DEPT. of HEALTH, EDUCATION, and WELFARE
NATIONAL INSTITUTE of HANDICAPPED RESEARCH
DIVISION OF REHABILITATION ENGINEERING

Joseph E. Traub, Division Director

Rehabilitation Engineering Center
New York University Medical Center
Institute of Rehabilitation Medicine
400 East 34th Street, New York, N.Y. 10016

Joseph Goodgold, M.D., Project Director

Investigators: V. Byrne, R.P.T., M. Clagnaz, B.E.E., R. Dickey, O.T.R., R. Kolwicz, H. Louie, A.A.S., K. Ragnarsson, M.D., T. Reich, M.D., G. Heiner Sell, M.D., C. Stratford, O.T.R., M. Youdin, M.E.E., and M. Zimmerman, M.A., O.T.R.

Evaluation of Electronic Self-Help Devices for Use by Severely Disabled Persons

All of the items within the following listing are currently undergoing long-term comparative clinical evaluation trials. Current findings on a single device or complete device category are available on written request. Summarized findings and other pertinent product information have been compiled for contribution to ABLEDATA and are available through ABLEDATA brokers, nationwide.

Environmental Controls—BSR / Sears Remote Control System; Bard-Carba Environmental Control System; Commutron ENCO-IV; Commutron TOSC-2; MED Micro DEC; Possum PSU-2; Prentke-Romich ECU-1; Prentke-Romich ECU-2; Prentke-Romich PA-2; Universal Controls Whistle Switch.

Electronic Telephones and Controls—Ford Code-A-Phone Memory Phone; GTE Speakerphone; Radio Shack One-piece Phone ET-100; Rapidial; Royce Freedom Dialer; Panasonic Deluxe EasaPhone; Prentke-Romich ADT; Tele-Concepts Memory Dialer; Troller AutoPulse 30.

Mobility Controls for Powered Wheelchairs—MED 24 Volt Quad Systems with Pneumatic, Short-throw and Rocker Control Switches; Romich, Beery & Bayer Du-It Systems with Chin Controller and Joystick.

Audio Recorders / Controls—Clinical Convenience Products Control for a Lanier Dictaphone; Norwood XLP Cassette Recorder; Romich, Beery & Bayer Easicorder.

Electric Door Controls—Besam Commercial Opener; Keane Monroe Light Duty Operator Series 100; Power Access Automatic Door Opener Model 4300.

Alphnumeric Output Aids—Sharp Memo-Writer EI-7000; Sinclair ZX80.

Electric Page Turners—Bard-Carba R-2; GEWA; MED-Brusse.

Clinical and Engineering Evaluation of Stationary Stand-up Frames and Stand-up Wheelchairs for the Disabled

Clinical and engineering evaluation of several types of stand-up devices continues. The LaBerne Gearlift Stand-In Table (stationary frame) and the Levo Stand-Up Wheelchair are being evaluated using patients with paraplegia and quadriplegia.

LaBerne Table—In the initial phases of evaluation of the LaBerne Table several problems, which required structural modification, were identified and changes have now been completed.

1. Anterior Support (chest)—The anterior support did not have adequate adjustability for all patients (Fig. 1), and the anchoring bracket of the support often protruded into the patient's abdomen (Fig. 2). The chest support bracket was modified to be held by two rods, avoiding the center support for the knee pad assembly. The brackets were lowered to avoid the table top supports. The length of the supports was increased. Support can now be provided above and below table level (Fig. 3, 4 and 5).

2. Posterior Support—The increase in horizontal adjustability of the anterior support required a corresponding increase in the length of the support rods for the posterior from 7 in to 13 in (Fig. 6). The only posterior support was located at table height with no vertical adjustment. This did not provide adequate trunk and hip extension in most patients (Fig. 7). Two additional posterior support bars were added which are supported from clamps which ride on the vertical table supports. From these then is attached additional posterior support which allows vertical adjustment (Fig. 8 and 9).

3. Clinical evaluation—A total of 16 paraplegics (from C3 incomplete to T6 lesion levels) have been in the LaBerne. The paraplegic patients continue to be generally independent in operation of all aspects of the device, but quadriplegics require from one to two people to assist with placement of the body lift support straps, wheelchair placement, and operation of the switch on the lift mechanism. Functional evaluation continues to evaluate the patient's ability to achieve independence in getting in and out of the device, collecting working materials, and working in the device. All patients evaluated have been able to work on functional tasks with one or both upper extremities unsupported. The functional activities done in this device have primarily been those involving work tasks such as typing, writing, drafting, drawing, and assembly (Fig. 10).

Levo Stand-Up Wheelchair—On initial clinical evaluation of the Levo Stand-Up Wheelchair (Fig. 11) when patients were brought to the standing position they required additional support to prevent them from falling forward (Fig. 12). The supplied extension to the back height provided no attachment for a chest strap. That attachment has been added bilaterally to the back extension along with the supports (Fig. 13). Some chair frame pressure has been encountered with heavier patients (Fig. 14). Use of a seat cushion has alleviated this problem. Clinical evaluation to date has involved 6 paraplegics and quadriplegics from C-6 to L-1 level of lesion. All patients except one were able to transfer into the device without assist-

FIGURE 2.

FIGURE 1. (above) The anterior support lacked adequate adjustability. In Figure 2 (above, right) a view from below the work surface shows anchoring bracket for anterior support protruding into patient's abdomen.

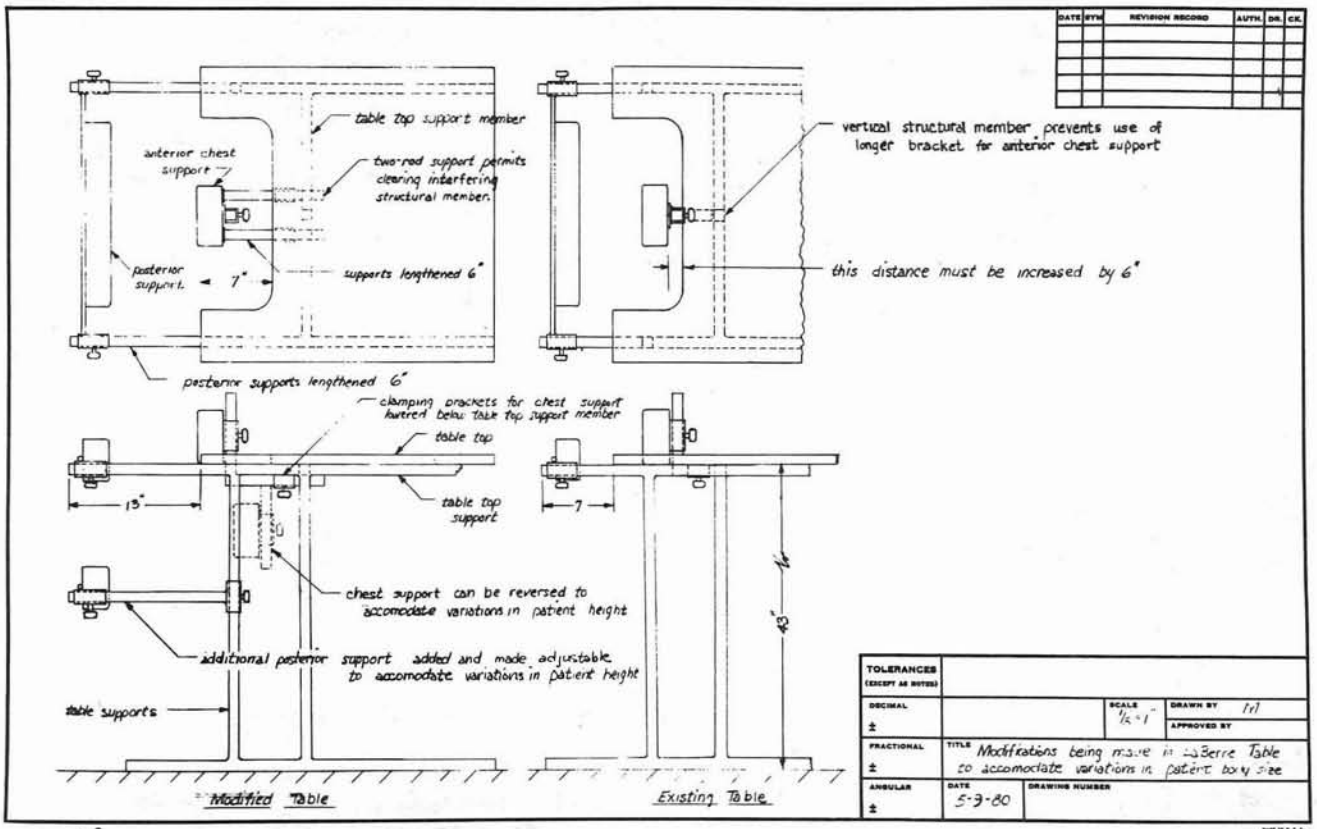


FIGURE 3. Schematic of modifications made on the LaBerne Stand-in Table.

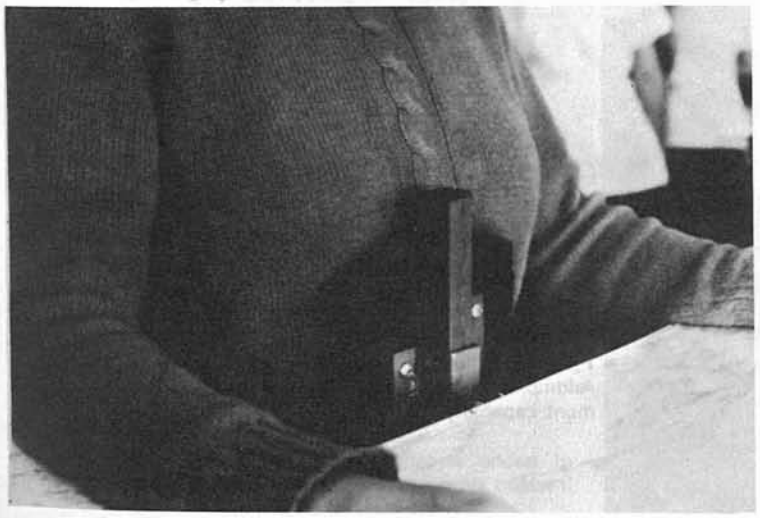


FIGURE 4.
Anterior support above the table level using new chest-support bracket described in text and shown in Figure 3.

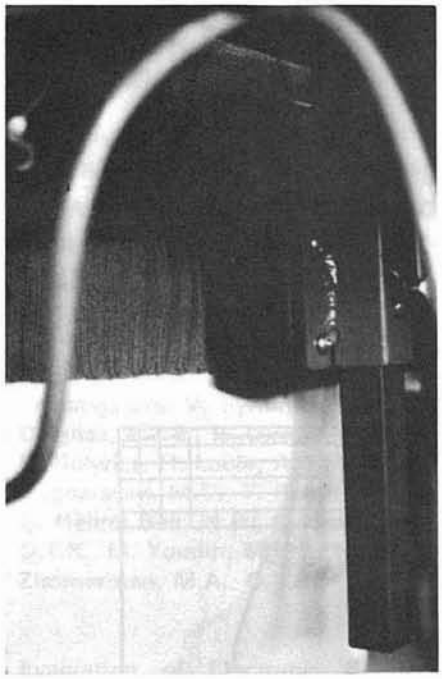


FIGURE 5. Anterior support below table level: see above-table portion in Figure 4.

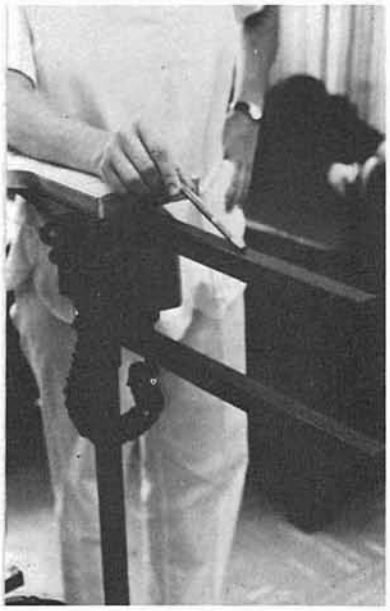


FIGURE 6. Therapist holds pencil to show amount by which posterior support rod was lengthened to increase horizontal adjustability of anterior support.

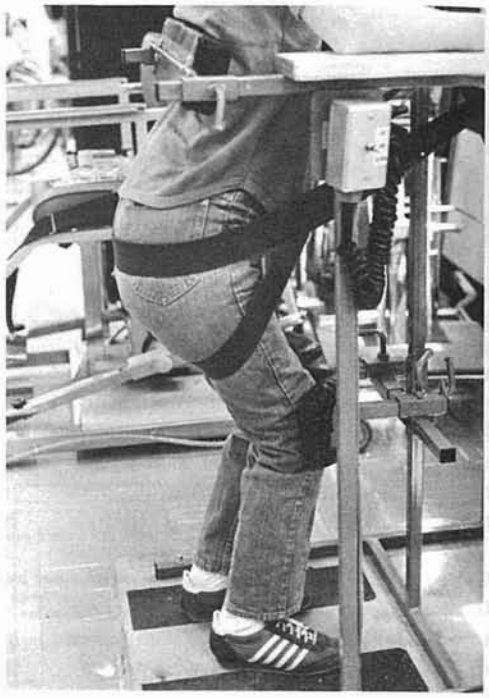
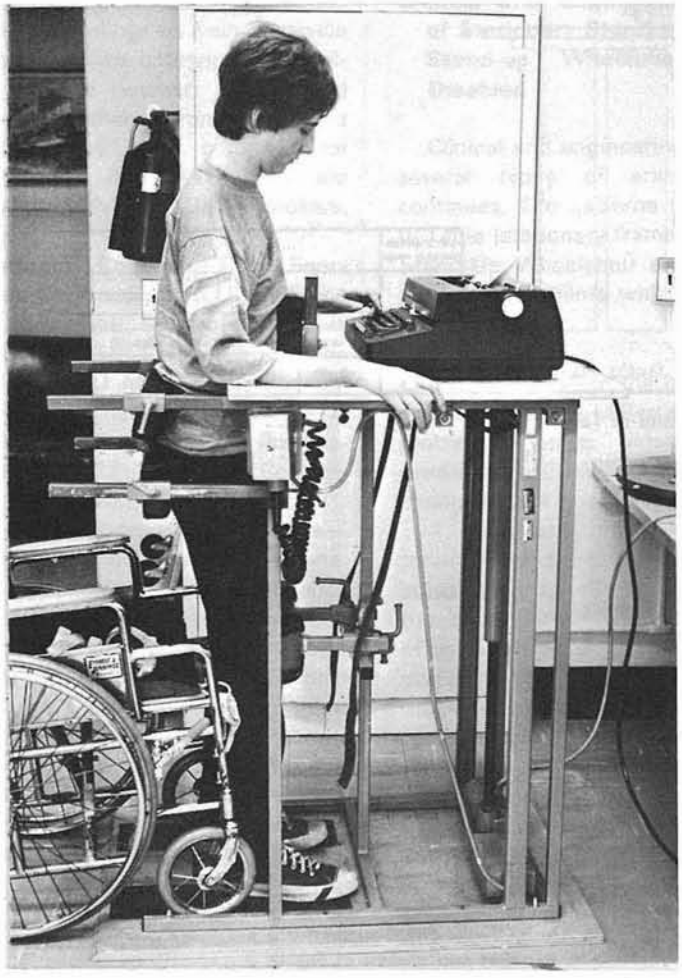


FIGURE 7.
The posterior support did not provide adequate trunk and knee stability.



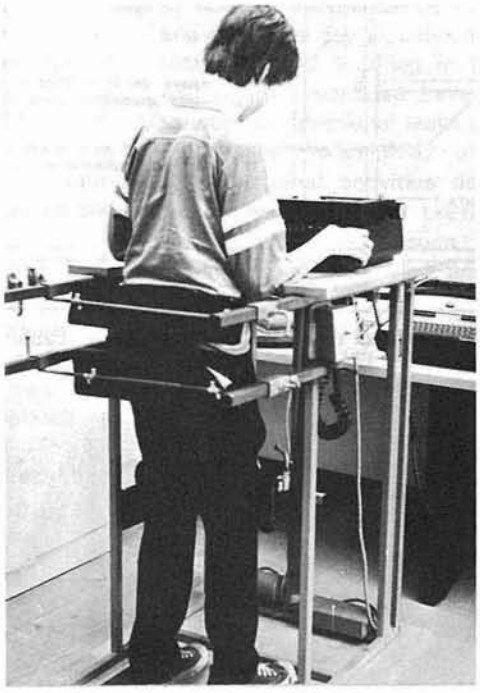


FIGURE 8 (above)
FIGURE 9 (left)
Additional posterior support with vertical adjustment capability.

FIGURE 10.
Functional activity in the LaBerne Table.

FIGURE 11.
Levo Stand-Up Wheelchair rigged to function as a conventional manually propelled chair.

FIGURE 12.
In the standing position, hand function was limited by a lack of trunk support.

ance. The transfers need to be accomplished with the foot plates joined. No one has been able to repin the footplates following completion of transfer into the chair (Fig. 15).

All patients have found functional value in having the ability to stand. Problems in functional use have been the following:

1. Difficulty pushing due to weight of wheelchair.
2. Difficulty pushing without increased handrim friction.
3. Inconvenience of not being able to be mobile in the standing position.

Functionally the Levo has been evaluated for tasks such as ADL, homemaking, and vocational application. (Figs. 16, 17 and 18).

FIGURE 13.
Bilateral trunk supports added to the back extension permit bilateral upper-limb function.

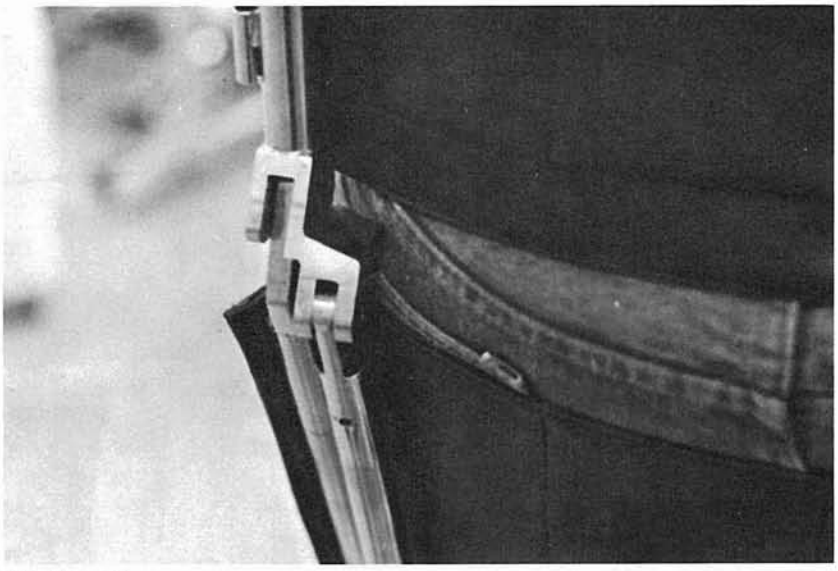


FIGURE 14.
Some chair frame pressure has been encountered with the heavier clients: use of a seat cushion has alleviated the problem.

FIGURE 15. (right)
Footplate repinning

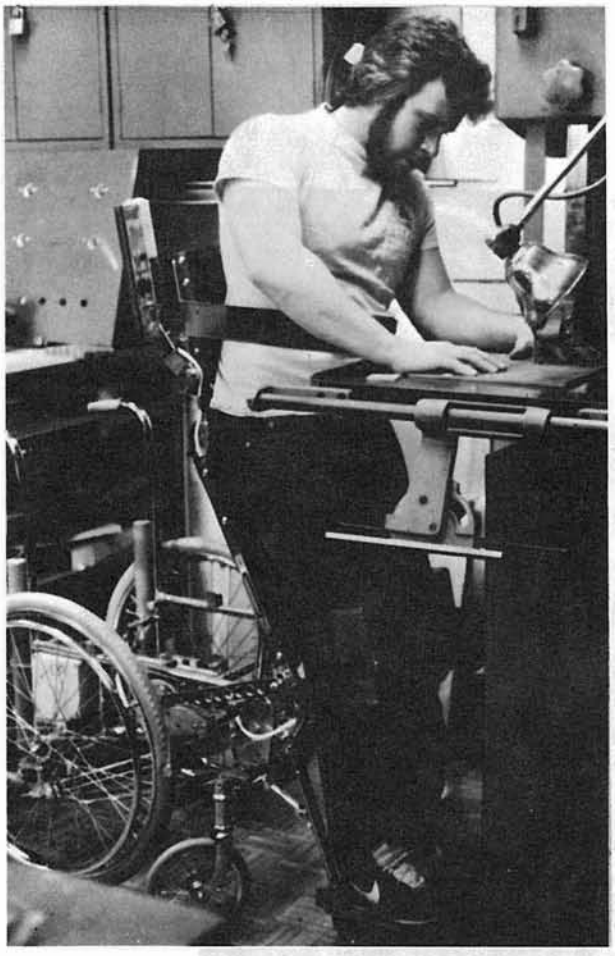


FIGURE 16 (left) and
FIGURE 17 (below)
Functional activities in the Levo Stand-Up Wheelchair in standing and seated positions.

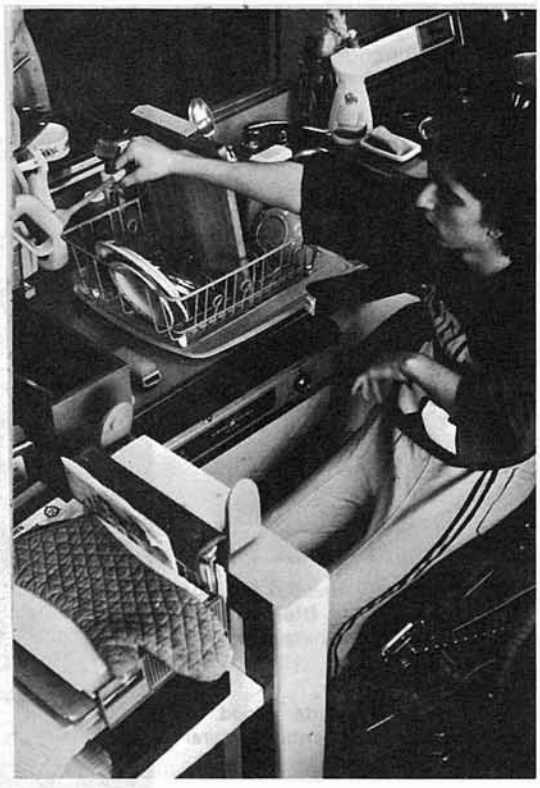


FIGURE 18.
Functional activities in the Levo.

Docking System to Connect Mobile Voice Control System to Stationary Environmental Control System

The IRM / NYU Voice Control System is a 36-word isolated word voice recognition module which is carried on board the powered wheelchair (Fig. 19). In order to interconnect the mobile voice recognition system to the stationary environmental control system it is necessary to make a 26-conductor cable connection. The means for allowing this connection to be done by the disabled user is now being evaluated. A proposed method of accomplishing this task mechanically is by "docking" the chair to complete the electrical interconnection. A prototype "docking" system is now being evaluated (Fig. 20). The unit consists of a small plate bearing two guide pins and the connector plug which is fastened to a vertical strut on the wheelchair. The mating connector receptacle is mounted on a bracket that has 3 degrees of mechanical freedom and mating holes for the guide pins (Fig. 21). Interconnection is accomplished by maneuvering the wheelchair so that the guide pins are driven into the stationary bracket, thus producing the proper alignment between the connector plug and the receptacle (Figs. 22 and 23). Disconnection is accomplished by reversing the drive (1). Evaluation to date has proved docking is possible by manual (joystick), breath, and voice control of the powered wheelchair.

Bedside Evaluation of IRM / NYU Voice Control System

The IRM / NYU Voice Control System has been installed in a patient room for continued clinical evaluation. The initial evaluation was done under direct supervision; this second phase will be done with restricted supervision. The patient will be operating an evironmental system capable of controlling 14 peripheral functions from the bed or immediate area around the bed.

Information Dissemination

1. A seminar on Independent Living for the Severely Disabled: Utilization of New Technology was held on January 28, 1981. The program was developed to acquaint rehabilitation personnel and consumers with new and specialized know-how, and to provide a forum for

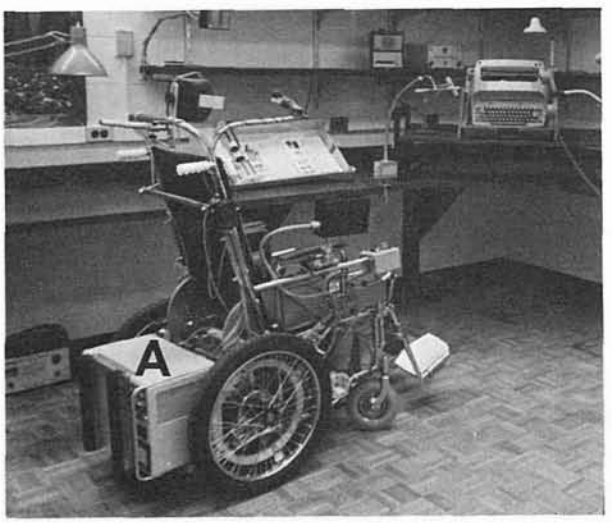


FIGURE 19.
A 36-word isolated-word voice-recognition module (A) rides on board the powered wheelchair

FIGURE 20. Prototype docking system.

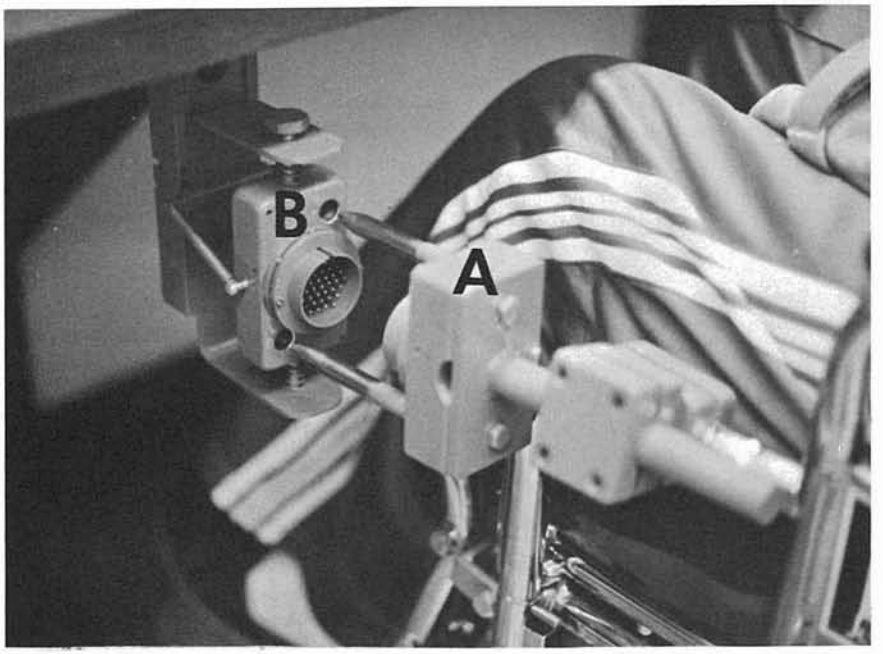


FIGURE 21.
The prototype docking system consists of (A) a plate holding the two guide pins and (B) the mating connector receptacle whose bracket has three degrees of mechanical freedom. Figure 22 shows guide pins aligned, and Figure 23 shows final connection position.

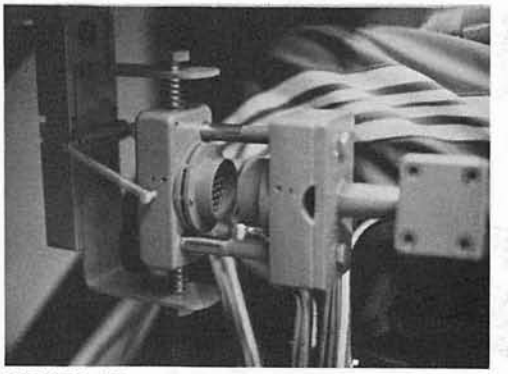


FIGURE 22.

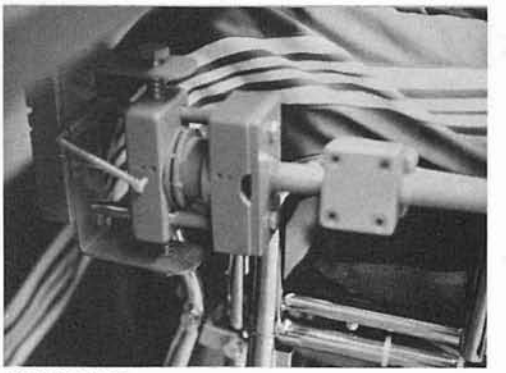


FIGURE 23.

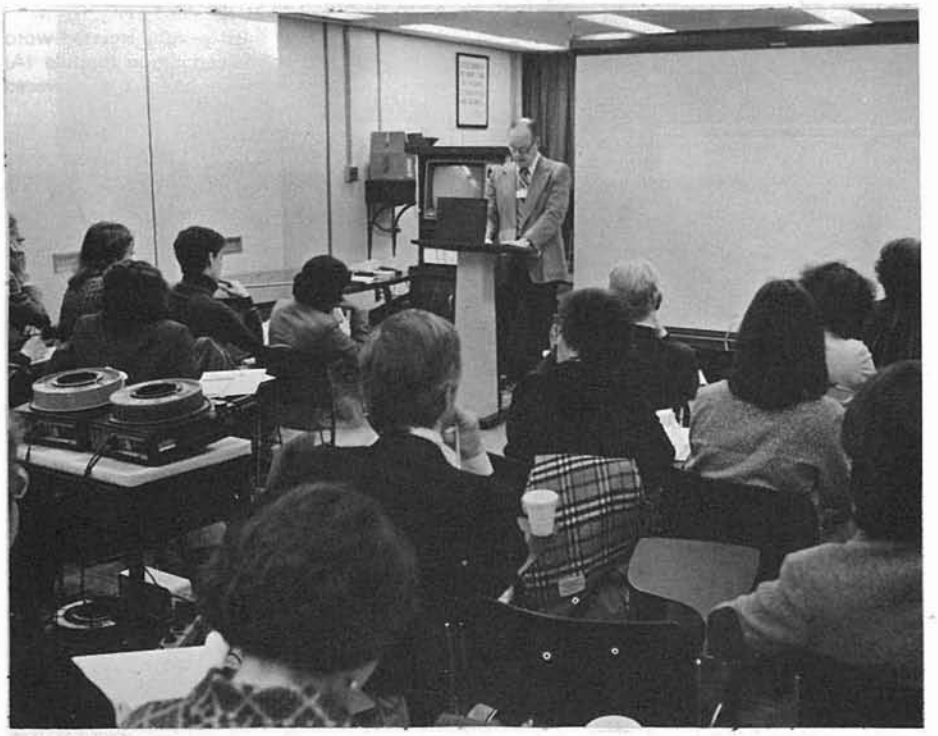


FIGURE 24.
Mr. Joseph E. Traub, Director of the Office of Technology, NIHR, making a presentation to the IRM / NYU REC Seminar on "Independent Living for the Severely Disabled: Utilization of New Technology".

the multidisciplinary interchange of information and ideas among professionals and consumers.

The seminar was attended by representatives from various rehabilitation facilities, New York State OVR, the Veterans Administration, the Easter Seal Society, United Cerebral Palsy, IRM, Polytechnic Institute of New York, Architectural Record, and representatives of municipal agencies and disabled consumer groups.

Mr. Joseph E. Traub, Director of the Office of Technology, NIHR, made a presentation on "The Public / Private Sector Partnership for Independent Living" (Fig. 24). Presentations by IRM / NYU staff included:

Mobility: Control systems for powered wheelchairs, integration of mobility, environmental and other systems.

Environmental Controls and Telephone Aids: Current devices and their practical application.

What's New at the REC: Remote controls for environmental control; docking systems; and a "Know-How Manual" on electricity for the disabled and their families.

Stand-Up Devices: Clinical evaluation and demonstration of the "Levo", "LaBerne", "Mobilpodium" and "Stand-Aid".

Utilizing New Technology in the Home: Demystifying home modifications.

The program concluded with a panel discussion in which disabled consumers discussed their present use of and future needs for new technology.

2. A lecture on "Refined Adaptations" was presented by C. Stratford within the "Environmental Adaptations Workshop" presented by N.Y. State Office of Mental Retardation and Developmental Disabilities, Staten Island Developmental Center, Staten Island, N.Y., September 1980.

3. A lecture on environmental controls was presented by C. Stratford within the workshop "Utilization of Special Devices and Technology for the Severely Disabled," University of Arkansas, Hot Springs, December 1980.

References

1. Youdin M, Clagnaz M, Dickey R, Kolwicz R, Louie H, Reich T, Sell GH: Ongoing Research to Provide Greater Freedom of Movement and Increased Independence for the Severely Disabled. Presented at the 33rd Annual Conf on Engr in Med and Biol, Washington DC, Sep 30–Oct 3, 1980.

Rehabilitation Engineering Center, Room 1441
Northwestern University
345 E. Superior Street
Chicago, Illinois 60611

Clinton L. Compere, M.D., Project Director

Distributed Environmental Control System

Objective—Our objective has been the development of an inexpensive distributed environmental control system for disabled persons. The control system would use the power-mains for transmission of information to peripheral equipment. It is considered distributed because the actuator units are dispersed with the equipment to be controlled. The advantages of such a system are:

1. simple installation
2. elimination of visible wires
3. reduction in cost in comparison to non-distributed systems
4. purchase of additional system components is possible, as funds become available or as need increases.

We have completed the design of a microprocessor-based distributed environmental control system (μ-DEC) which is based on the coding scheme of the commercially available BSR home control system and which is compatible with the BSR receiver modules.[a] The system consists of a special transmitter module, up to 16 receiver modules, and a speaker phone.

Progress Report—In April, of 1979, BSR, Ltd., of Britain announced a distributed home control system using a pushbutton transmitter module and receiver modules for lamps and appliances. The cost of the system was remarkably low.

A complete system was purchased for evaluation and was determined to be compatible with our objective of a distributed environmental control system. But, because the system we envisioned would be used by disabled individuals unable to operate the small pushbutton array of the BSR transmitter module, a microprocessor-based (Motorola 6800) controller and transmitter was designed to replace it. The coding scheme is identical to that of the BSR system so that the inexpensive BSR receiver modules can be used.

The microprocessor allows the system to be operated with either one or two switches (touch, pressure, pneumatic). In the two-switch system, one switch is used to step through the selections of devices or functions, and the second switch is used to activate the device or function desired. In the one-switch system, the selections are scanned automatically at a rate programmed by the user, and the single switch is used for activation. System status is presented to the operator through a segmented LED display.

In addition to appliance and lamp control, the system also interfaces with a speaker phone. The user can open and close the phone line and can build and store a single telephone number sequence and have it dialed automatically.

The μ-DEC system can also be operated from the 3P wheelchair through a radiofrequency link using the same switch arrangement that controls the chair.

Several special peripheral devices have also been designed to facilitate use of the system with BSR receivers. There are (1) a module that plugs into the BSR receiver to give an electrical contact closure, (2) an alarm buzzer that plugs into a BSR receiver so it can be used as a portable alarm unit, (3) a bed-control unit that permits six functions of an electric bed to be serially controlled from one BSR receiver, and (4) a TV-controller that can control six functions from a single BSR receiver.

During the early part of 1980 ten μ-DEC systems were constructed in the laboratory for evaluation. Three were placed in homes of high-level quadriplegics, one was placed in a nursing home,

[a] See BPR 10–34, Bull Prosth Res 17(2):53–57, Fall 1980, for A Technical Note: A Special Controller for the BSR X–10 Adapts an Environmental Control System Intended for the General Public to the Needs of the Severely Handicapped. (The author, Dave Rye, is Senior Applications Engineer for the manufacturer.)

three were placed at Rehabilitation Centers (New York University Medical Center, Schwab Rehabilitation Center, and Rehabilitation Institute of Chicago), two were used for demonstrations, and one was provided to a manufacturer as a sample (Fig. 1 and 2).

Early feedback from the permanent users and the Rehabilitation Centers prompted numerous changes in the operation. This was all accomplished with software. Features were added, such as the capability of storing three phone numbers instead of just one. Operational changes were made to make μ-DEC easier to operate and more useful to the individual.

Early in the year (1980), it was felt that the μ-DEC hardware was satisfactory and reliable and that any changes could be made by reprogramming. Therefore, the laboratory proceeded with commercial development. Arrangements were made with Medical Equipment Distributors, Maywood, Illinois, to contract for construction of 100 units. These were completed in July 1980 and became available nationwide. Two seminars were held for their dealers from across the country to familiarize them with μ-DEC and all the peripheral devices that make up the total system. A user's manual was written for μ-DEC.

Because the initial response to μ-DEC was high, Medical Equipment Distributors contracted in September 1980 for a second production run.

Changes and improvements to μ-DEC will be added to future production runs as more feedback is received from users of the early units. Already planned are:

Increased telephone number storage capacity from the present three to six numbers.

A built-in telephone ringer.

An optional battery back-up feature.

FIGURE 1. μ-DEC Environmental Controller

FIGURE 2.
μ-DEC System (early 1980). From left to right: a television set controller; an electric bed controller; the μ-DEC controller, and in the white case at right a speaker phone. Smaller objects in foreground are a BSR appliance module and lamp module (receivers) and one of the specialized small devices such as a buzzer designed to plug into a BSR module.

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Rehabilitation Engineering Center
The Institute for Rehabilitation and Research
1333 Moursund Avenue, Houston, Texas 77030

Thomas A. Krouskop, P.E., Ph. D., Program Director
Jesse H. Dickson, M.D., Co-Program Director

Since 1972, the Texas Rehabilitation Engineering Center, located at The Institute for Rehabilitation and Research (TIRR) in Houston, has continued to develop and introduce new methods and products of technology into the comprehensive rehabilitation process of the severely disabled. One of the pioneers in rehabilitation engineering, the Texas REC is involved in fundamental and applied projects that concentrate on the effects of pressure on soft tissue. Because prolonged pressure on tissue can cause life-threatening pressure sores which interfere with the rehabilitation process, it is the Center's primary goal to develop devices and methodologies to prevent and treat the debilitating effects of pressure.

A major focus of the REC is to expand the possibilities of personal activities, vocational opportunities, and mobility for the severely disabled, especially the high-level spinal-cord injured. The Center's activities continue to address problems encountered during the entire rehabilitation process from early post-injury stabilization to independent living as productive citizens in the community.

Tissue Management Program and Clinic

The Tissue Management Program and Clinic is a clinical, patient-oriented service provided at TIRR by the REC. This service is a comprehensive approach to the prevention and treatment of soft tissue breakdown that results in pressure sores. The program is based on early detection of tissue and pressure problems, education of patients to prevent problems, and evaluation and prescription of pressure relief devices and materials. The program also provides medical and surgical treatment for existing sores.

The Tissue Management Program and Clinic has been so successful that it has been duplicated in institutions in New York and Philadelphia.

Clinical Device Development

As a satellite referral center for IMPART, the REC designs and develops devices to ameliorate problems that occur during the daily experience of the severely disabled. Some of the Center's most recent developments are described below.

Foot-Operated Check Proofing Device—Paralysis in one hand prevented a client from returning to his job at a bank because he could not operate the check proofing equipment with the use of only one hand. Since both hands were necessary to process the checks, the client needed equipment modifications to effectively operate the machine.

