Journal of Rehabilitation Research and Development

Rehabilitation R & D Progress Reports 1990

IV. Functional Electrical Stimulation

A. General

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IV. Functional Electrical Stimulation

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A. General

[112] Comparison of Percutaneous Pudendal Nerve and Surface Electrical Stimulation for Bladder Inhibition

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B996-PA)*

Purpose—We have been investigating functional electrical stimulation (FES) techniques to inhibit the bladder hyperreflexia that causes major morbidity and incontinence in the spinal cord injured (SCI) patient. Initial observations in our SCI cats have shown that FES techniques can inhibit the bladder. Therefore, we have begun testing SCI patients with various FES methods to attempt to alter their bladder hyperreflexia.

Methodology—Seven chronic upper motor neuron SCI males, in good health and stable urologically, underwent baseline cystometry (CMG) using 4-channel cystometry at 60cc/m fill rate. Then, inhibition of bladder activity was investigated using sacral surface stimulation, surface tibial nerve stimulation, rectal stimulation, surface penile base stimulation, and percutaneous pudendal nerve stimulation. Not all patients underwent all methods of stimulation. Stimulation was investigator-controlled using standard surface electrodes, rectal plug or percutaneous needles. Stimulation started at low voltage and frequency, adjusting voltage and frequency until the desired bladder inhibition or side affects resulted. Repeat CMG at various intervals recorded any changes.

Results—Successful bladder inhibition is indicated by an increase in bladder filling volume and a decrease in bladder pressure. In six of the seven patients we could cause some decrease in the bladder hyperreflexia using these methods. Sacral surface inhibition was least effective in diminishing bladder hyperreflexia. Penile stimulation, using surface electrodes at low frequency ($<$5PPS) and between 50-60 mA, may be most effective in inhibiting bladder hyperreflexia. Rectal, pudendal nerve, and peripheral nerve stimulation may be less effective inhibitors of bladder hyperreflexia.

Future Plans—Our goal is to find the most efficacious method of inhibiting bladder hyperreflexia. Surface stimulation at the penile base at low frequency appears to be the best FES method. We plan to design an appropriate electrode for chronic use of this FES method in an attempt to diminish the urological morbidity secondary to the hyperreflexic bladder.

Recent Publications Resulting from This Research

Treatment of Incontinence in a Spinal Animal Model: Comparison of Pudendal and Sacral Nerve Electrodes. Walter JS et al., in Proceedings of the American Paraplegia Society, Las Vegas, 1990.

[113] Improving Exercise Performance of Quadriplegics

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B587-RA)*

Purpose—The purpose of this 3-year project is to finalize development and to evaluate an arm+leg exercise system for spinal cord injured (SCI) quadriplegics that maximizes active muscle mass and aerobic metabolism and allows adequate central and peripheral circulation. Arm-cranking is used to drive the leg-cycling motion, while a computer controls the functional neuromuscular stimulation (FNS) of appropriate leg muscle groups during the crank cycle to assist leg cycling. Phase I consists of modification of our current prototype voluntary-arm + FNS-leg ergometer to permit operation in either the upright sitting or supine posture. Phases II and III consist of evaluation of acute and chronic physiologic responses of quadriplegics during exercise testing and training with this device.

This project will produce a relatively low-cost system, techniques, and protocols for exercise testing and training of SCI quadriplegics. We will modify the present prototype of our upright arm+leg ergometer to overcome two physiologic obstacles facing exercising quadriplegics: posturally induced venous pooling and paralysis of a large muscle mass that potentially can be used for exercise. Technical modifications of the arm+leg ergometer will enhance venous return and activation of muscle mass. The data derived from this study should contribute toward optimizing methods for exercise testing and training of quadriplegics so that they can achieve substantially higher cardiopulmonary fitness levels.

Methodology—Each of the three phases of this project will take about one year. Phase I will entail the modification and reconfiguration of our present prototype arm+leg ergometer to accommodate supine posture. Modifications will involve: 1) placement of the arm-crank over the chest of supine subjects; 2) elevation of the leg crank to heart level to further enhance venous return; 3) supplementation of the FNS for quadriceps, hamstring, and gluteal muscle groups, with additional channels to stimulate calf muscles for enhancement of venous return; and, 4) improvement of current computer programs to acquire/analyze data and to control multi-channel FNS exercise.

Phase II will involve assessment of acute physiologic responses during three modes of submaximal and maximal exercise performed in both upright sitting and supine postures. After recruitment of prospective subjects, informed consent procedures, medical screening, and habituation to FNS exercise, each quadriplegic subject will undergo graded submaximal and maximal exercise testing in both *sitting* and *supine* postures with (*a*) voluntary arm-cranking alone, (*b*) FNS leg cycling alone, and, (*c*) combined arm+leg ergometry.

Phase III will involve training of subjects for 15 weeks (3 days per week) using *upright* sitting arm+leg ergometry, then repeating the exercise stress tests.

Finally, subjects will train with *supine* arm+leg ergometry for 15 weeks (3 days per week) and repeat the exercise tests. Changes in physical fitness gained in the supine posture (over and above that gained in the upright sitting posture) will be determined.

All data collection procedures will be noninvasive (except for fingertip blood sampling) consisting of open-circuit spirometry, impedance cardiography and plethysmography, and auscultation. Dependent variables will include mechanical power outputs, systemic oxygen uptake and related respiratory variables; left ventricular stroke volume and cardiac output, myocardial contractile indices, and systolic time intervals; arm and leg segment arterial blood flows and fluid volumes; estimates of the proportions of cardiac output serving the arm and leg segments; arterialized capillary blood acid-base status and lactate concentrations; and arterial blood pressures. Data will be analyzed with parametric statistical techniques, that is, analysis of variance (ANOVA).

Progress—Design work on the ergometry system is in progress.

[114] Evaluation of FES Techniques for Exercise

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B433-RA)*

Purpose—The purpose of this project is to objectively evaluate the effectiveness of functional electrical stimulation (FES) exercise techniques for improving health, physical fitness, and rehabilitation potential of patients with spinal cord injury (SCI). Specific objectives include: 1) assessment of acute physiologic responses and maximal performance during FES leg cycling (FES-LC) exercise, FES knee extension (FES-KE) exercise, voluntary arm-crank exercise (ACE), and combined FES-LC + ACE (HYBRID) exercise; and 2) determination of physiologic and psychologic adaptations resulting from training with the various FES/voluntary exercise modes.

Progress—Upon completion of 2.5 years of this 4-year project, 25 SCI subjects have completed at least one of the four 12-week training programs involving FES-induced exercise. Eight subjects have completed FES knee extension training, 20 have completed ERGYS training, 12 have completed serial FES-LC and ACE training, and 15 have completed hybrid training. An additional phase of interval training using FES-LC has been completed by eight subjects.

Preliminary Results—The acute physiological effects of FES-KE were examined during load resistances of 1 to 15 kg/leg in seven quadriplegics and seven paraplegics. Oxygen uptake, pulmonary ventilation, cardiac output, stroke volume, mean arterial pressure, and rate-pressure product increased slightly. Despite hypotension in quadriplegics, FES-KE appeared to be easily tolerated by all subjects. Training responses to FES-KE exercise were examined in seven SCI individuals. Following training, maximum load was significantly higher (5.7 versus 10.2 kg), thigh skinfold was significantly lower (20 versus 15 mm), and knee range of motion was significantly increased (125 versus 140 degrees). Since this form of FES training appears to strengthen paralyzed quadriceps muscle and improve knee range of motion, it may be appropriate in preparation for more strenuous FES activities.

Acute physiologic responses to FES-LC were examined in 30 SCI subjects (17 quadriplegics and 13 paraplegics) during a graded FES exercise test from rest to fatigue on an ERGYS 1 ergometer (Therapeutic Technologies, Inc.). For both groups, peak FES cycling significantly increased (from rest levels) mean oxygen uptake by 255%, and cardiac output by 69%. Mean peak power output for paraplegics (15 W) was significantly higher than for quadriplegics (9 W), eliciting higher peak levels of pulmonary ventilation and sympathetically mediated hemodynamic responses such as cardiac output, heart rate, and arterial blood pressures. Passive cycling without FES produced no statistically significant increases in physiologic responses above the resting level in either group.

Training responses to FES-LC were examined in 15 SCI individuals. Comparison of pre/post FES-LC training data showed significantly increased peak power output (43%), oxygen uptake (18%), and pulmonary ventilation (24%). Mean arterial blood pressure and total peripheral resistance during peak exercise tended to decrease after training, with no change in peak stroke volume. Most of the improved exercise performance following 12 weeks of training appears to be due primarily to peripheral adaptations that enhanced muscular strength and endurance. However, greater magnitudes of cardiopulmonary responses at the higher power outputs achieved post-ERGYS training could improve cardiopulmonary system training capability. This may be accomplished with more training time.

Simultaneous submaximal ACE and FES-LC exercises ("hybrid" exercise) results in additive metabolic and cardiopulmonary responses in most SCI subjects. Thus, hybrid exercise may provide for greater aerobic training capacities than ACE or FES-LC alone, especially in quadriplegics.

Future Plans/Implications—Psychological test results are being evaluated to identify correlates with subject attrition and fitness improvements. Physical indices are

being constructed to provide an overall representation of the physical progress made by each individual. These indices will be correlated with other physiologic and psychologic measures to determine relationships. Changes in paralyzed muscle strength and endurance are being documented using a computerized force-current measurement system.

Recent Publications Resulting from This Research

Efficiency of FNS Leg Cycle Ergometry. Glaser RM et al., in Proceedings of the 11th Annual Conference of the IEEE/EMBS, 1961-1963, 1989.

Force-Current Measurement System for Evaluating Muscle Performance During Functional Neuromuscular Stimulation. Ezenwa BN et al., in Proceedings of the 12th Annual RESNA Conference, New Orleans, 179-180, 1989.

Hemodynamic Responses of Paraplegics and Quadriplegics to Passive and Active Leg Cycle Ergometry. Figoni SF et al., ASIA Abstr Dig 80, 1989.

Hemodynamic Responses of Quadriplegics to Arm, ES-Leg, and Combined Arm + ES-Leg Ergometry. Figoni SF et al., Med Sci Sports Exerc 21:2(Suppl.):S96, 1989.

Peak Hemodynamic Responses of SCI Subjects During FNS Leg Cycle Ergometry. Figoni SF et al., in Proceedings of the 12th Annual RESNA Conference, New Orleans, 97-98, 1989.

Physiologic Responses to Simultaneous Voluntary Arm Crank and Electrically-Stimulated Leg Exercise in Quadriplegics. Hooker SP et al., in Proceedings of the 12th Annual RESNA Conference, New Orleans, 99-100, 1989.

Tibial Trabecular Bone Density vs Time Since Spinal Cord Injury. Rodgers MM et al., in Proceedings of the 12th Annual RESNA Conference, New Orleans, 403-404, 1989.

Acid-Base Balance After Electrically-Induced Leg Cycle and Voluntary Arm Crank Exercise in Paraplegics. Am Spinal Inj Assoc Abstr Dig 65, 1990.

Acute Physiological Responses of SCI Subjects to FNS Knee Extension Exercise. Figoni SF et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 157-158, 1990.

Automated Adaptive Equalization System for Asynchronous FNS-Induced Knee Extension Exercise for SCI Subjects. Ezenwa BN et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 159-160, 1990.

Functional Neuromuscular Stimulation for Physical Fitness Training of the Disabled. Glaser RM, in Fitness for Aged, Disabled and Industrial Workers, 127-134, M. Kaneko (Ed.). Champaign, IL: Human Kinetics Publishers, 1990.

