IV. Spinal Cord Injury

A. General

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

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Purpose—This project investigates the relative effectiveness of computerized electromyographic (EMG) biofeedback, functional electrical stimulation, and physical and occupational therapy in various combinations for the purpose of restoring function in persons with long-term spinal cord injury.

The project is based on previous research from our laboratories using a sophisticated form of computerized EMG biofeedback as a specific operant conditioning procedure for establishing more efficient use of the nervous system, specifically the spinal cord, in persons with long-term spinal cord injury.

The results of this previous work had suggested three very important phenomena: 1) for people with cervical spinal cord injuries it is possible that neural repair can take place over periods of time longer than 6 months or 1 year; 2) the brain is not efficient at utilizing these repaired neurons in the spinal cord; and 3) existing alternate pathways from the brain to extremity muscles in quadriplegics are viable but not functional prior to biofeedback identification and utilization. Furthermore, it appears that specific training using operant conditioning methods with advanced computerized biofeedback technology could increase the brain's efficiency in utilizing these neurons resulting in greater voluntary motor neuron control over paretic muscles. In addition, our research with functional electrical stimulation had indicated that in cases where there has been significant atrophy to muscle tissue, computerized functional electrical stimulation could restore these muscles. It had also appeared that some of these late spinal cord injury cases had the potential for regaining function with physical and occupational therapy techniques.

Progress—The present study was designed to test the relative effectiveness of EMG biofeedback, functional electrical stimulation (FES), and physical and occupational therapy (PT and OT) in specific combinations for the purpose of restoring function in long-term spinal cord injured people. Eighty persons with spinal cord injuries at level C3 through C7 with resulting quadriparesis are matched according to level of injury, muscle strength, EMG recruitment, and activities of daily living, then randomly assigned to one of four groups: 1) EMG Biofeedback-FES; 2) EMG Biofeedback-OT, PT; 3) FES-OT, PT; and 4) OT, PT-OT, PT.

Eight weeks of each treatment modality are provided two to three times per week in sequence. Measurements of muscle strength, EMG recruitment, an EMG test utilizing needle electrodes, active and passive range of motion, and functional performance in activities of daily living are taken prior to the start of the experiment, after each treatment segment, and at the 6-month followup.

EMG recruitment is measured by a specially designed multiprocessor computer system. This unit also provides the EMG biofeedback on

several muscle sites simultaneously according to preestablished operant conditioning procedures. Passive and active range of motion is measured with goniometers and standard testing procedures. Functional activities of daily living are assessed by instruments specifically designed for this study. The OT and PT treatments are provided by therapists with expertise in spinal cord injury according to standard treatment protocols for increasing function. FES is provided by a computerized system according to preestablished protocols.

Currently, persons with chronic cervical level spinal cord injuries are participating in all phases of the project, from initial screening through the therapeutic modalities and clinical treatments.

Future Plans—The implications of this study could be wide ranging, considering the current theory underlying the treatment of the spinal cord injured, which obviates providing rehabilitation to the long-term paralysis victim. In addition, the study will identify the relative contributions of biofeedback, functional electrical stimulation, occupational and physical therapy, and will determine the most effective combination of these for restoring function in long-term spinal cord injury.

Microwave Myelography: A Feasibility Analysis

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Purpose—A means for noninvasively imaging the spinal cord and subarachnoid space would be a marked improvement over the currently used invasive forms of myelography for the evaluation and followup of spinal cord injuries resulting from trauma or degenerative disease. Although the bony protection provided by the vertebrae prohibits the use of X-rays or ultrasound for this type of imaging, the intervening bone would not be as great a barrier to the use of microwaves in this region of the body.

Future Plans—This project will evaluate the feasibility of using both wide-band continuous-wave techniques and impedance-sensitive reflection techniques for the two-dimensional microwave mapping of the spinal subarachnoid space. This investigation will primarily involve the analysis of relevant literature based on the results of a literature search and a patent search. Based on this initial analysis, an experimental protocol will be developed to further establish the feasibility of this approach for application to noninvasive myelography. It is anticipated that these efforts will then serve as a basis for the preparation of a larger proposal for a study that will better support the investigational equipment and time required for completed evaluation.

Corticospinal Systems

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Purpose—Interruption of the corticospinal tract, the major pathway descending from the cerebral cortex to the spinal cord, results in immediate loss of skilled movement. Although some recovery of motor function is possible after corticospinal lesions, hand movements are permanently impaired. For that reason this pathway has long been recognized as an impor-

tant motor pathway for generation and control of forelimb movements.

Progress—Preliminary studies suggest that 1) the corticospinal tract originates from wider areas of the cerebral cortex than previously recognized, an observation that is relevant to patients with motor difficulties after spinal cord injury, and 2) a special component of the corticospinal tract terminates only in upper segments of the cervical spinal cord.

Preliminary Results—This research is designed to confirm and expand these observations, which have important clinical implications. Severe neck injuries often damage lower segments of the cervical spinal cord and result in paralysis of hand and lower body movements. This type of injury interrupts many long descending pathways as well as short pathways that interconnect spinal cord segments. Early results suggest that the component of the corticospinal pathway that terminates in upper segments of the cervical cord is not damaged by most neck injuries. Thus, this pathway could provide normal signals for the control of paralyzed limbs.

Future Plans—In the future, after these studies have provided the crucial basic information of the corticospinal tract, one might attempt to restore hand function with, for example, nerve bridges that cross the injury site.

Role of Intrinsic Motoneuron Properties in Abnormal Rate Regulation After Spinal Injury

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Purpose—Incomplete spinal cord injury often produces weakness of voluntary muscle contraction below the site of the lesion, a weakness usually attributed to a loss of descending excitatory input to those neurons responsible for activating the muscles, namely, the motoneurons. As a result, fewer motoneurons can be voluntarily activated and those that can be activated are not driven maximally. Previous work has demonstrated that even over the range that motoneurons are activated, their patterns of activation are abnormal so that muscle tension is produced inefficiently; in an animal model of spinal cord injury, evidence was strong that motoneuron response properties are altered by spinal lesions.

In the new research the nature and mechanism of this alteration of motoneuron discharge properties will be investigated.

Progress—Research is proceeding according to plan, although some of the experiments proved more difficult than had been expected. During the first 6 months, work focused on the characterization of motor unit discharge patterns, and the related disturbances of EMG and force production after surgical lesions of dorsolateral spinal white matter. Twenty preparations have been studied, 13 of which were used for motor output studies and 7 for studies of afferent mechanisms.

Work has begun on the effects of contraction-induced receptor discharge in spinal motor output after lesions of dorsolateral spinal white matter. In five cats, fatigued MG muscle induced more powerful inhibition of synergistic muscles than did unfatigued muscles; this inhibition is more potent when it follows a dorsolateral quadrant spinal lesion. This must be confirmed by additional preparation.

Future Plans—Further clarification of the importance of the motor unit type will be by application of new methods that are being developed. Inasmuch as only one to three axons can be followed in any one animal, it will require greater effort to accumulate an adequate sample.

An Implantable Sensor for Two-Degree-of-Freedom Position Transduction

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Purpose—The investigators will design, develop, and evaluate a permanently implantable device to provide two independent control signals for use as a command control and feedback source in upper extremity assistive systems for high-level spinal cord injuries.

The implanted device will measure relative skeletal position changes of opposing bony segments. Movement will be generated by voluntary movement of that part of the body over which the user retains voluntary control. This information will allow the user to control hand positions and force a functional neuromuscular stimulation (FNS) hand assist system (e.g., in C4 injury or lower, the shoulder; in C6 or lower, the wrist).

Alternatively, the system may be used in a position feedback loop, such as for control of wrist position by FNS in a C5-level quadriplegic patient. The implanted devices can also be used to control upper extremity prostheses and powered wheelchairs.

Trial of a 5-Lipoxygenase Inhibitor in Experimental Spinal Cord Injury

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Purpose—It appears that shortly after spinal cord injury, cholesterol and certain phospholipids begin to break down, which compromises the ability of the cell membrane to act as a selective barrier. Moreover, certain products of the phospholipids are converted into potent compounds (prostaglandins and leukotrienes) that greatly reduce blood flow to the injured area and cause the injured segment to swell and become inflamed.

These early biochemical changes and subsequent pathological events (ischemia, edema, and inflammation) seem to contribute significantly to the nerve damage that results from severe injury to the spinal cord. This secondary injury can be treated by drugs, providing that all the attendant pathological events are fully understood.

This research is to examine the breakdown of these membrane phospholipids and the production of prostaglandins and leukotrienes using an experimental model of spinal cord injury compression of the spinal cord of a cat.

The second part of the study is to test the ability of a new powerful inhibitor of leukotriene production (L652, 343) to prevent the formation of these compounds after injury to the spinal cord.

Circulation and Metabolism in the Decentralized Spinal Cord

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Purpose—This research is designed to describe the degrees of adjustment between metabolic needs and blood supply in sensory and motor centers of the spinal cord in the absence or presence of a complete transection, and to determine how this adjustment is maintained in

situations in which complications such as spasticity and autonomic disreflexia are present. In addition, we will establish which areas in the spinal cord become metabolically hyperactive when such complications develop.

Progress—To date the researchers have found correlations between spinal cord energy metabolism, a direct index of neuronal activity, and motor behavior in paraplegic rats. This phenomenon is now being studied in greater depth with the hope that it will provide better insight into the mechanisms of spasticity.

Preliminary Results—A more detailed quantitative analysis of limb movement in the spinal cord of injured rats was added to the study, as well as a study of metabolism in the paraplegic rat. Preliminary results have been most interesting, but the researchers report that it is too soon to make a definitive statement about these early findings.

Retrospective Analysis of the National Spinal Cord Injury Care System Database

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Purpose—Systematic and comprehensive management of acute spinal cord injury (SCI) is directed towards reducing morbidity and mortality, increasing life function capacity, and minimizing costs of care associated with this catastrophic condition. Accordingly, it is desirable to establish a mechanism to evaluate performance of the organized management system addressing desired outcomes in such a way that the impact of the system compared to other presystem or parallel nonsystem activities is clear.

Furthermore, assessment of system performance over time is essential to establish patterns of behavior which may then serve as a basis for implementing practice, policy, or programmatic change(s), if necessary.

This study is evaluating, retrospectively, the performance of the Model Regional Spinal Cord Injury Care System, emphasizing quantifiable outcome variables.

Progress—Overall system performance is being evaluated using appropriate statistical procedures. The evaluation methodology includes, but is not restricted to: 1) the relative proportion of all new SCIs brought into and managed by federally sponsored model systems in a given year (i.e., national capture); 2) average time between injury and system admission (i.e., mean time into system); 3) post-admission death rate (i.e., mortality); 4) post-admission medical complication and surgical procedure rate (i.e., morbidity); 5) level of post-discharge independence, place of post-discharge residence, vocational outcome (i.e., life function); 6) post-injury hospitalization experience (i.e., length-of-stay and re-admission experience); and 7) costs characterized on the basis of appropriate epidemiologic variables to facilitate comparisons between early admission and delayed admission patients.

Preliminary Results—Data indicate that day one admissions have substantially shorter acute care lengths of stay. Overall lengths-of-stay are also substantially lowered in day one admissions. The mortality experience of system patients is markedly lower than that reported by others. Specific epidemiologic and demographic characteristics of patients admitted to the system are available in a recently published book, *Spinal Cord Injury: The Facts and Figures*, available from the National Spinal Cord Injury Statistical Center.

Future Plans—In the coming year we will conduct research on the sponsors of SCI hospitalization expenses and post-discharge care and their relationships, if any, to outcome variables. In addition, we plan to examine the effects of aging on spinal cord injury.

Devices to Assist Transport, Diagnosis, and Treatment of Acute Spinal Injury Patients

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Purpose—This project is part of a program to improve treatment of spinal cord injury (SCI) patients during the earliest phase of rehabilitation—from the time that SCI is diagnosed in a hospital emergency room, through transport to a specialized spinal center, and whenever the patient must be moved under traction for therapeutic or diagnostic procedures such as computerized tomography (CT) or magnetic resonance imaging (MRI).

