VII. Functional Electrical Stimulation

A. General

B. Upper Limb Applications

C. Lower Limb Applications
A. General

The Use of EMG Biofeedback and Functional Electrical Stimulation in Spinal Cord Injury

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Purpose—This is an ongoing study comparing the relative effects of FES, EMG biofeedback and conventional therapeutic modalities (physical and occupational).

Progress—Subjects in this study are assigned to one of four groups. Subjects are required to participate a total of 16 weeks divided into 2 sequential 8-week blocks. Within each of those individual 8-week blocks, subjects are provided with only one of the three study therapy modalities. The study is designed to include four distinct groups experiencing different treatment mixtures during the two 8-week blocks. The four groups are: 1) EMG biofeedback followed by 8 weeks of FES; 2) EMG biofeedback—followed by 8 weeks of conventional therapy; 3) 8 weeks of FES—followed by 8 weeks of conventional therapy; and, 4) two consecutive 8-week blocks of conventional therapy.

The goal of this study is to examine the effects of those modalities both individually and in combination upon predefined outcome variables (i.e., dependent measures). The total number of subjects who have entered the study thus far is 34 (17 completed, 16 current, and 1 dropout).

Preliminary Results—It is not reasonable to conduct formal statistical analysis of the data at this time due to highly discrepant numbers associated with each of the four study group cells as a result of the randomization procedure. However, examination of the raw data allows the investigators to speculate with some degree of assurance upon the probable general trends. At the present time, it appears that the four regimens employed will not show a differential effect on changing muscle strength as measured by manual muscle test. Examination of the raw data indicates that a differential outcome trend appears to be occurring regarding increases on the EMG measure for the two groups exposed to biofeedback training in contrast to the two groups not afforded that modality of therapy.

If this trend continues, and the statistical analysis supports the notion that there was a differential effect in EMG but not a differential effect in measured muscle strength, we must conclude that, while increased neural and/or muscle electrical activity is a necessary component of voluntary muscle contraction, it is not sufficient to produce an increase in measured behavioral performance among muscles that did not experience neural input for a prolonged period of time. Voluntary muscle strength, as measured by the manual muscle test, is a function of muscle condition (i.e., muscle bulk and fiber circumference) as well as neural input. The absence of neural input in the weeks and months following injury results in muscle atrophy. It seems entirely reasonable that simply increasing neural/muscle electrical activity may not be sufficient to produce the same effect that would be observed in a normal or near normal muscle.

This explanation for lack of increased muscle strength in the presence of increased voluntary motor neuron recruitment seems more appropriate for the biofeedback-conventional therapy group. Accounting for the lack of consistent increased voluntary muscle strength in the FES biofeedback group requires further considerations. When the
ongoing study was originally proposed, little was known concerning the time and work protocol necessary to produce sufficient muscle bulk and fiber types to resemble a normal upper extremity muscle. The 8 weeks of FES training were limited to 24 sessions, which we now feel, based on our experience and the experiences of others, is not enough to produce a sufficiently strong muscle. Since that time it has become evident that the FES protocol used in the ongoing study was not intensive enough to produce sufficient muscle strength.

The completed subjects in the ongoing study report that they can perform some tasks that they could not perform prior to the program and could perform others with less effort. Based on these comments, we prepared an open-ended questionnaire regarding acquired skills and general attitude toward the research program. The initial response to that survey indicates unanimous satisfaction in having participated. Additionally, every responder indicated functional improvements ranging from greater ease of performance to newly acquired abilities such as independently opening doors. Overall, the replies to the first question (i.e., Are you able to do anything now that you could not do prior to your participation?) indicate that the measurements were not as sensitive to individual gains as they should be and could result in overlooking important data. The diversity of the reports of functional gains preclude the development of a standardized test to measure improvement at the present time.

Muscle Re-education in Incomplete Quadriplegia by Electrical Stimulation

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Purpose—Electrical muscle stimulation (EMS) has been used in the re-education of lower extremity muscles in paraplegics and hemiplegics and upper extremity muscles in quadriplegics. In addition, there have been several reports of improved voluntary movement as a result of electrically stimulating lower extremity muscles in incomplete quadriplegics. While the latter example of EMS is considered an accepted adjunct to conventional physical therapy, there have been no studies verifying the effectiveness of lower extremity stimulation in muscle re-education as compared to conventional therapeutic techniques in this group.

The problem addressed by this study is whether EMS to the gluteus maximus and quadriceps femoris in incomplete quadriplegics can improve the strength of those muscles over isometric techniques alone. We also wish to determine whether EMS to those muscles can improve specific activities of daily living, such as maintaining sitting balance and transferring.

Progress—Incomplete quadriplegics (levels C5 to C8) who are a minimum of one year post-injury, will be alternately assigned to control or stimulated groups. All subjects will be screened by a ward physician and a principal investigator. Screening will include a patient history, manual muscle test, lower extremity electromyographic assessment to rule out lower motor neuron involvement, and a CT scan to check for gross osteoporotic changes. Subjects will receive voluntary isometric exercise of the hip and knee extensors (in conjunction with electrical stimulation of these muscle groups for the stimulated group of patients) for 6 weeks, as well as training in activities of daily living. Measurements of leg spasticity (Bajd, T. and Vodovnik, L. Pendulum testing of spasticity. J. Biomedical Engineering 6:9-16, 1984) and voluntary torque of the hip and knee extensors will be made weekly, while ability to perform activities of daily living will be documented by videotaping patient performance at the beginning and end of the training program. Project tasks include: 1) obtain/calibrate equipment; 2) recruit subjects; 3) test and train subjects; 4) analyze data; and, 5) publish results.

Preliminary Results—Equipment (transducers and strain gauge indicators for measurement of hip extensor torque, 4-channel electrical stimulator) has been obtained and calibrated. Testing and training of patients are in progress. Preliminary results show
improvement in performance of activities of daily living over the course of the training program. This improvement may be related to task repetition/motor learning rather than specifically to strength gains in the stimulated muscle groups.

Electrical Stimulation of Fast and Slow Skeletal Muscle

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Purpose—Previous studies have demonstrated that electrical stimulation effects on muscle strengthening are a function of the muscle itself. That is, muscles of different fiber type distributions and fiber architecture are differentially affected by stimulation therapy. We have, therefore, returned to a simple immobilization model in order to more clearly understand the differential response of fast and slow skeletal muscles (of different architectures) to altered activity.

Progress—These experiments (on the dog quadriceps musculature) indicate that the following three factors are most influential in determining a muscle’s susceptibility to atrophy: 1) number of joints crossed; 2) muscle fiber length; and 3) percentage of slow muscle fibers. The muscle most susceptible to atrophy is the muscle which crosses only a single joint, has relatively short fibers, and a high percentage of slow fibers (e.g., the soleus or vastus intermedius muscles).

Intramuscular Electrical Activation of the Diaphragm

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Purpose—This proposal is a continuation of our previous work in the development of an intramuscular diaphragm pacing system which would not entail surgical manipulation of the phrenic nerve, nor application of an electrode directly upon this structure. The application of this technique in the clinical setting would immediately open the possibility of pacing the diaphragm in a much larger group of non-quadriplegic patients for whom the present conventional technique is generally considered potentially too hazardous to attempt. The possibility of temporary pacing for patients recovering from prolonged mechanical ventilation could also be evaluated. Having demonstrated the feasibility of the approach in an acute preparation, we now propose to further develop the system with a view towards human implantation.

A unique electrode system will be required for this purpose. The prospect of noninvasive implantation with laparoscopy and the stresses placed on the electrode materials by the contracting diaphragm demand a reliable electrode design with considerable durability. We have a prototype electrode which incorporates design features based on previous experience with intramuscular stimulation in this laboratory as well as specific work in the area of diaphragm activation. This proposal uses state-of-the-art techniques to evaluate in vivo, mechanical, and corrosive properties of the prototype electrode. Adaptations may conceivably be made to the prototype and to the laparoscopic technique used to implant the final electrode design. Concurrent with the development of an optimal electrode design, and the testing of mechanical and corrosive properties, we will proceed with chronic animal studies to evaluate functional viability of the electrodes and their durability in the actively contracting diaphragm. Electron microscopic and crystallographic techniques will be employed to determine causes of electrode failure.

We also incorporate a systematic physiological evaluation of the efficacy of long-term intramuscular diaphragm pacing. Serial studies will be performed during a 3 to 6 month period of chronic stimulation.
to evaluate the effect on diaphragm contractility, ventilation and gas exchange, lung volumes, and cardiac function. In addition, detailed morphological and histochemical studies will be performed to examine the effects of chronic intramuscular electrical stimulation on muscle structure and fiber composition. Bacteriological studies will also be performed along the entire length of the subcutaneous electrode tract to examine for infection in this percutaneous system. The proposal addresses the most important questions relating to eventual human implantation of the pacing system and its evaluation in a potentially wide range of clinical situations.

Electrical Stimulation of Paralyzed Muscle After Spinal Injury

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—Exercising muscles by stimulating them electrically has been a valuable adjunct to conventional physical therapy in rehabilitating many individuals whose limbs were immobilized from fractures or surgery or who had upper motor neuron paralysis caused by spinal cord injury or cerebrovascular injuries. Such stimulation can retard disuse atrophy, improve muscle strength, decrease time to reuse, and maintain range of motion, all of which combine to reduce the cost and time of rehabilitation.

No one has yet demonstrated a satisfactory way to predict the outcome of reconditioning programs for individuals with spinal cord injury, or for that matter, what constitutes an optimal reconditioning protocol. A lack of reliable predictive criteria can result in unrealistic hopes, or alternatively, prejudices, by the patient, therapist or physician. Any use of electrical stimulation for functional purposes (such as walking or standing) requires that the appropriate muscles first be reconditioned. Knowing what factors are important for reconditioning, and how best to achieve reconditioning, thus can serve as guidelines for selection for functional electrical orthoses. We are considering two general questions: 1) Is there an optimum way to recondition paralyzed muscle? and 2) Can we determine which patients with spinal injury have the best chance of reconditioning?