Muscle Fatigue Characteristics with FNS-Induced Contractions. Kuntzman AJ et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 161-162, 1990.

Physiologic Responses of Paraplegics and Quadriplegics to Passive and Active Leg Cycle Ergometry. Figoni SF et al., J Am Paraplegia Soc, 13(3):33-39, 1990.

Training Responses of SCI Individuals to FNS-Induced Knee Extension Exercise. Rodgers MM et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 365-366, 1990.

Characteristics of Functional Neuromuscular Stimulation-Induced Spasticity in Spinal Cord Injured Subjects. Rodgers MM et al., in Proceedings of the 8th Congress of the International Society of Electrophysiological Kinesiology (in press).

Exercise Conditioning of the Spinal Cord Injured Via Functional Electrical Stimulation. Glaser RM, in Athletic Injuries to the Head, Neck and Face. 2nd ed., J.S. Torg (Ed.). Chicago: Yearbook Medical Publishers (in press).

Fitness Following Spinal Cord Injury. Davis GM, Glaser RM, in Physiotherapy: Foundations for Practice Series, Neurology Volume, L. Ada, C. Canning (Eds.). London: Heinemann Medical Books (in press).

Functional Neuromuscular Stimulation Threshold Elevation with Fatiguing Paralyzed Muscle. Kuntzman AJ et al., in Proceedings of the 8th Congress of the International Society of Electrophysiological Kinesiology (in press).

Perspectives on Cardiovascular Fitness and Spinal Cord Injury. Figoni SF, J Am Paraplegic Soc (in press).

Physiologic Responses to Prolonged Electrically-Stimulated Leg Cycle Exercise. Hooker SP et al., Arch Phys Med Rehabil (in press).

Spinal Cord Injuries and Neuromuscular Stimulation. Glaser RM, in Current Therapy in Sports Medicine: 2, J.S. Torg (Ed.). Toronto: B.C. Decker, Inc. (in press).

[115] FNS Effects Upon Venous Pooling in Geriatric and Mobility-Impaired Patients

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B242-3RA)*

Purpose—The overall purpose of this research program is to evaluate the acute effects of pulsatile functional neuromuscular stimulation (FNS)-induced contractions of leg muscles upon central and peripheral hemodynamic responses to determine if venous pooling/stasis can be minimized and/or reversed in mobility-impaired and geriatric patients. Specific objectives are to evaluate the effectiveness of this FNS application for facilitating circulation during head-up tilt, upright sitting, standing, arm-crank exercise, and wheelchair propulsion.

Progress—Instrumentation that has been designed and constructed for implementing this research program include: 1) eight-channel neuromuscular stimulators, utilizing a less painful low-current electrical waveform to alternately contract thigh and calf musculature; 2) a motorized tilt table with adjustable arm-crank ergometer to allow arm-crank exercise during tilting; 3) an eight-segment impedance cardiographic/arteriographic data collection and analysis system to monitor central and peripheral circulation; and, 4) a system that measures bioelectrical resistance, reactance, and impedance in eight segments of the body simultaneously for assessment of segmental fluid shifts and fluid volumes. Both impedance systems are being used to assess physiologic responses during postural change, arm exercise, and effectiveness of FNS-activation of the skeletal muscle pump for minimizing venous pooling and enhancing venous return. Thirty-four elderly hemiplegic and other disabled geriatric subjects were initially screened by a physician and were given an orthostatic tolerance test. Twenty-eight of these subjects recently completed head-up tilt tests and are presently undergoing prolonged upright sitting tests incorporating periodic FNS-induced contractions of the leg muscles. Data from these tests are currently being analyzed. Subjects will next undergo the prolonged standing test, followed by the arm exercise and wheelchair locomotion tests.

Future Plans/Implications—If this FNS application can reduce venous pooling in the legs and improve circulation to exercising arm muscles, it may be able to enhance arm exercise capacity, decrease the stressfulness of manual wheelchair locomotion, and improve the tolerance for upright postures for prolonged durations. Future medical and rehabilitative applications may also include prevention of deep venous thrombosis in immobilized or postsurgical patients and treatment of orthostatic hypotension, excessive pedal edema, and decubitus ulcers in susceptible individuals.

Recent Publications Resulting from This Research

Arm Exercise Training for Wheelchair Users. Glaser RM, Med Sci Sports Exerc 21:S149-157, 1989.
Cardiovascular Effects of ES-Induced Isometric Leg Exercise During Lower Body Negative Pressure. Davis GM et al., Med Sci Sports Exerc 21:S57, 1989.
Cardiovascular Responses to FNS-Induced Isometric Leg Exercise During Lower Body Negative Pressure. Davis GM et al., in Proceedings of the 12th Annual RESNA Conference, New Orleans, 95-96, 1989.

[116] Management of Central Ventilatory Insufficiency: Abdominal and Thoracic Stimulation

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Sponsor: *VA Rehabilitation Research and Development Service (Core Funds)*

Purpose—Current methods of phrenic nerve stimulation to relieve chronic ventilatory insufficiency have created problems with nerve damage and diaphragm inefficiency and fatigue. Diaphragm inefficiency may be related to the paradoxical inward chest movements during inspiration that occur when intercostal muscles are not activated. The goals of the present study are to develop improved functional electrical stimulation methods. Our approach will evaluate direct diaphragm stimulation to reduce problems of chronic nerve damage and to coordinate intercostal with diaphragm stimulation to improve efficiency and reduce fatigue problems.

Progress—In acute dogs following anesthesia, single intramuscular electrodes were implanted in each hemidiaphragm close to the entry of the phrenic nerves and bilateral electrode pairs were inserted deep into the chest wall to activate intercostal muscles. We found direct diaphragm stimulation alone capable of producing significantly large tracheal air flows. Intercostal stimulation alone produced thoracic excursions but reduced tracheal air flows. Combined diaphragm and intercostal stimulation produced tracheal air flows greater than diaphragm stimulation alone. These results indicate the feasibility of direct diaphragm stimulation and the

assistance provided by intercostal activation. We are now trying to optimize stimulating parameters and electrode placement to maximize the mechanical response.

Future Plans—We plan to determine if intercostal activity increases ventilatory efficiency and reduces fatigue during long-term diaphragm stimulation. In addition, active expiration with "cough" may be possible with selective abdominal stimulation, thereby introducing a naturally induced clearing mechanism for the airways.

[117] A Study to Investigate the Effects of Functional Electrical Stimulation Exercise on Bone Mineral Density in Spinal Cord Injured Individuals with Disuse Osteoporosis

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—This study is examining the effects of two different functional electrical stimulation (FES) exercise protocols on the bone mineral density of 1- to 15-year postinjury spinal cord injured individuals who have lost significant bone density due to disuse. The study is attempting to determine whether bone that has undergone major resorption can recover significantly. The key element being tested is the introduction of a resistive mechanical force to the exercise in addition to the forces generated by muscle activity. The results from this study will provide information that may help improvements in the design of existing FES exercise systems, thereby reducing the rate of loss of bone soon after injury, and consequently, the risk of fractures when walking is attempted.

Methodology—The two FES exercise systems being used in this study are the Regys 1 Clinic Rehabilitation System, and an ergometer system developed as part of this study that incorporates mechanical stimuli that emulate temporal loading patterns thought to optimally trigger bone remodeling. The latter system incorporates current knowledge of appropriate stimuli for bone remodeling which will test the applicability of Wolff's Law for the recovery of bone lost due to disuse osteoporosis following spinal cord injury. This system provides exercise for the legs against a varying resistive force without compromising the aerobic benefits of the exercise activity.

Both male and female complete spinal cord injured individuals of between 1- to 15-years postinjury with significant bone loss are currently being recruited. The subjects are distributed between the two treatment groups and a control group who receive no specific exercise beyond their normal daily activities. The exercise treatment lasts 40 weeks for each subject.

Bone mineral density is measured at 10-week intervals in the neck of the femur, the shaft of the femur, and the lumbar spine, using dual photon absorptiometry (DPA). Total body calcium is also measured using DPA. In addition, the following laboratory investigations are performed: ionized calcium, parathyroid hormone, metabolites of vitamin D, bone Gla protein, calcitonin, and analysis of urine metabolites.

[118] Prevention of Secondary Complications in Spinal Cord Injury by Electrical Stimulation: Wheelchair-Attached Balance Frame

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Our objective is to establish a protocol for selecting and training appropriate patients to use a wheelchair-attached balance frame in conjunction with a two-channel stimulator to achieve transient periods of standing on a repeatable basis. We hypothesize that the wheelchair-attached balance frame will be accepted by patients as a device that does in fact enhance their activities of daily living and mobility.

Progress—Three individuals have now had field experience with the wheelchair-attached balance aid. Five individuals have had experience with the device in a controlled clinical setting. Standing time data indicate a frequency of use of greater than 10 times per week; however, patient comments have not been as positive as we had hoped. A total of four standing frames are now in the field evaluation.

Results—The major problem that appears to be preventing wider patient acceptance of the wheelchair-attached balance aid is postural stability when attempting to release one hand to perform functional tasks. We have tried adding ankle-foot orthoses to enhance stability in two subjects, but trunk balance is a more difficult problem to solve. The transition from quiet standing in a controlled laboratory or clinical situation to field use will depend on correctly identifying the improvements that need to be made.

Future Plans—We plan to place additional balance frames in the field and to develop a satisfaction questionnaire for subjects to complete before and after their experience with the wheelchair.

Recent Publications Resulting from This Research

Functional Neuromuscular Stimulation for Standing After Spinal Cord Injury. Yarkony GM et al., Arch Phys Med Rehabil 71:201-206, 1990.

[119] Rehabilitation Engineering Center for Restoration of Neural Control

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Program Overview—The objectives of the Rehabilitation Engineering Center for Functional Electrical Stimulation at Case Western Reserve University (CWRU-REC) are to: 1) develop, test, implement, and evaluate clinical systems employing functional electrical stimulation (FES) technology which provide control of the extremities and stabilization of the trunk; 2) establish a model information exchange program providing information on FES for consumers, medical care providers, third-party payers and manufacturers; 3) deploy FES systems to other rehabilitation and research institutions; and, 4) transfer FES technology to private industry.

FES can be used in several ways to effect control of the nervous system. FES can control abnormal motor system function resulting from stroke, head injury, cerebral palsy, or scoliosis. It can also restore motor and sensory function loss due to paralysis resulting from spinal cord injury or stroke. In this program, we will address the problems presented by individuals with these injuries.

The program is organized to promote investigation in four priority areas: 1) development of a comprehensive FES information collection, referral, and dissemination program; 2) upper extremity FES and hybrid systems for

manipulation and grasp; 3) systems employing FES and orthotics to stabilize the trunk and correct trunk deformities; and, 4) control of spasticity in stroke and head injury by FES.

[119a] I. Development of a Functional Electrical Stimulation (FES) Database and Dissemination Service

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Purpose—The FES Information Center was formed in December of 1988 to provide a wide range of information services to people interested in functional electrical stimulation (FES). The objectives of the FES Information Center are to: 1) develop and maintain a comprehensive information base on FES which will include journal articles, conference proceedings, progress reports, popular literature, videotapes, and other materials related to the use of electrical stimulation in rehabilitation; 2) disseminate the information in an accessible format to disabled consumers, medical care providers, service providers, third-party payers, researchers, and medical equipment manufacturers; and, 3) develop appropriate presentation formats for relating the current status of FES as described by the collated work of multiple investigators and facilities throughout the world.