Apparatus for moving an acute SCI patient must satisfy the size, strength, and weight constraints of helicopter transport, and the need for X-ray transparency without compromising stability of the spine. There is evidence that at least part of the neurological deficit accompanying SCI is due to factors other than the initial trauma, such as continuing compression of the spinal cord by displaced vertebrae and progressive edema.

It is imperative to begin fracture reduction as early as possible after injury and to maintain it uninterrupted during transport. Furthermore, if appropriate therapies to ameliorate neurological damage were to become known, treatment could be begun during transport before the onset of irreversible deficit.

Equipment for moving patients in traction existed previously, but it was often inaccurate, sensitive to acceleration, and poorly adapted to the newer helicopters being employed to good effect in transporting acute patients. After admission to a spinal care center, the patient is commonly placed on a turning frame or kinetic bed to assist respiration and minimize pressure sores. This apparatus frequently does not succeed in eliminating adverse vascular, respiratory and skin effects and entails lifting the patient whenever he/she is moved for further treatment.

Progress—Constant-force traction was provided by a prototype laminated-wood backboard delivered to Santa Clara Valley Medical Center (SCVMC) for trial in 1980. A second design was developed in 1982 using different criteria which emphasized manufacturing techniques.

The current series of transport backboards are made of orthogonal carbon-fiber/epoxy skins over a curved foam core. Bending tests demonstrated stiffness equal to a flat steel plate of the same thickness. The traction device has nine cables each producing a nominal tension of 2.6 pounds; internally, two constant-force springs apply torque to a common output spool, on which 18 inches of cable are wrapped. Unacceptable friction (greater than 0.5 lb) in the first model was corrected, but a modification of an earlier design having a single spool with extension limited to 6 inches should yield smoother force output at less cost.

Because stainless-steel skeletal fixation devices interfere with radiography of potential head injuries, they are to be replaced with a carbon-fiber halo or tongs. Although much lighter than stainless steel, the composite matrix requires a larger diameter plastic outer screw with a metal core of minimum X-ray cross-section. The tongs have integral keyholes for attachment of traction cables, reducing weight and length. A lateral head-restraint having motion constrained to be parallel to the backboard axis can be retrofitted on the backboards.

Integration of the backboard with long-term patient support is to be accomplished by enclosing the patient and backboard in a sectional cylinder which can be rotated. Rotation may be either periodically, as a turning frame, or continuously, as a kinetic bed, with the patient in prone, supine, or lateral position. Accelerometers and load cells are used to measure actual forces transmitted to the patient. Unused cylinder sections are held by a separate crane.

A grant from the Paralyzed Veterans of

America has supported the fabrication and delivery for clinical trial of six carbon-fiber/epoxy backboards with improved constant-force traction devices. Arrangements have been made to commercially produce small lots of additional backboards for expanded trials. Several carbon-fiber/epoxy halos and tongs were made and laboratory tested; the tong design is a good candidate for mass production. The cable-output traction device is clinically usable, but the proposed third design iteration may result in a simpler, semidisposable product.

New backboard/traction systems have been in use by SCVMC and by the "Life-Flight" helicopter group at Stanford University since February, 1985. During the following 8 months, SCVMC's Department of Rehabilitation and Physical Medicine had 47 acute SCI patients (admitted less than 7 days after injury). Of the 27 cervical injuries, all but two were placed on the backboard for CT scanning (exceptions had early halo/vest stabilization).

The Life-Flight team transported more than 40 SCI patients (lower spine as well as cervical) and occasionally used the backboard for other injuries, specifically arm and multiple trauma.

In January 1986, another backboard/traction set was placed with Rancho Los Amigos Hospital, for use by the UCLA-"MedStar" helicopter. An instructional videotape has been prepared for training of such multicenter users.

Documenting and Utilizing Programs that Provide Community Adjustment and Independent Living Services for Persons with Spinal Cord Injury

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Purpose—The purpose of this project is to collect and maintain information about independent living and community adjustment programs that serve spinal cord injured people, to provide an effective means of communicating new ideas and experiences among individuals operating these programs, and to provide access to a dependable source of technical assistance related to these programs.

Progress—Nonexperimental survey methodology is being used. The data from earlier administrations of this survey were summarized in frequencies according to specified categories of interest, and some correlation studies were done to determine trends in independent living program development. Data from project surveys were used to assess the types of services being provided for persons with spinal cord injury, and the source and amount of funds being used. The survey instrument has been revised, expanded, and pilot tested. It will be readministered to all identified independent living programs. Data will be analyzed using univariate and multivariate techniques and will be compared to earlier findings.

In order to facilitate use of the information that is developed, the project maintains a computerized bulletin board, a telephone communication network with all the extant independent living programs, and approximately 150 additional individuals. Knowledge transfer strategies depend on the specific topic or set of information, but they usually involve extensive reviews of existing literature, interviews with independent living program administrators, staff members, and consumers, and supplementary reviews by additional experts both in and out of the independent living field.

Preliminary Results—The findings of this work are being disseminated in several forms. A directory listing all identified independent living programs is revised on an ongoing basis. A registry profiling 164 independent programs in detail is available to spinal cord injury treatment programs, persons with spinal cord injuries, and others interested in independent living. An analysis of the data listed in the registry has been prepared as a monograph in the

ILRU Occasional Paper series. A new edition of the registry and analysis will be published after completion of the current survey. The ILRU project is continuing its training, networking, and information dissemination activities in the area of independent living and maintains an ongoing effort to update its databases.

Assessment, Development, and Clinical Applications of Strategies to Coordinate Services for Spinal Cord Injured Clients After Discharge

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Purpose—There are three major project objectives: 1) assess current strategies employed after discharge to achieve psychosocial adjustment and productive lives for spinal cord injured persons; 2) develop and test new strategies or refine current strategies to enhance outcomes post-discharge; and 3) facilitate the integration of new and tested strategies into the service delivery system at The Institute for Rehabilitation and Research (TIRR) and disseminate the strategies to other appropriate sites. Methods include interviewing rehabilitation professionals and spinal cord injured clients to assess needs and resources, collaborating with service providers to develop and test improved strategies to address unmet needs, and assisting integration of the improved strategies into the service delivery system. Approximately 150 spinal cord injured persons more than 14 years of age who were admitted to TIRR for comprehensive rehabilitation from 1979 to the present will be interviewed. Rehabilitation professionals from a variety of disciplines will be interviewed and/or serve as an advisory committee.

The benefits expected from this project include meeting needs early to avoid compounding problems, utilizing resources efficiently by tailoring programs to meet the actual needs of clients, and improving rehabilitation outcomes by providing appropriate services.

Progress—A protocol was developed for interviewing rehabilitation professionals. Eight professionals from six rehabilitation disciplines were asked to describe the needs of SCI clients following discharge, the resources available to meet those needs, and the systems for linking the clients with the appropriate resources. Eight broad categories emerged: health; activities of daily living; living arrangements; vocational; psychosocial; transportation; financial; and societal issues and policies. The list of needs described by the professionals was used to develop an interview protocol for use with clients to determine needs, utilization of formal and informal resources, links, resources, satisfaction with resources, and special difficulties encountered in meeting their needs.

Preliminary Results—From a pool of approximately 600 eligible clients, 136 interviews have been completed. Data collection will continue throughout 1986. Preliminary analyses of the first 97 interviews indicated major differences in selected variables when subjects were grouped by race, sex, marital status, extent of injury, and time since injury. For example, 31 percent of the whites were employed. Males had an average monthly income of $1156; females averaged $611. Married clients were more likely to live in a house, have family as visitors, and be concerned with the psychosocial aspects of sexual problems than were the unmarried clients.

We are working collaboratively with the National Spinal Cord Database and the RTC project on Outcome Studies Pertinent to the National Model Spinal Cord Injury System. Requested preliminary data have been shared with the medical director, outpatient clinic, and vocational department.

Longitudinal Assessment of Physical Therapy Factors in the Rehabilitation Process that Affect the Quality of Life of Spinal Cord Injured Persons

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Purpose—The primary objectives of this study are to: 1) determine the importance of the patient's compliance in performing weight-shifts in a wheelchair to prevent breakdown of skin in weightbearing areas of the body; 2) improve the criteria and procedures for selecting which spinal cord injured patients should be braced and trained to become functional ambulators; and 3) determine the incidence, characteristics, and outcome of pain complaints in patients with severe spinal cord injury.

Progress—Reductions in the original level of funding necessitated reduction in the scope of the project being undertaken. Considering the resources and expertise available, we elected to defer action on objective 1 and concentrate on objectives 2 and 3. As we complete work on objectives 2 and 3, we will redirect staff effort to pursue objective 1. Patients being studied are individuals who received severe injuries to their spinal cord resulting in paraplegia or quadriplegia.

A total of 70 patients between the ages of 20 and 58 years with paraplegia have been studied in pursuing objective 2. A list of patient attributes and equipment services associated with the gait training program was compiled for each patient. Follow-up evaluations 6 months to several years after bracing are being made to assess brace utilization. We expect the results to improve the criteria for selection of those who will remain users of braces.

A total of 135 patients between the ages of 11 and 80 years (74 with quadriplegia and 61 with paraplegia) are being studied in pursuing objective 3. Information on pain status, method of treatment, and reported success of treatment is gathered on a weekly basis until time of discharge. We expect the results to illustrate trends in etiology and resolution of pain complaints. An additional 25 patients are participating in a prospective study of the effectiveness of specific therapeutic interventions in relieving specific types of pain complaints.

Preliminary Results—Thus far we have: 1) analyzed the results of brace utilization by 70 patients who received bilateral knee-ankle-foot orthotic devices and drafted a report of the findings; 2) begun pilot studies with an orthotist to devise a simplified, modular lightweight orthotic device for early bracing and gait training; 3) gathered and categorized data concerning the pain complaints made by 135 patients with spinal cord injury during their initial hospitalization for comprehensive rehabilitation; 4) examined correlations between population variables, etiology of injury, level and neurological completeness of injury, and location and suspected etiology of pain complaint; 5) documented the status of each pain complaint at the time of discharge; 6) identified therapeutic procedures that patients reported as most effective in alleviating individual pain states; and 7) initiated a prospective study (N currently = 25) designed to test the relative effectiveness of specific therapeutic interventions in alleviating particular types of pain.

We plan to continue analyzing these data to look for relationships that will shed additional light on the mechanisms responsible for the state of discomfort and the mechanisms responsible for alleviation of discomfort.

Longitudinal Assessment of the Utilization of Upper Extremity Assistive Devices Prescribed for the Spinal Cord Injured Quadriplegic

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Purpose—Upper extremity assistive devices are frequently prescribed during the rehabilitation of SCI quadriplegics. However, though these devices are used daily during hospitalization, they may be discarded once the individual leaves the hospital environment. The primary objectives of this study are to: 1) identify functional categories of assistive devices prescribed for quadriplegics; 2) determine utilization and satisfaction with those devices 1 year and 2 years following rehabilitation; and 3) determine factors responsible for discarding devices.

This is a longitudinal prospective investigation in two parts. Phase I of this study is a review of 102 quadriplegics to determine functional categories and frequency of prescription of upper extremity assistive devices. Phase II employs an oral questionnaire of 75 patients to ascertain utilization of and satisfaction with devices prescribed during a first rehabilitation experience. This questionnaire is administered 1 and 2 years following discharge.

Satisfaction is determined using a Likert scale. It addresses the device characteristics of fit, cosmesis, and mechanical and functional performance. Factors that result in discarding a device include improved physical function, mechanical failure, alternative solutions, modification of living arrangements, noncompliance, and device outgrown or unattractive.