Progress—We wish to determine whether leg muscles can be reconditioned to a criterion level of performance in eight weeks or less. We thus measure a number of physical and neurological variables before, during, and after a four-to-eight-week reconditioning period. Our experimental design reflects a compromise between the often limited length of the subject’s hospitalization and what is currently known of the time needed for reconditioning. We establish baseline levels for the test variables during the first week a subject is in our program and again after four weeks of reconditioning. Finally, we monitor weekly those patients who have finished an eight-week conditioning program.

We have measured many physiological and psychological parameters in individuals with spinal cord injury before, during, and after attempting thigh muscle reconditioning. Our experiences have suggested the difficulty in quantifying “therapeutic benefits.” We have monitored changes in stimulated and voluntary muscle force and fatigability, spasticity, urodynamics, and psychological status brought about by participation in our protocol. We were able to increase the force and fatigue resistance of the thigh muscles of over half of our participants. Voluntary torque increased in 7 of 16 legs in individuals with incomplete quadriplegia. Increases in quadriceps spasticity and torque were most pronounced in recently injured paraplegics. Quadriceps stimulation had mixed effects on urodynamics. More than one half the patients tested before and after attempted reconditioning showed improved urodynamics; others showed no change or a worsening. Both positive and negative changes were seen in psychological status. In dealing with potential predictive factors for reconditioning outcome, we have been investigating how such factors as time since...
injury, level of injury, extent of spasticity, residual voluntary muscle force, residual muscle mass, age, psychological status, and days of reconditioning might relate to the ultimate force and fatigability achieved in a muscle undergoing reconditioning. Perhaps our most striking preliminary finding to date is that all the patients in which we saw marked changes in peak stimulated torque were within a year or two post-injury and had initial peak torques (to a 100 mA test stimulus) above 6 N-m. This finding still appears to hold even if we adjust for the days of stimulation or for the initial baseline peak. In fact, those with paraplegia of less than a year’s duration often had initial baseline torques below that shown by patients whose injury was of longer duration. Legs with initial peak torques below 6 N-m showed no increase in peak torque, even if stimulated for 21 to 66 days.

**Preliminary Results**—Our findings point out some important factors that need to be considered when electrical stimulation of paralyzed muscle is proposed. First and foremost, early reconditioning may be essential. And, secondly, muscles may weaken past a point where it is no longer viable for them to be reconditioned.

We are presently writing up our data for publication. We would like to compare the results obtained with unresisted isotonic exercise (current work) with about 10 subjects reconditioned using Glaser’s eccentric/concentric exercise protocol.

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**Therapeutic Electrical Stimulation (TES) in the Rehabilitation of Children with Cerebral Palsy**

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**Sponsor:** The Easter Seal Research Institute, Toronto, Canada

**Purpose**—The objective of this pilot study is to assess the feasibility of long term night-time usage of therapeutic electrical stimulation (TES).

The specific goals of the project are twofold: 1) to assess if night-time application of TES is tolerated as a treatment at home by patients and their families; and, 2) to begin to assess the effectiveness of night-time TES in increasing muscle bulk, muscle strength, bone growth, decreasing muscle spasticity and improving the functional ability of the affected limb.

**Progress**—Five children between the ages of two and five years, with a primary diagnosis of moderate spastic hemiplegia, will participate in this study. Each child will have spastic triceps surae.

Upon entry to the study, each child will undergo a full neurodevelopmental rehabilitation assessment, a Peabody motor development assessment, a descriptive analysis of any movement pattern disorder, and description and measurement by goniometry, a routine assessment of muscle and bone growth, and a full gait lab assessment. Application of electrical stimulation to the prime antagonists to gastrocnemius-soleus, that is, the anterior tibial and peroneal muscle groups, will be carried out at home on a daily basis. A self-reporting diary, indicating duration and frequency of treatment, and any complications, will be completed. A full evaluation will be done at the end of six months, upon completion of the study.

**Preliminary Results**—A pilot study is underway, with one child having received TES for 8 to 10 hours nightly for approximately four months. Hypertrophy of the stimulated muscles is apparent clinically, and marked improvements in function have been seen. Funding for this project has been received from the Easter Seal Research Institute, and initial assessments were begun in 1987.
Comparative Electromyography of Orderly and Reverse Recruitment Studied with FES

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Purpose—This study was done to quantify the performance of electrically-stimulated muscle under orderly and reversed recruitment. The EMG recorded simultaneously from the soleus and m. gastrocnemius of the cat upon stimulation of the sciatic nerve. Force was measured at the calcaneal tendon, and the EMG from each muscle picked up with intramuscular electrodes. Two stimulation strategies were considered: the first employed orderly recruitment of motor units concurrently with rise in firing rate using the newly-developed stimulation system described before (IEEE Trans. BME 34:128-139, 1987), while the second utilized linear increase in pulse amplitude at several fixed repetition (firing) rates.

Progress—It was shown that during orderly recruitment the EMG from the soleus (with small motor units) registered first and, one second later, the EMG from the m. gastrocnemius (with large motor units) indicated initiation of activity in that muscle. The records confirmed that our stimulation system, indeed, recruited units according to their size, as well as providing a smooth, two-step force increase corresponding to each muscle.

Reverse recruitment trials, in which the stimulus pulse amplitude increased linearly, demonstrated early activation of the m. gastrocnemius relative to the soleus, initial twitches and unfused force and fast-setting fatigue, all characteristic to reverse recruitment.

Preliminary Results—It was concluded that reverse recruitment required high initial firing rates to induce smooth force which, when combined with the initial activation of larger motor units, were prone to excessive fatigue in this unphysiological approach. The anticipated advantages of the orderly recruitment stimulation mode was apparent and confirmed.

Development of a Stimulation System for Manipulating Muscle Force With Various Firing Rate and Recruitment Control Strategies

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Purpose—Different skeletal muscles utilize different action potential firing rate and motor units recruitment stratagems. Such strategies should be followed closely in electrical stimulation systems if fine, stable, and fatigue-free contractions are anticipated.

Progress—A stimulation system capable of manipulating muscle force in an infinite combination of strategies was designed and tested last year utilizing linearly increasing firing rate and recruitment (IEEE Trans. BME 34:128-139, 1987). Expanded efforts this year resulted in further evolution of the system and now more complex stimulation strategies as described in the physiological literature for some muscles can be obtained. Specifically, the firing rate controller can provide a two-segment piece-wise linear increase, such that strategies resembling so the FDI and deltoid/biceps can be closely duplicated. A manuscript describing the evolution of the system is currently in press.
Value of Electrical Stimulation on Fertility in Male Patients with Spinal Cord Dysfunction

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Purpose—Infertility is a major problem among males with spinal cord injury (SCI). In fact, infertility rates range from 99 percent for neurologically complete quadriplegics to 90 percent for neurologically incomplete paraplegics. This study seeks to: 1) determine optimal conditions for producing seminal emission via electrical stimulation of the pelvic sympathetic nerves; 2) compare electrical stimulation with strong vibratory stimulation of the genitalia in eliciting seminal emission in male SCI patients; 3) determine if repeated stimulation improves semen quality (sperm count, motility, and morphology); 4) determine if intermittent testicular cooling improves semen quality; 5) relate success or failure of seminal emission production to neuro-level and the extent of spinal lesion, urodynamic assessment of lower urinary tract function, and incidence of recurrent urinary tract infection; and, 6) artificially inseminate a male SCI’s partner who had been unable to be impregnated since the patient’s injury.

Progress—Male SCI patients voluntarily participating in the study are randomly assigned to electrical stimulation or vibratory stimulation groups. Seminal emissions are acquired and the sperm examined for viability. Patients failing to produce viable sperm in either group undergo stimulation with testicular cooling. Viability of sperm produced is determined. Success/failure of seminal emission production is assessed statistically. Female partners of patients with satisfactory sperm production by either modality will be evaluated physically and, if in good health, artificially inseminated.

Preliminary Results—As of November 10, 1986, 14 patients had been entered into the study. Of these, 11 were entered into the electrical stimulation group, one of whom was subsequently switched to the vibratory stimulation group. Semen was obtained from all 10 remaining patients in the electrical stimulation group. Most had adequate sperm counts but none had more than 15 percent motility (viz. sperm viability). Therefore, no female partners were artificially inseminated. One patient in this group was interested only in sperm-banking for future use.

Instructions for use of the vibrator are distributed to all study patients when they enroll in the vibratory stimulation group. Of the four patients in the vibratory stimulation group (one of whom, as indicated, crossed over from the electrical stimulation group), two have completed treatment. Semen was obtained from one of these patients; however, the second patient was not able to ejaculate. In an attempt to improve semen quality, three patients have been entered into the intermittent testicular cooling trial. The first patient’s compliance was poor and no improvement was observed in semen quality. The remaining two patients have not yet completed the trial.

Future Plans—Data collection will continue until 1990. The last year of the project will include data analysis.

A Multichannel Biotelemetry System

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Sponsor: National Institutes of Health

Purpose—The objective of this research is to develop an implantable telemetry device for use in acquiring command control and feedback information in neuroprosthetic applications.
Progress—An eight-channel telemeter has been designed and fabricated, using thick film circuitry and semi-custom CMOS technology. The system architecture is organized into five distinct modules, front-end analog processing, signal quantization, system control circuitry, power supply, and data communications. The modularity allows the system to be configured to acquire a variety of input signals with a minimum amount of engineering design. Irrespective of the application, only the analog processing circuitry, provided for each channel, needs to be reconfigured to accommodate the amplitude and frequency characteristics of the individual input signals; the balance of the telemeter circuitry remains unchanged.

