

## XII. Orthotics

*For additional information on topics related to this category see the following Progress Reports: [7], [8], [9], [14], [85], [95], [104], [148], [149], [150], [151].*

### [377] Adjusted Versus Unadjusted Foot Orthoses in the Prevention of Foot Ulcers in Diabetics

---

**Stephen F. Albert, DPM**

VA Medical Center, Denver, CO 80220

*Sponsor: VA Rehabilitation Research and Development Service (Project #607-RA)*

**Purpose**—Preulcerative and ulcerative foot lesions in diabetics invariably occur at weightbearing sites with maximum pressure. There is evidence to suggest that custom foot orthoses mitigate such pressures, presumably through their redistribution. We hypothesize that individually adjusted orthoses reduce the incidence of foot ulcerations. We also suggest that the effectiveness of orthoses and their best adjustment are possible with “in-shoe” capacitive sensor measurements which not only quantitate pressure, duration, and location, but can be performed on an outpatient basis.

The purpose of this study is to: 1) determine if in-shoe foot orthoses control distribution of plantar foot pressure in the stance phase of gait to such an extent that hyperkeratotic stance phase foot lesions are noticeably affected; 2) determine if orthosis adjustments significantly improve distribution of plantar foot pressure in the stance phase of gait, and if further orthosis adjustments are necessary with time; and, 3) determine, in diabetic

patients who have previously ulcerated their feet, if custom foot orthoses (adjusted versus unadjusted) decrease the incidence of reulceration.

**Methodology**—Two study groups will be used. Group One will consist of 40 subjects randomly assigned to the adjusted orthotic group. Group Two will consist of 40 subjects assigned to the unadjusted orthotic group. The adjustments will be made as needed, following determinations of foot pressure distribution during the dynamics of gait (pressure—N/cm<sup>2</sup>, time—ms, and location in coordinates). The measurements will be obtained monthly using “in-shoe” capacitive sensor measurements.

**Implications**—We anticipate that adjusted orthoses will prove superior to unadjusted ones in preventing pedal ulcerations in the diabetic population. We also expect to find that in-shoe measurements of foot pressure distribution is the best method for guiding the appropriate adjustments.

### [378] Clinical Evaluation of the Vannini-Rizzoli Stabilizing Limb Orthosis

---

**Joseph Binard, MD; Stanley Gordon, MD; A. Connor Higgins, MD; Bernard A. Nemchausky, MD; Michael Vulpe, MD; Robert R. Young, MD; Andrew Fischer, MD; Andrea Dory, RN; Lester T. Richard, RK; Yvonne Lucero, MD; Herbert Kent, MD**

James A. Haley Veterans' Hospital, Tampa, FL 33612; VA Medical Center, Bronx, NY 10468; VA Medical Center, Memphis, TN 38104; Edward Hines, Jr. VA Hospital, Hines, IL 60141; VA Medical Center, Long Beach, CA 90822; VA Medical Center, West Roxbury, MA 02132

*Sponsor: VA Rehabilitation Research and Development Service (Project #B597-EA)*

**Purpose**—The purpose of this project is to evaluate the Vannini-Rizzoli Stabilizing Limb Orthosis (VRSLO) as a means to permit standing and ambulation, with a minimal expenditure of energy, in spinal cord injury (SCI) patients with paraplegia or paraparesis due to

lesions of the cord at, or caudal to, the mid-thoracic level.

Also included in the study is the establishment of the appropriate criteria for candidate selection, alteration of the treatment plans for those selected, selection of proper

exercises, establishment of the duration of the client's program, and incorporation of this information into the clinical application of the VRSLO or, as it is commonly referred to, "The Boot."

**Methodology**—The Boot works solely by arrangement and rearrangement of body mechanics. Use of the Boot causes plantar flexion of the foot and stabilization of the ankle; the patient is taught extension of the knees, hips, and back to achieve a stable stance. When proper weight-shifting techniques are combined with stance, the person may ambulate with a pendular motion of the unweighted limb and an assistive device (e.g., canes, walker, etc.) for support. SCI injuries ranging from C-6 to L-3 have been fitted, but ambulation status obviously differs from person to person.

There are several important variables which correlate with potential for success or failure. Patients with recent, low-level injuries and no major joint contractures or severe spasticity are good candidates. Persons must be highly motivated toward standing and walking, as well as willing to devote approximately 2 months to the program, 5 or more days per week.

Relative, but not absolute contraindications to participation include cardiovascular disease, history of long-bone fracture within one year of fitting, and placement of rods for spinal stabilization (which may limit back extension). Obesity, uncontrollable spasticity, chronic skin breakdown, and fixed joint contractures are definite contraindications.

The program consists of extensive exercises on a mat to facilitate weight-shifting movements, abdominal strengthening, and general stretching of the limbs and back. Daily sessions in the standing frame help develop tolerance for the upright position and allow further practice of weight-shifting techniques. Therapists assist with and supervise these activities.

Training with the orthotic devices begins after 4 to 6 weeks of the conditioning program. Patients are issued their Boots, and adjustments to the laces and soles are made to assure good fit and stability while standing. Both orthotists and therapists work with the patient in this phase. Candidates, in general, progress from using parallel bars for support to walkers, forearm crutches, or even canes.

Further refinement of skills may incorporate stair climbing, ramp walking, and car transfers, in addition to performing activities of daily living (ADL) while standing. Not all patients have, as yet, reached these goals; a major obstacle for some is adherence to the rigorous

program. For others, back or joint pain sometimes limits duration of use of the orthosis.

**Progress/Preliminary Results**—*James A. Haley Veterans' Hospital, Tampa, FL.* The Tampa VA Hospital has been approved to accept 30 patients for evaluating the Rizzoli orthosis. Thus far, 19 patients have been accepted in the research program. Ages range from 19 to 60 years old with length of injury from one year to 38 years. Levels of injury range from complete C-7 quadriplegia to L-1, L-2 paraplegia.

The Vannini-Rizzoli Boot has been very successful. Patients are ambulating with quad canes 60 to more than 1,000 feet (average distance 300 feet) for a success rate of 80%. Some patients are capable of negotiating stairs independently.

This new orthosis has increased independence, allowing patients who have been in wheelchairs for as much as 38 years to ambulate independently in their homes and moderate distances outside their homes. It has eliminated the need for some patients to make structural changes to their homes since they can ambulate independently. Several patients have stated that they have not had a urinary tract infection since using the Boots. Others have stated that they do not need to look for a wheelchair-accessible hotel when on the road. These are just several advantages the Boot has given our patients.

*VA Medical Center, Bronx, NY.* Dr. Vannini, developer of the Vannini-Rizzoli Boot, visited our center initially to assess interested candidates for the program. She was accompanied by a therapist and prosthetist-orthotist who were involved in her program. Twenty-four candidates, recruited through efforts of our staff and the Eastern Paralyzed Veterans Association, appeared. Although definitive criteria for admission into the program had not yet been finalized, 18 of these candidates were accepted. Of the first 18 patients, 6 completed the program and were given the Boots to use outside of the hospital. The others had to drop out for various reasons—the primary reason being their lack of endurance in mastering various stages of the protocol.

Subsequently, several more candidates entered the program; at the present time, we have 9 patients using the Boots.

We are continuing the program, but have had only a rare candidate. At the present time, we have two patients actively engaged in the training process.

*VA Medical Center, Memphis, TN.* As of fall 1990, 54 patients have been evaluated for the VRSLO and 25 have been selected, with an additional two patients in the

evaluation phase. Of the total selected, 21 are paraplegics with an injury level ranging from T-4 to L-3, complete and incomplete, and four are quadriplegics with injury levels of C-6 to C-7, complete and incomplete.

Of the 21 paraplegics selected, the functional levels are as follows: two require minor assistance for standing with the use of parallel bars or walkers, five are independent in ambulation in the parallel bars, five are independent in ambulation utilizing a walker, one is ambulatory with crutches, one is independently ambulating with bilateral quad canes, and one is independent in ambulation with a single quad cane and can also ambulate behind a wheelchair. Of the paraplegics selected, two can ambulate short distances with no assistive devices such as walkers or canes. There are also five paraplegics who can negotiate stairs, and two paraplegics who withdrew from the study; one for medical reasons and the other voluntarily.

For the quadriplegic group, the four patients selected have attained the following levels: two are independently standing with the use of a walker, one requires minimal assistance to stand in the parallel bars, and one has a permanent orthosis on order.

