and moderately predictive of caregiver and patient reports of functional independence ($r=0.50$).

FUTURE PLANS—Recruitment of subjects will continue in order to increase the power and reliability of the analyses. When the battery has been shortened for clinical use, it will be validated, and normative data will be collected on a large sample of LHD stroke patients and controls. The investigation into the reasons for limb apraxia will continue as this is the first step toward designing rehabilitation programs that address the patient's deficits and strengths. Finally, this line of research will examine whether limb apraxia is a better predictor of functional outcomes than other neuropsychological measures of cognitive abilities (e.g., attention, memory, language). This is vital because it will help clinicians to make more informed suggestions to patients and families about living arrangements and environmental support, and it will alert therapists to the specific reasons for a patient's functional deficits so that more focused therapies can be designed.

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[66] RELATION OF REHABILITATION INTERVENTION TO FUNCTIONAL OUTCOME

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

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

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

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

METHODOLOGY—Three impairment groups of patients are included: those with stroke, with traumatic brain dysfunction, and with spinal cord dysfunction. These groups are among the largest populations served by inpatient rehabilitation programs. Seven inpatient rehabilitation programs will collect patient data. All are subscribers to the Uniform Data System for Medical Rehabilitation.

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 convened through March 1995 to review the pilot data, discuss procedural difficulties, and revise instruments and procedures to assure that full-scale data collection proceeds smoothly. Full scale data collection began in March 1995 and continues through January 1997. Data analysis and report writing will begin in February and continue through August.

PRELIMINARY RESULTS—Initial analysis of scales used in this study is underway to evaluate their psychometric properties. Folstein's Mini-Mental State Examination (MMSE) is used at admission and discharge to describe severity of cognitive impairment in patients with stroke and traumatic brain injury. The objectives of this analysis were to: 1) develop linear measure of cognitive impairment from the MMSE, 2) describe item calibration and fit, person separation, and item reliability, 3) evaluate the comparability of item calibrations at admission and discharge, and 4) compare measures of cognitive impairment and disability in a sample of persons with brain injury and stroke.

The computer program BIGSTEPS (Linacre, 1996) provides the means to conduct rating scale analyses quickly and efficiently, and produces estimates of person ability and item difficulty, as well as fit estimates of item to measure, and fit of person to measurement model. It resolves the difficulty of working with ordinal scores by producing linear measures. A partial credit model was used to evaluate the 11 MMSE items. The initial Rasch analysis of the MMSE items yielded a person separation of 1.19 and an item reliability of 0.98. A person separation value of 2.00 or greater is desirable; such a value means that the ratio of information to noise is 2:1. The poor person separation here reflected the mistargeting of the test on the sample: the average person measure was 1.41 logits above the mean difficulty of the items. Such a mistargeted test, while useful in defining the abilities of very low functioning patients, is not able to separate patients into many strata of cognitive impairment. All items fit well; no item had mean square infits greater than 2.0.

Examination of individual items revealed no poorly fitting items; however, a confused step structure was found for the three items assessing orientation and registration. A second analysis was completed with the two orientation items rescored by combining intermediate categories. Responses of zero and one were combined in the first item, and responses of zero, one, and two combined in the second item. Rescoring slightly improved the person separation to 1.22. In a third analysis, the step structure of the registration item was collapsed by combining responses of zero and one; doing so improved the person separation to 1.45 with no decrement in item reliability. The items were still mistargeted on this sample (mean measure = 1.39). The item reliability coefficient was excellent at 0.98. The most difficult item was the figure copying (1.92 logits); the easiest item was naming of two objects (−1.68 logits). The items are spaced fairly equally with the exception of serial sevens and sentence writing (0.54 logits). The item contributing the least amount of unique information was the hardest item; figure copying had a mean square infit of 0.86, indicating that its informational value was only 86 percent of what one would expect from a perfectly functioning item. This work will continue with the measures in preparation for multivariate analyses of results.

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[67] ASSESSMENT OF AMBULATION MOTION PARAMETERS FOR CLINICAL EVALUATION

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PURPOSE—The overall goals of this work include: 1) developing simple motion parameters and indices for general and specific patient populations; 2) evaluating the computational complexity of such parameters while investigating sources of error and variability; 3) examining the feasibility of implementing these parameters in clinical data processing; 4) assessing the usefulness of these parameters in diagnosing motion disorders, prescribing interventions, evaluation of long-term prognoses, and assessing disability levels; and 5) developing a database of normal values for these parameters.

METHODOLOGY—The specific goals of this phase of the project involve two different approaches. The first is a practical application of Neural Networks in order to treat the massive amounts of data available and identify relevant motion parameters. One powerful method of assessing relevance is through using such key parameters as motion simulation variables and then comparing the resulting simulated motions with the observed data. These simulations can be utilized to study and parametrically evaluate variations and errors in these important indices.

The second approach is to study the impact of gait analysis recommendations and the functional outcome assessment of surgery. A preliminary prospective comparative quantitative study was conducted that showed laboratory gait analysis can be a valuable quantitative tool to enhance clinical decision making and outcome assessment.

PROGRESS—For our neural network investigations, we are using a Stochastic Real Valued (SRV) Reinforcement Algorithm suggested by Gullapalli to control a specific movement. The SRV unit not only produces a continuous output for a given input vector but also manifests an exploratory behavior while learning to produce the best output value possible. As learning proceeds, the exploratory behavior of the unit becomes smaller, that is, the variance reaches zero, and the mean becomes the actual output of the neuron.

For the investigation of outcomes, a combined retrospective/prospective quantitative interventions study was conducted in which each subject served as his/her own control. The subjects were 19 children with spastic diplegia selected at random. During the study, all subjects underwent surgery with varying protocols and number of procedures, as well as physical therapy preceding and/or succeeding surgery. Two consecutive periods were monitored, one in which intervention occurred and one in which only physical therapy was performed. The subjects were divided into two groups depending on whether they had surgery during the first or second period.

RESULTS—Certain network-related problems still need to be solved in the neural network study. Defining the reinforcement signal is one of the most important issues. The reinforcement signal is just a scalar value so should be selected to be informative enough. Credit assignment to individual neurons in the network is the other important issue. As a single reinforcement signal is used to update the whole network architecture, incorrect learning is possible. Thus, a correct procedure for structural credit assignment is required.

In the outcomes research, 17 out of 19 subjects in-

corporated gait analysis recommendations into the clinical decision-making process for surgery. Repeated measures analysis showed no significant difference in: 1) the performance or characteristics of the two groups; 2) the impact of differences in years between studies; 3) utilization of raw versus normalized data; or 4) surgery versus nonsurgery periods. The single-subject analysis, however, showed clinically relevant changes in velocity, stride length, cadence, ambulation status, and physical therapy intervention.

FUTURE PLANS—After necessary solutions to the problems stated above are found, muscle models will be introduced in the simulation in the neural network and the controller outputs will be set as the activation levels sent to these muscles.

[68] DEVELOPMENT OF CLINICAL PROTOCOLS BASED ON ERGONOMICS EVALUATION IN RESPONSE TO AMERICAN DISABILITY ACT (1990)

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PURPOSE—The objective of this project 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 mandated by the ADA that would enable individuals to perform the essential functions of the job.

METHODOLOGY—*Lifting models.* Previously, the development of job-specific lifting tests have incorporated the weight of lift, speed of lift, and lifting style. The functional capabilities also change as a result of repetitive lifting tasks or prolonged isometric physical exertions. Hence, novel techniques have been introduced that test the important aspect of endurance in lifting. The first protocol examines the prolonged static trunk exertions. The second protocol is a time-varying isometric trunk extension until fatigue, allowing the determination of the effects of fatigue on the neuromuscular performance.

Strength asessment. Biomechanical simulation models provide a time and cost effective tool for answering hypothetical questions about strength. In the light of the ADA, this is of great value in predicting the consequences of task modifications and/or workstation alterations without subjecting an injured worker or a disabled individual to unnecessary testing. Consequently, a computer-based simulation program of multilink coordinated lifting that predicts the optimum motion pattern(s) required to perform a wide range of lifting tasks, subject to constraints based on experimental strength profiles, has been developed. The model uses nonlinear optimization techniques to investigate the feasibility of task performance as a function of existing impairments, and limitations on functional capacity such as the range of motion, strength, and speed of lifting.

PROGRESS—In the first protocol, the recruitment patterns of the trunk extensor muscles were quantified. Spectral analysis and multiple linear regression methods of analysis were used for the identification of the most appropriate muscles to measure for the quantification of fatigue. It was determined that the most medial column of the trunk extensor muscles demonstrated the greatest fatigue. Using similar methods, individuals with low trunk endurance during static postural tasks may be identified, and appropriate measures taken so that the workers can safely perform the job.

In the second protocol, the recruitment patterns of the trunk muscles were quantified. Subsequent modeling showed greater activation of secondary and less efficient trunk extensor muscles, which contributed to an increase in the compression force at the intervertebral disc. The results of this study further elucidates the importance of incorporating endurance tests in functional assessment protocols. More detailed modeling, using MRI-based descriptions of individualized subject anatomy, may further enhance the capability of these sets of models of answering hypothetical questions.

The sensitivity of the model to various types of strength constraints was studied in terms of upper and lower bounds of joint strength, joint strength as a function of joint position, and dynamic joint strength as a function of joint position and velocity. The simulation was validated by comparing the predicted motion patterns with the experimental data generated for a similar lifting task. The results could be used as a biofeedback tool for training injured workers during rehabilitation, return to work assessment, as well as workplace modifications or "reasonable accommodations" as dictated by the ADA.

RECENT PUBLICATIONS FROM THIS RESEARCH

The reliability and validity of a lift simulator and its functional equivalence with free weight lifting tasks. Sparto PJ, Parnianpour M, Khalaf KA. IEEE Tran Rehabil Eng 1995:3(2):155–65.

Biomeehanieal simulation of manual multi-link eoordinated lifting. Khalaf KA, Parnianpour M, Wade L, Sparto PJ. In: Proceedings of the Fifteenth Southern Biomedieal Engineering Conference; 1996, Dayton, OH.

The importance of dynamic strength models for proper ergonomic task analysis. Khalaf KA, Parnianpour M, Wade L, Sparto PJ, Simon S. International Society for the Study of the Lumbar Spine; 1996, Burlington, VT.

Modeling of funetional trunk performanee: Interfaeing ergonomies and spine rehabilitation in response to the ADA. Khalaf KA, Parnianpour M, Wade L, Sparto PJ. J Rehabil Res Dev. In Press.

[69] 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 22202*

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.

METHODOLOGY—Specific objectives of this study are:

1. To investigate the Functional Assessment Inventory (FAI) and evaluate it for its suitability for application to the stroke population.
2. Based on results of objective 1, to identify appropriate areas of the FAI which require modifications to improve the assessment tool for the stroke population.

PROGRESS—As of May 1996, all of the data collection and data entry for the 110 nonexperimental cases has been completed. Seventy-five cases in the experimental group have had the modified FAI administered. Data analysis has been completed on 67 of these 75, finding that the experimental and the nonexperimental groups are similar in areas such as gender and race. The experimental group has slightly more subjects with aphasia. The nonexperimental group has more individuals who have completed college and were employed in professional occupations before their stroke.

Data analysis also found the average FAI total scores differ by 10 points between the Employed Group and the Not Able to Work Group (NW) at case closure. The NW group included those placed in sheltered workshops, volunteer positions, and retirement. Those who could not be placed but were continuing in training had an intermediate score. Based on this preliminary analysis, it seems that the FAI is helpful for predicting the probability of vocational outcomes for individuals who have sustained

a stroke. It appears that this will serve as a valuable tool for assessing vocational outcomes and planning vocational rehabilitation services for the stroke population. The group receiving the FAI had a shorter length of time from intake to case closure than the nonexperimental group. In addition, the group receiving the FAI required a lower number of units of vocational rehabilitation services. It appears that using the FAI did facilitate the identification of the direction for vocational planning, therefore resulting in greater cost effectiveness.

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

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PURPOSE—The major objective of this study is to examine the efficacy of neurological tests in predicting functional outcome for stroke patients.

METHODOLOGY—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.

In September 1995 we were approved by the IRB to modify the enrollment criteria. Previously we had to exclude a large number of subjects because they had a history of substance abuse or had a previous stroke. We felt that allowing subjects with such a history into the study would not significantly interfere with our ability to attribute observed cognitive deficits to strokes. By allowing more subjects into the study, we will increase our predictive power. Moreover, by liberalizing our enrollment criteria, we improve our external validity in that our sample will more closely resemble the actual patient population seen in clinical settings.

PROGRESS—The rate of enrollment of subjects increased after the inclusion criteria was modified with almost twice as many subjects enrolled per month. If we are able to maintain the same rate of enrollment over the next 15 months as we have has for the past 17 months, we will collect data on another 78 subjects for a total sample of 167.

RESULTS—As expected, we are finding substantial variability among subjects in their ability to complete the different tests in the neuropsychological battery. Deficits in motor function, vision, and receptive language ability appear to have a strong effect on test completion. One of our goals is to determine which tests can still be used when these functional limitations exist. A review of the first 58 subjects in our database show completion rates ranging from 50 subjects able to complete the Benton Facial Recognition Test to only 9 subjects able to complete the Tower of Toronto. Further data collection and analysis will take place in the next year.

[71] MEASURING FUNCTIONAL OUTCOMES AFTER REHABILITATION FOR SPINAL CORD INJURY: ASSESSING THE FUNCTIONAL INDEPENDENCE MEASURE

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PURPOSE—In order to accurately assess the impact of rehabilitation programs, it is important to have valid and sensitive outcome measures. The Model Spinal Cord Injury (SCI) Systems measure functional outcome after SCI with the Functional Independence Measure (FIM), an assessment scale that evaluates the amount of assistance required by a disabled individual to perform basic life activities. Typically the FIM obtained at discharge from rehabilitation is based on direct observation of patients by multiple raters in the hospital. The follow-up FIM is obtained by interview, based upon self-report of the SCI individual of in-home function. These differences can result in changes in FIM scores without a real change in function. As a result, the sensitivity of the FIM to detect changes in function between discharge and outpatient follow-up may be impaired.

Comparing an observational discharge FIM to a self-report follow-up FIM confuses capacity and performance. There is a difference between the ability to perform a task (capacity) and the day-to-day completion of the task (performance). Because of the evaluation structure and expectations placed upon the individual as an inpatient, the discharge FIM is largely a capacity measure. Research suggests that certain activities that individuals with disabilities learn during rehabilitation are sometimes discarded after discharge. This is especially true if the task is difficult, is not highly valued, and can be accomplished more easily by a care giver. As a result, the follow-up FIM is a performance measure. Furthermore, because of the trend toward shorter hospitalization, motor recovery and functional recovery should continue post-discharge. No prospective study has attempted to quantify the extent that learned activities are discarded and new activities added, or to relate changes in performance after rehabilitation discharge to changes in neurologic status.

METHODOLOGY—Subjects will include individuals with traumatic cervical SCI, motor levels C4-T1, ASIA Impairment Scale A, B, or C, admitted to a participating SCI center within 1 month post injury. Neurological examinations will be performed at 1 month post injury, admission to and discharge from rehabilitation, and at 1 year post injury. Disability will be evaluated by the FIM at rehabilitation admission and discharge, and by the self-report FIM at discharge from rehabilitation, within 2 weeks of discharge, at 6 months and at 12 months postinjury. A questionnaire exploring perceived changes in function and reason for changes will be administered with the postdischarge self-report FIM. Demographic information and information on etiology, insurance, disposition, and postdischarge rehabilitation services will be used as covariables in the data analyses. Regression analyses, correlation, and agreement analyses, and other appropriate analyses will be performed to test the hypotheses.

PROGRESS—This study began enrolling subjects April, 1996. To date, 15 subjects have been enrolled.

FUTURE PLANS—Recruitment and follow-up of subjects will continue until 1999. It is anticipated that the information gained in this study will enable rehabilitation programs to better focus on meaningful activities for individuals with SCI, and will assist in making outcome assessments more accurate.

[72] ASSESSMENT OF UPPER LIMB FUNCTIONAL CAPABILITIES AFTER CERVICAL SPINAL CORD INJURY

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PURPOSE—Efforts to assess the impact of interventions in spinal cord injury (SCI) are hampered by the current state of measurement instruments. The clinical significance of changes in impairment measures, which focus on the strength of specific muscles or the sensation in specific dermatomes, is unclear. Disability scales, which focus on burden of care and on performance rather than capacity, do not determine what an individual with SCI can do. There is a need to measure outcomes at the person level in order to link impairment to disability. However there are few attempts to systematically assess the functional capacity or limitations of individuals with SCI. The object of this study is to evaluate the reliability and validity of a questionnaire designed to measure upper limb capabilities in individuals with cervical SCI.

METHODOLOGY—This is a cross-sectional study of individuals with traumatic cervical SCI who are followed in an outpatient clinic. A questionnaire of upper limb function designed to measure self-perceived difficulty in completing various actions, such as reaching and grasping, will be administered around the time of an annual evaluation in the outpatient clinic. The motor portion of the Functional Independence Measure (FIM) will be obtained by phone interview at this time. The questionnaire will be administered again 2 weeks later to assess reliability and will be evaluated for internal consistency and discriminatory power. Validity will be determined by correlation with FIM scores, and correlation to motor scores obtained from a standard neurological examination performed during the outpatient visit.

PROGRESS—To date, 70 subjects have been enrolled in the study. A total of 150 subjects will be enrolled over the next 6–12 months. This will allow for evaluation of scale structure and internal consistency. The questionnaire has been easily understood and all enrolled subjects have been able to complete the interview.

FUTURE PLANS—After the questionnaire has demonstrated satisfactory reliability, it will be administered during a more acute phase after SCI to determine its sensitivity to change in function. The assessment of functional capabilities will assist in the evaluation of rehabilitation interventions in SCI and will shed light on reasons for continued disability.

[73] THE DEVELOPMENT AND VALIDATION OF A MUSCULOSKELETAL EXTREMITY HEALTH STATUS INSTRUMENT: THE MUSCULOSKELETAL FUNCTIONAL ASSESSMENT INSTRUMENT

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PURPOSE—The research goal was to develop a functional assessment questionnaire of broad use for musculoskeletal conditions.

METHODOLOGY—Health status instruments measuring a patient's perception of his/her health through self-reported data are being increasingly used to assess and

evaluate the effectiveness of medical care. No single instrument is currently available for use with the broad range of patients with musculoskeletal disorders commonly seen in clinical practice. In this paper, we report on the development and validation of the Musculoskeletal Functional Assessment (MFA) instrument, a 100 item self-reported health status instrument designed to meet this need. This instrument was developed in three phases: 1) item development and selection; 2) a field trial testing reliability and content validity and 3) a field trial testing responsiveness.

PROGRESS—Items were selected based on patient (n=135) and clinician (n=12) interviews and reviews of existing health status instruments. Reliability and content validity were tested in the first field trial by 327 patients with 1 of 5 musculoskeletal disorders (e.g., lower extremity trauma, upper extremity trauma, repetitive use disorders, osteoarthritis, rheumatoid arthritis) from both community and academic sites. Responsiveness was tested in the second field trial in 444 patients with the same musculoskeletal diagnoses with 2 completed MFA instruments separated by 3 to 6 months.

PRELIMINARY RESULTS—The instrument met standards for reliability, based on both test-retest data and internal consistency analyses. Content validity was also demonstrated based on a review of item selection procedures, expert opinion, and the instrument's distribution of scores. Criterion validity was tested against physician ratings of patient functioning (e.g., upper functioning, lower functioning, daily activities, recreational functioning, emotional adjustment, overall functioning) and standard clinical measures (e.g., grip strength, walking speed, fine motor skills, knee and elbow strength, range of motion) as the criterion standards. Significant correlations between MFA scores, physician ratings, and clinical measures support the MFA's criterion validity. Construct validity was demonstrated with an analysis of patient groups against existing health status measures and in accordance with widespread clinical hypotheses about the effect of musculoskeletal disorders on functioning. Construct validity was also confirmed by an analysis of demographic characteristics (e.g., gender, education, income, health insurance, employment) against MFA scores. In the second field trial, the MFA was compared to the SF-36, SIP, and WOMAC. The MFA was equally reliable ($r>0.70$); scores were well distributed with good "ceiling" and "floor" ranges, similar to the SF-36 and superior to the SIP; and MFA scores correlated more strongly than the SIP or the SF-36 with physician ratings of patient function. The MFA was more responsive than the SF-36, using standardized response means and relative efficiency analyses. These findings support the use of the MFA for assessing health status in patients with musculoskeletal disorders.

FUTURE PLANS—Utilizing data derived from this study, a short MFA (SMFA) has been developed and is being validated. This instrument will take 1/2 the time to complete and will likely be useful for community based outcomes assessment and office use, whereas the MFA may be more appropriate for clinical trials.

RECENT PUBLICATIONS FROM THIS RESEARCH

Development of a musculoskeletal extremity health status instrument: the musculoskeletal function assessment instrument. Martin DP, Engleberg R, Agel J, Snapp D, Swiontkowski MF. J Orthop Res 1996:14(2):173–81.

Musculoskeletal function assessment instrument: criterion and construct validity. Engelberg R, Martin DP, Agel J, Obremsky W, Coronado G, Swiontkowski MF. J Orthop Res 1996:14(2):182–92.

[74] CLIENT-CENTERED OCCUPATIONAL THERAPY FOR INDIVIDUALS WITH SPINAL INJURY

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PURPOSE—This study will examine the effectiveness of a client-centered, home-based, occupational therapy program for individuals with traumatic tetraplegia who have been discharged for 2 months from their initial rehabilitation hospitalization. The study is designed to determine if a home-based, occupational therapy intervention that reflects the individual's goals, habits, roles, and interests can increase independence and role performance, reduce the degree of handicap, and increase life satisfaction.

METHODOLOGY—Approximately 100 subjects with traumatic spinal cord injury (SCI) C4–C8, ASIA Impairment grades A–C, ages 18–50, will be randomly assigned to a control or experimental group. Subjects in the experimental group will receive client-centered, in-home occupational therapy, while those in the control group will receive untrained sitter contact for an equivalent length of time. Both groups will receive pre- and post-intervention interviews which will consist of a battery of five instruments that provide information on the functional performance of the subject in daily life (Functional Independence Measure), degree of handicap (Craig Handicap Assessment and Reporting Technique, Oakley Role Checklist, and Occupational Performance History Interview), and quality of life (Life Satisfaction Index A). Following the intervention, subjects will be asked about their degree of satisfaction with the intervention and goal attainment.

PROGRESS—Subjects are being recruited.

[75] STRATIFIED NORMS FOR THE RIVERMEAD BEHAVIOURAL MEMORY TEST

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PURPOSE—We investigated the value of stratified normative data for the Rivermead Behavioural Memory Test (RBMT). The RBMT has a demonstrated capacity to predict everyday memory problems and is recognized world-wide as a useful and ecologically relevant clinical tool. As the measurement of rate of change will often be the principle objective in neuropsychological rehabilitation, preferably in comparison to the group or the functional situation aimed at, the availability of stratified norms should enhance the adequate interpretation of test performance.

METHODOLOGY—To investigate this, 214 elderly, nonimpaired individuals and 680 patients with traumatic brian injury (TBI) participated in this multicenter study using a clinical trial approach. Significant differences for test scores were expected for different groups according to age, aetiology, health-care services, and some combined variables (e.g., coma duration following TBI).

RESULTS—Group effects in the expected directions were found for RBMT performance according to all stratification variables. Some implications and limitations of

these results are described in recent publications. Because the results clearly show the existence of homogeneous subgroups, taking stratified norms into account may improve the measurement of rate of change as well as decision making in clinical neuropsychological rehabilitation.

RECENT PUBLICATIONS FROM THIS RESEARCH

Stratified norms for the Rivermead Behavioural Memory Test. Van Balen HGG, Westzaan PSH, Mulder Th Neuropsych Rehabil 1996:6:203–17.

[76] PHYSIOLOGICAL ACTIVITY RECORDER

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Sponsor: *Workplace Health, Safety and Compensation Commission of New Brunswick*

PURPOSE—The purpose of this project is to provide a data logging unit and software, usable in a clinical setting, to measure effects of back injury prevention training programs.

METHODOLOGY—This project builds on a previous project to test whether or not back injury prevention training programs alter the way people perform lifting tasks. In the original project, a small battery-operated data logging system was developed in order to test nurses before and after back injury prevention training. The results of that study showed that there were measurable effects due to training and that the effects diminished as time went on.

The current project is to rework the data logging unit and the software to display the results in order to make the system more usable in a clinical setting. To this end, staff at the Workers' Rehabilitation Centre in Grand Bay have tested various modifications to both the data logging device and the display software.

The final version of the device will allow several sampling protocols to be selected by the user. These include a protocol for long duration tests in which data are recorded approximately once a second. With the modified logger this allows data recording over a full shift. Other modes include faster sampling rates that make it easier to interpret results of muscle activity in a rehabilitation setting.

PRELIMINARY RESULTS—The device was field tested in the fall of 1995 in a follow-up study on the original group of nurses. This study showed that over the 2 years since initial training, the effects of the back injury prevention training had diminished so that the group was back to where it had been initially.

FUTURE PLANS—Work continues to assess whether it is possible to use information such as this to determine optimum timing of refresher training. Tests to determine the effects of training and workplace redesign are proposed for the future.

IV. Functional Electrical Stimulation

A. General

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

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PURPOSE—The objectives of this study included: 1) establishing baseline parameters of normal colonic responses in the 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—The effect of direct electrical stimulation on colonic transit and manometric recordings following spinal cord injury (SCI) were assessed in five adult male cats. Intra-colonic catheters were surgically placed, stimulating electrodes were sutured to the colonic serosa, and a laminectomy with spinal cord clamping at a T4 level was done to induce SCI. Twenty radiopaque markers were inserted through an intra-colonic catheter located 1 cm distal to the cecum and were monitored with daily fluoroscopy as a measure of colonic transit. Transit measurements were compared before SCI, after SCI, and after SCI with electrical stimulation of 40 pps, 1 ms, and 0–50 mA.

PROGRESS—Patterns of long duration, nonpropagating colonic contractions were identified. Spontaneous colonic phasic motor activity was observed both before and after SCI and was similar. Manometric defecation patterns were also observed to be similar between animals before SCI and after SCI with electrical stimulation.

RESULTS—Colonic transit following SCI was significantly prolonged ($p<0.05$) when compared to the transit before SCI. Electrical stimulation following SCI improved colonic transit to values not significantly different from those before SCI. These findings demonstrate that colonic transit was prolonged following SCI and that direct electrical stimulation of the colon following SCI improved colonic transit in an animal model.

FUTURE PLANS—The goal is to expand from the progress made during this pilot project using suture electrodes for direct colonic stimulation and evaluate wireless microstimulators as a state-of-the-art approach to constipation treatment after SCI.

RECENT PUBLICATIONS FROM THIS RESEARCH

Placement of colonic manometric catheters and electrodes in cats. Riedy L, Bruninga K, Walter J, Keshavarzian A. Lab Animal Sci. In press.

[78] FECAL INCONTINENCE TREATMENT IN SCI PATIENTS: A PILOT STUDY

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PURPOSE—The objectives of this study include: 1) determining whether the frequency of fecal incontinence can be reduced in SCI patients by using surface electrodes placed around the anal sphincter; 2) evaluating anal rectal function using manometry in SCI patients with fecal incontinence; and 3) determining if there are any other benefits associated with external anal sphincter stimulation, such as decreased urinary incontinence, decreased lower limb spasticity, and/or effect on stool impaction.

METHODOLOGY—Study subjects will include a group of 15 SCI patients from the Hines VA Hospital. Inclusion criteria will include 10 male and 5 female SCI patients with fecal incontinence. Exclusion criteria will include patients with active urine infection, decubiti, cardiovascular disease, cardiac pacemakers/defibrillators, and pregnancy. Subjects will participate in the study for a total of 12 weeks. The study will consist of a 1 week prestimulation period during which the patient will document any episodes of fecal incontinence. During the next 10 weeks, patients will use the surface stimulation to manage their fecal incontinence. For the final week of the study, electrical stimulation will be discontinued in order to assess any benefits and improvements associated with the treatment. Throughout this study, patients will maintain a daily log to document bowel function and will be contacted weekly, by phone, to assure protocol compliance and sort out any technical problems that may occur.

PROGRESS—We plan on evaluating surface stimulation using a small battery-powered stimulator and self-adhering surface electrodes in 15 patients over a 12-week period.

RESULTS—Recently, one SCI patient has been enrolled into the study. He has been trained in the use of the device and will begin evaluating the device at home. Based on a bedside evaluation of the device, surface stimulation around the anal sphincter resulted in anal pressure changes of 60 cm water with a stimulation protocol of 100 mA, 35 pps, and a pulse duration of 300 μsec.

FUTURE PLANS—The primary goal is to continue recruiting patients for this study.

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

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PURPOSE—Functional neuromuscular stimulation (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. We observed that chronic stimulation using 20 $\mu C/cm^2$ led to the onset of irreversible faradic processes which resulted in tarnishing. This observation was the same for electrodes pulsed either with anodic- or cathodic-first pulsing. To develop high charge injection density electrodes, we have investigated iridium (Ir) on stainless steel electrodes.

METHODOLOGY—Wire electrodes of 316LVM stainless steel were coated with Ir metal by DC magnetron sputtering at EIC Laboratories. A thin film of Ti was sputtered onto the 316LVM as an adhesion layer prior to Ir deposition. 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—IR coatings have shown resistance to high charge injection protocols. The coated electrodes appear suitable for bipolar pulsing protocols. There is a typical tissue reaction to chronically implanted electrodes although adherence of the Ir coating in the *in vivo* environment needs to be improved.

RESULTS—In our *in vitro* characterizations, the principal finding was that the iridium coated stainless steel electrodes are resistant to corrosion at charge injection densities, as high as 320 $\mu C/cm^2$ for anodic and cathodic-first pulsing. Active surface disruptions indicating corrosive processes were present at higher charge injection densities. These charge injection densities are much higher than the maximum of 40 $\mu C/cm^2$ for uncoated 316LVM stainless steel electrodes. Potential transients were low for all of the charge injection protocols.

The histological responses to implantation and the adherence of the iridium coating to the electrodes were evaluated. Seven electrodes composed of 3 cm of Ir coated and 3 cm of uncoated stainless steel were surgically implanted in the hind leg muscles of cats. Electrical stimulation was not applied to any of the electrodes. Forty-two days after implantation, the animals were euthanized and the electrodes with surrounding tissue were harvested. All of the muscle strips adjacent to the electrode showed signs of chronic inflammation including fibrocites and connective tissue. Although, this inflammatory response was a concern, there was no apparent difference between the 316LVM stainless steel and Ir portions of the electrode. Since these electrodes were implanted into the quadriceps muscles of active cats, movement may have contributed to this immune response. None of the cross-sections of the sham control muscles adjacent to the electrode area exhibited signs of injury.

The Ir film was visibly altered by implantation in some animals. Corrosion was not observed on the 316LVM stainless steel but sparse delamination of the Ir layer was noted on two of the seven electrodes with extensive delamination noted on one other electrode. These results indicate that adherence of the coatings continue to be a concern.

FUTURE PLANS—Coatings with improved adherence are under investigation.

RECENT PUBLICATIONS FROM THIS RESEARCH

Effects of low charge injection densities on corrosion responses of pulsed 316LVM stainless steel electrodes. Riedy L, Walter JS. IEEE Trans Biomed Eng 1996:43:660.

[80] REHABILITATION OF URINARY INCONTINENCE USING STIMULATED MUSCLE FLAPS: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Projeet #E1583-PA)*

PURPOSE—This study is evaluating 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 are being evaluated. This goal is particularly relevant to the patient following radical prostatectomy where urinary incontinence can be a problem.

METHODOLOGY—Dogs were implanted with a fully implantable myoplasty stimulator. The gracilis muscle was loosely wrapped around the urethra to avoid the potential for stricture formation. An 8-week training period was conducted and followed by continuous stimulation for 6 weeks. Efficacy of the neosphincters was determined with urethral and leak point pressure measurements. Urethral stricture formation was assessed by dissection postmortem.

PROGRESS—Male dogs with stimulated skeletal muscle flap have been evaluated with the gracilis muscle wrapped around the urethra. High urethral closure pressure was obtained with low stimulation parameters. The surgical procedures were easy to perform.

RESULTS—Studies have been conducted in five dogs. Under anesthesia, urethral pressure increases of 10 to 150 cm H_20 were recorded with stimulation at 12 Hz and stimulating voltages from 0.5 to 3 mA. Little or no fatigue in the peak pressure response was noted during 10 min of stimulation. One of the animals completed training and continuous stimulation with high pressure responses to stimulation. Four other animals failed at varied times after implantation and were sacrificed. Problems in all four animal appeared to be related to electrode dislodgment or connections to the stimulator. Nerve injury possibly related to excessive stretch with the muscle wrap around the urethra may have occurred. Urethral stricture was not observed in any of the animals, but the urethra was seen to be pulled from the midline of the perineum by the skeletal muscle flap.

FUTURE PLANS—Two additional animals are being investigated.

[81] 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 (Projeet #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 which assist chest expansion and promote inspiration.

METHODOLOGY—All patients selected had low cervical lesions, were at least 1-year postinjury, and were medically stable. A spirometry evaluation that included basic lung volumes and capacities was performed. Both upright and supine evaluations were performed. In addition to spirometry, thoracic excursions were monitored by a low resistance respiratory belt placed mid-thorax. Stimulation was carried out with small needle electrodes pushed through the skin and into the superficial intercostal muscle layer. Battery powered neuromuscular stimulators set at 35 pps, 100 μs duration, 12 mA was delivered bilaterally for a 2 s period at the end of a maximal inspiration. Changes in lung volume and chest excursions were noted before, during, and following stimulation.

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

RESULTS—A total of seven patients were studied. In two, some chest excursion occurred during spontaneous inspirations. Thoracic stimulation in these individuals at the end of a maximal inspiration did not produce an increase in inspired volume or evidence of chest expansion. In two other individuals, afferent activity present in the upper chest produced sufficient discomfort during stimulation that the procedure was terminated. In the remaining three subjects inspiration was associated with a collapsing chest wall. Stimulation after maximal inspiration produced an additional inspired volume of 284±38 ml (mean ±SEM) and chest movement toward expansion. There were no differences between the upright and supine positions. The greatest response was found for electrodes in the third intercostal space close to the midline. Spontaneous breathing connected to the spirometer produced an average tidal volume of 501±31 ml. Thus, the stimulated volume represented 57 percent of the individuals normal tidal volume.

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.

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

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PURPOSE—The purpose of this research is to evaluate bladder, bowel, and sexual function in patients with spinal cord injury (SCI) before and after implantation of an electrical stimulator for activation of the sacral anterior nerve roots. The goal of the research is improved bladder, bowel, and sexual function, reduction of bladder and bowel complications, and increased independence following SCI.

METHODOLOGY—Subjects with complete SCI and complications of bladder, bowel, and sexual function are being implanted with an electrical stimulator intended to reduce these complications. This device consists of electrodes implanted surgically on the sacral 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.

PROGRESS—Eight subjects have received these implants, the first of this type in the United States. Recruitment has also been extended to nonveterans.

PRELIMINARY RESULTS—All subjects are using the stimulator routinely at home for emptying the bladder. Residual volumes are low and infection rates have been reduced. All have discontinued routine use of indwelling or intermittent catheterisation and those with good hand function no longer use leg bags. All have found that regular use of the stimulator reduces constipation, and four use it to produce defecation. In four of the five males the stimulator also produces penile erection.

FUTURE PLANS—Recruitment and follow-up of subjects will continue among veterans and nonveterans, and has been 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.

[83] EVALUATION AND OPTIMIZATION OF FES TECHNIQUES FOR EXERCISE

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PURPOSE—The purpose of this program was 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 were to continue evaluation of acute and chronic physiologic responses (musculoskeletal, aerobic metabolic and cardiopulmonary) to existing FES exercise modes including knee extension (KE), leg cycle ergometry (LCE), and combined FES-LCE + voluntary arm-crank ergometry (HYBRID), assessing potential benefits and risks of these therapies to persons with SCI; to modify the design of existing FES exercise devices to optimize muscular, aerobic, metabolic, and cardiopulmonary responses to the various FES exercise modes, while maintaining user safety; and to design more progressive FES exercise training protocols to optimize adaptations of the muscles utilized and the cardiopulmonary system.

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

changes in medical problems during participation in FES exercise programs.

RESULTS—The final phase of this project involved evaluation of acute physiologic responses for using a modified Therapeutic Alliances Incorporated model ERGYS 1 FES-LCE, as well as the changes in these responses following a specially designed interval training program. Modifications included: increasing the FES current limit from 140 to 300 mA; adding the tibialis anterior and gastroc-soleus muscles to the quadriceps, hamstrings, and gluteus maximus muscles; and widening FES firing angles from about 70 to 120° to increase contraction duty cycle from about 0.23 s to 0.40 s. These modifications were accomplished with a specially constructed 10-channel current booster and a specially programmed ROM chip. Exercise stress testing demonstrated that this modified FES-LCE elicited significantly higher magnitudes of metabolic and cardiopulmonary responses.

For exercise training, we tested an aggressive interval training program protocol, which presented greater and more continuous "overload" of the subjects. To enable this, an electronic circuit was designed and constructed to permit adjustment of LCE load resistance during pedaling, without the necessity to stop exercise and reprogram the computer. Prior to and following interval training program, we also evaluated the 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. Significant improvements in muscular, metabolic, and cardiopulmonary responses were found, even in subjects who have plateaued in performance during long-term FES-LCE use. These results suggest that the modified FES-LCE used in conjunction with the interval training program can elicit accelerated and greater physiologic training adaptations than the original FES-LCE.

IMPLICATIONS—This project has resulted in greater knowledge concerning the muscular, metabolic, cardiovascular and pulmonary responses to various FES-induced exercise modes. It also demonstrated that the magnitudes of these physiologic responses can be increased, while maintaining safety, by altering the FES parameters, muscle mass utilized, contraction duty cycle, and the exercise protocol. Optimizing these factors can result in accelerated and greater levels of training adaptations. Our results suggest that patients with SCI should derive important benefits from FES-induced exercise, beyond those derived from conventional arm exercise therapy, including higher levels of physical fitness, lower incidence of secondary medical complications, and improved rehabilitation outcome.

RECENT PUBLICATIONS FROM THIS RESEARCH

Peak physiological responses of trained quadriplegics during arm, leg and hybrid exercise in upright and reclined postures. Figoni SF, Glaser RM, Collins SR. Clin Kinesiol 1995;48:94–5.

Development of a hybrid strength training technique for paretic lower-limb muscles. Bennett TL, Glaser RM, Janssen TWJ, et al. In: Proceedings of the 15th Southern Biomedical Engineering Conference, 1996:49–52.

Development of a hybrid leg cycling exercise technique for patients with lower-limb paresis. Herr CJ, Glaser RM, Janssen TWJ, Bennett TL, Suryaprasad AG. In: Proceedings of the 15th Southern Biomedical Engineering Conference, 1996:187–90.

A development system to enhance FES leg cycle ergometer technology. Glaser RM, Couch WP, Janssen TWJ, et al. In: Proceedings of the 19th Annual RESNA Conference; 1996, Salt Lake City, UT. Washington, DC: RESNA Press, 1996:279–81.

Improving FES leg cycle ergometer performance in individuals who have plateaued during long-term training. Janssen TWJ, Glaser RM, Almeyda JW, Pringle DD, Mathews T. In: Proceedings of the 19th Annual RESNA Conference; 1996, Salt Lake City, UT. Washington, DC: RESNA Press, 1996:288–90.

A system to evaluate paralyzed lower-limb muscle performance during FES-induced contractions. Pringle DD, Janssen TWJ, Glaser RM, Almeyda JW, Couch WP. In: Proceedings of the 19th Annual RESNA Conference; 1996, Salt Lake City, UT. Washington, DC: RESNA Press, 1996:75–7.

[84] MANAGEMENT OF URINARY DISORDERS IN SCI

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Sponsor: *National Institutes on Health, National Center For Medical Rehabilitation Research*

PURPOSE—This project has two overall goals: 1) to apply functional electrical stimulation techniques for bladder voiding and incontinence management after spinal cord injury (SCI), and 2) 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 such as emptying and continence are 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 tethered male cats. Animals received either an upper motor neuron lesion or a lower motor neuron lesion. Animals were instrumented under anesthesia with five "suture" type electrodes consisting of multistranded 316LVM stainless steel with a needle placed at the electrode tip and sutured into the serosa of the bladder wall. Four electrodes were implanted 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. Laboratory stimulators were used.

PROGRESS—Prolonged bladder contractions and voiding to direct bladder stimulation occurred before and after SCI in both groups of animals. High maximal voiding rates were also seen in both groups of animals. Voiding responses to stimulation were less effective at small bladder volumes. Fluoroscopy of the urethra during stimulation induced voiding showed a narrow penile urethra indicating that this animal model of the lower urinary tract is quite different from humans.

RESULTS—In instrumented tethered animals, responses to direct bladder stimulation were recorded. All 10 cats responded to direct bladder stimulation before SCI using a single 3 seconds stimulation period, at 40 Hz, 1 ms pulse duration and a stimulating current from 7.5 to 40 mA. The maximum voiding rates were from 0.5 to 1.5 ml/sec with complete bladder emptying, particularly after the first 2 or 3 weeks. Peak detrusor pressures were from 40 to 70 cm H_20. Voiding could be obtained without discomfort to the animal.

Five of the 10 male cats also received an upper motor neuron lesion and 5 received a lower motor neuron lesion. Stimulation induced voiding in these SCI 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 30 to 70 cm H_20. Similar responses were seen after upper and lower motor neuron lesions. Fluoroscopy of the urethra during stimulation induced voiding showed a narrow penile urethra that restricted urine flow in both groups of animals.

FUTURE PLANS—Alternative stimulators may improve direct bladder stimulation techniques. Microstimulators are small implantable stimulators that do not have connecting wires as they are activated by external RF fields. We are proposing to evaluate these devices in the future for direct bladder stimulation.

RECENT PUBLICATIONS FROM THIS RESEARCH

Direct bladder stimulation with suture electrodes promotes voiding in a spinal animal model: a technical report. Walter JS, Wheeler JS, Cai W, Scarpine VE, Wurster RD. J Rehabil Res Dev 1997:34(1):72–81.

[85] MICROSTIMULATION OF THE LUMBOSACRAL SPINAL CORD: MAPPING

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PURPOSE—The objective of this project is to investigate the feasibility of neural prosthetics based on stimulation of the spinal cord with penetrating microelectrodes. Specific attention is given to control of bladder, bowel, sexual function, and control of skeletal muscle. The results of this project will answer fundamental questions about microstimulation of the spinal cord, and lead to development of a new generation of neural prosthetics for individuals with neurological impairments.

METHODOLOGY—Chemical and viral retrograde tracers are used to determine the location and rostrocaudal extent in the spinal cord of the neuronal populations that control genitourinary and motor functions in the male cat and rat. Stimulation of the spinal cord with penetrating activated iridium microelectrodes is used to determine the physiological effects of activation of different neural populations in male cats.

PROGRESS—The transneuronal retrograde tracer pseudorabies virus (PRV) was used to determine the central nervous system (CNS) innervation of the bladder and urethra in male rats. In rats with CNS infection documented by immunohistochemistry, retrogradely labeled neurons were identified along the neuraxis, including the spinal cord, medulla, pons, and hypothalamus. After longer postinjection intervals, neurons in amygdala, hippocampus, primary motor cortex, and piriform cortex were also labeled. The distribution of labeled neurons following injection of PRV into the wall of the urethra was quite similar to the pattern of innervation observed after injection into the wall of the urinary bladder.

These studies indicate that urinary bladder and urethra are innervated by diverse, but similar CNS cell groups. Experiments with PRV and the conventional retrograde tracers fluorogold and cholera toxin beta-subunit are underway in male cats. The results of these experiments will identify neuronal populations to be targeted for microstimulation, as well as reveal the consistency of organization across species.

The pressures generated in the bladder and along the urethra by microstimulation of the sacral spinal cord were recorded in male cats anesthetized with alpha-chlorolose. Bladder pressures were measured via a suprapubic catheter, and urethral pressures were measured with a urethral catheter containing 2 solid-state micromanometers. Vertical, dorsal-to-ventral penetrations were made at different mediolateral and rostrocaudal locations and responses were evoked at 200 μm intervals. Bladder pressures could be generated by stimulating over a widespread region of the S2 segment. However, the largest pressures (30–40 cmH_20) were generated at locations in the dorsolateral aspect of the ventral horn, consistent with the location of the axons of the preganglionic parasympathetic motoneurons innervating the bladder. At more ventral locations, direct activation of urethral and pelvic somatic musculature was observed. The co-activation of the bladder and the pelvic musculature measured at these locations was consistent with responses generated by stimulation of the S2 ventral root. Bladder pressures could also be generated by stimulation within the dorsal horn of S2, although these pressures were not as large as those evoked in more ventral locations.

In the more dorsal region, bladder pressures were accompanied by varying amounts of urethral pressure responses. The responses generated in more dorsal locations were presumably generated by transsynaptic activation of preganglionic motoneurons via afferent terminals and/or interneurons. This interpretation is consistent with genitourinary responses generated by stimulation of the S2 dorsal root.

The results of these experiments indicate that large bladder pressures can be generated by microstimulation of the spinal cord with a single penetrating microelectrode. However, the largest responses are accompanied by increases in the urethral pressure. Current efforts are to correlate the profile of pressures along the urethra with the urethral anatomy in male cats, and to investigate modulation of urethral pressure by microstimulation of the spinal cord.

[86] THE DYNAMIC MODEL OF SKELETAL MUSCLES AND JOINTS

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PURPOSE—Discerning the correct frequency response model of a single skeletal muscle has been a long-standing problem, because only unphysiological control inputs (firing rate or reverse recruitment) could be used, or alternate analogue models preassumed the interaction mode of firing rate and recruitment, which were unknown until recently. The model is needed for the design of advanced FES systems.

METHODOLOGY—We tested the soleus (slow twitch) and M. gastroc (fast twitch) under several physiological control strategies with the aid of our newly developed stimulation system, which recruits motor units in an orderly fashion.

RESULTS—The frequency response model consisted of a second-order system with double poles at 1.8 Hz. This was independent of the control strategy used, the predominant muscle fiber type, or the force perturbation level. A pure time delay differentiated the models for fast and slow twitch muscles being 11 ms and 16 ms, respectively. Firing rate control input was reaffirmed to result in a nonlinear model as previously described in the literature.

PROGRESS—Additional work has identified the frequency response of nine different muscles in the hind limb of the cat. The impact of muscle/tendon ratio, mass, pennation, and twitch properties varied the model poles from 1.6 Hz to 2.8 Hz. Recent studies focused on load moving contractions and on the effect of the joints in various configurations. Muscle architecture and its predominant fiber composition seem to be the primary variable in determining its dynamics, whereas the tendon is a secondary factor.

RECENT PUBLICATIONS FROM THIS RESEARCH

Dynamic response of the cat ankle joint during load-moving contractions. Zhou B-H, Baratta R, Solomonow M, D'Ambrosia R. IEEE Trans Biomed Eng 1995:42:386–93.

Effect of tendon on muscle force in dynamic isometric contraction. Van-Soest A, Huijing P, Solomonow M. J Biomech 1995:28:801–7.

[87] EMG-FORCE MODELS IN MUSCLES WITH VARIOUS FIRING RATE AND RECRUITMENT STRATEGIES

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PURPOSE—The EMG-force relationships were a controversial and unsolved problem for many years, having been reported as linear by many investigators and as nonlinear by many others. Recent data suggest that the different firing rate and recruitment strategies of different muscles may be the source of the controversy. Precise knowledge of the relations assists in the diagnostics of movement disorders, understanding muscle properties, and designing orthotic systems.

METHODOLOGY—With the aid of our new stimulation system, we determined the effect of various control strategies on the EMG-force relationships to show that strategies employing recruitment of all the motor units of the muscle to generate the initial 50 percent of the maximal force, in conjunction with pure firing rate increase to generate the final 50 percent of the force, yield a linear EMG-force model. A progressive increase in the force proportion by motor units recruitment over 50 percent re-

sulted in a predictable, progressive increase in nonlinearity of the relationships.

PROGRESS—Complete models were developed for various control stratagems, as well as for fast and slow twitch muscles. Current work focuses on the effect of contraction rate and joint angle (muscle length) on the EMG-Force relationships.

It was also shown that a single muscle can change its control strategy when performing different types of contractions, thereby changing its EMG-Force relationships. The EMG-Force relations, therefore, are dependent on several variable that should be considered for a given contraction type.

RECENT PUBLICATIONS FROM THIS RESEARCH

Motor unit recruitment strategy changes with skill acquisition. Bernardi M, Solomonow M, Nguyen G, Smith A, Baratta R. Eur J Appl Physiol 1996:74:52–9.

Motor unit recruitment strategy of knee antagonist muscles in a stepwise increasing isometric contraction. Bernardi M, Solomonow M, Sanchez J, Baratta R, Nguyen G. Eur J Appl Physiol 1995:70:493–501.

[88] THE USE OF EMG AS FORCE FEEDBACK IN CLOSED-LOOP ELECTRICAL STIMULATION SYSTEMS

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PURPOSE—Force feedback is necessary if regulation of a stimulated muscle force output is anticipated. Since implantation of force sensors requires trauma to the tendon, the EMG was considered, tested, and evaluated as a parameter representing force in a closed-loop paradigm.

METHODOLOGY—The EMG was found to follow the isometric force rather faithfully as long as fatigue did not set in the muscle. In order to prevent muscle abuse and possible damage due to prolonged and frequent fatigue, a parallel feedback/fatigue detector has been implemented. The role of such a circuit is to function as a "fatigue fuse," terminating contractions if excessive fatigue is detected.

PROGRESS—The EMG-Force relationship was further investigated in order to delineate the effects of changing muscle length, and the muscles moment arm about the joint's center of rotation in order to extend the concept to non-isometric contractions in a moving limb. It was shown that various factors influence the EMG-Force relations, and that a multivariant model should be constructed to provide accuracy to the feedback loop.

RECENT PUBLICATIONS FROM THIS RESEARCH

Motor unit recruitment strategy changes with skill acquisition. Bernardi M, Solomonow M, Nguyen G, Smith A, Baratta R. Europ J Appl Physiol 1996:74:52–9.

[89] EMG POWER SPECTRA CHANGES DUE TO SKILL ACQUISITION

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PURPOSE—Changes in motor unit recruitment patterns due to increased skill of human subjects in performing a specific function were assessed by recording the surface EMG of normal subjects while they performed isometric elbow flexion.

METHODOLOGY—The contraction consisted of linearly increasing force from rest and up to 100 percent maximal voluntary force within 3 s. Subjects exercised 3 s linear increase in force three times a week over 6 weeks. At each session, 20 contractions were performed in a total of 360 practice contractions. The median frequency (MF) of the EMG power spectra density was calculated for five contractions every 2 weeks. Because the MG is linearly related to the conduction velocity of action potentials in the muscle, increasing MF may indicate recruitment of larger motor units during the contraction.

RESULTS—The results show that the MF was increasing from rest and up to 65–70 percent for maximal voluntary force prior to the training. It gradually increased and, at the end of the six weeks of training, the MF increased from rest to 90 percent of the maximal voluntary force.

Motor unit recruitment could be an adaptive process, capable of increasing range as skill is acquired. Slower and longer recruitment strategies allow more accurate control of force generation and thereby improve skill. This further confirms that motor unit recruitment is not a fixed property in a specific muscle, but rather an adaptive process that could be optimally modified according to the task to be performed.

The motor unit recruitment pattern of the antagonist did not exhibit statistically significant changes but showed an increase and then a decrease in the recruitment range as skill was acquired. This confirms that improvement in skill may decrease the antagonist coactivation level in general.

RECENT PUBLICATIONS FROM THIS RESEARCH

Motor unit recruitment strategy changes with skill acquisition. Bernardi M, Solomonow M, Nguyen G, Smith A, Baratta R. Eur J Appl Physiol 1996:74:52–9.

[90] CONTROL OF JOINT MOTION WITH SYNERGISTIC STIMULATION OF ITS AGONIST/ANTAGONIST MUSCLES

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PURPOSE—Joint motion requires complex and simultaneous activation levels from the agonist and antagonist muscles in order to accomplish the intended task, while subject to various internal and external disturbances. This project initiated trials using antagonistic stimulation of the muscle groups crossing the joint with various levels of weighted motor unit recruitment in the agonist and antagonist to reaffirm our data collected from the elbow joint of humans. The objective was to improve the external control of a joint with regards to various loading conditions.

METHODOLOGY—Agonist/antagonist muscle coactivation strategies were implemented through electrical stimulation. These strategies were based on the compromise between the physiological need for joint stabilization by the antagonist at high force levels and the need to prevent joint laxity at low force levels. These two conflicting requirements resulted in two coactivation parameters. The first one, antagonist gain, was the linear gain of the antagonist muscle with respect to the input command. This parameter came into play when high net joint torques were called for. The second parameter, overlap, was a range of crossover of the antagonist unto the agonist domain. Strategies combining antagonist gain and overlap were tested as to their ability to track linear, step, sinusoidal, and pseudo-random input signals.

RESULTS—It was found that moderate amounts of antagonist gain (5 percent) and overlap (25 percent) would provide optimal tracking and minimal distortion during isometric and various types of load-moving contractions. When controlled by these strategies, the dynamic frequency response of the cat ankle joint showed small yet statistically significant differences on the dynamic response of the agonist/antagonist muscle-joint system.

RECENT PUBLICATIONS FROM THIS RESEARCH

Evaluation of antagonist coactivation strategies elicited from electrically stimulated muscles under load-moving conditions. Zhou B-H, Kelz S, Baratta R, Solomonow M, D'Ambrosia R. IEEE Trans Biomed Eng. In press.

Evaluation of isometric antagonist coactivation strategies of electrically stimulated muscle. Zhou B-H, Baratta R, Solomonow M, Olivier LJ, Nguyen G, D'Ambrosia R. IEEE Trans Biomed Eng 1996:43:150–60.

[91] 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 spinal cord disease, such as multiple sclerosis (MS), regardless of age, race, sex, or length, level, and completeness of injury. In medically appropriate cases, FES can be used for persons with SCI or 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 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.

METHODOLOGY—The objectives of the project are: to increase the knowledge base of persons with SCI/disease on the use of FES; to increase access for persons with SCI/disease to FES providers; to increase the decision-making ability of persons with SCI/disease to make informed decisions regarding the appropriateness of FES interventions. Project oversight was provided by a 16-member Community Advisory Committee. A 34-member Technical Review Committee assisted with content review.

PROGRESS—A sourcebook entitled *Functional Electrical Stimulation (FES) Resource Guide for Persons with Spinal Cord Injury or Multiple Sclerosis* (ISBN 1-888470-03-8) was completed and published in 1995. In August 1996 more than 500 copies had been distributed. A survey of individuals with SCI indicated that use of the book increased their FES knowledge.

FUTURE PLANS—We are planning electronic dissemination of the *FES Resource Guide* via the world wide web at http://feswww.fes.cwru.edu.

[92] COMPARISON OF DISCOMFORT ASSOCIATED WITH PERCUTANEOUS AND SURFACE NEUROMUSCULAR STIMULATION

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PURPOSE—Surface neuromuscular stimulation has been shown to have both therapeutic and functional benefits for stroke survivors. However, associated pain limits its implementation in the clinical setting. Percutaneous intramuscular stimulation may be better tolerated since pain fibers on the skin are not stimulated. The purpose of this study is to compare the level of pain or discomfort associated with percutaneous and surface neuromuscular stimulation in chronic stroke survivors with intact sensation.

METHODOLOGY—Extensor digitorum communis (EDC) of three subjects with chronic hemiplegia and intact sensation were stimulated with percutaneous and surface electrodes. All subjects were beyond 6 mo from their index event and were medically and neurologically stable. Percutaneous electrodes were of helical configuration wound from FEP-Teflon insulated, multistranded, type 316L stainless steel wires with a stimulation surface of 10 mm^2. A balanced biphasic, cathodic-first, capacitively coupled, constant-current pulse was applied. The amplitude and frequency were maintained at 20 mA and 16 Hz, respectively. Intensity of stimulation was modulated by varying the pulse width from 0 to 200 μs. Empi® 1.25 in (3.2 cm) reusable gel electrodes were used for surface stimulation. A symmetric biphasic waveform with pulse duration of 300 μs was applied at 25 Hz. Intensity of stimulation was modulated by varying the pulse amplitude from 0 to 100 mA. All pain measurements were taken with a 10 cm visual analogue scale. Measurements were taken during surface and percutaneous stimulation of the EDC, with the index finger in 45° flexion and constant extensor moment maintained at the metacarpalphalangeal joint. The constant extensor moment was defined as 75 percent of the lower of the 2 maximum moments generated by percutaneous or surface simulation. Three pairs of percutaneous- and surface electrode-induced pain measurements were taken per subject. Subjects were asked to describe the nature of their pain with each electrode type, and to choose the electrode type they prefer for long-term stimulation. All data were analyzed with parametric and nonparametric paired statistics.

RESULTS—Surface stimulation caused significantly greater discomfort than percutaneous stimulation for comparable finger extensor moment (mean 1.0 vs 4.9; 95 percent CI for difference: 1.9, 5.9; $p=0.002$; paired-t). Similar findings were noted with nonparametric statistics (median 0.5 vs 5.0; $p=0.01$; Wilcoxon sign rank). Subjects described the discomfort associated with percutaneous stimulation as "aches, dull pain, muscle cramps, or none." Pain from surface stimulation was described as "sharp, burning, or pins and needles." All preferred percutaneous over surface stimulation.

IMPLICATIONS—Percutaneous neuromuscular stimulation is well tolerated by chronic survivors with intact sensation. The degree of pain is significantly lower compared to surface stimulation, and may enhance patient acceptance and compliance. Two more subjects will be enrolled.

B. Upper Limb Applications

[93] 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 restore forearm and elbow control with hand grasp for people with cervical level spinal cord injury (SCI). Our objective is to increase the range and type of functions they can perform by stimulating paralyzed pronator quadratus and triceps in addition to 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 is stimulated to provide elbow extension. Stimulation is adjusted to overcome gravity, and is controlled two ways. An accelerometer mounted on the upper arm detects the orientation of the arm in the gravitational field. When the arm is abducted, the triceps is stimulated. Alternatively, the user can initiate stimulation via a switch on the wheelchair. Elbow angle is controlled in a natural manner by the subject voluntarily contracting the biceps to counteract the elbow extension. Forearm rotation is provided similarly, 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 pronation. 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.

Forearm and elbow functions are evaluated in terms of basic mechanical capabilities, ability to use the restored function to achieve stable postures and produce smooth movements, and 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 midpoint of this project. Four neuroprostheses have been constructed. One is currently being used at home by one person to provide hand grasp, elbow extension, and forearm rotation. The triceps and pronator are stimulated via percutaneous intramuscular electrodes. The individual has used the elbow extension system for 15 mo, and the pronation system for 3 mo. A second individual recently received an implanted neuroprosthesis for hand grasp and elbow extension. In this case, triceps stimulation will supplement voluntary extension provided by a posterior deltoid to triceps tendon transfer.

We designed a series of functional tests to evaluate the upper extremity workspace. The person picks up an object at one location, moves the object, and places it in another location. Object orientation is also specified at both locations. Success or failure is recorded at both the starting and ending location, and the 3-D 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. The first person was evaluated at 2 and 14 mo.

RESULTS—Elbow extension is of great benefit when objects are located high and are oriented horizontally. This is consistent with the need for elbow extension to counteract gravity. Active extension also improves performance when the person is trying to manipulate objects at shoulder level or even lower by stabilizing the position of the hand in space and allows the person to push with greater force. Pronation has enabled the person to write with the arm in a more normal position, reducing fatigue.

FUTURE PLANS—Neuroprostheses with elbow and forearm control will be implemented and evaluated in at least two more individuals. Evaluations will include as-

sessment 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

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Restoration of pronosupination control by FNS in tetraplegia: experimental and biomechanical evaluation of feasibility. Lemay MA, Crago PE, Keith MW. J Biomech 1996:29:43–42.

A dynamic model for simulating movements of the elbow, forearm, and wrist. Lemay MA, Crago PE. J Biomech. In press.

[94] FUNCTIONAL NEUROMUSCULAR SYSTEMS FOR UPPER EXTREMITY CONTROL

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B011-6RA)*

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 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 10 years. The goal of this project is to develop a more advanced stimulator with an implanted control transducer and additional stimulus channels. A 10-channel implantable stimulator-telemeter and an implanted joint angle transducer have now been developed that provide activation of the triceps for elbow extension and the finger intrinsics for improved grasp opening. With the implanted controller, most users will be able to don the system without assistance.

The surgical implantation and the implementation of the advanced neuroprosthesis follow protocols developed for the 8-channel device. Patient function is evaluated using a variety of assessments designed to measure impairment, disability, handicap, quality of life, and device utility. These assessments are performed presurgery, during an intense training session postsurgery, after 6 months, and 1 year.

PROGRESS—A 10-channel implant stimulator-telemeter was implanted in the first human subject in July 1996, and provides 2 channels of finger intrinsic muscle activation and 1 channel of triceps activation. A second implant is scheduled for September 1996.

Animal trials of the implanted joint angle transducer/controller continue. The transducer and 10-channel implant stimulator-telemeter were operational in an animal for 17 months, at which point the experiment was terminated. The histological response of the bone to the implanted transducer is now being analyzed. Additional animals will be implanted with a transducer that has been redesigned to allow easier surgical placement.

Clinical trials continue with the 8-channel device. Currently, 43 subjects have received implant stimulators at 10 sites around the world, and the multicenter clinical trial has been transferred to industry. In Cleveland, 17 subjects have received implant stimulators (14 males, 3 females; 8 C5 subjects, 9 C6 subjects.)

RESULTS—Neuroprosthesis users generate lateral and palmar pinch strengths in the range of 2.5 to 30 Newtons. In a six task grasp and release test, users 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. Users demonstrate the ability to perform activities of daily living with less assistance with the neuroprosthesis than without it. This includes the reduction or removal of physical assistance, the removal of adaptive

equipment and/or the reduction in the need for self assistance (such as using the mouth to manipulate a utensil). Users consistently indicate a preference for using the neuroprosthesis for a variety of tasks and user surveys indicate consistent use of the neuroprosthesis at home, with eating and office tasks being the most frequently performed with the neuroprosthesis. Users generally indicate a high level of satisfaction with the neuroprosthesis. Preliminary results indicate that the neuroprosthesis reduces impairment and disability, and that the device shows good usage and satisfaction. We expect that the neuroprosthesis will reduce handicap, and improve quality of life.

FUTURE PLANS—Human studies for the 8-channel hand neuroprosthesis will continue through 1996. Human studies with the 10-channel implant will continue, and human implantation of the joint angle transducer will commence in early 1997.

RECENT PUBLICATIONS FROM THIS RESEARCH

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 MJ. Hand Surg 1996:21A:89–99.

[95] THIN-FILM PERIPHERAL NERVE ELECTRODE

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Sponsor: *Hines VA Rehabilitation Research and Development Center, Hines, IL 60141 (Core Funds)*

PURPOSE—Complex hand movements might be obtained with 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 fabricated by vacuum depositing platinum-iridium 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 currently 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 in an anesthetized raccoon. Forearm and paw movements are observed with intramuscular electrodes and the implanted cuff electrodes. Five forearm muscles were isolated and their tendons connected to force transducers. Current response studies were conducted for each electrode arrangement. In addition, the cuff has been implanted chronically in three raccoons. The response of the cuff and median nerve to implantation is being evaluated.

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. Acute studies comparing the new thin-film cuff to the standard cuff constructed of silastic with platinum electrodes showed nearly identical recruitment curves.

RESULTS—In acute studies, four raccoons have been evaluated under anesthesia with the 12-electrode (standard) cuff. A variety of paw movements could be obtained using different electrode arrangements, including forearm pronation, wrist flexion, and digit flexion. 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 (4-elcctrode) thin-film cuff to the standard cuff showed nearly identical recruitment curves. Chronic implantation of the thin-film electrode on the median nerve for 6 weeks was conducted in four additional raccoons. Although all of the forearms had responded to stimulation at thc day of initial implantation, the forearms had little or no response after the 6 weeks of implantation. Postmortem observations indicated that one clectrode cuff had come off of the nerve. The remaining three electrodes were sutured together to help keep them on the nerves, but all three of these electrodes had opened up and were adjacent to the nerve. All of the cuffs had extensive connective tissue around them. The nerves appeared unaffected by the implantation by gross observation. Histological evaluations of the nerves arc continuing.

FUTURE PLANS—The electrode location in the middle of the upper arm is a position that has lots of movement, which probably contributed to the electrode dislodgment and buildup of connective tissue. New electrode designs are under consideration, including better electrodes for areas where there is muscle movement.

[96] PERCUTANEOUS NEUROMUSCULAR STIMULATION FOR SHOULDER SUBLUXATION IN HEMIPLEGIA

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Sponsor: *Claude D. Pepper Older American Independence Center, Case Western Reserve University, Geriatric Care Center, Cleveland, OH 44106; FairHill Institute for the Elderly, Cleveland, OH 44120; National Institutes of Health, National Institute on Aging Bethesda, MD 20892*

PURPOSE—Surface stimulations of the posterior deltoid and supraspinatus have been shown to reduce post-stroke shoulder subluxation and associated complications. However, cutaneous pain and associated poor compliance, poor muscle specificity, and the labor-intensive task of consistently localizing motor points limit the practical application of surface stimulation for shoulder subluxation. The purpose of this case study is to assess the effectiveness of percutaneous neuromuscular stimulation in reducing shoulder subluxation, and the patient tolerance of 6 hrs of stimulation per day for 4 wks.

METHODOLOGY—A 77-year-old male who suffered a right anterior circulation cortical infarct was enrolled in the study. Subject suffered his stroke within 3 wks of study entry with residual neurologic impairments including flaccid left hemiplegia, left hemi-neglect, dysarthria, dysphagia, bladder incontinence, and two-finger breadth anterior-inferior shoulder subluxation. Sensation and language were intact. Helical percutaneous clectrodes wound from FEP-Teflon insulated, multistranded, type 316L stainlcss stcel wires were implanted into the posterior deltoid and supraspinatus using a 19-gauge hypodermic needle. Electrodc exit site on the superior aspect of the shoulder just medial to the acromian and paths between the exit site and the 2 motor points were anesthetized with 2 percent lidocaine. After entry, the hypodermic needle loaded with a percutaneous electrodc was tunneled toward the motor point. A balanced biphasic, cathodic-first, capacitively-coupled, constant-current pulse was applied. The amplitude and frequency were maintained at 20 mA and 25 Hz, respectively. Intensity of stimulation was adjusted to clinical reduction of the subluxation by adjusting the pulse duration between 50–200 μs. Duty cycle of 10 s on and 2 s off was employed with total stimulation time of 6 hrs per session. True anterior-posterior view radiographs of both shoulder were taken with and without stimulation to assess the efficacy of stimulation in reducing the subluxation.

RESULTS—Subject tolerated the implantation proccdure well. Radiograph of the left shoulder revealed marked anterior inferior subluxation with significant widening of the gap between the acromian and the humcral head. With stimulation the gap was markedly reduced, being essentially equivalent to that of the uninvolved side. Subject is presently tolerating 6 hrs per day of stimulation without any discomfort. He is on his third wcek of stimulation.

IMPLICATIONS—Long-term percutaneous stimulation for shoulder subluxation is well tolerated. There is

minimal discomfort, muscle specific stimulation is provided, and motor points do not need to be localized with each stimulation session. Percutaneous neuromuscular stimulation may render functional electrical stimulation more practical. Controlled pilot trials are underway to assess the efficacy of percutaneous neuromuscular stimulation in decreasing shoulder subluxation, preventing or minimizing shoulder pain, and enhancing motor and functional recovery of acute and chronic stroke survivors.

[97] 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—Measurements of the interactions between simultaneous modulations of stimulus amplitude and stimulus frequency have been completed. Since these two physical dimensions are chosen most often for providing information via sensory feedback, it is important to understand to whether their corresponding psychological dimensions of loudness (perceived intensity) and pitch, respectively, are independent or interact with each other. Bekesy tracking was used to measure isoloudness and isopitch contours to investigate distortion, that is, the effects of stimulus frequency on perceived stimulus intensity and the effects of stimulus amplitude on perceived pitch.

PROGRESS—Measurement of isoloudness and isopitch contours have been completed.

RESULTS—Contours of equal loudness (perceived amplitude) and equal pitch (perceived frequency) were measured in the present study for electrocutaneous stimuli covering most of the usable range of amplitudes and frequencies: 3–12 dB SL and 4–64 Hz. Eight naive subjects generated isoloudness contours at four reference amplitudes via Bekesy tracking, and eight additional subjects generated isopitch contours at three reference frequencies. The isoloudness contours declined slightly but significantly with stimulus frequency, consistent with previous results. The shape of the contours was also slightly dependent on the amplitude of the reference stimulus. Isopitch contours were unaffected by stimulus amplitude on average, but the contour shape did vary modestly, though erratically, with reference frequency.

FUTURE PLANS—The isoloudness and isopitch contours will be used in implementing electrocutaneous sensory in portable hand neuroprosthesis. The current design uses a fixed amplitude and variable frequency to code finger span, and a fixed frequency and variable amplitude to represent force. Look up tables representing the inverted isosensation contours will be used to compensate for distortion by covarying amplitude and frequency to produce the desired orthogonal changes in loudness and pitch.

RECENT PUBLICATIONS FROM THIS RESEARCH

Perceptual interactions between electrocutaneous loudness and pitch. Poletto CJ and Van Doren CL. IEEE Trans Rehabil Eng 1995:3(4):334–42.

Contours of equal perceived amplitude and equal perceived frequency for electrocutaneous stimuli. Van Doren CL. Percept Psychophys. In press.

[98] RESTORATION OF SHOULDER MOVEMENT IN C5 TETRAPLEGIA

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Sponsor: *National Institutes of Health, National Institute of Child Health and Human Development, National Center for Medical*

PURPOSE—This study will implement, evaluate, and optimize a neuroprosthesis based on functional neuromuscular stimulation (FNS) which will restore shoulder function to individuals with C5 tetraplegia. Such individuals retain little or no voluntary control over motions acting to move the upper arm toward the midline, due primarily to paralysis of the pectoralis major (PM) and latissimus dorsi (LD) muscles. This loss of control significantly reduces the range of motion of the hand, excluding an important workspace volume near the midline, and prevents arm stabilization in the natural adducted postures used in many tasks like eating and writing. Restoration of these functions would significantly improve the independence of these individuals in a number of daily activities, improving their quality of life and reducing their attendant care costs.

METHODOLOGY—Percutaneus electrodes will be implanted into the PM and LD muscles. Controlled stimulation of these muscles will be used to provide shoulder function in horizontal flexion, adduction, and internal rotation in individuals with C5 tetraplegia. The stimulated contractions will restore the lost motions, while retained voluntary control of antagonistic muscles will be used by the individual to overcome the stimulated contractions and achieve intermediate positions and external forces in a completely natural manner. The performance of the shoulder neuroprosthesis will be evaluated by quantifying the expansion of the workspace volume accessible to the hand, the increased postural stability within this workspace, and the increase in speed and accuracy of arm movements.

Several general methods for improving control of the partially paralyzed shoulder will also be developed. Shoulder stiffness properties will be used to identify deficits in postural stability in a systematic manner and to suggest changes in electrical stimulation patterns to correct the deficits. The feasibility of using electromyographic recordings from voluntarily controlled shoulder muscles to modulate stimulation of the paralyzed muscles will be investigated, since such modulation could improve movement performance, prevent fatigue, and compensate for changes in contraction strength in different shoulder positions.

PROGRESS—This is a new project of the Cleveland FES Center.

[99] CLOSED-LOOP CONTROL OF FUNCTIONAL NEUROMUSCULAR STIMULATION

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Sponsor: *National Institutes of Health, NINDS Neuroprosthesis Program, Bethesda, MD 20892*

PURPOSE—Hand grasp neuroprostheses enable individuals to grasp and release objects that they could not otherwise use and allows them to accomplish many tasks of daily living with improved function. This project continues development of upper extremity neuroprostheses by addressing deficiencies in 1) the grasp output, 2) proximal control of the limb, 3) voluntary control input, and 4) control of the contralateral limb. The project outcome will provide a significant improvement in the quality and controllability of restored movement, and an increase in the types of functions individuals can perform, thus providing greater independence.

METHODOLOGY—*Synthesis of upper extremity control:* a previously developed dynamic biomechanical model of the upper extremity is being applied to improving the quality of hand grasp in individual people who receive the neuroprosthesis. The application to specific individuals requires parameterizing and validating the model.

We are developing noninvasive techniques to obtain biomechanical parameters for individual persons. Specifically, moment arms, muscle excursions, and tendon lines of action will be derived from 3-D MRI data. Along with the geometric data, the active and passive joint moments will be measured across a group of subjects and serially in time to evaluate the stability of grasp output and the relationship between active and passive forces, and to guide and judge the success of surgical and therapeutic interventions. Passive moments arise from the tissues surrounding a joint and the inherent passive properties of muscles crossing the joint. The contributions will be separated in the model to allow better surgical and therapeutic planning to correct abnormalities. The passive moments measured experimentally in people will also be separated to provide better treatment planning and evaluation.

The biomechanical model and the parameters measured for individual neuroprosthesis users will be analyzed to refine their neuroprosthetic grasp patterns and for planning tendon transfers. The personalized biomechanical model will be used to predict the range of surgical solutions to given problems presented by individuals.

Control of upper extremity function: prior laboratory work has established the feasibility of providing closed-loop control and sensory feedback to improve hand function. A portable neuroprosthesis with these control features will be used to evaluate the potential benefits outside of the laboratory.

In further laboratory work, we will assess the impact of sensory feedback (including finger span, grasp force, and command) on grasp performance. The proposed evaluation method is unique in that it will separate the effects of the electrocutaneous feedback from the effects of visual feedback alone.

The generation of logical signals to control hand grasp is a limiting factor in patient task performance. We will evaluate alternative sources of command signals and alternative hand grasp command control algorithms. Improvements are expected to decrease the demands on the person, and increase the likelihood that the intended command is generated, thereby increasing confidence in the system.

We will implement hand grasp and release in both hands of individuals with C6 level function. Bimanual hand function will increase the person's working volume and enable the person to perform bimanual tasks more efficiently. A key aspect to implementing bimanual control is to simplify the command control process compared to the currently implemented system.

Control systems to restore independent control of wrist and hand function in tetraplegic individuals with C5 and weak C6 function will be designed. Control systems must compensate for mechanical interactions between the wrist and hand muscles, and allow weak voluntary wrist extensors to drive electrically stimulated synergists. Achieving this objective will allow wrist command control to be extended to individuals who must presently use

shoulder command control, and would allow bimanual hand grasp to be extended to people with C5 level function as well.

PROGRESS—This is a new project of the Cleveland FES Center.

RECENT PUBLICATIONS FROM THIS RESEARCH

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An experimentally based nonlinear viscoelastic model of joint passive moment. Esteki A, Mansour JM. J Biomech 1996:29:443–50.

Restoration of pronosupination control by FNS in tetraplegia: experimental and biomechanical evaluation of feasibility. Lemay MA, Crago PE, Keith MW. J Biomech 1996:29:435–42.

A dynamic model of the hand with application in functional neuromuscular stimulation. Esteki A, Mansour JM. Ann Biomed Eng. In press.

[100] HAND NEUROPROSTHESIS IN CHRONIC HEMIPLEGIA

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Sponsor: *Rehabilitation Medicine Scientist Development Program, National Institutes of Health, National Institute on Child Health and Human Development, Bethesda, MD 20892*

PURPOSE—A fully implantable hand neuroprosthesis system enhances the ADL function of persons with C5-C6 tetraplegia. However, it is unclear whether a similar system will be beneficial to stroke survivors with a nonfunctioning hand. The purpose of this study is to assess the functional benefit of a percutaneous hand neuroprosthesis system in chronic hemiplegia.

METHODOLOGY—Three chronic stroke survivors with volitional control of the hemiparetic shoulder and elbow, but with nonfunctioning hand were implanted with percutaneous intramuscular electrodes into various muscles of the hand and forearm. One subject received electrodes into the extensor carpi radialis (ECR), extensor digitorum communis (EDC), extensor indicis propius (EIP), extensor pollicis longus (EPL), and abductor pollicis brevis for hand opening. Flexor digitorum superficialis (FDS), adductor pollicis and first dorsal interosseous were implanted for hand closure.

Two other subjects received EDC, ECR, EIP and EPL electrodes for hand opening. They both had voluntary hand closure in synergy. Percutaneous helical electrodes wound from FEP-Teflon insulated, multistranded, type 316L stainless steel wires were implanted into each muscles using a 19-gauge hypodermic needle. All extensor electrodes exited from the same site on the dorsal surface of the forearm. The path between the exit site and the motor points of target muscles were anesthetized with 2 percent lidocaine. After initial entry, the hypodermic needle loaded with a percutaneous electrode was tunneled toward the motor point where the electrodes were implanted. For the one subject with implanted flexor muscles, there was an additional exit site on the flexor surface of the forearm. A balanced biphasic, cathodic-first, capacitively-coupled, constant-current pulse was applied to each electrode. The amplitude and frequency were maintained at 20 mA and 25 Hz, respectively.

Stimulation intensities of each electrode were adjusted by varying the pulse duration from 0 to 200 μsec. A hand grasp and release pattern was formulated for each subject and programmed into the stimulators. The stimulator can be placed in an exercise mode to allow cyclical hand opening and closure or be interfaced with a transducer to allow volitional control.

RESULTS—Selective stimulation with good contraction of each implanted muscle was achieved with minimal spill over to adjacent muscles. The degree of discomfort

varied with specific muscles, but was minimized by adjusting stimulation parameters, while maintaining desired range of motion and torque. In one subject with marked flexor hypertonia, finger extension lead to appropriate MCP extension, but with significant flexion at the PIP and DIP resulting in a "claw" hand. Activation of the intrinsics via ulnar nerve stimulation improved hand opening. All subjects are presently tolerating 2-3 hours of stimulation-induced hand opening and closing exercises per day. Two subjects are learning to use a potentiometer manipulated by the good hand to perform simple tasks such as picking up blocks.

FUTURE PLANS/IMPLICATIONS—Results to date show that chronic stroke survivors with intact sensation tolerate percutaneous electrode implantation and stimulation well. Our plan is to explore control paradigms which will allow subjects to reliably open and close the hand without compromising the function of the unimpaired upper extremity. This will be followed by formal testing of ADL function. A total of 8 subjects will be enrolled.

[101] EFFICACY OF NEUROMUSCULAR STIMULATION IN ENHANCING THE UPPER EXTREMITY MOTOR AND FUNCTIONAL RECOVERY OF ACUTE STROKE SURVIVORS

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PURPOSE—Surface neuromuscular stimulation has been shown to enhance the motor recovery of stroke survivors. However, controlled studies have not demonstrated that electrical stimulation enhances functional recovery. The purpose of this double blind, placebo controlled, randomized trial is to assess the efficacy of surface neuromuscular stimulation in enhancing the upper extremity motor and functional recovery of acute stroke survivors.