Progress—Since our last report in 1989, the FES Information Center has experienced a surge of incoming requests for information, totaling 725 individual requests. About 95% of the inquiries were from United States residents representing 46 states. The remaining 5% of inquiries were from residents of about 15 different countries. Of the 725 inquiries, nearly 50% were made by individuals with disabilities or their family member/friend. About 30% of the inquiries were from persons providing services to individuals with disabilities, i.e., clinicians, rehabilitation counselors, or advocates. The remaining 20% represents inquiries from scientists, medical device manufacturers, third-party payers, journalists, and others. Due to the diverse nature of the inquiries and the lack of readily available information on the topic of interest, most inquiries were handled in a customized fashion whereby clients received some combination of reference materials, bibliographies, and referral information (see Future Plans).

We continue to collect information on FES for inclusion in our databases. Our FES Reference Database contains over 4,500 citations to FES-related reference materials. Our FES Research Directory database contains names, addresses, and descriptions of research projects for over 100 current FES researchers. Our FES Manufacturer's Directory database has been initiated with the identification (including names, addresses, and telephone numbers), of over 280 businesses producing FES equipment and supplies. We have established a referral arrangement with 45 FES service providers who have enrolled in our FES Clinical Services Directory database. We also maintain a FES Calendar of Events database and a FES Job Posted/Job Wanted database.

Other accomplishments during this period include publication of the *FES Update* newsletter (circulation 2,200), organization and videotaping of a 4-hour conference on FES for the lay public, representation at three national conferences and a survey of consumers of FES products and services.

Future Plans—Our future plans call for a comprehensive analysis of our information and referral experience thus far in an attempt to reduce the level of customization necessary to respond to incoming requests. The analysis will include more detailed client demographics and multidimensional profiles of client requests. We will use client evaluations to assist us in refining the type and level of service offerings we will make available in the future.

Recent Publications Resulting from This Research

Keeping Up on FES. Teeter JO, RESNA News 1(6), 1989.
FES and Stroke Rehabilitation. Teeter JO, Be Stroke Smart—Newsletter of the National Stroke Association (in press).
FES . . . What's It All About? Teeter JO, Buckeye Banner: Newsletter of the Buckeye Chapter, Paralyzed Veterans of America (in press).

[119b] II. Development of Upper Extremity Control Employing Functional Electrical Stimulation

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Purpose—The objective of this project is to clinically evaluate the efficacy of FES hand systems which provide restoration of grasp and release for the high-level spinal cord injured individual. The first systems to be evaluated, designed for the C5 and C6 level quadriplegic, utilize chronically-indwelling, percutaneous, intramuscular electrodes and are configured to provide two functional hand grasps: palmar and lateral prehension/release. We have transferred this technology to four Centers in addition to our own, and carefully regulated and supervised trials are being performed to validate the findings of our own research. The four Satellite Centers are: (*a*) The University of Alberta (Edmonton, Alberta); (*b*) The University of Toronto, Hugh MacMillan Rehabilitation Centre, Lyndhurst Hospital (Toronto, Ontario); (*c*) Shriners Hospital for Crippled Children (Philadelphia, PA); and, (*d*) Rancho Rehabilitation Engineering Program (Los Angeles, CA).

During these studies, we will evaluate the level of functional hand control that can be restored to the high-level quadriplegic patient, and identify any limitations associated with the transfer of this type of clinical technology to other Centers. Controlled studies will be performed, using identical measurement methodology at each Center, to evaluate the efficacy of these system in providing enhanced independence in activities of daily living and quantitatively measured tasks. We will also document the reliability of the system and any sources of failure.

Progress—*Major Achievements:* The second in our series of Technology Transfer Workshops was successfully completed in March 1990, during which updates on protocols, procedures, hardware, and software were presented. Each Center reviewed their progress to date, and problems and experiences were discussed. To date, each Center has demonstrated the ability to successfully implement patients with the FES hand system (five in Philadelphia, two in Edmonton, two in Toronto, and one in Los Angeles). The results of the initial evaluations indicate that these patients are using their systems for various activities (e.g., eating, drinking, writing, painting, shooting billiards). Functional evaluations and recruitment of additional subjects are ongoing.

We have succeeded in converting from a specific laboratory-based FES system to a standard, commonly accessible PC-based FES system that all collaborating Centers can utilize. These FES systems satisfy the technical specifications established for them and have exhibited few significant technical problems. Availability of the systems has been enhanced due to a successful technology transfer collaboration with industrial partners. Lastly, we have greatly increased our base of knowledge regarding the usefulness of our FES hand system to quadriplegic patients, thanks to the experiences and results reported by our colleagues at the collaborating Centers.

Barriers to Successful Technology Transfer: We have encountered several of the barriers that complicate successful technology transfer. In the clinical research setting, differing levels of available resources, facilities and personnel can affect the successful transfer and investigation of the device. Differences in the objectives and goals of the various groups evaluating the technology can create conflicts with the overall goals and objectives of the transfer project. In addition, the fundamental emphasis of each of those groups (e.g., basic research versus service delivery) impact the outcome of their investigations. Cultural differences amongst the evaluating Centers will influence how the particular device is deployed and evaluated at each, perhaps complicating evaluation of the data. Finally, the limited financial resources have required that the study be strictly focused and perhaps less encompassing than the collaborative investigators would have preferred.

Future Plans—During the coming year we will continue to recruit additional subjects into this study and to perform functional evaluations on all subjects who are enrolled. We will also continue to scrutinize the technology transfer process and to document any further limitations associated with it.

[119c] III. Electrical Stimulation in the Treatment of Scoliosis

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Purpose/Methodology—The objective of this study is to determine the efficacy of treating adolescent idiopathic scoliosis by electrical activation of the deep paraspinal muscles on the concave side of the curve. Prior investigations have demonstrated that at least one group of these muscles—the multifidi—are longer and less active on the concave side of the curve than on the convex side. In this study, we will measure the effect on spinal curvature of increasing the activity and decreasing the length of the multifidus muscles on the concave side of the curve. The multifidus muscles will be activated through percutaneous intramuscular stimulating electrodes attached to a multichannel, neuromuscular stimulator that was developed in our laboratory.

Fifteen adolescent subjects with idiopathic scoliosis will participate in this pilot study. Each will have three helically wound wire electrodes inserted percutaneously into the deep paraspinal muscles on the concave side of the curve. Electrical stimulation will be applied to the electrodes throughout the day in a pattern of 4 hours on, and 2 hours off. Curve correction will be monitored by inspection and by periodic radiographs. In the event of curve progression, the electrodes will be removed and the patient transferred to the Milwaukee brace program.

Each subject will participate in this study from the time of diagnosis until skeletal maturity (approximately 2 years), and will be followed for at least 1 year after stimulation has ended.

Progress—Progress on this project to date has been in three main areas: device design and construction, investigation of electrode placement, and fulfillment of regulatory requirements.

Device design and construction: One prototype stimulator and five patient stimulators have been constructed. The safety and durability testing required by the FDA is within 3 weeks of completion at the time of this writing. Following the completion of the testing, the devices will be ready for patient use. The stimulator weighs 300 grams and has the physical dimensions of 15 × 10 × 2.5 cm. The device is powered by two C-lithium batteries; under operating conditions they are expected to last 6 to 8 weeks. Connectors and cables are being assembled at this time.

Investigation of electrode placement: Intraoperative studies continue to develop techniques for electrode placement. The innervation of the multifidus in the thoracic region appears to be isolated from the innervation to other paraspinal muscles; isolated contractions of the muscles have been easy to achieve in the cases studied to date.

Fulfillment of regulatory requirements: Full approval to initiate human investigations was received from the FDA in August 1990. We submitted an amendment to cover connector changes and began human studies in October 1990.

[119d] IV. Characterization and Reduction of Spasticity by Stimulation in the Hemiplegic Upper Extremity

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Purpose—The goal of this study is to improve upper extremity function in patients with hemiplegia by reducing spasticity and improving voluntary control by electrical stimulation. Efforts have concentrated on developing methods of quantifying spasticity so that the effects of stimulation can be documented.

Quantification of spasticity by measurement of the increased resistance to joint rotation (stiffness) is

frequently complicated by changes in initial conditions. If this dependence can be quantified, and if it is repeatable, the spasticity and therapeutic methods may be measured more reliably.

Progress—By studying normal subjects, we have developed and tested quantitative methods of: 1) separating the passive, intrinsic, and reflex components of joint stiffness during single muscle contractions; 2) measuring the separate contributions of co-contracting antagonists to total joint stiffness; and, 3) measuring the reflex interactions between a pair of antagonist muscles during co-contraction. In a series of five subjects, the contributions of each of the three components to the total stiffness was significant, and could not be ignored. Since each component can be altered separately by stroke, it is important to measure each of them separately. In a second study, we also observed that reflexes are exacerbated at moderate to high levels of co-contraction. The strength of reflexes measured during co-contraction was greater than the strength predicted on the basis of measurements made when each of the two muscles was contracting individually. The implication of this finding for measuring spasticity is that the loss of coordination is spasticity (resulting in co-contraction), which makes it important to take into account the contraction state of each muscle.

Recent Publications Resulting from This Research

Stiffness Regulation by Reflex Action in the Normal Human Hand. Carter RR, Crago PE, Keith MW, J Neurophysiol 64:105-118, 1990.

[120] Bladder Evacuation by Direct Sacral Root Stimulation

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—Electrostimulation to empty the neuropathic bladder has been the focus of our research for the past 12 years. In extensive animal studies, various sites of electrode implantation were evaluated—the spinal cord, pelvic nerves, detrusor muscle, and individual sacral roots. The most effective voiding was obtained by stimulation of the ventral component of selected sacral roots after their somatic contribution to the urinary sphincter had been sectioned.

During the past two years, six human volunteers underwent laminectomy and implantation of sacral root electrodes. Various combinations of dorsal rhizotomy versus separation, pudendal neurotomy versus selective somatic sectioning, were added to sacral root implantation. We also studied high- and low-frequency stimulation and pudendal nerve blockade by Xylocaine™ injection.

Preliminary Results—The preliminary results are most encouraging. This proposal is designed to investigate: 1) the possible harmful effect of dorsal rhizotomy on detrusor contraction; 2) the incomplete elimination of the urethral sphincter by unilateral pudendal neurotomy, or unilateral selective sectioning of the somatic component alone; and, 3) the long-term effect of rhizotomy and somatic neurotomy on the sphincter muscles. Our animal experiments will carefully examine the effect of dorsal rhizotomy, pudendal and selective somatic neurotomy on bladder and sphincter function, as well as the metabolic and histologic changes in the sphincter muscles after these procedures. Ten patients (five men, five women) will undergo implantation over a 3-year period with a combination of different techniques aimed at achieving maximal bladder response and eliminating urethral resistance during stimulation while maintaining continence in the bladder filling phase.

Implications—We hope that, at the completion of this study, an effective, universally successful technique, devoid of harmful effects on the bladder and sphincter, will be available for general use to benefit the tens of thousands of patients with bladder and urethral dysfunction.

[121] Microstimulator for Functional Neuromuscular Control

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—This project seeks to develop and evaluate implantable, single-channel, untethered microstimulators for functional neuromuscular stimulation.

Methodology—The individual microstimulators will be small enough to be implanted by expulsion through a hypodermic needle. Up to 32 individually addressable stimulators will be powered and controlled by a single external coil. The microstimulator will consist of two electrodes sealed into opposite ends of a cylindrical glass capsule formed by drawing and melting a glass capillary tube. Within the capsule, a high-mu coil will receive power and command signals from an external transmitter coil by air-gap transformer coupling. These signals will be processed by a custom ASIC chip within the capsule. One electrode will be tantalum-pentoxide and will also function as the main energy storage element of the implant.

