Assistive Technology

27. The design of a forward folding ultralight wheelchair

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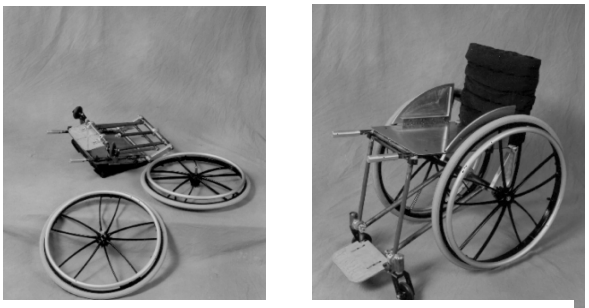
Relevance: Manual wheelchairs have traditionally been able to fold in some way in order to store and transport the wheelchair easier. The problems with many types of wheelchairs are that their users, often traveling Veterans, cannot take their wheelchair onto the airplane with them. They must transfer into an airport wheelchair and then check their wheelchair with their other luggage. Wheelchairs are also very cumbersome. Lifting and storing a wheelchair at home or in the car can be very challenging for many older Veterans.

Objectives: The purpose of this project is to design an ultra light wheelchair that is able to collapse and fit into an overhead compartment of an airplane. This would eliminate the need to transfer out of one's own wheelchair when boarding an airplane because the wheelchair could be stored in the overhead compartment. Also, a collapsible wheelchair would make storage and handling easier either in the home or in the car. Some of the design parameters were the wheelchair must be lightweight, durable, adjustable, stable, comfortable, and cost effective.

Methods: Preliminary drawings and sketches for the Forward Folding Ultra light Wheelchair (FFUWC) were made taking into account anthropometry and basic configurations of wheelchairs. The first prototype was built so that by removing two fasteners from the chair, it can fold forward much like a lawn chair. The second prototype was then built with a similar folding design but with adjustable backrest angle, adjustable backrest height, adjustable seat pan angle, and adjustable wheel axle. Parts for the wheelchair were drawn up using computer aided drawing software and then manufactured using manual and computer numeric controlled machining. The materials used in the FFUWC included an aluminum alloy for most machined parts, stainless steel for small but high stress parts, and chromium-molybdenum alloy steel for all the tubing.

Results: Presently, the first prototype is being used by a 55 kilogram experienced wheelchair user who has successfully traveled around the world and boarded many planes without having to transfer into a temporary wheelchair. The second prototype is now being tested according to the ANSI/RESNA standards.



First prototype in normal and folded positions.

Future: The results that will be generated from the testing will be analyzed and design changes will be made if any failures should occur. The axle adjustment mechanism will be improved to allow for more precise adjustments as well as wheel camber. Also, a suspension system has been proposed for the wheelchair to reduce the amount of vibration while overcoming obstacles.

Acknowledgments: This project was funded in part by a grant from the Rehabilitation Services Administration, United States Department of Education (H129E990004), and the VA Rehabilitation Research and Development Service, United States Department of Veterans Affairs (F2181C).

28. The characterization of reverse instability in electric powered wheelchairs

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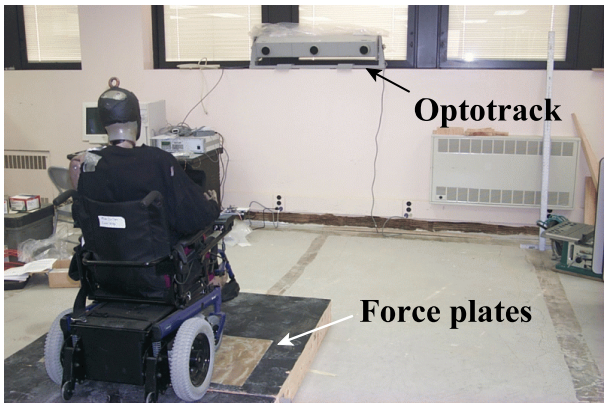
Objectives: Electric-powered wheelchair (EPW) accidents occur during forward, reverse, and turning driving conditions. Twenty-five percent of tips and falls reported to the FDA occurred while the EPW was reversing. The EPW reverse instability may be caused by a number of factors including the user, environment, speed, caster wheel orientation, and the use of the back electromotive force (EMF) as a means of measuring wheel speed for closed-loop control. The back EMF signal is inherently noisy at low speeds and the caster wheel orientation may cause abrupt, side to side, bucking or swaying of the EPW. For these reasons, the back EMF signal and caster wheel orientation at the onset of reversing may play an integral role in the EPWs reversing instability.

The purpose of this study is to characterize the reverse stability of several EPWs, to determine which EPW is most stable while reversing, to determine which caster wheel orientation offers the greatest stability when driving in reverse, and to develop control algorithms to dampen or eradicate the reverse instability. With the high occurrence of tips and falls in the reverse driving direction and the possibility of reducing this occurrence through better engineering techniques, there is a need to characterize and eventually solve the reverse instability issue among EPWs.



Methods: Several rear wheel drive EPWs were chosen for this study due to their popularity among the EPW user population. Each EPW was driven in reverse at one-quarter, one-half, and full reversing speed while its caster wheels were aligned at six different orientations on AMTI forceplates (Figure 1). In addition to forceplate data, kinematic data were also recorded using a 3-D motion analysis system (Optotrak, Inc.). Joystick voltage was measured for speed and direction, and the back EMF signal was also recorded for both motors. A Hybrid II test dummy was used as a surrogate driver and the reverse driving condition was initiated remotely keeping the direction signal constant.

Results: To date, only one EPW has been fully tested and the data has been visually inspected. As expected, the motor voltage is much noisier at lower speeds and caster wheel orientation at the onset of reversing seems to determine the ultimate direction of the EPW. However, force, moment, velocity, and acceleration values are still being analyzed at this time.

Conclusion: To date, this study is a work in progress. After characterizing the instability in the reversing direction of several EPWs using kinetic, kinematic, and signal data, control algorithms will be developed to minimize the disturbance. Better control algorithms may decrease the severity and frequency of EPW tips and falls in the reversing direction.

Funding Acknowledgment: This study was funded by NIDRR RERC on wheelchairs (H133E990001).

29. A computer controlled power wheelchair navigation system

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Objective: This effort is directed toward the development of a Computer-controlled Power Wheelchair Navigation System (CPWNS) for persons whose severe disabilities have heretofore rendered independent mobility impractical or impossible.