The preliminary results of the study have shown that the VRSLO is more widely accepted by the SCI clients than conventional bracing. The Boot is lighter in weight, more cosmetically acceptable, and easier to don and doff than conventional bracing systems. It is also apparent that the Boot is more functional, and due to the ability to attain static equilibrium with proper fitting, that the knee joint is free and mobile with no external locking mechanism.

*Edward Hines, Jr. VA Hospital, Hines, IL.* Our experience at Hines has been a mixture of results: some positive, others not entirely satisfactory. Of 20 pairs of Boots fitted, 9 persons appear to be daily users. At least one person has sustained hairline tibial plateau fractures (possibly a result of tibial torsion in the Boots), and does not ambulate at present. One patient relinquished his place in our program to attend to a severely ill spouse; another was employed in research which did not allow an extended leave to master the orthosis. Obtaining assistive devices with the length necessary to accommodate the additional height of a person in Boots has limited progress in several cases.

*VA Medical Center, Long Beach, CA.* Thirty patients aged 22-68 years are in this study. Spinal cord levels of injury vary from C-5 to L-1. Patient selection and other pertinent data are given. Our results indicate a success rate of more than 90%. Acceptance of the Boot has been

extremely good. The average distance ambulated was 100+ feet.

*VA Medical Center, Brockton/West Roxbury, MA.* Twenty-five patients were initially evaluated: 17 were entered into, and 7 completed the study. After discharge from the intensive exercise program, patients were evaluated at least monthly for the first 3 months, and then at least every 3 months. Of the seven who completed the study, four are ambulating at a community level and one at the household level using canes. Five were unsuccessful in using the VRSLO to ambulate because contractures could not be eliminated, skin breakdown occurred on the feet, or a tibial fracture occurred after admission to the study but before the Boot arrived. Three of these "failures" were temporary. These patients will be reentered into the study after the musculoskeletal or cutaneous lesions heal.

**Future Plans**—*VA Medical Center, Bronx, NY.* Our therapists and orthotists are well trained and can handle new candidates expertly. We anticipate relatively few new participants. However, the therapists will continue to do periodic follow-up evaluation on all patients who have been issued the Boots, and we shall cooperate with the other five medical centers in achieving the goals and evaluating the effectiveness of this pilot program.

*VA Medical Center, Brockton/West Roxbury, MA.* Admission criteria will be liberalized to include older patients and those with lesions between T-2 and T-6 to learn if they also can benefit from the Boot. Evaluations of oxygen and energy consumption will be made to compare metabolic efficiency of the Boot with long leg braces.

**Implications**—Data combined from the six original sites suggest that the VRSLO is a viable means of achieving gait in the spinal cord injured. Several sites are interested in quantifying energy requirements of the VRSLO when compared to long leg braces and/or wheelchair propulsion. The Boot is not a means of rapid propulsion, but bears certain aesthetic and functional advantages over previous orthoses of similar intent. Therefore, it may be more accepted (and utilized) by the SCI population.

Additionally, patients note subjective benefits of standing, such as reduced spasticity, better urinary and bowel elimination, and feelings of greater well-being.

This study has been recently expanded to include three more sites and should continue to provide information over the next few years regarding not only the orthosis itself, but many related SCI topics as well.

## [379] Orthotic Stabilization of Thoracolumbar Injuries

Avinash G. Patwardhan, PhD; Thomas Gavin, CO; Mark A. Lorenz, MD; Vijay Goel, PhD; Mark Sartori, BS; Robert Havey, BS

Department of Orthopaedics, Loyola University Medical Center, Maywood, IL 60153; Rehabilitation Research and Development Center, Edward Hines, Jr. VA Hospital, Hines, IL 60141

Sponsor: VA Rehabilitation Research and Development Service (Project #A509-RA)

**Purpose**—Spinal orthoses have traditionally played an important role in the early mobilization of patients with thoracolumbar injuries. However, the treatment protocol for orthotic management of spinal fractures remains subjective due to a lack of objective data defining the three-dimensional (3-D) instability of spinal fractures and the extent to which different spinal orthoses can improve the biomechanical stability of the injured spine. The objective of this study is to evaluate the effectiveness of spinal orthoses in controlling the progression of deformities at the injured segments under the action of different loads and for different severity levels of injury.

**Progress**—To date, we have demonstrated the methodology for a 3-point hyperextension orthosis. A finite element model (FEM) of the ligamentous spine with ribcage was used. The model consisted of 17 beam elements; each beam element representing the overall contribution of all anatomical components of a spinal segment. An injury of increasing severity was simulated by progressively reducing the stiffness of T11-T12-L1 segments. Interaction of a 3-point hyperextension brace with the spine was simulated using experimentally measured stiffness properties of the brace. The model was used to predict displacements at the injured segment and loads exerted by the orthosis on the trunk.

We are currently extending the above model to incorporate the detailed anatomical structures of the thoracolumbar region (T11-L2). This will allow us to simulate the damage to individual anatomical components associated with each type of injury, and thus, will facilitate clinical interpretation of model results. This model will be developed using the commercially available package, ANSYS. The cortical shell and the cancellous core of the vertebral body, and the posterior bony elements will be modeled as 3-D isoparametric 8-nodal brick elements. The annulus fibrosis will be modeled as a composite material consisting of fiber bands (lamellae)

embedded in the ground substance (3-D, isotropic 8-nodal elements) around the nucleus. Nucleus material will be modeled as a 3-D incompressible fluid element. The ligaments will be modeled as bilinear cable elements similar to annular fibers. Material properties for this modeling work will be derived from data in the literature.

We have also performed preliminary experimental studies to measure loads exerted by two types of hyperextension orthosis (Jewett and CASH) for different tasks using normal subjects. The loads were measured using thin arrays of Force Sensing Resistors sandwiched between the orthosis pads and trunk. The different postures were quantified using the WATSMART motion measurement system. Electromyographic signals were also recorded from the erector spinae and rectus abdominus muscle groups using bilateral surface electrodes while subjects performed different tasks. Data from a total of three subjects have been acquired and are currently being analyzed.

**Future Plans**—This project will investigate the biomechanical stability of spinal fractures stabilized with different spinal orthoses and surgical constructs, used alone or in combination. The response of orthotically supported injured spine to loads in three planes, and evaluation of other orthotic designs such as the total contact thoracolumbosacral orthosis (TLSO) will be investigated in the future. Further, experimental studies will be performed to measure changes in orthotic loads as subjects perform various tasks. The long-term goal of this study is to develop objective treatment guidelines to adequately protect patients with spinal trauma during the healing process of spinal injuries while preventing unnecessary surgery or bracing.

### Recent Publications Resulting from This Research

Orthotic Stabilization of Thoracolumbar Injuries-A Biomechanical Analysis of the Jewett Hyperextension Orthosis. Patwardhan AG et al., Spine 15(7):654-661, 1990.

## [380a] Concerted Action Mobility Restoration for Paralyzed Persons (MORE Project)

**Antonio Pedotti, Prof**

Centro di Bioingegneria, Politecnico di Milano, Milano 20148 Italy

*Sponsor: Italian Ministry for University and Scientific Research, Italian National Research Council*

**Purpose**—The Concerted Action MORE (MObility REStoration for paralyzed persons) has been launched by the COMAC BME (Committee for Management of Concerted Actions in BioMedical Engineering) in the framework of the fourth Medical and Health Research Programme of the Commission of the European Communities. This 4-year program started in 1988 and involves more than 50 Institutes located throughout the countries of the European communities. The Concerted Action is directed toward those who are paralyzed as a result of spinal injuries (i.e., paraplegics, quadriplegics), cerebral palsy, or neuromuscular diseases—people who represent a high percentage of the physically disabled. However, many other disabled persons could also benefit from the results of this action.