To compensate for the client's inability to use one hand, the REC developed and fabricated a foot-operated check proofing device. The new device was designed to be used with the existing check proofing machine without altering original equipment. The device is an aluminum floor unit that houses an array of 22 foot switches connected to a solenoid unit that fits onto the original keyboard panel. (See Figures 1 and 2.) As the foot switches are depressed, corresponding solenoids activate the keys on the keyboard making the necessary

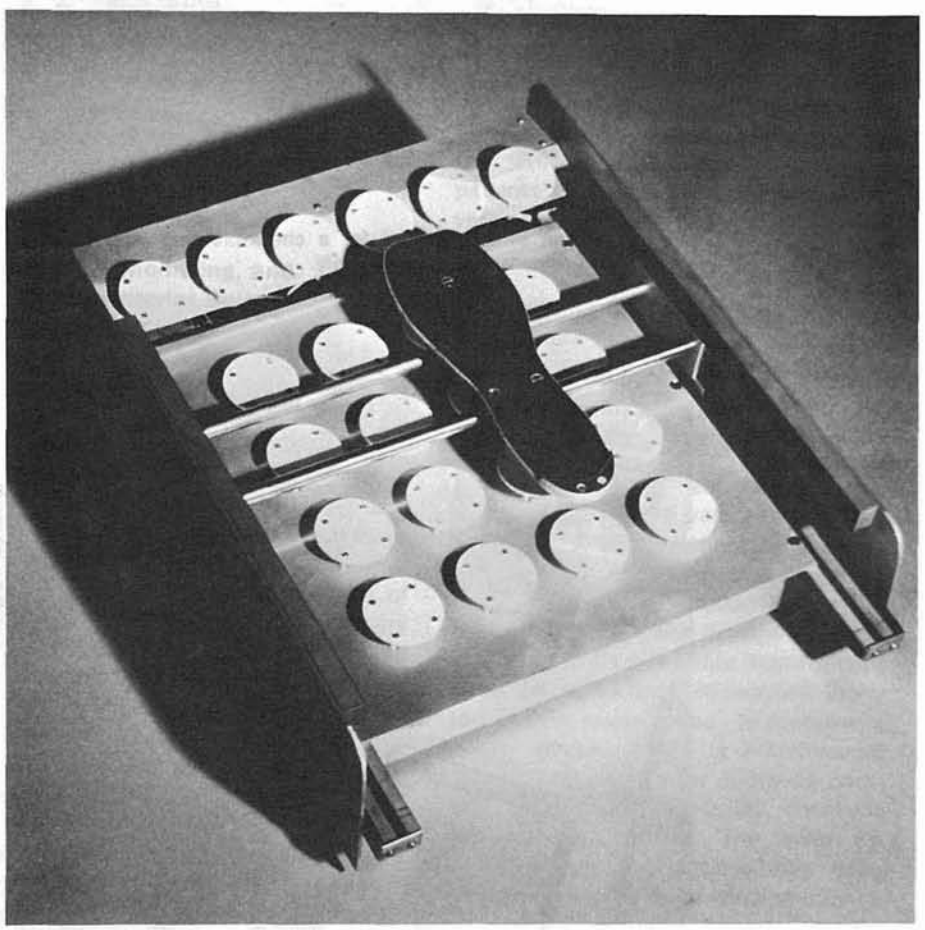


FIGURE 1
Top view of foot-operated check-proofing device showing footpedal and switches. The idea is applicable to other keyboard-operated equipment.

functions. A replica of the keyboard on the front of the solenoid unit indicates which function is in progress. The checks are cancelled and sorted according to the transactions made. With this foot-operated check proofing device, the client is able to secure and maintain his job at the bank. Two clients of Florida Vocational Rehabilitation are using this system to maintain competitive employment and are able to perform within normal production standards.

Although this device is specifically designed to aid in operating a check proofing machine by someone unable to use at least one hand, the basic design of the foot-operated keyboard can be adapted to almost any keyboard controlled equipment.

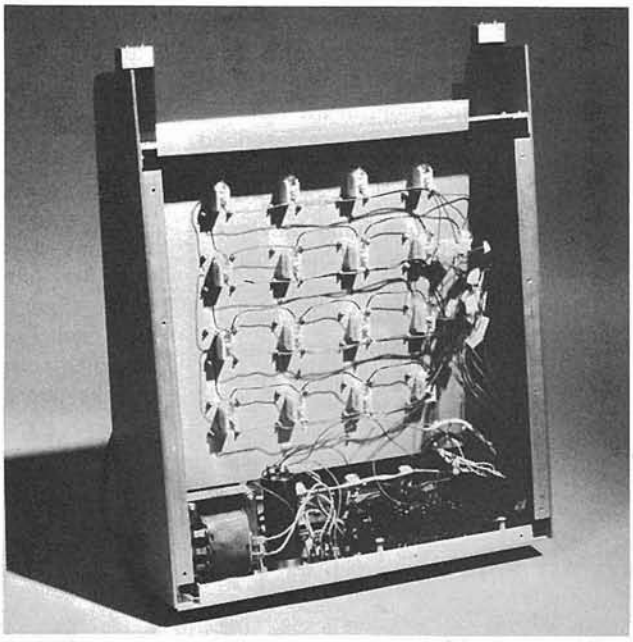


FIGURE 2
Underside of foot-control for a check-proofing device shows wiring system and power supply.

Wheelchair Mobility Aid—A post-polio patient with no arm extension and very limited hand function and strength could not operate her motorized wheelchair with a joystick and needed assistance performing certain job tasks. Since the client lacked the strength and function to operate a joysick control, an alternate method was needed to control her wheelchair.

An electronic touch-sensitive wheelchair controller was designed and fabricated to replace the joystick unit without altering the wheelchair or its power source. Basically, the new device consists of two handcontrol units connected to a wheelchair controller that is secured to the wheelchair side. With her index and second fingers on the left hand, the client controls the forward / backward motion of the chair by depressing the microswitches. Using the thumb on her right hand, the client controls the degree of direction variance by touching one of the eight sensors on the sensor unit.

The wheelchair controller is also capable of interfacing with the client's workstation electronics. By connecting the wheelchair controller electronics to the workstation electronics, the client is able to control certain workstation devices, such as a revolving lazysusan and an automatic telephone dialer.

Pressure Research

Pressure problems are not only a concern of the REC but also of nurses

FIGURE 3
Monitoring the trochanteric pressure under the sidelying patient using the Pressure Evaluation Pad. The position shown was found to be helpful in distributing weight away from vulnerable areas.

responsible for patient care. One of the most recent REC pressure projects was conducted in conjunction with the TIRR nursing staff to determine the effects of leg positioning on trochanteric pressure in the sidelying spinal-cord-injured patient. (See Figure 3.) Since breakdown of skin that overlies the trochanter is a frequent complication of sidelying patients, nurses have tried to avoid tissue breakdown by flexing the patient's top leg in the traditional hip and knee extension. However, the pressure over the trochanters created by this traditional sidelying position was still too great to prevent pressure ulcers. To reduce the risk of developing pressure sores, the REC and the TIRR nursing staff sought to identify leg positions that would reduce the amount of pressure over the trochanter.

Utilizing the Pressure Evaluation Pad (PEP) developed by the Texas REC, quantitative measurement of pressure under the trochanter with variations in the positioning of the legs was monitored and recorded. The results indicate that the position of the top leg supported on a pillow with hip and knee extension to the back produced lower trochanteric pressure than the traditional position with hip and knee flexion.

Using the information gathered from this project, the REC plans to promote better tissue pressure management for sidelying individuals through positioning techniques that distribute weight away from vulnerable areas. The REC intends to submit the statistical analysis of this project for publication in the near future.

Information Dissemination

The Texas REC has a substantial commitment to making the results of its activities available to all who might be able to benefit from them. The Center's staff participate in the meetings of the International Conference on Rehabilitation Engineering (ICRE), American Spinal Injury Association (ASIA), and the American Congress of Rehabilitation Medicine (ACRM). Members of the Texas REC team contribute articles to recognized professional journals. The staff also works with the Texas Rehabilitation Commission project IMPART to make information available on the regional level. The Center's annual report is sent to more than 40 groups and individuals around the world and to numerous visitors who tour TIRR.

Rehabilitation Engineering Center Harvard University / Massachusetts Institute of Technology

300 Longwood Avenue, Boston, Mass. 02115

William Berenberg, M.D., Director; Robert W. Mann, Sc. D., Melvin J. Glimcher, M.D., and John E. Hall, M. D., Associate Directors

The major core area of this Rehabilitation Engineering Center is neuromuscular control using sensory feedback systems. A secondary core area is communications. Areas of responsibility among REC associate directors are as follows: Dr. Mann, Engineering Research; Dr. Glimcher, Medical Research; and Dr. Hall, Clinical Engineering Services.

The three participating institutions with which investigators mentioned in this report have their particular affiliations, are:

Children's Hospital Medical Center
300 Longwood Avenue
Boston, MA 02115

Massachusetts Institute of Technology
77 Massachusetts Avenue
Cambridge, MA 02139

Brigham and Women's Hospital
75 Francis Street
Boston, MA 02115

Monitoring, Modifying, and Testing Anterior Spinal Instrumentation

Project responsibility: Derek Rowell, Ph.D., and John Hall, M.D.

The long-term goal of this project is to improve the surgical techniques and postoperative outcome and patient management procedures associated with the Dwyer instrumentation method of anterior spinal fusion. The necessary data to accomplish this are to be obtained from an implantable telemetry unit which monitors tension in the cable incorporated in the Dwyer apparatus.

A workable telemetry unit was designed and successfully tested in vivo in dogs for a period of one year, establishing both reliability and biocompatibility. The unit has also been used to measure cable tensions during a Dwyer apparatus surgical procedure in a human patient.

To date we have accomplished the redesign and fabrication of the electronic circuit contained in the prototype telemetry unit. Problems of large power drain, and inaccuracies for certain positions of the transducer, have been eliminated by the development of a more sophisticated design which has been implemented on a semi-custom integrated circuit.

The load cell and transducer have been modified to be more physically compatible with the relevant anatomical structures in humans. The final design with the new electronics is currently being fabricated for extensive testing and calibration. We plan to proceed with implantation in six patients who have scoliosis associated with myelomeningocele and paraplegia. After the units have been installed in the spines of the six patients, we will proceed with our protocol to obtain readings during and after the operation, and with the patients in various positions and doing various activities.

Developing and Monitoring an Effective Pressure System for Use in the Boston Scoliosis Orthosis

Project responsibility: John Hall, M.D.

Depending on their location and severity, spinal curvatures may be amenable to improvement by the use of bracing. The Boston Brace system, developed in conjunction with the National Orthotics and Prosthetics Corp. is proving to be a valuable improvement upon the well-known Milwaukee Brace for use in such cases. It features a pelvic module which is prefabricated from thermoplastics for improved comfort, serviceability, durability, cosmesis and patient hygiene. The need for individual patient castings has been largely eliminated by arriving at a range of 20 sizes which will accommodate 95 percent of those for whom the brace is indicated. The current design combines

built-in pressure pads for curve and rotation correction, with strategic areas of "relief" to permit spine migration.

Evaluation efforts are presently focused on incorporating inflatable pads in the Boston Brace as a means of controlling and varying the pressure applied at various locations during the course of treatment.

Neurophysiological Feedback from Extremities

Project responsibility: Neville Hogan, Ph. D.

The goal of this project is to develop a complete myoelectric prosthesis-control system whose design is consistent with contemporary neurophysiological knowledge. The major implication of present data is that the high concentration required for the operation of myoelectrically controlled devices cannot be attributed to the sensory lacunae of the handicapped user. Instead, the solution to the problem must lie in the command pathway. Most myoelectric control systems in common use have two major identifiable flaws: the myoelectric signal processor yields an inaccurate and unreliable measure of muscle activity, and the controller interprets muscle activity incorrectly as a velocity command. To improve myoelectric control systems, the command pathway should be made as accurate as possible and should be designed to interpret muscle activity correctly in keeping with contemporary neurophysiological findings. The assistive device should have adjustable stiffness characteristics similar to those of the natural neuromuscular system.

Use of a Microcomputer-Controlled Above-Knee Prosthesis and Biofeedback / Gait-Analysis System for Immediate Post-Operative Training

Project responsibility: Woodie Flowers, Ph. D.

Through collaboration with the National Science Foundation funded M.I.T. Knee Project, a microcomputer-controlled above-knee prosthesis was developed and tested in 1977. The versatile knee-joint control made possible by this new type of prosthesis suggested that it might be valuable as a training aid for immediate postoperative amputees. In particular, the prosthesis seemed ideal for allowing an amputee to make a smooth and more gradual transition from a locked pylon to a prosthesis having knee control characteristics similar to those of the appropriate permanent prosthesis.

Clinical experience with this prosthesis has shown that improvements in the postoperative training process may more readily result from improved prosthesis state-sensing instrumentation than from increased knee control versatility. Therefore, a weight bearing transducer and a knee-torque transducer have been developed and added to the microcomputer-controlled prosthesis, and a biofeedback/gait-analysis instrument has been designed to facilitate interpretation and display of the new data.

At the Massachusetts General Hospital, seven amputees have used the prototype prosthesis in their postoperative training. Two patients have participated in training programs utilizing the new transducers and data-display capabilities. Results to date indicate that the new instrumentation may have a significant impact on the rehabilitation of the above-knee amputee. The amputee clearly benefits by knowing the levels of the prosthesis' weightbearing and knee torque, and the clinical staff are more effective when they have access to more information about the amputee's gait.

Evaluation of Gait and Posture in Selected Groups of Children with Cerebral Palsy, Myelomeningocele, and Scoliosis

Project responsibility: Sheldon Simon, M.D.

The long-term goals of this project are to establish accurate, objective, clinical methods for determining the biomechanical parameters of gait, and to evaluate the clinical efficacy and relative importance of each parameter in understanding the basic pathodynamics of locomotor dysfunction in handicapped individuals, most notably children, and the effects of various therapeutic modalities upon that dysfunction.

This project has established a computer-based gait analysis system for evaluating the basic, directly measurable, kinetics and kinematic parameters of gait. It has illustrated the usefulness of this system in evaluating clinical problems. Emphasis has been placed on developing methodology for evaluating the indirectly measurable biomechanical parameters of gait, consisting of (i) the multilimb segment changes in potential and kinetic energy, (ii) the dynamics of the body's center of mass, (iii) relationships of muscle length, velocity, and accelerations to EMG activity, and (iv) inertial properties of various limb segments. Concomitantly, clinical projects evaluating the gait patterns of children with cerebral palsy, myelomeningocele, and scoliosis (specifically designed to provide the means for assuring the proper utilization and clinical meaning of the biomechanical methodology proposed) have been underway. Although much of the system hardware development has been accomplished, additional projects are in process to expand and more accurately monitor EMG activity of 16 muscles, and to provide more comprehensive and more clinically meaningful dynamic graphic displays of locomotion data.

Collaborative Research between the M.I.T. Mobility Facility and the Children's Hospital Medical Center Gait Analysis

Project responsibility: Robert W. Mann, Sc. D.

Gait analysis is becoming an important, if not essential, precursor to and evaluator of invasive procedures and noninvasive therapies for the correction of pathological movement. But, nationwide, each gait analysis group has evolved its own data-acquisition system, analytical procedures, and interpretation processes. That diversity often makes it difficult, if not impossible, to directly compare the reliability and efficiency of individual data collection systems and the efficacy of findings derived therefrom.

The CHMC Gait Analysis Laboratory and the MIT Mobility Facility, developed with separate funds, provide an opportunity to compare directly two separately evolved systems. The CHMC system is oriented toward clinical research with a committed staff. The MIT facility is focused on basic research with individual investigations conducted by graduate students in the context of theses.

Specific areas under investigation include accuracy requirements in kinematic-data acquisition, musculoskeletal modelling, sensitivity of optimization analyses, accurate prediction of individual muscle action, and comparative adequacy of myoelectric signal acquisition, processing and interpretation. Continuous collaboration between the laboratories enhances the progress toward the achievement of their respective goals.

Suppression of Abnormal Involuntary Movement by Application of Mechanical Loads

Project responsibility: Michael J. Rosen, Ph. D.

The goal of this project is to test, and develop into clinically applicable form, the application of mechanical loads across tremor-disabled joints in order to produce restraining torques which selectively attenuate the oscillatory abnormal component of muscle torque. At present, this approach is being evaluated on subjects with intention tremor by objective measurement of hand-tracking performance during the application of varying amounts of viscous damping or isometric restraint. If results from further subjects continue to show the dramatic tremor-reduction seen in seven diverse subjects to date, the design of a multi-degree-of-freedom orthosis for whole-arm tremor suppression will be undertaken.

Development of more limited clinical applications of viscous damping for tremor suppression is already underway. A simple viscous exercise device, a damped joystick for two-dimensional steering and control (wheelchairs, environmental control systems, nonvocal communication devices) and a clinical tremor assessment instrument are presently being tested and refined.

Variation of amplitude and frequency of spectral components of abnormal tremor are also being interpreted to establish the tremorogenic mechanism.

An Automated Muscle Fatigue Indicator

Project responsibility: Carlo J. De Luca, Ph. D.

The objectives of this project are to develop techniques for quantitatively evaluating the disease state of an affected muscle and for measuring the rate of exhaustion of a contracting muscle, to build a non-invasive device to implement the techniques, and to develop a clinical tool for quantitatively and objectively testing impaired muscles.

In rehabilitation programs involving treatments for improving the performance of the disabled muscles, it is necessary to evaluate the extent of impairment and the effectiveness or limitation of a prescribed treatment. Manual muscle testing procedures occupy a prominent role in this process and the findings are dependent on the training, skill, experience or bias of the clinician. A much more objective procedure may now be possible with the analysis of the electromyographic (EMG) signal. Frequency domain analysis has revealed that there is a consistent time-dependent shift in the frequency spectrum of the EMG signal recorded during a sustained contraction. There is evidence that this shift results from the accumulation of metabolic by-products as a sustained contraction progresses.

There are numerous possible applications of our technique which have the potential of improving the quality and quantification of therapeutic techniques (and health care in general) for the physically handicapped. For example, physically handicapped children are frequently subjected to prolonged, enthusiastic physical therapy programs. If they are exercised beyond reasonable limits, that can produce muscle fatigue which the patients cannot or are not willing to communicate to the clinician. The Muscle Fatigue Monitor (MFM) could be used to indicate the safe level of muscle fatigue.

At the other end of the age spectrum, elderly patients with a wide variety of disabilities (including stroke) have levels of safe fatiguability which differ from those of the general population. In fact, fatiguability varies with different age groups and among subjects. An objective, non-invasive, automatic technique for measuring muscle fatigue would provide significant assistance in treating these patients safely.

In addition, the objective and reliable nature of the MFM allows the quantitative investigation of the behaviour of debilitating diseases such as athetoid or spastic cerebral palsy.

Communication Systems for the Severely Motor Handicapped

Project responsibility: Derek Rowell, Ph. D.

This project is designed to define and evaluate new techniques for non-vocal communication, and to demonstrate the innovation that can be introduced to this area through microprocessor technology.

The UNICOM concept allows sophisticated communication and control strategies to be implemented in permanently stored programs within a microcomputer. The idea is to define a common modular approach that will allow different devices to be created around a single piece of hardware. Seventeen devices have been constructed, and eleven are currently under evaluation in the field in school, hospital and home environments. These devices can be changed from a scanning mode, to an encoding mode, to directed scan, and to direct selection mode by simply plugging the appropriate activation device into a socket. The concept has been extended so that the UNICOM can function either as a computer terminal while operating in the scanning mode, or as a controller for external devices (lamps, televisions, etc.).

The second area of investigation is to define new methods of using limited motor functions for interaction with an electronic communicator. The EYECOM system uses encoded eye movements, monitored by infra-red detectors, to communicate characters and words. Other methods under investigation include joystick and force actuators.

The current emphasis is on independent ADL evaluation of the devices and concepts generated in this project, and on technology transfer for commercial deployment of the device.

Objective Measurement of Spasticity

Project responsibility: Mark Hallett, M.D.

A substantial number of people with neuromuscular disorders, including cerebral palsy and spinal-cord injury, have reduced function due to exaggerated stretch reflexes. Present methods for accurately quantifiable measurement of this spasticity are inadequate, so this project is aimed at development and

application of an objective measuring system.

The goal is to identify a simple quantitative measure of spasticity that can be utilized easily in any clinic to provide an objective measure of tone, for assessment of patients and their responses to different modes of therapy. The method is to analyze the short and long latency muscle responses to muscle stretch. The system utilizes the gastrocnemius and tibialis anterior muscles, which play an important role in gait. This project seeks to analyze the contribution to motor output from the sensory input of stretch. The normal responses, and the responses in pathological states like spasticity, are the subject of analysis.

This is a collaborative program between the Children's Hospital Medical Center, the Brigham and Women's Hospital, and the Massachusetts Institute of Technology.

Mobility Aids for the Blind and Severely Visually Handicapped

Project responsibility: Robert W. Mann, Sc. D.

This REC has explored the feasibility of incorporating the Polaroid Sonar Camera ultrasonic echo-ranging hardware into Electronic Travel Aids such as the Pathsounder and Sonicguide. As reported previously, although the economics and availability of the Polaroid transducer and associated electronics are extremely attractive, the retrofitting costs of accommodating this hardware into ongoing and market-available devices are prohibitively expensive, given the still small consumer market, and the reluctance of manufacturers who do not want to change their current models.

In a collaborative effort of the Boston College Peripatology Program and M.I.T., a computer-implemented study of optimum cane length for drop-off detection was undertaken and published in the Journal of Visual Impairment and Blindness (1). Further work on long-cane travel optimization is underway. This work is motivated by recognition that the long cane (along with the guide dog) continue as the premier travel aids for the blind and severely visually impaired person. Since World War II, the stress has been on orientation and mobility training with little and sporadic theoretical advances in cane technique.

Reference

1. Uslan MM and Schriebman K: Drop-Off Detection in the Touch Technique. J. Vis Impair & Blind 74(5):179–182, May 1980.

Cerebrospinal Fluid Shunt for Hydrocephalus

Project responsibility: Robert W. Mann, Sc. D.

Hydrocephalus is the distention and enlargement of the ventricles in the brain due to obstruction to the flow of cerebrospinal fluid (CSF). If untreated, it may lead to brain damage, neuromotor disability, and even death. Infantile or congenital hydrocephalus is most common, representing three out of four cases, the remainder being acquired at any age. About 20,000 cases of infantile hydrocephalus are reported annually in the United States, representing about one out of every 200 births. The primary intervention is the surgical insertion of a tube to by-pass CSF from the ventricle to the right atrium of the heart or the peritoneal cavity, with the volume flow of fluid controlled by a pressure-sensitive valve in the shunt. Conceptual models have been developed for the appropriate valve configuration. Control system and fluid mechanical analyses of performance will be undertaken in order to achieve an optimum design. Valve prototypes will be fabricated, most likely at Cordis Corp., with some physical experimentation at MIT and animal experimentation in Florida and in Bogota, Columbia.

Clinical Engineering in Rehabilitation

Project responsibility: Philip A. Drinker, Ph. D.

The purpose of this project is to respond to the rehabilitation needs of individuals in clinical settings by application of engineering principles and technology. Current activity includes modifying and maintaining adaptive typing systems and non-vocal communication systems for use by quadriplegic persons; utilizing simple eye-movement communication boards with severely disabled non-vocal people; testing strategies of remote communication for deaf persons working in a hospital environment; practising patient-by-patient adaptive equipment design; and collaborating with Children's Hospital Medical Center in design of equipment and procedures for a Non-Vocal Communication Clinic.

Evaluation and Applications of Myoelectric Biofeedback

Project responsibility: Carlo J. De Luca, Ph. D.

Much of the information in literature indicates that myoelectric biofeedback devices have been instrumental in obtaining dramatic results in a research environment under the supervision of strongly motivated individuals. However, when used on a daily basis in the clinical environment, the results are much less impressive—and certainly far from dramatic.

The primary goal of this study is to optimize the performance and assess the efficacy of a simple myoelectric biofeedback device for patient and / or clinician. Specifically, the device appears to enhance the extent of effective voluntary control a patient can maintain over a partially paralyzed or hypertonic muscle with minimal but representative feedback, and provide an effective means of monitoring the contribution and role of a specific muscle during a therapeutic functional exercise so as to minimize the time required for therapy.

The study is intended to determine whether such a relatively simple device will be accepted as an assistive tool by both the patient and the clinician, whether the device is more effective in accomplishing the specified functions than currently employed techniques and procedures, and to explore productive clinical applications. The results to date have been most encouraging and appear to be received with enthusiasm by therapists and patients alike. The system is currently in a phase of technology transfer.

Refreshable Braille Data Display System

Project responsibility: Derek Rowell, Ph. D.

A microcomputer-based refreshable braille display of the visual information required by the operatior of a TSPS (Traffic Service Position System) telephone console developed by this REC has been under evaluation and in use

for more than 50 operator months at the Southwestern Bell Telephone Company (SWB) in a collaborative project with Arkansas Enterprises for the Blind.

The field evaluation has been successful. It has been demonstrated that blind workers can perform at the same or higher productivity than sighted operators. This has led to involvement on the part of American Telephone and Telegraph (AT&T) to deploy the technique on a wider scale. Telesensory Systems, Inc. (TSI) under contact from AT&T, has produced three prototypes of a system that incorporates aspects of our braille-only system with TSI's audio-output-only system tested at Pacific Bell Telephone Company's Mountain View facility. This commercial continuation of our TSPS project is an example of rapid and successful technology transfer.

The development phase of this project has been successfully concluded. Support to assure continued employment of the two blind operators in Little Rock will be provided until the new equipment produced by TSI can be purchased and installed by SWB ■

Rehabilitation Engineering Center Rancho Los Amigos Hospital 7601 E. Imperial Highway Downey, California 90242

Robert L. Waters, M.D., Director, and Donald R. McNeal, Ph. D., Co-Director

Introduction

The Rancho Los Amigos Rehabilitation Engineering Center, founded in 1971 with a grant from the Rehabilitation Services Administration, is located on the grounds of Rancho Los Amigos Hospital, a teaching hospital of the University of Southern California Medical Center and one of seven hospitals administered by the County of Los Angeles. The hospital is a 650-bed facility devoted entirely to rehabilitation, providing a unique and effective base of operations for the development of rehabilitation technology.

James B. Reswick, Sc. D., who has guided the REC since its inception, resigned from his position as Director of the Center in December, 1980, to accept the position of Associate Director for Technology at the National Institute of Handicapped Research. He is succeeded by Robert L. Waters, M.D., as Director, and Donald R. McNeal, Ph. D., as Co-Director of the Center. The appointment of Drs. Waters and McNeal continues the tradition of a physician and an engineer working closely together as co-directors of the Center.

The primary core area of the center is functional electrical stimulation.. This work is carried on by the Neuromuscular Engineering Group directed by Bruce Bowman, M.S. A second core area is pathokinesiology, directed by Jacquelin Perry, M.D. During the past 11 years, Dr. Perry has created one of the leading human function laboratories in the world. Daniel Antonelli, M.S., is Co-Director for engineering in pathokinesiology. A third group was added in 1977 when it was decided that the center should become more active in the delivery of rehabilitation engineering services. Accordingly, a new project called Project Threshold was initiated. It is directed by Nancy Somerville with Heidi McHugh Pendleton, O.T.R., as Co-Director.

The list of on-going projects is far too long to be covered in this brief review. Included below are descriptions of representative projects from the neuromuscular engineering and pathokinesiology groups and a brief summary of Project Threshold activities. A complete description of all projects is found in the 1980 Annual Reports of Progress which can be obtained from the center by request.

Primary support for the center is provided by the National Institute of Handicapped Research. Additional support is provided by funds from the Veterans Administration Prosthetic Center (now VA Rehabilitation Engineering Center) and National Institutes of Health, and a contract with the California State Department of Rehabilitation.

Neuromuscular Engineering

The mission of Neuromuscular Engineering is:

1. To work with medical personnel to define potential clinical uses for electrical stimulation of the neuromuscular system.
2. To develop equipment necessary to apply electrical stimulation in an appropriate way.
3. To develop instrumentation necessary to measure and evaluate the effectiveness of stimulation programs.
4. To collaborate with responsible manufacturers to allow useful equipment to become available to others and disseminate knowledge regarding clinical use of that equipment.

A secondary objective is to provide technical support to on-going clinical programs in areas where the group has particular competence.

Upper Extremity Control—R. L. Waters, M.D., and Bruce Bowman, M.S. Functional recovery of the upper extremity following stroke or traumatic brain damage can be a slow, variable process. Some patients gradually regain complete voluntary motor control of the arm and hand, while others show little or no recovery. Cyclical electrical stimulation with surface electrodes has been demonstrated to be effective in increasing joint range of motion. In addition, the combination of auditory and visual feedback with electrical stimulation

during an augmented voluntary contraction also has been shown to increase volitional motor control. The purpose of this project is to develop a comprehensive treatment program for the hemiparetic upper extremity using functional electrical stimulation and biofeedback. Individual treatments and devices, previously demonstrated to be individually effective, are combined in an integrated framework of automated therapies which allow more carefully controlled treatment and reduce the requirements for direct therapist supervision.

The individual treatment programs comprising the multi-level regime include: (i) single or multi-channel cyclical electrical stimulation for patients with little or no voluntary motor control; (ii) positional feefdback stimulation training (PFST) of the elbow or wrist, incorporating auditory and visual feedback of joint motion with electrical stimulation for patients with a minimum of five degrees of voluntary control; (iii) selectivity training, concentrating on single joint motion without involvement of other joints for patients with 10–15 degrees of selective motion at the elbow, wrist or fingers; and (iv) tracking training, to facilitate rapid reciprocating motion for patients with moderate selective control of the elbow, wrist or fingers.

The lowest level of treatment consists of cyclical electrical stimulation of upper extremity muscle groups demonstrating significant weakness, lack of voluntary control, or decreased sensory awareness using single or multiple channel stimulation as appropriate. The antagonists of spastic muscle groups are also passively stimulated to reduce excessive tone of the spastic muscles.

Single-channel cyclical stimulation is used to treat individual muscle groups. Stimulation (constant-current square-wave pulses at a rate of 35 pulses per second and 200 microsecond pulse duration) is initially applied for 15 minutes twice daily, and increased in intensity and duration of treatment (to tolerance) over 5–10 days to one hour of stimulation twice daily. The treatment is continued until discharge or until a patient advances to higher levels of training.

When cyclical stimulation therapy is appropriate for multiple muscle groups, a three-channel stimulator is used. Typical combinations of stimulation patterns provide humeral elevation, with synchronous elbow and wrist / finger extension, or elbow and wrist / finger extension followed by wrist flexion. Treatment follows the general plan above for single-channel stimulation.

When a patient demonstrates at least five degrees of active motion at either the elbow or the wrist, treatment is initiated with the appropriate positional feedback stimulation trainer (Fig. 1). Training is performed using isotonic load exercise tables with adjustable orthoses to position the joints adjacent to the target joint. Auditory feedback is provided by a tone which increases in pitch as joint extension increases. Visual feedback of the instantaneous joint angle is provided by a meter and a digital display. Electrical stimulation of the extensor muscle is triggered by an adjustable-goal threshold detector set to a point near the patient's maximum capability. As a patient exceeeds threshold during an exercise effort, a counter is incremented and a light illuminated to indicate success. Treatment is given in a 30-minute session, one to three times per day during the five-day treatment week.

As a patient develops increased control, treatment is begun to minimize synergistically patterned motion and facilitate selective motion. Equipment for selectivity training includes free elbow, wrist, or finger electrogoniometers, and the positional feedback display unit. A patient, wearing a goniometer, is instructed to extend the target joint without moving adjacent joints. A therapist provides verbal cues if patterned motion is observed and terminates the attempt if the undesired motion becomes excessive. After a 30-second rest, another attempt is made. The goal threshold detector, which triggers electrical stimulation of the

FIGURE 1.
Positional feedback stimulation trainer for the wrist. The adjustable orthosis which mounts to the table stabilizes the arm. A potentiometer built into the table is used to sense joint angle to provide motion feedback. The display unit gives feedback of an exercise effort by lights, an audio tone, an analog meter and a digital display of actual joint angle. Electrical stimulation is given to complete the joint motion after a patient achieves a threshold angle by voluntary effort. Weights may be added to a cable beneath the table to provide resisted exercise. Similar equipment is used to train elbow motion.

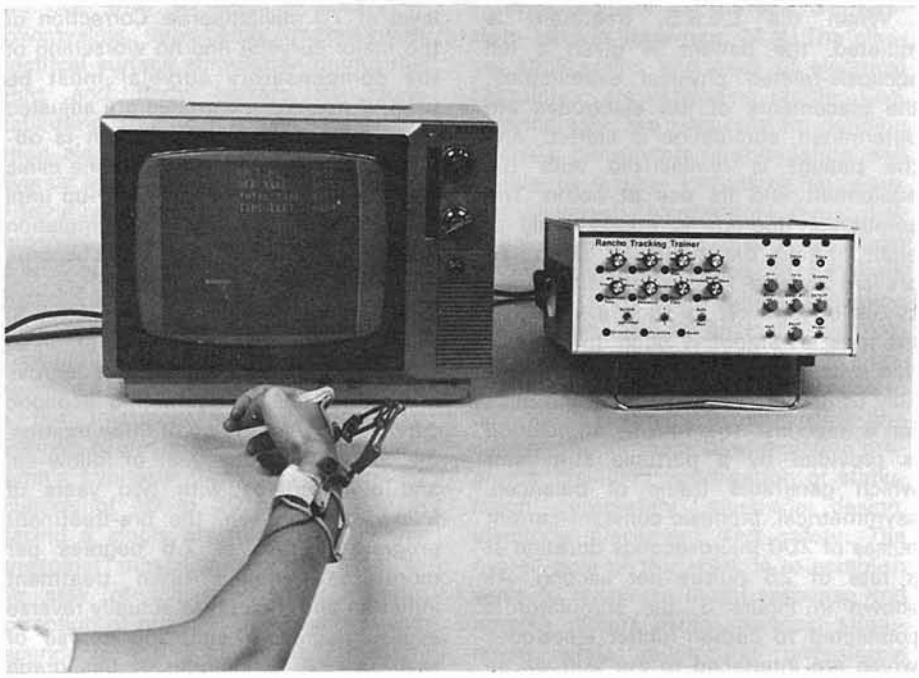


FIGURE 2.
Microprocessor controlled tracking trainer. The use of a microprocessor and a standard television set makes this device more versatile than previous prototype. The patient must control his joint angle to follow the motion of a target moving randomly across the TV screen. A cursor displayed beneath the target represents angular joint position, determined by the goniometer. This new design will eventually allow patients to use their own TV sets to train at home.

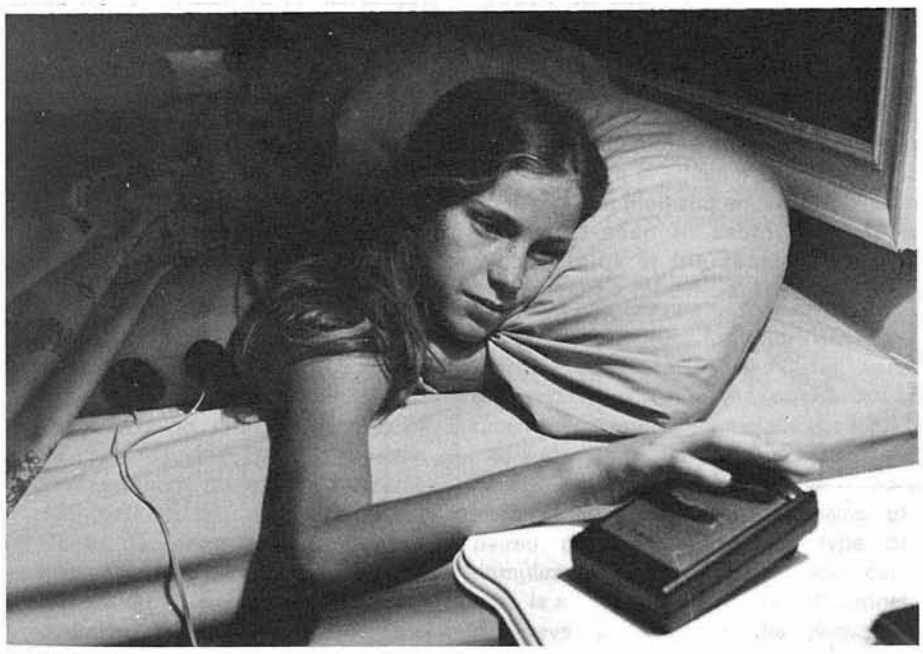


FIGURE 3.
Applicaton of the L.E.S.S. surface stimulator for scoliosis treatment. Muscle stimulation during the hours of sleep is provided by a battery-powered pulse generator connected to flexible electrodes attached to the skin by conductive adhesive.

target joint extensors to complete the movement, is set to approximately five degrees below the patient's maximum voluntary selective motion. Because selectivity training requires close therapist supervision, patients receive a single 15-to-30-minute treatment daily.

Patients who demonstrate more than 30 degrees of selective extension of the elbow, wrist or index finger, exercise with the feedback tracking trainer (Fig. 2). This device displays two light bars on a tabletop screen. One light bar randomly travels across the screen and forms a target which the patient is asked to follow with the motion of a specific joint. The second light bar indicates the patient's joint position, which is monitored using either the elbow or wrist feedback stimulation training table or one of the portable electrogoniometers. The maximum excursion, range, and rate of change of position of the target band are adjustable. The width of the tracking band can be set from 1 to 45 degrees of joint motion, allowing an adjustable tracking error. As long as the patient maintains his joint position display within the target band, time accrues on a clock. Whenever the error exceeds the band, a buzzer sounds. A second timer measures the total training period.

Correction of Spinal Deformities—J. Axelgaard, M.S. and J. C. Brown, M.D. In the teatment of abnormal curves of the spinal column, scoliosis (lateral curvature) accounts for about 80 percent of all cases of spinal deformity. Kyphosis ("round back") is seen in approximately 15 percent, and the remaining 5 percent is divided between lordosis ("swayback"), kyphoscoliosis and lordoscoliosis. These deformities have in their mildest form an impact on cosmetic appearance alone, while severe curvature results in pain and cardiopulmonary impairment, remedied only by corrective spine surgery. Electrical muscle stimulation seems to be a feasible alternative to bracing in the early treatment of scoliosis in the growing child or teenager.

The project proposes to develop a clinical program for the treatment of all progressive spinal curvature deformities using electrical stimulation. This includes the design and production of portable muscle stimulators and the development

and use of appropriate surface electrode systems. The clinical effort is supported by animal studies, supplementary clinical studies, and development of additional hardware as required on the basis of obtained clinical data.

For the treatment of scoliosis, in particular, the technique of Lateral Electrical Surface Stimulation (L.E.S.S.) is used. A strict protocol, implementing standards determined by an international advisory board of prominent spine surgeons, sets guidelines for proper patient management, data analysis, and involvement of additional investigators. A treatment followup of at least 2 years for several hundred patients will provide data for a control evaluation of the effectiveness and feasibility of this treatment method. Neuromedics, Inc., with whom collaborative efforts have been initiated, manufactures the stimulator units and is currently coordinating an international multi-center clinical evaluation to collect data required by the FDA.

In order for a scoliosis patient to be admitted to the L.E.S.S. program as a protocol patient, the following selection criteria must be fulfilled:

1. Idiopathic scoliosis;
2. 20 to 45 degrees of curvature;
3. Documentation of curve progression; and
4. At least one year of bone growth remaining.

All patients are given an equal choice between bracewear and electrical muscle stimulation. Only a small percentage prefer the brace (Milwaukee or low profile) over L.E.S.S. treatment.

When the L.E.S.S. treatment is initiated, the patient is given a full scoliosis-related physical examination, the placements of the electrodes are determined, stimulation is started, and the patient is familiarized with the equipment and its use at home. The stimulation therapy is applied only at night, during the hours of sleep. To prevent muscle fatigue, the stimulator cycles on and off in such a way that the muscles smoothly build up contraction over a period of 2 seconds, remain fully contracted for 4 seconds, and relax for 6 seconds. The muscle stimulation is provided by a portable stimulator which generates trains of balanced, asymmetrical, biphasic constant-current pulses of 200 microseconds duration at a rate of 25 pulses per second. As shown in Figure 3, the stimulator is connected to carbon-rubber electrodes which are interfaced to the skin via an electrically conductive adhesive coupling media.

Patients with single curves use the ScoliTron™ stimulator which Med-General, Inc. manufactures per Rancho specifications, while patients with double major curves make use of the NME-201 dual-channel stimulator developed by Neuromuscular Engineering.

After a 2-week adaptation phase, a scoliosis patient returns for a check of the stimulation efficiency. A prone X-ray is taken without stimulation to verify curve flexibility (change in degrees from standing to supine position) and location of the electrodes. If necessary, the electrode placement is adjusted. A second X-ray is taken with a stimulation level of 70 milliamperes. Correction of the major curve(s) and no worsening of the compensatory curve(s) must be seen; if not, the electrodes are adjusted until an acceptable correction is obtained. The patients return to the clinic every 3 to 6 months for follow-up until bone maturity, at which time stimulation is discontinued and further visits become annual.

Follow-up results of the L.E.S.S. treatment are displayed in the graph of Figure 4. The average change in degrees is plotted for 77 idiopathic scoliotic curves with a follow-up of three months, 34 curves with one year of follow-up, and eight curves with two years of follow-up. As seen, the pre-treatment progression rate of 2.5 degrees per month is arrested upon treatment initiation and the curves actually reverse a few degrees during the course of treatment. A breakdown of this graph reveals improvement (⩾ 5 degrees decrease) in 12 percent of the curves, stabilization (between +5 degrees and −5 degrees change) in 84 percent progression (⩾ 5 degrees increase) in 4 percent. In other words, the L.E.S.S. treatment method has stopped curvature progression in 96 percent of the cases in the idiopathic population. The overall L.E.S.S. program success is 90 percent since 6 percent of the patients (this group not included in Figure 4) have not complied with the treatment requirement of using stimulation every night at sufficient strength.