Methods: Using sensed wheel rotations and video detection of small wall-mounted markers or "cues", the CPWNS provides fully autonomous navigation along paths it has been "taught" by an able-bodied human instructor. Ultrasonic sensors prevent collision with near obstacles. System setup is accomplished by placing cues throughout the environment about one foot above the floor and manually pushing the instrumented chair once along each route of travel to be stored in the system's repertoire. Use of a human teacher provides this unique navigation system a high level of path planning, including close approach to furniture, passage between objects with minimal clearance, and complex motions such as the multiple changes of direction required to maneuver into tight spaces. Though additional routes of travel may be taught at any time, the system's path joining capability obviates the need to teach a specific path from each location in the environment to every

other location in the environment. The disabled rider selects his/her desired destination using either spoken commands or switch activation in response to aural scanning of available options. Many switches are available that can be triggered with minimal movement of virtually any body part, and alternative switching mechanisms are easily "swapped" in and out of the system. At any time during travel, the rider may at his/her discretion, halt and resume travel or halt and retrace the current path toward the point of departure. These features, in effect, provide a virtually infinite number of "destinations" along taught paths.

Results: After extensive device testing, we recruited a small number of disabled riders to use the CPWNS to travel a simulated home test course incorporating a variety of practical maneuvers such as narrow doorway passage and positioning oneself before a table. Maneuvering space in portions of the environments was extremely limited, travel surfaces included both tile and high pile carpeting, and the test course included several 180-degree changes in orientation. Subjects were able to master operation of the CPWNS within 15-20 minutes. Mean subject responses were >6 on a visual analog 10-point scale for all questions of comfort, safety and ease of use of the CPWNS with the exception of overall vehicle speed, which was considered too slow.

Conclusions: Of clinicians we surveyed, 85% indicated that they evaluate numbers of patients every year who cannot use a power wheelchair because they lack the motor skills, strength, or visual acuity needed to control it. One must conclude that, for these patients, *no options for independent mobility exist at this time*. Veterans and others with severe or multiple disabilities who find steering a power wheelchair prohibitively difficult or impossible may yet be strongly motivated to exercise independence. Pilot testing has indicated that CPWNS technology is capable of providing safe, versatile, and robust wheelchair control for these persons, granting them a degree of autonomy otherwise unattainable and maximizing their functional independence following catastrophic injury or progressively disabling illness. Since the CPWNS is implemented using relatively low-cost components retrofitted to a standard power wheelchair, the long-term goal of our continuing research is to produce a commercially viable product at a reasonable cost.

Funding: VA Rehabilitation Research & Development Service (Pilot #B1684P)

30. Optimization of pedorthic insole design

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Objectives: Epidemiological studies have shown podalgia is common in the elderly, with many who also suffer Diabetes Mellitus being at especially high risk of trauma due to peripheral neuropathy, pedal plantar fat pad and muscle atrophy, and vascular insufficiency. Over half of all lower limb amputations each year in the United States are performed on diabetics, because of foot and ankle injuries that fail to heal. Pedorthic insoles are frequently prescribed for curative and prophylactic treatment of podalgia and pedal injury in such patients. There are few guidelines for prescription, design, fabrication, and fitting of pedorthic insoles, however. The purpose of this study was to analyze the efficacy of various insole designs in dissipating and distributing stresses and strains in patients' pedal tissues, to provide information essential for development of more exact prescription, design, and fabrication guidelines for pedorthic insoles.

Methods: Tests of the four most common materials used in fabrication of pedorthic insoles were conducted, and their nonlinear mechanical characteristics measured. In addition, the mechanical properties of the pedal plantar tissues of six subjects were measured at the heel and at the first metatarsal head. Optical and magnetic resonance scans were made of the subjects' feet, and were subsequently segmented, digitized, and used with the respective measured tissue material properties to develop segmental, nonlinear, finite element models at the subjects' heels and metatarsal heads. FEA variational design studies were then performed to determine insole efficacy in dissipating and distributing pedal stresses and strains as a function of insole material and design geometry. FScan plantar interface pressure and magnetic resonance studies were also performed with corresponding insoles fabricated with the VA Pedorthic CAD/CAM System measuring actual tissue stresses and strains with one subject to validate FEA results.

Results: Sixteen insole materials and design geometries were tested, using a 200 Newton load vertically applied at the heel (approximately ¼ th of the body weight of an 180 lb subject). All insole materials tested were 5 mm

nominal thickness at their center. Maximum tissue stresses and strains were found to be reduced slightly with use of relatively soft insole materials (one times to approximately ten times plantar tissue stiffness) compared to those incurred with the subject standing barefoot on the floor. Stiffer insole materials differed little from the barefoot case. Maximum stresses and strains occurred directly underneath the calcaneus. Incorporation of reliefs by removing insole material or introducing secondary softer materials under the heel and metatarsal heads (as is common practice) had minimal effect on tissue stresses and strains, but did reduce strain energy densities. Because of the Dunnell effect, use of non-contoured, cylindrical reliefs was shown to produce large localized stresses, strains, and gradients in the tissue adjacent to the relief boundary. Custom fabrication of insoles, with contouring to match "natural" pedal contours, was shown to be able to reduce tissue stresses and strains by approximately 50%, and strain energy densities by approximately 90%. The greatest reductions in stress, strain, and strain energy densities throughout pedal tissues, were achieved with custom contouring of insoles, extending them proximally around the border of the foot to limit fat pad proximal displacement under load. In cases of vertical heel spurs, and/or arthritic osseous deformities, reductions of as much as 95% in stresses, and 98% in strain energies were shown to be able to be attained with custom insole designs constraining tissue movement.

Acknowledgment: This work was performed with funding from the US Army Medical Research and Materiel Command, and with support from VA Rehabilitation Research and Development Service Project #A1989D.

31. Design of a stand-up motorized prone cart

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Objectives: The goal of this study was to design a Stand-Up Motorized Prone Cart to be safely and efficiently used by individuals with spinal cord dysfunctions who cannot use a stand-up wheelchair or a standing frame. The newly designed Stand Up Motorized Prone Cart has the ability to adjust the body support angle from 0 to 45 degrees in order to provide patients a graduated angle of body positioning. This is particularly important for patients who, after being bedridden for long periods of time, may not be ready to reach a high level of verticality immediately.

Methods: An iterative process of design, prototype fabrication and clinical evaluation was used to design the Stand-Up Motorized Prone Cart. Following evaluation modifications were made as necessary to finalize the design.

Results: Two sizes of prone carts were designed. One model is 178 cm long (70") to accommodate small to medium-sized individuals while the other is 203 cm long (80") to accommodate taller people. Each Stand-Up Motorized Prone Cart is powered by two electric wheelchair motors that control forward, reserve propulsion, turning and braking. Finally an electric actuator adjust the body support angle from 0 to 45 degrees. Each cart incorporates a padded front deck with elbow support; a front pull-out drawer; contoured and padded body support; a frame forming an all around

protective bumper and an adjustable foot support. Each cart is made with 38 mm (1.5") steel tubing and has a 106 cm (42") wheel base for access to a van.