The objectives of MORE can be summarized as follows:

- Stimulate research of new technologies having meaningful and beneficial application for disabled users, particularly in the areas of: 1) new electrode materials, implantable multichannel stimulators, control strategies and implantation techniques for walking restoration in paraplegics; and, 2) new materials, ergonomics and design, seating and support systems, and control systems for technical aids for independent mobility.
- Multi-center trials of existing devices and new technologies and the exchange of evaluation results among the Centers involved in order to improve their value and reliability.
- Coordination of methodologies and protocols for technical, functional, and clinical evaluation of mobility aids. Technical evaluation is concerned with the technical quality and performance (e.g., materials, durability, safety, reliability, etc.) of equipment; functional evaluation is concerned with the effectiveness of equipment in meeting the actual needs of its disabled user; clinical evaluation is concerned with the effects on the user's health and compatibility with the body as it applies to some devices implanted or directly interfaced with the body (e.g., FES equipment).
- Gathering of research and evaluation results and dissemination to industries and/or rehabilitation

professionals. For such purposes, a close relationship has been established with: 1) the ongoing Handynet project—a section of the second program of Action in Favor of Disabled People (HELIOS) run by the Commission of the European Communities through the DGV, aimed at setting up a computerized information network concerned with the technical and social resources for rehabilitation and social integration; and, 2) the CALIES program (Computer-Aided Locomotion by Implanted Electrical Stimulation) launched in the framework of the EUREKA program.

**Progress**—In the field of *Walking Restoration* (WREP), particular consideration was given to the following aspects:

- Investigation into the basic mechanisms governing the control of normal gait (e.g., kinematics, dynamics, etc.), and identification of the optimal control signals used for stimulating a minimum set of muscles in paraplegic patients to restore walking in an acceptable manner. This study should lead to a general simulation approach for the best choice of the control laws in individual patients as a function of lesion, anthropometric characteristics, and eventual use of mechanical devices.
- Study of biocompatible materials, miniaturized hardware, and technical solutions for implantable systems, taking into account the problems raised by the wiring, connections, and implantable electrode interfaces.
- Study of the best electrical signals able to modulate muscle force and fiber recruitment in such a way as to minimize muscle fatigue.
- Clinical trials and development of suitable protocols for training and adapting devices to the individual patient.

In the field of *Mobility Restoration*, the following activities took place: participation in international meetings concerning the technical aspects of mobility and transport for paralyzed persons; the study and critical comparison of techniques and methodology for technical and functional evaluation of wheelchairs; and, investigation into new materials and technologies for wheelchair construction for achieving the best ergonomic performance.

**Methodology/Results**—In designing Concerted Action, we decided to concentrate specifically on the following topics on the basis of the present state of the market, the highest priority needs of a large number of paralyzed persons, and ongoing activities currently in progress in Europe: 1) Walking Restoration in Paraplegics (WREP), which includes mechanical devices, functional electrical stimulation (with implanted or surface electrodes), hybrid systems (combining mechanical devices and FES); and, 2) Technical Aids for Independent Mobility

(TAIM), which includes wheelchairs (manual and electric), cars (adaptation, modification of controls, special cars), and transfer aids (hoists for personal transfer, stair-climbers, etc.).

**Implications**—Technical aids for mobility restoration assume great importance in achieving independence for a better quality of life, social integration, access to job opportunities, school integration, and social relationships.

### [380b] Muscle Recruitment Optimization in Walking Restoration by FES

**Maurizio Ferrarin, Dr Eng; Antonio Pedotti, Prof**

Centro di Bioingegneria, Politecnico di Milano, Milano 20148 Italy

**Sponsor:** *Italian Ministry for University and Scientific Research, Italian National Research Council*

**Purpose**—The aim of this study is to develop proper procedures for choosing the best stimulation pattern for functional electrical stimulation (FES) in paraplegic patients with the goal of restoring their ability to walk.

**Progress/Methodology**—We have developed, and implemented on a computer, a simulated model of a person walking. The skeletal schematic had seven rigid links (three for each leg, one for head, arms, and trunk), and six joints (two hips, two knees, and two ankles). This model solves the direct dynamic problem of starting from initial conditions (position and velocity), when the time course of the segment positions is computed on the basis of mechanical torques applied to the joints.

To provide the necessary adaptability to an individual patient, the body segments' anthropometric parameters (mass, length, inertial moment, and gravity center position) are estimated automatically, starting with the subject's height and weight. Under the hypothesis of symmetry, periodicity of gait has been considered the interval between right and left heelstrike. The model is bidimensional, considering only movement in the sagittal plane.

The model is being tested with the time course of joint torques measured from healthy subjects, compared with measured kinematics of simulated ones. Starting from noncorrected kinematics, a trial and error procedure is used to correct the simulated kinematics modifying the input torques to obtain an optimal torque pattern.

**Future Plans**—A hybrid FES research program is being planned (in collaboration with clinical and rehabilitative groups), for the restoration of walking in incomplete spinal cord injured patients.

The model will be used as follows: 1) patient movement will be evaluated and the time course of the torque exerted at the joints during walking will be computed to measure kinematics and ground reaction forces; 2) computed torques will then be introduced as input for the simulation model, and making use of a trial and error procedure in combination with optimization criteria, the best muscle activation pattern will be derived; and, 3) this optimal pattern will then be applied to the patient, with the resulting kinematics evaluated with a quantitative analysis of the gait.

We also want to consider the "standing-up" movement and standing equilibrium with an adequate model, and study the relationship between stimulus and torque generated at the joint by induced muscular contraction.

#### Recent Publications Resulting from This Research

- Strategies in Muscle Recruitment for FES in Walking Restoration. Pedotti A, Ferrarin M, in Proceedings of the 11th Annual Conference of the IEEE Engineering in Medicine and Biology Society, Seattle, WA, 1989.
- A Modelling Approach to Stimulation Pattern Optimization. Ferrarin M, in Proceedings of the COMAC-BME Workshop "Restoration of Locomotion," Thessaloniki, Greece (in press).

### [381] FES-Aided Paraplegic Gait Using a Controlled-Brake Orthosis

**William K. Durfee, PhD; Robert Young, MD; Allen Wiegner, PhD**

Massachusetts Institute of Technology, Department of Mechanical Engineering, Cambridge, MA 02139;  
VA Medical Center, West Roxbury, MA 02132

*Sponsor: National Center for Research Resources, National Institutes of Health*

**Purpose**—Restoration of gait to paraplegics using functional electrical stimulation (FES) is a challenging problem. A crucial difficulty is controlling the FES system for stability and smooth gait. One option for improving control is to develop implanted systems with large numbers of stimulation channels and complex control algorithms. However, simple surface stimulation programs should continue to be explored because they involve no surgery. One means of improving walking function using surface stimulation is to add a mechanical orthosis in combination with FES.

Based on the preliminary work of our group, we are proposing to address the problem of designing a functional FES-aided gait system using surface stimulation by investigating a new device which may improve the quality of gait. The device incorporates a knee orthosis containing a controllable friction brake at the joint. The purpose of the brake is to shift the burden of control in a gait trajectory from controlling the stimulated muscles and spastic reflexes to controlling the brake, a well-behaved mechanical element. The controllable brake also provides a means of locking the knee joint during periods of quiet standing, which may reduce overall muscle fatigue. Further, the brake can provide a rigid brace mode which may be safer in the event of a stimulation failure.

To evaluate brake designs and performance, we will quantitatively test and compare the ability of SCI paraplegics to achieve FES-aided gait both with and without the brace. The assessment will include kine-

matic, dynamic, and metabolic variables.

**Progress**—Pilot studies based on stimulation of able-bodied subjects to control the knee joint demonstrated the utility of the controlled-brake approach. By combining fine control of the brake with gross control of muscle stimulation, performance on position tracking tasks was greatly improved over both open- and closed-loop control schemes which used stimulation alone. We have completed a computer-controlled, 8-channel stimulator and have begun clinical experiments at the West Roxbury VA Medical Center using ambulating paraplegics. To date we have implemented the standard 4-channel flexor withdrawal FES-aided paraplegic gait in a single subject who is T10 motor-complete.

**Future Plans**—Preliminary designs for a wearable version of a controlled-brake orthosis have been completed. After further development, we will build a brace and test our hybrid gait assist concept in experiments using paraplegic subjects.

#### Recent Publications Resulting from This Research

Open-Loop Position Control of the Knee Joint Using Electrical Stimulation of the Quadriceps and Hamstrings. Hausdorff J, Durfee W, Med Biol Eng Comp (in press).

Regulating Knee Joint Position by Combining Electrical Stimulation with a Controllable Friction Brake. Durfee W, Hausdorff J, Ann Biomed Eng (in press).

