II. Orthotics

A. Lower Limb

B. Spine
II. Orthotics

A. Lower Limb

[See also pg. 212]

The LETOR System for Lower Limb Support and Locomotion Assessment

**Purpose** — A lower extremity telescopic orthosis (LETOR) has been designed to offer a simpler, lighter, effective, and comfortable stabilizing aid for paraplegia.

**Progress** — Over the past few years the modified versions of the LETOR have been tested with 34 paraplegic and quadriplegic patients at six rehabilitation units including EFTO in Jönköping, Sweden. During these trials, the design has proved its main advantages:

1) Easy fitting to a patient without any individual fabrication; and
2) Comfort both in the standing and relax-sitting position.

In a number of cases, when knee-joint extensors were being activated due to the telescopic action, the afferent stimulation was gradually increased to eliminate overbracing.

The extra light carbon fiber version of the LETOR is under development at the Svensk Handikappteknik AB.

Appropriate instrumented orthosis is now the research objective in extending the assessment procedure of paraplegic locomotion. The proposed method is based on the hypothesis that the level of aperiodic elements in paraplegic locomotion plotting remains in relation to the degree of reconstruction of the reflexive gait pattern generator in the spine.

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Development of a Powered Orthosis for Lower Limbs

**Purpose** — A powered orthosis for paralyzed lower limbs is being developed that supports the patient’s body and controls lower limb movement to obtain an appropriate gait pattern. As the final goal, the powered orthosis will make it possible for a paraplegic to walk on level ground with a variable cadence, and to go up and down a staircase on appropriate command.

**Progress** — The first prototype of the powered orthosis has been developed. It consists 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 is used to control the center of gravity displacement so that a stable powered walk can be obtained. It is attached to the orthosis and operates independently of environmental conditions.

Two control studies on normal subjects evaluate the effectiveness of each method: 1) autonomous powered walk by the use of posture sensor; and 2) interactive control with crutches. In the first method a stationary level walking and transient movement from the upright state to stationary walking have been realized on a normal subject by controlling the trajectory of the center of gravity. The study also verified that posture sensor powered walking is stable even in the presence of some disturbances. In the second method several essential level walking movements, such as beginning and ending of walking, stationary walking, and change of cadence have been realized and its easiness of the command has been verified. The patient can start or end the powered walking by lifting one of the crutches or by keeping them in contact with the ground longer than a certain 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 facilitate communication between the patient and the powered orthosis. This is done through a walking state display that enables the patient to grasp how the upper torso is inclined, how the center of gravity is moving via posture, and when the feet are in contact with the ground. It allows the patient to control the powered orthosis to accomplish stable walking.

Electromechanical Walking System for Paraplegics

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Purpose — Evaluation of several functional electrical stimulation-based (FES) walking prototypes developed in other laboratories has revealed the weakness of a total FES approach in this problem. The primary concern is that simple and frequently occurring electronic malfunctions such as broken electrode lead, or loose or improperly calibrated stimulus could cause the patient to lose the upright posture, collapse, and incur additional injury. Other disadvantages included human factors, considerations such as hard-to-reach electrode sites, confusing multi-electrode configurations, and the need to suspend the patient from the ceiling for safety.

More serious shortcomings of current prototypes include the stimulation modes to induce hip flexion necessary for the swing phase. The use of induced flexion reflex could be applied to a very limited number of patients and becomes unreliable within 6-9 steps due to habituation of the nervous system to the stimulus. The use of the pendulum effect of fast release of knee flexion induced by FES results in high-impact force of the foot with the ground, high-energy losses, and the need for the patient to constantly lean forward, which is risky and uncomfortable.

Our conclusion was that although the potential of FES-induced walking is promising, current prototype systems are still substantially remote from being practical and reliable for routine clinical applications.
Progress — Our approach consisted of providing selected patients with the three necessary subfunctions for safe and reliable walking, i.e., upright posture, ipsilateral hip flexion (swing phase), and contralateral hip extension (forward progression). Hip flexion was to be made with FES application whereas upright posture and contralateral hip extension were provided with the use of the Louisiana State University (LSU) reciprocating gait orthosis. The orthosis consists of a long leg brace with pelvic band and the support straps on the lumbar and thoracic levels for balance and stability. The two hip joints of the brace are connected with Bowden cable in such a way that hip flexion results in simultaneous contralateral hip extension. Under such circumstances, if the FES subsystem fails, the patient will lose his ability for FES-assisted walking, but will remain standing, balanced and stable.

Application of the brace to 44 paraplegics demonstrated its functional utility; several patients were able to walk without FES assistance using swing around gait. Parallel preliminary animal studies last year show that stimulation of the L-2 and L-3 roots can effectively stimulate 75 percent of the iliopsoas muscle group and induce substantial hip flexion. The results are applied toward using such a stimulation approach in human patients.