Progress—To establish the functional categories and frequency of prescription of upper extremity assistive devices, 102 charts of quadriplegic patients were reviewed. Feeding devices were prescribed to 49 percent, splints and slings to 87 percent, dressings to 30 percent, hygiene/grooming to 22 percent, and communication devices to 20 percent. An oral questionnaire developed to determine device utilization and level of satisfaction was administered to 77 former patients 1 year following their first rehabilitation experience. For these patients 262 devices had been prescribed. Sixty-seven devices were for feeding. One hundred and sixteen patients received splints and slings; 18 received dressings; 19, hygiene/grooming; 17, communication; and 8, miscellaneous. At the end of 1 year, 151 devices (58 percent) were still in use (36, feeding; 75, splints and slings; 7, dressings; 8, hygiene/grooming devices; 17, communication devices; and 8, miscellaneous). On a scale of 1-5 (5 being the most satisfactory), those devices still in use were rated an average of 4.24. The most frequently cited reasons for discarding devices were improved physical function and alternative solutions found. Discarded devices represented a cost of $5400 or 35 percent of the total expenditure for all devices.

Of the original population, 43 were queried 2 years post-rehabilitation. Of the devices prescribed during their first rehabilitation experience, 71 percent were still in use 2 years later with an overall level of satisfaction of 4.24 with retained devices. The remaining 22 subjects will be queried and the data recorded.

The overall costs of devices prescribed for subjects during their hospitalization were $17,831. The costs of devices discarded during the first year following rehabilitation were $5,860 or 32 percent of the total expenditure.

Preliminary Results—The results of this study have already influenced some of the prescription practices within the occupational therapy department. Therapists consider less expensive short-term devices rather than ordering the most expensive models of the same item. Furthermore, the OT staff is relying more on department-owned equipment from which patients may be weaned prior to discharge. Data on specific devices are being scrutinized to establish practical guidelines for their continued prescription.

Outcome Studies Pertinent to the National Model Spinal Cord Injury System

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Purpose—This project encompasses three studies, two retrospective and one prospective, aimed at providing additional evidence about the effectiveness of the National Model Spinal Cord Injury System Project administered previously by RSA and currently by National Institute of Handicapped Research (NIHR).

The two retrospective studies capitalize upon existence of the common database established by the national systems. One study is an attempt to demonstrate that the highly advanced system of care practiced at the Royal Perth Hospital in Australia results in better patient outcomes than obtained in the less advanced care systems in the United States. The second study is concerned with documenting post-rehabilitation outcomes for quadriplegic patients who, at discharge from inpatient rehabilitation, require ventilatory assistance.

The prospective study will compare the outcomes of two groups of patients. One consists of patients whose acute and rehabilitation care was provided by the Texas South Central Regional Spinal Cord Injury (T/SCRSCI) System. It is comprised of four acute care hospitals in the Houston-Galveston area and The Institute for Rehabilitation and Research (TIRR) as the rehabilitation setting. The second group will consist of patients who were discharged from the same four acute care hospitals but who did not receive rehabilitation services at TIRR.

Data for TIRR patients are being obtained in a companion project entitled, "Assessment, Development, and Clinical Application of Strategies to Coordinate Services for Spinal Cord Injured Clients After Discharge." Data for non-TIRR patients will be obtained during home interviews using an adapted form of the interview used in the companion project.

Progress—During the project's first year, the U.S.-Australian systems study directed by Dr. William Donovan was completed, and an article was published in *Paraplegia* in 1984. In that study, one data set reflected experience with 65 consecutively admitted patients who were cared for during 1979 and 1980 in the spinal cord unit at the Royal Perth Rehabilitation Hospital in Perth, Western Australia. A second data set pertained to 1606 US patients who had been cared for in one of the regional systems during the same year.

Preliminary Results—The results indicate that decubitus ulcers, atelectasis, pneumonia, pulmonary emboli, ulcers of the gastrointestinal tract, and heterotopic ossification all occurred more frequently in the US group. The difference was particularly marked for decubitus ulcers and urinary tract infections. These outcomes demonstrate that the sooner spinal cord injured patients are referred to a center capable of meeting all their needs, the less likely it is that they will develop complications that slow rehabilitation progress.

Analyses for the study concerned with post-rehabilitation outcomes for ventilatory dependent quadriplegics have been completed, and an article has been accepted for publication in *Archives of Physical Medicine and Rehabilitation*. Compared with ventilator independent quadriplegics, ventilator dependent individuals had a longer duration of hospitalization, less self-care capability, more hours per week of hired attendant care, and more hours of actual physical assistance per day. The groups did not differ significantly in terms of duration of inpatient rehabilitation, duration of rehospitalization, and vocational or prevocational status at the time of followup.

The prospective study comparing outcomes for system and nonsystem patients is continuing. Complete data are available currently for 136 system patients and 25 nonsystem ones.

Development of Reconditioning Exercise Program for Patients with Paraplegia

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Sponsor: *National Institute of Handicapped Research*

Purpose—The overall purpose of this project is to develop a testing methodology and to evaluate an exercise training program for the physical reconditioning of the patient with paraplegia. The expected outcome is the formulation of guidelines for the prescription of exercise and the documentation of the effects of physical conditioning programs for the patient with paraplegia. Male paraplegics between 18 and 50 years of age, free from disorders which contraindicate relatively high levels of exercise, and who have reached a suitable status in their rehabilitation process, will be selected for participation in the project. A minimum of five patients is to be studied in each of five categories of training modalities.

Each participant will be initially administered an exercise stress test consisting of interviews, blood sample for biochemical analyses, resting ECG, physical exam, and a graded arm ergometry test using an interrupted steady-state protocol. Expired gas will be collected during the last minute of each exercise phase. The training program modalities will consist of prescribed unsupervised exercise at home or exercise in a gamefield especially designed for wheelchair patients. Other patients will perform prescribed exercise under supervision in the laboratory or gamefield. Initially, the exercise period is for 5 to 10 minutes increasing to 20 to 25 minutes with training. Training will be 3 to 5 days per week for 3 to 12 weeks. After training, the patient will be subjected to a post-training study in which the testing of the first study will be repeated.

Progress—Two arm exercise training ergometers have been purchased and are currently being used in prescribed home training programs. One patient has procured his own trainer and is following a prescribed exercise program at home.

The assessment of the cardiovascular tolerance to physical work with arm exercise has been extended to 30 untrained paraplegic males, some more than one time for a total of 41 tests. In addition, 13 healthy males have been tested in the same manner, a total of 22 tests, for obtaining comparative data. Nine of the paraplegic males and seven of the healthy males have been tested in the gamefield for evaluation of energy requirements of specific athletic events. To date, five paraplegic males have been placed on a prescribed training program at home. Two patients on home programs were previously trained in the laboratory with extension of the program at home. Healthy subjects have been tested in the laboratory using leg and arm exercise protocols for comparing the mechanical efficiency of different muscle groups.

Vocational Evaluation for Quadriplegics with a High School Education or Less

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Sponsor: *National Institute of Handicapped Research*

Purpose—The project objective is to develop a vocational evaluation process that will expand the vocational options for spinal cord injured persons who are quadriplegic, who have a high school education or less, and who have either a limited work record or a job history incompatible with current functional limitations. Methodology involves: 1) identifying and documenting jobs that can be performed by the described population group; 2) conducting a comprehensive review of existing vocational assessment tools and determining relevance of the tools to

assess the potential of quadriplegics; 3) selecting and organizing a meaningful process; 4) incorporating the model vocational process into the Vocational Department's service delivery program; and 5) evaluating the effectiveness of the model evaluation process.

The expected outcome of this project is the establishment of a more effective and realistic vocational evaluation process that can be used to assess the job potential of quadriplegics. The project also may have implications for other groups with severe physical impairments.

Progress—The developmental phase of the project has been completed. Of 12,278 jobs listed in the *Directory of Occupational Titles*, 497 were judged to be options for quadriplegics with a high school education or less. Labor market surveys were conducted to identify the occupational outlook among these jobs. Findings indicated that jobs in clerical and sales occupations were the largest in demand. The outlook for jobs in machine trades and benchwork occupations was discouraging.

A total of 334 vocational assessment tools were reviewed, and 105 of these tools were determined by the project staff to be within the physical capabilities of persons with quadriplegia.

The project staff has matched those assessment tools that appear to measure the duties of those jobs that have the best occupational outlook for the future. This has resulted in a vocational evaluation process that includes psychometric testing, work sample testing, simple work modifications, training in compensatory techniques, and limited situational assessment.

A Center for Acute Spinal Cord Injury: Epidemiology and Economic Costs of Spinal Cord Trauma

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Sponsor: *National Institutes of Health*

Purpose—This program is a multidisciplinary approach to the problems of spinal cord injury (SCI). Included are an epidemiological study of spinal cord injury in Connecticut with delineation of incidence, cause, evaluation of treatment, and cost comparison of treatment in an organized SCI center and community hospitals in Connecticut. We will determine when stability of neurological function occurs; study animal models of spinal cord injury, evaluating various treatment modalities; observe the effects of trauma on spinal cord blood flow and metabolism; determine spinal column stability through studies that include computer models of primate spinal column; determine post-traumatic alteration in blood-spinal cord barrier and the effect of biogenic amines on the resulting neurological dysfunction and ultrastructural analysis of impact trauma; develop a model system in larval lamprey (*Petromyzon Marinus*) for study of regeneration in the central nervous system; study the formation of regeneration in the central nervous system, the formation of peripheral neuroma and the factors controlling its size, and the olfactory bulb reestablishment of central synaptic connection following injury.

B. Medical Treatment

A Collision Block Technique for Micturition Assist: Preclinical Studies

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Sponsor: *Paralyzed Veterans of America Spinal Cord Research Foundation and the National Spinal Cord Injury Association*

Purpose—This animal study is in two parts: 1) to test the long-term effectiveness of implanted collision block electrodes in producing relaxation of the external urethral sphincter; and 2) to evaluate the long-term effects of the collision block stimulation and electrodes on peripheral nerve tissue to estimate the risk a patient must assume if a collision block electrode device were implanted.

The study is an important next step in an effort that addresses urinary complications of bladder paralysis, a major health problem facing a majority of patients with spinal cord injury.

Progress—The initial design and construction phase of collision block electrodes has been completed. Testing the short-term efficacy of the device in producing the type of pudendal nerve excitation necessary at the urethral sphincter is now underway. Some progress has been made in demonstrating that the initial design is sufficient to cause a response by the sphincter indicative of that needed to produce a collision block.

Future Plans—Short-term testing will continue, aimed at a best design for long-term implantation in animals.

A Laboratory Test to Predict and Monitor Bone and Skin-Related Complications in Spinal Cord Injured Patients

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Sponsor: *Paralyzed Veterans of America Spinal Cord Research Foundation*

Progress—This research project is in its second year. Patient intake has been completed. The investigators monitor the list of clinic appointments. All patients who make an appointment are sent a letter asking them to bring a 24-hour urine sample when they come. This is followed by a phone call two days before the appointment. In addition to the above procedures, a general mailing is sent to all the patients in the project accompanied by a plastic sample bottle. Twenty-four hour urine samples are collected from any patient readmitted to the Institute for any reason. We hope that as a result of these efforts, each of the investigators will have several urine samples on each patient recruited into the project.

Preliminary Results—Medical charts are reviewed to assess the temporal relationship between the appearance of clinical symptoms of bone and skin related complications and the urinary concentration of the galactosyl hydroxylysine and glucosyl-galactosyl hydroxylysine, respectively. Results are following the same general trend that was found in the first year of the study. The excretion of both glycosides increases after the trauma, reaching a peak at approximately 3 months after injury and then gradually declines, reaching control values sometime between 6 months and a year after injury, if there are no complications. If there are skin or bone related complications, the excretion of the glycosides remains high.

Future Plans—Work is proceeding according to schedule. When the project is completed, the investigators expect to have enough data for a valid statistical analysis which should contribute valuable information on collagen metabolism in spinal cord injury.

Skin Temperature in Spinal Cord Injury Related to Skin Breakdown

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Purpose—This study applies an existing technology—liquid crystal thermography—to detect early signs of skin breakdown and thus reduce the incidence of decubitus ulcers that are a major cause of morbidity and even mortality in spinal cord injured patients.

First, skin temperature pressure response norms in nonspinal cord injured and at-risk SCI subjects will be established. Then a controlled study of the at-risk group will compare thermogram-monitored and nonmonitored groups, using commonly practiced protocols. It is believed that the thermally monitored group will build skin tolerance faster and with less risk of skin complications than the control group.