### [382] Electrical Stimulation Strategy to Inhibit Spasticity During Gait

**Jacqueline Csonka, BAsc; Morris Milner, PhD, PEng, CCE; Stephen Naumann, PhD, PEng**

Hugh MacMillan Rehabilitation Centre, Toronto, Ontario M4G 1R8 Canada

*Sponsor: Easter Seal Research Institute of Ontario*

**Purpose**—Spasticity can be defined in terms of its characteristics, the most salient of which is an exaggerated stretch reflex. Previous work has shown that it is possible to inhibit the stretch reflex of triceps surae by electrically stimulating the antagonist tibialis anterior muscle. With recent evidence suggesting the influence of

the monosynaptic stretch reflex during gait, the aim of this project is to modify spastic gait by inhibiting the stretch reflex.

The project can be divided into two parts, each with its own specific goal. These goals are: 1) to determine the relationship between latency of stimulation, number of

pulses in one stimulus burst, pulse frequency, and amount of inhibition; and, 2) assuming that the stretch reflex of the triceps surae influences gait, to develop a stimulation strategy during gait which would modulate triceps surae tone.

**Methodology**—The study will involve subjects with mild spastic cerebral palsy. For the first part of the study, subjects will be seated in an Ankle Actuating Device, a computer-controlled system which can impose rotary movements about the ankle joint, causing a passive stretch of triceps surae. The tibialis anterior will be stimulated to inhibit the stretch reflex of triceps surae. Exploratory experiments will be performed to determine the relationship between the number of pulses, the stimulus

frequency, the latency, and the amount of observed inhibition. These results will allow us to determine electrical stimulus parameters that are efficacious in inhibiting the stretch reflex for use in the second part of the project. During gait, stimulation will be timed relative to depression of a footswitch placed on the bottom of a subject's foot. Exploratory experiments will be performed to determine the optimal latency relative to the footswitch depression for each subject. Using the VICON and EMG systems in the Gait Laboratory, an assessment of each subject's gait with and without stimulation will be made.

**Progress**—Equipment and software for both parts of the project has been completed, and the first part of the project has begun.

### [383] Criticality of Fit of Ankle-Foot Orthoses

Johanne McKechnie, BSc; Morris Milner, PhD, PEng, CCE; Stephen Naumann, PhD, PEng  
The Hugh MacMillan Rehabilitation Centre, Toronto, Ontario M4G 1R8 Canada

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

**Purpose**—The purpose of this project is to determine the critical parameters required for effective bracing of the lower limb with ankle-foot orthoses (AFOs). Research on the criticality of fit of AFOs will be conducted to investigate the feasibility of a non-intimately fitting AFOs. AFOs being prescribed today are custom-made for each child, with the leg and foot fitting intimately into the brace. It has been proposed that this intimate fit is required for the proper positioning of the foot to achieve optimal ambulation, and to prevent pressure sores in cases where the skin is insensitive. The fact that AFOs fit intimately creates several undesirable problems: a high production cost, a lengthy production time, and a short usable period.

The remaining sections of the AFO are presumed to play a much less important role. The points critical to the fit will be determined in this research. This project will limit itself to investigating AFOs used to treat valgus foot deformity associated with spina bifida.

**Methodology**—A three-stage approach is planned: 1) a mathematical model for the valgus foot deformity will be defined. X-rays of valgus feet will be examined and current models of feet will be researched to aid in this task;

2) the acceptable corrected foot position and allowable tolerances will be determined. Some subjective input from orthotists and therapists will be required, together with X-rays of foot position in currently used AFOs; and, 3) points where pressure must be applied to bring the foot into a corrected position will be determined. Static analysis will be used in conjunction with the previously defined model and corrected position.

The effectiveness of this bracing approach will be evaluated. An adjustable jig which will allow different children to be tested will be built for this purpose. With the required corrective forces determined and evaluated, follow-up will include building functional AFOs based on the derived information. The AFOs will be evaluated on the children with respect to comfort and function.

**Implications**—Positive results will encourage further design work into a non-intimately fitting AFO. The outcome could be a less expensive AFO constructed in a shorter period of time and with a longer usable period than presently available AFOs. The procedures used in this study could be extended to other foot deformities with the goal of obtaining corrective models and standardized AFOs for the most common foot deformity.



### [384] Quick-Attaching Brace for Improved Paraplegic Mobility

**David Peifer, MD; Andrew Schoenberg, PhD**

VA Medical Center, Salt Lake City, UT 84148; University of Utah Medical Center, Salt Lake City, UT 84132

**Sponsor:** VA Rehabilitation Research and Development Service (Project #B486-DA)

**Purpose**—The goal of this project is to develop a lightweight, full-leg brace with an electrically locking knee joint. The major design requirements for this brace include the ability to: 1) hold 1300 in-lbs of torque around a medial-lateral axis with a brake actuator force of less than 5 lbs; 2) be locked or unlocked in less than 100 ms in any angular position; and, 3) be easily donned and doffed in a few minutes by a paraplegic while sitting in a wheelchair. This brace is intended to be used in combination with electrical stimulation of the leg muscles to allow paraplegics to stand and walk in areas inaccessible by a wheelchair.

**Progress/Results**—The major effort during the last year was made in the development and testing of the knee-joint. A band brake design was used for its simplicity and high mechanical advantage. It consists of a 1.35-inch radius drum covered with neoprene rubber, and a stainless steel band that is tightly wrapped around the drum when locked. The locking force of approximately 3 lbs is supplied by a spring attached to a lever. The brake is normally locked, and is unlocked by pulling on a string wound around a small motor shaft. To reduce weight at the knee joint, the actuator motor is located at the hip. Testing of the latest design has shown that the desired locking torque of 1300 in-lbs is achieved with a spring force of 2.5 lbs. The total lever arm movement required for actuation is approximately 1 inch.

This actuation is achieved with a dc motor that weighs 240 gm, and draws approximately 1 A of current at 12 V during actuation. The motor is able to unlock the

brake in 40 ms. The mechanical design and development of the knee joint are reported in greater detail in a 1990 master's thesis at the University of Utah.

**Future Plans/Implications**—During the remaining 6 months of the current grant, we expect to integrate the Rancho Los Amigos 8-channel stimulator, the actuator electronics, and the leg brace into a working unit, and perform preliminary durability bench testing of the total system. Modifications to the brace and electronics will be made as needed for a configuration that can be tested on human subjects.

The availability of a leg brace that is easily donned and doffed, is lightweight, and is locked or unlocked by electrical actuation would provide a basis of extending ambulatory function for many paraplegics who are now limited to wheelchair mobility. Such a brace may also see wider use. Prosthetists see the need for such a device in older post-polio patients. In these cases, electrical stimulation of paralyzed muscles may not be needed. However, a brace of the weakened leg and knee that locks and unlocks during the gait cycle may significantly improve the ambulation of this population.

#### Recent Publications Resulting from This Research

Design of a Locking Knee Joint for Use with Hybrid FES Systems. Long J, Schoenberg AA, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 375-376, 1990.

A Locking Knee Joint Design for Use with a Hybrid Functional Electrical Stimulation System. Long J, Masters thesis, University of Utah, 1990.

### [385] Comparative Study of 49 Walkers

**John T. Ward, PhD; Elaine Cremaldi; Margaret A. Wyld, PhD; Lee Norrgard**

Institute for Technology Development, Oxford, MS 38655; American Association of Retired Persons, Washington, DC 20049

**Sponsor:** American Association of Retired Persons

**Purpose**—Forty-nine walkers provided by 20 manufacturers were tested by 19 walker users.

**Methodology**—All subjects are using or had used a walker in the past year. Seven of the subjects were 55 to 70 years

old, and 12 were over the age of 70. Conditions leading to walker use included arthritis, hip surgery, fractures, weakness, balance problems, amputation, and paralysis.

Subjects were asked to open and fold, and to lift each walker. They used the walker for assistance in sitting

down and standing up. Each task was timed and subjects estimated their effort level for performing the task. Additionally, a physiograph was used to measure heart rate to determine level of exertion while completing the tasks.

Each walker was used to traverse four different surfaces. Subjects walked 50 feet each on a smooth indoor surface, a thickly carpeted floor, and an outdoor lawn. Subjects also walked 40 feet up and down a 12-degree ramp. Subjects tested walkers while carrying a weighted load and held the walkers in a locked position.

Walkers were categorized by number of wheels. The traditional rigid and folding walkers have no wheels (the "no-wheel" group). "Two-wheeled" walkers are structurally like the no-wheel walkers, but have a wheel on each of the front legs. The newest walker design has a wheel on each leg (the "4-wheel" group). The 4-wheel walkers vary the most in design, not only from the other two groups, but also within the 4-wheel group.