A Viscoelastic Knee Brace for Anterior Cruciate Ligament Deficient Knee

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Purpose — Damage to the anterior cruciate ligament is a major cause of knee instability in athletes. The most common procedure is the application of a knee brace, which will limit the knee’s range of motion to 15 to 20 degrees of full extension. Although such a brace provides some stability in the varus-valgus and less in the rotational planes, it restricts the knee in the anterioposterior plane and causes several undesirable side effects. During athletic activity, high angular velocities in extension cause a substantial terminal impact, and subluxation and tibial rotation are avoided because of the limit imposed on range of motion; vibrations and forces are thus transmitted from the brace to the soft and bone tissue, causing unacceptable discomfort to the athlete. Furthermore, maintaining the knee at less than full extension (15 to 20 degrees flexion) effectively shortens the leg’s radius from the hip joint to the foot compared with the contralateral normal leg and results in deficient gait and excessive fatigue of the quadriceps muscle group, which compensates with increased activity to lock the knee at partial flexion.

Progress — Assuming the viscoelastic properties of the anterior cruciate ligament and the absence of instability during low angular velocities of the knee in extension as in normal cadence, a speed-regulated viscoelastic knee brace was designed. The viscoelastic chamber provides constant velocity for forces in the range of four to 1200 pounds and is programmed to be activated by a cam during the last 20 degrees before full extension. The constant velocity can be adjusted over a range and should be set below the highest angular velocity that results in instability for the individual patient. Such arrangement allows full range of
motion under controlled conditions at terminal extension without the risk of instability due to subluxation and tibial rotation.

Current work focuses on improving the hinge mechanism of the brace and evaluating several offset and polycentric joints.

Load Analysis of Knee-Ankle-Foot Orthoses

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Progress — Eight post-polio adult patients, one normal adult subject and ten spina bifida children have participated in the project. Although the 3D load actions on the knee-ankle-foot orthosis (K.A.F.O.) uprights have been obtained from the custom-built transducers, interpretation of the loads at the various attachment points of the orthosis and on the orthosis/patient interfaces is complex due to the statically indeterminate load system. To facilitate in the analysis, shear force transducers to measure the forces at strap attachment points have been added.

The short-term aim of the project is to provide data on the loads on the orthosis for design purposes. The patient activities under investigation are: walking on a straight line, walking round a double bend, walking round a U-shaped path, stepping up and down a low platform, and ascending and descending stairs and slopes. So far the maximum values of the critical bending moments on the K.A.F.O. uprights were found to be 33 Nm in the anterioposterior direction (while descending a slope) and 15 Nm mediolaterally (while walking around a double bend).

Foot and Shoe Interface Study

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Purpose — Peripheral neuropathy associated with diseases, such as diabetes mellitus, often causes severe deficiency in transmission of sensory modalities in the lower extremities. Such losses impair the protective mechanisms and render the extremities vulnerable to the effects of applied forces of every day ambulatory activity. This not only results in skin ulcerations but may also cause hyperemia and inflammation secondary to trauma. Many diabetic patients with foot ulcers are seen at the VA Medical Center and often there is difficulty in achieving healing because means to reduce repetitive plantar pressures are inadequate. Required are criteria for prescribing interface materials and means for evaluating effectiveness of materials chosen.

The hypotheses in this study are:

1) Plantar pressure ulcers in hypo or insensitive feet may be effectively treated by use of appropriate interface materials.

2) Physical properties appropriate for the selection of interface materials can be determined.
3) Adequacy of static load distribution properties of an interface material can be determined by use of a barograph.

Progress — During clinical testing, patients with established findings of peripheral neuropathy, diabetic or non-diabetic, are seen periodically to monitor condition of the insole. For those with ulcerations of the plantar surface the width, breadth, and depth of the ulcer are measured and recorded. Patients’ weight and ambulatory habits are noted and the thickness of the used insoles are measured at points of maximum compression set. If the thickness is 50 percent or less than the original thickness, the insole is collected and a new one issued. Vibratory perception thresholds on the foot and legs of patients seen for the first time are mapped. Attempts are made to refine definition of the “at risk” boundary among patients. Appropriate plantar barograms are obtained. For patients with severe ulcer areas, total contact casts to unload the ulcer area during ambulation are used. After the ulcer heals and scar tissue matures, thick heat molded insoles and sandals are used during ambulation. For selected patients composite insoles, consisting of a heat molded element cemented to an open cell noncompression set material such as PPT to SPENCO to evaluate their efficacy, are issued.

During laboratory testing, time-related and nontime-related properties of a variety of candidate materials for insoles are evaluated. Recovery properties of collected insoles are determined.

Preliminary Results — Method of treatment influences success in patient care. For the not “at risk” patients, unmolded, small-cell foamed polyethylene insoles are satisfactory. Issuing four sets for daily change allows partial recovery from compression set. The “at risk” patients require two-stage treatment: the total contact cast during ulcer healing followed by thick heat molded insoles and sandals while scar tissue matures.

Future Plans — Since this project is nearing completion, the plan is to continue collection and analysis of data toward the objective of defining prescription criteria.