Progress—During the past year, progress has been made in areas of microstimulator packaging and transmitter circuit design. Progress has also been made in obtaining a hermetic seal around the tantalum and iridium electrodes that exit at the ends of the transmitter. Good hermetic seals have been achieved around each wire. Further efforts will be directed at decreasing the length of glass-metal interface to minimize the package size. Using Class E driver circuitry, relatively efficient powering of the implants has been demonstrated. Methods to provide amplitude modulation of the carrier have been developed which will be used to transmit commands to the microstimulators. Preliminary plans for the ASIC chip are complete.

[122] Noninvasive Stimulation of the Human Central Nervous System

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Purpose—Recently, techniques have become available for the noninvasive stimulation of the human cortex and deep proximal peripheral nerves. Stimulation can be a high voltage, extremely brief electrical or magnetic pulse. One purpose of this study is to use these methods for noninvasive localization of different parts of the human cortex (including motor cortex, sensory cortex, and language cortex). Another purpose is to study cortical physiology in different disease states.

Results—The following are results of our study: 1) we established normative data for our own laboratory for measurement of central motor conduction velocities; 2) we found that electroencephalograms (EEGs) do not change after a session of cortical stimulation in normal volunteers and patients, which indicates the safety of the procedure; 3) we succeeded in mapping the hand, arm, leg, and mouth areas of the human motor cortex in normal volunteers, correlating these motor maps with the sensory maps in patients with mirror movements, stroke, and with different types of amputations; 4) we found that patients with congenital mirror movements have a bilateral cortical representation of each hand in the motor cortex, and that they have physiologically active and fast conducting connections between the motor cortex and ipsilateral muscles in the upper extremity; 5) we studied hemispheric dominance for laryngeal muscles, finding that there seem to be bilateral projections from both hemispheres to motoneurons controlling muscles in both sides of the larynx, and that stimulation of the left hemisphere activates a larger percentage of the motoneuron pool bilaterally; 6) we mapped sensory cortex by utilizing the phenomenon of blockage of cutaneous stimulus; and, 7) we used magnetic stimulation to probe the processes in motor cortex during a reaction time task in patients with Parkinson's disease.

[123] Coatings for Protection of Integrated Circuits

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—Micromachined, thin-film recording and stimulating microelectrode probes, and miniature wires or cables connecting these electrodes with a source of control and power, must be protected for decades from the hostile ionic environment of extracellular fluids, if they are to be used reliably in humans. The long-term goal of this research is to develop biocompatible insulating materials which will permit these neural prosthetic implants to function reliably over the lifetime of an implant recipient.

Preliminary Results—A computer-based monitoring system has been developed that permits monitoring of leakage currents between an insulated wire and a saline soak bath. Leakage currents in the fA range can be reliably measured, although the measurement may take as much as 2 days to allow transients to settle and to acquire adequate statistics. Eight commercially available polymers used for wirecoating are presently undergoing biased soak tests to evaluate leakage through the insulation. Of these, two materials (Teflon and a polyester) have shown leakage currents of below 1-2 pA/per cm^2 for over 1 year in soaking at potentials of plus and minus 5 V. This corresponds to a shunt resistance of about 100 million megohms per cm of 25 micron diameter connecting wire. Test chips that contain comb patterns have been insulated with a silicone polymer. These devices have maintained impedances of greater than 10 teraohms (10 trillion ohms) between conductors for over 6 months in a saline soak environment.

[124] Development and Evaluation of Safe Methods of Intracortical and Peripheral Nerve Stimulation

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—The evaluation of the effects of electrical stimulation on neural and surrounding tissues is the principal focus of this research project. The investigators are also evaluating the safety and effectiveness of silicon microcircuit stimulating probes and new biomaterials as they become available.

Results—Small elongated cysts containing red blood cells have been found in the cerebral cortex of animals near the sites of microstimulating electrode tips. It is felt that electrode insertion and/or movement can produce damage to small blood vessels. The reason these microhemorrhages were not previously seen was because the tissue was not collected until several weeks after electrode insertion. This allowed macrophages time to clear out the erythrocytes, with subsequent collapse of the cysts.

Recent Publications Resulting from This Research

Histologic and Physiologic Evaluation of Electrically Stimulated Peripheral Nerve: Considerations for Selection of Parameters. Agnew WF et al., Ann Biomed Eng 17:39-60, 1989.

[125] Studies of the Electrochemistry of Stimulating Electrodes

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—The objective of this research is to develop and evaluate electrochemically-safe stimulating electrodes for use in neural prostheses.

Results—New methods of applying activated iridium surfaces to stimulating electrodes have been developed. The corrosion properties of 316 LVM stainless steel have been studied as a function of the voltage across the electrode-electrolyte interface. Some tentative "electrochemically-safe" operating limits have been established.

Recent Publications Resulting from This Research

Impedance of Hydrated Iridium Oxide Electrodes. Aurian-Blajeni A et al., Electrochim Acta 34:795-802, 1989.
Physicochemical Characterization of Sputtered Iridium Oxide. Aurian-Blajeni A et al., J Mater Res 4:440-446, 1989.

[126] Cultured Neuron Probe

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—The objective of this research is to determine the feasibility of establishing direct and specific inputs to, and outputs from, the mammalian central nervous system (CNS). This would be accomplished by establishing connections between cultured neurons and target neuronal populations in the CNS, by developing and evaluating a brain probe containing the cultured neurons, and electrodes for recording and stimulating them.

Progress—Rat neonatal hippocampal cells have been cultured on glial cells. Test wells simulating brain probes have been fabricated, and rat cervical ganglion cell neurites successfully grow out of the wells.

[127] Stimulating Electrodes Based on Thin-Film Technology

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—The goal of this research is to develop multichannel arrays of stimulating electrodes situated along the shank of a thin probe, capable of stimulating multiple small populations of cells in the central nervous system. Micromachining in silicon permits construction of arrays with electrode dimensions and spacings that will permit highly selective stimulation of small populations of neurons. Active probes will be developed that integrate the electronics for 16 stimulators into the back of the probe.

Progress—Using activated iridium stimulating sites, charge delivery of greater than 3 mC/cm^2 has been achieved. Passive probes with electrode surface areas

ranging from 1,000 to 8,000μ^2 have been fabricated and characterized *in vitro*. Probes with five electrodes along the shank have been evaluated acutely *in vivo*. Design of the active electronics for a 16-channel probe has been completed.

Future Plans/Implications—Fabrication of the probe is expected in the coming year. This probe will permit simultaneous control of the current levels at 16 electrode sites along the shank at an 8-bit level. The circuitry occupies about 6.4 mm^2 at the back of the probe.

Recent Publications Resulting from This Research

Batch-Fabricated Thin-Film Electrodes for Stimulation of the Central Auditory System. Anderson DJ et al., IEEE Trans Biomed Eng 36:693-704, 1989.

[128] Single-Channel Microstimulator for Functional Neuromuscular Stimulation

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose/Methodology—This project seeks to develop and evaluate implantable, single-channel, untethered microstimulators for functional neuromuscular stimulation. The individual microstimulators will be small enough to be implanted by expulsion through a hypodermic needle. Up to 32 individually-addressable stimulators will be powered and controlled by a single external coil. The implanted stimulator will consist of iridium electrodes fabricated at the ends of a micromachined silicon base. On this base, a power-and-control receiving coil, a charge storage capacitor, and a receiver-stimulator integrated circuit chip will be mounted. A glass capsule will cover these elements and will be hermetically bonded to the base.

Progress—During the past year, hermetic bonding of the Pyrex glass cover to the silicon oxide/nitride passivated silicon base has been demonstrated using anodic bonding. Hermetic encapsulation has also been demonstrated at thin-film conductive feedthroughs. Circuit blocks for portions of the stimulator have been designed and simulated in preparation to fabrication. A waffle structure is being investigated to increase the current carrying capacity of the electrodes. Using class E amplifier circuitry at 1 MHz, relatively efficient power transfer to the receiver coil has been demonstrated.

[129] Multichannel Multiplexed Intracortical Recording Arrays

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Purpose/Methodology—Penetrating microelectrodes with multiple recording sites for simultaneous, chronic recording of single unit activity from large numbers of neurons in the central nervous system (CNS) are desired by neural prosthesis researchers who need long-term connections with neurons for prosthetic control signals. This project aims to develop an implantable, multiple recording site probe suitable for chronic recording. Passive probes that contain five recording sites along the shank will be evaluated *in vivo*. Active probes containing up to 32 sites along the shank(s) will be fabricated and tested.

Progress—Over 20 different passive probes have been fabricated. Shank widths of 100 to 150μ for the standard probes and widths of 15 to 30μ for the nanoprobes have been fabricated. Shank lengths of up to 4.7 mm have been produced, as have probes with up to six shanks. Histopathological evaluation of nanoprobes implanted in guinea pigs for 5 weeks show minimal tissue reaction at distances greater than 10 to 15μ from the probe. Probes that incorporate a ribbon cable with the probe have recently been produced. These probes will be evaluated *in vivo* during the coming year. Probes that contain active

electronics at the back of the probe for three channels of amplification have been fabricated and used for chronic recording of single unit activity in the guinea pig. A 10-channel active probe that has amplification and multiplexing at the back of the probe has been fabricated and tested *in vitro*.

Recent Publications Resulting from This Research

Scaling Limitations of Silicon Multichannel Recording Probes. Najafi K, Ji J, Wise KS, IEEE Trans Biomed Eng 37:1-11, 1990.

Strength Characterization of Silicon Microprobes in Neurophysiological Tissue. Najafi K, Hetke JF, IEEE Trans Biomed Eng 37:474-481, 1990.

[130] Electrodes for Functional Neuromuscular Stimulation

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—Percutaneously-implanted intramuscular electrodes can provide smooth, rapid, and precise control of hand grasp in spinal cord injured individuals. The goal of this project is to improve percutaneous intramuscular electrodes and lead wires for use in functional neuromuscular stimulation to achieve reliable operation of a system utilizing up to 16 electrodes over a period of at least one year.

Results/Implications—Gold-coated stainless steel wire insulated with Teflon™ has been evaluated for strength, ductility, electrical resistance, and resistance to corrosion under stimulation. Test electrodes in five cats have shown good survival rates. Histological examination of the tissue surrounding implanted electrodes has shown considerable variation along the length of the electrode, suggesting that localized contaminants on the electrode are responsible for reactivity. A pulse clamp method has been developed to measure electrode charge storage capacity.

[131] Dynamic Properties of Electrically Stimulated Muscles

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Sponsor: *National Science Foundation*

Purpose—In order to design a high-performance, implantable functional electrical stimulation (FES) system to restore function in paralyzed extremities, it is necessary to define the muscle models for optimal controller design.

Progress/Results—We determined the dynamic model of skeletal muscles subject to isometric and isotonic conditions and to various firing rates and recruitment control strategies. We also identified the model variations of nine different muscles and the effect of tendon length on the model poles.

Recent Publications Resulting from This Research

Frequency Response Model of Skeletal Muscle: Effect of Perturbation Level and Control Strategies. Baratta RV, Zhou B, Solomonow M, Med Biol Eng Comput 27:337-345, 1989.

The Dynamic Response Model of Nine Different Skeletal Muscles. Baratta RV, Solomonow M, IEEE Trans Bio Med Eng 37:243-251, 1990.

[132] Control of Limb Joint by Co-Stimulation of Agonist-Antagonist Muscles

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Sponsor: *National Science Foundation*

Purpose—Voluntary motion of limb joint is accomplished by coactivation of its agonist and antagonist muscles. This should be duplicated when attempting to restore function to a paralyzed limb using electrical stimulation of muscles. This project investigates the patterns and function of voluntary coactivation for duplication in functional electrical stimulation (FES)-based systems.

