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A. Lower Limb

Design and Evaluation of a Knee Orthosis

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Sponsor: Northwestern University
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The primary objective of this project is to improve orthotic treatment in the rehabilitation of the knee joint. Many knee orthosis designs do not achieve their intended goal because of mechanical or kinematic mismatches, which lead to motion restriction or binding, misalignment of the orthosis on the limb, and discomfort due to skin pressure problems. In response to the above situation, this laboratory has designed and developed an improved orthotic knee joint and complete knee orthosis. It was intended that this orthosis system be applied to total joint replacement cases, as well as other ligament-related problems of the knee joint.

The improved orthotic joints are semi-constrained and anatomically shaped, and were shown to have minimized the pistoning constraint normally associated with orthotic joints. Stability is added to the joints by the sequential tightening of a set of inextensible Dacron straps crossing the joint, simulating the knee ligaments. Anterior cruciate, posterior cruciate, and collateral ligament strap configurations were designed. Since the orthotic joints minimize the pistoning constraint, significant improvements to the orthotic interface could be realized, increasing its suspension to the lower limb. Interface improvements, based on a four-point suspension principle, include the use of a medial femoral suspension pad and a proximal tibial suspension member, each with its associated strapping arrangement.

At the beginning of this reporting period, the designs of the orthotic joints and the complete orthosis were finalized. The search for a competent and reputable manufacturer/orthotics laboratory was completed. The orthotic system was scheduled to be available to the public at large in mid-1984.

In the last reporting period, our biomechanics unit established a formal, ongoing Knee Rehabilitation Clinic, in collaboration with the Rehabilitation Institute of Chicago. Through this clinic, an evaluative clinical series has been ongoing during the present reporting period for the purpose of making design refinements to the orthosis system. The clinic team has worked with Northwestern’s Center for Health Services and Policy Research to develop an improved methodology for the clinical evaluation of people receiving the orthosis, as well as other knee rehabilitation procedures. The knee clinic and evaluation will continue during the coming reporting period, but will be refocused to follow and evaluate selected people receiving the finalized orthosis design, using the improved clinical evaluative methodology mentioned above.

A laboratory evaluation method for knee orthoses was in the process of being developed during this reporting period. The technique was an instrumented spatial linkage and microprocessor to measure knee motion before and after application of an orthosis and to directly determine whether the orthosis is actually performing as it should.

During this reporting period the electrogoniometer, a calibration procedure, and the associated computer software have been constructed or developed. Actual evaluations will be performed during the upcoming reporting period.

An Investigation into the Mobility of the Cerebral Palsied Child

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The principal activity of this research program is the investigation of the influence of polypropylene ankle-foot orthoses (AFO) on the gait of cerebral palsied children. The ultimate objective is the production of guidelines for the prescription, production, and use of the AFOs with cerebral palsied children suitable for routine clinical purposes. In addition to this main activity, a limited number of prototype wheeled mobility aids have been evaluated clinically for more severely involved cerebral palsied children.

Gait analysis is being conducted using the TV-computer gait analysis system installed in the biomechanics laboratory. Information is being obtained on the nature of the external moments in the sagittal plane at the hip, knee, and ankle generated by the ground-to-foot force vector. The influences on these
moments of the characteristics of AFOs and associated footwear adaptations are being measured. Load transducers and EMG are being used to monitor the interface conditions between the AFO and ankle-foot complex in the laboratory setting, and also over a longer period of time in other environments.

Initial investigations have been conducted on eight cerebral palsied and six normal children resulting in over 200 test runs. Further measurements are being obtained from additional children.

Analysis of the initial data has been completed. This has indicated that significant alterations to the ground-to-foot force vector and the external moments generated at the joints result from the use of an AFO. In addition, significant changes may also result from very small alterations in the characteristics of the associated footwear, such as their wedge and rocker properties.

Technical and Clinical Evaluation of the Self-Fitting Modular Orthosis

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Research activity on the Self-Fitting Modular Orthosis (SFMO), described in this report, is taking place at the Faculty of Electrical Engineering, Belgrade, and at the Rehabilitation Institute “Dr. Miroslav Zotovic,” Belgrade.

