

## II. Orthotics

### The Role of Pressure Distribution Measurement in Diabetic Foot Care

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Peter Cavanagh, Ph.D. and Lee J. Sanders, D.P.M.  
Veterans Administration Medical Center, Lebanon, PA 17042  
Sponsor: VA Rehabilitation Research and Development Service

**Progress**—Research activities to date have included the completion of Phase 1, instrumentation development, at Penn State University (PSU). Activities at PSU have included the development of a new calibration jig, configuration of new computer hardware, and the development of software for the collection, processing, averaging, and display of pressure data. Activities at the Lebanon VAMC have included the identification of 100 possible diabetic subjects for Phase 2 participation.

Phase 2, data collection and treatment, began with a comprehensive medical screening of 87 patients. Examination included a comprehensive neurological screening with testing for deep tendon reflexes; plantar response; proprioception; hot/cold discrimination; sharp/dull discrimination; and vibratory sense with quantitative assessment of vibratory perception thresholds (VPTs), using the Bio-Thesimeter. Sensibility testing for protective levels of sensation (light touch and deep pressure) was accomplished using Semmes-Weinstein monofila-

ments. Patients were then placed in risk categories based upon loss of protective levels of sensation and elevated VPTs. An orthopaedic/biomechanical examination was also performed to identify underlying structural and functional abnormalities of the lower extremities, and Harris Mat footprints were made for all patients. In addition, dermatological examination and vascular assessment with computation of ankle/arm indices were accomplished for all patients.

**Preliminary Results**—The records and data collected for all of these patients were then reviewed, and criteria were established for the inclusion or exclusion of patients. Criteria for inclusion will include VPTs  $> 20$ , loss of protective levels of sensation, history of previous plantar ulceration, and structural deformity that would predispose the patient to plantar ulceration. Patients selected were then randomly assigned to two groups—enhanced care and standard care.

### Biomechanics of Knee-Ankle-Foot Orthoses

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S. E. Solomonidis; C. Szary; D. Gozal; J. P. Paul  
University of Strathclyde, Wolfson Centre, Glasgow G4 ONW Scotland  
Sponsor: Scottish Home and Health Department

**Purpose**—Work is still in progress on the previously reported project at the University of Strathclyde to determine the loads on knee-ankle-foot orthoses (KAFO) during patient activity (see *VA Rehabilitation R&D Progress Reports—1985*). The experiments are being carried out at the Biomechanics Laboratory of the university in association with various Glasgow-area clinicians. The purpose of the investiga-

tion is: 1) to determine and analyze the loads acting on various components of the orthosis during ambulation; and 2) to determine the load actions between the orthosis and the patient with a view to establishing realistic design criteria, the ultimate aim being the development of lighter and more comfortable orthoses.

**Progress**—An extensive survey of the available

literature on the subject showed that the loads applied on KAFOs to date have not been fully evaluated. Thus, at present, it is not possible to predict with any certainty the magnitude and direction of the major load actions. Therefore, it was decided to design and build a measuring system capable of analyzing loads in three dimensions. The system employs several specially built multichannel load transducers capable of measuring three forces and three moments (i.e., axial force, A/P and M/L shear, torque along the long axis on the orthosis, and A/P and M/L bending moments). The transducers are fitted to each section of the uprights—that is, proximally at the medial and lateral sides, and distally at the medial and lateral sides. Additionally, special miniature transducers measure the tension of the knee apron and other straps. When the instrumented patient/orthosis system is used in conjunction with gait analysis facilities, such as force platforms and kinematic measuring systems recording the spatial configuration of the KAFO and patient's limbs, it is

possible to determine the loads transmitted by the orthosis and the supported limb. This system has been used to acquire loading data on several categories of patients wearing various types of KAFOs (conventional or modern "cosmetic" type).

**Preliminary Results**—It was found that the most critical loads on a KAFO from a structural point of view are the A/P and M/L bending moments. Stress analysis on the various components of the KAFO indicated that in certain cases, the magnitude of loads recorded during the experiments can cause fatigue failures despite the apparently robust construction of these orthoses. Detailed design study has shown that generally there is an inefficient distribution of material. Several cases of KAFO failures experienced during patient activity were studied, and appropriate recommendations for design modifications were made. This study has also given us a better understanding of the biomechanics of the orthotic devices.