Clinical Relevance:: The benefits of a Stand-Up Motorized Prone Cart over a regular horizontal prone cart include: improved circulation, respiration, and digestion; prevention of contractures; more complete emptying of the bladder; improved pressure relief; and increased independence in activities of daily living. The new Stand-Up Motorized Prone Carts were successfully evaluated at the Tampa and Milwaukee VA SCI centers with 20 patients and caregivers at each VAMC.

Collaborative manufacturer
Everest&Jennings division of Graham Fields Health Products

Funding acknowledgment: This study was funded by the Rehabilitation R&D, project #B2223T

32. Impact of bathing fixtures on transfer mobility of older adults

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Objectives. Accessibility standards are primarily based on the capabilities of nonambulatory young adults, and as such may be inappropriate for older people with mobility disabilities. In response to this need, the US Access Board, which promulgates the ADA Accessibility Guidelines, sponsored a national survey as an initial step in assessing the effectiveness of current guidelines for transfer mobility in common bathing fixtures.

Methods. A survey was mailed to a nationwide sample of 4100 people with mobility impairments, randomly selected from a large commercial database. The survey included information about the individual (age, gender, and disability) as well as about use of tubs and showers. Questions related to six commonly used shower/grab bar configurations: 1. shower in a typical bathtub; 2. typical shower stall with a 3" - 4" high curb; 3. shower stall with a folding seat; 4. roll-in shower with a side transfer seat; 5. roll-in shower without a transfer seat; and 6. roll-in shower with a rear transfer seat. In addition, four bath-tub/grab bar configurations were included: 1. typical tub; 2. tub with a movable shower chair; 3. tub with a movable in-tub seat; and 4. tub with a rear built-in transfer seat.

Results. 789 of the 1193 respondents included in the sample were over 55 years of age and had a variety of mobility impairments. Approximately 60% of the older sample was either ambulatory or semiamblulatory. In addition, three out every four respondents (74.3%) reported being able to lift their leg over the curb of a shower. This represents a relatively high percentage of both ambulatory individuals and wheelchair users, including 84.2% of the former, and 61.6% of the latter. The typical tub/shower combination with grab bars was rated as the most difficult fixture to use by almost 60% of the respondents, while almost half of respondents had difficulty using the standard tub with a rear transfer bench ($p < .001$). In contrast, significantly fewer respondents had difficulty with the two fixtures with adaptive in-tub seats ($p < .001$). As expected, roll-in showers were less difficult to use than standard shower stalls, although a larger percentage of respondents had difficulty using a roll-in shower without a seat than a standard shower stall with a seat ($p < .001$).

Conclusions. Findings suggest that fixtures intended for people who transfer directly from a wheelchair or who use a shower commode chair may not be applicable for older individuals who are ambulatory or semiambulatory. In fact, data suggest that older people need in-fixture seats not because they cannot stand, but because they have difficulty standing for extended periods of time or because getting up and down from the bottom of the tub is difficult. Therefore, fixtures without seats may not be as effective for older people as fixtures with seats, even when the latter are wheelchair accessible. This has clinical relevance for both the provision of healthcare and for veterans' ability to age in place. First, even though VA clinical facilities must comply with Federal Accessibility Standards, they must also accommodate the needs of an increasing number of older adults with mobility limitations. Second, home settings that promote rehabilitation, safety, and independence of older veterans can facilitate aging in place and reduce healthcare needs.

Acknowledgments: This project was funded by the US Access Board, Contract #QA96003001

33. User interface testing of an assistive workstation robot for persons with high-level tetraplegia

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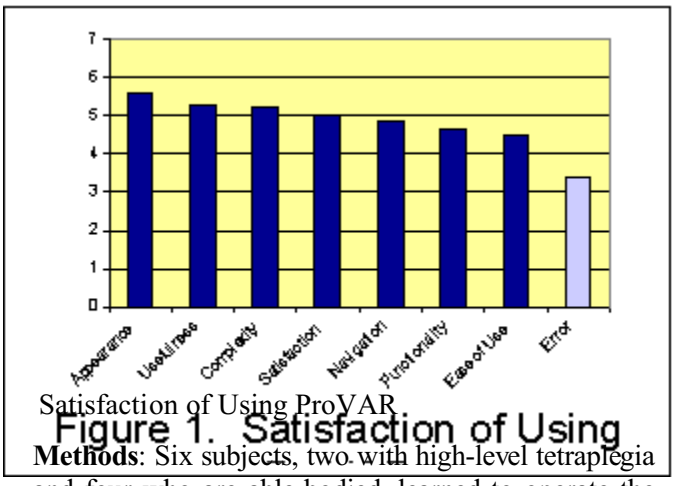
Objectives: The goal of this project is to pilot test the data instruments that were developed for the upcoming user interface testing of the Professional Vocational Assistive Robot (ProVAR). This robot, a workstation-based manipulator to aid the return to vocational activity of persons with high-level SCI tetraplegia, will undergo significant development and testing in the coming 3 years. ProVAR has a novel interface designed to facilitate the learning of its functions and the operation of its features. The data instruments are geared to understanding how users react to the system and gain personal benefit in terms of quality of life and functional independence.



Satisfaction of Using ProVAR

Figure 1. Satisfaction of Using

Methods: Six subjects, two with high-level tetraplegia and four who are able-bodied, learned to operate the robot's interface. Subjects with tetraplegia were offered use of a head motion cursor control device, a trackball, and voice recognition software. Able-bodied subjects were given a standard mouse and keyboard. Subjects were trained on the robot for 20 minutes by the same instructor. They were familiarized with the computer, the 2-window browser environment, and the robot interface itself. They were given 90 minutes to program the task of having the robot insert a videotape into a player. A 65-question survey was then administered covering the categories indicated in Figure 1. A score of less than 4 indicates that the feature "needs improvement." In addition, individual programming steps were logged by the interface computer to calculate time-to-completion and learning effects.

Results: Subjects reported overall satisfaction with the interface in all the categories except "error messages" (Figure 1). When considered individually, only 9 of the 65 questions rated below 4 on average, revealing that ease of use and feedback were the primary areas of needed improvement. There was a discrepancy in certain areas between able-bodied and tetraplegic subjects. Notably, people with tetraplegia were more patient and became less frustrated, but they found the interface more complex than did able-bodied subjects. The average amount of time to program each step decreased from 120 seconds to 90 seconds between the beginning and end of the session, likely indicating a learning effect (no statistical analysis was done due to the small sample size in this pilot study).