Progress—To date, we found that the antagonist muscle is a most important organ in providing stable and regulated joint motion. First, it regulates against various external and internal disturbances, such as direction of gravity, muscle moment arm, level of force required, etc. Secondly, it provides important stability to the joint, and especially to its ligaments, preventing damage and instability.

Recent study shows that the antagonist also regulates for joint velocity, allowing fast initial acceleration of the joint, as well as terminal braking to stop the motion.

Recent Publications Resulting from This Research

The Effect of Joint Velocity on the Contribution of the Antagonist Musculature to Knee Stiffness and Laxity. Hagood S et al., Am J Sports Med 18:182-187, 1990.

[133] EMG as a Force Feedback in Electrically Stimulated Muscle

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Sponsor: *National Science Foundation*

Purpose—Force feedback is necessary if regulation of stimulated muscle force output is anticipated. Since implantation of force sensors requires traumatization of the tendon, electromyography (EMG) is considered as a parameter representing force in a closed-loop paradigm.

Progress—To date, we determined the relations between EMG and stimulated muscle force after developing a sophisticated artifact suppression system. The relations were evaluated as a function of stimulation strategies (recruitment and firing rate), contraction rate, muscle length, joint angle, and muscle moment arm. Additional work determined that the mean absolute value of the EMG is the most representative signal-processing mode for prediction of force.

Recent Publications Resulting from This Research

The EMG-Force Relations of Skeletal Muscle: Dependence on Contraction Rate and Motor Units Control Strategy. Solomonow M et al., EMG Clin Neurophysiol 30:141-152, 1990.

EMG Power Spectra Frequencies Associated with Motor Unit Recruitment Strategies. Solomonow M et al., J Appl Physiol 68:1177-1185, 1990.

[134] Computer-Controlled Orderly Stimulation of Motor Units in Various Strategies

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Sponsor: *National Science Foundation*

Purpose—The objective of this project was to develop and refine an electrical stimulation system that would allow orderly recruitment of motor units simultaneously with firing rate changes in various control strategies similar to physiological modes known to occur under voluntary contraction. Such an approach will allow

smooth force generation, drastic reduction in fatigue, and possible damage to muscles.

Results—A computer-controlled stimulation system was designed, developed, and validated in a series of experiments which explored muscle dynamic properties which were not available to date. Further development reduced the number of nerve electrodes from two bipolar cuffs into a single tripolar cuff. It was found that similar results could be obtained with intramuscular wire electrodes inserted in the motor point as well.

Recent Publications Resulting from This Research

Orderly Stimulation of Motor Units with Tripolar Nerve Cuff Electrodes. Baratta RV et al., IEEE Trans Bio Med Eng 36:836-843, 1989.

A Method for Studying Muscle Properties Under Orderly Stimulated Motor Units with Tripolar Nerve Cuff Electrodes. Baratta RV et al., J Biomed Eng 11:141-147, 1989.

[135] Modelling and Identification of Electrically Stimulated Muscle

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Sponsor: *Whitaker Foundation*

Purpose—In this project we are using animal preparations and human subject experiments to develop better models of electrically stimulated muscle. In particular, we are interested in how stimulated muscle force varies with stimulation activation, muscle length, muscle velocity, and muscle fatigue. A secondary goal is to develop rapid identification procedures for parameterizing the muscle models. Our goal is to use these models in designing controllers for FES systems which restore gait and grasp.

Progress—In a series of animal experiments we have developed a novel means for identifying the isometric recruitment curve of electrically stimulated muscle. This new method is faster by a factor of ten and provides more resolution than traditional techniques. Knowledge of the isometric recruitment curve is crucial in designing effective open- or closed-loop controllers for FES systems. We have also developed means to identify the muscle force-length and force-velocity properties using nonlinear system identification methods. These methods were tested both in simulation and in animal experiments.

Future Plans—We will continue our animal experimentation with the objective of defining and identifying parameters for minimal muscles models which are still suitable for control. We will also validate our methods in human surface stimulation experiments.

Recent Publications Resulting from This Research

Methods For Estimating Isometric Recruitment Curves of Electrically Stimulated Muscle. Durfee W, MacLean K, IEEE Trans Biomed Eng BME-36(7):654-667, 1989.

Task-Based Control with an Electrically Stimulated Antagonist Muscle Pair. Durfee W, IEEE Trans Biomed Eng BME-36(3):309-321, 1989.

Modelling Electrically Stimulated Muscle. Robbins A, Masters thesis, Massachusetts Institute of Technology, 1990.

Modelling and Identification of Electrically Stimulated Muscle. Palmer K, Masters thesis, Massachusetts Institute of Technology, 1990.

[136] Muscle Stimulation Strategies for High-Contact Density Microstimulation Electrodes

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Sponsor: *Whitaker Foundation*

Purpose—There is a striking contrast between the normal, physiologic activation of muscle by the central nervous system (CNS) and activation of a muscle by functional electrical stimulation (FES). Artificially induced contractions fatigue rapidly, are difficult to modulate for fine control, and demonstrate gross variation over short time-scales. One of the causes for this difference is the neural interface through which the

muscles are activated. The CNS has access to the motor neuron pool of hundreds or thousands of motor units per muscle which it modulates both by recruitment and by timing sequences to produce smooth, low-fatiguing contractions for finely controlled motion. In contrast, artificial stimulation is generally achieved with a single, gross electrode either wrapped around the peripheral nerve or applied over the surface of the muscle. Here, all muscle fibers are activated synchronously at high, fatiguing, stimulation frequencies to avoid muscle force ripple and with almost no control over individual motor units, resulting in an undesirable large to small motor unit recruitment order.

Recent advances in very large scale integration (VLSI) technology have led to the miniaturization of electronic components and opens the possibility of designing new neural stimulation interfaces which can contain hundreds or even thousands of electrode contacts, each of which could uniquely activate one or a few motor units. The goal of the research proposed here is not to develop this electrode technology, but rather to determine how these future, high-contact density, nerve stimulation electrodes should be used to effectively recruit muscle activation in FES applications.

Progress—During the past year we have developed an acute animal model preparation where multiple axons of the rat sciatic nerve are stimulated and isometric force is measured in the triceps surae. Our relatively crude neural interface consists of arrays of standard wire microelectrodes. We plan to use three arrays of five electrodes each for a total of 15 stimulation channels.

Future Plans—When the preparation development is complete, we will commence experiments with the objectives of: 1) comparing stimulation algorithms; and, 2) developing advanced identification methods for determining the properties of the motor unit connected to each electrode channel.

B. Upper Limb Applications

[137] Functional Neuromuscular Systems (FNS) for Upper Extremity Control

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B011-4RA)*

Purpose—The objective of this project is to implement a neuroprosthetic system which restores motor control in the paralyzed upper extremity of the high-level spinal cord injury (SCI) patient and to assess the efficacy of the system in improving the user's ability to independently perform activities of daily living (ADL) which are essential for independent functioning. The system provides controlled grasp/release by electrical stimulation of the paralyzed muscles of the forearm and hand. Clinical implementation is carried out first using a system employing percutaneous electrodes, and then progressing to an implantable receiver/stimulator system as consistent performance and usage of the hand system is demonstrated.

Progress/Methodology—*Part 1: Clinical Implementation and Evaluation.* There have been a total of 11 patients recruited into the upper extremity study, six of whom continue to be studied under our clinical protocol. Four of the active patients have been monitored extensively using a patient survey technique. Clinical evaluation of system performance has focused on four primary methods of quantitative assessment of system usage: the Standardized Object Test (SOT), the Common Object Test (COT), the patient user survey, and the Subsystem Function Test (SFT).

In the SOT, repetitive object acquisition is performed over several sequential trials, allowing us to assess standardized functional performance. The SOT detects significant changes in consistency of patient performance over time, differences in performance across patients, and differences in performance with and without the hand system. In the COT, the patient's ability to perform

various integrated activities of daily living is evaluated, allowing us to assess more advanced functional performance. The COT is a descriptive test which includes measurements of the patient's level of independence and quality of performance in performing the activities. In addition, the patients indicate their preference in performing the activities with or without the neuroprosthetic system, how important the activities are to them, and how frequently they normally perform the activities. The patient user survey was introduced in 1990 to provide further documentation of which ADL tasks the patients perform during the day, which tasks they use their system for, and how often they use the system.

The SFT has been developed to allow quantitative evaluation and documentation of the system's input-output properties, the patient's control of their hand grasp, and the frequency response of the man-machine system. This test enables us to quantify user operation during laboratory evaluation and to identify elements of the system that are affecting performance. The input to the neuroprosthesis is a command signal generated by voluntary movement of the patient's shoulder and the outputs of the system are the position and force generated by the thumb (during lateral prehension) or the fingers (during palmar prehension). For the SFT, the system's output is defined as a single parameter, formulated by summing grasp opening (position) and normalized grasp force. The SFT utilizes visual pursuit tracking tasks, in which a target track and the system's output are displayed simultaneously on a color video display. The subject is asked to match the system's output to the target track as accurately as possible. These tests are presently underway.

Part 2: Neuroprosthetic System Development and Fabrication. Progress has been made in fabricating portable neuroprosthetic systems for outpatient usage, in development of the communications and the interface between laboratory computers and the portable systems, and in fabrication of implantable systems. Almost all aspects of development are completed with the transfer of tested prototype systems to industrial manufacturers' ongoing systems.

The manufacture of in-house devices for patient usage has been completed and all systems are presently in field test. Since the industrially-manufactured system is based on this in-house system, substantial effort has gone into tracking system performance. To date, no serious flaws in the system have been reported. The majority of system malfunctions have been traced to ongoing software revisions. The last development project with respect to the existing neuroprosthesis that is in progress is the refinement of the dual microprocessor software which governs its operation.

The implant stimulator system has continued to function successfully both *in vivo* and *in vitro*. Clinical evaluation of an 8-channel system implanted in a C6 complete SCI subject indicates that it continues to function to specification. The electrodes and implant stimulator have been implanted for 4 and 2 consecutive years respectively, with no significant changes in any of the system's input/output characteristics (e.g., recruitment properties, stimulation thresholds, and electrode impedance). No new subjects have been implemented with the implant stimulator system to date.

Preliminary Results—*Part 3: Technology Transfer and Regulatory Affairs.* Three primary objectives have been accomplished in the area of Technology Transfer and Regulatory Affairs. First, FDA approval was obtained in August 1989 to carry out a study of 10 subjects with the implanted system under an Investigational Device Exemption (IDE). This protocol allows us to use the devices manufactured in-house at Case Western Reserve University for the study. Second, transfer of the external patient portable system (NPS-IV) to a local manufacturer (Life Systems, Inc., Beachwood, OH) is complete and systems delivered. Third, the fabrication of 20 implantable receiver/stimulator devices (including all electrodes, leads, and in-line connectors) by a regional manufacturer (Biocontrol Technology, Inc., Indiana, PA) is complete and the units delivered. These devices are essentially identical to those manufactured in our own facility, with equivalent fabrication guidelines having been followed. These devices are earmarked for use in future implant applications in both upper and lower extremity projects.

[138] Optimizing Myoprosthetic Management with Microcomputers

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Sponsor: *Hospital for Sick Children Foundation*

Purpose—The setup and assessment procedures employed for fitting myoelectric controls to child amputees were originally developed for adults, and are primarily implemented using subjective methods. This project evaluated old and newly developed management strategies, as well as establishing objective standards for the analysis of prosthetic operation.