A large reduction in circuit complexity and increased communications accuracy is obtained through discrete representations of the multiple channels of input information. This is most efficiently obtained through an analog to digital (A/D) conversion of the input signal. To facilitate hybridization and increase circuit accuracy and reliability, an eight-bit commercial converter was incorporated into the design. Although possibly providing inadequate resolution for the more sophisticated biosignal processing algorithms, an eight-bit device was felt to be sufficient for initial system implementation. The conversion rate of the A/D dictates the overall system bandwidth, which for the device selected, is limited to 24KHz. Individual channel sampling rate is then a function of the number of input channels acquired. For example, a four-channel system would be sampled at 6.0KHz per channel, an eight-channel system at 3.0KHz per channel.

The converted data is latched and time multiplexed in a serial format onto a pulse code modulated (PCM) subcarrier. This processing, along with the supervisory control for the A/D, is handled by the system control circuitry. This circuitry is implemented onto a single CMOS semi-custom integrated circuit. This provides a significant decrease in power, required substrate area and circuit complexity, and as a result, system reliability is greatly improved.

The remaining two modules, power supply and data communications, may be essentially combined into one. System power is derived from transcutaneous inductively coupled radio frequency (RF) energy. Through a technique of reflectance modulation, we utilize this inductive link to telemeter out the acquired data. As the primary (transmitting) coil is brought within the vicinity of the secondary (implant receiving) coil, electromagnetic energy is drawn from its radiated field. A loading effect proportional to the level of coupling between two coils manifests itself as a net change in the voltage across primary windings. By allowing the PCM data stream to modulate the amount of loading on the primary coil, data may be passed back over the inductively coupled RF power link.

Preliminary Results—A four-channel version of the implantable telemetry system, configured to acquire electromyographic signals, has been realized in thick film hybrid circuitry. To facilitate communications and prototype development, the sampling rate of the ADC was reduced to 11KHz. This corresponds to a 2.75KHz per channel sampling rate. The front-end analog circuitry provides differential amplification and bandpass filtering. Signal gain is fixed to 2000, providing a 10µV per bit sensitivity, with low and high frequency cutoff points set at 4.8Hz and 1.3KHz respectively. The entire system consumes slightly less than 80mW of power with 85 percent of this being required by the analog circuitry. The system is currently undergoing laboratory evaluation and initial results indicate an overall error of less than ± 1LSB. The hybrid substrate measures 1.0 x 1.0 inches, compatible with the current version of our implantable stimulator.

Future Plans/Implications—The RF powering and data recovery circuitry is currently undergoing redesign to optimize efficiency and coil displacement tolerance. We will package this completed circuitry in the identical titanium capsule which is used for packaging our implantable stimulator. This device will then undergo a series of in vitro and in vivo testing using a similar model as used to evaluate our implanted stimulator.

Publications Resulting from This Research

Mechanism of Torque Generation: Implications for Stimulation Therapy

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Sponsor: National Institutes of Health

Purpose—Based on the hypothesis that muscle is strengthened in proportion to the amount of stress it experiences, our goal was to understand the interrelationship between muscle force generation and joint kinematics in production of torque. We hypothesized that skeletal muscle should be stimulated at the joint angle which produces maximum muscle force. This angle may or may not coincide with the optimal joint angle (i.e., the angle at which maximum torque generation occurs).

Preliminary Results—In the frog hindlimb, where sarcomere length, joint kinematics and joint torque were directly measured (n = 10), optimal joint angle occurred at 140 degrees of knee flexion, while maximum muscle force was generated at 160 degrees of flexion. Thus, for the frog system, increased muscle strengthening would presumably be obtained by activating the muscle at 160 degrees of flexion.

Future Plans—Analogous studies are planned for rabbit and human models.

The Use of EMG as Force Feedback in Closed-Loop Electrical Stimulation System

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Sponsor: National Science Foundation

Purpose—Force feedback is necessary if regulation of a stimulated muscle force output is anticipated. Since implantation of force sensors requires traumatization of the tendon, the EMG was considered, tested, and evaluated as a parameter representing force in a closed loop paradigm (IEEE Trans. BME, 33:735-745, 1986).

Progress—The EMG was found to follow the force rather faithfully as long as fatigue did not set in the muscle. To prevent muscle abuse and possible damage due to prolonged and frequent fatigue, a parallel feedback/fatigue detector was implemented. The role of the circuit was to function as a “fatigue fuse,” terminating contractions if excessive fatigue was detected.

EMG-Force Models in Muscles With Various Firing Rate and Recruitment Strategies

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Sponsor: National Science Foundation

Purpose—The EMG-Force relationships were a controversial and unsolved problem for many years, having been reported as linear by many investigators, and as non-linear by many others. Recent data reported by scientists in the NeuroMuscular Research Center at Boston University and elsewhere pointed out that the different firing rate and recruitment strategies of different muscles may be the source of the controversy.

Progress—With the aid of the new stimulation system we developed (described elsewhere in this report), the effect of various control strategies on the EMG-Force relationships was investigated. It was shown that strategies employing recruitment of all the motor units of the muscle to generate the initial 50 percent of the maximal force, in conjunction with pure firing rate increase to generate the final 50 percent of the force, yields a linear EMG-Force
model. Progressive increase in the force proportion by recruitment over 50 percent results in a predictable progressive increase in nonlinearity of the relationships. Complete models were developed for various control stratagems as well as for fast and slow twitch muscles and described in several articles now in press.

Control of Joint Motion With Synergistic Stimulation of Its Agonist/Antagonist Muscles

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Sponsor: National Science Foundation

**Purpose**—Joint motion requires complex and simultaneous activation levels from the agonist and antagonist muscles in order to accomplish the intended task while subject to various internal and external disturbances (Am J Phys Med 65:223-244, 1986). This project initiated trials using antagonistic stimulation of the muscle groups, crossing the joint with various levels of weighted motor unit recruitment in the agonist and antagonist, to reaffirm our data collected from the elbow joint of humans. The objective was to improve the external control of a joint with regard to various loading conditions.

Closed-Loop Control of Functional Neuromuscular Stimulation Using Implantable Force Sensors

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation (Proposal NBR-623)

**Purpose**—The goal of this work will be to develop and evaluate, in an animal model, an implantable force sensor suitable for the feedback control of functional neuromuscular stimulation (FNS) of paralyzed muscles. The FNS approach is being used experimentally in selected patients for the restoration of grasp or gait and posture. However, in the present applications, the forces generated with FNS are very sensitive to changes in limb position, external load, and muscle fatigue, forcing the user to rely heavily on visual feedback in order to control the desired function. To provide closed-loop control of FNS, it is necessary to use suitable position and force sensors. In this research, implanted nerve cuff electrodes will be used to record the electrical signals naturally generated by touch receptors in the skin. In the first year of this research, the detailed properties of the recorded signal will be evaluated for a range of force conditions that will simulate the natural manipulative or gait situations likely to be experienced by human users.

**Future Plans**—In following years, implanted nerve cuff electrodes will be used to provide a feedback signal suitable for controlling the force generated with FNS of paralyzed muscles. Experiments will be done first in animals under anesthesia and later in intact animals, where the forces produced with FNS can be directly compared to the natural forces produced during walking and postural adjustments. Once the effectiveness and limitations of this experimental approach are determined, this technique may be ready for immediate implementation in human users.
Neuromuscular Stimulator with EMG Pick-Up Circuitry

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Progress—In 1985, a research project was undertaken to develop optimized strategies for electrical muscle stimulation using a prototype instrument that could simultaneously stimulate and record the myoelectric responses from the surface of a muscle. This stimulation technique has a variety of applications in our laboratory’s study of neuromuscular control strategies and clinical assessment of neuromuscular diseases.

Based on the success of this prototype instrument, a new neuromuscular stimulator with EMG pick-up circuitry was designed and fabricated as a joint project with researchers at the Department of Electronics, Politecnico di Torino, Italy, during the summer of 1986. This fall, the completed stimulator has been undergoing extensive evaluation in the Center’s Motor Unit Laboratory.

The new instrument offers improved performance and overcomes several technical limitations of the prototype. It contains a neuromuscular stimulator, which gives monopolar stimulation pulses at prescribed frequency and width, and specialized myoelectric signal detection circuitry, which rejects the undesirable electrical artifacts that accompany each stimulation pulse. The myoelectric signals resulting from each stimulation pulse are detected using a four-bar surface electrode technique. One of the most important design considerations of the new instrument is insurance of patient safety. The circuitry was carefully designed to isolate the electrodes and patient from potentially harmful power-line voltages.

The new instrument will be the foundation for a series of research projects aimed at investigating stimulated myoelectric activity.

Properties and Control of Stimulated Muscles

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Purpose—The objective of this research program is to develop controllers for electrically-stimulated muscles, using mathematical simulations and experimental animal models. Given the embryonic stage of neural prostheses (devices which use electrical stimulation to return function to paralyzed muscles), simulation and animal models are crucial research steps which must be taken before neural prostheses become a clinical reality.

Progress—In our experiments, we are studying the stochastic nature of the response of a single isolated cat muscle to electrical stimulation and attempting to develop mathematical models to explain the experimental data, with the hopes of determining the model complexity required to develop neural prosthetic controllers. Using these models, we will explore suitable algorithms for neural prosthetic controllers. Given that the muscle is a nonlinear actuator, whose properties cannot be perfectly modeled, appropriate nonlinear control techniques will be tested both by computer simulation and in animal models.

Publications Resulting from This Research

Recruiting Isometric Muscle Force by Electrical Stimulation.
B. Upper Limb Applications

Portable Functional Neuromuscular Systems for Upper Extremity Control

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Sponsor: VA Rehabilitation Research and Development Service and National Institute on Disability and Rehabilitation Research

Purpose—The purpose of this project is to develop portable functional neuromuscular stimulation (FNS) systems for restoration of upper extremity function in high level spinal cord injured subjects.