San Francisco Molded Shoe

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Purpose — Research continues on the development of a molded therapeutic shoe. The purpose of this work is to lower both fabrication costs and time as well as providing improved biomechanical molded footwear for patients with diabetes mellitus. Many diabetic patients with foot ulcers have had to undergo foot and leg amputations as a result of the prolonged manufacturing process required for custom footwear. Additionally, the positioning of the foot during the traditional casting method has not been standardized and thus optimum foot support, accurate arch height, and biomechanical efficiency have not been achieved.
**Progress**—The research and development thus far has been directed at the following:

1) Development of a casting platform to assist in accurate positioning of the foot to standardize and assure reproducibility of the molding process.

2) Development of an electronic ultrasound measuring instrument which assists in obtaining the neutral position of an individual's subtalar joint. This is achieved by measuring the internal and external rotation of the leg. This instrument will be used in the casting phase of the shoe development.

3) Designing a molding system to accept polyurethane foam for different shaped feet and lasts.

4) Developing a system for low cost shoe fabrication.

A casting platform has been constructed with the intention of having patients in a seated position while having the thigh, leg, and foot maintained at 90 degrees. A constant force is applied from the plantar surface of the foot. The incorporation of an adjustable chair, thigh restraints, and foot plate has allowed reproducible positioning.

An ultrasound measuring instrument has been developed that measures transverse plane leg rotation. The internal and external leg movement that accompanies supination and pronation of the foot is measured by ultrasound waves transmitted to leg-mounted receivers. An electronic display of the movement has been incorporated into the instrument. The measured range of motion is evaluated and the foot is then placed in its neutral position during casting guided by the instrument.

A polyurethane resin casting material is being used to obtain the accurate shape of the foot and ankle. Once the exact replica of the foot has been obtained, the cast is removed and modified. A vinyl barrier is created around the last and the polyurethane is injected into this mold just after a shoe upper has been attached to the last. The midsole and upper are then removed and a sole adhered. A sandal design has been selected as the first shoe to be created and tested by patients.

Patients will be characterized as to their neurological, vascular, foot structure, and biomechanical status. This will be accomplished through ultrasound technology, doppler, aesthesiometry, thermography, biothesiometry, physical examinations, as well as other noninvasive methods. Once stratified into risk groups, selected patients will be placed into a San Francisco Molded Shoe of different styles (e.g., sandals, oxfords). The patients will be monitored and evaluated as to the therapeutic effectiveness of the shoe. The shoes will likewise be evaluated relative to wear characteristics, design, patient acceptance, and biomechanical efficiency.
B. Spine

[See also pgs. 202, 206]

Analysis and Design of Optimal Halo Systems

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Progress — Suspension or traction halos applied to patients with cervical fractures are fairly effective in stabilizing the spine in the early period of application. Screw loosening, normally seen after the initial period, is followed by infection and removal of the halo.

We studied the role of the following factors in improving the bone-screw interface: screw length; screw diameter; screw thread-turn density; and, angle of rotation in suspension halo.

Computer simulation showed that a short screw of larger diameter with high thread-turn density can improve the bone-screw interface substantially. Some 40 percent to 72 percent cumulative reduction in shear stress, torque, and compressive force is possible. The data obtained are evaluated from the realistic standpoint to provide guidelines for the design of an improved halo system.

Retrodisplacement and Spondylolisthesis — Brace Treatment

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Purpose — This project proposes to study the effect of bracing on homogenous low back pain patients classified by the presence or absence of either excessive anterior or posterior translation on flexion-extension radiographs.

Progress — Patients with back pain of four weeks' to one year duration are classified into four groups: retrodisplacement — worse in extension; retrodisplacement — worse in flexion; spondylolisthesis (of any type); and, normal translation. Each classified group is randomly assigned to flexion, extension, or non-specific education treatment. Flexion and extension treatments include specific education and exercises as well as brace treatment.

To accomplish these specific aims, the following hypotheses will be tested:

1) Patients with radiographic retrodisplacement (reverse spondylolisthesis) and low back pain of greater than four weeks' duration who demonstrate greatest displacement on an extension radiograph will respond more favorably to a flexion orthosis than three other patient groups: (a) those with the same X-ray findings treated with an extension orthosis, (b) those with the same X-ray findings treated with nonspecific low back education, and (c) patients with normal radiographic translation treated with the same disregard orthosis.

2) Patients with radiographic retrodisplacement and low back pain of greater than four weeks' duration who demonstrate greatest displacement on the flexion radiograph will respond more favorably to an extension orthosis than three other patient groups: (a) those with the same radiographic findings treated with a
flexion orthosis, (b) those with the same radiographic findings treated with nonspecific low back education, and (c) patients with normal radiographic translation treated with the same extension orthosis.

3) Patients with radiographic anterodisplacement (spondylolisthesis of any type) and low back pain of four weeks’ duration will respond more favorably to a flexion orthosis than three other patient groups: (a) those with the same X-ray findings treated with an extension orthosis, (b) those with the same X-ray findings treated with nonspecific low back education, and (c) patients with normal radiographic translation treated with the same flexion orthosis.

4) The response to either a flexion or extension orthosis can be predicted by: (a) radiographic measurements, and (b) clinical symptoms and signs, or psychosocial variables.