We have focused on four steps that are normally performed during the fitting process. These are: 1) finding suitable muscle sites; 2) choosing a control system; 3) calibrating the control system; and, 4) training and assessing the amputee's ability to operate the system.

Methodology—During Year One, 30 amputees over the age of 6 years were tested to evaluate the reliability of a Myoelectric Control Assessment System, and to establish a database of prosthetic control measurements. Subjects in this group were asked to visit the Centre on three occasions (i.e., day 1, month 1, month 3). Two practice trials preceded testing on each visit.

Also during Year One, a Myoelectric Signal Assessment System (MSAS) was developed which encompasses the tools required by a clinician to objectively: 1) find the most appropriate muscle sites; 2) determine the amputee's suitability for a class of control systems; 3) determine the amputee's controlling myoelectric signal levels with the socket donned and weighted; 3) determine myoelectric signal variations produced during sustained muscle contractions and in various forearm positions; 4) determine antagonist muscle signal cross-talk and nonvoluntary co-contraction signals in order to minimize inadvertent activation of the prosthesis; 5) use the calculated calibration levels to calibrate the myoelectric control system; and, 6) check and verify calibration of the control system during follow-up visits and when either walk-in and mail-in service is required.

During Year Two, a second group of 19 amputees requiring refitting of their prostheses were tested to evaluate MSAS. We investigated how these procedures affected the operation of the myoelectric control system in comparison to that of the traditional procedures. This group of amputees was seen during normally scheduled fitting visits.

Results—Factor analysis of the data revealed five clear factors that most appropriately describe the performance of experienced myoelectric prosthesis users. These major measurement dimensions are: 1) Activity Factor: a measure of the total time to complete the task; 2) Undershoot: a derived measure of the amputee's ability to control the open and close functions; 3) Accuracy (or Error): a derived measure of the amputee's ability to correctly select movements in the open or closed direction; 4) Overshoot: a derived measure of the amputee's ability to precisely control the system; and, 5) Strategy: a measure of the amount of time the amputee activated the control system relative to the amount of time required to complete the task.

We have also derived a simple method for calibrating the control system which minimizes poor operation for those amputees who experience co-contraction of antagonist muscles and who also find it difficult to discriminate muscle control. This simpler method may also prove useful for calibrating the control systems used by children.

Implications—The analysis of Year Two results clearly indicate that the microcomputer method resulted in performance levels which matched the traditional methods implemented by an experienced therapist using observations and amputee feedback. More importantly, the microcomputer method provided more complete information which documented the amputees' abilities, facilitated and complemented the clinicians' observations, and overcame the problems experienced with the traditional methods based on trial and error. In addition, case analyses indicated that for instances involving misleading feedback from the amputee, the microcomputer method was superior for calibrating the control system. This was particularly evident for subjects experiencing high levels of co-contraction of antagonist muscle groups, who then could not differentiate the switching levels of their control systems.

[139] Neural Net Control of FES-Aided Grasp Restoration in Quadriplegics

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Purpose—Neural nets show promise for controlling complex, nonlinear systems. By connecting large numbers of "neuron" elements in interconnected nets, through an iterative learning process, the controller can converge to a desired system behavior. In this project we are evaluating the use of neural net controllers in FES-aided quadriplegic grasp restoration devices. In the past, these systems have proved difficult to control, and require a lengthy period of trial and error calibration to determine appropriate stimulation sequences to restore useful grasp. By monitoring hand position and force output, a neural net controller should be able to iterate automatically to a set of acceptable stimulation sequences.

Progress—We are beginning a series of experiments using a simplified model of controlling stimulated thumb motion in a single degree-of-freedom. We have built an apparatus to measure thumb motion resulting from surface stimulation. We have also developed simulations of appropriate neural net controllers. An important objective of these experiments is to determine the length of time required to iterate to an acceptable control.

Future Plans—We will measure complete hand motion and force output due to stimulation using an Exos Dexterous Hand Master and instrumented objects. In a series of computer-controlled experiments, we will test the ability of neural nets to control FES grasp.

[140] Evaluation of Command Channels for Upper Limb Neural Prostheses

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Purpose—Upper limb neural prostheses use electrical stimulation to restore grasping function to quadriplegics. The user of such a system must have a signal channel to command the device to open and close the hand. The most common method for generating a command signal is to monitor motion of the contralateral shoulder. This project has the objective of: 1) exploring the limits on performance of upper limb neural prostheses imposed by the command channel; 2) evaluating novel command channels such as electromyogram (EMG); and, 3) developing assessment and prescription systems for optimizing command channel parameters for a particular user.

The basic approach is through an emulator of a functional electrical stimulation (FES) hand-grasp system. Subjects sit in front of a personal computer and the appropriate command channel being tested is monitored. For example, a sternum-mounted position sensor is used to detect shoulder position. An animation of a grasping task appears on the personal computer display. As the subject moves his real hand, the hand on the screen moves, and as the subject manipulates his command channel, the animated hand opens and closes. The subject performs a simulated grasping task by manipulating and moving objects appearing on the screen. Performance is measured by the speed and dexterity with which the task is performed. The advantage of this emulator system is that parameters of the command channel can be changed while keeping the task constant, resulting in efficient cross comparisons.

Progress—We have conducted a series of tests of shoulder as a command channel in both able-bodied and quadriplegic subjects. The results demonstrate that optimal combination of shoulder-command channel parameters such as direction and range vary with individual subjects. This suggests the need for a prescription system which can evaluate each subject and determine the appropriate combination. We have also conducted a preliminary study of EMG as a command channel using able-bodied subjects. Results show that sufficient information transfer

is possible with EMG but at a reduced bandwidth. We are completing a redesign of our system hardware and software to ease the procedure for transferring our system into a low-cost prescription system and to enable 3-D tasks.

Future Plans—We will conduct a series of experiments in disabled human subjects to evaluate their ability to control tasks in 3-D. We will also generalize this research approach to quantify the ability of disabled individuals to control multi-degree-of-freedom devices such as robotic aids, machine tools, and automobiles.

Recent Publications Resulting from This Research

Shoulder Movement as a Command Control Source for Upper Limb Neural Prostheses. Zahradnik J, Masters thesis, Massachusetts Institute of Technology, 1989.

[141] Prevention of Secondary Complications in Spinal Cord Injury by Electrical Stimulation: Wrist Extensor Strengthening

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The objective of this project is to develop an electrical stimulation protocol that will test the effectiveness of functional electrical stimulation (FES) and biofeedback in obtaining recovery of wrist extensors in the C4-C6 quadriplegic individual. Subjects for this research study are newly spinal cord injured quadriplegic individuals (less than 1 month postinjury) exhibiting manual muscle grade of greater than poor minus for biceps and/or anterior deltoid, and manual muscle grade of zero to fair for radial wrist extensors. Following intake evaluation and testing, all subjects will receive traditional splinting. The four groups consist of: 1) a control group; 2) a treatment group receiving only biofeedback; 3) a treatment group receiving only electrical stimulation; and, 4) a group receiving both biofeedback and electrical stimulation.

Methodology/Progress—Subjects with a total of 26 limbs being studied have successfully completed participation in this study. As of July 1990, data from 20 limbs have been analyzed with a two-way analysis of variance (ANOVA). The dependent variables were: 1) amplitude of voluntarily produced EMG (i.e., change in microvolt read-outs); 2) manual muscle test; and, 3) evaluation of four graded self-feeding abilities—*a*) feeds self without use of wrist support (may use utensil); *b*) light finger foods (popcorn, chips); *c*) moderate finger foods (cookie, 1/2 sandwich); and, *d*) drink from 12 oz soda can.

The following scoring system was used: 0 = patient unable to perform; 1 = patient able to perform, not functional; 2 = patient able to perform functionally in clinic and other settings. These measurements were taken at the beginning and at the end of the 6-week test period.

Results—So far, the results of this statistical analysis do not show any significance for effectiveness among groups or interaction. It is unfortunate that two individuals in one group dropped out before final data could be collected. Thus, while the number of limbs was actually 28, the missing 2 data points caused 6 others to be omitted because of the need for equal sample sizes in each cell in this design. Data collection is still underway.

[142] Prosthetic Sensory Transducers

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Purpose—Prosthetic force and position transducers that can be attached to the fingers and hand are being developed for use by individuals with an insensate hand. This research is directed toward making practical prosthetic sensors which are properly calibrated, miniaturized, and protected (encapsulated) for use in evaluating conscious

sensory feedback and closed-loop control of functional neuromuscular stimulation systems both in the laboratory and in tasks of daily living.

Progress—A multi-element force sensor that permits evaluation of the force at multiple points over the thumb has been developed. A skin surface-mounted angle transducer that measures joint angle relatively independent of radius of curvature has been developed, and is being tested. Psychometric measurements to provide a mapping between force and position and electrical stimulation have been completed.

[143] Functional Neuromuscular Stimulation for Restoration of Hand Grasp

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—The feasibility of neural prostheses based on functional neuromuscular stimulation (FNS) for the restoration of both palmar (pinch) grasp and lateral (key) grasp in spinal cord injured, quadriplegic individuals has been demonstrated over the past several years. The principal goal of this research project is to develop and evaluate ways to enhance the utility of FNS systems for hand grasp.

Specific tasks include: 1) evaluating closed-loop control systems, utilizing newly-developed artificial force and position transducers in quadriplegic human subjects; 2) determining the feasibility of integrating FNS wrist stabilization, FNS elbow control, and surgical procedures such as tendon transfer and arthrodesis into the FNS grasp system; 3) developing a biomechanical model of the hand for use in evaluating advanced FNS systems; and, 4) evaluating multiple degree-of-freedom closed-loop FNS control systems.

Progress—A computer-based system has been developed to allow advanced control algorithms and closed-loop control to be evaluated on individuals who are using a percutaneous system for FNS. Data on muscle moment arm length as a function of joint angle are being collected for muscles of the hand. This information will eventually be used to develop a model of hand function that can be used to test new approaches to hand control. Implementation of an extended physiological perception (EPP) system for coupling information about hand force and hand position back to the contralateral shoulder has begun. Initial studies have been directed at characterizing shoulder muscles that can be electrically stimulated.

Recent Publications Resulting from This Research

Elbow Extension in the C5 Quadriplegic Using Functional Neuromuscular Stimulation. Miller LJ, Peckham PH, Keith MW, IEEE Trans Biomed Eng 36:771-780, 1989.

Implantable Functional Neuromuscular Stimulation in the Tetraplegic Hand. Keith MW et al., J Hand Surg [Am] 14A:524-530, 1989.

Synthesis of Hand Grasp Using Functional Neuromuscular Stimulation. Kilgore KL et al., IEEE Trans Biomed Eng 36:761-770, 1989.

Electrode Characterization for Functional Application to Upper Extremity FNS. Kilgore KL et al., IEEE Trans Biomed Eng 37:12-21, 1990.

[144] Effects of Nerve Electrical Stimulation on Upper Extremity Recovery Following Quadriplegia

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Purpose—Patients with cervical spinal cord injury commonly recover at least one segmental level of spinal cord function following their injury, and maximizing this recovery of arm and hand function can greatly enhance independence. Standard therapy for this weakness includes range-of-motion exercises to maintain joint

mobility, strengthening exercises to reverse muscle atrophy, and functional training to restore functional use. Therapy may also include electrical stimulation to weak muscles. This nerve stimulation is clearly of benefit later in the recovery process in reversing muscle disuse atrophy. However, other recovery mechanisms are active during the early post-injury period, including resolution of upper motoneuron weakness, resolution of neurapraxia, and motor axon sprouting with reinnervation of denervated muscle fibers. The effects of nerve electrical stimulation on these early neural mechanisms are not well-known. This study examines the time-course of strength recovery in upper extremity muscle groups following cervical spinal cord injury, and the effects of nerve electrical stimulation on that recovery.