Progress—Progress in the past year has been made in the fabrication of portable FNS systems, enhancement of the portable system software and enhancement of the portable system programming system software. The portable FNS system consists of several elements. They include: the command sensor, the controller package, and the programming system. The command sensor is a miniature proportional two-axis joystick which measures shoulder position relative to the sternum. One axis of shoulder position continuously controls hand prehension/release while the orthogonal axis controls system logic.

The controller package is based on two CMOS microprocessors (CDP6805E3) and contains a microprocessor-based input processor, a microprocessor-based stimulus parameter modulator, and the stimulation interface. The input processor is responsible for the processing of the transduced input commands. This can range from simple gain and filtering to realization of nonlinear input/output transfer functions. These processed input commands are used as inputs to the supervisory control algorithm which provides the user with a quick and convenient means of controlling the grasp function realized by the FNS system. The control scheme utilized in the neural prosthetic hand system provides the user with the mechanisms to turn the stimulations on and off, to select one of several predefined hand-grasp patterns, to control the grasp pattern in a continuous proportional manner, and to lock the proportional command at any desired level. The supervisory control algorithm is responsible for control of the machine operating state and state transition of the FNS system. It is also responsible for the feedback of the machine state to the user.

The output(s) of the control algorithm are used as the input stimulus parameter modulator. The modulator coordinates and regulates multiple channels of stimulus waveform parameters. The output of the stimulus parameter modulator is used by the stimulation interface to produce graded coordinated muscular movement and/or a perceived stimulus for sensory feedback. The stimulus outputs can be either external, for stimulation through chronically indwelling percutaneous electrodes, or generated by a totally implantable stimulator. In the case of a percutaneous output, the stimulation interface is a sixteen-channel constant current capacitively coupled biphasic stimulator. Alternatively, up to four, eight-channel implantable stimulators can be used. The interface in this case can be up to four radio frequency (RF) transmitters. Pulse width, interpulse interval, and current amplitude for each output channel, as well as various input controller parameters, are predetermined on a laboratory-based stimulation system. An IBM PC is then used to program the various operating characteristics into the portable FNS system.

Future Plans/Implications—Our plans are to continue the evaluation of this system in human subjects and to transfer this technology for fabrication outside of our Center.

Publications/Patent Resulting from This Research


Quantitative Assessment of a Functional Neuromuscular Stimulation Motor Prosthesis for Restoration of Grasp in the Quadriplegic Hand

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Sponsor: VA Rehabilitation Research and Development Service and National Institute on Disability and Rehabilitation Research

Purpose—The purpose of this project is to enhance the functional capability of the paralyzed hand in the quadriplegic, through the use of functional neuromuscular stimulation (FNS) and surgery.

Progress—Subjects are provided with a neural prosthetic hand system which consists of a command control device, portable patient-based stimulation unit, stimulation interface (percutaneous intramuscular electrodes or antennae for implantable stimulation unit), and cabling to connect the stimulation unit to the interface. The control scheme is typically a proportional control source (usually the transduction of the motion of the opposite shoulder from the stimulated hand).

The FNS hand system is applied during dressing, enabling the subject to use his hand throughout the day. The system provides both lateral prehension/release and a palmar prehension/release. The grasping mode is selected by a scanning technique, activated by depressing a switch mounted to the chest. The system can be placed in a locked mode which applies a constant non-varying stimulus to the hand muscles regardless of the command controller activity.

Tests are under development to provide a quantitative measure of the effectiveness, consistency, and ability of the user to operate the grasp and release function of the FNS hand system during activities of daily living (ADL). The areas of assessment consist of a physiological evaluation and a functional evaluation. The physiological evaluation involves sensory testing, passive range of hand motion for shoulder, arm, and hand, active range of motion using FNS, and motor mapping to determine the extent of upper and lower motor neuron lesions by surface stimulation and EMG recordings.

The functional evaluation concentrates on the ability of the user to grasp and release singular items of varying geometries and masses and a coordinated activity determining the ability of the user to manipulate items which he uses during ADL.

Results—The FNS system has been fitted to 26 subjects with spinal cord injury at the C5 or C6 level. Five of these subjects additionally have had surgical procedures such as arthrodeses, tenodeses, and tendon transfers of paralyzed but excitable muscles. One subject has had a multichannel receiver-stimulator surgically implanted. Subjects have been in the program for as long as nine years and averaging 3.6 years.

The results are that:
1) FNS enables C5 and C6 level quadriplegic individuals to control lateral (key-grip) and palmar prehension and release. The individuals use their hand to perform independently functional tasks that they cannot perform without the use of the hand system. The ability to acquire and use a common item such as a fork or glass without the aid of adaptive equipment greatly enhances a subject's level of independence.
2) C5 and C6 level quadriplegics can perform functions independently (e.g., eating, drinking, grooming, writing), using the FNS hand system that they cannot accomplish otherwise, unless assisted by an attendant. Objects need not be modified, nor are special adaptations needed for acquiring the objects.
3) Performing transitional tasks such as eating with a fork, drinking from a glass, and reacquiring the fork are achieved.
4) Using the hand system allows increased unilateral activity, freeing the opposite arm for stabi-
5) C6 level quadriplegics with tenodesis pinch require the FNS hand system when the task requires any greater than minimal pinch strength.

6) Most users have weak proximal musculature and poor balance which degrades functional performance.

7) Comparing performance with and without the system, C5 subjects improve in every task. C6 subjects may perform better in some tasks with FNS, and worse in other tasks. However, the quality of performing the task is always enhanced with FNS.

8) Factors that hamper the effective usage of the system, such as joint stability and lower motor neuron lesions, may be improved by surgical procedures used in conjunction with FNS.

9) Usage of the hand system has required introduction of new training modalities into the rehabilitation program.

10) FNS techniques for hand control have been transferred and are presently being utilized and evaluated with patients in rehabilitation centers in Edmonton, Alberta, and Toronto, Ontario.

Future Plans/Implications—The implications of these results indicate that the technique of using an intramuscular electrode FNS system does provide the user with higher quality function. The use of an implantable stimulator has eliminated maintenance of the percutaneous interface. However, the process regarding reliability and ease of maintenance of these systems must be enhanced as a research tool in order to demonstrate the long-term effectiveness of the system. New training and conditioning programs are required to achieve optimal performance. Surgical intervention such as arthrodesis, tendon transfer, and tenodesis coupled with the use of our FNS techniques can overcome some physiological limitations.

We plan to extend our program to new subjects in our program and those of our collaborators in Edmonton and Toronto. We also plan to further evaluate the surgical techniques that we have introduced, and to further extend our quantification measures and training procedures.

Publications Resulting from This Research


Feasibility Assessment of a FNS Hand Orthosis for Quadriplegics

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Sponsor: Department of Rehabilitation Medicine, University of Toronto and The Canadian Paraplegic Association

Purpose—The objective of this study is to determine, in conjunction with Dr. H. Peckham and Dr. M. Keith, Highland View Hospital and Case Western Reserve University, Cleveland, Ohio, the feasibility of implementing a clinical program to provide hand prehension abilities to quadriplegics through functional neuromuscular stimulation (FNS).

A pilot study will explore the feasibility of implementing a clinical program in FNS by: 1) observing the prehension ability and activities of daily living (ADL) skills in three C5 quadriplegics using an FNS orthosis; 2) observing the compliance of three C5 quadriplegic individuals to use of an FNS orthosis to provide prehension ability; 3) observing the amount of clinical and technological support required to maintain a functional FNS orthosis in three C5 quadriplegic individuals; and, 4) documenting the patients’ and families’ reaction to the FNS orthosis.

This study will attempt to define factors which should be addressed in a prehension ability assessment for individuals using the FNS orthosis. In addition, existing technology will be used to develop a system to track upper extremity movements during performance of specific functional tasks.

Progress—Three individuals with C5 quadriplegia
Functional Electrical Stimulation

will be given implanted stimulating electrode systems and will be trained to use the FNS orthosis. Prehension ability and ADL skills of the orthotic users will be observed at regular intervals for two years following electrode implantation. Compliance to use the FNS orthosis, as measured by data acquisition devices, and acceptance of the orthosis, determined through patient and family interview, will be addressed. Clinical and technological support required to maintain a functional orthosis will be measured.

New evaluations designed to distinguish between unilateral and bilateral prehension abilities in quadriplegia are being developed. The new proposed evaluations, and existing hand function tests are to be administered to C5 quadriplegic patients using the FNS orthosis. Modifications to the tests will be made, as required, to create evaluations capable of measuring the prehension abilities and ADL skills of C5 quadriplegic patients using an FNS orthosis.

Kinematic studies will be conducted to track functional upper extremity movements requiring prehension abilities. Prehension abilities, compliance to use of the FNS orthosis, and clinical and technological support required will be used to determine the feasibility of establishing a clinical FNS program. Results of the kinematic studies may indicate new learning strategies for future orthosis users. Finally, the evaluations created to measure prehension abilities and skill in ADL in the C5 quadriplegic will be of value for future related clinical trials.

Preliminary Results—One subject was implanted in early December, 1986, with a total of 21 percutaneous intramuscular electrodes. The number of electrodes has since been reduced to 12: six to provide prehension, and six to provide release. Threshold and impedance measurements have been undertaken on a regular basis to confirm electrode integrity. A transducer to measure the force exerted by the thumb during stimulation to effect prehension was designed and constructed. These measurements will enable us to profile the influence of an exercise program on muscle strength and to record actual pinch strength.

Future Plans/Implications—A method for determining upper extremity movements during targeting tasks is reaching completion. Experiments to compare extremity trajectories of the first subject in this study with a group of normal subjects performing the same tasks was begun in early 1987.

Concurrent with the technological tasks described above that reflect the efforts of personnel at the Hugh MacMillan Medical Centre, the functional assessment and other related research projects are underway at Lyndhurst Hospital.