## Technical and Clinical Evaluation of Self-Fitting Modular Orthoses (SFMOs) \_\_\_\_\_

**Dejan Popovic**

University of Belgrade, 11000 Beograd, Yugoslavia

*Sponsor: National Institute of Handicapped Research and Scientific Community of Serbia*

**Purpose**—Self-fitting modular orthoses are intended to compensate for partial or total impairments of locomotor functions. The mechanical system can be used in higher thoracic and lower cervical lesions in combination with the plastic corset to maintain the body in an upright position. Total SFMOs can be applied to middle and lower thoracic lesions with pelvic caps (if the hip control is needed), or in any combination of six independent SFMO modules (the ankle, the knee, and the hip module).

The SFMO application is indicated for partial and total paraplegics (lesions above T4) and for patients with multiple sclerosis, transversal myelitis, muscular dystrophy, and similar impairments.

Currently, investigators are combining SFMOs with the Hybrid Assistive System (HAS), a new method of gait restoration being

developed to provide hybrid orthoses for motor restoration.

**Progress**—Prefabricated elements are used in the SFMO technology. Production methods permit the use of the device immediately after the onset of the disability. Fitting and assembling the orthosis requires no tools. In a supine or sitting position, the patient is able to put the device on with no assistance in less than 3 minutes. This orthosis is attached to the lower extremities in trousers similar to ordinary blue jeans. The usual method of trousers adaptation is the simple sewing of textile pockets to the lateral side of the trouser legs.

SFMOs are equipped with cybernetic actuators (CA). Three phenomena could be achieved with CA: anisometric contraction (flexion and extension of the joint), isometric contraction

(locking of the joint in the desired position), and damping-control/stiffness-regulation. The CA is equipped with nonlinear limiters to prevent jerking and is electrically powered, enabling several hours of daily locomotion between battery charges.

It is accepted that walking with calipers is less effective than wheelchair propulsion or functional electrical stimulation (FES) gait, that patients do not like the weight of an active brace, that they are permanently exposed to the danger of suffering from pressure sores, and that psychological acceptance is extremely low. The proposed new method of gait restoration, HAS, is a combination of FES and external bracing controlled by an expert system. First experiments with quadriplegics and quadriparetics encourage promoting such an approach as a step in the development of efficient motor neuroprostheses.

As it is known, FES is a very effective movement generator. Recruitment properties are superior compared to exoskeleton joint actuators if the upper motor neuron is affected. Total neurophysiological lesion of the upper neuron, lower motor neuron impairment, and muscle denervation prevent FES from being applied. An exoskeleton is excellent for providing body support without causing muscle fatigue, and when a soft interface is used, no pressure sores occur. Parallel action of these two systems with appropriate controls is called hybrid orthoses for motor restoration.

HAS components include the following:

- 1) A six-channel stimulator with surface electrodes. Each channel is activated independently; pulse rise is exponential; pulse width, IPI, and pulse frequency are under microcomputer control. This type of stimulation repre-

sents the modified principle used and developed by the Ljubljana group.

- 2) SFMOs with CA in hip and knee joints. Used for external bracing.

- 3) Sensors for feedback. Potentiometers, pendulum potentiometers, tacho generators, and a set of force transducers and switches built into the insole are used.

- 4) Microcomputer based on Intel 8085 microprocessor including appropriate input/output, parallel port, analog-to-digital converter, a clock, random access memory, and read-only memory.

- 5) Nickel-cadmium rechargeable batteries, used as a power supply.

Control methodology is based on non-numerical principles formulated in the form of an expert system. The knowledge base consists of production rules and expert knowledge in the form of so-called artificial reflexes. The learning is built into the system as well.

**Preliminary Results**—Testing of the system has been done in the “Dr. Miroslav Zotovic” Rehabilitation Center in Belgrade, Yugoslavia, proving some of the postulated qualities of the rehabilitative device: dynamics, safety, new range of functional movements, walking on slopes and stairs, etc.

In the present form of the system, there are certain limitations in range of movements arising from problems with stability, dynamic properties of the system, microcomputer capabilities, etc. The posture stability problem has not been solved, and hand support is in fact *sine qua non*. Decreasing hand-support forces—power expenditure through the upper part of the body for gait—is one of the main targets of system evaluation.

## A Viscoelastic Knee Brace for ACL-Deficient Patients

M. Solomonow, Ph.D. and R. D'Ambrosia, M.D.

Louisiana State University Medical Center, New Orleans, LA 70112

Sponsor: *United Cerebral Palsy of New Orleans*

**Progress**—An orthotic design incorporating a constant velocity hydraulic chamber activated near the final segment of the swing phase to be

worn on the knee of patients with anterior cruciate ligament deficiencies was designed and evaluated. The brace reduces terminal impact

velocity of the knee's extension to speeds that will not induce joint instability without limiting the joint range of motion.