In addition to the main idiopathic treatment program, 11 patients with scoliosis secondary to spinal cord injury,

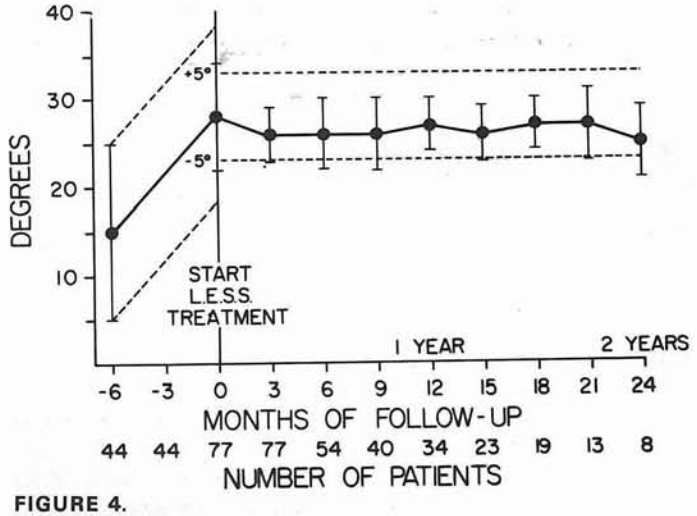


FIGURE 4.
L.E.S.S. treatment results. Graph with standard deviation bars shows average degrees of 77 idiopathic curves for up to two years of treatment.

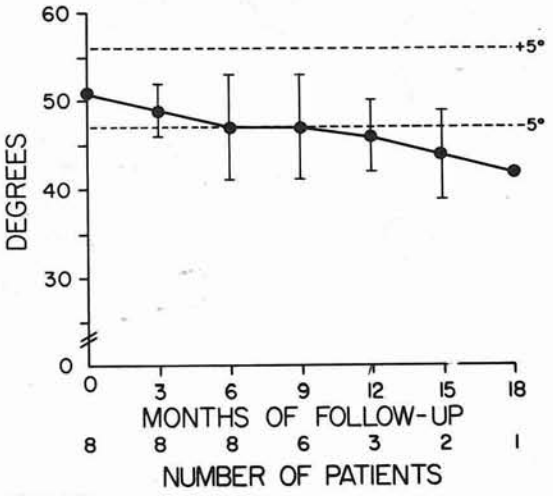


FIGURE 5.
Follow-up results of patients with Scheuermann's kyphosis being treated with electrical surface stimulation.

and one with scoliosis secondary to poliomyelitis, are being treated with electrical surface stimulation during the night and body jackets for trunk stabilization during the day. This population also shows a trend of arrest, or reversal of progression.

In a previously performed clinical screening to determine the best location of surface electrodes for the treatment of scoliosis, it was observed that a side effect from stimulating the paraspinal musculature was a hyper-extension of the spine. This result is now being used in the treatment of Scheuermann's kyphosis or postural feedback. Scheuermann's kyphosis often has associated scoliosis of 10 to 20 degrees, so by placing a single electrode pair on the paraspinal musculature unilaterally to the side of the scoliosis convexity, correction of primarily the kyphosis and secondarily the scoliosis is obtained. When no scoliosis exists, either bilateral stimulation of the paraspinal muscles by a dual-channel stimulator or alternating (every other day) single-channel stimulation is applied. Long-term treatment followup results of a group of eight patients with progressive Scheuermann's kyphosis are shown in Figure 5, where the average curvature has decreased from 51 degrees at start to 46 degrees after 1 year and 42 degrees after 1½ years. All patients show correction of their kyphosis with either reduced or unchanged wedging of the apical vertebrae.

The expansion of this project into an International Study on Lateral Electrical Stimulation for Scoliosis (ISO-LESS) continues to be successful. The Rancho REC data have now been confirmed by three major European scoliosis treatment centers: Sahlgren Hospital, at Goteborg, Sweden, with 23 patients of up to 2 years followup; Orthopaedischen Universitaetsklinik, Muenster, Germany, with 20 patients of up to one years, and Centro de Recupero Funsionale per Scoliosi, at Florence, Italy, with 16 patients of up to 6 months follow-up. In total, the ISO-LESS program now includes about 50 centers in the United States and 20 centers abroad.[a]

[a] Anyone interested in becoming involved in this program should contact Ms. Annette Woodword, Neuromedics, Inc., P.O. Box 617, Freeport, Texas 77541 (800-231-2330).

Effectiveness of Surface Stimulation—Bruce Bowman, M.S. The clinical applications and uses of electrical stimulation are expanding rapidly. Correspondingly, the necessity for defining effective parameters of stimulation, and access to reliable stimulator hardware, are becoming increasingly more pronounced. Stimulators need to be easier to use, electrodes need to be more effective, and the noxious sensation sometimes accompanying electrical stimulation needs to be reduced.

Studies continue to be made to determine methods of enhancing the clinical effectiveness of stimulation programs, including optimization of stimulation parameters, electrode design, electrode placement and safety. The overall goal of this work is to establish ways to maximize motor response and training effects using electrical stimulation while minimizing undesirable sensory effects and fatigue.

Two previous studies have been conducted in which differences in sensation were compared among pulse durations, monophasic and biphasic pulse waveforms, and constant-current and constant-voltage sources during electrical stimulation of the quadriceps muscle of healthy subjects. The results of these studies indicated a significant subject preference for 300 microsecond (μs) pulses in preference to 50 μs pulses—regardless of the waveforms and current source. No significant preference was found when constant-current and constant-voltage pulses were compared.

A new investigation underway is designed to compare the previously preferred stimulus form of 300 μs biphasic pulses with two new, very different types of stimuli which have recently become commercially available. The first of these latter types, commonly called "high voltage stimulation," consists of monophasic spike trains of paired pulses. The second type of stimulus, known as "interference" current, is a combination of two orthogonal sinewave currents. In the proposed study, five stimulus currents will be compared: (i) 300 μs biphasic current; (ii) and (iii) twin 20 μs pulses of "high voltage" current at two different two different periods of separation between the coupled spikes, and (iv) and (v) two different frequencies of sinewave "interference" current.

Following previously established protocol for stimulus-comparison studies, testing will be performed on 10 healthy female volunteers who are between 20 and 30 years of age. Each sample current will be given in 1½ second trials, separated by 1 minute rest periods. A strength-amplitude curve, carried to a subject's maximum tolerance, will be generated for each current. Comparison of these curves will be made to judge effectiveness and comfort of the different types of current. Although no data have been collected yet, the findings of this study may significantly influence development of improved stimulator hardware and parameters of stimulation for clinical programs.

Two major problems in the clinical use of surface stimulation are: (i) obtaining an adequate muscular contraction, and (ii) maintaining electrodes in place for multiple treatments. As new electrode systems have become available, clinical evaluations of their effectiveness for motor stimulation have been made at Rancho Los Amigos Hospital. A new study is underway to compare several recently designed electrode systems, which show promise for effective therapeutic use, with electrodes previously found superior in our clinical stimulation programs.

The electrode systems being compared include: (i) carbon rubber pads with Spectra™ gel (system most frequently used at this facility at this time); (ii) carbon rubber pads with Electron II™ gel; (iii) carbon rubber pads with Caria conductive adhesive; (iv) Neuro Ice™ (neuro-conductive electrode); (v) 3M Company multiple-application electrode (neuro-conductive), and (vi) 3M Company maintained-application electrodes (neuro-conductive).

Two comparison studies will be made. Each electrode system will be used to generate a strength-amplitude curve (to subject tolerance) on the right quadriceps muscles of 10 healthy, non-obese females who are between 20 and 30 years of age. Not more than one electrode per subject will be evaluated on a test day, and testing will be made on no more than two sequential days. The second comparison will be made among the maintained application electrodes—numbers (i), (ii), (iv) and (vi)—to evaluate their effectiveness over a 5-day period. Electrode impedance will be

measured each of the 5 days, and a strength-amplitude curve will be repeated on the fifth day. No data are yet available.

Pathokinesiology

The Pathokinesiology Service was developed to advance patient care by establishing means of replacing subjective impressions with objective measurement of neuro-musculo-skeletal function. Application of this overall objective has led to three more specific goals.

1. To develop a comprehensive performance measurement system that will provide more accurate definition of the disabilities associated with the different types of physical impairment.
2. To provide means of measuring therapeutic effectiveness of reconstructive orthopedic surgery, orthotic and prosthetic management, and physical therapy procedures.
3. To develop instrumentation appropriate for objective measurement of patient performance in the standard clinical environment.

The Dynamics of EMG / Force Movement Relationships for Knee Extension—D. Antonelli, M.S., and J. Perry, M.D. Quantitation of the relationship between EMG and muscle force is imperative for many research and clinical applications: prediction of muscle force, assessment of disability, evaluation of therapy, development of prostheses, physical training, and preventive procedures. An exhaustive study has been designed to collect and analyze data on the dynamics of EMG / force relationships during knee extension, so that the complex interactions among the various factors may be incorporated into a mathematical model. Influences of fatigue, antagonistic muscles, velocity, passive resistance, and signal acquisition equipment must be considered. Thorough analysis of the data acquisition system and the effects of its various components—individually and in concert—on the signals of interest will be used as guidelines in selecting the optimal electrode configuration for use in future studies and routine clinical testing. Evaluation of the signal acquisition system can also be valuable in establishing universal standards for EMG recording, which has been fraught with inconsistent and inappropriate techniques.

The initial task involved investigation of the electrode parameters and their effects on the signal characteristics, specifically impedance and power spectral density. A series of tests on five normal subjects compared various combinations of electrode types, sizes and inter-electrode spacings at several spacings at several levels of effort and two knee angles. Computed electrode impedances and power spectra were subjected to t-tests, analyses of variance, and linear regression procedures to assess parameter interactions and select the optimal electrode configuration for further studies. Data from each subject were normalized to allow comparison and averaging. A rather complex equivalent RC circuit is necessary to approximate the behavior of the electrode-tissue system. Simplification of this network for mathematical analysis predicted that measured electrode resistance and capacitance will be frequency-dependent. Experimental results confirm this prediction and the validity of the model.

The phase angle of the impedance remained relatively constant with frequency, varying little even between electrode types and sizes. As expected, the magnitude of the impedance is inversely proportional to the exposed surface area of the electrode (Fig. 6). Inter-electrode spacing was found to influence the impedance of large surface electrodes only, while effort level had no effect.

Using high-performance amplifiers designed and built in this laboratory, EMG's were recorded from the vastus lateralis during voluntary isometric or isotonic contractions. Power spectral densities of the digitized signals were calculated on a computer. Regression analysis confirmed that total signal power is linearly proportional to the level of effort (force). Although qualitatively consistent, this relationship is subject to great quantitative variation between different subjects and test conditions. The sensitivity of EMG power to changes in force was more apparent with wire than with surface electrodes, and more evident for both types of electrodes at greater inter-electrode distances. Among the various wire electrodes tested, those having the longest exposed area at the end (6.4 mm) showed the greatest sensitivity to force changes (Fig. 7).

In addition to total signal power, we also investigated variations in the distribution of that power across the frequency range. As has been shown previously, wire electrodes transmit a wider range of frequencies: 95 percent of the power from surface electrodes is

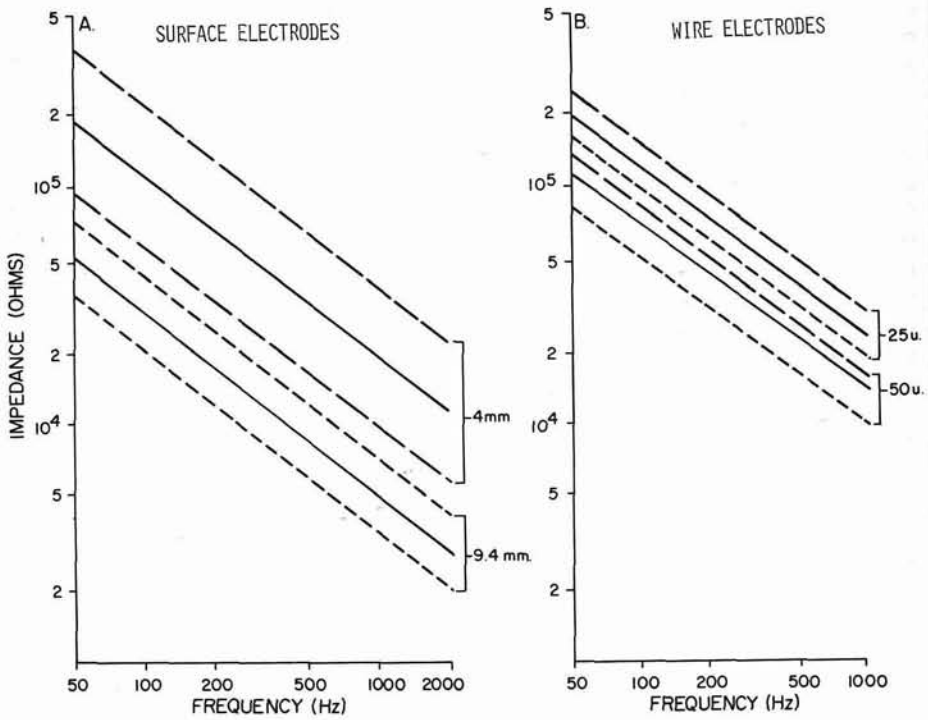


FIGURE 6—Electrode impedance showing 95% confidence intervals.

limited to frequencies below approximately 300 Hz as compared to 650 Hz for wire electrodes. Increasing effort tends to concentrate more of the power in the lower frequency ranges. This phenomenon has also been noted in circumstances where the muscles are fatigued and metabolic changes cause a reduction in conduction velocity. Since our studies were carefully designed to avoid fatiguing the subject and biasing the data, this observed shift is undoubtedly due to other factors, probably including motor unit synchrony at high effort levels. This theory is supported by the increased amplitude of the EMG at greater efforts.

The primary goal of these investigations was to decide which of the various electrode configurations was optimally suited to the remaining project in this study, as well as to our routine clinical applications. Not only the above results, but also practical questions regarding facility of use, reliability and patient comfort were considered. In the pathokinesiology laboratory, it has been decided to use double-wire insertions of 50 nylon-insulated nickel-copper-alloy wire, with 3.2 mm of exposed wire at the active tips. Of all electrodes tested, this provides the optimum desired impedance and frequency response characteristics, sensitivity to changes in force level, ease and reliability of use, flexibility of application, and minimum patient discomfort. In situations where wire electrodes are impractical or otherwise undesirable, small (4 mm active diameter) surface electrodes, spaced 5 cm apart, will be employed. These two electrodes will become the standards in this laboratory.

In addition to fulfilling the mission of choosing the optimum electrode, the data we have collected can be used as a basis for a mathematical model of the EMG / force relationship. Equations describing the impedance-frequency dependence have been determined, as have regression lines relating total signal

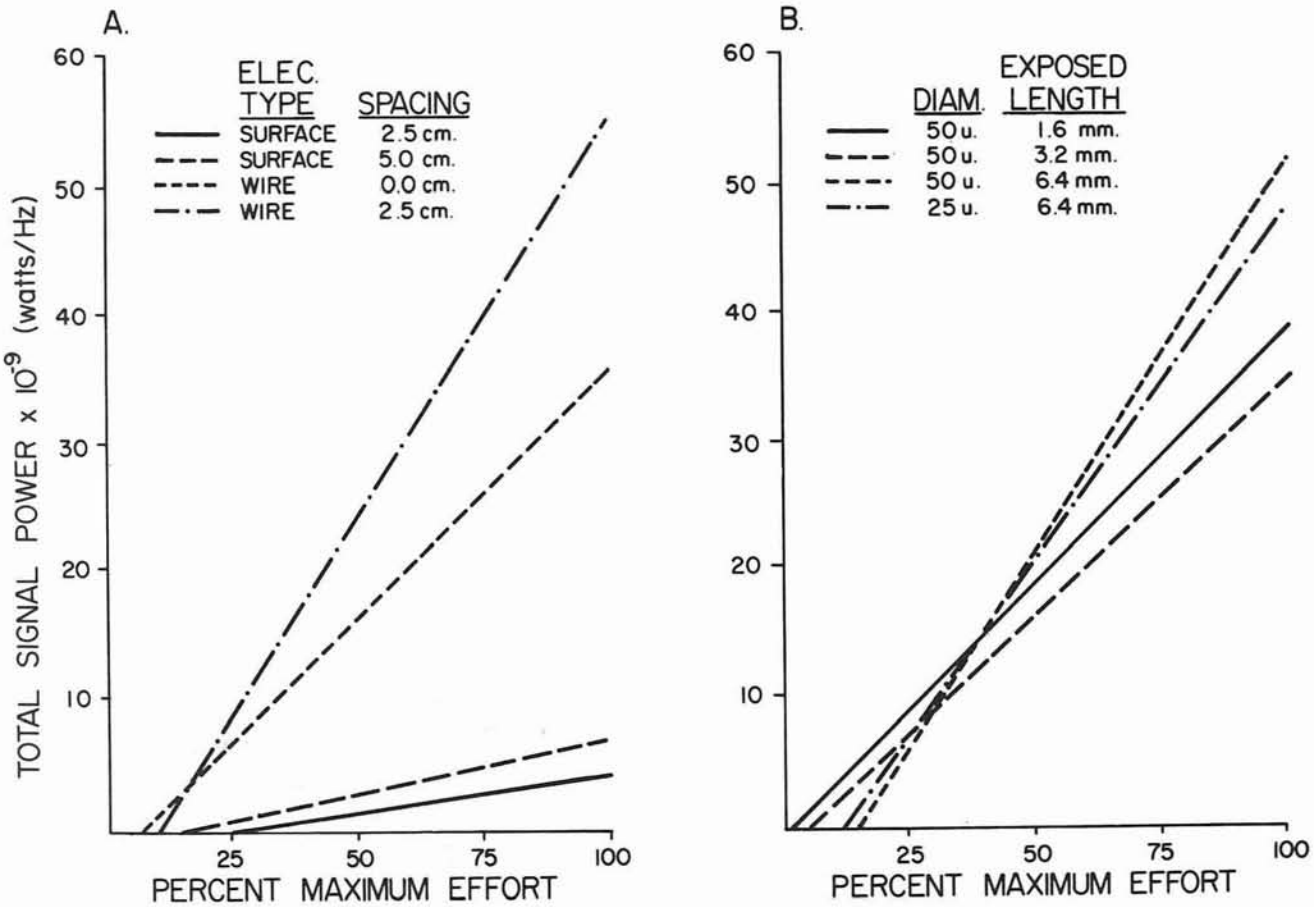


FIGURE 7—EMG signal power as a function of muscle force

power to measured force for voluntary isometric or isotonic contractions. Data from subsequent tasks will build and elaborate on this groundwork.

EMG data acquisition is relegated to a minor role in the literature. Another goal of this project is to establish minimum standards for an amplifier which will process EMG from wire and surface electrodes without distorting the signal. These standards will then be used to design and build a high performance EMG amplifier.

The system was modeled using a computer circuit-analysis program (ECAP). The effect of varying each parameter was examined by comparing input and output signals. The input signal source was previously described above, and the amplifier input stage model is shown in Figure 8.

Resulting "worst case design" parameters for the EMG source are as follows:

1. 50 μV to 5 mV @ 10 Hz to 10,000 Hz
2. Baseline voltage: <50 mV @ <10 Hz
3. Common mode voltage: <1 V @ power frequency
4. Differential impedance: $\leqslant$0.5 MΩ @ 50 Hz
5. Imbalance in differential impedance: $\leqslant$0.1 MΩ

The resulting amplifier design specifications were:

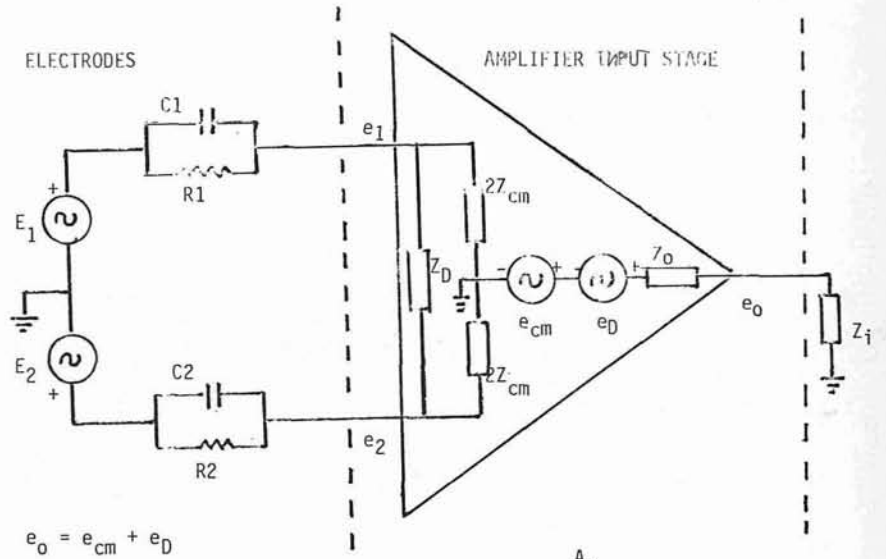
1. Noise (referred to input): <2 μV RMS
2. Common mode rejection ratio: > 120 db @ 60 Hz
3. Differential mode impedance: >50 MΩ
4. Common mode impedance: $>10^{11}$ Ω
5. High frequency limit: >2 kHz
6. Low frequency limit: $\simeq$10 Hz
7. Selectable gains of 500 and 1000

The resulting amplifier (Fig. 9) performed true to the analysis and incorporates parameter specifications far in excess of those minimums determined for distortion-free data acquisition. The basic design features are:

1. A DC differential coupling at the input;
2. A single-ended AC coupling at the output;
3. Incorporation of an input guard or driven shield around the signal lines; and
4. Provision for capacitive null adjustment to optimize the CMRR.

The resulting performance specifications are

R_D = 300 MΩ
C_D = 10 Picofarads
R_{cm} = 100 MΩ



$e_o = e_{cm} + e_D$

$e_D = A_D * (e_2 - e_1)$

$e_{cm} = 1/2A_{cm} * (e_2 + e_1)$

$A_{cm} = \frac{A_D}{CMRR}$

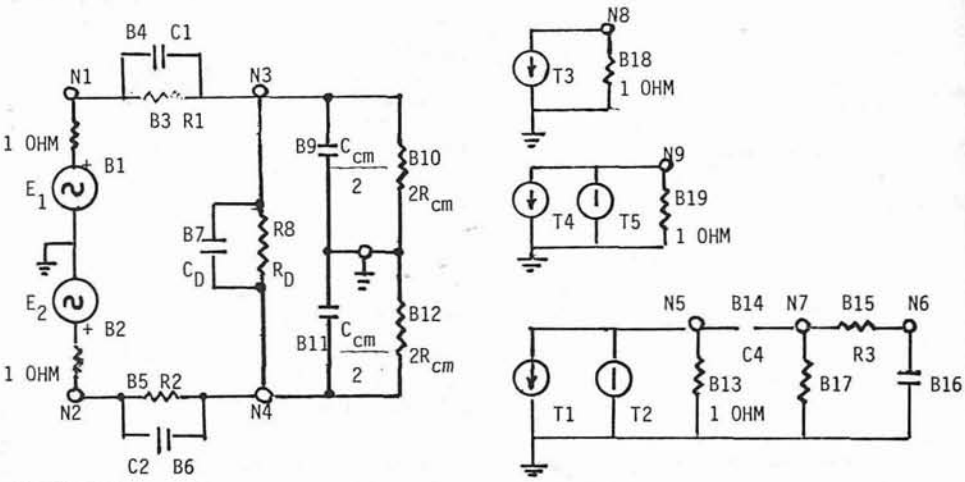


FIGURE 8.
Equivalent circuit & ECAP form of equivalent circuit for input stage of EMG amplifier

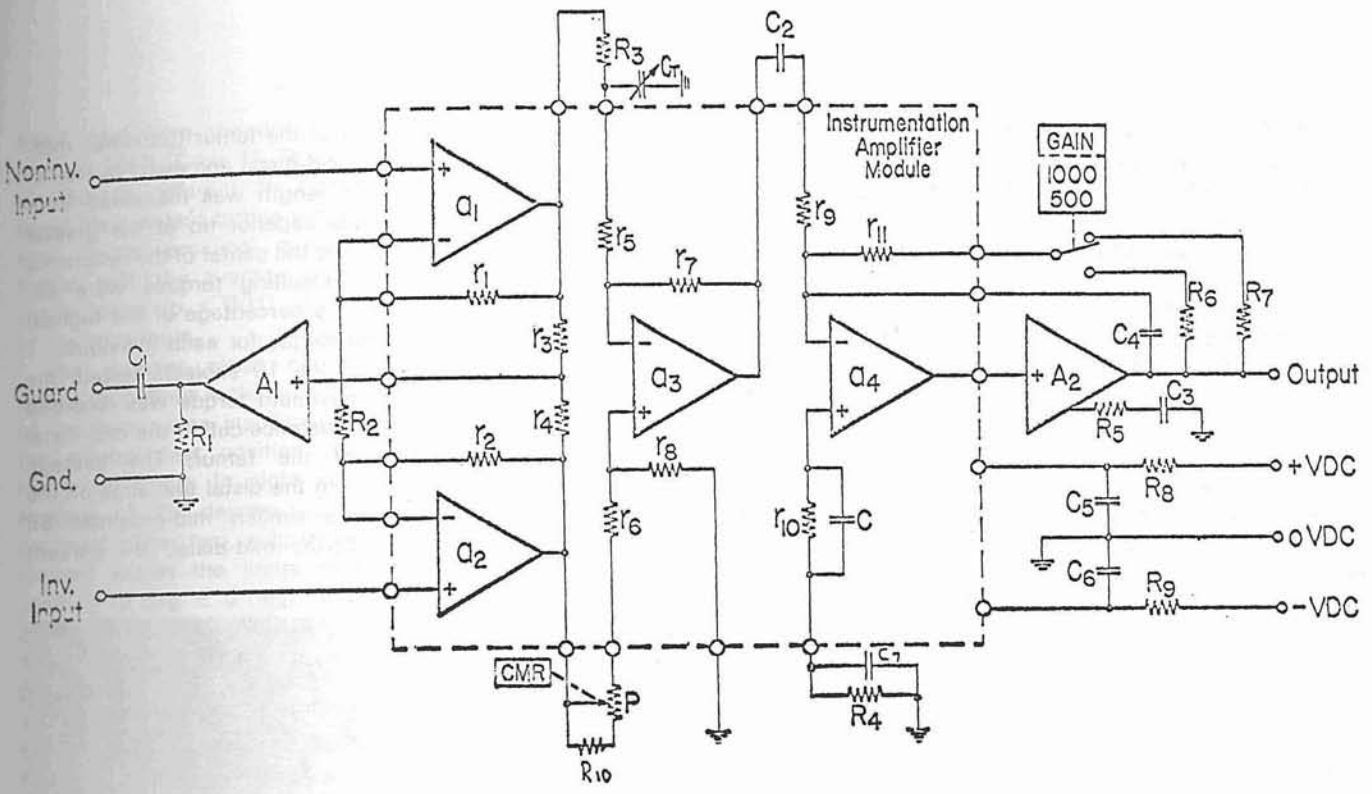


FIGURE 9—EMG amplifier schematic

C_{cm} = 10 Picofarads (using the guarded input)
= 100 Picofarads (without a guarded input)
Frequency response 12 Hz to 10 kHz

Common Mode Rejection Ratio

f	Balanced Input	Unbalanced Input
10Hz	130 db	120 db
100 Hz	130 db	105 db
1000Hz	110 db	84 db

This amplifier is stable, repeats its specifications channel after channel, is relatively inexpensive to construct, and establishes a standard of performance that is uncompromising in its ability to transfer an EMG signal from wire or surface electrodes to recording, processing, or display instrumentation. Two 4-channel units are now in service in the pathokinesiology laboratory.

Energy Costs of Ambulation in Children with Myelodysplasia—Lynn Thomas, M.S., R.P.T. The purpose of this study was to determine the energy cost of walking and wheelchair propulsion in children with myelodysplasia, and to identify which clinical factors, if any, relate to the energy cost of walking. Energy cost was measured in 15 myelodysplastic children during free walking using their habitual gait pattern. An alternate gait pattern and wheelchair propulsion were tested when appropriate.

In all free-walking trials, the myelodysplastic children walked at 59 percent of normal velocity while utilizing 218 percent more oxygen per meter traveled than did normal children. No significant difference in oxygen consumption per minute was observed when the patients were compared to free velocity walking in normal children of similar age. The use of a swing-through gait resulted in a 33 percent improvement in energy efficiency of walking over the use of a four-point gait. Use of a wheelchair allowed myelodysplastic children to approximate the velocity and efficiency of normal children.

The level of neurological lesion ($r = -.498$) and amount of hip flexion contracture ($r = -.706$) were negatively related to velocity and were positively related ($r = .546$) to O_2 consumed per meter (milliliter O_2 / kg·m) and / or energy cost (milliliter O_2 / kg·min). Hip extension strength ($r = .565$) and knee extension strength ($r = .599$) were positively related to velocity and negatively related to energy cost ($r = -.521$ and $-.525$) and efficiency ($r = -.566$ and $-.788$).

These results indicate (i) that myelodysplastic children tend to select a gait velocity which minimizes the energy cost of walking; (ii) for those children who regularly use a wheelchair, this activity requires similar energy demands to that of normal free walking; (iii) children with myelodysplasia are more efficient using a swing-through than a four-point gait pattern; and (iv) the energy requirements for free walking in children with myelodysplasia are related to several clinical factors including level of lesion, hip and knee extension strength.

Evaluation of CARS-UBC Triaxial Goniometer—J. Perry, M.D. and D. Antonelli, M.S. The purpose of this study was to determine the efficacy of the CARS-UBC[b] triaxial knee goniometer. A series of tests was developed to examine the mechanical characteristics and the clinical viability of the device. Previous research in this laboratory has shown that the triaxial linkages of the type used in this goniometer have had recurrent problems with cross-talk between the three presumably independent channels. The mechanical evaluation consisted of a series of three tests that specifically addressed this topic. To facilitate the standardization of this testing, a mechanical model that simulated the knee joint and the associated limb segments was implemented. The clinical phase of the evaluation involved a comparison of the CARS-UBC unit

and the RLAH knee goniometer (Fig. 10). Ten normal subjects were examined while performing normal, slow, and fast gait patterns. Goniometric and footswitch data were analyzed and compared.

The mechanical testing demonstrated conclusively that cross-talk was indeed a significant problem in the CARS-UBC triaxial module. Examination of the flexion-extension and abduction-adduction axes indicated negligible cross-talk between channels, with the greatest deviation being 4 degrees at the extremes of the range of motion. However, internal and external rotations of more than 10 degrees resulted in significant inaccuracies in the other axes. This is due to the fact that the parallelogram linkages and sliding mechanisms do not adequately absorb the translations that are necessitated by the incongruency of the anatomical and mechanical axes of rotation.

Misalignment tolerances of the module were also examined. Proximal, distal, anterior, and posterior displacements of up to 1 cm were found to have minimal effects on accuracy. Rotational misalignments of greater than 15 degrees introduced significant errors.

Mean application and alignment time of the CARS-UBC unit (16.5 min) was found to be excessive when compared to the RLAH unit (2.0 min). Once applied, repositioning was difficult due to the strapping arrangement. Eight of the 10 subjects complained of skin discomfort and 4 felt confinement during the ambulation trials.

Since the RLAH knee goniometer is uniaxial, only the flexion-extension data were considered in our comparison. At heel strike, loading response, and terminal stance the two goniometers showed very similar results with the mean differences being 0.94 deg, 3.9 deg and 1.6 deg respectively. At preswing the mean difference was 8.2 deg and during swing phase this increased to 10.3 deg. In all phases but heel strike, the CARS-UBC unit demonstrated the larger of the values for flexion. Subsequent analysis and measurement of the videotapes of three subjects who showed large discrepancies revealed that the RLAH values more closely approximated the measured values in all cases. The error in the CARS-UBC values may be attributed to cross-talk from the rotation axis caused by the tibial rotation and translation that are associated with knee flexion.

Normal Hip Abduction Torque—J. Gronley, M.A., R.P.T. The purpose of the study was to evaluate the variability in isometric torque measurements obtained from different anatomical sites along a limb segment. Maximum hip abduction force, recorded by a tensiometer in series with a thigh cuff, was obtained from each of four sites along the length of the femur (proximal, mid-proximal, mid-distal and distal quarters). Lever arm length was measured from the anterior-superior tip of the greater trochanter to the center of the resistance cuff. The resulting torques were expressed as a percentage of the highest maximum torque for each individual.

In 7 of the 10 subjects tested, the highest maximum torque was recorded with the resistance cuff in the mid-distal quarter of the femur. The average torques from the distal test sites on the femur were similar: mid-proximal, 88 percent MAX; mid-distal, 96 percent

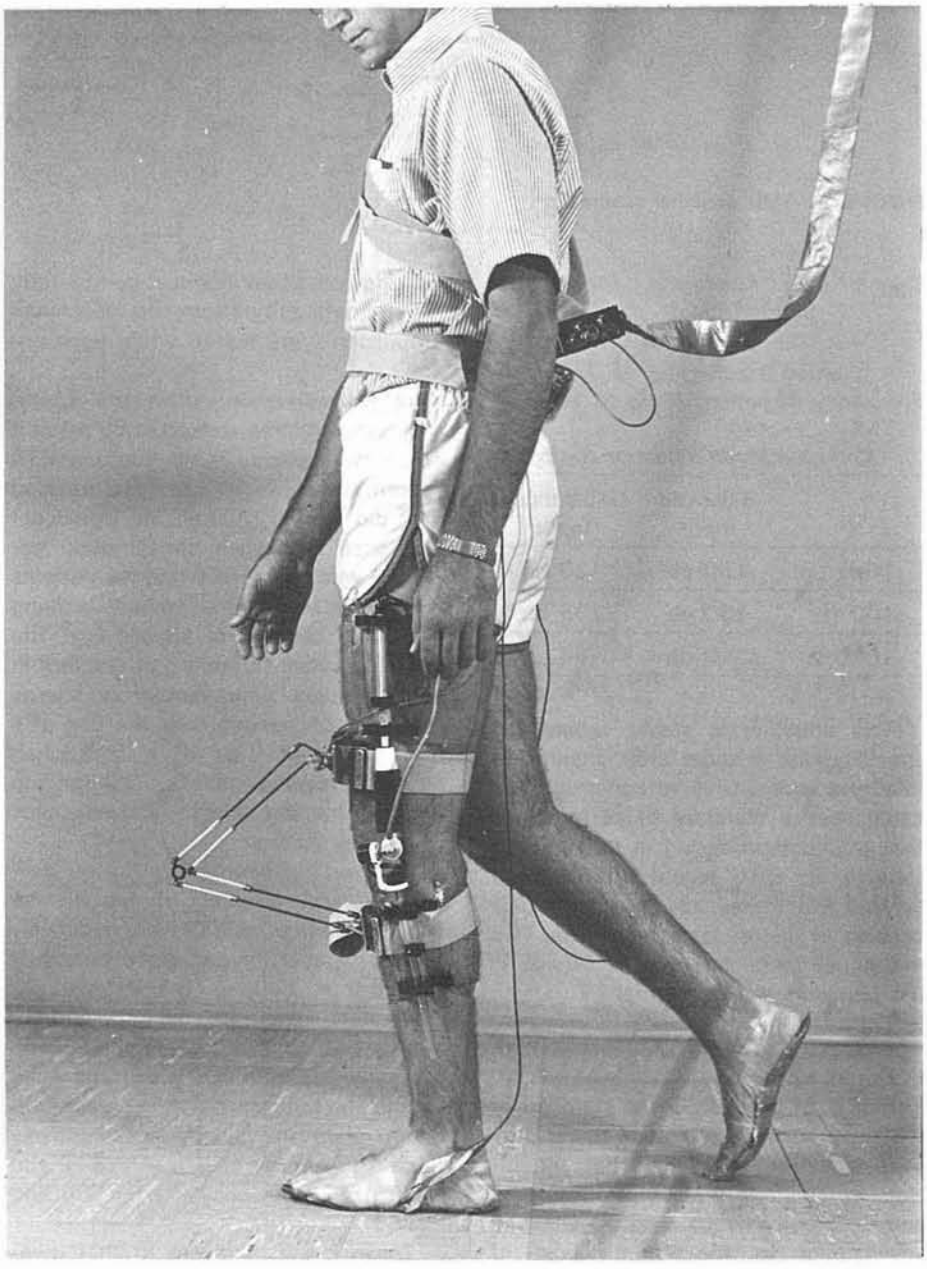


FIGURE 10.
Simultaneous recording of data from CARS-UBC and RLAH goniometers.

[b] Canadian Arthritis Rheumatism Society-University of British Columbia

MAX, and from the distal femur, 89 percent MAX (Table 1). These were not significantly different. No subject registered his greatest torque when the cuff was in the proximal quarter of the femur, with the average being significantly lower ($p < .001$) at 59 percent of the maximum.

The primary cause of the lower torque recordings in the proximal quarter of the femur was inability to maintain the neutral test position during the maximum effort. In eight subjects an average of 20 degrees of abduction occurred. The two subjects who remained within the limits of the test position (0 deg ± 5 deg), recorded 75 percent and 96 percent of their maximum effort with the proximal cuff placement.

Factors contributing to loss of test position include the greater amount of subcutaneous tissue in the proximal thigh, and disparity between the line of the soft tissues and the line of the femur in the subtrochanteric region.

A second factor contributing to low torque recordings proximally was the high cuff forces resulting from the very short lever arm. Eight subjects noted soft tissue discomfort along the superior edge of the resistance cuff.

With the short AK amputee, strength testing is very unreliable due to the short lever increasing cuff pressures and the difficulty in maintaining the test position.

Project Threshold—Nancy Somerville and Heidi McHugh Pendleton, B.A., O.T.R. The mission of Project Threshold is to help disabled persons gain independence in activities of daily living and / or vocational pursuits. This is accomplished by providing information and advice on equipment which can enable an individual to be more independent or can significantly reduce the assistance required of others; by having equipment available for use on a short-term basis; and by providing custom design and fabrication of equipment when there is no commercial source.

Project Threshold comprises two separate but interrelated projects: the Rehabilitation Equipment Demonstration Unit (REDU), and Client Services. The REDU is one of two sites selected by the National Institute of Handicapped Research to serve as a model program for developing a means of documenting and disseminating information regarding rehabilitation equipment within the United States. The primary functions of the REDU are: (i) to provide opportunities for consumers to try out this equipment to determine suitability prior to purchase, (ii) to provide information to consumers and professionals in the area of commercially available assistive devices (rehabilitation equipment), and (iii) to perform evaluation of equipment and provide feedback to manufacturers and developers concerning the equipment.

The REDU is housed in a 1400-square-foot building called the Model Home which has been stocked with numerous equipment items available for trial use. A number of unique features have been incorporated into the Model Home. For example, all of the fixtures in the bathroom are moveable. This allows arranging the toilet, bathtub and sink into positions that approximate the client's home situation. In this way, clients can be taught techniques of maneuvering the wheelchair in the bathroom and methods of transferring onto the toilet or into the bathtub which will really work in their homes. In addition, the cabinets below the kitchen sink have been removed to allow head-on access to a wheelchair. The drain pipes under the sink were shortened and re-routed to eliminate the safety hazard of burning legs on the pipes when pulling up under the sink in a wheelchair. The padding under half the shag carpeting in the bedroom of the Model Home was removed to allow a comparison of propelling a wheelchair on carpet with and without the padding. (Removing the padding offers a viable alternative to removing all carpeting in a client's home.)

Catalogs and brochures on commercially available equipment useful to the disabled have been collected from over 550 manufacturers and incorporated into a master file. A cross-referenced index system for classifying all equipment information, is currently being developed by the REDUs. This index will list categories of equipment with a description of the major feature of the equipment. Two sections of the index pertaining to equipment useful for personal care and home management have been completed and are part of a computerized data base entitled ABLEDATA accessed through National Rehabilitation Information Center (NARIC). Additional sections of the index such as aids for mobility, communication, etc., are being developed in cooperation with other RECs.

A major addition to the REDU project is the recent inclusion of an Information Broker position. The Information Broker will be responsible for processing information requests using the ABLEDATA and REDU resources.

As a result of funding received in October, 1979, from the National Institute of Handicapped Research (NIHR), the Rancho REDU was able to add full-time staff to develop and expand the existing program. During the period from February 1 to October 31, 1980, 237 consumers received assistance in selecting and trying out assistive devices prior to purchase, and 153 equipment information requests were processed. In addition, 1073 individuals, including inpatients at Rancho Los Amigos Hospital, allied health professionals, and other rehabilitation professionals visited the REDU.

Project Threshold's Client Service is a program designed to identify and solve the independent living and work-related problems of individuals with severe disabilities. This program, funded by the Department of Rehabilitation, utilizes a systematic evaluation process which has evolved over the past 3 years. The process utilizes a team approach which includes the client, counselor, selected Project Threshold staff, and appropriate allied health consultants on an as-needed basis. In using this process, solutions involve

TABLE 1
Number of individuals recording their greatest torque in each quarter of the femur, and the mean torque (expressed as a percent of maximum) for each cuff location.

	Proximal	Mid-Proximal	Mid-Distal	Distal
MAX Test Site	0	2	7	1
$\bar{x}$ Torque (percent MAX)	59 ± 16*	88 ± 9	96 ± 9	89 ± 6

* Significance = $p < .001$

exploring the use of adaptive behavior, recommendations of commercially available assistive devices, and when there is no commercial source, custom design and fabrication of equipment.

Many times an item designed for an individual client may meet the needs of numerous individuals. One example is an automatic leg bag emptying device shown in Figure 11. A rubber extension tube extends from the leg bag through a solenoid-operated valve mounted on the wheelchair footrest. The device is powered by the wheelchair battery and is activated by a switch mounted on the wheelchair armrest.