METHODOLOGY—Stroke survivors admitted to an inpatient stroke rehabilitation program within 6 wks of their acute stroke were randomly assigned to treatment or placebo group. Motor status at entry was limited to synergy movements or if isolated movement was present, wrist extension muscle grade was less than antigravity strength. The treatment group received 1 hr of surface electrical stimulation to the finger and wrist extensors per day, 5 times a week for 3 wks. Stimulation parameters were adjusted for patient comfort and full wrist extension range of motion. The control group received electrical stimulation away from the motor point of the wrist and finger extensors, with intensity adjusted to just above sensory threshold. Outcomes were assessed at end of treatment, 1 mo posttreatment and at 3 mo posttreatment with the self-care component of the Functional Independence Measure and the upper extremity component of the Fugl-Meyer Motor Assessment in a blinded manner.

RESULTS—Based on a power analysis with expected difference between treatment and control group of 1 standard deviation on the upper extremity Fugl-Meyer Motor Assessment, alpha of 0.05 and beta of 0.20, a sample size of 23 subjects per group were calculated. To date 12 subjects have completed the study. Two subjects are presently enrolled.

IMPLICATIONS—Poststroke motor impairment is a strong predictor of poststroke physical disability. Whether electrical stimulation will render sufficient improvements in the motor status to translate into improved daily function is unclear. Preliminary analysis will be performed when half the expected subjects have completed the study.

[102] A QUANTITATIVE ANALYSIS OF SHOULDER MOVEMENTS USED TO CONTROL A FES SYSTEM IN ADOLESCENTS WITH C4 LEVEL SPINAL CORD INJURIES

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PURPOSE—The purpose of this project is to quantitatively assess shoulder movements used to control functional electrical stimulation (FES) rehabilitative system in adolescents with C4 level spinal cord injuries (SCIs). Individuals with C5 level SCIs have successfully used their shoulders to control stimulated hand grasp and release. A pilot study done at Shiners Hospitals for Children indicated that an adolescent with C4 level SCIs could use his shoulder to control stimulated arm movements.

METHODOLOGY—A total of 13 subjects participated in the experiment, 5 of whom were nonimpaired. The other 8 subjects were individuals with C5 and/or C4 level SCIs from whom 6 C5 and 6 C4 shoulders were examined. A dual-axis angular position transducer designed at Case Western Reserve University for use as a control device by patients with cervical SCIs was used to measure elevation/depression and protraction/retraction of the shoulder. The electrical signals from the two axes of the transducer were recorded while the subject performed three different experimental tasks. First, subjects were asked to repeatedly elevate, depress, protract, and retract their shoulders maximally to establish an active range of motion (AROM). Next, subjects were asked to elevate, depress, protract, and retract their shoulders through a series of discrete "target" shoulder positions with the aid of a computer-generated representation of both the target and current shoulder position. Finally, subjects were asked to elevate, depress, protract, and retract their shoulders to mid and end range and maintain these positions without the computer generated visual feedback.

PROGRESS—Data have been collected for all of the aforementioned subjects through all three sections of the experiment.

PRELIMINARY RESULTS—For the active range of motion section, a Kruskal-Wallis analysis (95 percent confidence interval) of the three populations detected no significant difference in either the magnitude or direction of movement between C4 and C5 subjects during elevation, depression, protraction, or retraction. The only motions which the test did not detect a significant difference between the nonimpaired and SCI populations were with the C4 in depression and with the C5 in depression and protraction. As expected, both C5 and C4 subjects exhibited the greatest active range of motion while elevating with mean values of 14.7 and 7.9° respectively.

Furthermore, all but one of the SCI patients displayed a consistent pattern of motion regardless of both the motion they were asked to perform (i.e., elevate, depress) and the section of the experiment (i.e., active range, incremental stepping), indicating that C5 and C4 individuals may not be able to elevate/depress and protract/retract independently. Preliminary results indicate that there is no appreciable difference among the three populations in the error associated with reaching a target shoulder position. Early analysis also indicates that there is no appreciable difference among the three subject groups in the ability of an individual to maintain a particular static shoulder position without the use of visual feedback. Overall, the results indicate that the shoulder movements of the subjects with C4 level SCIs are comparable to those with C5 level SCIs and may be adequate to control FES arm movements.

FUTURE PLANS—Further analysis of the response of the subjects to the later two sections of the experiment is to be completed. In addition a simplified mechanical model of the shoulder is being explored in an attempt to explain the apparent trend in the shoulder motion of subjects with SCIs.

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

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PURPOSE—Tetraplegia due to cervical spinal cord injury (SCI) results in the loss of voluntary control over a number of muscles of the hand and arm, severely limiting the ability of individuals to perform many routine activities of daily living such as feeding and grooming, and reducing their ability to work independently. Tendon transfer surgery can be used to restore voluntary control over some arm and hand functions by detaching a nearby donor muscle (which has remained under voluntary control) from its normal connection to the skeleton and reattaching it to the tendon of a paralyzed muscle that normally provides the desired function. The specific objectives of this project are to evaluate the ability of a posterior deltoid-to-triceps tendon transfer surgery to restore voluntary control over elbow extension function in individuals with SCI, to measure and assess the impact of this surgery on the other functions of the limb, to examine adaptation in the neural control of the limb in response to the muscle transfer, and to identify and evaluate changes to the surgical procedures which could improve the ultimate functional outcome.

METHODOLOGY—In one set of experiments, the ability of individuals with SCI and subsequent tendon transfer surgery to produce adequate elbow extension moments is measured. The forearm of the subject is fixed to an experimental device so that the elbow and shoulder rotate in a horizontal plane at the level of the glenohumeral joint. Isometric elbow and shoulder moments generated by the subject can then be measured for different combinations of elbow and shoulder angles using a 6-axis force-moment transducer mounted at the interface between the subject and the fixture. In another set of experiments, subjects are seated with their arm attached to the endpoint of a specially designed robotic manipulator. This manipulator is used to generate constant load forces that the subject must balance in order to maintain a desired hand position and to impose small random force perturbations which allow the estimation of the stiffness properties of the arm. The identified stiffness properties are directly related to the postural stability of the arm and can also be used to localize deficits which limit performance.

PROGRESS—We have actively begun experiments to measure the elbow extension strength and its dependence on elbow and shoulder angles in subjects with SCI, treated with posterior deltoid-to-triceps transfers. The experimental and analytical methods developed to measure human arm stiffness have been validated using known mechanical systems, and initial stiffness measurements have begun using nonimpaired human subjects.

RESULTS—Elbow extension strength was found to vary widely (from less than 1 Nm to greater than 16 Nm) across subjects, and to depend on the level of SCI. Elbow extension moment was also often found to be highly dependent on both elbow and shoulder angles, in a manner consistent with the length-tension properties of the posterior deltoid muscle. Unfortunately, paralysis and weakness in other shoulder muscles in these subjects force them to adopt arm positions for which the transferred posterior deltoid is shortened and therefore at a mechanical disadvantage. We have also validated the experimental and analytical methods used to estimate endpoint arm stiffness. We have successfully identified a number of known mechanical systems, and preliminary results from able-bodied subjects indicate that the stiffness properties of the elbow-shoulder system operating in a horizontal plane are well characterized by a two-input, two-output linear system. Arm stiffness parameters vary with the size and direction of the load that must be balanced by the subject.

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C. Lower Limb Applications

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

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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 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 8-channel CWRU/VA receiver/stimulators. These will activate electrodes (in most cases, epimysial electrodes sewn directly to the muscle). New surgical techniques will be developed to enable the electrodes and stimulators to be implanted in a few sessions within a few weeks time. A new external control unit (ECU) will be designed to generate radio frequency signals to synchronize the actions of both implanted 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 stimulus patterns will also result from the technical development.

RESULTS—During this second year of the project, enhancements to mobility for individuals with complete paraplegia, including walking and side-stepping, have been demonstrated on a small pilot population of subjects using a 16-channel percutaneous system. Specific assessment criteria to evaluate the effectiveness of FES as a rehabilitative intervention, focusing on enhancement of mobility, have been developed. The inclusion criteria for subjects in this study have been finalized, with several potential participants identified. The first subject to receive the completely implanted system has been identified, and plans for surgical implantation of this patient are in place for completion within this project year. Techniques for the surgical deployment of the epimysial electrodes in the muscles required in the lower extremity have been developed and piloted. Detailed functional requirements for the revised ECU have been developed, and the final hardware development is underway by an outside contractor.

FUTURE PLANS—In the third project year, three additional subjects will receive the completely implanted FES system for mobility enhancement. All four subjects will participate in the development and refinement of the clin-

ical protocol for rehabilitation with FES, and the outcome assessment techniques will also be refined and documented on this pilot population. Follow-up assessment will occur at home and workplace. Complete documentation of the FES Mobility System and its implementation will be prepared, sufficient for the start-up of larger scale clinical trials involving multiple centers, to commence at the end of this project.

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

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B683-RA)*

PURPOSE—The purpose of this research is to develop and evaluate improved methods of functional neuromuscular stimulation (FNS) for locomotion in complete paraplegic subjects. The goal 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—Improvements to the current FNS locomotion system take the form of a feedback control system. Sensors worn by the FNS patient provide signals from which decisions concerning stimulation patterns can be made by the control system. The control system consists of three primary components: the **Gait Phase Estimation Module** processes the sensor signals through a fuzzy logic rulebase, to determine the phase of gait while the patient is walking; the **Gait Evaluation Module** uses this information and the sensor information to determine if an anomaly has occurred during walking which requires a change to the stimulation being sent to the patient's muscles; and the **Pattern Adjuster Module** then generates the adjustment in the stimulation pattern.

PROGRESS—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.

A computer biomechanical simulation of human gait (both normal 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.

FUTURE PLANS—The next year of the project will involve continued development and refinement of the gait evaluation and pattern adjuster components of the system, and its evaluation in paraplegic subjects. These subjects will include individuals using 16 channels of stimulation, consistent with the implanted stimulator systems that are under development in a related project.

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Using evoked EMG as a synthetic force sensor of isometric electrically stimulated muscle. Erfanian A, Chizeck HJ, Hashemi RM. IEEE Trans Biomed Engr 1996. In press.

[106] 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 8-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 8-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.

RESULTS—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 postinjury, 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. 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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[107] RESTORATION OF GAIT FOR THE STROKE PATIENT

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PURPOSE—We tested a new technology, a multichannel, implanted Functional Neuromuscular Stimulation (FNS) system for stroke gait rehabilitation. We compared treatment using surface electrodes (surface-stim) with treatment using implanted, intramuscular (IM) electrodes (FNS-IM).

METHODS—Chronic (1 year or more post stroke) stroke subjects were studied, each subject serving as his/her own control. A single case study design was used, across subjects. In phase 1, eight patients were treated with surface-stim; in phase 2, six of those patients were treated with FNS-IM. Four muscles were stimulated: anterior tibialis; gastrocnemius/soleus; quadriceps; short head of the biceps femoris and long head of the biceps femoris.

Outcome measures were threefold: 1) volitional movement at a single joint with the body in a static position; 2) kinematics of gait; and 3) functional capability at home. EMG, kinematic data, clinical gait scale, manual muscle test, coordination, balance, and functional capability data were collected.

PRELIMINARY RESULTS—Eight subjects were studied in phase 1, surface-stim treatment. Preliminary analysis indicated that following surface-stim, 25–63 percent of the subjects improved in volitional measures of lower extremity strength and coordination. In kinematic measures of gait, 12–50 percent improved during phase 1, surface-stim treatment. Six of those subjects were progressed to phase 2, treatment using FNS-IM. During this phase, in every measure of strength, coordination, and gait kinematics, subjects demonstrated statistically significant improvement in volitional motor control, beyond that attained during surface-stim treatment ($p<0.0001$). In addition, functional gains were documented, beyond those attained during surface-stim treatment.

IMPLICATIONS—Rehabilitation techniques in use today are often not sufficient to restore a safe, normal gait pattern to stroke patients. Subjects in this study showed improved gait and functional capability following treatment with both surface-stim and FNS-IM. The results of this study support further study of FNS, using both surface-stim and FNS-IM, for gait rehabilitation following stroke.

[108] 3-D FORCES AND MOMENTS DURING FES-INDUCED LEG CYCLE ERGOMETRY: A PILOT STUDY

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PURPOSE—The purpose of this pilot project is to study the three-dimensional (3-D) biomechanics of functional electrical stimulation-induced leg cycle ergometry (FES-LCE) in individuals with spinal cord injuries (SCI) to determine potential orthopedic risks and methods to improve operating safety and efficiency. The specific objectives are to: 1) describe the 3-D forces and moments applied to the pedals during FES-LCE in persons with SCI; 2) determine 3-D knee and 2-D hip and ankle moments during FES-LCE; 3) describe the changes in these forces and moments with increasing power output (PO) and with fatigue; 4) compare these forces and moments during FES-LCE by persons with SCI to those during voluntary LCE by nondisabled (AB) persons; 5) determine the mechanical efficiency (using the metabolic rate) at various levels of PO and fatigue and correlate this with the amount of extraneous forces; and 6) make recommendations as to how operating safety and efficiency may be improved (e.g., patient-LCE configuration, muscles utilized, timing, and strength and duration of the contractions).

METHODOLOGY—Ten subjects with SCI will perform FES-LCE exercise on a Therapeutic Alliances Incorporated ERGYS LCE. The ERGYS I was equipped with specially constructed pedals that can measure 3-D forces and moments, and with force transducers in the leg restraints that can measure medio-lateral forces on the upper-legs. For comparison, ten AB persons will perform this activity voluntarily. The LCE operating configuration will closely follow the clinical situation, and will be the same for all subjects, except that the AB subjects will perform LCE voluntarily. To evaluate the influence of PO on the biomechanics and mechanical efficiency, the subjects will perform a progressive intensity LCE-test. To evaluate the influence of fatigue, subjects will perform a prolonged LCE-test at various, but constant, PO levels. Metabolic and cardiopulmonary responses will be monitored to calculate mechanical efficiency. 3-D motion analysis, using an infrared active marker motion analysis system, will occur simultaneously to enable determination of forces and moments at the ankle, knee, and hip joints using inverse dynamics techniques.

PROGRESS—The initial testing phase of this project has now been completed. The pedal and leg restraint force measurement systems have been coupled to the Optotrak system to enable synchronous recording of forces and movements. Two men with SCI (one with paraplegia and one with quadriplegia) and two AB men participated in the initial testing phase. Preliminary results suggest that in the subjects with SCI medio-lateral forces exerted on the leg restraints tended to be higher than in the AB subjects and occured at different angles in the pedal cycle. It was also apparent that subjects with SCI exhibited a less smooth force exertion pattern with more periods of brief peak forces than the AB subjects.

IMPLICATIONS—The results of this research could provide greater understanding of the forces in lower-extremity joints during FES-LCE and how muscle activation can be improved to reduce potentially hazardous forces and to increase mechanical efficiency. This can ultimately lead to the development of a more efficient therapeutic exercise system that can be safely used on a regular basis to enhance fitness in persons with SCI, and reduce the risk of secondary health problems.

[109] DEVELOPMENT OF A CLOSED LOOP CONTROL SYSTEM FOR FES AND APPLICATION TO KNEE JOINT MOVEMENTS IN PARAPLEGICS

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PURPOSE—The purpose of this study is to develop and test a closed-loop control system for Functional Electrical Stimulation (FES), in order to recover some movements of paralyzed muscles and to realize a functional and physiotherapeutic tool for injured people.

METHODOLOGY—The system is based on a PC, a programmable 8-channel stimulator, a controller, and a set of sensors. A PID software regulator has been experimentally realized and used to control the stimulator. Ziegler and Nichols' method has been used to determine the controller's parameters.

Electrogoniometers interfaced by a dedicated board were used to catch the feedback signal: we applied the system principally to the quadriceps; therefore, the controlled feedback signal (outputs) was the knee angle. The obtained knee angle is compared with the desired ones in real time, and the PID controller calculate the right input for the stimulator.

The programmable stimulator produces trains of rectangular pulses, the width of which is controlled by the feedback signal.

Up to now three working configurations have been set: tracking of a prefixed knee angle value, tracking of a prefixed knee angle trajectory, and a master-slave configuration, in which the tracked angle is real time caught by an electrogoniometer from another joint (or even from another person).

PROGRESS—Applications of this technique to standing-up movement has been considered. In particular two methods have been tested: the tracking of a trajectory acquired from a nondisabled subject, and the real-time tracking of the elbow angle with Master-Slave configuration, since in nondisabled subjects we found a good correlation between knee and elbow angle during the standing-up movement.

Moreover, a standing posture system was implemented: it switches on when the standing up movement is completed, and is based on the knee angle variation and on a prefixed pattern for the alternation of the supporting leg, in order to minimize the muscle fatigue. Now we are working on a pressure sensor under the feet, sensitive to the subject's weight distribution.

PRELIMINARY RESULTS—A frequency domain study was done on the system applied to the quadriceps muscle of a nondisabled subject. For this purpose, a set of sinusoid signals with frequency from 0.1 to 1 Hz has been used as input trajectory. Comparing obtained knee angles with imposed one, a Bode diagram has been built. The system behaves as a low-pass filter with a frequency cut at 0.5 Hz due to a complex pole couple. The system shows a good robustness to external disturbance.

FUTURE PLANS—The use of the pressure sole for the posture of a paraplegic subject is the next step of this study: the weight position on the foot will be used as control signal to stimulate quadriceps and calf muscles. Moreover, the application of this system to a paraplegic subject is planned in order to verify its applicability during physiotherapy treatments and/or in domestic situations.

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[110] FES POWERED RGO: A PRACTICAL WALKING SYSTEM FOR PARAPLEGICS

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PURPOSE—The objectives of this project are to provide some paraplegics with a reliable and safe walking system, reducing metabolic energy consumption by utilizing electrical stimulation of selected muscle groups.

METHODOLOGY—While the LSU Reciprocating Gait Orthosis (RGO) has been successfully applied to a large population of paraplegics for a number of years, work has expanded on development of two muscle stimulation strategies designed for use in combination with the orthoses. The first approach employs surface stimulation of the quadriceps simultaneous to the contralateral hamstrings to induce hip flexion and extension. The second approach employs implanted stimulation of the vasti and illiopsoas muscles for independent control of knee and hip flexion and extension.

RESULTS—Two hundred patients have already been tested, evaluated, and fitted with the RGO and portable stimulation system. One demonstration of the efficacy of the system was its enthusiastic acceptance by the patients. The addition of FES reduced the energy cost of locomotion and improved the acceptability of the system by patients. It was also shown that there were significant reduction in spasticity and cholesterol along with improvement in cardiopulmonary and metabolic functions.

[111] PARAPLEGIC WALKING MADE PRACTICAL WITH FNS AND ORTHOSES

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Sponsor: *National Institute of Child Health and Human Development; the National Institute of Neurological Disorders and Stroke, Bethesda, MD 20892*

PURPOSE—We seek to determine if the combination of eight channels of implanted functional electrical stimulation (FES) and a functionally activated trunk-hip-knee-ankle-foot orthosis can result in a practical mobility aid for use in the complete paraplegic individual. Our focus is to provide sufficient control to the existing FES capability to allow meaningful functions such as crutch walking and stair climbing, and develop a brace system acceptable to the patient, and society, from the aspects of function, reliability, safety, ease of use, appearance, and cost.

METHODOLOGY—We shall fit multiple subjects with the combination of an 8-channel, radio-frequency-controlled/powered, implantable stimulator, or a percutaneous FES system, with a prototype low weight, functional orthosis having active, computer-controlled joint locks. A hybrid orthosis will result from combining this technology with expertise in electro-mechanical brace design from CWRU, Henry Ford Hospital of Detroit, and New York University (NYU). Physical therapists will be able to utilize accepted and modified outcome assessment and energy consumption measures to determine the ability of users to function in the household or the community at large.

PROGRESS—Six complete paraplegic individuals with percutaneous systems have evaluated the prototype brace. The single lateral leg support prototype helped determine the materials necessary to attain the stiffness required for a functional low-weight orthosis. Current de-

sign efforts focus on three specific areas of development. The first is a variable trunk support, flexible when the user is sitting in a wheel chair, allowing lateral and forward bending with minimal constraint, which becomes a rigid support when standing and ambulating. Secondly, a hip joint which actively assists in the stabilization of the upper torso and supplies a beneficial moment when positioning the leg for stair climbing. Finally, knee joints will be locked and unlocked by the external control unit (ECU) of the stimulator according to the phase of gait. The functionality of the prototype brace and FES combination is being assessed. Experiments to determine energy consumption comparing brace alone to brace and FES are being done. A second line of investigation is looking into the range and repeatability of ambulation to characterize the ability of a user to function in a community setting. Maneuverability testing around obstacles and standing activities are being conducted.

RESULTS—Development of surgical techniques for implantation of an 8-channel, RF-powered/controlled FES system have progressed since the initiation of the project, and the ability now exists to implant the system in one to two surgical sessions. Two subjects are scheduled for implantation in late 1996. These subjects will have the first braces with ECU synchronized knee joint locks. A prototype trunk support, reducing movement constraints on the user when not ambulating without loosening straps, is being readied for application to a prototype brace. Computer simulation of a hip joint which aids in stair climbing and trunk stability without the need of the reciprocating mechanism has proved successful. A prototype is being fabricated for testing. Physical therapists familiar with brace training and FES have shown that subjects can be taught to utilize the orthosis in combination with FES and crutches when they were previously unable to use the orthosis alone. Sit-to-stand maneuvers and ambulation are also simplified with the application of FES. Subjects using this system have shown the ability to ambulate 500 m when allowed standing rest periods of 5 min between 50 m walks. Energy consumption continues to be an area of concern with 7 MET outputs being measured for short walks.

IMPLICATIONS—A less constrained brace combined with and implantable FES system will, as indicated by these results, allow a completely paralyzed user to attain a limited level of community ambulation.

V. Geriatrics

[112] PERFORMANCE-BASED PREVENTION/REHABILITATION OF FALLS IN ELDERLY VETERANS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E827-RA)*

PURPOSE—The objective of the study is to further refine a functional obstacle course developed to balance and mobility of elderly community-dwelling persons; to determine the efficacy of a rehabilitation program in reducing frequency and severity of falls and fall-related injuries by improving the balance and mobility of elderly persons who fall, and to determine the efficacy of a rehabilitation program in preventing falls by maintaining/improving balance and mobility among persons with no history of falls.

METHODOLOGY—A retrospective comparison of performance data from the new and old versions of the obstacle course will be made. Baseline obstacle course testing on community-dwelling, ambulatory elderly veterans with falls (fallers) and without (nonfallers) will be completed. One hundred-twenty consecutive fallers will participate in a 6-week falls prevention/balance rehabilitation exercise program lead by a physical therapist. One hundred-twenty nonfallers will be randomized into either an identical 6-week falls prevention/balance rehabilitation exercise program or a nonexercise control group. All persons completing an exercise group will be offered an optional maintenance exercise program. Obstacle course and other clinical testing will be repeated immediately postintervention and 6 and 12 months afterward. Exercise adherence will be monitored, as will the prospective monthly falls and fall-related injuries of all participants for 18 months. Preintervention to postintervention measures will be compared.

PROGRESS—Recruitment has been extended to include the spouses of veterans. This may improve participation and adherence. The originally planned nonexercise control group for nonfallers has been extremely difficult to recruit and retain. A delayed or modified exercise group is planned instead.

PRELIMINARY RESULTS—To date, 158 persons have been screened for eligibility for the study; 126 of them have entered the study and completed their pretest evaluation, and 77 have started or completed their 6-week intervention program and a posttest evaluation. Eighteen persons have completed a 6-month follow-up evaluation. Four have dropped out of the study to date. No analyses have been completed on this incomplete sample.

RECENT PUBLICATIONS FROM THIS RESEARCH

The obstacle course: a tool for the assessment of balance and mobility in the elderly. Means KM. J Rehabil Res Dev 1996:33:413–28.

Use of a low to moderate intensity exercise program in the rehabilitation of elderly fallers: a pilot study. Means KM, Rodell DE, O'Sullivan P, Cranford L. Arch Phys Med Rehabil 1996:77:1030–36.

Use of an obstacle course to assess balance and mobility in the elderly: a validation study. Means KM, Rodell DE, O'Sullivan P. Am J Phys Med Rehabil 1996:75:88–95.

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

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (#E601-2RA)*

PURPOSE—The sense of balance declines with age due to combined vestibular, proprioceptive, and visual losses, resulting in impaired mobility and increased risk of injurious falls. A wearable accelerometric instrument has been developed to record movements outside the laboratory, identify motion patterns that accompany loss of balance before a fall occurs, warn the individual of prefall behavior, and if necessary, signal that the wearer has fallen. Clinical use of accelerometric instrumentation is anticipated to occur as a diagnostic tool to quantify hitherto qualitative measures of balance, as a biofeedback device during therapy, and as a fall-prevention aid or a balance orthosis for fall-prone elderly individuals.

METHODOLOGY—The accelerometric motion detection system consists of two small 3-axis sensors attached to both corners of eyeglass frames to measure head motion, and a sensor above each hip on a belt at the waist. Also on the belt is a self-contained data acquisition package that digitally records sensor outputs. An infrared remote control is used to command the wearable unit, so the wearer is unencumbered by cables. In a typical test, subjects perform 65 tasks in 8 categories derived from qualitative balance assessment protocols, including: stand eyes open, then closed (15 s); ascend stairs, turn, then descend; rise from and sit in chair; normal walk 10 m; tandem (toe-to-heel) walk 3 m; walk over obstacles 1 m apart. After testing, data are transferred to a fixed computer for analysis.

PROGRESS—Advances in computer and sensor technology have improved the size, speed, and power consumption of the equipment. Data sampling rates have been increased from 50/s to 200/s. A second-generation device incorporates digital pulse-output acceleration sensors, two semicustom digital signal processing chips, and PCMCIA memory cards. The chips perform time integration, scaling, and transfer of data to the computer for storage, and in addition can detect peaks in any channel's signal. The PCMCIA card is removed from the wearable computer and plugged into a fixed computer, eliminating the present slow serial data transfer process. Subject populations were comprised of acute stroke patients, Parkinson's disease patients, and hip arthroplasty patients, as well as nondisabled subjects induced to stumble in the laboratory. Local collaborators have used the method in a study of therapeutic interventions in fall-prone elderly subjects, and other researchers have studied fatigue in walking by the elderly, frail hospitalized patients, and standing balance in a variety of subjects. Duplicate sets of accelerometry apparatus have been placed with researchers engaged in balance and mobility testing of diverse elderly populations. These include collaborators at the Travelers Center on Aging at the University of Connecticut Health Center, Department of Movement Sciences and Education at Teachers College of Columbia University, and Zablocki VA Medical Center, Madison, WI.

FUTURE PLANS—In addition to its use as a diagnostic and therapeutic tool for balance-impaired elderly individuals, realtime accelerometric pattern analysis and feedback can be applied to prevention of reinjury following occupational rehabilitation, and to athletic training. A collaboration has been established to develop a special-purpose device for identifying and preventing lateral falls likely to result in hip fracture.

RECENT PUBLICATIONS FROM THIS RESEARCH

Accelerometric motion analysis of balance-impaired elderly subjects. Troy BS, Sabelman EE, Kenney DE, Dunn-Gabrielli S. In: Proceedings of RESNA '96 Annual Conference; 1996, Salt Lake City, UT. Washington, DC: RESNA Press, 1996.

Accelerometric balance diagnosis compared to qualitative methods. Winograd CH, Gadd JJ, Dunn-Gabrielli S, Kenney DE, Sabelman EE. J Am Geriatr Soc. In press.

[114] EXERCISE PROGRAM DESIGNS FOR OLDER ADULTS

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PURPOSE—This 2-year study will develop an expert system that creates individualized exercise plans for healthy older adults using factors, or determinants, that affect exercise initiation and adherence. The exercise plans produced by this system can be used by practitioners at VA hospitals and other healthcare facilities during regular physical examinations and routine medical visits of older adults to help them initiate and adhere to exercise programs. The system will focus on personal, environmental, and activity characteristics that act as incentives and barriers to exercise initiation and adherence and will be a model of determinants and recommended strategies that provides the understanding needed to help improve exercise initiation and adherence for healthy older adults, including older veterans.

METHODOLOGY—The knowledge base will be reviewed by local and national experts in the fields of medicine, exercise physiology, health promotion, exercise psychology, psychometry, and gerontology. Using case study analyses, the experts will develop a rule base to define the relationships between the determinants and the recommended strategies. The knowledge base will then be translated into a diagnostic questionnaire and implemented into a computerized expert system. Local and national experts will validate the knowledge base by consensus. Case studies of healthy older adults will be analyzed using this system, with a focus on how the exercise plans created by the system respond to each subject's profile on exercise initiation and adherence determinants. A priority ordering will be assigned to the determinants based on their importance in creating recommended strategies. Discrepancies between recommended strategies in the plan and expert opinion will be cross examined until consensus is reached among the experts concerning the appropriateness of the exercise plan developed for each subject.

PROGRESS—A notebook containing the updated initial knowledge and other pertinent information was sent out to 16 experts, both local and national. Most have critiqued the initial knowledge base for organizational structure, completeness, and importance of the exercise determinants, editing the material by writing comments directly on the printout or by using the software contained in the notebook. They ordered the determinants according to how they affect initiation or adherence, and they have returned their case studies. Currently project staff is updating the knowledge base to reflect their input.

PRELIMINARY RESULTS—Pilot work has been conducted to determine the practical usefulness of the expert system within the Atlanta VA Medical Center as well as creating the initial knowledge base. This base has been updated by the addition of additional references and findings from studies recently conducted at the Atlanta Rehab R&D Center and is being revised based on the experts' review.

FUTURE PLANS—This system will allow customization of exercise plans for healthy older adults that will increase the likelihood that they will initiate and adhere to exercise. It can later be expanded to include recommendations specific to other subpopulations, including those with physical disabilities and chronic illnesses. Several follow-up studies will further validate the system and expand it to include subgroups of frail and disabled elderly individuals.

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

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E723-2RA)*

No report was received for this issue.

[116] NONINVASIVE RECORDINGS OF BLADDER PRESSURE IN ELDERLY MALES

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PURPOSE—Obstructive voiding is best evaluated with urodynamics, including bladder pressure and urine flow rates. Until recently, the recording of bladder pressure required the use of a urethral catheter. We evaluated a noninvasive back-pressure method using an external condom catheter around the outside of the penis to determine bladder pressure. Design criteria for clamping devices, back-pressure condom devices, and recording techniques were investigated.

METHODOLOGY—Back-pressure recording was conducted with a modified commercial condom catheter. An outlet tube was inserted into the side of the condom for pressure recording while clamping the exit tube. Silastic cement was also placed around the condom to prevent ballooning and reduce compliance during back-pressure procedures.

Four subjects with voiding complaints underwent testing in our urodynamic clinic. In the standing position and at peak urinary flow rate, the outlet tube of the external condom was clamped for 1–3 s and the back-pressure measurement was repeated once or twice while the patient voided to completion. The condom catheter was then removed and the urethra catheterized for cystometry and pressure/flow studies. Rectal pressure was also recorded. Filling of the bladder was conducted with sterile water at 30–60 ml/min.

PRELIMINARY RESULTS—This study shows that back-pressure results were similar to pressure/flow results using a urethral catheter into the bladder. Results for the four subjects showed no statistically significant differences ($p=0.836$) when comparing pressure results between back-pressure procedures and standard pressure/flow procedures. This study also indicated that the clamping procedures on the outlet tube caused a back flow of urine which facilitated the back-pressure recordings. Compliance of the catheter and longer clamping times may be issues that will continue to merit study.

FUTURE PLANS—We propose to study simultaneous back-pressure recording with bladder pressure recording via a urethral catheter. Additional parameters for back-pressure recording are being determined, including clamping procedures and condom catheter design.

RECENT PUBLICATIONS FROM THIS RESEARCH

Preliminary noninvasive back-pressure recordings of bladder pressure.
Wheeler JS. Tech Urol 1996:2:108–12.

[117] EFFECT OF CHAIR DESIGN ON CHAIR RISE PERFORMANCE IN DISABLED OLDER ADULTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E760-RA); National Institute on Aging, Claude Pepper Older Adults Independence Centers, Bethesda, MD 20892*

PURPOSE—Difficulty in rising from a chair and a bed is a significant problem for many older veterans. Few have empirically studied how to reduce rise difficulty. General training techniques often used in disabled older adults include task-specific training, (i.e., learning the task through practice of the components of the task) and progressive resistance (strength) training. Our goal was to improve chair and bed rise ability in frail older adults by combining task-specific and progressive resistance training. We hypothesized that task-specific resistance training can improve the ability of frail older adults to rise from a bed and a chair.

METHODOLOGY—Congregate housing resident volunteers were randomized into a training group or a control group for a 12-week controlled trial. Residents were eligible if they reported difficulty in least one of four mobility-related areas: transferring, bathing, toileting, walking. The training group performed a series of bed and chair rise-related tasks with vest, belt, and ankle weights, while controls performed seated flexibility exercises. Testing at baseline, and at 6 and 12 weeks, was performed on bed and chair rise tasks of graded difficulty (e.g., alter head of bed elevation and seat height, alter hand use). The main outcomes were whether the subject was able to successfully rise, and if successful, the time taken to rise.

PROGRESS—Thirty-eight volunteers have been allocated, 19 to each group (mean age 84 both groups). Due mainly to intercurrent medical illness, 10 subjects dropped out before completing 12-week testing, 4 in the control group and 6 in the intervention group, for a drop out rate of 26 percent.

RESULTS—Results are taken from data at the first site (n=17 total participants). The majority of training and control group subjects (11 of the 17) successfully completed more tasks (usual range 1–2) from baseline to 12-week test. Chair and bed rise task performance time was analyzed using a linear model covarying for baseline performance. The mean group difference in task performance time when adjusted for baseline values, varied from 0 to 17 s and more often favored the training group for bed rise tasks. For example, for some tasks when the head of the bed was at 45° elevation, (i.e., sit-up in bed, no hands) and supine to sit at edge (hands used), the mean group difference was 0.4–0.5 s in favor of the training group (p values 0.08 and 0.05 respectively). For sit-up in bed (no hands used) at 30° head of bed elevation, the mean group difference was 1 s (p=0.05) in favor of the training group. Mean performance time differences for the chair rise tasks favored either training or control groups, depending on the task.

IMPLICATIONS—We have demonstrated that subject recruitment, allocation to study groups, participation in training, and compliance to participation is feasible in frail older adult congregate housing residents. While there are improvements in rise ability in both control and training groups, there are suggestions of timed performance improvement in the training versus control

groups. The incremental benefit of training over control interventions, especially in regard to the factors contributing to intervention outcome, must await further training and testing in additional sites.

RECENT PUBLICATIONS FROM THIS RESEARCH

Chair design affects how older adults rise from a chair. Alexander NB, Koester DJ, Grunawalt JA. J Am Geriatr Soc 1996:44:356–62.

[118] LONG-TERM EVALUATION OF MAXILLARY SINUS BONE GRAFTS WITH DENTAL IMPLANTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project A649-3RA); Nobelpharma, USA, Inc.; Dentsplay, Inc.*

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, in turn, will support a fixed prosthesis that will withstand the masticatory forces of a similar prosthesis in the mandible. It is expected that subjects' biting force, mastication, deglutition, dietary intake, nutritional knowledge/attitudes, and reported self-esteem will improve subsequent to implant therapy and nutritional education, while speech articulation and acceptability will remain unaffected. The current patient population of the VA can benefit greatly from these procedures.

METHODOLOGY—After pretherapy evaluation of bite force, speech, deglutition, mastication, dietary intake, nutritional knowledge/attitudes, and reported self-esteem, subjects undergo the following: 1) bone transplant from the ilium to the maxillary sinus, and placement of five titanium cylindrical implants into the anterior mandible; 2) a soft tissue procedure on the mandible 2 months following bone augmentation and implant placement, if necessary; 3) 2 months later, placement of abutments through the soft tissue and attachment to the mandibular implants; 4) construction and placement of a fixed bridge to the mandibular implants and construction of a new maxillary conventional denture; 5) 5 1/2 months after bone grafting, placement of 6–8 implants in the bony maxilla, 4 of which are in the bone grafts; 6) 6 months later, placement of abutments through the maxillary soft tissue and attachment of abutments to implants; and 7) implant-supported maxillary fixed bridge construction. Computerized axial radiographs, as well as periapical radiographs and clinical examination, 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 subjects have completed the treatment protocol and have undergone post-testing at 1 month. Fourteen of the 20 subjects have undergone post-testing at 1 year. A repeated measures ANOVA on the bite force measurement at baseline, 1 month, and 12 months revealed significant increases in peak force and average force at all sites (front, right and left). All tests were significant at the $p<0.01$ level. Peak and average bite force of 1-month and 12-month values are significantly higher than the pretreatment measurements at all sites. Subjects, on the average, show a 3 to 4-fold increase in peak and average bite force across all sites at the 1 month assessment. These differences are maintained at the 12-month assessment. At least one subject increased by a factor of 10. Subjects also show a significant 3 to 4-fold increase in masticatory efficiency and effectiveness at 1 month that is maintained at the 12-month assessment.

FUTURE PLANS—We will finish the required measurements, start the evaluation of the data obtained and present for publication. We shall follow these implant

subjects for an additional 3-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. This is in an effort to comply with the recommendations of the 1988 NIH/NIDR Consensus Conference on Dental Implants, which recommended a 5-year follow up on all dental implants.

[119] ADJUSTMENT AFTER SPINAL CORD INJURY: THE 20-YEAR MINNESOTA LONGITUDINAL STUDY

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Sponsor: *National Center for Medical Rehabilitation Research, National Institute of Health, Bethesda, MD 20892; American Association of Spinal Cord Injury Psychologists and Social Workers; Minnesota Medical Foundation; National Institute for Handicapped Research*

PURPOSE—The purpose of this project is to identify how aging impacts multiple aspects of life adjustment after spinal cord injury (SCI). Three separate parameters have been studied in relation to aging: (1) chronologic age, (2) time since injury, and (3) environmental change.

METHODOLOGY—*Participants.* Four study samples have participated over the 20-year period, the first three of whom were identified through two large midwestern rehabilitation hospitals. The inclusion criteria were traumatic onset SCI of at least 2 years duration and a minimum of 18 years of age at the time of the study. The first sample consisted of 256 individuals in the preliminary stage of the study in 1974. An additional sample of 193 was added in 1985 during the second stage of this study. Although no new participants were added during the third study stage in 1989, a third sample of 201 was added for the fourth stage in 1994. A fourth sample from the Southeastern United States was also added to the 1994 data collection (n=607). Unlike the midwestern samples, the southeastern included significant minority representation (178 males, 67 females).

Instruments. The Life Situation Questionnaire (LSQ) was the primary outcome measure used during each of the four stages. It was developed in 1974 to measure information on multiple aspects of life adjustment. The LSQ was revised during each subsequent stage with core items maintained to allow for direct longitudinal comparisons over time. The most significant revisions were implemented during the 1985 stage.

Procedures. The LSQ has been sent to participants during each stage. A supplemental measure of personality was added in 1989 only, and a measure of social support was included in 1994. Attrition over time was primarily due to mortality and geographic mobility.

PROGRESS—Longitudinal analyses of the 9-year and 20-year periods have just been completed. Time-sequential analyses, comparing different samples added at different points in time, have also just been completed. Joint analysis of data from the midwestern and southeastern samples is currently underway in an attempt to identify geographic, gender, and race differences in life adjustment. The end result will be a refined LSQ.

RESULTS—Whereas the previous study stages had identified primarily positive changes over time, longitudinal analyses from the current study suggest that there has been a decrease over the last 9 years in subjective well-being, but not objective aspects of community reintegration. Time sequential comparisons, using time-lagged rather than longitudinal data, suggest that environmental and situational factors likely account for the declines in subjective well-being.

IMPLICATIONS—This research has suggested that adjustment is a dynamic process that is influenced by multiple factors. In particular, the aging process appears to be impacted by at least three independent factors, including chronologic age, time since injury, and environmental change. Ultimately, any study of aging and SCI must account for each of these three factors to fully understand the aging process.

FUTURE PLANS—A fifth follow-up study is planned for 1997 to 1999.

RECENT PUBLICATIONS FROM THIS RESEARCH

Krause JS. Employment after spinal cord injury: transition and adjustment. Rehabil Couns Bull 1996:39:244–55.

[120] THE NATURAL COURSE OF AGING IN SPINAL CORD INJURY: FUNCTIONAL ISSUES

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PURPOSE—The purpose of this study is to assess how aging affects functional capacities such as ADLs, IADLs, Work/Leisure/Social Roles and associations with social support.

METHODOLOGY—The design and sampling frame are grounded in the establishment of a comprehensive database employing a sequential research design. Participants undergo annual history and physicals. Comprehensive examinations including psychological, support, and functional profiles are conducted at 5-year intervals.

PROGRESS—To date, 150 individuals have been assessed.

PRELIMINARY RESULTS—Approximately 27 percent report a change in function. Nearly all report gradual changes. The average duration from onset to time of change is 15.8 years. There does not appear to be a relationship between current age and reports of change or between duration and change, but there may be an interaction between age at onset and number of years before change occurs. Bathing and toileting account for the largest percentages of changes in ADLs. Shopping, chores, and transportation accounted for 86 percent of the IADL changes.

FUTURE PLANS—Our goals are to continue to collect data, to describe more of the functional and social changes occurring and correlate these changes with physiological, psychological, and demographic data.

[121] CHANGES IN PHYSIOLOGIC AND HEALTH STATUS IN INDIVIDUALS AGING WITH SPINAL CORD INJURY

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PURPOSE—The purpose of this research is to document and assess physiologic and health status of individuals aging with spinal cord injury (SCI), with a special emphasis on cardiovascular disease and to evaluate the relative effects of current age and time since injury.

METHODOLOGY—The design and sampling frame are grounded in the establishment of a comprehensive database employing a sequential research design. Participants undergo annual history and physicals with serum profiles, including sophisticated lipid profiles conducted

and donated by Corning-Metpath Laboratories. Comprehensive examinations including glucose tolerance and insulin resistance, abdominal ultrasound, pulmonary function testing, bone density and body fat assessment by DEXA, psychological support, and functional profiles are conducted at 5-year intervals.

PROGRESS—Annual examinations have been performed on 742 participants aged 18 to 83; durations of injury 1 to 57 years; and age at injury <1 to 65. Annual examinations have been repeated on 144 participants. Comprehensive examinations have been performed on 157 participants.

PRELIMINARY RESULTS—Lipid profiles of SCI individuals indicate higher risk at younger ages than the general population. Levels of HDL cholesterol are significantly related to residual impairment, with complete tetraplegics having the lowest levels and approximately 40 percent having levels below 35 mg/dL. Regression analysis indicates age is a more important factor than duration of injury with regard to most dependent measures. Level of injury, gender, age at injury, and ethnicity are differentially associated with lipid profiles. Cardiovascular risk is associated with personality rather than with depression. Pulmonary function varies with age and level of injury. Bone loss at the knee is rapid and extreme within 18 months of injury and continues as expected with age, resulting in fracture thresholds being reached at earlier ages than the general population. Bone density in the lumbar spine of SCI individuals without other mitigating conditions increases with injury duration.

FUTURE PLANS—Recruitment and follow-up of participants will continue. To adequately assess the effects age and duration of injury in the context of other important variables (e.g., level of injury, age at injury, gender, ethnicity) requires a large and diverse sample. Projects to assess the extent of actual cardiovascular disease in the sample and the associations with risk factors, age, duration, level of injury, gender, and ethnicity have been initiated. Several manuscripts detailing the results summarized above are in process and a number are in press.

RECENT PUBLICATIONS FROM THIS RESEARCH

Aging with spinal cord injury: pitfalls of conducting and interpreting research (Abstract). Murphy M. In: Proceedings of the American Association of Spinal Cord Injury Nurses; 1996, Las Vegas, NV.

Cardiovascular risk factors: prevalence in 400 subjects with SCI (Abstract). Bauman WA, Adkins R Waters R. In: Proceedings of the American Paraplegia Society; 1996, Las Vegas, NV.

Ultrasonic coronary screening as an epidemiological tool (Abstract). Barndt R, Huang J, Adkins R, Waters R. In: Proceedings of the American Paraplegia Society; 1996, Las Vegas, NV.

Abnormal blood pressure profiles associated with sci and cvd risk (Abstract). Szlachcic Y, Adkins R, Waters R. In: Proceedings of the American Paraplegia Society; 1996, Las Vegas, NV.

Relation of psychological measures to cardiovascular risk factors in spinal cord injury (Abstract). Kemp BJ. In: Proceedings of the American Paraplegia Society; 1996, Las Vegas, NV.

[122] POLICY BARRIERS TO ACCESSING TECHNOLOGY SERVICES FOR PEOPLE AGING WITH SCI

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Sponsor: *National Institute on Disability and Rehabilitation Research, Washington, DC 22202*

PURPOSE—We shall examine the scope of current policies and financing mechanisms for access to rehabilitation services, independent living services, and assistive technology (AT) to maintain persons aging with SCI in employment and community-based living, seeking to identify barriers to responsiveness to the dynamic and changing needs of those persons in the matter of upgrades, modifications, or access to additional ATs. We shall attempt to identify alternative strategies for providing appropriate ATs, and we shall recommend alternative methods of financing and organizing these services.

METHODOLOGY—Policy review and survey.

PROGRESS—We have conducted a nationwide survey of state legislative analysts about a variety of state poli-

cies affecting AT, and we have made a follow-up study of 10 State Units on Aging (SUAs) with a high level of effort in home modifications and their interactions with their state-level rehabilitation agencies.

We have analyzed RESNA consumer data by two age groups; 40–60 and 61+ to determine particular problem areas, unmet needs, types of problems encountered (lack of knowledgeable professionals and getting letters or calls returned), and receipt of AT information and referral services. We have also analyzed the raw data from an unpublished AT study conducted by the American Society on Aging of SUAs and State Tech Act Projects.

PRELIMINARY RESULTS—We are writing a report on policies affecting AT for persons aging with SCI and other disabilities. It covers three models of disability policy and their effects on the availability of, and access to, AT. It includes an historical overview of AT-related policies, summaries and analyses of major reports on federal and state policies and programs, consumer research relevant to policy issues, conclusions and recommendations for additional research and analysis, and tentative policy recommendations (e.g., the need to create policies sensitive to changing disability status over the lifespan).

FUTURE PLANS—We continue to analyze data: the above report should be completed by mid-1997.

[123] USE OF TECHNOLOGY SERVICES TO MAINTAIN EMPLOYMENT AMONG PEOPLE AGING WITH A SPINAL CORD INJURY

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PURPOSE—The purposes of this study are to document the degree and extent of need for job accommodation of people aging with a disability and to develop strategies for providing job accommodation services. Information about accommodation needs will be gathered through structured interviews. Based on these data, strategies for providing job accommodation services will be developed.

METHODOLOGY—We interview and survey individuals and employers, and assess worksites.

PROGRESS—Fifteen individuals have been assessed to date.

PRELIMINARY RESULTS—Thirteen of 15 had at least some college education and were currently working. The total sample had worked an average of 16 years and almost all required accommodations when work resumed following SCI. Seven reported functional decline since SCI.

FUTURE PLANS—The study will continue to add to the sample and beginning worksite assessments.

[124] ASSESSMENT OF RESIDENTIAL CARE FACILITIES AS AN ALTERNATIVE COMMUNITY SERVICE MODEL FOR DISABLED OLDER ADULTS

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

PURPOSE—The purpose of this project is to investigate how Assisted Living (AL) facilities for the elderly operate as a community-based service model for disabled persons no longer able to remain in their homes. The major objective is to explore how well these homes meet the multiple health and psychosocial needs of their clientele with varying levels of functional impairments, thereby enabling them to "age in place," and avoid institutionalization.

METHODOLOGY—This study will combine an environmental assessment of AL facilities with a health and psychosocial needs assessment of residents. Data are collected by self-report from directors of randomly selected facilities, and from interviews with a sample of residents within each facility. Projected sample size will be 80 facilities representing small, medium, and large bed sizes, and 280 residents within these facilities. Facilities are recruited within the Los Angeles and Orange County areas in California. Secondly, data from another study about functional care needs of older adults living in their own homes will be used for comparative purposes to residents living in AL facilities.

PROGRESS—Data have been collected from 13 facilities and 65 residents. Preliminary descriptive data is available at this phase. Characteristics of surveyed facilities were 83 percent for profit, 91 percent had residents receiving Supplemental Security Income, and the average rate of residents with memory problems was 21 percent. A majority of facilities reported adequate environment accommodations, with fewer facilities having personal assistive devices available for resident use as needed.

A preliminary comparison of health care needs among facility residents with a comparative group of disabled older adults living in their own homes found the following: persons living in either arrangement have similar levels of chronic health problems, incontinence problems, and ADL and IADL health care needs. Thus, living in a AL facility did not necessarily indicate greater functional care needs. Differences in health care were found in an increased need for facility residents to use minimum nursing care. Family involvement (when family existed) ranged from moderate to high for both groups of residents; however, a sizeable minority of facility residents had never married and had no family available. Type of family involvement varied between the two groups, with more social visits and money management given to AL residents and additional functional help given to at-home residents.

[125] MEDICAL COMPLIANCE BY OLDER ADULTS: THE IMPACT OF TREATMENT EXPECTATIONS AND PSYCHOLOGICAL FACTORS OF BOTH FAMILY AND PATIENTS

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PURPOSE—The health care needs of elderly adults encompass a multitude of chronic health problems, impairment, and disability. To meet these needs, treatment may be multidisciplinary, leading to several, concurrent treatment recommendations to implement. The purpose of this study was to investigate how psychological factors and treatment expectations of both patient and family members affect medical compliance with concurrent treatments.

METHODOLOGY—Data were collected from 25 older adult patients and a corresponding family member who attended a three-visit multidisciplinary outpatient assessment clinic at Rancho Los Amigos Medical Center. Treatment recommendations were given in the areas of medical, OT, PT, and psychosocial needs. Typical recommendations were referrals to specialists (medical), need for OT equipment (OT), help with mobility (PT), and referrals to counseling or socialization activities (psychosocial).

RESULTS—Patients received an average of three treatment recommendations in 2.3 different modalities. Compliance was noted if the patient met the recommendation within 4 months. Compliance was highest with medical treatment (69 percent) and lowest with psychosocial treatment (52 percent). Overall compliance rate was 58 percent. Medical compliance correlated with positive health locus of control by both family ($r=0.63$, $p<0.05$) and patient ($r=0.55$, $p=0.08$). Both medical and psychosocial compliance correlated with patient's level of depression ($r=0.61$, $p<0.05$; and $r=0.55$, $p<0.05$ respectively). OT compliance correlated with increased impairment in ADLs ($r=0.65$, $p<0.01$) and IADLs ($r=0.45$, $p=0.10$). No measured variables influenced PT compliance.

Data were collected from two medical professionals on their clinical impressions of family member and patient treatment expectations in: a) treatment goals, b) time to achieve goals, and c) efforts to achieve goals. Family had more realistic expectations in these 3 areas (60–72 percent) than patients (36–44 percent). However, findings revealed that high expectations correlated with increased compliance. In those seven cases where family goal expectations were high, overall treatment compliance increased from 50 percent to 75 percent. High treatment expectations among patients were associated with increased total compliance rates of 67 to 87 percent compared to 50 to 59 percent compliance when expectations were realistic or low.

[126] UTILIZATION OF IN-HOME PAID ASSISTANCE BY HISPANIC AND ANGLO OLDER ADULTS, AND MODEL DEVELOPMENT TO ENHANCE UTILIZATION

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PURPOSE—The purpose of this research is to investigate the utilization of custodial paid in-home assistance by Hispanic and Anglo disabled older adults, as representing a major long-term community care model that can prevent premature institutionalization. The project has three objectives: **Medical:** to investigate how well in-

home paid assistance meets the functional needs of older disabled adults and document evidence of unmet health care needs; **Ethnic:** to document ethnic differences in service utilization, family involvement, satisfaction with care received, and evidence of unmet care needs; and **Problems and Preferences** to identify the problems older adults experience with paid assistance utilization, their preferences with paid attendant traits, and the gatekeepers utilized by adults to acquire adequate knowledge to successfully use paid in-home assistance

METHODOLOGY—Data collection will be by in-home structured interviews with older adults who use a paid attendant, with a final sample size of 130 (65 per ethnic group). Participants in this study represent both publically and privately paid attendants, and different methods of acquiring paid in-home help (i.e., the independent provider method, use of a home health agency, use of extended programs through Visiting Nurses Associations, use of MSSP sites, and so forth). Participant recruitment has been accomplished through Rancho Los Amigos Medical Center Gerontology Services and local community agencies providing gerontology case management.

PROGRESS—Interviews have been completed with 59 participants, 18 Hispanic and 41 non-Hispanic whites. Preliminary results suggest evidence of mild to serious unmet ADL and IADL care needs among both ethnic groups, (with Hispanic elderly reported more unmet home care needs), difficulties with both current and previous paid attendants, and lack of educational materials to assist disabled older adults and their families with successfully acquiring and maintaining paid in-home help. Positive findings were that elderly preferences of desired paid attendant traits were found among the current paid helpers. For example, those that desired a relative or a woman as a paid helper typically had one. Family involvement existed for both ethnic groups, with slightly more involvement among the Hispanic participants.

[127] USE OF TECHNOLOGY SERVICES TO MAINTAIN EMPLOYMENT AMONG PEOPLE AGING WITH A DISABILITY

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PURPOSE—Functional changes experienced by individuals as they age with a disability may make performance of job tasks difficult and may jeopardize their employment status. Job accommodations, however, can often compensate for functional decline and may be able to assist workers with disabilities to maintain employment. The purpose of this study is to document the degree and extent of need for job accommodation and how these needs have changed as the workers have aged with their disabilities. This project, under the Rehabilitation Research and Training Center (RRTC) on Aging will focus on individuals who had polio and on those who have rheumatoid arthritis (RA). Individuals with spinal cord injury (SCI) will also be included through an identical study under the RRTC on Aging with SCI.

METHODOLOGY—A questionnaire and structured personal interviews will be used to gather information about job accommodation needs from 150 participants, 50 from each disability category, to be recruited from the RRTC shared databases. Participants will either be currently working or have been unemployed less than 5 years. A worksite evaluation will be offered to each participant who is working to assess current needs and to determine if there are accommodations that will meet their needs. Results of the study will be disseminated as well as any strategies identified for providing job accommodation services.

PROGRESS—Data collection is underway. A total of 56 participants have been interviewed. Of these participants,

39 have a history of polio, 15 have SCI, and 2 have RA. A total of 10 worksite evaluations have been conducted as a follow-up to the interviews of participants who are currently working and agree to the worksite visit. A database for data analysis has been established and the first wave of data has been entered.

FUTURE PLANS—Data collection will continue with a focus on increasing the sample pool through community contacts. Dissemination of information will also be a priority this year.

[128] VARIATIONS IN SECONDARY CONDITIONS, RISK FACTORS, AND HEALTH CARE NEEDS FOR FOUR GROUPS OF PERSONS AGING WITH PHYSICAL DISABILITY

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PURPOSE—This study responds to gaps in our knowledge regarding the new health problems and functional limitations experienced by persons aging with the long-term effects of cerebral palsy (CP), polio, rheumatoid arthritis (RA), and stroke, and the consequences of these secondary conditions for a broad range of quality of life outcomes. These four impairment groups were selected to represent differences in the average age or stage of life when disability occurs, ranging from infancy to mid- to later-life. Specific objectives include: 1) describing variations in the timing, prevalence, type and magnitude of secondary conditions; 2) examining the impact of these health-related changes on productivity, family relations, social participation, psychological well-being, and utilization of and need for services; and 3) identifying the risk and resiliency factors associated with both positive and negative outcomes, focusing on the effects of social support and community integration.

METHODOLOGY—The study incorporates a community-based cross-sectional survey within a group-comparison design based on impairment, and within impairment on gender and race/ethnicity, and it utilizes a cross-sequential framework for sample selection and data analysis. This combination of methods allows us to both identify variations in secondary conditions, risk factors, and needs within and between groups, and to separate age-related changes in health and function associated with aging from those associated with duration of disability.

The study is being conducted in two phases. The first involves the identification and recruitment of subjects from two study populations: a hospital-based population of primarily low-income, ethnic minority patients receiving rehabilitation services from a county facility and a contrasting community-based population recruited from support groups, newspaper solicitation, radio and electronic bulletin board announcements and physician offices. Eligible candidates must meet minimum age and duration of disability criteria which vary by impairment group. The second involves the development and implementation of a comprehensive cross-disability survey instrument. Data collection procedures involve both telephone and face-to-face interviews, the later conducted in respondents' homes.

PROGRESS—Accomplishments include: 1) the formation and operation of a 10 member, cross-disability consumer advisory committee, the members of which participate as decisions-makers in all stages of the research program; 2) development of two versions of the survey instrument, one for polio and RA and the other for CP and stroke; 3) completion of subject identification for the hospital-based subject pool (n=1,602) and ongoing recruitment of volunteers for the community pool (to date: n=500); 4) random selection of 494 candidates, and completion of 266 polio and RA interviews for an overall response rate of 54 percent (data collection for CP and stroke began in November 1996); and 5) ongoing dissem-

ination of preliminary research findings at professional meetings of both aging and disability organizations and to local consumer support groups.

PRELIMINARY RESULTS—With 41 percent of the target sample completed, analyses conducted to date have been limited to quantitative descriptions of subject pool characteristics and qualitative case studies of selected polio and RA participants. Consistent with the life course perspective guiding this investigation, these analyses suggest that timing of acute onset of disability has important consequences for both the health status and life chances of individuals. For example, RA participants with early onset (i.e., age < 40) report significantly more secondary health conditions and lower levels of life satisfaction compared to their counterparts whose onset occurred after age 60. Members of both the Polio (n=892) and RA (n=375) hospital subject pool, with ages of onset of 7.4 and 40.1, respectively, were also significantly more likely to have never married compared to stroke patients (n=268) with an average age of onset of 56. Official analysis began in November 1996 once all the data entry screens were completed.

RECENT PUBLICATIONS FROM THIS RESEARCH

Incorporating consumer expertise into applied social research an aging with disability. Campbell ML, Sheets D, Mitchell J, McNeal D. McLean, VA: Conwal, Inc. In press.

Depression and life satisfaction in people aging with polio versus age-matched controls: the relation to post-polio syndrome, family functioning and attitude toward disability. Kemp BJ, Adams BA, Campbell ML. Arch Phy Med Rehabil. In press.

VI. Head Trauma and Stroke

[129] 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. 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, 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 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.

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

METHODOLOGY—Measurements of NAA will be obtained by MRS of all patients entering rehabilitation after coma due to closed head injury. MRS will determine both gray and white matter NAA in the cortex. The functional independence measure (FIM) 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 will be performed at this time.

PROGRESS—Previous work in animals has shown than 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.

RESULTS—Quantitative MRS measurements have been completed on 36 head trauma patients and age-matched controls. NAA is significantly decreased in frontal gray matter: controls demonstrated 8.35±0.0 millimolar (mM) vs. 6.16±0.40 mM for the patients, but decreases in NAA did not reach significant levels in frontal white matter or midbrain. The functional independence measure and neuropsychological outcome data on these patients are being collected 1 year after entry into rehabilitation. It has been impractical to study a number of patients eligible for the study due to motion artifacts or contraindications to MR.

[130] 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 #C1761-PA)*

PURPOSE—This pilot study is designed to determine the relationship among auditory evoked responses (AERs), severity, and prognosis for improvement in aphasia. We asked two primary research questions: do AERs to verbal stimuli predict severity of aphasia, and do AERs to verbal stimuli predict improvement in aphasia?

METHODOLOGY—A battery of AER tasks is administered to samples of young, nonimpaired adults; to aphasic patients representing three levels of severity (mild, moderate, and severe); and to a sample of nonimpaired adults matched for age, education, and gender with the aphasic sample. The AER battery comprises phonologic, semantic, and syntactic stimuli. AER responses of interest are the mismatched negativity (MMN) and P 300 to phonologic stimuli, N 400 to semantic stimuli, and P 600 to syntactic stimuli. In addition, the aphasic and matched nonimpaired samples receive a battery of language measures. Aphasic patients are evaluated with the AER and language measures at entry and again after 20 treatment sessions. The matched nonimpaired subjects are evaluated at entry and again after 1 to 2 months. Analyses include analysis of variance to compare language performance and AERs between and among the aphasic severity groups and the matched nonimpaired group. Correlations are used to determine whether AERs predict severity in the aphasic subjects. Additionally, multiple regression analysis is used to determine whether the AER measures predict improvement in aphasia after 20 treatment sessions.

PROGRESS—All AER stimuli and tasks have been developed and standardized with a sample of young, nonimpaired adults. Aphasic subjects and matched, nonimpaired subjects are being evaluated and reevaluated with the AER and language measures to determine the relationship between AERs and severity of aphasia and the ability of AERs to predict improvement in aphasia.

PRELIMINARY RESULTS—All young, nonimpaired subjects show MMN responses to phonologic stimuli and N 400 responses to semantic stimuli. Eighty percent of the young, nonimpaired subjects show P 300 responses to phonologic stimuli, and 60 percent show P 600 responses to syntactic stimuli. In the aphasic subjects evaluated to date, all show MMN responses to phonologic stimuli regardless of their severity of aphasia. However, the presence of P 300 responses to phonologic stimuli, N 400 responses to semantic stimuli, and P 600 responses to syntactic stimuli appears to be related with the severity of aphasia.

FUTURE PLANS—We continue to recruit, evaluate, and reevaluate aphasic subjects and matched, nonimpaired control subjects to obtain a sufficient sample size for conducting multiple regression analysis to determine the prognostic precision of the AER in predicting improvement in aphasia.

RECENT PUBLICATIONS FROM THIS RESEARCH

Mismatch negativity, aphasia severity, and site of lesion. Auther LL, Wertz RT, Hall JW. ASHA Leader 1996:1(16):98.

[131] PROPRIOCEPTIVE NEUROMUSCULAR FACILITATION EFFECTS UPON MAXIMAL ISOMETRIC STRENGTH AND ENDURANCE

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PURPOSE—This study compared the efficacy of increasing muscular strength through motor learning versus proprioceptive mechanisms. The research question being addressed was: should agonist-antagonist coordination be considered an important factor in neuromuscular reeducation? Maximal isometric elbow extension strength and endurance were tested under a measurement schedule previously demonstrated to result in rapid strength and endurance gains through motor learning. Agonist and antagonist muscular strength and endurance were tested in an experimental group (N=13) on the same day using a proprioceptive neuromuscular facilitation (PNF) technique termed the reversal of antagonists. Testing the agonist and antagonist in successive combination on the same day may counterbalance the development of agonist-antagonist coordination and interfere with extension strength gains. However, it is equally possible that this technique may result in facilitation of extension strength. A control group (N=13) was used to verify that the measurement schedule did indeed result in rapid strength and endurance gains. Testing the extensors alone may allow for the development of some type of efficiency in the firing patterns between flexor and extensor muscle groups. This hypothesis provides for the development of strength through enhanced coordination, or skill, between agonist and antagonist muscle groups.

METHODOLOGY—There were 4 test days with a 2-week interval between each day. The control group performed five baseline maximal isometric elbow extension strength trials; each contraction was 2 s in duration with a 24-s intertial rest period. After a 5-min rest, subjects then performed a 30-trial fatigue protocol. The maximal isometric elbow extension endurance trials were limited to 2 s with 6 s between each trial. The experimental group performed five baseline reversals of antagonists, which consisted of a 2-s maximal isometric elbow flexion immediately followed by a 2-s maximal isometric elbow extension; a 22-s rest period was allowed between each trial. After a 5-min rest, subjects then performed a 30-trial fatigue protocol with a 4-s rest period between each trial.

Subjects were seated at a table designed to isolate the elbow extensors in an isometric contraction, and forces and moments were measured in six degress-of-freedom. We measured elbow extension moment, and root-mean-square amplitude of electromyographic (EMG) activity, mean power frequency (MPF), and median power frequency (MF) obtained from surface recordings of the biceps brachii long head, brachioradialis, triceps brachii long head, and triceps brachii lateral head. These measures were analyzed using a split-plot factorial analysis of variance with one between-block treatment, groups, and two within-block treatments corresponding to days and trials. An orthogonal polynomial breakdown for means across days and trials was used to further assess the experimental affects.

PROGRESS—Data reduction and analysis has been completed for baseline strength. Both groups exhibited a quadratic increase ($P<0.05$) in baseline maximal isometric elbow extension strength. Strength increased ($P<0.05$) between test days 1, 2, and 3 then plateaued between test days 3 and 4. Based on the strength data alone, both methods of training resulted in a rapid increase in strength.

[132] PREVENTION OF THROMBOEMBOLISM IN STROKE REHABILITATION PATIENTS

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Sponsor: *Department of Education, National Institute on Disability and Rehabilitation Research, Washington, DC 22202*

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 (CC) and low molecular weight heparin (LMWH), to see which is most safe and effective.

METHODOLOGY—The end points will be to determine efficacy as the presence or absence of thrombus, as defined by venous flow studies, venography, positive V/Q scan or pulmonary angiography. 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—To date, 53 subjects have entered the study and 42 have had venograms, of which 39 were negative and 3 were positive. Two of the positive venograms were in the LMWH group and one was in the CC group. One subject in the LMWH group has had bleeding. These numbers are still too small for statistical analysis, and recruitment is ongoing. The goal is still to recruit a total of 100 subjects.

Of the 11 subjects in whom venograms were not performed, 6 were dropouts and 5 could not have venography because of technical reasons. Of the six dropouts, four left because of patient or family withdrawals, one had a leg infection which precluded performance of the test, and one had gastrointestinal bleeding.

RECENT PUBLICATIONS FROM THIS RESEARCH

Medical problems affecting stroke rehabilitation. Green D. Top Stroke Rehabil 1996:2:61–76.

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

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PURPOSE—The study explores the effectiveness of a unique intervention for the stress of older spousal caregivers of stroke survivors.

METHODOLOGY—One hundred thirty-six caregivers of spouses with stroke, 60 yrs and older, are randomly assigned to a treatment or control group. The treatment group participates in an 8-week educational/support group professionally led by telephone conference calls. They are assessed upon recruitment, after the group intervention, and at 6 months. The control group receives written material on caregiver stress and is assessed upon recruitment and after 6 months. At the end of their control group commitment, they are entered into the treatment group, participate in a support group, and are followed for an additional 6 months. The study hypotheses are that the treatment group shows less depression, loneliness, burden, increased health behaviors, and increased competence. The research protocol has also been revised to make the control group into a "wait list" control. In this

design, control subjects go on to participate in the treatment group after completing the control condition.

PROGRESS—Seventy-six subjects have been recruited and 64 have remained in the study, resulting in a 19 percent attrition rate. The major reasons for subject drop out have been: too busy, death of spouse, and unable to contact in 6-month follow-up. Of the 64 subjects, 30 were assigned to the treatment group and 34 to the control group. A total of seven support groups have been conducted and 44 subjects have completed the study.

Of 76 subjects fully assessed and entered into the study database, the average age is 69.6 yrs. Seventy-six percent of the sample are women and 72 percent are white. They have been married on average for 41.2 yrs to the stroke survivor (range: 4–64 yrs.) and have an average of 14.3 yrs of education (range: 8–20 yrs); 21 percent of them work full or part-time. Seventy-nine percent rate their health to be good or excellent. Their median time caregiving is 2.0 years with a (range: 1 mo–27 yrs). Sixty-one percent provide up to 15 hrs of care per day; 37 percent report receiving paid outside assistance.

At the first assessment, the caregivers indicated on average that their spouses require supervision with functional activities, although the range of functional limitations reported is quite wide. Twenty percent rate their spouses as severely impaired as measured by the Functional Independence Measure. Thirty-two percent scored above the usual cutoff of 16 indicating significant number of depressive symptoms. On the UCLA Loneliness Scale, the mean score was 17.4 which is close to a community average. Thirty-nine percent had an above average score indicating greater loneliness.

RESULTS—Limited analyses have now been conducted on small subsets. A sample of 30 caregivers was analyzed for their most pressing problems. Social isolation, worry and over protectiveness, finances, and frustration with various caring tasks are frequent problems. Health, conflicts with others, and loss of companionship with their spouse are also frequently mentioned. The most frequently identified problems are not necessarily the most stressful ones. There are a few types of problems that caregivers rate as more stressful but do not feel confident to handle, including spousal noncompliance, interpersonal conflicts with others, specific stroke impairments, and future health uncertainty. These tend to be complicated problems without easy solution.

[134] 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 22202*

PURPOSE—Young stroke survivors participated in an aerobic fitness program to determine the effects of aerobic exercise on fitness levels, ambulatory speed, and life satisfaction. A pre-post design was used to allow each subject to act as his/her own control.

METHODOLOGY—The first 10-week session was the initial control period. Subjects were instructed to maintain the same activity level. The aerobic walking program was introduced at the onset of the second 10-week period. Subjects ambulated three times per week for a minimum of 20 minutes at their target heart rate with a warm-up and cool-down phase included in each session. Blood pressure and heart rate were taken at the beginning and completion of each exercise session to ensure a return to baseline measures. Heart rate and rating of perceived exertion were used to monitor subjects during baseline. An educational component was provided on a weekly basis; topics discussed were relevant to stroke rehabilitation and exercise. The final 10 weeks served as the second control period. During this interval, subjects were encouraged to continue with independent exercise as performed during the previous structured walking program. Local health clubs were visited by the authors to form a liaison between community-based facilities and any interested participants, and to ensure that the specific needs of stroke survivors would be sufficiently addressed. Community reentry is an important facet that was pro-

moted through an ongoing emphasis on safe, independent exercise for the participants throughout the study.

Submaximal treadmill tests were performed at the onset of participation in the study, after the first control period, after the completion of the aerobic walking program, and at the end of the second control session (0 wks, 10 wks, 20 wks, and 30 wks).

PROGRESS—Ten subjects were able to finish the entire protocol. The 10 included 7 men and 3 women, ranging in age from 29 to 62 years (mean=49). Due to the length of the study (30 weeks), a number of subjects had to discontinue participation because of schedule conflicts, including return to work or school, or transportation difficulties. The initial stress test using the treadmill produced abnormal results in several cases, necessitating a return to their primary physician for further evaluation and exclusion from data collection. The stress tests themselves proved difficult with some subjects due to gait deviations and fear while using the treadmill.

RESULTS—Eight of the 10 subjects demonstrated improvement in life satisfaction as measured by the Quality of Life Index (QLI). A program written by Ferrans and Powers was used to calculate an overall QLI score from the surveys administered to the subjects at the completion of each 10 week period. A maximum score for the QLI is 30, and a change of 2 points is considered clinically significant. The changes in QLI between pre-test and post-test 1, and between the post-test 1 and post-test 2 were not found to be significant. The change in score between the pre-test and post-test 2, however, was determined to be statistically significant at a t value of 3.98.

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

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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.

METHODOLOGY—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 26 stroke patients with low motor function have been randomized, 20 of whom have completed 18–20 treatment sessions. Seven patients have completed the 1-year follow-up. Pre- and postevaluation data are being analyzed.

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

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PURPOSE—The disability of the upper limb after a hemiparetic stroke is often perceived as one of the most frustrating experiences by stroke survivors. There are well defined reasons for the disproportionate impact of cerebral stroke in upper limb function, such as the greater relative area of cortex devoted to upper limb control, coupled with the fact that arm motions play a major role in 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 has been made toward the determination of the optimum intervention protocols for impaired limb motion. 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.

METHODOLOGY—The investigation of the effect of sensory manipulations with topical drugs has been initiated with a mixture of Lidocaine and Prilocaine (EMLA) on normal control subjects to determine the analgesic effect on various cutaneous afferent types. Subsequently, we plan to investigate the effect of EMLA on abnormal torque synergies using the new synergy quantification approach discussed above.

An alternate way to determine the relation between sensory input and disturbed muscle synergic relations in hemiparetic stroke has been obtained by studying flexion withdrawal reflexes following stroke. Flexion withdrawal reflexes were compared in the impaired and unimpaired upper extremities of eight hemiparetic stroke subjects. Six nonimpaired subjects served as the control group. The effects of mildly noxious electrical stimuli delivered to the index finger were studied using EMGs from 12 arm muscles along with elbow and shoulder torques measured at the wrist with a 6 degree of freedom load cell. A quantitative analysis of torque and EMG responses was performed.

PROGRESS—We have studied the effects of electrical stimulation of the skin on upper extremity spasticity in nine hemiparetic stroke subjects. In seven subjects, we observed a significant reduction in ensemble mean peak flexor torque while significant reductions of mean peak extensor torque were observed in four of the five subjects with consistent extensor reflex responses. In the other two subjects, one exhibited significant increases in mean peak torque for both extensors and flexors while the other showed a corresponding increase in mean flexor peak torque with reductions in mean extensor peak torque. In five subjects we were able to evaluate changes in stretch reflex threshold angle and reflex gain. Analysis of reflex stiffness identified no significant differences in stiffness for either elbow extensors or flexors. In contrast, we observed significant shifts in angular threshold angles such that greater angular stretches were required to elicit the stretch reflex after cutaneous electrical stimulation. In all subjects, angular shifts of the extensors, when present, resulted in later onsets of the stretch reflex. Angular shifts in the flexors followed the same trend for four of the five subjects.

We have gathered data on the effect of sensory manipulation on arm movements, mostly additional control data from normal and hemiparetic stroke subjects. We have been studying movement trajectories during supported and unsupported ballistic planar arm movements in stroke.

RESULTS—In general our preliminary movement results seem to suggest that during supported planar arm motions, abnormal torque synergies play no significant role. However, spasticity may play a role depending on the target matching direction and movement velocity. Weakness appears to play no role in movement trajectory formation. In the case of unsupported planar arm motions, abnormal trajectories are observed in directions which require torque elbow/shoulder combinations away from abnormal torque synergies as measured during static conditions. These results indicate that interventions which reduce spasticity and/or abnormal torques synergies may result in improved functional usage of the impaired upper limb in stroke.

RECENT PUBLICATIONS FROM THIS RESEARCH

Abnormal muscle coactivation patterns during isometric torque generation at the elbow and shoulder in hemiparetic subjects. Dewald JPA, Pope PS, Given JD, Buchanan TS, Rymer WZ. Brain 1995:118:495–510.

Joint-dependent passive stiffness in paretic and contralateral limbs of spastic hemiparetic stroke subjects. Given JD, Dewald JPA, Rymer WZ. J Neurol Neurosurg Psych 1995:59:271–9.

[137] COURSE OF RECOVERY OF COGNITIVE-COMMUNICATIVE PROBLEMS IN RIGHT BRAIN DAMAGED INDIVIDUALS

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PURPOSE—Historically, it was assumed that only left hemisphere (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 is also very little information regarding the course of recovery of cognitive-communicative problems in patients with RH damage.

METHODOLOGY—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 slowly but steadily. The charts of all consecutive admissions to RIC with unilateral RH stroke are reviewed weekly. During this period of time, 17 new subjects have been recruited and have participated in the initial evaluation session, bringing the total number of participants to 38. Seven of these subjects have been followed longitudinally over an 18-month period and have now completed their 4 test sessions; 8 subjects have been tested 3 times and 13 subjects have been tested twice. Most of the repeated evaluations have been conducted in the current reporting period.

RESULTS—Data analysis is underway. All cognitive tests have been scored and the discourse of all subjects has been transcribed. Preliminary analyses have focused on 1) changes in unilateral visual neglect over time, 2) the relationship between unilateral visual neglect and production of informational content in a story retelling task, and 3) performance trends on word list recall and recognition both in the acute stage and longitudinally over time.

With regard to neglect, results indicate that there is a relationship between production of meaningful content and performance on a test of unilateral visual neglect. Furthermore, subjects with persistent neglect (over a period of at least 1 year) produced less meaningful content than subjects with a transient neglect (i.e., no neglect evident at 6 months post-onset). These findings are consistent with the objectives of the study.

With regard to word list recall and recognition, results indicate that poor performance is associated with difficulties in the encoding process rather than in the retrieval process; therefore, individuals in a rehabilitation program would benefit from practice, repetition of important information, and the imposition of a strategy that facilitates encoding. The precise relationship between performance on this task and production of meaningful discourse is yet to be examined.

RECENT PUBLICATIONS FROM THIS RESEARCH

Word list recall and recognition by subjects with right hemisphere stroke. Cherney LR, Halper AS, Drimmer DP. Brain Lang 1995:51(1):51–3.

[138] 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.

METHODOLOGY—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 980 new patients admitted to the inpatient stroke rehabilitation service from December 1993 through May 1996. Demographic, stroke, medical comorbidity, and other information has been collected on 809 patients and entered into the database. Laboratory results and data on secondary complications have been reviewed for 697 of those patients. Impairment disability measures have also been collected on these same 697 patients.

RESULTS—The most common pre-existing complications found in our stroke population are hypertension, a history of smoking, and diabetes. Other pre-existing complications of clinical significance include coronary artery disease, myocardial infarction, and congestive heart failure. The most frequent complications developed during the acute hospitalization are urinary tract infection, pneumonia, and hypertension. The most common complications developed during acute inpatient rehabilitation include urinary tract infection, joint and soft tissue pain, electrolyte abnormalities, and depression. It is significant that 23 percent of stroke survivors seen for acute inpatient rehabilitation did not develop any complications.

Information from routine laboratory tests also has been collected. Almost one-third of patients have low serum albumin on admission to rehabilitation and 19 percent have low levels of hemoglobin.

We have investigated the usefulness of the Charleston Comorbidity Index in predicting functional outcomes and resource utilization. While preliminary data analysis indicates that this particular severity of illness index may not be very useful in the stroke population, further data analysis is ongoing.

[139] INFLUENCES OF CANE LENGTH ON THE STABILITY OF STROKE PATIENTS

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PURPOSE—One of the common problems for stroke patients is falling. Using canes can help stroke patients to improve their stability and reduce the risk of falling. In the selection of an appropriate cane for a stroke patient, cane length is an important consideration. There are significant discrepancies between cane lengths prescribed using different methods for determining appropriate cane length. The purposes of this study were to investigate the influence of cane length on the standing and walking stability of stroke patients and determine the appropriate lengths for individual patients.

METHODOLOGY—Ten male stroke patients with hemiplegia due to cerebrovascular accidents were recruited as volunteer subjects for the study. The mean age of these patients was 59 years with a standard deviation

of 7 years. The mean following-up time since the onset of symptoms was 49 months (4 to 126 months). Each subject was using a cane for ambulation in his daily activities. Two different cane lengths based on the measurements of the distance from distal wrist crease to the ground (WC cane), and the distance from greater trochanter to ground (GT cane) were given to each patient. The elbow flexion angle corresponding to each cane length was also recorded for each patient. Three force plates were used to collect the path of the center of pressure (COP) for each patient in standing and walking. The maximum sways, the total travel distances, and the mean travel speeds of the COP were determined and used as stability measures for each patient in standing and walking with and without canes. Analyses of variance with repeated measures were conducted to compare these parameters between WC and GT canes. Regression analysis was conducted to determine the effects of elbow flexion angle on these parameters.

RESULTS—It was found that the total travel distance and the mean travel speed of the COP in the medial-lateral direction were significantly lower when standing with a cane than when standing without one. It was also found the values of these parameters and the maximum sways of the COP in both anterior-posterior and medial-lateral directions were significantly lower when standing with the WC cane than when standing with the GT cane. No significant difference was found in the maximum medial-lateral sway, the total travel distance, and the mean travel speed of the COP in walking. These results suggested that the standing stability of stroke patients was improved by using canes, especially by using WC cane, although no significant influence of using canes was detected for the walking stability.