A patent was issued and assigned to a manufacturer for commercial distribution of the brace.

## Standing Frame Lift Mechanism

Scott Griffith

Westinghouse Defense and Operations Division, Baltimore, MD 21203

Sponsor: *Volunteers for Medical Engineering, Inc.*

**Purpose**—A team of volunteers from the Volunteers for Medical Engineering, Inc. (VME) have been donating their time and talents to design and fabricate a Mobile Standing Frame that will allow the paraplegic person to stand and to wheel around as one would do with a wheelchair. A second purpose of the work is to develop a means for the handicapped person without upper body strength to transfer from the wheelchair to the Mobile Standing Frame without an electrically powered device.

**Progress**—The initial design is similar to one produced many years ago except that it now incorporates regular bicycle wheels and a unique braking system. We are presently building a production prototype for evaluation.

Some of the persons who could use this mechanism have a problem getting into the device from their wheelchair either because they have very little upper body strength or are insufficiently stable to maneuver into the standing position. A team of people is currently working on a tethered waistband system wherein the person using the frame is rigidly attached to the waistband section of the frame. This section is in turn attached to a cable that is also attached to the return coil spring mounted to the frame. Thus, when someone unlatches from the main frame, the individual is still at-

tached via the cable to the frame and the associated coil spring.

As the person bends at the knees to begin to sit down in the wheelchair or any other seat, the spring extends and the spring-loaded tether begins to increase its tension. The force exerted by the spring is tailored to the forces needed to just suspend the person. Therefore, when the person wishes to again rise from the seated position, very little upward force is required for this action.

A person may disconnect from the tether by latching the spring-loaded cable tether in the fully extended position and, with the twist of a lever, disconnecting the waistband from the tether attachment. One is then free to leave the standing frame. An individual may get back onto the Mobile Standing Frame by simply reattaching the waistband to the tether and releasing the catch so that the cable is again free to pull on the waistband and in so doing raise the person to the standing position.

**Future Plans**—The design and analysis will be continued, and the layout of the tether mechanism will be completed. Proposals will be submitted to the VA, to the Paralyzed Veterans of America, and to other agencies soliciting their aid for funding of this ongoing project.

## Design of External Joint Assemblies Using CAD-CAM Techniques

Peter S. Walker, Ph.D.; Joshua Rovick; Robert Schrage ; Mark Madson  
Veterans Administration Medical Center, West Roxbury, MA 02132

Sponsor: *VA Rehabilitation Research and Development Service*

**Purpose**—The goal of the project is to automate the design of orthotic surfaces and external

hinges for application to the knee, elbow, and other joints.

Efforts thus far have centered on the design and prototyping of a data acquisition system for three-dimensional digitization of body surfaces. Initially, various commercially available technologies were investigated. They lacked 1) ease of use and adjustability for different body surfaces; 2) cost-effectiveness; and 3) any means for collecting information on the material properties of the tissue. For these reasons, we pursued a prototype design for a general-purpose, medium-cost, and direct-contact method of digitization.

**Progress**—The initial prototype may be described as a mechanical hand whose spring-loaded fingers run along the surface to be digitized while maintaining a constant contact force. When a button is pressed, the host computer (Apple IIe) stores the angular position of the fingers with respect to the hand and concurrently locates the hand's position in space using a six-degree-of-freedom electromagnetic sensor available from Polhemus Navigation Systems. The surface points may then be reconstructed relative to a fixed axis system. Data acquisition speed is limited by the 60-Hz sampling rate of the sensor; with the two fingers presently incorporated, data acquisition speed is limited to 120 points per second, but the speed could be increased to 480 points per second by utilizing eight fingers. Information about the material's compliance can be obtained by varying the constant force exerted by the fingers in subsequent digitizations and noting shape change.

Software was written to allow data acquisition, geometrical reconstruction of the digitized points, and graphical presentation of the X, Y, Z data points. For resolution, accuracy, and reproducibility analysis, programs that calculate digitization error from standard shapes such as planes, solid blocks, and cylinders, were developed and are being used to identify error sources. The data so far have indicated that the coordinate error has a standard deviation of about 1 mm.

**Preliminary Results**—Three problems need to

be overcome before the data generated by this technique can be used. The first is that of data reduction: the user, in order to ensure that enough data points have been taken to describe the surface adequately, will make multiple passes over the same area, resulting in what will often be "too much" data. By filtering recursive points, the programs will run faster and more efficiently. Before this algorithm can be fully developed, a number of initial estimates must be examined to determine the magnitude of data that is sufficient to describe a surface.