Conclusions: These assessment and logging tools, adapted from more general computer user interface literature, were shown to be effective in capturing the various aspects of the interaction between a user and a workstation robot. Outcomes of this initial interface testing will be used to implement improvements in the interface as well as the evaluation process before extensive evaluation of ProVAR begins with veterans who have high-level tetraplegia.

Funding: The pilot study was funded by the Paralyzed Veterans of America Summer Scholars program. The ProVAR project is funded by VA Rehabilitation R&D Service grant A2684I.

34. Pilot production of isometric joysticks to enhance wheelchair driving ability of individuals with impaired hand function

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Objective: As many as 40% of the individuals who seek powered mobility are unable to be fitted because their disabilities preclude them from driving safely with commercially available controls[1]. Preliminary studies

conducted at HERL with a concept model isometric joystick showed improved wheelchair driving especially during turning maneuvers [2] [3].

To perform additional studies in clinical and community settings, it was imperative to design and build a more robust prototype and to have multiple units available for take-home trials. Reliability and subject safety were a key issues since the devices would be used to drive electric powered wheelchairs in unsupervised settings.

Methods: We made use of Computer Aided Design (CAD) and Computer Aided Manufacturing (CAM) technology to achieve consistency in our new joysticks. We designed our printed circuit boards in-house and used surface mount components to save space and reduce current consumption. Data collection is provided through a sealed, DB9 serial port. Intra board connectors were shrouded and polarized to reduce the risk of short circuits.
The all-metal enclosure was designed using Feature CAMÔ software and machined on our Bridgeport, Computer Numerical Control (CNC), milling machine. The base plate, crucial to stability of the immobile joystick post, was machined from a single piece of aluminum and reinforced with a stainless steel collar. A tapered housing on the rear of the enclosure provides a full compliment of standard user controls

Results: We populated and tested the first new PC boards in August of 2000 and proceeded immediately with a production run of ten additional units completed in May 2001. These units meet standards for endurance, reliability and subject safety. We found that by using multilayer PC boards with independent power and ground planes, both circuit noise and the risk of uncommanded wheelchair movement were reduced.

Conclusions: CAD and CAM technology can significantly improve the reliability and safety of small production runs of research prototype devices and simplify future updates.

Funding Acknowledgment: Funding was partially provided by VA #E1960G

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35. A clinical evaluation of a wheelchair mounted robotic arm

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Objectives: The purpose of this service directed project is to improve the functional independence of veterans with spinal cord injury (SCI), accomplished by evaluating a wheelchair mounted robotic arm (WMRA) for its ability to enhance function in vocational, daily living, and leisure activities.

Methods: A case study design, using quantitative and qualitative measures and an 8-week protocol, was used for this project. Functional ability to perform tasks was assessed prior to robotic arm use and at the end of 4 and 8 weeks at home with the WMRA. Quantitative measures were obtained initially, and at 1, 4, and 8 weeks. Qualitative measures were obtained at the beginning and end of the study.

Results: Mr. S. is a 59-year-old man who sustained a C5 complete (ASIA A) SCI in 1983. He holds a Master's Degree in social work and worked as a counselor prior to his SCI. He is retired, married and lives with his wife in a one-story, wheelchair accessible home. Mr. S. was asked to perform 16 pre-selected tasks as he would perform them customarily. These were scored as 0=dependent, 1=needs assistance; 2=independent; N/A=participant does not need or want to do that task. The scores were summed and an average functional score (0-2) obtained. Initially, Mr. S. was dependent in all tasks. The WMRA then was mounted onto his wheelchair for one week of training. At the end of Week 1, his average functional score increased to 1.75 at which time he took the WMRA home for the remaining 7 weeks. At Week 4, his average score was 1.67; by the end of Week 8 he was independent with the WMRA in all tasks he elected to perform (score=2). The average time required to perform the elected tasks improved from 203 seconds at Week 4 to 198 seconds at Week 8. On the Satisfaction with Life Scale, there was a noticeable increase in his score indicating a higher degree of satisfaction with his current life situation.

Mr. S. had no prior experience with robotics although he had used other assistive technology. At the end of Week 8 he was asked to give his impressions of the WMRA. He reported satisfaction with the WMRA's weight, appearance, safety, and ease of use and operation. He was somewhat dissatisfied with its size especially the added chair width. The standard factory mounting hardware was modified for installation on Mr. S.' wheelchair and a joystick extender was fabricated for easier manipulation of the WMRA controls. On one occasion, Mr. S. reported an intermittent power failure. The investigator made a home visit and determined that the cord connecting the motor of the WMRA to the wheelchair's battery, via the chair's recharge socket, was loosening. This was corrected by using electrician's tape to line the socket edge so that the plug would fit tighter into the socket.

Conclusions: Mr. S. stated that the WMRA increased his level of independence and his ability to perform tasks he never thought possible. Overall, Mr. S. reported a very favorable experience with the WMRA. This was supported by his wife who reported that Mr. S. required less assistance from her during the day.

Funding Acknowledgment: This study was funded by the VA Rehabilitation Research and Development Service, project #B2311-T.

36. Biomechanics of wheelchair propulsion in individuals with and without upper extremity impairment

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Objectives: Many manual wheelchair users (MWCU) have upper extremity impairment (UEI) due to paralysis or motor control deficits. In spite of their upper extremity impairment these individuals are capable of community wheelchair mobility. However, the effect of UEI on propulsion mechanics is unknown. Whether UEI places these individuals at greater risk of developing overuse injuries is also unknown. The purpose of this research was to compare the propulsion mechanics of MWCU with and without UEI.

Methods: Thirty-five individuals (13 with arm impairment, 22 without arm impairment, mean age = 38.3±8.6 years, WC use = -10.3±6.7 years) who used a manual wheelchair for at least 50% of home and community mobility served as subjects. The subjects' diagnoses included spinal cord injury (cervical = 7, thoracic = 13, lumbar = 2), spina bifida (3), cerebral palsy (3), multiple sclerosis (2), other (5). Following informed consent and medical screening, propulsion mechanics were measured at a standard velocity of 3 km/hr during a submaximal exercise test to exhaustion (defined as volitional inability to sustain the designated velocity). Load for the fatigue test corresponded to 60% of the maximal load achieved during a prior graded maximal exercise test on the wheelchair ergometer. Three Peak 3D Charge Coupled Device (CCD) cameras and a video acquisition system (Peak Performance Technologies, Colorado Springs, CO) were used to measure upper extremity and trunk movement. Reflective markers were used to measure trunk, shoulder, elbow, wrist flexion/extension, shoulder abduction/adduction, and wrist radial/ulnar deviation. Temporal features of propulsion were determined from this kinematic data and both were collected at 60 Hz. Peak joint angles during wheel contact and at release, and temporal data, were averaged over three cycles (contact to contact). ANOVA ($p < 0.05$) was used to determine if differences existed between the groups in

movement and temporal characteristics during propulsion.