Significant correlations were found between the maximum sways of the COP in standing tests and the elbow flexion angle when the elbow flexion angle was less than 40°. This relationship indicated that the greater the elbow flexion angle, the lower the maximum sways of the COP. There were still large variations in the maximum sways of the COP when the elbow flexion angle was greater than 40°. These results suggested that (a) the elbow flexion angle for cane prescription should be no less than 40°; and (b) the elbow flexion angle was not a reliable parameter for determining appropriate cane length when it was greater than 40°.

No significant difference was found in any of the selected stability measures for walking with different canes.

Based on these results, it is recommended that the WC canes be used for stroke patients. However, the cane length may need to be adjusted to have an elbow flexion angle greater than 40°.

RECENT PUBLICATIONS FROM THIS RESEARCH

Influences of cane length on the stability of stroke patients. Lu C-L, Yu B, Basford JF, Johnson ME, An K-N. J Rehabil Res Dev. In press.

[140] A DISABILITY-ORIENTED EPIDEMIOLOGICAL STUDY ON THE LONG-TERM SEQUELAE OF TRAUMATIC BRAIN INJURY

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Sponsor: *Stichting Fonds Johannastichting, Arnhem, and Sint Maartenskliniek, Nijmegen, Netherlands*

PURPOSE—We seek to determine the differences in long-term consequences between a selected group of traumatic brain injured (TBI) patients, those belonging to a support organization, and an unselected "epidemiological" group.

METHODOLOGY—We surveyed a randomly selected retrospective sample from a Nijmegen hospital discharge list and members of a support group from across The Netherlands, taking a random sample of all patients living in the Nijmegen area discharged with a diagnosis of TBI aged 15–30 years at the time of injury, and selection from total membership of support group of persons who had suffered a TBI at the same age and who did not live in Nijmegen.

Initial contact was made by letter; all interviews were undertaken at home. We employed the Sickness Impact Profile, the Wimbledon Self-Report Scale, the Employability Rating Scale, and the Barthel ADL index to elucidate residual problems.

PROGRESS—Of the 124 hospital patients identified, 61 were randomly selected for study, and 51 participated. Of the 500 support group members listed, 22 fulfilled the criteria. The hospital group contained fewer men (55 percent vs 73 percent) and the hospital patients had less severe brain injuries (55 percent vs 0 percent coma under 24 hours), more were at work (71 percent vs 10 percent), fewer were in long-term care, and most were or could live independently. Nonetheless 34 (67 percent) of the hospital sample suffered cognitive, behavioral, or "situational" disabilities, whereas only 10 percent received any rehabilitation services at all after the acute-care period.

RESULTS—Members of a support organization are not representative of all TBI patients. Their views on services and service development should be interpreted in this light, in particular with respect to patients with less visible or less pronounced disabilities. In addition, service development should be based both on disease and disability-oriented data.

FUTURE PLANS—We plan to develop, introduce, and administer more comprehensive cognitive rehabilitation programs.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Towards a disability-oriented epidemiology of traumatic brain injury. Van Balen HGG, Mulder, Th, Keyser A. Disabil Rehabil 1996:18:181–90.

VII. Independent Living Aids

A. General

[141] COMPUTER ACCESS SELECTOR AND VOCASELECT

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PURPOSE—Computer Access Selector and VOCAselect are computer programs that aim to assist in the selection of alternative computer access and voice output communication devices for individuals with disabilities, which selection involves a compromise of many different parameters and generally requires professional assessment of the patient's the needs and abilities. Even when the capabilities of the patient are understood, the choice of specific products is not necessarily straightforward due to the number of them available. Computer Access Selector and VOCAselect narrow down this large number of products by feature selections made by the prospective user.

METHODOLOGY—The programs give the user an opportunity to specify the requirements of the devices they are looking for by selecting from a series of parameters. They then use expert knowledge to suggest potentially suitable products. The suggestions are dynamically adjusted as user selections are changed, providing a means for the user to explore different possibilities and tradeoffs.

With one click of the mouse the user is able to view details about any given product, and see a picture of it onscreen. Manufacturer and Australian supplier contact information is also provided. The software can generate a report of the user's findings for printing or inclusion in a word processing document.

PROGRESS—Computer Access Selector version 1.0, a Windows program, was released in October 1995 at the Second Australian Conference on Technology for People with Disabilities. It was subsequently offered free for evaluation purposes and has now been distributed to approximately 300 interested individuals, professionals, and organizations.

VOCAselect version 1.0, a Macintosh program, was released in November 1995, and has now also been distributed widely. Both programs underwent alpha and beta testing prior to release and are available for $35 + $10 postage and handling each.

RESULTS—Feedback and responses to Computer Access Selector and VOCAselect have been sought from users primarily via a survey questionnaire sent with the software. The survey results are now being collated.

FUTURE PLANS—Refinements based on user comments and feedback will be made to ensure that the programs continue to be relevant and valuable tools for all who need to choose alternative access and voice output technology. A significant percentage of VOCAselect users have requested that the software be made available for Windows, and such a version is now being written for release by December 1996.

The product information contained in both softwarepackages is expected to be updated annually. Version 2.0 of both packages with updated product information will be available by early 1997.

[142] REMOTE REHABILITATION SERVICES NETWORK

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PURPOSE—Telecommunication technology has the potential to provide remote access to resources and expertise along with access to social, cultural and health services. Video and interactive video allows people to consult and attend meetings, telecommute, demonstrate, and trouble-shoot devices remotely, and could provide ways to train professionals or parents and to distribute software upgrades and training materials.

This project will evaluate the need, feasibility, and costs of remote rehabilitation services. We will determine the needs, opportunities, costs, and potential savings that may be realized by using multimedia telecommunication technology in Children's Treatment Centres and possibly other community healthcare environments.

Some of the arguments that reinforce the need for a multimedia remote service network are:

1. Rehabilitation Technology (RT) devices are being used everywhere in Ontario; assistive technology breaks down or requires support for training, demonstration, adaptation, and is used in different contexts of home, school, and work;
2. Expertise about this technology often resides in urban rehabilitation centres;
3. Parents are not able to pay for the flights/rides to urban centre and shipping a device means that the child is without the device for 2 to 5 weeks;
4. Parents and professionals need help in their difficult roles of bringing up or providing services for children with severe disabilities.

The Easter Seal Society (ESS) of Ontario assists with the travel expenses of parents who require rehabilitation and health care services for their children, advancing the travel funds and claiming approximately two-thirds back from the Northern Travel Grant program of the Ministry of Health (MoH). In 1993 alone, this amounted to $328,887, and includes only travel of families. It does not include travel of occupational, physical, or speech therapists, physicians, nurses, and technologists, costs which are funded by MoH. Nor does it include the hidden costs of parents, losing several days to a week of work each, since in many instances the severity of involvement of the child compels both parents to accompany their child. Finally, the hidden cost of the loss of education days to the child is not expressed in the above figure.

The lack of availability of appropriate expertise and/or the limited access to technological expertise is more likely to result in the abandonment of the device or the disillusionment of parents or teachers with this, often complex, assistive technology. Broad band information technology that is available today has the potential to eliminate much of the travel and device abandonment by allowing experts to consult much more directly and appropriately.

PROGRESS—One VISIT station has been placed with a family with 12 children with disabilities. A draft of a paper reviewing applications of several multimedia technologies in health and education is in preparation. Additional funding was obtained from the Bank of Montreal to set up a network of Proshare multimedia televideo stations in Northern Ontario. This project started with surveys of inhouse and remote clinical staff to determine immediate uses of multimedia telecommunication technologies.

FUTURE PLANS—Our team plans to apply to the upcoming CANARIE INC. competition to develop new assessment products and software-based tools that can be used in televideo rehabilitation services.

[143] ASSISTIVE CONTROL IN USING COMPUTER DEVICES FOR THOSE WITH PATHOLOGICAL TREMOR

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PURPOSE—The purpose of this research is to help those with pathological tremor use computer devices like a mouse. Tremor patients are hindered from performing everyday tasks that many of us take for granted. Handwriting is among the most difficult of activities for many persons with pathological tremor. Using computer devices such as a mouse/pen is also a difficult task. With these two difficulties in mind, the goal then is to develop a computer assistive interface where handwriting is aided as well as is general control over a computer mouse/pen.

METHODOLOGY—The assistive computer interface was devised by implementing a filtering algorithm in mouse driver software to cancel tremor movements. Tremor is modeled as a sinusoidal signal with a changing amplitude and frequency (usually higher than voluntary motion). As input is received from a computer mouse/pen, the software models the tremor at every time step and acts to cancel it. While the movements of the user may be unsteady, but when processed by the computer they become smoother and more controllable on the computer screen as cursor or arrow.

PROGRESS—The filtering algorithm has been implemented in computer mouse drivers. Numerous tests on pathological tremor subjects have been completed with favorable results.

RESULTS—The filtering algorithm has demonstrated its effectiveness. In qualitative tests, the handwriting of a tremor subject has increased in legibility when the algorithm has been implemented on or off-line. The filtering algorithm has also improved performance in various on-line target tracking tasks that measure the algorithm's effectiveness quantitatively.

FUTURE PLANS—Further quantitative results are desired for a complete and comprehensive set of data. Also direction of the research is being geared toward handwritten optical character recognition (OCR). OCR is the ability for a computer to recognize and read text or handwritten letters. OCR can be used as a quantitative testing tool as well as a general assistive interface.

RECENT PUBLICATIONS FROM THIS RESEARCH

Adaptive real-time canceling of physiological tremor for microsurgery. Riviere CN, Radar RS, Thakor NV. Proceedings of the Second International Symposium on Medical Robotics and computer assisted Surgery; 1995, Baltimore, MD, 89–96.

Suppressing pathological tremor during dextrous teleoperation. Riviere CN, Thakor NV. Proceeding of the 17th IEEE Engineering in Medicine and Biology Society International Conference; 1995, Montreal.

Modeling and canceling tremor in human-machineinterfaces. Riviere CN, Thakor NV. IEEE Eng Med Biol 1996:15(5):29–36.

StylPen: on-line adaptive canceling of pathological tremor for computer pen handwriting. Hsu DS, Huang WM, Thakor NV. In: Proceedings of the 22nd annual South East Biomedical Conference; 1996 April, Rutgers, NJ, 113–4.

Effects of age and disability on target tracing with a computer mouse: accuracy and linearity. Riviere CN, ThakorNV. J Rehabil Res Dev 1996:33(1):6–15.

[144] CONSUMER INNOVATION LABORATORY OF THE ROBOTICS RERC

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PURPOSE—The Consumer Innovation Laboratory (ConLab) is a consumer-led research effort intended to draw upon the experiences of consumers with disabilities to establish designs for robotic devices that will enhance their independence.

METHODOLOGY—This project is an exciting and novel demonstration of consumer empowerment. It exposes consumers to the engineering of new technologies, assists with technology advocacy, and guides the traditional Rehabilitation Engineering Research Center (RERC) staff toward consumer-focused design. The ConLab is designed to be a "think tank" and not a service delivery model. The intent is to develop ideas and create prototypes while leaving direct supply of devices to people in the hands of full-scale manufacturers.

The recruitment of consumers with disabilities is an ongoing process of inviting participation through consumer organizations. A small group of people with physical disabilities has come forward and these volunteers are being provided temporary part-time employment with the RERC. Along with the traditional staff, they are exploring new methods of integrating consumer knowledge and expertise that facilitate a more hands-on approach at the earliest stages of research and development.

PROGRESS—At present 24 consumers in 3 groups are attending 1 to 1 1/2 hour meetings at the duPont Institute on a bi-weekly basis. A standardized questionnaire for moving through the research process has been developed. As their major project focuses, these groups have chosen three devices, an egg-breaking device for use in food preparation, a remotely controlled vacuum cleaner, and a page turner.

All three devices are in various stages of development. A working prototype of the Auto-Vac is being home tested by the members of the ConLab at this writing. The prototype of the page turner is being mocked up and should be in final operation soon. Ideas for the final design of the egg breaker are still being discussed.

FUTURE PLANS/IMPLICATIONS—This project will provide our researchers at with direct input from the consumers about the devices and systems that they are trying to design. In addition, it will provide new sources of ideas and problems.

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

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PURPOSE—Past research has categorized predispositions to the use of assistive technologies (AT) as depending upon characteristics within four major areas: a) the particular technology (e.g., design, service delivery), b) the capabilities and personality of the person (e.g., aptitudes, outlook, expectations), e) the nature of the disability (e.g., type, severity), and d) the psychosocial environment of the person (e.g., support from family and friends,

life experiences, education). When variables within each of the above areas are organized by category of technology use (optimal and partial/reluctant) and non-use (avoidance and abandonment), individuals can be profiled according to the likelihood of a good match with a particular AT.

METHODOLOGY—The Assistive Technology Device Predisposition Assessment (ATD PA) is a consumer self-report checklist with items of varied format, including 5-point Likert scales. Its purpose is to identify potential sources of person and technology mismatches for early intervention. The ATD PA has subscales to separately assess characteristics of the AT, the temperament of the individual, and the environment in which he or she will use the AT. Side One of the consumer form consists of questions given per consumer on temperament, psychosocial resources, and inquires into individuals' subjective satisfaction with current functioning in many areas and where the person wants the most improvement to occur. Side Two contains 10 questions for consumers to complete per technology on their views of and expectations for that particular AT. Companion professional forms are similarly constructed and allow the assessment of shared perspectives between consumer and professional.

The ATD PA is one set of assessment instruments in the Matching Person and Technology (MPT) Model. Other instruments are the Survey of Technology Use (SOTU) and the Educational Technology Predisposition Assessment (ET PA).

PROGRESS—The ATD PA, SOTU, and ET PA have been administered to users of technologies from childhood to advanced age and in environments ranging from educational settings to acute rehabilitation.

RESULTS—The results of several studies confirm the importance of consumer perceptions and psychosocial factors on decisions to use (or not use) a technology. Characteristics of the technology under consideration further determines its appeal, usability, and utilization.

Specifically, individuals precategorized into five groups according to level of hearing loss were asked to complete the ATD PA and two additional instruments assessing hearing limitations in various environments. The ATD PA was the best predictor of group membership, correctly classifying 85 percent of the participants and providing psychosocial markers associated with awareness of and adaptation to hearing loss.

Another study looked at successful educational outcomes of instruction delivered via telecommunications technologies. One hundred twenty students completed the SOTU, ET PA, the Tennessee Self-Concept Scale (TSCS), and Canfield's Learning Styles Inventory (LSI). The SOTU and ET PA were the best predictors of a) success in the course and b) proficiency/satisfaction with use of the course technologies. Additionally, the SOTU and ET PA were found to provide an efficient and inexpensive alternate means of measuring self-concept and learning style preferences as measured by the TSCS and LSI.

FUTURE PLANS—We are about to undertake a pilot study regarding consumer-directed outcome research on perceived needs, AT use, functional gain over time, and consumer rated quality of life attainment. It is hoped that this information will help lead to better person-technology matching and enhanced consumer AT use and training for use.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[146] 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 positioning problems. 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. This project is designed to identify and incorporate desirable features identified by consumers into a commercially viable product.

PROGRESS—We held focus groups with parents and clinicians to develop consumer criteria and evaluate popular commercial toileting systems. A presentation model was built to illustrate our vision of the product. Parents and clinicians who evaluated it loved it. We subsequently developed a fitting prototype and organized classroom trials to see how well it positioned about 20 children with disabilities. Our findings suggest that the prototype seems to position most children well. This led us to develop a functional prototype for families to use at home. Comments from families who have used it have been encouraging. Links with industry were also cultivated during this time.

FUTURE PLANS—During fiscal 96/97, we will help our industry partner to source appropriate materials and develop a manufacturing and marketing plan. Pre-release testing of the product will be conducted to finalize its commercial design. Product literature and marketing information will be created and tested with consumers.

[147] RAPID PROTOTYPING FOR REHABILITATION AIDS FOR THE PHYSICALLY DISABLED

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PURPOSE—The purpose of this project is to explore the use of modern manufacturing techniques in the design and rapid prototyping of customized rehabilitation aids. In particular, computer-based techniques which integrate computer-aided design, computer-aided manufacturing, and virtual prototyping are being explored.

METHODOLOGY—The goal of this work is to create algorithms and techniques that support the rapid manufacture of customized devices. These techniques apply to three areas: measurement of customer parameters, design of the product, and manufacture of the product. In addition, the process through which a customized rehabilita-

tion aid is designed is being evaluated with respect to traditional engineering design theory.

To evaluate the techniques and algorithms, a number of design case studies are being carried out with new or modified products, including wheelchair trays, feeding aids, ergonomic helmets, and mechanical input devices.

PROGRESS—A demonstration custom manufacturing process is close to completion. This process includes the following components:

Interaction with Customers. Project staff have met with a number of consumer focus groups to determine important characteristics of both the case study devices and the process through which measurement of the consumer may take place. It is the intention to provide consumers with real devices that may be evaluated, but will also enable exploration of the manufacturing process.

ProEngineer Detail Design. A detailed design of the device is prepared on ProEngineer.

Virtual Prototyping. The detail design from ProEngineer may be ported directly into the Jack human animation program, which allows the device to be examined in a virtual environment. Several demonstrations with different products have shown that this is a powerful tool for evolving a device design without needing to physically prototype the device. The simulation software has been modified to allow a range of interface devices to be attached, which provides a consumer with the ability to interact directly with the simulated device. The virtual simulation also serves to allow for assessment and training on the prototype device.

ProManufacture. Once the final detail design is complete, the machining process for the device is specified in the ProManufacture module of ProEngineer, from which all tool paths, holding points, tool sizes, and cutting speeds are specified. The machining commands are directly ported into a CNC milling machine through a separate post-processor. This process has been demonstrated with several test devices and provides a quick and efficient route between the design and manufacturing process.

Manufacture. Depending on the type of device, it is manufactured either directly on the CNC milling machine, or the mill is used to create a mold, which in turn is used on a vacuum forming machine.

This entire process has been demonstrated and is now in a stage where it will be refined.

FUTURE PLANS/IMPLICATIONS—Immediate plans for thisproject are to continue to refine the above described manufacturing process and to determine the critical points in the process that affect the costs, in terms of efficiency, time, material, and equipment. Examination with respect to the engineering design process to date has revealed a need to better understand the consumer's role in specifying not only the functional requirements of the product or device, but also the methods through which the customized features are provided.

A further outcome of this project will be the identification of critical technologies that enable cost-effective rapid manufacturing capabilities to be more broadly available.

RECENT PUBLICATIONS FROM THIS RESEARCH

Virtual prototyping of rehabilitation aids. Beitler MT, Harwin WS, Mahoney RM. In: Proceedings of the 19th Annual RESNA Conference; 1996, Salt Lake City, UT. Washington, DC: RESNA Press.

[148] SPECIAL PROJECTS AND DEMONSTRATION: APPLICATIONS OF TECHNOLOGY TO ENHANCE QUALITY OF LIFE—A COMMUNITY MODEL

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Sponsor: *U.S. Department of Education, Department of Special Education and Rehabilitation, Washington, DC 20202*

PURPOSE—The project focused on demonstrating that the education and rehabilitation planning processes for individuals with significant disabilities can be enhanced by appropriate applications of technology. The project was designed to demonstrate that persons with severe disabilities using customized adaptations (assistive de-

vices) can participate more meaningfully in integrated work, school, and other community settings; we sought to involve educators, rehabilitation counselors, case managers, teachers, parents, employers, future engineers, and community members with technieal expertise in the development of adaptations; and worked to develop a replicable approach for enhancing the applications of assistive technology through direct service, information collection and dissemination, and referrals.

PROGRESS—The above goals were realized through several avenues. To identify individuals who could benefit from customized teehnical adaptations, the project staff worked closely with teachers and resource specialists of the San Diego Unified School District as well as with staff from local supported employment and supported living agencies. The project targeted transition-aged students (18–22 years) and young adults who, with suitable individualized assistive teehnology, could become more active partieipants in school, work, and eommunity settings. Resources were utilized to build up the technical capabilities of local schools and service ageneies, expanding the network of rehabilitation and assistive technology professionals, and reducing possible duplication. The project successfully exceeded its goals in terms of number of persons helped and technical adaptations completed.

One key project component of the project was the use of multidisciplinary Tech Teams, individually focused on the specific needs of the eonsumer. The Tech Teams included friends, family members, interested volunteers, and employers in addition to the special educators, engineering students, OTs/PTs, speech therapists, and community-based rehabilitation professionals who were enrolled in a special seminar jointly taught by the Departments of Special Edueation and Electrieal Engineering. In addition to providing valuable hands-on experience of designing and fabricating a customized assistive device, the seminar facilitated exchanges of ideas and diverse viewpoints. The Interwork Technology Mini-center coordinated various demonstration, training, researeh, and dissemination activities associated with the project while also serving as a repository of numerous referenee materials available for use by the community and Tech Teams. Information about on-going projects and eompleted projects have been disseminated in print and via the Internet at http://www.interwork.sdsu.edu/projeets/.

RESULTS—Major accomplishments of the 36-month project inelude: 1) better collaboration with the school district, supported employment, and supported living agencies through better utilization of each others' assistive technology resources and expertise; 2) expanded key intra-state and inter-state linkages; 3) design, fabrication, and delivery of over 40 customized technical adaptations; 4) documentation of individualized adaptations using photographs, videotape, teehnical drawings, and case study descriptions; 5) presentations at the local, state, and national levels; 6) evaluation of the eompleted projects; and 7) establishment and maintenance of a local web site that describes projeet activities and aceomplishments.

Examples of recently completed adaptations include: A stamping adaptation that ensured accurate rubber stamp imprints on student passes modified for use in a counseling office by a high school student with eerebral palsy. Plywood foot guides attached to Nordic Track™ exereiser for use by a man with hemiparesis. Padded arm guides attached to power wheelchair for a woman with cerebral palsy. The adaptation held a water bottle in place while also enabling easier passage through narrow doorways. A head control switch used by a man with head injury modified to keep his head in an upright position. A plastic transfer device designed to enable a transition-aged high school student to fill salt and pepper shakers at a restaurant. The door of a van modified for easier opening and closing by a man with paraplegia. A flat bed cart (or dolly) modified for use by a man with cerebral palsy using a manual wheelchair in his job at a nursery. A custom harness fabricated and a trumpet modified (by adding levers attached to its keys) so that a high school student who has a spinal cord injury could once again play that musical instrument. A ticket tearing device modified for use by a man with eerebral palsy at movie theater job. Flexible and inexpensive eleetronie eommunication deviees designed and built to meet the rudimentary communication needs of students with significant disabilities in general edueation classes. A lazy susan to hold files and papers for a man with quadriplegia; also designed custom speaker mounts for his augmentative eommunieation deviee.

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Including all students in the high school reform agenda. Fisher D, Sax C, Pumpian I, Rodifer K, Kreikemeirer P. Educ Treat Child. In press.

Outcomes for students with severe disabilities: case studies on the use of assistive technology in inclusive classrooms. Sax C, Fisher D, Pumpian I. Technol Disabil. In press.

[149] TRANS-TRAIN: TRANSDISCIPLINARY TRAINING OF REHABILITATION PERSONNEL IN ASSISTIVE TECHNOLOGY

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PURPOSE—TRANS-TRAIN is a 36-month project that seeks to provide preservice and inservice training to rehabilitation personnel in Assistive Technology (AT). It is a university-based program that combines academic classroom instruction with experiential field activities. Although discipline specific training will be given, 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 AT. To complement an existing College of Education certificate program in "Supported Employment and Transition," a specialization area in "Rehabilitation Technology" is being developed for the Department of Electrical and Computer Engineering.

METHODOLOGY—Because the incoming students come from various educational and vocational backgrounds (e.g., engineering, special education, rehabilitation counseling, and communicative disorders), the certificate program can be customized to fit their backgrounds, skills, interests, and intended application areas. In addition to the six to nine unit curricula (supported in part by project funds), students seeking a "Certificate in Assistive Technology" 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.

One key component for training personnel in the development of customized assistive adaptations is the use of transdisciplinary Tech Teams individually organized according to the specific needs of an individual with disabilities. These Tech Teams encompass friends, family members, employers, and volunteers, special educators, engineering students, OTs/PTs, speech therapists, and community-based rehabilitation professionals enrolled in TRANS-TRAIN sponsored classes. In addition to providing valuable hands-on experience of designing and fabricating a customized assistive device, the classes foster exchanges of ideas and viewpoints among persons from varied backgrounds. To monitor progress and insure that the assistive technology is consumer-driven and integrated into the planning processes, a series of 12 milestones (e.g., a request for assistance, research and data collection, design, prototype construction, field-testing, and evaluation) is used. To promote dissemination and replication by others, customized adaptations designed and constructed through this project are being incorporated into a database that will track information about each adaptation.

PROGRESS—Between fall 1995 and spring 1996, 12 undergraduate and 2 graduate engineering students, 18 graduate students in Special Education, and 13 graduate students in rehabilitation counseling participated in the transdisciplinary seminar.

Tech Teams were formed around individuals with disabilities who needed some sort of adaptations. Some of the adaptations designed, fabricated, field tested, and delivered include:

1. Portable acrylic wrist-rest adaptation, designed to fit laptop computer and augmentative communication device for a man with cerebral palsy.
2. Wood and acrylic wheelchair laptray and book holder, adjustable to different angles, with hinged cover to hold materials in place for a high school student with significant physical and cognitive disabilities.
3. Power wheelchair arm modified with a slider mechanism tomove the joystick out of the way when it's unneeded. This modification enabled a man with quadriplegia to drive a van fitted with hand controls.
4. To enable a young man with cerebral palsy to effectively work at shoe store, a lightweight foldable work surface facilitated his task of taking shoes

from plastic bags, removing the stuffing inside the shoes, and disposing the stuffing into the proper container.

5. An aluminum and acrylic mounting system enabled an 8-year old girl with physical disabilities to independently carry her lunch tray on her walker.
6. Replaced the remote control system of a radio-controlled toy jeep with a joystick so that a nonverbal 9-year old boy could operate the jeep from his wheelchair. A switch controlled multimedia box contained lights and emitted sounds reminiscent of a race track.
7. Added a third wheel and a plastic trunk to a golf bag cart so that it could be easily attached to the wheelchair (as a luggage carrier) of a teacher with paraplegia.
8. Modified the Bogen Magic Arm® so that it could support a still camera or videocamcorder on a Quickie wheelchair for use by a man with SCI.
9. New wheelchair armrests to support a custom laptray for an 11-year-old boy so that he could maneuver his wheelchair without assistance.

FUTURE PLANS—During its third year, TRANS-TRAIN will seek formal recognition and approval of a certificate program in AT from the Department of Electrical and Computer Engineering, the College of Engineering, and the University. TRANS-TRAIN will continue to offer an advanced version of the transdisciplinary seminar in AT, set up initial internships at local agencies with appropriate experts, and give a course in engineering on "Electronic Devices for Rehabilitation."

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Customizing adaptation for job development: a case study. Sax C, Grant J, Hanzlik J. In: Proceedings of the 19th Annual RESNA Conference; 1996, Salt Lake City, UT. Washington, DC: RESNA Press, 1996.

Project TRANS-TRAIN: assistive device assessment program. Szeto AYJ, Allen EJ. In: Proceedings of the 11th Annual International Conference of Technology and Persons with Disabilities; 1996, State University at Northridge, Northridge, CA.

[150] A LOW COST, HORSE-DRAWN CART FOR INDIVIDUALS WITH DISABILITIES

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Sponsor: *None listed*

PURPOSE—A low cost horse-drawn driving cart was needed by a therapeutic riding program for individuals whose disabilities would not let them ride a horse comfortably or prevented them from being covered under liability insurance any other way. The cart was designed to permit the individual with disabilities to control the horse with the reins.

METHODOLOGY—The design criteria which were considered included issues related to the design for "generic" disabilities. However, the cart was primarily designed for someone who is confined to a wheelchair and has little upper extremity motion and trunk control. Design criteria related to such issues as wheelchair tiedowns, seating, cart dimensions, tires, braking system, and suspension system. While this cart will be moving at much smaller velocities than a mechanically powered vehicle, information on transportation of wheelchairs, such as that being developed by the Subcommittee on Wheelchairs and Transportation (SOWHAT) was included in the design.

PROGRESS—The cart has been designed and built. It is currently under evaluation by a therapeutic riding center.

RESULTS—The cart was built from wood and steel with a materials cost of approximately $400. A fifth wheel was attached to the top of the front axle to allow it to rotate independently of the cart body. A ratchet strapping system was used to tie the wheelchair of the driver down to a pieceof angle iron on the floor of the cart. Trailer tires were used to keep the cart low to the ground

and provide rough terrain capabilities. The braking system is a locking system for loading and unloading the driver on a ramp in the rear of the cart. The cart does not have a dynamic braking system.

RECENT PUBLICATIONS FROM THIS RESEARCH

Designing a horse cart for people with disabilities. Brock HN, Smith SL, Wallace PD. Dev Theor Appl Mech 1996:18:310\N5.

B. Robotics

[151] ASSISTIVE ROBOTICS IN A VOCATIONAL SETTING

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Sponsor: *National Institute on Disability and Rehabilitation Research, U.S. Department of Education, Washington, DC 20202; Nemours Foundation, A.I. duPont Institute, Wilmington, DE 19899*

PURPOSE—The purpose of the Vocational Robotics project is to study the issues involved in the employment of individuals with manipulation disabilities through the use of interactive robotic devices. The goals of this project are two-fold. First, this project aims to employ individuals with disabilities in real mainstream jobs, through the use of assistive robotics. This will be accomplished through surveying a wide range of vocations and evaluating the manipulation requirements of their job tasks. Also, a collaboration with a local rehabilitation center that is actively involved in job placement of people with disabilities will provide a site for assessment and training of potential employees. Second, this project intends to identify the process through which a suitable robotic system may be designed so that a potential job may be made accessible to a person with a manipulation disability. This task involves identifying the organization that addresses both engineering and non-engineering issues related to the potential employees disability. It is expected that a successful job placement will require input from an engineering design team, vocational rehabilitation specialists, representatives from the potential employer, and funding sources.

METHODOLOGY—Three areas of concern are being addressed in this work: assessment and training, system integration, and job identification and analysis. The ultimate goal of the project is to stimulate the development of areas of expertise within normal vocational rehabilitation establishments. This expertise must extend to job site evaluations appropriate for implementation of robotic systems, knowledge of existing commercial robotic technology or the ability to design and construct suitable one-off systems, knowledge of available user interface approaches and software, and facilities for assessing the aptitude of a potential employee not only to work with a robot but also to carry out preliminary training. It is hoped that through this project, the appropriate application of robots in vocational settings will grow to the point where it is a viable and acceptable alternative.

PROGRESS—We have completed 3 years of the vocational robotics project. In the first year, we focused on identifying individuals who work in the vocational assessment field. An occupational therapist trained for a year on the robot and designed several assessment/evaluation tasks. During the second year, we furthered the training for the occupational therapist as well as demonstrating the use of many different interface devices to operate the robot. A demonstration robotic workstation was installed in the Easter Seal rehabilitation facility to assess individuals as well as to be seen by many persons who may be in need of a manipulator. A data acquisition routine for Cambridge University Robot Language (CURL) use was customized to obtain the maximum amount of information about its use at Easter Seals. In addition to the assessment aspect of the training, a couple of different routes were explored to find particular types of jobs

for individuals with a robotic workstation. First of all, the Rehabilitation Services Administration database of the clients of all of the Vocational Rehabilitation Centers was analyzed as to the characteristics of the individuals who did and did not receive jobs. Also, the Dictionary of Occupational Titles was explored using the Valpar System 2000 software to find out what types of jobs an individual with disabilities and arobotic workstation could find. Finally, individual jobs in the surrounding area were explored to find their particular responsibilities to see if and how a robotic adaptation could help.

Our goal in the third year has been to gain exposure for the assitive robot and to receive feedback on its development. A morning seminar was held to inform service providers and a group of people from various vocational evaluation centers about the system and get their responses.

FUTURE PLANS/IMPLICATIONS—The primary objective is to provide an appropriate robotic accommodation in a real work environment. This accommodation will provide expertise and exposure that will become the foundation for future robotic accommodations.

RECENT PUBLICATIONS FROM THIS RESEARCH

Vocational robotics: job identification and analysis. Schuyler JL, Mahoney RM. In: Proceedings of RESNA International '95; 1995, Vancouver, BC. Washington, DC: RESNA Press, 1995:542–4.

[152] A BODY-POWERED REHABILITATION ROBOT

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PURPOSE—The goal of this project is to develop atechnologically simple, wheelchair-mounted manipulator to allow a person with no or very little arm function to interact with his surroundings. The robot will be controlled and at least partially powered through bowden cables by the intact motion capabilities of the user, such as the head or hand. This method of robot control relies on extended physiological proprioception (EPP), the same control principle used in cable-driven prostheses. It has been shown that a system which compliments visual feedback with sensory channels is superior to visual feedback alone. The intended population that would benefit from such a device has physical disabilities such as spinal cord injury, multiplesclerosis, and cerebral palsy.

METHODOLOGY—The following design specifications drive the methodology of the project:

Intuitive and easy to use. The inputs of the user should map in an integrated manner to the outputs of the manipulator: a proportional, three-dimensional position mapping of the user's input position signal to the position of the arm's gripper is desired. A direct connection between the user interface and arm facilitates a system which is easy to use, since proprioception and force reflection are naturally built into the control system.

Modular. The system will be modular in two senses. First, the arm will accept several different user inputs. These inputs depend upon the available user body motions, which to a large extent, depend upon the user's disability. For example, if the best available user input is from the head, the arm needs to accommodate whatever interface is designed for head input. Another way the system needs to be modular is in its ability to accept power assist units. In this way, if the user cannot supply sufficient power to the interface to directly cause the arm to move, power amplifier modules will be added to specific joints to assist the user in operating the arm. The issue of desiring minimal user input power naturally leads to the requirement of arm gravity compensation throughout its range of motion.

Cost. The high cost/usefulness ratio of most rehabilitation robots makes their use very limited. It isthe goal of this project to maintain a simple design philosophy so costs can be kept to a minimum.

Aesthetics. The arm is designed to geometrically and functionally resemble a human arm. The interface unit will be designed to be as unobtrusive as possible, and the cable routing will be neat.

PROGRESS—Two arm prototypes and two interface units have been designed and constructed. The second has been tested with both interface units, one for the head and the other for the hand. One of the design objectives was to have an end-point controlled, mechanical linkage which resembles the human arm. To facilitate this objective, a spherical coordinate system was chosen for the arm with an extra degree of freedom added to kinematically couple head input to arm motion. A direct mapping exists between the yaw, pitch, and roll axes of the arm and head interface, while a proportional mapping is present between the linear, horizontal motion of the user's head and the radial motion of the arm. Low friction bowden cables connect the arm to the head interface unit. A four bar linkage design of the arm's main beams is to allow gravity compensation of the mechanism throughout its full range of vertical motion.

FUTURE PLANS/IMPLICATIONS—It was decided through in-house evaluation to build a third generation arm and a second generation head interface unit. In the present system, high friction makes it difficult for the user to rotate the arm along some axes. A different gravity balancing technique will be used to decrease the friction throughout the system and a minor design constraint has been relaxed, thus making the system significantly simpler. Some additional issues to be addressed include attaching a gripper to the arm, donning/doffing, adjustability to accommodate different users, further development of power assist units, and exploring methods of allowing the user to lock the system.

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Body powered rehabilitation robot. Stroud S, Sample W, Rahman T. In: Proceedings of the RESNA '96 Annual Conference; 1996, Salt Lake City, Utah. Washington, DC: RESNA Press, 1996:363–5.

[153] REHABILITATION ROBOTICS INFORMATION PROGRAM

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PURPOSE—The Information Program in Rehabilitation Robotics collects, organizes, synthesizes, and disseminates information on rehabilitation robotics to professionals, consumers and their families, manufacturers, and other researchers.

METHODOLOGY—The information program produces technical reports, book chapters, journal articles, and conference and symposium presentations that describe the research, development, and evaluation work underway at ASEL. The project also produces a number of resource materials and activities, including: videotapes, a newsletter, a web site, conferences, and workshops on robotics topics.

PROGRESS—Robotics research staff have produced 22 publications that have been disseminated through the Robotics Information Program. Inquiries for informational materials and technical assistance have been personally answered. A Rehabilitation Robotics Research Program web site has been developed and refined. Two videotapes on robotic products and laboratories have been completed. The Rehabilitation Robotics Newsletter continues to be produced and disseminated. The program established the Consumer Innovation Laboratory, which publishes a quarterly newsletter, maintains a web site, and holds bi-weekly design meetings.

FUTURE PLANS—The RERC will hold a workshop on design, control, and implementation of wheelchair-based manipulators. The robotics web site will continue to be expanded and updated. A series of videotapes on specific robotics projects are planned. Research progress and findings will be more widely disseminated through a redesigned information program.

[154] 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 the extended proprioception. Proprioception is the ability to sense forces and other perceptual cues present at the tip of the extension device. The conventional mouth stick, for example, can successfully be used in daily activities due to its good proprioceptive properties: it provides an intimate contact of the device with the user's mouth which is rich in tactile and proprioceptive sensing ability, and it is lightweight and very stiff, and therefore conveys tactile and kinesthetic information from the environment. However, there are two important limitations for this type of device. The first is the spatial limitation caused by the fixed length of the mouth stick plus the restricted motion of the human head. The second is the amount of mechanical power that can be transmitted to the end of the mouth stick. The longer the mouth stick, the more the power required to achieve similar tasks.

We are developing a robotic teleoperation system that, in principle, can overcome both limitations of conventional mouth sticks. Teleoperated robots can deal efficiently with the problem of spatial limitation, and since power is generated at the robot-arm itself, the second limitation can also be alleviated. However, proprioception and the exchange of kinesthetic information using teleoperation robots are issues that need to be carefully examined.

METHODOLOGY—We have developed a teleoperation system based on two subsystems: a head controller (master) and a robotic arm (the slave). Head motion is sensed at the controller end and transmitted digitally to the robotic arm, which attempts to track the original head motion. The amplification and filtering of motion and forces can be easily implemented at the information processing stage. The master controller is a six-degree-of-freedom (DOF) manipulator, originally designed for hand control, and modified for head operations using an attached helmet. The slave robot is a Zebra Zero robot with six DOF, lightweight, and initially designed for simple industrial applications. Forces and positions at the slave end can be measured, digitized, and sent back to the master-controller computer. The computer uses this data to produce forces in the helmet that mimic the ones encountered by the robot arm, providing a certain degree of proprioception.

PROGRESS—This force-reflecting teleoperation system has been successfully implemented. While no accidents have resulted from testing this equipment, the safety issue has been an important concern during the last year, mainly because the ultimate users will be human beings. Mechanical safety devices have been investigated, and electrical safety devices and monitoring software have also been implemented to prevent the system from reaching high power values.

Besides safety, different teleoperation architectures have been implemented: 1) a Cartesian-based control where head motion is mapped to robot-arm motion, 2) a rate control system where head motion is mapped to robot-arm velocities, and 3) a spherical control unit where rotational head motion is prioritized and mapped to robot-arm motion.

Finally, a head stick unit has been designed and developed with the purpose of comparing the performance of teleoperation systems with conventional head sticks. Different tasks related to daily life activities have been established for performance evaluation. The tasks attempt to measure proprioception ability, power transference capacity,space limitations, and the conveyance of kinesthetic information.

FUTURE PLANS—We are in the process of evaluating the performance of the different architectures for the head-controlled teleoperation system. Our immediate goal is to establish a series of comparative results that may be used as the basis of future developments in this area. Future issues to examine include: 1) the design and development of full-bilateral architectures where forces and positions are transmitted from the master to the slave and vice versa, 2) the mounting of a similar structure to a wheelchair, and 3) power control and amplification to compensate for motion limitations of the head.

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Calibration of closed loop controllers for setting impedances in force-reflecting systems. Jayachandran V, Rahman T, Salganicoff M, Heredia M, Harwin W. In Proceedings of the 1996 International Mechanical Engineering Congress and Exposition, November 1996.

[155] MULTI-MODAL 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 preprogrammed tasks. Others have sought to give the user direct control of the manipulator. In this project, a new hybrid interface strategy is designed. This new man-machine interface combines command and control approaches to provide for user direction of the robot through the use of multiple modes of interface in conjunction with sophisticated capabilities of the machine. Users of this system use gestures (pointing) to indicate locations, and spoken commands to identify objects and actions. The use of multiple modes of control and command allows the user to operate the robot in a manner which more closely matches the needs of the user. 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 multi-modal approach is based on the assumption that the world of the user is unstructured, but that objects within that world are reasonably predictable. There are two major components of this hybrid interface strategy, including a system that determines the three-dimensional (3-D) 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 3-D 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. He wishes to move the pen, which is on the desk, to the box: using a head laser pointer, he points to the pen and says, "move." The user then points to the box, and says, "there." The combination of the ini-

tial pointing accompanied by the command tells the robot to pick up an object at a specific location. The combination of the subsequent pointing and command tells the robot where to move the object.

PROGRESS—*Integration.* The different developmental subsystems have been integrated into a working system which is now undergoing in house-testing. The components RoboMind (the intelligent robot planner), RoboArm (the robot arm control mechanism), RoboEye (the vision system), and RoboEar (the speech recognition mechanism) have now been integrated into a working system by means of RPC connections.

HCI subsystem. Significant progress has been achieved in the user interface portion of the system: 1) The communication protocol between the user and the system has been completed. 2) A grammar has been developed to codify the human-computer communication protocol. 3) A parser based on this grammar has been constructed which understands a subset of natural language-like instructions (e.g., move the blue book to the right of the pen).

Planning subsystem. The knowledge-based planning mechanism is nearing completion. Multi-modal instructions combining speech and gesture are parsed and interpreted by the planner. The planner understands a variety of low level robot arm manipulatory instructions as well as a number of high level pick and place instructions. Work is progressing in allowing users to teach the system new high-level tasks for later re-use and/or adaptation. A basic knowledge base of objects has been constructed that allows researchers to test planning activities on a variety of everyday objects. Partial plan-monitoring, error detection, and recovery techniques have been constructed and will be completed during this year. A plan adaptation mechanism has been completed that allows the planner to adapt previously used plans to synthesize new plans. A plan learning mechanism has been implemented which allows the user to "teach" the robot to learn new tasks.

Vision subsystem. The performance of the 3-D vision system has been improved significantly in terms of speed and versatility; we have 1) incorporated the SGI Media Video Library routines to perform automatic video channel alternating for real-time image capturing; 2) modified the laser spot location searching strategy to reduce the locating time to less than 1 second; 3) implemented a color vision module for better object-disambiguation for the planner system; 4) completed a contour-based stereo-matching method for rapidly (in the range of 15 to 30 sec, depending on the number of objects involved) recovering 3-D information for circular and linear image components; 5) developed a Hough transformation based 3-D information segmentation for providing the planner with the object pose parameters; and 6) ported the structured-light stereo matcher from the Visilog environment to C for faster performance and faster user interaction cycle.

Simulation subsystem. The graphic display system has been completed and is soon to be undergoing user testing. The display mechanism has also been partially integrated with the planning mechanism.

FUTURE PLANS—Fine tuning and testing with consumers.

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[156] 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. This system is to be 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 the Brandywine Public Schools 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 someday 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 which is field tested and validated. The framework of the educational curriculum involves a two-phase process in which students are first trained to use the robot hardware and software using simple object manipulation activities. The second phase involves the development of science education activities which 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 are under investigation in addition to doing the hands-on experimentation using the robotic system. The students include both disabled and nondisabled students who will be working in research teams at the field site in the schools.

PROGRESS—*Interface Development.* Development of a software interface that is able to engage the students at the appropriate level, as well as provide sufficient flexibility for adaptations by teachers, continues. Development time has been spent investigating an approach using Labview software rather than the commercial version of the Cambridge University Robot Language (CURL) because of inadequacies in CURL.

Site Evaluation with Students. Experimental evaluation of student use of the system has commenced in the field site school at OSU. Preliminary indications are that, within the teams of both disabled and nondisabled students, the robot-based science activities support and emphasize science learning.

ASEL field site. Progress has been made in evaluating various interface alternatives, such as DragonDictate and Intellikeys.

RESULTS—The first stage of field testing at OSU will be completed. The results of this study will be used to specify more exactly a science-based curriculum based on the robot. Further efforts will be made to package the findings into a curriculum that may easily be transferred to other sites, and that will eventually form the basis of a commercial product.

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[157] CONTROL AND SIGNAL PROCESSING STRATEGIES FOR TREMOR SUPPRESSION

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PURPOSE—Tremor is a rhythmic uncontrollable oscillation that appears superimposed to voluntary movement. Approximately 0.4 percent of the population in the U.S. is affected by some kind of pathological tremor. The amplitude of the tremor distortion can be high enough to disable the subject in normal daily operations such as eating, writing, computer operation, and wheelchair operation. This project is designed to allow people with pathological tremor to have normal manipulation in human-computer interaction using hand-controlled input devices such as joysticks, mice, and telemanipulators.

METHODOLOGY—Three approaches have been developed for tremor suppression, two of which are signal processing approaches and the other is force feedback approach. In each case, a subject is asked to perform either a pursuit tracking task or a writing test. A PerForce hand controller, a force reflecting device originally designed for the space station, is used as the input device. In the signal processing approaches, the hand controller is used as a simple unpowered input device and digital filters are applied to the hand/arm motion signal collected by the computer. In the force feedback approach, force is generated by the motors built in the hand controller and applied on the handle to cancel out the tremor in the arm motion. The subject would feel resistance from the controller, while in the signal processing case, the subject could only see the effect of the filter on the computer screen.

PROGRESS—The first signal processing approach is tremor equalizers. Equalization is a technique that has been successfully used over the years in the field of telecommunications. However, several important contributions, such as Filtered Mean-Square Error with delay correction, have been achieved to make it appropriate for tremor cancellation. Based on the data collected from the pursuit tracking tasks, optimal equalizers are developed to cancel exactly the tremor frequency bands and leave the intention movement as intact as possible. Pulled optimization technique is used and it brings an elegant way to design the equalizer delay.

The second signal processing approach is an adaptive finite impulse response (FIR) filter. The adaptive FIR filter is able to learn about the tremor signal and eventually to produce a signal that cancels it. This approach can handle tremor with multiple frequencies and with slowly time-varying characteristics. Because it is parallel to the main signal flow, the filter introduces no time delay to the voluntary movement signal. Another advantage of the adaptive filter is that no information other than the frequency range of tremor has to be known beforehand.

In the force feedback control, the damping force has been explored and tested. The effect of applying damping force is equivalent to increasing the damping of the mechanical system. This is called active damping and is more flexible than the usual mechanical damping. Tremor can be significantly reduced by increasing the damping force. One important accomplishment in this approach is system modeling, which is the basis of controller design.

Besides, some efforts have been made to explore the possibility of replacing PerForce with a new sensible device, Phantom. PerForce has proved to have several hardware restrictions on implementing more effective force controllers. Damping force has been implemented on Phantom and it has been proved that sufficient force can be provided to suppress tremor.

FUTURE PLANS/IMPLICATIONS—A more complicated controller will be designed to have more effective force feedback control on tremor. Stability will remain a big issue and needs further investigation. The working environment will be changed from DOS to Microsoft Visual C++ under Windows NT workstation.

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[158] AUTOMATIC MODE SELECTION IN A SHARED CONTROL SYSTEM

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PURPOSE—Shared control systems are defined as those human-machine systems where control is shared between a human operator and the machine components. The NavChair Assistive Wheelchair Navigation System is an example of a shared control system developed to provide improved mobility for people with severe disability. The NavChair shares control decisions with the human operator to reduce the motor and cognitive effort required to operate a power wheelchair. During development of the NavChair it was observed that one set of operating parameters could not provide all of the functionality desired of the chair. For this reason, the NavChair offers several different modes of operation: general obstacle avoidance, door passage assistance, and automatic wall following. The presence of multiple operating modes necessarily creates the need to choose between them. Requiring the wheelchair operator to perform the task of mode selection could place unacceptable performance burdens on a large portion of the target user population. Instead, we are developing and evaluating methods to infer the correct operating mode automatically.

METHODOLOGY—The mode selection method used by the NavChair must meet several design criteria. Obviously, it must make the correct operating mode decision as often as possible. Another important criterion is that it avoid frequent mode changes, which could lead to an uncomfortable ride for the operator. Finally, decisions must be made in real-time, which is not a trivial concern given the NavChair's computer hardware (a 486/33 personal computer) and the need to share processing time between navigation assistance and automatic adaptation.

The approach we have taken is to combine several limited information sources together into one coherent automatic adaptation mechanism. These information sources are combined using probabilistic reasoning techniques developed by the artificial intelligence community.

PROGRESS—Currently, the NavChair makes use of two information sources to make adaptation decisions: (1) its location within its global environment and (2) the identities of objects in its immediate surroundings. The NavChair's location is tracked within an internal map, and each location within the map has its own set of probabilities as to how likely each operating mode is in that location. For example, within a narrow hallway, wall following and door passage mode are more likely than general obstacle avoidance, while the opposite is true in a spacious room. Objects in the wheelchair's proximity are identified from the same sonar signals that the NavChair uses to avoid obstacles. Currently, the NavChair has robust and efficient methods for identifying both walls and doors. During operation, the NavChair constantly updates its beliefs in its location and the presence (or absence) of doors and walls in its surroundings. Every time these values change, they are used to make a new decision regarding the most appropriate mode for the wheelchair. If the decision to change operating modes is made,

the operating parameters that define the new mode (what behavior to exhibit, how fast the chair is allowed to travel, how close the chair can approach obstacles) replace the parameters that defined the previous operating mode.

RESULTS—Preliminary results indicate that our approach to automatic adaptation meets the design criteria specified above. Experiments using nondisabled subjects indicate that the NavChair can perform nearly as well adapting on its own as it can when mode selection is controlled by an experimenter. In addition, combining the individual information sources has been shown to produce better performance than either of the individual sources could provide alone.

FUTURE PLANS—Our recent work has focused on incorporating as much information as possible into the mode selection process. In the future, we hope to include even more information sources such as user control models and additional sensors.

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[159] A STUDY OF SHOULDER FUNCTION AS AN INPUT TO AN ASSISTIVE ROBOTIC SYSTEM

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PURPOSE—The purpose of the Shoulder Control project is twofold. First, the study attempts to quantify the capacity of the shoulder to provide a control signal for an assistive robotic system based on extended physiological proprioception (EPP). This kind of robotic system (in particular, one having the bilateral master-slave architecture) is considered to have unique features, including position unbeatability and force-feedback, which may greatly improve the quality of interaction between the machine and its human operator. The utility in controlling a robot with the shoulder would be most apparent with regard to individuals with quadriplegia who retain some control of the shoulder in addition to control of the head and neck, in which case the shoulder site could complement the head and neck as a source of control inputs into the assistive system. To achieve the desired quantification of shoulder behavior, the performance of the isolated shoulder is compared to performance of the full upper limb in accomplishing identical control tasks which simulate the kind of control which would be typically required in operation of an EPP-based assistive system.

The second aspect of the study is an assessment of the impact of "ontrol impedance" on performance of both the isolated shoulder and full upper limb. The motivation for this phase of the study is the finding that varying control parameters (i.e., qualities, like damping, which contribute to the "feel" of a control) can impact performance in performing tasks using the control. Because of the heavily software-oriented architecture of the master-slave robotic system, there is a great flexibility in

making adjustments of this kind. Therefore, there is an opportunity here to illuminate what impact, if any, tuning the system impedance in various ways will have on performance with an EPP-based system. The information obtained from this second dimension of the study has relevance as well to control originating from other sites, such as the head and neck.

METHODOLOGY—To investigate these aspects of shoulder performance, a variable-impedance test device, the Shoulder Interface Mechanism (SIM), was designed to interface with a subject's right shoulder. Additionally, the SIM can be fitted with a joystick-type handle for tests using the hand and arm. The SIM is a parallel linkage actuated by two electric motors driven by HCTL 1000 motor control chips, and carries a two-axis force sensor above the shoulder harness. In use, the SIM behaves as a passive load coupled to the operator's shoulder (or hand), responding to the force applied by the shoulder (hand) to the harness force sensor in a manner determined by the compliance and damping properties established for it by the microcomputer controller.

Shoulder performance is being assessed through use of tracking tasks that are chosen to be representative of the range of movements the shoulder might be called upon to make as a control source in a manipulation system. During testing, position, velocity, and force data are reeorded from the SIM by the eomputer at a rate of approximately 17 Hz. The data collected will be used to analyze how the two control sites (isolated shoulder and full upper limb) are impacted by system impedance alterations throughout their ranges of motion.

PROGRESS—This work is in its final stage. All relevant data have been acquired and the statistical analysis is being completed. Early results show that tracking performance, especially with the shoulder, is responsive to impedance tailoring.

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C. Communication Methods and Systems

[160] ADVANCED INFORMATION RETRIEVAL

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Sponsor: *EC Human Capital and Mobility Programme*

PURPOSE—Our aim is to develop a highly efficient interfaee by whieh a physieally disabled nonspeaker ean use a computer to communicate reusable conversational material, as well as to evaluate the use of different intelligent, lexicon-based information retrieval techniques for a communieation aid.

METHODOLOGY—Users can potentially communicate faster by selecting whole prestored utterances, rather than by constructing every message character by character. However, current systems impose a high cognitive load on the user who must remember aceess codes. The projeet will taekle this problem by using advanced text retrieval methods, ineluding automatic morphological analysis and searches for semantically related words.

PROGRESS—A new interfâce for a Windows 95 environment is being developed. A larger lexicon containing information about semantic relatedness and morphological code has been compiled. Evaluation of the new interface began in autumn 1996.

[161] SIGN PS—THE DEVELOPMENT OF AN INTERACTIVE PRINTING SYSTEM FOR SIGN LANGUAGES

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PURPOSE—Research has shown that most deaf people do not reach functional literacy. Most communication within this group occurs by means of sign languages, but currently there is no conventional written form of these languages. The aim of the SIGN PS project is to develop a system which will support the production of documents which have been created with, and are written in, sign language.

METHODOLOGY—This will involve investigation into the computer recognition of sign language using specialized methods, such as instrumental gloves and video images; the development of an attractive sign font to graphically represent sign language in printed format; the development of a predictive mechanism to reduce user effort in creating documents and to improve the sign recognition accuracy of the system.

PROGRESS—A font for representing signs had been developed, in conjunction with software to allow the user to manipulate the font elements. This consists of a sign editor, which is used to group the font elements into an individual sign, and a preliminary document editor which is used to form the signs into a document written in Sign Language. To allow users to enter signs, a virtual keyboard has been developed. In addition, two prototype sign input devices are being researched, one based on video technology, and one based on datagloves. A prediction system has been developed, which, when combined with any of the input systems, reduces the effort required to enter signs, and also improves the recognition accuracy.

RESULTS—A prototype Sign PS system has been evaluated by users, with promising results. Very little instruction was required before the subjects were able to create signs and documents. In general the subjects were happy with the concept and the execution although some reservations were expressed. The glove and video systems are progressing well, with handshape recognition for both modules exceeding 90 percent for all 84 handshapes. Further parameters are currently being investigated. The prediction system has been shown to reduce user effort by as much as 96 percent.

FUTURE PLANS—Within the lifetime of the project, the document editor will be completed, and further research on the two input device prototypes will be done. The work could also be extended beyond the lifetime of the project with further work on the input devices, an improved font design, and a better display method, perhaps incorporating animation.

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[162] ALADIN: ADVANCED LANGUAGE DEVICE FOR INTERACTION

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PURPOSE—The ALADIN project is developing a novel, linguistically based software system which will enable a nonvocal, physically impaired person to hold effective conversations.

METHODOLOGY—The software will run on a wide range of commercially available hardware platforms (computer plus speech synthesiser). 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 which will help the user to navigate through a conversation with minimal attention to the interface and maximum attention on the other speaker. The user of this system will be persons who are non-vocal from birth through cerebral palsy, and also people who have permanently lost the ability to speak through degenerative conditions or accidents.

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[163] THE FURTHER DEVELOPMENT OF TALKSBAC: A COMPUTER-BASED COMMUNICATION SYSTEM

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PURPOSE—The TalksBac project was awarded funding to continue a collaborative research project involving the University of Dundee and the Dundee Speech and Language Therapy Service.

The project is a continuation of the original TalksBac (Talking and Language Knowledge System for Better Aphasic Communication) project, which designed and evaluated a computer-based communication system, with four nonfluent Broca-type dysphasic adults. The project is staffed by a full-time researcher, a part-time researcher and a part-time speech and language therapist.

The broad aims of this project are to further develop the TalksBac system for dysphasic adults by implementing the improvements suggested in the outcomes of the previous project, to improve the training of carers in the choice of conversational material to be entered into the TalksBac database, and to evaluate the improvements in the new system by assessing its effectiveness in facilitating communication between client and partners.

METHODOLOGY—TalksBac is an augmentative communication system that uses predictive retrieval tech-

niques to anticipate the sentences and narratives the dysphasic client may wish to use in conversation. Written in C++, TalksBac runs on a Macintosh PowerBook with an internal speech synthesizer. The first goal of this project was to further develop the user and caregiver software to encompass the findings of the previous project. The second goal was to develop a formal training procedure for caregivers to enable them to identify relevant conversational information which would be used by the dysphasic clients.

The second phase involves four dysphasic subjects using the system for 6 months. In order to measure the effectiveness of TalksBac, two types of evaluations are to be conducted at the end of this period. The first will focus on software: the speed of information retrieval and the performance of the prediction algorithm will be analyzed. The second evaluation will focus on the use of the software by the caregivers (i.e., the amount of data and the regularity in which the information has been entered into the system) and the users (the number of times the system is used in practice). The use of the system will also be evaluated in a similar way to the previous project in that the difference between unaided (without TalksBac) and aided (using TalksBac) communication will be analyzed using conversational profiles and videotaped conversations.

PROGRESS—The TalksBac software has been improved and tested and is now being used by four dysphasic adults. The caregivers are modifying and updating the databases on a regular basis. The dysphasic adults have been using their machines for a 6-month period, and the evaluation period is currently taking place.

RESULTS—Results of this project will be published in April 1997. Preliminary results are encouraging in terms of the increase in data entered into the databases. The implementation of the improved software has resulted in faster retrieval times.

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[164] 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 exist 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 servo-controlled motorized mirrors that can follow the movement of the head in order to maintain the eye in the camera's field and make an eye tracking system that is considerably more appropriate for use with individuals with cerebral palsy and other disabling conditions.

METHODOLOGY—The major portions of this project involve the calibration and programming of the two servo-controlled mirrors connected to a 386-PC. A former graduate student wrote software libraries to control the mirrors, maintaining the eye in the camera's field of view. Rapid motion is still an unresolved problem: the eye-tracking software needs further development to compensate for the significantly more complex geometry.

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.

[165] SINGLE SWITCH MOUSE CONTROL INTERFACE

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PURPOSE—The purpose of this project is to investigate the use of a intelligent agent within a single switch mouse control interface. It is believed that this type of interface will be more efficient than current single switch mouse emulation systems. With these, the burden of moving the mouse pointer is placed on the user, typically employing movement schemes based on a set of directions. If the user desires to move the mouse pointer to a window or icon on the screen, he/she is responsible for choosing the appropriate directions from the set of directions provided by the interface. Choosing a direction is typically achieved through scanning, which can be inefficient and forces the user to concentrate on the selection method rather than the desired task.

Our interface focuses on a goal-directed movement scheme. It operates on the assumption the user wants to move the mouse pointer to an object currently visible on the screen. The intelligent agent is responsible for detecting the potential targets on the screen and identifying the target desired by the user. Once identified, the interface is able to move the mouse pointer along a direct path to the destination point. This is possible because the interface is able to determine the mouse pointer's current location and the desired destination point.

METHODOLOGY—Input to the interface is achieved by means of a single switch. The user has the choice of depressing and holding down the switch or releasing the switch. Depressing and holding the switch sends a signal to the interface to begin moving the mouse pointer toward one of the targets on the screen. Releasing the switch stops all action. The user acts as a supervisor to the interface's actions. No action by the interface is allowed until the user depresses the switch. Once the user does so, the intelligent agent adjusts priority values associated with each target attempts to identify the target desired by the user. At this point the interface begins moving the mouse pointer along a direct path toward the target. The user is responsible for releasing the mouse pointer over the desired target.

PROGRESS—A preliminary planner has been developed and a single switch mouse control interface (SSMCI) has been implemented. An experiment has been carried out which tests the SSMCI against the task of target acquisition. A second interface, the directional arrows found on the numeric keypad, was also used in the experiment. A total of nine subjects, three of whom had disabilities, participated in the experiment.

RESULTS—Results include reduced average target capture times and reduced average number of switch activations when controlling the mouse pointer with the SSMCI as compared to the directional arrows.

FUTURE PLANS/IMPLICATIONS—Future plans include further refinement of the planner and testing the interface in a more complex environment. Also, we plan to develop an interface based on a single switch and an intelligent control interface for controlling a rehabilition robot. With the SSMCI, the intelligent agent was concerned with picking the desired target. While controlling a robot, the intelligent agent would be concerned with choosing the task desired by the user.

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[166] DEVELOPMENT OF AAC SYSTEMS BASED ON PERSONAL COMPUTERS

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PURPOSE—This project focuses on the development of new techniques and strategies that advance the incorporation of technology in augmentative and alternative communication (AAC) 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.

PROGRESS—*Multimodal Input in Computer Access* This project focuses on issues related to the integration of two computer input strategies: speech input and head pointing. This project has worked in tandem with an evalutation project to provide a foundation for multimodal input integation for computer access and for future related research for multimodal input for AAC. A study that tests the hypothesis that each input technique is best suited to a set of related tasks is near completion. Head pointing is assummed to be advantageous for target acquistition tasks in a graphical interface, and speech recognition is presumed to be better for typing tasks involving text input. The development project produced a series of software programs used to conduct the study. Each program was designed to allow subjects to perform the same set of tasks using each of the input technologies. One program, MITE (Multimodal Input Text Editor), allowed subjects to transcribe paragraph sets, recorded a transaction record of the experiment, and collected performance data that was further analyzed by the evaluation project. A second program generated a series of target and destination objects in a graphical environment and allowed the user to select an object and drag it to a destination. This program also recorded a transaction of the experiment and collected performance data. In addition, the developement project worked with the evaluation project to design experiment protocols, develop the experiment environment, and conduct a series of pilot experiments.

ZapCom Work continues on another prototype communication system called ZapCom, the evolution of a photographic-quality, image-based system designed for

individuals who have difficulty dealing with abstract symbol sets but work well with more life-like images. At this point, the system has been developed as a demonstration program.

A previous version, GraphCom, used gray-scale images, but ZapCom now uses color images captured by a small, inexpensive camera and put into the vocabulary set in a designated location. New images can be imported at any time. The vocabulary set is comprised of pages of images arranged in rows and columns. A VGA monitor displays one page of the vocabulary set at a time and the user constructs a message by selecting one or more images from the set.

ZapCom is a Windows application running on a laptop computer and integrates video capture and voice recording capabilities. The prototype version will be enclosed in a unit that contains the laptop computer, the video camera, battery supplies, and speakers. The video capture will be "point and shoot" procedure that allows a care provider to preview a capture window, take the picture and add it to the vocabulary dynamically.

FUTURE PLANS—Once development of ZapCom is complete, it will be transfered to the evaluation project for user testing. Additional multimodal research may continue to investigate the integration of multiple input strategies for augmentative communication. This project may also investigate communication applications for hand held, pen-based computers applications.

[167] EVALUATION OF HUMAN-SYSTEMS INTERACTION IN AAC

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PURPOSE—The challenge in technology development is the creation of innovative techniques that both maximize function and minimize the demands on the user. Realizing that each user of augmentative and alternative communication (AAC) brings a different set of skills to the communicative process, we must be careful about relying on unsubstantiated assumptions about the effectiveness of technology. Instead, we must begin to understand the efficacy of techniques in terms of the context in which they will be used and in terms of the capabilities that the user brings to the process. The goal of this project is to analyze the relationship betweentechnological capability and functional use by individuals using AAC devices. Two projects are currently being evaluated: Language Facilitation through Graphics and Graphical Animation and Multimodal Input in Computer Access.

The results will provide guidance to those selecting and customizing AAC 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. The results will also provide feedback to research and developers with respect to the application of existing technology and to the design of strategies that incorporate cutting-edge technology.

PROGRESS—*Language Facilitation through Graphics and Graphical Animation* 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 system presents a number of static graphics, animated graphics, and video clips to the subject. At present, evaluations are being performed with subjects (four years of age) from Easter Seals of DelMar. Preliminary data analysis has shown that across the different levels of graphical representations being used, digital video seems to be the most understandable. Another interesting observation is that for some subjects animation presented too much stimulus, making the task of identifying the requested "action" more difficult. This type of information will be valuable for clinicians, allowing them to assess individual skills prior to the recommendation of a particular augmentative communication system.

This evaluation study will continue to inelude 4-year olds but will also expand to inelude adults with eognitive disabilities.

Multimodal Input in Computer Access This projeet is investigating the issues surrounding the combination of two input technologies, speeeh recognition (using DragonDictate) and head pointing (using HeadMaster with WiVik). The hypothesis is that each deviee is better suited to one task (i.e., speeeh reeognition for keyboard tasks and head pointing for mouse emulation). If this hypothesis is aecurate, then one can infer that integration of the two input technologies will be benefieial.

Sixteen subjeets without disabilities partieipated in the initial, three-phase study. In the first phase, subjeets used each deviee for typing. In the seeond, subjects used each deviee separately to perform mouse-based pointing tasks. In the third phase subjeets used both deviees jointly for a spatial positioning task. Preliminary data eoneurred with our original hypothesis that speech recognition is faster for typing tasks then head pointing on an average of approximately 4 words per minute faster. Also, the average time for 25 repetitions of random spatial tasks showed that head pointing was faster than speech recognition. It took subjeets, on average, approximately 2 min using head pointing and 7 min using speech recognition to complete these 25 repetitions. Interestingly, the time for eondueting the repetitions using both modalities together was approximately 3 min.

The next phase of this evaluation study will be performed using subjeets with disabilities. The protocol will be consistent with the one used with subjeets without disabilities.

FUTURE PLANS—Following analysis of data eollected from the studies, the results will be shared with the community of AAC professionals. In parallel, evaluation projects will be condueted on other projeets developed within the ASEL.

In addition, efforts will be taken to explore the issues surrounding teehnology transfer, partieularly for ZapCom and a previous projeet ealled Flexible Abbreviation Expansion. Potential manufaeturers will be eontaeted to diseuss the issues surrounding teehnology transfer.

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[168] HUMAN FACTORS STUDIES IN EYE MOVEMENTS RELATED TO AAC HEAD MOUNTED UNIT

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PURPOSE—In order to overeome the many human faetors obstacles in using eye movements to eontrol AAC devices, a head-mounted unit is being developed that will eompensate for many of the eomplieations whieh affect the ultimate utility of an eye-traeking AAC system. A small, commercially available, head-mounted display (the Private Eye from Refleetion Technologies) provides a eonvenient way to offer a eomputer display to an individual with a disability. The unit is worn on a head band and presents the image of the computer sereen in the field of view of the wearer. This form of "heads up" display presents information that is independent of head movement.

METHODOLOGY—The primary goal of this projeet is to retrofit the display to ineorporate a small eamera capable of viewing the user's eye. The same software that is used to ealculate the line of gaze in other eye traeking projects ean be used to determine the line of gaze with re-

spect to the "heads up" display. This system is potentially a portable eye gaze communication system that allows face-to-face communication.

PROGRESS—The optics and camera have been added to the display unit and the system tracks the corneal reflection and pupil center. Work is now underway to improve the optics and to teach the geometry of the system to the gaze calculation software so that it can translate the pupil center/corneal reflection vectors into gaze points.

FUTURE PLANS—The prototype system will be refined in the coming months. It must then be evaluated for its stability (the ability to tolerate the expected vibration and minor movements of the head mounted display.) Clinical studies using the entire system as a communication device will follow.

[169] 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 (AAC) systems.

METHODOLOGY—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. Natural language processing provides the computational techniques necessary to give communication systems the capability to reason about lexical, syntactic, semantic, and pragmatic knowledge.

PROGRESS—Our previous work involved studies of language use in AAC systems and basic research into how natural language processing might be applied to AAC. One of the major results of our previous work was the development of the Compansion system which is a research prototype that takes uninflected content words (i.e., telegraphic input) and translates it into well-formed sentences. The prototype relies on both syntactic word-order information and semantic information about the meaning of individual words to determine an appropriate output sentence. We have begun to develop a more practical version of this system.

Additional work focuses on integrating pragmatic knowledge into a system based on conversational schemata. This powerful tool (named SchemaTalk) captures common language experiences and situations that can be accessed quickly to communicate effectively. The current focus involves determining methods for the system to help the user "schematize" his/her experiences so that appropriate language chunks can be accessed easily.

Also, we are developing an extensive object-oriented language database (Lexical Access Database or LAD) that will provide the detailed information necessary to support each natural language processing technique. The resulting database should provide information to allow efficient application of natural language processing techniques in the context of AAC.

FUTURE PLANS—Anticipated efforts include the integration of LAD into the compansion and schema-based projects, completion of the development and evaluation of a Compansion-based intelligent parser/generator (based on language data collected from AAC users), and significant improvement and testing of SchemaTalk, especially with respect to its user interface capabilities.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[170] 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.

METHODOLOGY—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 that consist of head-mounted displays providing 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. Recent work has focused on collecting data on various mouse control methods for navigation of virtual keyboards and similar interfaces. 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.

[171] 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 synthesized voices.

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 and storing the transitions from the recorded words. Diphones can be appended together to create any word or phrase with the characteristics of the original speaker. Thus, diphones can be used to create a uniquely identifiable, natural sounding voice with an unlimited vocabulary.

PROGRESS—Previously the method for creating diphone libraries was completed. This process resulted in two synthesized voices: a male's and a child's. More recently, the focus of the program has been on improving the quality of the system that converts text to synthesized speech. The previous system calculated the phonemes, duration, and pitch on a word-by-word basis. The new system now performs a linguistic analysis on paragraphs of text and converts it into a number of linguistic representations: 1) the phoneme string with syllabification and stress information, 2) intonational features such as pitch accents and boundary tones, 3) prosodic phrasing, and 4) part-of-speech information.

The modeling of the intonation of questions, statements, exclamations, and the like, is greatly improved over the previous system and the modelling of the rhythmic characteristics is much more accurate. In addition, there is a great degree of user control over the prosodic characteristics of the speech. The previous system only allowed for control of the basic speaking rate and average pitch. The new system allows controls for pitch range, rate of declination, type of pitch accent, and many other options. The user may also override all of the automatic calculations of the synthesizer; this allows the addition of prosody not predictable from the text (such as emphasis on a particular word) or a simple means of correcting a wrong prosodic 'guess' of the text analysis.

A macro capability has been provided to allow the specification of complex controls with a minimal number of characters. Using this macro capability, preliminary commands to add emotion (happiness, sadness) to the prosodic characteristics of the speech have been developed. In order to facilitate the use of the text-to-speech system, a graphical user interface was developed under Windows 95. 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 all the various linguistic representations have been completed and are being evaluated. The new system has been successfully ported to a Windows 95 environment within the graphical user interface of the old system. The user interface is being refined to allow easy control of the new system features. 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 ex-

tractor 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, thoroughly testing and refining the graphical user interface, testing and improving the efficiency of the automatic diphone extractor, and developing the methods for conveying emotions in the synthesized speech. Work will continue on the Windows 95 version of the synthesizer, to allow easy technology transfer. In addition to this application, DDE and DLL versions of the synthesizer will be developed and tested.

[172] 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 attach a switch to, 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 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 ms after the onset of a meaningful stimulus. It was first reported in 1965 as a late positive component occurring in response to task-relevant stimuli. 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. Peak amplitudes are expected to be greatest for P300s in response to the direction that the subject is attending to.

METHODOLOGY—Subjects will be seated in a sound attenuated chamber facing a monochrome monitor 18 in (45.7 cm) distant. The central fixation point 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 cm from the central fixation point. Each stimulus will be presented for 250 ms with an interstimulus interval of either 750 or 1,000 ms. 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 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 ms before presentation of the target stimulus and continue for a total of 650 ms. Thus, 600 ms 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 in which 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 that we have 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.

[173] RESEARCH IN INTERFACE METHODOLOGIES FOR AAC

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Sponsor: *National Institute on Disability and Rehabilitation Research, U.S. Department of Education, Washington, DC 20202; Nemours Foundation, A.I. duPont Institute, Wilmington, DE 19899*

PURPOSE—The goal of this research is to explore new and innovative methods for human interaction with AAC devices. This program is comprised of projects in two areas: basic research in developing methods for human gesture to be used as an interface for AAC devices and a human factors study in the use of eye movements to control an AAC device.

METHODOLOGY—Gesture Project: This project explores the use of gloves and other sensors (such as those used in virtual reality applications) as input devices to control an AAC device. Input taken from the gloves and sensors 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 (ASL) 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 current work in ASL recognition is focused on improving the accuracy of the system, and its adjustment to handling signing at natural speed. Two techniques have been developed which provide an accuracy of 85–90 percent and significantly reduce thetraining time of the system. The motion recognition unit has been designed and tested on 8 basic motions used in ASL and yielded satisfactory performance.

Additionally, work has proceeded on synthesis of Signed English in the form of an animated virtual signer. Individual signs are described tersely in terms of handshape, position, and attitude of the hands, and motion of the hands during the sign. It is expected that the database for sign synthesis will be used as a part of the full recognition system. This will provide a straightforward way to extend the recognition repertoire.

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. Work on developing a head-mounted tracker is also being pursued.

[174] AUGMENTATIVE AND ALTERNATIVE COMMUNICATION TECHNICAL ASSISTANCE AND OUTREACH PROGRAM

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PURPOSE—Our goal is to serve as a leading source of materials and assistance to professionals, consumers, families, and agencies dealing with augmentative communication (AAC) and to disseminate technical reports and articles on research results obtained by ASEL staff. The program participates 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, including publications, a World Wide Web site, booklets, and special reports are developed and disseminated. The Information Program also offers support to "Tech Act" state projects in the AAC arena.

PROGRESS—The researchers in AAC have produced 15 publications for dissemination through the Information Program. Inquiries from other researchers, clinicians, therapists, consumers, teachers, and families are answered with a personal response and appropriate information materials. *The 1996 Guide to Augmentative & Alternative Communication Devices* has been published, along with accompanying vendor information notebook and color slide set, and distributed to over 500 interested parties. A World Wide Web site, "AT On-Line," has been established as an electronic information base. ASEL was also selected to host the International Conference on Spoken Language Processing in October 1996.

[175] ENGAGING, RECRUITING, AND RETAINING STUDENTS WITH DISABILITIES IN SCIENCE, ENGINEERING, AND MATH

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PURPOSE—Individuals with disabilities are currently underrepresented in science, engineering, and math (SEM) academic programs and professions. While this underrepresentation 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. 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 mentoring program

utilizes the Internet as a "distance free" pathway for communications, over which students and mentors can communicate. The attitudes of school counselors and teachers, which currently discourage students with disabilities from pursuing SEM curricula, are changed through education and abilities demonstrations. Similar methods are used to educate and change the attitudes of family members and employers. Physical and informational barriers are broken down through the design and development of new information access methods and virtual laboratories, which are both physical and information barrier free. New information access methods include tactile and haptic interfaces for individuals with visual impairments.

PROGRESS—The Internet mentoring program enrollment currently stands at 25 students. All the students have either physical, sensory, or learning disabilities. A matching number of mentors, approximately half of whom have disabilities, are participating in the program and paired one-to-one with students. In addition to the online mentoring activities, students participated in a Summer Science Fest program that featured team building, computer training, aerospace activities, biology/nature education, and information about college, including admissions, ADA services, academic information, and campus tours. To address the problems affecting teachers, counselors, and families, the project sponsored several workshops and conferences focusing on learning disabilities, assistive technology, education, and college transition. Prototype tactile and haptic visualization systems have also been developed. The tactile system utilizes image manipulation to produce comprehendible tactile output of images on medium such as capsule paper while the haptic system is based on the PHANToM force reflecting device. Interested parties are encouraged to send e-mail to seminfo@asel.udel.edu or examine the project web page (http://www.asel.udel.edu/sem/) for more information.

[176] SPEECH PROCESSING PROGRAM

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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 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. 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 dis-

ordered 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.

[177] EFFECTIVENESS OF USING VOICE RECOGNITION SYSTEMS

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Sponsor: *Ontario Ministry of Health, Neurodevelopmental Clinical Research Unit, Hamilton, ON L8S 4K1*

PURPOSE—The purpose of this pilot study is to evaluate the use of voice recognition to create text and the effects of discrete utterance speech on participants' voices. Components that will be evaluated include speed of creating text, fatigue, ability of the system to complete tasks, and ease of use. In addition, vocal characteristics will be analyzed to determine whether the voice has been affected from use of voice recognition.

METHODOLOGY—Participants will be clients who have been prescribed voice recognition systems to use as writing aids. Six will be recruited for this preliminary study and will be asked to complete various typing tasks and to answer questions regarding the use of their system. Speed and accuracy of text generation, and the voice recognition system's accuracy, will be calculated. Tape recordings of speech samples will be obtained in order to evaluate voice quality. Responses to interview questions will be analyzed descriptively.

PROGRESS—Four participants have completed the above protocol; each has a different diagnosis (e.g., muscular dystrophy, upper motor neuron disease, scleroderma, and thoracic output syndrome).

PRELIMINARY RESULTS—Data has only recently been obtained and analysis is in process.

FUTURE PLANS—A future research study with a larger sample will be conducted.

[178] ESTABLISHMENT OF A DATABASE FOR IDENTIFICATION OF AUGMENTATIVE COMMUNICATION AID USERS AND FACILITATORS WILLING TO PARTICIPATE IN RESEARCH

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Sponsor: *Ontario Rehabilitation Technology Consortium, Toronto, ON M4G 1R8; Industry Canada, Ottawa, ON K2H 8S2*

PURPOSE—The purpose of this pilot project is to establish a database containing the names of individuals, age 16 or over, with cerebral palsy who do not speak or are unable to speak successfully in at least some situations important to them. The database is being established so that researchers interested in improving the communication systems of such individuals will be able to call upon those persons to: 1) help determine what research needs to be done; 2) participate in the design and carrying out of projects; and/or 3) cooperate in interpreting the data gathered during projects. The database will also help ensure that consumers are represented at all levels of research and provide employment for persons with disabilities. It is expected that the results of this project will provide a model for extension to other disability groups.

METHODOLOGY—A draft questionnaire was designed from existing literature. Key informant interviews were held with consumers and their facilitators who helped modify the draft. The modified draft was examined by representatives of consumer groups, a group of scientific researchers, and manufacturers of augmentative and alternative communication (AAC) devices, and further changes were made. The revised questionnaire was pretested with AAC users and final revisions were made. The database was then designed, using MicroSoft Access and WiViK access software, by a design team which included paid employees of UserNet, a company whose employees are persons with disabilities. Cooperating agencies provided names of potential participants who were contacted and provided questionnaires.

PROGRESS—Early questionnaire returns have been encouraging. Additional major consumer groups are providing contacts. Data on returned questionnaires are successfully being entered into the database primarily by UserNet employees.

FUTURE PLANS—The marketing and business plans will be completed by Autumn 1996, when the database is anticipated to begin operations. Reviews after 1 and 2 years of operation will be conducted in order to determine whether the database is succeeding and should be expanded to other disability groups. When the database is in operation, a review panel will evaluate requests for specific lists of names from scientific researchers, market researchers, and consumer group representatives based on a published set of criteria. If the project is approved, database employees will contact the individuals on the list and ask them if they are willing to be contacted about the approved project; only when the individual agrees may the name of the individual be released to the requesting source.