**Results**—The presence of wheels is the strongest predictor of user performance. On all tested surfaces, 4-wheel walkers outperformed 2-wheel walkers, which in turn outperformed no-wheel walkers. The reverse order was observed in opening and folding times, with the more complex 4-wheel walkers requiring the most effort. As an aid to sitting and standing, subjects gauged the

no-wheel and 2-wheel walkers more stable than the 4-wheel walkers.

Among walkers with wheels, there was a strong interaction between wheel size and type and walking surface. Small wheels tended to rattle and jam on uneven surfaces. Large wheels were harder to maneuver in tight spaces, but performed better than small wheels outdoors. Wheels with pivot mounts were easier to turn on all surfaces than rigidly mounted wheels, but were perceived by users as less controllable on uneven surfaces.

Walker height affected both user support and stability. A too-tall walker did not provide proper support; too-short walkers made the user uncomfortably stooped. Walker stability was a function of walker design, adjusted height, and supported weight.

For no-wheel walkers, the greater the weight of the device, the poorer the subject's walking performance.

**Future Plans**—Grip location and orientation on most of the tested walkers violates the standard ergonomic design guidelines for handles. Most of the best-performing walkers exhibited more than average rake on their front legs. Walkers with the base of the front legs or front wheels extended well in front of the hand grip position were perceived as more stable and easier to turn. Further research on these two design aspects is warranted.

## [386a] Free Knee Brace System

**E.N. Biden**

Institute of Biomedical Engineering, University of New Brunswick, Fredericton, NB E3B 5A3 Canada

**Sponsor:** *Canadian Paraplegic Association*

**Purpose**—Individuals who have unstable knees must often resort to long leg braces for support. Walking with two long leg braces, without the ability to bend the knee, is clumsy and tiring. Our purpose, therefore, is to develop a knee brace which can lock and unlock automatically to allow the user's knee to flex as she/he walks.

**Progress**—The system we are building allows knee flexion when the leg is unloaded and being swung ahead, and locks the knee when the limb is loaded. The brace,

which consists of long leg braces for each leg, and a clutch at each knee, has been designed as an electro-mechanical device. Switches under the foot sense what part of the foot is in contact with the floor, a circuit "decodes" the signal, and locks or unlocks the knees as required. A "wrap spring clutch" has been chosen as the most appropriate clutching mechanism, and suitable electronics have been designed. A prototype brace has been built for use in evaluation of the system by our clinical collaborators.

### [386b] Comparison of Velocity and Position Control Strategies for the Case Western Reserve University (CWRU) Upper Extremity FNS Orthosis

Brad Limpert, MASc; Michael Joy, PhD; Morris Milner, PhD, PEng, CCE; Joanne Bugaresti, MD, FRCP(C); Walter Literowich, BEEngT; Stephen Naumann, PhD, PEng; Henry O'Beirne, MA, MASc; Isaac Kurtz, MHSc, BASc, PEng

The Hugh MacMillan Rehabilitation Centre, Toronto, Ontario M4G 1R8 Canada

Sponsor: Canadian Paraplegic Association; Natural Sciences and Engineering Research Council

**Purpose**—Our goals were to: 1) implement a velocity control strategy on the Case Western Reserve University (CWRU) Micromini FNS orthosis; 2) compare the effectiveness of velocity control with position control in the performance of a functional task and a step-tracking task; and, 3) determine the effects of varying the gain and dead-space parameters for a velocity control strategy.

**Methodology**—The Micromini FNS orthosis was designed to provide a C4-C7 quadriplegic person with some limited hand function (i.e., a palmar grasp to prehend large or cylindrical objects, and a lateral grasp to grasp small flat objects).

The CWRU strategy is position control, with hand position directly proportional to shoulder position. Each combination of hand position and force is achieved by modulating the pulse widths of electrical signals stimulating muscles in the hand and forearm.

An alternate strategy (velocity control) was developed wherein the shoulder position determines the rate and direction of change of the output function. In the center of the range of motion is a dead-space, within which a change in shoulder position does not affect the output function. Outside the dead-space, increasing protraction results in an increasing rate of hand closing while retraction causes hand opening.

A computer-based system consisting of software, A/D and D/A converters, and interface hardware was developed to evaluate position and velocity control strategies. Programs were also written to control low-level A/D and D/A routines and to calibrate the joystick.

For the functional assessment, a book (10.5 × 3 × 18 cm weighing 300 g) was moved from a midline resting

position on a table 79 cm high, to a book-holder on a separate shelf.

For the computer simulation tests, a non-random, one-dimensional step-tracking task was used. Three targets appeared on the screen. When a target was highlighted, the participant moved his shoulder so that the cursor would enter the target. To successfully acquire a target, the participant had to keep the cursor within the target for 0.25 s. Fitts' constant (a normalized measure of time) was used to measure performance and was calculated from Fitts' law, that is, time to target = Fitts' constant × log<sub>2</sub>(2 × target distance)/width.

**Results**—Position and velocity control were compared for reaching distances of 46 and 82 cm. At both distances, the mean time with velocity control was less than the mean time with position control. For 46 cm distance, the mean difference was 2.14 s (n=4, p<0.038), while at 82 cm the difference was 24.3 s (n=4, p<0.16).

An additional assessment was performed to determine if the addition of a dead-space to a velocity control strategy improved performance on a reaching task.

**Implications**—Protraction and retraction of the shoulder can be used by C4 and C5 quadriplegics to control velocity or position of a hand or cursor on a computer screen. Performance of velocity control is superior to that of position control. This is probably because in velocity control, any hand position can be maintained when the shoulder is relaxed. In position control, relaxing the shoulder causes the hand to return to its initial position.

### [387a] Further Development of a Protective Helmet for Disabled Persons

Dieter Bochmann, CPO(C), FCBC; Rod Moran, DDS, FRCS(C); Stephen Naumann, PhD, PEng; Steve Ryan, BSc, PEng; Greg Belbin, CO(C); Krista Holdsworth-Bordy, CO(C); Sandy Robinson  
The Hugh MacMillan Rehabilitation Centre, Toronto Ontario, M4G 1R8 Canada

*Sponsor: National Health Research and Development Programme, Department of Health and Welfare, Canada; Cooper Canada*

**Purpose**—The purpose of this project is to develop protective headwear which provides effective head and facial protection for children who frequently fall. The specific goals are to: 1) develop a second generation helmet which provides appropriate anatomical protection, is custom-fitted, comfortable to wear, looks attractive, and is reasonably priced; 2) evaluate the biomechanical performance of the helmet in the laboratory; and, 3) assess the subjective acceptance and performance of the helmet through clinical trials.

**Progress/Methodology**—Creation of the “second generation” prototype has focused on the enhancement of its impact properties and structural integrity. Improvements in liner fit, ventilation, and hygiene are also intended without compromising the helmet’s general cosmesis.

Initially, a preproduction helmet was designed for children with nominal head circumferences in the 490-540 mm range (approximately 5-12 years of age). The prototype consists of a 3-piece, thermoformed Kydex shell—an anterior section, posterior section, and a chin cup—with a full-contact polyethylene foam liner of uni-

form thickness. The assembled helmet is shaped to provide both cranial and facial protection in the event of a fall. Heat dissipation is promoted at the top of the helmet through convection channels in the liner.

To ensure a good anatomical fit on the head, the three shell/liner parts are adjusted, located, and secured in place by an orthotist during the fitting. Further customization of the helmet is possible through the addition of liner inserts and trimming the helmet.

Both biomechanical and clinical testing of the prototype helmets were conducted to verify the concept. While the biomechanical tests demonstrated performance consistent with effective cranial protection, feedback from the clinical trials indicated modifications which should be incorporated into the production version of the helmet to enhance its serviceability.

Production tooling for modified, rotomolded shells and die-cut liners are being produced for both the small and large size helmets. It is expected that these sizes will meet the needs of most children between the ages of 5 and 19.

Biomechanical tests and clinical trials using the production helmets have begun.

### [387b] Evaluation of a Powered Orthotic Device for the Enhancement of Upper-Limb Movement

Robert Galway, BA, MD, FRCS(C); Stephen Naumann, PhD, PEng; Bill Sauter, CPO, FCBC(C); Josephine Somerville, BSc, MD, FRCS(C); Isaac Kurtz, BSc, MHSc, PEng; Ihsan Al-Temen, PEng; Greg Bush, BA, DipO&P; George McMillan; Chris O’Brien, BScOT  
The Hugh MacMillan Rehabilitation Centre, Toronto, Ontario M4G 1R8 Canada

*Sponsor: National Health Research and Development Programme, Department of Health and Welfare, Canada*

**Purpose**—The objectives of this project are to: 1) determine the benefits of a powered orthotic hand and elbow developed at HMRC for people with severe upper limb weakness due to amyotrophic lateral sclerosis (ALS); and, 2) identify future enhancements to the powered orthosis in order to further enhance the independence of individuals with ALS.