Results: Kinematic measures revealed that individuals with UEI propel with smaller wrist extension ($p< 0.01$) and ulnar deviation ($p< 0.03$) angles and smaller shoulder extension ($p<0.04$), flexion ($p< 0.01$) and abduction ($p< 0.01$) during the contact phase of the cycle as compared to those without UEI. At contact, individuals with UEI demonstrated less wrist extension ($p< 0.01$) and shoulder abduction ($p< 0.01$) with greater elbow flexion angles ($p<0.01$). At release, smaller wrist extension ($p< 0.01$), larger elbow flexion ($p< 0.01$) and smaller shoulder abduction ($p< 0.01$) angles were seen in those with UEI. Temporal characteristics were different between the groups with a higher stroke frequency and shorter contact time (in seconds and in percent of cycle, $p< 0.01$) in those with UEI.

Conclusions: Despite differences in propulsion mechanics, MWCU with UEI successfully complete the task of manual wheelchair propulsion. Although smaller joint angles were noted in the shoulder and wrist, the increased repetitive loading (increased stroke frequency) may predispose these individuals to overuse injuries. Further research is warranted to determine the association between these propulsion characteristics and injury potential.

Funding Acknowledgment: This study was funded by the VA Rehabilitation R&D Service Merit Review Board Grant # B2168RA.

37. Effect of neuromuscular abdominal muscle stimulation on bowel care after spinal cord injury (SCI)

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Background: Abdominal muscle contraction contributes to bowel evacuation by increasing abdominal pressure. After SCI, defecatory dysfunction significantly impairs quality of life, in part due to impairment of abdominal muscle contraction. Neuromuscular stimulators produce muscle contraction through the delivery of percutaneous electrical impulses. We studied the effect of the stimulation of the abdominal wall muscles on bowel evacuation of persons with SCI.

Method: This is a single blind randomized trial on 8 participants with SCI (6 quadriplegics, 2 paraplegics), all have lesions greater than T7, and all have 2 or less spontaneous bowel movements per week. The abdominal belt with implanted electrodes (Bioflex Garments, Bioflex Inc.) was fastened around the participant at the level of the umbilicus. Subjects were not informed whether or not stimulation was being applied during their bowel training, which itself was randomized. Parameters measured were time to first stool (TFS) and total bowel care time (TBC). TFS and TBC were compared in the presence and absence of neurostimulation. Statistical significance was analyzed by Student's paired t test.

Results: We found that the TFS for all subjects was significantly less with stimulation (29 m vs. 52 m, $p < 0.005$). Likewise, the TBC for all subjects was significantly less with stimulation (88 m vs. 117 m, $p < 0.01$).

Conclusion: The stimulation of the abdominal wall muscles significantly reduces bowel care time of individuals with SCI. With decreased time needed for bowel care and quality of life may improve for individuals with spinal cord injury, as well as other veterans with defecatory dysfunction. If confirmed in a larger population, the use of the abdominal belt device may serve as an adjunct to the currently available methods needed for bowel care.

Funding acknowledgment: The VA Rehabilitation Research & Development Service, Eastern Paralyzed Veteran's Association, and the American Paraplegia Society.

38. A novel neural prosthesis for bladder control

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Objectives: Neurological disease or spinal cord injury (SCI) can result in loss of voluntary control of bladder

evacuation, bladder hyper-reflexia and bladder sphincter dysynergia. The long-term goal of this research is to develop a neural prosthesis to restore bladder function in persons with neurological disorders or spinal cord injury. Traditionally, coordinated micturition (bladder contractions coupled with external urethral sphincter relaxation) is assumed to require a spinal-brainstem-spinal reflex loop. SCI interrupts this reflex. However, recent studies suggest that micturition can be evoked by activation of urethral afferent nerves and that this response is preserved following spinal transection. The objectives of these experiments were to verify that stimulation of pudendal urethral afferents elicits bladder contractions and to determine the effects of bladder volume and stimulus parameters on the evoked response.

Methods: Three adult male cats were anesthetized with alpha-chloralose. The bladder was cannulated to control bladder volume and record bladder pressure. Bipolar hook electrodes were placed on the principal sensory branches of the pudendal nerve (urethral and dorsal penile nerves) which were stimulated separately using regulated current stimuli consisting of 5 or 10 s trains of 100 μs rectangular pulses applied at 1, 2, 5, 10, and 20 Hz and various stimulus amplitudes.

Results: In all three experiments, stimulation of the pudendal urethral sensory nerve elicited robust bladder contractions (>15 cm H_2O). Bladder volume had to be near or above the volume threshold for reflexive bladder contractions to elicit a response. No responses were observed at low bladder volumes. Robust bladder contractions were elicited at low (<=2Hz) stimulation frequencies and not elicited or inhibited at high (>=20 Hz) stimulation frequencies.

In one experiment the spinal cord was transected (T12), eliminating reflex bladder contractions. However, electrical stimulation of the urethral sensory nerve still evoked bladder contractions. These results suggest the neuronal circuitry required to elicit reflex bladder contractions exist within the spinal cord and may be accessed peripherally.

Activation of the genital afferent nerve inhibits or abolishes bladder contractions. Bladder contractions evoked by urethral sensory nerve stimulation were abolished by activation of the dorsal penile nerve. Therefore selective activation of the urethral sensory branch without activation of the genital branch is required to elicit bladder contractions.

The urethral and genital afferent nerves are represented as individual fascicles within the pudendal nerve. Multi-contact nerve cuff electrodes are able to selectively stimulate individual fascicles within a peripheral nerve trunk. Therefore bladder control may be possible using a single nerve cuff on the pudendal nerve.

Conclusions: We propose an innovative approach to restoration of bladder function using a single multi-electrode nerve cuff implanted on the pudendal nerve to arrest nascent hyper-reflexive bladder contractions by electrical stimulation of pudendal genital afferent nerve fibers, and to produce on-demand bladder evacuation by electrical stimulation of pudendal urethral afferent nerve fibers.