[179] HOME AUTOMATION AND WORKPLACE INTEGRATION

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Sponsor: *Ontario Rehabilitation Technology Consortium funded by the Ontario Ministry of Health; the Natural Sciences and Engineering Council; the Hospital for Sick Children Foundation; The National Strategy for the Integration of Persons and Disabilities; Industry Canada*

PURPOSE—Assistive technologies have significant benefits for persons with disabilities. Presently, these benefits are offset by the effort required to integrate these independent and often proprietary devices into coherent systems that address the needs of their user. The main obstacle to integration is the lack of interoperability due to devices not speaking the same "anguage." Here, the technical analogy of a language is a communications standard, under which devices that comply to the same standard are able to communicate with each other.

PROGRESS—In Europe, the Multiple-Master Multiple-Slave (M3S) standard has been developed and proposed as the communications standard for assistive technologies. It is presently being considered as a preliminary standard by the International Standards Organization (ISO).

A wide variety of other nonrehabilitation specific devices/systems also exists that may assist persons with disabilities, such as personal computers and environmental controls. In order to incorporate the full functionality, and hence benefits, of these other technologies, a gateway is needed. Gateways are functional bridges between two systems, allowing the user to interact with both.

This project also cultivated closer ties with TPD-TNO, the main European M3S developer, and other European organizations. This has already resulted in the definition of future collaborative projects, such as TIDE (Telematics Initiative for Disabled and Elderly Persons), INCONTROL (Innovative Control of Mobility, Manipulation, and the Environment), and ARTISTE (Access to Rehabilitation Technology Information Services and Transfer of Expertise).

FUTURE PLANS—Continued development is needed to further refine the designs and minimize their size. Efforts are also underway to set up clinical and client demonstration sites. This will provide much needed user input and feedback. In addition, further evaluation is needed regarding system safety and reliability, and a rational and objective method of evaluating M3S compliance needs to be defined.

[180] HAMLET: SIMULATING EMOTION IN SYNTHETIC SPEECH

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Sponsor: *None at present*

PURPOSE—This project aims to derive a set of rules to include vocal emotion effects in synthetic speech producedby rule.

METHODOLOGY—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.

PROGRESS—A Windows version has been developed.

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 1995;16(4):369–90.

[181] DIRECT BRAIN INTERFACE BASED ON DETECTION OF EVENT-RELATED POTENTIALS

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Sponsor: *None listed*

PURPOSE—This research explores the detection and use of intracranial subdural event-related potentials (ERPs) to demonstrate the feasibility of a direct brain interface for people with disabilities. Many people with disabilities could potentially benefit from an interface that does not require physical movement and accepts commands directly from the brain.

The short-term goal of this research is the development of methods capable of accurately detecting the ERP related to a simple voluntary action. Such methods would then be used as the basis of a direct brain interface which would detect the ERP corresponding to the planning of a voluntary action and produce a single switch closure in response.

The long-term goal of this research is the development of a direct brain interface which could be used by people with severe disabilities (such as locked-in syndrome) to operate complex external devices without the need for physical movement.

METHODOLOGY—The subjects in this study are patients in an epilepsy surgery program who have had subdural electrodes placed on their cortical surface for presurgical monitoring. Electrocorticograms (ECoG) are recorded from these electrodes while the subjects repeat simple voluntary actions at intervals of 3 to 10 s. The time at which each repetition of the action was performed is recorded, using either a simple switch, microphone, or electromography (EMG) electrode. For each subject/action data set, triggered averaging is used to produce an average ECoG segment corresponding to the repetition of the action for each electrode location. These averages are then evaluated to determine which electrode locations recorded ERP's corresponding to the voluntary action.

Currently, cross-correlation is being evaluated for the detection of the ERP's. First, an ERP template is cross-correlated with unprocessed ECoG from the same electrode location. Then an experimentally determined threshold is applied to the cross-correlation statistic and points which exceed this threshold are considered possible detection points. The performance of cross-correlation as a detection method is evaluated by comparison of the detection points with the actual times at which repetitions occurred as documented by the trigger channel.

PROGRESS—Data have been collected from seven subjects. Identification of ERPs and evaluation of a cross-correlation-based detection method was performed with ECoG from these subjects. The software was updated to permit selection of the template duration based on signal content. Evaluation of cross-correlation-based detection using templates whose duration is selected as a function of the signal content of the template is in initial stages.

RESULTS—ECoGs from 28 subject/action data sets have been analyzed. Cross-correlation-detection methods were evaluated, using averages which began 2.5 s prior to the trigger point and ended 1.5 s after it. For three subject/action data sets, all from different subjects, one data set was found for which the percentage of actions correctly detected by the cross-correlation-detection method (the hit percentage) was greater than 95 percent, and the percentage of incorrect detections (the false positive percentage) was less than 5.

FUTURE PLANS—Evaluation of the cross-correlation-detection methods will continue with the comparison of fixed-length templates and templates whose length is determined based on signal content. Analysis of the effects of low-pass filtering of the ECoG prior to cross-correlation is also planned. Preparations are being made for intraoperative data collection during which electrodes can be placed over the motor cortex. Intraoperative data collection would increase experimental control with regard to electrode location, which are currently placed solely for the purpose of presurgical monitoring.

RECENT PUBLICATIONS FROM THIS RESEARCH

Identification of cortical signal patterns related to human tongue protrusion. Huggins JE, Levine SP, Kushwaha R, BeMent S, Schuh LA, Ross DA. In: Proceedings of RESNA International '95; 1995, Vancouver, BS. Washington, DC: RESNA Press, 670–2.

Detection of event-related potentials as the basis for a direct brain interface. Huggins JE, Levine SP, BeMent SL, Kushwaha RK, Schuh LA, Rohde MM. In: Proceedings of the 19th Annual RESNA Conference; 1996, Salt Lake City, UT. Washington, DC: RESNA Press, 489–91.

D. Private and Public Programs

[182] 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 Institutes of Health, National Center for Medical Rehabilitation Research, Bethesda, MD 20892*

PURPOSE—The purpose of this longitudinal study is to determine the strength of relationships among use of personal assistance services for activities of daily living, health status, and use of health care services by persons with a variety of severe physical disabilities.

METHODOLOGY—Survey packets were mailed to 120 subjects with the objective of having at least 100 complete the study, allowing for attrition. Data collected was used to construct a profile on each participant and his/her health service use and health conditions over a 12-month period. These profiles were used to identify differences between participants based upon whether personal assistance services are provided exclusively by family members or by nonproviders alone or supplementing family assistance.

In year 2, open-ended, qualitative interviews were conducted with 20 participants who represented two subsets of the original sample: 5 whose scores on the Personal Assistance Satisfaction Index (PASI) fall into the top quartile and 5 in the bottom quartile, and (2) 5 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 strictly limited to 20 participants to allow in-depth exploration of PAS and health issues.

PROGRESS—One hundred persons, aged 18 to 65, living independently in the community, who use at least 1 hour of personal assistance daily, completed weekly checklists for 1 year, recording any changes in their personal assistance or health status, any visits to hospitals, emergency rooms, or physicians, and, when health incidents occurred, any effects on productivity and levels of distress. Data analysis has been completed on the initial PAS and Health Study questionnaire, as well as the monthly health and personal assistance incident checklists. Hypothesis testing is ongoing.

RESULTS—Participants were generally satisfied with the quality of their personal assistance services, possibly

because most participants had many years of experience to find an arrangement that best met their needs. However, they were less satisfied with the availability of attendants and costs of services. Overall, participants were in very good health, with few or no acute illnesses in a year. More than one third reported no acute health incidents, and another third had 20 or fewer days of poor health. In year 3, the total number of health and personal assistance incidents that occurred over the 12-month reporting period was analyzed and showed that the top five personal assistance incidents included: assistant did not perform a task (299), assistant did not perform a task in the manner requested (263), assistant did not show up/patient had to find a back-up (186), assistant arrived late for work (141), and assistant was verbally abusive: yelling, cursing, or threatening (131). The top five health incidents that occurred were: pressure sores (1147), urinary tract infections (832), joint contractures (217), fractures (189), and colds or flu (115). Same day occurrences of health and personal assistance incidents were counted in order to provide a frequency of paired incidents. The kinds of paired incidents were noted.

Overall, quality of personal assistance had an impact on the health status of persons with severe physical disabilities in maintaining mobility and nutritional status. There was a correlation between the mean number of monthly health and personal assistance incidents. However, the majority of health incidents were not associated with personal assistance incidents. Only 4.5 percent of health incidents occurred within a week of a personal assistance incident. A small subset of participants had a large occurrence of health incidents, personal assistance incidents, and health incidents that could be attributed to inadequate personal assistance services. Characteristics of this subset need to be explored further.

[183] INCREASING THE CAPACITY OF INDEPENDENT LIVING CENTERS TO SERVE MINORITY POPULATIONS

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PURPOSE—The Center for Research on Women with Disabilities is collaborating with the ILRU Research and Training Center on Independent Living to conduct a study to find out how independent living centers could improve the effectiveness of their services for minorities with disabilities.

METHODOLOGY—We are focusing on a different minority group for each year of this 5-year study. This year we will be looking at issues facing African-Americans. We will begin each year with focus groups of consumers to help us identify the factors that affect their independence.

PROGRESS—Recruitment of African-American men and women with a variety of physical disabilities has begun. Focus groups are being conducted to determine how independent living centers can better serve their needs.

FUTURE PLANS—The information gathered from the focus groups will be presented to independent living centers around the country for comment and analysis of how their services address these needs and barriers they encounter in delivering those services to this population.

[184] THE ACCESSIBILITY OF PRIMARY CARE PHYSICIANS' OFFICES FOR PEOPLE WITH DISABILITIES: AN ANALYSIS OF COMPLIANCE WITH THE AMERICANS WITH DISABILITIES ACT

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Sponsor: *National Institutes of Health, National Center for Medical Rehabilitation Research, Bethesda, MD 20892*

PURPOSE—The purpose of this project is to answer two questions: 1) What is the level of accessibility of private physician offices to patients with physical disabilities? and 2) Are physicians in compliance with the Americans with Disabilities Act of 1990 (ADA)? Physician offices are public accommodations and must comply with Title III of the ADA.

METHODOLOGY—A random sample of 220 primary care physicians in general practice, family practice, internal medicine, and obstetrics-gynecology were chosen from the Harris County (TX) Medical Society roster. Each was sent a 57-item questionnaire with 136 variables related to accessibility, the ADA, and care and treatment of patients with physical disabilities.

PROGRESS—Data analysis for the project has been completed. Sixty-two physicians, or 28.2 percent, responded to the questionnaire. Frequencies were recorded for each question.

RESULTS—In general, physicians reported a high level of compliance with 17 readily achievable structural features in their offices. The majority (82.3 percent) reported no difficulty in serving patients with disabilities. However, 11.3 percent reported they were unable to serve 1\N2 disabled patients in the last 12 months. Also, 19.4 percent said that patients with disabilities were too difficult to treat or handle, and 22.4 percent felt more comfortable referring patients with a disability to another physician. In addition, 3.2 percent of patients were unable to enter premises because of physical barriers. These results indicate a strong need for continuing medical education on the requirements of the ADA, and strategies for assisting physicians to come into compliance with it.

[185] A CURRICULUM FOR TRAINING PHYSICIANS IN REPRODUCTIVE HEALTH CARE FOR WOMEN WITH PHYSICAL DISABILITIES

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PURPOSE—The purpose of this project is to enhance the ability of primary care physicians to meet the reproductive health care needs of women with disabilities. Such women face serious obstacles to receiving such services. Our Center is in the final phase of a 3-year national study to examine psychosocial behaviors of women with physical disabilities. During the course of this study, several problems with reproductive health surfaced with unexpected strength. These problems include 1) lack of physical access to physicians' offices and equipment; 2) gaps in the knowledge of physicians and other health professionals about how disabilities affect reproductive health care needs; 3) assumptions by health care professionals that such women do not need reproductive health care; 4) deficits in knowledge and faulty beliefs of these women about the functioning of their bodies and their

need for reproductive health care services; and 5) problems inherent in health care service systems. In our national survey, we found that these women face certain unique problems in sexual response, pregnancy, delivery, and the detection of sexually transmitted diseases, breast cancer, and cervical cancer.

METHODOLOGY—A case-study-based medical education curriculum for primary care physicians was developed that offered the most current information on serving the reproductive health care needs of women with disabilities. In developing this curriculum, our Center used findings from the national study, information gathered from 15 faculty members at Baylor College of Medicine, recommendations from a national medical advisory committee, and the expertise of the staff for this project.

PROGRESS—A training curriculum has been developed by our Center. This training was offered to the faculty and residents in the Baylor College of Medicine departments of Family Practice, Community Medicine, and Obstetrics/Gynecology. Four completed trainings have been conducted, and four more are scheduled. At the end of the project year, a continuing medical education seminar will be offered that will be advertised to primary care physicians throughout the Houston area and nationally.

FUTURE PLANS—National dissemination of training materials to primary care physicians is planned.

[186] HEALTH PROMOTION FOR WOMEN WITH PHYSICAL DISABILITIES

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PURPOSE—The concept of wellness in the context of physical disability among women has only recently been introduced into the field of health promotion. The purpose of this project is to develop an intervention to enhance wellness among such women based on expanded theoretical models and measures of health-promoting behaviors that accommodate some of their unique life circumstances. Findings from our recently completed national survey indicate that segments of the population of women with physical disabilities are at a higher risk for certain acute and chronic conditions, limited access to preventive health services, negative social attitudes toward their potential for fitness and wellness, and reduced motivational factors affecting health promoting behaviors, such as self-esteem, self-efficacy, and body image. There is a pressing need for the development of health promotion programming that is responsive to the needs of women with significant functional limitations and an accompanying research protocol to measure the effectiveness of such programming.

The specific aims of this study are to

1. Identify the psychological, physical, social, and environmental factors that contribute to health-promoting behaviors of women with physical disabilities.
2. Develop and test methods for measuring the health-promoting behaviors of these women and their attitudes toward improving those behaviors.
3. Develop and pilot-test an intervention to inform and motivate these women to take action to improve their psychological, social, and physical health.
4. Develop and pilot-test a theory-driven, multicomponent program to promote wellness among these women, targeting increased self-efficacy related to health promoting behaviors.

This research will be grounded in the Transtheoretical Model which identifies five stages that characterize an individual's willingness to change a given behavior: precontemplation, contemplation, preparation, action, and maintenance.

METHODOLOGY—To accomplish the aims of this study, we will begin with qualitative focus groups and individual interviews to understand how women with physical disabilities define wellness and practice health promoting behaviors.

PROGRESS—Recruitment of participants has begun and focus groups will be conducted.

FUTURE PLANS—In the next phase, we will use quantitative methodology to establish a baseline for the perceived health status, health promoting behaviors, and stage of change of a sample of 400 women with a range of physical disabilities and severity levels. We will then develop a motivational intervention, consisting of a newsletter, a wellness hotline, a fax-on-demand service, and a home page on the World Wide Web, to offer information and encourage action for women who may be in early stages of change or believe that their disability prevents them from engaging in health promoting activities. In the final phase, we will develop and test the feasibility of a wellness action group program that will focus on individualized goal-setting, peer support, and enhanced self-efficacy for pursuing healthier living.

[187] A STUDY OF POLICY BARRIERS IMPEDING USE OF ASSISTIVE TECHNOLOGY BY PERSONS AGING WITH DISABILITIES

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PURPOSE—The purpose of this research is to investigate current policies and practices that affect the use of and access to assistive technologies (AT) that support employment and maintain community-based living among adults with disabilities. The goal of the research includes: 1) describing current patterns of AT use and recent changes in patterns of use; 2) examining the impact of AT on health status and on quality of life issues; 3) identifying the barriers, both attitudinal and financial, which may limit access to AT; 4) investigating the adequacy of current policies on AT; and 5) identifying the need, if any, for policy changes.

METHODOLOGY—Both state- and consumer-level policy research are being conducted, drawing upon a variety of methods, including review of existing federal, state, and consumer-level policy reports and research, interviews with key informants, additional analyses of national survey data, and additional project studies to identify consumer issues and investigate state policy efforts.

PROGRESS—We have completed a nationwide survey of state legislative analysts about a variety of state policies affecting AT and a follow-up study of 10 State Units on Aging (SUAs) with high levels of effort in home modifications, and we have conducted analyses of RESNA consumer data on adults age 40 and older to determine particular problem areas, unmet need, types of problems encountered, and receipt of AT information and referral services; of AT data from the 1990 National Health Interview Survey (NHIS) to examine the types and use of AT among older adults and identify barriers to access; and of data from a study of SUA and State Tech Act Projects conducted in 1995 by the American Society on Aging.

RESULTS—The report entitled "Assistive Technology and Adults Aging with Disabilities: A Report on Federal and State Policies and Programs" describes and assesses current knowledge about federal and state policies relevant to the AT needs of middle-aged and older adults with disability; identifies gaps in our knowledge of AT policies and programs; reports findings from additional project studies;and considers what research on AT policy should be conducted in the future.

FUTURE PLANS—Two studies will be completed during 1996/97. First, data collection is currently underway on the collaborative survey entitled "Changing Needs and Life Circumstances of Persons Aging with Disabilities." Our section of the survey focuses on policy rele-

vant issues including information-seeking related to acquisition of AT; use and abandonment of devices; funding patterns; changing needs over time, and unmet needs for AT. Approximately 250 surveys have been completed so far and analysis will begin in fall 1996. Second, the national "Survey of State Rehabilitation Agencies" is in development and data collection will begin in fall 1996. The purpose of this national survey is to identify the extent to which state rehabilitation agencies are knowledgeable about the AT needs of and serve as providers for middle-aged and older adults. AT issues examined include: agency policies, interagency networks, state initiated AT policies and programs, agency decisionmaking, budget allocations affecting provision of AT, and organizational structures.

VIII. Muscles, Ligaments, and Tendons

A. Muscles

[188] MUSCLE STRENGTH AND FUNCTIONAL PERFORMANCE IN PARKINSON'S DISEASE: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #B2064-PA)*

PURPOSE—The purpose of this 1-year pilot study is to gain more insight into the different characteristics of muscular strength and force production in relation to functional performance of individuals with Parkinson's disease (PD), so as to improve validity of clinical evaluations. Specific objectives are to: 1) develop an objective and reliable evaluation method of upper- and lower-body voluntary isometric and isokinetic (concentric and eccentric) strength of persons with PD; 2) determine the influence of movement velocity and contraction type on the rate and pattern of force production; 3) evaluate differences in strength parameters and fatigability between persons with PD and age-matched able-bodied (AB) controls; 4) correlate muscle strength parameters to gait performance and daily activity for those with PD; and 5) correlate scores on conventional PD clinical rating scales to the objective measures obtained for muscle strength and gait performance.

METHODOLOGY—Sixteen (8 male, 8 female) sedentary persons with PD (Hoehn and Yahr stages 1–4) will be solicited from outpatient services at the Dayton VAMC. Care will be taken to include 4 subjects (2 male, 2 female) from each of the Hoehn and Yahr stages. Additionally, 16 sedentary (8 male, 8 female) nondisabled (AB) persons, matched for age, gender, race, and body mass index will be elicited and tested to evaluate differences in muscle strength characteristics between persons with and without PD. In order to eliminate activity/exercise level as a confounding variable, only sedentary subjects will be used. This results in a total of 32 subjects; 16 PD and 16 matched controls.

Following the medical examination, all subjects with PD will be evaluated and classified by use of both the Hoehn and Yahr Scale and the Unified Parkinson's Disease Rating Scale by an experienced neurologist. Subsequently, all PD subjects will perform a sit-stand-walk test to determine gross functional performance. Within 2 weeks, the PD and corresponding AB paired subjects will report for muscle strength testing. Additionally, on a separate day, a random sample of 2 PD subjects from each of the 4 stages (8 PD total) will report for gait analysis. This gait analysis will take place within 3 days following the strength testing session. Subjects selected for the gait analysis will be fitted with a Mini-Logger, a portable physiological data recorder, which will monitor heart rate and body movements during one typical day. Subjects will be instructed on the procedures for using the Mini-Logger during the strength testing session and will take the instrument home.

PROGRESS—The initial subject recruitment criteria and demographics for age-type matching have been established. The design, development, and construction of the finger and foot tapping devices were completed. Subjects with PD have performed the specific evaluation pro-

tocols and adjustments in the timing and procedures have been made. Technicians have been trained in the data collection process and data collections will begin in the near future.

IMPLICATIONS—With the development of improved evaluation techniques, interventions that may impede PD progression or prevent and/or minimize secondary impairments could be better tested for efficacy. A detailed database of normal and abnormal values for strength and functional performance could lead to an improvement in diagnostic accuracy using the developed quantitative measures combined with clinical assessment. This more objective evaluation technique could provide a more valid starting point on which to base interventions (medication, surgery, physical training) to reduce strength deficits and improve functional performance in persons with PD.

[189] BIOCHEMICAL AND MYOELECTRIC EVENTS DURING FATIGUE

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PURPOSE—*In vitro* research studies are being conducted using a rat animal model to provide a better understanding of how the biochemical events associated with fatigue influence the median frequency and conduction velocity estimates of the electromyographic (EMG) signal. This approach can accurately measure biochemical correlates of fatigue while controlling for processes that typically confound *in vivo* studies in humans. Our studies are currently focused on how the fiber type composition of a muscle influences the EMG signal and its spectral parameters. These results are a first step toward predicting the fiber type percentages in humans using similar surface EMG procedures.

METHODOLOGY—Whole muscles and nerves are surgically removed and placed in a test chamber in which the muscle temperature, oxygenation, and extracellular ionic fluids are maintained. EMG signals and isometric twitch and tetanic forces during elicited contractions are detected and sampled by a personal computer workstation. Muscles are then prepared for later histochemical analysis and fiber typing.

PRELIMINARY RESULTS—In the past year we have doubled the number of neuromuscular preparations studied from two different hindlimb muscles of the rat and the diaphragm muscle. Results from eight specimens of each muscle show that muscles with fast glycolytic enzyme content produce M-waves that are modified to a greater extent during fatigue than muscles with slow oxidative enzyme content. Time and amplitude scaling coefficients using wavelet analysis were significantly different for these muscles. Differences in the initial values and rate of decay of the median frequency and conduction velocity paralleled the distinct differences in the fiber type composition of these muscles. We were able to estimate the fiber type percentages of these muscles to a high degree of accuracy using just the EMG parameters.

RECENT PUBLICATIONS FROM THIS RESEARCH

Effects of muscle fiber type and size on EMG median frequency and conduction velocity. Kupa EJ, Roy SH, Kandarian SC, De Luca CJ. J Appl Physiol 1995:79(1):23–32.

[190] EFFECTS OF MUSCLE FIBER SIZE ON EMG PARAMETERS

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PURPOSE—Empirical studies are needed to validate the use of surface electromyographic (EMG) techniques to noninvasively quantify muscle atrophy. We hope to achieve this goal by studying the relationship between parameters describing EMG signal characteristics and measurements of muscle fiber cross sectional area (CSA). Previous studies by others have been successful in this regard, but were limited primarily to isolated, single fibers. We have expanded upon these earlier studies by detecting EMG signals from the surface of whole muscles, a procedure which more closely approximates the typical application of surface EMG procedures for human studies.

METHODOLOGY—Isolated whole muscle sections from the rat were studied *in vitro* and EMG signals and muscle force were recorded from the soleus, diaphragm, and extensor digitorum longus muscles during tetanic contractions. The average muscle fiber CSA and muscle fiber type were measured afterward by standard histochemical methods.

PRELIMINARY RESULTS—Data for all three muscles were pooled to provide a sample of muscle fiber CSA covering a broad range of values. In contrast to previous findings by others using single fiber techniques, the muscle fiber CSA in our study was unrelated to either the initial median frequency or the initial conduction velocity. However, when the proportional differences in fast fiber type for these three muscle groups were accounted for by calculating a weighted measure of CSA, a significant, positively correlated relationship was observed. This finding demonstrates that the proportional area of fast fibers in a whole muscle has a strong influence on surface EMG median frequency and conduction velocity. The results suggest that surface EMG median frequency and conduction velocity measurements from whole muscle are influenced by the combined effects of muscle fiber size and type on muscle membrane depolarization and propagation.

RECENT PUBLICATIONS FROM THIS RESEARCH

Effects of muscle fiber type and size on EMG median frequency and conduction velocity. Kupa EJ, Roy SH, Kandarian SC, De Luca CJ. J Appl Physiol 1995:79(1):23–32.

[191] MUSCLE ADAPTATION FOLLOWING LIMB UNLOADING AND ITS INFLUENCE ON EMG PARAMETERS

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PURPOSE—Electromyographic (EMG) signal analysis may provide a noninvasive method of monitoring muscle adaptations associated with disuse. However, further information must be gained to determine how specific changes in muscle fiber characteristics associated with disuse affect the EMG signal. In this study, *in vitro* techniques were applied to compare the changes in muscle fiber type with alterations in the EMG signal from muscles exposed to long- and short-term muscle unloading.

METHODOLOGY—A "tail-suspension" method of limb unloading was used to prevent weightbearing of rat

muscles. Animals were suspended for either 7 or 21 days to induce atrophic and fiber type changes in the muscle fibers. Neuromuscular preparations of the soleus and extensor digitorum longus muscle were surgically removed from the hindlimb and placed immediately in an *in vitro* oxygenated bath. EMG signals were recorded directly from the muscle membrane during tetanic contractions. A control group which did not undergo unloading was also studied. Following EMG signal detection, muscles were histochemically analyzed to determine the muscle fiber cross sectional area and type.

PRELIMINARY RESULTS—Preliminary results demonstrated that the initial median frequency of the EMG signal was significantly decreased in unloaded muscles compared to controls. There was also a marked decrease in peak to peak amplitude of the signals from unloaded muscles. These signal changes reflect the extreme reduction in muscle fiber cross-sectional area caused by hindlimb unloading. Muscle fiber type percentages in unloaded muscle were shifted toward a greater proportion of fast fiber type. Unexpectedly, this did not result in a concomitant increase in median frequency. The rate of fatigue of the muscles, as measured by the decay in median frequency during a sustained contraction, remained unchanged.

[192] EFFECTS OF INTRAMUSCULAR APONEUROTOMY AND RECOVERY ON PENNATE SKELETAL MUSCLE

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PURPOSE—Intramuscular aponeurotomy is used clinically either to lengthen muscle or to weaken overactive muscle. Little is known about effects on muscle physiology and mechanisms of muscle recovery after such a intervention. The purpose of this project is to evaluate acute and longer term effects and mechanisms by which these effects are reached.

METHODOLOGY—The medial gastrocnemius muscle of three groups of Wistar rats (age 15 weeks) was studied. Length force characteristics and muscle geometry were determined: 1) 6 weeks after proximal aponeurotomy at 50 percent length and 3 days immobilization in maximal dorsiflexion, 2) 6 weeks after sham operation and identical immobilization, and 3) 6 weeks of no special treatment (controls). After determining length force characteristics in groups 2 and 3, proximal aponeurotomy was performed to assess its acute effects.

PRELIMIMARY RESULTS—Acutely, aponeurotomy (group 2 and 3) caused a scaled length-force curve at approximately 55 percent (i.e., force decreased but length-force curves normalized for force showed only minor changes). This is compatible with the observation that the distal part of the muscle, despite being active, contributes only little to the muscle force.

After recovery for group 1, the length force curve shifted to higher muscle lengths (i.e. became longer) but optimum force recovered to values similar to controls. The severed ends of the aponeurosis were connected with scar tissue. Muscle geometry showed extensive alterations compared to controls.

IMPLICATIONS—Despite acute effect of decreased muscle force, aponeurotomy is an appropriate method for lengthening short muscles. Full recovery of maximal muscle force can be expected, but on the ascending limb force may be decreased because of shifts of the length-force curve to higher lengths. This fact needs to be taken into account when muscle weakening is a major indication for surgery.

[193] MOTOR UNIT CONTROL PROPERTIES DURING SUSTAINED CONSTANT-FORCE ISOMETRIC CONTRACTIONS

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PURPOSE—There are contradictory reports in literature regarding the firing behavior of motor units during sustained isometric contractions. Increasing, decreasing, and haphazard behavior in motor unit firings have all been reported. The purpose of this study was to characterize firing patterns of motor units in isometric isotonic contractions lasting up to 15 s and to investigate the mechanisms responsible for such patterns. This insight regarding the normal control of nonimpaired motor units in isometric isotonic contractions will provide a basis for repairing dysfunctional muscles.

METHODOLOGY—A total of 122 contractions at 30, 50, and 80 percent of maximal voluntary contraction (MVC) of the tibialis anterior (TA) and first dorsal interosseus (FDI) muscles level were analyzed. Mean firing rates were calculated and analyzed as a function of the recruitment threshold of the motor unit and the force level of the contraction.

PRELIMINARY RESULTS—In the region where the force output was kept constant, mean firing rates of motor units showed a continual decrease. Motor units with higher recruitment thresholds decreased their firing rates faster than motor units with lower thresholds. The rate of decrease in firing rates was also found to be proportional to the force level of the contraction, the rate of decrease increasing with increasing force level. The case of 80 percent MVC contractions of the FDI presented an exception to this rule, possibly due to fatigue being more predominant in this case. In investigating the mechanisms allowing for the maintaining of constant force levels while motor unit firing rates decrease, three possibilities were hypothesized: recruitment of motor units to compensate for a decrease in the force contributions of motor units decreasing their firing rates; compensatory activity in the agonist or antagonist muscle groups; and twitch potentiation which would increase the force contribution of a motor unit per firing and hence result in forces comparable to initial values even when the firing rates decreased.

No recruitment was observed after the targeted force level was initially reached in any of the contractions, ruling out the possibility that recruitment was responsible for maintaining of a constant force level. Wrist extensor and flexor muscles were employed to investigate if compensatory action, such as a decrease in antagonist activity or an increase in agonist activity, could explain the sustained force output. However, no such activity was observed. In the absence of recruitment and complementing agonist/antagonist activity, twitch potentiation was accepted as the only plausible mechanism that could require the firing rates to decrease during sustained contractions.

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

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PURPOSE—Insight into the architecture of the motoneuron pool and the inherent characteristics of individual motor units was gained from our previous studies. In the present study we aimed to complement this knowledge with an understanding of the signals that drive the motor units, given the formerly established pool architecture and

input/output properties. This work is intended to increase our knowledge of the normal control of motor units so that better procedures may be established to diagnose and rehabilitate persons with neuromuscular deficiencies.

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

PRELIMINARY RESULTS—The data revealed that at a given force level, the average and standard deviation of the instantaneous firing rate both decreased as a function of the recruitment threshold of the motor unit. However, the coefficient of variation parameter, defined as the standard deviation normalized by the mean, was not significantly different among the motor units active in a contraction, irrespective of their recruitment thresholds. This observation led to the suggestion that the coefficient of variation of the firing rate may be the parameter which the system controls and maintains constant. It was observed that the coefficient of variation increased as the force level increased, lending further support to the view that the instantaneous firing rate coefficient of variation may be a defining parameter in the control of motor units. The increased coefficient of variation with increasing force levels, combined with our previous observations of high cross correlation among the firing activities of motor units, which further increased at higher force levels, were interpreted as an indication that the variability in common drive increases at higher force levels; and that common drive increases faster relative to the unshared noise component as higher muscle forces are produced.

[195] SYNCHRONOUS BEHAVIOR OF MOTOR UNIT FIRINGS

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PURPOSE—Synchronization of motor unit firings at low levels has been observed in humans, yet it remains unclear whether the synchronous motor unit activity serves a physiological purpose. It has been suggested that synchronization of motor units is used to increase force output or maintain the force level of contraction. Understanding the role of motor unit synchronization will lead to a fuller understanding of the strategies employed by the central nervous system in controlling motor units.

METHODOLOGY—A strict criterion to determine if motor unit pairs exhibit an interdependence that is significantly above random behavior was applied to motor unit pairs recorded from the first dorsal interosseous and from the tibialis anterior muscle. The Synch Index (indicating strength of synchronization) and Motor Unit Synch (indicating the percentage, within a contraction, of motor unit pairs exhibiting synchronization) were computed for synchronized motor unit pairs. Changes in synchronization were characterized as a function of the contraction force level, time of contraction, and motor unit recruitment threshold.

PRELIMINARY RESULTS—Individual subjects exhibited no significant difference in Synch Index at different force levels or between the first dorsal interosseous and tibialis anterior muscles, although inter-subject variability of the Synch Index was large. In addition, the temporal location of synchronous motor unit firings did not exhibit any consistent pattern over the time course of contractions. Furthermore, the recruitment thresholds of the motor units did not influence the strength of synchronization. These findings show that there is no systematic behavior to motor unit synchronization and suggest that the observed synchronization has no purpose or function, but is most likely a byproduct of the physiological control system.

[196] DEVELOPMENT OF TEST PROTOCOLS TO ASSESS THE BEHAVIOR OF BACK MUSCLES

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PURPOSE—Most test protocols currently used to evaluate the function of back muscles are either based on the concept of measuring muscular strength or on fatiguing the muscles during high level contractions. Subjects in acute pain at the time of testing have problems complying with such procedures, due to their inability to perform a maximal exertion. We are currently in the process of investigating complementing protocols based on the concept of load sharing to assess the function of back muscles. We predict this will allow us to more easily investigate muscular function in acute phases of pain, thus improving specificity of diagnosis and allowing for better and earlier individualized treatment.

METHODOLOGY—The behavior of electromyographic (EMG) spectral and amplitude parameters has been investigated during different types of low level force contractions. Spectral parameters, including median frequency (MF) and amplitude (RMS) of EMG signals were monitored during isometric trunk extension using the Back Analysis System (BAS). Two kinds of tasks, namely step-wise incrementing "staircase" contractions for short durations (20–30 s) at nonfatiguing force levels, and low level long-duration contractions at constant force levels, were studied.

PRELIMINARY RESULTS—During staircase contractions, control subjects showed a balanced increase in the RMS level of the lumbar back muscles which was highly correlated to the developed force. Patients, however, displayed inconsistent increases in RMS levels with increasing force indicating a skewed load sharing pattern in the patient population. During long duration contractions, control subjects displayed different phases of EMG parameter behavior. These included initial increases in RMS as MF decreased; a constant RMS level while MF continued to decrease; and toward the end of the contraction, a decreasing RMS level while MF stabilized at a low level. RMS decrease was most marked in the multifidus muscle. Patients displayed a much more rigid behavior. Their EMG parameters appeared to stay more constant until the subject ended the task due to pain or discomfort. The results suggest that test protocols based on the concept of load sharing may be used to assess information related to the normal function of lumbar back muscles.

[197] ACTIVATION OF NECK MUSCLES DURING A FORCE CONTROL TASK

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PURPOSE—The primary purpose of this study is to map the vectors of electromyographic (EMG) activity for the neck musculature throughout the polar range of head motion and determine the agonist, synergist, and antagonist function of each muscle under consideration. As a secondary problem, this research will then determine whether the magnitude and direction of the greatest EMG activity corresponds with the muscle's joint moment potential (JMP), defined as the product of its moment arm and physiological cross-sectional area (PCSA) obtained

from fresh-frozen cadaveric specimens. Baseline data on normal subjects will be of practical benefit to those interested in establishing what muscles are involved in the various presentations of spasmodic torticollis.

METHODOLOGY—The application of force by the head will be perpendicular to the long axis of the neck through the use of a modified halo attached to a testing chair. Subjects (N=18) produce a force on the halo which will appear on a computer screen as a vector with a magnitude and direction that is related to tension at the load cell. There will be 12 targets, 1 placed on the circumference of a virtual circle every 30°. The tip of the vector will elongate in the desired direction until a force corresponding to 50 percent of maximum for that particular direction has been obtained. The basic plan is to give 5 days of testing. The first two pre-test sessions will be used to practice exerting a maximal isometric contraction in each of the 12 desired directions. The third pre-test session will then be used to practice exerting a force which is 50 percent of maximum for each of the 12 targets. Collection of EMG activity will then occur on the last 2 days of testing. The order of presentation of the direction of force application will be randomized.

Forces will be recorded by a 6 degree-of-freedom load-cell mounted on top of the modified halo. Two intramuscular wires in bipolar configuration will be used to record the EMG activity of the following muscles on the right and left sides of the neck: 1) the sternocleidomastoid; 2) the superior fibers of the trapezius; 3) the splenius capitis; 4) the semispinalis capitis; 5) the scalenus medius; and 6) the levator scapulae. The criterion measures will be force, and the magnitude and direction of greatest activity (EMG_i) for each muscle (i) as measured by the root-mean-square EMG amplitude. The inner product will then be used to determine the relationship between the vectors EMG_i and JMP_i in a correlational sense.

PROGRESS—The testing device and data collection programs have been completed. The electrode configuration has been validated. Two pilot dissections have taken place on fresh-frozen cadaveric specimens, where the physiological cross-sectional areas of the muscles listed above have been obtained.

FUTURE PLANS—Data collection on a normal and a spasmodic torticollis population is planned through spring 1997. The cadaveric work is in progress with collection of moment arm data begun.

[198] MUSCLE FIBER DAMAGE DUE TO ECCENTRIC CONTRACTIONS

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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 P_o) 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. The frequency was also chosen to produce the force level observed during moderate intensity exercise. We also eccentrically exercised the slow soleus muscle and measured contractile and structural parameters.

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 min 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. Soleus muscles showed no such abnormalities. Soleus muscle stiffness decreased by only 30 percent over the 30 min treatment period while isometric force decreased by 85 percent. These data indicate that, while soleus muscles decreased their force generating capability significantly, there were a number of cross-bridges still attached that were not generating force.

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[199] LIGAMENTO-MUSCULAR PROTECTIVE REFLEX IN THE KNEE, SHOULDER, ANKLE, AND ELBOW

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PURPOSE—The ligaments are considered to be the primary restraints of a joint, keeping the bones aligned in their natural kinematic state throughout the joint's range of motion. A growing pool of evidence shows that the musculature significantly contributes toward joint stability as well as protection of the ligaments. Our early work with the anterior cruciate ligament (ACL) shows the variety of mechanoreceptors present in this ligament, and also that a reflex arc exists from these mechanoreceptors to the muscles crossing the knee. Strain applied directly to the ACL resulted in reflex contraction of the hamstrings in animal models and in humans. We investigate whether such a protective reflex exists in other joints.

METHODOLOGY—We undertook several new studies to determine if such a ligamento-muscular reflex arc exists in other joints while stimulating articular nerve branches emerging from the ligaments. To date we have found that the protective reflex exists in the shoulder, elbow, and ankle, in addition to the knee.

RESULTS—Therefore, a synergisitic relationship probably exists between the ligaments and muscles of every joint to ensure preservation of the tissue, prevention of damage, and proper kinematic alignment of the joint's bones when various internal and external disturbing loads are applied. During surgery, the neural integrity of the ligament-joint should be preserved as much as possible in order to avoid joint arthropathy, and then utilized to design the appropriate postsurgical therapy.

RECENT PUBLICATIONS FROM THIS RESEARCH

Glenohumeral-biceps reflex in the feline model. Knatt T, Guanche C, Solomonow M, Lu Y, Baratta R, Zhou B-H. Clin Orthop 1995:314:247–52.

Synergistic action of the capsule and the shoulder muscles. Guanche C, Knatt T, Solomonow M, Lu Y, Baratta R. Am J Sports Med 1995:23:301–6.

Ligamento-muscular protective reflex in the feline ankle. Lewis J, Donatto K, Solomonow M et al. Orthop Int 1996:4:1–8.

[200] SURFACE AND WIRE EMG CROSSTALK IN NEIGHBORING MUSCLES

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PURPOSE—EMG crosstalk between neighboring muscles presents a long-standing controversy without final conclusion as to its existence and, if so, to the mechanism underlying the process. We set an experimental protocol to clearly delineate whether cross talk exists and under what circumstances.

METHODOLOGY—We undertook an investigation in animal model in which the muscle nerves of the soleus, medial, and lateral gastrocnemius and tibialis anterior muscles were supramaximally stimulated while surface and wire EMG from all the muscles were recorded. Later, the muscle nerves were all cut, except for the nerve to the medial gastrocnemius, which was supramaximally stimulated while surface and wire EMG from all the muscles were recorded. Any EMG in the muscles which their nerves were cut was considered pure and true crosstalk.

RESULTS—It was shown in a cat model that the extent of the crosstalk in the soleus, tibialis anterior, and the lateral gastrocnemius was less than 4–5 percent during maximal stimulation of the medial gastrocnemius when recording with surface electrodes. When recording with wire electrodes, the crosstalk was limited to 1–2 percent of maximal EMG activity in the corresponding muscles.

In several animals with a confirmed fat layer over the muscles, the crosstalk values in the inactive muscles ranged between 16–32 percent, suggesting that adipose tissue is responsible for inducing significant crosstalk in surface recordings of the EMG. There was no impact on the wire recordings.

It was concluded that, when using electrodes appropriately sized to the muscle dimensions and correctly placed, the amount of crosstalk in surface and wire recordings is negligible. However, when recording surface EMG from muscles covered with adipose tissue, the EMG will be contaminated with significant crosstalk and may lead to false conclusions.

[201] THREE-DIMENSIONAL DESCRIPTION OF MUSCLE PROPERTIES

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PURPOSE—Traditional descriptive models of muscle properties are limited to the length-tension relationship obtained from isometric contractions, and from force-velocity curves obtained from isotonic contraction. Unfortunately, combining both curves to yield the force-length-velocity relationships is invalid, as data obtained in isometric contractions could differ by as much as 50 percent from those of shortening contraction. This problem was solved by describing length-force and velocity in a load-moving contraction.

METHODOLOGY—We have set up a protocol by which a muscle was stimulated electrically through its nerve, allowing shortening while applying displacing loads of different size. The initial length of the muscle when loaded and the final length after supramaximal stimulation provided a set of points with which the passive and total length-load (force) ratios were plotted as a function of load values. The shortening curve of the muscle during stimulation was recorded and differentiated mathematically to yield its velocity at any given length and for any given load, thereby allowing the construction of a load-length-velocity curve.

RESULTS—The initial results provide the first valid description of load-length-velocity of an isolated muscle, which could be used in large scale modeling of human movement, neuroprosthesis design, and general understanding of muscle functions.

[202] SIMULATION OF EMG SIGNALS ELECTRICALLY EVOKED IN THE HUMAN BICEPS MUSCLE

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PURPOSE—Many clinically important anatomical and physiological parameters of muscle cannot be measured directly. However, these unaccessible parameters can be estimated through the use of model equations. A mathematical model was developed that represents surface electromyographic (EMG) signals as a summation of contributions from single fibers of individual motor units (MU). The model was used to simulate single and double differential to study the influence of signal shape on the relative changes of median frequency and conduction velocity (CV) during fatigue.

METHODOLOGY—A 16-channel, active electrode array, EMG amplifier with stimulation artifact suppression, and neuromuscular stimulator were used to detect maximal M-waves from the human biceps brachii muscle. The muscle's main motor point was stimulated monopolarly with the EMG array placed distally to the motor point. For model simulations of the M-wave, estimates of the size and location of the neuromuscular junction, termination zones, muscle fibers, CV, and other motor unit parameters were specified. Surface monopolar and bipolar signals were computed for 12 of the channels, which spanned the entire distal aspect of the muscle.

PRELIMINARY RESULTS—Three "equivalent motor units" with different geometry, innervation zones, and CV were simulated to obtain a good match with signals from the beginning of the contraction. The same set of motor units allowed excellent simulation of the signals from the end of the contraction, with only CV being changed in order to match the morphology of all detected signals. This finding shows that, during sustained contractions, individual motor units change their CV by different amounts and not necessarily in the same direction. This phenomenon explains changes of signal shape that cause the relative change of EMG median frequency to be much greater than that of CV.

[203] SIMULATION OF EVOKED EMG SIGNALS FROM IN VITRO PREPARATIONS

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PURPOSE—The electromyographic (EMG) signal detected from the skin overlying a muscle is the result of numerous electrophysiological processes that cannot be experimentally measured simultaneously. Mathematical models can simulate the surface detected EMG signal on the basis of numerous electrophysiological factors, but so-

lutions are only theoretical estimates needing empirical verification. The utilization of *in vitro* techniques, in combination with mathematical model simulations, may therefore provide a greater understanding of the relationship between the surface EMG signal and muscle physiological characteristics than either technique can provide alone.

METHODOLOGY—Signals were recorded from isolated neuromuscular preparations of the soleus and diaphragm muscles of the rat. Muscles were placed in an isothermal, oxygenated bath in contact with an EMG electrode array spanning the entire muscle length. Electrical stimulation of the nerve elicited M-waves which were detected in both monopolar and bipolar configurations. Measurements were made on the muscles to obtain geometrical information for input into the model. The model was used to simulate signals obtained from the *in vitro* preparation.

PRELIMINARY RESULTS—The model provided a close approximation of the actual signals recorded in vitro when multiple motor units with slightly different characteristics were simulated. There was a very narrow set of model input parameters that fit the experimental sequence of M-waves. Preliminary results to date suggest that further iterative studies combining the *in vitro* technique with the muscle model may lead to noninvasive estimation techniques for assessing the geometrical and functional properties of superficial muscles.

[204] LOW-LEVEL MUSCLE ACTIVITY AS A RISK FACTOR IN THE DEVELOPMENT OF CUMULATIVE TRAUMA DISORDERS

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PURPOSE—Pain syndromes in the shoulder and neck region may develop in occupational situations with a low level of muscle activation. Previous studies, combining epidemiological methods with recording of the electromyographic (EMG) signal from the trapezius muscle by surface electrodes, have suggested that prolonged activity in low-threshold motor units can be causally related to the development of shoulder pain syndromes. The present series of experiments aim to obtain direct evidence for this hypothesis by utilizing the motor unit decomposition technique.

METHODOLOGY—Experimental situations known to be stressful to many individuals, or mimicking occupational work situations where some workers develop shoulder and neck pain, are created in the laboratory. A combination of surface EMG and single motor unit recordings is carried out to relate overall activation of the trapezius muscle with the activity pattern of single motor units, activated at low activity levels. The analysis of the EMG recordings will look for the following evidence, considered to support the above hypothesis: 1) signs of fatigue in motor units, active for extended periods of time; 2) higher firing rates or more regular activity patterns of motor units in experimental situations known to be stressful for the individual or mimicking work situations with a high risk of musculoskeletal pain syndromes developing; and 3) similar changes to 2), but observing normally pain-free subjects in situations with discomfort developing, or observing subjects with pain syndromes in the shoulder and neck.

PRELIMINARY RESULTS—The Precision Decomposition Technique, normally used in experiments of 30-s duration, has been modified to be used in experiments that last 1 hour or longer. Also, considerable time and effort has been spent to determine an intramuscular electrode configuration that is sufficiently sensitive to detect motor units at activation levels of 1–2 percent of maximal muscle activation, and at the same time sufficiently discriminating to reliably identify a motor unit when many motor units are active. Currently, experimentation is continuing to look for evidence as detailed above.

tory of injury or surgery to either knee was excluded from the study. Any pre-existing knee pathology, either self-reported or clinically diagnosed, also excluded the knee from the study.

PROGRESS—A total of 492 knees were evaluated, 418 knees (253 from male subjects, 165 from female subjects) qualified for statistical analysis.

RESULTS—The female athletes produced significantly lower scores than the male athletes on both questionnaires (Noyes: female mean=97.82, male mean=99.10; Lysholm: female mean 97.16, male mean 99.10). Analysis of the subsections of each score revealed that women produced significantly lower scores than the males in the pain category of both questionnaires in the stair-climbing and running categories of the Noyes questionnaire, and in the squatting and instability categories of the Lysholm questionnaire. The males scored lower than the females in the walking category of the Noyes questionnaire, but these differences were not significant. When comparing the mean values in each category to that of the maximum value for that category, the males scored significantly lower than the maximum value in all of the Noyes categories except walking, stair climbing, and running; and the females scored significantly lower than the maximum value in all categories except walking. Similarly, for the Lysholm questionnaire, the males scored significantly lower than the maximum in all categories except support and stair-climbing; and the females scored significantly lower than the maximum in all categories except limb and thigh atrophy. An analysis also was performed comparing the total scores and the scores in each category for right versus left knees. For the Noyes questionnaire, there was a significant difference for the male subjects in the pain category, and for the female subjects in the jumping/twisting category. There were no significant differences in total score or any categories of the Lysholm questionnaire when comparing right versus left knees for either male or female subjects. This study exemplifies the need for more accurate instruments in the evaluation of knee surgical outcomes. Modification of the subsections of the existing questionnaires that seem to induce error is one option. The development of a tool that will increase the validity of reported scores without modifying existing scores is thus proposed.

IX. Neurological and Vascular Disorders

A. General

[208] FIRING PATTERNS OF UPPER AND LOWER MOTONEURONS AND THEIR TRANSLATION FACTOR

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PURPOSE—Two characteristics shape the response of a motoneuron to a descending input: one is probabilistic, ascribed to its own physical and electrophysiological properties; the other is deterministic, ascribed to the descending impulses on it. In this work, we set out to study the probabilistic response of the motoneuron to derive a "translation factor" that determines the firing rate response of a given motoneuron to the descending drive. A better understanding of this response should give us insight to the adaptive mechanisms of the nervous system in strokes and other disorders of the corticospinal tract.

METHODOLOGY—Contractions in the first dorsal interosseous muscle were studied in four male subjects. The Precision Decomposition Technique was applied to the EMG signal to derive information about the firing rates of a family of motor units. After the individual firing rates for each motor unit were calculated, we calculated the average firing rate of the active motor units. The residual firing rates for the individual motor units not accounted for by the common drive were then calculated as the deviations from the mean (i.e., as the differences between the actual firing rates of each motor unit and the average firing rate). As the value of the mean is affected by the number of motor units in the study, it is primarily the distribution of the residual values which was of interest. To relate these properties, inherent to the motoneuron itself, to the motor unit size, we collected the macro potential of the active motor units via a special cannula recording that was trigger averaged on the firing rate of individual motor units. The macro potential, it has been shown, gives an estimate of the number and size of the muscle fibers in a motor unit.

PRELIMINARY RESULTS—Histograms were made of the actual, and the residual, firing rates, of one particular motor unit within the steady state period of the force. While both sets of steady-state data are roughly gaussian in shape, the residual firing rates fit the normal curve more closely than the actual firing rates. When a histogram was created of the average firing rate, a gaussian pattern was observed again. A translation factor between the average firing rate and the firing rate of each individual motor unit was then calculated as follows: first, the ratio was calculated, at each discrete point in time, between the average firing rate for all motor units and the firing rate of an individual motor unit; the translation factor was then taken to be the average of these ratios. The translation factor had an inverse correlation with the macro size of each unit confirming the intimate relationship between the electrophysiological characteristics of the motor unit as measured by the translation factor and its size as measured by the macro potential.

[209] THE ELECTROTWITCH: A DYNAMIC CONCEPT IN FORCE GENERATION BY THE MOTOR UNIT

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PURPOSE—In this project, we set out to demonstrate the relationship between the motor unit firing rates and the force they generate to determine the role played by the various electromechanical properties of the motor unit. In addition, we investigated the electromechanical lag between individual motor units in a contraction and their corresponding force to better understand the role played by motor units of different types in the generation of force. This should lead to a better understanding of the compensatory mechanisms utilized by the nervous system in diseases of muscle and nerves.

METHODOLOGY—A series of human-subject experiments at the NeuroMuscular Research Center yielded data on the firing trains of motor neurons in the first dorsal interosseous muscle and concurrent data on the force applied by the index finger of the subject on a force plate. The instantaneous firing rates of the motor units were calculated, and the resulting sequences were analyzed both individually and in comparison with the force data. Force graphs were then obtained and compared to a weighted sum of the motor unit firing rates. The weights used being the areas of the macro signals for each motor unit. Electromechanical lags were computed numerically by performing cross-correlations between the firing rate of each motor unit and the overall force, altering the time-offset between the two variables. The actual value of the electromechanical lag is taken to be that offset at which the correlation is greatest.

PRELIMINARY RESULTS—Since force generation is a function of the electrophysiological properties of a motor unit and the dynamic changes which result from its firing rates, a factor is derived to take into account the size and firing rate of the motor unit. We propose to use the product of the firing rate of the motor unit by its macro area to give an estimate of the force it generates. We refer to this factor as the electrical twitch of a motor unit or its "electrotwitch." Analysis of the firing rates versus the force data show that major features in the weighted sum of the firing rates are highly correlated with similar major features in the force. As for the electromechanical lag, it varied between 90 and 140 ms in our sample, with the smaller units having the shortest electromechanical lag and the larger units the longest. This is in keeping with studies which show that smaller motor units respond more quickly to a given change in the central drive than do larger motor units.

[210] EFFECTS OF AGING ON MOTOR UNIT FIRING BEHAVIOR: HAND DOMINANCE EFFECT

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PURPOSE—Daily preferential use of a muscle has been associated with higher fatigue resistance and possibly increased percentage of slow-twitch fibers in muscles of the dominant hand. The present study was aimed at revealing any differences in the control properties of contralateral muscle pairs in individuals who show a clear preference for one hand.

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

PRELIMINARY RESULTS—The recruitment thresholds and the firing rates of motor units in the dominant hand were lower when compared to motor units in the nondominant hand. Contralateral differences were less pronounced in the left-handed subjects, possibly due to the certain level of ambidexterity among this group. A greater delay between common fluctuations of mean firing rates and the force were observed in the dominant hand. No difference was seen in the maximal voluntary contraction strength between the dominant and nondominant sides. The measured lower firing rates, lower recruitment thresholds, and greater firing rate-to-force lead times in the dominant hand are consistent with the notion of an increased percentage of slow-twitch fibers in the preferentially used muscle. Since slow-twitch fibers exhibit twitch fusion at lower contractile rates, motor units in the dominant muscle are able to generate force at lower firing rates than their counterparts in the nondominant hand.

RECENT PUBLICATIONS FROM THIS RESEARCH

Motor unit firing behavior in the first dorsal interosseous: effects of preferential hand use. Adam A, De Luca CJ. In: Proceedings of the XVth Congress of the International Society of Biomechanics; 1995, Finland.

[211] EFFECTS OF AGING ON MOTOR UNIT FIRING BEHAVIOR

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PURPOSE—A number of changes occur in the neuromuscular system with the natural aging process. There is a marked reduction in strength, agility, precision in muscle control, as well as an increased tendency to fatigue sooner. There have been a number of age-related studies on the morphological characteristics of the motor unit. However, little is known about the alterations that take place in the control strategies the central nervous system employs to produce force. It is hypothesized that along with the changes in motor unit properties with age, there is also an alteration in the activation pattern and firing behavior of motor units, possibly to accommodate the changes in the morphological properties. The results of this study will provide insight into these age-related changes and lay the groundwork for improving the quality of life for the elderly.

METHODOLOGY—The first dorsal interosseous muscle was chosen to be studied in both male and female subjects belonging to four age groups: 20–35, 35–50, 50–65, and older than 65. Contractions were performed at 20, 50, and 80 percent of the maximal voluntary contraction level of the subject. Electromyographic signals detected via needle and surface electrodes were recorded along with the force generated by the muscle.

PRELIMINARY RESULTS—Presently, we have tested six subjects in the age group 20–35 years, four in group 35–50, one in the 50–65 group, and three older than 65 years of age. The decomposition of the collected data into the firing activity of individual motor units was achieved using Precision Decomposition. Further testing of subjects and decomposition and data analysis are in progress.

[212] EFFECTS OF AGING ON MOTOR UNIT FIRING BEHAVIOR: RANK-ORDERED REGULATION OF MOTOR UNITS

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PURPOSE—Henneman's monumental contributions to the field of motor unit control led to his well-known size principle indicating the correlation between the size of the motor unit and its recruitment order. The present study was undertaken to complement this work by investigating whether a parallel correlation existed between the recruitment rank, or threshold, of the motor unit and the firing rate at which it operated once recruited. A thorough understanding of the control of motor units in normal force generation is hoped to form the groundwork for developing tools to diagnose and treat individuals with impaired motor function.

METHODOLOGY—Myoelectric signals were detected from the tibialis anterior muscle while subjects generated isometric forces that linearly increased up to the maximal voluntary level. The firing behavior of motor units was studied as a function of the corresponding force output. The use of specialized data acquisition and processing techniques enabled the investigation of a wide range of motor units, in contrast to previous studies which had been limited to only the low-threshold motor units, due to the increased difficulty of reliable identification of motor unit activities at higher force levels.

PRELIMINARY RESULTS—The analysis of data revealed that the recruitment threshold of the motor unit was closely correlated to its other operational parameters, such as mean firing rate, initial firing rate, and response to the requirement to increase the force output. The observation of rank-ordered motor unit properties supports the theory of common drive, which states that motor units of a motoneuron pool are controlled not by individual control signals but by a common command signal. The rank-dependent distribution of motor unit properties would make it possible for motor units to generate different responses, suited to their individual physical properties, to a common input.

RECENT PUBLICATIONS FROM THIS RESEARCH

Rank-ordered regulation of motor units. Erim Z, De Luca CJ, Mineo K, Aoki T. Muscle Nerve 1996;19:563–73.

[213] 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 nonambulatory) will perform several pretraining tests to measure baseline body composition, joint range of motion, ambulation, 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 posttraining 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).

PROGRESS—We have recruited 18 individuals with MS. All 18 have received a preliminary neurological examination and finished body composition testing, resting ECG, medical history, maximal aerobic power, aerobic endurance, and psychological status; and 17 have completed gait analysis. At this point in time, 4 people have had to drop out and 1 has not started the exercise portion of the study due to health problems; therefore, 13 individuals are participating in the exercise portion of the study. Three individuals have completed 6 months of exercise (3 months with the cooling garment and 3 months without it) and have also completed their post testing, which includes the same tests conducted as before training with exception of resting ECG. The other 10 individuals have all completed at least 3 months of training and have finished their mid-point testing. Mid-point testing consists of maximal and endurance aerobic testing and psychological status. Efforts are being made to recruit more individuals for this study in order to have another group of individuals ready to train when the present group is finished. Six water flow and volume control devices are being used to keep water temperature and flow volume precise. All units are paired with an exercise bicycle for the training session. All six body cooling suits have been finished and tested several times to insure proper working condition. Many revisions have been made, and they are functioning as intended. The computer program necessary to run the maximal aerobic tests has been functioning properly, and over 100 maximal or endurance aerobic tests have been conducted. As for the psychological testing, all of the necessary testing forms have been received and psychological testing has been conducted as necessary.

FUTURE PLANS/IMPLICATIONS—Further research should evaluate other modes of exercise for testing and training, more aggressive protocols, and the efficacy of commercially available body cooling devices upon acute and chronic physiological, psychological, and functional outcomes following aerobic exercise training.

[214] SYNCHRONIZATION AND COMMON DRIVE OF MOTOR UNITS

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PURPOSE—The synchronization of motor units is an experimentally robust phenomenon. However, it seems to have no apparent physiological purpose. It is the contention of this study that the observed synchronization is an epiphenomenon of common drive which has been previously proposed to explain the correlation of firing rates between different motor units.

METHODOLOGY—A simple common drive model was used to examine synchronization. The model consisted of integrate-and-fire neuronal oscillators driven by a common drive, which was composed of a DC signal and a correlated noise source. Each oscillator also received independent white noise. Synchronization was then analyzed in the model using methods similar to those utilized previously for the experimental data. The statistical ten-

dencies of synchronization of the model were calculated analytically and with numerical simulations. These were then compared to the experimental data.

PRELIMINARY RESULTS—The common drive model predicts the behavior of synchronization in the data quite well. The model predicts that the probability of finding synchronization increases with the length of the spike train. The model also predicts that the number of observed consecutive synchronization events should occur with an exponential distribution. Both of these results have been confirmed experimentally.

[215] EVALUATION OF CARPAL TUNNEL SYNDROME

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PURPOSE—The number of cumulative trauma disorder cases reported by the U.S. Bureau of Labor Statistics in 1993 represented a 63 percent increase from the figures in 1990. Carpal tunnel syndrome (CTS), resulting from the compression of the median nerve at the carpal tunnel, is the most common type of cumulative trauma disorder. In spite of its prevalence in the modern work environment, the clinical tests currently used to assess the syndrome are subjective and often inconclusive. The purpose of this project was to design an objective, quantitative, and noninvasive method to evaluate a patient's involvement with CTS.

METHODOLOGY—An arm and hand restraint device was built that enables surface electromyographic and force measurements from the thenar and hypothenar muscle groups. This device allows the combined output force to be displayed on-line to the subject for visual feedback. The subject was asked to trace a trajectory displayed on a computer screen by controlling the strength of a pinching motion to be performed with the thumb and fifth digit. Specific instructions regarding how much force to exert with each finger were not provided to the subject. Five CTS and five nonimpaired subjects (controls) were tested using this experimental protocol. Force and surface electromyographic (EMG) signals from the thenar and hypothenar muscle groups were recorded.

PRELIMINARY RESULTS—Preliminary analysis of experimental data revealed different trends in patients and controls as expected. Regression analysis performed on force and EMG signals yielded several parameters that had statistically different means in the two populations. These parameters could ultimately be used to classify a subject in the nonimpaired or CTS groups, and to devise an index to provide a scaled measure of severity of damage.

[216] EFFECT OF MICROCLIMATE COOLING ON PHYSICAL FUNCTION IN MULTIPLE SCLEROSIS (MS)

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PURPOSE—As clinicians actively engage in the care of a large number of MS patients, we consistently note that heat-sensitive patients (HSMS) are more adversely affected in certain activities than others; specifically, those activities requiring repeated effort. Typical acute physiologic, motor and self-perceived stress among

HSMS patients include: worsening of existing neurologic signs and symptoms, the development of new signs and symptoms, and lassitude.

This study focused on active cooling-induced effects upon motor function as measured by changes in: skeletal muscle strength, systemic endurance, and dynamic and standing balance.

METHODOLOGY—For inclusion in this study as HSMS, subjects met the following criteria: all had definite MS, were females aged 18–55, had a rating on the Kurtzke Expanded Disability Status Scale (EDSS) of 4.0–5.5, inclusive, a self-perception of heat sensitivity that impairs activities of daily living (ADL), and positive responses on the Thermal Sensitivity Inventory (TSI). All were medically stable with no change in signs, symptoms, or medications for chronic conditions including MS, and less than 20 percent over ideal body weight.

We employed a one-group, two-treatmcnt, repeated-measures, within-subjects design. The treatment (tcmperature) condition was randomly ordered and had two levels: sham body cooling (SC; 26.5 °C) and active body cooling (AC; 7 °C) and the order factor had two levels. Twenty-two HSMS subjects (4.0< EDSS on the Kurtzke Expanded Disability Status Scale <5.5) were recruited, 19 began experimentation; 18 subjects could perform the evaluations and 17 completed the experiment series. The data were analyzed employing a repeated measures analysis of variance method. The randomization sequence was used as a blocking factor.

Subjects were fitted with a Mark 1 Medical Cooling Garment (Life Enhancement Technology, Mountain View, CA). The garment was fitted snugly to the torso and head to effect conductive cooling of each patient. The HSMS wore the garment for 60 min while resting comfortably in a chair. Body core temperature, heart rate, and brachial blood pressure were monitored every 5 min. The coolant temperature is regulated by, and pumped from, a temperature control unit. The coolant flow rate, pressure, and garment inlet and outlet temperaturcs werc monitored continuously thoughout all experiments.

PROGRESS—Data collection and anaylsis are complete.

RESULTS—There was significant before and after evaluation by treatment condition interactions in several measurement domains: strength (quadriceps), $F_{[1,15]}4.53$ ($F=3.07$, $p<0.05$), endurance task (leg cycling), $F_{[1,15]}8.84$ ($F=6.77$, $p<0.01$), dynamic balance task (tandem gait), $F_{[1,15]}6.71$ ($F=3.07$, $p<0.05$), single leg standing balance, $F_{[1,15]}7.48$ ($F=6.77$, $p<0.01$), and ambulation velocity, $F_{[1,15]}3.18$ ($F=3.07$, $p<0.05$). There were no pure order effects, however, an order by temperature by pre-post interaction in tandcm gait, $F_{[1,15]}6.48$ ($F=3.07$, $p<0.05$) and ambulation velocity, $F_{[1,15]}5.61$ ($F=3.07$, $p<0.05$).

IMPLICATIONS—We conclude that active body cooling (7 °C) in a controlled microclimate cooling device will effectively increase motor function as measured by strength, coordination and endurance to effect repetitive activities.

FUTURE PLANS—We shall study similar performancc outcomes whcn active liquid cooling is used chronically (long-term) among heat-labile MS patients.

[217] CENTRAL NERVOUS SYSTEM CONTROL RULES FOR VOLUNTARY MOVEMENT

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PURPOSE—To understand how the brain controls the limbs to perform purposeful movement, we need to know what kinds of commands are sent to the muscles and what variables are used to plan and construct them. For example, does the control system plan a movement's path and velocity through space and then from this computes the forces necessary to produce it? Docs the system plan a path and rely on neurophysiological feedback mechanisms to generate the desired forces? Or, does it plan forces that from past experience it expects will produce a

satisfactory movement, and then monitor the outcome to see if it was correct?

The work of the Motor Control Lab focuses on this third alternative and performs experiments to test its hypotheses and implications. We predict that not only will a better understanding of brain function emerge from this research, but that it will lead to new insights and a better way of evaluating patients with motor deficits.

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

PRELIMINARY RESULTS—We have developed a model for how the muscle activation patterns are planned, based upon features of the planned movements such as its distance and speed, and the dynamic properties of the load. These are nonlinear rules because of constraints imposed by muscle contractile properties. Muscle forces are produced and from these, movement characteristics are emergent. Reflexes play a supportive and adaptive but subordinate role in this process. Movement skill emerges from practice in which individuals learn the proper muscle activation patterns by trial and error.

RECENT PUBLICATIONS FROM THIS RESEARCH

"Adequate Control Theory" for human single-joint elbow flexion on two tasks. Gottlieb GL, Chi-Hung C, Corcos DM. Ann Biomed Eng 1995:23:388–98.

Relations between joint torque, motion and EMG patterns at the human elbow. Gottlieb GL, Chi-Hung C, Corcos DM. Exp Brain Res 1995:103:164–7.

[218] A THEORY OF SPATIOTEMPORAL CHAOS

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PURPOSE—The majority of the theoretical results in the study of chaotic dynamics has been confined to low dimensional systems. However, many systems, including those found in biology, are spatially extended with many degrees of freedom. Here a theory to understand a specific type of spatiotemporal chaos (STC) is proposed. This theory could impact the understanding of other models related to neurophysiology.

METHODOLOGY—The Kuramoto-Sivashinsky (KS) equation describing propagating chemical fronts was analyzed. Due to its simplicity it is often considered a paradigm of STC. The STC in the KS equation is manifested as the chaotic dynamics of coherent structures. The equation was analyzed using novel averaging and perturbation techniques in conjunction with numerical simulations. An understanding of the dynamics in the large system limit and in a statistical sense was desired.

PRELIMINARY RESULTS—The deterministic KS equation exhibits STC that has specific statistical behavior and scaling that can be measured numerically. These were shown to be equivalent to those of a stochastically driven nonlinear diffusion equation. The latter was tenable to theoretical analysis by known techniques of statistical field theory. This result gives hope that other multiple degree of freedom systems, such as the collective dynamics of many coupled neurons, can be understood analytically.

[219] APERIODIC STOCHASTIC RESONANCE IN MODEL NEURONS

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PURPOSE—Stochastic resonance (SR) is a phenomenon wherein the response of a nonlinear system to a weak periodic input signal is optimized by the presence of a particular level of noise. SR has been examined theoretically and experimentally in a wide variety of systems, including sensory neurons. All of this work, however, has been limited to the treatment of systems with periodic inputs. This focus has served to limit the applicability of SR to practical situations, given that real-world external signals are often not periodic. The objective of this study was to develop a theory and method for characterizing SR-type behavior in model neurons with aperiodic inputs. For this general type of behavior, we coined the term aperiodic stochastic resonance (ASR).

METHODOLOGY—We developed two measures, the power norm and normalized power norm, for characterizing ASR. These measures enable one to quantify the two noise-induced effects associated with SR, such as signal amplification and optimal stimulus-response coherence. We conducted a series of computer experiments with the FitzHugh-Nagumo (FHN) neuronal model. We studied its dynamics under the influence of a subthreshold aperiodic signal plus noise. We also developed an analytical theory to account for the obtained dynamics of the FHN model.

PRELIMINARY RESULTS—We found that the results from the FHN model exhibited characteristic signatures of SR-type behavior: as the input noise intensity was increased, the stimulus-response coherence rapidly increased to a clear peak and then slowly decreased. We also found that our analytical theory matched the numerical results. This work clearly shows that SR-type behavior is not limited to systems with periodic inputs. Thus, in general, noise can serve to enhance the response of a nonlinear system to a weak input signal, regardless of whether the signal is periodic or aperiodic.

RECENT PUBLICATIONS FROM THIS RESEARCH

Aperiodic stochastic resonance in excitable systems. Collins JJ, Chow CC, Imhoff TT. Phys Rev E 1995:52(4):R3321–4.

[220] STOCHASTIC RESONANCE WITHOUT TUNING

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PURPOSE—Stochastic resonance (SR) is a phenomenon wherein the response of a nonlinear system to a weak periodic input signal is optimized by the presence of a particular level of noise. SR has been proposed as a means for improving signal detection in a wide variety of systems, including sensory neurons. However, for SR to be utilized in a single-unit system (e.g., a sensory neuron), the intensity of the system's input noise must be dynamically modulated as a function of the changing nature of the signal to be detected. The objective of this study was to show that a fixed level of input noise can optimally enhance the ability of a summing network of excitable units to detect a range of subthreshold (weak) signals, which can be periodic or aperiodic.

METHODOLOGY—We considered a summing network made of identical excitable units, which were taken to be FitzHugh-Nagumo (FHN) model neurons. Each unit was subjected to a common input signal and its own independent noise source. We assumed that information

was transmitted by each unit via temporal changes in its firing rate. The network operated by summing the mean firing rate (MFR) signal from each unit to obtain a resultant MFR signal for the entire system. We conducted a series of computer experiments with this model.

PRELIMINARY RESULTS—We found that the stimulus-response coherence for the system was enhanced as the size of the network was increased. We also showed that a fixed level of independent noise on each unit of a relatively large summing network could optimally enhance the network's ability to detect a range of subthreshold signals. Importantly, we also found that the presence of such noise did not significantly affect the network's ability to detect suprathreshold signals. These findings suggest that constant levels of internal or external noise on each neuron in a sensory system could optimally enhance the overall response of the system to a range of subthreshold signals, even for conditions wherein the individual responses of the neurons are not optimized.

RECENT PUBLICATIONS FROM THIS RESEARCH

Stochastic resonance without tuning. Collins JJ, Chow CC, Carson C, Imhoff TT. Nature 1995:376(20):236–8.

[221] A NOVEL MECHATRONIC DEVICE FOR ASSESSMENT OF BALANCE SKILLS AND DEFICIENCIES

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PURPOSE—Subjects losing balance during standing display different preprogrammed behaviors to recover equilibrium, depending on the severity of the balance perturbation and the experience and condition of the subject. This project is focused on increasing our understanding about strategies used by the central nervous system to maintain equilibrium in situations when upright standing balance is challenged.

METHODOLOGY—Subjects standing on a computer controlled moveable balance platform (BALDER) were exposed to balance perturbations at the feet in eight different directions. Whole body 3D kinematic information was recorded together with ground reaction forces. Electromyographic (EMG) activity was recorded bilaterally from muscles controlling movements of the arms, trunk and legs.

PRELIMINARY RESULTS—Results to date appear to confirm previous findings in the literature and further expand on the concept of the utilization of strategies for the maintenance of balance following a perturbation. EMG activity of muscles controlling movements of the arms appeared within 100 ms after the perturbation. The ensuing arm movements displayed directional specificity with respect to the perturbation suggesting that they were a part of the postural program triggered by the postural perturbation.

B. Swallowing Disorders

[222] EFFECTS OF AGE ON OROPHARYNGEAL SWALLOWING

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PURPOSE—The long-term objective of this project is to increase understanding of the effects of aging on swallowing physiology in an effort to advance the diagnosis and treatment of swallowing disorders in age-related disease. Swallowing profiles will be compared in normal adults and unilateral stroke patients from 45 to 95 years of age. One hypothesis is that lingual pressure predicts hyolaryngeal and upper esophageal (UES) kinematic parameters, bolus transit measures, and dietary choices.

METHODOLOGY—Recent efforts have focused on development of new instrumentation which allows for concurrent recording of video and physiologic data (multiple lingual pressures and submental EMG). Subjects perform two kinds of tasks, isometrics and barium swallows, with a thin strip of pressure-sensitive air-filled bulbs attached to the midsaggital line of the hard palate. The three pressure bulbs measure tongue strength simultaneously at anterior, mid-, and posterior palate. Pressure from each bulb is transduced and recorded on the Kay Elemetrics Workstation and linked with video data in order to facilitate understanding of amplitude by time relationships as they impact bolus transfer during swallowing. Two electrodes placed submentally record EMG in a time-linked fashion.

PROGRESS—Pilot testing with new instrumentation has been completed on six nonimpaired young subjects (mean age 31) and six nonimpaired old subjects (mean age 78) in the bulb-in and bulb-out conditions to determine how the presence of the pressure bulbs affects swallowing. Principle components analysis of the submental EMG recordings indicated no significant systematic differences in the bulb-in and bulb-out conditions. The absence of a "bulb condition effect" indicates that swallowing physiology with the intraoral pressure measuring instrument in place is similar to normal swallowing, and we may therefore proceed with the new instrument as an integral part of our methodology. Significant differences in the EMG signal were found, however, for bolus viscosity (liquid/semisolid) and age. Older subjects tended to have reduced EMG amplitude and a smaller range of phase shifts relative to their young counterparts.

While instrument development was underway, we used the Iowa Oral Performance Instrument (IOPI), a single air-filled pressure-sensitive bulb, to obtain maximum lingual pressures during isometric and saliva swallows in 15 nonimpaired old subjects (mean age 75) and 25 stroke patients (mean age 69). Performance on the isometric task did not distinguish normal from stroke groups nor did it differentiate stroke subjects from each other by site of lesion. However, the patients showed a trend toward reduced swallowing pressures at the blade position ($p=0.07$). Also, patients who generated lower isometric pressures tended to have slower oral transit duration on videofluoroscopy.

IMPLICATIONS—Our preliminary findings suggest that task demands of a coordinated movement like swallowing may differentiate stroke patients from normal age-matched individuals, while isometric tasks do not. This notion has important diagnostic and treatment implications. That is, these data suggest that resistance exercises, specifically lingual strength-building exercises, may be useful for dysphagia prevention with aging while therapy goals focused on improving swallowing coordination may be more useful for a stroke patient.

FUTURE PLANS—With development and pilot testing of intraoral pressure sensitive instrumentation completed, recruitment of normal and stroke subjects into the finalized protocol has begun. Analysis of multiple lingual pressures and EMG data is currently being facilitated by development of software. Isometric and swallowing pres-

sure tasks in combination with videofluoroscopic data may reveal a diagnostic approach for determining the presence and type of neuropathology underlying dysphagia. Additionally, this research may contribute to improved rehabilitation strategies for stroke patients and facilitate development of a dysphagia prevention program for relatively healthy geriatric individuals.

RECENT PUBLICATIONS FROM THIS RESEARCH

Age effects on lingual pressure generation as a risk factor for dysphagia. Robbins J, Levine RL, Wood J, Roecker E. J Gerontol 1995:50A(s):M257–62.

A penetration-aspiration scale. Rosenbek JC, Robbins J, Roecker E, Coyle J, Wood J. Dysphagia 1996:11:93–98.

Thermal application reduces the duration of stage transition in dysphagia after stroke. Rosenbek J, Roecker E, Wood J, Robbins J. Dysphagia. In press.

C. Vascular Disorders

[223] LUMBAR SYMPATHECTOMY IN THE PREVENTION OF MAJOR AMPUTATION OF THE EXTREMITY: A PILOT STUDY

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PURPOSE—The purpose of this study is to determine the role of lumbar sympathectomy in diabetic and nondiabetic patients with peripheral vascular disease, ischemic gangrene of the lower extremity, and impending limb loss, with or without bypass, and to investigate the content of substance P in the ventral root sympathetic ganglia and chain and peripheral tissue per and post-lumbar sympathectomy tissue biopsies at the ulcer site. We seek to determine whether diabetic patients with peripheral vascular disease have a lower sympathetic response to lumbar sympathectomy than those with peripheral vascular disease only.

METHODOLOGY—Ten patients with peripheral arterial occlusive disease (presenting with ischemic gangrene of the foot or toes) and ten diabetic patients with peripheral arterial disease (presenting with gangrene or ulcers and impending limb loss) undergoing lumbar sympathectomy will be stratified in four equal groups. Biopsy of the affected area will be performed before and after the procedure for measurement of substance P content. Noninvasive vascular tests will be performed preoperatively and on postoperative days 1 and 4a; and at 3.6, and 12 months.

The sympathectomy ganglia will be examined for substance P using immunohistolchemical assay, and the results will be compared among groups. Improvement of the subcutaneous and muscle blood flow as well as oxygen tension will be evaluated with TcPO2 laser Doppler and thermistor thermometry. A positive result will be considered improvement in healing of the chronic ulcers, prevention of a major amputation, or reduction of level of amputation.

RESULTS—Of the 20 patients required for the study, 2 nondiabetics and 7 diabetics are currently enrolled. To date, two patients have had a 9-month follow-up. Some interesting observations made so far related to the quantitative measurements of substance P. Elevated levels of substance P were detected in diabetic foot ulcers compared to nondiabetics. In addition, statistically significant results in substance P have been seen in diabetic ulcers after sympathectomy, associated with healing of treated ulcers.

[224] A PROSPECTIVE STUDY OF RISK FACTORS FOR DIABETIC FOOT ULCER

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A318-4RA)*

PURPOSE—We are conducting prospective research designed to identify 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 are enrolled in a general internal medicine clinic, and meet the criteria for diabetes mellitus by physician diagnosis or treatment with hypoglycemic medication or insulin. Participants attend a Diabetic Foot Clinic where we assess the presence of suspected risk factors grouped into four categories: circulation, neuropathy, foot deformity, and self-care behaviors. Circulation factors include lower extremity Doppler blood pressures, toe blood pressures, transcutaneous oximetry ($TcPO_2$) 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 measurements, 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.

To assess development of the outcome of interest, all subjects receive yearly repcat examinations and a quarterly mailed questionnaire asking them to report the occurrencc of ulccr. We compare rates of outcome occurrence (incidence) by exposures of interest to determine which particular factors are related to risk of diabetic foot ulcer.

PROGRESS—To date we have cnrolled 835 diabetic subjects from the Seattle VAMC general internal medicine outpatient clinic.

PRELIMINARY RESULTS—As of January 1996, we observed 110, 6.1 per 100 person years (PY), foot ulcers occurring over a cumulative 1,812 PY. Using stepwise Cox regression analysis, the following factors were independently and significantly (<0.05) related to foot ulcer risk: insensitivity to the 5.07 monofilament, relative risk (RR)=3.0, 95 percent confidence interval (CI) 1.6–5.4; diminished vibratory sensation RR=2.1, 95 percent CI 1.2–3.5, orthostatic blood pressurc drop of 30 mmHg RR=2.0, 95 percent CI 1.2–3.2; history of amputation RR=2.6, 95 percent CI 1.4–4.7; hallux rigidus RR 1.8, 95 percent CI 1.1–2.8; poor vision <20/40 bilaterally RR 1.7, 95 percent CI 1.1–2.7; and 30 mmHg $TcPO_2$ decrease on the dorsal foot RR=1.7, 95 percent CI 1.1–2.5.