A substudy on cushion selection will determine which of several types of cushion will allow fastest return to baseline skin temperature. Forty nonspinal cord injured and 40 at-risk spinal cord subjects will be tested. A comparison of thermogram and standard cushion selection techniques will be made.

Prospective Randomized Clinical Trial of Thyrotropin-Releasing Hormone as a Therapy for Spinal Cord Injury

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Progress—It has been found that thyrotropin-releasing hormone (TRH) acts as a partial physiological antagonist of the endogenous opioids without altering pain thresholds. After traumatic spinal cord injury in cats, TRH has proven superior to other compounds in improving motor recovery. Earlier studies of TRH in human spinal cord injury indicated that the compound is safe at doses beneficial in experimental spinal injury. It's safety has further been demonstrated in studies of patients with amyotrophic lateral sclerosis, but no controlled clinical studies have been done to evaluate the use of TRH in human spinal cord injury.

Future Plans—Patients admitted to San Francisco General Hospital who have received a nonpenetrating spinal cord injury will begin participating in the study within 24 hours of injury. After baseline evaluation that will include somatosensory-evoked potential recordings and quantitative neurologic examination, patients will be assigned randomly to either a TRH-treatment group or to a placebo control group. Treatment will consist of 6-hour intravenous infusions of TRH (0.2 mg/kg bolus followed by 0.2 mg/kg/hour) versus physiologic saline. Medical and/or surgical therapy as directed by the attending physician will not be affected. Follow-up studies will be performed at 24 hours, 1 week, 3 months, and 6 months after initial treatment. At least 30 patients per year are expected to participate.

Respiratory Dysfunction in Spinal Cord Injury: Control of Ventilation

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Progress—Individuals with spinal cord injury (SCI) frequently suffer complications resulting from respiratory system dysfunction. Although weakness of the breathing muscles is the most obvious contributing factor, it is not the only one. The act of breathing is a complex process involving the brain or controller, which determines when and how much one breathes; the chest wall and muscles of ventilation, which move air in and out of the lungs; and 'loads' or obstacles to the movement of air, such as narrowing of the bronchial tubes seen in individuals with asthma. The respiratory problems in spinal cord injury are now believed to result from derangement in one or more of these components of the respiratory system.

Future Plans—In this research some of the physiologic interactions among the controller, generator, and load will be analyzed. The extent to which the very low responsiveness to carbon dioxide by chronic paraplegic and quadriplegic patients is the consequence of mechanical factors, muscle weakness, changes in functional residual capacity during the maneuver, and paradoxical movement of the chest wall as opposed to an alteration in the 'gain' of the system, i.e., the controller, will be assessed. The latter will be investigated in part through manipulations of neurohumoral compounds (endorphins) which may be elevated in SCI. Finally, the effect of ventilatory muscle training on ventilatory responsiveness in SCI will be examined.

Urinary Bladder Ganglion Reorganization Following Lesions

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Progress—Urinary bladder dysfunction is one of the more important and common problems occurring in spinal cord injured patients. The degree and type of bladder dysfunction depends on the level and severity of the spinal injury, as well as on the length of time following the injury. For example, complete lesions above the sacral segment elicit an initial block of bladder reflexes with urinary retention followed by slow recovery of involuntary reflex bladder retractions. Bladder emptying is usually incomplete due to the loss of coordination between bladder and sphincter functions.

Future Plans—These studies will examine the pathological changes in bladder and pelvic ganglia of the cat and rat resulting from sacral lower motor neuron (SLMN) lesions. Symptoms manifested in these species after SLMN lesions resemble those observed in humans who have sustained similar lesions. Frequently the immediate clinical consequence of SLMN lesions is bladder areflexia and urinary retention. Over a period of weeks or months, some bladder activity may appear, which results in partial bladder emptying if urethral sphincter innervation is not damaged, or incontinence if the sphincter pathways have been interrupted. Gradually, bladder tone tends to increase abnormally. The mechanisms responsible for the hypertonic autonomous bladder are far from clear and the treatment of the symptoms remains problematic. These studies combine intracellular recording, dye injection, and immunohistochemistry to examine the resulting pathophysiology.

Pharmacokinetics of Drugs in Spinal Cord Injured Persons

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Purpose—The aim of this investigation is to determine whether the pharmacokinetics of certain drugs are different in SCI patients compared to nonspinal cord injured individuals. Previous studies have indicated that after an intravenous injection of tobramycin, the concentration of the drug in the bloodstream of the spinal cord injured person may be lower than that found in other individuals. Examination of the pharmacokinetics of aminoglycoside antibiotics (gentamicin, tobramycin, amikacin, and netilimicin) will be undertaken and the antispasticity drug, dantrolene sodium, will be investigated in hospitalized SCI patients.

Future Plans—During the first year, the pharmacokinetics of each antibiotic after intravenous and intramuscular administration is being examined. Dantrolene sodium is often prescribed for SCI patients to treat spasticity, but it is known to be slowly and incompletely absorbed by able-bodied persons, which suggests that the high doses often prescribed for SCI patients may be inappropriate. The absorption and metabolism of this compound administered intravenously and intramuscularly will be examined and the results compared with those obtained with able-bodied volunteers when an oral route of administration was used.

Actions and Metabolism of TRH in the Spinal Cord

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Purpose—This research is aimed at understanding and finding solutions to the problems associated with long-term use of thyrotropin-releasing hormone (TRH) for the treatment of spinal cord injury. Three interrelated areas will be explored, with a view to greatly improving the treatment of acute spinal cord injury with TRH.

In the first phase, the downregulation of TRH and upregulation of pharmologic agents, such as desamethasone, estrogen, Hydergine, and Propylthiouracil (PTH) of rat spinal cord TRH-receptor will be examined during *in vivo* administration of these drugs. The ability of the above compounds in attenuating the downregulation of receptor TRH metabolism will be explored. A number of TRH-analogues will be screened for their ability to inhibit TRH metabolism in spinal cord extracts. The third goal will be to study TRH-mediated recovery of acute SCI using a superactive and superstable TRH-analog under conditions where both receptor downregulation and TRH metabolism are pharmacologically attenuated.

Progress—The rationale for this approach is that treatment of animals with inhibitors of TRH-metabolism will not only increase the level of endogenous TRH but also augment the half-life of exogenous TRH and thus facilitate recovery from spinal cord injury.

The investigators have screened a variety of TRH-analogs that do not bind to TRH receptors for their ability to inhibit TRH metabolism and thus raise the level of endogenous TRH. Preliminary screening has uncovered four such analogs, and these results will be published shortly. In solving the problem of TRH-receptor downregulation, the potential effects of glucocorticoids, Hydergine, and PTH on receptor downregulation will be evaluated. These three agents were selected because they are known to upregulate TRH receptors in the brain and pituitary gland.

Factors Affecting Sodium and Water Homeostasis in SCI

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Purpose—The major thrust of this research will be to examine in each patient the multiple factors capable of influencing the release of antidiuretic hormone. Patients participating in these studies have sustained *a priori* (minimum of 6 months) cervical cord transection and will be evaluated for their response to a number of superimposed stimulator and/or inhibitory variables capable of affecting changes in the release of antidiuretic hormone. Such provocative stimuli include the fusion of hypertonic saline, tilt-table induced hypotension, ethanol infusion, angiotensin II infusion, and the administration of the dopamine antagonist, metoclopramide.

Future Plans—Serial blood sampling will occur in the course of performance of each test. Once the patterns of antidiuretic hormone release have been distinguished, it will become possible to extrapolate this information to those clinical situations most likely to be associated with hyponatremia. Furthermore, this appraisal of antidiuretic hormone will eventually afford considerable insight into the enigmatic relationship of this hormone with blood pressure.

Circulorespiratory Effects of Dynamic Arm Exercise in Spinal Cord Injured, Quadriplegic Males

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Purpose—The purpose of this study was to determine the effects of sitting rest and dynamic arm exercise on selected circulorespiratory functions of spinal cord injured, quadriplegic men. These acute physiological responses were examined at rest, during two submaximal exercise stages, and during maximal exercise. Mean values and trends were compared with a group of able-bodied reference subjects.

Progress—The two groups of subjects included 11 untrained, male, C5-C7 complete quadriplegic university students and 11 able-bodied men of similar age, height, weight, and training status. Four exercise tests were administered to each subject using a Monark cycle ergometer modified for armcranking in the sitting position. Experimental methods included open-circuit spirometry, impedance cardiography, and electrocardiography.

Preliminary Results—The quadriplegic men nearly quadrupled their resting metabolic rates (oxygen uptake) through exercise to 30 percent of the maximal levels of able-bodied men. This was achieved primarily through tripling the rate of peripheral oxygen extraction toward physiological limits, while central oxygen delivery increased by very small amounts from rest to maximal exercise. The nearly constant cardiac output (4 1/min) resulted from an inverse relationship between the increasing heart rate and decreasing stroke volume. Low myocardial contractility, decreasing (although relatively high) ejection fraction, decreasing cardiac preload (end disastolic volume), and constantly low end systolic volume also characterized a 'hypokinetic circulatory syndrome' in upright exercising quadriplegics.

Future Plans—Research will delineate separate effects of orthostatic and exercise stress.

Neural Mechanisms Underlying Bladder Dysfunction After Spinal Trauma

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Purpose—This project's goal is to learn more about the underlying mechanisms of bladder dysfunction following spinal trauma and to use this knowledge to develop ways to enhance the recovery of bladder function after spinal trauma. It complements our other studies, which focus on ways to overcome paralysis in humans.

We have two objectives for this project: 1) develop an animal model to study micturition dysfunction after spinal trauma and, 2) use this model to study the effects of various drugs on the spinal control of micturition. We chronically measure the relationship between bladder volume and pressure before and after the spinal administration of opiate agonists and antogonists, and before and after spinal trauma, using pairs of ultrasonic crystals that have been implanted in the bladder wall and a miniature pressure transducer implanted into the bladder.

Our research should lead to a better understanding of the neurophysiology and neuropharmacology of bladder function, because we can measure and manipulate many of the neural and muscular events underlying bladder function in the unanesthetized animal. Such understanding is needed because renal complications remain the number one cause of death during the long-term management of the spinal cord injured patient. These complications are a direct result of the bladder dysfunction that almost always accompanies spinal cord injury.

Differences Between Chest Heat Patterns Shown by Complete and Incomplete Spinal Cord Injured Veterans

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Sponsor *VA Rehabilitation Research and Development Service and US Army Clinical Investigation*

Final Results—Thermograms showing heat patterns in the trunk of the body were taken of 15 veterans diagnosed as having complete spinal cord injuries (SCI) and 7 veterans diagnosed as having incomplete SCIs.

All of the subjects with complete SCIs had a line across the trunk which represented a temperature gradation between a relatively warm upper level in which sensations were normal and a relatively cool lower level in which sensations changed.

One of the subjects diagnosed as being complete SCI showed almost no transition zone and the temperature difference was less than that required for clinical interpretation. None of the subjects having incomplete SCIs produced this pattern. Only one incomplete SCI subject showed even a minimal difference in temperature between the normal sensation and abnormal sensation levels.

A panel blind to whether the subjects were intact, incomplete SCI, or complete SCI was unable to differentiate between intact and incomplete SCI subjects but was able to sort complete from incomplete subjects in all but one case.

The Spasticity of Spinal Cord Injury

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Purpose—Spasticity or the appearance of hyperactive spinal reflexes commonly develops gradually following spinal cord injury (SCI). This hyperreflexia often interferes with sleep, transfers, ambulation with braces, and other daily activities. Several neurophysiologic mechanisms, including loss of normal reflex inhibition, denervation supersensitivity, and collateral sprouting, have been proposed to explain the appearance of various clinical manifestations of spasticity.

This study will describe the temporal course of spinal reflex changes for 1 year following acute SCI, and will correlate electrophysiologic measures of hyperreflexia with clinical manifestations of spasticity. Reflex excitability in acute SCI subjects (less than 1 year post-injury) will be compared to observations in chronic SCI subjects and to control subjects without SCI.