**Progress/Methodology**—The powered orthosis consists of two spring-loaded ball-and-socket elbow joints, two steel rods, a rigid rod corresponding to the ulna and a telescoping rod corresponding to the radius, and a hand brace with a single axis joint. The hand joint is opened and closed in a palmar grasp by a linear actuator, and the elbow is activated by the power winch unit. When the

elbow joint is flexed, the forearm is partially supinated due to the diagonally-applied force on the ulnar rod and the extension of the telescoping radial rod.

**Powered Linear Actuator.** Housed in a slender aluminum tube, the linear actuator is powered by a commercially available motor/gear box combination. A one-quarter-inch ACME screw is attached directly to the gear-box output shaft and is supported by an anti-thrust ball bearing to support axial loading in both directions. The screw engages with a nut located at the end of the orthosis to achieve the desired moment at the hand. At the end of the actuator, a swivel bracket is provided to mount the assembly onto the orthotic frame. The system operates on six volts, has a stroke of 1.5 inches (which is greater than other actuators) and is able to deliver a force of 14 lb. Plans are underway to commercialize the linear actuator through Variety Ability Systems Incorporated (VASI).

**Powered Winch Unit.** The powered winch unit also utilizes a commercially available motor/gear box combination. The motor is mounted to an aluminum housing and a shaft extension, integral with a worm, is attached to the gear box output shaft. The shaft extension is supported by an anti-thrust ball bearing to support axial loading in both directions.

The worm engages with a worm wheel, which is coaxially coupled to a small timing pulley. The worm

gear/pulley assembly is straddle-mounted in the aluminum housing by two ball bearings. A timing belt is threaded over the timing pulley and is secured by two fixed idler rollers located on each side of the pulley.

One end of the belt is attached to the housing, while the other end of the belt is attached to an appropriate point on the forearm. A limit switch triggered by the belt when the elbow is in full flexion, is provided as a safety feature. The unit is designed to be used interchangeably for the left or right arm of a powered orthosis user.

Myoelectric signals from the frontalis and procerus muscles are being used for control of the elbow and hand. The left and right sides are used for flexion and extension respectively. The user contracts the muscles on both sides of his forehead to switch between elbow and hand control.

Five individuals with ALS will be fitted with the powered orthosis. The usage of these devices will be monitored electronically with a miniature data-logging device. Subjects will be asked to fill out a questionnaire to evaluate the usefulness of the device for various functional activities and the cosmetic appearance of the device. A therapist will assess the subjects' ability to type, eat and manipulate objects with and without the device.

**Results**—This study is in progress and no results can be reported at this time.

### [388] Development of a Water-Resistant Covering for AFOs During Recreational Activities

**Greg Belbin, CO(c); Mendal Slack, BSc(HK), CO(c)**  
Hugh MacMillan Rehabilitation Centre, Toronto, Ontario M4G 1R8 Canada

**Sponsor:** *Hugh MacMillan Rehabilitation Centre, Prosthetic/Orthotic Service Department*

**Purpose**—The purpose of this research is to develop a durable and cosmetically appealing cover that provides protection and support for asensitive limbs and ankle-foot orthoses (AFOs) during recreational activities in and around the water. Abrasions from concrete and sand can develop into pressure sores, cause disuse of orthoses, restrict activities, increase deformity, and even necessitate surgical procedures.

**Progress/Methodology**—Five different prototypes underwent various static and dynamic tests on two

subjects. The final prototype design is now being tested on several subjects and will be assessed for durability, ease of application, cosmesis, functional ambulation, water, and sand resistance.

**Future Plans**—These covers will eventually become a marketable product available to all certified orthotists for fitting and dispensing.

### [389] Development of a Powered Orthosis for Lower Limbs

Hiroyuki Miyamoto, MD; Yasuhisa Sakurai, MD; Ikumasa Nakajima, MD; Noriya Akamatsu, MD; Yoichi Shimazaki; Kenji Tokimura

Department of Computer Science, Chiba Institute of Technology, Chiba 275 Japan

Sponsor: *Institute of Physical and Chemical Research, Agency of Science and Technology, Japanese Government*

**Purpose**—In order to restore an appropriate gait pattern, a powered orthosis is being developed for paralyzed lower limbs that will support the patient's body and control lower limb movement. As a final goal, the powered orthosis will enable paraplegic patients to walk on level ground with a variable cadence, to stand and sit, and to go up and down a staircase by appropriate command.

**Progress**—Considering the results obtained experimentally through preceding years, a second prototype was designed and constructed. Its main purpose was to have a powered orthosis for lower limbs of an appropriate size, so that control methods explored in the past several years could be tested on paraplegic patients. The orthosis was fabricated in carbon-fiber reinforced plastic (C-FRP), and in thigh and femur parts, and four electrohydraulic actuators were incorporated. These actuators now have digital controls, in contrast with the first prototype which used an analog type. Each actuator is controlled by a single-board microprocessor, and all of these are totally controlled by a host microcomputer. Sensory systems such as foot-switch sensors to detect plantar contact, optical encoder to measure relative joint angle, and posture sensor to measure torso inclination in sagittal and frontal planes are used to accomplish a stable powered walk. The orthosis itself weighs 19.5 kg, and its control wagon 68 kg, which should be moved with the powered walk. A powered orthosis will be realized using these two components.

**Preliminary Results**—After having checked the basic function of the powered orthosis on a normal subject, it was tested on two paraplegics: both patients could walk with this powered orthosis, grasping the rail of the wagon for balance. This second version of the powered orthosis has sufficient torque for powered walk. After some modifications of the software program, one of the patients realized a powered walk at a cadence of 4.5 second/step, while the former cadence was 6.0 second/step.

**Future Plans**—Since the first tests on paraplegics have been successful, the control methods developed on the first prototype will be applied to the second prototype to improve the function of the orthosis. As two orthoses have been constructed which are identical except for geometrical size, all the control methods will be thoroughly tested on normal subjects prior to the clinical tests.

The interface between the patient and the powered orthosis should be improved for practical use of this device.

#### Recent Publications Resulting from This Research

Powered Orthosis for Lower Limbs. Miyamoto H, Ueda K, Sano A, Mori S, Nakajima I, Akamatsu N, Sakurai Y, in Proceedings of the 11th Biomechanism Symposium (SOBIM Japan), 221-230, 1989 (in Japanese).

Powered Orthosis for Lower Limbs. Miyamoto H, Sakurai Y, Nakajima I, Akamatsu N, in Proceedings of the 3rd French-Japanese Biomedical Technologies Symposium, 245-248, 1989.

### [390] Development of a Practical, FES-Powered Walking Orthosis for Paraplegics

M. Solomonow, PhD; R.V. Baratta, PhD; R. D'Ambrosia, MD; P. Beaudette, RT(OP); N. Rightor, CO; W. Walker, CO  
Bioengineering Laboratory, Department of Orthopaedics, Louisiana State University Medical School, New Orleans, LA 70112

Sponsor: *Louisiana Board of Regents (LEQSF Grant)*

**Purpose**—The purpose of this study was to develop the first practical, commercially available walking orthosis for paraplegics which could be used at home, without medical supervision and assistance, and at realistic metabolic energy cost to allow prolonged function in standing up, sitting down, and walking on flat and inclined surfaces.

**Progress/Preliminary Results**—The Louisiana State University reciprocating gait orthosis (LSU-RGO) powered with electrical stimulation of the thigh muscles was further developed to allow independent standing and walking on inclines at reduced energy cost. A large number of patients were fitted and followed up in the last 3 years.

**Recent Publications Resulting from This Research**

The RGO Generation II: Muscle Stimulation Powered Orthosis as a Practical Walking System for Thoracic Paraplegics. Solomonow M et al., *Orthopedics* 12:1309-1315, 1989.

Energy Consumption of Paraplegics Ambulating with the Reciprocating Gait Orthosis Powered with Electric Stimulation of the Thigh Muscles. Hirokawa S et al., *Arch Phys Med Rehabil* 71:687-694, 1990.