The Client Service program has been widely utilized by vocational rehabilitation counselors. During this reporting period, 79 new referrals were submitted by counselors, and a total of 119 severely disabled clients received comprehensive services. Due to the increased popularity of this program, there continues to be a substantial waiting list of clients. An annual report entitled "Project Threshold—A Model System for Delivery of Rehabilitation Engineering Services" was published in November, 1980. This report details client cost data, includes representative case examples, and describes the program organization as well as the close and unique collaboration between REC personnel and the State Department of Rehabilitation.

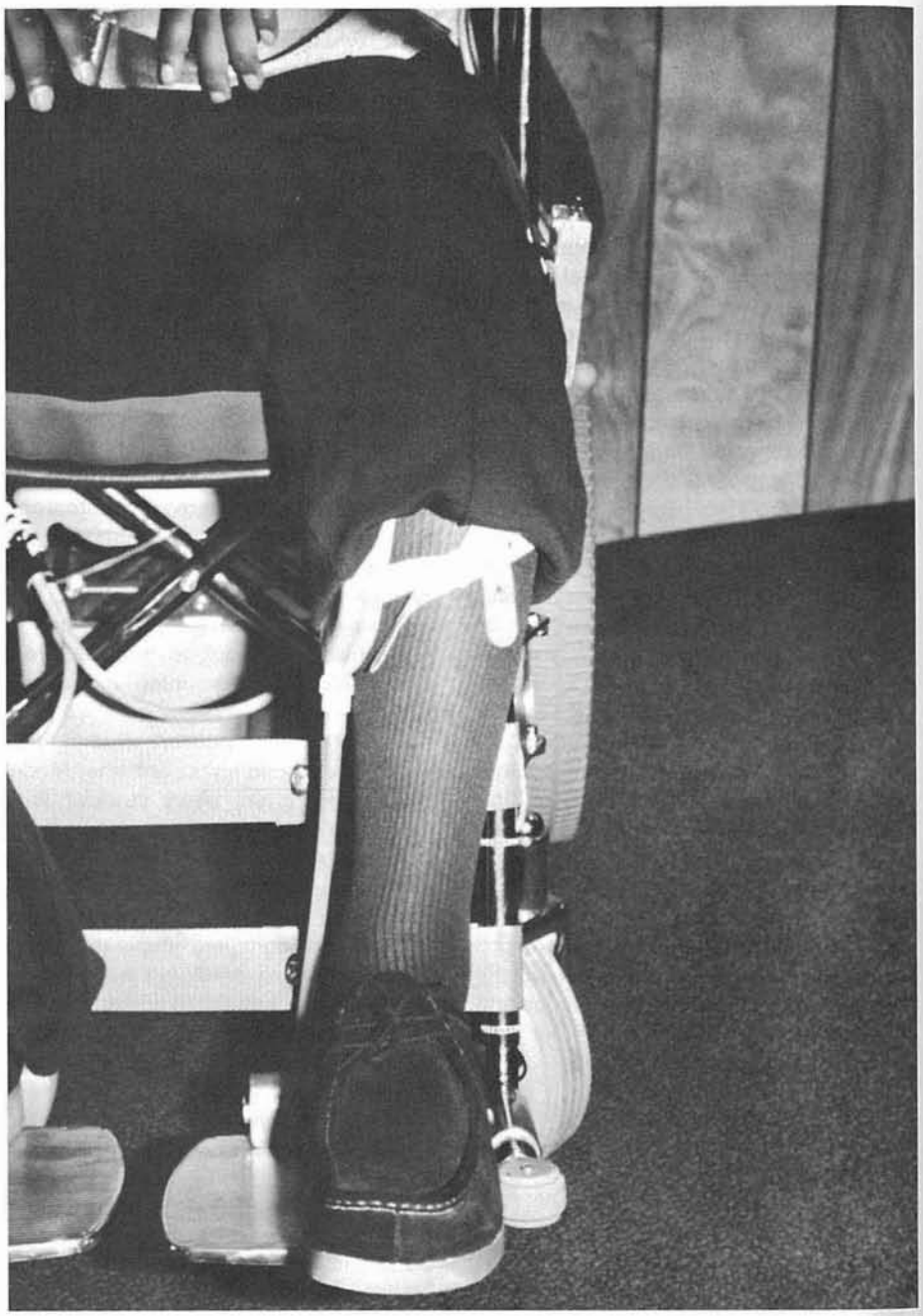


FIGURE 11.
Automatic leg bag emptying device.

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Rehabilitation Engineering Center Univerza v Ljubljani Fakulteta za Elektrotehniko 61001 Ljubljana, Trzaska 25 Yugoslavia

Alojz Kralj, D. Sc., Project Director, Stanislav Plevnik, M. Sc., Slobodan Ugrinovski, Dipl. Eng., and Ruža Ačimovič-Janežič, M.D., Co-directors.

This report[a] covers the period from April 1, 1979 to March 31, 1981.

During the last quarter of 1979 the Ljubljana REC reorganized their activities. Former subprojects have been reorganized in a new order, organization, and named tasks. Each task covers a specified area of research and is headed by the task leader. The core area of the Ljubljana REC is functional electrical stimulation (FES) of human extremities and of urogenital mechanisms. In 1979 and 1980 the activities were carried on by 7 task groups on which we are reporting.

Multichannel FES of Lower Extremities for Gait Rehabilitation of Paretic Patients

Resp. for task: U. Stanic, D. Sc., R. Ačimovič, M. D., M. Malezic, Dipl. Ing., J. Krajnik, Dipl. Ing.

Objective of the task is to develop the methodology of multichannel electrical stimulation for therapy and orthotic use in paretic patients for correction of locomotion. With it, the initiation of gait is enabled in the early phase and the pathological gait is corrected into a more normal one in the later phase of rehabilitation. The stimulation may influence the reorganization of neural control resulting in long-term therapeutic effects. For the patients in whom these effects are not sufficient, the methodology for orthotic multichannel stimulation is to be developed. New measuring methods and systems have been introduced for analysis of gait and influences of stimulation.

A controlled study of therapeutic effects of multichannel FES including 18 hemiparetic patients, one half with multichannel and the other half with classic therapy, has shown faster and higher recovery and considerable therapeutic effects for the former group. However, after several months without stimulation, the effects have diminished, mostly with more distal muscle groups. In the study, test of motor functions, qualitative kinesiological analysis of gait, average step length and velocity, average goniograms in all 6 joints, average ground reaction forces and their distributions under both feet and crutch, and EMG recordings over 6 muscle groups on each side have been observed. Force shoes and crutch have been developed together with a software package, as well as new software for goniograms to enable a statistical approach to those measurements (Fig. 1 and 2).

A new six-channel stimulator, programmable with arrays of switches giving graphical representation of stimulation sequences, has been clinically evaluated and the methodology for its use developed. Due to the possibility of triggering by two heel-switches, the stimulation sequences for paraparetic gait have been determined on a patient with T-7 lesion. As a result of experiences with previous multichannel stimulators, a new microprocessor based six-channel surface stimulator has been developed with similar features as previous ones including also subroutines for statistical calculations of some gait parameters with the mean values and their standard deviations presented on a LC display.

Dynamic and stochastic properties of FES-evoked muscle contractions have been studied with special regard to the

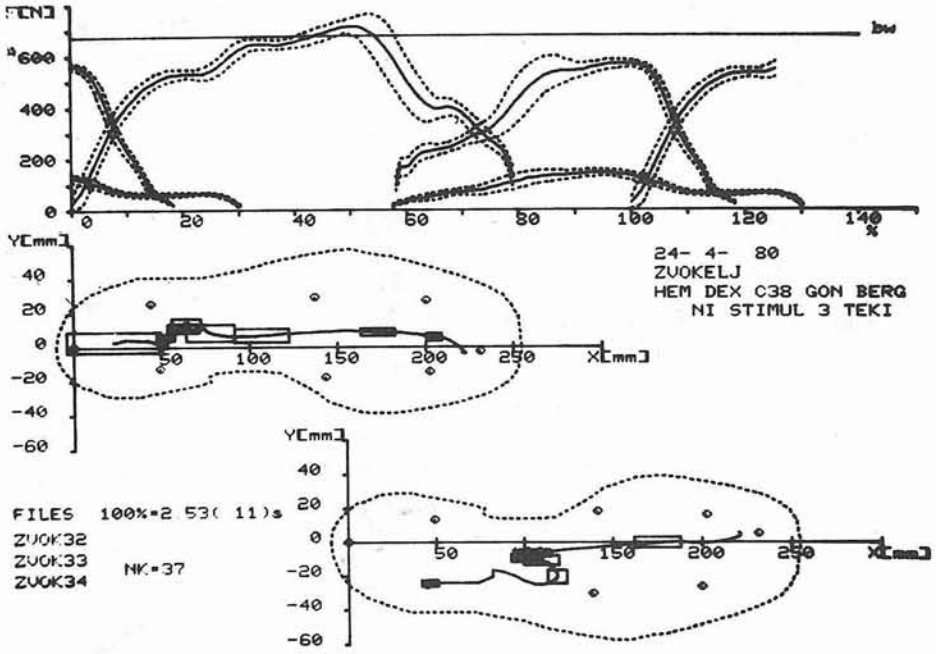

FIGURE 1.
Graphic presentation of force under both feet and crutch (upper diagrams) and their spatial distribution under both feet where locations of 16 sensors are displayed as well.

[a] Progress reports of the Ljubljana REC, according to the REC mailing list, are distributed in 100 copies to all RECs, to different agencies, and to the research groups within the USA. The next progress report of the Ljubljana REC will be available in January 1982.

The Bulletin of Prosthetics Research last reported on this REC in BPR 10–32, Fall 1979, pp. 277–289.

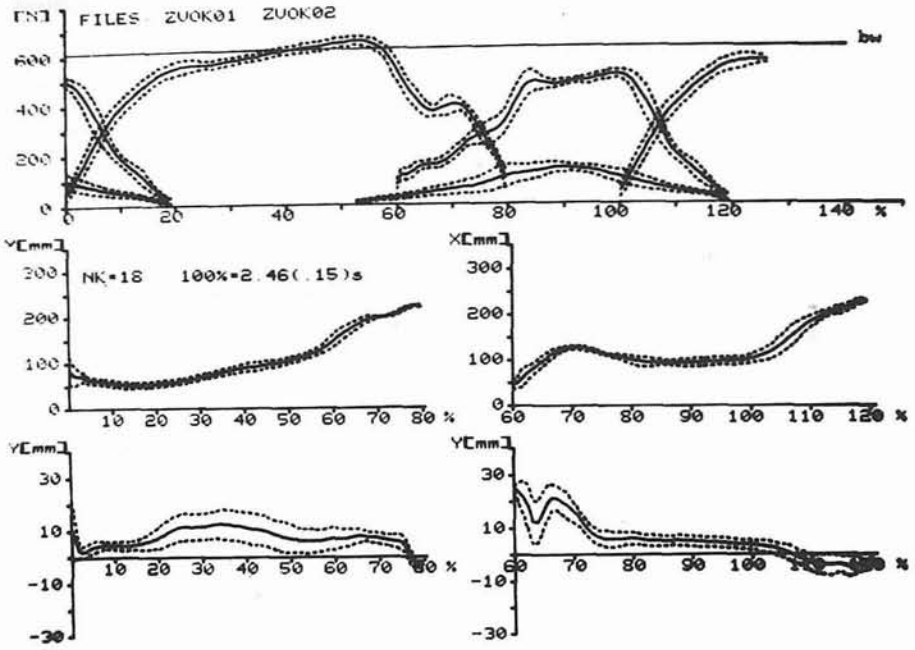

FIGURE 2.
Separate values of X and Y components of the center of gravity at both feet (lower diagrams) during average step. Mean values (solid lines) as well as their standard deviations (dotted lines) are displayed for 37 steps of a right hemiplegic patient.

use of a close-loop principle for better precision in FES orthoses. Besides, a new one-channel implant for FES has been developed on the basis of the first version of the Ljubljana implant and the Medtronic peroneal implant taking into account the advantages of both.

FES of Spinal-Cord-Injured Patients — Fundamental Locomotion Patterns

Resp. for task: A. Kralj, D. Sc., R. Turk, M.D., T. Bajd, D. Sc.

The goal of this task is the design and application of FES orthotic devices for complete and incomplete paraplegic and quadriplegic patients. The patient population which can benefit from this research covers about 70 percent of all complete and 40 percent of incomplete paraplegic patients. In previous research it was shown that all upper-motor neurone-denervated and disuse-atrophied muscles can be restrengthened by cyclic FES. A two-channel stimulator was also designed providing standing and exercising of atrophied muscles for paraplegic patients with complete central neural lesion.

Seven two-channel stimulators for home use by patients have been completed towards the end of the last year. They were already given to four complete paraplegic patients for home use and evaluation. Half an hour of secure standing is enabled by two supporting systems providing equilibrium to patients. One consists of parallel bars attached to the wall (Fig. 3), while the other is a part of the wheelchair. The supporting frame which is attached to the wheelchair can be easily moved backwards when the patient is driving the wheelchair (Fig. 4).

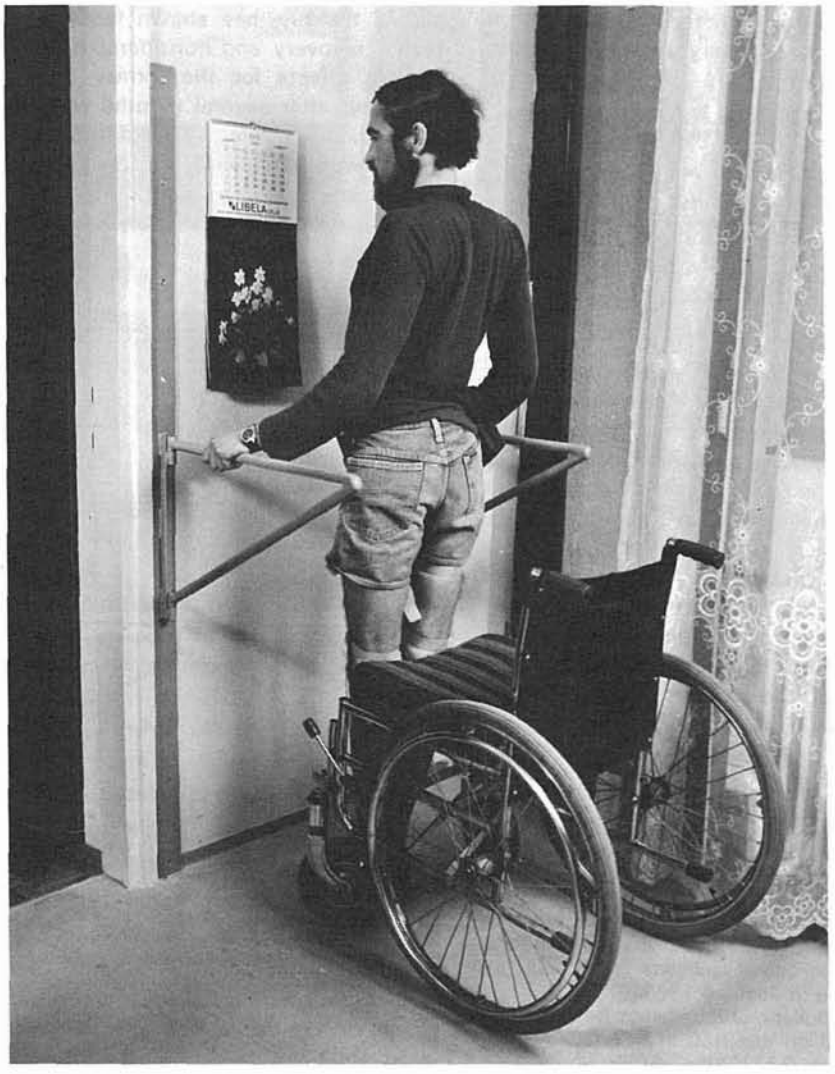

FIGURE 3.
T-5 paraplegic patient standing with the help of knee extensor stimulation and the parallel bars mounted on the wall.

FIGURE 4.
Patient standing with the help of the supporting frame attached to the wheelchair.

Neurophysiological Investigations of Improvements in the Pathological Motor Activity Due to FES and Other Rehabilitation Methods

Resp. for task: F. Gračanin, D. Sc., M.D., F. Bizjak, M.D.

The objective of this task is an improved understanding of the neurophysiological mechanisms responsible for the changes in the organization of the motor activity, which are influenced through a repeated, artifical, programable and reinforced information inflow to the central nervous system which is either direct, through afferent pathways, or indirect, through activation of proprioceptive mechanisms. The development of optimal methods such as functional electrical stimulation and biofeedback therapy in conjunction with the proposed experimental and clinical work is directed to the following goals: (i) accelerating the development of insufficiently developed motor functions of the locomotor system; and (ii) restoration or substitution of the impaired motor functions of the locomotor system.

In 1980 the following was done within the scope of these investigations:

1. Evaluation of functional electronic peroneal brace of FEPA 14 type for CCA FES (contralaterally controlled alternating functional electrical stimulation), used in bilateral stimulation of n. peronei or ipsilateral stimulation of n. tibialis and n. peroneus with cerebral palsy children or adult hemiplegics. This approach should make possible, beside externally controlled movements, also the control of flexion and extension synergy in single phases of gait.

2. An analysis was made of the role of electrophysiological measurements as well as analyses of the patterns of EMG activity of paravertebral and abdominal muscles during functional loading of the spine and of trunk movements of children with idiopathic scoliosis, in order to establish the mechanisms of this type of spinal deformation. Other clinical investigations should contribute to the choice of an optimal therapeutic approach where conservative measures are concerned (corset at FES, exercises or a combinations of such methods).

With individual patients suffering from impaired motor functions of the central nervous system, an analysis was dedicated to the influence of audiovisual EMG biofeedback therapy upon relaxation, selective control of muscle contraction, and reinforced voluntarily controlled motor activity in combination with other methods of external control of movements (Fig. 5).

Automatic Vaginal Electrical Stimulator to Control Incontinence

Resp. for task: P. Suhel, D.Sc., B. Kralj, D.Sc., M.D., E. Roskar, M.Sc., M. Benedik, M.D.

Apart from the plug and electrodes, nonimplantable systems for control of incontinence have an external unit containing electronic circuit and a power supply. The external unit is usually a larger or smaller box which is cumbersome to the personal appearance, especially of female patients. This disadvantage necessitated the development of electrical stimulator systems without an external unit. The efforts in this direction resulted in the construction of the automatic electrical stimulator VAGICON-X. The device is built into a plastic housing where the battery supply and the electronic circuit are placed. The housing has the form of a vaginal plug as seen in Figure 6. The stainless steel electrodes are in a convex shape to provide a better contact with the stimulated tissue. Figure 7 shows the electronic circuit used. The stimulator is based on a stable multivibrator with complementary transistor having an

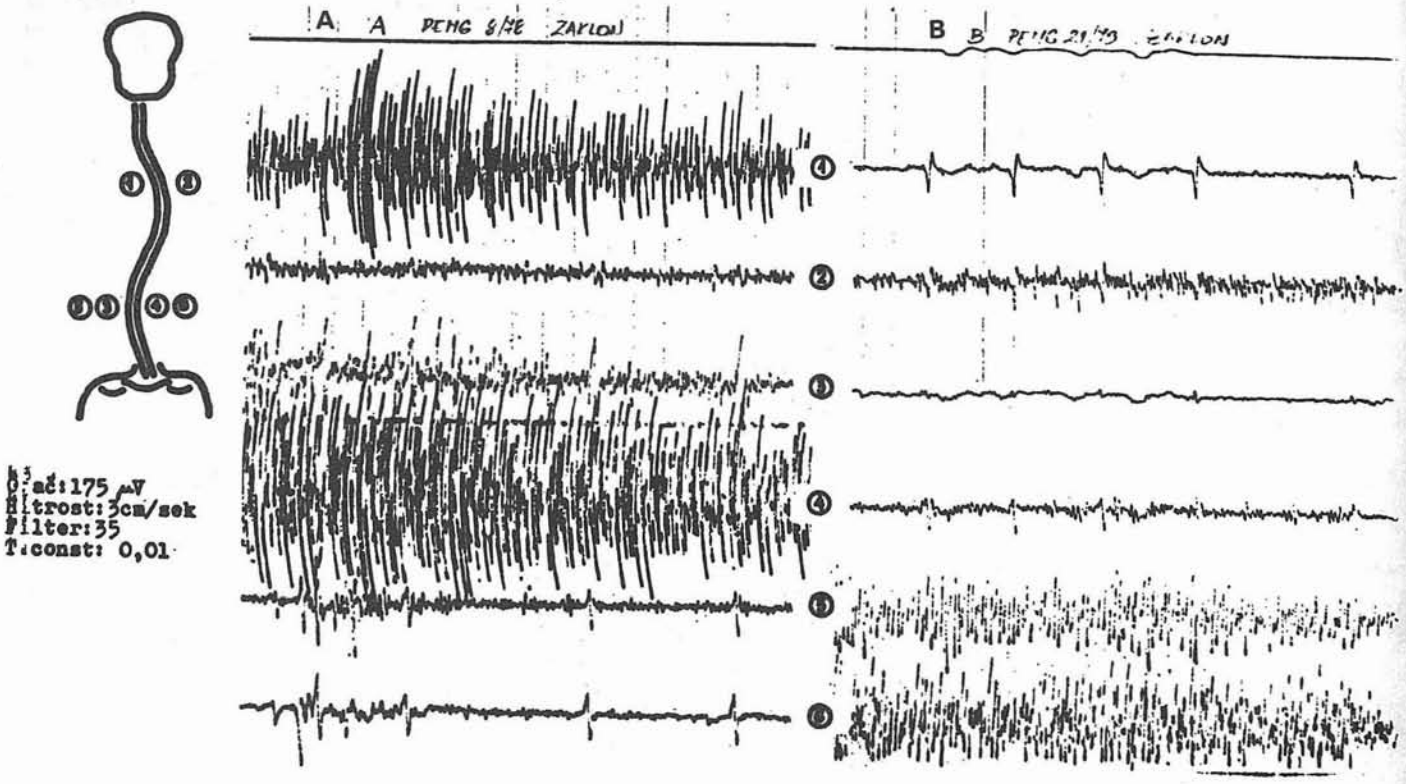

FIGURE 5.
PEMG of paravertebral and abdominal muscles at a backward bend of the trunk in a boy with scoliosis thoracalis dex. idiopathica adolescens.

In A the EMG activity before using FES dominates in paravertebral muscles thoracically to the left and lumbarly to the right while it is minimal in the abdominal muscles.

In B the EMG activity of the same muscles after using FES for 8 months: the EMG activity occurs in the thoracic paravertebral muscles on the right side, but it is much less intense; however, it appears almost symmetrically in abdominal muscles. Beside lessening of the spinal curvature (more successful in the lumbar region) we modified the patient's pattern of the EMG activity which is expressed in a lesser activation of the muscles in maintaining upright posture and the postural tonus of the muscles. The same results were obtained at loading the spine and during trunk movements (backward bending). Therefore, the pattern of the EMG activity is thoroughly changed, meeting the requirements of a normal posture and the lessening of the spinal curvature.

extremely great pause to pulse ratio. The circuit is loaded with the stimulated area, which at the same time acts as an "on" switch. Thus, when the stimulator is inserted, it automatically starts generating stimulation pulses, and when it is removed the circuit is switched off. The output signal of the stimulator is a train of monophasic pulses.

The success of treament with the automatic vaginal electrical stimulator VAGICON-X depends on careful selection of patients suitable for the treatment. Correct selection presents the key to the success of the treatment with VAGICON-X. Long-term efficiency of VAGICON-X can be laboratory-tested by means of urodynamical investigations before the application of the stimulator. Prior to the application, neurophysiological examinations must be carried out

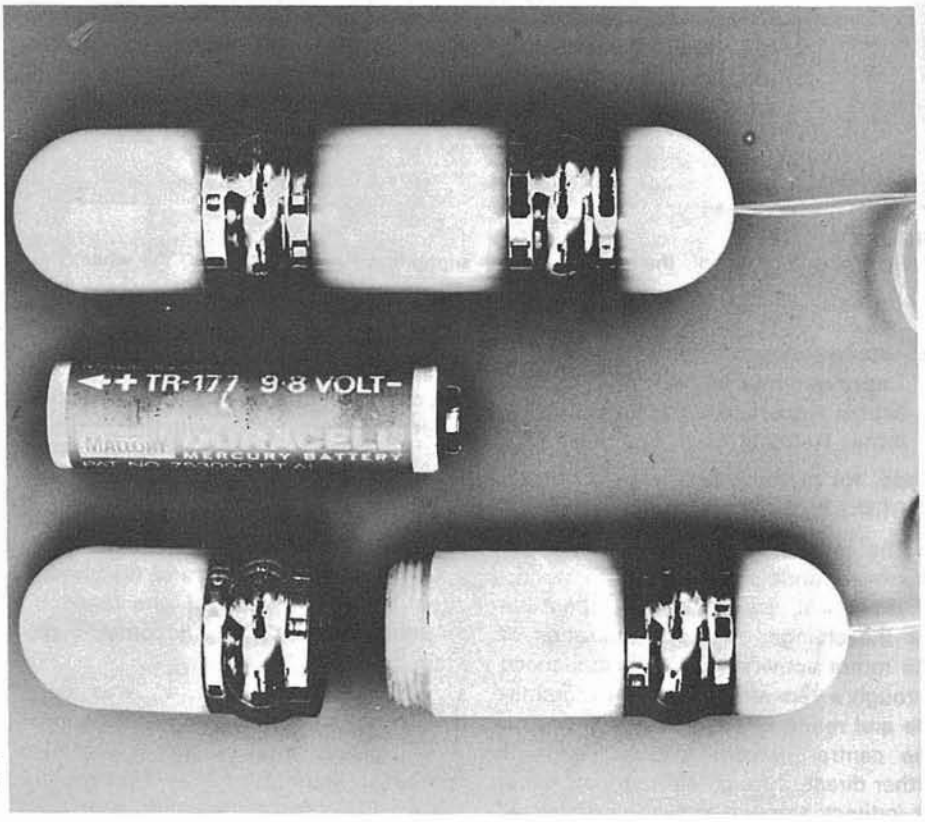

FIGURE 6.
VAGICON-X—the outward appearance of the housing.

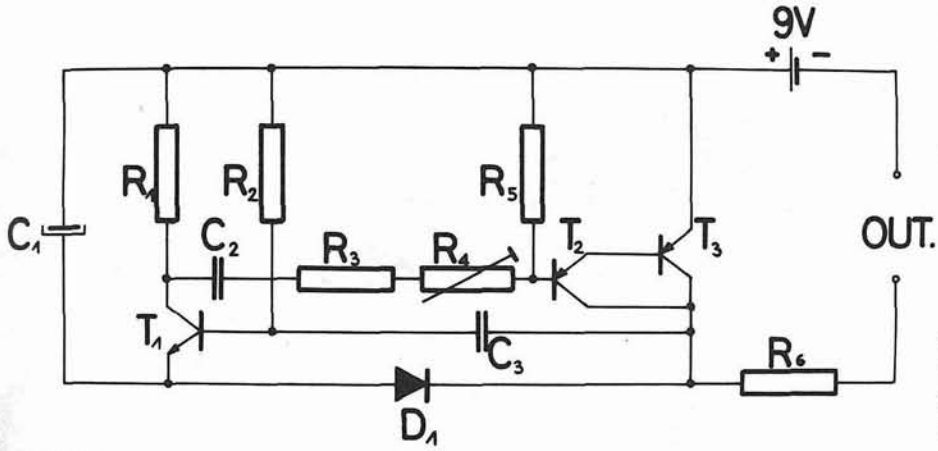

FIGURE 7.
VAGICON-X—the electronic circuit

in order to establish that the spinal center is preserved and that the peripheral denervation of the pelvic floor muscles is not too extensive.

Indications for the application of VAGICON-X are the following: bladder dysfunctions, dysfunctions of the pelvic floor muscles, dysfunctions of the bladder and pelvic floor muscles, urge incontinence.

The urethral pressure profile, i.e., the most significant parameter in evaluation of bladder closure mechanism, is subject to considerable changes after the application of the stimulator. The urethral pressure profile (UPP) curve increases after the application of the stimulator (Fig. 8).

The bladder capacity in general increases by 17 percent after the application of VAGICON-X. The spasms of the detrusor muscle which can be observed on cystometrical curves are diminished, and relaxation of detrusor is observed.

Generally speaking, the patients were advised to use the stimulator 2–3 times daily for periods of 2–3 hr daily and 8 hr at night. As can be seen from Table 1, the stimulator was used in cases of stress and urge incontinence, these being the most frequent types. An 80 percent success can be expected in suitably selected female patients.

TABLE 1—Clinical Results

Type of incontinence	No. of patients	Success
Stress incontinence	32	26 (81.2%)
Urge incontinence	12	9 (75.0%)

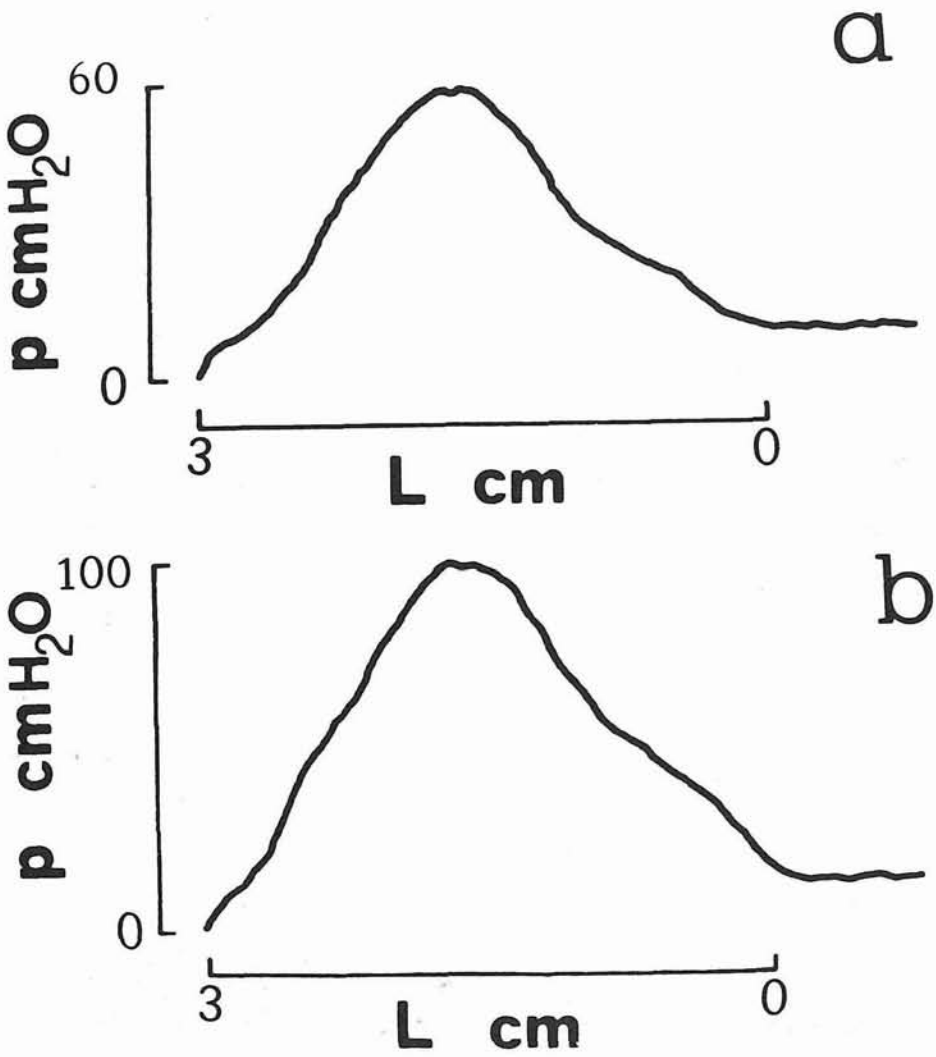

FIGURE 8.
Urethral pressure profile (UPP) curves before (a) and after (b) application of the stimulator. L indicates urethral length, p indicates urethral pressure.

FES of Urogenital Mechanisms: Physiology, Techniques of Stimulation, and Methods of Urodynamic Evaluation

Responsible for task: S. Plevnik, M.Sc., J. Janez, M.D., S. Rakovec, M.D., D.Sc., P. Vrtacnik, Dipl. Ing., L. Ravnik, M.D.

During the years 1979 and 1980, progress has been made in the improvement of the method of maximal electrical stimulation which can be used for the treatment of different types of

urinary incontinence as well as for diagnostic purposes. Urodynamic and neurophysiologic measurements were used for that purpose. Patients with stress incontinence, urge incontinence, and reflex neurogenic bladder were studied (Fig. 10). New modalities of the maximal electrical stimulation received preliminary testing as well. New types of vaginal and anal electrodes which were developed through the project at the Institute "J. Stefan" (Task No. 6) improved clinical effects and comfort of the patient during stimulation.

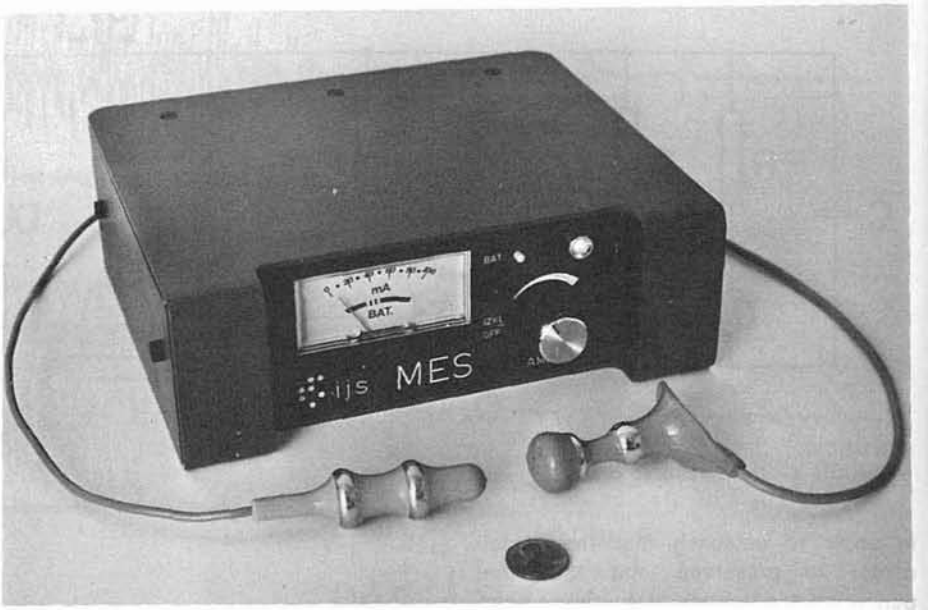

FIGURE 9.
Stimulator for short-term maximal electrical stimulation (MES) with vaginal and anal stimulation electrodes.

FES of Urogenital Mechanisms—Studies of Urodynamics and Evaluation of Orthotic Aids

Resp. for task: L. Ravnik, M.D., D.Sc., J. Janez, M.D., S. Plevnik, M.Sc.

During the years 1979 and 1980, progress has been made in the improvement of the method of maximal electrical stimulation which can be used for the treatment of different types of urinary incontinence as well as for diagnostic purposes. Urodynamic and neurophysiologic measurements were used for that purpose. Patients with stress incontinence, urge incontinence, and reflex neurogenic bladder were studied (Fig. 10). New modalities of the maximal electrical stimulation received preliminary testing as well. New types of vaginal and anal electrodes which were developed through the project at the Institute "J. Stefan" (Task No. 6) improved clinical effects and comfort of the patient during stimulation.

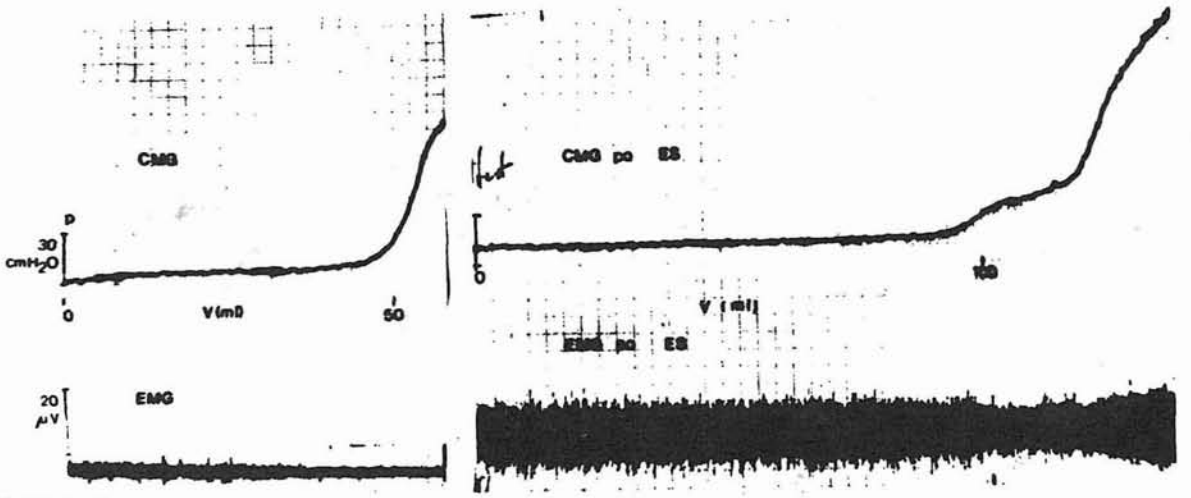

FIGURE 10.
Patient with motor urge incontinence. After the maximal electrical stimulation the increased tonic activity of the pelvic floor muscles as well as the guarding reflex occurred.

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Rehabilitation Engineering Center Moss Rehabilitation Hospital—Temple University —Drexel University Philadelphia, Pennsylvania 19141

Gordon D. Moskowitz, Ph. D., Director, T. Vachranukunkiet, M.D., Medical Director, and Dolores Scott, Administrative Assistant

RESEARCH & DEVELOPMENT

Biomechanical Study of Flexion and Extension of the Human Ankle Joint (New Project)

Responsible Investigator: Gordon D. Moskowitz, Ph. D.

Specific Aims—The project is designed to achieve two general objectives:

1. To determine the contribution of active muscle contraction and the rheological properties of the muscle to the total force in the ankle plantarflexor and dorsiflexor muscles during human level walking.

2. To predict the forces developed by ankle plantarflexors and dorsiflexors during gait, from their electrical activity during gait and from their isometric characteristics.

The fulfillment of these objectives will contribute to the fundamental knowledge of muscle function in controlling normal human movements. The activity selected for this study is level walking, and the muscles under investigation are the ankle plantarflexors and dorsiflexors.

The specific goals that have to be accomplished to achieve those general objectives are the following:

1. Determine the magnitude of the total forces developed by the ankle plantarflexors and dorsiflexors, as functions of time, during gait.

2. Determine the forces due to the viscoelastic properties of these muscle groups during gait.

3. Determine the Integrated EMG (IEMG) Force relationship for the ankle plantarflexors and dorsiflexors under isometric conditions over the entire range of foot movements.

4. Determine the difference between the force as measured under isometric conditions and the active force developed during gait, for each muscle group, at identical levels of IEMG and muscle length.

Significance:—Information regarding the force-generating properties of a muscle is of great importance in the field of orthopedic surgery. For example, bone fractures in the lower extremities, and the design of artificial joints, placed emphasis on the analysis of joint forces (1). For analysis, the forces developed by muscles crossing the joint had to be determined. Also, information regarding excursion and force generation capability of muscles can be used to determine the optimal way in which the function of the extremity should be restored through tendon transfer or tendon lengthening (2).

For clinical applications, it is of extreme importance to develop an easy and fast method of determining muscle forces. The major obstacle in achieving this goal is the fact that, in man, one has to work with the intact organism. Therefore, only indirect measurements of muscle force can be obtained.[a] Two major approaches have been used in the past to determine muscle forces.

The first approach consists of developing a simplified mechanical model of the musculoskeletal system. Then, from kinetic and kinematic measurements, the total torque around the joints is determined. The problem of determining muscle forces from joint moments is complicated due to simultaneous action of agonistic, antagonistic, and synergistic muscles which yield an indeterminate system. Two basic methods have been used to solve this indeterminate problem. Elftman (3), Paul (4), and Morrison (5) reduced the indeterminate problem to a determinate one by using different anatomical and functional simplifications. Other investigators such as Crowninshield (6), Seireg (7), and Penrod (8) have solved the indeterminate problem by estimating muscle forces such as to optimize various kinetic criteria. Several problems prevent this approach from being clinically applicable. First, these methods are very complex and time consuming, and they require sophisticated instrumentation for kinetic and kinematic measurements; second, the inaccuracy introduced in this method is largely due to the gross anatomical and functional simplifications made.

The second approach to predicting muscle forces is based on the fundamental assumption that certain features of the EMG are directly related to the tension generated by the muscle. This was clearly summarized by Bouisset (9): "If it is true that the force exerted by a muscle during contraction depends directly on the excitation which is applied to it, then the surface EMG, which measures the level of excitation of the muscle, should provide an effective indirect measurement of the force contributed by a given muscle."