Progress—To date, spinal reflex studies have been initiated in 6 acute and 5 chronic SCI subjects, and 14 control subjects. Preliminary observations suggest that tibial and femoral H-reflex excitabilities, measured as H/M ratios, are greater in chronic than in acute SCI subjects. As expected, the clinically elicited tendon reflexes are most excitable in the chronic SCI subjects. Electrical stimulation of the sural nerve is followed by the recording of long latency cutaneomuscular (flexor withdrawn) reflexes in the biceps femoris (BF) and tibialis anterior (TA) muscles. In some, but not all, chronic SCI subjects these reflex responses to the TA muscle are of much larger amplitude than they are in any acute SCI or control subjects. Compound muscle action potentials (M-responses) are of much smaller amplitude in chronic SCI subjects than in acute SCI or control subjects, presumably reflecting disuse atrophy.

Additional serial observations are needed to confirm these preliminary observations. Another focus of the study will be to record *cauda equina* potentials to tibial nerve stimulation in acute and chronic SCI subjects. By calculating efferent/afferent ratios, as a measure of central excitability, and by comparing the size of the afferent volleys to tendon taps of measured force, as a measure of peripheral muscle spindle sensitivity, we will assess their relative contributions to the developing reflex hyper-excitability following acute SCI.

Effect of Intermittent Catheterization on Renal Stone Formation in Spinal Cord Injury Patients

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Purpose—Because spinal cord injury patients commonly experience alterations in calcium metabolism (hypercalciuria) which may persist for many months after injury, it is necessary to determine how, if at all, intermittent catheterization in the presence of hypercalciuria affects the risk of urinary tract stone formation. This study seeks to examine the effects of intermittent catheterization and determine the significance of hypercalciuria in SCI patients.

Progress—The study population consists of patients with neurologically complete spinal cord injuries who are identified and entered into the study within 1 week of injury. Twenty-four-hour urine specimens are collected at admission and twice weekly thereafter until patient discharge. Serum calcium is measured. Urine pH

and species concentration measurements are obtained at regular intervals. Relative supersaturation of the urine with respect to calcium oxalate and calcium phosphate is determined. Activity product and the formation product ratio of brushite is determined for each urine specimen.

Preliminary Results—We are currently determining how intermittent catheterization in the presence of hypercalciuria affects the risk of urinary stone formation in the acute spinal cord injury patient. As of June 1986, a total of 15 patients have been entered in the study. Although a preliminary analysis of the data has been done, as yet there are no significant findings to report.

Future Plans—We will continue entry and followup of patients in this study through May of 1987.

Natural History and Clinical Course of Urinary Tract Complications in Patients With Spinal Cord Dysfunction

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Purpose—Appropriate clinical management of patients with neurogenic bladders resulting from spinal cord dysfunction requires 1) knowledge of the natural history or clinical course of urinary tract complications in this group and 2) data from which to determine whether urinary complications in this group are predictable from early post-injury urinary tract status and method of early bladder drainage management.

The objectives of this study include: 1) determining the effect of method of bladder drainage management on the incidence of orchitis and/or epididymitis, penoscrotal abscess, penoscrotal fistula, ureterectasis, pyelocaliectasis, and effective renal plasma flow (ERPF); 2) determining the effect of various urinary tract infecting organisms on orchitis/epididymitis, penoscrotal abscess, penoscrotal fistula, ureterectasis, pyelocaliectasis, and ERPF; and 3) determining the effect of vesico-ureteral reflux on upper tract changes including ureterectasis, pyelocaliectasis, calculi, and ERPF.

Progress—Rigorous statistical analyses are being performed on a massive urologic database derived from a large series of SCI patients having a spectrum of neurologic levels and extents of injuries, and those neurogenic bladders are/were managed in a variety of ways.

Preliminary Results—Complete studies have been performed and data recorded on 327 patients from a retrospective study group and 571 patients from a prospective group, yielding a total of 898 completed studies to date. Of those patients who had used the same type of bladder drainage for at least 5 years, provisional analysis showed the mean ERPF greatest in patients who emptied their bladders by straining, followed by those who voided at will, then those who used indwelling catheters. Further data suggest that maintaining sterile urine in SCI patients results in far fewer cases of urologic complications and surgical procedures, but that patients with untreated bacteriuria do not fare appreciably worse than patients with bacteriuria treated with antibiotics. SCI patients with *Serratia*, *Pseudomonas*, and *Providencia* had more urologic complications while those with *Staphylococcus*, *Enterobacter*, and *Enterococcus* had fewer complications. Additional data suggest that vesico-ureteral reflux improves with time (67 percent), though some patients continue to deteriorate (11 percent) and some continue with the same severity of reflux (22 percent).

Future Plans—Data collection is continuing. Currently, we are focusing attention on methods of bladder management and their association with urologic complications. We are exam-

ining the causes of diverticula, which have been identified as risk factors in the development of pyelocaliectasis. Finally, we will examine the relationship between vesico-ureteral reflux and renal complications and function in the chronic phase of spinal cord injury.

A Bladder Sensor for Urinary Incontinence

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Purpose—The research team is developing and evaluating an unobtrusive portable device to continuously monitor bladder volume using ultrasound. Such a device will assist persons with mental retardation who have not learned independent toileting skills to learn the critical association between the internal state of bladder distention and the act of engaging in a toileting routine. It will also allow persons with inadequate sensation to monitor their internal state, independently.

The device is expected to offer independence in toileting to many elderly persons as well as to persons with spinal cord injury, cerebral palsy, advanced diabetes, and *spina bifida*.

Progress—Among the primary considerations in the design of the device were attempts to keep the end-user cost of the device as low as possible and to obtain the most informative scan of the bladder for as little energy expenditure as possible. Toward the first of these objectives we are incorporating many off-the-shelf components.

In terms of energy consumption, a technique has been devised that will allow the system to use much less power than has previously been required, and will do this without sacrifice of imaging capability. This new approach also permits the system to rely on only a single transducer. At the present time, the system consists of a small logic analyzer and a single miniature transducer.

The final version of the logic analyzer is expected to be the approximate size of a credit-card calculator, and the transducer will be located on a belt to be worn by the user. Alternate configurations will be customized to accommodate user needs.

In the first half of the project, a database of incontinence-related research reports, product manufacturers, and research projects, was compiled and computerized; anatomical parameters of bladder position were established; a prototype of the system was configured; and the experimental design of the field evaluations was developed.

Future Plans—During the remainder of the project, tests will be conducted to determine the reliability of the portable system as compared to proven ultrasound scanners that are large and stationary. Field-tests of the efficacy of the device in use in client service settings will provide information regarding the applicability of the system to persons who have not achieved independence in toileting due to cognitive and/or physical limitations.

The system will be refined in response to the information gained from the evaluation process.

Clinical Evaluation of an External Device for Urinary Care in Incontinent Women

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Purpose—Chronic urinary incontinence, a frequent complication of spinal cord injury, multiple sclerosis, neurological defects affecting frontal lobe cortex, and advancing age, may be the pivotal factor determining whether a patient requires long-term institutional care. An estimated 2.4 million American women are incontinent of urine and that number is likely to exceed 3 million by the year 2000.

External urine incontinence devices for women, which have been described in the literature, are not commercially available. The customary methods for management of urinary incontinence in women, chronic use of indwelling urethral catheters or diapers, invariably lead to bacteriuria or infected decubiti in nonambulatory patients. Current methods of urinary care for incontinent women are costly in supplies, personnel time, and infections resulting from long-term indwelling catheter use. An effective external urine incontinence device for women would have an important impact in reducing both private and public medical care costs and may reduce catheter-associated urinary tract infections and their sequelae.

Progress—We have entered into joint studies with device manufacturers for development and clinical evaluation of external urinary incontinence devices for women. These joint studies include fabrication of prototype devices by the manufacturers and our clinical evaluation of prototypes in healthy volunteers and urinary incontinent inpatients.

We have clinically evaluated the performance of three different design concepts of prototype external urinary incontinence devices. A total of 255 of those devices have been evaluated. Preliminary design feasibility studies have been conducted in seven healthy female volunteers. Clinical efficacy studies have been conducted in 19 urinary incontinent, bedridden women in long-term care facilities. Patients selected had a history of urinary management problems resulting in chronic bed-wetting.

Results—In clinical efficacy studies, 88 percent of device applications resulted in complete patient dryness. Only three percent of applications or removals were scored as difficult. Device use resulted in patient comfort in 93 percent of applications. Mean effective device wear time was 22.3 hours. Minimal erythema (slightly red mucosa) was observed at the vaginal introitus in 12 percent of applications in studies evaluating devices for 5 consecutive days. In studies evaluating devices for 21 consecutive days, minimal erythema was observed on the peri-urethral floor and at the vaginal introtius after 47 percent of applications. Minimal erythema did not progress to more severe erythema, was not associated with patient discomfort, and may have been related in part to peri-urethral cleansing prior to each device application. Low level edema ($<$ 1 mm) was observed following two of 26 applications in one patient. Device usage did not induce bacteriuria or infection of the vagina or peri-urethral mucosa. Based on results from our clinical evaluation of prototypes, we have recommended to manufacturers modifications in device configuration which may improve device wear time and effectiveness and reduce adverse reactions.

Evaluation of device modifications in healthy volunteers and bedridden, urinary incontinent women, evaluation of other prototype design concepts, and evaluation of prototype devices in ambulatory, urinary incontinent women are in progress.

Incidence, Characteristics, and Clinical Significance of Anemia in Patients with Spinal Cord Dysfunction

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Purpose—Anemia commonly develops within the first 6 months following spinal cord injury (SCI), even in the absence of detectable blood loss. Whether anemia is due to stress, inadequate nutrition, blood loss, depressed red blood cell (RBC) production, or increased RBC destruction has not been determined. Anemia may be an important factor in the development of secondary complications. It may also delay or prolong the rehabilitation program. Thus, finding the cause of anemia in this population is a requisite to its prevention.

This study seeks to: 1) determine those epidemiologic and/or demographic variables affecting the duration and/or severity of anemia; 2) determine the natural history of changes in the hematologic profile of SCI patients; 3) establish the natural history of RBC kinetics after SCI; and 4) determine whether alterations in nutritional profile are associated with the incidence, duration and/or severity of post-injury anemia.

Progress—A series of neurologically complete quadriplegics (who have not received blood transfusions following their SCI) constitute the study population. Demographic characteristics and the hematologic correlates of the population are being documented as are basic hematologic profiles. Ferrokinetic studies are being performed. Nutritional profiles and their hematologic correlates are established. Erythropoietin quantitative assays are being performed. All data will be analyzed utilizing appropriate statistical techniques.

Preliminary Results—The project was initiated in June 1984. As of June 1986, a total of 21 patients had been entered into the study. Nineteen patients were males between the ages of 18 and 55 with neurologic levels of lesion between C3 and C7. The female patients were ages 22 and 81.

The patients were evaluated an average of 42 days post-injury. They had serum erythropoietin values ranging from 4-75 milli-immunochemical units erythropoietin/ml. The normal reference values are 7-36 units/ml. Eight of the 14 patients agreed to participate in the plasma volume red cell mass, total blood volume, and total hematocrit studies using I-125 and Cr-51. These patients had a slightly lower red cell mass than normal but had higher plasma volumes. Total body hematocrit was also generally low. It appears that despite normal peripheral red cell, hematocrit and hemoglobin counts, the serum erythropoietin level is low during the acute stage of spinal cord injury. Shrinkage in red cell mass is also possible during this time period.

Future Plans—Patients will continue to be entered in the protocol until May 1988. Preliminary data analysis will begin in the fall of 1987.

Effects of Nutritional Intervention During the Acute Phase of Spinal Cord Injury

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Purpose—This study, an outgrowth of "The Relationship of Nutritional Status and the Occurrence of Secondary Complications in Spinal Cord Injury Patients," is examining the association(s) between improving nutritional status via aggressive nutritional intervention and the prevention of secondary complications and preservation of optimal immune, motor,

and psychological function. We are: 1) conducting a randomized 4-week trial of aggressive nutritional intervention (ANI) in SCI patients; 2) determining the effect of ANI on body weight, skin-fold thickness, serum diet-dependent proteins and blood vitamin and zinc levels; 3) determining the effect of ANI on incidence of secondary complications; 4) determining the effect of ANI on muscle circumference, strength and urine creatinine excretion; 5) determining the effect of ANI on T and B lymphocyte numbers, delayed cutaneous hypersensitivity, neutrophil bactericidal activity and production of salivary IgA; and 6) determining the effect of ANI on psychological parameters.