The second problem concerns surface reconstruction. Because of the error inherent in the system, as well as the potential for motion of the surface during digitization, there will most assuredly be some three-dimensional displacement of successive groups of points, e.g., those generated from different strokes of the fingers. Because this displacement can include components of both translations and rotations, the problem of correlating data is a significant one. To date, the majority of the work done on this problem has been in the form of a literature search. Some mathematical algorithms involving bicubic parametric patch geometry principles have been developed that will be coded and tested on data generated by artificially inducing error into mathematically described surfaces.

The third problem is that of surface smoothing. The necessary conditions of the patch algorithm perform smoothing to some extent, assuring that adjacent patch segments are continuous in position, as well as first and second derivatives. Nevertheless, some additional smoothing, in the form of postprocessing, will most likely be necessary. As with the above problem, a number of algorithms that perform surface smoothing are available and are currently being studied.

**Future Plans**—A computer numerically controlled milling machine (CNC) will be interfaced to a MicroVax II computer system. Using a redesigned prototype digitizer and computer surface reconstruction algorithms, body surfaces will be replicated with the CNC. These

tools will then be used to study and parameterize body surface shapes, build anthropometric

databases, and begin automated External Joint Assemblies (EJA) design.

## Orthotics

**J. D. Harris; C. Eng; M. W. Whittle, M.D.**

Oxford Orthopaedic Engineering Centre, Oxford University, England

**Sponsor:** *U.K. Department of Health and Social Security*

**Progress**—Assessment has been carried out on a wide range of lower limb orthoses in a gait laboratory with the “Vicon” motion analysis system and two “Kistler” force platforms. As a direct result of this work, an anti-hyperextension brace has been developed that reduces the shock impact to the posterior capsule of the knee on full extension while permitting normal knee flexion.

Another orthosis developed at the Centre is the “Cherwell” ankle foot orthosis, which provides valgus foot support while allowing flexion of the ankle. This is achieved by means of a

closely fitting polypropylene calf support and a separate foot cup, joined by a carefully aligned hinge at the ankle. The freedom of movement of the ankle joint while supporting the subtalar joint and the foot greatly improves walking, particularly over uneven ground, and allows activities such as driving. A “modular shoe” concept has been developed that allows patients who cannot be fitted with stock size shoes to be provided in approximately 1 to 2 hours with a pair of well-fitting shoes from a range of styles. The shoe is of a three-part modular construction assembled by means of adhesives.

## Lightweight Knee Joint for Child-Size Orthoses

**Ian R. Mortimer; William E. Fisher; Barry R. Seeger**

Rehabilitation Engineering Department, Regency Park Centre for Young Disabled, Kilkenny, S.A. 5009 Australia

**Sponsor:** *Rehabilitation Engineering Department, Regency Park Centre for Young Disabled*

**Purpose**—Current knee-ankle-foot orthoses usually consist of molded thermoplastic cuffs with metal knee joints, which are the heaviest components. Excessive weight in orthoses can be an impediment to greater mobility with smaller children. This project aims to develop a lightweight plastic knee-locking joint that is easily fixed to the plastic thigh and lower leg cuffs of the orthoses.

The new joints will be lighter in weight

than existing metal joints, will have a more acceptable appearance, will be smoothly finished to avoid clothing damage, and will be available in free or locking types. Prototype joint design and testing is in progress, with completion of the development expected in 1987.

This project is being conducted in collaboration with the School for Mechanical Engineering, Regency Park Community College.

## Development of a Powered Orthosis for Lower Limbs

**Yasuhisa Sakurai; Hiroyuki Miyamoto; Yoichi Shimazaki; Kenji Tokimura**

Institute of Biomedical Engineering, Tokyo Women's Medical College, Tokyo, 162 Japan

**Sponsor:** *Office for Life Science Promotion of the Institute of Physical and Chemical Research, Agency of Science and Technology, Japanese Government*

**Purpose**—To obtain an appropriate gait pattern, a powered orthosis for paralyzed lower

limbs is being developed that supports the patient's body and controls 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**—The first prototype of the powered orthosis has been developed, consisting of an exoskeletal frame to support the body and four electrohydraulic linear actuators to motorize hip and knee joints. A microcomputer and sensory system are used to generate and control the prescribed gait pattern. This gait pattern should be modified according to the patient's actual walking condition. A posture sensor has been developed and used to control the center of gravity displacement so that a stable powered walk can be obtained. It is attached on the orthosis and operates independently of environmental conditions.