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39. An implanted neuroprosthesis for functional electrical stimulation and myoelectric recording

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Objectives: The objective of this study was to evaluate an implanted device capable of both electrical stimulation and myoelectric recording. Specifically, we have designed and fabricated an implanted neuroprosthesis capable of 12 channels of stimulation and has two channels of myoelectric signal (MES) recording. This device was evaluated in a dog model to verify the ability to reject stimulus artifact while stimulating and recording. The device will be used to provide hand and arm function in the cervical level spinal cord injury as part of an advanced neuroprosthetic system.

Methods: The neuroprosthesis packaging was based on our first generation of implanted devices, and utilizes ASIC circuitry for flexibility. The primary innovation in this generation is the recording of MES while stimulating. The stimulus artifact reduction was accomplished by reducing the gain on the MES inputs and integration amplifiers during stimulation and pausing recharge phase of the stimulus pulses while the MES is integrated for a period of approximately 30ms between pulses. Stimulation pulses are balanced charge,

asymmetric, biphasic, constant current pulses which for these experiments were typically 20mA with a pulse duration of 200μsec and frequency of 16 Hz. The neuroprosthesis was fabricated and bench tested in our design laboratories at Case Western Reserve University. The neuroprosthesis was implanted in a dog in a pocket above the right shoulder. Stimulating electrodes were placed in the triceps and brachialis of the right leg and in the distal paw, shoulder, spine and ribcage. Bipolar epimysial MES recording electrodes, which were 4mm diameter with 10mm center to center spacing, were also placed on the triceps and brachialis. Stimulation and recording from the implant were conducted both with the dog awake, to record normal activity, and sedated, using an injected signal. The MES was recorded during various combinations of stimulation. During the sedated experiments, a 100 Hz, square wave signal, gated at one Hz, was injected into the tissue using a pair of hypodermic needles in the right paw and the upper shoulder. The MES from the triceps and brachialis were also recorded externally using fine wire bipolar electrodes for comparison.

Results: The stimulation artifact recorded from the MES electrodes, while stimulating from adjacent muscles, was less than 1% of the maximum recorded MES activity. The implant was able to record both integrated MES signal between pulses at up to 20 Hz and raw MES signal with no stimulation at a rate of 200 Hz.

Conclusions: The implanted neuroprosthesis performed as designed and provided a reliable, stable MES signal from adjacent muscles during stimulation. Pending successful completion of bench testing, this device is ready to proceed to human feasibility studies.

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40. An advanced neuroprosthesis for cervical spinal cord injury

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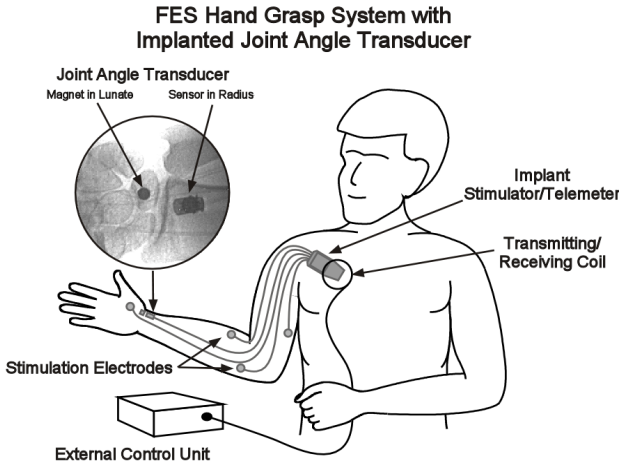
Objectives: The goal of our program is to provide hand and arm function for tetraplegic individuals. This is accomplished using a combination of implanted neuroprosthetic technology and surgical reconstruction techniques. Neuroprostheses use electrical stimulation of paralyzed muscles to produce controlled limb movement. A second generation neuroprosthetic system has now been developed which provides advanced hand and arm functions and improved ease of use. The primary feature of this new system is the implantation of the control source, which is accomplished through implantation of a joint angle transducer in the wrist.



Methods: The second generation neuroprosthesis, shown in Figure 1, consists of a ten-channel stimulator--telemeter (IST), an implanted joint angle sensor (IJAT), ten electrodes, an external control unit and a transmit/receive coil. The IJAT consists of a sensor implanted in the distal radius, and a magnet implanted in the lunate. Grasp opening and closing is controlled by voluntary movement of the ipsilateral wrist.

Results: The second generation neuroprosthesis was implemented in five subjects who were tetraplegic secondary to traumatic spinal cord injury at the C5 or C6 level. The neuroprosthesis is operational in all five subjects, and has been implanted for a median of 43 months (range 35 to 49 months). Every subject demonstrated an increased level of independence in activities of daily living when using the neuroprosthesis. Device usage at home, as indicated by patient report, regularly averaged between 4 days and 7 days per week.

Conclusions: The second generation provides functional benefit to C6 level spinal cord injured individuals. Eliminating the need for an external sensor was well-received by both the users and their attendants.

Acknowledgments: This study was funded by the Department of Veterans Affairs Rehabilitation Research and Development Service and by the National Institutes of Health, including the Clinical Research Center at MetroHealth Medical Center (M01 RR00080).

41. The suitability of synergistic myoelectric signals for use as control sources for a hand grasp neuroprosthesis

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Objectives: The overall objective of this research is to develop and evaluate an advanced FES neuroprosthesis to restore hand function in individuals with C7 tetraplegia. The purpose of this project is to develop and test a control methodology that will use voluntary myoelectric signals from muscles that act in synergy with hand function as the control signals to operate the hand grasp neuroprosthesis. Our objectives are to: 1) demonstrate the feasibility of acquiring myoelectric signals that are suitable for controlling a neuroprosthesis through hand-crafted control algorithms, 2) develop control algorithms and test them using a simulated neuroprosthesis controller, and 3) implement myoelectric control of the neuroprosthesis in C7 subjects and evaluate their hand performance.

Methods: Our first aim is to demonstrate that the voluntary myoelectric signals recorded from the wrist flexor (flexor carpi radialis, FCR) and extensor (extensor carpi radialis, ECR) muscles are suitable for use as control signals. To do so we evaluate the stability of the baseline activity, the repeatability and distinguishability of intended control signals, and the degree of independent control the subject has over the two signals. Methods for data collection and analysis are being established. EMG signals were recorded from the FCR and ECR of one able-bodied subject using fine-wire bipolar intramuscular electrodes. The subject was asked to produce as consistently as possible trains of low-amplitude and high-amplitude brief (transient) and sustained (logic) bursts of activity from the FCR and ECR under two conditions of arm orientation (arm at side and arm outstretched) while the hand was unloaded. The amplified (gain = 3300), filtered (100 – 1000 Hz), and sampled (2000 Hz) signals were rectified and averaged over 80 msec intervals to produce a smoothed signal. The reproducibility of the intended control signals was quantified by computing an average +/- std control signal amplitude. The distinguishability of the control signals was quantified by defining rules for identifying the intended control signal and then calculating the probability of correctly identifying the control signal that was intended according to those rules. The degree of independent control the subject has over the two myoelectric signals was quantified as a co-contraction ratio.