Progress—Forty-eight SCI patients with neurologically complete, sensory sparing only, or nonfunctional motor lesions, who are between 18 and 60 years of age and less than 60 days post-injury, are being entered into the study population. Half ($N=24$) will have cervical injuries and the remaining patients will have thoracic injuries. Patients with concomitant brain injuries or multiple fractures are excluded. Patients are being randomly assigned to 'treatment' and 'control/no treatment' groups.

Patients in the treatment group are given aggressive nutritional support for 4 consecutive weeks. During and after this time comprehensive nutritional, medical complication, muscle mass and function, immune function and psychological data are collected and analyzed. Appropriate data will be compared for possible identification of association(s) between physiological and psychological findings/responses and aggressive nutritional intervention.

Incidence and Clinical Significance of Impaired Brain Function in Spinal Cord Injury

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Purpose—Incidence statistics on concomitant brain impairment in spinal cord injury (SCI) patients are lacking. Such data are needed both in the individual case and in the aggregate so that adequate planning and service offerings can be provided to patients who suffer this significant, associated injury. The goals of this study are to: 1) identify, validate. and utilize a battery of neuropsychological tests to diagnose impaired brain function in a series of recently injured SCI patients; 2) estimate the incidence of impaired brain function in recently injured SCI patients; 3) determine whether neuropsychological assessment data correlate, in a meaningful way, with demographic, epidemiologic, and medical data from the same series of SCI patients.

Progress—A neuropsychological test battery was identified, evaluated for appropriateness/applicability and validity, and subsequently administered to 150 newly admitted SCI patients. Medical, epidemiologic, and demographic data on all patients in the series were reviewed retrospectively. All data, including neuropsychological test results, were or are in the process of being evaluated quantitatively and qualitatively. As this summary was being written, data sheets were being presented to a panel of neuropsychologists who do not know the neurologic condition of the patients. Based upon their review of patient-specific data, they will attempt to diagnose probable brain pathology. The incidence of concomitant brain and spinal cord injury will be estimated from their review and a determination made regarding the ability of neurological and descriptive measures to predict concomitant brain impairment in the SCI population.

Preliminary Results—As of November 1985, some 150 complete initial neuropsychological test batteries had been administered and scored, and all accompanying medical and demographic data recorded. Sixty-seven retest administrations were completed as well. Provi-

sional data inspection suggests more impairment across a wider variety of cognitive tasks for a larger percentage of patients than reported previously.

Pain Secondary to Gunshot Wound During the Initial Rehabilitation Process in Spinal Cord Injury Patients

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Purpose—Surgical management of gunshot-related spinal cord injury (SCI) is controversial. There is concern that routine decompression laminectomies (in which the bullet and/or bullet fragments are removed) may aggravate the patient's prognosis rather than improve it. Removal of the bullet tends to be a standard practice whether or not its presence represents a life-threatening situation. It is widely accepted that removal reduces the intensity of associated pain later in life. However, there is virtually nothing in the rehabilitation literature supporting this contention.

By contrast, other clinicians believe laminectomy may contribute to general instability of the vertebral column in addition to being partially responsible for some reported pain. Finally, there is a clinical impression that pain occurring secondary to gunshot wound (GSW) may differ in character from that occurring secondary to SCI resulting from other causes.

This study will help clinicians understand intractable pain following SCI. It will also verify or refute the efficacy and desirability of decompression laminectomy and bullet removal after SCI. Specifically, this study seeks: 1) to determine whether the incidence of pain reported in GSW/SCI patients is significantly different from the incidence in patients whose SCIs result from other etiologies; 2) to characterize the incidence of pain reported by GSW/SCI patients epidemiologically and demographically; 3) to determine the relationship between the incidence of pain in GSW/SCI patients and surgical removal of the bullet; and 4) to determine, prospectively, the incidence of pain in gunshot wound SCI patients with or without decompression laminectomy.

Progress—This is a two-phase, prospective study. In Phase 1, pain data are collected on all SCI admissions (except those excluded because of overlying psychosis or senility) on a weekly basis from time of admission to first definitive discharge, with pain behavior changes being assessed over time. Data are evaluated with regard to epidemiologic and demographic characteristics of the population. GSW/SCI patient data are studied to determine absence or presence/location of the bullet or bullet fragment(s). If surgically removed before this phase, the pre-surgical location is documented. Pain history is documented and analyzed statistically. Eventually, all findings will be reviewed with our Department of Neurosurgery and a Phase 2, controlled study with random assignments of patients to surgical/nonsurgical management groups will be undertaken. Patient outcome will be evaluated.

Preliminary Results—At present, we evaluate all admissions to determine if specific patients can be relied upon to provide accurate data. We collect weekly pain data (pain behavior, subjective (0-10) ratings, and the McGill Pain Inventory) on GSW/SCI patients during their initial hospitalization, and at 6 and 12 months post-injury. As of April 1986, 44 GSW/SCI patients had been entered into the five GSW study groups with the following: bullet in canal ($N=10$); bullet present elsewhere ($N=8$); bullet removed from canal ($N=15$); bullet removed from other locations ($N=9$); bullet exited body ($N=2$). We also are collecting identical data on a control group of 50 non-GSW/SCI patients matched by neurologic level and extent of lesion, and in most cases by sex.

Didronel in the Prevention of Heterotopic Ossification Following Spinal Cord Injury: Determination of an Optimal Treatment Schedule

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Purpose—Heterotopic ossification (H.O.) following spinal cord injury or other severe neurologic injuries and diseases can limit joint range of motion and exacerbate the disability, often impairing function and limiting ambulation or wheelchair independence to the extent the patient must remain bedfast. Recently, however, a new drug, Didronel (etidronate disodium), has been shown effective in preventing H.O. when administered prophylactically after spinal cord injury.

This study seeks to: 1) determine the optimal time post-injury that Didronel therapy should be initiated to achieve the maximal prophylactic effect; 2) determine the optimal duration of Didronel therapy for maximal prophylactic effect; and 3) establish dosage recommendations for Didronel that are capable of yielding maximal prophylactic effect.

Progress—The study population consists of patients admitted to the UAB-Spinal Cord Injury Care System between zero and 120 days post-injury, whose lesions are neurologically complete (or neurologically incomplete with residual function equal to a Frankel Classification of 'sensory only') who are at least 16 years of age and who are not pregnant. Patients in the series are subcategorized into early and late treatment groups and further divided into 3- and 6-month administration groups. X-ray films of both hips are obtained 1 day prior to initiation of Didronel therapy, at the end of each treatment period, and at 1 year post-injury.

Preliminary Results—As of June 30, 1986, some 190 patients had been entered into the study. Substantially more patients ($N=112$) were entered into the early treatment groups (15-44 days post-injury) than there were patients ($N=78$) entered into the late treatment groups (45-120 days post-injury).

The study's major problem has been the high dropout rate. Of 190 patients entered into the study, 84 have been dropped from the protocol, primarily for reasons beyond our control. Eleven other patients acquired clinically significant H.O. and required continued drug treatment for at least 1 year.

Our preliminary results are based upon 95 patients with complete data. For patients who do not develop H.O., drug treatment for 180 days appears to be no more advantageous than treatment for 90 days regardless of when treatment begins. Clearly, early treatment is superior to late treatment regardless of duration.

Presently, the active study population consists of 109 patients who remain on the protocol and appear capable of and willing to be followed post-discharge. Ten patients have completed the drug treatment phase but have an annual followup examination pending. Four patients are currently completing the drug treatment phase.

Future Plans—This project was originally scheduled to be completed in May 1985. However, because of a somewhat greater than projected dropout rate, we have not achieved our target of 100 patients with complete data. Though we are following 109 patients currently, we expect to lose some of these due to dropout. Therefore, we have extended this project through May 1988 or until our 100 patient target is achieved.

The Relationship of Nutritional Status and the Occurrence of Secondary Complications in Spinal Cord Injury Patients

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Purpose—Nutritional needs of spinal cord injury (SCI) patients are almost entirely a matter of speculation. There are many unanswered questions concerning protein requirements, lipid mobilization, and vitamin and mineral requirements. This study attempted to: 1) determine the frequency of nutritional deficits in recently injured SCI patients; 2) document secondary medical complications and examine the association between them and low or deficient nutritional parameters; 3) examine the association between muscle mass, strength and endurance, and low or deficient nutritional parameters; 4) assess T and B lymphocyte numbers, cutaneous hypersensitivity, neutrophil bactericidal activity and production of salivary IgA as indicators of immunologic function, examining the association between decreased immunologic function and low or deficient nutritional parameters; and 5) assess depression, self-concept, and anxiety as indicators of psychological functioning, examining the relationship between psychological parameters and low or deficient nutritional parameters.

Progress—A series of 60 SCI patients with neurologically complete lesions, sensory sparing only, or nonfunctional motor capabilities who were between 15 and 60 years of age, without multiple fractures and without concomitant head injury, were studied throughout the course of hospitalization in the rehabilitation setting. A wide spectrum of nutritional variables was measured at regular intervals. Nutritional deficiencies and secondary medical complications developing after admission were documented and analyzed statistically. Muscle mass and work capacity were determined and analyzed. Immune fractions were determined at regular intervals after admission. Also, psychological evaluations were performed at regular intervals after admission.

Preliminary Results—Data were collected on 51 patients. Twenty-one had cervical injuries, 16 had thoracic injuries at or above T10, and 14 had injuries below the tenth thoracic segment. Preliminary findings indicated that caloric intake was frequently less than 1000 calories per day for prolonged periods. Other values found frequently to be low include carotene, folate, ascorbate, transferrin, and copper. Anergy to mumps antigen, as reflected in delayed cutaneous hypersensitivity (DCH), was present in 87 percent of the patients, compared to 30 percent of healthy controls. Patients with low maximal inspiratory pressure (MIP) tended to have more nutrient deficiencies than those with normal MIP, and those with low maximal expiratory pressure (MEP) tended to have more nutrient deficiencies than patients with normal MEP.

Our findings suggest nutrient deficiencies are common in the acute phase of SCI and appear to be associated with depressed immune response and muscle function.

Collagen Dysfunction in Quadriplegia

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Purpose—This study seeks to elucidate the ways in which collagen metabolism is altered in spinal cord injury and determine the causes and consequences of such alteration.

Project I: A method has been developed to measure hydroxylysine glycosides in an automated amino acid analyzer to establish the fact that increased concentration of a specific glycoside is an indication of the tissue origin of the collagen being degraded. It is hoped that physicians will be able to use this information to decide what preventive measures are of greatest importance for the individual patient and thus reduce the number of complications following SCI.

Project II: Density of adrenergic receptors in the insensitive skin of SCI patients is being measured by radioligand binding assays. The objective is to show that altered sympathetic responses lead to altered nutritional status of skin, thus increasing its susceptibility to pressure damage.

Project III: The activity of the enzyme lysyl hydroxylase and the concentration of some amino acids characteristic of collagen are being measured in skin biopsies from above and below the injury in SCI patients. The objective of this project is to show that SCI leads to abnormal enzyme activity which in turn leads to defective collagen biosynthesis and decreased tensile strength of the skin. If the specific defects in the collagen metabolism of SCI can be identified, they may be amenable to pharmacological intervention.

Progress—Project I: Eighty-six patients have been followed for up to 3 years after injury. Data are being summarized and analyzed at this time.

Project II: Data have been published in the *Archives of Physical Medicine and Rehabilitation* (67:177-180, 1986). Control biopsies have been obtained and efforts to increase the patient database continue.