We prospectively categorized 759 subjects for thcir risk of developing diabetic lower extremity complications by two standard risk stratification schemes. We found that one provided no information on the risk of foot complications and subjects categorized as high risk by the other had a risk of these complications only slightly higher than their average pretest risk. Multivariate logistic regression analysis identified five clinical factors predictive of diabetic foot ulceration and five clinical factors predictive of amputation. When all five factors are present the probability of a foot ulcer is 68 percent and the probability of an amputation is 84 percent.

FUTURE PLANS/IMPLICATIONS—The etiology of diabetic foot ulcer is complex, and includes sensory and autonomic neuropathy, forefoot rigidity, low skin oxygenation, poor vision, and past history of amputation.

RECENT PUBLICATIONS FROM THIS RESEARCH

Increased mortality associated with diabetic foot ulcer. Boyko EJ, Ahroni JH, Smith DG, Davignon D. Diabet Med. In press.

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, 2nd ed., Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, NIH Publication No. 95-1468, 1995.

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, Davignon, DR, Pecoraro RE. Foot Ankle Int 1995:16(12):787–91.

Predictors of transcutaneous oxygen tension in the lower limbs of diabetic patients. Boyko EJ, Ahroni JH, Stensel VL, Smith DG, Pecoraro R. Diabet Med. In press.

Strategies for teaching elders from a human development perspective. Ahroni JH. Diabetes Educ 1996:22(1):47–54.

X. Oncology

[225] THE STRENGTH OF HUMAN CORTICAL BONE WITH SIMULATED METASTATIC LESIONS

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PURPOSE—Current clinical practice uses crude radiographic measures to assess the integrity of bones with metastatic lesions. To address the inadequacy of these methods, this study investigated the use of finite element (FE) models for the prediction of strength of femoral shafts both with and without cortical defects. These models utilized CT scan data in the characterization of bone geometry and heterogeneity to achieve greater precision in the prediction of the flexural and torsional behavior of femoral shafts.

METHODOLOGY—This research involved three distinct phases: 1) validating the use of CT scan data in linear FE models of femoral shafts in flexion, 2) evaluating the effects of nonlinear material properties on model behavior, and 3) extending the linear CT scan-based FE models to a torsional loading configuration.

The first phase involved six matched pairs of femoral shafts, one of each pair containing a hemispherical defect. CT scans were taken of all the bones prior to mechanical testing and were used for the generation of FE models. A cylindrical model was generated by using the CT scan data solely to ascertain periosteal and endosteal diameters. A second model utilized CT scan data to generate geometries more representative of the true bone geometry. A third model used the CT scan data both to characterize the true geometry and allow variation in material properties. The strengths predicted by all three models were then correlated to failure loads measured in four-point bending.

For the second phase of the research, nonlinear material properties were used in the modeling of bones tested in flexion. Bilinear stress-strain relationships were assigned to each element, and loads were applied in 1 kN increments. Yield and failure loads determined from the models were then correlated to measured yield and failure loads.

The final phase of this research involved five pairs of bones tested in torsion. Preparation of specimens and formulation of models was similar to the flexural experiment of the first phase. Likewise, correlations between predicted and measured failure torques were derived.

PROGRESS—All work on this study has been completed.

RESULTS—This investigation demonstrated the benefit of using CT scan data to desribe bone geometry and heterogeneity in the FE modeling of femoral shafts, both with and without defects. The linear models for the flexural loading configuration showed that model predictions were most precise when CT data was utilized for both geometry and heterogeneity ($r=0.97$). Nonlinear models were also precise in the prediction of ultimate failure load ($r=0.99$) and were more descriptive of structural behavior. Linear predictions of ultimate torque were precise ($r=0.99$) but were twice the magnitude of measured torques, perhaps as consequence of the anisotropic nature of cortical bone.

Because of its ability to characterize irregular and changing cross-sections and material heterogeneity, this promising FE technique can potentially be extended to bones whose defects manifest odd geographies, moth-eaten borders, or permeative qualities.

FUTURE PLANS—The precision of the models in these two loading configurations suggests that clinical

application of this technology may improve patient care. Future work may focus on improving model accuracy through revised material properties assumptions (i.e., plasticity, asymmetry, and anisotropy).

RECENT PUBLICATIONS FROM THIS RESEARCH

Improved method for predicting the strength of femoral shafts with cortical defects. Rossi SA, Jones KA, Keyak JH, Skinner HB. Trans Orthop Res Soc 1996:21:602.

XI. Orthopedics

A. General

[226] HIP FRACTURE RISK ASSESSMENT USING AUTOMATED 3-D FINITE ELEMENT MODELING

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PURPOSE—The purpose of this project is to develop and validate a technique for predicting the strength of the proximal femur. If shown to be valid, this technique may eventually be used for assessing the risk of proximal femoral (intertrochanteric and femoral neck) fracture in elderly patients.

In this study, three-dimensional (3-D) finite element (FE) modeling was used to predict the strength of cadaveric femora, and mechanical testing was used to validate the FE model predictions.

METHODOLOGY—Matched pairs of cadaveric femora from 18 subjects over 50 years of age were obtained. One randomly selected femur from each pair was examined under loading conditions simulating the stance phase of gait. The contralateral femur was studied under conditions simulating a fall. A patient-specific 3-D FE model of each femur was automatically generated from CT scan data. The mechanical properties of the elements in these models were 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 was estimated and the location of fracture was predicted. The FE models were then verified by mechanically testing the femora to failure. For comparison, simple bone density measurements (obtained from the CT scan data) were evaluated for their ability to predict femoral strength.

PROGRESS—This study has been completed.

FINAL RESULTS—Significant correlations were found between measured strength and FE-computed strength for both loading conditions. The correlation for the fall loading condition ($r=0.95$, $p<0.001$) was stronger than that for the stance condition ($r=0.87$, $p<0.001$). For these same femora, correlations between densitometry-based measures and femoral strength were somewhat weaker ($r=0.91$ for the fall condition, $r=0.78$ for the stance condition). The fracture locations predicted by the FE models agreed with the actual fracture locations obtained during mechanical testing in 70 percent of cases.

IMPLICATIONS—We anticipate that this technology will assist in identifying patients at risk of hip fracture so that preventative measures can be taken. The software developed in this study enables 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

Prediction of femoral strength in two load configurations using CT scan-derived finite element models. Keyak JH, Jones KA, Rossi SA, Skinner HB. Trans Orthop Res Soc 1996:21:249.

3D anatomic coordinate system for hip QCT. Lang T, Heitz M, Keyak J, Genant HK. Osteoporosis Int 1996:6(Suppl 1):S203.

[227] IMPROVED BONE CEMENT FATIGUE RESISTANCE VIA CONTROLLED STRENGTH INTERFACES

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PURPOSE—The problem to be addressed in this study is to find a way to modify commercial bone cement to increase its fatigue resistance, especially its resistance to low stress, high cycle fatigue, without impairing its intraoperative handling characteristics.

METHODOLOGY—Polyethylene terephthalate (PET) fibers of 12 μ diameter, 6 mm length were obtained. Through inconsistent results of mechanical testing and infrared spectroscopy analysis, it was discovered (and reluctantly confirmed by the manufacturer) that the PET fibers were coated with a fatty acid ester. Techniques were developed to remove the coating completely so that fiber surface treatments could be effective.

Techniques were developed to disperse 1 volume percent of the 6 mm PET fibers in bone cement powder and mix the combination with monomer in a specially designed vacuum mixing system. Most of the initial work was done with 6 mm PET fibers; recently it was discovered that reducing the fiber length dramatically improved the mixing and handling characteristics of the cement. Use of the shorter fibers makes is possible to use conventional commercial vacuum mixing techniques. Viscosity tests are underway to quantify the effect of various fiber lengths and fiber surface treatments on the handling characteristics of bone cement.

Study of the effect of surface treatment of component solids, radiopaque powders, and reinforcing fibers by low temperature plasma has been initiated. Free radicals on the treated surface are being investigated by Electron Spin Resonance (ESR) spectroscopy. PET fibers were treated by plasma of argon, oxygen, and trimethylsilane (TMS). Free radicals created on the surface of fibers are converted to peroxides when the treated fibers are taken out of the reactor. Polymeric peroxides formed on the surface of fibers are broken down to free radicals by the action of dimethyl para-toluedine, the accelerator used in the bone cement liquid, just as benzoyl peroxide is broken down to free radicals. This process is being investigated by using different kinds of spin-trapping molecules which convert very reactive free radicals to more stable free radicals of adducts of spin-trapping agents.

Fracture toughness tests were performed on bone cement composites with 6 mm PET fibers with the surface treatments listed above. Fracture toughness testing was also performed on composite cement with scoured PET fibers of 6 mm, 3 mm and 1.5 mm lengths. Treated and untreated milled carbon fiber bone cement composites of 1 and 2 volume percent fiber loading were also tested for fracture toughness. The milled carbon fiber additions do not significantly change the handling characteristics of the bone cement.

The MTS MiniBionix machines for use in fatigue testing were ordered and installed. Special grips and environmental chambers for these machines were designed and manufactured. A method of direct molding of cylindrical fatigue specimens without fiber alignment was developed and preliminary fatigue testing is currently underway.

PROGRESS—Great progress has been made toward the development of the proper treatment of PET fibers and an accurate fatigue test specimen and protocol. If, for example, testing had initiated earlier, the tests would not have produced useable data because of the recognized presence of the fatty acid coating on the fibers. We are now commencing fatigue testing of the composite bone cement, confident that the variables that may produce erroneous data are under control.

RESULTS—Results of fracture toughness testing of 1 volume percent fiber loading, 6 mm PET fiber composite bone cement with various fiber surface treatments demonstrated a minimum 30 percent increase in fracture toughness of fiber bearing cement as compared to neat bone cement. Composites with two types of surface treatments tended to increase fracture toughness as compared to scoured (washed) PET fibers. It has also been demonstrated that reducing fiber length to as little as 1 mm has

no deleterious effect on fracture toughness of the composite bone cement.

Addition of milled carbon fibers significantly increased fracture toughness of bone cement. Addition of TMS treated milled carbon fibers significantly increased fracture toughness of bone cement as compared to untreated milled carbon fibers.

From ESR and spin-trapping, oxygen plasma treatment was found to be the most effective in producing peroxides which can be utilized in the bone cement curing process.

FUTURE PLANS/IMPLICATIONS—Work in the second and third year of this project will continue on course with bone cement composite material static, fracture, and fatigue testing.

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[228] IMPLANT TO FACILITATE ARTICULAR CARTILAGE REGENERATION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A424-3RA)*

No report was received for this issue.

[229] IMMUNOLOGICAL RESPONSES TO IMPLANT BIOMATERIALS FOLLOWING ARTHROPLASTY

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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 inflamma-

tory cellular immune reaction, which may lead to osteolysis with eventual failure of the prosthesis.

METHODOLOGY—Cellular responses to biomaterials were measured in peripheral blood mononuclear cells from patients who present as candidates for a total joint arthroplasty (TJA); either a primary operation or the revision of a painful or loosened total joint prostheses. The cellular responses were then reassessed during patient follow-up after a minimum of 9 months. Cells were cultured *in vitro* with particles derived from polymethylmethacrylate (PMMA) cement, ultra high molecular weight polyethylene (UHMWPE), cobalt-chrome alloy (Co-Cr), or titanium alloy (Ti-6-4) for 7 days at 37°C. Cell proliferation was assayed during the final 16 hours using an MTT conversion assay, and the responses to each biomaterial are calculated. The levels of inflammatory cytokines (IL-1 and TNFα) and immune cytokines (IL-4, γIFN) in tissue culture supernatants were measured using ELISA assays at the conclusion of the incubation.

PROGRESS—Changes in the cellular and cytokine responses to biomaterials in particulate form have been evaluated in 42 patients, 12 with primary TJA and 30 with revision surgery. In addition, 53 patients have been evaluated as candidates for TJA, and control responses were assessed in 18 patients with connective tissue disease who were not candidates for TJA.

RESULTS—Significant differences were seen in the cellular responses to biomaterials subsequent to primary surgery compared with the responses subsequent to revision surgery. In the primary patient population, the response to both PMMA and Co-Cr was elevated at the follow-up assessment compared with the preoperative level. In patients with a painful or loosened total joint prostheses, the prerevision surgery response to both PMMA and Co-Cr was significantly elevated compared with a control population with a similar underlying diagnosis. However, the mean response to PMMA was significantly ($p<0.025$) reduced at follow-up compared to prerevision, while the response to Co-Cr continued to increase. Essentially all revision patients showed a marked improvement in pain, joint motion, and function at follow-up compared to pre-revision. No significant changes in the proliferative responses to UHMWPE or Ti-6-4 were seen in either the primary or the revision surgery populations. IL-1 levels in culture supernatants from cells stimulated with PMMA were significantly elevated compared with culture supernatants from cells stimulated with other biomaterials. Although the follow-up IL-1 levels were higher in primary patients and lower in revision patients, these results did not achieve statistical significance. Similar findings were observed for TNFα levels in culture supernatants; however, TNFα levels were very low at both time points in the primary patients. IL-4 was not induced at a measurable level by stimulation with biomaterial material particles *in vitro*. γIFN levels were detectable in response to stimulation with either PMMA or UHMWPE in the revision patient population, and γIFN levels in response to UHMWPE were significantly lower ($p<0.05$) at follow-up compared with revision surgery.

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Cellular proliferation and cytokine responses to polymethylmethacrylate particles in patients with a cemented total joint arthroplasty. Chadha HS, Wooley PH, Sud S, Fitzgerald RH. Inflamm Res 1995:44:145–51.

The immune response to implant materials. Wooley PH, Nasser S, Fitzgerald RH. Clin Orthop 1996:326:63–70.

[230] BIOCHEMICAL ANALYSIS OF SYNOVIAL ACTIVATION IN JOINT DYSFUNCTION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A52-7RA)*

No report was received for this issue.

[231] AN IN-VIVO MODEL FOR CARTILAGE REGENERATION

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PURPOSE—The reason for this study is to evaluate the potential for development and maturation of cartilage or cartilage-like tissue on an articular surface *in-vivo*, with the study joint allowed full mobility.

METHODOLOGY—The model for this project is the articulating surface of the dog patella. The joint in this animal was selected for the early phase of our investigations because the mechanical stresses upon the dog patellae are very large, much like the human counterpart. Also, this model provides sufficient material for the extensive histologic, biomechanical, and chemical studies required to evaluate the tissue which grows on the subchondral bone surface after all normal cartilage has been removed. The uncovered subchondral bone surface on the experimental patella is prevented from coming into contact with the femur by inserting high density, polyethylene spacers. Thus, a shielded space is created in the moving joint which allows new tissue to grow in an otherwise normal joint where mechanical stress will will not damage the new tissue.

PROGRESS—The pilot project has been completed with very promising results. That is, the tissue grew to completely cover the experimental patellae, while little or no tissue grew on the control patellae the surface of which was not shielded from mechanical stresses. The model was further refined in this second phase of study, so that there is a high degree of successful growth of tissue which completely covers the experimental subchondral surface and grows to a thickness equal to the height of the shielding devices.

RESULTS—To date, histologic examination has confirmed the presence of 2–3 mm thick fibrocartilagenous tissue on the subchondral bone surface. Biomechanical analysis has generally shown that the new tissue is much softer than normal cartilage. Chemical analysis is in process on the available specimens.

FUTURE PLANS—Two more steps are planned. Once phase two has been completed, and we have a good understanding of the nature of the new tissue and the rate at which it grows, we will try to manipulate it. First, we will remove the shielding devices. This will reintroduce mechanical stress so that we can study its effect upon the new tissue. Second, we plan to try to modify the new tissue further by introducing growth factors such as TGF, bFGF, and IGF-1.

[232] PRECONDITIONING AS A TECHNIQUE TO MINIMIZE TOURNIQUET-INDUCED MUSCLE INJURY

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Sponsor: *Foundation for Sports Medicine Education and Research, Rosemont, IL 60016*

PURPOSE—Tourniquets are frequently applied in extremity surgery to minimize blood loss and to improve surgical field visualization. Unfortunately, a degree of risk is associated with the ischemic period experienced by the limb during tourniquet application. The pupose of this research is to develop a methodology to minimize the risks associated with the use of tourniquets during extremity surgery.

METHODOLOGY—Preconditioning is a technique which consists of a brief period of ischemia (5–10 min), followed by reperfusion for an equal amount of time before the prolonged ischemic episode. Our research regarding this technique includes three incremental steps which address immediate and postrecovery effects in an animal model through clinical application during arthroscopic surgery.

PROGRESS—The intraoperative effects of muscle preconditioning have been investigated in a cat model where the medial gastrocnemius muscle strength is tested during and immediately after tourniquet application. Our results show that preconditioned muscles maintain a significantly higher ($p<0.005$) ability to contract 1 hour after tourniquet application.

In the second phase of our research, the postrecovery effects of muscle preconditioning are presently being investigated in a cat model where medial gastrocnemius muscle strength is tested 48 hours after a 2-hour ischemic episode. Results are pending statistical analysis.

Finally, a prospective, randomized study is being developed to assess the effect of preconditioning on the leg muscles of arthroscopy patients.

[233] VERMONT REHABILITATION ENGINEERING RESEARCH CENTER FOR LOW BACK PAIN

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PURPOSE—The Vermont RERC is committed to improving employability of people with back disorders through basic and applied research and information services. Activities include device design and development, clinical and workplace intervention, and a wide range of information services and activities.

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.

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 and some researchers believe that vibration exposure can damage the lumbar spine. The research team has designed a simple, low-cost vibration assessment tool to measure workplace vibration and collect research data.

Project 4. Manual Material Handling. Lifting characteristics are studied to determine whether they distinguish between experienced and inexperienced lifters. Accommodations for workers who 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 work environments. A resulting Expert System will help both to prevent injuries and specify accommodations.

Intervention Studies.

Project 6. A Comparative Study of Exercise Programs. This project compares an exercise program that address physical signs and symptoms with one that does not.

Project 7. Evaluation of an Assistive Device for Drivers. A backrest that provides lumbar continuous passive motion 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. The Information Services Division comprises a variety of activities in information and referral, publications, education and training, and public relations. The Center offers assistance in locating programs and provides bibliographic and fact-finding services. 1-800-527-7320 (voice/TDD).

RECENT PUBLICATIONS FROM THIS RESEARCH

Early prediction of chronic disability after occupational low back injury. Hazard RG, Haugh LD, Reid S et al. Spine 1996:21(8):945–51.

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Field measurements of seated vibration. Huston DR, Choukalos C, Tranowski JT, Weisman J. In: Automotive design advancements in human factors: improving drivers' comfort and performance. Detroit MI: Society for Automotive Engineers, 1996.

Classification scheme for acute and subacute low back pain. Moffroid M, Haugh L. Ortho Phys Ther Clin N A 1995:4(2):179–92.

[234] PRESSURE-VOLUME CHARACTERISTICS OF THE INTACT AND DISRUPTED PELVIC RETROPERITONEUM

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Sponsor: *None listed*

PURPOSE—Hemorrhage has been identified as a major cause of mortality in pelvic fractures. Control of bleeding in hypotensive patients by direct ligation, angiographic embolization, pelvic packing, and acute external fixation has been advocated. The acute application of an external fixator allows the orthopedic surgeon to reduce pelvic volume and reduce bleeding fractures to effect tamponade. Assumed in this therapy is that the pelvis represents a closed space. This is clearly not true anatomically. However, the premise may hold functionally. This study was designed to explore the relationship between pressure and volume in the intact and disrupted pelvic retroperitoneum.

METHODOLOGY—Open book pelvis fractures (Tile type B-3) were created in intact cadaveric specimens using a hydraulic mechanical testing machine. Pressures within the pelvic retroperitoneum were measured using an arthroscopic infusion pump with a pressure transducer. Measurements were made in the intact and after pelvic fracture, both with and without external fixation applied. In a subset of specimens, pressures were also recorded after a laparotomy at the end of the experiment.

PROGRESS—The study suggests that low pressure venous hemorrhage may be tamponaded by an external fixator, given enough volume is present in the pelvic retroperitoneum. However, external fixation may not generate sufficient pressures to stop arterial bleeding. In addition, the pelvic retroperitoneal hematoma may not generate sufficient pressure to tamponade bleeding. Finally, we were able to determine the force required to create the open book pelvis fracture: 3481 N.

RESULTS—Cannulation and rupture of the external iliac vein allowed controlled flow of fluid into the undisturbed disrupted retroperitoneum and measure pressures. Large volumes of fluid (20 liters) could be infused at pressures not exceeding 35 mm Hg. In the intact retroperitoneum, pressures rapidly rose to 30 mm Hg on average, with only 5 liters being infused. Depending on the volume of fluid in the retroperitoneal space, external fixation to close the pelvic volume increased pressures from 3 mm Hg at low volumes to 11 mm Hg at higher volumes. Laparotomy resulted in a precipitous pressure drop to 11 mm Hg from 35 mm Hg. Pressures increased 0.9 mm Hg/L and, with the external fixator in place, the pressure in the retroperitoneal space rose at a rate of 1.25 mm Hg/L.

B. Hip Implants

[235] FATIGUE STRENGTH OF COMPOSITE FEMORAL COMPONENTS FOR HIP ARTHROPLASTY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A670-2RA)*

PURPOSE—The purpose of this research is to investigate how the design of a fiber-reinforced, polymer-composite femoral component influences its fatigue behavior, and how composite femoral components should be mechanically tested *in vitro* to closely simulate *in vivo* stress-states. The goal of this research program is to develop the necessary technology base to enable low stiffness/high strength composite femoral components to be confidently designed and tested for clinical use with the potential for reducing stress-shielding-induced proximal bone resorption following hip arthroplasty. The reduction of bone resorption following arthroplasty should promote longer femoral component life and significantly reduce complications in revision surgery.

METHODOLOGY—This research is being undertaken in three interrelated phases. In Phase 1, a detailed anatomic 3-D computer model of the proximal femur with an *in situ* composite femoral component is being developed and utilized to investigate relationships between the design of composite femoral components and fatigue damage initiation and propagation within the components under simulated in vivo loading conditions. In Phase 2, similar numerical modeling and analysis techniques will be applied to determine the proper experimental parameters to be used in Phase 3 for actual fatigue testing of composite stems for model verification. Test parameters and fixture design will be studied to provide component stress states during fatigue testing which closely match those expected *in vivo*. Once the proper experimental parameters have been established, composite femoral components will be fabricated and fatigue tested in Phase 3. Experimental results will be compared to the numerical models for model verification. Results are expected to provide a detailed understanding of how composite structural design will influence fatigue behavior under simulated *in vivo* loading conditions. This knowledge is essential to enable composite femoral component technology to be developed for successful clinical application toward the goal of improving hip joint replacements.

PROGRESS—As planned for the first year of the program, a detailed 3-D computer model of the proximal femur/femoral-component structure is being currently developed along with numerical methods for fatigue performance evaluation. In addition, preparations are being made for the fabrication of composite femoral components for subsequent fatigue testing. Loading simulation representative of the activities of heel-strike, mid-stance, toe-off, and chair-rise/stair-climb will be applied to the model and femoral component fatigue performance will be predicted as a function of applied loading and component internal design.

FUTURE PLANS—The long-term objective of this research program is to develop the necessary technology base to enable the benefits offered by low-stiffness/high strength composite femoral components to be able to be clinically utilized in order to benefit both the VA and nonVA patient population requiring hip joint replacement and revision surgeries. The first long-term milestone will be to establish the design and testing principles which will be developed from this 3-year study. Subsequent milestones will be the incorporation of these design and test strategies into actual practice such that fatigue resistant compliant composite femoral components can be confidently fabricated, tested, and clinically used with the potential for improving hip joint replacement life and ease in surgical revision.

RECENT PUBLICATIONS FROM THIS RESEARCH

Long-term compressive property durability of carbon fibre-reinforced polyetheretherketone composite in physiologic saline. Zhang G, Latour RA Jr., Kennedy JM, Schutte HD Jr., Friedman RJ. Biomaterials 1996:17:781–9.

[236] 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 #A473-3DA)*

PURPOSE—The overall objective of this study is to assess the long-term feasibility of porous coating as a mechanism for fixing orthopaedic prostheses to bone. Additionally, the role of design and material on the performance of these prostheses is being determined through this analysis.

METHODOLOGY—This examination of clinically retrieved, porous-coated hip and knee prostheses will assess the importance of such variables as material composition, design, location of porous coating, pore size, and surface roughness on the resulting interface between the prosthesis and bone. The study will address the issues of stress shielding, ion release, and wear debris formation and, where possible, clarify causal relationships with prosthesis parameters.

Retrieved prostheses are fixed in formalin, examined macroscopically, and graded for wear, corrosion, fretting and tissue adherence. The metal components are mapped for both soft and hard tissue apposition prior to being embedded, cut into standard histological sections, and stained. Serial sections permit the assessment of bone resorption or of stress shielding for prostheses that are retrieved intact as postmortem specimens. The polyethylene bearing surfaces are graded for damage and defects and then sectioned on the microtome to determine the degree of polyethylene consolidation.

PROGRESS—One major focus this year continues to be the search for the source of failures of polyethylene acetabular and tibial knee bearings. Our previous research described the presence of a white band that followed the contour of thin sections of many of the polyethylene components and which was separated from the surface of the prosthesis by a clear zone of polyethylene approximately one millimeter thick. More than 90 percent of the retrieved hip and knee components which presented cracking and delamination revealed the white band upon sectioning. However, not all of the components with the white band revealed severe wear.

Further analysis of the components using Fourier Transform Infrared Spectroscopy (FTIR) revealed that the white band zone was an area of high oxidation that occurred subsurface in the samples but was not found in bar stock, unsterilized components, nor in many components produced more than 20 years ago. The rosetta stone for this search came in the form of two identical acetabular components, both of which were produced by the same manufacturers from the same bar stock. Upon sectioning these 14-year-old components, one revealed the white band and the other did not. Neither component had ever been implanted and therefore *in vivo* environment and stress were eliminated as potential sources of the band.

However, the component that showed the white band had been gamma sterilized in air, while the other had not. Examination of gamma-sterilized and Ethylene Oxide sterilized retrieved components revealed the presence of the white band only in gamma-sterilized components and only in those components which had been retrieved more than 3 years post gamma sterilization in air. Further studies revealed that there was little damage from irradiation at the time of sterilization and that dam-

age increased as the oxidation of the components increased with time after sterilization. Components of similar age, which are sterilized in ethylene oxide revealed no such embrittlement over time.

Mechanical testing of thin sections of both hip and knee components revealed that the components with the white band were significantly weaker and less ductile than components without the white band. Fatigue testing of through-thickness sections of knee components documented a significant reduction in the fatigue-resistance of components with a white band. Fatigue failure in these tests reproducibly initiated in the white band region.

Over the last year we have expanded the number of components which we have tested and continue to observe the correlation between extent of damage of the components with the presence of high oxidation. This oxidation is reproducible in samples which are freshly gamma sterilized in air and then aged in an environment with increased temperature and oxygen concentration. All of the major orthopaedic implant manufacturers have moved away from the technique of gamma sterilization in air and are now using alternatives including ethylene oxide, gas plasma, and gamma sterilization in inert atmospheres. Our testing, using the accelerated aging technique reveals that the use of sterilization in an oxygen-free environment reduced the level of oxidation by about 50 percent. The use of low dose radiation also reduced the level of oxidation by approximately 50 percent. The lowest oxidation levels were observed in components sterilized with EtO and gas plasma techniques.

RECENT PUBLICATIONS FROM THIS RESEARCH

Impact of gamma sterilization on clinical performance of polyethylene in the hip. Sutula LC, Collier JP, Saum KA, Currier BH, Currier JH, Sanfor WM et al. Clin Orthop 1995:319:377–89.

Impact of gamma sterilization on clinical performance of polyethylene in the knee. Sutula LC, Collier JP, Saum KA, Currier BH, Currier JH, Sanford WM et al. J Arthroplast 1996:11(4)28–40.

[237] SOFT TISSUE ATTACHMENT TO PROXIMAL FEMORAL ALLOGRAFTS FOR HIP REVISION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A548-2RA)*

PURPOSE—The purpose of this research is to evaluate the long-term differences between three methods of gluteal muscle reattachment to a proximal femoral reconstruction using an allograft/prosthetic composite in an *in vivo* canine model. The goal of the research is to identify the optimal method of gluteal muscle reattachment that will increase functional limb use and long-term outcome of patients with total hip replacements and revisions.

METHODOLOGY—Forty-eight dogs will undergo unilateral hip reconstructive surgery including replacement of the proximal 25 percent of the femur with an immunologically mismatched, size-matched allograft. The gluteal muscles will be attached to the allograft by one of three methods: 1) suturing host tendon to allograft tendon; 2) attaching the host greater trochanter with the gluteal tendons intact to an allograft (with a trochanteric osteotomy) by means of a cable grip system; and 3) creating a cortical half-shell of the host proximal femur with the gluteal tendons intact and securing the half-shell to the allograft/prosthesis composite with full cerclage wires. Each method will be performed on 16 dogs with 8 being euthanatized after 9 months and the remainder at 18 months for histologic and biomechanical testing. During the study, serial radiography, densitometric analyses, and weight-bearing analyses will be performed bimonthly. Differences among the reconstructive methods for mechanical parameters, radiographically determined union, new bone formation, porosity and unlabeled bone percentage, weight-bearing parameters, and bone mineral density will be determined with analysis of variance and, when necessary ($P<0.05$), a post hoc t-test.

PROGRESS—The surgeries were completed on all dogs by June 1996. Rechecks are progressing as scheduled. The 9-month group of dogs will be sacrificed during January and February 1997, and the final dog of the 18-month group will be sacrificed early September 1997.

PRELIMINARY RESULTS—All dogs are using the operated limb to some degree. Subjectively, the tendon-to-tendon group and the half-shell group were weight bearing more quickly than the trochanteric osteotomy group. However, a preliminary analysis of the force plate data did not show a significant difference in vertical ground reaction force between the three groups. One dog in the tendon-to-tendon group has a fractured, but minimally displaced greater trochanter and one dog in the cable grip group has a comminuted fracture of the allograft. Both dogs are using the affected limb, but are not fully weight bearing.

FUTURE PLANS—The bimonthly rechecks will continue as scheduled until euthanasia. Data from the bimonthly rechecks will be analyzed as it is accrued. All dogs will remain in the study unless there is catastrophic failure of the implant with uncontrollable pain and lameness.

C. Knee Implants

[238] EFFECT OF COMPONENT PLACEMENT ON THE PATELLOFEMORAL JOINT WITH TOTAL KNEE ARTHROPLASTY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A859-RA)*

PURPOSE—This research is quantifying the effects of knee joint replacement component alignment on patellofemoral joint kinetics and general knee kinematics. The goal is to increase long-term survival of knee replacements by 1) determining the required accuracy in the placement of these components and 2) evaluating joint replacement component selection.

METHODOLOGY—Cadaveric knee specimens are mounted in a knee simulator after careful specimen preparation. After ascertaining the integrity of the knee tissues so that no orthopaedically unsound specimens are used, the proximal half of the femur and distal half of the tibia are removed. Through a medial incision at the knee, the retinaculum is carefully scribed with ink lines at 10 mm increments. Knee arthroplasty is performed with components from Zimmer, Inc., using standard sizing techniques and recommended instrumentation. The femur is overcut by 6 mm so that specially designed and accurately machined plates can be inserted between the femur and femoral component. These plates secure the femoral component to the osseous surface and allow precise 2.5° changes of femoral component alignment to be accomplished. The patella is cut in the recommended way, removing the articular surface. After recording the native thickness and locating the geometric center of the patella, four 5 mm-diameter holes are drilled through the patella, and a loadcell is mounted on the anterior patellar face. The loadcell supports four rods that pass through clearance holes in the patella. The rods, in turn, rigidly attach to a support plate on which the patellar prosthesis is mounted. The support plate has holes for fixation of the patellar prosthesis at desired lateral-medial positions. Once the patellar prosthesis is attached and the rods have been adjusted to restore the native patellar thickness, the joint capsule is closed with suture and by aligning the scribed lines. A nylon strap is sutured to the central quadriceps tendon for attachment to the actuator of the

knee simulator, and the knee is placed in the simulator.

A complete kinetic record of the patellofemoral joint behavior is recorded as well as a record of all tibiofemoral kinematics. A three-camera video system tracks markers rigidly fixed to the patellar loadcell, the femur, and the tibia so that all relative movement at the joint is quantified. The video system sends a synchronizing signal to a computer which records the patellar loads. Upon starting the recording equipment, the actuator of the knee simulator drives the knee through a flexion-extension cycle of 105°. The knee components are repositioned after each test until all desired alignments are studied.

PROGRESS—Nine specimens have been tested with all combinations of femoral external rotation of 0°, 2.5°, and 5° and patellar button placement at the geometric center and at 3.75 mm medial to the geometric center. The data have been completely processed for seven of the nine specimens and processing is underway for the remaining two.

PRELIMINARY RESULTS—The combination of femoral component external rotation with patellar button medialization reduces the lateral-medial shear force on the patella. This result indicates that this combination would reduce patellar subluxation. Furthermore, all combinations of small changes in femoral and patellar component alignment provide generally very good patellar tracking. A preliminary study found generally poor patellar tracking after much larger deviations in component placement. Thus, the previous study and the current study begin to define limits of stability with respect to component alignment for this Zimmer prosthesis and show that the prosthesis employed in the study had a fairly robust stability window.

FUTURE PLANS—Posterior cruciate retaining and sacrificing components will be tested in future experiments. These experiments will include variation in tibial component alignment.

RECENT PUBLICATIONS FROM THIS RESEARCH

Effect of component placement on the patellofemoral joint. Zhang AX, Miller MC, Rubash HE. Advances in Bioengineering 1996, Proceedings of the American Society of Mechanical Engineers.

Patellofemoral joint kinetics before and after MGII arthroplasty. Miller MC, Zhang AX, Berger RA, Crossett L, Rubash HE. J Biomech Eng. In press.

D. Arthritis

[239] IMPACT INDUCED POST-TRAUMATIC ARTHRITIS MODEL

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PURPOSE—Post-traumatic arthritis is a rapid joint degeneration which occurs as a result of a traumatic event. The purpose of our research is to develop a model to predict the impact stress magnitudes which result in post-traumatic arthritis.

METHODOLOGY—An impact tower is used to guide a falling mass, which delivers a blow of specific energy to an impactor instrumented with strain gages to record force. Bone cement is used to create a custom impactor to apply uniform stress over the impacted area. The area of impact is measured by making an imprint onto a sheet of paper with a wax marker. Accurate estimation of impact force and area lead to an estimate of impact stress, believed to be the most important factor in predicting the occurrence of post-traumatic changes.

PROGRESS—To date, an *in vitro* rabbit model was used to develop the impact tower instrumented to record impact force, along with the technique to fabricate cus-

tom impactors which provide uniform stress to a given area of the rabbit's femoral condyle. A pilot *in vivo* study was performed to show that histochemical changes associated with the early development of arthritis could be found in rabbits six weeks following an impact. Currently, we are housing 36 rabbits whose knees have been impacted. These rabbits will be sacrificed in 1 year; histology will be obtained with the aims of documenting changes in the impacted femoral cartilage.

[240] THE INFLUENCE OF KNEE EXTENSOR STRENGTH AND PAIN ON STRIDE CHARACTERISTICS IN WOMEN WITH RHEUMATOID ARTHRITIS

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PURPOSE—The purpose of this study was to establish the relationship between isometric knee extensor strength, knee pain, and stride characteristics in women with rheumatoid arthritis (RA).

METHODOLOGY—Eight women with the diagnosis of RA and the clinical complaint of knee pain participated in the study. These subjects underwent stride analysis during free speed walking. Temporal-spatial stride characteristics were recorded with the Stride Analyzer System. (B&L Engineering, Div of Pinsco Inc, Santa Fe Springs, CA 90670). Knee pain was assessed before testing, after walking, and after isometric torque testing using a visual analog pain scale (Pre, Post-A, Post-T). A Lido isokinetic dynamometer (Loredan Biomedical Inc, Davis, CA 95617) was used to determine maximal isometric knee extensor torque for each subject. The strongest predictors of velocity, cadence, and stride length were determined with stepwise regression analysis. The relationship between knee pain and knee extensor strength was also determined using stepwise regression.

PRELIMINARY RESULTS—Free ambulation velocity of this group was close to half of normal velocity at 43.0±17.2 m/min (54 percent N). Mean knee extensor torque was markedly reduced to 5.0±1.8 KgM (37 percent N). The average pain value, marked on a line and taken as a percentage of the total line distance was 31.5±28.1 percent of the maximum pain value. Knee extensor torque was the only predictor of free ambulation speed (r=0.91) and cadence (r=0.80). Knee extensor strength was the strongest predictor of stride length (r=0.89). Pre-test pain values were the best predictors of knee extensor torque (r=0.90).

FUTURE PLANS—Recruitment and testing of additional subjects with RA will continue until 15 subjects have been tested. Data analysis will continue to determine the relationship of other lower extremity strengths (hip extension and plantar flexion) on the temporal-spatial stride characteristics in this population.

IMPLICATIONS—These data demonstrated the importance of strength in this population and suggested that strengthening lower extremity musculature may lead to their functional improvement.

[241] LONG-TERM FOLLOW-UP OF THE RESULTS OF TOTAL MENISCECTOMY AND SECONDARY OSTEOARTHROSIS

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Sponsor: *Tayside Health Board, Vernonholme, Riverside Drive, Dundee*

PURPOSE—This research concentrates on a cohort study of patients undergoing total meniscectomy on average 30 years ago, all patients were under 18 at the time of surgery.

METHODOLOGY—Cohort of 63 patients have been intensively studied with functional assessment, clinical examination, radiological assessment, magnetic resonance imaging, and biomechanical and biochemical investigations.

PROGRESS—Two presentations have been given on the biochemical aspect of this work regarding nitric oxide activity in secondary osteoarthrosis. The radiological follow up is complete, biomechanical assessment using a 3-dimensional gait analysis system has been carried out with preliminary results available. Further biochemical assays are being performed at present on samples of synovial fluid, serum, and urine from the patients and their controls. Preliminary scoring of MRIs has been carried out and internal observer errors are now being calculated for this.

FUTURE PLANS—Data arising from the various aspects of the studies are being analyzed statistically.

E. Low Back Pain

[242] DEVELOPMENT OF A CLINICAL DATABASE FOR THE BACK ANALYSIS SYSTEM

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B748-RA)*

PURPOSE—A comprehensive database of surface electromyographic (EMG) parameters is needed to improve the classification of muscle impairments based on Back Analysis System (BAS) test results. EMG parameters from a standardized test protocol are compared to a normative database to identify an impairment classification profile for the subject. Our efforts to establish a comprehensive database for specific clinical populations with low back pain (LBP) will help to identify the role of muscle impairment in these syndromes and provide a more accurate assessment procedure for future applications.

METHODOLOGY—Amplitude and spectral information from six EMG electrode sites are processed and stored into a database for each of several sustained isometric contractions specified by the BAS protocol. Other parameters, such as patient diagnosis, physical characteristics, occupation, and back muscle strength are also

recorded. Data acquisition is conducted at several clinical sites in the Boston area as well as at the NeuroMuscular Research Center.

PRELIMINARY RESULTS—This year we have added over 76 new subjects to our database. Many of these subjects were drawn from an elderly population, some with significant co-morbidity or significant structural spinal organic disease such as ankylosing spondylitis. We have measured the extent to which age, gender, and physical characteristics influence the EMG parameters used to classify impairments. The relational database structure for providing a framework for data storage, retrieval, and clinical report generation has been specified and software implementation is in progress. We have also developed a procedure in software to detect and correct EMG data before it is permanently added to the database. As a result, we are significantly closer to realizing the long-term goal of having a comprehensive system available for clinical use.

[243] BACK EXERCISE PRESCRIPTION AND IMPLEMENTATION BY SURFACE ELECTROMYOGRAPHIC PROCEDURES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B2029)*

PURPOSE—Although there is a consensus among clinicians and researchers in favor of exercise for the conservative management of low back pain (LBP), there are few if any specific protocols that have undergone scientific scrutiny for treatment efficacy. There is a need to develop back exercise procedures that are firmly based on objective, noninvasive systems of muscle impairment classification. The purpose of this study is to develop an LBP exercise protocol and procedure for restoring muscle impairments classified by a device known as the Back Analysis System (BAS). The system is able to identify and monitor muscle deconditioning and pain-related muscle imbalances associated with LBP. The aim of the study is to advance the technique to include the prescription and implementation of muscle-specific, individualized exercises to improve strength and endurance while restoring normal muscle function.

METHODOLOGY—We will recruit a small number of nonimpaired subjects without a recent history of LBP or previous spinal surgery and an equal number of subjects with nonspecific, sub-acute LBP. One half of the subjects from each group will be studied to develop and evaluate exercises to be conducted in and out of the BAS device. Two or three subjects from each group will have simultaneous fine wire and surface EMG measurements conducted during the exercises to validate the specificity of the exercise. The remaining subjects from each group will be recruited to evaluate the ability of a 2-channel, portable EMG system to facilitate the exercise goals.

In the second phase of the study, a large number of patients with sub-acute, nonspecific LBP will be recruited at the time of their referral to physical therapy. Subjects will be randomly assigned in equal numbers to either the experimental exercise, general strengthening, or control group. All subjects will be tested at baseline and again at the completion of their treatment at 6 weeks. Questionnaires and physical therapy assessments will be administered at each of the BAS test sessions to assess pain, disability and other signs of physical impairment associated with LBP. Follow-up testing will be conducted at 3 and 6 months from the date of discharge.

[244] DEVELOPMENT OF EMG PARAMETERS REFLECTING THE FUNCTION OF LUMBAR BACK MUSCLES

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PURPOSE—An interaction between the activation of different muscles of the lower back during a sustained contraction may be monitored as changes in spectral properties of the surface electromyographic (EMG) signals. Previous analysis of surface EMG signals assessed with the Back Analysis System (BAS) has mainly focused on the behavior of the initial median frequency (IMF) and the rate of decrease of the median frequency (MF-Slope) during fatiguing contractions. Results have suggested the presence of spectral imbalances between muscles of the lower back in patients with lower back pain (LBP). In this project, new parameters are being investigated that further describe these imbalances. Discrimination scores between different categories of patients with LBP and nonimpaired subjects should improve as a result of this study.

METHODOLOGY—Cross-correlation techniques were applied to extract parameters from the root mean square (RMS) of the surface EMG signal. The behavior of ratios between spectral properties in contralateral as well as ipsilateral pairs of muscles of the lower back were also investigated. Parameters with clinical relevance describing segmental imbalances and bilateral "compensations" in spectral parameters were introduced. The behavior of these parameters was monitored using the BAS during isometric contractions at 40 percent of maximal voluntary contractions (MVC) in a group of 96 LBP patients and 23 controls.

PRELIMINARY RESULTS—Results for nonimpaired subjects indicate periodically occurring positive cross-correlations between contralateral muscles of the lumbar back that become more pronounced during the contraction. This behavior appeared to be more prominent in the nonimpaired than in LBP patients, and it was not present between simulated EMG signals or between EMG signals from different subjects. We are presently developing methods to extract parameters that quantify this behavior. A discriminant analysis using RMS and MF ratio parameters successfully classified 81 percent of the subjects in the study. Overall, patients displayed more segmental imbalances and fewer compensations. A similar behavior of these parameters was seen in test protocols using several different low level force contractions.

[245] ALTERATIONS IN EMG SIGNAL CHARACTERISTICS COINCIDING WITH LOW BACK PAIN

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PURPOSE—A muscular injury is commonly followed by acute inflammation and pain. In a situation where several muscles act as synergists, the central nervous system may, through feedback mechanisms, redistribute the activation level of muscles at and/or around an injured site to decrease pain and risk of further injury. The aim of this project is to study the activation of muscles in the lumbar back in categories of subjects with and without pain in an attempt to better understand muscular function in the presence of acute pain. Such information may assist the

clinician in decisions regarding intervention and treatment for patients with acute low back pain (LBP).

METHODOLOGY—LBP patients with asymmetric pain patterns in the lumbar back at the time of testing, as well as nonimpaired subjects with muscular LBP induced through strenuous physical exercise (delayed onset muscle soreness), were tested in the Back Analysis System (BAS) at different low level isometric contractions. Surface electromyographic (EMG) signals collected from six muscle sites of the lumbar back were analyzed and spectral symmetry parameters were extracted and compared between pain and nonpain conditions. Magnetic resonance images (T2-weighed echo planar MRI) were obtained from pain and nonpain muscle sites.

PRELIMINARY RESULTS—Significant spectral EMG imbalances commonly coincided with the site of pain both in normal subjects with induced pain as well as in back pain patients. Pain site specific changes in T2-weighed MR image intensity consistent with muscular damage were also observed. Our results suggest that the presence of muscular back pain, in these categories of subjects, alters activation characteristics in a way specific to the location of the pain, and that these alterations are detectable with surface EMG techniques.

[246] MUSCLE PERFORMANCE IN THE BACK ANALYSIS SYSTEM COMPARED TO LIFTING TASKS

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PURPOSE—Health care providers are seeking more objective ways of measuring functional limitations due to impairments of the musculoskeletal system. Surface electromyographic (EMG) techniques, such as the Back Analysis System (BAS), provide measures of impairment that may be useful in assessing functional ability. For instance, back muscle impairment may limit the ability to function during tasks requiring forceful or repetitive trunk extension. We completed an earlier pilot study that demonstrated the feasibility of applying BAS techniques to tasks involving repetitive lifting. We are now concentrating on developing new signal analysis procedures for processing the EMG signals during such dynamic activities.

METHODOLOGY—Surface EMG signals obtained from earlier pilot studies were reanalyzed using time-frequency transformations. Transformations were selected according to their ability to limit cross-terms that result when frequency spectral parameters are calculated from signals that are nonstationary. EMG signals from extensor muscles of the trunk and legs were monitored during isometric tests in the BAS and during repetitive trunk extension in a lifting device. Changes in the median frequency and amplitude of the EMG signals were analyzed to compare the characteristic patterns of fatigue and muscle activation for the two tasks.

PRELIMINARY RESULTS—Time-frequency plots of the EMG data following transformation provided a new way of measuring the compression of the power frequency spectrogram that occurs during muscular fatigue. Comparisons between data collected from sustained isometric contractions in the BAS and repetitive contractions in the lifting device indicated differences in the rate and distribution of fatigue among the different paraspinal muscles. Further studies are in preparation to compare test results from patients with low back pain to nonimpaired controls.

[247] EVALUATION OF LOW BACK PAIN TREATMENT OUTCOME

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PURPOSE—Providers of medical care are demanding that treatment regimens for low back pain (LBP) be evaluated on the basis of quantitative, objective outcomes. We have developed a surface electromyographic (EMG) procedure to evaluate back muscle function. The procedure is implemented by a precommercial, prototype device referred to as a Back Analysis System (BAS). A longitudinal study has been underway to assess the efficacy of this technique for monitoring treatment progression during LBP rehabilitation. The results from this work will determine the most effective way of incorporating this technique for clinical use.

METHODOLOGY—We have focused our research on LBP injury in the workplace. Patients with chronic and subacute LBP who are participants in either multidisciplinary work-hardening or work-reconditioning programs were recruited. These patients were typically in a structured rehabilitation program where a number of physical, psychological, and functional parameters can be routinely recorded. Patients are tested in the BAS at baseline and again at fixed time intervals into their rehabilitation program. Clinical outcome results are correlated with the BAS measurements.

PRELIMINARY RESULTS—We have recently completed BAS testing at the Center for Occupational Rehabilitation at the Braintree Hospital and at the private orthopedic practice of Howard Taylor, MD. Preliminary results indicated a significant increase in muscle activation at the L1 and L2 muscle sites and increased resistance to fatigue in the L5 muscle site following treatment. Standardized pain intensity scores and disability scores were significantly correlated with EMG median frequency and force data. Differences in EMG impairment classifications following rehabilitation were also significantly correlated with standardized disability scores. Preparations are underway for continuing this research at other referral centers for work-related back injuries.

RECENT PUBLICATIONS FROM THIS RESEARCH

Spectral EMG assessment of back muscles in patients with LBP undergoing rehabilitation. Roy SH, De Luca CJ, Emley M, Buijis R. Spine 1995:20(1):38–48.

[248] NORMATIVE DATABASE FOR LOW BACK PAIN EVALUATION IN BLUE COLLAR WORKERS

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PURPOSE—In order to better evaluate muscle performance in patients who have work-related low back pain (LBP) injury, we have accumulated a normative database that encompasses a broader spectrum of occupations having different baselines of back muscle capability. Our current normative database evolved from a study begun several years ago in which there were limited numbers of men and women representing blue collar occupations. We have recently extended the normative database to encompass the segment of the working whose occupations demand extensive daily use of their back muscles. With the inclusion of these data, we expect to be better able to identify muscle impairments in patients from similar occupations.

METHODOLOGY—We are currently conducting normative BAS tests at a number of sites, including the NeuroMuscular Research Center, the orthopedic practice of Dr. Howard Taylor in Methuen, MA, and the Edith Nourse Rogers Memorial Veterans Hospital in Bedford, MA. The blue collar database to date consists of 90 male and female subjects between 18 and 65 years of age having a variety of occupations involving manual labor. Our relational database management software enables us to store and retrieve subject descriptors and electromyographic (EMG) parameter information. This allows us greater ease in retrieving data to evaluate subjects with similar occupational backgrounds.

PRELIMINARY RESULTS—The results of this study have been useful in our ongoing efforts to develop more accurate muscle impairment classification functions for patients with work-related LBP injuries. As a result, we are better able to generate clinical reports that categorize individuals into low back pain and normal groups for industrial applications. The results of this work have also extended our understanding of the extent to which the EMG parameters from a BAS test are influenced by such factors as the subject's age, gender, strength, and body size.

[249] PREDICTABILITY OF THE SUSCEPTIBILITY TO LOW BACK PAIN

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PURPOSE—This study is designed to determine if the development of low back pain (LBP) can be predicted on the basis of electromyographic (EMG) spectral parameters of lumbar muscles. Sweep rowers were targeted for this study because of their high incidence of LBP possibly linked to repetitive asymmetrical loading of their spine. We hope to be able to develop effective assessment procedures to screen individuals with a tendency toward back injury either in athletics or in the workplace.

METHODOLOGY—Back Analysis System (BAS) tests were conducted on the men's and women's crew teams from Boston University and Northeastern University during the spring and fall rowing seasons. To date, we have a database containing 340 assessments of BAS tests from 127 rowers, approximately 40 percent of whom have had at least one episode of LBP that has interfered with daily activities or rowing. We have examined a subset of the database consisting of 15 rowers with no prior history of LBP who developed LBP during the study interval. We have compared them to 15 rowers of similar athletic and physical characteristics who were pain-free.

PRELIMINARY RESULTS—The BAS test scores were entered into a two-group step-wise discriminant analysis procedure to determine the extent to which the EMG parameters could separate the rowers into two groups with and without a future onset of LBP. The analysis correctly classified 100 percent of the rowers who developed LBP and 87 percent that were pain-free. The discriminating EMG parameters from this analysis were predominantly measures of muscle fatigue recovery, the same as those identified in an earlier study. Further statistical analyses are being conducted to determine whether EMG results that are predictive of LBP development are associated with standard performance measures currently used by the coaches and athletes.

[250] THE QUANTIFICATION AND INTERPRETATION OF BACK MOTION AS AN EVALUATIVE TOOL IN LOW BACK DISORDERS

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PURPOSE—Low back disorders (LBD) are extremely common and limit the ability of millions of Americans to lead productive lives and engage in meaningful work. Impairment ratings of these conditions can vary by as much as 70 percent using current systems. Diagnoses and classification schemes are rarely based upon quantitative indicators, and we are unable to easily assess and diagnose LBD. Yet it is important to do so, in order that proper treatment can be administered and the risk of exacerbating the problem can be minimized.

METHODOLOGY—We performed a study to develop a means to quantify the extent of a LBD that is easy to use and can quantitatively "benchmark" the progress of a patient as he or she is exposed to different treatment modalities. This study observed the trunk angular motion features of 350 nonimpaired subjects as well as 350 patients experiencing chronic LBD. These subjects flexed and extended their trunks in five symmetric and asymmetric planes of motion. Based upon previous work, we believe that trunk motion provides a picture of the status of the trunk musculoskeletal system. Trunk motion is reflective of the recruitment pattern of trunk muscles and their usage recruitment intensity.

The trunk angular motion features of the low back disorder group were normalized relative to the nonimpaired subjects and used to evaluate the repeatability and reliability of trunk motion as a measure of trunk musculoskeletal status, to quantify the extent of the disorder, and to determine the extent to which trunk motion measures might be used as quantifiable means to assist in the classification of LBD.

PROGRESS—All subjects wore a triaxial goniometer on their trunks that documented the angular position, velocity, and acceleration of the trunk as they flexed and extended their trunks in each of five planes of motion. Trunk motions features were first normalized for subject gender and age. A two-stage, 8-variable model that accounts for trunk motion interactions was developed to classify the normal and low back injured subjects into one of 10 anatomic and symptom-based LBD classification categories. Using conservative cross-validation measures it was found that the stage-one, 8-variable model was able to correctly classify over 94 percent of the subjects as either nonimpaired or LBD, while the stage-two 8-variable model was used to classify the LBD patients into one of 10 LBD classification groups. This model correctly classified 70 percent of the subjects into the correct classification. In addition, we are currently performing an additional study to explore whether trunk motion information can be used to determine if one could quantify sincerity of effort of a nonimpaired or impaired subject.

RESULTS—We hypothesize that the motion-related parameters may relate to biomechanical or learned sensitivities to spinal loading. This study suggests that higher order trunk motion characteristics hold great promise as a quantitative indicator of the trunk's musculoskeletal status and may be used as a measure of the extent of a disorder as well as a measure of rehabilitative progress. Furthermore, once one considers the interactive nature of these trunk motion characteristics the model could assist in the diagnosis of LBD.

RECENT PUBLICATIONS FROM THIS RESEARCH

The classification of anatomic and symptom based low back disorders using motion measure models. Marras WS, Parnianpour M, Ferguson SA et al. Spine 1995:20(23):2531–46.

[251] USING NOISE AND CHAOS CONTROL TO CONTROL NONCHAOTIC SYSTEMS

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PURPOSE—Chaos control techniques constrain the output of a system by exploiting the system's extreme sensitivity to small perturbations. Previously, chaos control techniques have been limited to the control of chaotic systems. The objective of this study was to explore the possibility of using chaos control techniques, along with additive white noise, to control nonchaotic systems.

METHODOLOGY—In this study, we examined the nonchaotic Hénon map in its stable, period-4 regime. We used additive white noise to determine the dynamics of a chosen underlying unstable periodic orbit, and to move the system's trajectory into the neighborhood of the orbit so that control could be initiated. We then used chaos control techniques to compute and apply adaptive parameter perturbations to the system. These perturbations were determined and applied so as to constrain the system within the selected unstable periodic orbit.

PRELIMINARY RESULTS—We found that chaos control techniques, together with additive white noise, could be used to shift the output of the noise-free Hénon map from a stable high-period orbit to lower-order unstable periodic orbits. Importantly, control required no knowledge of the underlying system equations, and could be achieved using only small parameter perturbations. These novel developments open up a number of new, real-world applications for chaos control. For instance, our method may offer an efficient means for removing higher-order periodicities from the output of nonchaotic, experimental systems. From a physiological standpoint, this could be important, given that a number of pathological conditions are associated with the appearance of unwanted higher-order oscillations.

RECENT PUBLICATIONS FROM THIS RESEARCH

Using noise and chaos control to control nonchaotic systems. Christini DJ, Collins JJ. Phys Rev E 1995:52(6):5806–9.

[252] USING CHAOS CONTROL TO SUPPRESS A PATHOLOGICAL NONCHAOTIC RHYTHM IN A CARDIAC MODEL

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PURPOSE—Atrioventricular (AV) nodal alternans is a pathological cardiac condition characterized by a beat-to-beat alternation (period-2 rhythm) in AV nodal conduction time. The objective of this study was to explore the possibility of using chaos control techniques to suppress AV nodal alternans by stabilizing an underlying unstable period-1 rhythm.

METHODOLOGY—We examined an AV nodal conduction model in a regime where the AV nodal conduction time alternated on a beat-to-beat basis. After using additive white noise to learn the dynamics of the underlying unstable period-1 orbit, we used chaos control techniques to compute and apply adaptive parameter perturbations to the system. These perturbations, which were

applied to a variable which represents an experimentally accessible stimulation interval, attempted to suppress the alternans by stabilizing the underlying period-1 rhythm.

PRELIMINARY RESULTS—We found that chaos control techniques could be used to effectively suppress AV nodal alternans in the cardiac model. Importantly, control required no knowledge of the underlying system equations, and it could be achieved using only small parameter perturbations. Moreover, we demonstrated that these techniques are robust to imprecise measurements and experimental noise. These novel findings suggest that chaos control techniques may be useful for suppressing alternans in a clinical environment.

RECENT PUBLICATIONS FROM THIS RESEARCH

Using chaos control and tracking to suppress a pathological nonchaotic rhythm in a cardian model. Christini DJ, Collins JJ. Phys Rev E 1995:53(1):R49–52.

XII. Orthotics

[253] 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 (i) the temperature and humidity conditions with the use of an environmental chamber and (ii) 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. 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—The software for the compliance monitor, transfer module, and IBM host computer has been developed and tested. The new compliance monitor prototype as well as the new design of the transfer module are undergoing final testing. All components for the construction of compliance monitors have been ordered and the layout of the final circuit board is currently under way. The FSR sensors have been ordered and a more reliable connection between the sensors and wires is being researched.

Design of the environmental chambers is ongoing. All major components have been ordered, including the freezers, temperature controllers, temperature sensors, humidity sensors, and miscellaneous electronics. An enclosure for the signal conditioners and electronics is being designed. Recruitment of volunteers for device testing is ongoing.

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.

[254] ORTHOTICS DESIGN WITH ADVANCED MATERIALS AND METHODS: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #A94-816PA)*

PURPOSE—While other orthotics challenges might be addressed subsequently, the present intent is to improve the Spiral Ankle-Foot Orthosis, beset by materials problems since its inception decades ago.

METHODOLOGY—Methodology stems as much from organizational structure as from means of device development, featuring a government/private consortium based at the Brooklyn VA. Since a variety of promising new materials have been appearing on the market, it was anticipated that a search would be a fruitful complement to any theoretical efforts.

PROGRESS—While solid polypropylene has drawbacks for the Spiral application, it is unbreakable (a rare and central characteristic) given the pronounced bending it must undergo. Employing this characteristic as a foundation, means are being considered to moderate the undesirable features of this material for this application—that is, its dimensional instability when overheated (when it attains the consistency of chewing gum) which reduces workability during manufacture and subsequent correction.

The first means considered to moderate the undesirable features of polypropylene was found in the marketplace, consisting of polypropylene reinforced with woven carbon fibers. Reportedly (though unpublished) Spirals have been constructed by other parties for patients. It was found that the material straight from the marketplace is "notch sensitive," tending to break if the surface is marred. This breakage has reportedly been offset by coating the completed device with another plastic material. We are following up on this approach to verify any validity. Although the high cost of such carbon-reinforced materials might not fulfill the stated economy criterion, polypropylene, in itself, does.

The second means considered is to employ a prestressed form of polypropylene to reinforce the solid polypropylene. This is especially encouraging from the theoretical standpoint in that virtually the only material polypropylene will firmly bond to is itself. Thus, the matrix/reinforcement bond in this instance is more efficient that in any other composite employing a polypropylene matrix. Also, the constituents of the composite material are not overtrained.

PRELIMINARY RESULTS—While not biomechanically ideal, the above laminating procedure is being applied to patients. However, the procedure is cumbersome, and costly in terms of materials and effort. Therefore it is reserved principally for patients who have become accustomed to the Spiral Orthosis and will accept no substitute. Materials for the carbon/polypropylene approach are on order. Prestressed polypropylene/solid polypropylene samples have been produced. While only slightly stiffer than solid polypropylene, the composite remains dimensionally stable at working temperatures.

FUTURE PLANS—While we are not yet positioned to produce full scale Spiral blanks for patient fittings, efforts will be made in this direction. It was not anticipated that such promising materials would be adapted, in addition to being found, this soon.

[255] COMPUTER-AIDED DESIGN AND COMPUTER-AIDED MANUFACTURING OF ORTHOPEDIC FOOTWEAR

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A674-2DA)*

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 well fitting, comfortable, and functional orthopedic footwear for US veteran pedorthic patients.

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

1. Compile a computerized database of the medical/podiatric/pedorthic conditions and footwear prescriptions, digitized records of respective lasts and shoe patterns, (and when available, casts of the feet of patients), together with digitized records of the stock library lasts from which previous, custom orthopedic lasts were constructed, for a sample of 250 of the 10,000 pedorthic patients served by the NY VA Medical Center National Footwear Center (NFC);
2. Analyze the data compiled in the project database to establish last, inlay, and shoe pattern quantitative design principles, deriving statistical averages and deviations for the most common types of modifications and design features, to establish and quantify NFC orthopedic footwear design and manufacturing requirements;
3. Develop an intuitive, user-friendly, functional, clinically effective, and efficient pedorthic CAD/CAM system meeting NFC requirements;
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—So far, 289 subjects from the NFC 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. The data have been analyzed to establish the most common types of medical/podiatric/pedorthic conditions and the respective footwear prescriptions and last/footwear modifications used in treatment thereof. Parametric statistical distributions of the last/footwear modifications identified have been compiled for use in establishing quantitative design and manufacturing specifications.

From the specifications identified, a pedorthic CAD/CAM system has been developed. The system consists of the VA-Cyberware optical 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 CAM milling machine, and an Hewlett Packard Draft Pro pattern plotter/cutter. The constituent components have been interfaced and various enhancements introduced to comply with NFC design and manufacturing requirements. Additional adjunct software modules have also been developed enabling optical scan model variable reference center selection and realignment; last feature and regional boundary identification and registration; model surface grading, modification, and smoothing; and stress transducer calibration and data incorporation for insole design.

CAM toolpath correction, clearance, and surface smoothing software for last manufacture has also been written and tested. Clinical trials with four control subjects and seven pedorthic patients have been successfully conducted using the pedorthic CAD/CAM system.

FUTURE PLANS—Refinement and enhancement of the project pedorthic CAD/CAM system shall continue. The results and the 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, shall be utilized to develop new, improved, biomechanically based orthopedic footwear designs.

[256] MINIMIZING FALLS IN THE ELDERLY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A831-RA)*

PURPOSE—Almost one-third of all ambulatory people over the age of 65 and not in nursing homes fall each year. Such falls are a major source of serious injury, morbidity, and mortality in the elderly population. Even in cases which do not cause injury, the fall itself may result in an increased sense of fear, less independence, curtailed activity, and a higher morbidity rate associated with inactivity. In previous studies, peripheral neuropathy, decreased proprioception, increased reaction time, and decreased strength have all been independently associated with an increased risk of falling. In addition, separate but related research has shown that taping the ankle can improve reaction time and strength in young athletic subjects with a history of ankle sprain. The aim of the present study is to determine the efficacy of two different ankle wrapping techniques as interventions to falling.

METHODOLOGY—A commercially available elastic ankle wrap and a common method of ankle taping were used on two different groups of elderly subjects: fallers (those who have fallen two or more times during the 6-month period prior to testing) and nonfallers. Subjects performed a series of tests that were designed to allow measurement of physical parameters that have been correlated to falling, including:

1. amplitude and velocity of sway during quiet standing, with and without visual feedback
2. amplitude and onset latency of muscle response to a rapid (standing) talar tilt
3. amplitude and onset latency of muscle response to rapid (supine) dorsiflexion and plantarflexion
4. proprioceptive response to slow (supine) dorsiflexion and plantarflexion
5. torque generated across the ankle joint in response to rapid (supine) dorsiflexion and plantarflexion
6. functional reach

Measures of sway were made using a commercially available platform equipped with force transducers, designed to monitor center of pressure data. Muscle responses were measured for the gastroc, peroneus longus, anterior tibialis, and gluteus minimus muscles, and recorded through a series of four surface electrodes placed accordingly. The neuromuscular condition of the lower leg was evaluated for each subject prior to testing. Comparisons of the measured parameters were made among the ankle wrap, the tape, and a control group (no ankle support at all) to determine which of these wrapping techniques, if either, may act as an effective intervention to falling in the tested population.

PROGRESS—Twelve subjects have been tested to date. The protocol was modified after testing the first subject, and again after testing the second. As such, these two subjects were considered trial subjects, and have therefore been excluded from the main testing groups. Of the remaining 10 subjects, there are 3 fallers and 7 nonfallers; all were able to complete the entire testing procedure.

PRELIMINARY RESULTS—Tape was found to statistically decrease sway amplitude in nonfallers. Both the elastic-wrap orthosis and the taping technique showed clear trends toward improved values for the measured parameters as compared to control (no ankle support). In all cases, the tape, which is applied directly to the skin and therefore greatly enhances sensory feedback, was more effective than the elastic wrap. As the number of subjects tested increases, we expect to find that our interventions cause statistically significant improvement.

FUTURE PLANS—We plan to test 100 patients (75 fallers, 25 nonfallers); subject recruitment is ongoing. In addition to the experimental testing summarized above, a clinical trial of the commercially available orthosis is planned. We expect that the experimental and clinical data will provide information that will allow our group to design and test a low-cost orthosis that more closely mimics the effects of tape and thus has increased effectiveness in preventing falls.

[257] EVALUATION OF THE BLEDSOE PRO-SHIFTER BRACE FOR ACL-DEFICIENT PATIENTS

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PURPOSE—The effectiveness of the Bledsoe Pro-Shifter (BPS) brace designed for anterior cruciate ligament (ACL)-deficient patients was tested. Of the many knee braces available for this disability, the literature describes minimal or no effectiveness in alleviating the symptoms. The BPS was chosen for evaluation because it attempts to duplicate the lost function of the ACL by providing posteriorly directed force to the proximal tibia from 60° flexion to full extension.

METHODOLOGY—Twelve ACL-deficient subjects performed concentric isokinetic knee extensions at maximum effort both with and without the BPS brace. Electromyogram signals from the quadriceps, hamstrings, knee angle, and the extension force were recorded and evaluated to determine the effects of such dynamic bracing on muscle activity and joint stability.

RESULTS—High activity, or asymptomatic, subjects (n=5) experienced no change in muscle activity, but displayed a decrease in extension force throughout the active range of the brace. Low activity, or symptomatic, subjects (n=7) exhibited increased quadriceps activity and decreased hamstrings activity, and displayed a minor increase in force in the mid-range (80° to 40° flexion). These results indicate that dynamic bracing prevents quadriceps inhibition in symptomatic subjects by exerting a posteriorly directed force to the superior tibia; thus, the brace compensates externally for the absence of the ACL.

[258] CRUTCH AMBULATION

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PURPOSE— Crutches are often not used long-term because, with current designs, energy costs are very high. Therefore, many of those with significant lower limb impairment (e.g., those with spinal cord injury, spina bifida, post-polio, or cerebral palsy), often opt to use a wheelchair as the primary mode of transportation. It is hypothesized that crutch ambulation can be improved and made easier through the application and expansion of what is currently known about bipedal locomotion. Bipedal locomotion is presently several times more efficient than locomotion on crutches. The goal of this research to find out why this is so.

Passive dynamic bipedal walking machines have been built that walk down shallow inclines with only the influence of gravity supplying energy. These machines look very similar to an individual using swing-through gait on crutches; the inner "legs" are coupled and the outer "legs" move together like the crutches. Both sets of legs end in rocker "feet." Since these passive devices can be built, there does not appear to be any reason why other ambulation styles (including crutch ambulation) cannot be performed with similar low energy requirements. The passive walking machines rely on rockers and the concept of the "virtual wheel." Some investigators of human gait hypothesize that the human body also uses some of these methods. The body has been described as "rolling" forward over various foot rockers during normal gait. Rockers have also been successful in restoring functional walking to some individuals suffering from multiple sclerosis by using rocker-soled shoes. Rockers are also used

in orthotics. Rocker soled ankle-foot orthoses are often used to treat diabetics with foot ulcerations. Rocker crutches have been developed in the past. However, the design of the crutch has rarely been systematically addressed. It is hypothesized that the design (i.e., size and shape of the rocker) will have a profound effect on the efficacy of the crutch. This hypothesis is somewhat supported by the literature since some investigators have found improvement with rocker crutches while others have not.

METHODOLOGY—Initial designs are being developed for forearm crutches. The initial test subjects will be normal volunteers until the safety of the design is confirmed. Later designs will be tested on volunteers who use crutches and swing-through gait frequently. Using theoretical ideas and practical testing, the design of the crutch will be evaluated and modified.

PROGRESS—Currently, crutches are being designed and built in our laboratory to test the application of rockers to crutch ambulation. The initial designs include rocker bottom crutches with variable levels of spring as well as rocker units attached to the feet. This design is based on the theoretical considerations of the passive walking machines discussed. The goal is that, like the passive mechanical device, crutches can be developed requiring low energy so that the user can also "roll" with greatly reduced effort.

FUTURE PLANS—The ultimate goal is to develop theoretical principles upon which improved crutch designs can be based. The new design should allow users to ambulate farther and easier than with conventional crutches, offering alternatives to everyday wheelchair use. We are now beginning to coalesce the knowledge gained from projects on the effect of rocker shape on prosthetic ambulation, vertical compliance and spring, and floor clearance toward the development of new crutches.

[259] CRITERIA FOR INTERFACING AND CONTROL OF A POWERED UPPER EXTREMITY ORTHOSIS

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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/her abilities with the aid of appropriate technology. This attitude is superior to a total substitution of his/her manipulative function with a robot. This project explores ways of doing this using powered orthoses that can support the arms against gravity and provide a broad range of arm movement.

METHODOLOGY—Our 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 residual strength of the person 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 running concurrently. 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. In the first phase, the range 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, 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. In the second phase, we shall develop a series of prototypes that will ultimately lead toward a marketable device. Consumers and their families are to be involved at all stages in this work.

PROGRESS—A series of prototypes has 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 the utilization of nonlinear springs to control the effective impedance of a joint. Experiments are being carried out to find the lowest possible impedance parameters that the robot can present to the user while successfully following the his or her intentions while negating forces due to gravity.

RESULTS—A set of tasks desired by the target population has been identified. An active test-bed and several passive orthotic prototypes have been designed which enable 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/her muscular system, although eventually the system must have the capacity for active control of the person's arm.

FUTURE PLANS/IMPLICATIONS—User evaluation will be carried out to verify the usefulness of the control schemes. This evaluation will yield answers to the sufficiency/insufficiency of one-sensor information. Future plans include making an anthropomorphic orthosis with gravity compensation and a robust control scheme which is intuitive to the user.

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[260] DEVELOPMENT OF LOWER EXTREMITY ORTHOTICS FOR CHILDREN WITH MYELOMENINGOCELE

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PURPOSE—The aim of this project is to design improved bracing for the myelomeningocele patient. Orthotic support for this population has always been difficult, but it is important for the physiological and social development of the child.

Target goals for the new KAFO and AFO designs include stronger, lighter AFO shells with improved ankle joints and development of improved KAFO braces with easily-operated knee joints. An emphasis in this project, as in the other design projects, is to explore the use of advanced composite materials in novel ways to create orthoses that are lightweight, high-strength, low-profile, and aesthetically appealing.

PROGRESS—Clinical tests will assess the ankle articulation requirements of this patient group and help determine the appropriate selection of joint parameters, thus guiding development of future designs. Parameters to be investigated include amount of dorsiflexion assist, suitable range of motion, and the need for "soft-stop" limits. The design of an articulating ankle joint is underway, beginning with preliminary estimations of design parameters.

Concerning the problem of a dorsi-assist, the first design concept was inspired by the simple, low profile design of the commercially available Oklahoma ankle joint. Dorsiflexion restoring force was added by incorporating into the unit a simple flexion spring (resembling the design of a popular type of Japanese clothespin). Another promising concept borrows from the design of anti-backlash gears with integral compression springs. Perhaps even more challenging than the design of an integral dorsi-assist is the incorporation of a strong, easily adjusted stop into the ankle joint without adding undue weight or size. Contact with manufacturers of commercial limited-range joints has been helpful in guiding the design process. These include joints manufactured by Pro-Com and USMC as well as a Becker Orthopedic ankle joint that came on the market in April 1996. It is possible that modifications to an existing design may produce a joint that meets our specifications.

Progress has been made in developing a lightweight KAFO with the structural integrity to support larger, heavier children. The first prototype embodies an innovative single-upright design which smoothly blends uprights, knee joint and bands in an attractive shape. The design uses composite fibers in a manner which takes advantage of the unique properties of this material: it is moldable, very stiff, very light, and very strong. The bearing employed for the first prototype knee joint is lightweight, self-cleaning, and needs no lubrication, yet appears to be capable of withstanding the required radial and moment loads.

[261] ORTHOTICS FOR MYELOMENINGOCELE PATIENTS, TEENAGE VERSUS CHILDHOOD

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PURPOSE—The purpose of this research is to determine the optimum orthotic system for the myelomeningocele (MMC) child and its carry-over to teenage patients. We seek to delineate the differences in gait requirements and performance of pediatric versus teenage patients (kinematics, kinetics, muscle control patterns); compare the available strengths and range of motion of the lower extremity muscles and joints of the two subject groups; and differentiate orthotic forces, foot stability, and biomechanics of two knee-ankle-foot orthoses (KAFO) and three ankle-foot orthoses (AFO).

METHODOLOGY—Children (4–7 yrs) and teenagers (12–17 yrs) with MMC lesions at the lumbar or sacral functional levels, who rely on KAFOs or AFOs to walk, will be recruited as subjects. Individuals using a KAFO will be randomly tested with standard and supracondylar orthoses. Individuals using an AFO will be randomly tested with three AFO designs: the solid polypropylene posterior shell, the posterior entry anterior shell (floor-reaction), and the dorsiflexion restraining articulating orthosis (Rancho design). Subjects will wear each brace for a minimum of 1 month prior to testing. Testing will include surface dynamic electromyography on five lower extremity muscles to record muscle activation patterns. Footswitches with compression closing sensors will be used to obtain foot-floor contact patterns and spatio-temporal gait characteristics. An EMED insole pressure measuring system will depict the pressure distribution on the sole of the foot during gait (also collected on nondisabled subjects for comparison). Kinematic data will be combined with ground reaction forces and anthropomorphic measurements to obtain three dimensional kinetics. These data will provide a measure of the joint demands in gait (moments and powers) using an inverse dynamics model (custom software). Energy cost will be measured with a modified Douglas bag system while the heart rate, respiratory rate, and cadence are recorded. Strength testing will be performed on the lower extremity muscles and range of motion measured for the lower extremity joints.

PROGRESS—Insole pressures have been collected for 10 nonimpaired subjects (5 children, 5 teens) to establish a normal database of foot pressures. Subjects are being recruited from area hospitals and outpatient clinics. The initial contact is for casting and fabrication of the first or-

thosis. A minimum of 1 month following receipt of the first test brace is required before testing.

FUTURE PLANS—Recruitment and testing of subjects will continue. Data analysis of the normative foot pressure data will proceed for publication and dissemination. From the data obtained in this study, a biomechanical model will be conceived to guide the design of more optimal orthoses to facilitate the patients' ability to walk and provide long-term foot protection.

[262] MOBILE ARM SUPPORTS FOR CHILDREN

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PURPOSE—Mobile arm supports (MAS) are wheelchair-mounted devices which support the weight of the user's arm and provide assistance to shoulder and arm motions through a mechanical linkage. These units have enhanced function and independence of many individuals with flaccid paralysis or paresis of the shoulder and elbow flexor muscles. Problems with the current commercially available designs have greatly limited their use in spite of the benefits that they can potentially provide. These include complexity of setup, difficulty in adjustment, and lack of appropriate models for children. The primary objective of this project is to improve MAS design to address these deficiencies.

PROGRESS—The first objective of the project was to establish design specifications for a new MAS. To help develop meaningful design goals and desirable attributes, a survey questionnaire was developed for interviewing users of the MAS and members of their family. To date, 43 surveys have been completed and 7 users have had follow-up visits either at home or in the Rancho Los Amigos Medical Center, during which the users performed a range of motion exercises to enable assessment of device utility. Respondents were of both sexes, aged 4 to 60, and included both unilateral and bilateral users. Two types of MAS were represented: the "standard" model employing links hinged together with ball bearings, and a "radial" support employing one rotary and one sliding joint. We have identified a user's group that has consented to additional follow-up and prototype testing.

The survey documented that over half the respondents feel they derive benefit from and continue to use their MAS for a variety of activities ranging from eating to typing to exercise. Seven users employ the device to help them pilot their power chairs. A desirable, but currently unavailable, feature of the MAS remains the incorporation of an easily engaged lock to secure the MAS during driving. Complaints included difficulty in adjusting the MAS to properly balance the arm, device bulk (especially in clearing doorways), and poor appearance.

The survey results and direct observations of users provided valuable input to establishing design specifications. Design goals have been formulated emphasizing ease of adjustment, low profile, and attractive cosmesis, along with the requisite ease of motion. A useful option would be the ability to quickly relocate the MAS from the wheelchair to a preadjusted mount on a desk or table. New design concepts and prototype development have explored several different paths. A telescopic design of minimal rest size has been fabricated from aluminum tube and Delrin bearings. It is promising in concept, but will require good linear bearings to deliver sufficiently smooth performance under load. A multilink articulated unit has also shown promise. This prototype is made of stainless steel tubing and Delrin blocks in 4 in (18.16 cm) segments. The unit performs well under load and exhibits little vertical deflection. It is low profile, and will not interfere with passage through doorframes. The segmented unit was described by a patient as "friendly" in appearance, and indeed its shape is more organic in some sense than the rigid, right-angle machine-like alternatives. A novel wheelchair mount incorporates a 2-dimensional "bubble" for easy adjustment of gravity-free performance. A third design incorporates the wheelchair armrest as a base for mounting a movable support with smaller excursion radius. Prototypes of each design have been developed, and clinical evaluation using members of our user's group began in September 1996.

[263] DEVELOPMENT OF A MODULAR-DESIGN CUSTOM-FIT ANKLE-FOOT ORTHOSIS

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Sponsor: *The Ontario Ministry of Health through the Ontario Rehabilitation Technology Consortium; The Hospital for Sick Children Foundation*

PURPOSE—The current method of producing custom ankle-foot orthosis (AFOs) involves taking a negative plaster cast of the shank and 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 leads to high costs. The aim of this project is to develop a modular AFO that can be fitted 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—Most of our effort has been divided into two streams. The scientific stream has sought to understand how AFOs work, what kind of stresses they undergo, and why they fail. At the same time, hundreds of AFOs have been digitally encoded, resulting in an extensive database of relevant body measurements. The results of laboratory tests with instrumented AFOs worn by actual users have been combined with information gathered from computer modelling to generate an accurate picture of what happens in and to an AFO during everyday activities. The second stream, materials engineering, has been carried out in collaboration with Bloorview MacMillan for Biomaterials, University of Toronto, with the goal of developing a new material for custom AFOs that can be rapidly, inexpensively, and effectively dispensed to the end user. An innovative new composite has been developed and undergone extensive material properties testing.

Testing and modification are now underway to ensure that the final product will be user-friendly and nontoxic. Ancillary activities include the construction of a sophisticated test protocol and apparatus for life-cycle testing of current and new prototype AFOs. Partnerships have been formed with a manufacturer and distributor, and they continue to advise on product development. Special consideration is also being given to alleviate some of the secondary concerns raised by consumers, such as heat build-up, incompatibility with shoes, and poor cosmesis inherent in current AFOs.