Many investigators have studied the relationships between EMG and other biomechanical properties of the muscle in an attempt to validate this assumption. Investigators such as Lippold (10), Maritani and DeVries (11), and Hof (12) demonstrated a linear relationship between the integrated EMG in a muscle and its isometric tension. A linear relationship was also found between the IEMG and the tension in a voluntary isotonic contraction of muscle when the rate of contraction was kept constant (Bigland and Lippold (13)). Komi (14) studied the relationships between muscle tension, EMG, and velocity of contraction under concentric and eccen-

[a] For a rare exception (involving cineplasty) see: Heckathorn CW and Childress DS: Relationships of the Surface Electromyogram to the Force, Length, Velocity, and Contraction Rate of the Cineplastic Human Biceps, Am J Phys Med 60(1):1–19, February 1981. Cited by Malone elsewhere in this issue of BPR. Editor)

tric work and found a linear relationship between muscle tension and IEMG when the velocity of shortening or lengthening was kept constant.

A unifying theory on the relationships between IEMG and the tension in a muscle has been suggested by Gans and Noordergraaf (15). However, not enough experimental evidence was supplied to support that theory. The relationships between the EMG of a muscle and its biomechanical properties are influenced by fatigue. Viitasolo and Komi (16) demonstrated that with a sustained contraction, where the force was kept constant, the IEMG increased with fatigue time. Kwatny et al. (17) demonstrated that fatigue is also characterized by a shift of power to lower frequencies.

Application of these studies to a description of muscle function in a natural human act such as locomotion encounters several problems. First, muscles are composed of passive components and contractile components, each contributing to the total force developed by the muscle as a whole. In studying the relationship between EMG and active muscle force in a natural movement, it is necessary first to determine the magnitude of the forces that the passive and contractile components contribute to the total muscle force. However, this information is not yet available (Morrison (18)). Second, most of the studies of the relationships between EMG and the mechanical properties of a muscle have been conducted on isolated muscles or on muscles in non-functional states. In these studies muscle length or muscle force were carefully controlled (isometric, isotonic, concentric, and eccentric movement at constant velocities). Such movements, however, are seldom encountered outside the laboratory. Most functional human activities such as locomotion involve non-isometric, non-isotonic movements in which the muscle length and muscle force are changing continuously.

From this review it is clear that there is a lack of information regarding the function of muscles in controlling normal human movements. Also, in spite of the past efforts, there is still a lack of an effective method of estimating the forces developed in muscles during a normal activity.

The outcome of this study is intended to extend the information regarding the function of muscles in controlling normal human activities by determining the quantitative contribution to the total muscle force of the passive and contractile components of the muscle. Furthermore, this study may lead to an easy, fast, and reliable method of estimating muscle force from information on the electrical activity of the muscle during the movement performed, and knowledge on the isometric properties of the muscle.

Preliminary Studies

Preliminary studies were performed to achieve the following objectives: (i) to indicate the contribution of the passive properties of the ankle plantarflexors to the total isometric force developed by this muscle group, and (ii) to determine the phasic action of the ankle dorsiflexors and plantarflexors during level walking. The experiments were performed on three normal subjects.

1. Contribution of the passive properties of ankle plantarflexors to the total isometric force.

Each subject was instructed to lie prone and his left foot was firmly attached to a servocontrolled positioning device (a detailed description of the system and experimental procedure is provided in the following sections). The ankle angle was then changed by small increments over the whole range of foot movement. At each angle the subject was first instructed to relax his ankle muscles and the resisting torque was recorded. This has been done while measuring the EMG of the ankle plantarflexors. Absence of EMG activity confirmed the state of relaxation of the leg muscles of the subject. Then the subject was instructed to exert the maximum possible isometric torque by volitionally contracting his plantarflexor muscles.

In Figure 1 the typical results obtained from such an experiment are presented. From these results it is obvious that the contribution of the passive stretch properties of the muscle to the total isometric force is small in the vicinity of the resting length (corresponding to an ankle angle of 90 degrees) but it increases rapidly towards dorsiflexion. (At maximum dorsiflexion it reaches a value of 25 percent of the total isometric force.) Based on these results it is reasonable to assume that

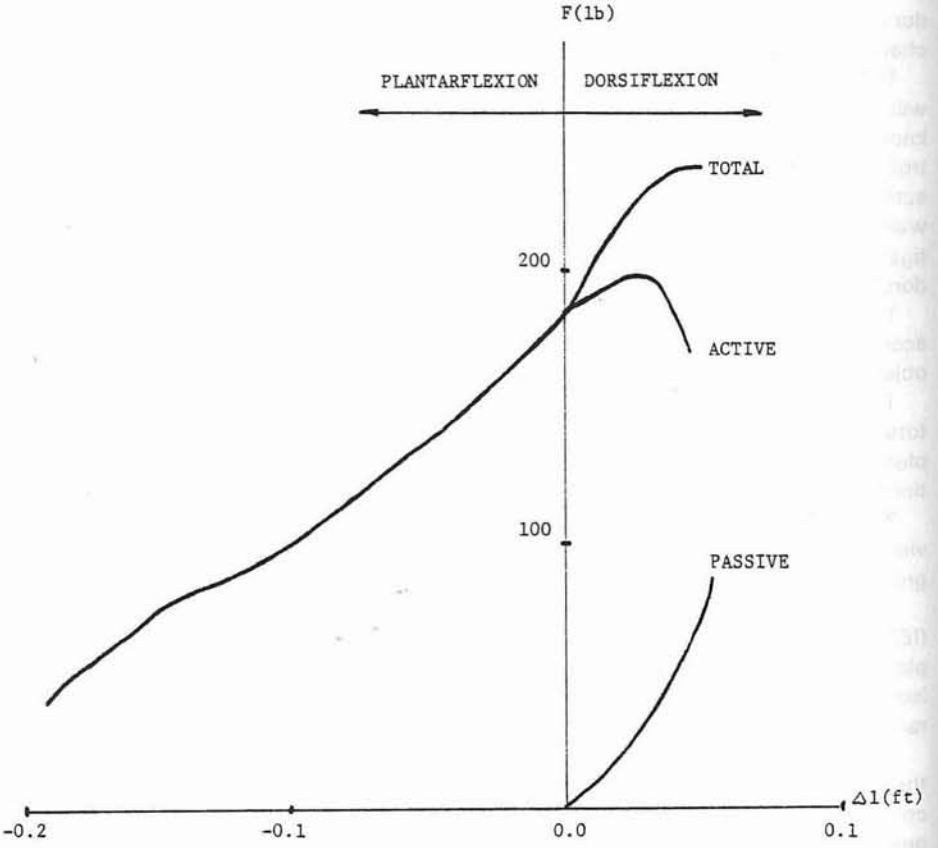

FIGURE 1.
Force-length relationship for maximum isometric contraction of ankle plantar flexors.

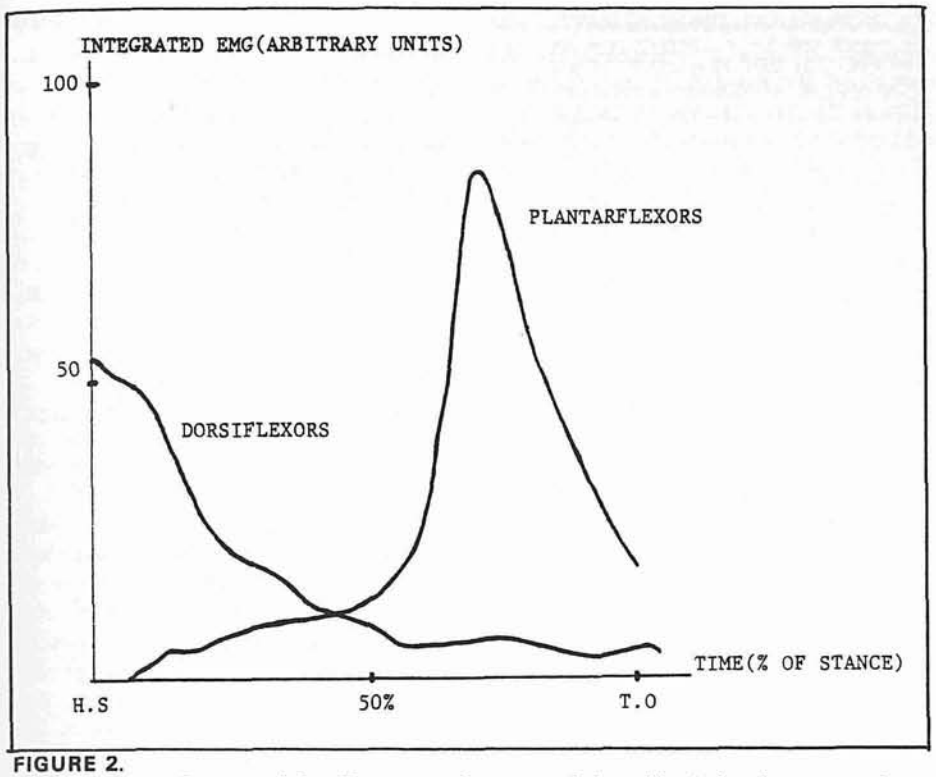

FIGURE 2.
IEMG of plantar flexors and dorsiflexors muscle group of the ankle during the stance phase of level walking.

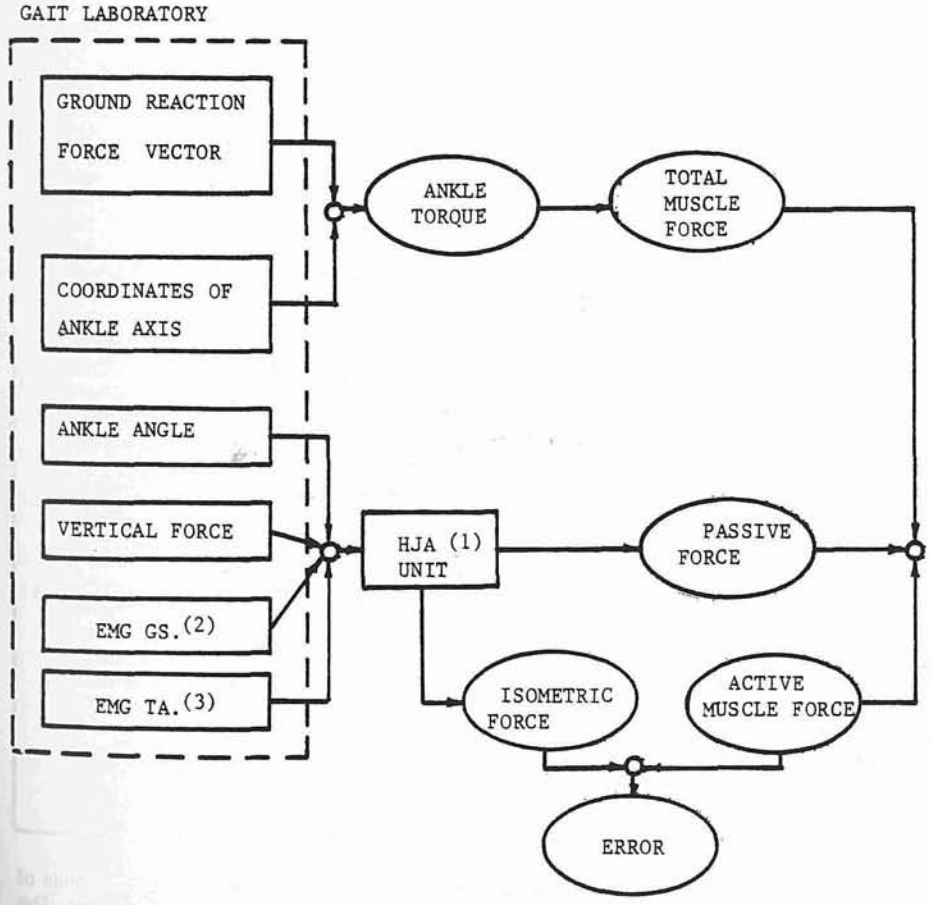

FIGURE 3.
Schematic representation of the flow of information. (Keyed notations are as follows: (a) HJA-Hydraulic joint apparatus; (b) triceps surae; and (c) pre-tibial muscle group.

the elastic properties of the ankle musculature have a significant contribution to the total muscle forces during level walking. It is expected that this contribution during gait will be even higher than in the present experiment for two reasons:

a. The passive force in a muscle depends on its length and rate of shortening or lengthening (viscoelastic). In the preliminary study the velocity was zero and therefore the contribution of viscosity was excluded. However, in locomotion this velocity is non-zero and therefore the contribution of viscosity will further increase the total passive force.

b. During gait it is expected that the ankle muscles are performing submaximal contractions. This fact will increase the relative contribution of the passive component to the total force.

2. The phasic action of the ankle dorsiflexors and plantarflexors during level walking.

Surface electrodes (detailed description is provided in the next section) were attached to the skin over the midportion of the triceps surae. Each subject was instructed to walk at his convenient (free) speed along a walkway. The rectified and integrated EMG signals were recorded simultaneously on a strip-chart recorder. (A typical trace is provided in Figure 2.) From these results it appears that the ankle dorsiflexors are active during swing phase (not shown in figure) and during a small period following heel strike. The ankle plantarflexors are active during most of the stance phase. Furthermore, from these results it appears that simultaneous contraction of the ankle plantarflexors and dorsiflexors (co-contraction) is negligible, and therefore, the forces developed by these muscle groups can be calculated from a determinate system.

The analog signal representing the passive ankle torque will be sampled through an A / D converter, and the passive force will be derived from Equation 1 in Appendix. Then, subtracting the passive force from the total muscle force, the force generated by active muscle contraction is obtained. This force will then be compared to the isometric force, developed under identical levels of EMG activity and at identical muscle lengths. The difference between these forces will provide a

quantitative measure of the error introduced in determining active muscle force during gait from its electrical activity during gait, and knowledge on the *isometric* characteristics of the muscle. A graphic description of the flow of information is presented in Figure 3.

APPENDIX

l = length AD

$y = \sqrt{b^2 + c^2}$

$x = b / \mathrm{Sin}\alpha$

$l^2 = (a+x)^2 + Z^2 - 2 \cdot Z \cdot (a+x) \cdot \mathrm{Cos}(180-\alpha)$

(I) $l = \sqrt{(a+b / \mathrm{Sin}\alpha)^2 + (c-b\ \mathrm{Ctg}\alpha)^2 - 2 \cdot (a+b / \mathrm{Sin}\alpha) \cdot (c-b\ \mathrm{Ctg}\alpha) \cdot \mathrm{Sin}\alpha}$

From triangle AFD

$Z / \mathrm{Sin}\beta = l / \mathrm{Cos}\alpha$

$\mathrm{Sin}\beta = Z / l \cdot \mathrm{Cos}\alpha$

From triangle ABE

$r / a = \mathrm{Sin}\beta$

$r = a \cdot \mathrm{Sin}\beta = a\ Z / l \cdot \mathrm{Cos}\alpha$

Or:

$r = a \cdot (c-b\ \mathrm{Ctg}\alpha) \cdot \mathrm{Cos}\alpha / l$

$M = F \cdot r$

(II) $F = M \cdot l / (a \cdot (c-b\ \mathrm{Ctg}\alpha) \cdot \mathrm{Cos}\alpha)$

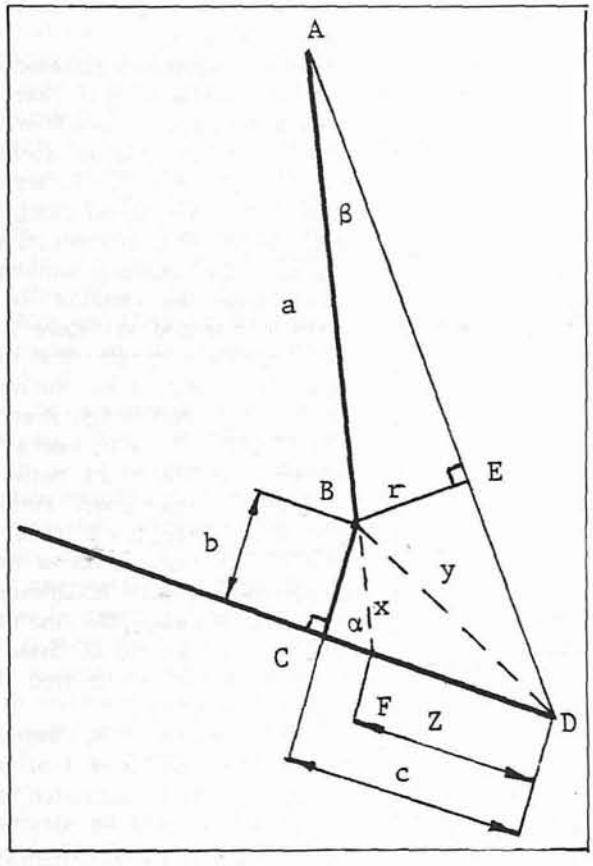

FIGURE 5.
Schematic diagram of the relationship between calf (triceps surae) muscle length and ankle angle and between muscle force and ankle torque, as derived herein.

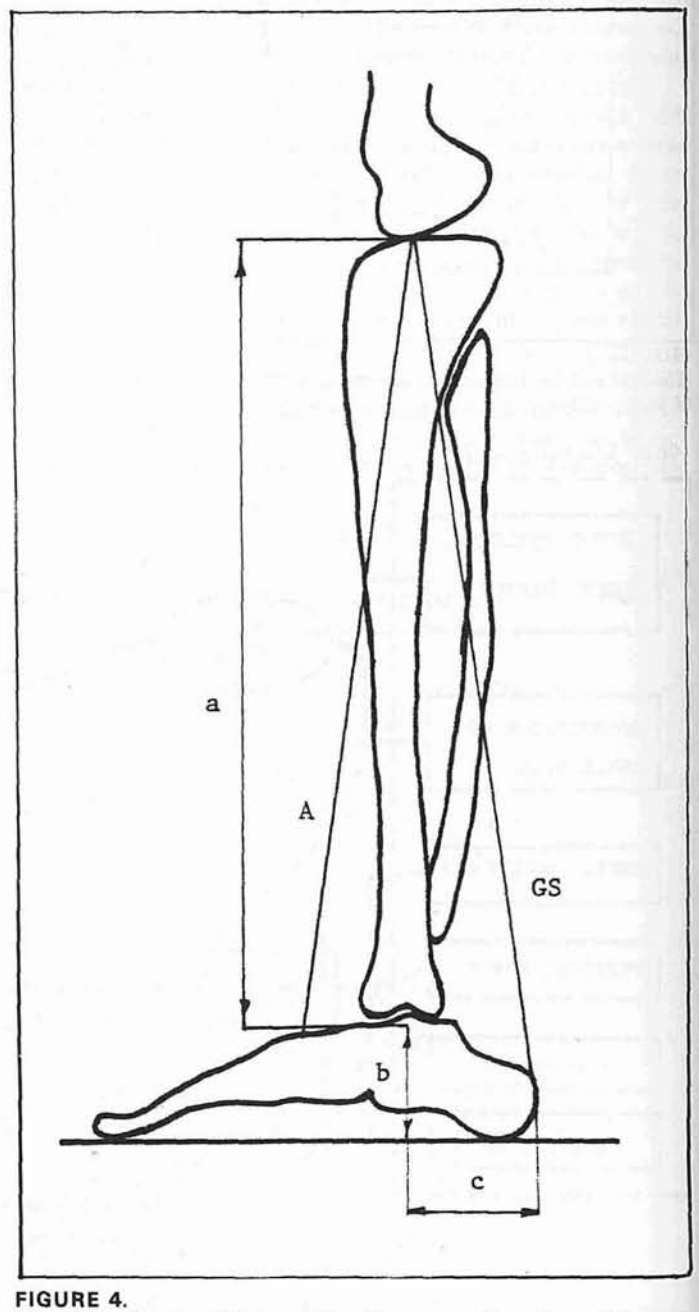

FIGURE 4.
Schematic diagram of lower limb with assumed lengths and lines of action of pre-tibial (A) and triceps surae (GS) muscle groups. The line GS is the assumed line of action of the triceps surae, and the line A is the assumed line of action of the pre-tibial muscle group.

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Effects of Altered Sensory Input on Stair Descent

Responsible Investigators:
William Freedman, Ph. D. and Rebecca Craik, Ph. D., M.S.P.T.

(Continuing project: see previous BPR progress report.)

The test paradigm has been refined along with the data analysis techniques. Data have been collected on 14 healthy subjects at this point. The nine female and five male subjects had a median age of 25 years, height 1.67 m, and weight 53.7 kg. (Table 1). Due to the height limit of the test apparatus, subjects were selected who were less than 1.8 m.

Regardless of the test condition, each subject walked down three steps using a reciprocal lower limb gait. Each subject selected the limb that he / she preferred to swing first, and every trial began with that designated limb executing the first swing phase. To describe the parameters selected for data analysis, an example typical of each subject's performance during non-perturbed stair walking is illustrated in Figure 6.

TABLE 1.
Anthropometric characteristics of the sample are described in this table. Also listed is the preferred swinging leg used by each subject for the initiation of stair walking.

Subject	Sex	Age (yr)	Height (m)	Weight (kg)	Preferred Leg
BS	M	20	1.70	58.3	R
BW	F	18	1.75	58.1	R
DG	F	22	1.66	56.5	R
KD	F	33	1.65	52.2	R
DD	F	28	1.57	50.3	R
MM	F	23	1.68	59.0	R
PD	F	29	1.57	48.1	R
CK	M	26	1.65	81.6	L
JZ	M	21	1.71	70.0	L
RK	M	21	1.70	77.1	L
JM	F	31	1.68	63.3	R
SM	M	30	1.71	58.1	R
LK	F	23	1.64	49.4	R
BC	F	30	1.60	49.9	R

The designated swinging limb for the subject described in Figure 6 was the left limb, so that the interval between left toe off (lto) and left heel strike (lhs) is the time during which performance was examined. Ease-of-landing parameters were derived from those traces in Figure 6 which represent force, ankle motion, and left footswitch events: at touch-down, loading rate was 23.3 body weights / s (BW / s); average ankle velocity was 485 deg / s and the interval between left toe strike and heel strike was 70 ms. Swing time occurred in 637 ms for this subject, and the terminal acceleration was 0.42g. The precontact electromyogram (EMG) in the gastrocneminus-soleus complex was found to precede ground contact by 142 ms and contained 3.7 millivolt-seconds (mv·s) of integrated EMG activity. As can be seen in Figure 6, the majority of ankle and knee motion preceded this burst of EMG so that this burst is considered related to preparing the limb for landing.

The manner in which altered visual information affects this precontact burst and the subsequent landing is the purpose of this next year's effort. Early results from the data analysis indicate that performance is significantly different from the control condition when visual information is altered, and shows the following:

1. Vision is necessary for optimal stair walking performance. During the "No Vision" data set, the subjects were deprived of visual and auditory cues and could not develop a motor plan for an unknown step height. The Elizabethan collar blocked visualization of the stairs during stair walking in the "Ahead" trials. Visual input was apparently necessary for optimal motor performance, even though the subjects had practiced stair walking for more than 2 days and were instructed to preview the step height prior to each trial. The visual-vestibular sensory conflict which was encountered by the subjects resulted in decreased EMG during the "Room Movement" test conditions. Therefore, no other test condition produced as much anticipatory muscle activity as was seen during the Comfortable test condition (*C*). Compared to this control state, the amount of triceps surae muscle activity was reduced during No Vision (*B*), Ahead (*A*), and Room Movement (*M*) stair descent.

2. The subject's expectations can alter the stair walking performance. This is indicated because there was a significant decrease in the precontact EMG burst during the "No Movement" set in which the subjects expected the room to move compared to the control condition (Ahead) during which room movement was not anticipated. Also, during the "No Vision" sequences, subjects changed their landing strategy. Rather than briskly walking down the stairs as was seen during the "Comfortable" data set, during "No Vision" trials subjects cautiously approached the step as indicated by protracted swing time, lower terminal acceleration, slower loading rate, and decreased average angular velocity at the ankle.

3. The directionality of the visual cue and, therefore, the visual feedback system, was primarily responsible for the altered triceps surae precontact EMG activity.

The only difference between the "Room Up" and "Room Down" sets was the direction of room movement. The fact that the characteristics of the anticipatory muscle activity were significantly different from each other under these two conditions suggests that the conflict between vestibular and visual sensory information was responsible for the differences in muscle activity.

4. There appears to be a threshold of specific visual information necessary for the visual system to override the other sensory systems.

This was indicated by the finding that neither the amount of EMG activity nor its onset was different when the room

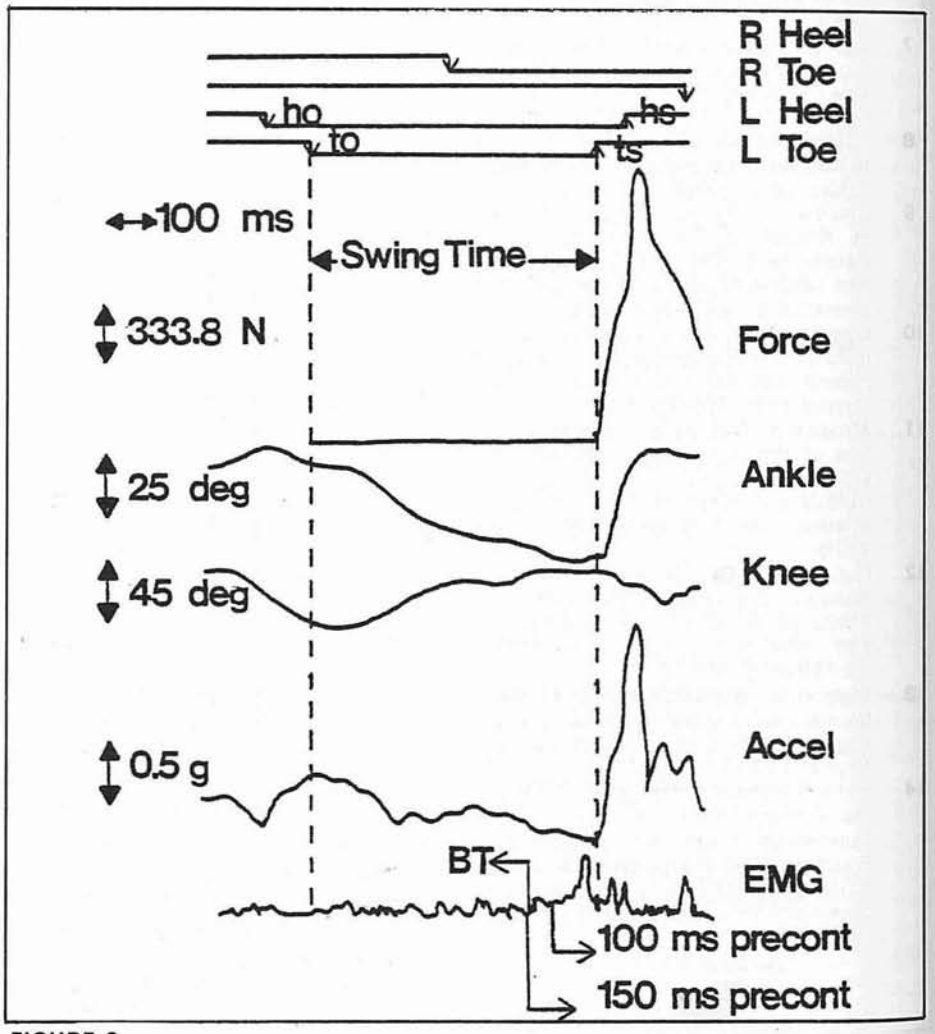

FIGURE 6.
Recordings from foot switches of both feet and characteristics of the designated swinging limb (left) for a portion of the complete gait cycle during nonperturbed stair descent using reciprocal lower limb gait. Burst Time (BT) (142 ms in this case) is the interval between the onset of the gastrocnemius-soleus burst, which is related to landing, and the subsequent toe strike.

moved up compared to not moving (movement expected)—whereas the difference in the amount and timing of the precontact triceps surae EMG activity were significantly different when comparing the results between room moving down and no room movement (movement expected).

5. The relationship between the anticipatory muscle activity in the triceps surae and the subsequent manner of landing appears to be related to landing strategy.

Phase-Dependent Reflex Reversals in Controlling Locomotion

Responsible Investigator:
Rebecca L. Craik, Ph. D., M.S.P.T.

(Continuing project: see previous BPR progress reports.)

The purpose of this project is to evaluate the utility of sensory nerve stimulation on improving neurologically based motor control problems. Although stroke patients achieve independence in ambulation through rehabilitation, the walking pattern achieved is not optimal. This study was undertaken to improve the walking pattern through electrical stimulation of sensory nerves. Patients who are medically stable following a cerebral vascular accident and who can ambulate independently without assistive devices participate in this study. Non-painful electrical stimulation is applied in the area of a sensory nerve at a specific time in the gait cycle to help the leg swing forward. Walking performance is examined prior to, during, and following stimulation, to determine whether the electrical stimulation helped the patient swing the involved limb.

This year's efforts were directed at achieving two objectives; to statistically analyze the data that had been previously collected on the patients with hemiplegia, and to develop and test a functional clearance model. This latter task was designed to determine whether the reported changes in hip and ankle motion functionally enhanced the patient's ability to clear rather than drag the hemiplegic limb through the swing phase of the gait cycle.

Ten patients, selected wiih the aid of the medical records at the Moss Rehabilitation Hospital, showed a significant difference in many biomechanical parameters when comparing the control to the stimulus condition. The other evident finding is that the change in biomechanical parameters depends on the subject which led to the question of timing of stimulus delivery; i.e., do stimuli delivered at heel-off in a specific patient enhance hip flexion while the same stimuli delivered at toe-off diminish hip flexion? To answer this question a lower-limb link model and a computer program were developed to provide calculation of a Limb Clearance Parameter (Miyazaki, 1980).

Plans for the coming year include the following:

1. to expand the present patient sample and identify the major determining factor(s) of success and failure in producing improved limb clearance.

2. to explore the possibilities of increasing the stimulus intensity without causing pain. One possibility is to increase train duration. Another is to optimize the combination of amplitude and width of current pulses.

3. to examine the effectiveness of double-train stimulus in a systematic way. Another extension of the idea of double stimuli is to use two sets of electrodes and stimulate afferent nerves at different sites.

The Role of the Upper Extremity in Gait: A Survey of the Forces Applied to Various Assistive Devices

Responsible Investigator:
Thomas Cook, M.S.P.T.

(This is a new project.)

This project consists of a descriptive survey of the time and magnitude characteristics of the forces applied to assistive ambulation devices (parallel bars, walkers, crutches, and canes) by a representative sample of inpatients as they undergo rehabilitation. Since the vast majority of patients with ambulation problems use the upper extremity for assistance during gait, the data base resulting from this study should be useful for several purposes. These include: assessing the nature and degree of walking assistance needed by disabled subjects; measuring the improvement resulting from therapeutic procedures; establishing objective criteria for prescription of assistive devices; training patients in optimal use of assistive devices; providing information for the design of new types of assistive devices; and serving as the basis for a series of future investigations into the role of the upper extremity in gait.

Development of Myoelectric Knee Control for A / K Prostheses

Responsible Investigator:
Gordon Moskowitz, Ph. D.

(Continuing project: see previous BPR progress reports.)

The amputee is currently undergoing a period of accommodation with the new prosthesis and reestablishing motor patterns not used with his conventional prosthesis. After training is completed, the experimental prosthesis will undergo a preliminary objective evaluation with respect to his conventional prosthesis and with respect to documented norms. Performance thus far is good.

Provided that it can be demonstrated that the experimental device performs well with respect to criteria previously outlined, work will be continued through the year 1981. The following is proposed work to be completed next year:

1. Development of the electronics in a miniature package suitable for incorporation into a self-contained prototype prosthesis. Included in this electronics package will be:

(i) Analog circuitry necessary for detecting and conditioning EMG, (ii) analog circuitry to process transducer outputs (necessary for feedback of state information from the actuator to the controller), and (iii) digital hardware capable of handling the processing requirements of the pattern classification and control algorithms and the input / output demands of the system.

2. The remanufacture of the actuator-pylon system into a cosmetic shell which functions as the pneumatic reservoir.

Publications for 1980 include:

1. D.R. Myers and G.D. Moskowitz, "Myoelectric Pattern Recognition for Use in the Volitional Control of A / K Prosthesis," IEEE Trans. on Systems, Man, and Cybernetics, to be published April, 1981.

2. D.R. Myers and G.D. Moskowitz, "Myoelectric Knee Controller for A / K Prostheses," Proc. Intl. Conf. on Rehab. Engineering, pp. 51-54, Toronto, Canada, June 1980.

3. D.R. Myers, "Development of Volitional Knee Control for Above-Knee Prostheses: Phases II and III—Actuator Design and Evaluation," Ph. D. Dissertation, Drexel University, in preparation.

Manuscripts will be prepared dealing with actuator and control system design and the results of their experimental evaluations.

Development of an Ambulation Training Program for Persons having Lower Extremity Amputation

Responsible Investigator:
Carol Leiper, MEd, L.P.T.

(This is a new project.)

The purpose of this study is to determine whether the measurement of specific gait parameters throughout the learning period can be utilized to accelerate the acquisition of stable and mature walking performance, in persons being trained to walk with an above- or below-knee prosthesis. The task during the initial phase will be to document the changes that occur from walking day one to inpatient discharge, in performance measures such as load, loading rate, step length, step time, swing-stance times, and velocity. These measures will continue to be observed at regular intervals up to one year following reception of the definitive prosthesis.

Later phases of the project will be aimed at the development and testing of therapeutic programs to acclerate the relearning process of walking, based upon the specific, measurable deficiencies, and a comparison of the new techniques with the original documentation to determine if the learning process can be accelerated without sacrificing stability and efficiency.

Preliminary data have been collected on eight pilot subjects having lower-extremity amputation. Measurements of velocity, step length, and step rate were obtained from the gait mat recently developed at this Center. Measurements of load, loading rate, and swing-stance times were derived from polygraph tracings using force transducers in the shape of insoles within each subject's shoes. These data are being analyzed to determine the reliability of the methodology.

Instrument for Clinical Observation of Weightbearing in Locomotion

Responsible Investigator:
Donald Taylor, B.S.E.E.

(This is a new project.)

The objective is to design and build an economical semi-portable walkway, capable of recording and displaying vertical force patterns during locomotion at a cost of about one-tenth that of conventional instrumentation. In addition to its economic advantage, the Force Mat will observe several consecutive steps of a subject rather than a single isolate step out of several in a traverse. The "Poor Man's Force Plates" should be easy to use and possess sufficient accuracy and reliability to service clinical purposes. The device will make this basic phenomena of gait available to a wide range of clinicians without access to a sophisticated locomotion laboratory.

Experience with inexpensive force transducers used in the Limb Load Monitor has indicated that sufficient accuracy and repeatability can be obtained to consider these techniques for economical clinical instrumentation. Previous attempts at fabricating "force sandals" have been discouraging because of accommodating ranges of foot size and because of trailing wires. By instrumenting the substrate, instead of the shoe, more accurate results and elimination of attachments to the subject will result.

To date, substrate designs have been reviewed and transducer materials and configurations have been chosen for the initial device. The walkway construction will be similar to the "Gait Mat" (reported earlier) but will be slightly narrower to move easily to accommodate parallel bars and walking aids.

The configuration for the electronic circuitry design has been worked out and trial transducers have been tested for suitability. Compatibility with the Gait Mat has been a principal aim, and the initial design appears to be suitable for use either separately or in combination with the other instrument.

Clarification of Alignment and Control Principles for Lower-Limb Prosthetics and Orthotics

Responsible Investigator:
Charles Pritham, C.P.O.

(This is a final report.)

The purpose of this project is to prepare educational material relevant to the alignment of lower-limb prostheses and orthoses, for use in the instruction of students and clinicians. It is hoped to specifically describe:

1. Principles of external shoe modifications and their effects on the forces passing through the foot and leg.
2. The principles of alignment of ankle-foot orthoses.
3. The effects of variations in alignment and mass distribution of below-knee prostheses on the gait and energy consumption of several patients.
4. The effects of variations in alignment of above-knee prostheses on the gait and energy consumption of several patients.

As of September, 1980 six subjects were fitted and data collected in the Gait Laboratory while selected changes were made. One subject was fitted with three differently aligned orthoses, and shoes with different heel heights. The orthoses and shoes were matched and mis-matched and the effects on gait recorded. Another subject was fitted with a shoe instrumented with strain-gages to measure plantar pressure, and a number of external shoe modifications were made. These include (i) beveled heel, (ii) SACH heel, (iii) rocker sole with anteriorly placed apex, and (iv) rocker sole with posteriorly placed apex.

Four amputees (two above knee, two below knee) were fitted with adjustable prostheses and the following variations from dynamic alignment made:

1. 5 degrees flexion.
2. 5 degrees extension.
3. ½-inch displacement of socket posteriorly.
4. ½-inch displacement of socket anteriorly.

Collected data are now being processed for incorporation into professional publication.

Lower-Limb Prosthetic Components

Responsible Investigator:
Charles Pritham, C.P.O.

(This is a continuing project: see previous BPR progress reports.)

Activities on this project may be summarized as follows:

1. A prototype of a lightweight single-axis knee unit has been fabricated and subjected to initial stress analysis. Specifications for the production of a second prototype have been drawn up.
2. Samples of the British fabricated Simplex knee (Hanger of Roehampton) have been obtained. Further action is pending.
3. Considerable time has been spent in investigating the possibility of foaming a soft compressible cosmetic covering in place about the structure of an endoskeletal prosthesis. This work was carried out in casual collaboration with

Michael Wilson, C.P.O., of Houston, Texas. Eventually, we arrived at virtually identical techniques. As Michael Wilson and the personnel of Medical Center Prosthetics have been actively engaged in refining their technique, no further action by ourselves is contemplated.

4. Several samples of prefabricated thermoplastic foam covers have been obtained from England and cosmetic covers have been fashioned from them.

5. A method for fashioning a reinforced prosthetic skin from a polyurethane elastomer (Lynadure) has been developed.

6. A foot attachment plug which facilitates the production of a cosmetic cover has been developed.

7. A first prototype of a telescoping knee unit has been fabricated, in order to explore the feasibility of this approach. Briefly, a shackled, or constrained, male element plugs or telescopes into a female element. In the engaged or collapsed position, the knee is locked. Pulling the male element distally unlocks the knee for sitting. The shackle prevents unwanted motion. This original prototype has been fitted to one patient to test out the validity of the approach. A second prototype is now being fashioned in light of the findings. The unit has been christened Telescoping Endoskeletal Knee (T.E.K.).

8. It seems desirable to develop a very lightweight foot. It is believed that this will lead to a reduction in energy expenditure by the patient. To this end preliminary efforts have been made to design a foot that will be not only safe and light, but also practical to mass-produce.

9. A local prosthetics facility has developed a means of fabricating a lightweight above-knee prosthesis utilizing polypropylene and a commercially available knee unit. Concern about the strength of the resulting prostheses has blocked clinical utilization at Moss Rehabilitation Hospital. In order to resolve this impass, the REC has been asked to make arrangements to have such a prosthesis subjected to fatigue testing.

At this point the elements (items 4, 5, and 6 above) involved in the production of cosmetic covers are judged ready for field evaluation.

The Effects of Prosthetic Knee Locking on the Gait Performance of Above-Knee Dysvascular Amputee: Vascular and Biomechanical Functions in the Intact Limb

Responsible Investigator:
Theerasakdi Vachranukunkiet, M.D.

(This is a new project.)

Clinical measurement of hemodynamic changes in lower limbs with peripheral occlusive arterial disease after stress in non-amputee population has been well documented (1,2,3,4,6,7). In review of the literature, the investigators found no study concerning the pattern of hemodynamic changes and its recovery patterns in the intact but dysvascular lower limb of amputees.

In addition, there has been no study correlating the hemodynamic changes, physiologic and biomechanical parameters of gait in amputees walking with locked and unlocked knee prostheses.

The objectives of this study are:

1. To study the hemodynamic changes and recovery patterns in the intact dysvascular lower limb of unilateral above-knee amputees, after stress induced by ambulation.

2. To compare the pattern of changes and recovery studied in objective 1 (above) between walking with two different kinds of prosthetic knee control mechanisms; i.e., between locked knee (LK) and unlocked knee (ULK).

3. To study and compare the physiologic (myoelectric activity) and biomechanical parameters of gait in amputee walking with a LK and ULK prosthesis.

4. To compare the maximum ambulation capacity (MAC) of the geriatric above-knee amputee walking with a LK and with a ULK prosthesis.

5. To determine the correlation between the MAC and hemodynamic changes, physiologic and biomechanical parameters of gait.

It has been found and generally accepted by clinicians in the field of peripheral vascular disease, as stated by Sumner and Strandness (7), that "there is strong inverse relationship between the post exercise ankle systolic pressure and the calf blood flow." Therefore, the systolic blood pressure (SBP) measurement at ankle employed in this study will reflect the blood flow to the calf and lower leg.