Project III: Biopsies have been obtained from healthy, nonparalyzed volunteers. The number of patients is small, but data so far indicate that lysyl hydroxylase activity is highest in healthy controls, next highest in the skin above the level of injury in SCI patients, and lowest in skin below the level of injury of SCI patients.

Effects of Spinal Cord Injury on Drug Metabolism

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Purpose—The pharmacokinetics of medications administered to spinal cord injured (SCI) patients have not been widely investigated. There are numerous reports regarding alterations of normal physiological, neurological, and biochemical functions in the SCI population, which raise the possibility that one or more aspects of drug distribution, metabolism, and excretion may be altered in this group. The overall objective of this research is to investigate, in a systematic fashion, a number of representative drugs commonly used at various times throughout the life of SCI patients.

Progress—Eighteen subjects with SCI who were to receive tobramycin either prophylactically prior to a urological procedure or to treat infection were given an explanation of the research project and gave written informed consent. All subjects had normal renal function as evidenced by creatinine clearance measurements. Eighty milligrams of tobramycin were infused intravenously by a pump over a 60-minute period. Serum samples were collected before the infusion and at 30, 60, 75, 90, 120, 150, 180, 240, 360, and 480 minutes after the start of the infusion. Serum samples were assayed for tobramycin by the EMIT method of analysis. Data were analyzed by model-independent pharmacokinetic methods.

The mean age of our subjects was 31 years (range 18 to 54), the mean weight was 66 kg (range 45.5 to 82.7), and the level of injury was from T4 to C3. Following the infusion peak, to-

bramycin in serum concentration averaged 3.4 ± 0.8 g/ml. At the end of the 8-hour dosing interval, trough levels averaged 0.3 ± 0.2 g/ml.

In the 18 subjects studied, the mean half life of tobramycin was 113 minutes. The serum clearance (CI) averaged 147 ± 40 ml/min or 23.5 ± 7.3 liters or 0.36 ± 0.10.

Preliminary Results—The data in the limited population studied strongly suggest that the disposition of tobramycin in persons with SCI may be quite different from the disposition in people with intact spinal cords. Both the volume distribution (V_{ss}) and clearance appear to be higher in SCI. Data published for tobramycin in the intact spinal cord subject indicate average clearance values of approximately 1.87 ml/min/kg and a mean volume of distribution of 0.26 l/kg. The physiological basis for the differences is not known, but these data suggest that dosages of tobramycin in patients with SCI requiring aminoglycoside therapy may have to be increased to provide serum concentrations to adequately cover susceptible organisms. Trough serum tobramycin concentrations were <0.30 μg/ml. If one assumes that trough tobramycin serum levels should be approximately 1 μg/m, we found that in our study population the aminoglycoside concentration falls below this level at 4 hours post-dosing. Thus, a change in tobramycin dosage regimen in SCI patients would be appropriate.

Mechanism of Active Expiration in Tetraplegic Subjects

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Sponsor: *None listed*

Purpose—Traumatic tetraplegia produces paralysis of all the well-recognized muscles of expiration. Yet, tetraplegic subjects usually have a small expiratory reserve volume on spirographic examination.

Progress—To understand the mechanism that enables these patients to empty their lungs actively, we studied the pattern of chest-wall motion during voluntary expiration. We found negligible changes in abdominal dimension, but all subjects had a marked and reproducible decrease in the dimension of the upper rib cage. Electrical measurements established that the subjects had active use of the clavicular portion of the *pectoralis major*, and changing the orientation of these muscle fibers by maintaining the shoulders in abduction reduced their expiratory reserve volume by about 60 percent ($P > 0.001$). We, therefore, conclude that the clavicular portion of the pectoralis major plays a crucial part in the mechanism of active expiration in tetraplegic subjects. Training of this muscle bundle could, by increasing its strength and endurance, improve the effectiveness of coughing in such subjects and perhaps diminish the prevalence of bronchopulmonary infections.

Evaluation and Rehabilitation of Reproductive Function in Paraplegia

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Purpose—This is an interdisciplinary effort in urology, physiology, biomedical engineering, and rehabilitation medicine. Earlier work focused on the development of rectal probe electrostimulation (RPE) from a trial research mode into a state of clinical feasibility for routine evaluation of patients regarding production of erections and seminal emissions. Continued recent work has been directed at antegrade semen collection, with evaluation of semen

quality and the possible use of acceptable specimens in artificial insemination of the patient's mate. Efforts also will be directed at further refinement of RPE instrumentation to a device appropriate for use by the patient and his mate in their home, to produce erections and, if antegrade ejaculation could occur, to allow for insemination.

Progress—Although patients with injury level between T2 and L3 are being studied, results thus far with nearly 50 patients suggest that RPE can be of greatest benefit to those with injury levels between T5 and T12. Those with injury level lower than T12 often have too much remaining sensorium to tolerate current delivery, while those with injury higher than T5 have an increased risk of RPE-induced autonomic dysreflexia.

Patients volunteering for study fit into three categories: those primarily interested in achieving antegrade ejaculation of semen of sufficient quality that artificial insemination of their mate is appropriate; those interested essentially in obtaining or improving the quality of erection; and those interested in both.

For those patients desirous of siring children, the timing of RPE to coincide optimally with the ovulation period of their mate is rather simple. Less easy has been the improvement of sperm motility, which generally is quite low (typically less than 15 percent progressive motility is observed). In some instances sperm motility has been improved simply by minimizing contamination with bladder urine. This has involved Foley catheterization to prevent retrograde semen flow, with optimum balloon inflation volume and placement determined in part by urodynamic studies and transrectal urethral sonography. In other instances, for whom retrograde ejaculation cannot be prevented, pre-RPE irrigation of the bladder with a solution of 90 percent Ringers Lactate and 10 percent sodium bicarbonate serves to maintain urine pH at a favorable level (7.2-7.4) for sperm survival until retrieval and transfer to a more appropriate medium.

Insemination of one such semen specimen, consisting of approximately 164 million sperm with 51 percent sperm motility, collected from a T11 paraplegic and transferred to his mate using a cervical cap, resulted in a pregnancy, with eventual delivery of a healthy male infant. In the majority of cases, however, for reasons not yet identified, sperm motility remains consistently quite low. Refinement of RPE instrumentation to permit more frequent and routine semen collection is allowing useful pursuit of this problem.

In addition to the electrical-outlet-operated stimulator, we are now designing and constructing an RPE device appropriate for use by the patient and spouse in the home. Other workers in the field have envisioned such a device, particularly for patients who are able to produce erections and antegrade semen emissions using RPE. This could permit such couples to achieve a more functional sexual relationship in a private setting.

A detailed analysis of both safety constraints and patient needs has been completed, and all electronic circuitry has been designed. Construction of the first unit will be completed and clinical testing will be initiated during the next year of funding.

A Feasibility Study on Detection of Impending Pressure Sores Using Ultrasound

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Purpose—Pressure sores are a major complication for spinal cord injured and certain other disabled persons. Frequently these areas of tissue breakdown begin deep in pressure sensitive areas of muscle tissue and cannot be detected clinically until the process has become

irreversible. The objective of our current study is to develop ultrasonic techniques (measurements of attenuation and backscattering) that are capable of assessing the state of deep muscle tissues with respect to early changes signaling the incipient development of muscle necrosis.

The proposed research will approach this problem by means of our established experimental model in pigs. Tissue damage in the animals is created by applying a constant force, over a period of hours, through specially shaped indentors under the control of a microprocessor. This technique is being employed to create a known degree of tissue damage on which specific acoustic parameters can be measured for comparison to normal.

Preliminary Results—Initial tests have confirmed that when a critical time-pressure parameter is exceeded, necrosis of tissue takes place. Our preliminary studies clearly show that the deep muscle tissues are more sensitive than skin to pressure effects and that the type of decubitus ulcer that results from direct pressure (rather than superficial shear) begins in the deep muscle layer. In fact, muscle necrosis in our model is usually seen in the absence of permanent skin damage. Our work now in progress involves correlation of acoustic parameters with histology of pressure damaged tissues. These measurements will lay the groundwork for future development of clinical testing apparatus and procedures.

Future Plans—If this feasibility study is successful, it will lead to a clinically usable ultrasonic scanning test that can warn of impending pressure sores at the preclinical stage, in time to take corrective action to permit healing before tissue necrosis occurs.

Skin Deformation and Blood Flow Under External Loading

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Purpose::—Spinal cord injury patients are known to be more prone to the development of pressure sores than are able-bodied individuals because of the loss of mobility and sensation. But within the SCI population, some patients are significantly more prone to such problems than others, and the reasons for these differences are not known.

Since the initiation of pressure sores is known to be associated with a compromise of skin blood flow, this investigation is directed toward the measurement of skin blood flow response to controlled external pressure loading in spinal cord injury patients. If there are indeed differences in skin blood flow response to loading which can be easily measured, then it may be possible to identify those patients who are more susceptible to pressure sores upon admission to the hospital. That would permit a shifting of nursing care in such a manner as to diminish the incidence of pressure sores in VA hospitals. At the present time, the average cost per patient of treatment for pressure sores is in the vicinity of $15,000 to $25,000 per year, not to mention the cost in patient discomfort and loss of time. A method of identifying patients at risk could be most valuable in diminishing these costs.

There have been a limited number of studies in which skin blood flow under external loading has been measured by a number of different techniques, all of which have involved rather indirect methods. The findings of such investigations have shown that there is generally a decrease in skin blood flow with loading, and although there seems to be considerable variation in the quantitative results, blood flow in the skin apparently ceases at a local pressure loading of about 100 mm Hg in able-bodied young subjects.

These occlusive pressures are evidently much lower in older and in paralyzed subjects,

but the large variability of the curves of skin blood flow versus pressure makes it difficult to draw any meaningful conclusions.

The present study differs from previous studies in two major respects. The first of these is that a dimensional analysis is carried out to insure that all of the necessary quantities are measured and are treated in the appropriate nondimensional forms to give meaningful results. The second is that a new noninvasive technique is used for the direct measurement of skin blood flow. We are attempting to make full use of newly available noninvasive laser doppler flow meter (LD 5000, MedPacific, Seattle) which is claimed to make continuous measurements of skin blood flow. Some information on use of this instrument is contained in this report.

Measurements of skin blood flow response to loading in able-bodied subjects and in spinal cord patients who do and do not have a continuing problem with pressure sores are first made on the proximal femur in the side-lying position, for ease of measurement and accessibility, and then on the ischial tuberosities with the subject bent over a table, in order to apply controlled loads in a known fashion.

Dimensional analysis is used to determine the appropriate nondimensional forms of the most important parameters.

Progress—The dimensional analysis has been completed. It shows that the ratio of skin blood flow to baseline flow (at no load) is a function of only two nondimensional quantities: the ratio of skin indentation to bone depth, and the ratio of bone depth to the diameter of the cylindrical indentor. Therefore, we are measuring the bone depth on each subject, as well as the skin indentation at each loading.

Bone depth is measured using echo doppler equipment, and indentation is obtained, for the femur measurements, from the vertical displacement of the loading weights at each load. These measurements are not usually made in such studies, but are felt to be essential to proper interpretation of the results. The dimensional analysis also shows that it is not necessary to measure the applied pressure. However, pressure measurements are now being incorporated in order to facilitate comparisons with previous studies.

Displacement measurements on four subjects have indicated that the "stiffness" of the tissues increases systematically, regardless of injury. It can be seen that:

1) The elastic behavior of the tissues is in all cases nonlinear, with the tissues getting stiffer as the load increases; and

2) The required load for a given displacement increases with age.

Early measurements on able-bodied and spinal cord injured subjects have shown that the laser doppler does not accurately measure blood flow at high loadings because the skin blood flow is sufficiently decreased that artifacts become important. That is, the laser doppler is exquisitely sensitive to all motion to such a degree that random red-cell motion, due to temperature or to individual red cell interaction, is responsible for a significant portion of the doppler signal. Therefore, the method of loading by adding weights to a platform has been modified to use a precision micrometer technique for applying known small indentations to the skin. (The doppler will now be used at low loadings, where the artifacts should become insignificant.)