Miniature Sensor for Two-Degree-of-Freedom Position Transduction

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—The purpose of this project is to develop a two-degree-of-freedom position transducer for use as a command source in upper extremity assistive systems for individuals with high-level spinal cord injury. Command signals are generated by the user from some remaining voluntary function.

Progress—In the case of spinal cord injury, individuals with injury levels as high as C4 retain some degree of shoulder motion. The concept of shoulder position as proportional command source has been studied recently in detail as a control source for neural prosthetic hand systems. A miniature two-orthogonal axis proportional position transducer measures the scapular movement of the shoulder. The shoulder position transducer body is mounted to a small plate. The plate slips into a small leather pad which is attached to the user’s chest with double-sided adhesive tape. A position sensing arm extends from the transducer’s body and a mounting pad at its end is secured to the shoulder with tape. The outputs of the transducer are proportional to shoulder elevation/depression and protraction/retraction, relative to the sternum.
The transducer is based on linear Hall Effect devices. A permanent magnet is contained within the ball member of a ball and joint socket. Four Hall Effect sensors are arranged in differential pairs and contained in the socket member perpendicular to the magnet with the ball in the center of its range of motion. When the ball and magnet assembly are in the center position, equal amounts of magnetic flux density couple into the differentially configured Hall Effect sensors. The net output of the sensors is zero. As the sensing arm of the transducer is moved away from the center position, more magnetic flux density is coupled into one sensor and less into the second, resulting in a net output in the direction of movement. The second differentially connected pair of sensors, which is at a right angle to the first pair, allows the position of the sensing arm to be related to two proportional outputs. This relationship is approximately linear over the 20 degrees of movement in any direction from the center point. The interface circuitry provides a proportional bipolar voltage output. Current consumption of the transducer and interface circuitry for a two-channel five-volt bipolar output is approximately seven milliamperes. Pulse powering the device during analog to digital conversion allows a magnitude of order decrease in the current consumption.

The fabrication effort and cost to produce the shoulder position transducer has been greatly reduced in comparison to our previous coil style transducer through the use of commercially available Hall Effect sensors. Our earlier transducer utilized small coils which were fabricated one at a time by hand. The sensors are mounted on a small circuit board which fixes their position. Also mounted to the circuit board is a small multipin connector for the cable attachment. This sensor/connector assembly is contained within the transducer body (the socket member), which is molded in acrylic.

Future Plans/Implications—Our plan is to incorporate this control device in our upper extremity motor prostheses and evaluate its function as the command control source in control of grasp/release in the quadriplegic user.

Publications Resulting from This Research

Sensory Augmentation for FNS Upper Extremity Prostheses

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Sponsor: National Institute on Disability and Rehabilitation Research; National Institutes of Health

Purpose—The purpose of this project is to develop substitute and augmentative sensory feedback to enhance the utility of functional neuromuscular stimulation (FNS) upper extremity prostheses.

Progress—A sensory feedback system based on electrocutaneous communication techniques has been developed that provides information about prehensile force, the output of the FNS system user’s command transducer and stimulator status. Stimulation of the skin to evoke the electro-tactile sensations is achieved using a five-element array of subdermally placed indwelling coiled wire electrodes. Stimulus coding parameters and waveform characteristics have been optimized for comfort, stability, and discriminability of the feedback signals. This feedback system is presently being implemented in portable FNS systems using percutaneous leads, but will ultimately utilize an implanted stimulator to minimize external hardware and enhance system reliability and cosmetic acceptability.

The output of the user’s command transducer is displayed by a spatial position code, while feedback of grasp force is simultaneously displayed by varying the pulse repetition rate of whichever electrode is active, using five or six discrete frequencies.

Machine-state information consists of a set of electrocutaneous messages that assist the user with: 1) selection of the grasp mode (lateral versus palmar); 2) specification of the position of the shoulder
that corresponds to the start point of command range; and, 3) realignment of the shoulder prior to regaining active hand control after the system has been put into a "lock grasp" state. Lock grasp refers to the condition during which the user can maintain the muscle stimulation parameters at any arbitrary level and disengage the shoulder position controller.

Preliminary Results—A simplified sensory feedback system has been designed and implemented in one C6 individual who received an implanted FNS system. This wholly implanted electrocutaneous communication system uses a display that consists of a single subdermal electrode, so that it can be driven using just one of the eight independent output channels of the implantable stimulator. A platinum-iridium disk electrode (identical to the epimysial type used for stimulation of the muscles) was surgically attached to the underside of the skin of the user’s chest to provide the electrocutaneous interface. This feedback system provides a five-level frequency encoded signal that tracks the command controller output and provides machine-state information similar to that described for the multi-electrode sensory system. The user has had approximately one year’s experience with the implanted system and states that he is pleased with the comfort of the cutaneous sensations and the utility of the information provided. He has also expressed satisfaction with the privacy inherent in the cutaneous communication scheme in comparison to the percutaneous FNS system which he used previously that provided machine-state information via auditory tones.

Future Plans/Implications—Future work will concentrate on performing functional evaluations of the sensory feedback systems in selected quadriplegic individuals.

Publications Resulting from This Research


Artificial Sensory Transducer

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Sponsor: National Institutes of Health

Purpose—The principal goals of this research project are to develop artificial sensory transducer systems and to evaluate them in conjunction with a paralyzed hand under functional neuromuscular stimulation (FNS) control. In addition to developing force and position transducers, the contractor will investigate the feasibility of measuring shear forces on the grasping surfaces of finger tips as an indication of incipient slippage. Although the development of FNS systems is not a part of this contract, the contractor will be encouraged to work closely with other investigators in the Neural Prosthesis Program to integrate the transducers into closed loop feedback control systems for restoration of grasp in quadriplegic individuals.
Implantable Systems for Stimulation of Skeletal Muscle

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Sponsor: National Institutes of Health

Purpose—The objective of this project is to develop an implantable stimulator system for electrical excitation of paralyzed skeletal muscle. This system will be utilized by high level (C5 and C6) spinal cord injury patients to provide controlled grasp and release in the hand. In this application, functional neuromuscular stimulation has previously been demonstrated to be effective by employing chronically indwelling percutaneous electrodes. Through the use of the implantable system, we expect that the ease of use of the system and its reliability will be improved, leading to greater independence for the quadriplegic patient.

The objective of development of the implantable system will be met by: 1) development of circuitry using a high density of integration to perform the stimulation function; 2) development of techniques for encapsulation of the stimulator in a hermetic package suitable for extended periods of implantation (greater than 5 years); 3) development of stimulation electrodes and lead wire interconnections which are suitable for use with the implantable stimulator; 4) development of a programmable control transmitter which is worn externally by the subject and regulates the output of the implant stimulator in response to the control signals generated by the subject; 5) evaluation of the entire system and individual subsystems (eg., electrodes, packaging) in vitro and in vivo; and, 6) modification of the design where necessary.

The principal application of this study is the upper extremity in the quadriplegic subject. However, the technology being developed in this project is expected to be directly applicable to other neurological deficits, such as stroke and cerebral palsy, thus enabling researchers and clinicians to have a powerful new technique more available for rehabilitation of motor function.

An Externally Powered, Multichannel, Implantable Stimulator for Control of Paralyzed Muscles

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Sponsor: VA Rehabilitation Research and Development Service; National Institutes of Health

Purpose—This research is to develop a small patient-portable Functional Neuromuscular Stimulation System. The system which has been developed uses a flexible, programmable microprocessor control unit (“Portable Functional Neuromuscular Systems for Upper Extremity Control,” reported on elsewhere in this issue) and an eight-channel radio frequency powered and controlled implantable stimulator unit. The initial target application of this implantable system has been the restoration and control of hand function in quadriplegic subjects. The system in this application incorporates major external elements of our present multichannel patient-portable stimulator that uses percutaneous electrodes.

Progress—The implant stimulator is an eight-channel device, powered and controlled over a transcutaneous radio frequency (RF) link. The circuitry has been realized using thick film hybrid circuit techniques, with the circuit design based on the use of a CMOS Semi-Custom integrated circuit. Command signals are serially input to the implant stimulator via the transcutaneous RF link. Each command elicits the output of a single electrode to be stimulated and the duration of the stimulus pulse. The rate of repetition of the command determines the interpulse interval. Each output channel is independent of the others and is a capacitively coupled biphasic stimulus with controllable amplitude (0.2 to 20 mA), pulse width (0 to 255 msec.), and
Functional Electrical Stimulation

The interpulse interval (infinite to 20 msec.).

The circuitry is packaged in a hermetic, laser-sealed, titanium capsule, having multiple feedthroughs. A stainless steel receiving coil is external to the package, connected to the circuitry by spot weld connections to the feedthroughs. Electrode leads are connected to feedthroughs at the opposite end of the capsule. This assembly is stabilized in medical-grade epoxy and coated in silicone elastomer. An unencapsulated area of the package is used as the anode. Size is 8cm x 3.5cm x 1cm, with an approximate weight of 40 grams.

The electrode lead wire consists of multistrand, stainless steel, teflon-insulated wires, that are helically wound in a close coil configuration. This wire is jacketed in silicone rubber tubing and filled with silicone rubber. In-line connectors are used on each lead wire. The connector consists of two male pins that mate with a center spring and are covered by a silicone elastomer tubing. The connector is flexible along its length, does not introduce large loads into the electrode leads, requires no special tools for opening or closing, and will withstand repeated opening and closing. Overall diameter is only slightly larger than that of the electrode leads, allowing placement of several connectors side-by-side in one implantation site. The lead wires are terminated at the stimulating electrode, which is a Pt/Ir epimyseal design. Encapsulation of the electrode provides for strain relief into the lead wire, a means of anchoring (suturing) the electrode at the motor point, and directs the stimulus current into the target muscle body.