Results: At each arm orientation, logic signals were more repeatable than transients, with coefficients of variation ranging from 0.11 to 0.27 for logics and from 0.19 to 0.36 for transients. Also at each arm orientation, low logic signals could be distinguished from high logic signals 100% of the time and low transients could be distinguished from high transients with approximately 85% accuracy. Further analysis is required to assess the distinguishability of high from low signals across the two arm conditions. The co-contraction ratio of agonist to antagonist was greater than one during 97% of the intended contractions.

Conclusions: Further control signal characterization is required in this subject while the wrist is loaded with applied flexion and extension torques. Several able-bodied and at least two C7-injured subjects will be tested in the near future.

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42. Application of percutaneous FES for walking in individuals with partial spinal cord injury

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Objectives: The purpose of this study is to correct gait deficit in persons with partial spinal cord injury (SCI)

with the use of temporary percutaneous intramuscular electrodes.

Methods: Individuals with partial SCI who can stand up but cannot bring their legs forward for walking are candidates for this study. They are evaluated for gait deficits and tested with surface stimulation for response of major muscles controlling the hips, knees, and ankles. If it is determined that they could benefit from Functional Electrical Stimulation (FES), they receive percutaneous intramuscular electrodes to activate the muscles required to correct their deficits. One 47 years old male volunteer who sustained an incomplete T2-T4 level injury has been enrolled into the study. He is a physiological ambulator limited by left hip and knee extension weakness and bilateral lack of dorsiflexion and hip flexion. His walking is also severely compromised by spasticity. He was first implanted with percutaneous electrodes in the left iliopsoas, quadriceps, hamstrings and tibialis anterior. Second implant of right iliopsoas, quadriceps and tibialis anterior followed after a month of exercise and walking. His rehabilitation protocol consists of electrical exercise at home, and gait training in the laboratory for a period of 3 months. Three possible outcomes of this intervention are being tested. First, the use of FES has no significant effect on an individual's gait. Second, the use of FES improves individual's volitional control sufficiently to where stimulation is no longer required for functional walking. Third, the use of FES is required to maintain functional walking. In all outcomes the percutaneous electrodes will be removed following completion of the rehabilitation protocol. However, if an individual requires FES for functional gait he is given an option of receiving an 8-channel implanted system.

Results: Repeatability and control of volitional muscle strength was poor. Significant increase in repeatability and strength was attained by simultaneous combination of volitional and stimulated contractions. Typical gait without stimulation in our volunteer was characterized by significant forward leaning and weight on the arms and walker, vaulting on the right leg and hiking of the left hip to clear the left swing limb due to increased extensor tone. The use of percutaneous stimulation of the left leg obviated the need for hiking and significantly improved ambulatory ability. His walking distance and speed with stimulation were limited by fatigue of his right leg. Implantation of the right leg further enhanced walking performance. His volitional walking without the FES has not changed from baseline. He is now limited by poor cardiovascular fitness as a result of prolonged inactivity.

Conclusion: The preliminary results indicate that significant improvement in walking can be achieved with percutaneous stimulation in an individual with partial SCI. A percutaneous system allows tailoring FES to the individual's needs and test its use in activities of daily living. If individual finds that FES can significantly improve his activities of daily living he has an option to receive a permanent implanted FES system.

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43. Cortical interfaces for assistive technologies: applications to upper extremity neuroprostheses

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Objective: Applications of new technologies to individuals with disabilities are a means to provide greater independence. Often, the control of these devices must be accomplished in a manner that is efficient, natural, and cosmetically acceptable. One method of providing control and meeting the needs of the individual are to use signals derived from the cortex. The purpose of this study was to develop a method by which individuals could operate a neuroprosthesis with a cortical signal.

Methods: Studies focused on extracting a control signal from the electroencephalogram (EEG). Three individuals with an upper extremity neuroprosthesis for the restoration of hand function were recruited. These individuals were initially trained using visual feedback to control the amplitude of the 20-30 Hz frequency component of the EEG signal recorded from the frontal areas to generate a binary signal. An interface to the upper extremity neuroprosthesis was developed which processed the binary signal into a command to open and close the hand. This was achieved by using a proportion in time signal, where time above or below a threshold value generated the command to open and close the hand at a fixed rate. Testing of the interface was performed using the Grasp and Release Test (GRT) and a

questionnaire. The GRT was used to provide a quantitative measure of interface performance, while the survey was used for more subjective measures. Further analysis of the interface was also performed with one individual using an activity of daily living (ADL) assessment.

Results: Performance on the GRT with the cortical interface 30 to 50% lower when compared to existing neuroprosthesis interfaces. This was due to slow signal generation and long processing times. This result, however, was better than expected indicating rapid adaptation by the user. Results from the user survey provided a more favorable comparison of the cortical interface to existing controllers. The subjects enjoyed the use of the cortical interface, however cosmesis was a major concern. The results of the ADL assessment demonstrated near comparable performance when compared to the implanted joint angle transducer (IJAT). This implied that the use of the cortical signal would not decrement the performance of the neuroprosthesis for everyday activities, in spite of its slow speed and limited information content.

Conclusions: The results obtained from this study indicate that further work is required to define the essential characteristics of an ideal interface, and that cortical interfaces are a feasible next step for assistive technologies. This has led to a continued effort to develop implanted cortical interfaces that will address the user concerns brought out by this study, while still maintaining the benefits of such an interface. This work will expand applications of the upper extremity neuroprosthesis, with additional benefits to other assistive technologies.

Funding Acknowledgment: This study was funded by the VA Pre-Doctoral Associated Health Rehabilitation Research Fellowship.

44. Functional magnetic cough in patients with spinal cord injury

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Objective: Assess the effectiveness of the functional magnetic stimulation (FMS) technology in restoring cough in Spinal Cord Injury (SCI).

1. Determine the type of patients that will be best benefited by this technology.
2. Condition the expiratory muscles by long-term FMS.
3. Optimize the magnetic coil placement and stimulation parameters for FMS.
4. Monitor for expiratory muscle fatigue and safety in these FMS protocols.