It was estimated that 80 percent of total amputees in the United States are lower-limb (8). In the study by Kay et al. (5), it was found that 91.6 percent of amputee population are lower-limb. In the lower-limb amputees, 86.4 percent are B / K and A / K amputees with the average ratio of 1.65 B / K to 1 A / K. In the same study, it was found that in this region (Northeastern), the ratio was ranging from 1:1 to 1:2 B / K to A / K.

In the above-knee population, about 90 percent are geriatric, over 50 years old, with peripheral vascular disease being the leading cause of amputation.

The experience of the principal investigator, on the amputee service at MRH (unpublished data from medical audit studies of MRH, 1978 and 1980), has shown that 90 percent of A / K amputees admitted to amputee service are over 50 years of age (range from 51–90 years) and approximately 95 percent are caused by peripheral occlusive arterial disease.

It is, therefore, very critical in the prosthetic rehabilitation program of this type of amputee population, being geriatric and with peripheral occlusive arterial disease of intact or remaining lower limb, that the training program and type of prosthesis prescribed will not precipitate a detrimental effect to the longevity of the already dysvascular contralateral limb—many of which are already end-stage diseased.

The understanding from results of this study will be useful in assisting the clinician in (i) prescribing the appropriate type of prosthetic components, and (ii) designing or developing the physical activities and / or rehabilitation program and / or gait training program for patients without causing detrimental effect to blood flow of the remaining dysvascular lower limb.

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Clinical Gait Analysis Service

Responsible Investigator: T. Vachranukunkiet, M.D.

(Continuing project: see previous progress reports in BPR.)

During the past year a total of 64 patients were evaluated as part of the Gait Analysis Service. Seventeen of these patients were referred from the Moss Hospital Orthotics and Prosthetics Services, 15 from the Orthopedic Department of Einstein Medical Center, and the remaining 32 were referred from various other sources throughout the area including A.I. Dupont Institute in Wilmington, Delaware, St. Christopher's Hospital for Children, Delaware County Medical Center, and Temple University Hospital. The principal diagnoses for these patients were: musculoskeletal disorder, 29; amputation, 17; cerebral palsy, 13; stroke, 5. In each case an effort was made to select those measurements most pertinent to the patient's problems. In all instances, an attempt has been made to maintain close contact with the managing physician to ensure that the information supplied by the gait analysis service is understandable and relevant to patient management. To date, physician cooperation has been good and several area physicians have visited the laboratory to gain a better appreciation of the type of service which can be provided. Progress on development of this Gait Analysis Service model was presented at the annual meeting of the Biological Engineering Society.

During the past year two cases referred to the Gait Analysis Service resulted in the formulation of questions needing further research. These questions concerned (i) tibial torsion as a causative factor in pain and degeneration of the knee joint and (ii) the comparative effectiveness of walkers and parallel bars in reducing the biomechanical stresses on the prosthetic limbs of below-knee geriatric amputees. Both of these questions were pursued and each resulted in published findings.

Sixteen subjects, including nine normal subjects and seven with unusually large external rotation of the foot, were tested in the gait laboratory. Abnormally large torques, tending to compress the medial compartment of the knee, and abnormally large shear forces were demonstrated in the subjects with outward foot rotations. This previously unrecognized source of knee stress poses a distinct threat of causing degenerative and painful conditions of this joint. Preliminary findings of this study were presented (1) at the 33rd Annual Conference on Engineering in Medicine and Biology in Washington, D.C. A manuscript of the complete results is in preparation.

Fifteen below-knee amputees were tested in the laboratory to compare selected temporal and kinetic factors in gait when these patients used parallel bars and walkers. Complete results of this study were presented (2) at the annual meeting of the American Physical Therapy Association. The findings can be summarized as follows:

1. The majority of patients had a greater walking velocity using parallel bars.

2. For the prosthetic limb, the percent of the walking cycle spent in the stance phase of gait tended to be less when the patients used the parallel bars.

3. For the prosthetic limb (when compared to using a walker) using parallel bars tended to cause:

a. an increase in the rate at which vertical force was applied;

b. a higher peak vertical force;

c. an increase in the rate at which vertical force was removed; and

d. an equal incidence of increases and decreases in the integral (force-time product) of the vertical force.

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EDUCATION & DISSEMINATION

Drexel Senior Engineering Design Affiliation

Responsible Investigator: Gordon Moskowitz, Ph. D.

This is a new project.)

In the last year of undergraduate study, the College of Engineering of Drexel University requires that all senior engineering students be engaged for three academic quarters in an engineering design project. Typically, each project involves three to six students who propose, plan, and execute the solution of a significant technical problem. Dr. Gordon Moskowitz, the Director of the REC, Professor of Mechanical Engineering at the University, and member of the Engineering Design Course faculty, has taken the opportunity to inform the students about the technical needs of the disabled and encourage them to seek solutions useful to the disabled. At the start of each academic year (October 1979 and October 1980) a 2-hour lecture sequence is presented on rehabilitation engineering and the needs of the disabled. Dr. Moskowitz and several members of the REC deliver portions of the lecture. At the end of the presentation, the students are provided with a selection of abstracts describing devices and aids needed by the disabled.

During the academic year, 1979 / 1980, four projects related to rehabilitation were undertaken by the students. Each student project group drew on the expertise of the REC and Moss Hospital for advisors. The REC advisors who participated with Dr. Moskowitz during the 1979 / 1980 academic year were:

Wallace Barrie, Mechanical Technician; **Dave Biser,** Electrical Engineer; **Adele Fricker,** Electronics Technician; **Carol Leiper,** Physical Therapist; **Nathaniel Mayer,** Physiatrist; **Serge Minassian,** Rehabilitation Engineer; **Charles Pritham,** Orthotist / Prosthetist; **Sharon Sanduski,** Occupational Therapist.

The students also consulted with the following Moss Hospital personnel: **Paul**

Macks, Audio / Visual Specialist; **Bruce Connors,** Patient Advocate.

Three of the four student projects pursued last academic year were submitted for the Student Design Competition at the 1979 International Conference on Rehabilitation Engineering. One of the projects became a semi-finalist in the competition.

The student design projects completed last year were:

1. Philadelphia Rowhouse Accessibility for the Physically Handicapped

Philadelphia rowhouses, by the nature of their design, have many problems for the disabled associated with mobility, accessibility, communication, environmental control, safety and security, and activities of daily living. There are roughly six different types of rowhouses, differing primarily because of the time period in which they were built. These buildings are characteristically long, narrow, and two or three stories high.

The principal requirement for the project was the formulation of a redesign of a Philadelphia rowhouse for two levels of physical disability (quadriplegia and paraplegia). The redesign included structural modifications and the implementation of electric / electronic environmental control elements. Ideas were evaluated on the basis of degree of problem-solving, cost effectiveness, minimal creation of new problems, and aesthetics. The range of possible solutions was constrained by the actual rowhouse dimensions and regulations of the Philadelphia Building Code.

Blueprints were prepared for a redesign of a specific residence in the Moss Hospital locale.

The redesign methodology was transmitted to the Rehabilitation Engineering Service of the REC for evaluation and use in home modification recommendations. The longer range goal for the results of this project will be to establish an experimental rowhouse residence for disabled persons.

This project was submitted to the Student Design Competition of the International Conference on Rehabilitation Engineering (ICRE), chosen as a semi-finalist and presented at the ICRE meeting in Toronto, Canada in June 1980.

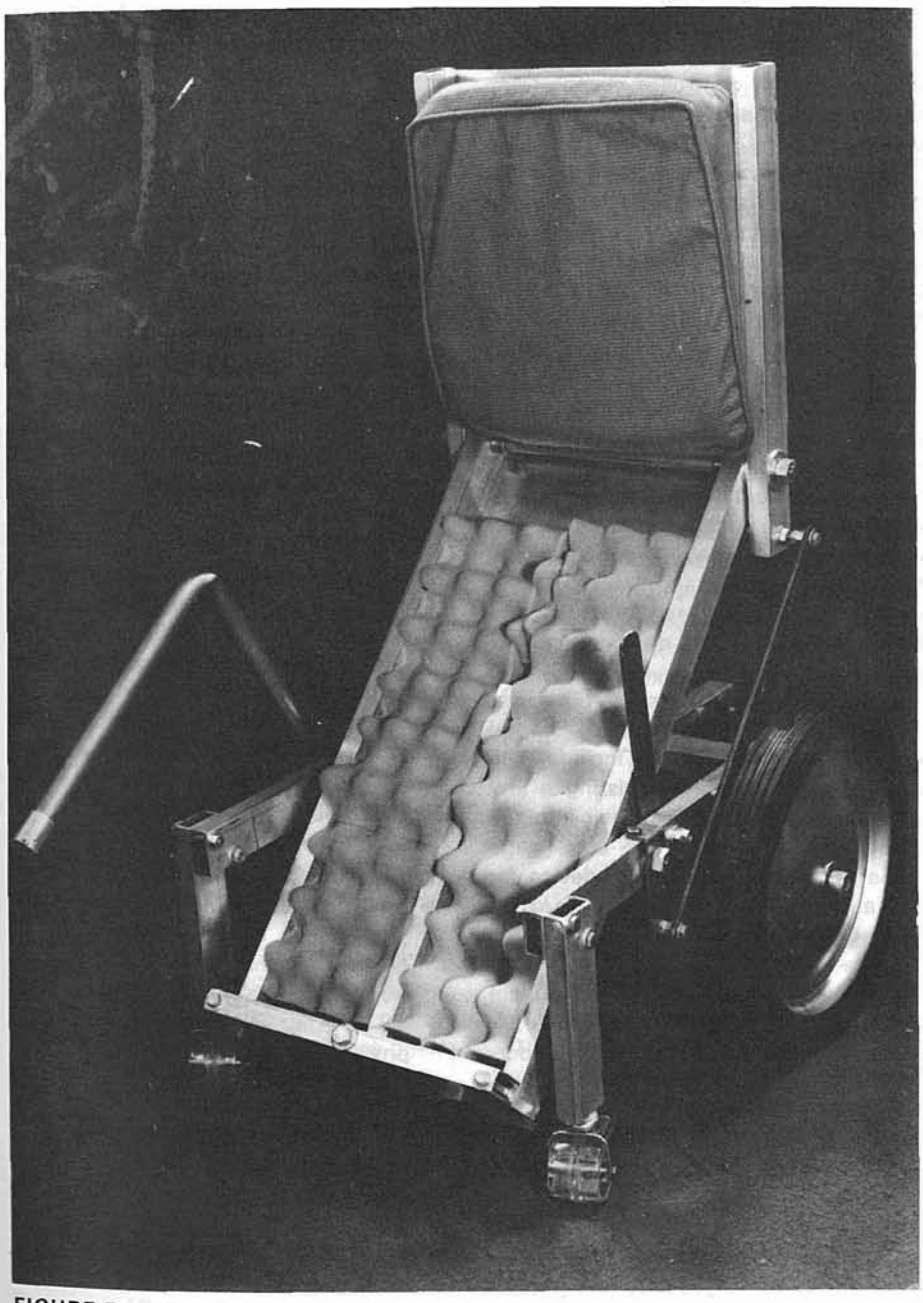

FIGURE 7.
Podicar in an intermediate position.

2. The Podicar: An Independently Manipulated Podium / Mobility Device for Paraplegic Children

The Podicar was designed and built for a 3-to-5-year-old paraplegic child. The Podicar braces the child in a stable standing position, and also allows seated indoor mobility at a near-floor level. The feature of the Podicar that distinguishes it from other braces and mobility aids is that it allows the child to change from a braced standing position to a seated mobile position (and vice versa) without help from another person or device. Its advantages include relative independence for the child, promotion of upper body development, and a potentially greater variety in body position so necessary in preventing tissue decay and restricted blood circulation. Movement from the standing position to the floor level position is accomplished through use of a hydraulic jack system which is totally controlled by the user. The device can be stopped at any intermediate position as demonstrated in Figure 7. An inexpensive automatic jack was modified for use in the design. The Podicar was designed and constructed by the

student group and subsequently fitted and given to a child with spina bifida, a clinic patient at St. Christopher's Childrens Hospital, Philadelphia, PA.

3. Control of Dyskinesia

The goal of this project was to design and build a device that will allow a person who has dyskinesia to function with reduced upper-extremity oscillation that accompanies volitional arm movements. To achieve this goal the following objectives were pursued:

a. Determine what, if any, existing solutions were available;

b. Determine the particular functional task(s) for which the individual required assistance;

c. Develop the necessary software and hardware to analyze a specified subject's arm motion while performing the specified functional task(s);

d. Using the test data from (c), design the orthopedic device; and

e. Build and test a prototype system.

Several factors were involved in limiting the scope of this project. First, due to the nature of dyskinesia, the device was designed and built for a particular individual. Another person needing similar arm-motion control would most likely require different design parameters. Also, because of the educational background of the group and the time limit placed on the project, control of three-dimensional motion was not attempted. Finally, money and time constraints allowed the group to build a device for one arm only.

After measuring and analyzing the subject's arm motion, a number of different methods were considered for the controlling of the dyskinesia. The dynamics of the right arm were selected as criteria for design because the right arm was in need of more control than the left. It was decided to use rotational double-acting hydraulic dampers combined with the basic idea of a two-bar balanced forearm orthosis to control the dyskinesia. The damper selected can be adjusted about its nominal values so that the damping can be more closely tuned, in use, to the subject's need. The two-bar balanced forearm orthosis is pivoted in two main places; one pivot point is located where the orthosis attaches to the wheelchair, and the other is between the two bars. The damped balanced-forearm orthosis replaces these two free-moving pivot points with two rotational dampers. The combination of rotational dampers and balanced-forearm orthosis gives the subject more control in the right arm, where there previously was very little.

4. Home Transportation System for Quadriplegics

In a typical Philadelphia rowhouse, floor space is at a premium. A quadriplegic using a powered wheelchair has great difficulty negotiating the passages and stairways of a rowhouse. An alternative home transport was considered which would not employ a powered chair, which would provide an increased level of independence, would minimize seat-to-seat transfer, and would increase safety by enabling the user to make a controlled escape from the home in the event of fire or other danger.

This design project developed the details of a transportation system to be used by a quadriplegic in his home. The system is controlled by the quadriplegic through a "sip and puff" control unit. It enables the quadriplegic to move between specific rooms and sites within his home. In using the system, the quadriplegic is seated in a chair (sling) and suspended below a motor drive which provides fore, aft, up, down, and tilting movements. The device moves along a track system attached to the ceiling of the house. The continuous track connects selected rooms and sites (work, bath, bed, etc.) through the house. Details of the drive tracks and control system were developed.

The student projects proposed in October 1980, and planned for the coming academic year include the design of a device for assisting a low paraplegic out of a wheelchair into the standing position, a low-cost page turner, a wheelchair storage device for an automobile, and a safety knee-locking system for an above knee amputee.

Another student senior-thesis project not connected with the senior engineering design course has been undertaken by a student in the Material Engineering Department, in collaboration with Professors Kamel and Moskowitz and Mr. Charles Pritham of the REC. The object of this project is to adapt the technology recently developed for use of silicone rubber in maxillofacial restorations to the problem of improved cosmetic covers for prostheses used by lower-limb amputees.

Affiliation Program for Students in Physical and Occupational Therapy

Responsible Investigator: Rebecca Craik, Ph. D., M.S.P.T.

(This is a continuing project; see previous BPR progress reports.)

The purpose of this program is to expose physical and occupational therapy students from affiliating universities to research methodology and rehabilitation engineering, and their application to the field of physical and occupational therapy. This goal is approached in at least two formalized ways: a 3-hour seminar offered to students affiliating at various hsopitals in the city, and a 4–8 week affiliation program offered to eight universities. During their 4–8 week affiliation at the Rehabilitation Engineering Center, students are assigned to specific research investigations and are guided by project supervisors. Students gain experience in writing and carrying out a protocol designed to answer a particular research question.

Twenty-two students attended the 3-hour seminar this year. Schools represented by these students included Duke University, Northeastern University, University of Delaware, University of Maryland, State University of New York at Buffalo, University of Pennsylvania, and University of Vermont. In addition, Mrs. Helen Little, MCSP, Charing Cross Hospital, London, visited the Engineering Center for two days, September 15 and 16, 1980, to learn more about the role of the physical therapist in research. Finally, three students participated in the affiliation program during this year.

The following presentations were made during the year to stress the need for research in the field of physical therapy:

1. R. Craik, "The Role of the Physical Therapist in Research," Department of Physical Therapy, Temple University, Main Campus, November 5, 1979; April 7, 1980. Audience: pre-physical therapy students; Martha Shane, Instructor.
2. R. Craik, "The Role of the Physical Therapist in Research," Department of Physical Therapy, Temple University, Ambler Campus, November 19, 1979; April 14, 1980. Audience: pre-physical therapy students; Holly Cintas, Instructor.
3. C. Leiper, "EMG Feedback," Department of Physical Therapy, Temple

University, Main Campus, April 18, 1980.

4. R. Craik and C. Leiper, "The Relevance of Research to Clinical Needs," Magee Memorial Rehabilitation Center, In-service training to staff physical therapists, May 2, 1980.
5. R. Craik, "Sensory Feedback: Rationale and Treatment Applications," Department of Physical Therapy, Duke University. Audience: First year graduate students in physical therapy; E. Villaneuva, Assistant Professor, May 19, 1980.
6. R. Craik, "The Need for Clinical Research in Physical Therapy," Department of Physical Therapy, Temple University, Main Campus, May 12, 1980; September 11, 1980. Audience: Senior physical therapy students; Kevin Cody, Assistant Professor.

Dissemination and Evaluation of Clinical Instrumentation

Responsible Investigator: Carol Leiper, MEd, LPT

(Continuing project; see previous BPR progress reports.

Over the past several years, a steady stream of requests has been received asking for the various items of clinical instrumentation initially developed for use internally. Since these devices were not available elsewhere, an attempt has been made to supply the needs of other investigators and clinicians. This activity has been organized under one heading of "dissemination" with the threefold purpose of providing instrumentation otherwise unavailable; obtaining information from followup on device utilization and efficacy that may be used to improve instrumentation, and stimulating interest in production by commercial manufacturers.

During the past year, the responsibility for all dissemination of information related to clinical instrumentation (and the production of the devices) has been assumed by a physical therapist and a senior design engineer.

Activity related to the specific aim of education encompassed the areas of publications, presentations, and loans of equipment.

The instrumentation actually provided for clinicians from 1 January 1980 to 31 December 1980 is shown in Table 2.

TABLE 2. Record of Devices

	1980 to 8/31/80
Limb Load Monitor	57
Dual Force Monitor	2
Knee Angle Monitor	2
Dual KAM	—
EMG Monitor	8
Visual Feedback Display	7
Dual EMG	6
Functional Electrical Stimulator	16

In 1977 a questionnaire was sent to institutions that had purchased a Limb Load Monitor in 1975 or 1976. Information was gathered on the ease of operation, reliability, type of patients, etc. During the past year the questionnaire was revised and in September 1980 it was sent to all institutions which had purchased the LLM between 1975 and March 1980. Results of the followup questionnaire will be analyzed and fully reported next year.

The instruction manual for the LLM was rewritten, eliminating the large section on the rationale for using sensory feedback devices. The increased use of biofeedback applications and articles in the past 5 years has resulted in the clinician having a better understanding of the general principles. Thus, it was decided to revise the manual, concentrating on the operation of the device and on particular therapeutic application examples. A section was also added to emphasize the use in the recording of objective performance to document treatment progress.

It is proposed to continue the dissemination activity via the same channels for the coming year.

ENGINEERING SERVICE DELIVERY

Adaptive Seating

Responsible Investigator: Carol Leiper, MEd, LPT

(This is a final report.)

The adaptive seating service was developed to meet the needs of selected children referred to the Moss Rehabilitation Hospital Pediatric staff. Throughout the year, other individuals also approached the team with specific seating problems, and an informal liaison was created with the Chief of Orthopedic Surgery at Children's Hospital of Philadelphia.

Over the past year 16 children have been referred for specific seating assessment and / or fabrication. Nine of the referrals came from the pediatric physician at Moss Rehabilitation Hospital. The remainder of the referrals came from therapists and physicians at the following institutions: Children's Hospital of Philadelphia; St. Christopher's Hospital for Children; Children's Seashore House, Atlantic City; 1 private physician; and 1 private physical therapist.

Activity has been divided into six kinds of service. Some children have appeared in more than one group. The services provided were:

1. Seating evaluations leading to adapting an existing insert (or to specific recommendations for someone else to build an insert) were given for five children.
2. Seating evaluations leading to specific recommendations for assembly of commercially available custom modifications were given for three children.
3. Fabrications of custom inserts were completed for four children.
4. Fabrications of seats and inserts designed at the University of Tennessee REC were completed for three children.
5. Trial use and eventual recommended purchase of the University of Tennessee REC commode seat occurred with three children.
6. Assessments of ability to control a power chair were performed with two children.

Except for the two areas of fabrication, all of the service activities could have been carried out by experienced therapists, and in most clinical situations this procedure occurs. Problems arise due to the necessity of completing the recommendations and providing a finished seating product. During the past 2 years, therapists at St. Christopher's Hospital for Children have been successful in attracting a retired carpenter to build simple pieces of equipment, and in developing a small budget to allow for purchase of materials. Within the last year, following discussions with personnel at Children's Hospital of Philadelphia, simple seating adaptations are also being constructed by that institution.

The need for very specialized inserts is most apparent in the group of children described as severely disabled. The current trend is to the development

of techniques to provide intimate-contact inserts derived from a body mold. Two such inserts were made during the past year, using different techniques. The foam-in-place technique described by the REC / UT was tried initially, and one seat and back supplied. The seat was successful in that it enabled a severely involved child to be mobile in a chair; however, we were disappointed in the lack of flexibility to accommodate for the apparent femoral length discrepancy caused by a dislocated hip. (This physical manifestation was almost always present in the children referred to us for special seating.) The second method used a variation of the vacuum extraction method. Rather than use the bag for a total body mold, it was split into back and seat sections making the bags and the positioning easier to handle. One seat (Fig. 8a,b) was fabricated in this manner, and the short-term reports from parents and the case worker indicate that it is a successful solution for an adolescent who was always carried and propped up with pillows on a sofa. Currently one prosthetic and orthotic firm in the area is making spinalized total-contact seats.

The development of activity within the pediatric community in Philadelphia in the area of specialized seating is growing. Considering these encouraging signs, the role of this REC will now be one of support rather than active service. Cases within the region that require special design will now be referred through the regular operation of the Rehabilitation Engineering Service.

The Rehabilitation Engineering Service

Responsible Investigator: Serge Minassian

(This is a continuing project.)

During the last year the RES has continued to provide an outpatient service through a grant from the Pennsylvania Bureau of Vocational Rehabilitation. Additional sources of referrals include the Delaware public school system, private insurance companies, and private individuals.

In March 1980 a full-time occupational therapist was hired for the RES. The addition of this position has enabled the RES to expand the model research to encompass in-patient engineering problems and to provide early intervention. RES personnel attend hospital rounds to facilitate engineering problem identification, to improve channels of communication among the various health professionals and to encourage

FIGURE 8a.
Molding chair with separate bags for back and for seat sections used to mold custom seat.

FIGURE 8b.
Custom-fabricated molded seat made using the two-bag chair, Fig. 8a, for adolescent. Molded seat, foot support, and block for higher left foot are mounted on a standard stroller frame.

immediate engineering problem identification, to improve channels of communication among the various health professionals, and to encourage immediate engineering input during patient discussions. In addition to Moss Hospital, the RES participates at Magee Rehabilitation Hospital and Jefferson Medical Center. Rounds attended include spinal-cord injury, stroke, amputee / peripheral vascular disease, traumatic brain injury, and arthritis services.

Thorough documentation is kept for both the inpatient and outpatient models for service delivery. Followup procedures have been instituted for the RES. These involve mailed questionnaires and logs of telephone calls to document studies of the effectiveness of the recommendations and services provided.

During the fourth quarter of the Rehabilitation Engineering Service (RES) with grant support the following accomplishments were made:

1. Fee-for-Service contract arrangements were made for the continuation of the service to clients of BVR.

2. Followup forms have been prepared and forwarded to BVR clients who have been previously referred to the RES. To date 30 have been sent out and 17 received. The data are being processed.

3. Followup forms have been prepared and forwarded to BVR Counsellors who have made referrals to the RES. To date 25 have been sent out and 19 received.

4. The RES won the 1980 Achievement Award of the Hospital Association of Pennsylvania.

5. The RES made an in-service presentation at the Willingboro and Camden regional offices of the New Jersey Department of Vocational Rehabilitation Services (DVRS). NJ DVRS is interested in incorporating RES with their system.

Rehabilitation Engineering Service client activity for the fourth quarter and the cumulative total to date are shown in Table 3.

The RES continues to be involved in special evaluation programs. One of these is the Rehabilitation Equipment Demonstration Unit (REDU). This project is being conducted by the Veterans Administration Hospital in New York through the REC in Charlottesville, Virginia. The participating centers include the RECs at Rancho Los Amigos, University of Tennessee, the University of Virginia and Moss Hospital in Philadelphia. This center coordinates evaluation of environmental control units and manual wheelchairs. Another special project is ABLEDATA, a computer-based information center for use by the consumer. This center is also responsible for the collection of material and entries on ambulation aids.

Some of the design ideas that were developed at this center in 1980 in the course of RES operation are listed below:

1. Short-Term Projects

a. Lazy Susan Bookholder—This device was made for a child with phocomelia to assist him with school work. Three bookholders were mounted on a lazy susan with a latching mechanism to lock each book in a desired position by pushing a lever with his chin or tongue.

b. Lower-extremity abductor bar with mirror for self-catheterization—This device was developed to assist mildly spastic spinal-cord-injured females. This is a wooden device shaped like a dog bone, approximately 8 in long, with an adjustable mirror. By placing this device correctly the patient could achieve a functional position for self-catheterization.

c. Lower-extremity pneumatic abductor for female catheterization—This device consisted of a blood-pressure cuff, approximately 7 in × 14 in, with Velcro fasteners at each end. Positioning the device by attaching the Velcro around the thighs and inflating, enabled the severely spastic female with spinal injury to perform the catheterization. This device was utilized by the nursing staff, as well as by individual patients, as an aid to the catheterization process.

d. Communication access aid for

TABLE 3
Projected process, program, and efficiency benchmarks

	Actual Fourth Quarter	Actual Cumulative	Projected Cumulative
Process Benchmarks			
Number of clients referred	48	140	100
Number of clients served	48	139	96
Number of clients that could have been served	52	208	208
Number of case reports issued	9	70	96
Number of clients served per source			
1. BVR	12	52	72
2. Other	36	87	24
Service Times			
1. Weeks between referral and preview	<1	—	<1
2. Weeks between referral and appointment	2	—	2
3. Weeks between referral and issue of case report	3	—	4
Program Benchmarks			
Solutions accepted	*	*	90
Solutions rejected	*	*	6
Solutions in progress	*	*	20
Solutions completed	*	*	70
Number of recommendations of "no solution"	*	*	5
Efficiency Benchmarks			
Cost per client	[a]	357	406
Number of months to solution completion / implementation	*	*	3

* Followup procedure, in progress, will provide information for this category. Only partial returns are available at this time.

[a]Fee covered by grant from BVR.

the foot—This was developed for a non-verbal head-injured patient with spastic quadriplegia. The only reliable movement was with the right foot. The solution was to develop a slip-on pointer that fitted over her shoe. The pointer was positioned perpendicular to the sole of the foot. She had adequate lower extremity movement, on the right side, to use the pointer for a variety of uses including the typewriter and a communication board.

2. Long-Term Projects

a. Low friction transfer board—This project is intended to experiment with various finishes on transfer boards to reduce the amount of friction during the transfer process. Two examples of transfer boards that were developed by the RES, and are currently being clinically evaluated are: (i) Teflon coated surface on a wooden transfer board; (ii) Polyurethane and talcum powder mixture was used to coat this wooden transfer board.

b. Eye blink interface—This was developed for non-vocal paraplegics to be used with communication devices. It is a sensor mounted on a pair of eyeglass frames. The sensor has been designed to detect sustained eye blinks while ignoring normal, eye-lubricating blinks.

Future Plans

The plans for 1981 are to continue expanding both the in- and outpatient service delivery models, to document to third party payers the need for engineering services and the reimbursement for them. The RES will adopt the hospital medical records standards for the documentation of engineering services. Followup procedures will continue and systems for data-collection and interpretation will be developed. It is anticipated that two full-time positions will be developed, an additional therapist and a research assistant. The RES staff will continue its education and dissemination activities and will begin to develop a student program for the training of occupational therapy students in rehabilitation engineering.

The following generic areas have been identified as problems which require future investigation:

1. Para-assist standing equipment;
2. Male urinary collection device;
3. Female urinary collection device; and
4. Development of a computerized workstation which is operable with a variety of interfaces.

Dissemination

The following is a list of dissemination and utilization activities in 1980:

1. Presentation to the Congress of Rehabilitation Medicine. "Biomedical Engineering Clinical Application on a Rehabilitation Engineering Service." Hawaii, November 13, 1979. (T. Strax, M.D., N. Mayer, M.D., S. Minassian).
2. Presentation to the Easter Seal Society. "Rehabilitation Engineering Services." Phila., Pa. March 6, 1980. (S. Minassian).
3. Presentation to the Pennsylvania Bureau of Vocational Rehabilitation. "Rehabilitation Engineering Services." Allentown, Pa. March 25, 1980. (S. Minassian).
4. Presentation to the Pennsylvania Bureau of Vocational Rehabilitation for the RT-8 Stroke Program. "Rehabilitation Engineering Services." Phila., Pa. April 9, 1980. (S. Minassian, C. Leiper).
5. Presentation to the RT-8 Spinal Cord Injury Program for BVR Counselors. "Vocational Implications of Spinal Cord Injury Rehabilitation." Phila., Pa. June 4, 1980. (S. Minassian, S. Sanduski).
6. Paper Presentation to the International Congress of Rehabilitation Engineering. "The Development of a Rehabilitation Engineering Service." Toronto, Canada. June 16–20, 1980. (N. Mayer, M.D., S. Minassian, C. Leiper).
7. Presentation to the Pennsylvania Bureau of Vocational Rehabilitation. "Rehabilitation Engineering Services." Reading, Pa. August 15, 1980. (S. Minassian, S. Sanduski).
8. Participant in an RT-8 Temple University Educational Program. "Visual Screening, Visual Perceptual Testing and Treatment of Visual Perceptual-Motor Disorders in the Adult with Brain Damage." Phila., Pa. May 30–31, 1980. (S. Sanduski).
9. Participant in A Short Course in Design. Tufts University, Boston, Mass. August 4–8, 1980. (S. Sanduski).
10. Presentation to the Kent County School, Dover, Delaware. Staff In-Service Day, October 13, 1980. (S. Minassian, C. Leiper, S. Sanduski, W. Barrie).
11. Presentation to the New Jersey Department of Vocational Rehabilitation. Camden, N.J. October 29, 1980. (G. Moskowitz, S. Minassian, S. Sanduski).
12. Presentation to the New Jersey DVR, Willingboro, N.J. October 29, 1980. (G. Moskowitz, S. Minassian, S. Sanduski).
13. Achievement Awards for the Patient Care Division Hospital Association of Pennsylvania. October 23, 1980. (S. Minassian, S. Sanduski, D. Biser).
14. Presentation to the Sacred Heart Hospital, Physical Medicine Department, Norristown, Pa. November 6, 1980. (S. Minassian, S. Sanduski).

EVALUATION

REC 2 Functional Electrical Stimulator

Responsible Investigator: Nathaniel Mayer, M.D.

(This is a final report: see previous BPR progress reports.)

In 1961, Liberson, Holmquest, Scott, and Dow described an electrical nerve stimulator operated by a footswitch which treated the problem of "foot drop" in hemiplegic patients (1). Subsequent favorable report (2) led to the development of a number of commercially available stimulation units including the Ljubljana FEPA series, the Medtronic NMA system, and the MENSOR ENA series. Previous work supported by this Center demonstrated the clinical usefulness of functional peroneal nerve stimulation in patients with upper motoneuron syndromes having many different etiologies (3). In addition to ankle dorsiflexion, peroneal nerve stimulation during swing phase also appeared to increase proximal hip and knee flexion in some patients and contributed to foot-floor clearance.

A disturbing observation during those studies related to the lack of clinical reliability of the commercially available units and their high frequency of servicing. When marketing decisions (rather than clinical efficacy) curtailed the commercial availability of functional electrical stimulation systems, this Center designed a unit. The attempt was made to incorporate many of the better features of previously available units, as well as to include new features whose usefulness was suggested from clinical studies (4). Clinical technical reliability is an important feature of any patient device because it strongly influences patient acceptance of the device and compliance with treatment regimens. It was, therefore, considered important and necessary to study the technical reliability and servicing needs of this functional electrical stimulator in a clinical trial situation.

Seven of twelve patients completed 6 months of daily usage with the REC 2 Functional Electrical Stimulator (Table

4). Each patient was selected because he or she had inadequate dorsiflexion at the ankle during swing phase secondary to an upper motoneuron lesion. Additional requirements for selection included the availability of range of motion at the ankle to neutral, stance-phase control, equipment and stimulation tolerance, integrity of the peroneal nerve, and the absence of a cardiac pacemaker.

The REC 2 Functional Electrical Stimulator is designed to apply a train of pulses to the surface of the skin along the course of a motor nerve in order to produce contraction of muscle innervated by that nerve. The unit has been primarily applied to the peroneal nerve in the lower limb to control dorsiflexion of the foot. When the device is set for stimulation during walking, an insole footswitch located under the heel triggers stimulation of the peroneal nerve. When the patient lifts his heel during terminal stance, a train of electrical pulses is activated and the train is terminated by subsequent weightbearing on the heel during the next ground contact. Electrical stimulation to the peroneal nerve is, therefore, delivered throughout the swing phase of gait. The pulse frequency of the stimulus train is variable between 30 and 200 pulses per second (pps). Nominal adjustment of the unit when received is 40 pps. Pulse duration is 80 microseconds.

The unit includes an "easy on" feature which applies the stimulation pulses in gradually increasing intensities at the beginning of the train. The time to reach 90 percent of maximum amplitude is adjustable from 100 to 500 milliseconds. An "anti-slap" feature was incorporated into the unit in order to prevent foot slap when the heel switch closes at heel contact. The stimulator can be adjusted to continue the pulse train for a variable time between 100 and 333 milliseconds. Nominal adjustment of the unit when received is 200 milliseconds. In the walking mode, if the patient fails to close the heel switch (for example, after sitting down and removing weight from the limb), the stimulator will cease delivering pulses after a period of time determined by the "Max Duration" adjustment control. This time out feature is adjustable from 1½ to 15 seconds. Nominal setting when the unit is received is 10 seconds. Normal operation is resumed with the next heel switch closure.

Controls available to the patient on top of the unit are an on-off switch, a 10-position intensity selector knob, a walk-cycle operation selector (cycle mode enables the patient to exercise a group of muscles in a therapeutic but nonambulatory mode), a manual test button, and an LED battery tester and adjustments for cycle on / off time intervals. Maximum intensity of stimulation can be adjusted by means of the "Max Trim" control switch in order to reduce the range of output for those patients who are more sensitive to the stimulation voltage. The unit operates from an 8.4-V mercury battery and, with a load of 560Ω, has a maximum output voltage of 40 V.

Seven of twelve patients who were initially selected as clinically appropriate candidates for functional stimulation completed 6 months of usage and provided feedback on the unit's performance. Of the other four, two patients left the area and two patients gave up usage of the unit shortly after beginning the study (reasons cited included difficulty with putting the unit on and locating the electrodes properly, and poor "gadget tolerance."

Despite considerable staff time devoted to patient instruction, six problems of electrode placement occurred during the study. However, re-explanation and demonstration corrected the electrode placement problem.

Technical problems which emerged during the study were classified under five headings: (i) Internal Electronics which included stimulator components, circuitry and internal controls; (ii) Insole Subunit which included the leather insole, heel switch, and connecting cable; (iii) Electrodes and Cables which included two circular carbon rubber electrodes (2.5 cm diameter), Y type connecting cable with male pinjacks; and (iv) Battery Replacement which included an 8.4-V mercury battery with snap terminals; and (v) External Controls which included the intensity control knob, on / off button, manual test button, on / off control for cycle timing, and a light-emitting diode for battery power testing.

Over the 6-month period, 17 repairs were required for seven units. Findings are presented in the repair record (Table 5). Two units required multiple repairs. One unit required four separate repairs and an internal cleaning because it had been damaged when the patient accidentally dropped the unit on the ground. The patients notified the investigators of 10 battery changes although it is

TABLE 4.
Characteristics of patients using the REC 2 Functional Electric Stimulator.

Functional diagnosis (etiology)	Age	Sex	Duration prior to FES	Ambulatory aids
Diplegia (cerebral palsy)	19	M	congenital	none
Right leg monoparesis (multiple sclerosis)	38	M	5 years	none
Left hemiparesis (traumatic cerebrovascular accident)	32	M	3 years	cane
Left hemiparesis (post-surgical)	45	F	5 years	none
Left hemiparesis (cerebrovascular accident)	47	M	2 years	none
Right hemiparesis (Upper motoneuron syndrome of unknown etiology)	62	M	10 years	none
Right hemiparesis (cerebrovascular accident)	58	M	10 weeks	none

suspected that the number of battery changes was higher and went unreported. Two patients gave consecutive replacement information about battery changes for part of the study. The average battery life span for these two patients was 7.2 weeks or approximately three batteries for 6 months of daily unit usage. One patient required electrode replacement because the knob into which the pin from the electrode cable inserts developed a split. Our previous experience suggests that this is a more common occurrence than was actually found in this study.

TABLE 5.
Repair Record of REC 2 Functional Electric Stimulator.

INTERNAL ELECTRONICS	
I.M. Trimmer Pot (Max Duration)	1
ICI—a4011BE	1
Broken lead	1
Coarse intensity switch	1
I.M. Trimmer Pot ("antislap")	1
INSOLE SUBUNIT	
Footswitch replacements	6
Footswitch cable repair	2
ELECTRODES AND CABLES	
Electrode replacement	1
BATTERY REPLACEMENT	10
EXTERNAL CONTROLS	
LED	3

A number of technical problems identified during the project led to redesign of system components. For example, during the study we became aware of frequent problems with the insole subunit. Because of heel-switch corrosion, a redesign of the heel switch was undertaken towards the latter part of the project. Subjectively, we seem to have had fewer problems with the heel switch since it was redesigned. Tears in the heel-switch cable were solved early in the project by using a solid cable extending from the insole directly to the stimulator box. Similarly, individual cables running to the electrodes were combined into one cable housing with a single connector into the stimulator box. This redesign considerably eased the patient's donning of the unit because the single cable system was more easily manipulated by the patient. Changes in the heel switch and insole cabling to the stimulator box should continue to be observed for long-term durability. Additional recommendations from project findings are to recess the battery-tester LED, which currently projects outward from the stimulator box. The LED has inadvertently been broken a number of times because it projects beyond the box surface. In addition, the female jacks for the electrodes and heel switch tended to loosen and should be reevaluated.

The current FES unit compares favorably with other units we have used in the past. A retrospective review of the Medtronic Stimulator (10 units), the original Ljubljana unit (4 units), the FEPA 10 (1 unit), and the Mensor unit (8 units) reveals that the largest number of problems related to breakage of cables, connectors and electrodes. Insole and internal electronics problems were also prominent. Based on an estimated 15 weeks of usage per unit, the average number of repairs for each of the above units was approximately six. In the present study, the average number of repairs is about 2.4 (based on more than 20 weeks of usage per unit).

Our findings suggest that use of functional electrical stimulation will require the support of a service facility for electromechanical repairs. Based on the small sample in this study, we have observed an approximate rate of five repairs per-year-per-unit. Clinical experience would suggest that this rate is greater than for a mechanical ankle-foot orthosis; however, it is not unreasonable. It should be noted that patients in the study lived at home and were not undergoing physical therapy during the project. Clinical considerations such as achieving improved hip and knee flexion, improved muscle bulk and ankle range of motion, improved endurance and ease of limb advancement, could certainly outweigh the disadvantage of increased repair rates required of the electrical unit as compared with a mechanical orthosis. Our clinical experience (3) has suggested that certain younger patients who are active at work or at home, who are able to or required to walk at moderate gait speeds (greater than 0.5 meters / second), who frequently have spinal cord lesions (though different etiologies), and who have difficulty with clearance or limb advancement because of poor neurological control of proximal musculature—these patients do adapt to the technical maintenance and management required of an electromechanical orthosis because they perceive benefits to their ambulation which they do not experience with mechanical ankle-foot systems.

Our study also identifies the need for clinical instruction in using the electrical stimulation unit. Repeated instruction for electrode placement was often necessary within the first month of application. Thus, a service station which provides clinical instruction as well as electromechanical repairs appears to be a necessary prerequisite for patient use of functional electrical stimulation systems at the present time.