Methodology—One weak muscle group is selected for nerve electrical stimulation for 4 weeks, in addition to standard treatments. Another comparably weak muscle group in the opposite extremity receives only standard treatments. The rate and final level of strength recovery are compared for the electrically stimulated and the non-stimulated muscles.

Results/Future Plans—To date, 7 patients have completed the nerve electrical stimulation protocol. This data is being analyzed and additional subjects are being recruited. This study will document whether early nerve stimulation is beneficial in promoting recovery of strength. The long-term objective is to maximize functional recovery by directing appropriate therapies toward active recovery mechanisms.

C. Lower Limb Applications

[145] Computer Models for Designing FES Systems for Paraplegic Mobility

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B289-2RA)*

Purpose—The long-term objective of this project is to develop computer tools to assist the rehabilitation team in designing functional electrical stimulation (FES)-control systems so that paraplegics can stand, walk, and perform other lower-extremity motor tasks.

Methodology—The dynamical equations of motion of the body segments for standing, walking, and other motor tasks important to the paraplegic will be generated and implemented on a computer. The musculoskeletal system will be modeled (including the paths of the lower-extremity musculotendon actuators) and the dynamics associated with these actuators will be computer-coded. A procedure will be developed to generate computer codes so that models can easily be constructed, thus making it possible to study a variety of lower-limb motor tasks. Computer codes will be generated to display, on a workstation, the computer simulations of FES-induced standing, walking, and the other motor tasks.

Progress—Using computer models and simulations, we have done the following: 1) studied the dynamical properties of FES-induced standing and walking; 2) found a feedback control for stimulating muscles that ensures stability of standing to large perturbations, and of walking to small perturbations; 3) studied standing, and the single- and double-support phases of walking; 4) determined the minimum number of muscles and strength needed to effect normal gait; 5) implemented, on a graphics workstation, an "animated" display of the lower-extremity musculoskeletal system to visualize the simulated standing and walking paraplegic; and, 6) studied how to establish an interactive computer environment for the development of models of neuro-musculoskeletal motor tasks.

Results—Our simulations suggest that FES-control automatic feedback controllers can be designed which would stimulate muscles in paraplegics to enable them to stand

for a long time without fatigue while they use their hands functionally to manipulate objects. Restoration of normal gait, however, will be much more difficult. We believe that a combination of FES and orthoses is necessary to restore functional ambulation to paraplegics in the near future.

Future Plans—We propose to provide clinical FES teams with interactive machine-independent software that will enable each team singly, or all teams in concert, to design FES controllers for pedaling, standing, and walking.

Recent Publications Resulting from This Research

An Interactive Graphics-Based Model of the Lower Extremity to Simulate Tendon Transfer Surgeries. Delp S et al., in Advances in Bioengineering, 1989 ASME Winter Annual Meeting in San Francisco, BED-15:167-168, B. Rubinsky (Ed.). New York: The American Society of Mechanical Engineers, 1989.

Muscle and Tendon: Properties, Models, Scaling, and Application to Biomechanics and Motor Control. Zajac FE, CRC Crit Rev Biomed Eng 17(4):359-411, 1989.

Paraplegic Standing Controlled by Functional Neuromuscular Stimulation: Part I—Computer Model and Control System Design. Khang G, Zajac FE, IEEE Trans Biomed Eng BME-36:873-884, 1989.

Paraplegic Standing Controlled by Functional Neuromuscular Stimulation: Part II—Computer Simulation Studies. Khang G, Zajac FE, IEEE Trans Biomed Eng BME-36:885-894, 1989.

Restoring Natural Gait to Paraplegics through Functional Neuromuscular Stimulation: A Feasibility Study. Yamaguchi GT, Zajac FE, in Issues in the Modeling and Control of Biomechanical Systems, 1989 ASME Winter Annual Meeting in San Francisco, DSC-17:49-57, J.L. Stein, J.A. Ashton-Miller, M.G. Pandy (Eds.). New York: The American Society of Mechanical Engineers, 1989.

Modeling FES Actuation and Control of Multisegmental Limb Movements. Yamaguchi GT, Zajac FE, in Proceedings of the American Control Conference, San Diego, 1990.

A Musculoskeletal Model of the Human Lower Extremity: The Effect of Muscle, Tendon, and Moment Arm on the Moment-Angle Relationship of Musculotendon Actuators at the Hip, Knee and Ankle. Hoy MG, Zajac FE, Gordon ME, J Biomech 23:157-169, 1990.

[146] Improvements in the Gait and Strength of Post-Surgical Patients Due to Electrical Stimulation

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Purpose—The purpose of this study was to ascertain the effects of electrically-elicited co-contraction of the thigh muscles on isokinetic thigh muscle strength and gait in patients after anterior cruciate ligament surgery. Ten patients who had undergone ligament reconstruction were randomly assigned to one of two treatment groups: neuromuscular electrical stimulation (NMES), and volitional co-contraction (VC).

Methodology/Results—After 4 weeks of rehabilitation of the quadriceps femoris and hamstring muscles, a post-test design was employed to assess the differing effects of the two rehabilitation regimens on muscle strength and gait parameters. Muscle performance analysis consisted of isokinetic measurements of peak torque and average torque at different degrees of knee flexion. The average torques and the peak torques were found to be significantly greater in the NMES group than in the VC group. There were no significant differences between the two groups in any measures of the hamstring muscle performance.

Gait analysis was performed with the use of the WATSMART optoelectronic motion analysis system and the TRACK rigid body analysis software. There was a significant difference in stance time between the involved limbs as a function of treatment. The cadence and walking velocity of the NMES group were greater than that of the VC group. The stance phase knee flexion and extension data for the involved knee were qualitatively different from that of the uninvolved knee in all subjects. Quadriceps femoris muscle performance measures and knee flexion excursion during stance were highly correlated. The decrease in quadriceps femoris muscle performance found in patients after anterior cruciate ligament reconstruction was significantly attenuated by the addition of NMES to the treatment regimen.

[147] Fatigue of Paralyzed Muscles Activated by Functional Electrical Stimulation in Paraplegics

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Sponsor: *Israel Ministry of Defense; Segal Foundation; Technion VPR Fund; Montreal Biomedical Research Fund; Archie Micay Biomedical Research Fund*

Purpose—The objectives of this project are to study noninvasively the process of fatigue of paralyzed muscles of paraplegic patients, externally activated by functional electrical stimulation (FES).

Progress/Methodology—Dynamometers were designed and constructed for on-line monitoring of the decaying muscle force output under both isometric and isotonic conditions. The myoelectric activity was measured by means of surface electromyogram (EMG) of the fatiguing muscle. The metabolic state of the activated muscle was obtained by using noninvasive P-31 magnetic resonance spectroscopy (MRS) of the stimulated muscle, on a Gyrex 2T magnetic resonance imaging (MRI) instrument. Each of the myoelectric and metabolic measurements was coupled with the measurement of the muscle force output. In this way, correlations between force and EMG, as well as force and metabolic state, were obtained.

Results—Under sustained stimulation conditions, the force in the quadriceps muscle was found to decline to 50% of its initial value after the first minute, to 30% after the second minute, and to 25% after the third. From the EMG parameters measured, the peak-to-peak amplitude of the compound muscle action potential (CMAP) was selected to represent the myoelectric activity of the muscle, and was found to decrease in the course of fatigue. Our results on EMG-force correlation reveal a nonlinear correlation (power curve-fit), between these two parameters in the first 60% portion of the fatiguing process.

P-31 MRI measurements included the high energy compounds (adenosine triphosphate [ATP] and phosphocreatine [Pcr]). The inorganic phosphate (Pi) level at rest was too low to be detected on this machine. However, FES induced a pronounced variation in these components: as Pcr levels declined, the Pi peak increased with fatigue. The intracellular pH could be calculated from the chemical shift between the Pcr and Pi peaks; this parameter was found to decrease during fatigue and to increase back towards its rest value in the recovery process. One additional peak was found to build up during fatigue, that of phosphor-mono-ester (PME), reaching values even higher than those of Pi. Correlation of this force with each of the metabolic factors was found to be strongly nonlinear.

The recovery of the muscle following fatigue could be established by using the very same parameters. Among all the metabolic parameters analyzed, PME had the slowest rate of disappearance, with the longest half recovery time. This parameter, which accounts for the long-term fatigue of the system, could thus be considered as an indicator of full recovery of the muscle.

Recent Publications Resulting from This Research

Recruitment, Force and Fatigue Characteristics of Quadriceps Muscles of Paraplegics Isometrically Activated by Surface FES. Levy M, Mizrahi J, Susak Z, J Biomed Eng 12(2):150-156, 1990.
The Time-Dependent Output of Paraplegic's Quadriceps Muscles Activated by FES. Levy M et al., in Advances in External Control of Extremities X, 555-569, D.B. Popovic (Ed.), Nauka, Yugoslavia, 1990.

[148] Functional Tasks Restored in Paralyzed Man Using Electronic Orthotics: Neural Network Controllers for FNS Locomotion

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Purpose—Recent advances in artificial neural network technology indicate that this is a promising technique for use in functional neurmomusclular stimulation (FNS) control systems. Neurobiological studies have demonstrated some of the intrinsic neuron properties and interneuronal connections used by biological systems

to generate cyclic motions. Models of these neural networks have been used to simulate the locomotion of insects as well as other cyclic motor acts. Such pattern-generating networks may be particularly useful in lower extremity FNS systems. With the eventual incorporation of feedback and learning, such networks may provide significant improvements to current lower extremity FNS systems. The purpose of this work is to explore the potential of pattern-generating neural networks for producing stimulation patterns to be used for lower extremity FNS locomotion. Preliminary studies reported here were directed at designing pattern-generating neural networks which exhibit specific characteristics that may be important characteristics for the FNS control system.

Progress/Methodology—Our preliminary studies have focused on the development of three pattern-generating networks: one which allows for straightforward modulation of cycle period, a second which generates a six-phase oscillation to correspond to six phases of gait, and the third network incorporates reflexes and modulates their effects with phase of oscillation.

The first network consists of two neurons in mutual inhibition. The intrinsic properties of the neurons and their influence on each other result in a oscillatory pattern of activation; the period of this oscillation can be varied by changing one parameter of each of the neurons. Such a network may be useful as the core of a locomotion controller so that step-cycle frequency could be varied. The second network consists of six neurons, each oscillating at the same frequency, but phase-shifted with respect to each other. The timing of the activation of the neurons is such that each of the neurons would correspond to one of six phases of gait (left-weight acceptance, push-off and swing; and right-weight acceptance, push-off and swing). The third network incorporates modulated reflexes into the oscillatory pattern of activity. A stimulus given to the network results in a change in the nominal cyclic pattern, but the nature and magnitude of the change depend upon the phase during which the stimulus was given. This modulation of reflexes might be useful, for example, to elicit stronger flexion if the leg is flexing when the stimulus arrives, or stronger extension if the leg is weightbearing when the stimulus arrives.

Future Plans—Future work will focus on applying these neural network pattern generators to models of FNS-activated neuromuscular systems. Issues to be considered will be multi-joint coordination, incorporation of feedback for event detection and servo-type control, and adaptation to make adjustments for changing system parameters.

[149] Functional Tasks Restored in Paralyzed Man Using Electronic Orthotics: FNS Walking in Paraplegics

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Purpose—The long-term goals of this study are: 1) to develop practical neuromuscular stimulation systems (FNS) to restore ambulatory movement in paralyzed people; and, 2) to use functional neuromuscular stimulation (FNS) as a motor retraining tool in paretic individuals. Our objective is to develop current percutaneous FNS systems into implantable, reliable, cosmetic, self-adjusting devices which will provide paralyzed people with ambulatory mobility in the home and workplace.