FUTURE PLANS—Upon successful completion of biocompatibility testing, the new AFOs will be clinically tested. Design and procedural changes will then be made before production and distribution are turned over to the corporate partners. Future work may include isolating other applications for the new composite and further functional improvements to AFOs.

[264] 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: *The Post Polio Clinic of the Albert Einstein Healthcare Network; the Calhoun Fellowship Endowment of Drexel University in Philadelphia, PA 19104*

PURPOSE—Minimal progress in a continuing project to utilize EMG signals to assist in the orthotie alignment procedure has been made. Changes in muscle demands due to minor modifieations to the range of motion in an articulated ankle foot orthosis has been measured in a Post Polio Syndrome population. Initial work showed that statistical analysis of integrated linear enveloped stride EMG signals from differing test eonditions allowed comparison of muscle activity eorresponding to these conditions. The initial and post-accommodation responses to new alignment conditions were assessed.

METHODOLOGY—Subjects walked in their own orthoties in several different range of motion restrictions. Surface EMG signals from tibialis anterior, soleus, reetus femoris, vastus medialis, vastus lateralis, and the long head of biceps femoris were recorded. Data were collected immediately after administering the ehange in range of motion to the orthosis and again after the subjects had used the orthosis in one of the new alignments for a period of one to several months. Linear enveloped and integrated stride EMG data from different conditions were statistically compared. Ensemble averaged profiles were also visually checked to eliminate spurious statistical signifieanee.

PROGRESS—Additional Post Polio Syndrome subjects have been evaluated to assess whether neuromuseular deficiencies affect the trends found in nonimpaired subjects. For these subjects, heart rate, joint moments, and brace preferenees were measured to eorroborate statistical findings from EMG.

PRELIMINARY RESULTS—Muscle response was well defined and consistent in the Post Polio Syndrome subjects. The processing method used faeilitated the statistical eomparison which showed significant changes between test conditions. Statistical comparison of ensemble averaged EMG profiles indicated differences which were not readily obvious through the more elinieally prevalent visual analysis. Furthermore, some common elinical heuristies, such as increasing ankle plantarflexion to relieve knee extensor muscles, were found to not always hold true. Although joint moment date was incomplete since subjects were not asked to target force plates, 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 musele aetivity.

FUTURE PLANS—Testing of additional subjects and developing a museuloskeletal model to predict the effeet of orthotic range of motion constraints on musele demands are pending.

XIII. Psychological and Psychosocial Disorders

[265] REHABILITATION EFFECTS OF PAY, ACTIVITY, AND SUPPORT INTENSITY ON SCHIZOPHRENIA

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #D828-2RA)*

PURPOSE—This research investigates the benefits of productive activity in the rehabilitation of patients with schizophrenia. Key questions are: 1) does pay increase participation in work activity and lead to higher rates of work placement in the community, 2) do higher intensity services yield better clinical outcomes than standard services, 3) is greater productivity associated with better clinical outcomes, and 4) is performance on psychological and neuropsychological measures a useful predictor of rehabilitation outcomes.

METHODOLOGY—One hundred and twenty patients with DSM III-R confirmed diagnoses of schizophrenia and schizoaffective disorder are being recruited from the general psychiatric service and stratified by prior work function. Subjects are randomly assigned to one of two levels of pay ($3.40 hour up to 20 hours weekly or no remuneration) and one of two levels of support (standard or high). High support subjects have access to a job coach, attend weekly group where vocational issues are addressed, and are provided biweekly work performance feedback. All subjects are offered 6 month work placements. Research staff perform biweekly evaluations of job performance using the Work Behavior Inventory (WBI), symptom levels using the Positive and Negative Syndrome Scale (PANSS), and quality of life (QOL). Subjects are evaluated at baseline, 5 month, 1 year and follow-up on demographic, neuro-behavioral, and productivity variables.

PROGRESS—Since January 1995, a new staff has been hired, measurement instruments gathered, staff trained on the instruments, physical space procured, and procedures created for the program.

We have had 76 subjects (63 percent) complete intake procedures and enter the study. At this rate, we expect to recruit the planned 120 subjects on schedule. Thirty-nine subjects have been assigned to the pay, and 37 to the no pay condition; 38 subjects have been assigned to the standard support, and 38 to the high support condition. Of the 76 subjects who have completed intake procedures, 57 have elected to continue to participate following randomization. As a group, these subjects have worked 11,086.75 hours. We have performed 381 WBIs on them.

We have conducted 80 weekly high support meetings, with excellent (85 percent) attendance, and there has been surprisingly lively participation on the part of even the most withdrawn and symptomatic subjects. Our 1,008 weekly assessments include 422 PANSS interviews, 220 QOL interviews, 210 group questionnaires, and 156 Job Satisfaction Inventories.

Follow-up data are being gathered: 48 of 57 subjects (86 percent) have completed the 5-month follow-up procedure; of the rest, 2 have died, 4 have moved out of state, and 3 have refused. Thirty-three of 41 subjects (81 percent) have completed the 1-year follow-up battery.

PRELIMINARY RESULTS—Subjects in the high support condition work approximately 20 percent more than those in the standard condition, and all participants in the pay condition had at least 1 week of work, while only 54 percent of the no pay participants worked at least 1 week. Other issues have been more fully addressed using data from the current project, including validation study verifying the psychometric properties of the WBI and several investigations into affect recognition in schizophrenia. These last indicate: a) affect recognition is more difficult

for schizophrenia samples than for substance abuse or normal samples, b) subjects with schizophrenia are less accurate at labeling negative vs positive affects, c) affect recognition deficits in schizophrenia are related to specific cognitive deficits, but not measures of global cognitive impairment.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Clinical benefits of paid work activity in schizophrenia. Bell MD, Lysaker PH, Milstein RM. Schizophr Bull 1996:22(1):51–67.

Paid work activity in schizophrenia: program costs offset by costs of rehospitalization. Bell MD, Lysaker PH. Psychosoc Rehabil J 1995:18(4):25–35.

Performance on the Wisconsin Card Sorting Test as a predictor of rehospitalization in schizophrenia. Lysaker PH, Bell MD, Bioty SM, Zito WS. J Nerv Ment Dis 1966:184(5):319–22.

Cognitive impairment and substance abuse history as predictors of the temporal stability of negative symptoms in schizophrenia. Lysaker PH, Bell MD, Bioty SM, Zito WS. J Nerv Ment Dis. In press.

Work behavior inventory: a scale for the assessment of work behavior for client's with severe mental illness. Bryson G, Bell MD, Lysaker PH, Zito W. Psychiatr Res J. In press.

[266] LONGITUDINAL ANALYSIS OF WELL-BEING IN PERSON 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) examination of the relationship between factors of well-being in persons with SCI and their caregivers, measured at preselected times postinjury; 2) determination of 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) determination of the interrelationships between feelings of well-being of the person with SCI and his caregiver(s) in different cohorts over time; and 4) determination of 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, 91 caregivers have been enrolled in the project and 50 of them have completed all four phases.

PRELIMINARY RESULTS—88 percent of the caregiving sample is female, 66 percent have a high school education or better, and 47 percent were employed outside the home at the time of injury. With regard to relationship to the person with SCI, spouses comprise 32 percent, mothers 29 percent, and brothers 12 percent. Of the persons with SCI, 78 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 continue to be enrolled through August 1996 with follow-up completed by the end of August 1997. Preliminary analysis will be descriptive and correlational.

Longitudinal/causal analyses will not be able to be carried out until the project is completed.

[267] 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 three primary research hypotheses:

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 ofthe 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, in-home interviews were conducted by three project staff who are also women with disabilities. Interviews were transcribed, analyzed in terms of wellness, and used to generate the 300-item questionnaire pilot-tested on 60 women with disabilities and 60 women without. Their data were then used to further refine the questionnaire, which was sent to 1,200 women with disabilities and 1200 women without. Questionnaires were received from 950 women.

RESULTS—During the course of this study, several problems with reproductive health surfaced with unexpected strength. These problems include 1) lack of physical access to physicians' offices and equipment; 2) gaps in the knowledge of physicians and other health professionals about how disabilities affect reproductive health care needs; 3) assumptions by health care professionals that women with disabilities do not need reproductive health care; 4) deficits in knowledge and faulty beliefs of women with disabilities about the functioning of their bodies and their need for reproductive health care services; and 5) problems inherent in health care service systems. In our national survey, we found that women with disabilities face certain unique problems in sexual response, pregnancy, delivery, and the detection of sexually transmitted diseases, breast cancer, and cervical cancer. Data analysis has been completed in the following areas: sexual functioning, sense of self, body image, dating, marriage, secondary conditions, health care utilization, access to reproductive health care, and health main-

tenance behaviors. An executive summary and final reports are being developed and documentation is being prepared.

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 nonimpaired comparison group. Women with physical disabilities reported having sexually transmitted diseases at about the same rate, 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, and for 60 percent of them, 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 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) reported 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 overall (and 33 percent of those with SCI) reported that a physician had refused to see them for reproductive health care. Thirty-eight percent reported that the physician does not speak directly to them if someone else is accompanying them. Thirty-seven percent 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. These women 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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Sexual abuse of women with physical disabilities. Nosek, MA Sex Disabil Phys Med Rehabil 1995:9(2):487–502.

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 1996:77(2):107–15.

Women with physical disabilities: achieving and maintaining *health* and well-being. Krotoski DM, Nosek MA, Turk MA, eds. Baltimore, MD: Paul H. Brookes, 1996.

XIV. Sensory, Cognitive, and Communication Aids

A. Hearing Impairment

[268] 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: 1) Do imagery laden verbal passages enhance accuracy of comprehension on verbal tasks? 2) 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—The PC/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 non-impaired subjects. In addition, multiple choice questions are asked following each language passage. These questions are used as measures of the subjects' comprehension of the material as well as an indicator of their 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 55-85th 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/retest data.

PROGRESS—Nonimpaired controls and left-hemisphere-damaged subjects have been participating in the project for the past 10 months. Background behavioral testing continues as new subjects are being identified. Evoked potential testing of these subjects is ongoing.

FUTURE PLANS—Additional subjects will continue to participate in the study for the oncoming year. Once a small but representative number of subjects from each experimental group completes the paradigm, preliminary data will be analyzed. Final results will not be reported until the running of the experiment is completed for all subjects.

[269] COMPUTERIZED ADAPTIVE METHODS FOR SELECTING HEARING AIDS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C432-4RA)*

No report was received for this issue.

[270] CHANGES IN AUDITORY ABILITIES WITH HEARING AID USE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C847-RA)*

PURPOSE—Recent investigations suggest that the benefit of amplification for speech understanding increases over the first few weeks or months of hearing aid use for some listeners. The purpose of this project is to determine the effects of daily hearing aid use on speech recognition abilities and to test one hypothesis regarding an explanation for any changes in these abilities. Specifically, we will explore whether increases in hearing aid benefit occur over a 6-month period in novice hearing aid users, and, if so, whether these increases in benefit are accompanied by an increased reliance on high-frequency information in speech.

METHODOLOGY—Sixty subjects with hearing impairment will be divided into three groups of 20 and evaluated using the Nonsense Syllable Test (NST). One control group will be comprised of experienced hearing aid users who wear their aids daily. Another control group will be novice hearing aid users who do not wear their aids outside the laboratory during the study. The experimental group will be novice users who wear their hearing aids daily. All hearing aids will be fit binaurally according to the NAL-R prescriptive formula. These groups will be followed over a period of 6 months and tested at monthly intervals. At each visit the following measures will be performed: 1) The NST in the unaided condition, in an aided condition with the NAL-R frequency response, and in an aided condition with a flatter frequency response. Hearing aid benefit will be defined as aided minus unaided performance. 2) Crossover frequency for NST syllables presented at a level that insures audibility of the signal for each listener. This is a measure of the contributions of various frequency regions of speech to speech intelligibility and is the frequency that divides the speech spectrum in half with regard to information used by the listener. 3) Subjectively preferred frequency response (NAL-R vs. a flatter response) while listening to a sample of running speech and a sample of music.

Changes in benefit of amplification to nonsense syllable recognition will be compared for the three subject groups. If daily use of amplification results in an increase in hearing aid benefit, it is expected that an increase in benefit will be demonstrated only for the experimental group using their prescribed frequency response. If increased reliance on high frequency speech cues is responsible for this change in benefit, it is anticipated that crossover frequency will increase for the experimental group over the study period, but not for the two control groups.

PROGRESS—Nonsense syllables have been recorded in eight randomizations on digital audio tape and the test

has been adminstered to three pilot subjects with unimpaired hearing to begin to explore the reliability of performance on these lists. The project has recently been moved from the Syracuse VA Medical Center to the Iowa City VA Medical Center. The laboratory has been equipped and subject recruitment is underway. There are no preliminary data at this time.

FUTURE PLANS—Testing will soon begin on subjects with hearing impairment to determine reliability in this population and to establish the optimal signal-to-noise ratio for test administration. Subjects will continue to be recruited into the three study groups. Work will simultaneously begin to bring more of the experimental operations under computer control.

[271] IS THERE AN "ACCLIMATIZATION EFFECT" WITH HEARING AIDS?

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C840-RA)*

PURPOSE—In 1992, Gatehouse coined the term "acclimatization effect" to refer to improvement in speech recognition scores seen over time in a small sample of persons using hearing-aids following their fitting. He believed that the improvements were due to their learning to use amplified speech cues now available to them, rather than depending simply on the stimulation of auditorily deprived ears. Since that time, however, conflicting data have been reported as to whether or not such a phenomenon exists. The present study will examine the acclimatization effect in new users of hearing-aids with a carefully designed study which controls for test-retest variability of the speech recognition tasks, evaluates the effects of changes in user preferred volume wheel setting over time, and uses both linear and nonlinear amplifiers.

METHODOLOGY—Data will be collected on 30 adults with bilaterally symmetrical sensorineural hearing losses ranging from mild to severe, who have not previously used amplification. Subjects will be fit with binaural linear and nonlinear sets of hearing aids via probe-microphone using NAL-r prescribed gain for a 65 dB SPL input signal. Aided speech recognition will be evaluated using the adaptive Hearing-In-Noise-Test (HINT) to determine signal-to-noise ratio (SNR) for 50 percent correct sentence intelligibility and the Speech-Perception-in-Noise (SPIN) test at a fixed SNR of either +4, +18, or +12 dB depending on individual performance, to avoid ceiling and floor effects. A unique aspect of this study is that each subject will serve as his/her own control. There will be several repeat sessions measuring aided speech recognition during a 2–3 week period prior to the subjects wearing one of the hearing aid sets home; this will assess across session test-retest reliability. Subsequently, repeat measurements will be made over a 4-month wearing period. At each of these sessions, testing will be accomplished with both hearing aid sets, and at user-preferred as well as prescribed-gain volume wheel setting for the hearing aid set worn daily. Questionnaire data will be collected over time to examine any changes in perceived hearing aid benefit. Another group of 10 experienced users of hearing-aids will be evaluated as a control group.

PROGRESS—During the past year, the research laboratory was fully equipped and calibrated. Pilot data were collected to establish appropriate measurement parameters, resulting in some minor changes to the researchprotocol. Data collection is nearly completed on seven subjects, and subject recruitment continues.

PRELIMINARY RESULTS/IMPLICATIONS—There are not enough data at this time to report any preliminary results. 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 measurement of user benefit and decision making regarding changes in electroacoustic parameters.

[272] 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 #C665-2RA)*

PURPOSE—This study was to investigate the effect of presence and absence of amplification on various measures of audition in aided and unaided adults with unilateral sensorineural hearing impairment.

METHODOLOGY—Aided and unaided subjects between 25 and 75 years of age with unilateral, sensorineural hearing impairment were evaluated annually in Years 1, 2, and 3. Measures included puretone thresholds, speech-recognition threshold, W-22 speech-recognition score (SSRS), nonsense syllable test (NST) score, acoustic admittance, brainstem auditory evoked potentials, and middle latency responses.

PROGRESS—This study supports the presence of auditory deprivation in unilateral sensorineural hearing loss ears. Amplification appears to slow or prevent the process of deprivation.

RESULTS—Of the 83 subjects (41 aided and 42 unaided) seen in Year 1, 48 (27 unaided and 21 aided) completed the study. Comparisons were made between the aided ears and the unaided hearing-impaired ears of the subjects. The analysis of variance showed that in unaided ears, the mean SSRS declined significantly ($p=0.0003$). There was no significant change in the NST in unaided ears; this is probably related to the initial poor NST in this population and/or to the fact that 3 years were not enough to produce change. There was no significant change in aided ears for both NST and SSRS; however, a trend was noticed toward improvement in both.

FUTURE PLANS/IMPLICATIONS—Further analysis of data will be made, and we plan to publish the data in the near future in several articles.

[273] 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, sensorineural hearing impairment (BSHI). These measures have been evaluated annually for the last 4–6 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—This study supports the previously published retrospective studies on the presence of auditory

deprivation in the unaided ear of monaurally aided subjects with bilateral sensorineural hearing loss.

RESULTS—Although we are in the process of completing the final stage of the study and writing the final report; we will highlight some important findings.

With subjects who were tested at least 3–6 years, the upper limits (UL) and the lower limits (LL) of the 95 percent critical differences limits (CDL) were used for the SSRS. 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. A total of 64 subjects completed the study (33 subjects binaurally aided, 31 monaurally aided.) A total of 12 out of 31 monaurally aided ears (37 percent), showed deprivation in speech-recognition score. Interestingly, 3 subjects who showed deprivation on the SSRS in the fourth year, recovered in the sixth year and were included in the 31 undeprived ears. However, the recovery amounts to improvement of approximately 2–4 percent, which caused them to be included within the 95% (CDL). However, the score in the sixth year was remarkably poorer than the initial score.

Five out of 66 ears of the 33 subjects of binaurally aided ears showed deprivation, (3 percent), and the result of the NST indicated that 8 out of unaided 31 ears fell outside the LL, while none of the aided ears did. As for the binaurally aided ears, 10 percent fell outside the LL. Eight subjects changed status from monaural to binaural and are being monitored. No significant changes were obtained for the other measures.

[274] 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 primary goal of this investigation is to identify critical nonauditory factors which affect hearing aid benefit in elderly veterans. Nonauditory factors include mental status, fine motor coordination, visual acuity, social support, and motivation. A secondary goal is to compare traditional auditory measures, and self-report measures of perceived hearing aid benefit. Outcome measures include the Hearing Handicap Inventory-Elderly (HHIE), The Hearing Disability Interview/Hearing Aid Benefit Interview (HDI/HABI), and the Hearing Aid Satisfaction Questionnaire (HAS).

Our specific aims are to evaluate several auditory and nonauditory factors in a group of elderly veterans who are to receive hearing aids through the VA. A multiple regression analysis will be used to assess the predictability of each of the nonauditory factors as well as some of the auditory factors measured during the hearing aid evaluation. Decisions of which veterans could benefit most from hearing aids could be improved by giving the clinician more objective data for predicting outcomes with hearing aid use, and programs of aural rehabilitation could be maximized by attacking those factors that limit hearing aid benefit.

METHODOLOGY—Two samples of subjects will be studied. One sample is composed of outpatient veterans who are scheduled for clinic visits to be evaluated for hearing aids. The second sample consists of veterans in institutionalized settings such as Nursing Home Care Units, Domiciliaries, and Contract Nursing Care Facilities. Each will receive an initial evaluation which will include the following: an assessment of auditory function; assessment of nonauditory factors; and self-assessment of hearing handicap. At 4 months following fitting and dispensing of selected hearing aid(s), subjects will be reevaluated on all auditory and nonauditory measures.

PROGRESS—Complete data are available on over 200 subjects, and analysis of these data shows significant decrease in perceived hearing handicap after 4 months of

hearing aid use. Correlation coefficients were computed for each of the variables measured at enter into the study, and the difference score on the total HHIE between entry and follow-up. Eight of the 10 highest correlations were with nonauditory factors. The 10 variables with the largest correlations were then used in a stepwise linear regression. The result was a correlation of 0.52 based upon five variables. Four out of the five variables entered in the stepwise regression are nonauditory variables. These five variables are able to predict approximately 30 percent of the variance of the improvement in the HHIE.

[275] 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 #C1693-PA)*

PURPOSE—Tinnitus refers to the chronic experience of phantom sound. Severe tinnitus is a pathological condition suffered by at least 10 million Americans. Although veterans are particularly impacted by tinnitus, the VAMC system provides minimal clinical management for the condition. The DVA pays approximately $90 million per year in compensation benefits to over 80,000 veterans who are service-connected for tinnitus. This laboratory is addressing the need for standardization of tinnitus management procedures. This study is designed to develop a reliable technique for the measurement of tinnitus, using computer automation.

METHODOLOGY—A computerized psychoacoustical testing system has been developed to run a tinnitus measurement protocol. The system has been programmed to automatically obtain hearing thresholds, and tinnitus loudness and pitch. A video monitor, directed at the patient, displays instructions for responding and serves to receive responses via touch-control with a pen device. Subjects with stable tinnitus are recruited and evaluated with the automated technique. To assess intra- and inter-session reliability of the measures, each measurement is obtained repeatedly within and across sessions for each subject. Reliability of the measures is also assessed between examiners.

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, 20 patients with tinnitus have been evaluated with the automated system. Results of preliminary statistical analyses have indicated reliability of responses: a) within-subject, within-session; b) within-subject, across-session; and c) between-examiner (between groups). Using a manually controlled protocol, an independent group of 20 patients has also been evaluated for tinnitus loudness and pitch. Because the automated testing protocol was patterned after the manual procedure, a comparison of test-retest reliability of the measures between the two techniques was appropriate. An analysis of between-session differences (absolute values) in loudness matches for each subject revealed that the differences were significantly reduced at frequencies $\geq$2 kHz using the automated procedure.

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 tinni-

tus 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 methodology 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.

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[276] EARLY DETECTION OF HEARING LOSS FROM OTOTOXIC AGENTS BY HIGH-FREQUENCY AUDITORY EVALUATION

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PURPOSE—Patients receiving treatment with ototoxic drugs are at risk for acquiring communicatively disabling hearing loss and/or balance disorders. Early detection of ototoxicity allows implementation of intervention strategies that can prevent hearing disability. When intervention is not possible, early detection allows time to prepare the patient and/or family for aural rehabilitation strategies. A multicenter (four-site) study has been established 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 hearing sensitivity is monitored prior to, during, and following treatment with the aminoglycoside antibiotics (AMG) amikacin, gentamicin or tobramycin, or the chemotherapeutic agent cisplatin (CDDP). Subject inclusion criteria for study was hearing threshold sensitivity at or below 100 dB SPL at test frequencies up to 9 kHz. Ototoxic change criteria are those recommended by the American Speech-Language-Hearing Association (ASHA) in the national guidelines for ototoxicity monitoring, adopted by ASHA from data provided by this research.

PROGRESS—Currently, 452 subjects (237 AMG and 215 CDDP) have provided data, with 294 of these subjects demonstrating threshold change in one or both ears. From the AMG-treated subjects, 35 percent of initial hearing losses were bilateral and 65 percent were unilateral, while 73 percent of initial losses from CDDP-treated subjects were bilateral and 27 percent were unilateral.

Presenting the data relative to ears rather than subjects, hearing change was seen in 461 ears. Results were analyzed to determine whether changes were initially detected in the high frequency, conventional frequency, or in both high and conventional frequency ranges concurrently. In the AMG-treated ears, 53.3 percent of initial changes occurred in the high frequencies, 29.7 percent in the conventional frequencies and 17.0 percent in both frequency ranges concurrently. In the CDDP-treated ears, 41.2 percent of initial changes occurred in the high frequencies, 24.7 percent in the conventional frequencies, and 34.1 percent in both frequency ranges concurrently.

Preliminary analyses indicated that at frequencies where hearing thresholds were greater than 100 dB SPL, little or no hearing change was seen throughout treatment. Also, in most cases, initial change seemed to appear within very few frequencies. Further analyses revealed a range of five frequencies within which approximately 90 percent of all hearing changes would have been initially detected. This 5 Frequency Range (5FR) is specific to the hearing threshold configuration of each individual, and includes the highest test frequency

with hearing threshold sensitivity at or below 100 dB SPL and the next four lower test frequencies. Frequencies above this range accounted for about 2 percent of all changes, while frequencies below this range accounted for about 8 percent of all changes.

IMPLICATIONS—Data from this project have resulted in the development and publication of national guidelines for ototoxicity monitoring. Identification of a five-frequency range 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 (i.e., limited-responsive patients). A software program has been developed that flags the 5FR of each individual and automatically reports any significant changes in hearing thresholds. This program is supported by a miniaturized hospital ward-testing system which reduces testing time and increases patient accessibility without compromising the sensitivity of the monitoring effort.

FUTURE PLANS—In the next phase of this multicenter research effort, we will prospectively explore, in a large sample of patients receiving ototoxic agents, the comparative sensitivity of objective measures of monitoring hearing (ABR; OAE) for early detection of ototoxicity. This research will result in measures that will allow the inclusion of all types of hospital patients (responsive, limited-responsive, and unresponsive) in comprehensive ototoxicity monitoring programs. Secondary goals of this research are planned to explore the relationship between ototoxicity and nephrotoxicity.

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Ototoxicity. Fausti SA, Henry JA, Frey RH. In: Northern JL, ed. Hearing Disorders. 3rd ed. Boston: Allyn & Bacon, 1996.

[277] MEASUREMENT AND PREDICTION OF BENEFIT FROM AMPLIFICATION

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PURPOSE—Our goals are to describe and develop methods of quantifying and predicting hearing aid benefit and satisfaction for the everyday life of elderly listeners.

METHODOLOGY—To explore the relationship between cognitive variables and objective hearing aid benefit, experienced hearing aid wearers provided data on working memory, speed of mental processing, use of auditory context, and mental flexibility. We employed multiple regression techniques to explore the extent to which cognitive variables add to the prediction of hearing aid benefit.

An evaluation of the Visual Input/Output Locator Algorithm (VIOLA) method for selecting and fitting nonlinear hearing aids was performed. Linear and nonlinear hearing aids were worn by a manikin and subjected to speech inputs at various levels. Sound levels developed at the eardrum were compared to levels predicted by the VIOLA method.

Relationships between several psychological variables and self-assessed hearing aid benefit were explored. Hearing aid wearers provided data on the Abbreviated Profile of Hearing Aid Benefit (APHAB) inventory as well as on measures of extroversion, anxiety, and locus of control. Multiple regression techniques were used to determine whether personality attributes are significantly related to subjective benefit.

Two clinically useful inventories are under development: one to measure post-fitting satisfaction and another to measure pre-fitting expectations of hearing aid performance.

PROGRESS—Forty-five hearing aid wearers provided data on cognitive variables and hearing aid benefit.

To evaluate the VIOLA fitting strategy, data were collected for six commercially available linear and compression behind-the-ear hearing aids fitted to a KEMAR manikin.

Eighty-three elderly hearing aid wearers (successful and unsuccessful) provided data on self-assessed hearing aid benefit and the three psychological variables.

Structured interviews about the important components of hearing aid satisfaction were conducted with 21 hearing aid owners. In addition, a survey of the importance of 14 elements in satisfaction was completed by 160 hearing aid owners. Principal components analyses were used to determine underlying commonalities among the elements. Item selection and testing is underway.

RESULTS—Of the four cognitive variables explored, only mental flexibility made an independent contribution to the prediction of objective hearing aid benefit. It was estimated that mental rigidity costs about 8 points of benefit for a typical person and about 18 points for a rigid individual.

The VIOLA fitting strategy was found to give good predictions of earcanal speech levels when hearing aids were operating linearly and well below pure tone saturation level. Nonlinear hearing aids produced levels lower than the predicted level and the amount of error was proportional to the compression ratio. The VIOLA procedure could be modified to account for these effects.

It was found that certain personality attributes are related to the way that individuals interpret the efficacy of amplification. Outward oriented (extroverted) persons reported more speech communication benefit. Individuals who felt more under the control of other persons tended to display greater negative reactions to environmental sounds.

Four basic factors have been identified that contribute to hearing aid satisfaction: sound merit (benefit and quality), comfort (physical and psychological), cost (personal and financial), and cosmetics.

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Measuring hearing aid benefit with the APHAB: is this asgood as it gets? Paul RG, Cox RM. Am J Audiol 1995:4(3):10–3.

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Using loudness data for hearing aid selection: the IHAFF approach. Cox RM. Hear J 1995:48(2):10,39–44.

Benefit acclimatization in elderly hearing aid users. Cox RM, Alexander GC, Taylor IM, Gray GA. J Am Acad Audiol. In press.

[278] NOISE REDUCTION FOR HEARING AIDS

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Sponsor: *National Institute on Deafness and Communication Disorders*

PURPOSE—The main complaint of persons with hearing impairment is difficulty hearing speech in a noisy environment. Our overall goal, therefore, is to improve the performance of hearing aids in noise by using some form of directional processing. More specifically we will develop and evaluate a multi-microphone array for hearing aids that can be worn either on the head (e.g., in a pair of eyeglasses) or used as a hand-held device. Past research has shown that microphone arrays can improve the S/N ratio by suppressing the interfering noise coming from directions other than the desired source. However, past researchers have used computer simulations rather than real rooms for their evaluations, and often have carried out only acoustic measurements, rather than speech intelligibility testing. The array to be evaluated here consists of five omnidirectional microphones uniformly spaced over a unit that is 10 cm long. A previous study in which this array was examined using acoustic measurements showed significant improvements in weighted S/N ratio for superdirective array processing.

METHODOLOGY—The speech and noise signals were processed in four ways, in each of two rooms that differed in reverberation time. Rooms 1 was a non-reverberant office, Room 2 was a reverberant conference room. For each condition, recordings were made in the

room of interest and the data processed offline. For the recordings, the microphone system was surrounded by six loudspeakers. The speech signal was played through the speaker at 0° azimuth, noise was played through the speakers at 60, 105, 180, 255, and 300°. In two conditions, the 5-microphone array was used and the recordings obtained were processed using both delay-and-sum beamforming and superdirective processing. In a third condition, a single omnidirectional microphone, and in the forth condition, a single directional (cardiod) microphone was used. The processed speech and noise files were stored on computer and played back to the subjects during testing.

Eighteen hearing impaired male subjects took part in the experiment. They carried out two different measures of speech intelligibility: a speech reception threshold in noise for 50 percent correct performance was measured using spondees and a subjective threshold for 50 percent understanding was obtained using short passages of connected discourse.

PROGRESS—All 18 subjects have been tested with the computer stored stimuli. The results are sufficiently promising that a wearable array will be built and evaluated.

RESULTS—The experimental results showed the superdirective array processing technique to be superior to the other techniques evaluated. It provided improvements of 4 dB S/N over the delay-and-sum beamforming, and 5 dB S/N over the single omnidirectional microphone. The relative performances of the processing techniques were not affected by the type of room, although performance in the non-reverberant room was significantly better than in the reverberant room. The two methods of measuring speech intelligibility produced similar results.

FUTURE PLANS/IMPLICATIONS—The next stage in the study is to build a binaural array that will be tested in the laboratory, following this a wearable binaural array will be built and its efficacy in the real world evaluated.

B. Speech Impairment

[279] AN INTERACTIVE VIDEO SYSTEM TO TEST AND TREAT NONLITERAL LANGUAGE DISORDERS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C788-RA)*

PURPOSE—The goal of this research is to assess and treat deficits in language comprehension in both left and right hemisphere stroke patients utilizing nonliteral language. The objective is the increase in comprehension of nonliteral language, leading to increases in functional communication.

METHODOLOGY—Left and right hemisphere stroke patients are randomly assigned to a treatment or nontreatment group. All patients receive extensive language testing, along with computerized assessment of nonliteral and literal language comprehension. In the computerized testing, videotaped scenes are presented to subjects along with written and spoken phrases; subjects must decide if the phrases (either literal sentences or nonliteral expressions) match the scenes presented. In the training component, subjects receive additional exposure to computer-presented scenes from popular movies (e.g., North by

Northwest); subjects receive feedback about their performance. Assessment of treatment continues throughout, so that incremental progress is measured. Normal age and education-matched controls receive only the testing portion of the protocol and several measures of nonliteral language comprehension for comparison purposes.

PROGRESS—The developmental phase of the project is complete. Two full Nonliteral Language Workstations and one Testing Only Workstation are fully operational. To date, 30 left-hemisphere, 10 right-hemisphere stroke patients and 28 controls are in the process of completing, or have completed, the protocol.

PRELIMINARY RESULTS—Subjects have been found to successfully navigate the computerized program, despite often severe expressive and subjective language impairment.

FUTURE PLANS—Continued running of subjects to reach goals of 60 right- and 60 left-hemisphere subjects is planned. Recruitment of subjects has been extended beyond the original two VA Medical Centers to a third (West Los Angeles VAMC) as well as to nearly all stroke rehabilitation groups in the northern Los Angeles metropolitan area. A prototype of a production version of the workstation for use is in development.

RECENT PUBLICATIONS FROM THIS RESEARCH

Computers, movies, and nonliteral language rehabilitation: an in-depth look at the development of an interactive video workstation. Hall E, Goldojarb M, Van Lancker D. J Med Speech-Lang Pathol 1995;3:53–65.

[280] COMPUTER-ASSISTED SPEECH REHABILITATION SYSTEM

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PURPOSE—This project is to develop, test, and refine a clinical 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 protocols are being developed to assist self-directed and clinician-directed training in the control of breathing, voice, prosody, and nasality during speech. Acoustic, aerodynamic, nasal accelerometric, and electroglottographic signals are monitored depending on the protocols selected. The software will be compatible with the more than 40 existing work stations developed in previous grant periods for Computer Assisted Speech Evaluation and Rehabilitation (CASPER).

METHODOLOGY—Programs are written in Delphi-Pascal. Algorithms are being developed and tested. Single-subject clinical trials will be completed on 20 subjects.

PROGRESS—A highly flexible system for defining and analyzing patient responses has been incorporated into the software. This considerably expands the general utility of the system and allows the clinician to easily assemble hundreds of custom protocols tailored for individual patients. Raw voltage from transducers, windowed RMS, or time-integral signals may be selected for display and analysis. Tokens within a data sweep are defined in terms of signal amplitude and duration above or below quiescent signal levels. Additional criterial amplitude and duration limits are entered allowing the clinician to require correct responses with mean or peak signal characteristics above, below, or between these limits. Real-time graphics required to implement the analog feedback have also been completed this year. The interface for designing the teaching paradigm has also been improved to allow user-generated sets of audio-visual alerting signals, cues, models, and feedback to be scheduled for cyclical, random, or ratio presentation. The time intervals between all stimulus

events, the data collection sweep, feedback events, and restimulation are also controlled by the software.

RESULTS—Five pilot subjects and two clincians have participated in training sessions thus far. Suggestions for software improvements have been incorporated into the system. Informal results suggest that patients find the software useful and enjoyable. Some patients can use the software with only intermittent supervision by a speech clinician. There are not sufficient data to asses treatment efficacy at present.

FUTURE PLANS—An experienced speech clinician will be hired and assist in completing 20 single-subject experiments with speech disordered subjects. In addition, we will provide beta-site versions of the software to selected users. Both activities will result in further refinements of the clinical software and help define the default, predesigned protocols to be included in the software.

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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, 1996:329–39.

[281] USING SELF-MONITORING TO IMPROVE COMMUNICATIVE EFFICIENCY IN APHASIA

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C693-RA)*

PURPOSE—Our objectives were 1) to determine the efficacy and effectiveness 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—Subjects were selected based on proportion of disfluencies (greater than 10 percent of total words) in pretreatment picture descriptions. They were exposed to four conditions: baseline, training, independent self-monitoring, and follow-up. The treatment task in all conditions was Norman Rockwell picture descriptions. At the end of baseline, subjects were taught to self-monitor: each subject listened to one of his own (audiotaped) baseline picture descriptions and was asked, "What bothers you about your speech?" Subjects identified a target disfluency (multiple repetitions, revisions, or filled pauses): "I'm stuttering," or "It sounds broken up." Subjects were trained to listen to themselves in on-line picture description and to stop at the first occurrence of a disfluency. Proportion of disfluencies in the treatment task and in two generalization tasks constituted the data points for each session. The project used a multiple-baseline design across subjects and across behaviors. Effectiveness of self-monitoring treatment was shown by 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 of an initial six subjects completed the treatment program. Subjects 1 and 3 pretests indicated moderate aphasia, Subject 2, mild-moderate, and Subject 5, mild aphasia. Subjects 1, 3, and 5 showed an immediate and dramatic drop in target disfluencies when self-monitoring was introduced. All four subjects showed proportion of overall disfluencies generally at or below lowest baseline levels during independent self-monitoring and in follow-up. Treatment efficacy (impact of picture description) was more robust than treatment effectiveness (generalization tasks). Subject 5 (mild) showed the most stable decrease in disfluencies in both picture description and generalization tasks. Communicative efficiency, defined as Content Information Units/minute,

improved in posttreatment picture description for Subjects 1, 3, and 5. Social validity was defined as ability of naive listeners to perceive improvement (significant at <0.05) in subjects' posttreatment speech. For all subjects listeners heard fewer filled pauses. Ratings for Subject 1 showed significant improvement in organization, intelligibility, and naturalness. Subject 2 ratings indicated improvement in stuttering. For Subjects 3 and 5 listeners indicated significantly fewer repetitions, revisions, and improved naturalness; Subject 3 also showed improvement in organization and fewer wrong words. Ratings for Subject 5 indicated perceived improvement in intelligibility.

FUTURE PLANS—The project is completed. All subjects, regardless of severity, were able to identify disfluencies, label them in a personally meaningful way, and monitor themselves on-line for occurrences of disfluencies. All subjects identified at least one important strategy: "slow down," or "think about my speech." It appears essential to train for generalization of self-monitoring, during picture description, personal narrative, and conversation. Subject 5, who improved most, had a more active social life and may have been more motivated to improve. For people with more severe or more long-standing aphasia, group treatment and family involvement may help to increase the stakes, and enhance motivation for better speaking. Self-monitoring resulted in subjects identifying for themselves the need to slow down and think about what they were saying. Future research might compare efficacy, effect, and efficiency of self-monitoring training and pacing, a treatment approach designed specifically to decrease rate, to decrease disfluencies and improve communicative efficiency.

[282] CONNECTED SPEECH DEVIATIONS OF APHASIC AND NON-BRAIN-DAMAGED ADULTS

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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 adults, and to assess how aphasic adults and non-brain-damaged adults differ with regard to these behaviors; and 3) to evaluate the extent to which normal listeners' judgments of the quality and adequacy of aphasic and non-brain-damaged adults' connected speech are related to objectively measured characteristics of the connected speech such as macrostructural integrity, communicative efficiency, and the presence of disruptive speech behaviors.

METHODOLOGY—Connected speech samples from non-brain-damaged adults and adults with aphasia are transcribed and scored for the presence of several specific behaviors, as well as for overall communicative efficiency and informativeness. Audiotape recordings of non-brain-damaged or brain-damaged speakers are then played to nondisabled persons who make subjective judgments about the communicative success of the speakers and the degree to which the speech characteristics cause various subjective reactions in the listeners.

RESULTS—We are currently evaluating the effects of speakers' production of what we call performance deviations (false starts, revisions, unnecessary repetition, producing error words, and so on) on listeners' subjective reactions to the speaker. We have devised a standard, rule-based system for quantifying the occurrence of performance deviations in connected speech, and have analyzed the connected speech of large groups of adults with and without brain damage. We have found that nondisabled speakers and those with aphasia do not meaningfully differ in their productions of several categories of

performance deviations, but that large and potentially meaningful differences exist for other categories. We have completed a preliminary study of normal listeners' subjective judgments of ease of comprehension and listening effort as they listen to brain-damaged or nondisabled adults produce spoken narratives, and are preparing a larger study based on the results of the preliminary study.

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 normal listeners' subjective judgments of communicative success will enable clinicians to focus treatment on aspects of connected speech that have the greatest potential for improving daily-life communication.

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Performance deviations in the connected speech of adults with no brain damage and adults with aphasia. Brookshire RH, Nicholas LE. Am J Speech-Lang Pathol 1995:4:118–23.

[283] APHASIC NAMING DEFICITS: EFFECTS OF DEEP- AND SURFACE-LEVEL TREATMENTS

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PURPOSE—This research compared the effects of an associative learning procedure, personalized cueing with a traditional surface-level training procedure, phonological cueing, on the long-term naming of realistic stimuli by subjects with aphasia and without brain damage.

METHODOLOGY—Thirty-nine adults with aphasia (APH) and 40 adults with no brain damage (NBD) meeting certain selection criteria participated in the study. All subjects were randomly assigned to personalized cueing (PERS) or phonological cueing (PHON) conditions. Experimental stimuli consisted of 40 photographs of subordinate members of the semantic categories dogs and birds that subjects were unable to name on pretesting. Subjects were taught the names of 20 of the dogs via PERS or PHON cueing procedures. Ten additional dog pictures and 10 bird pictures served as untrained, semantically related, and untrained semantically unrelated, control items, respectively. In the PERS condition, the examiner verbally provided individualized personalized cues created by each subject in a pretraining procedure before asking the subject to name the dog in the photograph. In the PHON condition, the examiner provided surface-level phonological information in the form of the first sound of the dog name and the number of syllables in the word. For the 20 untrained stimuli, the examiner presented the picture of the dog or bird and named the item for the subject. Subjects completed 12 training sessions. During each session all trained and untrained items were presented twice in random order. Naming probes, which involved presentation of stimulus pictures without cues or feedback from the examiner, were administered 1 week, 30 days, and 6 months after training was completed.

RESULTS—Both groups of subjects attained a high degree of accuracy during training with the NBD group outperforming the APH group by approximately 20 percent. To ascertain the effects of training, separate three-way ANOVAs with repeated measures were performed for APH and NBD subjects. These examined differences among conditions (PERS vs. PHON cueing) stimuli (trained dogs, untrained dogs, untrained birds), and naming probes (1 week, 30 days, 6 months). Results failed to support the superiority of PERS cueing shown in prior in-

vestigations using "novel" training stimuli for either group. Naming probe scores for both APH and NBD groups declined from probe-to-probe suggesting that items learned in training were forgotten without training. Naming probe scores (f percentage of items correctly named) for APH subjects for the 1 week (M=53; SD=29), 1 month (M=40; SD=27), and 6 month (M=20; SD=18) probes were all significantly different from each other (P<0.001). APH subjects performed significantly better on the trained dogs (M=44 correct; SD=28) than the untrained dogs (M=32; SD=26), and the untrained birds (M=37; SD=31). Analyses of results are presently considered in their preliminary stages; many additional analyses are forthcoming.

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Comparison of personalized and provided cueing on the facilitation of verbal labeling by aphasic subjects. Freed DB, Marshall RC, Nippold MA. J Sp Hear Res 1995:38(5):1081–90.

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Effect of personalized cueing on long-term naming of realistic visual stimuli. Freed DB, Marshall RC. Am J Sp Lang Path 1995:4(4):105–8.

[284] ANALYSIS AND TREATMENT OF APRAXIC SOUND ERRORS

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PURPOSE—The primary objectives of this investigation are to 1) determine the stimulus generalization effects of a minimal contrast treatment for apraxia of speech; 2) evaluate the effects of sequential modification of treatment in terms of additional stimulus generalization; 3) study the effects of treatment on general measures of verbal production; 4) perform acoustic comparisons of correctly and incorrectly articulated sounds, as produced by apraxic patients pre- and post-treatment, in order to examine the relation among such sounds; and 5) determine the relation between acoustic measures of apraxic speech and raters' direct magnitude estimates of degree of accuracy of sound production.

METHODOLOGY—Combined single subject and group experimental designs are being utilized to examine the effects of treatment. Multiple baseline designs across subjects, behaviors, and conditions are being used to evaluate the effects of treatment on production of specific sounds in treated and untreated words across several stimulus conditions within individual subjects. Concurrently, a repeated measures group design is being employed to evaluate the effects of treatment on additional aspects of speech production.

Sixteen apraxic/aphasic subjects will receive treatment, applied individually in a manner consistent with a multiple baseline design. Continuous baseline, treatment, and maintenance probes will be conducted for each individual subject to evaluate production of specific sounds. Additional measures of speech production (e.g., percent consonants correct on consonant inventory, PICA verbal score) will be obtained from each subject at pre- and post-treatment intervals in order to determine group effects of treatment.

In addition to the preceding pre- and post-treatment measures, samples of incorrectly and correctly produced sounds are being collected and analyzed by acoustic means. Pre-treatment word lists are prepared for each subject on the basis of performance on a consonant inventory probe. These lists are designed to elicit incorrect productions of sounds that individual subjects misarticulate. Following acquisition of incorrectly produced sounds, word lists are prepared to elicit correct productions of homonymous words. Non-brain-damaged speakers are being matched for age, sex, and regional dialect to each apraxic subject. Correct productions of each of the words utilized in the apraxic speaker's sample are being elicited from the normal speakers for purposes of com-

parison. Acoustic analyses will be specific to selected sounds and the Computerized Speech Lab is being utilized for the measurements.

PROGRESS—Five apraxic/aphasic subjects have been entered into treatment to date. Treatment has been completed for three of the subjects, as have corresponding acoustic analyses.

PRELIMINARY RESULTS—All of the subjects have demonstrated positive acquisition and response generalization effects of treatment for all sounds trained, with the exception of one subject whose positive results were limited to two of the three trained sounds. Unlike previous investigations, across-sound generalization has been observed for three of the subjects. To date, sequential modification of treatment across stimulus contexts has resulted in positive stimulus generalization effects for subjects who have reached that phase of treatment.

Acoustic analyses of incorrect and correct sound productions have been completed for three subjects. Results indicate that for two of the three, sound errors appeared to be characterized as distortions rather than substitutions. Findings for the third subject were inconclusive.

RECENT PUBLICATIONS FROM THIS RESEARCH

Spectral analysis of sound errors in persons with apraxia of speech and aphasia. Wambaugh JL, Doyle PJ, West JE, Kalinyak MM. Am J Speech Lang Pathol 1995:4:186–92.

A minimal contrast treatment for apraxia of speech. Wambaugh JL, Doyle PJ, Kalinyak MM, West JE. Clin Aphasiol 1996:24:97–108).

A critical review of acoustic analyses of aphasic and/or apraxia of speech. Wambaugh JL, Doyle PJ, Kalinyak MM, West JE. Clin Aphasiol 1996:24:35–63.

A VOT analysis of apraxic/aphasic voicing errors. Wambaugh JL, West JE, Doyle PJ. Aphasiology. In press.

C. Vision Impairment

[285] SMITH-KETTLEWELL EYE RESEARCH INSTITUTE: SELECTED PROJECTS

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PURPOSE—The Smith-Kettlewell Eye Research Institute is dedicated to research on human vision. It was founded to encourage a productive collaboration between the medical clinic and the scientific laboratory. The research staff, numbering some fifty professionals, is drawn from diverse scientific and medical backgrounds, including ophthalmology, neurology, experimental psychology, engineering, physics, optometry, biophysics, and audiology.

Here are some highlights of only a few of the many vision research projects currently being undertaken at Smith-Kettlewell.

Development and Evaluation of Active VEP Electrodes For Pediatric Vision Research

Our program of vision impairment assessment for infants and young children is influenced by the convenience with which electrodes to measure visual evoked potentials (VEPs) can be applied and removed. This is especially true of the multihandicapped population targeted for our present 5-year research plan. The availability of suitable electrodes, easy to apply and remove and without the need for electrode paste, would provide a quantum leap in practicality and convenience in addressing the vision problems of this and other target groups.

Accordingly, we have initiate collaboration with Wen H. Ko & Associates of Cleveland to explore new electrode technologies.

We have evaluated initial prototype multigigohm active electrodes previously fabricated by this firm for an EKG application. We designed and built an interface specifically for our VEP application, and obtained pilot data in our RERC Pediatric Vision lab. These data were supplied to the manufacturer for the development of new active electrodes specifically for the VEP application. These electrodes incorporate a semiconductor amplifier on the electrode itself and require only water to enhance contact with the skin. We believe this device has a high likelihood of providing enhanced practicality in the vision screening of infants and neonates, especially those with combined vision, cognitive, hearing, and physical disabilities.

Talking Signs® Development, Applications and Evaluation

The Talking Signs system is our principal project on orientation and mobility for blind and visually impaired individuals. The system consists of infrared transmitters placed at the locations of signs, and a pocket-sized receiver carried by the blind user. The receiver decodes the message from the transmitter and verbally informs the user of its message.

We have developed a new and upgraded system of Talking Signs transmitters for use in crosswalks on controlled intersections. The new transmitters utilize improved infrared LEDs to reach across streets up to 100 feet wide, and provide the following information to the user: the name of the street about to be crossed, the block in which the user is located, the direction in which the user is walking, and the crosswalk signal condition. The transmitter is designed so that the walk/don't walk message fades out when users veer off the crosswalk, providing them with guidance for remaining within the designated boundaries of thecrossing. The prototype transmitters have been installed on the intersection of 5th and Market Streets in San Francisco in collaboration with the San Francisco Department of Parking and Traffic. This is a complex 5-way intersection which borders on the entrance to the Powell Street BART/Muni transit station (also comprehensively outfitted with Talking Signs) and thus provides an ideal test site. User evaluations have been extremely positive.

With supplementary funding from Project ACTION, and the collaboration of the San Francisco bus system (Muni), we have conducted pilot studies of Talking Signs needs for buses and bus stops. A focus group composed of eight research subjects was used to identify the perceived needs of users. In addition to the San Francisco Muni, we have also worked with several other transit authorities.

A pilot study in the Powell Street BART/Muni station to determine the usefulness of Talking Signs to those with cognitive impairments has been completed. Results were extremely encouraging and indicated that Talking Signs have a definite role to play in assisting the cognitively impaired gain improved access to public facilities.

Among many new Talking Signs installations are San Francisco's new public toilets, a city office building, the new Main Public Library, and the new Muni light-rail stops being installed on the Embarcadero. Recent installations elsewhere include The Lighthouse, New York, Washington Metro (one station as a trial), and the Texas School for the Blind.

Access to Visual Displays, Laboratory Instruments, and other Consumer and Vocational Products

We are undertaking several projects aimed at improving access to a wide variety of instruments and displays. One example is the possibility of making modern laboratory instruments such as digital oscilloscopes accessible to the blind. Our earlier Auditory Oscilloscope project made regular analog oscilloscopes usable by blind individuals, using variable-pitch tones to represent vertical displacement of the trace on the screen as a cursor was scanned across from left to right. With the advent of digital instruments with RS-232 or other interfaces, the opportunity exists to adapt these earlier solutions for a wider range of instrumentation. We are presently working with a sample oscilloscope with both RS-232 and IEEE bus connections to devise a practical approach to the accessibility problem. A recurring problem for persons without sight is the need to conduct simple measurements. We have developed a device to duplicate a carpenter's steel measuring tape.

We and others have often proposed the development of a standard for infrared links to and from products with visual displays, based on our experience with Talking Signs technology. The concept would require the information normally sent to a visual display to be routed through an infrared LED whose transmissions could be monitored by a suitable transceiver with speech and other output. This approach appears to offer the hope of a practical, low-cost solution if the needed standards and protocols can be devised and adopted. Accordingly, we are now participating in a new initiative spearheaded by the

Trace RERC known as the Universal Disability Infrared Link Protocol, to develop suitable standards to benefit all persons with impairments.

Dexter, the Robotic Fingerspelling Hand

Dexter, our robotic fingerspelling hand project is undergoing development to improve its overall performance as well as interfacing with a TDD to enable telecommunications reception. New electro-mechanical components have been designed to improve the hand's physical performance, and an ALVA braille display configured in preparation to develop the software for the proposed TDD interface. Upstart Robots plans to have prototype hands completed in the near future for field testing. Results of earlier tests have provided useful information for necessary upgrades in the hand's functions.

The SKILL Card: Measuring Hidden Visual Impairments

Based on our findings with the SKILL Card in an earlier pilot study of 15 "recovered" optic neuritis (ON) patients, we embarked on a collaborative study with an ON study group that has been following a group of 448 individuals with acute demyelinating ON. The original purpose of this multicenter clinical trial was to determine the efficacy of corticosteroids in the treatment of ON. The SKILL Card has been incorporated in the vision test battery being used to track the course of recovery and/or recurrence of vision loss in these patients. The patients tested with the Card had their initial attack of ON a minimum of 5 years earlier. Nonetheless, though 72 percent had normal (better than 20/20) visual acuity, and 47 percent had normal contrast sensitivity, only 29 percent had normal SKILL score, indicating that this score is sufficiently sensitive to detect long-term (permanent) subtle abnormalities. The results confirm the ability of the SKILL Card to measure the real-world vision impairments of which many patients complain, even though their visual acuity as conventionally measured may be normal.

The SKILL Card has been requested by and sent to more than 50 persons and/or research groups. It is being employed in a variety of settings including driving studies, drugstudies, glaucoma and diabetes studies, and aging studies. In fact, the Card has been shown to be a very sensitive indicator of the presence of amblyopia.

Compendium of Technology

We have developed a compendium of technology to act as a resource guide and "idea stimulator" for blind persons and rehabilitation professionals involved in placing blind individuals in employment situations. Although the main focus of the compendium is on vocational instruments, other areas of device applications are also included. It is hoped that the existence and distribution of this compendium will help to stimulate employment of blind individuals in less stereotyped areas, and stimulate demand for specialized vocational instruments: increasing such demand would ease the way toward having such devices manufactured commercially. To date, we have completed the braille, computer disk, and cassette versions of the compendium; the illustrated large print version will be completed shortly.

RECENT PUBLICATIONS FROM THIS RESEARCH

Ergonomic considerations in blind and low vision rehabilitation. Heller M, Brabyn J. In: Kumar S, ed. Perspectives in rehabilitation ergonomics. Bristol, PA: Taylor & Francis. In press.

The SKILL card: an acuity test of reduced luminance and contrast. Haegerstrom-Portnoy G, Brabyn JA, Schneck ME, Jampolsky A. Invest Ophthalmol Vis Sci. In press.

[286] VISUAL CORRELATES OF MOBILITY IN THE VISUALLY IMPAIRED

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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 veterans with varying degrees of vision loss from mild to severe and 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 4 block outdoor mobility route are completed under the two illumination levels. Performance measures are time to complete a course and number of errors made.

PROGRESS—]The indoor experiment is complete, with 88 subjects tested. The outdoor experiment is nearly complete with 65 subjects tested.

RESULTS—Both time and errors on the mobility tasks are equally effective measures of performance. The following comparisons are based solely on the error data. Performance on the indoor tasks was modeled by considering the quality of visual information at three levels of the visual system: type of vision loss, sensory visual function, and perceptual visual function (information processing). Each level is significantly correlated with performance. However, combining the sensory and perceptual levels provides the best predictive model of performance accounting for 46, 36, 25, and 30 percent of the performance variance on the high and low illumination obstacle course and high and low illumination hallway course, respectively. Adding type of vision loss to the model does not improve prediction. Subjects' self-ratings of their travel abilities were also correlated with errors and adding self-ratings as a level in the model in combination with the sensory and perceptual levels improved prediction modestly, but significantly to 48, 41, 27, and 37 percent for the tasks in the order listed above. Other findings include: 1) a significant increase in errors (roughly double) as a result of decreasing light level; 2) step-over and low contrast objects are contacted most frequently on the obstacle course; 3) searching with hand or foot and stops are the most common errors on the hallway course, but tripping is the behavior most adversely affected by reducing illumination; 4) subjects without a peripheral field restriction perform significantly better than those with one; and 5) self-report results indicate the subjects in this study had their greatest difficulties with single steps (up or down), adapting to illumination changes, poor illumination, small objects in the travel path, unfamiliar environments, and glare.

FUTURE PLANS—One of our future goals is to continue developing models of mobility in the visually impaired, with specific emphasis on the inclusion of nonvisual factors such as cognitive function, problem solving, and personality. We also plan to examine travel-related injuries/incidents, such as falls, and whether or not current variables in our model predict these. Finally, we plan to determine if training on visual information processing tasks such as visual search can improve mobility performance.

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.

Visual processing and mobility performance in visually impaired adults. Kuyk TK, Elliott JL, Bichl J, Fuhr PS. Optom Vis Sci 1995:72:19.

Environmental variables and mobility performance in adults with low vision. Kuyk TK, Elliott JL, Bichl J, Fuhr PS. J Am Optom Assoc 1996:67:403–9.

[287] AGE VARIANCE IN NYSTAGMUS SUPPRESSION: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #C1830-PA)*

PURPOSE—The purpose of the research is to evaluate the need for age specific normative values for an electronystagmography subtest called fixation suppression. A continuum of subject age, with the sixth decade of life being the dividing point, serves as the comparison for this single test procedure. The long-term goal is to enhance electronystagmography test sensitivity and specificity.

METHODOLOGY—This between-groups pilot study is evaluating a total of 80 subjects, who are 20–49 and 60–90 years of age, with a single test protocol. Nonimpaired volunteers who meet inclusionary criteria will, upon informed consent, provide the following data sets: otoscopic, medical history, acoustic immittance, basic audiometrics, smooth horizontal visual pursuit, and vestibulo-ocular reflex induced nystagmus with an index of nystagmus reduction produced by visual fixation during caloric irrigations of the external ears. All data are saved using commercially available computers and allow for electro-oculographic eye movement recordings with automated eye movement data analysis. Testing takes about an hour.

PROGRESS—Currently the project is in the data collection phase with 100 percent of volunteers meeting the inclusionary criterion. At this writing, 28 subjects have been tested with 24 in the younger age group and 4 in the elder. Plans for public awareness are in place to increase the harvest of subjects in the elder group. Currently, statistical analysis is not possible.

PRELIMINARY RESULTS—All 28 subjects were able to complete the protocol without adverse reaction. Mean and standard deviation data for horizontal smooth visual pursuit demonstrate consistent findings among subjects, and in comparison with the literature, with a gain factor near one for horizontal pursuit tasks and without evidence of vestibular weakness, direction preponderance, nor failure of fixation suppression. The raw data are currently being placed into a spreadsheet. It is anticipated that the elder age group will provide horizontal pursuit gains of between 0.8 and 1 (80 to 100 percent), produce normal caloric responses in terms of vestibular weakness and directional preponderance, and finally provide evidence that failure fixation suppression index data set are separate and distinct from the younger group. Lastly, a methodological change has been requested to retest a limited subgroup to allow an evaluation of validity.

FUTURE PLANS—Should the research hypothesis be accepted as true, there will be recruitment of a larger group of subjects to add to this data set (including sixth decade data) in order to construct age-specific normative values for the failure fixation suppression index (FFSI). Further, we wish to evaluate additional experimental factors related to the FFSI such as room light and color, subject-to-target distance, fixation target size and lumen requirements, and visual background effects along the age continuum.

[288] DEVELOPMENT OF A DATABASE OF CANE TECHNIQUES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C813-2RA)*

PURPOSE—The goal of the 3-year study is to construct a database of cane techniques used by blind individuals. This database will be used to establish norms and to evaluate cane techniques over time. This information will be applied to problems of evaluation, development, and design of mobility techniques, accessibility standards and Electronic Travel Aids (ETAs).

METHODOLOGY—A mobility client profile has been developed in conjunction with the orientation and mobility staffs of five of the VA Blind Rehabilitation Centers (BRCs). Data in the profile is obtained from the mobility instructor, the client, and through site visits to the home environment of the client. Information about travel patterns and use or disuse of cane techniques is recorded before, during, and after training at the BRCs and through follow-up with the client after discharge. Included in this profile is information contained in the RoboCane™ software package.

RESULTS—The profile was successfully developed in the first year of the project. However, due to clinical staff cutbacks at the BRCS, gathering of information on the full mobility client profile has proved to be very problematic. In order to facilitate data gathering, the investigators have expanded the scope of the project to include data gathering and analysis of national Blind Rehabilitation Service information on all programs, not simply mobility. By doing this, we have broadened the scope of our data gathering to include mobility in the context of the full rehabilitation experience. We have also expanded our sample size to include not simply the clients of the original five BRCs. We are now recording and have access data on clients seen at all of the VA BRCs plus all of the clients seen by the Blind Rehabilitation Outpatient Service (BROS) and Visual Impairment Service Team (VIST) programs. All data gathering procedures will be in place by October 1996.

IMPLICATIONS—The mobility profile not only includes measurable individual variables and environmental characteristics, but also can be used to generate demographic norms for visually impaired individuals in different environments. This data set will be invaluable as a universal learning tool for mobility students, practicing mobility specialists, patients, and their families. These objective measures provide documentation for increased accountability, which results in improved quality assurance, increased capacity for the training and monitoring of professional staff, and diminished threat of liability. In addition, the use of the RoboCane software modeling package provides a unique opportunity to analyze the techniques that visually impaired individuals may have adapted that may be superior and safer than the traditional techniques currently being taught.

RECENT PUBLICATIONS FROM THIS RESEARCH

Three aspects of coverage provided by the long cane: obstacle, surface and foot placement preview. Blasch B, LaGrow S, De l'Aune W. J Visual Impairm Blindn \1996:90(4):295–301.

New concepts and cane techniques based on research from RoboCane. Blasch B, De l'Aune W, Blasch E. In: Proceedings of the International Mobility Conference VII; 1996, Trondheim, Norway. In press.

The effect of hand position on detection distance for object and surface preview when using the long cane for non visual travel. LaGrow S, Blasch B, De l'Aune W. RE:view. In press.

The efficiency of the touch technique for footfall and surface plane preview. LaGrow S, Blasch B, De l'Aune W. J Visual Impairm Blindn. In press.

[289] A STUDY OF ILLUMINATION SOURCES FOR LOW VISION INDIVIDUALS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C815-2RA)*

PURPOSE—The objective of this 2-year project is to determine whether specific recommendations for appropriate illumination sources and levels of illumination can be derived for low vision individuals when reading. This project proposes to study illumination sources in order to provide low vision professionals an objective decision-making rationale for lighting recommendations based on type of visual impairment, type of lighting, and amount of light.

The research is designed to answer four questions about visual performance of individuals with low vision performing near tasks:

1. Is there a difference in performance associated with different illumination sources?
2. Are differences in performance associated with different illumination sources also associated with specific visual pathologies?
3. Is there a difference in optimum and preferred illumination?
4. Are differences in optimum and preferred illumination associated with specific visual pathologies?

METHODOLOGY—Eighty subjects with low vision are currently being recruited in the following categories: 20 with macular loss, 20 with restricted fields, 20 with cataract or other media opacity, and 20 with general amblyopia with no field loss. Each subject who agrees to participate is tested without low vision devices for acuities, field of view, and contrast sensitivity.

The participants are then evaluated by reading a shortened version of the Pepper Visual Skills for Reading Test with a 5× spectacle magnifier under each of the following lighting sources: an incandescent lighting in a flex arm lamp, fluorescent lighting in a flex arm lamp, halogen lighting in a flex arm lamp, sodium vapor lighting in a flex arm lamp, full spectrum lighting in a flex arm lamp, a krypton spectacle mounted lighting device, an electroluminescent lighting device (developed by researchers at this Center), and a 5× Eschenbach illuminated hand-held magnifier.

After reading the Pepper Test under each lighting condition, participants then complete a visual fatigue diary to indicate a variety of physiological reactions to the type of lighting and to indicate their subjective preference for each lighting device. The data will be analyzed to ascertain whether individuals with some pathologies require certain types of lighting for best performance, and to determine whether any relationship exists between specific pathologies and illumination preference.

PROGRESS—To date we have tested 38 participants: 18 in the macular loss category, 10 in the restricted fields category, 8 in the cataract category, and 2 in the amblyopic category. Current recruitment is ongoing for additional VA and non-VA participants.

RESULTS—Using data from the macular loss category, we ran means and found the following trends. For accuracy, the lights were ranked in order as follows: Krypton, Fluorescent, Incandescent, Halogen, Sodium Vapor, ELVIS, Hand-held Magnifier, and Full-Spectrum. The lights were ranked for reading-rate as follows: Krypton, Fluorescent, Incandescent, Halogen, Sodium Vapor, ELVIS, Hand-held Magnifier, and Full-Spectrum. We found that the self-reported preferences were ranked as follows: Halogen, Full-Spectrum, Incandescent, Hand-held Magnifier, Sodium Vapor, Fluorescent, Krypton, and ELVIS. This information is just preliminary, and has no statistical significance at this point, but this does indicate certain trends in the data.

[290] MEASURING LOW VISION READING ASSESSMENTS USING A SCANNING LASER OPHTHALMOSCOPE

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PURPOSE—The objective of our research is to evaluate the efficiency and efficacy of available low vision reading rehabilitation assessment tools using the scanning laser ophthalmoscope (SLO). We seek to discover the answers to the following: 1) Do rate, accuracy, and error scores on a visual skills for reading test relate to preferred retinal locus (PRL) ability and characteristics as measured by the SLO? 2) Do reading training techniques efficiently and effectively assist readers with macular loss in improving their visual skills for reading? 3) Can the effectiveness of reading training be measured by the improvement in visual skills such as PRL ability/characteristics and/or improvements in reading assessment scores? 4) Are improvements in reading performance related to improvements in different PRL abilities/characteristics or improvements in reading assessment scores which might allow the prediction of the type of reading training that is most appropriate for individual low vision patients?

METHODOLOGY—Software for the SLO will be developed for low vision reading rehabilitation and assessment, so that the Pepper VSRT, the Morgan LVRCA, and the MNRead reading tests can be presented in the SLO. This capability will allow the investigators to see the visual stimuli (letters and words) on the retina that the patients see when looking into the instrument, and thus determine the interaction between the macular scotoma and PRL. Eighty subjects with macular degeneration and an interest in reading with low vision devices will be recruited from the Eye Clinic of the Atlanta VA Medical Center. Before rehabilitation intervention, subjects will be assessed with standard clinical testing instruments (e.g., acuity, contrast sensitivity, and glare) and specialized clinical testing, (e.g., SLO macular perimetry, binocular retinal correspondence, and preferred retinal locus testing including fixation stability, pursuit ability, saccade ability, and word retinal location). Reading performance will be assessed by the Pepper VSRT, the Morgan LVRCA, and the MNRead Continuous Text Test. These reading tests will be performed both in their standard method of presentation and in the SLO (using the software developed by this project). Reading rehabilitation will then be provided at the Atlanta VA Medical Center using normal accepted training strategies that assist the subjects in maximizing their visual skills for reading. After the reading rehabilitation is complete, the standard clinical testing, specialized clinical testing, and reading performance assessment will be repeated.

RESULTS—Programming for the input of the reading tests on the SLO has been completed. The MNRead test, the Morgan Low Vision Reading Comprehension Test, and the Pepper Visual Skills for Reading Tests can now be administered via SLO.

FUTURE PLANS/IMPLICATIONS—Subject testing will begin when the software has been installed and debugged. Following the methods described above will provide this research project with a database of reading performance information as it relates to visual function characteristics of patients. We will be able to determine whether any of the visual function characteristics have an influence on reading performance, training strategies or outcomes. For example, the error patterns within the Pepper test can be related to macular scotoma and PRL characteristics. This database of reading performance information will also allow the investigators to propose detailed clinical procedures for the optimal training strategies and outcome assessment tools for each individual low vision patient's reading capabilities. The final results of this project will lead to a better understanding of the reading skills and abilities of individuals with macular loss.

[291] 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 3-year 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 under restricted lighting conditions. The purpose of this project is first to develop LC sunglasses that very quickly and precisely control the amount of illumination reaching the eyes, and second, to test the usefulness and practicality of these LC sunglasses in actual use by persons with low vision.

PROGRESS—Investigators have completed an evaluation of LC materials, constructed an initial prototype based on the evaluation, completed subject testing of the initial design prototype, revised the LC sunwear design based on the results of the initial subject tests, re-evaluated LC materials, constructed improved prototypes, established indoor testing protocols simulating outdoor mobility tests, and are currently testing subjects. The project should be completed by fall 1996.

RECENT PUBLICATIONS FROM THIS RESEARCH

Light/dark-adapting eyewear for persons with low vision. Ross D, Mancil G. In: Proceedings of the 19th RESNA Annual Conference; 1996, Salt Lake City, UT. Washington, DB: RESNA Press, 1996:167–9.

[292] LOW VISION ENHANCEMENT SYSTEM (LVES)

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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 research is to evaluate the effectiveness of the Low Vision Enhancement System (LVES) device on the visual rehabilitation and improvement of quality of life in low vision patients. The goal is to improve the ability of the patient to function in daily living tasks and reduce dependence on multiple low vision aids.

METHODOLOGY—Subjects with subnormal or low vision (including those who are legally blind) were fitted and dispensed manual Beta-1 or autofocus Beta-2 LVES units. The device consists of a head-mounted series of video cameras, video displays, and integrated optical elements. The headset is connected to and powered by a cable connected to a self-contained battery control box which is mounted as a beltpack. The subject adjusts the controls on the beltpack as necessary for optimal viewing of the image. Subjects were evaluated before and after fitting and dispensing with regard to visual acuity and contrast sensitivity.

PROGRESS—We have entered 117 patients into the study thus far from two VA blind rehabilitation centers, 3 VICTORS (Visual Impairment Center To Optimize Re-

maining Sight) centers and one outpatient clinic. Recruitment is ongoing.

PRELIMINARY RESULTS—Of the 117 patients in the study, 63 percent suffered from macular degeneration, 11 percent from diabetic retinopathy, and 26 percent from various other diseases (including glaucoma, histoplasmosis, and Stargardts disease) Of the patients fitted with the LVES, 96 percent (112) had improvement in visual acuity over their best spectacle correction. (Median visual acuity with spectacle correction was 20/200 OU and median acuity using the LVES was 20/40 OU. Mode visual acuity was 20/200 and 20/20 respectively). Further, 93 patients were evaluated for change in contrast sensitivity using the LVES. Of these patients 78 percent demonstrated improved contrast sensitivity of several log units with the LVES.

FUTURE PLANS—Recruitment will continue up until the end of the study. Further testing is underway to evaluate the impact of the LVES on reading speed and time, visual-motor tasks, and activities of daily living. New developments are underway to improve the autofocus response times, and to assess the impact of the device on the visual field.

[293] DEVELOPMENT OF SCANNING LASER OPTHALMOSCOPE FOR LOW VISION REHABILITATION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C838-RA)*

No report was received for this issue.

[294] 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 employees, state directors of vocational rehabilitation programs, and college administrators, telephone interviews were completed with 45 employees with visual impairments and 27 of their employers. Questionnaire responses were analyzed using frequency analysis, correlation analysis, and

factor analysis. The format of the surveys also encouraged respondents to provide lengthy answers to certain questions. Responses to these open-ended questions were analyzed and categorized.

RESULTS—The project is complete. Employees stated that the following were the most important in obtaining a job: making a career choice, developing a resume, locating transportation, communicating with others about the type of job desired, communicating with employers about accommodation needs, practicing being interviewed, visiting job sites, and making housing arrangements. The most common problems experienced by employees at work included the following: having enough money; locating transportation; being discriminated against because of the visual impairment; assessing books, written materials, diagrams, and charts; being lonely; and managing time.

The most frequently provided work accommodations by employers were travel instruction or orientation to the worksite, computer access devices or CCTVs, and alternative print media. The majority of employers reassigned some job duties, provided readers or transportation, allowed flex-time scheduling, and removed architectural barriers. Employers advised potential workers to not expect special considerations for impairments, to obtain skills needed to perform the job, to emphasize abilities and assets during job interviews, to select jobs that match 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, and parents; and to college students, advisors, and rehabilitation personnel to help increase the number of students with visual impairments completing college and beginning work.

[295] TACTILE AND HAPTIC VISUALIZATION PROJECTS

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PURPOSE—Individuals with visual disabilities face challenges that can be insurmountable in interfacing to 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 (Engaging, Recruiting, and Retaining Students with Disabilities in Science, Engineering, and Math), the Tactile and Haptic Interface Project addresses the needs of the person with visual impairment 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 one another, and abilities of blind and deaf-blind persons to compre-

hend 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 individuals with the need for it.

PROGRESS—The haptic visualization project has made a great deal of progress in the past year. Since the PHANToM haptic interface did not include a software library or programming interface, one was created using Microsoft's Visual C++ running under Windows NT. Several methods of haptic modeling of different types of scientific data have been created, as well as a graphical display on a Silicon Graphics machine for demonstration and debugging. Models for haptic enhancements, such as friction and texture, have also been created to help an unsighted person understand the data that he or she is feeling. Speech output of information is also possible. Several persons with visual impairment have had the opportunity to feel different haptic simulations, and the feedback has been positive.

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—Tactile studies will be conducted and will be extended to the haptic sense system. We will continue to develop the software interface for haptic visualization with the PHANToM, as well as conduct more human factors studies of the algorithms for haptic rendering of data. We will need to determine if an unsighted person can extract enough information about the rendered data using the developed algorithms. The image simplifcation system will be completed, as will systems that make use of touch screen technology and tactile overlays.

XV. Spinal Cord Injury and Related Neurological Disorders

A. General

[296] EMPLOYMENT OF IBM SPEECH RECOGNITION IN USER-BASED REMOTE CONTROL: A PILOT STUDY

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PURPOSE—The overall purpose of this 1-year study was to improve the quality of life of veterans with spinal cord injury (SCI) through the development of a device that would give them the ability to verbally control their environment wherever they chose to go: around the home, in their van, their office, friends' homes, public buildings, and on public streets. The specific objective was to evaluate the feasibility of making such a device available to veterans.

METHODOLOGY—Three components comprised the U-VOICE hardware: 1) a Voice Connexion® speech recognition/synthesis PC/104 board (in place of discontinued IBM hardware), 2) a miniature, wearable PC, and 3) a small custom board with Radio Frequency (RF) and Infra-Red (IR) transmitters. RF switch-receivers were employed for control of fans, lights, doorbells, door locks, devices on the wheel chair, cross-walk buttons, parking gates, and so forth. Transmitted IR codes were employed to control home electronics, van doors and lifts, and public elevators.

No visual display was used, as all actions taken by U-VOICE were initiated by voice command and verbally confirmed via speech synthesis. U-VOICE provided voice assistance during all aspects of training and use. Context-based word recognition software was written to improve word recognition rates, especially for emergency commands.

Investigators evaluated the prototype, determining speech recognition reliability for normal commands and for emergency commands and the reliability of the IR and RF transmitters under varying indoor and outdoor conditions. Then, with the assistance of a focus group of five professionals and three consumers, they evaluated the usability of the interactive voice-control interface and the usability of the device as a whole.

PROGRESS—This project has been successfully completed.

RESULTS—Word recognition rates for the Voice Connexion hardware alone was a disappointing 84 percent in general, and only 63 percent for emergency words spoken under stress conditions. However, with context-sensitive software the recognition rates improved to 96 and 92 percent respectively. Finally, by changing the emergency command to "alarm, alarm, alarm," a 98.5 percent first-time and a 100 percent second-time recognition rate was achieved.

RF control was nearly 100 percent reliable at 50 feet (even through walls), and became less so at 75 feet. IR control was reliable at 7 feet or less, but at distances past 10 feet dropped significantly. Also, it was important that U-VOICE be pointed toward the IR receiver. This was inconvenient at times: for this reason, the focus group recommended use of RF control whenever possible.

The focus group agreed that remote control of devices in all environments was a valuable goal and suggested an extended list of devices for control, including telephones, appliances, home thermostat, computer, teller machines, and point-of-sale payment machines. However, they also thought that voice control alone was too restrictive and awkward at times. Two users argued for puff and sip control as an alternative to, or an addition to, voice control.

FUTURE PLANS—We propose the research and development of a modular Remote Control Interface (RCI) to meet the needs of the larger population of veterans with upper body hand and arm impairments, including veterans with SCI. We hypothesize that a modular combination of 5 or 6 input modes could meet the needs of 95 percent of this population of nearly 10 million veterans.

RECENT PUBLICATIONS FROM THIS RESEARCH

Personal freedom: a wearable interactive universal access device. Ross D. In: Proceedings of the 19th Annual RESNA Conference; 1996, Salt Lake City, UT. Washington, DC: RESNA Press, 450–2.

[297] CORTICAL SENSORIMOTOR REORGANIZATION IN SPINAL CORD INJURY: A PILOT STUDY

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PURPOSE—This is a pilot project to determine the feasibility of detecting reorganization of motor control in the cerebral cortex following spinal cord injury (SCI).

METHODOLOGY—We are applying the new technology of 128-electrode, high resolution electroencephalography to determine how the motor representation in the cerebral cortex changes by mapping cortical potentials associated with actual, imagined, and attempted movements of the fingers and toes in nondisabled controls and SCI patients. Movements are cued by visual stimuli which trigger the averager. The dipole sources (generators) of the movement related cortical potentials are determined and coregistered with the subjects magnetic resonance images (MRI) of the brain.

PROGRESS—We have recorded and mapped movement related potentials in actual and imagined finger and toe movements in 30 nondisabled subjects and 5 SCI patients.

PRELIMINARY RESULTS—Actual and imagined movement potentials differ in localization in normal controls. Actual movements are associated with potentials, which are more contralateral to the side of finger movement than imagined movement potentials, which tend to be midline in location. This is confirmed in dipole source localization. Data in SCI patients shows that midline potentials generated by attempts to move the paralyzed toes tend to be more contralateral than in normal toe movements, raising the possibility that toe representation may have been absorbed into the hand area.

FUTURE PLANS—More subjects will be recruited with paraplegia and quadriplegia. Ideally we would like to repeat the testing in acute cases to identify when cortical representation changes following SCI. The next step would be to investigate ways to prevent loss of representation of paralyzed limbs.

RECENT PUBLICATIONS FROM THIS RESEARCH

An electrocephalographic study of imagined movement potentials. Green JB, Thatcher R, Bialy Y, Ricamato A. Neurology 1996:46(Supp2):A339.

[298] 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 to: a) 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; and b) 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.

METHODOLOGY—Subjects with spinal cord injury and history of lower limb hypertonicity complete three procedures: a) to test the effect of moderate-intensity AUBX on signs of UMNS, subjects perform 20 min of submaximal wheelchair ergometry exercise; b) to examine the effect of low-intensity activity, subjects complete 40 min of supported standing; c) a timeout (control condition) is included to isolate effects of physical activity from changes occurring during quiet rest and testing procedures alone. Baseline measures of tone and reflexes are followed immediately by an experimental condition (AUBX, standing, or timeout). To examine the temporal pattern of changes in tone and reflexes following the experimental condition, all measurements are repeated immediately following activity or timeout and at 90-min intervals for 3 hrs.

Tone at the knee is assessed by pendulum drop test (normalized relaxation index or R2n). Electrophysiological measurements include H/M ratios and F wave amplitudes and persistence.

PRELIMINARY RESULTS—Of six subjects completing the experimental protocol, three exhibited substantial improvement in tone following AUBX and standing as evidenced by increased mean R2n with respect to baseline. Mean R2n in this group of "responders" increased 13 and 28 percent immediately following AUBX and standing, respectively. Alternatively, mean R2n declined 11 percent immediately following the timeout period. Even greater relative improvement was observed at 3 hours postactivity: mean R2n for the group was increased 6 percent and 59 percent above baseline following AUBX and standing, respectively, while mean R2n under control conditions had decreased 21 percent. In contrast, the three remaining subjects also experienced improvement in tone following AUBX and standing but in many cases, these improvements were less than those observed under control conditions. In this group of "partial responders," mean R2n was increased 10 and 7 percent immediately following AUBX and standing, respectively, but was increased 9 percent immediately following timeout. Similarly, increases of 11 and 2 percent were seen in mean R2n 3 hours post AUBX and standing, respectively, while an increase of 12 percent was seen 3 hours after the timeout period. With respect to electrophysiological measures, decreased H/M ratios and the facilitation of F waves are consistent with decreased motor neuron pool excitability and decreased recurrent inhibition, respectively. All responders exhibited either decreased H/M ratios or a facilitation of F waves or both following AUBX or standing. In contrast, none of the partial responders exhibited decreasing H/M ratios; and F waves were facilitated in only one of these subjects. In none of the six subjects were decreases in H/M ratios or a facilitation of F waves observed under control conditions.