Preliminary Results—One device has been implanted in a human subject and has been operational for over nine months. We have also implanted 16 implantable stimulators in the forelimbs of dogs. Eight earlier devices were packaged, using a glass ceramic capsule, with the remaining devices implanted with the titanium capsule. Presently, we have three devices in vivo, which have been operational for 28, 23, and 22 months, respectively, as of July, 1987.

Future Plans/Implications—Our objective is to continue the development and evolution of the implantable system in animals and human subjects. Studies in animals are to develop implantation technique, evaluate long-term function, and determine methods of failure analysis. In-human studies are to evaluate the performance of the system in augmenting grasp/release function.

Publications Resulting from This Research


Elbow Control in the C5-C6 Quadriplegic Using Functional Neuromuscular Stimulation

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Sponsor: National Institutes of Health and National Institute on Disability and Rehabilitation Research

Purpose—The purpose of this project is to provide control of elbow position in the C5-C6 quadriplegic using electrical stimulation of the triceps muscle. Studies have focused on development of a system which uses stimulation to provide overhead reach.

Progress—Elbow control is compromised in an individual with a C5-C6 spinal cord injury due to loss of antagonistic control of the joint. While the elbow flexors remain under voluntary control, the elbow extensors are paralyzed. When the elbow is below shoulder level, elbow position is controlled by allowing gravity to act as an elbow extensor; however, when the individual attempts to reach above this level, gravity acts with the elbow flexors and no forces are available to provide the needed elbow extension. By stimulating the triceps muscle, extension torques can be produced which allow overhead reach to occur.

A laboratory-based system has been developed
which provides the subject with control of elbow position. Control is obtained by establishing a relationship between the position of the arm and the level of stimulation delivered to intramuscular electrodes. The level of stimulation is always sufficient to overcome active, passive, and gravitational forces at the elbow and thus provide full elbow extension. If an intermediate position of the elbow is desired, the subject can use voluntary elbow flexion to counteract the stimulation-induced elbow extension torque. Since arm position alone determines the stimulation parameters, no additional conscious command is required by the user. This is an important feature if the subject is also using a system to provide hand grasp, which does require a conscious command control signal.

The sensors which furnish the position information are mounted on the upper arm and measure humeral abduction, humeral rotation, and elbow flexion angles. This position information provides the input parameters to a look-up table which stores the stimulus levels output to each electrode. The stimulus value was obtained from isometric force studies which determined the position-dependent passive torques about the joint as well as the extension torques which can be obtained from each electrode at given positions. The position dependence of the gravitational torques is obtained from an analytical model which predicts the torque produced by the weight of the forearm and hand about the elbow joint. Thus, by knowing the position of the arm, the passive and gravitational torques which oppose elbow extension at that position are counteracted with extensor torques produced from the triceps stimulation.

Preliminary Results—One subject is currently working with this system in the laboratory. Two intramuscular electrodes have been implanted in each arm to provide the stimulation. Each electrode can produce torques sufficient to produce full elbow extension in any arm position. Studies are underway to determine the best stimulation parameters to ensure good control of the elbow without inducing muscle fatigue.

Future Plans/Implications—Experiments are underway to study subjects to reach overhead targets. We also plan to implement this system in the patient-portable system to provide both grasp and overhead reaching ability.
obtained for electrodes in four thenar muscle groups. These muscle groups are: extensors (extensor pollicis longus, extensor pollicis brevis, abductor pollicis longus), median thenar intrinsics (abductor pollicis brevis, opponens pollicis, flexor pollicis brevis), adductor pollicis, and flexor pollicis longus. The recruitment curves were obtained in three thumb positions: resting, full extension, and full abduction. The results indicate that the force output changes in both magnitude and direction as the stimulus level changes. The results also showed that the direction of the force vectors at maximum stimulus rotated in the direction of pronation when the thumb is moved from the resting to the abducted position. When the thumb is moved from the resting to the extension position, the force vectors at maximum stimulation always rotated in the direction of supination. The data obtained can be used to characterize the electrode/muscle combination output in terms of threshold, gain, direction of force, maximum force and length dependency. These parameters are important considerations in the development of grasp parameters.

**Future Plans/Implications**—Future plans include determining the feasibility of combining vectors from individual muscles by summing them mathematically to predict the total output when the two muscles are stimulated together. Active force measurements will be combined with measurements of passive force and joint position to determine if this information can be used to predict net resultant force of the thumb in grasp. We are also using this technique in the analysis of finger movement.

### C. Lower Limb Applications

**Electrical Stimulation of Osteogenesis Using Selected Techniques**

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**Sponsor:** VA Rehabilitation Research and Development Service

**Purpose**—This project involves the use of various selected electrical stimulation techniques for growth and repair of bone. The overall goal is to determine an effective technique to be employed in research planned to evaluate the appropriateness of electrical stimulation therapy to remobilize patients with loose prosthetic devices (trauma and irritation present) and patients with osteopenia (trauma and irritation absent). The specific aims are to: 1) define a dose response relationship in magnetic field amplitude for electromagnetic stimulation (EMS) produced by a sinusoidal waveform; 2) determine whether trauma and irritation are required with EMS produced by either a sinusoidal or a square-pulse waveform; and, 3) compare the efficacy of direct current stimulation (DCS), EMS by sinusoidal waveform, and EMS by a square-pulse waveform in the same animal model.

**Progress/Methodology**—Throughout this project, the tissue site selected for electrical treatment is the rabbit tibial medullary canal. Surgical intramedullary insertion and implantation of a flexible, nonmetallic rod is used to produce trauma and irritation in intact tibia where indicated by experimental design. Such trauma and irritation may be required to elicit cells responsive to electrical stimulation treatment. The biological response within the medullary canal after electrical treatment is evaluated by histomorphometric quantitation of new bone formation, necrotic tissue, and selected cell types.

Originally, restraint and anesthesia of the animals, used previously by others in similar experiments, were to be employed in this research to permit daily placement of electrical devices and appliances as well as the stimulation treatment. However, the excessive restraint, prolonged anesthesia, and consequent inactivity of the animals usually results in a loss of weight, health, and, not infrequently, life. To avoid these complications, a system consisting of a jacket, tether, and swivel was developed to permit routine electrical stimulation treatment of animals with devices and appliances from any stim-
ulation technique. It was believed that such a system would help to establish a more accurate index of the biological response to electrical stimulation with \textit{in vivo} models. The jacket-tether-swivel system allows the animal to have freedom of movement within its cage with access to both food and water \textit{ad libitum}. A Group of 12 animals has completed treatment with electromagnetic stimulation by a sinusoidal waveform of three different amplitudes using the above system. The group sustained the treatment without restraint or anesthesia and there was no loss of weight, health, or life.

\textbf{Preliminary Results}—As a result of contact with the edges of the external electrical appliances, skin irritation was observed in several animal cases. Traumatic periosteal bone formation was not found. The magnitude of new bone formation, necrotic tissue, and selected cell types within the medullary canal after electromagnetic stimulation is currently being evaluated by histomorphometric analysis.

\textbf{Future Plans}—One appliance required with electromagnetic stimulation, the coil pair, will be altered in overall size to prevent skin irritation. These new coil pairs, together with the jacket-tether-swivel system will be employed in the remaining experiments of this research project.

\section*{Fitness Improvements and Physiological Responses to FES Exercise}

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\textbf{Sponsor:} VA Rehabilitation Research and Development Service

\textbf{Purpose}—The overall purpose of this research project is to develop exercise techniques that incorporate functional electrical stimulation (FES) of paretic or paralyzed skeletal muscles to improve strength, endurance, hemodynamic function, and cardiopulmonary fitness of patients with spinal cord injury (SCI) or other neuromuscular dysfunction. The goals of this project are to evaluate the effectiveness of protocols that use: 1) only FES exercise of paralyzed muscles; 2) simultaneous combinations of FES-induced leg exercise and voluntary arm exercise; and, 3) simultaneous combinations of voluntary and FES-induced contractions of the same paretic muscles.

\textbf{Progress}—The 1986 progress report from this laboratory summarized the results of several studies that relate to muscular strength and endurance, as well as metabolic and cardiopulmonary responses to FES alone and FES combined with voluntary exercise ("hybrid" exercise). This current report focuses on three studies where FES-induced static or dynamic contractions of leg musculature were used to activate the venous muscle pump and enhance central hemodynamic responses of subjects during rest and/or arm exercise. In Experiment I, FES was applied to the legs of ten able-bodied and six SCI paraplegic subjects to induce static pulsatile contractions of calf and thigh muscles during rest in the upright sitting posture. In Experiment II, twelve SCI paraplegics performed voluntary arm-crank exercise during both static pulsatile FES contractions (calf and thigh muscles) and FES-induced dynamic contractions of the rectus femoris muscles. In Experiment III, static pulsatile FES was performed during rest and arm-crank ergometry under various orthostatic loads on a tilt table. In each experiment, eight channels of static FES were applied bilaterally to rectus femoris, biceps femoris, gastrocnemius, and anterior tibialis, alternating between thigh and calf muscle groups at 1.5-sec intervals. Computerized real-time monitoring of central (cardiac) and peripheral (arm and leg) arterial blood flow is also being evaluated utilizing impedance cardiography and plethysmography.

\textbf{Preliminary Results}—In Experiment I, FES-induced contractions resulted in 12-30 percent increases in left ventricular stoke volume (SV) and cardiac output (CO) in both able-bodied and paraplegic groups. In Experiment II, the six paraplegic subjects who were most responsive to FES displayed 18-30 percent
higher SV and CO during simultaneous voluntary arm-cranking (0-90 watts power output) and FES-induced leg exercise (hybrid exercise) compared with arm-cranking alone. Additionally, the lack of heart rate and blood pressure changes between arm-crank exercise with or without FES suggests that the improved circulatory function was achieved with no increase in myocardial stress. During combined arm-cranking and dynamic FES knee extensions, blood lactate concentrations were lower than during arm-cranking alone, suggesting that the dynamic FES leg exercise improved lactate clearance and/or central hemodynamics. Preliminary results of Experiment III indicate that the FES-induced venous muscle pump increases venous return, SV and CO during rest and light arm-crank exercise during light-to-moderate orthostatic loading in SCI subjects whose leg muscles are most responsive to FES. This suggests that in SCI subjects, appropriately applied FES may reduce venous pooling/stasis and improve central hemodynamic responses to rest and exercise in the upright posture.