Two control methods have been studied on normal subjects to evaluate the effectiveness of each method: 1) an autonomous powered walk by the use of a posture sensor; and 2) interactive control with crutches.

**Preliminary Results**—By method 1, continuous even-level walking and a transient movement from the upright state into level continuous walking was realized on a normal subject by controlling the trajectory of the center of gravity. We verified that powered walking is stable

even in the presence of some disturbances. In 1985-86, transient movement from walking into the upright state was realized using the posture sensor.

By method 2, several essential level-walking movements such as beginning and ending the walk, continuous walking, and change of cadence were realized. Climbing up and down a staircase was accomplished in 1985-86. The ease of operating the command was verified; the patient can start or stop the powered walking by lifting one of the crutches or by keeping them in contact with the ground for a specified period of time. The patient can regulate the cadence by changing the timing of lifting the crutches during walking.

Some additional studies are being carried out to simplify the communication between the patient and the powered orthosis-walking state display to enable the patient to feel upper torso inclination, to feel how the center of gravity is moving via posture, and to feel when the feet are in contact with the ground. It allows the patient to operate the powered orthosis in order to accomplish a stable powered walk.

**Future Plans**—A second prototype of the powered orthosis will be constructed and evaluated on paralyzed patients. Most of the analog control instruments will be replaced by digital ones to improve control and reliability of the system.

## Molded Shoe

Peter M. Graf, D.P.M. and Richard M. Stess, D.P.M.  
Veterans Administration Medical Center, San Francisco, CA 94121  
Sponsor: VA Rehabilitation Research and Development Service

**Purpose**—This project was undertaken to fabricate a molded shoe, using foam injection technology already established in the commercial shoe industry, at markedly reduced cost (approximately \$10 per pair) and at significantly shortened delivery time (48 hours or less) with no loss of therapeutic effectiveness. Such a shoe would be useful in the treatment of patients suffering from foot problems secondary to vascular disease, diabetes, deformity, arthritis, and

peripheral neuropathy.

**Progress**—A prototype ultrasonic range-of-motion measuring instrument was developed and utilized to assist in capturing the foot in a biomechanically efficient position. A tubular fiberglass resin foot casting system was developed in collaboration with the 3-M Corporation. Both control and at-risk patients were selected via screening procedures established jointly

with the departments of metabolic endocrinology, radiology, and podiatry. Ultrasound, thermography, aesthesiometry, and doppler imaging were utilized in risk stratification.

A small on-station shoe manufacturing laboratory was established to evaluate various methods and materials in custom shoe design. The purchase of a Resimix polyurethane injection molding unit allowed evaluation of foam material and its usefulness in custom-molded shoe design. Functionally molded sandals were

fabricated for a material cost of less than \$10 and in less than an hour of bench time.

**Future Plans**—The following devices will be developed, tested, and refined: 1) an electronic measuring instrument to accurately position the foot while it is being cast; 2) a mechanical casting system to duplicate the boot being cast; and 3) an injection molding system and variable shape mold.

### Bioengineering Research and Development at Instituto Mecánica Aplicada (IMA)

L. C. Nava and P. A. A. Laura

Instituto de Mecánica Aplicada (CONICET) Base Naval Puerto Belgrano 8111 Argentina

*Sponsor: Consejo Nacional de Investigaciones Científicas y Técnicas, Argentina*

**Purpose**—Work in the Applied Bioengineering Section of the Instituto de Mecánica Aplicada has continued in the last 3 years in the following directions: rehabilitation engineering, sports for the disabled, and optimization of general medical and/or hospital equipment.

*Cuff-Adjustable Forearm Crutches.* The efficient mechanical operation of forearm crutches requires a quasi-perfect compatibility between the hand and forearm of the handicapped and the orthotic device. This compatibility requirement is based on geometric, kinematic, and dynamic conditions. The forearm-cuff fit is a fundamental parameter. Crutches with cuffs adjustable in a continuous fashion developed at IMA have proved extremely successful in the

case of handicapped children.

*The IMA Brace for Deambulatory Treatment of Legg-Perthes Diseases.* The IMA II brace offers several advantages in comparison with conventional braces designed for use by children. Highly improved kinematic characteristics are obtained by the use of six joints placed symmetrically at two levels of the brace. A basic feature of the present device is that it simulates the pumping effect produced by the congruent movement between the femoral head and the acetabulum, resulting in activation of the circulation in the femoral head. On the other hand, the design of the brace is such that it minimizes the restrictions placed on the child's daily activities.