FUTURE PLANS—Although it is not possible at this juncture to make definitive statements about the potential role of moderate intensity AUBX and supported standing in the treatment of spasticity, the fact that there is consistency of some measures in this small sample is most encouraging. These preliminary data reflect the anticipated complexity of UMNS in SCI and support further study of our hypothesis. Application of our experimental protocol to a larger sample of subjects with SCI should clarify physiological similarities as well as diversity in this population. Such information is expected to be of great value in the effective classification and treatment of these patients.

RECENT PUBLICATIONS FROM THIS RESEARCH

Analyses of lower extremity muscle tone with upper extremity exercise. Fisher MA, Fehr L, Langbein WE, Sibley P. In: J Am Paraplegia Soc: Abstracts of American Paraplegia Society 41st Annual Conference, 1995.

Electrophysiological Quantification of Spasticity: H reflexes and F waves. Fisher MA. In: Proceedings of the 58th Annual Assembly of the American Academy of Physical Medicine and Rehabilitation, 1996.

[299] CAUSE FOR MALE INFERTILITY AFTER SPINAL CORD INJURY AND ITS PREVENTION

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PURPOSE—The fertility rate of men becomes impaired after spinal cord injury (SCI). Analysis of their semen obtained by electro-stimulation reveals a general decrease in sperm count and progressive sperm motility and an increase in number of sperm with abnormal morphology. These findings suggest that defects in spermatogenesis may be responsible for the abnormal semen quality seen in ejaculates of SCI men. The aim of current year was to investigate the causes for the decrease in sperm production and the abnormal sperm parameters after SCI in the rat model.

METHODOLOGY—SCI was induced in male adult rats by surgical transection of spinal cord at the level of T9 vertebra. Animals were sacrificed at various times after the surgery. Testicular tissues were fixed in Bouin's solution and processed for histology or whole mounts of seminiferous tubules.

Qualitative normalcy of spermatogenesis was determined by the presence and location of each cell type in specific cellular association in each stage of the seminiferous epithelial cycle.

Quantitative analysis of spermatogonial proliferation was performed by enumerating the number of type A1 spermatogonia and preleptotene spermatocytes in whole mounts of stages VII-IX seminiferous tubules. Results were expressed as cell number per 100 Sertoli cell nucleoli. Quantitative analysis of differentiating spermatogenic cells was achieved by counting the number of preleptotene and pachytene spermatocytes, and step 7 and 19 spermatids in cross sections of stage VII-VIII epithelial tubules. Results were normalized as cell number per 100 Sertoli cell nuclei.

PROGRESS—Spermatogenesis became impaired as early as 3 days after the induction of SCI. Spermatocytes and spermatids were the first cell types to show abnormalities. Spermatogenesis became totally regressed 2 to 3 months after SCI, characterized by the absence of all spermatogenic cells, including the proliferating spermatogonia. This occurred in the presence of normal pituitary-testis hormone axis, suggesting that nonendocrine factors may be involved in the SCI-induced regression of spermatogenesis.

Preliminary quantitative analysis of spermatogonial proliferation revealed a 25–30 percent decrease in the number of type A1 spermatogonia and preleptotene spermatocytes 4 weeks after SCI. These results indicate an impaired spermatogonial proliferation. Since there was an acute suppression of pituitary-testis hormone axis shortly after the injury, it is postulated that stem cell renewal may be impaired, resulting in the decrease in the number of proliferating spermatogonia. The decrease in spermatogonial proliferation is apparently responsible for the subsequent regression of spermatogenesis.

Restoration of qualitatively complete, but quantitatively reduced, spermatogenesis was noted in 9 of 18 rats killed 6 mo after injury. These results demonstrate that the SCI related azospermia is reversible. The presence of persisting abnormality in the restored spermatogenesis is consistent with the observations in SCI men. This finding demonstrates that the SCI rat is an appropriate model to study the effect of SCI on human spermatogenesis.

FUTURE PLANS—Because the early spermatogenic lesions after SCI resemble those occuring after testos-

terone deprivation and/or hypophysectomy, we are currently investigating the possibility of preserving spermatogenesis in the SCI rats by combinations of testosterone and FSH. This experiment is currently underway.

Because normal Sertoli cell functions are essential for normal spermatogenesis, the regression of spermatogenesis in SCI rats may be attributable to abnormal Sertoli cell function. To examine this possibility, we will examine the effects of SCI on Sertoli cell function, using rats with Sertoli cell enriched testis as a model. This model is produced by X-irradiation of pregnant female rats at the 20th day of gestation. We have irradiated 17 pregnant females and all of them have delivered babies normally. The male pups will be weaned at 20 days of age and will be subjected to SCI operation when they reach 70–80 days of age.

[300] MANUAL WHEELCHAIR USER UPPER EXTREMITY PAIN

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B869-2RA)*

PURPOSE—The incidence of upper limb pain among manual wheelchair users has been estimated to be between 30 and 70 percent, and the probability that they will experience debilitating arm pain increases over time. Although several activities of daily living may contribute to this pain, several studies have implicated the use of manual wheelchairs as a primary contributor. Moreover, recent studies tend to indicate that wheelchair athletes do not experience a higher incidence of pain than their sedentary counterparts. This may be due to the greater care and consideration given to the selection and fitting of wheelchairs by athletes. This study focuses on two issues: the relationship between biomechanical factors, carpal tunnel syndrome, and rotator cuff injury; and cross-sectional changes in arm pain among wheelchair users with increasing years of experience. It is hypothesized that biomechanical factors related to wheelchair design and the wheelchair user's stroke will be identified and related to the incidence of arm pain.

METHODOLOGY—Veterans with thoracic level spinal cord injury are being recruited to participate in this study. Subjects are asked to complete a medical history and pain survey, and each has a unilateral magnetic resonance image and plane radiographs made of the arm. Clinical electromyograms are being used to determine the presence of neuropathies. Biomechanical analyses are performed using a SMART^{Wheel} to collect 3-D force and moment data, and the OptoTrac (Northern Digital) active marker system is being used to collect 3-D motion data. Kinematic and kinetic data are collected in real-time. Anthropometric data are collected, and used with Hanavan's model. The kinematic, kinetic, and anthropometric data are combined to calculate joint moments and forces. These data are also used to calculate several variables which are hypothesized to be able to discriminate between the biomechanics of people with and without clinical symptoms of upper limb pain. Statistical procedures are being used to compare the biomechanics of groups of subjects with and without arm pain. The MRI and EMG data are used in the determination of the two groups, and are being used to investigate the effects of chronic manual wheelchair use on arm joint structures.

PROGRESS—We have constructed a database of eligible subjects and are using it to sort eligible subjects based upon their length of time using a manual wheelchair. All of the necessary instrumentation has been installed and the appropriate interfaces have been developed. Software and hardware have been developed to perform anthropometric data collection using the new equipment. Algorithms for analyzing the data have been developed and additional development is ongoing. Complete data have been collected on a single subject, and data on several others: data collection is ongoing. We were also given recent institutional review board approval to begin a ca-

daver study to improve our biomechanical models of the upper limb.

PRELIMINARY RESULTS—Preliminary results show that there are likely to be potentially injurious forces present at the wrist during normal manual wheelchair propulsion. We have also performed an analysis of the frequencies distribution of pushrim forces. This has allowed us to select optimal filter frequencies. We have also developed a 3-D equivalent for the center of pressure.

FUTURE PLANS—We plan to continue to collect data on a greater number of subjects and to complete model development. When we have sufficient data, we will examine changes in upper limb joint structure with year of wheelchair use, and determine whether our biomechanical models are effective in discriminating between manual wheelchair users with and without arm pain.

RECENT PUBLICATIONS FROM THIS RESEARCH

Frequency domain analysis of wheelchair pushrim forces and moments. DiGiovine CP, Cooper RA, Robertson RN, Boninger ML, Shimada SD. In: Proceedings of the 19th Annual RESNA Conference; 1996, Salt Lake City, UT. Washington, DC: RESNA Press, 238–40.

Wheelchair pushrim forces as a function of body mass. Cooper, RA, Boninger ML, Robertson RN, Shimada SD. In: Proceedings of the 19th Annual RESNA Conference; 1996, Salt Lake City, UT. Washington, DC: RESNA Press, 241–3.

Projection of the point of force application of the PFA onto a palmar plane of the hand. Cooper et al. IEEE Trans Rehabil Eng. In press.

[301] 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 nontreatment 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.

RECENT PUBLICATIONS FROM THIS RESEARCH

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.

[302] 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.

This study seeks 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 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=1594) were injured and admitted between May 1979 and July 1995. The latter group will continue to grow in size as the project continues. Overall, 2,190 persons have been entered into the project database, although records are only retained if there is adequate follow-up information, which includes 1315 persons.

RESULTS—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 the project year the most extensive analysis accomplished to date was completed on the urology database. A consecutive sample of 1,114 persons with SCI who were injured between 1969 and 1994 were studied. Total and individual effective renal plasma flow (ERPF), which is a measure of renal function, were compared to determine the effect of different bladder management methods on long-term renal function. With very sophisti-

cated methods of data analysis, supervised by the Department of Biostatistics, it was concluded that renal function was adequately preserved in the great majority of persons with SCI and did not appear to be influenced to any great extent by the method of bladder management. These findings have very important clinical implications, and although somewhat unexpected, are very encouraging to the person with SCI and to the clinician trying to decide on the method of bladder management. Extensive studies were also conducted on urologic complications and have been published.

FUTURE PLANS—New patients with SCI are continually added to the study population and 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 27 years. Further investigation and analysis of data will continue during the next 2 years. Employers of the research will focus on long-term renal function outcome resulting from various methods of bladder management and other secondary complications of neurogenic bladder management.

RECENT PUBLICATIONS FROM THIS RESEARCH

Compliance with annual urologic evaluations and preservation of renal function in persons with spinal cord injury. Waites KB, Canupp KC, Devivo MJ, Lloyd Lk, Dubovsky EV. J Spinal Cord Med 1995:18:251–4.

Neurogenic urinary tract infection. Stover SL, Lloyd LK, Waites KB, Jackson AB. In: Young RR, Woolsey RM, eds. Diagnosis and management of disorders of the spinal cord. Philadelphia: W.B. Saunders Co., 1995:198–210.

[303] 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 there is no established linkage in that data set between reported occurrences of secondary complications and rehospitalizations. The purpose of this study is to provide baseline data documenting the leading causes of unplanned rehospitalizations among person with SCI and the average costs associated with each cause so that frequent and costly complications can be given higher priority for further study and the effectiveness of techniques to reduce the incidence of complications and hospitalizations can be assessed using rigorous cost-benefit analyses.

The objectives of this study are: 1) to identify the most frequent causes of unplanned rehospitalizations among persons with SCI, 2) to determine the average length of stay and cost for each cause of unplanned rehospitalization among these persons, and 3) to describe, epidemiologically, the causes and costs of unplanned rehospitalization among these persons.

METHODOLOGY—The basic study design is cross-sectional with a 2-year prospective data collection period. All persons with traumatic SCI currently being followed at the University of Alabama at Birmingham Spinal Cord Injury Care System (UAB-SCICS) 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 person 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 identi-

fied, 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 postinjury, 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—The project began in 1994. As of July 1996, 250 rehospitalizations had occurred. We have begun the process of obtaining medical records for those hospitalizations and now have completed data collection forms for 76 cases.

FUTURE PLANS—Continue data collection and begin analysis when the sample size is sufficient.

[304] SECONDARY CONDITIONS AFTER SPINAL CORD INJURY: RELATIONSHIP TO LIFE ADJUSTMENT

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Sponsor: *Shepherd Center, Atlanta, GA 30309; National Center for Medical Rehabilitation Research, National Institute of Health, Bethesda, MD 20892*

PURPOSE—The purpose of this study is to identify both prevalence and risk factors for secondary conditions after spinal cord injury (SCI). Key elements of this research include: (1) the utilization of two large SCI samples, one of which oversamples females and minorities, (2) the development of a measure of secondary conditions, and (3) building upon a prominent longitudinal study of life adjustment and SCI.

METHODOLOGY—*Participants.* Two distinct participant samples were used in this study. The first sample consisted of a large stratified (by gender, race, and age) sample of 723 cases from outpatient files of a large Southeastern rehabilitation hospital. A total of 437 participants who were currently active in the Minnesota Longitudinal Study (MLS) as of 1994 comprised the second participant sample. The same three screening criteria were used for both samples: a traumatic SCI, the injury was at least 2 years duration, and at least 18 years of age at the time of the study.

Instruments. The Life Situation Questionnaire (LSQ) was developed in 1974 to measure information on multiple aspects of life adjustment. The Secondary Conditions Questionnaire (SCQ) was developed specifically for this study; its two parts request different types of information regarding the same 50 secondary conditions for a total of 100 items. The first part requests epidemiologic information and the second information on the extent to which the condition impacts individuals' lives. Psychometric data, except for test-retest data, is yet to be collected.

Procedures. The LSQ and SCQ were sent to each potential participant. Follow-up calls and second sets of materials are used to recruit all initial nonrespondents. Participants are offered $20 and a copy of study results as inducements to participate.

PROGRESS—Of the southeastern sample, 579 completed the SCQ, as did 352 of the MLS participants. Data from the two samples has just been processed and entered into a system file.

RESULTS—Preliminary data analyses have just been completed. They were consistent with findings from previous epidemiologic studies, many of which used differ-

ent methodologies. Analyses to identify risk factors for secondary conditions are currently underway.

IMPLICATIONS—The results of this study will help rehabilitation professionals to develop prevention programs based on knowledge of risk factors related to a wide range of adjustment variables.

FUTURE PLANS—Data analysis and dissemination will be completed over the next 12 months.

RECENT PUBLICATIONS FROM THIS RESEARCH

Krause JS. Secondary conditions and spinal cord injury: a model for prediction and prevention. Top Spin Cord Inj Rehabil. In press.

[305] RACE, GENDER, AGE, AND ADJUSTMENT AFTER SPINAL CORD INJURY: THE SOUTHEASTERN LONGITUDINAL STUDY

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PURPOSE—The purpose of this study is to identify the relationships between gender, race, age and life adjustment after spinal cord injury (SCI).

METHODOLOGY—*Participants.* Participants were selected from outpatient files of a Southeastern rehabilitation hospital. All participants had traumatic onset SCI of at least 2 years duration and were a minimum of 18 years of age at the time of the study. 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.

Instruments. The Multidimensional Adjustment Profile (MAP) was developed specifically for this study and is an updated version of the Life Situation Questionnaire (LSQ). The MAP contains six sections including: (1) biographic and injury-related status, (2) vocational and avocational activities, (3) educational history, (4) psychological adjustment, (5) problems, and (6) 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.

Procedures. All participants completed the MAP. Subsamples completed one of three other instruments. Participants were offered $5 as well as descriptive study results as inducements to participate in the study. All materials were obtained by mail.

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 were observed for both subjective and employment 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 two years.

RECENT PUBLICATIONS FROM THIS RESEARCH

Krause JS, Anson CA. Attributions related to unemployment after spinal cord injury: relationship to gender, race, age, and severity of injury. Rehabil Couns Bull 1996:39:217–27.

Krause JS, Anson CA. Employment after spinal cord injury: relationship to selected participant characteristics. Arch Phys Med Rehabil. In press.

Krause JS, Anson CA. Adjustment after spinal cord injury: relationship to gender and race. Rehabil Psych. In press.

B. Treatment and Rehabilitation

[306] FUNCTIONAL ELECTRICAL STIMULATION OF SPINAL CORD INJURED PATIENTS

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

PURPOSE—The purpose of this project is to study the effects of functional electrical stimulation-induced lower limb cycling (FESILEC) on complete, spastic SCI subjects and determine the therapeutic benefits and associated risks of this form of rehabilitation.

METHODOLOGY—Subjects participated in a 48-session training protocol on a computerized REGYS ergometer, powered by lower limb muscles and activated by cutaneous electrodes. A total of 37 subjects were screened, of which 25 (3 with quadriplegia and 22 with paraplegia) 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—*Metabolic Studies.* 1) Oxygen uptake (VO_2) kinetics: the VO_2 kinetics during arm ergometry and FESILEC were compared in nine subjects during a 10-min session of FESILEC before and after training. Exercise VO_2 was the same for both arm and leg exercise; however, FESILEC exhibited slower VO_2 kinetics and was accompanied by an attenuated increase in heart rate and a greater rise in blood lactate. The improvement in blood lactate levels with leg, but not arm exercise, in the absence of changes in exercise heart rate, suggests peripheral changes to the contracting leg muscles with FESILEC training. 2) Hybrid exercise training (arm ergometry combined with FESILEC): eight subjects completed a hybrid exercise training program immediately following the FESILEC training. Results showed that hybrid exercise training performed 2×wk provided sufficient exercise intensity to significantly improve aerobic capacity, achieved higher VO_2 values during actual training sessions and increased caloric expenditure as compared with FESILEC training, alone. Long-term FESILEC and/or hybrid exercise may ultimately reduce the risk of cardiovascular disease in these patients.

Muscle Blood Flow. Studies on $H_2{}^{15}O$ positron emission tomography (PET) muscle perfusion: the PET technique was used on 4 SCI subjects and 5 nonimpaired controls before and immediately after exercise and 20 min after recovery from a standardized exercise. This exercise was induced by FES in the SCI subjects and by voluntary contraction to perform a comparable amount of work in the nondisabled subjects. The purpose of this study was to compare the skeletal muscle blood flow parameters in both groups and to determine if the limited efficiency of FES-induced exercise in SCI subjects was due to a restriction of muscle perfusion. The kinetics of $H_2{}^{15}O$ by muscle was studied in 16 consecutive frames obtained simultaneously in 32 tomographic planes through the activated area. Registration of PET images with CT images allowed identification and measurement of the volume of areas activated by exercise in both groups of subjects. The preliminary results (more SCI subjects are being recruited) showed that the volume of muscle with enhanced blood flow was greater, and had less variability than that of nondisabled controls. The kinetics of $H_2{}^{15}O$ uptake by muscle were comparable in both groups, but an enhanced rate of tracer uptake was still evident 20 min after exercise in the SCI subjects while it had returned to baseline levels in the controls at this time. Taken together, these results suggest that there is no limitation to the maximal blood flow level attainable but a slower recovery of blood flow

indicative of a greater O_2 debt following FES stimulation when compared to nondisabled subjects performing the same work voluntarily.

Muscle Mass. Final analysis of the computerized tomographic and magnetic resonance imaging studies before and after FESILEC training to assess muscle mass changes in thigh (stimulated muscles) and in the shank (nonstimulated muscles) is being performed in 15 subjects.

FUTURE PLANS—Our plans are to complete work in the areas of muscle blood flow and muscle mass.

RECENT PUBLICATIONS FROM THIS RESEARCH

Gas exchange kinetics during functional electrical stimulation in spinal cord injured subjects. Barstow TJ, Scremin AME, Mutton DL, Kunkel CF, Cagle TG, Whipp BJ. Med Sci Sports Exerc 1995:27(9):1284–91.

Measurement of resting and activated skeletal muscle blood flow by H215O 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 Meeting, 1995.

Peak and submaximal physiologic responses following functional electrical stimulation induced cycle ergometer training. Hooker SP, Scremin AME, Mutton DL, Kunkel CF, Cagle TG. J Rehabil Res Dev 1995:32(4):361–6.

[307] FES ON SPINAL CORD INJURED PATIENTS: EFFECTS ON MUSCLE BLOOD FLOW AND METABOLISM

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B2002-RA)*

No report was received for this issue.

[308] CLINICAL TRIAL OF ARTIFICIAL PERIPHERAL NERVE GRAFT

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PURPOSE—The recovering damaged nerve normally has a high population of Schwann cells that made up the myelin sheaths of axons prior to injury. These cells secrete growth factors and repair the extracellular matrix in preparation for the extension of regenerating axons into the damaged region. This project is based on replacing the Schwann cells in an otherwise acellular artificial nerve graft as a substitute for an autograft taken from elsewhere in the patient's body. The latest graft formulation is to be tested in lieu of an autograft in patients having trauma to the hand or arm, or to replace sural nerves removed for autografting.

METHODOLOGY—Preparation of the graft essentially consists of re-polymerization of solubilized collagen fibers with added cultured Schwann cells and insertion into a biodegradable conduit. Type I collagen is preferred because it is readily available, relatively inexpensive, and its properties are reasonably well understood. The matrix or conduit walls could include regener-

ation-promoting agents such as nerve growth factor. The conduit limits penetration of inflammatory cells into the region of axonal regrowth, as well as facilitating microsurgical reanastomosis with the proximal and distal ends of the nerve.

PROGRESS—In a series of animal implantations, a graft formulation has been achieved having the same functional recovery as an autograft. Based on this result, a proposal for a limited clinical trial (up to 10 patients per year) has been approved. A preclinical phase is underway, in which culture methods for adult human Schwann cells are being optimized, potentially immunoreactive components are being omitted from the fabrication process, long (30 mm) grafts are being tested for efficacy and durability in a rat model, and clinical sensorimotor measurements for functional recovery are being refined.

FUTURE PLANS—There is potential for tissue-engineered grafts to bridge traumatic defects in the central nervous system. Our laboratory is collaborating with Hines VA Rehabilitation R&D Center by fabricating grafts for testing Schwann cell-seeded implants in spinal cord injuries in rats.

RECENT PUBLICATIONS FROM THIS RESEARCH

Rat peroneal nerve regeneration in artificial nerve grafts in vivo. Sabelman EE, Üstüner TE, Keeley RD, Koran PA. In: Proceedings of the Society for Biomaterials, 21st Annual Meeting; 1995, San Francisco, CA. Paper 300.

[309] FUNCTIONAL RESTORATION OF GRASP IN QUADRIPLEGIA

V. Rodney Hentz, MD; Felix E. Zajac, PhD; Inder Perkash, MD; Charles Burgar, MD; Kevin McGill, PhD; Machiel Van der Loos, PhD; Francisco J. Valero-Cuevas, MS; Kai-Nan An, PhD;
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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B898-2RA)*

PURPOSE—Our overall objective is to improve functional grasping in quadriplegics by providing them, through surgical musculoskeletal intervention, with the biomechanical ability to grasp objects. Reconstructive surgeries, including tendon transfers, are commonly performed to restore partial grasping function. To predict functional outcome, the surgeon relies heavily on what the biomechanical properties of the hand and arm are before and are expected to be after surgery. However, surgeons are understandably reluctant to risk performing new techniques if they are unable to guarantee the best possible outcome to the patient. Uncertainty in the functional outcome of new surgical approaches hinders our ability to achieve improvements in the treatment of quadriplegics.

METHODOLOGY—A biomechanical model of the hand musculotendinoskeletal system will be developed to provide surgeons with an "*in vitro*" testbed for improving existing techniques or trying new ones and predicting functional outcomes. Such a model will allow surgeons to determine the precise musculotendinoskeletal parameters to which the functional outcome of a surgical or rehabilitation procedure is most sensitive. Thus, those aspects of the surgical procedure needing close clinical scrutiny can be identified. We will develop and test the validity of a computer-implemented musculotendinoskeletal model, first of the normal hand and next the quadriplegic hand, where the emphasis is on identifying the biomechanical factors bounding grasping. The ability of the index finger and the thumb to exert maximum grasping (pinch) forces will be the focus because of its importance to quadriplegic grasping (e.g., tip and key pinch) and because of the anatomic similarity between the index finger and the other fingers. Maximum pinch forces are emphasized because they specify the biomechanical limit of grasping performance.

PROGRESS—We have developed a computer model of the index finger. The index finger is modeled as a metacarpal and three phalanges articulated by pin joints, two at the metacarpophalangeal and one at each interphalangeal joint. All index finger musculotendons are

included. Force generation of a muscle is assumed to depend on its excitation level (to be determined by the model) and on experimentally obtained musculotendon architectural parameters. The moment arm of each tendon at each spanned joint, as a function of joint angle, was found from a fresh cadaver.

RESULTS—We analyzed the model to find the maximum static index finger tip force biomechanically possible at any finger posture, the excitations required of muscles to generate the finger forces, and the sensitivity of force production to musculotendon parameters and the excitation pattern. The model predicts that the muscle excitation pattern producing maximum finger forces is quite robust to the direction of the finger tip force being generated (palmar vs. radial) and to musculotendinoskeletal parameters. However, the amount of force the finger can produce in a given direction depends mostly on a few muscle moment arms.

FUTURE PLANS—We will test the validity of the model by recording finger tip forces and EMGs with intramuscular electrodes from the muscles acting on the finger in subjects instructed to press as hard as possible against either a low or high frictional surface with the finger in different postures. We will also develop a musculotendinoskeletal model of the thumb. With a model of the finger and thumb, the complex biomechanical and neural interactions that make grasping possible can be analyzed.

[310] 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—Two-day experiments were performed in eight chronic SCI patients, C4-T12. In day one (bladder day), each subject received a screening history and physical examination, bulbocavernosus reflex latency, as well as a full urodynamic study. This was followed by magnetic stimulation of the bladder using a Cadwell stimulator, with a 9-cm magnetic coil placed near the L2-L4 vertebrae while measuring BP and RP. The frequency and power output parameters were initially fixed at 20 Hz and 175 Joules/pulse while optimizing the focus of stimulation, and were later varied to generate the frequency and intensity profiles. The second day (bowel day) consisted of a full rectodynamic study, and magnetic stimulation of bowel. Functional micturition and defecation were also attempted at the end of each experimental day. Laboratory tests, including a set of Chem 20, CBC with differentials, PT, PTT, UA, and urine cultures, were performed both before and after the experiment.

PROGRESS—We have demonstrated that HFMS of the sacral nerves was effective in elevating the bladder and rectal pressures; 20 Hz frequency and 70 percent of maximal power provide adequate sacral nerve stimulation in most subjects. Functional magnetic micturition and defecation was achieved in more than 10 subjects.

RESULTS—Thirty SCI subjects with reflex bladders were recruited. The bladder capacity varied from 150 to greater than 600 ml. Peak voiding pressure varied from 24 to 94 cm H_2O. And post void residual varied from 0 to 360 ml. Rectodynamic studies revealed an average rectal capacity of 310 ± 30 ml, and peak defecating pressure of 85 ± 13.3 cm H_2O. HFMS of the bladder via sacral nerve stimulation using 20 Hz, 70 percent intensity and 2 second burst length resulted in an averaged increase in BP of 24.4 ± 4.88 cm of H_2O. Similarly the mean rise in RP was 22.8 ± 6.05 cm of H_2O. The frequency and intensity pro-

file results demonstrated that 20 Hz frequency setting, and 175 Joules/pulse intensity offer adequate pressure changes in most subjects, although higher intensities and frequencies usually generate higher BP and RP. We observed micturition in 10 subjects and defecation in 2 individuals. Either suprapubic or lumbosacral stimulation would result in urination.

FUTURE PLANS—We plan to optimize the magnetic stimulation characteristics and anatomical approach to produce functional micturition and defecation, critically evaluate the relative response of HFMS data to existing information using the electrical field stimulation methodology, and determine whether bowel motility is modified by HFMS by evaluating colonic transit time.

RECENT PUBLICATIONS FROM THIS RESEARCH

Functional magnetic defecation in paraplegia. Lin VWH, Wolfe V, Perkash I. J Spinal Cord Med 1995:18(4):263–4.

Functional magnetic micturition in spinal cord injured patients. Lin VWH, Wolfe V, Prionas S, Perkash I. Arch Phys Med Rehabil 1995:76(11):1039–40.

[311] 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 #B576-3RZ)*

PURPOSE—We seek to develop and apply newly discovered, bone cell-specific serum markers and new densitometry/imaging procedures for the skeleton to clinical studies of musculoskeletal assessment in patients with spinal cord injury (SCI) from trauma or illness.

METHODOLOGY—We have recently obtained a bone densitometer and have applied it to our studies of bone markers. The bone markers we have developed and used are immunochemically based. They are classical and novel immunoassys for the respective bone proteins and regulatory hormones under study.

PROGRESS—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. We have conducted studies in the following conditions:

Spondylopathy. We analyzed AP radiographs of lumbar spine (obtained within 1 month of DEXA, dual energy X-ray absorptiometry) in 116 SCI patients for various aspects of spondylopathy, and matched the result to the each vertebral level (L1, 2, 3, and 4). There were 227 (49 percent) abnormal individual vertebrae. Significant elevation (15, 15, 18, and 20 percent; $p<0.001$–$p<0.05$) of bone mineral density (BMD; g/cm^2) was observed at all levels, particularly at those abnormal without hardware compared to valid. The L4 was most severely affected.

Heterotopic Ossification (HO) We analyzed plain radiographs of the hip (obtained within 1 month of DEXA) in 107 SCI patients for HO, and matched the result to the three regions of interest: the femoral neck, Ward's triangle, and the trochanter. Significant elevation of densitometric values ($p<0.05$) observed at all sites.

Bone markers. We have purified BAcP from surgical specimens from human bone by tracking tartrate resistant acid phosphatase enzymatic activity (TRAP). Three basic steps were involved in our purification procedure: gel filtration on Sephadex, SDS-PAGE electrophoresis, and affinity chromatography. This preparation was then used to immunize mice for monoclonal antibody production. We have developed a panel of monoclonal antibodies and we are evaluating them for their specificity by immunohistology and Western analyses.

FUTURE PLANS—We hope to continue the application of the new procedures we have developed and are in the process of developing to continued studies of the SCI patient.

RECENT PUBLICATIONS FROM THIS RESEARCH

Hypercalcemia. Deftos LJ. In: Clinical endocrinology update. Bethesda, MD: Endocrine Society Press, 1995:159–62.

Patterns of osteoporosis in spinal cord injury. Martin EME, Szollar SM, Parthemore JG, Deftos LJ. In: Proceedings of the 32nd Annual Meeting of ASIA; 1996, Seattle, WA.

Predicting PTH pulses and patterns in osteoporosis. Deftos LJ, Schiff L. J Clin Invest 1995:95:2433–4.

[312] VERTEBRAL FUSION BY NEW OSTEOGENIC AGENTS TO ACCELERATE REHABILITATION

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PURPOSE—The purpose of this project is to stimulate inervertebral bone formation and increase the likelihood of spinal fusion using an osteogenic agent with a carrier. Our hypothesis is that pain relief and vertebral stability, allowing early rehabilitation, often depend on a solid fusion, which can be significantly stimulated by nanogram quantities of an osteogenic agent when delivered to the fusion site by a suitable carrier.

METHODOLOGY—Our rabbit vertebral fusion model utilizes a surgical procedure that minimizes the animal vs human anatomical differences. It involves T11–12 and T12–L1 (or L1–L2 and L2–L3) 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 a resorbable carbonated hydroxyapatite (MHA) carrier of crystal size and composition similar to the mineral of newly formed bone.

PROGRESS—Since the initiation of this project in 1993, we prepared ample quantities of the osteogenic agents DBM and BMP and of the biodegradable carrier microcrystals of hydroxyapatite (MHA) and tested the feasibility of: (a) using a modified lateral approach for intradiscal spinal fusion in the rabbit, similar to that used clinically by our orthopaedic-neurosurgical team; (b) adapting to the rabbit model our digitized imaging method for radiographic density measurements; and (c) stimulating fusion with a composite of a recombinant human $TGF_{\beta 1}$ (commercially available as $rhTGF_{\beta 1}$) with MHA and comparing it to AB. Adult male NZW rabbits were randomly assigned to six groups according to graft type (AB control, MHA carrier and $rhTGF_{\beta 1}$+MHA) and time allowed for fusion (6 and 12 weeks post-grafting). Grafts were placed in a 3.5 x 5 mm tunnel drilled into each disc and adjoining end plates without additional fixation. Spines of euthanized rabbits were cleaned of adhering soft tissues, sawed sagittally into two halves and x-rayed using high resolution mammography film. Radiographic density was quantitated by digitized imaging, and new bone formation and graft consolidation were examined histologically (H&E and Masson-trichrome stains). Fusion was evaluated by radiographic densitometry and biomechanical testing (rigidity by four-point bending) and statistical analyses by Student's t-test and ANOVA.

RESULTS—The bone-forming capacity (bone induction activity) of our preparations of the osteogenic agents DBM and BMP and the commercially obtained $rhTGF_{\beta 1}$, with and without the MHA carrier, was tested using our intramuscular implantation rabbit bioassay model. The total number of rabbits required for the adaptation of our clinical surgical procedure to the rabbit model and for the preparation of DBM and the extraction and purification of BMP and subsequent implantation exceeded 75. An initial study comparing AB chips to AB powder (T12 rib bone ground intraoperatively in liquid N_2) at 6 and 12 weeks post-grafting in 18 rabbits found substantial fusion rate differences in favor of powdered AB at both time intervals. The roentgenographic density data showed statistically significant differences between all discs grafted with either chipped or powdered AB ($p<0.01$) compared

to nongrafted controls. Histologically, cartilage and bone were seen 6 weeks after grafting of powdered AB with some consolidation on the vertebral bone, compared to the presence of unresorbed AB chips, cartilage, and bone with les consolidation in grafts of chipped AB. At 12 weeks post-grafting, new bone associated with consolidation was seen in most discs grafted with powdered AB. Moreover, evaluation of data at 6 and 12 weeks post-grafting in 72 rabbits, randomly assigned to animals grafted with AB (10 mg), MHA (3 mg), MHA (3 mg)+rhTGF$_{\beta 1}$ (100 ng) and non-grafted controls showed that in all cases intervertebral fusion was effected by endochondral bone formation. Radiographic density and rigidity data indicated that the composite rhTGF$_{\beta 1}$+MHA produced: (a) radiographically, a high rate of fusion as early as 6 weeks post-grafting and (b) biomechanically, fusion more rigid than AB and significantly better ($p<0.02$) than that by MHA alone 12 weeks after surgery.

IMPLICATIONS—Because of its fast resorption and effectiveness as an osteogenic agent and the relatively easy intraoperative preparation, AB powder has the potential of becoming clinically useful for stimulation of bone formation and early spinal fusion. Intradiscal grafting of small amounts of the growth factor rhTGF$_{\beta 1}$ with resorbable microcrystals of hydroxyapatite as carrier could be clinically preferable to AB for the stimulation of spinal fusion leading to earlier rehabilitation.

RECENT PUBLICATIONS FROM THIS RESEARCH

Effects of indomethacin on early events in demineralized bone matrix-induced osteogenesis. Yazdi M, Kossari S, DiCesare P, Cheung DT, Strates BS, Nimni ME. Eur J Exp Musculoskel Res. In press.

[313] SPINAL CORD INJURY-INDUCED BONE LOSS

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PURPOSE—The central as well as the peripheral nervous system are altered after spinal trauma. We hypothesize that changes in neuropeptides and neurotransmitters in nerves supplying bone are involved in the osteopenia which develops as a result of spinal cord injury (SCI). We propose to understand how these changes affect bone metabolism after SCI, since a considerable number of veterans suffer SCI, are paralyzed, and are treated in the VA system. The significance of the research lies in the potential for discovering the mechanism(s) involved in the osteopenia following SCI. These results could lead to a therapy to prevent the loss of bone in newly injured veterans, or aid in the recovery of bone in those with chronic SCI. Such treatment would result in enhanced rehabilitation, and potentially increased independence in many 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 characterize bone loss following SCI, as well as changes in neuropeptide distribution and levels in bone and periosteum. We have focused on calcitonin gene-related peptide (CGRP), substance P (SP), vasoactive intestinal peptide (VIP), and neuropeptide Y (NPY), all known to be in nerves in bone and implicated as modulators of bone metabolism. Immunohistochemistry, receptor binding assays, and autoradiographic 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 human bone cell model to evaluate the effect

of neuropeptides on mRNA of proteins involved in cell-cell communication via gap junctions. We have shown gap junctions to be present and functionally regulated by neuropeptides (e.g., VIP and CGRP) in these bone cells.

RESULTS—Characterization of the effects of SCI on bone metabolism indicate that as the animals age they lose approximately 60 percent of their trabecular bone compared to nonlesioned animals. This loss results in loss of mechanical strength in the femurs of lesioned animals. Immunohistochemical and retrograde tracing studies of nerves in bone showed sensory nerves containing 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 gap junction protein, connexin 43, in osteoblasts. CGRP is capable of regulating osteoblast function via potassium channels and intracellular calcium, but with moderate increases in cAMP, suggesting other second messengers for CGRP. We have cloned the gene for a receptor component protein of CGRP.

FUTURE PLANS—We will continue our studies with bone cells of lesioned and nonlesioned animals for neuropeptide effects on mRNA levels and functional status of cell-cell communication, as well as on mineralization of collagen matrix formed *in vitro*. We are beginning studies to identify post-SCI changes in bone cell receptors for these neuropeptides. We will continue our studies on the mechanism of CGRP modulation of osteoblasts. We will evaluate the role of the CGRP receptor component protein in bone metabolism in both an animal model and in human bone cells.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Diverse actions of calcitonin gene-related peptide on intracellular free Ca2+ concentrations in UMR 106 osteoblastic cells. Kawase T, Howard GA, Roos BA, Burns DM. Bone 1995:16:379S–84.

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 rapidly inhibits calcium uptake in osteoblastic cell lines via activation of ATP-sensitive potassium channels. Kawase T, Howard GA, Roos BA, Burns DM. Endocrinology 1996:137:984–90.

Parathyroid hormone-induced matrix mineralization by osteoblastic cells in vitro is dependent on gap-junctional intercellular communication. Schiller PC, D'Ippolito G, Roos BA, Howard GA. J Bone Min Res 1996:11(Suppl 1):S143.

[314] PROPHYLACTIC MONITORING OF BLADDER PRESSURE AND VOLUME

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PURPOSE—It is known that patients with spinal cord injury (SCI) and multiple sclerosis (MS) have a high incidence of high bladder pressures, urinary incontinence, and other urological pathologies. However, the use of the clinical urodynamic equipment to monitor bladder function is limited to the clinic and is, therefore, not likely to be utilized as frequently as is required to prevent urological pathologies. To aid in the early detection and possibly the prevention of these pathologies, we evaluated a simple home-use pressure gauge with tubes to measure bladder pressure along with urine volume recording as an adjunct to intermittent self-catheterization (IC) in SCI and MS patients.

METHODOLOGY—Our home-monitoring pressure gauges and clinical urodynamics equipment were calibrated with a standard water column. All pressure recording devices were adjusted to read the same pressure within 1 cm of water. Two different home pressure gauges were used. The first was a digital gauge, which

had a zero adjustment, a highly accurate pressure reading and a small volume displacement for pressure recording. However, subjects found this device hard to read. The second home gauge was a mechanical bellows type with pressure indicated in cm H_2O on the dial face, which the subjects found easier to read. We currently use this second gauge. Initial clinical urodynamic evaluation was conducted with simultaneous recording of pressure using the clinical equipment and our home monitor. Detrusor pressures were also determined, taking the pressure of the bladder when empty as a measure of abdominal pressure and subtracting this from the full bladder pressure.

For home use, subjects were given instructions on connecting a sterile tube from the pressure gauge to their catheter for IC. They were asked to record their bladder pressure and volumes on a weekly basis, more often if they were having a urological problem. Subjects are monitoring their pressures for up to 1 year.

PRELIMINARY RESULTS—Five subjects have entered this study: four SCI and one with MS. In the urodynamic clinic, the home pressure gauge was found to record the same pressures obtained with standard clinical urodynamic equipment. Accurate detrusor pressures could also be obtained. The average age of the five subjects was 46.4±9.3 (SD). The SCI subjects were upper motor neuron lesioned. All subjects were on IC for bladder emptying, and home monitoring was conducted without adverse effects. Daily pressure recordings with home monitoring in four subjects showed little change over time and one subject is just beginning our study. Three of the five subjects recorded low pressures at volumes from 150 ml to 450 ml. Detrusor pressures were less than 23 cm H_2O with a high pressure of 34 cm H_2O recorded in one subject at the high bladder volume of 340 ml. The fourth subject regularly recorded high detrusor pressures from 30 to 44 cm H_2O at large volumes up to 825 ml. This subject has refused to conduct more frequent IC to lower his filling volume before SCI but has not had upper urinary tract problems. Use of the home device is ongoing in two SCI subjects. Home monitoring was stopped within 6 months in the three others. Reasons for stopping related to the time available to subjects, and their feeling that they were not receiving benefits from continued monitoring. In summary, these findings indicate that the home monitoring of bladder pressure may be an important evaluation technique.

FUTURE PLANS—Because regular home monitoring of the detrusor pressure and volume may aid in the early detection or even prevention of urological pathologies, additional subjects are being recruited for this study.

[315] TREATMENT OF SCIATIC NERVE INJURY WITH GONADAL STEROIDS

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PURPOSE—Gonadal steroids are neurotrophic agents capable of modulating many aspects of neuronal growth and function, and thus have therapeutic potential in the treatment of nerve injuries involving lower motor neurons. The key question that will be addressed is the following: Will systemic administration of the gonadal steroid, testosterone propionate (TP), augment the regenerative properties of spinal motor neurons, analogous to the effects of the steroid on cranial motor neurons? The goal of this research is to determine if TP can be used as a therapeutic agent in spinal cord injury (SCI).

METHODOLOGY—The experimental approach that will be used will range from functional, for the determination of rehabilitation potential, to molecular, for the determination of mechanism. The long-term goal of this research is to determine the therapeutic potential of gonadal steroids in spinal motor neuron regeneration in animal models and subsequently extrapolate this information to human peripheral nerve and SCI situations. There are four sets of experiments to be conducted on the rat sciatic motor neuron. The sciatic nerve is axotomized at mid-thigh levels in castrated male rats, with half of the

animals receiving subcutaneous implants of TP and the other half sham implanted. Functional assessment of lower limb movement and locomotor behaviors is being done. Molecular analysis of the effects of TP directly on injured sciatic motor neurons is being accomplished using *in situ* hybridization with specific probes.

PROGRESS—Currently, all the details of the behavioral and molecular analyses are being accumulated in pilot studies. The appropriate behavioral tests have been identified and the conditions for use of DNA probes in the in situ hybridization experiments established.

PRELIMINARY RESULTS—The surgical conditions for sciatic nerve injury have been accomplished. All probes to be used in the *in situ* hybridization experiments work in rat tissue and can be used in subsequent experiments.

FUTURE PLANS—With the pilot experiments accomplished, the behavioral analysis and regeneration rate studies will be done next. If TP improves functional recovery from paralysis induced by sciatic nerve damage, the mechanisms underlying this will then be determined.

[316] ACUTE EFFECTS OF SCI ON SPERM FUNCTION

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PURPOSE—With advances in techniques of electroejaculation, semen may be obtained in approximately 90 percent of men with spinal cord injury (SCI). Unfortunately, semen parameters, particularly sperm motility, are usually of poor quality following SCI. An acute decline in semen quality has been documented to occur shortly after SCI both in humans and in an SCI animal model. Advances in assisted reproductive technologies such as *in vitro* fertilization have allowed some men to father children. However, these techniques are extremely expensive and often have limited availability. The purpose of this study is to identify the causes of the decline in sperm quality following SCI and to identify treatment strategies which may help to prevent this decline.

METHODOLOGY—We have studied both an SCI animal model (Sprague Dawley rat) and men with recent SCI. Animal studies involve mature male rats with a T9 transection and sham operated controls. Short- and long-term testicular blood flow studies using a doppler probe were performed in the rats. Drug studies investigating the possible impact of medications, specifically verpamil and L arginine, on preventing decline in sperm motility have also been evaluated in our animal model.

Scrotal temperature studies in men with SCI have just begun. Since electroejaculation has been found to be unreliable in obtaining ejaculates in SCI rats, sperm is obtained by epididymal puncture. Possible use of a new SCI animal model (guinea pig), which will allow repeated electroejaculation rather than animal sacrifice at specific time intervals, has been evaluated.

PROGRESS—Testicular blood flow studies have revealed that there was a persistent decrease in testicular blood flow in the SCI animals compared to sham controls at 2 weeks and 4 weeks post SCI. However, at 2 months post SCI there was normal testicular blood flow. The decline in blood flow was found to correspond closely to a decline in sperm count and motility. This decline in semen quality shortly after SCI may be prevented by maintaining normal testicular blood flow after SCI. Our study has evaluated several medications to maintain testicular blood flow. Pilot studies have shown improvement in semen quality with L arginine but not verpamil when SCI animals were treated and compared to non-treated SCI animals. While there has been difficulty obtaining ejaculates using electroejaculation in the SCI rat model, there was a high success rate (70 percent) in obtaining ejaculates in the SCI guinea pig.

FUTURE PLANS—Work will continue to focus on medical interventions to prevent a decline in sperm func-

tion. Testicular blood flow studies using doppler and ultrasound in men with SCI will begin shortly. Studies are also going to begin to evaluate the impact of SCI on testicular temperature regulation, in both the animal model and in men. Further studies are planned to evaluate the guinea pig SCI animal model.

[317] PREVENTION AND TREATMENT OF SPINAL CORD ISCHEMIA AND PARAPLEGIA IN THORACOABDOMINAL ANEURYSM REPAIR: A PILOT STUDY

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PURPOSE—This pilot project examines the prevention of neuronal degeneration after ischemic injury to the spinal cord (SC) by treatment with clenbuterol. Paraplegia is an important devastating complication of SC ischemia during thoracoabdominal aortic aneurysm repair. Clenbuterol is a selective β_2-agonist which has been shown to increase gene expression of nerve growth factor (NGF) and basic fibroblast growth factor (bFGF) in the central nervous system. NGF can oppose neuronal degeneration caused by Alzheimer's disease and promotes axonal regeneration and synaptic plasticity. bFGF antagonizes glutamate-induced increases in intracellular calcium that cause neurotoxicity. Since glutamate toxicity is thought to occur extensively during and after SC ischemia, clenbuterol treatment may prevent neuronal cell death and paralysis occurring within several days of ischemia. The phenomenon of neuronal preservation after ischemic injury was studied in the New Zealand rabbit, an excellent experimental model for reproducing ischemic paraplegia since these rabbits have a segmental distribution of SC blood supply.

METHODOLOGY—Thirty evaluable rabbits (15 control, 15 experimental) weighing 4 to 6 kg were premedicated with atropine sulfate (0.005 mg/kg) administered subcutaneously and anesthetized with i.m. ketamine hydrochloride (40 mg/kg) and xylazine (3 mg/kg). The experimental group was given clenbuterol (9 mg) in drinking water 24 hours before surgery. Intermittent intravenous readministration of one-quarter dose of the anesthetic agents maintained an adequate level of anesthesia and prevented the need for endotracheal intubation and mechanical ventilation. All rabbits were kept on 100 percent oxygen during the procedure. Preoperative chloramphenicol and heparin (70 units/kg) were given 5 min prior to surgery. The fur on the abdomen was clipped with electric shears and the skin prepared with Betadine solution. In the supine position, a midline incision of approximately 5 cm was made between xiphistemum and pubic symphysis. The abdominal aorta was identified. A flowmeter probe was placed 1 cm below the renal arteries and direct blood flow measurements recorded at the infrarenal aorta before and after aortic clamping. The degree of reproducible ischemic injury was graded by cross-clamping infrarenal aorta for 22 or 30 min. Using a vascular clamp, the abdominal aorta was clamped just distal to the renal arteries for the specified time interval. Confirmation of aortic occlusion was obtained by a zero reading of the flowmeter. Abdominal aortic blood flow was recorded at the time of declamping the aorta, until it approached baseline again. At the end of the procedure, the abdomen was closed in layers with absorbable fascial and nonabsorbable skin sutures. All rabbits were kept in close observation postoperatively and neurological assessment recorded. The anal and bladder sphincters functions were also assessed daily. The rabbits were euthanized at the end of 30 days and the SC histologically analyzed.

RESULTS—Assessment of degree of paralysis of the hind limb was recorded. All of the rabbits with 30-min cross-clamping of the aorta (2 control and 2 experimental) developed complete paraplegia. Of the 13 control group rabbits with 22-min cross-clamping 77 percent developed paraplegia, 9 with no movement and 1 with

slight movement of the limb, and 23 percent did not develop paraplegia: 3 were able to stand but not walk normally and 2 recovered completely.

Of the 13 experimental group rabbits on clenbuterol with 22-min aortic cross-clamping, 38 percent developed paraplegia (3 with no movement and 2 with slight movement of the limb); 62 percent did not develop paraplegia (2 were able to stand but not walk normally and 6 recovered completely). An interesting and fairly consistent laboratory observation was that the rabbits that did not develop paraplegia had minimal increase in aortic blood flow; whereas the rabbits that developed paraplegia had a significant increase following aortic declamping. Although the exact mechanism of paraplegia following intraoperative aortic clamping and declamping is unknown, our preliminary laboratory observations in the rabbit ischemic injury model suggests that the variations in aortic blood flow due to aortic clamping and declamping may play a role in the development of paraplegia. This may be due to ischemia and/or declamping hyperperfusion. Further aortic blood flow studies will help to clarify the causes of paraplegia following thoracoabdominal aortic repairs, and it may turn out that better control of the variation in aortic blood flow may help prevent paraplegia following aortic clamping and declamping.

FUTURE PLANS—Dosage and temporal administration of clenbuterol was empirical in our pilot study. We have designed a detailed protocol to evaluate optimal dose and temporal chronology of clenbuterol. Histological analysis for evidence of neural preservation in the experimental animal group versus the control group will also be evaluated in our future study.

[318] PERFORMANCE CAPACITY AND PHYSICAL STRAIN IN SUBJECTS WITH A SPINAL CORD INJURY

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PURPOSE—We study the evolution of physical capacity in association with physical strain over time. Parameters of performance capacity and physical strain in activities of daily living (ADL) are evaluated with repeated standardized wheelchair exercise tests as well as ADL tests in different groups of subjects with spinal cord injury (SCI). This involves both subjects with long-term SCI (both sedentary and physically active) as well as those in the course of rehabilitation. Thus, the effects of wheelchair use and a wheelchair-confined lifestyle on cardio-respiratory, musculo-skeletal, and health risk parameters are evaluated.

METHODOLOGY—A longitudinal study of male subjects with a longstanding spinal injury has been concluded, as has a study of subjects with a cervical SCI. 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 according to standardized procedures at fixed times during and/or after rehabilitation. The physical strain of daily life in rehabilitation, and more specifically in the therapy sessions, is evaluated with the Percentage Heart Rate Reserve (%HRR) with a simple SportTester PE4000. Risk factors for cardiovascular disease and musculo-skeletal problems are repeatedly determined with questionnaires, which are also used to study different physical and personal characteristics.

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 males with a longstanding SCI. 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 intertherapy variance. Physical therapy appears the most straining and therefore seems 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. Intensity, duration, and frequency of physical activity should be tuned more carefully to the individual. Preliminary findings on risk indicators for cardio-vascular disease do not show an increased risk among the subjects with SCI. Sports activity has a reducing effect on such risk factors among subjects with longstanding SCI.

FUTURE PLANS—A further analysis of the rehabilitation process and its effects upon subjects with SCI 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, possibly within an experimental design. Additionally, the evolution of wheelchair propulsion technique will be studied over time as a mediating component of performance capacity. Thus, we hope to grasp the process of learning in this complex motor task. To increase the strength of the results, a multicenter approach is planned in which seven rehabilitation centers will cooperate to study a group of subjects with SCI during and after rehabilitation during a 3-year period. With four research groups, different aspects associated with the restoration of mobility will be evaluated.

RECENT PUBLICATIONS FROM THIS RESEARCH

The effect of quadrugby training on physical performance capacity and physical strain during standardized ADL-tasks in persons with spinal cord injury. Dallmeijer AJ, Hopman MTE, Woude LHV van der. In: Proceedings of the First European Congress on Adapted Physical Activity and Sports; 1995, Acco, Leuven, 95–101.

Physical capacity and physical strain in persons with quadriplegia. Dallmeijer AJ, Hopman MTE, Woude LHV van der. In: Proceedings of RESNA International '95; 1995, Vancouver, BC. Washington, DC: RESNA Press, 1995:752–4.

Changes in physical strain and physical capacity in men with spinal cord injuries. Janssen TWJ, Oers CAJM van, Rozendaal EP, Willemsen EM, Hollander AP, Woude LHV van der. Med Sci Sports Exerc 1996:28(5):551–9.

Lipoprotein profile in physically active and sedentary persons with tetraplegia. Dallmeijer AJ, Hopman MTE, Woude LHV van der. Med Sci Sports Exerc 1996:28(5 Suppl):S108.

[319] 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 the population with SCI. Objectives of this study are to document changes in immunologically related laboratory values of patients vaccinated at varying intervals after spinal cord injury; and to compare the incidence of pulmonary complications in unimmunized patients with SCI with the incidence in a series of patients with SCI vaccinated at varying times following injury.

METHODOLOGY—This study entails random assignment of SCI patients into one of four groups following their entry into the University of Alabama at Birmingham (UAB) Hospital care system. Groups 1 and 2 will receive the vaccine or placebo at 17 days (±24 hours) of injury. Groups 3 and 4 will receive the pneumococcal vaccine or placebo at 4–6 months postinjury. The groups for which a patient is eligible to be randomized as a subject (to

receive vaccine) or control (to receive placebo) are determined according to the time at which the patient is admitted to the UAB Hospital or Spain Rehabilitation Center. Following enrollment, four blood samples are collected: the first at the time of vaccination or administration of placebo, the second 1 month later, the third 2 months later, and the fourth at 1 year following enrollment.

Laboratory tests performed at each blood sampling interval include: antipneumococcal antibody titers to four major representative serotypes, quantitative immunoglobulins, complete blood count with differential leukocyte count, liver profile, total serum protein and albumin. Subjects and controls are monitored during their initial hospitalization for the occurrence of respiratory or other systemic complications of pneumococcal disease. Appropriate microbiological and/or immunological diagnostic procedures are implemented whenever possible to determine whether or not such complications are indeed due to infection with Streptococcus pneumoniae.

PROGRESS—Recent developments in the acute care of persons with SCI made it necessary to alter the study design and eliminate the group immunized immediately postinjury 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 postinjury.

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 1996, 87 persons completed the study with a complete dataset and the study is complete.

FUTURE PLANS—Measurement of antibody levels will be completed by October 1996. All four samples from each person will be assayed at the same time. All laboratory data and pulmonary complications are being recorded and entered into the computer database. A final report on the results of this study will be completed by December 1996.

[320] 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: 1) to determine the sensitivity and specificity of the RUSE compared to CRSP for detecting upper urinary tract abnormalities of persons with SCI; 2) to determine the sensitivity and specificity of the RUSE compared to EXU for detecting upper urinary tract abnormalities of persons with SCI; and 3) to determine the role of the RUSE in the long-term urologic follow-up of persons with SCI.

METHODOLOGY—Standardized data collection instruments and syllabus have been developed. At this Center, CRSP is routinely performed on all patients with SCI who have neurogenic bladders prior to first definitive discharge and annually thereafter.

The RUSE will be performed on a random sample of 10 percent of patients scheduled for routine CRSP. The RUSE will be performed using an ACCUSAN 128 Real Time ultrasound scanner utilizing 3.5 and 5.0 Mhz transducers. Renal size, parenchymal thickness, presence, size, and location of calculi; presence, size, location, and character of renal masses; presence and severity of hydronephrosis; size of ureters (normal or enlarged); bladder volume and anterior wall thickness; presence of other abnormalities; and the overall quality of the examination will be recorded. Overall, at least 100 patients will receive both the RUSE and CRSP within 4 weeks of each other during the 5-year project time frame. Most will receive both the RUSE and CRSP within 2 weeks of each other.

EXU is routinely performed only once per person just prior to the first definitive discharge from the rehabilitation hospital. The RUSE will be performed on a random sample of 25 percent of persons scheduled for EXU. Overall, at least 100 persons will receive both the RUSE and EXU within 2 weeks of each other during the 5-year project time frame. Most will receive the RUSE and EXU on the same day.

FINAL RESULTS—A total of 72 patients were entered into the study, 66 males and 6 females. The mean age was 35 (16–64 years). The mean years from time of injury was 4.4: 35<1 yr; 15 1–5 yrs; 9 5–10 yrs; 13>10 yrs. There were 33 patients who received EXU/RUSE/CRSP all within a 2-week period. Other correlative study groups include: 63 patients who received EXU/RUSE within 2 weeks; 42 patients who received RUSE/CRSP within 2 weeks; 44 patients who received RUSE/CRSP within 4 weeks; 18 patients who received RUSE/ CRSP greater than 4 weeks. A comparison of RUSE to EXU in the detection of urinary tract calculi was performed, including the number and size of calculi. A comparison of RUSE and CRSP was performed using mean parenchymal thickness for "normal" RUSEs and established normal ERPF values for CRSP. A comparison of RUSE to EXU in the detection of hydronephrosis was performed. Seven cases with moderate/severe hydronephrosis by either RUSE or EXU were reviewed and compared to CRSP to evaluate RUSE versus EXU for detection of obstruction.

Study limitations included logistical difficulty of scheduling EXUs. There was no established form for EXU. There were small numbers of patients with pathology.

IMPLICATIONS—RUSE and CRSP may replace EXU for routine urinary tract surveillance. RUSE is better accepted by patient and logistics are easier. RUSE is equivalent for detection of calculi though inaccurate for size and number. CRSP is more sensitive for renal function loss. EXU is useful for selected cases with calculi, obstruction. A baseline EXU is helpful.

[321] OBSTETRIC/GYNECOLOGIC COMPLICATIONS IN WOMEN WITH SPINAL CORD INJURY

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PURPOSE—Aside from the immediate and obvious consequences of spinal cord injury (SCI), many physiological systems ultimately are altered for varying periods. It is becoming increasingly evident that the reproductive axis is one such system. In addition to problems with menorrhea, galactorrhea, fertility, and sexual function in women after SCI, disordered hormone production could potentially result in systemic changes such as accelerated bone loss, accentuated catabolism and nitrogen imbalance, and possibly hypercholesterolemia and atherosclerosis. To date there is little information concerning these complications. The purpose of this research is to determine the changes in reproductive endocrine function both immediately following SCI and in the remainder of the first year postinjury. This research will also examine how these changes affect menstruation, ovulation, vaginal and cervical pathology, and sexual function. As it is believed that many complications of SCI, such as autonomic dys-

reflexia, muscle spasticity, and bladder management problems are influenced by fluctuations in the woman's hormonal cycles, these correlations will be examined as well. Possible factors that could be responsible for postinjury endocrine changes will be explored.

Objectives of this study are 1) to document hormonal changes that influence ovulation and menstrual cycles, as well as cause complications such as hyperprolactinemia, with or without galactorrhea; 2) to document endocrine imbalances that may occur following SCI as a result of cardiovascular instability, chest trauma, nutritional or metabolic changes, or concomitant head injury; 3) to document the relationship between reproductive hormone levels following SCI and fertility, sexual well-being, and sexual activity; and 4) to determine the relationship between reproductive hormone levels following SCI and complications such as autonomic dysreflexia, increased muscle spasticity, and occurrence of bladder spasms.

METHODOLOGY—The basic design of this proposed project will be that of a prospective cohort study to assess the natural history of reproductive hormonal imbalances that cause changes in the menstrual cycle leading to sexual dysfunction and infertility in women during the first year after SCI.

All women who agree to participate in the study will be interviewed initially by a designated nurse/clinician who will obtain a complete obstetrical and gynecological history. Other information collected during this interview will be first day of the last menstrual period, age, height, weight, etiology of injury, and loss of consciousness, or occurrence of closed heat trauma or chest trauma at the time of injury. Also during the initial evaluation, vaginal wall samples will be obtained by gently scraping the upper third of the lateral vaginal wall.

To evaluate postinjury reproductive endocrine status, blood sampling for hormone assays will be performed once a week for 6 weeks. A single electrolyte profile, including serum sodium, chloride, potassium, blood urea nitrogen, albumin, creatinine, and glucose will be obtained on admission to the study to assess the metabolic status of each woman.

Throughout the initial inpatient stay, careful documentation of the onset, duration and amount of flow of any menses will be recorded. Upon discharge, each woman will be given a menstrual calendar and instructed on recording this same information.

Over the 3.5-year study, at least 28 women should be enrolled and 336 monthly calendars obtained.

PROGRESS—To date, entry into the study has been slow and determined by the low census of women with SCI who meet the study criteria. One patient has completed the study.

RESULTS—Data have not been analyzed. It is anticipated that the patient numbers will increase in the next few months as measures for early detection have been initiated.

[322] PREDICTION OF MORTALITY AFTER SPINAL CORD INJURY: A 20-YEAR PROSPECTIVE STUDY

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Sponsor: *National Center for Medical Rehabilitation Research, National Institute of Health, Bethesda, MD 20892; American Association of Spinal Cord Injury Psychologists and Social Workers; Minnesota Medical Foundation; National Institute for Handicapped Research*

PURPOSE—The purpose of this study is to identify psychosocial, vocational, and medical risk factors related to mortality after spinal cord injury (SCI). The primary focus of this research is the utilization of prospective data on life adjustment to predict later mortality.

METHODOLOGY—*Participants.* All study participants were identified from outpatient files from the University of Minnesota Hospital. To be included in the study, they had to meet the following criteria: (a) had a traumatic SCI, (b) the injury was at least 2 years duration, and (c) were at least 18 years of age at the time of the study. Two study samples have been utilized. Sample 1 (n = 256) began participating in 1974; Sample 2 (n = 193) began participating in 1985.

Instruments. The Life Situation Questionnaire

(LSQ) was developed in 1974 to measure mostly objective information on a broad range of areas relevant to persons with SCI. Although the original form of the LSQ was rather limited in scope, subsequent revisions were made in 1985 and 1989 to expand the content areas. The resulting questionnaire includes eight outcome scales, five of which were developed via factor analysis of life satisfaction and problems items.

Procedures. Prospective data on life adjustment were collected at three separate times: 1974, 1985, and 1989. A total of 256 individuals completed the LSQ in 1974. In 1985, 154 of these individuals completed a second LSQ. In addition, 193 new participants from Sample 2 completed LSQs in 1985 (a total of 347 participants in 1985). In 1989, 286 of the 347 participants again completed the LSQ, (Sample 1 = 135; Sample 2 = 151). The survival status of all former participants was ascertained in 1996.

PROGRESS—Survival status was ascertained during 1996 in order to use prospective data collected during the three previous study stages (1974, 1985, 1989) to predict 1996 survival status. Among the 256 participants from the 1974 data collection, 95 were deceased by 1996. Fifty-two of the 347 participants from the 1985 follow-up study and 27 of the 286 participants from the 1989 follow-up were deceased by 1996.

RESULTS—Consistent with previous findings, survival status was highly correlated with a positive overall adjustment pattern. Participants who were more active socially and vocationally and who had a higher overall level of subjective well-being were more likely to have survived their injuries until 1996. More detailed analyses are currently underway.

IMPLICATIONS—Findings from this study have been instrumental in identifying life adjustment patterns which place individuals at differential risk for early mortality after SCI.

FUTURE PLANS—Dissemination of the results of the current study will be carried out over the next 12 to 18 months. Further information is being collected on causes of death. The next major follow-up study is planned for the year 2000.

[323] MEASURING THE EFFECTS OF VESTIBULAR STIMULATION ON CHILDREN WITH CEREBRAL PALSY

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Sponsor: *National Institute on Disability and Rehabilitation Research, U.S. Department of Education, Washington, DC 20202; Nemours Foundation, A.I. duPont Institute, Wilmington, DE 19899*

PURPOSE—The Vestibular Stimulation project seeks a correlation between whole body vertical oscillations and the reduction of spasticity in those with cerebral palsy.

METHODOLOGY—We have constructed an electromechanical system which can apply a predetermined vertical acceleration to a child and his/her normal seating system and tested it on 30 subjects. As a means of evaluating changes in spasticity, a leg drop pendulum test was performed on each subject, twice before (at 15-min intervals) and twice after 15 min of up and down motion. In addition, breathing capacity and postural stability tests were made before and after vertical oscillations. Parameters of the vertical oscillations were set at a frequency of 1.57 hertz and an amplitude of 8.82 cm. This is equivalent to about 0.79 g acceleration.

PROGRESS—We are presently studying 30 subjects, 6 to 21 years of age, with a primary diagnosis of spastic diplegia. At this writing 27 subjects have been tested, and while changes have not been as dramatic as those of the pilot study of 1993, they are being observed. It appears that whatever causes these changes seems to last about 15 min. One interesting aside that has resulted from this study is the observation that changes in spasticity in muscles which cause lateral motion during the leg drop

pendulum tests are much more consistent, and much easier to detect than the major muscle groups of the limb. In the first 27 subjects, changes in quadricep and hamstring spasticity was detected in 11 of the 27 subjects. Changes in lateral motion, most likely due to changes in spasticity in the sartorius, were detected in 17 of the 27 subjects

FUTURE PLANS/IMPLICATIONS—Our next set of experiments *will* attempt to show functional improvement after vestibular stimulation. The 10 subjects showing the greatest amount of change in the present study will undergo a gait analysis performed before and after stimulation. If changes in gait are demonstrated, further investigations will be made with variations of frequency and amplitude of oscillation to determine optimum values.

RECENT PUBLICATIONS FROM THIS RESEARCH

Passive leg motion changes in cerebral palsy children after whole body vertical accelerations. Fee Jr J, Samworth K. IEEE Trans Rehabil Eng 1995:3(2):228–32.

[324] CHEMICAL TRIGGERS OF REFLEX DEFECATION IN SPINAL CORD INJURY: COMPARISONS OF EFFECTIVENESS

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Sponsor: *None listed*

PURPOSE—Neurogenic bowel dysfunction resulting from spinal cord injury (SCI) can produce constipation, incontinence, and inability to willfully defecate. Many persons with SCI rank bowel and bladder dysfunction among their major life-limiting problems. The upper motor neuron (UMN) bowel results from a lesion of the spinal cord above the conus medullaris. This condition typically presents with fecal distention of the colon, overactive segmental peristalsis, underactive propulsive peristalsis, and a hyperactive holding reflex with spastic anal constriction. These impairments of sphincter control, along with gross immobility from paralysis, interact to compound their functional significance.

Rehabilitative interventions to regain personal control of fecal elimination emphasize the importance a carefully designed bowel program with regularly scheduled bowel care. A bowel program is a comprehensive individualized treatment plan focused on prevention of incontinence, effective efficient colonic evacuation, and prevention of complications of neurogenic bowel dysfunction. Bowel care, a subcomponent of the bowel program, is the individually developed and prescribed procedure carried out by the patient or attendant to periodically evacuate stool from the colon. The goals of bowel care are to facilitate normal defecation of the maximal stool volume in the least amount of time with avoidance of stool incontinence thereafter. The bowel care procedure typically consists of introduction of a colonic stimulant medication into the rectum and mechanical facilitation of reflex defecation with intermittent digital rectal stimulation. Unfortunately, some bowel care sessions can require up to 3 hours for completion, and still yield insufficient stool results. More than 20 percent of persons with SCI report difficulty with evacuation of their bowels.

There are many medications on the market utilized as chemical stimulants to enhance reflex defecation. Bisacodyl is a common active ingredient. The effectiveness of hydrogenated vegetable oil-based bisacodyl (HVB) suppositories, polyethylene glycol-based bisacodyl (PGB) suppositories, and polyethylene glycol-based, glycerine, docusate sodium mini enemas (TVC) was compared in subjects with UMN SCI. Thereafter, general strategies for bowel programs and techniques of bowel care were published for consumers and practioners.

METHODOLOGY—The HVB suppositories contained 10 mg bisacodyl in a hydrogenated vegetable-oil base. The PGB suppositories contained 10 mg bisacodyl dissolved in a mixed polyethylene glycol polymer base of two molecular weights: E1450 and E400. TVC consists of a solution of polyethylene glycol, glycerine, and docusate sodium. Separate open label and randomized, prospective, double-blind studies comparing bowel care initiated by these agents were completed.

The outcome parameters were as follows. The total bowel care period was divided into intervals by discrete timed events: First Flatus (end of the interval from insertion of the suppository until the first flatus is passed), Begin Stool Flow (beginning of the defecation interval), End Stool Flow (marks the end of the defecation interval), Time off toilet (marks the end of the interval from the last stool flow to transfer off toilet or completion of clean-up if in bed), Total Time (includes the time from insertion of the suppository to the last stool flow). Both duration and frequency of digital stimulations and manual evacuations were recorded. Stool results were recorded as: 0, 1 minimal, 2 small, 3 moderate, 4 large, 5 very large. All episodes of incontinence were recorded and defined as: any passage of substance through the anus (include stool, mucus, liquid, and so forth) at any time outside the designated bowel care session.

PROGRESS—Both studies revealed a significant decrease in total bowel care time using the PGB suppository with comparable stool volumes and numbers of bowel incontinence episodes. TVC mini enemas and PGB suppository initiated bowel care sessions were similar in all time intervals, stool production, incontinence, and the number of digital stimulations required.

The mean bowel program interval that was most reduced when comparing the suppositories was the Time to Flatus (PGB 15 min, HVB 36 min) suggesting that the rate of dissolution of the base is directly related to the bioavailability of the bisacodyl and the subsequent peristaltic response of the colon.

FUTURE PLANS—We are currently developing automated quantitative instrumentation to record the progress of bowel care, with the intent to test other pharmacologic triggers of defecation and the effectiveness of various techniques of bowel care.

IMPLICATIONS—The findings to date suggest that the delivery of bisacodyl to the colonic mucosae in a polyethylene glycol base initiates defecation sooner and can reduce the average duration of bowel care by up to one half as compared with HVB.

RECENT PUBLICATIONS FROM THIS RESEARCH

Reduction in bowel program time with polyethylene glycol-based bisacodyl suppositories. Stiens SA, Luttrell W, Binard JE. J Spinal Cord Med 1995:18(4):299.

Constipation and spinal cord injury: a guide to symptoms and treatment. Harai D, Quinlan J, Stiens SA. Washington, DC: Paralyzed Veterans of America, 1996.

Neurogenic bowel dysfunction. Stiens SA, Goetz LA. In: O'Young B, Young M, Stiens SA, eds. PM&R Secrets. Philadelphia: Hanley & Belfus, 1996.

Neurogenic bowel dysfunction after spinal cord injury. Stiens SA, House JG. Paraplegia News 1996:50(1):65–7.

Hindgut dysmotility after spinal cord injury: clinical management and surgical solutions. Stiens SA, Bierner-Bergman S, Goetz LL. Arch Phys Med Rehab. In press.

C. Spinal Cord Regeneration

[325] ELECTRIC FIELDS AND CARBON FIBERS IN THE TREATMENT OF SPINAL CORD INJURY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B423-3RA)*

PURPOSE—The purpose of this study was to evaluate the functional benefit of combining carbon filament implants with pulsed DC electrical stimulation following severe contusion injury to the spinal cord in cats.

METHODOLOGY—Seventeen cats were anesthetized and given a severe contusion injury to their spinal cord at the T8 level by dropping a 30 g weight from a height of 18 cm. A mid-dorsal myelotomy was performed 1–2

hours after the injury; by this time edema and hemorrhage develop extensively in the center of the injured spinal cord. Utilizing an operating microscope, the hemorrhagic and edematous tissue was removed by aspiration leaving a small cavity. A bundle of approximately 30,000 carbon filaments of 5 μm in diameter, cut to the appropriate length to completely fill the lesion cavity, was lowered into the injury site and anchored into place with a piece of dura film.

The animals were divided into four groups. In Group One, cats sustained the injury, received a dorsal myelotomy, and subsequently received implantable stimulators *1 hour* after injury. In Group Two, cats sustained the injury and then received a dorsal myelotomy and carbon filament implants 1 hour after injury. In Group Three, cats sustained the injury and then received a dorsal myelotomy and carbon filament implants, in addition to implantable electrical stimulators, 1 hour after injury. Group Four served as a control group in which cats sustained the injury and subsequently underwent a dorsal myelotomy 1 hour afterward.

In groups One and Three, battery-powered stimulators, with 2 mm diameter platinum discselectrodes, were surgically implanted with the electrodes configured to produce current flow parallel to the long tracts of the spinal cord across the injury site. The stimulation parameters were 25 μA pulsed direct current, which result in a 100 Hz unipolar square wave with a 20 percent duty cycle.

All animals received daily care in accord with AAALAC guidelines. Electrophysiological and behavioral tests were performed before injury and then bi-monthly after injury throughout the 6-month experimental period.

RESULTS—Various degrees of electrophysiological recovery have been observed in the animals that received implantable stimulators after severe contusion injury. However, the animals that received both carbon filament implants and electrical stimulation have consistently shown weight bearing and minimum ambulation, in addition to electrophysiological recovery. The control animals have all remained paraplegic at the end of the experimental period.

These preliminary findings indicate that the application of an electrical field, in combination with a suitable substrate such as carbon filaments, provides a favorable environment at the lesion site that results in functional recovery.

FUTURE PLANS—We will continue to evaluate (electrophysiologically, behaviorally, and histologically) the beneficial effects of the use of carbon filament implants, combined with electrical stimulation of the injury site as a means of repairing the damaged spinal cord.

RECENT PUBLICATIONS FROM THIS RESEARCH

Behavioral recovery after severe contusion injury to the cat spinal cord. Khan T, Dauzvardis MF, Liu LS, Sayers S, Myklebust. J Soc Neurosci Abstr 1995:21:172.

Functional recovery after spinal cord injury using carbon filaments and electrical stimulation. Khan T, Sayers S, Liu LS, Myklebust J. In: Proceedings of the American Paraplegia Society, 1996.

[326] ENHANCED CARBON FILAMENT PROSTHESES AS SUBSTRATES FOR REGROWTH OF INJURED SPINAL CORD: ELECTROPHYSIOLOGICAL RECOVERY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B742-2RA)*

PURPOSE—The purpose of this study was to determine whether culturing fetal spinal cord on carbon filaments, and then subsequently implanting these filaments into the injured spinal cord, would enhance funtional recovery with axonal regrowth across the lesion site.

METHODOLOGY—Adult rats were anesthetized, and subjected to a severe contusion injury at the T8 level. The rats were divided into five groups: Group One consisted of normal rats (n=7); Group Two consisted of rats that sustained contusion injuries and the lesion sites were subsequently filled with a bundle of approximately 10,000 carbon filaments of 5 μm in diameter, cultured with 15-day-old rat fetal spinal cord explants (n=5); Group Three consisted of rats that received fetal spinal cord tissue implants after contusion injury (n=4); Group Four consisted of rats that received carbon filament implants after contusion injury (n=4); and Group Five consisted of rats that sustained a contusion injury only (n=4). The implantation was performed one hour after injury. Both somatosensory evoked potentials (SSEPs) and motor evoked potentials (MEPs) were recorded 10 weeks after injury. The MEPs were recorded from both the left and right tibialis anterior muscles. Animals received injections of 1 percent WGA-HRP in the motor cortex or lumbar spinal cord, or injection of Fast Blue in the lumbar spinal cord.

RESULTS—SSEPs and MEPs were recorded from all animal groups at the end of the 10-week survival period. The most significant electrophysiological recovery, as determined by SSEPs and MEPs, was seen in the group of animals which received carbon filament implants cultured with fetal spinal cord tissue, suggesting that this combination plays an important role in promoting electrophysiological recovery after injury. In addition, retrograde labelling showed labelled axons and cells across the lesion in the group which received carbon filament implants cultured with fetal spinal cord tissue, as compared to the other three injury groups.

FUTURE PLANS—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 recovery after injury, as demonstrated by increased axonal conduction of the motor and somatosensory tracts in the injured host spinal cord, and by retrograde labelling techniques. We will continue to evaluate the use of these implants for spinal cord repair after injury.

RECENT PUBLICATIONS FROM THIS RESEARCH

Electrophysiological improvement after co-implantation of carbon filaments and fetal tissue in the contused rat spinal cord. Liu LS, Khan T, Sayers ST, Dauzvardis MF, Trausch CL. Neurosci Let 1995:200:199–202.

Electrophysiological improvement following spinal cord injury using carbon filament implant and ORG 2766. Khan T, Sayers S. In: Proceedings of the Sixth International Symposium on Neural Regeneration; 1995, Asilomar, CA.

Axonal growth after co-implantation of carbon filaments and fetal tissue in the contused rat spinal cord. Liu LS, Khan T, Sayers S. Soc Neurosci Abstr. In press.

[327] 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 #B94-1743PA)*

PURPOSE—Damage to the nervous system, either through trauma or disease, often results in extensive neurological disabilities that severely compromise the quality of life for the affected person and his/her family. While many rehabilitation approaches exist for improving outcomes, these 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 (SCI), 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—This pilot project involved development of molecular methodology to amplify expressed genes from brain tissue of hamsters. The specific steps consist of: 1) rapid isolation of nondegraded mRNA from brain tissue; 2) making a full length antisense cDNA copy from the isolated mRNA templates, by using a special primer encoding a T4 polymerase promoter; 3) making a second full length cDNA strand complementary to the first cDNA strand; 4) using the copy of the T4 polymerase promoter encoded on the first cDNA strand to synthesize (and amplify) radioactive RNA copies of the original mRNAs present in the tissue; 5) transfection of bacteria with plasmids containing the known genes of interest, to produce cDNAs to affix to a nylon membrane; 6) attaching the cDNAs to the membrane; 7) testing the bound cDNAs by hybridization to known, synthesized, radiolabeled RNAs; 8) hybridizing the radiolabeled, amplified RNAs to the membrane; 9) washing and exposing the membrane to autoradiographic film to detect bound RNAs; 10) analyzing the autoradiographs to detect which RNAs are present.

PRELIMINARY RESULTS—The results to date are as follows: 1) isolation of undegraded RNA from tissue has been accomplished by two methods, using guanidinium thiocyanate or lithium dodecyl sulfate to inhibit degradative enzymes. To increase the efficiency of the process and minimize sample losses, magnetic beads bound to the cDNA primer have been synthesized, which allows efficient retrieval of cDNA from solutions. 2) Full length first strand cDNA copies of the mRNA templates have been verified, radiolabeling the synthesis, separating the cDNAs by size on an agarose gel, and detecting the radiolabeled species by autoradiography. 3) Combinations of T4, Klenow and DNA polymerase I enzymes, with 3 different buffer systems and various temperature conditions, have been tested to increase the length of the second cDNA strand product. To date, second strand synthesis incorporates only 15-64 percent as much radionucleotide as the first strand synthesis. Currently, Taq polymerase is under study as an alternative enzyme to increase efficiency of this step. 4) Amplification of short second cDNA strands has been demonstrated by incorporation of radiolabeled nucleotides and separation on agarose gels, as above. 5) Several cDNAs for initial testing purposes (c-fos, negative injury control; β-tubulin positive injury control; HSP, constitutively expressed, and a vector, negative control) have been synthesized. 6) Synthesized cDNAs were blotted onto nytran membranes and covalently cross-linked by UV radiation. 7) Integrity of the cDNA-bound nytran membrane was verified by binding of radiolabeled synthesized RNA encoding c-fos, washing, and film autoradiography. 8–10) Hybridization of radiolabeled, amplified RNAs to the cDNAs affixed on nytran membranes has met with limited success.

FUTURE PLANS—Steps 8-10 need validation and replication. Once this has been accomplished, we shall seek to apply this method to the nerve regeneration field in order to identify why some neurons die after injury and others survive and vigorously regenerate.