Future Plans/Implications—Our future research will focus on the short-term effects of FES on central and peripheral hemodynamics, and their interactions with posture and exercise. Additionally, we will implement long-term exercise training programs using dynamic FES-leg cycling in combination with voluntary arm-cranking to maximize the benefits of cardiopulmonary fitness training. The improved circulatory state during FES may help prevent the potential medical complications of venous pooling/stasis such as deep venous thrombosis, pulmonary embolism, excessive edema, and orthostatic hypotension. The alleviation of circulatory hypokinesis during hybrid exercise due to venous pooling may also enhance arm exercise performance or lessen the stress of arm exercise such as wheelchair locomotion by improving blood flow to exercising upper body muscles.

Publications Resulting from This Research


Functional Tasks Restored in Paralyzed Man Using Electronic Orthotics

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—This program aims to restore functional tasks, such as walking and climbing and descending stairs, to individuals with paralyzed lower limbs. Further development of our existing neuromuscular orthotics system is focused on achieving smoother performance, improved stability, specific functional activity and reduced fatigue. A longer term goal is to provide the system in a fully implantable form.

Progress—Since 1982, eleven subjects, with neurologically complete spinal cord lesions between T4 and T11, have been able to stand, seven subjects have been able to walk, and three subjects have been able to climb and descend stairs with the functional neuromuscular stimulation (FNS) system. Percutaneous intramuscular electrodes were implanted, by means of hypodermic needles, into 13 muscles bilaterally in the hips and legs. These electrodes received signals from a microprocessor-controlled muscle stimulator. Individualized stimulation patterns were developed and modified as needed to allow gait practice, functional activities and laboratory experimentation.

Preliminary Results—In the past year, the development of a new method for implantation enabled
successful implantation of electrodes with a reduction in the number of trials necessary for each implant from 3.3 to 1.25. The portable stimulator was redesigned to allow inclusion of six surface electrodes placed on the lower back, which were added to improve trunk stability. Addition of the surface electrodes enabled subjects to walk for longer distances before they fatigued.

A new portable stimulator based on the V40 NEC microprocessor with 48 channels of stimulation was designed and built to allow expansion of the system. A miniature prototype joystick for subject command input was designed and built to enhance ease of selection of functional activities. New stimulation patterns were developed for backstepping, sidestepping, and pressure relief while seated. Effects of trunk stimulation on hip extension and abduction were tested and showed considerable increase in torques over hip stimulation alone.

Development and testing of closed-loop controllers for lateral motion at the hip was carried out. Prototypes of linear sensors and pressure sensors to provide feedback signals for closed-loop control of stimulation were tested both in the laboratory and on human subjects.

Design modifications were made to the ankle-foot orthoses used by all paraplegic subjects in order to protect against possible foot and ankle damage due to inversion of the foot. An instrumented garment of elastic material was designed and modified to include both surface trunk electrodes and connectors to intramuscular electrodes.

**Future Plans/Implications**—We plan to: 1) improve the anchoring properties and the resistance to material fatigue of the intramuscular electrodes; 2) develop new stimulation patterns for additional functional tasks, particularly maneuvering in small spaces; 3) test controller designs with computer simulation prior to implementation and compare to the open-loop system; and, 4) miniaturize the best controller, interface it with existing sensors, and integrate it into the current portable stimulators for use outside the laboratory.

**Functional Tasks Restored in Paralyzed Man Using Electronic Orthotics (Project Extension)**

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**Sponsor:** VA Rehabilitation Research and Development Service (Project #XB193-4RS)

**Purpose**—The feasibility of using functional neuro-muscular stimulation (FNS) to provide basic mobility for paralyzed persons in the laboratory has been clearly demonstrated by work at the Cleveland Veterans Administration Medical Center during the past four years. The overall objective of the proposed program is to develop FNS systems which will provide paralyzed persons with independent mobility and useful function, such as walking, climbing and descending stairs, and maneuvering in small spaces—capabilities that will enable them to increase their level of independence in the community.

Two phases of clinical application are planned. Towards the middle of the proposed funding period, we will evaluate clinically the open-loop version of our FNS system in individuals with partial paralysis from either incomplete spinal lesions or cerebrovascular accidents. To achieve this objective, several specific goals must be met. Improvements in electrode design and implantation techniques for both percutaneous and implantable systems to increase system reliability and repeatability are essential. Similarly, the hardware components of the system must be miniaturized and made more reliable, robust, user-friendly, and cosmetically acceptable before clinical trials can begin. Open-loop software sequences for functional tasks must also be developed and/or refined.

Parallel with these developments, we will design and test the transducers and controllers necessary to create a closed-loop system capable of adjusting to changes both in the internal and external environments; such a system will allow a reduction in the total amount of stimulation delivered to the muscles, hence delaying the onset of fatigue. Stimulation algorithms for joint motion and for integra-
Functional Electrical Stimulation

The implementation of these closed-loop components together with the developments described above will increase the usefulness offered by our FNS system by providing standing and ambulation capabilities, increased stability, reduced metabolic energy costs, and reduced muscle fatigue and by increasing its reliability and user-acceptance. We anticipate that this system will be available for implantation and clinical evaluation in individuals with complete spinal cord lesions at the end of the proposed funding period.

EMG as Force-Feedback in Closed-Loop Functional Electrical Stimulation

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—The purpose of this project is to develop a closed-loop, functional neuromuscular stimulation (FNS) system to improve dynamic force and position control of paralyzed limbs. Closed loop control should greatly increase the functional capabilities and performance of FNS systems and earn greater patient acceptance.

The cat limb segment from the knee to the ankle, including the gastrocnemius, plantaris, soleus, tibialis anterior muscles and the tibial nerve (TN) is sufficiently similar to the human to serve as the in vivo model for exploring the relationship between nerve stimulation, muscle force, and myoelectric response. The TN was first stimulated using nerve cuff (NC) electrodes and the force generated about the ankle was monitored. The TN was then divided into its natural fascicles which innervate the muscle subdivisions (heads and compartments). The fascicles were stimulated with platinum hook electrodes. Constant current, bipolar, rectangular 100 microsecond pulses of variable amplitude with a 5-second interpulse interval were used. Intramuscular electrodes were used to monitor electrical activity at 3 points along each muscle subdivision. The electrodes pairs were placed 3 mm. apart along the muscle fibers with 1 mm. of bare wire at the tips and 13 mm. between pairs.

Progress—Computer hardware and software for recording and digitizing up to 16 EMG signals and 4 force, position and torque channels has been implemented. A 16-channel EMG preamplifier has been designed, fabricated, and calibrated. Data reduction analysis and display programs are being developed.

Results—Nerve cuff stimulation of the TN typically resulted in an EMG range from 2.5 to 25 millivolts peak-to-peak, and a force range from 50 grams to 1.2 kilograms. There was little evidence of hysteresis with increasing versus decreasing stimulus amplitude. Changing stimulus polarity primarily altered the threshold level. In some cases, EMG responses as a function of stimulus amplitude, were non-monotonic due to changes in the shape of the EMG waveforms, i.e., phase reversal, with increasing stimulus current.

Activation of individual muscle subdivisions was achieved by dissecting apart up to seven nerve bundles (fascicles) of the TN before it enters the gastrocnemius and soleus muscles. The locations of the recording electrodes in each muscle were verified by direct muscle stimulation. Stimulation of the individual fascicles showed the lateral gastrocnemius to have more than one independent compartment as described by A.W. English (Emery University). However, there was some apparent cross-stimulation from one bundle into two compartments, and one nerve bundle was found to generate no force.

Analysis of peak-to-peak EMG's of the independently-stimulated muscle subdivisions revealed high correlations between peak-to-peak EMG response, force, and stimulus current within the range of contraction threshold to 95 percent maximum force output. The linear first-order correlation coefficients of peak-to-peak EMG versus force in the active compartments varied from 0.76 to 0.99. Using the average of the peak-to-peak EMG's of the active compartments, the relationship was 0.98. The cor-
relation coefficient was slightly higher between force and total combined peak-to-peak EMG than between force and stimulation current.

**Future Plans/Implications**—Understanding the relationship between the factors of electrode location, electrode orientation, and muscle compartmentalization, along with the technique of sampling multiple muscle subdivisions, should improve FNS feedback control. However, it should be noted that the muscle EMG response is independent of muscle length and therefore a method of internally measuring the muscle length is needed to utilize EMG feedback in non-isometric conditions.

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**Computer Models for Designing Functional Electrical Stimulation Systems for Paraplegic Standing and Walking**

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Sponsor: VA Rehabilitation Research and Development Service

**Purpose**—Our long term objective is to develop computer tools to assist the rehabilitation team in designing user-specific FES-control systems so that paraplegics can stand and walk.