Project staff sought feedback from the device users towards the end of their trial period. Four patients responded to a voluntary followup questionnaire regarding their experience with the functional electrical stimulator. Responses were based on an average of 21 weeks of use. Three patients indicated improved mobility with FES use, including climbing steps and inclines, less "effort and exhaustion," walking "better," walking on uneven ground, standing with "weight equally balanced" and improved "standing and walking endurance." Activities which were harder to do while using FES included getting out of a car (electrodes became unplugged when arm was used to lift the leg out) and squatting (for a similar reason). On a typical day three patients put the FES on right after awakening and one patient put his on in the morning. Three respondents indicated that they put the device on in less than 15 minutes. One patient required anywhere from 3 to 30 minutes to don the unit. The respondents estimated that they used the device an average of 12 hours a day and 6¼ days a week. The FES unit was used both inside and outside the home. Two patients found the stimulation comfortable, one patient found it uncomfortable, three patients felt a sensation at the electrode site, and two patients also experienced the stimulation sensation elsewhere (e.g., in the foot).

A number of ideas for improvement were recommended, including a more neutral color to make the device less conspicuous, a more secure attachment of electrode to pad, strain relief at the footswitch, better electrode bonds so they do not slide around, and adjusting the cable length to the height of the patient so that the wires would "be

less of a nuisance." Three patients indicated that their device failed to operate on nine different occasions. One patient was aware of four footswitch failures and one unit failure. All patients had their problems reviewed and corrected by Center personnel. Three patients had irritation from the Velcro straps and one patient changed electrode gels because of "allergy." Three patients felt their condition had improved since using FES while one patient felt that the condition was about the same.

In addition to the finding described, project staff developed an instruction manual for physicians and therapists which covers five areas: (i) Indications and Contraindications for use of FES; (ii) Applications of System including skin preparation, electrode preparation, electrode placement, stimulator connection, and stimulator setting; (iii) Trouble Shooting including the absence of clinical response, skin discomfort and inconsistent responses; (iv) Technical Aspects; and (v) Parts and Service. A copy of the manual can be obtained from this Center. (A patient manual is under development.) The REC 2 Functional Electrical Stimulator is available for purchase to individuals with a physician's prescription, and to health care institutions with medical supervision.

References

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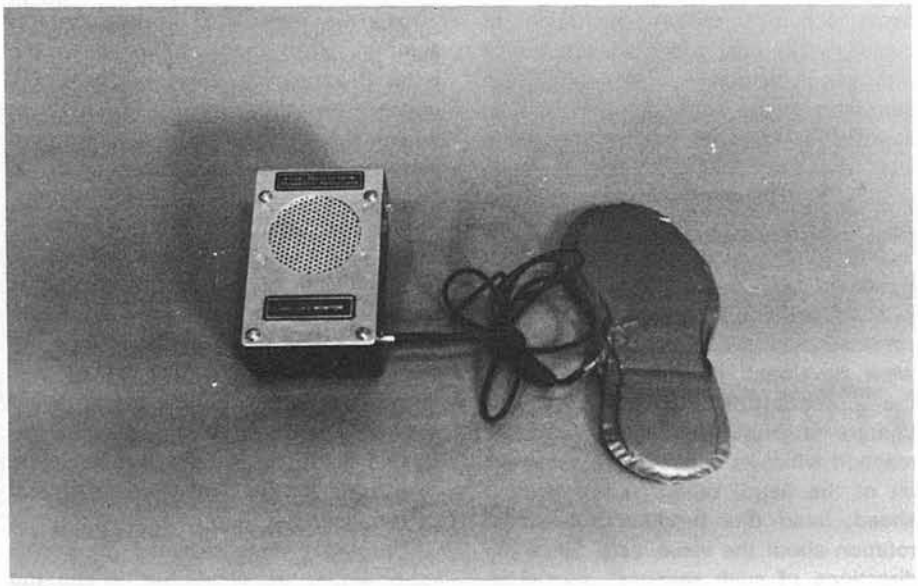

FIGURE 9.
The Limb Load Monitor (LLM)—a variable-capacitance auditory feedback device to register applied load, developed by REC #2.

Technical-Clinical Re-evaluation of the Limb Load Monitor

Responsible Investigator:
Carol Leiper, MEd, LPT

(This is a new project.)

The purpose of this study is to reevaluate and document the accuracy and reliability of the Limb Load Monitor (LLM)—a variable-capacitance auditory feedback device to register applied load, developed by REC 2 (Fig. 9).

The Limb Load Monitor (LLM) consists of a pressure transducer which is fabricated in the shape of an insole worn inside the subject's shoe, and an electronics package which provides a proportional auditory error signal which changes as a result of the changing capacitance as weight is transferred on and off the insole. The LLM is used equally frequently to encourage increased weightbearing or to limit weightbearing, with persons having a variety of disabilities.

In other applications, the transducer and electronics package are used to record the weightbearing forces exclusive of auditory feedback on walking substrates and stairs.

The technical portion of the testing procedures will be concerned with description of the device performance outside the shoe as a force measuring and monitoring instrument. The characteristics will be measured first for the signal conditioning circuit alone and then for the combination of circuit and transducer. Base line drift, linearity of output with input, frequency response, hysteresis phenomena, and time delay will be measured. The repeatability and drift characteristics of the audible tone-generating portion of the LLM circuits will be measured independently and then together with the transducer and signal-conditioning circuits. The clinical portion of the testing will describe the characteristics to be expected when used in the shoe with the added effects of shoe fit, break in, bending, and indeterminate foot-shoe forces which occur during clinical application.

Pilot testing is currently being conducted on four different sizes of insoles for linearity of response under static loading conditions outside of the shoe.

Rehabilitation Engineering Center University of Michigan Department of Mechanical Engineering W.E. Lay Automotive Laboratory Ann Arbor, Michigan 48109

J. Raymond Pearson, M.Sc.M.E., Director

Research efforts at the University of Michigan Rehabilitation Engineering Center (UMREC) focus on a number of factors related to the driving of personal licensed vehicles by persons with disabilities. The four core areas of this endeavor were outlined in the Spring 1980 issue of the Bulletin of Prosthetics Research (p. 138). Significant progress has been made in the study of drivers who are deaf by **Drs. T. Dean Clack and Wanda O. Milburn.**

Vestibuloocular Dysfunction among Deaf Drivers

The ear and eye are interrelated functionally via complex neurophysiological pathways. In particular, there are significant connections to the extraocular muscles which originate from the sensory receptors of the inner ear—the cochlear portion subserves hearing and the vestibular portion plays an important role in the control of eye movements. These vestibuloocular connections compensate for head motion by repositioning the eyes so that gaze is not disrupted by changes in head orientation. This aspect of visual functioning, therefore, can be expected to suffer decrements when abnormalities that impair hearing also affect the vestibular system.

Such abnormalities could have serious consequences in certain practical situations; e.g., in the operations of an automobile where vision is crucial and the head is in motion. Thus, it seems reasonable to assume that some deaf persons could have vision deficits associated with riding and / or driving a car. Whether or not this is a valid assumption is the topic of this preliminary investigation.

Procedures

Evaluation of the possible relation between hearing and seeing involves three concerns. One is appropriate assessment of vestibular function among persons with hearing handicaps. Another is examination of visual abilities under conditions of movement such as those encountered in a car. The third concern is the selection of deaf persons who are likely to demonstrate the hypothesized relation.

Vestibular Function Tests—Eyeball repositioning reflexes stem from two sets of sensory receptors located within the vestibular complex: the semicircular canals and the otolithic receptors. Each set plays a somewhat different role. The semicircular canals are most responsive to angular head movements and acceleration. The otolithic sensors are activated by velocity and / or gravitational forces. Assessment of the vestibuloocular reflex system necessitates tests of both receptor subsets.

The test method commonly used for clinical examination of semicircular canal activities utilizes elicitation of ocular nystagmus, a jerk-like rotation of the eyes in response to stimulating the ear with warm or cool water. The approach used here was to detect the eye responses with electronystagmographic techniques. The instrumentation was lent by the neurootologic testing facility of the University of Michigan Hospital.

Examinations of otolithic function, in contrast, are not common, and methods were developed here for carrying out the appropriate testing. Previous investigators have utilized a particular eyeball reaction which is elicited by a sideways tilt of the head. When gazing straight ahead, head tilts produce a torsional rotation about the visual axis. Since the directions of such torsions, or cycloductions, are opposite that of the head, these responses are often called counterrolls. Ocular counterroll is difficult to observe for several reasons, and special techniques are needed for its detection and measurement. A method and the tilt chair (Figure 1) constructed for examining these responses (1) have been developed under the auspices of the UM REC. This development has applications well beyond the research discussed here, and should be counted among the major accomplishments of the project.

Visual Riding / Recognition Tests—To measure the visual abilities of persons in a moving automobile, two signs were created: one is displayed in Figure 2. Both signs contain similar novel information in order to reduce effects of previous verbal-patterned learning. Sets of 16 questions were composed for each sign. The questions all required one word answers, such as "Does the number 6 appear on this sign?", "How many times does the letter R appear?", "Does the word EW appear on this sign?". Each such question was typed on a separate card allowing different randomizations of the orders of presentation to each subject. Before the test, one of the examiners read the questions to the subject. If necessary the questions were signed to the subject before the automobile began its path. Any uncertainties about the questions were clarified before the testing. When the questions were answered, correct responses were recorded and percentage scores were calculated as the measure of visual performance.

The signs were exposed for observation under two conditions. In one, the subject was driven past the sign at about 25 miles per hour with the sign held beside the road in clear view for 5 seconds; these passes allowed the sign to be seen from about 100 feet at first sight to 5 feet in distance at the closest point. In the other exposure, the subject was also seated in the same passenger seat but with the car parked. At a distance of approximately 50 feet the alternate sign was exposed, again for 5 seconds, after which the subject

answered the appropriate question. The orders of the "moving" vs. "still" conditions as well as which sign was presented in each were changed in a counterbalanced sequence for successive subjects. Both conditions were run within a few minutes of each other along the same stretch of road so that lighting conditions would not differ significantly.

Subjects—Licensed drivers were recruited and paid to participate in the study. Among these, nine were profoundly deaf; i.e., having verified air-conduction hearing losses exceeding 80 dB in frequency range above 500 Hz. The 10th subject had near-normal hearing but had previously received ototoxic levels of streptomycin for medical reasons.

Results and Discussion

While it is premature to formulate complete characteristics of performances, the data suggest that the sampled subjects fall into four groups. One group includes persons who exhibit reactions to the semicircular canal and otolithic tests. The visual recognition performance of "still" vs. "moving" conditions show little difference indicating that head motion has relatively little consequence for the visual abilities evaluated.

A second group consists of individuals who produced no detectable responses to semicircular canal testing but showed counterroll magnitudes within 80 percent of that expected. These subjects also show little average disparity between "still" and "moving" scores.

A third group contains persons who exhibit some detectable semicircular canal sensitivity but only about 50 percent of the expected otolithic responsiveness. These persons yield reading scores under the "moving" condition which are lower than for the "still" condition.

Finally, there are persons who exhibit no detectable semicircular-canal sensitivity and whose counterroll is about 40 percent, or less, of the expected. These persons produce considerably lower reading scores while "moving" than "still".

Conclusions

Results of this study indicate that persons with vestibular disturbances show decreases in visual recognition when looking from a moving car. Furthermore, these deficits are greater than those found among persons with measurable vestibular sensitivities. Thus, present findings support the hypothesis motivating this investigation. The results also indicate that the vestibuloocular responsiveness should be further differ-

FIGURE 1.
Wanda O. Milburn demonstrates how a subject would be seated at tilt (30°) with the camera mounted to photograph the right eye. Note the marker under the right eye which acts as a reference for comparing eyeball positions at various head / body tilts.

ΔRVN TCD 4OBC6

DZMR HKWX5 JPESK

EW HC9Z PΔTS SMTAB

FIGURE 2.
One of the signs to be used in the roadside reading task. The use of "nonsense" messages minimized the effects of previous learning while taking advantage of reading skills.

entiated into that associated with the semicircular-canal and the otolithic reflexes. Of the two, impairments in the otolithic system seem to have the more detrimental consequences for the visual-recognition scores. The results also show that a hearing handicap is not the sine qua non for vestibular disturbances; some deaf persons produced semicircular canal and / or otolithic responses within normal limits while others did not. Finally it is apparent that deafness per se is not the main cause of the visual difficulties, since the one participant with near-normal hearing actually performed the worst on the visual recognition task—an obvious case of the disability imposed by vestibuloocular disturbances.

Beyond the strong support for the previously unsuspected association between vestibuloocular impairments and motor vehicle operations, this investigation gives rise to several new questions. What is the particular relation between the various aspects of the vestibular disturbance and the visual deficit? In addition to recognition, are there other perceptual difficulties associated with vestibular handicaps? What is the incidence rate of vestibular handicaps among deaf persons and in the general population? How are individual driving habits influenced by the vestibuloocular impairments? In this latter regard we note that the deaf participants of the present study are all licensed drivers; this suggests safe driving records. What sorts of compensatory adjustments have they discovered—and should others be identified and taught similar tactics? In short, this demonstration of the ear-eye connection suggests more questions than answers but clearly establishes the practical import of vestibuloocular impairments for operations of motor vehicles.

Acknowledgments:

This research was supported in part by the Kresge Hearing Research Institute, the Department of Otorhinolaryngology at the University of Michigan Medical School, and by the University of Michigan Rehabilitation Engineering Center (UM REC).

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Rehabilitation Engineering Center Case Western Reserve University Cleveland Metropolitan General / Highland View Hospitals, Department of Orthopaedics 3385 Scranton Road, Cleveland, Ohio 44109

P. Hunter Peckham, Ph. D., and Alvin A. Freehafer, M.D., Co-Directors

The activities of the Rehabilitation Engineering Center at Case Western Reserve University are directed toward restoration of function in patients with mobility disorders. Studies are directed toward development of a comprehensive program for evaluation of the control of movement and restoration of upper extremity function involving both tendon transfer, functional electrical stimulation, sensory augmentation, and command control signal generation. Mobility studies include development of control sources for powered wheelchairs, and evaluation of the therapeutic effects of functional electrical stimulation in gait.

Restoration of Upper-Limb Function through F.E.S.

Principal investigators:
P. Hunter Peckham, Ph. D.
Alvin A. Freehafer, M.D.
Michael W. Keith, M.D.

These studies are the core area of research in the center. The purpose of the project is to develop and evaluate systems employing functional electrical stimulation (FES) to provide control of paralyzed muscles. The systems developed provide control of lateral prehension and release, or palmar prehension and release. Eight quadriplegic subjects with C5 or C6 level motor function are presently involved in outpatient evaluation of these systems. Patients from spinal injury units at both the Cleveland Veterans Administration Medical Center and Highland View Hospital are involved in these studies. These studies are being performed in conjunction with the V.A. Rehabilitative Engineering R & D program, and the current status is detailed elsewhere in this issue of The Bulletin (see Peckham: "Development of Upper-Limb Orthoses Employing Electrical Stimulation" under V.A. RE&D Service progress reports.) The work pursued in the area of FES is closely allied with that ongoing in the Applied Neural Control Laboratory and the Engineering Design Center at C.W.R.U. In these studies, the feasibility of new upper-limb systems is being investigated, and a radio-frequency powered and controlled implantable stimulator is being developed, respectively.

Tendon transfer provides a viable means of restoring motor control to paralyzed limbs. Proper surgical procedure requires that the available muscles for transfer be identified, the potential functional loss due to altered anatomy be established, the properties of the transferred muscle be measured, the resulting new function at surgery be observed, and the post-surgical training and care be carefully followed. All aspects of this problem are being investigated in order to provide improved methods of tendon transfer.

Restoration of Upper-Limb Function through Tendon Transfer

Principal investigators:
P. Hunter Peckham, Ph. D.
Alvin A. Freehafer, M.D.
Michael W. Keith, M.D.

The primary emphasis of this work has been on intraoperative monitoring of muscle properties during tendon transfer. An intraoperative technique has been developed for measuring the available excursion of a muscle, and for visualizing the function of the transfer.

Data in 61 upper-limb muscles of 41 subjects undergoing elective tendon transfer have been analyzed. The teams have been making measurements whenever performing upper-limb tendon transfers on spinal-cord-injured patients. Approximately one procedure is carried out every two weeks.

Sixty-one upper limb muscles of 41 subjects undergoing elective tendon transfer were studied. All subjects were quadriplegic due to spinal cord injury except two. For measurement of muscle excursion, the arm was placed in a standardized posture and a pin placed

in the bone along the length of the tendon of insertion. This pin served as a reference marker, and the tendon was severed at this point. Muscle excursion was measured in each subject for its passive lengthening (length from reference to maximum length due to stretching with an external force load), active unloaded shortening (from reference to minimum length due to an applied electrical stimulus), and total excursion (sum of the active plus passive). For muscle stimulation, a small flexible intramuscular electrode was placed into the muscle belly with a hypodermic needle. The stimulus applied was a constant current capacitatively-coupled pulse train with a frequency of 20 Hz. The muscles studied included brachioradialis, flexor carpi radialis, flexor pollicis longus, flexor digitorum superficialis, pronator teres, palmaris longus, extensor carpi radialis longus, extensor carpi ulnaris, extensor digiti quinti, and posterior head of deltoid.

The available excursions measured in our study are shown in the table, and these results were compared to those published by Bunnell (1), Kaplan (3), and Steindler (4). The average of our measurements generally agreed with one or more of these authors, whose results frequently did not agree with each other. The results of this study demonstrated that the excursion of the muscle often possessed substantial statistical variability (i.e., was not the same for all subjects), which has not been reported previously. No attempt has been made at this time to correct for anthropomorphic differences among the male and female adult subjects. Some muscles possessed less variability than others in their excursion measurements. The use of this technique enables one to establish an accurate measurement for the total available excursion of the individual muscle being transferred. The technique may be applied to muscles that may be difficult to assess by other means.

Soft tissue resection is performed in some tendon transfers, and the degree to which this procedure affected muscle excursion was evaluated. For some muscles this effect was substantial, while in others it caused little change in excursion.

Muscle stimulation was applied before skin closure to visualize the transfer function and modify the attachments if necessary.

It is concluded that this technique of measuring excursion and assessing function, which is simply implemented in the operating room, gives an appreciation for the individual differences between muscles. The technique is helpful in performing a more nearly optimal surgical procedure. A preliminary report has been presented (2).

In this period, a new project has begun to study changes in the activation patterns of muscles which are transferred. This information will provide greater insight into choice of appropriate muscles to use as the motor source.

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Evaluation of Abnormal Motor Control

Principal investigators:
Patrick E. Crago, Ph. D.
George H. Thompson, M.D.

Research studies of the control of movement have recently been undertaken with the objectives of characterizing voluntary and involuntary mechanisms of motor control in patients with movement disorders such as spasticity. This characterization will be used to develop improved methods of evaluation and diagnosis of movement disorders, and to gain a better understanding of the mechanisms underlying the disorders.

The characterization is obtained by measuring mechanical (torque and position) and electromyographic responses to changes in an externally applied torque load at the joint being studied. Studies of normal motor control have shown that the relationship between torque and angle at a joint can be characterized by an invariant relationship that depends on the voluntary "set" of the subject. We are presently evaluating this method of characterization in patients with movement disorders, since there are several possible advantages of such a characterization. The invariant relationship is influenced in predictable ways by muscle mechanical properties, stretch reflexes, and voluntary effort. Thus, changes in the relationship can be used to evaluate mechanisms underlying movement disorders. A second advantage is that the characteristic shows the dependence of the response to stretch on the angle and torque prior to stretch. If the typical daily variation in response to stretch in spastic patients are explainable on the basis of differences in initial torque and angle, corrections for these variations will give a repeatable measure of spasticity.

Stretch responses in the flexor pollicis longus muscle of normal subjects are being evaluated to test the methods of evaluation and to develop a data base of normal characteristics. The study will be extended to cerebral palsy patients in the near future. Design of evaluation apparatus for the ankle joints is also beginning.

TABLE 1.
Available excursion of individual muscles as measured at surgery.

Muscle	Available Excursion (mm)		
	Unfree (undissected)	Free (dissected)	Number
Brachioradialis	34	76	21
Flexor carpi radialis	41	65	6
Flexor pollicis longus	43		2
Flexor digitorum superficialis	43		2
Pronator teres	26	36	6
Palmaris longus	36		1
Extensor carpi ulnaris	35		1
Extensor carpi radialis longus	59		5
Extensor digiti minimi	35		1
Deltoid (Posterior head)	74		

Command Controller Development and Evaluation

Principal investigators:
Dennis Roscoe, Ph. D.
Michael W. Keith, M.D.

A new research program is being initiated for the development of control techniques for Functional Electrical Stimulation and powered prostheses. An implantable multichannel system is proposed, employing intramuscular electrodes and more advanced methods of EMG processing to obtain consistent and accurate proportional control signals. Traditionally, rectification and simple filtering of surface EMG signals is used to produce a proportional control signal (1). Low and high frequency noise components are inherent in this type of processing. Low frequency noise limits the accuracy of this control source, and introduction of large filtering time constants to minimize high frequency noise decreases the response time between the raw command signal and activation of the system, leading to poor overall performance (2).

The new processing scheme involves use of an optimal multichannel estimator of muscle force developed by Hogan and Mann (3). It produces highly accurate estimations of muscle force with an "effective filtering" time constant of 80 ms. Briefly, the processing of the raw EMG from several intramuscular electrodes involves (i) a prewhitening transformation, (ii) demodulation, (iii) combination, (iv) a running average, and (v) relinearization. Initially, raw intramuscular EMG signals will exit an animal model via a transcutaneous connector for analysis and processing. Ultimately, however, an implantable four-channel pulse-width-modulated telemetry system will be developed for use in human subjects.

Ongoing development of the shoulder position controller for powered wheelchairs, described in previous reports (BPR 10-33 and BPR 10-34) utilizing a two-axis proportional position transducer, includes investigating outside manufacturers to fabricate and market the system. The controller interfaces with any standard 12 or 24V Everest and Jennings powered wheelchair equipped with a hand controller. An additional interface circuit has been designed that will allow for compatibility with a MED M01-4104 chin controller. Presently, six high-level quadriplegic patients are evaluating the shoulder position controller.

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Sensory Substitution Using Electrocutaneous Stimulation

Principal investigators:
Ronald Riso, Ph. D.
Michael W. Keith, M.D.

The objective of this project is to develop feedback devices which will provide patients having asensory hands or prosthetic hands with an awareness of the extent of their hand opening and the amount of prehensile force applied to a grasped object.

A patient base consisting of amputees and a variety of patients with neurological disorders such as spinal cord injury, stroke, multiple sclerosis, peripheral neuropathy and peripheral nerve lacerations, is available through cooperation with the Hand Clinic and the Orthopaedics Department of Cleveland Metropolitan General Hospital, Cleveland, Ohio.

The feasibility of using electrocutaneous displays for sensory substitution has been demonstrated by a variety of investigators (1,5,6,7) and its specific applications to upper-limb prosthesis have included feedback information about the extent of hook opening, the amount of prehensile force developed and about the angular position of the elbow joint (2,3,4,8).

The specific objectives of this work are:

1. Determination of the characteristics of subdermal monopolar and bipolar wire electrodes, and comparison of these with the more conventional concentric surface electrodes which have been employed in previous studies by other investigators.

For the case of an amputee patient who will be using an externally worn prosthesis, electrodes built into the prosthesis so that they contact the intact skin surface of the residual limb is least encumbering and probably is the best arrangement. However, for patients whose own hands are to be instrumented for sensory feedback, externally worn hardware in the form of transducers, stimulators and electrode displays represent significant obstacles to patient acceptance and jeopardize the ultimate utility of the device.

The feasibility of producing systems that may be wholly implanted is therefore in part dependent on the applicability of the implanted electrodes which the present study will investigate.

2. Optimization of feedback codes is the second specific objective. Based on the results and recommendations of previous workers (8,10), a combination of burst-repetition-rate modulation and spatial-position coding will be evaluated initially. Under this scheme, the spacial extent of hand opening will be represented by the relative separation of two simultaneously activated electrodes from a linear array of six electrodes mounted longitudinally along the skin of the upper arm, on the same body side as the sensory impaired limb or prosthesis. Information about the amount of grasp force will be provided to the patient by modulating the burst repetition rate of the electrical stimuli of the activated electrodes.

Among some of the initial coding parameters to be studied are the relationship between the patient's performance and the degree of spatial resolution provided by a six-electrode display. Is the spatial resolution afforded by 6 electrodes adequate or can better patient performance be afforded by a larger or smaller number of electrode sites? Considering the encoding of force feedback, is a linear relation between burst repetition rate and force more accurately interpreted than, for example, an exponential function? What are the optimal stimulation and coding parameters that will minimize the demands of mental effort and attentiveness required of the patient?

3. Specification of which classes of tactual and kinesthetic feedback information are most beneficial to each subset of the patient population, and demonstration by means of objective tests (functional skills evaluations) the

utility of the feedback devices.

4. Specification of design criteria for developing implantable sensory substitution devices.

Progress to Date

1. Feedback controller—A sensory feedback controller has been designed and constructed for use in the laboratory. The device receives analogue information about the extent of hand opening and grasp force from appropriate patient mounted transducers, and it provides for control of up to eight independent output channels. The electrical parameters of pulse width, pulse repetition frequency (within each burst), and burst duration are each individually adjustable within wide ranges.

2. Electrodes—Concentric stainless steel surface electrodes have been machined, and hook-up cables and fastening straps prepared. Subdermal wire electrodes to be used will be of the same designs as are presently in use in our REC's FES hand orthosis program.

3. Performance evaluation scheme—A paradigm for objective evaluation of patient performance has been decided upon and is an adaptation of the tracking scheme described by Szeto and colleagues (9) for evaluation of sensory feedback codes. Hardware displays to implement this are all at hand.

4. Transducers—A goniometer which is attached to an externally worn splint will serve to limit the degrees of freedom of the patient's fingers and insure that maximally reproducible prehension-release motions are evaluated when optimizing the coding parameters. A suitable design for the force transducer is pending.

5. Software development—Computer software routines to permit automation of the patient performance evaluations, including data acquisition, storage, and reduction has begun.

It is expected that the investigation may be completed for patient participation by April, 1981.

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Control of Abnormal Muscle Contractions

Principal investigators:
Ronald R. Riso, Ph. D.
John T. Makley, M.D.

The objective of this study is to investigate the therapeutic effects of Functional Electrical Stimulation (FES) in the control of abnormal muscle contractions. Our principal efforts have been to evaluate the effects of (gait syncronized) FES of the peroneal nerve on the walking function of cerebral palsy children having drop-foot and / or ankle extensor spasticity.

Clinical gait analysis (including foot-to-floor contact patterns, ankle joint goniometry, and dynamic electromyography of the ankle flexor and extensor muscles) is employed to determine (i) to what extent the dorsiflexion produced during the period of application of the FES continues after the stimulation is turned off, and (ii) whether ankle extension hyperactivity can be diminished by the periodic application of FES to the ankle flexor muscles.

To determine any effect due to "short term" use of the FES, on each test day gait parameters are obtained immediately before and immediately after a 20-minute session of walking with the stimulator turned on. After two such sessions, patients are given stimulators to take home with them for daily use (approximately 40 minutes per day), and followup evaluations are made at 2 weeks for the first month and at 1 month intervals thereafter.

In agreement with our preliminary findings (1), the dorsiflexion and eversion of the foot, that is obtained with each step when the stimulator is actually in use, is never sustained once the stimulator is turned off. This result applies for all 5 hemiplegic patients who have been studied thus far for at least 6 months to more than 1 year.

An example of this lack of carry-over of dorsiflexion after short-term use of gait-syncronized FES is shown in Figure 1.

The parameter which is measured is derived from a tri-electrode foot-switch which consists of 3 separate strips of aluminum conductive tape affixed respectively to the heel, medial, and lateral aspects of each of the subject's shoes. The three graphs (H, H+L, L) which are associated with each "sequence" are histograms of the time delay (latency) between the events of heel strike and the initial contact of the fore-foot for all of the steps of the respective sequence.

The delay time between heel strike and fore-foot contact is a function of: the elevation of the fore-foot as heel strike is approached, the ability of the ankle dorsiflexors to resist foot slap, and the degree of relaxation of the ankle extensors.

Steps which begin with a normal heel strike event are plotted to the right of the origin, whereas those steps in which toe walking occurred (i.e., fore-foot contact preceded heel contact) are plotted to the left of the origin. This display neatly distinguishes drop-foot gait from the normal heel-strike-first gait, as can be seen when sequence 1 or 4 is compared to sequence 2 or 3. The correction of the drop-foot when

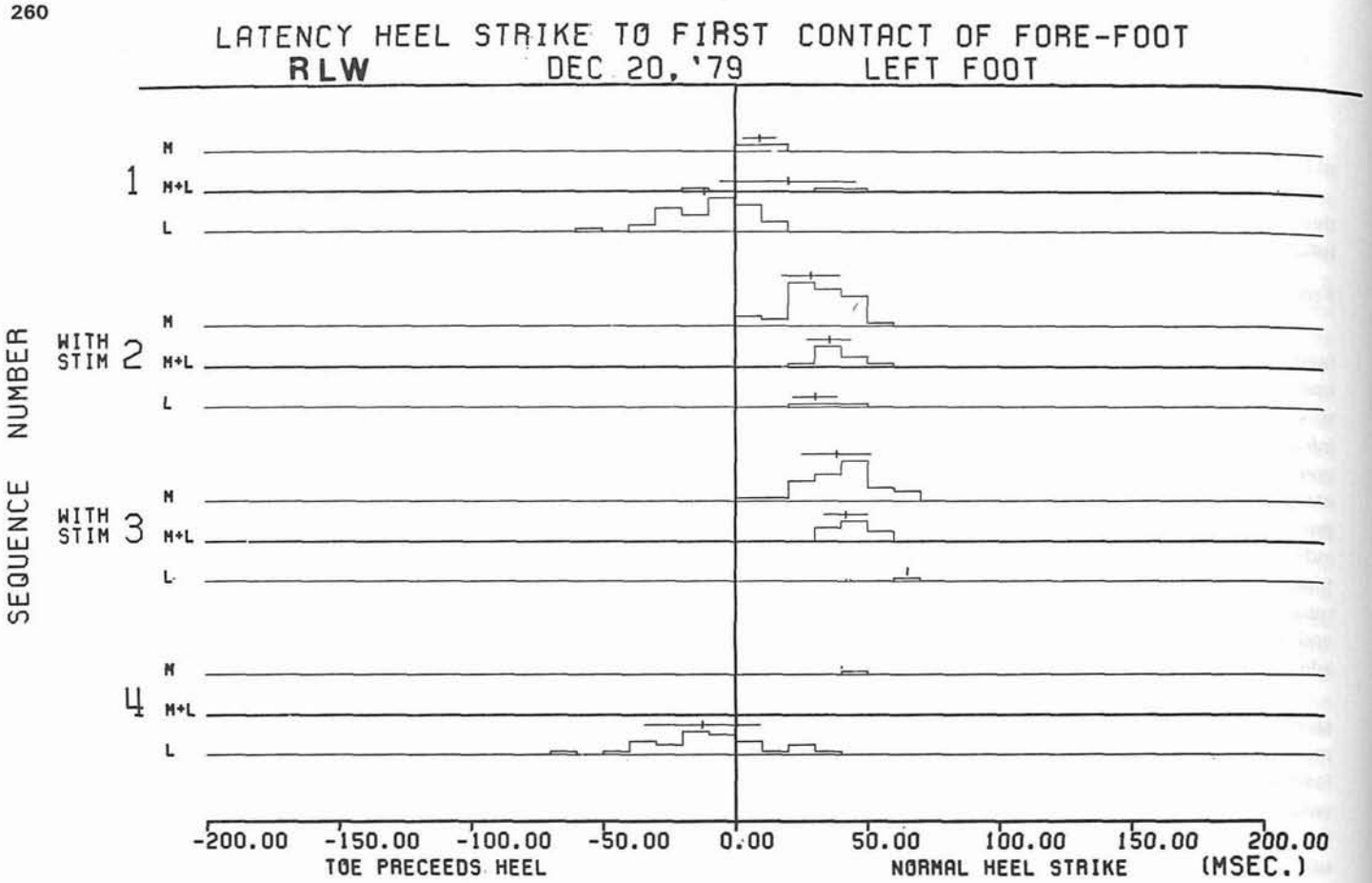

FIGURE 1.
Showing a lack of carryover of the dorsiflexion produced during walking with the FES peroneal apparatus turned on for 20 minutes. Histograms are the time intervals between heel contact and the initial contact of the fore-foot.

The resolution of the data into 3 graphs for each sequence permits registration of which aspect of the fore-foot came into weightbearing contact first (i.e., lateral "L" vs. medial "M" vs. lateral and medial simultaneously "M+L"). Small vertical tick marks indicate the mean and the horizontal bars show ± std. dev. Sequence 1 is taken before use of stimulation that day; sequence 2 represents initial part of a 20-minute walk period with stimulator turned on; sequence 3 represents last 5 minutes of 20-minute walk period using stimulator; sequence 4 represents data collected immediately after stimulator has been turned off. (Note resumption of drop-foot gait in sequence 4.)

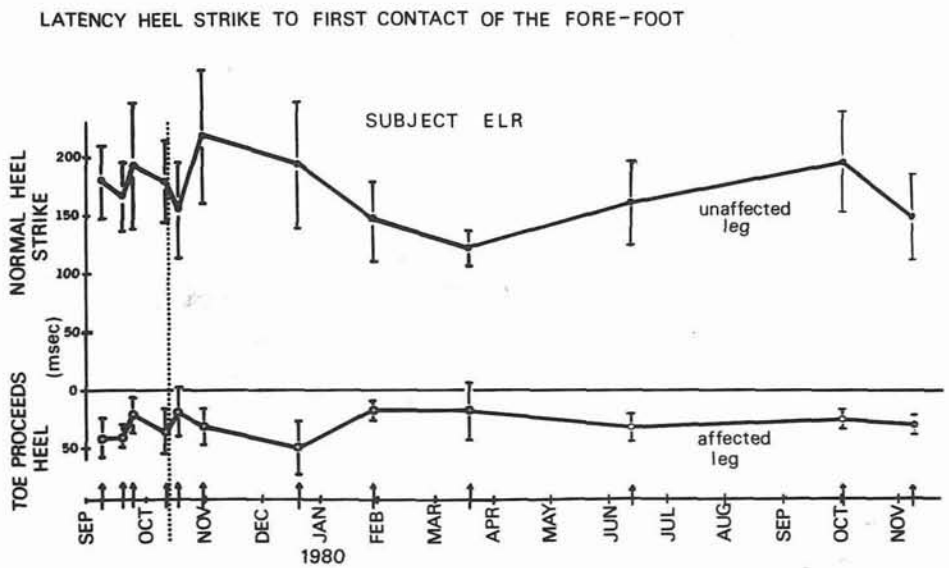

Figure 2.
Showing lack of carryover of FES-induced dorsiflexion following long-term use (several months) of FES. Data are the mean latencies of heel contact to initial fore-foot contact obtained during sequence 1 of each test day (i.e., before any stimulation is used that day). Data below abscissa indicates predominance of drop-foot gait whereas data above the abscissa represent "heel strike first" gait. Onset of home use of the FES indicated by vertical dotted line. Patient is 16 years old with spastic hemiplegia caused by gunshot wound to the head at age 8.

the patient's stimulator is turned on (sequences 2 and 3) is readily apparent, as is the resumption of the drop-foot condition when the stimulator is turned off in sequence 4.

The lack of carryover effects after "long term" (several months) use of the FES is shown in Figure 2. Here the mean latency of heel contact to fore-foot contact is plotted for each gait evaluation day. In every case the data are taken with the stimulator turned off, and the patient has not used the FES since at least the evening before the test day.

The necessity for storing the large amounts of data that are being used to characterize a subject's gait led us to expend considerable efforts over the past year to develop more powerful computer software for data acquisition and analysis. A special file system has been implemented for use on the PDP 11-45 computer facility of the Cleveland VA Medical Center.

This second generation of software permits up to 16 channels of analog data to be sampled at a maximum rate of 500 Hz: providing a conglomerate throughput of 8,000 samples per second. This represents a five-fold increase over the throughput previously obtainable.

To facilitate accessing and manipulating the stored data, a comprehensive file management system was developed (see reference 2) to allow both the information about the experiment, and the raw data, to be permanently stored in a single disk file. A significant advantage of this system is that it provides for automation of the data analysis procedures, as follows: a programmable, front-end command line interpreter, employed by all analysis programs, allows commands to be read from either a specially designed monitor, a file, or the user's terminal. A large number of instructions may thus be edited into a program command file and the desired analysis routines made to operate from this command file. This frees the user from having to wait for a given program to terminate in order to enter additional commands for successive tasks.

References:

1. Riso RR, Crago PE, Sutin K and Marsolais EB: An investigation of the carry-over or therapeutic effects of FES in the correction of drop-foot in the cerebral palsy child. Presented at the International Conference on Rehabilitation Engineering, Toronto, Ontario, Canada, June 16–20, 1980.
2. Sutin K, Crago PE and Marsolais EB: A flexible file system designed to enhance standard sequential files: application to gait analysis. Presented to the IEEE Engineering in Medicine and Biology Society, Washington, D.C., Sept. 1980.

Rehabilitation Engineering Center Children's Hospital at Stanford 520 Willow Road, Palo Alto, California 94304

Maurice A. LeBlanc, Project Director

The Center is 6 years old. The first 3 years were spent developing a wide range of patient services and providing a sound financial base upon which to build research activities. During the past 3 years, research activities have been undertaken toward improving patient services and the state-of-the-art of rehabilitation engineering systems. During the past year the Center has seen over 1,000 clients for various rehabilitation engineering services and has become a regional resource for Northern California.

Core Area of Research

The center has chosen to focus on "Controls and Interfaces for Communication and Other Systems for Severely Physically Disabled People," because (i) it is an important area which has not been approached comprehensively; (ii) it relates to many of this center's patient services, from which needs are generated and subjects for clinical evaluation can be found; (iii) communication devices, mobility aids, and environmental control systems have controls, but little attention has been given to "mixing and matching" controls and aids / systems from different manufacturers so that one control can operate several aids, or one control can be switched among aids.[a] There is also (iv) a large clinical need to maximize use of existing controls and to develop new controls to optimize residual motions of people with disabilities.

Direction of Work

The second year of the project has just been completed. The project was initiated by conducting a survey to determine what controls existed, what controls were being developed, and what controls were needed. This survey has resulted in—

(i) Preparation, publication and distribution of a catalog of controls commercially available in the USA and abroad; (ii) A compilation of controls under development in the USA and abroad. This list is in preparation and will be published and distributed during the third year grant. We expect that it will be helpful to determine who is doing what, to prevent duplication, and to inform new people in the field of the state-of-the-art. The survey also (iii) provided information which will aid in making rational decisions about where our own R&D effort should be focused, and about selecting controls developed elsewhere which we should clinically evaluate here.

Thus, much of our work to date has been "software" rather than hardware to determine for ourselves and others what the state-of-the-art is and where to intervene. An obvious need will still exist for dissemination of information, but the project will become more R&D hardware intensive to develop and test specific needed controls for the severely physically disabled population.

Survey on Controls (John Preston, Jr.)

Objective—This survey was designed to identify controls that are commercially available for physically limited persons to operate assistive devices, needs which are not being met, ideas for new controls, and ways for consumers and clinicians to receive information.

Progress—The survey is completed and results have been published in a monograph, "Assessment of Needs for Controls and Interfaces to Operate Assistive Devices for the Severely Physically Disabled."

Development of Controls Evaluator-Trainer Margaret Barker

Objective—The objective of this project is to design and build a portable system that can be used for evaluation and training of physical control abilities to operate mobility, communication, and

[a] See under department heading "Standardization" in BPR 10-34, Fall 1980, a report on the second meeting of the International Standard Connections Project, by project chairman Gregg C. Vanderheiden of the Trace Research and Development Center, University of Wisconsin.

environmental-control systems. The controls evaluator (Fig. 1,2,3) is envisioned as a self-contained, battery-powered system with an assortment of interfaces and outputs. A timer and a counter are to monitor quantitatively the operation of each interface. The outputs being considered include an array of colored lights and an array of audible tones. The evaluator is being designed so that it will be compatible with existing augmentative communication aids and microprocessors, so that the outputs are not limited to those provided with the evaluator. The proposed system would feature simple operation and flexibility for various assessment and training methodologies, and is to be approximately the size of an attache case.

Progress—An original prototype has been completed (Figs. 1-3) and now is being redesigned to include features for collecting quantitative information about the control of the various interfaces.

Development of Control Simulator
Margaret Barker

Objective—The objective of this project is to simulate outputs of systems used for mobility, communication and environmental control. A microprocessor will be utilized to evaluate a disabled individual's physical and cognitive abilities as they pertain to the control of particular interfaces. Software will be developed, and existing software modified, to use a microprocessor as a simulator of assistive device characteristics. The purpose of using this simulation is to isolate the specific characteristics of the aid required by the user.

Progress—The present system consists of an Apple II computer with color graphics, a disc drive, and commercially-available and custom-made interfaces. The programs have been modified or developed to include:

1. Control of a dot in the X and Y axes of a video monitor with either two switches or a proportional or nonproportional joystick. This program is used while positioning the interfaces in relationship to the client and familiarizing the client with the interfaces.
2. A game incorporating a paddle, ball and wall of bricks. The object of the game is to knock out all of the

FIGURE 1.
Controls evaluator unit with top closed.