**[391] Functional Biomechanical Characterization and Functional Design Specification: Orthotics**

**Dudley S. Childress, PhD; Robert L. Van Vorhis; M.D. Brncick; H.J. Krick; K. Mesplay; P.P. Peng; J.S. Rovick; V. Sanchez; J.W. Steege**

Northwestern University, Rehabilitation Engineering Program, Chicago, IL 60611

*Sponsor: National Institute on Disability and Rehabilitation Research*

**Purpose**—The objective of this project is to investigate the potential of orthotic devices to control the position/motion of the bones. The function of an orthotic device is to control, limit, or stabilize the position or motion of the skeletal structure. However, the intervening soft tissues between the orthosis and the bones of the skeletal system complicate this task.

By investigating the potential of an orthotic device to control the motion of the bones, we will determine bounds for the functional limitations and effectiveness of such devices. The emphasis of this study is on the knee joint and the potential for knee orthoses to control the relative motion of the femur and tibia.

**Progress**—The initial phase of this project examined the current practice of orthotic management of the knee joint. The intended function of knee orthoses may be broken into three categories: 1) skeletal stabilization; 2) motion restriction; and, 3) control of active motion. Skeletal stabilization devices, such as knee-ankle-foot orthoses, are used by persons with functional deficiencies who are unable to support their body weight on their legs. The success of a stabilizing orthosis is easy to judge: evaluate whether the human functional deficit has been compensated. The success of a motion restriction orthosis or motion control orthosis is more difficult to gauge and is the focus of this work.

A survey of orthoses for motion restriction and control was made, and revealed that a single method of attachment to the body is in common use: a proximal cuff for attachment to the thigh, a distal cuff for attachment to the calf, and a pair of hinges connecting the two cuffs together. The main difference between the motion control devices and the motion restriction devices is that the motion restriction orthoses employ limit stops on the hinges and, since restriction orthoses are primarily used post-traumatically and post-surgically, they incorporate thick foam pads between the orthosis and the leg. These pads are thought to exacerbate the problem of controlling bone motion, and therefore, the more tractable problem of the motion control orthosis is analyzed first.

Orthotic cuffs interface to the limb along the length of the thigh and calf, but the greatest conformity of the cuff geometry to the limb geometry is in the region of the knee joint and the anterior tibia. Conformity in these areas is intended to provide the best grip between the orthosis and the bone. However, due to the large degree of motion at the knee, the underlying soft tissue structures experience a high degree of spatial rearrangement (e.g., skin folding) when the knee is flexed or extended, and there is some question as to whether the orthosis is gripping the bones or gripping the mobile soft tissue. An experiment has been designed and is now being used to gauge the effects of tissue mobility around the knee joint.

## [392] MED Arm: A Six-Degree-of-Freedom Orthosis Simulator for Tremor Research

Michael J. Rosen, PhD; Scott Maxwell; Fletcher McDowell, MD; Mindy Aisen, MD

Newman Laboratory for Biomechanics and Human Rehabilitation, Mechanical Engineering Department, Massachusetts Institute of Technology, Cambridge, MA 02139; Burke Rehabilitation Center, White Plains, NY 10605

Sponsor: National Institute on Disability and Rehabilitation Research; Burke Rehabilitation Center

**Purpose**—The focus of this project is the design, fabrication, and testing of a 6-degree-of-freedom (DOF) computer-controlled energy-dissipating manipulandum known as the MED (Modulated Energy Dissipation) Arm. Its function is to serve as a test bed for assessment of the effects of resistive loads on people disabled by movement disorders during functional whole-arm movements. The device may be viewed as a human-interactive orthosis-emulator which will allow experimental evaluation of the effectiveness of practical designs for tremor-suppression orthotics with a single laboratory facility. It is also expected to serve as: 1) a tool for objective measurement of tremors; 2) a differential diagnostic system; and, 3) a prototype compliant restraint system for tremor reduction in functional activities.

In its initial configuration, the MED Arm controls its magnetic particle brakes to behave as viscous dampers. Control of brake torque is open-loop, with the system's end-point 6-axis force/torque sensor serving only for data acquisition. The "shoulder" and "elbow" joints of the Arm are linked mechanically, effectively providing one rotational joint, and one prismatic joint. As a result of this, and the design of the three distal DOF, the forces and torques produced by the brakes all operate through a single end-point, and all act along and about respective orthogonal axes. It is this property that gives the system its force-velocity colinearity.

**Progress**—Fabrication and bench testing of the MED Arm have now been completed. A number of objective tests have been conducted to characterize the performance of the MED Arm. Results include the following: 1) the brakes used for the distal three axes produce a maximum force with which translations at the end-effector can be resisted of 14 lbf; 2) the measured maximum translational friction at the end-effector is 0.25 lbf or less depending on direction; 3) force-deflection characteristics at the Arm end-point with the brakes at maximum current to prevent slip showed a worst-case stiffness of 19 lbf/in;

and, 4) the Arm is completely counterbalanced so that no *weight* is perceived, only inertia. The effective passive inertia of the Arm at the end-point is 10 lbm or less, depending on the direction of applied force.

**Methodology**—The initial experimental protocol included two components described as Abstract and Functional. All parts of both protocols were performed at four levels of damping chosen to span the range of values provided by the Arm. In the Abstract tests, subjects were asked to observe a randomly moving target on a video screen and track it by movements of the Arm in a vertical plane aligned with the screen. For the Functional testing, a protocol was developed based on a standard clinical rating system. Activities performed by the subjects "wearing" the Arm included nose-to-finger tests, handwriting, Archimedes Spiral, water pouring, soup eating, and name-spelling on an expanded QWERTY keyboard.

**Results**—Preliminary human testing has been performed with three subjects, two tremor-disabled and one able-bodied, to begin evaluation of the effects of using the Arm. Data shows clear improvement with increased damping in the Functional test performance for both disabled subjects and a corresponding change in Abstract test results for one of them.

**Future Plans/Implications**—Experiments of the types described above will continue with additional subjects. Additional development tasks will be undertaken, including revision of the control algorithms to produce more sophisticated loading schemes. The effects on tremor of long-term use as a functional aid will also be measured.

### Recent Publications Resulting from This Research

A Modulated-Energy-Dissipation Manipulator and Application to Suppressing Human Arm Tremor. Maxwell S, PhD diss., Massachusetts Institute of Technology, 1990.



---

**[393a] Knee Flexion Alarm**

---

**Subrata Saha, PhD; Winn Johnson; J.A. Albright, MD**

Department of Orthopaedic Surgery, Louisiana State University Medical Center, Shreveport, LA 71130

Sponsor: *National Science Foundation*

**Purpose**—Diseases that affect the peripheral nervous system (e.g., cerebral palsy), may only affect sensory feedback pathways rather than the entire system. For children in this situation, an appropriate feedback device can assist in proper walking without constant observation by another person. A student at the Caddo School for Exceptional Children has such perceptual problems, in addition to having very weak muscles. He often does not know where his body is in space; thus, he falls when he bends his knee beyond a certain angle. A knee flexion alarm device was designed for this student.

**Methodology**—The device requires two separate signals; one is a reference, the other corresponds to the flexion angle of the knee brace. By comparing the two signals, the device will signal the child when the proper condition is not present. With a variable reference to the angle of flexion at which the device signals the child, gradual training can be performed wherein the child learns, at his own rate, to maintain the proper knee position.

The circuit for such a device was built. The positive input is the reference voltage which can be set by adjustment of the 20 K-ohm potentiometer, each voltage corresponding to a particular angle. The negative input to the LM339 is connected to the 10 K-ohm potentiometer, which is mounted to a knee brace that the child wears. This voltage changes with the angle of the knee brace, which corresponds to the flexion angle of the child's knee. The 10 K-ohm potentiometer is connected so that as the flexion angle of the knee increases, so does the

voltage. Depending on the setting of the 20 K-ohm potentiometer, when the knee is flexed to an angle equal to or greater than necessary, the output of the LM339 drops enough to provide the required voltage across the piezoelectric buzzer to activate the buzzer, and the child hears an audible sound signaling that the knee is flexed too much. A switch allows the device to be turned off when needed, and an LED with a current-limiter resistor indicates whether the device is on or off.