Progress/Methodology—After several earlier electrode designs were found to be short-lived, we developed a compound helix electrode connected to a percutaneous lead for chronic muscular stimulation. This electrode is implanted without a surgical incision by probing the target muscle with a 26-gauge needle and then inserting the electrode to the motor point through a 15-gauge cannula. Postimplantation electrodes are monitored and removed if there is: 1) a persistent infection or rejection reaction; 2) an increase in impedance indicating breakage of the electrode or lead; or, 3) an adverse change in muscle response to electrical stimulation (e.g., decrease in muscle force, pain during stimulation, stimulation of unwanted muscles).

The compound helix design has been used for 2 years. Forty-five electrodes have been implanted in the ankle flexor/extensors (soleus, gastrocnemius, tibialis

anterior muscles) with 80% surviving; 215 in the hip flexors/adductors/abductors (quadriceps, sartorius, tensor fasciae latae, gracilis, adductor longus, posterior adductor, gluteus maximus, gluteus minimus, and gluteus medius muscles) with 68% surviving; 82 in the hamstring muscles with 55% surviving; and 37 near spinal roots to stimulate the quadratus lumborum, erector spinae, and iliopsoas muscles with 37% surviving.

This study currently involves six paraplegic subjects. All of them can stand using their FES systems. Three of them can walk, one consistently over 300 meters at a speed of 0.5 m/sec with a walker for support. He can climb stairs with two rails independently. On stairs with one rail, he needs a crutch or a person for support. He can do side-stepping and has used his FNS system outside the lab with assistance to overcome structural barriers.

We have made preparations to implement a one-hand support standing system using an 8-channel implantable stimulator. This involved modifying our external controllers to power and control the Case Western Reserve University (CWRU) 8-channel implantable stimulator/receiver, and refining the surgical protocol and testing hardware through animal implantation.

We are collecting normal data with the Motion Analysis (MA) system for comparison with paralyzed subject data. We developed software to synchronize MA data with stimulation patterns, to provide a tool for improving the programming of ambulatory functions in subjects.

During our study of muscle fatigue due to electrical stimulation, we observed increased muscle fatigue with reduction in rest time between stimulation bursts, with increase in stimulation frequency, and with increased resistance to motion.

We found control of knee flexion at the heel strike and during push-off to be critical to progression in walking; temporal coordination of muscle activity in certain phases of the gait cycle to be critical to less than 20 ms; and, that a delay determined by trial and error produced smoother walking than triggering of the next step by foot pressure sensors.

We measured the intra-compartmental pressure in the anterior tibial compartment in five paraplegic subjects during continuous and cyclic stimulation. The compartment pressure was within normal ranges both before and after FNS exercise.

Results—Over a 10-year period, we have evaluated three generations of a portable percutaneous FNS system in 24 subjects, including 15 paraplegics with complete neurological injuries and 5 hemiplegics/hemiparetics. The FNS system provided standing capability for all of the paraplegic subjects and nine of them were able to walk. In addition, three relatively new subjects are expected to be able to walk in the near future. All hemiplegic/hemiparetic subjects demonstrated improved mobility with FNS.

Recent Publications Resulting from This Research

Metabolic Responses to Arm Ergometry and Functional Neuromuscular Stimulation. Edwards BG, Marsolais EB, J Rehabil Res Dev 27(2):107-114, 1989.

A Double Helix Electrode for Functional Electrical Stimulation. Scheiner A, Marsolais EB, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 373-374, 1990.

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A Portable 32-Channel Data Collector. Ferguson KR, Borges GA, Kobetic R, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 391-392, 1990.

[150] Functional Tasks Restored in Paralyzed Man Using Electronic Orthotics: Implant Devices for Lower Extremity FNS Systems

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B193-4RS)*

Purpose—The purpose of this research was to develop intramuscular electrodes to be used with an implantable stimulator.

Progress/Methodology—We developed an electrode for skeletal muscle stimulation designed to be implanted without a surgical incision. The electrode is manufactured by forming stainless steel, Teflon-insulated wire into a double helix configuration. This geometry provides stress relief to the electrode during muscle contractions. The electrode tip is augmented with stainless steel barbs to increase anchoring strength. For implantation, we mount the electrode on a 26-gauge needle and insert it through a 13-gauge needle to the motor point. We then

pass the lead (7-stranded 316L wire wound around a prolene core and placed inside a Silastic sheath) subcutaneously (with a 16-gauge passing tube) to a connection site where it is attached to an implantable-stimulator lead. We fit the proximal end of the electrode with a "pin and spring" type connector to make the electrode/stimulator connection.

A second intramuscular design was developed at Case Western Reserve University (CWRU) with collaboration from this project. The major difference between this electrode and the one described above is that the stimulating end has a polypropylene anchor for stability and deinsulated wire wrapped around the Silastic tubing for the conducting surface. Two studies were conducted to evaluate this design *in vivo*. In the first, we conducted preliminary animal evaluation involving the implantation of four surgically-implanted intramuscular electrodes and four epimysial electrodes connected to an implantable neuromuscular stimulator. The intramuscular electrodes all operated properly throughout the 14-week study, producing functional responses indistinguishable from the epimysial electrodes. In the second study (still active) we implanted eight electrodes (connected to implantable stimulators) in two dogs (four for 1 year and four for 2 years). No problems (electrode breakage, infection, etc.) have been observed.

We have developed a modified arthroscope technique to increase the accuracy of electrode insertion for functional neuromuscular stimulation (FNS). The current FNS technique for determining the optimum site for percutaneous electrode implantation is to stimulate the target nerve or muscle with a 26-gauge probe using anatomic guidelines. This method lacks accuracy because there is no direct visualization of where the probe or electrode sits unless an open incision is made. Using a clear polyvinyl fluoride sheath over an arthroscope inserted through a 1 mm stab incision, a technique similar to that described by Okutsu, we have demonstrated the feasibility of visualization of the sciatic nerve and its branches in the feline model. The nerves can be identified by their distinctive vascular markings and followed with minimal disruption of the soft tissues. In this way, individual branches can be identified and targeted for instrumentation, allowing selective stimulation of specific muscle groups. We further demonstrated the practicality of percutaneously implanting an electrode beside a target nerve under direct visual control with the scope.

Implications—The polyvinyl fluoride sheath over the arthroscope allows effective soft tissue scoping by gently opening a path through the connective tissues and providing an unimpeded field of view. This alone offers diagnostic advantages for the study of nerves. For our needs, it offers a minimally invasive means of electrode insertion under direct visual control. Soft tissue scoping in the feline model is a practical procedure that has applications for diagnostic studies on nerves and will allow accurate FNS electrode placement.

Recent Publications Resulting from This Research

The Design and Evaluation of a Surgically-Implanted Intramuscular Electrode for Use with an Implantable Stimulator. Memberg WD, Masters thesis, Case Western Reserve University, 1989.

Using a Modified Arthroscope to Augment the Accuracy of Electrode Insertion for Functional Neuromuscular Stimulation. Doyle J, Scheiner A, in Proceedings of the 18th World Congress Societe Internationale de Chirurgie Orthopedique et de Traumatologie, Montreal, 1990.

[151] Functional Tasks Restored in Paralyzed Man Using Electronic Orthotics: FNS Systems for Gait Assist and Motor Retraining in Stroke and Head Injury Subjects

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Purpose—The long-term goal of this study is to determine the efficacy of using functional neuromuscular stimulation (FNS) in the rehabilitation of hemiparetic and hemiplegic patients. The hypothesis to be studied is: FNS used for gait and motor retraining in paretic stroke patients will improve motor control, the speed and cosmesis of gait, and the safety of walking, stair-climbing, and other functional maneuvers.

Results—Systems using intramuscular electrodes with percutaneous leads have been developed and tested in paretic patients who demonstrated significantly improved

function. In additional preparatory work, this laboratory has reported therapeutic use of implanted electrodes controlled through computerized stimulation patterns of gait for stroke subjects. We found improved gait and endurance for a mildly impaired subject; and for a severely involved (12-months poststroke) nonambulator, the percutaneous FNS system resulted in the ability to ambulate 80 feet numerous times, using a hemi-walker.

Restoration of function for hemiplegics. Case study video data showed that with FNS, functional status improvement was achieved for 100% (4/4) of the hemiplegic subjects treated. Functional improvement was from wheelchair mobility to ambulatory status of various levels.

Restoration of function for head injury diagnosis. Case study videotape showed, for a head-injured subject, a progressive 9-month improvement in motor function, ambulatory status, and functional activities of daily living (ADL). Hip flexor strength improved from gravity-eliminated joint movement to effective hip flexion against gravity during gait swing phase. Motor function improvements included achievement of right and left swing phases without FNS. Ambulatory status improved from wheelchair mobility to ambulation with Lofstrand crutches and stand-by assist. Functional ADL capabilities included stair ascension without FNS and descension with FNS. A home assessment was made and goals have been formulated for home use of the FNS system. Because of the possible confounding variable of spontaneous recovery, one or two case studies cannot conclusively determine the efficacy of FNS for treating head injury motor deficits. However, improvements in motor deficits occurred in this case, in close temporal relationship to specific FNS treatment, suggesting a cause and effect relationship.

FNS and movement retraining for hemiparetics. Case study videotape and kinematic data indicated gait pattern improvement following a combination of treatment with FNS-driven movement, movement retraining, and FNS-controlled movement retraining. Improvements were documented for swing-phase ankle dorsiflexion, hip and knee flexion, and pelvic control, during slow cadence (56 steps/min) gait with conscious attention on the part of the subject. Further study will determine if the new pattern can be learned for faster walking speeds and for use at the subconscious level.

Future Plans/Implications—Ongoing and future studies have the following goals: 1) specify and test a movement difficulty scale and treatment progression protocol; 2) design and test FNS drive and assisted exercises for retraining isolated joint movement; 3) identify decision-making criteria for creation of exercises which improve motor control; 4) adapt the FNS system with improved user/system interfaces for those with visual and upper extremity disability; and, 5) test the practicality of a totally-implanted FNS system for future use in a clinical setting. Outcome measures used to identify benefits will be gait analysis, muscle function evaluation, testing of functional maneuvers, and evaluation of the ease of use of the FNS system by patients and therapists. This research will yield new information regarding the benefits of specific FNS-driven and assisted exercise, and decision-making criteria for designing rehabilitation FNS exercise for individual cases for clinical use.

Recent Publications Resulting from This Research

FNS Application for Restoring Function in Stroke Patients. Marsolais EB, in Proceedings of the 11th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Seattle, 829-830, 1989.

Percutaneous FNS Implementation to Improve Ambulation in Stroke Subjects. Kobetic R, Marsolais EB, in Proceedings of the 12th Annual RESNA Conference, New Orleans, LA, 103-104, 1989.

Stroke Gait Correction with Multi-Channel FNS. Marsolais EB et al., in Proceedings of the 36th Annual Meeting of the Orthopaedic Research Society, New Orleans, LA, 553, 1990.

[152] Nonlinear Controllers for FES-Aided Gait

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Purpose—One of the difficulties in controlling FES-aided paraplegic gait is that muscles are nonlinear, time-varying actuators. We are evaluating the effectiveness of advanced nonlinear controllers to control these systems.

Progress—In a series of simulation studies and a preliminary series of human experimentation, we have implemented adaptive and nonadaptive forms of sliding controllers, a control structure which is well-suited to