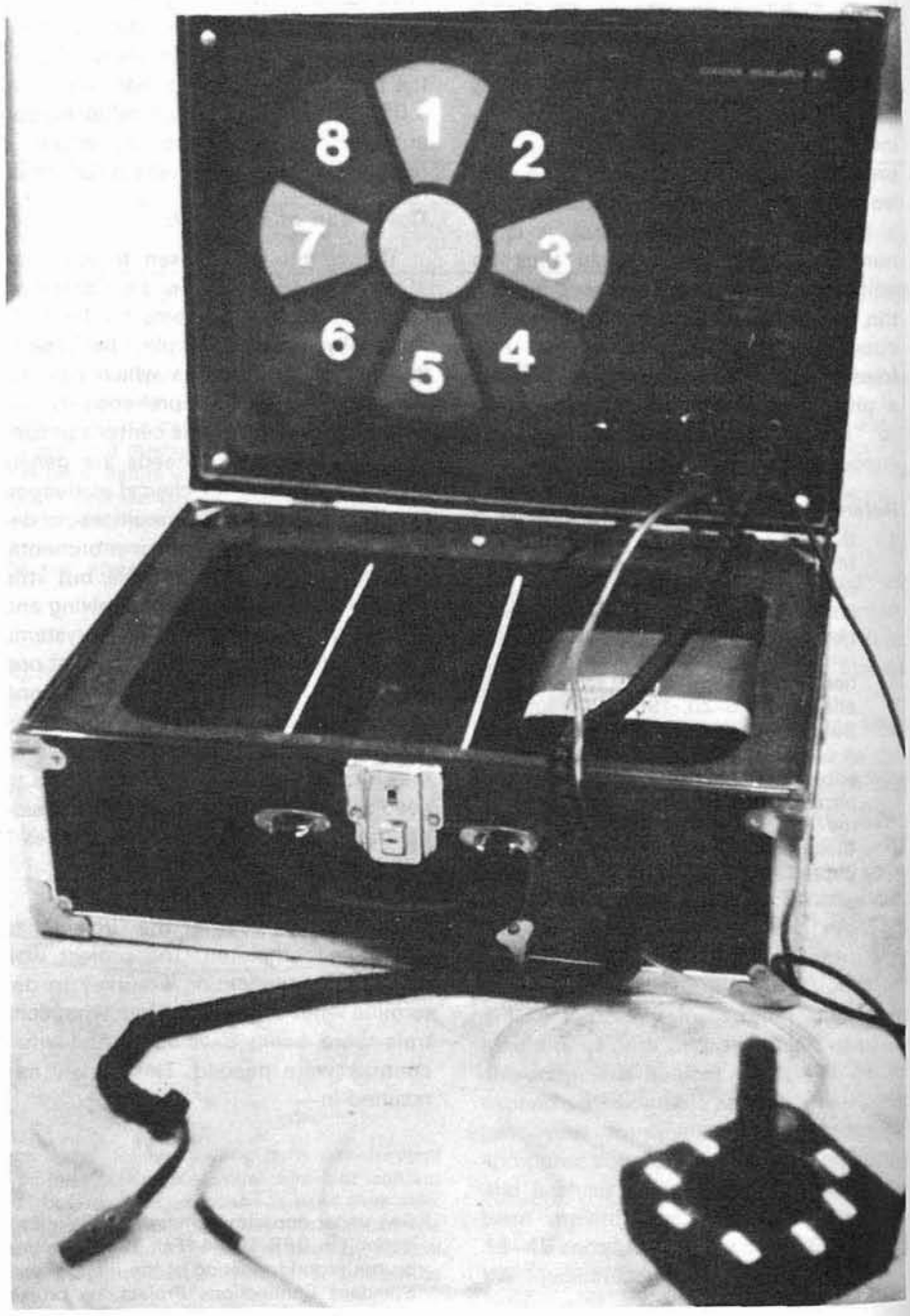

FIGURE 2.
Controls evaluator showing display on top inside cover.

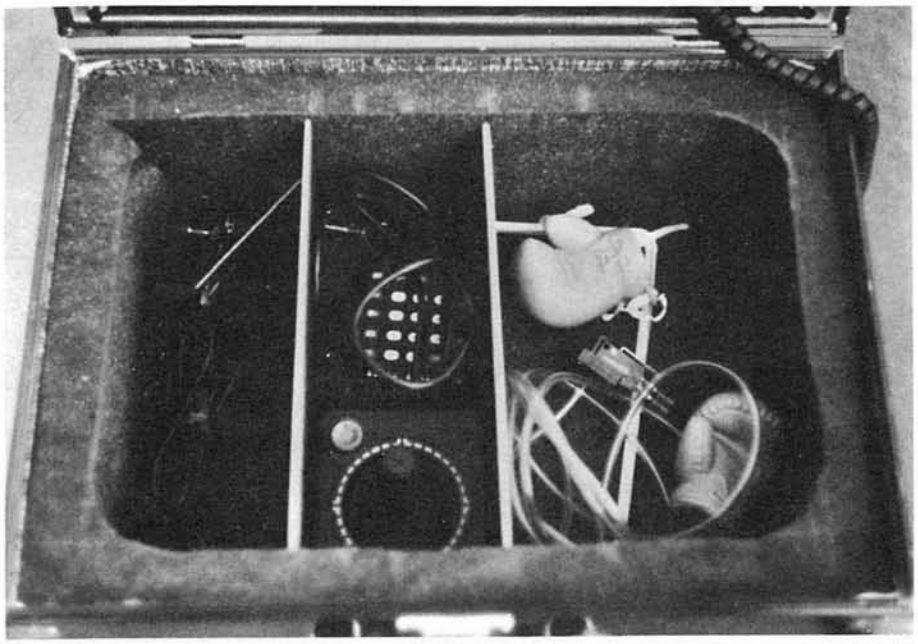

FIGURE 3.
Controls evaluator showing assortment of controls in bottom of unit.

FIGURE 4.
Control simulator showing maze game.

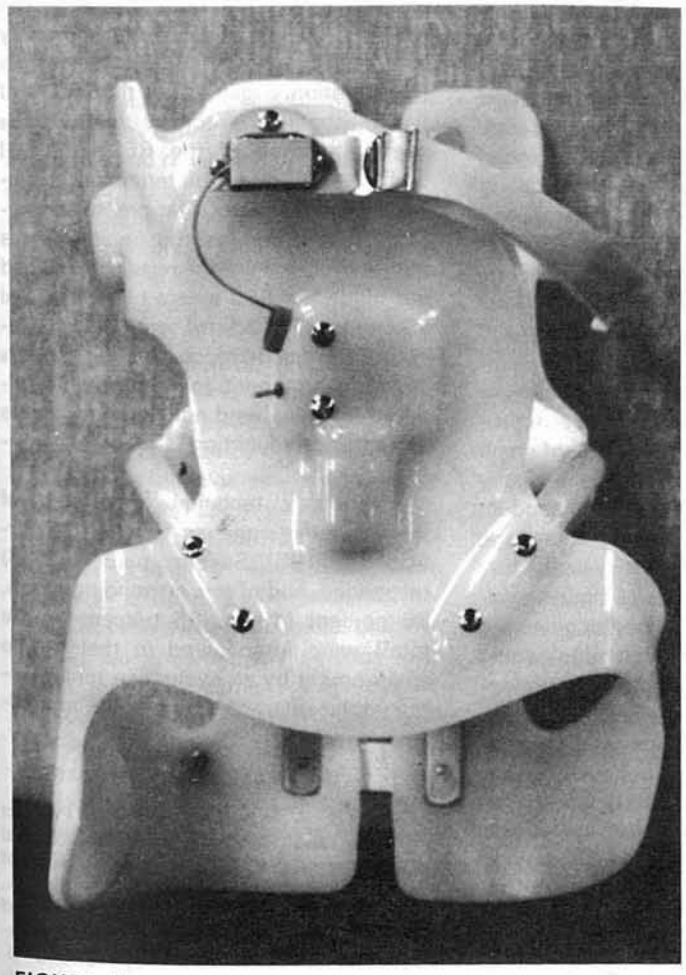

FIGURE 5.
TLSO scoliosis feedback orthosis—trimmed and ready for fitting with electronics components included.

FIGURE 6.
TLSO scoliosis feedback orthosis—fitted on patient subject.

bricks with the ball. This game can be played with the X- or the Y-axis control. It tests the coordination and the endurance of the client.

3. A game of control of a dot through a maze (Fig. 4) that is randomly generated on the video monitor. The game requires control of the movement of the dot in both the X and Y axes. The object of this program is to move the dot through the maze without bumping into the walls of the maze. When complete, the microprocessor gives a score related to the number of walls bumped as the client steers his course, and the time it takes to travel the course.

Scoliosis Feedback Orthosis
Eugene E. Bleck, M.D.

Objective—This project involves the use of an augmented tactile feedback orthosis to obtain optimal therapeutic function in correcting curvature of the spine through a dynamic force system, for patients with idiopathic scoliosis. The goal is to improve and simplify the treatment of idiopathic scoliosis in adolescents.

Progress—Two cervical-thoracic lumbar spinal orthoses (CTLSOs) and 14 TLSOs have been fitted. See Figures 5 and 6. Patients are trained to perform (i) pelvic tilt, (ii) spinal distraction, and (iii) lateral shifting of spine to concave side. An evaluation period including X-rays and follow-up examinations at regular intervals is being used. Initial results are encouraging.

Problems encountered are (i) six refittings out of the 16 initial fittings have been required because of growth, and (ii) the orthosis has required a significant amount of time to fabricate. The use of a modified, modular, commercially-available spinal orthosis is now being considered.

Team Evaluation of Device Effectiveness: A Retrospective Study
Jean Kohn, M.D.
Sandi Enders

Objective—This clinical research study is an attempt to determine if it is possible to: (i) define and document the benefits of assistive devices; (ii) relate benefit to cost; and (iii) develop an initial assessment procedure that identifies accurately both technical and psychosocial requirements of the client. An additional objective is to identify economic aspects related to the provision of devices: costs, source of funds, time sequences from requests for funds to authorization to payment, and financial obstacles to provision.

Progress—It has been the impression of rehabilitation engineers, physicians, and therapists that provisions of assistive devices must satisfy technical performance requirements and must also consider the client's lifestyle, physical environment, interaction with family, friends and fellow workers, and the effect on the client's self-image. The benefit of an assistive device is, therefore, both objective and subjective: objective in terms of professional assessment of optimal technical and functional performance, and subjective in terms of the client's satisfaction with the device in home and work surroundings on a day-to-day basis.

Measurement of benefit has been difficult to document. Effective evaluation of devices has been frequently identified as a major gap in the rehabilitation engineering service delivery systems. Clinical evaluation begins with the initial assessment procedure, follows along through provision of the device, and continues through a followup process which documents technical performance and client satisfaction. Clinical evaluation is therefore a crucial component in research utilization.

In order to develop a clinical evaluation model which could be used prospectively in the evaluation of new items, it was decided by the advisory committee and the grant staff to conduct a retrospective study, taking advantage of the Center's service delivery history to broaden the elements of clinical evaluation beyond technical and engineering specifications. It was felt this would provide an important input in the planning of comprehensive services, research activities, and clinical evaluations.

Since seating and mobility devices for severely physically disabled individuals have been a primary area of service delivery at the Center from its inception, it was decided to focus the followup study on people who had been evaluated at the Rehabilitation Engineering Center (REC) and for whom the recommendation had included a major mobility device with a significant control and /or interface in the system.

The figures in the table show some results of this study compared to a national survey[b].

	CHOS REC	National Survey
Device is ineffective	21%	39%
Device is effective	79%	61%
Device is mechanically unreliable	19%	30%
Device is mechanically reliable	81%	70%

While the above figures indicate a better mechanical performance record for the REC, the review team felt that a 1/5 unreliability record was unacceptable over a long period of time. Since the REC had opened in 1974 and the study was done in 1975–1978, the team's rehabilitation engineer felt that some of the mechanical problems might have been the result of the REC's internal problems in getting materials and training new personnel. Of far greater importance, however, was the finding that a number of the interviewed group had not made the REC aware of mechanical problems, and had not returned for necessary repairs or reconstruction. This is a strong argument for regular REC-initiated followup, and education of clients to report malfunction and other problems.

The study technique consisted of sending questionnaires to all study participants (196). Seventy percent (138) responded, and of this responding group, 36 percent (49, or 25 percent of the total) were interviewed in their home environment by an evaluation team. Demographic characteristics of the nonres-

[b] Grall TB: A Feasibility Study of Product Testing and Reporting for Handicapped Consumers. p.67. Consumers Union of United States, Inc., 256 Washington St., Mount Vernon, New York 10550. Prepared under contract from the Veterans Administration (V5244P–1628) by Terrand B. Grall, Ph. D., (project director) Interdisciplinary Design Consultants, 6405 Paradise Lane, Sheboygan Falls, Wisconsin 53085.

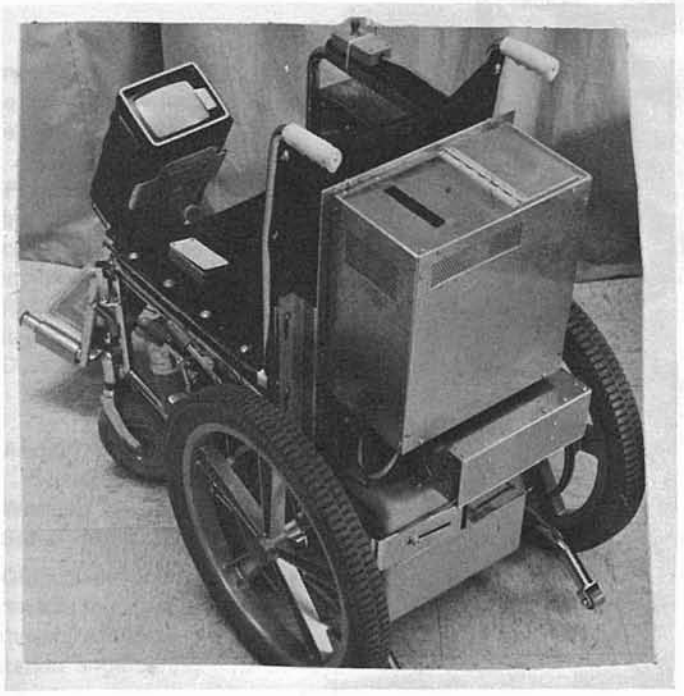

FIGURE 7.
Versatile portable speech prosthesis, rear view.

FIGURE 8.
Versatile portable speech prosthesis, side view.

pondents, the questionnaire group, and those given home visits were comparable.

A point system was used to quantitate the daily-use aspects of equipment use, change in lifestyle through equipment use, and reasons for nonuse of the prescribed equipment. Eighty-one percent of the devices were found to be in working condition, and 50 percent of the 81 percent (40.5 percent of the sample) were being used an average of 9 hours per day at the time of the study. Twenty-two percent of the devices had been outgrown, and the average life span per device was 30.9 months. Since the average cost per device was $1,650, the cost per day for use of the device through its life span was $1.50. Although the psychosocial values and changes in lifestyle which derive from an ability to enlarge environmental horizons are somewhat intangible, assistive devices do enable many persons with severe motor impairment to achieve educational and employment opportunities, and the overall cost / benefit ratio appears to be satisfactory. The study has been completed and the report published: "Team Assessment of Device Effectiveness."

Clinical Evaluation of Versatile Portable Speech Prosthesis
Maurice LeBlanc

Objective—The task is to clinically evaluate the Versatile Portable Speech Prosthesis and its "versatile" controls and interfaces. The research and development of the VPSP has been funded by the NASA Technology Utilization Program via Grant No. NSG-2313 from the NASA-Ames Research Center. Two consultants on the NIHR Grant are being used in the clinical evaluation of the VPSP. The NIHR component is an important complement to the total project.

Progress—The VPSP has been evaluated with a clinical protocol on five patient subjects and tested informally for feedback with several other nonvocal people. Results were very encouraging. Speed of speech using the system ranged from four words per minute with a single switch control to 30 words per minute with a keyboard control. The VPSP features:

1. Unlimited vocabulary
2. Fast, easy message construction
3. Mountable on, and powered by, standard electric wheelchair (Figs. 7, 8)
4. Choice of control switches, depending on user capabilities: (i) single-switch, (ii) 5-slot arm control, (iii) joystick, or (iv) full keyboard
5. A large vocabulary of pre-spelled words and phrases
6. Blank "user pages" which may be programmed by the user with his own most-used words, phrases, and sentences.

Following the clinical evaluation in Spring 1980, a conference was held in May 1980 to which 22 manufacturers were invited. Of the six manufacturers who attended, four expressed interest, and two eventually submitted proposals to make the VPSP technology commercially available. Final stages are in process for the VPSP research team to work with one of the manufacturers, Computers for the Physically Disabled, of Huntington Beach, California.

Interaction with Industry
John Preston, Jr.

Objectives—To aid in making worthwhile controls and interfaces commercially available to the severely disabled through soliciting information from researchers and developers of controls; clinically evaluating new and promising controls to determine their usefulness; disseminating information about controls under development as well as those commercially available; and working

with industry to assist the transfer of worthwhile controls from development to commercially available.

Progress—Listed below are projects with which we are currently involved:

1. Manufacturers and researchers participated in the survey of needs, and now have the results for basic technology development.
2. On June 16-20 1980, the Center participated in the workshop on "Technology Transfer" at the International Conference on Rehabilitation Engineering in Toronto.
3. Manufacturers shared and received information from us in developing the "Catalog on Controls."
4. On-going communication with manufacturers through participation in annual Rehabilitation Engineering Seminar.
5. Twenty-two manufacturers were invited to the Conference on Commercialization of Versatile Portable Speech Prosthesis.

The remaining projects are directly related to the transfer of technology developed through services at the Center. They are:

1. A Weight Relieving Ambulator for assisting and teaching children to walk. Everest and Jennings to make this commercially available (Fig. 9).
2. Slot Control. Five-position control which can be used as an interface between severely disabled persons and mobility, environmental control, communication, recreational, educational, and other assistive devices. Being made commercially available by Medical Equipment Distributors (Fig. 10).
3. Headwand. A lightweight device which allows residual head motion to operate controls, and keeps the field of vision and mouth free. Negotiations are underway with Zygo Industries for commercial availability (Fig. 11).

Development of Controls Reference Catalog

John Preston, Jr.

Objective—To develop a catalog of controls / switches which can be used as a reference by people involved in the use or provision of assistive devices. The controls catalog is intended to inform consumers, therapists, physicians, engi-

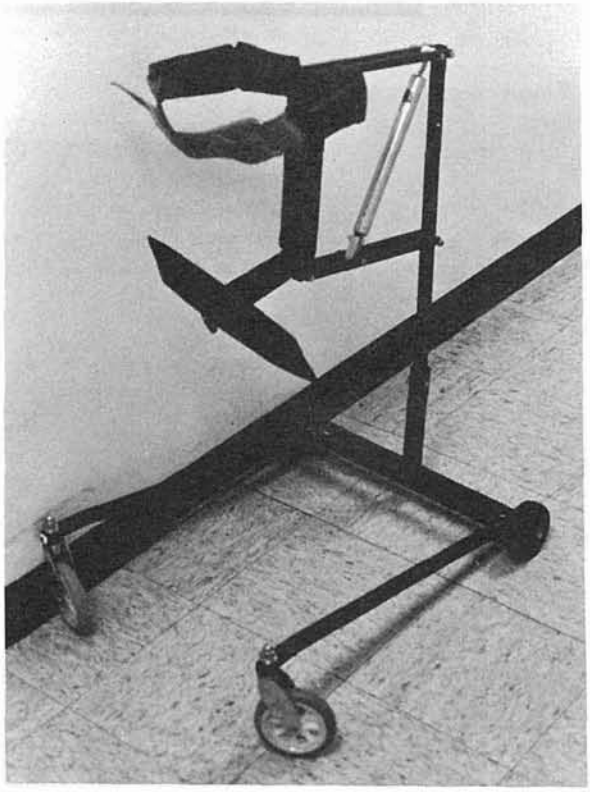

FIGURE 9.
Stanford Children's weight relieving ambulator.

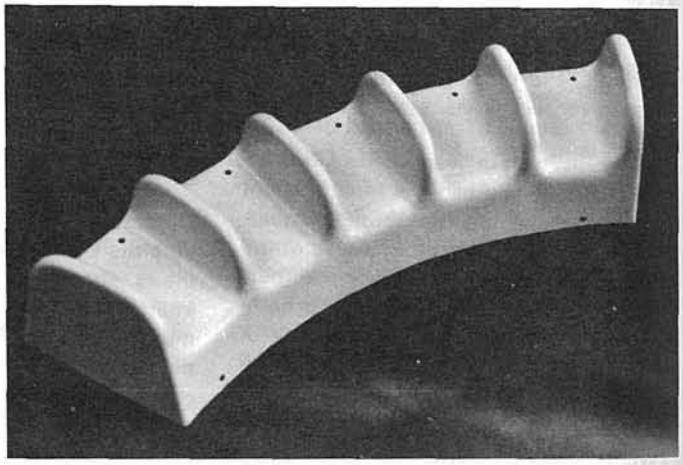

FIGURE 10.
Stanford Children's arm slot control.

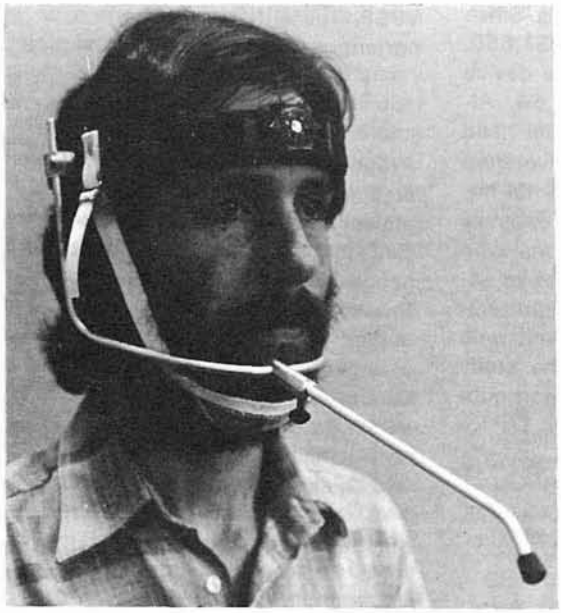

FIGURE 11.
Stanford Children's headwand.

neers, manufacturers, researchers and others as to what is commercially available.

Progress—The task is complete. A broad array of commercially available controls have been identified and are included in a catalog entitled "Controls Reference Catalog to Aid Physically Limited People in the Operation of Assistive Devices."

Annual Rehabilitation Engineering Services Seminar
Wallace M. Motloch
Sandi Enders

Objective—This annual seminar is conducted to provide a forum for state-of-the-art information exchange in rehabilitation engineering. The aims are: (i) to introduce new people to the field of technical aids and services; (ii) to update information to those already involved in rehabilitation engineering and related areas; (iii) to facilitate the development of a local resource network in the ten San Francisco Bay Area counties; (iv) to demonstrate the scope and cooperative effort of Rehabilitation Engineering.

Progress—The seminar was held March 12–22, 1980. All of the major rehabilitation engineering resource centers in the Bay Area had the opportunity to formally and informally exchange information with the large, varied audience and with each other.

Ninety-nine percent of the respondents indicated they would plan to attend the next annual seminar. Highest priority for topics to be added or expanded were: using technology in independent living; seating and mobility; home modifications; communication; do-it-yourself devices; and environmental controls.

For the first time, continuing education credits were available to participants at the seminar this year.

A followup mailing was sent out in October 1980. This included feedback from the critique sheets and an updated address list of all 270 seminar participants and speakers. This is expected to further the continued development of a local resource network.

Response to the first two seminars has been enthusiastic and the community has come to expect this annual spring event. The Third Annual Rehabilitation Engineering Seminar is scheduled for March 20-21, 1981.

To the best of our knowledge, the Rehabilitation Engineering Services Annual Seminar is unique. It appears to be the first program of its kind to be conducted by a Rehabilitation Engineering Center. It has already had a "spin-off effect" nationally; as a result of the success of these two events, several of the other RECs have expressed interest in presenting local programs with similar focus and objectives. The experience gained here in the past two years will be available to assist other centers in planning and implementation.

Rehabilitation Engineering Clinical Internship
Wallace M. Motloch
Sandi Enders

Objective—The aim of the Internship Program is to provide a comprehensive clinical training program for a graduate engineer interested in becoming a professional rehabilitation engineer.

Progress—The Center's first intern completed his program September 29, 1980. He had completed a one-month service rotation in each of these departments: Seating and Mobility, Tissue Trauma, Orthotics, Prosthetics. He completed a two-month program in the Communication Service. Two months were spent in field placements, the first at Santa Clara Valley Medical Center in San Jose and the second at Ralph K. Davies Medical Center in San Francisco. A final month was spent in documenting his projects and visiting other health care facilities. The second intern started September 30, 1980 for a one-year program.

Dissemination of Information
Sandi Enders and Staff

Development of Information Service—In conjunction with the California State Department of Rehabilitation, an information service is being developed on a trial basis at Rancho Los Amigos Hospital REC and Children's Hospital at Stanford REC. At the federal level this program is being coordinated by the University of Virginia REC with overall direction from NIHR.

This project is just getting underway. A State Department of Rehabilitation counselor was placed at this REC on October 6, 1980, as "Information Broker" with the telephone number (415) 327-1111 for the Information Service. Sandra Enders, OTR, is the person on the REC staff identified to work with the Information Broker. Steps have been taken to hire a research assistant to start putting entries into ABLEDATA as soon as possible in the areas of aids for children and controls.

Pamphlet on Tissue Trauma—With partial support from this grant and as an outgrowth of patient services, the Center has prepared and published a pamphlet on "How to Prevent (or Treat) a Pressure Sore." Copies can be obtained from Mr. Richard Pasillas, C.O., Head of Tissue Trauma Service.

Project Enable—This effort in designing for the disabled is part of the Center for Design in Palo Alto. There has been information flow with our REC to promote this work of mutual interest. Maurice LeBlanc is serving on the Board of Directors for the Center for Design primarily for interaction with Project Enable.

San Francisco Bay Area Non-Vocal Communication Group—About two years ago a group of multidisciplinary professionals and consumers was formed to promote the delivery of communication aids to nonvocal people. REC staff was instrumental in the development of this group and presently serves to continue and support its efforts. On April 19, 1980, the group held its first Communication Aids Fair, which was successful.

Student Projects and Interaction—Primarily through Stanford University Mechanical Engineering Design Division, and secondarily through San Jose State University Industrial Design, there have been several student projects involving rehabilitation aids. The role of the REC has been to encourage such projects, to talk to classes about rehabilitation engineering, provide information, arrange for contact with consumers, allow use of REC fabrication equipment, and provide professional advice. Maurice LeBlanc has an appointment as Lecturer in the Stanford University School of Engineering, and he and several REC staff members have courtesy appointments with the Stanford University Medical Center to promote interaction.

Rehabilitation Engineering Center
Wichita, Kansas
Cerebral Palsy Research Foundation of Kansas, Inc.
and
Wichita State University, College of Engineering

Co-Directors
Jack F. Jonas, Jr. **John H. Leslie, Jr., Ph. D.**
Roy H. Norris, Ph. D.

The Rehabilitation Engineering Center, Wichita, Kansas, was established on July 1, 1976, under the joint research auspices of the Cerebral Palsy Research Foundation of Kansas, Inc. (CPR) and the College of Engineering, Wichita State University. The core area of research, as established by NIHR, is the development of vocational opportunities for severely disabled persons through engineering.

The REC, during the past year, was under the co-direction of Mr. Jack F. Jonas, Jr., and John H. Leslie, Jr., Ph. D., representing CPR. Joining CPR this grant year is Leonard Anderson, Director of Engineering, coordinating the engineering activities of the various entities of CPR and Mr. Jim DeWees who is directly responsible for the engineering support of Center Industries Corporation. Representing Wichita State University as co-director is Roy H. Norris, Ph. D. Also representing Wichita State University are Don Malzahn, Ph. D., director of Project I; Mr. Rajiv Kapur, director of Project IV; Elmer Hoyer, Ph. D., director of Project VII; and Everett Johnson, Ph. D. directs a related project funded by Control Data Corporation. Projects II and III, economic study research of Rehabilitation Engineering Center, Wichita, Kansas, were discontinued at the beginning of the grant year.

The REC carries out its mandate through cooperative efforts with other agencies such as the University of Tennessee REC, particularly in the area of mobility associated with molded plastic seat inserts for children; and with the National Aeronautics and Space Administration in utilizing space age technology to create an independent lifestyle for severely disabled persons. The REC is currently completing the fifth and last year of its initial grant.

Utilization of the Center's major evaluation tool, the Available Motions Inventory, is to extend abroad with the government of Egypt having purchased the system. Also, the Center is manufacturing a set of the test apparatus for evaluation by the Singer Corp.

Workstation Modification

This research effort is developing human factors data relative to the modification of work stations in an industrial environment so that meaningful work may be performed by severely handicapped persons.

Simulated workstations (utilizing a drill press and a punch press) were designed to determine potential capabilities of handicapped individuals. Correlation of results achieved on the workstations and the Available Motions Inventory by handicapped persons were studied. A control group of ablebodied subjects performed the same group of activities. This study has provided validation of the items of the Available Motions Inventory and has enhanced the utilization of its results in predicting worker capability.

Evaluation of the Economic Concerns of the Individual Handicapped Person:

Principles developed by the activities of the former REC Project II are currently being used to determine the economic factors of a handicapped individual's choice to seek and hold an entry-level job, as opposed to receiving monies to which they are entitled from government social welfare sources if they do not work. This research is being carried out relative to specific handicapped persons living in the Timbers, receiving training in the Evaluation, Research and Training (E.R.T.) Unit, and / or working at Center Industries Corporation.

Access to Computer Operation for Handicapped Individuals:

This project is funded by Control Data Corp. using the client contact and physical facilities of the Cerebral Palsy Research Foundation of Kansas, Inc. Control Data Corp. has indicated their willingness to modify computer consoles so that they can be more readily operated by handicapped persons. Ways in which this may be accomplished are to be determined by this project.

Rehabilitation Engineering Center
College of Medicine
Department of Orthopaedic Surgery
University of Tennessee
1248 La Paloma Street
Memphis, Tennessee 38114

Douglas A. Hobson, P. Eng., Technical Director, and Robert Tooms, M.D.

Foam-in-Place Seating System

Results of Toxicity Studies and Preliminary Clinical Trials—The University of Tennessee Rehabilitation Engineering Department has developed further the Foam-In-Place technique first introduced at Shriner's Hospital in Winnipeg, Canada, as a possible solution to the problem of customized seating for paraplegics, quadraplegics, children and young adults with cerebral palsy, muscular dystrophy, multiple sclerosis, and other less common neuromuscular anomalies, or indeed, for anyone who is confined to the seated position throughout his daily activities and requires custom contoured support.

Essentially, this technique permits the direct foaming of contoured seating components using the individual himself as the mold. Through this technique, the

mold-making and final fabrication steps associated with other solutions have been bypassed. Since almost all of the customary handwork associated with producing the customized foam components has been eliminated, the final product can be obtained quickly, and with a minimum of technical skills. Initial experience has also indicated that customized foam components can be produced and interfaced into a wheelchair in less than two hours.

Recent research efforts have focused on the issue of potential toxic hazards associated with the use of polyurethane materials. Future efforts will emphasize the seat-user interface measurements, to assure safety for those with sensitive tissue.

The importance of proper seating for those confined to the seated position throughout their daily activities has been stressed in recent years. Much more remains to be done in terms of designing proper seating systems and making them available to those within the handicapped population that so urgently need them.

The high cost of pressure sores, combined with the interruption of the living process associated with patients with sensation loss, (primary paraplegics and quadriplegics) have inspired better solutions to the distribution of seating forces under areas of insensitive tissue and bony prominences. Both standardized and semi-custom wheelchair cushions have improved in recent years (11). These developments have parallelled basic studies that have provided an understanding of the basic causes of tissue breakdown that results from pressure sustained above tolerable levels for excessive time periods (3, 4, 5).

The most common approach used to avoid tissue breakdown is to distribute forces over larger weightbearing areas of the pelvis and thighs using force distributing cushions of various configurations. This approach results in a reduction of the pressure levels applied to the susceptible tissue areas, so that sitting may be safely maintained over longer time periods. A second approach, which has received much less emphasis, is to allow high pressures to exist but to permit them to be sustained only for short periods of time. This latter approach is a departure from the large contact area concept, and thereby potentially permits air circulation and related temperature / humidity control at the tissue / seat interface (6).

FIGURE 1.
Polymerizing polyurethane foam being poured into FIP mold.

FIGURE 2.
Polyermized polyurethane components in the foaming chair. Back component still in mold.

In addition to the abovementioned paraplegic and quadriplegic populations there is another larger group of developmentally disabled individuals requiring specialized seating. This group is made up of severely handicapped children and young adults with disorders resulting from cerebral palsy, muscular dystrophy, multiple sclerosis, and other less common neuromuscular anomalies. These disorders often result in severe obliquities of the pelvis, contractures of hip and knee joints, and scoliosis of the spine. These individuals usually have complete sensation, and therefore comfort and maintenance of good body alignment in the seated position is the primary goal, rather than protection of insensitive tissue as in the former group. To provide the required comfort and body alignment, forces of considerable magnitude often must be applied to specific areas on the pelvis and trunk. To maximize comfort, these forces must be maintained at the lowest possible levels. Considering these factors and the additional complications resulting from a lack of neuromuscular control, total contact support appears to offer the greatest potential.

Seating for the severely handicapped cerebral palsied and muscular dystrophy population has traditionally involved the custom-making of inserts which fit into a standard wheelchair (12, 9, 2, 7, 10). The amount of customization achieved is related to the capabilities of the seating technician, orthotist, or therapist responsible for specialized seating. Because of the labor-intensive nature of specialized seating, the cost is usually high. As a result, the services are generally available only through a few larger rehabilitation facilities which have sufficient volume and funding to justify the required specialized staff and facilities. Recent studies have indicated that approximately 50 percent of children and young adults requiring specialized seating can be accommodated by standardized components fabricated from vacuum-formable plastic materials in standard size increments. However, the remaining 40–50 percent require customized seating to compensate for their severe deformities or lack of neuromuscular control.

Foam-in-Place Technique

The FIP technique uses a foaming frame into which a series of standardized seat and back molds can be inserted. The box-shaped molds are fabricated from polyurethane plastic and are closed on all sides except one. A sheet of thin latex sheeting (5 ml) is lightly stretched over the open side of the mold. This stretchy surface is then in direct contact with the user during the foaming process. Once the user is in position in the foaming chair and seated upon the latex skin, a two-part polyurethane foam (CPR-1947 N) is injected into the front of the mold (Fig. 1). The injection hole is then closed off and the reaction between the two foam components causes the foam to rise up and force the latex skin around the shape of the user. Within 5 minutes, the foam gels into a soft foam cushion and the user can then be

removed from the foaming frame after 10 minutes. In the same manner, back components can be made to conform perfectly to the contour of the individual. (Fig. 2) The time-saving advantages are that the individual provides the mold shape for contouring the supporting foam surfaces, and the polyurethane mold provides the shape of all other surfaces of the foam. This latter point is important because the standardized outer shapes of the foamed components permit rapid interfacing into wheelchairs or other wheeled bases. That is, in addition to a series of standardized molds which cover the range of body sizes, there is a matching series of interfacing receptacles which receive the final foam components, so that they may be placed securely in a variety of wheeled bases.

The Toxicity Issue

Toxicity, although the word itself has "lethal" or "deadly" connotations, is, in fact, a matter of degree and not an absolute. It is the characteristic of a substance to cause some degree of injury to a living organism. The degree of injury may range from minor (barely detectable) to lethal, covering all mild or severe irritations in between. In most cases, toxicity is dose-dependent.

As with most industrial chemicals, some degree of hazard exists in the use, or particularly in the misuse, of polyurethane chemicals and components. The degree of hazard is influenced by the exact physical and chemical properties of the material and the circumstances of use or misuse. In the use of polyurethane systems, this hazard tends to arise principally from the **isocyanate** component, and to a lesser degree from the catalysts and other additives present in the polymer component.

Safety Issues Related to the Foam-in-Place Seating Application—There arose essentially two concerns pertaining to the potential health hazard of polyurethanes in the Foam-In-Place application. They are:

1. The inhalation hazard to technician and handicapped client from the vapors both before and during the foaming procedure; and

2. The possible hazard of toxic agents leaching out of the freshly polymerized foam and thereby coming in contact with vulnerable tissue surfaces of the seated client.

An indepth three-part study was initiated to address these concerns. The study comprised: (i) in vitro toxological evaluation, (ii) dermatological testing (Skin Patch), and (iii) vapor analysis.

Toxological evaluations were conducted in cooperation with the Department of Pharmacology–Material Science Toxological Laboratories at the University of Tennessee Center for the Health Sciences. Vapor analysis tests were undertaken in cooperation with the Department of Pathology at the University of Tennessee. Dermatological tests were conducted by the Department of Dermatology at the University of California at Los Angeles under the direction of Dr. Marvin Rapaport.[a]

Results—Toxological Evaluation

1. All samples tested (both CPR 1947 N and commercial samples) were cytotoxic as per the criteria for the Tissue Culture Agar Overlay Test. This is not surprising, in that this test is designed to detect leachable toxic substances and is one of the most sensitive in vitro acute toxicity tests available. (Note: A commonly used polyurethane wheelchair cushion was one of the commercial samples tested)

2. The acute cytotoxicity of the CPR 1947 N material as used in the Foam-In-Place procedure is not statistically different than for the other (commercial) foams tested.

3. The acute toxicity of the Foam-In-Place seat components (latex and foam components) declines in the first 2 weeks after fabrication.

4. Although the most probable components of the foam material which would be leachable and toxic are the catalyst or the isocyanate monomer(s) (non-reactive residuals), the Agar Overlay Tissue Culture Tests does not distinguish the nature of the leachable toxic components.

[a] It is not within the scope of this article to discuss in detail the testing methods, procedures, results, etc. A preliminary report entitled "Foam-In-Place Seating for the Severely Disabled" is available on request from the University of Tennessee–Rehabilitation Engineering Center, 1248 LaPaloma Street, Memphis, Tennessee 38114. This article will confine itself to a discussion of the conclusions of the three-part study.

Results—Dermatological Testing

As a result of the findings of the UCLA Patch Test combined with the clinical observations of the University of Tennessee–Rehabilitation Engineering Center over the past 3 years, it was concluded that:

> "CPR 1947 N polyurethane foam material, although showing a positive response in the in vitro Agar Overlay studies, does not present an undue risk to health as a sensitizer or an irritant when placed in contact with human skin within 1 hour after polymerization has taken place."

Results—Vapor Analysis

After testing methylene bio (4-phenylisocyanate) (MDI), tris (2-chloroethyl) phosphate, and trichlorofluoromethane, for inhalation toxicity, it was concluded that:

> "MDI will not cause major skin or eye irritation in the Foam-In-Place application provided proper ventilation of the work area is observed and safe laboratory practices are followed. It was also concluded that as long as good engineering practices are followed and the Foam-In-Place technique is carried out in a well ventilated area concentrations of trichlorofluoromethane will pose no health hazard to the technician or client."

Foam-in-Place Clinical Trials

To date, 40 subjects have received FIP Seating Components. The distribution is: 17 cerebral palsy, 10 muscular dystrophy, 4 myelomeningocele, and 9 others. In the "other" category, three individuals were adults with insensitive tissue and a history of tissue breakdown problems. The approximate average foaming time for a combined seat and back support was 2½ hours. Many of the subjects have been using the FIP components for more than 2 years with the longest in use being 38 months. In most cases, the components endured daily use for more than 2 years, before a replacement was required either due to the user's growth or deterioration of the foam material itself.

All subjects, when given a choice, desired to have a replacement of the Foam-In-Place component rather than resort to an alternate type system. No incidence of skin or respiratory problems was reported from the study group. The three subjects with insensitive tissue

have had no recurrence of tissue breakdown related to the FIP support, and have expressed a desire to continue with the system when replacement was required.

Future research plans call for the development of principles for custom designing of FIP seating supports, through the use of laboratory instrumentation that will permit the more accurate interpretation of interface conditions (pressure, temperature, humidity), particularly with reference to supporting individuals with insensitive tissue. A second objective will be to refine the existing system for clinical application in facilities working with the seating needs of individuals with severe physical deformities, primarily due to cerebral palsy.

Conclusions

The successful clinical trials to date with the Foam-In-Place technique, the findings in the industrial regulatory literature, the detailed responses from the manufacturers of the material, the safety record of polyurethane materials in the prosthetics field over the past 15 years (in addition to the results of the extensive experimental studies initiated by the UT-REC regarding vapor inhalation and toxological evaluation) all strongly support the position that flexible polyurethane foam CPR 1947 N presents hazards to health and safety that are within safe limits and are outweighed by the potential benefits to be gained by severely handicapped individuals requiring customized seating devices. It can further be concluded that, if routine safety precautions are observed as outlined above, no undue hazards to health can be expected to occur to either personnel or clients as a result of the application of the Foam-In-Place system as described.

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