**Progress**—We have:

1) **Generated a computer model of FES-induced paraplegic standing assuming bilateral symmetry (i.e., only sagittal plane motion).** The dynamic equations of motion for a three body-segment model (shank, thigh, torso) were developed. The dimensionless dynamics of musculotendon contraction, driven by an activation signal, was also developed. A convenient, analytical relationship between the pulse-stimulus parameters (i.e., pulse-width, or -amplitude, and time between stimuli) and the muscle's activation signal was derived. The basic structure of our dimensionless musculotendon actuator model is consistent with the notion of a memoryless element (given by the electrode's "recruitment curve") followed by a dynamic element (musculotendon contraction dynamics), and is therefore directly related to FES-control parameters. The musculoskeletal geometry for 18 muscles of the lower extremity was also modeled. Nominal parameters specific to each musculotendon actuator (muscle strength, muscle-fiber length, muscle-fiber pinnation angle) were found from the literature. Our effort focused on the development of a procedure for ascertaining the resting (slack) length for each of the 18 tendons. Special attention was also given to knee biomechanics, and how the patella affects the force to joint-torque transformation. Combining all these constituent relationships, we were able to develop the nonlinear state equations for this 3-segment, sagittal plane representation of the body.

2) **Generated a computer graphics display that shows in real- (or slowed-) time how the body moves in the sagittal plane when FES is employed to induce standing in paraplegics.** The dynamic display shows how the body responds when the arms are unexpectedly moved (such as might occur when paraplegics voluntarily move their arms) using a feedback controller that applies FES to the paralyzed leg musculature. In addition, we have also been able to display how a paraplegic would be expected to rise from a chair using the same feedback controller (i.e., the feedback controller is trying to restore the paraplegic to the upright posture). The display is shown on a high performance workstation well-suited for fast, dynamic color display of 3-D objects (though only 2-D objects are currently being displayed). We developed graphics computer-code for displaying the body skeleton. Musculotendon actuators (each represented as a series collection of straight lines) can be displayed simultaneously, in red if the muscle is excited and in blue otherwise. The multiple-windowed display is menu-driven so that data (e.g., 2-D curves of body-segmental positions, velocities, accelerations, joint torques) can be shown simultaneously. We have found that such graphic displays offer invaluable insight into the dynamic interactions occurring during FES-induced standing.

3) **Developed a feedback control law for FES-induced standing, assuming motion in the sagittal plane only.** We assumed that joint angles and velocities can be measured (or estimated in the control
Functional Electrical Stimulation

The state equations were linearized around the upright posture. A constant-gain feedback-controller was designed using linear optimal control with a quadratic cost function. This cost function is, in effect, the sum of the cumulative deviation from the upright posture and the cumulative amount of torque consumed, assuming a specific relative weighting of these two deviations. To find a unique feedback control we optimized average performance over the whole set of possible initial states. We showed, through computer simulation, that this feedback law developed by linearizing the nonlinear musculoskeletal system, when applied to the actual nonlinear musculoskeletal system, performs remarkably well in restoring the upright standing posture, even from a sitting position with all muscles initially inactive. There is one caveat, however. We use a minimization of energy criterion to partition the summed (net) muscle joint torques found from the feedback controller into specific muscle torques. At the moment, the computational time required to do this partitioning is much too long to be practical.

Future Plans—We expect to study the sensitivity of computer-simulated standing performance in the sagittal plane to perturbations arising from arm movement and arm contact forces, such as occur during opening a door or removing a book from a shelf. We will also study the sensitivity of standing performance in the sagittal plane to the number and kind of muscles available for FES, to muscle strength, and to anthropometry.

Publications Resulting from This Research


Development of an Improved Walking System for Paraplegics with FES Adjunct to the LSU Reciprocating Gait Orthoses

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Sponsor: LSU Department of Orthopaedics

Purpose—The objective of this project was to provide paraplegics with a reliable and safe walking system with reduced metabolic energy consumption by utilizing electrical stimulation of selected muscle groups.

Progress—While the LSU brace has been successfully applied for a number of years to a large population of paraplegics, work has been expanded mostly on development of two FES strategies designed for use in synergy with the LSU orthoses. The first approach employed surface stimulation of the quadriceps simultaneous to the contralateral gluteus maximus to induce hip flexion and extension. The second approach employed implanted stimulation of the iliopsoas muscle for more powerful hip flexion. One patient has been tested and evaluated following the animal work reported previously.

Future Plans—Work continues on the final development of both approaches on a selected patient group.
Feedback Control of Hand Grasp During Functional Neuromuscular Stimulation

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Sponsor: National Institutes of Health

Purpose—The objective of this project is to incorporate feedback control into palmar prehension/release and lateral prehension/release FNS hand grasp systems developed for C5 and C6 quadriplegic patients.

Progress—A single-degree-of-freedom stiffness regulation feedback control system is currently being implemented for both palmar and lateral pinch. In each grasp, several muscles are activated. Some of these are controlled in an open-loop fashion while others are under feedback control. The choice of which muscles to place under feedback control is made on the basis of function. Muscles that are important in the gradation of movement and/or force are under feedback control. Those muscles that act to stabilize a digit as a platform are not under feedback control. For palmar prehension-release, the finger flexors and extensors are under feedback regulation. The median thenar intrinsics and the thumb extensor are activated to hold the thumb in opposition. For lateral prehension-release the thumb muscles are under feedback control while the finger flexors and extensors are controlled open loop.

The input to the system is derived from the patient by a command transducer (typically measuring shoulder movement). This command is directly mapped to the stimulus pulse widths to be applied to the muscles that are under open-loop control. The patient-generated command is also converted to a position command for the closed-loop portion of the system by a command map. For the case of lateral prehension, the lower 10 percent of the command range is used to bring the fingers from the extended to flexed position. Throughout this range, the position command for the thumb is fixed in extension. The remainder of the patient command range is mapped in a straight line, with increasing patient command specifying a decreasing amount of position command (i.e., movement in the flexion direction).

The stiffness regulator provides control of the relation between force and position of grasp under a wide range of mechanical loading conditions rather than just force or position alone. Two important features of the controller are: 1) that the properties of the load determine the relative contributions of force and position to the total feedback signal; and, 2) that only a single command is needed to control the grasp.

Preliminary Results—To date, the complete system has been implemented in software and studies with patients have begun to develop a rule-based tuning procedure. Performance of the combined open- and closed-loop-system will be measured in the laboratory during computer control of the system and during patient use of the system to pick up and manipulate objects.

Physiological Benefits of Electrical Stimulation of Paralyzed Muscle

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Sponsor: Scottish Home and Health Department

Purpose—The aim of this project was to investigate the physiological effects of electrical stimulation of paralyzed muscle. The physiological parameters to be studied were the responses of muscle bulk, skin blood flow and spasticity to muscle stimulation in recent injury and established injury paraplegics.

Progress—A program of quadriceps stimulation was applied to recent injury and established injury paraplegics with complete spinal cord lesions between T1 and T10 for 16-46 weeks. Changes in muscle bulk were followed by measuring thigh circumference and skin blood flow was monitored using a
Laser Doppler Flowmeter. Muscle tone was assessed using a newly developed machine for torque induced motion analysis.

**Preliminary Results**—Daily electrical stimulation of paralyzed muscle in established injury subjects caused increases in thigh circumference (9.4 ± 0.9 percent) within 11-16 weeks. In recent injury subjects, the usually rapid muscle wasting was partially prevented by the use of electrical stimulation (daily following the onset of spinal injury). With continued muscle stimulation, initial thigh circumference (i.e., at time of injury) could be restored. If stimulation was begun after the initial wasting had occurred in these recent injury subjects, thigh circumference was again increased to preinjury dimensions.

Changes in skin blood flow in relation to the stimulation program were monitored in two ways: 1) The immediate response of skin blood flow on the thigh to the electrical stimulation was measured in both injured and noninjured subjects after a 15-minute period of quadriceps stimulation; the before and after flow levels being compared. In both groups of subjects, skin blood flow showed a transitory increase of 100-300 percent for 1-2 minutes. 2) Skin blood flow (thigh, foot, and arm) was measured weekly in the resting subject at two skin temperatures, normal temperature and at 44 degrees Centigrade. In the subjects measured there was no difference in skin flow at normal temperatures between noninjured subjects, paraplegics and tetraplegics. The skin blood flow response to the thermal stress test (i.e., at 44 degrees Centigrade) was also unimpaired in the spinal cord injured subjects. Stimulation appeared to cause a long-term increase in skin blood flow only in the recently injured subjects, no changes in skin blood flow being apparent over the weeks of the stimulation program in the established injury subjects.

In addition, foot skin blood flow reactions to passive head-up tilting (17 degrees) were also measured. Noninjured subjects showed a 42.0 ± 3.0 percent decrease in foot skin blood flow during this procedure. Paraplegics (T4-T8) had an unimpaired orthostatic response but tetraplegics (above T1) and subjects with low level lesions (T10-L3) showed a much reduced response skin blood flow only decreasing by 22.3 ± 2.9 percent upon tilting.

**Future Plans/Implications**—Further experiments are continuing in order to clarify the changes in skin blood flow which occur with the electrical stimulation. Assessment of muscle tone and spasticity in paraplegics and the influence of electrical stimulation up on it are also in progress.

**Publications Resulting from This Research**


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**Hybrid Brace for Paraplegic Gait Restoration**

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**Sponsor:** Whitaker Foundation, Health Sciences Fund

**Purpose**—To design a neural prosthesis which restores gait, one must accurately control the dynamics of electrically-stimulated lower limb muscles. In this research, we are exploring a novel means of controlling the system by combining electrical stimulation with an orthotic lower limb brace which includes a friction brake at each joint. The motivation behind this concept is to negate the uncertainties in stimulated muscle force by adding a brace with known mechanical properties. The electrically-stimulated muscle then serves as an unregulated power source, with the orthosis regulating gait trajectory and stability.

**Progress**—We are developing this idea with stimulation experiments which control knee joint dynamics in able-bodied human subjects. We have built an experimental knee orthosis with a magnetic particle brake coupled to the joint and will make performance comparisons between voluntary knee motions, knee motions controlled by electrical stimulation alone, and knee motions controlled by combining electrical stimulation with the friction brake. If the concept appears feasible, we will design a complete, multi-joint leg orthosis for testing on spinal cord injury (SCI) subjects.