Methods: The study subjects participated in a 6-week expiratory muscle conditioning protocol. A commercially available magnetic stimulator (Dantec MagPro) with a round magnetic coil (20.0 cm in outer diameter) was used. A cooling unit which circulated oil in and out of the coil was designed to allow continuous stimulation for 30 minutes or longer. This protocol began with one week of respiratory muscle evaluation, including pulmonary function tests, nerve conduction study of the lower thoracic nerves, and FMS of the expiratory muscles. This was followed by a four-week expiratory muscle conditioning period using FMS. Increasing FMS intensities was applied to progressively condition the expiratory muscles five days a week. Another week of post-conditioning respiratory muscle evaluation was again performed following FMS conditioning. Pulmonary function test results and changes in maximum expiratory pressures (MEP), expiratory reserve volumes (ERV), and forced expiratory flows (FEF) at both total lung capacity (TLC) and functional residual capacity (FRC) in response to FMS were compared with their voluntary maximum and previous FMS evaluations.

Results: For a preliminary result, ten subjects have completed 4-wek conditioning. The mean (± SEM) MEP-TLC, MEP-FRC, ERV, FEF-TLC, and FEF-FRC after four weeks of conditioning were 52.9 ± 8.0 cm H_2O, 27.9 ± 5.2 cmH_2O, 0.52 ± 0.08 L, 4.1 ± 0.45 L/s and 1.9 ± 0.19 L/s, respectively. These values correspond to 116%, 122%, 173%, 106%, and 123% of pre-FMS conditioning values. Upon discontinuation of FMS for two weeks, the MEP-TLC returned to the pre-FMS training values.

Conclusions: SCI disrupts the neuromuscular central nervous system control of the expiratory muscles. Many patients are not able to produce an effective cough to clear airway secretions, thus, resulting in respiratory tract infections. The proposed 4-week FMS of the expiratory muscles training study improves voluntary expiratory muscle strength significantly, indicating that FMS can be a therapeutic technology in respiratory muscle training in tetraplegics.

Funding Acknowledgment: This study was funded by the VA Rehabilitation Research and Development Service, project # MR-B1756.

45. Rapid prototyping with a modular external control unit for functional electrical stimulation

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Objectives: We are developing a set of hardware and software tools from which researchers and clinicians can create customized control systems to address their functional electrical stimulation (FES) needs. FES is used to restore function lost from injury, stroke or disease by delivering electrical impulses to nerves or muscles. A typical FES system repeatedly reads physiological data or command signals, processes and makes calculations based on those inputs, then adjusts and communicates stimulation parameters. As an alternative to having a different external control unit (ECU) for each different laboratory or clinical project, our modular approach will provide flexibility in allowing construction of many configurations of ECUs from the same set of tools. Our software will consist of symbolic blocks, such as a "generate stimulus pulse" block, designed for use with commercially-available rapid prototyping tools that can realize real-time controllers from block diagrams and state machines. With this abstract programming environment, researchers and clinicians will be able to quickly implement, test, revise and re-test ideas without the need for low-level coding that requires the assistance of a software engineer.

Methods: A hardware module that powers and controls implanted stimulator-telemeters is nearing completion, as is a microcontroller module that serves as a communications hub and the host for real-time programs. Modules for percutaneous and surface stimulation, as well as a user-interface module, are being designed. Software packages from The Mathworks, Inc. are used to provide rapid prototyping for ECUs composed of these modules. In a windows-based operating system on a personal computer (PC), "Simulink" allows drawing and simulating block diagrams. "Real-Time Workshop" then provides automatic translation of a block diagram into C code. Through a serial link to a second PC running only the "xPC Target" kernel, the compiled C code is downloaded for execution in real-time. On the first PC, "MATLAB" is used to control the downloaded application and process data. Custom blocks are being coded for use in this environment for researchers and clinicians to employ in their block diagrams. One such block that repeatedly outputs single stimulus pulses with a programmable channel number, amplitude, duration and frequency is nearing completion.

Results: Using an early version of our software, block diagrams were created, compiled and downloaded for use with prototype FES hardware. Stimulation of multiple channels was demonstrated with programmable spacing between channels and with parameters set in response to user input, read with an analog-to-digital converter.

Conclusions: Our initial results indicate the feasibility of the modular ECU and the rapid-prototyping approach to FES algorithm development. Work on both the hardware and software elements of this system will centralize technology development and support efforts that serve many projects throughout our Center.

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46. Initial performance of a surgically implanted neuroprosthesis for standing after spinal cord injury

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Objectives: The purpose of this report is to describe the preliminary performance of a surgically implanted neuroprosthesis employing functional electrical stimulation (FES) for exercise, standing and assisted transfers in an initial group of 12 volunteers with

longstanding spinal cord injury (SCI) in a small scale, Phase II multicenter clinical trial.

Methods: The standing neuroprosthesis consists of the 8-channel CWRU/VA implanted receiver-stimulator (IRS-8), epimysial and surgically-implanted intramuscular electrodes, a wearable external controller, and a laptop PC-based clinical interface to specify customized stimulus parameters and retrieve usage information. Electrodes are implanted into the knee, hip and trunk extensor muscles to stiffen the joints, support the body against collapse and facilitate exercise and upright mobility functions. A standardized surgical technique for system installation was defined based on quantitative cadaver dissections and intraoperative tests and new external controllers and programming systems suitable for clinical use were designed and fabricated. Written inclusion, rehabilitation and follow-up protocols were established, recruiting and educational materials were produced and a series of instructional workshops were organized and conducted to transfer the technology to satellite centers at the University of Kentucky/Lexington VAMC, Medical College of Albany, Washington University in St. Louis, and the Houston VAMC.

Results: To date the standing transfer neuroprosthesis has been installed in 12 volunteers. Mean height and weight were 5'8" and 175 lbs, mean time post injury at implant was 6.2 years, and mean age at implant was 35 years. Ten implant recipients are local to the lead center in Cleveland, and two are being followed at collaborating technology transfer sites which are implementing standardized screening and enrollment procedures, rehabilitation protocols and follow-up data collection methods. After reconditioning exercise and rehabilitation with the system, most implant recipients have been able to stand with less than 5% body weight on their arms, release on hand from a support device to manipulate objects in the environment, and perform standing transfers and swing-to ambulation in a walker. Stimulated responses are stable and sufficiently strong for function, with mean unilateral isokinetic knee extension moment approaching 40 Nm. Implanted components are reliable with a 90% probability of epimysial electrode survival at four years post-implant. Individual performance varies and there appears to be an interaction between subject height/weight and standing times/body weight distribution. Long-term follow-up to determine safety and efficacy is ongoing and one system has been explanted due to a late-onset systemic infection.

Conclusions: The technical and clinical components of the surgically implanted neuroprosthesis for standing after SCI appear to be effective for exercise, standing, transfers, and single-handed reach or swing-to gait in selected individuals. Implementation and follow-up procedures have been successfully refined and are suitable for further dissemination.

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