[328] TRANSPORT OF NGFs±MIF-1 INTO SPINAL CORD

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PURPOSE—Severe damage to the spinal cord has devastating consequences because of the lack of regeneration of the severed neural pathways. Experimental evidence now exists that axonal regrowth can be stimulated so as to re-establish supraspinal connections of the isolated segments to provide function.

In order to accomplish this regeneration of the spinal cord, an adequate supply of nerve growth factors (NGFs) of the neurotrophin family of small polypeptide proteins is required. Penetration of such substances from the circulation into the spinal cord would open up new approaches to treatment of injuries of the spinal cord.

Until relatively recently, the possibility that NGFs administered peripherally could enter the spinal cord has not been taken seriously, probably because of erroneous dogmas concerning size of the compounds and the blood-brain- (spinal cord-) barrier (BBB). Similar misconceptions had previously occurred with peptides and cytokines like the interleukins that are the same size as the NGFs. Although the rate of entry of these substances into the spinal cord and brain is relatively small, for many compounds it is similar to that of substances like morphine and dopa that have always been accepted as readily penetrating the BBB.

METHODOLOGY—We are in the process of characterizing the entry of NGFs into the spinal cord and brain from blood by state-of-the-art methods. These include measurement of rates of entry (K_is), washout, and capillary depletion methods to exclude substantial sequestration by vascular endothelial cells, and high performance liquid chromatography (HPLC) to determine the intact nature of the entering NGFs. Nonspecific entry is being tested with albumin to rule out a disrupting effect of the administered NGF, as we previously have done for interleukin at the spinal cord.

PROGRESS—Our preliminary results are showing that NGFs can enter the spinal cord. The rates of entry differ among the various neurotrophins being tested (NGF, BDNF, NT3, and NT 4/5). They also differ between different areas of the spinal cord (cervical, thoracic, and lumbar) and the brain.

IMPLICATIONS—It is hoped that characterization of the entry of NGFs into the spinal cord from the periphery will lead to new approaches to the treatment of spinal cord injuries. This should provide stimulus to studies of the beneficial effects of NGFs in spinal cord injury.

[329] GENETICALLY ENGINEERED NEUROTROPHIN SECRETING SCHWANN CELLS FOR THE TREATMENT OF SPINAL CORD INJURY

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Sponsor: *Hines VA Rehabilitation Research and Development Center, Hines, IL 60141 (Core Funds)*

PURPOSE—Neurotrophins are proteins which are 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 that provide a favorable attachment surface and provide directionality to regrowing axons. Recent studies have shown many populations of central nervous system neurons which 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 that 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 had 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 poly (A+) RNA was isolated from the total RNA. The mRNA levels for these two neurotrophic factors was evaluated by Northern blots. The levels of BDNF and NT-3 secreted by the Schwann cells will be measured by using an ELISA for these two neurotrophic factors.

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 Northern blots of the poly (A+) RNA prepared from the BDNF and NT-3 secreting Schwann cells showed the presence of the mRNA signal for either BDNF or NT-3 when the blots were hybridized with 32P-labeled riboprobes prepared to detect either BDNF or NT-3 mRNA. The levels of BDNF and NT-3 secreted by these Schwann cells are currently being measured using an ELISA for BDNF and NT-3.

FUTURE PLANS—The BDNF and NT-3 secreting Schwann cells will be evaluated *in vitro* for their effect on the growth of spinal cord axons by co-culturing them with rat fetal spinal cord explants. 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 *in vivo*.

The use of genetically modified cells, which secrete BDNF or NT-3, have 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.

RECENT PUBLICATIONS FROM THIS RESEARCH

Preparation of brain-derived neurotrophic factor and neurotrophin-3 secreting Schwann cells by infection with a retroviral vector. Sayers S, Khan T, DeVries G, et al. Soc Neurosci Abstr 1996.

XVI. Wheelchairs and Powered Vehicles

A. General

[330] COMPUTER-AIDED WHEELCHAIR PRESCRIPTION SYSTEM (CAWPS) ____

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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. However, opportunity does not always translate into reality due to three factors. First is an information overload: a number of companies make wheelchairs in a variety of models with many configurable options for each: therefore, a huge quantity of information has to be searched in order to make the best selection. This information continually changes as new models, options, and companies enter the scene, and information from different manufacturers may be difficult to compare. Wheelchair standards information is not easily available. Secondly, there is the possibility of incorrect prescription or purchase of wheelchairs, particularly among first-time, inexperienced wheelchair users. Thirdly, there is a procedural barrier: time-consuming written reports and justifications are required to obtain funding for wheelchairs.

The purpose of the Computer-Aided Wheelchair Prescription System (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 such prescription: the user, the therapist, and the 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. The computer program will provide assistance with the preparation of written reports and justifications necessary to obtain funding.

METHODOLOGY—CAWPS is being developed to address these problems. Based on information from ANSI/RESNA wheelchair standards, experts in wheelchair prescription, expert wheelchair users, and information from manufacturers, it will incorporate an interface that updates the system with new information on new wheelchair models that have been tested according to the ANSI/RESNA wheelchair standards.

PROGRESS—We have completed the CAWPS user interface, continue to develop linked databases of prescription rules, and have displayed and demonstrated CAWPS at RESNA, along with three papers on the system. We are engaged in ongoing negotiations with two companies to develop CAWPS as a product.

PRELIMINARY RESULTS—The analysis of approximately 200 questionnaires shows a need for the project among wheelchair prescribers, confirming our perception of a great interest in CAWPS: at RESNA approximately 20 organizations requested that they be considered as Beta test sites. The rules and information already exist to develop the system.

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. A proposal to develop an Internet-based database of wheelchair information ancillary to CAWPS is under development.

[331] DESIGN GUIDELINES FOR WHEELCHAIR RIDE COMFORT AND FATIGUE LIFE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B805-2RA)*

PURPOSE—The number of individuals who use wheelchairs as their primary mobility is rising. This change is a result of improved technology: more people live longer and may require a wheelchair in their later years, and more survive the violent incidents that result in spinal cord injury. However, wheelchair rider comfort is only recently being addressed. During the last 10 years, there has been a great quantity of literature devoted to whole-body vibration leading to the development of the ISO 2631 standard. Among this literature, though, only a few articles deal directly with individuals with disabilities or specifically with wheelchair users. ISO 2631 will be used as a starting point for this investigation. It is the purpose of this research to acquire and analyze acceleration and ground reaction force data so that a wheelchair may be designed to minimize user discomfort from road irregularities.

METHODOLOGY—A simulated road obstacle course has been constructed and will be used with four rehabilitation and three depot wheelchairs from three different manufacturers.These wheelchairs have been instrumented with ground reaction force sensors (SMARTHUB) to determine the force and moment input from the road surface at the axles. During separate tests, the wheelchairs will be loaded with an ISO-ANSI/RESNA test dummy instrumented with accelerometers, and with a human subject. The subjects will use a bite-bar to measure acceleration at the head. Acceleration at the seat will be determined through an adaptation of the ISO 2631 standards. Data-logging will also be used to determine the acceleration profile of a typical day for five individuals who regularly use a wheelchair as their primary mobility. The acceleration data from the data-logging studies and the acceleration and ground reaction force data from the simulated road course will be used to validate and calibrate the existing ISO-ANSI/RESNA wheelchair fatigue tests. This data will also be analyzed to determine dynamic models for the wheelchair and rider. In addition to a ride comfort analysis, nine depot wheelchairs and nine rehabilitation wheelchairs (three models each from each manufacturer) will be tested to failure using the ISO ANSI/RESNA wheelchair fatigue tests, providing life-cycle information on the different types of wheelchairs. These results will allow clinicians and wheelchair riders to compare the ANSI/RESNA test results with comfort criteria when selecting a wheelchair.

PROGRESS—The SMARTHUB ground reaction force sensor and the acceleration system necessary for data collection have been designed and constructed. The SMARTHUB takes the place of one of the wheels on the user's own wheelchair. The accelerometer system is designed to clamp onto a frame member below the wheelchair seating surface. Both systems use a data logger based on a 68HC11 microcontroller (Motorola), designed and constructed especially for this research.

PRELIMINARY RESULTS—Preliminary results show that the transmission of vertical acceleration through the human body can be represented by an auto-regressive model. This model consists of four poles and two zeros. Nine depot wheelchairs have also been fatigue tested using the ISO/RESNA Double-Drum and Curb-Drop Machines. Only one wheelchair of the nine surpassed the ISO ANSI/RESNA Standard requirement of 200,000 Double-Drum cycles and 6,666 Curb-Drop cycles. Of the remaining eight wheelchairs, only one wheelchair completed the initial 200,000 Double-Drum cycles.

FUTURE PLANS—We plan to expand our testing by considering the effect that the seat cushion has on the transmittance of vibration to the wheelchair user. We also plan to increase the number subjects and conditions

tested. These future studies will be aided by the extensive development of sensors done in the current research.

RECENT PUBLICATIONS FROM THIS RESEARCH

Determination of wheelchair dynamic load data for use with finite element analysis. VanSickle DP, Cooper RA, Robertson RN, Boninger ML. IEEE Trans Rehabil Eng. In Press.

The effect of shape factors on wheelchair cross brace strength. Lawrence B, Cooper RA, Gonzalez JP, VanSickle DP, Robertson RN, Boninger ML. In: Proceedings of the 19th Annual RESNA Conference; 1996, Salt Lake City, UT. Washington, DC: RESNA Press, 1996.

Life-cycle analysis of depot versus rehabilitation manual wheelchairs. Cooper RA, Robertson RN, Lawrence B et al. J Rehabil Res Dev 1996:33(1):45–55.

Manual wheelchair ride comfort. Lawrence B, Cooper RA, Robertson RN, Boninger ML, Gonzalez JP, VanSickle DP. In: Proceedings of the 19th Annual RESNA Conference; 1996, Salt Lake City, UT. Washington, DC: RESNA Press, 1996:223–5.

[332] 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-DA)*

PURPOSE—The purpose of this project was to design a new bowel care/shower chair that can be safely and efficiently used by SCI and other disabled users who cannot transfer to the toilet. The chair must provide access for caregivers. Because bowel care procedures by SCI individuals can take from 30 to 90 minutes, proper seating posture and comfort is necessary in order to prevent pressure ulcers, a serious threat in older designs of bowel care chairs. During a pilot study, several features of existing models were found to be less than optimal: space access for digital stimulation, seat design and cushioning, armrests, footrests, backrest, brakes and the size of the wheels in relationship to the positioning of the chair to the wall.

METHODOLOGY—The procedure used by the investigators to design this new chair included three phases: 1) design development and fabrication of bowel care/shower chair prototypes; 2) testing of the prototypes according to the ANSI/RESNA wheelchair standards; and 3) clinical evaluation of the prototypes with patients and caregivers at the Milwaukee and Tampa VA Medical Centers.

PROGRESS—Eight chair prototypes were fabricated by Ortho-Kinetics, the collaborating manufacturer, and clinically evaluated with SCI participants. This evaluation involved the use of data instruments to collect caregivers and participant's opinions. From this clinical evaluation, design adjustments were made to the chairs.

Wheelchair frame. The final design provides a proper seating position and hand access for digital stimulation without interference from frame and wheels. A production frame tubing of 3.2 cm was selected. This frame is designed for static stability of 15 degrees in forwards and rearwards tipping.

Seat design. A final "C" shape seat was designed that allows hand access in three positions (front, left, and right) and safe transfer from another wheelchair. Various foam densities were evaluated with a pressure mapping system to determine an ideal density. The selected density distributes evenly the pressure created by the buttocks and the legs on the seat.

Hand-ring development. A preference study, using three hand-ring diameters (27, 34, and 42 mm) led to the selection of the 34 mm as the preferred diameter for grasping. In addition, a coated finish provides grasping under wet conditions.

Footrest development. A footrest providing a larger support area for the feet and an overall contoured shape for comfort and positioning was finalized. In addition a

foot-lift to ease cleaning of legs and feet was successfully evaluated in the prototypes. This new foot-lift will be incorporated in the production chairs.

FUTURE PLANS—Following testing of the final chair design according to the ANSI/RESNA wheelchair standards, final production considerations will be addressed with Ortho-Kinetics the collaborating manufacturer before commercialization of the chair.

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 Nurs 1994:11(4):104–6.

Determination of static stability of bowel care/shower chairs in SCI. Malassigne P, Amerson T, Nelson AL. In: Proceedings of the 17th Annual RESNA Conference; 1994, Nashville, TN. Washington, DC: RESNA Press, 1994:318–20.

[333] ERGONOMICS OF MANUAL WHEELCHAIR PROPULSION

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Sponsor: *Institute for Fundamental and Clinical Human Movement*

PURPOSE—We are conducting a systematic analysis of manual wheelchair propulsion from a combined biomechanical and physiological perspective, with the objective of eventually improving the mobility of the wheelchair-user combination. Central areas of interest are the impact of wheelchair design characteristics upon the physiology and biomechanics of the wheelchair user, with special reference to functional load and mechanical efficiency and kinetics, loading of structures during mere manual wheelchair propulsion. From this, a set of theoretically based guidelines for wheelchair design and wheelchair fitting emerges.

We also study the factors that determine work capacity and power output (among others, functionality and propulsion technique) of the wheelchair user. This should lead to guidelines of wheelchair training in sports and rehabilitation, as well as serving in the development of design and fitting guidelines.

METHODOLOGY—Wheelchair propulsion is studied during standardized submaximal aerobic wheelchair exercise and sprint tests on a motor-driven treadmill and during simulated conditions on different computer-controlled wheelchair ergometers. During the treadmill tests (used in studies on prototype evaluation, performance capacity, and propulsion technique), physiological measures are combined with 3-D kinematics and electromyography. Force measurements and kinematics during propulsion on the wheelchair ergometer enable an additional 3-D reconstruction of the movement pattern of arms and trunk, and the study of force and power production. Together with electromyography of upper extremity and trunk muscles and overall physiology, phenomena of the mechanical efficiency in manual wheelchair propulsion may be studied from a biomechanical and anatomical perspective.

A detailed model of the shoulder-arm complex allows calculation of the contribution of different muscles on power production during static and dynamic activity of shoulder and elbow in wheelchair arm work and other tasks. Thus the high prevalence of repetitive strain injuries (RSI) in the shoulder and hand-wrist) among the wheelchair-user population may be understood more clearly. Arm work during different forms of manual wheelchair propulsion is thus studied: lever, crank, hubcrank, and handrim propulsion.

PROGRESS—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. Overall levers and cranks are much less straining and more efficient than handrims. The latter also holds for hubcrank propulsion: a continuous cyclic motion where both hands apply force to a crank mounted to the hubs of the rear wheels. This clearly is associated with

the more natural coupling of the hand to the hand grip, its continuous bimodal 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 hand rim propulsion. Recent study of hand-wrist motions indicated, as before, large excursions around the flexion/extension axis and ulnar/radial deviation axis.

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.

RECENT PUBLICATIONS FROM THIS RESEARCH

Physical strain and mechanical efficiency in hubcrank and handrim wheelchair propulsion. Woude LHV van der, Kranen E van, Ariens G, Rozendal RH, Veeger HEJ. J Med Eng Tech 1995:19(4)123–31.

Wheelchair propulsion in sports and daily life: does it matter? Woude LHV van der, Veeger HEJ, Dallmeijer AJ. In: Proceedings of the First European Conference on Apdapted Physical Activity and Sports; 1995, Acco, Leuven, 61–7.

Quasi-siatic Analysis of muscle forces in the shoulder during wheelchair propulsion. Helm FCT van der, Veeger HEJ. J Biomech 1996:29(1):39–52.

The effect of wheelchair handrim tube diameter on propulsion technique and force application. Linden MA van der, Valent L, Veeger HEJ, Woude LHV van der. IEEE Trans Rehabil Eng. In press.

[334] THE DETERMINATION OF ENVIRONMENTAL ACCESSIBILITY AND WHEELCHAIR USER PROFICIENCY THROUGH VIRTUAL SIMULATION

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PURPOSE—In an effort to utilize technology that can have a direct and immediate relevance to the problems confronting the disabled, we propose to examine human performance in negotiating barrier-free environments through the use of computer-generated virtual simulations. The project will be instrumental in defining standards for use in evaluating user proficiency, which will provide information for more suitable selections of enabling technology for the disabled. In addition, this research will demonstrate direct implications for the development of enabling technology through virtual testing and analysis, and provide improved methods for the design of barrier-free environments.

METHODOLOGY—We intend to interface Invacare's Action Power Evaluation and Training simulator with the capabilities for generating advanced computer simulations found at ACCAD. We will incorporate real world architectural databases, so as to maximize transfer from the simulator to actual user environments. We propose that this research will lead toward a practical interface for the disabled. The prototype can become a generic tool for use in analyzing and evaluating human performance, and provide us with new insight into the nature of disabilities and new understanding of certain limitations.

PROGRESS—We have developed a virtual-structure prototyping system that allows navigation by a person using a power wheelchair. The system is a tool for three groups of people: 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 the compliance with the Americans with Disablities Act of 1990, which requires handi-

capped accessibility for (almost) all public structures. For wheelchair users, it provides more appropriate device fitting and training with wheelchair control systems. For health care professionals, it provides a system for assessing user performance and for determining the best power chair control mechanism for a particular patient.

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. The display generates realistic interiors containing multiple light sources and surface textures and is viewed in stereo through lightweight polarized glasses. The system maintains a hierarchical data structure that detects collisions between the virtual wheelchair and the environment.

Pilot trials were run at the Ohio Supercomputer Center. Subjects included individuals with disabilities of varying severity and individuals from the nondisabled population. Simple steering tasks were performed and evaluated. Subjects were asked to navigate through a simple environment using the joystick controller. The hypothesis is that force feedback technologies can provide significant improvements in user performance.

RESULTS—To date, we have developed a robust system that provides previsualization of architectural data sets and assists in assessment for ADA compliance. In addition, the system provides an immersive environment for users to train themselves in the use of a power chair, therefore limiting the application of unsuitable technology that may never be fully, or even partially utilized.

Current efforts include the completion of a communications protocol to allow a health care provider, working on a remote machine, to place moving objects in the path of the user. Currently, the system tracks and records specific tasks, performance time, and number and exact location of collisions (e.g., front-right, back-left). Recording collision positions is useful in assessing cognitive disorders such as side neglect. Additional tracks will include reaction times, and location of the object upon initial recation in relation to the user's field of view.

RECENT PUBLICATIONS FROM THIS RESEARCH

The determination of environmental accessibility and ADA compliance through virtual wheelchair simulation. Stredney D, Carlson W, Swan JE, Blostein B. Presence Teleop Virt Environ 1995:4(3):297–305.

B. Seating Systems

[335] MULTIFACTORIAL ANALYSIS OF SEAT CUSHION FOR WHEELCHAIR USERS

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Sponsor: *Italian Ministry for University and Scientific Research*

PURPOSE—This project, started 2 years ago, seeks to develop and apply an evaluation protocol to compare different types of seat cushions for wheelchairs. The aim is to define and measure some parameters (physical measurements, postural parameters, functional parameters, and so forth) useful for evaluating and comparing the performances of the different cushions under analysis. Applications are in the design of innovative products and in the optimal choice and adaptation of a product for the single subject characteristics.

METHODOLOGY—The main considered biomechanical data are the interface pressure between subject and cushion. In order to measure this variable, we use a device consisting of a thin matrix (42 rows × 48 columns) of piezoresistive pressure sensors (1 cm^2 of area each)

put into a pad connected with a personal computer with a particular software that allows us to store and represent all collected data. The PC runs dedicated software that elaborates data after acquisition to deal with artefact rejection, temporal and spatial filtering, spline interpolation of missing data, and then computes automatically the desired parameters. The main computed parameters are maximum peaks and mean pressures in particular areas under the buttocks. The most involved areas under the bony prominences are the ischial tuberosities, great trochanters, sacrum, and coccyx. Pressure distribution maps are also used to evaluate some postural parameters such as the asymmetry of load distribution, position of pressure centre with respect to the anatomical reference system and seat contour characteristics. These parameters are acquired both in static and in dynamic conditions, that is, during wheelchair propulsion.

The cushions considered in this study are both commercially available and innovative prototypes. They present different characteristics: one is a contoured firm foam base covered by a gel pad, another is composed by rows of air-filled rubber balloons connected by narrow air channels in a flat rubber base, and the last two are formed by gel-filled and foam-filled rubber balloons with a foam base.

A subjective evaluation of matters such as comfort and stability, taken from a dedicated questionnaire, is also considered and will be correlated with the measured parameters.

RESULTS—Three groups of patients have been selected: spinal cord injured patients without sensibility in lower limbs, multiple sclerosis patients with intact sensibility, and elderly subjects with motor problems. A total of 30 patients have been acquired, both in static and dynamic conditions, and data elaboration is still in progress. The already available data show interesting differences both between cushions and between groups. Moreover, the dynamic data seem very promising to evaluate stability properties of cushion.

FUTURE PLANS—This procedure will be applied on a more consistent number of patients, and the obtained data will be statistically analyzed looking for significance. The trend in time during long-term acquisition will be considered too.

In the long term a new protocol will be developed to study particular variables that allow the change of some cushion parameters like thickness, gel distribution, and gel amount, in order to adapt the cushion to the single patient characteristics. The aim is to change in the best way the shape of the cushion to reduce pressures peaks and to improve patient comfort.

RECENT PUBLICATIONS FROM THIS RESEARCH

A Biomechanical approach to seat cushion comparison in wheelchair users. Abello G, Ferrarin M, Pedotti A. In: Proceedings of RESNA International '95; 1995, Vancouver BC. Washington, DC: RESNA Press, 1995:297–9.

[336] DEVELOPMENT OF BETTER POSTURAL BELTING AND OTHER ANTERIOR POSTURAL CONTROL DEVICES

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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 alternatives and improvements to the lap belts traditionally used to provide pelvic stabilization for some children who use wheelchairs. Consumers have identified a number of areas where current belting systems need to be improved. The end result will be a system that is easier to use and will provide children with better pelvic stabilization, resulting in better seating posture.

PROGRESS—Since fall 1994, we have completed the first phase of involved applying qualitative methodologies to acquire information regarding the product needs of consumers. The consumer groups included: occupational and physical therapists, parents and children, clinical technicians, and others. We have also completed an extensive review of relevant clinical and theoretical literature and have conducted a comprehensive product search. In consultation with consumers, a number of designs were proposed and critiqued, resulting in the development of four concepts to the prototype stage. Further in-house laboratory evaluations and the feedback from consumers have resulted in the further development of two prototypes: one concept enhances the function of traditional belts and the other replaces the belts with a completely different system. In collaboration with the Bloorview MacMillan (MacMillan site) Seating Service, one of the of the prototypes is currently in extended field trials with encouraging results. The second prototype is currently undergoing modifications with the expectation of field trials in the near future.

FUTURE PLANS—In the final phase of this project, we will complete the field trials and make the final design modifications before production. The dissimilar nature of the two current designs will allow us to market them both without competing with each other.

RECENT PUBLICATIONS FROM THIS RESEARCH

Pelvic stabilization: theory, practice and future. Reid DT, Rigby P, From W, Ryan S. In: Proceedings of the 12th International Seating Symposium; 1996, Vancouver, BC.

[337] DEVELOPMENT OF CUSTOM CAR SEATS FOR SCHOOL-AGED CHILDREN WITH PHYSICAL DISABILITIES

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PURPOSE—Many children with physical disabilities need custom-made seats to be comfortable and well-supported while in their wheelchairs. This creates safety concerns for automobile transport. Commercially available car seats are often not suitable because many of these children do not fit into them. As a result, parents use the custom-made seat from their child's wheelchair for this purpose. This arrangement may not provide adequate protection in case of a motor vehicle collision. The intent of this project is to develop a custom car seat for school-aged (5–12 years) children weighing from 40 to 75 pounds (18–34 kg) to meet general safety standards as well as their special needs for comfort and support.

Another issue that concerns parents is how to transfer their child safely to and from the car without incurring back injury. To deal with this problem, the project includes the development of a portable lift and transfer device that can be conveniently used for this purpose.

PROGRESS—We completed a study to understand the ability and willingness of seating clinics to build custom car seats using a carrier restraint system. This research was significant because it showed for the first time that this new technology could be used to offer children with physical disabilities both custom support and the same level of occupant protection as other motor vehicle passengers. We proceeded to engineer changes to the prototypes for the restraint system and lift and transfer device. We conducted a series of crash tests to optimize the design of the restraint system and re-engineered the lifting device to enhance its consumer appeal and versatility. With the endorsement of our consumer advisory panel, we are now developing a new product: a modular seat to fit into our carrier restraint. This strategic move will allow us to establish a presence in the specialty car seat market. Ontario-based companies are being approached to determine their commercial interest.

FUTURE PLANS—If we are to manufacture these specialty products in Ontario, we need to actively support our partners during the commercialization phase. The prototypes for the restraint and lifting device are mature,

but design enhancements and cost-cutting features will need to be incorporated before commercial products are realized. We will also finalize the standard restraint seat design. Since the production restraint must be certified to federal standards, we will oversee compliance tests and complete consumer and clinical instructions. In collaboration with our Ontario-based partners, new market niches and relevant distribution channels will be established for these products in North America and abroad. With appropriate industrial linkages, we hope to have these products available in 1997.

RECENT PUBLICATIONS FROM THIS RESEARCH

Evaluation of a program to teach seating clinics to build custom car seats. Ryan SE, From W, Day K. In: Proceedings of RESNA International '95; 1995, Vancouver, BC, Canada. Arlington, VA: RESNA Press, 1995:317–9.

[338] DEVELOPMENT OF A MODULAR PAEDIATRIC SEATING SYSTEM

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PURPOSE—Modular seating systems are attractive to seating service providers because a variety of components can be combined to produce a functional product for many of their clients. However, these systems are reported by both clinicians and consumers to be unreliable, incompatible with many commercial wheelchair bases, and unusable for children with simple seating needs.

The purpose of this project is to develop a new generation, modular wheelchair seating system to serve school-aged children who have mild-to-moderate seating problems. The system will include novel features that address needs identified by consumers and service clinicians.

PROGRESS—To help us understand how the product should be designed, we asked the opinions of more than 300 students, parents, and rehabilitation professionals through self-report questionnaires, focus groups, and group discussions. Various design concepts and models of the proposed system were created. During 1995, under contract from Special Health System Limited (Aurora, Ontario), we engineered two major design changes to adapt to more cost-effective manufacturing processes.

FUTURE PLANS—We plan to complete the development of a mature prototype of the new seating system over the next fiscal period. To evaluate the efficacy of the design, we will conduct both mechanical proof tests, clinical trials, and consumer testing. During this time, linkages will be established with a new industry partner.

RECENT PUBLICATIONS FROM THIS RESEARCH

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; 1995, Toronto, Ontario, 125–8.

A client-centred approach to developing assistive technology with children. Rigby P, Ryan SE, From W, Walczak E, Jutai J. Int J Occup Ther. In press.

Understanding the product needs of consumers of assistive devices. Ryan SE, Rigby P, From W. Can J Rehabil. In press.

[339] EXPERIMENTAL TESTING OF OPEN-CELL FOAMS TO DETERMINE THEIR MATERIAL PROPERTIES

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Sponsor: *None listed*

PURPOSE—Open cell foams provide cushioning and precise positioning in many medical applications. One of the major applications is for wheelchair seating, where prolonged use can cause serious problems such as decu*bitus ulc*ers, or pressure sores, in the elderly and disabled because of inadequate pressure relief between the wheelchair cushion and the buttocks. In order to design cushions and supporting surfaces with open-cell foams, a thorough investigation and understanding of the foam material properties is necessary. In this study, three different types of commercially available open-cell foams are tested in accordance with the American Society for Testing Materials (ASTM) standards.

METHODOLOGY—For this study, three types of open-cell foams were used. These foams are Fire Resistant (FR) Polyurethane (PU), #6 PU, and PU Beige. Both coated and uncoated samples of these materials were tested according to ASTM D-3574-91, "Standard Methods of Testing Flexible Cellular Materials—Slab, Bonded and Molded Urethane Foams." Large and small deflection compression tests are used for this study. Samples dimensions of 15×15×4 in (38.1×38.1×10.16 cm), 12×12×4 in (30.5×30.5×10.16 cm), 1.57×1.57×1.97 in (4×4×5 cm), and 4 in (10.16 cm) disks with a 4 in (10.16 cm) radius are being tested with the Instron Universal Testing Machine. For better data collection, a Data Acquisition System is being used.

PROGRESS—At this time, the compression testing of the foams is not yet completed. Data are still being collected and analyzed. However, some initial results are available.

PRELIMINARY RESULTS—As expected, the material property curves for the foam have both linear and nonlinear regions. It must also be noted that the sample size appears to affect the stress strain curve due to the contact between the foam and the sides of the indentor.

FUTURE PLANS—The current objective is to investigate the linear region of the material property curve. The analysis of the nonlinear portion of the data will also be performed along with further investigation of the viscoelastic behavior of the open-cell foam material.

RECENT PUBLICATIONS FROM THIS RESEARCH

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.

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; 1995, Tampa, FL. Tampa: USF, 1995:46–8.

Stress-strain relationships of open-cell foams. Todd BA, Smith SL, Bunn TS. In: 1996 ASME Symposium on Cellular and Microcellular Materials. In press.

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XVII. Wound and Fracture Healing

A. Pressure Sores

[340] COMPARISON OF SEMI-SYNTHETIC AND AUTOLOGOUS CONNECTIVE TISSUE GRAFTS: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #B1839PA); Plastic Surgery Education Foundation*

PURPOSE—Severe ulcerating pressure sores are now treated by reconstructive surgery, using a musculocutaneous flap rotated from an adjacent unaffected site. If this fails and the ulcer recurs, as is frequently the case when the causative compression of soft tissue against a bony prominence cannot be avoided, there may be no remaining donor site for a flap or graft.

METHODOLOGY—A tissue-engineered graft for repair of the deep or recurring ulcer is constructed of natural and synthetic biomaterials inoculated with autologous connective tissue and fat cells, which are nourished either from an external fluid loop through artificial capillaries, or by a microsurgically relocated arteriovenous loop. The synthetic capillary network is a branching mesh of permeable tubes, connected either to vessels at a distance from the injury, or to a supply of culture medium. The latter takes the place of the blood supply until replaced by it; it also provides a means for infusing high-dose antibiotics to combat infection and for raising hydrostatic pressure to resist compression.

PROGRESS—A 1-year pilot project has been completed, in which composite collagen/hyaluronic acid grafts were tested for cell compatibility *in vitro*. These composite materials were tested for creep compliance and tensile relaxation properties. A subproject now underway involves testing capability of these grafts to resist bacterial and fungal infections common in pressure sores. A second pilot project to perform microsurgical revascularization of semiartificial grafts in rats has begun. This phase includes an effort to develop a better small animal model for pressure sores by impeding revascularization from the periphery of an excision wound.

RESULTS—The matrix that best mimics mechanical and geometric properties of intact tissue is an interdigitated composite of collagen and hyaluronic acid, with the collagen cross-linked using ultraviolet light to avoid toxic chemicals. Three trials of implantation of 2 cm square grafts were made in abdominal pouches in rats; results showed good revascularization from a saphenous vein graft placed between two layers of collagen/hyaluronate matrix. There was some compression in thickness but no migration from the implant site.

FUTURE PLANS—A larger scale animal implantation experiment will show that restoration of tissue volume and vascular supply can be reliably replicated; this will be followed by a proposal for a limited clinical trial. Because the costs and level of surgical skill are anticipated to be lower than reconstructive microsurgery, we expect this type of graft to occupy a place in the therapeutic armamentarium midway between surgery and conservative debridement followed by semiocclusive dressings.

RECENT PUBLICATIONS FROM THIS RESEARCH

Cellular response to collagen/hyaluronic acid composites in vitro. Sabelman EE, Koran P, Diep N, Lineaweaver WC. In: Proceedings of the 5th World Biomaterials Congress; 1996, Toronto, Canada. Vol I. 910.

Collagen/hyaluronic acid matrices for connective tissue repair. Sabelman EE, Koran P, Diep N, Lineaweaver WC. In: Proceedings of the Materials Research Society; 1995, San Francisco, CA. Paper Z3.8.

[341] 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—For people who suffer from diabetes, especially those complicated by neuropathy, foot problems can be a common phenomenon. One of the more common is plantar ulceration, which can range from small superficial ulcers to deep penetrating ulcers with bony involvement. Shoe orthotics have been shown to be effective in the reduction of pressures. Currently, a new type of orthotic is being tried which involves a plastic insole filled with silicone gel, but little is known of its effectiveness. This study seeks to determine the efficacy of silicone gel shoe insoles as a therapeutic treatment in reducing plantar pressure and examine if factors such as walking rates and volume of silicone gel has an effect on the pressure-relieving abilities of the insoles.

METHODOLOGY—Fifteen healthy, voluntary consenting, adults participated in this study. None have had any substantial lower limb orthopedic problems or surgeries or sustained any lower limb injuries within the last 6 months. Foot pressure data was collected using the PEDAR System (Novel, Inc., Minneapolis, MN and Munich, Germany), an in-shoe pressure measurement device. Three silicone gel insole conditions were tested: low, medium (or normal), and high volume.

Each subject first walked approximately 20 feet at his/her own comfortable walking pace in order to determine normal walking velocity, the average of four trials. Slow and fast velocities were then calculated from this average.

After those velocities were calculated, the subject put on knee-hi stockings and shoes with only the PEDAR inserts in them and walked back and forth approximately 20 feet at the different velocities. Two walking trials were recorded for each velocity. Then one pair of the silicone gel insoles was inserted at random into his/her shoes, and two walking trials at each velocity were then performed over again by the subject. The entire process was repeated until all insoles were tested.

PROGRESS—For each representative step, pressure gradients were computed at each pressure sensor across the metatarsal and heel regions. Except those along the edges, each sensor is adjacent to eight other sensors, thus a total of eight gradient calculations were performed. From these calculations, the one with the largest gradient was used as the pressure gradient for that sensor. This method of computing pressure gradients was used on every pressure sensor except those along the edges which were not used. Pressure gradients were computed as a function of percentage of stance phase. Finally, the peak pressure gradient within each region was then selected as a function of percentage of stance phase.

RESULTS—The results of this investigation show that the silicone gel shoe insoles were effective in reducing plantar pressures under the heel region. However, under the forefoot region, the insoles were not as effective. The difference in the outcome for each region appears to be a function of the dynamic movement of the foot, the timing of the different phases during stance, and the viscosity of the fluid.

RECENT PUBLICATIONS FROM THIS RESEARCH

Efficacy of silicone gel-filled shoe insoles in reducing plantar pressure (thesis). Sawyer F. Columbus, OH: The Ohio State University, 1996.

[342] THE USE OF GROWTH FACTORS IN PRESSURE ULCER HEALING: CLINICAL TRIALS

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PURPOSE—Optimizing active treatment protocols for pressure ulcers requires speeding up the rate of regenerative healing in order to reduce both the likelihood and impact of other secondary complications. This project was designed to examine the use of fibrin matrices that serve as a drug delivery system for an angiogenic factor (FGF-1) as well as a regenerative scaffold.

METHODOLOGY—1) Development of biodegradable fibrin matrix for delivery of acidic fibroblast growth factor (FGF-I). 2) Development of a porous fibrin matrix. 3) Clinical evaluation of the pressure ulcer healing efficacy of the fibrin matrix with FGF-1.

Phases 1 and 2 are complete and phase 3 is currently underway. Clinical trials will be conducted with two treatment groups of 10 patients each. Group 1 will receive standard clinical treatment (saline soaked dressings) and Group 2 will receive a biodegradable fibrin matrix with FGF-1 applied to the surface of the wound.

PROGRESS—Progress during the first years has included: the determination of the optimal FGF-I loading of the fibrin matrix (8 g/ml), the *in vivo* release kinetics, the appropriate delivery techniques clinically, and testing of this system in several animal skin models. It was found that the fibrin and the FGF-1 act synergistically to enhance the healing response. The FGF-1 apparently needs a matrix for the cells and blood vessels to grow into, and the fibrin matrix does not stimulate the angiogenic and healing response as well without FGF-1 incorporation.

For the porous system, which was made by adding polyethylene glycol (PEG) beads (100–200 μm) into the fibrinogen during the formation of the fibrin matrix, further optimization is needed prior to clinical testing. The current system did not give a better response in open wounds, and, in a related study with meshed skin grafts, the porous system was less effective than the nonporous both due to its lower adhesive strength and the residence time of the PEG.

In preparation for clinical studies, effort has concentrated on development of the clinical protocol, development of clinical assessment tools, and obtaining FDA approval. For the assessment techniques, three aspects of pressure ulcer healing will be assessed: healing rate, tissue health, and overall clinical impression. For healing rate, the epithelialization rate, contraction rate, and tissue fill rate independent of wound size will be assessed. For tissue health, a scanning laser doppler will be used to assess the blood flow of the entire wound.

The clinical study is currently waiting on an IND for FGF-1. Based on requirements outlined by the FDA, the protocol has been modified and the project is on hold until certain GMP requirements are met.

FUTURE PLANS—The initial focus is on meeting the FDA requirements and beginning the clinical study. Additionally, efforts will continue to further optimize the porous fibrin matrix.

RECENT PUBLICATIONS FROM THIS RESEARCH

A biocompatibility hierarchy: justification for biomaterial enhanced regeneration. Feldman D, Czuwala P, Kelpke S, Pandit A, Wilson D. Encyclopedic Handbook of Biomaterials and Bioengineering. New York: Marcel Dekker, 1995:223–68.

Characterization of the delivery rate of FGF-1 through a porous fibrin scaffold. Pandit A, Feldman D, Thompson J. Trans Wound Heal Soc 1995:5:80.

Tissue adhesives in wound healing. Feldman D, Sierra D. Encyclopedic handbook of biomaterials and bioengineering. New York: Marcel Dekker, 1995:1347–84.

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.

Obtaining a skin wound healing rate independent of wound size. Kelpke S, Blum B, Osborne S, Pandit A, Feldman D. In: Transactions of the Second Joint Meeting of Wound Healing Society and the European Tissue Repair Society, 1996.

Wound Healing Applications of Fibrin Sealants. Feldman D. In: Sierra D, Saltz R, eds. Surgical Tissue Adhesives and Sealants. Lancaster, PA: Technomic, 1996:99–108.

[343] MICROPROCESSOR-BASED WHEELCHAIR PRESSURE RELIEF TRAINER AND MONITOR

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PURPOSE—An electronic device is being developed to prompt, monitor, and record wheelchair pressure releases to train and/or observe pressure release behavior. The ultimate goal is to reduce the incidence and magnitude of skin problems associated with inadequate pressure release behavior in wheelchair users.

METHODOLOGY—The device consists of a pressure sensor, a microprocessor, an audio beeper, and batteries. The pressure sensor system consists of a capacitive sensor and an oscillator circuit. The ~12×12×0.2 in sensor pad (38.5×38.5×0.5 cm) is connected to the ~4×6×2.5 in microprocessor and power unit (10.16×15.24×6.35 cm) with a thin cable. The sensor consists of two conductive sheets separated by a dielectric. This simple, cheap, and readily available sensor is placed under the wheelchair seat and changes its capacitance in response to the user's presence. The capacitor is part of a simple oscillator whose output frequency depends on capacitance; effectively forming a nonlinear pressure-to-frequency transducer. Unlike a simple switch, this allows for an adjustable pressure threshold due to a continuous change of frequency with pressure. The oscillator output is fed to the microprocessor's digital input bus. As the sensor is readily short circuited by conductive liquids, it doubles as a urine sensor.

The microprocessor samples the oscillator's output and decides whether a pressure release has been accomplished. The threshold pressure level is automatically determined when the device is turned on. The microprocessor can provide an audible indication of successful pressure releases as feedback to the user. The microprocessor can record the time and date of the pressure release for later inspection by downloading the stored data to a PC.

Audible beeps (or other cues) can be provided as reminders to the user that a pressure relief is needed. A voice chip has also been incorporated in one prototype device to provide verbal instructions. Pressure relief reminders can be disabled to provide a "monitor only" capability. Thus, the user's consistency in performing pressure reliefs without prompting can be determined.

The device has sufficient memory to store about 250 time-stamped events, and is expandable. Battery power is conserved by having the microprocessor idle if the user is off of their cushion for over 30 s. The device checks for the user to return periodically, at which time, normal operation resumes, with idle time recorded in memory. Under typical use conditions, the system will run for about 1 week.

PROGRESS—Refinements to the prototype are planned to extend its capabilities. More durable sensor pad designs are being investigated. The ability to detect squirming, as a pressure release strategy, will be investigated. A urine sensing capability will be investigated; this will be beneficial since the presence of urine accelerates skin breakdown. To adapt the device to a wider spectrum of sensory/cognitive disabilities, other prompting methods will be investigated. Possibilities include voice reminders using a voice chip (prototype already developed), visual cues (flashing LEDs), and vibratory cues. Finally, we plan to extend the duration of time that the monitor will sample behavior by investigating other power sources, such as a rechargeable battery pack.

B. Fracture Healing

[344] NEW METHODS TO TREAT IMPAIRED FRACTURE HEALING USING GROWTH FACTORS

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PURPOSE—The goal of the proposed research is to develop new, more effective methods to treat fractures that do not respond to normal fracture treatment with the best available methods. The specific objectives are to determine whether exogenous growth factors can restore normal healing in a delayed healing model and whether time-dependent changes in selected osteogenic indices, associated with this restoration, are correlated with changes in the amounts of selected growth factors.

METHODOLOGY—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 "racture 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.

PROGRESS—Sequential stages of repair in 2 mm and 4 mm defects grafted with 5 mm and 7 mm DBM cylinders were investigated during 8 weeks post-surgery. Osteoconductive and osteoinductive contributions of the DBM cylinder were examined by studying groups of animals with DBM grafts pretreated to selectively remove osteoinductive factors. Various osteoinductive substances were applied in the 4 mm defect to evaluate their usefulness as carriers for growth factors. TGFβ and PDGF were applied to the DBM cylinder in separate groups of rats at the time of grafting the 4 mm defect to determine if it would stimulate bone repair at 7 weeks. TGFβ 1 and BMP2 were applied in combination with microcrystalline hydroxyapatite (MHA) in the defect and the results evaluated at 7 weeks.

RESULTS—Repair sequence in the 2 mm defect is similar to the sequential stages of normal human fracture healing up to union with woven and lamellar bone. In the 4 mm defect model the repair tissue is dominated by fibrous tissue and the rigidity of the fibula is 45 percent less than in the 2 mm defect model at 7 weeks post-surgery. Application of 1 to 100 ng of TGFβ 1 or PDGF to the graft did not stimulate bone repair in the 4 mm defect. Application of 500 ng of BMP2 (+MHA) in the defect increased the rigidity of the fibula at 7 weeks significantly compared to the untreated control ($p<5\times10^{-4}$) and the MHA-treated control ($p<7\times10^{-5}$).

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.

XVIII. Miscellaneous

[345] VALIDITY OF KNEE HEIGHT MEASUREMENT IN THE PHYSICALLY CHALLENGED AND/OR NEUROLOGICALLY IMPAIRED CHILDREN

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Sponsor: *None listed*

PURPOSE—The purpose of this study is to assess the validity of Ross Knee Height Calipers to estimate stature in physically and/or neurologically impaired children. As well, this study will examine how the various methods of measuring height (knee height vs. traditional method—standing, supine, or segmental) influences the calculation of percentage of ideal body weight (%IBW) and thus predict nutritional status.

METHODOLOGY—Subjects included patients referred for nutritional assessment at Bloorview Childrens Hospital for 2 years beginning December 1994. Both males and females, aged 6–19 years, were included. Collection of patient data, including anthropometric measurements (both the traditional methods of measuring height and knee height using the caliper), weight, skinfold measurements, diet, number and type of diagnosis, age, gender, and presence or absence of contractures and spasticity.

PROGRESS—A total of 24 subjects were collected during the initial study period. Due to the small sample size, we extended data collection through the second year and included all patients that met the participation criteria. Currently, 58 subjects have been enrolled and we expect to meet the projected sample size of 100.

PRELIMINARY RESULTS—A positive correlation was found between traditional methods of measuring of height and using the calipers. Also, a positive correlation was found between the two methods of predicting %IBW. However, knee height measurements tend to overestimate IBW (i.e., indicating a better nutritional status) compared to the traditional methods, particularly in individuals at risk for malnutrition. When individuals are adequately or well nourished, %IBW between the two measurements tends to be closer together.

FUTURE PLANS—We continue to recruit a larger sample for further analysis to ascertain the influence of certain covariables on %IBW prediction and determine whether or not this tool can be used in our clinical practice.

[346] OPTOKINETIC TESTING FOR DIAGNOSIS AND REHABILITATION OF BALANCE DISORDERS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C691-2RA)*

PURPOSE—The purpose of this study is to generate data on postural sway induced by horizontal optokinetic stimulation in subjects standing on a fixed platform. Balance combines sensory input from the visual, proprioceptive, and vestibular systems with vision being a powerful stabilizer when the proprioceptive and/or vestibular systems are damaged. Postural sway consists of forward-backward and lateral motions, largely about the ankle joints. Although substantial data exist on the changes in postural sway with the eyes open and closed, and during forward-backward or torsional visual motion, sway induced by horizontal optokinetic patterns has not been studied and may provide a challenge to the vestibular and proprioceptive systems, thereby extending the diagnostic value of fixed-platforin posturography.

METHODOLOGY—Basic audiologic evaluations are performed and the vestibular function of each subject is determined by a questionnaire. The posturography system consists of a fixed platform with two independent foot plates with force transducers that resolve the forward-backward and lateral changes in the center of force of a standing subject; a 180° curvilinear projection screen located 1 m from the subject; a shadow projector for visual stimuli; and a support harness to prevent falls. Postural sway is recorded with eyes closed, eyes open against a fixed background, and a background moving at 20, 40, 60, 80, and 100°/sec to the right or left. The moving background consists of a random bar (1×8° visual angle) optokinetic pattern covering 180° in the horizontal plane and 40° in the vertical plane. Each trial consists of 30 sec of postural testing, followed by 30 sec of rest. Optokinetic stimuli are presented binocularly and randomized to prevent order effects. Subjects are given an alerting task to maintain vigilance and instructed to stand in a relaxed vertical posture, hands at their sides and looking in the direction of the screen.

Postural sway is measured as changes in center of force, a time-varying vector defined in the horizontal plane, and computed as a weighted average of the output from six force transducers (three in each foot plate). Data are transferred to a spreadsheet program for analysis and displays of positional sway and sway velocity in the form of a stabilograms (forward-backward, side-to-side, and lateral dimensions).

PROGRESS—Postural sway and sway velocity data have been collected from 135 subjects; 69 have normal hearing for their age and no complaints of dizziness, 6 reported dizziness/vertigo (with 1 undergoing a labyrinthectomy), 3 were postsurgical for acoustic neuroma removal, 10 participated in a test-retest protocol, 15 revealed sensorineural hearing loss, and 32 currently are enrolled in a pilot study to determine the influence of exercise on balance in the well elderly.

RESULTS—Data collection continues to increase the numbers in the nonimpaired control group with ongoing analysis to determine whether differences exist as a function of aging. Subjects with sensorineural hearing loss revealed no statistically significant differences from the control population when matched for age. Of the six subjects with complaints of dizziness/vertigo, three reported their dizziness was controlled with exercise and/or diet and medication and showed results similar to the general study population. Preliminary results from the three subjects with uncontrolled dizziness, revealed abnormal positional and velocity patterns. Analysis of test-retest and post acoustic neuroma removal subjects has not been completed. Data analysis for the 32 subjects enrolled in the exercise program has not begun, as the study is still incomplete.

Preliminary results from all the study groups suggest that evaluation of postural sway, particularly when velocity changes are recorded, could be used for diagnostic evaluation as well as post-surgical monitoring of vestibular compensation.

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 1996:7:39–48.

[347] 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 #C690-2RA)*

No report was received for this issue.

[348] EVALUATION OF CENTRAL AND PERIPHERAL ENHANCEMENT DEVICES FOR DRIVING

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C754-2RA)*

No report was received for this issue.

[349] WHEELCHAIR EXERCISE AND DIGITAL ECHOCARDIOGRAPHY FOR THE DETECTION OF HEART DISEASE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B716-RA)*

PURPOSE—This investigation will compare the sensitivity, specificity, and predictive value of wheelchair ergometry (WCE), with and without exercise, to digital two-dimensional echocardiography (ECHO) for the detection of myocardial ischemia. The purpose of this research is to establish a cost effective and clinically useful noninvasive diagnostic procedure for detection of coronary artery disease (CAD) in persons with lower limb disabilities.

METHODOLOGY—Patients complete a symptom-limited maximal WCE test with metabolic measurements. An intermittent protocol composed of 2 min stages with a 30 sec pause between stages is used. The initial workload is 6 W with increases of 6 W per stage. The ergometer computer automatically sets the braking resistance and target wheeling speed at the beginning of each stage. Supine pre- and postexercise ECHO images are obtained on a specially designed imaging table adjoined to the WCE. An abnormal exercise electrocardiogram (ECG) is defined as 1 mm horizontal or down sloping ST segment depression occurring 80 msec after the J point. An ECHO study is abnormal when 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 independent investigators. A wall motion score index (WMSI) is used to quantify the presence, location, and severity of myocardial abnormalities and a percent normal muscle score (%NMS) to define the percentage of normally functioning myocardium. The correlation between wall motion abnormalities and coronary circulation is determined using a two-region distribution model.

PROGRESS—Two hundred and one maximal WCE exercise tests with ECHO have been completed. Eighty-one patients (40 percent) underwent coronary angiographic procedures within 6 months of the WCE exercise tests with ECHO. Follow-up interviews have been completed on 114 subjects.

The demographic, peak hemodynamic, and metabolic measures (mean±one standard deviation) for the subjects were age 62±12 yr, height 175±9 cm, weight 85±16 kg, body mass index 28±5 (moderately obese), heart rate 135±24 beats/min, systolic 168±26 mmHg and diastolic 83±14 mmHg blood pressure, rate pressure product 22548±5407, percentage of age predicted maximal heart rate 85±14, oxygen uptake 16.0±5.0 mL/kg/min, and metabolic equivalents 5.0±1.0. An analysis of the sensitivity, specificity, and prognostic value of WCE with ECHO on the data from the 81 patients who underwent coronary angiography is being completed at the time of this report.

FUTURE PLANS—Substantial numbers of people are prevented from diagnostic treadmill or cycle ergometer stress testing due to a variety of lower limb disabilities. Two dimensional echocardiography in conjunction with WCE may offer a noninvasive, low risk, clinically useful diagnostic test in persons with lower limb disabilities. The relatively low cost and high level of patient acceptance of the test make it an attractive option for diagnosis of CAD, assessment of the efficacy of cardiovascular medications, risk stratification, and evaluation of global and regional ventricular function during stress after myocardial infarction or revascularization. To further establish the effectiveness of WCE with ECHO for detection of CAD in persons with lower limb disabilites the procedure described above should be evaluated at other medical centers.

[350] 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 enhancement of the VA-Cyberware Prosthetics-Orthotics Optical Laser Digitizer and to conduct fundamental 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 the residual limbs of persons with lower limb amputation and the limb segments of orthotics patients.

METHODOLOGY—To achieve these objectives, the following research protocol has been established:

1. Refine the specifications for, procure, and test a new and improved prototype of the optical digitizer that corrects the deficits identified in the original prototype and further enhances its capabilities and performance;
2. Enhance and optimize the control, data acquisition, data visualization and processing, and measurement and analysis software modules developed for use with the original prototype, and integrate them into a user-friendly, menu-driven composite program for clinical use;
3. Improve and further develop prosthesis and orthosis CAD design templates based on optically digitized measurements;
4. Refine and optimize the control, tool path clearance, and the surface contour interpolation and smoothing software for the VA 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. Investigate techniques for estimation of limb segment effective joint center trajectories for orthotics CAD and biomechanics research applications.

PROGRESS—Design specifications for a new prosthetics-orthotics optical digitizer prototype were developed, remedying the deficits identified in the original prototype, and further improving and enhancing the capabilities and performance of the digitizer. A new prototype based on these specifications was constructed, and is undergoing rigorous laboratory testing. Work on adapting and optimizing the software modules developed for the original optical digitizer prototype for control, data acquisition, data processing and visualization, and measurement and analysis is continuing. Work on integrating these modules into a single, composite, user-friendly, menu-driven program for use by prosthetics-orthotics clinicians is also underway. A new automated method of testing and calibration, optimizing of the field of view of the digitizer, and enabling correction of measurement data for optical nonlinearities has been developed. Enhancement and optimization of the control, tool path clearance, and the surface contour interpolation and smoothing software for the VA Prosthetics-Orthotics CAM milling machine is being performed. Scans and fittings of amputation and orthotics test subjects for development of CAD system socket and orthosis design templates based on optically digitized residual limb/limb segment measurements is being conducted. Investigations using the optical digitizer to estimate patient limb segment effective joint center trajectories are being conducted.

FUTURE PLANS—Refinement and enhancement of the optical laser digitizer shall continue. When development of the new 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 educational instructional aid for presentation and direct visualization of prosthetics and orthotics principles and concepts.

RECENT PUBLICATIONS FROM THIS RESEARCH

The VA-cyberware lower limb prosthetics-orthotics optical laser digitizer. Houston VL, Mason CP, Beattie AC, et al. J Rehabil Res Dev 1995:32(1):68–84.

[351] WIRELESS TENS (TRANSCUTANEOUS ELECTRIC NERVE STIMULATOR) STUDY FOR MANAGEMENT OF PAIN: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #B93-620PA)*

PURPOSE—The purpose of this research is to evaluate the efficacy of a wireless TENS unit to help reduce pain for veterans. It is hoped to simplify present TENS systems by eliminating the long wires that cause problems in their use.

METHODOLOGY—Over 125 clinical trials have been conducted involving 40 patients from the VA Medical Center, Dayton, OH, who were run with a wireless TENS device and compared to a traditional TENS. The subjects were given a pain questionnaire (Melzack) and objective measurements were taken. A comparison of just noticeable differences was conducted and electric power measurements collected.

PROGRESS—Data were collected only from those patients that received some benefit of TENS to mitigate pain. Of the 39 male and one female subject run, about 90 percent of acceptance to the wireless device was noted.

PRELIMINARY RESULTS—From the perspective of equivalent pain relief for the same amount of electric power utilized, the wireless TENS clearly showed this advantage. An equivalent pain curve comparing the wireless TENS to the traditional device demonstrated that subjects could achieve equivalent pain relief for lesser amounts of electric power, voltage, and current. Two patients experienced pain relief from the wireless TENS who had not received pain relief from the traditional device.

FUTURE PLANS—It is of interest to test that 50 percent of the VA population who do not normally experience pain relief from the traditional TENS devices but may have some pain relief from this new device. Also the prototype developed in this study can be further reduced in size, resulting in even greater efficiency and possibly power savings. Also a method of delivering pain relief by using spatial properties of the electric fields was developed, which expands the manner with which pain can be treated.

RECENT PUBLICATIONS FROM THIS RESEARCH

A wireless TENS (transcutaneous electric nerve stimulator). Repperger DW, Johnson DC, Ho CC. US Government Invention, Disclosure Number 23,201.

[352] HEALTH BEHAVIOURS IN SCHOOL-AGED CHILDREN WITH PHYSICAL DISABILITIES

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Bloorview MacMillan Centre, Toronto, Ontario, M4G 1R8 Canada; email:ortccs@oise.utoronto.ca
Sponsor: *Easter Seal Research Institute, Don Mills, Ontario, M3C 3P2 Canada*

PURPOSE—Children with physical disabilities are at risk for acquiring secondary disabilities in adulthood, such as heart disease, stroke, respiratory problems, and social and emotional difficulties. The risk of these secondary disabilities can be reduced by adopting healthy lifestyles during childhood. The purpose of this research is to identify the lifestyle behaviors of children with physical disabilities, in order to develop health promotion initiatives for them.

METHODOLOGY—In partnership with 16 Ontario children rehabilitation centres, we administered the same questionnaire (The World Health Organization Cross-national Study on the Health Behaviour of School-Aged Children) as a national research project to 319 children aged 11–16 with physical disabilities, such as amputations, arthritis, cerebral palsy, muscular dystrophy, or spina bifida. We developed the required methodology for interviewing children with a variety of physical disabilities: written format (child completed the survey independently); interview format (child read questions along with research assistant and indicated his/her answer); and interview-intervener format (child read along with research assistant and indicated answers through an intervener).

RESULTS—Our findings showed that lifestyle behaviors of concern to children with a physical disability are: diets high in sugar and fats, lack of exercise, social isolation, and lack of access to information about relevant sexual issues. Our findings also demonstrated that young people with physical disabilities have some healthy lifestyle behaviors and attitudes. They are considerably less likely to smoke or drink, demonstrated no differences in self-esteem and depression, and have more positive attitudes toward parents, teachers, and school.

FUTURE PLANS—During the next year, our goal is to: 1) conduct in-depth analyses of our questionnaire data; 2) develop health promotion initiatives aimed at reducing the prevalence of secondary disabilities; 3) expand our partnerships to guide and support our research, fostering the development and implementation of health promotion initiatives.

RECENT PUBLICATIONS FROM THIS RESEARCH

Lifestyle health behaviours of 11 to 16-year-old youth with physical disabilities. Steele C, Kalnins I, Jutai J, Stevens E, Bortolussi J, Biggar D. Health Educ Res 1996:11(2):173–86.

Adolescents with physical disabilities: some psychosocial aspects of health. Stevens E, Steele C, Jutai J, Kalnins I, Bortolussi J, Biggar D. J Adolesc Health. In press.

[353] RESOURCE UNIT FOR INFORMATION AND EDUCATION

Dudley S. Childress, PhD; Jan Little, MS

Northwestern University, Prosthetics Research Laboratory, Chicago, Illinois 60611; email: d-childress@nwu.edu

Sponsor: *National Institute on Disability and Rehabilitation Research, Washington, DC 22202*

PURPOSE—The Resource Unit for Information and Education (RUIE) disseminates information about the research projects conducted by the Northwestern University Prosthetics Research Laboratory and Rehabilitation Engineering Research Program, (NUPRL and RERP). It also disseminates general information about the field of prosthetics and orthotics. The information goes to amputees and others with disabilities, prosthetists and orthotists, students and individuals engaged in research.

METHODOLOGY—Information dissemination is accomplished through the publication of *Capabilities,* a quarterly newsletter, the *Activity Report* of progress on projects, and a *Prosthetics-Orthotics Resource Guide.* In addition, we hold consumer and technical advisory panel meetings, compile bibliographies on prosthetics and orthotics, and maintain a World Wide Web Site (http:www.repoc.nwu.edu/) featuring movies of research results, lists of support groups, our Prosthetics-Orthotics Resource Guide, lists of personnel, and bibliographies. We provide listings with National Rehabilitation Information Center (NARIC) and maintain a Help Line, available on (312) 908-6524 (voice) or (312) 908-6526 (FAX/TDD).

PROGRESS—Three publications, *Capabilities,* the *Activity Report*, and the *Prosthetics-Orthotics Resource Guide,* were re-initiated in the past year following a short period when we were without a project director. Extensive networking activities were initiated with VA, NIDRR, and other government agencies. Consumer services that have been initiated recently include a listings of support groups for persons with amputation, sources for acquiring assistive technology information, and agencies providing services to people with disabilities. All are available on the Web Site or in print.

Consumer feedback is formally acquired through regular meetings of the Consumer Advisory Panel (CAP) of the RERP. The group meets annually. The CAP, which consists of consumer advocates and persons with disabilities, held a joint meeting June 1996, with members of the NURERC Technical Advisory Panel. Their recommendations stressed the need for continued dissemination of research results to consumers and others, and that more research be conducted on orthoses. Such research is part of the schedule of studies on aided ambulation.

RESULTS—At this writing, visitors to our web site totaled 21,478 since January 1995. During the past year, over 950 consumers, prosthetists, orthotists, and others were served by email and U.S. mail. Subscriptions to *Capabilities* has doubled in the past year to 2,100.

[354] ORDERLY RECRUITMENT OF MOTOR UNITS WITH TRIPOLAR NERVE CUFF ELECTRODES

Moshe Solomonow, PhD; Richard V. Baratta, PhD; Robert D. D'Ambrosia, MD
Bioengineering Laboratory, Department of Orthopaedic Surgery, Louisiana State University Medical Center, New Orleans, LA 70112
Sponsor: *National Science Foundation, Arlington, VA 22330*

PURPOSE—We seek to develop an electrical stimulation methodology by which motor units are stimulated orderly (small ones first and progressively larger ones) as opposed to the commonly used "reverse" recruitment in widespread practice. This allows more precise control of force generation with near linear relations to stimulus amplitude, while minimizing fatigue and unreliability of the force output.

METHODOLOGY—A technique developed and evolved since the late 1970s consists of a tripolar or two bipolar cuff electrodes placed on the nerve. One electrode provides supramaximal stimulus pulses with variable frequency to constitute "firing rate control," while the second electrode provides high frequency pulses (600 pps) with increasing or decreasing amplitude to constitute the "motor units recruitment control."

PROGRESS—Since different skeletal muscles utilize different action potential firing rates and motor units recruitment strategies, such strategies should be followed closely in electrical stimulation systems if fine, stable, and fatigue-free contractions are anticipated. A stimulation system capable of manipulating muscle force in an infinite combination of strategies was designed and tested utilizing linearly increasing firing rate and recruitment. Further evolution of the system allows more complex stimulation strategies to be obtained such as those described in the physiological literature for some muscles. Specifically, the firing rate controller provides a two-segment piece-wise linear increase such that strategies resembling that of the FDI and deltoid/biceps could be closely duplicated.

Additionally, a new tripolar cuff electrode has been developed which effectively replaced the previously used two bipolar electrodes. The performance and validation of the system were determined as well, and the technique was validated by numerous studies investigating muscle properties, models and EMG characteristics. Based on the long-term experience with this evolving technique, its potential for use in a high performance FES system is highly promising.

RECENT PUBLICATIONS FROM THIS RESEARCH

Dynamic performance model of an isometric muscle-joint unit. Zhou B-H, Solomonow M, Baratta R, D'Ambrosia R. Med Eng Phys 1995:17:145–50.

Evaluation of isometric antagonist coactivation strategies of electrically stimulated muscle. Zhou B-H, Baratta R, Solomonow M, Olivier LJ, Nguyen G, D'Ambrosia R. IEEE Trans Biomed Eng 1996:43:150–60.

[355] MECHANORECEPTORS IN THE KNEE, SHOULDER, ELBOW AND WRIST LIGAMENTS

Moshe Solomonow, PhD; Carole Wink, PhD; Robert D. D'Ambrosia, MD; Carlos A. Guanche, MD;
Bioengineering Laboratory, Department of Orthopaedic Surgery, Louisiana State University Medical Center, New Orleans, LA 70112

Sponsor: *National Science Foundation, Arlington, VA 22330*

PURPOSE—Our early work shows that the anterior cruciate ligament is well endowed with various types of mechanoreceptors which are the elementary infrastructure necessary for the ligamento-muscular protective reflex discussed elsewhere in this report.

PROGRESS—More recently, we discovered that the ligament bands in the shoulder capsule are also endowed with mechanoreceptors and that a reflex arc exists there as well. Ongoing work explored and confirmed that there are mechanoreceptors in the elbow and wrist ligaments as well, further establishing the hypothesis that the ligaments of every joint may have a significant sensory role in the function of the joint.

RECENT PUBLICATIONS FROM THIS RESEARCH

Mechanoreceptors and reflex arc in the feline shoulder. Solomonow M, Guanche C, Wink C, Knatt T, Baratta R, Lu Y. J Shoulder Elbow Surg 1996:5:139–46.

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 successful 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/pre-commercial; 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:

Rehabilitation Research and Development Center, VA Medical Center Atlanta, Decatur, GA 30033

Joseph G. Ouslander, MD, Director

1996 has been an exciting year for the Atlanta Rehabilitation Research and Development Center. After a search process of close to two years, Dr. Joseph G. Ouslander was recruited from his position as Professor of Medicine in the UCLA Multicampus Program in Geriatric Medicine and Gerontology to assume the directorship. The entire Center relocated to purpose-built space in the Atlanta VAMC after being housed in off-site offices for 14 months.

The Center's internal steering group reexamined the Center's mission and refined it to more clearly focus on the intersection of rehabilitation and aging. The revised statement now reads:

The mission of the Atlanta VA Rehabilitation Research and Development Center is to improve the function, independence, and quality of life of Veterans aging with disabilities and those acquiring disabilities as they age. The mission will be accomplished by research directed towards understanding the mechanisms underlying impairments and disabilities and applying this understanding to the design, testing, and evaluation of creative rehabilitative interventions.

The steering group also reexamined the structure of the Center in order to sharpen the focus and capitalize on the strengths/and synergy of the research programs. This reexamination was given further impetus through discussions held during the site visit conducted by VA Research Service. As a result, the Center was reorganized into three primary research programs: a Sensory Program, an Environment and Behavioral Program, and an Exercise and Physical Performance Program.

The Sensory Research Program focuses on rehabilitation strategies associated with functional sensory losses of aging veterans. Research addresses all forms of vision impairment, especially macular degeneration. The program

staff are actively engaged in research on low vision, reading, mobility, orientation and wayfinding, technology development and evaluation of aids and devices, modeling of environmental sensor systems, and outcome measures for blind rehabilitation.

The Environment and Behavior Research Program conducts research on socially and behaviorally relevant aspects of physical environments, and their implications for the health, safety, independent functioning, and quality of life of older veterans aging with and into disability; the performance and satisfaction of caregivers; and care delivery. Physical environment is defined broadly to include spatial organization and characteristics, ambient conditions, and assistive and monitoring technologies. Program staff provide technical assistance to providers seeking to create environments that respond to user capabilities and support program activities.

The Exercise and Physical Performance Program conducts research on the effectiveness of exercise protocols designed for older individuals with impairments and disabilities, as well as on strategies to improve balance and reduce the risk of falls. Research projects include: testing a long term exercise intervention for older Veterans with chronic illness; the development of an expert system on exercise interventions for physicians' offices; and a training intervention to improve balance.

Amidst all of the change, the Center has continued to be productive. The Center has 11 active Merit Review projects, and our researchers submitted 12 Merit Review proposals. Staff published 35 articles, 4 abstracts, and 6 book chapters, books and manuals. In addition, Center staff made 10 presentations at regional meetings and 38 at national and international meetings.

The Center also reviewed 15 applications for developmental projects, and by assisting investigators to refine their research objectives and involving Center supported researchers, was able to support 7 of them. Most of the projects cut across the 3 primary research program areas. For example, one developmental project will examine how impaired useful field of view (associated with car crashes in the older population) interacts with abnormalities of gait and balance and other factors to increase the risk of falls; another project will use motion analysis equipment and software to analyze gait among visually impaired veterans in order to improve rehabilitative interventions.

The Rehabilitation Research and Development Center, Edward Hines, Jr. Hospital, Department of Veterans Affairs, Hines, IL 60141
Joseph B. Green, MD, Director

The mission of the Rehabilitation Research and Development Center of Edward Hines, Jr., VA Hospital is the restoration of disabled veterans to a higher level of performance by the application of new concepts, methods and technologies.

The Research and Development Program currently has 10 (10 active during FY96, 5 will begin in FY97) approved Merit Review projects and 5 Pilot projects funded through the Scientific and Evaluation Peer Review Program for the Rehabilitation Research and Development Service in FY 1996. The Center also received funding for four other projects from other sources including the Technology Transfer Section of Rehabilitation Research and Development Service and The National Institutes of Health. These current projects have generated 27 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 had five new Merit Review proposals and approved for FY 1997 funding and still others are pending.

The Center includes six laboratories. These are the Neurorehabilitation Laboratory, the Neuroscience Laboratory, the Neuroregeneration Laboratory, the Preventive and Rehabilitation Exercise Science Laboratory, the Biomechanics Laboratory, and the Autononmic Dysfunction Laboratory.

These laboratories generate a wide variety of projects from the basic molecular to purely clinical, but in common is the aim to restore disabled veterans to a higher level of performance. There are a total of 24 funded programs, ranging from the treatment of urinary and fecal incontinence to cortical sensorimotor reorganization in spinal cord injury (SCI).

The Neurorehabilitation Laboratory utilizes recent improvements in Electroencephalogram (EEG) recording systems and multimodal imaging systems to study cerebral reorganization of motor functions in stroke, traumatic brain injury and SCI. The comparison of results from nondisabled and brain injured subjects may lead to therapies to possibly prevent or reverse pathological changes in motor control and expedite recovery.

The Neuroscience Laboratory is devoted to the identification of neurotrophic factors and their role in neural development and function. Specifically, the laboratory is investigating the role of gonadal steroids and their ability to positively affect neuronal repair following injury. Their results have shown that testosterone can significantly accelerate the recovery of the hamster facial motor neuron after axotomy. Future plans include expansion of their studies to SCI.

The emphasis of the Neuroregeneration Laboratory is to enhance the regrowth of injured spinal cord fibers by using different treatment modalities, such as application of electrical fields, the implantation of nonbiological substrates both with and without cultured fetal spinal cord tissue and the delivery of growth factors through the implantation of genetically engineered neurotrophin-secreting cells. Ultimately, the laboratory hopes to achieve full or partial recovery of neurological motor function in the patient with SCI through designing realistic approaches to spinal cord regeneration in mammals.

Preventive and Rehabilitative Exercise Science Laboratory researchers are engaged in a variety of studies intended to evaluate and improve muscular and cardiopulmonary fitness in people with mobility limiting conditions. The goal of this program is to decrease the vul-

nerability of these persons to illness, further disability, and hospitalization. These investigations include an evaluation of the safety and efficacy of oxygen conserving devices during exercise, inspiratory muscle training in persons with chronic obstructive pulmonary disease, determination of improved methods for the assessment of cardiopulmonary fitness in persons with SCI, participation in the development of a clinical workstation for reducing wheelchair propulsion injuries, and the evaluation of mobility assistance devices such as the Parastep II System;tm (Sigmedics Inc., IL) and Vannini-Rizzoli Stabilizing Limb Orthosis, use of functional electrical stimulation to facilitate cough in patients with quadriplegia, handbike and row cycle prototypes, and innovative new wheelchairs.

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 laboratory is also investigating the controversy surrounding spinal fusion procedures following laminectomy and discectomy by determining the breakpoints for different spinal segments after tissue removal and the application of stress to the altered specimens.

The Autonomic Dysfunction Laboratory is involved with the development and use of electrodes in Functional Neuromuscular Stimulation (FNS) in SCI patients. The laboratory is successfully applying FNS to specific SCI pathologies such as respiratory paralysis, fecal and urinary incontinence, and fine motor control. Another project involves an evaluation protocol for the home monitoring of bladder pressure to help reduce infections. The procedure uses a digital pressure gauge developed in cooperation with private industry.

Rehabilitation Research and Development Center, Department of Veterans Affairs Health Care Facility, Palo Alto, CA 94304

Felix E. Zajac, III, PhD; Charles G. Burgar, MD; Dennis R. Carter, PhD

The Palo Alto Rehabilitation Research and Development Center of the Department of Veterans Affairs is dedicated to developing innovative clinical treatments and technological devices for physically disabled veterans and others, in order to increase their independence and improve their quality of life.

The Center focuses upon restoring function to persons with neuromuscular or musculoskeletal impairments. Our primary emphasis is on restoring and enhancing muscle coordination in persons who have had a stroke or have sustained a spinal cord injury (SCI), and on restoring and maintaining musculoskeletal function and integrity in persons with osteoporosis, arthritis or SCI.

Our principal goal is to develop new clinical treatments and devices for neuromuscular and musculoskeletal rehabilitation. To accomplish this, we also perform basic research to better understand the way in which the nervous system coordinates the muscles during complex motor tasks, and the way in which bone grows, maintains itself, and regenerates itself. We continually interact with our clinical collaborators at the VA Palo Alto facility and at Stanford University Medical Center to ensure the clinical relevance of our research and to clinically test our treatments and devices.

A common theme that runs through many of our projects is the use of mechanical manipulation to restore or maintain musculoskeletal function. By manipulating the limbs to provide appropriate sensory input, we can influence the way in which the nervous system reorganizes itself after injury. By controlling the mechanical loading on the skeletal bone, we can affect the way the bone heals and maintains its strength. We use mathematical and computer models to understand these complex systems in terms of fund amental physical and biological principles. For example, to study muscular coordination, we use models of the musculoskeletal system that relate limb movement to muscle activation patterns and external forces. To study bone growth, we use finite-element models that relate bone remodeling to the history of imposed stresses and strains. We use these models both to analyze the results of experiments and to investigate the effects of factors that cannot easily be experiment tally manipulated.

The Center consists of six organizational sections. Core funding is provided from the Rehabilitation R&D Service of the VA to provide essential support for a nucleus of investigators, staff, and operations. Personnel, laboratories and machine shop are housed in a dedicated building. This environment fosters collaboration and daily interaction between all segments of Center personnel. The roles of each of the six sections are:

Directorate: Establish the R&D areas to be emphasized and Center-wide policies; promote continuity and interaction among the projects; actively participate in research projects.

NeuroMuscular Systems: Perform R&D to understand how the nervous system interacts with the musculoskeletal system to coordinate the execution of motor tasks; develop new rehabilitation methods and devices to diagnose, assess, and treat persons with movement disorders.

MusculoSkeletal Systems: Perform R&D to understand how musculoskeletal function can be maintained or restored; evaluate current, and design new rehabilitation therapies and orthopaedic devices.

Design/Development: Collaborate with NeuroMuscular and MusculoSkeletal investigators in the design, development, and technology transfer of rehabilitation devices.

Technical Support: Specify, install, and maintain computers and networks; responsible for facility planning and implementation and coordination with VA acquisition and material management.

Administrative Support: Coordinate internal system of Center operation, including budgetary planning and procurement; government, academic, private, and public sector liaison; preparation and dissemination of pertinent Rehab R&D Center information.

All major research endeavors are supported by VA Headquarters in the form of peer-reviewed projects awarded to principal investigators. Investigators also attract funding from sources outside the VA for other projects, which complement and cross-fertilize those sponsored by the VA.

The Rehab R&D Center is affiliated with the Stanford University Schools of Engineering (SOE) and Medicine (SOM). Particularly strong is the interaction between Rehab R&D Center investigators and the faculty associated with the Departments of Mechanical Engineering (SOE), and Functional Restoration (SOM). In fact, many Rehab R&D Center investigators have faculty appointments in these departments. The Rehab R&D Center has an especially strong relationship with the new Biomechanical Engineering Division of the Department of Mechanical Engineering. Graduate and undergraduate students are routinely involved in Rehab R&D Center research, design, and development projects.

Cleveland FES Center, VA Medical Center, 10701 East Blvd., Cleveland, OH 44106

P. Hunter Peckham, PhD, Director; E. Byron Marsolais, MD, PhD, Medical Director, Lower Extremity Programs; Michael W. Keith, MD, Medical Director, Upper Extremity Programs

The VA Center of Excellence in FES is a project of the Cleveland FES Center, a functional electrical stimulation 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 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. FDA approval is expected in 1997 for the implantable hand grasp neuroprosthesis developed at the FES Center and subsequently transfered to NeuroControl Corporation. The Center has been involved in training five VA Medical Centers (out of 10 sites total) in the clinical implementation and testing of the upper extremity system. This year the Center commences animal trials of an implantable system developed by NASA and Life Systems, Inc.

Technology Development. The core Technology Development Laboratory offers software and hardware design facilities for prototype development of implantable FES systems. This year major equipment was updated and a new operating structure implemented to maximize engineering efforts across all Center projects.

Advanced Research. VA research projects in progress include a new 10-channel implantable stimulator/telemeter and an implantable joint angle sensor that are now undergoing clinical testing; techniques to provide enhanced upper extremity function through hand intrinsic muscle stimulation, elbow movement and closed loop control; and 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. Other research projects in progress are primarily supported by the National Institutes of Health, the Food and Drug Administration, and the Whitaker Foundation. Eight post-doctoral (seven MD) and ten doctoral researchers participated in advanced research projects at the Center.

Coordination and Dissemination of Research Activities. Weekly meetings of the 15 Center principal investigators facilitate resource sharing. The FES Council, which provides institutional representation to the FES Center, meets bi-monothly on project planning issues. The Scientific Advisory Board of the Center met this year for the first time, providing technical feedback on research direction. To serve rehabilitation professionals interested in FES, the Center coordinated a single topic issue on FES of the VA Journal of Rehabilitation Research and Development. In addition, the FES Center hosted the First Annual Meeting of the International FES Society. The FES Information Center disseminates information about FES to individuals with disabilities and the lay public, publishing the FES Update newsletter with a distribution over 7,000, and this year the FES Resource Guide for Persons with Spinal Cord Injury and Multiple Sclerosis.

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, National Performance Data Research Center, and National Center for Health Promotion. The mission of RSRDU is to promote VA-wide research that enhances the effectiveness and efficiency of rehabilitation care and functional outcome for veterans with disabilities. All VA medical centers provide rehabilitation services, and 72 centers support a physical medicine and rehabilitation bed service (PM&RS).

One of the important objectives of the RSRDU is to build and maintain capacity for rehabilitation services research by identifying and networking resource people from across the VA system, prioritizing research activities, and facilitating rehabilitation services research in the medical centers. The Unit provides technical assistance to researchers, clinicians, and administrators with interest in rehabilitation services research (RSR), including access to the ongoing RSR computer data base of 23,000 patients discharged from PM&RS bed units and RSR Information

Service with over 9,000 literature citations available on computer disk or hard copy bibliographies from: (919)286-2050.

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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Visual Correlates of Mobility in the Visually Impaired 264

John L. McClellan Memorial Veterans Hospital
4300 West Seventh St., Little Rock, AR 72205-5484

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Performance-Based Prevention/Rehabilitation of Falls in Elderly Veterans 106

West Los Angeles VA Medical Center, Brentwood Division
Wilshire and Sawtelle Blvd., West Los Angeles, CA 90073

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Functional Electrical Stimulation of Spinal Cord Injured Patients 284

Los Angeles VA Outpatient Clinic
351 East Temple St., Los Angeles, CA 90012-3328

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Interactive Video System to Test and Treat Nonliteral Language Disorders 255

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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High-Frequency Magnetic Stimulation of the Bladder and Bowel 286
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San Diego VA Medical Center
3350 La Jolla Village Dr., San Diego, CA 92161

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Management of Musculoskeletal Complications of Spinal Cord Injury 287

San Francisco VA Medical Center
4150 Clement St., San Francisco, CA 94121

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Hip Fracture Risk Assessment Using Automated 3-D Finite Element Modeling 209

Denver VA Medical Center
1055 Clemont St., Denver, CO 80220

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Improved Bone Cement Fatigue Resistance Via Controlled Strength Interfaces 210
Role of Imagery in Auditory Comprehension in Brain-Damaged Adults 247

West Haven VA Medical Center
950 Campbell Ave., West Haven, CT 06516

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Effects of Expectation, Reward, and Activity on Subtypes of Schizophrenia: Status Report 242

Bay Pines VA Medical Center
10000 Bay Pines Blvd., Bay Pines, FL 33504

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Age Variance in Nystagmus Suppression: A Pilot Study 265

Gainesville VA Medical Center
1601 S.W. Archer Rd., Gainesville, FL 32608-1197

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Vertebral Fusion by New Osteogenic Agents to Accelerate Rehabilitation 288

Miami VA Medical Center
1201 Northwest 16th St., Miami, FL 33125

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Using Self-Monitoring to Improve Communicative Efficiency in Aphasia 257
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Atlanta VA Medical Center
1670 Clairmont Rd., Decatur, GA 30033

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