The 10 K-ohm potentiometer is mounted to the knee brace. One part of the mounting holds the potentiometer and clamps to the upper part of the brace. The other part clamps to the shaft of the potentiometer and is strapped to the lower part of the brace. A cable runs from the potentiometer, terminating in a small box housing the circuitry, and worn on the child's belt. A belt clip mounted to the box allows the device to be worn without inconvenience or discomfort, yet allows for easy placement or removal.

**Results**—Whenever the student using this device hears a beep from the black box attached to his belt, he remembers to straighten his knee. This has allowed him to be more mobile and independent. The gait of this student also improved, because the alarm system helped him to increase knee extension during stance phase and he has learned to walk in a more erect fashion.

An electronic device has been built that, when attached to the long leg brace of a handicapped person with sensory deficit, provides an audio signal when the knees are in excessive flexion.

---

**[393b] Upper Extremity Training Device**

---

**Subrata Saha, PhD; Winn Johnson; J.A. Albright, MD**

Department of Orthopaedic Surgery, Louisiana State University Medical Center, Shreveport, LA 71130

Sponsor: *National Science Foundation*

**Purpose**—Some children confined to wheelchairs have difficulty using crutches or a walker due to an inability to support their body weight with their arms. With proper training, these children can learn to support themselves with their arms and eventually learn to use crutches or a walker. This transition from wheelchair to crutches or a

walker can be very beneficial to the child, allowing him to become more mobile and independent.

The purpose of this project was to design and build a device to measure the amount of vertical force a child applies while performing a shoulder depression motion. When the actual level of force being applied exceeds a

desired level preset by the therapist, the child receives reinforcement through the activation of a toy connected to the device. The therapist can increase the desired level until the child is able to apply enough vertical force to support his own body weight. After this goal is reached, the child can begin training in the use of crutches or a walker.

**Methodology**—The upper extremity training device consists of two force sensing plates (for the left and right sides), a control box for the therapist, and two stages of reinforcement.

Each force-sensing plate is constructed from one-quarter-inch aluminum tooling plate and contains a 200-lb load cell (A.L. Design, Inc., Model ALD-W-2) as the force transducer. The output of the load cell is fed into a three op-amp amplifier circuit. Two of the three op-amps provide high input impedance into the amplifier, and the third op-amp provides differential amplification of the two signals from the load cell. Since the voltage output of the load cell is proportional to the force being applied to it, an adjustable gain on the amplifier is required in order for the amplifier to maintain adequate

levels of output at low levels of input force. The amplified output from the load cell is compared with the potentiometer-controlled, desired-level set point using an LM339 comparator chip. When the actual level exceeds the desired level, the first stage of reinforcement is activated.

The first stage of reinforcement is simply an LED for each side. When the actual level from the load cell exceeds the desired-level set point, the comparator output goes to a “low” state and the LED lights up. When the actual load level exceeds the desired level on both sides, the second stage of reinforcement occurs.

**Progress**—A prototype model has been built and is presently being tested.

**Future Plans/Implications**—Actual use of this device cannot begin at the Caddo School for Exceptional Children until the beginning of the new school year. However, discussion with the physical therapist indicates that this device will be beneficial in teaching these children to support their body weight with their arms and eventually use a walker or crutches.

### [394] CEDO: A Controlled-Energy-Dissipation Orthosis for Tremor Reduction in Activities of Daily Living

**Michael J. Rosen, PhD; Fletcher McDowell, MD; Mindy Aisen, MD; Ivan Baiges; Allison Arnold**  
Newman Laboratory for Biomechanics and Human Rehabilitation, Mechanical Engineering Department, Massachusetts Institute of Technology, Cambridge, MA 02139; Department of Spinal Cord Injury, Burke Rehabilitation Center, White Plains, NY 10605

**Sponsor:** *National Science Foundation; Burke Rehabilitation Center*

**Purpose**—People disabled by large amplitude pathological intention tremor (e.g., people who have multiple sclerosis or have had closed head injuries), are often incapable of undertaking activities of daily living independently in spite of normal strength. As a means of selectively suppressing relatively rapid oscillatory movements and exposing voluntary activity, these investigators have developed a 3-degree-of-freedom wheelchair-mounted compliant orthosis which dissipates energy in a frequency-dependent way. It has the approximate geometry of a standard commercial mobile arm support (“ball bearing feeder”), but incorporates computer-controlled magnetic particle brakes at each joint. The “elbow” brake is mounted on the support fixture and coupled to the joint by a parallelogram linkage in order to make it unnecessary for the user to move its mass when using the

device. The brakes are controlled to behave as viscous dampers whose damping constant is adjusted as a function of end-point position. Functional activities in a large part of the normal seated range of motion are permitted.

**Progress**—Experiments have been conducted with eight tremor-disabled patients to determine the short-term effectiveness of the CEDO in selective tremor reduction. These tests have included both simulated functional activities and objective tracking tasks. In virtually all cases, tremor was significantly reduced and signal-to-noise-ratio was improved (i.e., voluntary movement was attenuated less than tremor, if at all). Often, a value of damping was found between the extreme value and none which appeared to offer the optimal effect. The bulk of these tests were conducted at the Burke Rehabilitation

Center without on-site engineering involvement, indicating the reliability and user-friendliness of the device.

**Future Plans/Implications**—Experiments will continue, using the above protocol. In addition, tests of longer-term effects will be conducted since the system may be viewed as a resistive exercise machine. Further, an investigation of the effect on user performance of the system's force-velocity noncolinearity will be conducted. (The device geometry does not produce resistive force aligned with velocity at the user's arm for all end-point locations.)

### [395] Mobile Arm Support

**P. Watson, BSc, PhD, AMIMEchE, AASME; R.G.H. Wallace, MCh(Orth), FRCS**  
The Rehabilitation Engineering Centre, Musgrave Park Hospital, Belfast BT9 7JB, N. Ireland

**Sponsor:** *None listed*

**Purpose**—This device provides a support for patients who have reduced arm control through neuromuscular weakness (particularly because of degenerative conditions like muscular dystrophy).

**Methodology**—The patient's arm is supported in soft slings above and below the elbow which allows for free movement in any direction—the volume of accessible space limited only by the patient. The patient's arm is weightless and therefore requires virtually no effort to move. The device can be adjusted to suit the arm weight of each patient individually. The benefits are patient independence and in the recreational and vocational areas. The use of physiotherapy is also promoted.

### [396] Lifting Seat

**P. Watson, BSc, PhD, AMIMEchE, AASME; R.G.H. Wallace, MCh(Orth), FRCS**  
The Rehabilitation Engineering Centre, Musgrave Park Hospital, Belfast BT9 7JB, N. Ireland

**Sponsor:** *None listed*

**Purpose**—This device assists patients to move from a seated to a full standing position.

**Methodology**—The patient is supported on a seat base which remains horizontal until the standing position. The seat armrests follow the movement, providing support

Discussions are presently underway with an orthotics manufacturer with a view to licensing the design for marketing.

#### **Recent Publications Resulting from This Research**

Development of a Whole-Arm Orthosis for Tremor Suppression. Baiges IJ, Rosen MJ, in Proceedings of the 12th Annual RESNA Conference, New Orleans, 290-291, 1989.

#### **Patents**

Whole-Arm Orthosis for Damping of Tremor. Michael J. Rosen and Ivan Baiges, MIT Docket Number: MIT-5229. Patent applied for: June 25, 1990.

**Progress**—The device has progressed from a laboratory prototype to a production prototype and is being tested by patients at a local day-care center. The units can be wheelchair-mounted or floor-mounted as a workstation.

**Preliminary Results**—Patients who have used the arm support show an almost immediate change in mood because of their new ability. Range of movement, where any existed previously, seems to increase within minutes.

**Future Plans**—These devices will be produced inexpensively by a local company.

when the patient is upright, allowing easy transfer to a walking frame if needed.

The seat is raised using an airbag arranged in a novel way which reduces the pressure required and also keeps the pressure in the bag almost constant throughout the lift. The airbag is inflated by a vacuum cleaner motor and

could, for example, in a nursing home situation, be adapted to run from a compressed air system supplying many seats. The lift is entirely patient-controlled and can be halted at any stage.

**Progress**—A production prototype is being developed. Variations in form will be examined (i.e., a unit that can be slotted into a wheelchair or an armchair), or built into an armchair, etc.

**Preliminary Results**—The laboratory prototype could raise an 85 kg man to a fully standing position in approximately 5 seconds. This can be adjusted so that the rate at which a frail or nervous patient rises is limited. The potential maximum lift in this configuration, with the pump supplying 2.5 psi, was 170 kg.