The Self-Fitting Modular Orthosis is an assistive device for lower limb functional impairments. It is an adaptive, modular, lightweight external skeleton with soft interface. The goal of this project is to introduce this particular assistive device to general use in rehabilitation. Some of the properties of the SFMO which have already been verified are: self adaptivity to the body parameters, self adjustment to the human joints, soft interface providing favorable pressure distribution when external power is applied, orthosis portability, simple maintenance, and modularity.

Perhaps most important, however, is the possibility of integrating the SFMO with functional electrical stimulation (FES), thereby creating a hybrid orthosis (HO). The term hybrid orthosis is used here in the sense of a device which organizes parallel effects of FES, SFMO, and any existing (impaired) human neuromuscular function which may be potentially useful in locomotion.

Such “organized parallel action” can be expected only when full compatibility of the artificial and natural systems exists in terms of energy, force transmission, and control. Achieving what we have just described is the central point of this project for evaluating control strategy with the man/machine system.

The model of the hybrid orthosis and the preliminary testings of the device, are based on the use of SFMO with cybernetic actuator, FES techniques developed at the Rehabilitation Engineering Center at Ljubljana, and nonnumerical control applying aspects of artificial intelligence. Recent experience suggests many advantages possible with successful application of hybrid orthosis: (i) the possibility of using available metabolic energy for functional movements; (ii) low external energy consumption; (iii) full application of available capabilities of the handicapped individual; (iv) increased patient safety; (v) reduction of fatigue during stance phase of gait; (vi) extended locomotion endurance; (vii) the use of hands in gait limited to a role in maintenance of balance instead of use to apply energy in gait; and, (viii) the “openness” of the biomechanical system possible with a hybrid system of the type modeled.

Prescription indications for hybrid orthosis include lesions and disorders of the central and peripheral nervous systems, including myopathies that have compromised severely the function of locomotion.

Preliminary studies with patients show that hybrid orthosis can be realized and that its possibilities are far greater than those of the individual components. One of the most important advantages of this approach is seen as the hardware and software “openness” of the system.

Further research activities are mainly directed toward a strategy of stimulation in order to achieve reliable bipedal locomotion with no hand support, cybernetic actuator development for orthotic purposes, software development based on artificial reflex arcs, and new special SFMO component development and evaluation.
A Motion-Guiding Load-Bearing External Frame for the Knee

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The objective is to design an external linkage that reproduces normal knee motion, which can be incorporated into knee braces and external hinge-distracters. It is believed that accurate motion will avoid excessive surface contact forces, and will guide the ligaments into correct length patterns.

A study of the motion of the normal knee was completed in the first year of the project. Internal-external rotation, varus-valgus, a-p translation, and vertical translation were described mathematically in terms of flexion angle. The data were used as input in computer programs to generate the geometries of external linkages which would reproduce this normal motion. The first linkage was a cam in a housing in conjunction with a pin in a slot, while the second linkage was a series of pins guided by slots. Conventional machining methods were used to produce prototypes of these designs, but the complex curvatures made accuracy difficult to achieve. Recently, N.C. machining has been used to produce accurate and reproducible parts. The important feature of the linkages is that the lateral and medial motions are different. On the lateral side there is considerable posterior translation of the femur with respect to the tibia with flexion, while on the medial side there is a smaller forward translation. The result is a net posterior translation of the femur on the tibia with flexion together with an internal rotation. This motion is considered to be important in its compatibility with the internal surface geometry of the knee, and in reproducing correct ligament length patterns.

The linkages, whether used in a brace or in a hinge-distractor, must be as small as possible, while having adequate wear resistance and strength. To test the wear, a 10-channel machine was constructed, which provided oscillatory motion under a constant load. Wear depth was regularly monitored using micrometer gauges. The geometry of the specimens was a metal rod located transversely on the edge of a plastic sheet, reproducing and rolling over the plastic surface. A variety of potentially viable materials were tested, including homopolymers, copolymers, and powder of fiber reinforced polymers. In all cases, the rate of wear under sliding conditions far exceeded that under rolling, some materials surviving only a few thousand cycles for 2 mm of wear. This was due to the combination of increased internal stresses and temperature buildup caused by the friction. The most successful materials to date have been Torlon™ and Delrin™, both of which are being tested further. Ultra-high molecular-weight polyethylene, used in total joint replacement, had too low a yield strength under the high contact stress conditions of our test.

The prototype linkages, using Delrin™, were incorporated into a leg brace. The importance of the cuff design and the accurate location of the linkages on the knee were recognized. The cuff design depends upon the application, whether prophylaxis in sports, post-injury or post-surgery, or for chronic instability. However, certain common principles such as correct overall geometry, location on bony landmarks, adequate surface area, cuff-to-skin friction, and adjustability must be accounted for. The prototype demonstrated good comfort, accurate motion, and lack of cuff slip in subjective testing to date. Instrumented linkages were constructed to obtain objective data. Strain gauges were applied to the upright bars which connect linkages to the tibial cuff to determine the forces and moments acting at the hinge location during activities. An electronic system consisting of bridge circuits, a-d converter, and microcomputer was assembled. Our anatomical motion design will be compared with fixed hinges and polycentric hinges with uniform lateral and medial motions. It is hoped to demonstrate the advantages or otherwise of reproducing more anatomical motion.

[See also IV. Spinal Cord Injury, B. Medical Treatment, Longitudinal Assessment of Physical Therapy Factors that Affect Quality of Life of Persons with Spinal Cord Injury]

B. Upper Limb

Assessment of Hand Function and the Development of Wrist-Hand Orthoses

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The Tayside Rehabilitation Engineering Services is responsible for the delivery of hand orthoses to a population of 180,000. Interest in improving existing knowledge of prescription criteria for hand orthoses,
as well as methods of fabrication and fitting, led to the initiation of this project.

A series of instruments have been developed that can be used in clinical practice to objectively assess hand function. The equipment consists of pinch, grasp, and skin shear transducers (the latter to assess recovery of skin sweating). The equipment is being used both to assess the immediate improvements in hand function that may be achieved by the application of orthoses, and to assess hand function recovery with time. Work is currently progressing in the development of software to permit the transducers to be interfaced to a microcomputer to produce graphical presentations suitable for use by the clinic team.

The same research team also is working on the development of modular hand orthoses, typically for application following traumatic injury. The correct timing of orthotic fitting in these cases is extremely important for the patient rehabilitation program, and the development of a modular system that can be assembled quickly is therefore highly attractive. A torque transducer has been fabricated to measure finger joint stiffness characteristics, and to compare these with the characteristics of orthoses. Commercial orthoses, as well as those developed in our own workshops, have been tested and their characteristics compared with the required characteristics derived from patient measurements.

A study of stimulus parameters for the frequency modulation aspect of the coding scheme has revealed that using bursts of pulses, in which the number of pulses in each burst is made to vary according to the burst-repetition rate presented, affords a more easily discriminated code. With that scheme, subjects can distinguish six different frequencies in the range of 2.0 Hz to 55 Hz with at least 90 percent accuracy.

An innovation of the electrotactile system being developed in this laboratory is the use of chronic indwelling electrodes that stimulate the skin subdermally. This technique provides sensations that are more distinct, more consistent, and more comfortable than can be obtained with more conventional surface stimulation.

It is our ultimate intention to drive these indwelling electrodes via an implantable stimulator to diminish the amount of externally worn hardware needed for the system.

Present efforts are concerned with the design of an implantable-array electrode which will afford access to several adjacent regions of skin for implementation of the spatial position aspect of the feedback system. The work includes an investigation to specify the optimum number of electrode sites to employ in order to maximize the rate of information transfer.

Sensory Substitution System for Grasp Force and Hand Position Feedback

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A sensory feedback system is being developed to provide conscious information about grasp force and extent of hand opening in quadriplegic individuals who use FNS (functional nerve stimulation) orthoses to achieve grasp. Electrical stimulation of the user’s skin in the region of the upper arm or upper back is being used as the basis for inputting the sensory information. The coding scheme being developed uses frequency modulation to signal the level of grasp force and uses the spatial position of the stimulation to signal the spatial extent of hand opening.