Biochemical Analysis of Sweat as an Indicator of Tissue Viability

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Sponsor: *New York State Department of Health*

Purpose—A simple method for early detection of pressure sores has been elusive. Measurements of tissue pO_2, skin temperature, mechanical indentation properties of soft tissue, blood flow rate and ultrasonic properties are under investigation at various centers. Biochemical

changes have attracted less interest as their detection would normally require invasive sampling of tissue fluids. In this study, we are investigating the potential of measuring changes in sweat biochemistry to determine whether substances generated during ischemia or in the early stages of trauma can be detected. If successful, this approach will offer the potential for early identification of areas of tissue in distress. Lactate acid production is one biochemical factor in sweat that responds to periods of ischemia. Lactic acid is a by-product of anerobic glycolysis of the sweat gland and its concentration in sweat increases during ischemia. One early previous study has demonstrated this effect for whole limb ischemia and our present work is investigating the relationship between lactate concentration and localized ischemia history. Na^+ concentration in sweat is also modified by ischemia and parallel studies for Na^+ and Ca_2^{++} are also underway.

Progress—Protocols for this study are established and preliminary data has been collected. Sweating is induced using iontophoresis of pilocarpine nitrate and collected using the Macroduct system (Westcor) used for cystic fibrosis screening. Sensitive assays for sodium, calcium and lactate have been established allowing accurate measurement of these substances from less that 20 μl of sweat. Preliminary data are inconclusive, sweat having been collected during the reactive hyperemia stage post-ischemia. Work is now in progress to confirm these results and to measure lactate, Na^+, Ca_2^{++} concentrations during application of ischemia. Investigation is also in progress to measure biochemicals such as histamine that are indicative of inflammatory responses associated with the early stages of tissue breakdown.

C. Spinal Cord Regeneration

An *In Vivo* Model to Assess the Neurotrophic Function of Mammalian CNS Glia

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Purpose—Severe injury to the mammalian spinal cord usually results in permanent loss of morphologic integrity and neurologic function. In some lower animals such as fish and amphibians complete regeneration of the spinal cord does occur. Based on the central role of ependymoglial cells in guiding axons during regeneration in these lower forms and a similar function proposed for nerve cell guidance by radial glial cells in the developing mammalian cerebellum, it is thought that certain glial surface properties or secreted trophic molecules underlie these neuron-glia interactions.

It was hypothesized that because of the specific developmental timeframe during which glial cells appear to positively influence neurite outgrowth and directionality, the capacity of glia to induce these neural responses is a function of the age and degree of differentiation of the glial cells. If "permissive" glial cells were found, for example, in the vicinity of severed axons in the injured mammalian spinal cord, the regenerative response might be significantly enhanced.

Progress—To test this hypothesis, small cavities were made in the adult rat spinal cord into which were implanted three different types of central nervous system glial preparations. These included embryonic rat glial cells from the presumptive *corpus callosum*, pure populations of neonatal rat cerebral astrocytes, and mature rat astrocytes from degenerative optic nerve. The degree and extent to which host

cord neurites penetrate each type of cellular graft was quantitated by individual fiber measurements made microscopically on specially stained histologic sections prepared from animals sacrificed at various intervals post-transplant. These results are being compared to control grafts implanted with either rat embryonic cortex or no cells.

Plasticity in the Injured and Aging Mammalian Spinal Cord

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Purpose—The research is aimed at substantiating the relationship between specific morphologic changes in the phrenic nucleus that occur within hours of spinal cord insult with the functional recovery of a portion of the paralyzed hemidiaphragm.

Progress—Our first task was to morphologically characterize and quantitate at the electron microscopic level the unique neuronal, synaptic, and glial alterations that have been observed in the phrenic nucleus within hours after spinal cord injury in the rat. Significant progress has been made toward realizing this objective. All of the normal young adult rat tissue has been processed and most of it has been analyzed by the computer. In addition, all the normal older adult rats have been sacrificed and at least three-quarters of the material have been analyzed by the computer.

Preliminary Results—The original hypothesis seems to have been correct. Qualitative results show that the rapid morphologic changes induced by the spinal cord injury in the young adult rat also were seen in the normal spinal cord of the older rat. Thus, it seems that the rapid changes that occur in injury also occur slowly and progressively in the normal spinal cord as a consequence of aging.

The research has progressed to where we can prepare highly purified neonatal glial preparations consisting of 79 percent astrocytes. The astrocytic origin of these cells has been confirmed by electron microscopy. These cells and embryonic glial cells will serve as donor cell preparations to introduce into transplantation cavities in the adult rat spinal cord.

We have experimented with a number of techniques to introduce astrocytes into the spinal cord, and are now using microsurgical techniques with cutting scissors and a microknife to sever axons in the corticospinal tract, then implanting the donor cells by means of microspatula.

Future Plans—A series of future experiments will use neonatal and embryonic glial cells to test their efforts on the maintenance of severed corticospinal fibers and on sprouting and regenerating these fibers.

A Study of Phosphoprotein in a Regenerating CNS Tract

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Purpose—The overall objective is to identify specific molecules that regulate regeneration and to understand how these molecules carry out their functions. Protein phosphorylation events associated specifically with the regenerative process will be investigated by identifying differences in the amount of phosphate incorporated into individual proteins: 1) between re-

generating and normal neurons; 2) under conditions modifying distinct phases of regeneration; and 3) with application of agents that retard or enhance regeneration. In addition, an attempt will be made to determine in each case whether phosphate incorporation is directly coupled to protein synthesis or to a subsequent modification of the protein inside the cell body or its axon, and to define the location of the phosphorylating system. These experiments will be conducted on the goldfish optic nerve, which has demonstrated the capability for extremely vigorous regeneration.

Spinal Cord Regeneration of Descending Locomotor Command Systems in a Lower Vertebrate, the Lamprey

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Purpose—This research deals with the function and regenerative capacity of the locomotor command system in the brainstem of a lower vertebrate, the lamprey. The transected spinal cords of lampreys, unlike those of most other vertebrates, regenerate significantly, which results in almost complete recovery of motor function. In addition, it is possible to place the isolated lamprey nervous system in a recording chamber, which will remain alive and generate the motor pattern for locomotion.

The three aims of this research are: 1) to determine the locations of the descending brainstem command neurons that project to the spinal cord and activate locomotor patterns, using two complimentary methods—an anatomical tract-tracing using horseradish peroxidase, and a chemical stimulation technique using iontophoresis of excitatory amino acids to activate small groups of neurons in specific areas of the brainstem; 2) to determine the anatomical and physiological properties of the brainstem command neurons for locomotion from data accumulated on the biophysical properties, activity patterns, and morphology of brainstem neurons; and 3) to examine the mechanisms that account for behavioral recovery after spinal cord injury in the lamprey, and the properties of brainstem command neurons and their connection to spinal cord cells after regeneration. Intracellular and extracellular recording from an *in vitro* system preparation will be used, which will generate locomotor patterns similar to those observed in intact animals.

Fetal Spinal Cord Transplantation into the Chronically Injured Rat Spinal Cord

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Purpose—This research specifically addresses the issue of regeneration in the chronically injured spinal cord. The immediate objectives are: 1) to examine how the special biological problems related to the advanced histopathological changes in the host cord affect various parameters of fetal CNS tissue grafting; and 2) to develop an experimental transplantation strategy that applies to situations similar to those found in human injury.

The first goal is to determine the survival and developmental characteristics of fetal spinal cord implants when placed into the original lesion site. The second goal is to explore whether axonal interactions between host and graft can be augmented after transplantation into the chronically injured spinal cord. The third goal is to determine the efficacy of fetal tissue transplantation into contusion lesions of the adult spinal cord.

Thus, these studies address several fundamental issues related to intraspinal transplantation as a means for ultimately stimulating functional recovery in the injured spinal cord.

Study to Determine if Localized Extracellular Proteolysis Is a Requirement for Successful Regeneration of Nervous Tissue

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Purpose—It is the working hypothesis of this research that proteolytic activity is an essential process in repairing a damaged nervous system. However, proteolytic activity must be localized rather than general or random. General injection of these enzymes can lead to uncontrolled tissue destruction, whereas localized proteolysis, e.g., a plasmin-generating system expressed by the cell in a highly controlled manner, will remove only the unwanted tissue in the path of the regenerating axons. To assess this hypothesis, two model systems of regenerating nervous systems will be used: peripheral, i.e., sciatic nerve; and central, i.e., the olfactory bulb, with regeneration induced by various grafts into it. Assuming that localized proteolysis is essential for regeneration, any treatment or cell type (e.g., mature astrocyte) that inhibits this activity should intervene and prevent the regenerating process. On the other hand, any other cell type that is known to produce this specific proteolytic activity, i.e., premature astrocyte and tumor cell lines, should support neuronal regeneration when implanted in the injured tissue.

Future Plans—If this hypothesis is verified, novel avenues will be opened for research into possible therapeutic procedures to induce repair and/or recovery in any injured nervous system. One of these could be the development of a device to apply these proteolytic enzymes of the plasmin-generating system in a localized manner at the locus of injury.

Axon Regeneration in the Mammalian Spinal Cord in Response to Surgical Denervation and Nerve Growth Factor

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Progress—Sensory nerve cells entering the spinal cord travel in the dorsal root and convey information such as touch, pressure, heat, and pain to the central nervous system. The sensory cells that carry information from the periphery to the spinal cord have their cell bodies in the dorsal root ganglion (DRG) outside of the spinal cord. There are two categories of nerve processes that these nerve cells send into the spinal cord: 1) unmyelinated axons; and 2) myelinated axons. These axons travel in the dorsal root and enter the spinal cord to make many synapses (or specialized contacts) on nerve cells in the cord.

Preliminary Results—Unless sprouting can be quantitated, it is not possible to determine accurately the parameters of this phenomenon. The electron microscope is being used to count the numbers of myelinated and unmyelinated axons in the dorsal roots and spinal tracts of rats that are subjected to spinal cord or dorsal root injury on one side. The normal side of the animal is compared to the injured side so that each animal serves as its own control. In these experiments, the number of axons in the dorsal roots on the injured side was 15 to 20 percent greater than the number on the normal side. Furthermore, the increase was in the unmye-

linated axon population and not the myelinated axon population. This increase was apparent for some distance cranial and caudal to the surgery. Since sprouting results in an increase in axon number, these results indicate that sensory axons sprout in response to spinal cord denigration. Other work in the laboratory indicates that neurons of younger mammals sprout more vigorously than older animals.

The next step is to determine if the sensory sprouting can be manipulated by a growth factor. Nerve growth factor (NGF) is being studied because this protein is well characterized; can be purified in stable form; and most importantly, has been shown to stimulate sprouting of sensory neurons in culture. Questions asked specifically relate to the NGF affecting the number of nerve cells and/or nerve processes in the uninjured mammal and the injured mammal. Data now indicate that NGF is involved in the sprouting of sensory axons.

Rats, spinal cord injured on one side, were divided into three groups: the first received NGF; the second received rabbit whole sera; and the third rabbit whole sera that included antibodies against NGF. All groups received daily doses for a 1-month-period. After this period, rats were sacrificed and the number of axons in dorsal roots from the injured side were counted and compared to counts from the other side as a control. The first two groups of rats confirmed results from the previous study of rats that were spinal cord injured with no additional treatment: the number of unmyelinated axons is greater in dorsal roots of the injured side as compared to the control side. However, in the third group of rats, who had been receiving antibodies against NGF, the number of unmyelinated axons in the dorsal roots on the control side was greater by about 20 percent than the increased number observed on the hemisected side. This increase indicates that the nerve cells on the control side sprouted more vigorously than those on the injured side.

Preliminary Results—Nerve growth factor is important in maintaining the nerve supply to a tissue. The tissue synthesizes molecules of NGF, which the nerve processes transport back to the nerve cell nucleus. Then, the transported NGF acts to "inform" the nerve cell that it is innervating the correct tissue. Any cessation in this process is a removal of the innervated tissue and/or damage to the nerve processes. If the antibodies to NGF (anti-NGF) are introduced to the animal, the anti-NGF binds itself to NGF and biologically inactivates the NGF molecules. The nerve cells can no longer receive their NGF information and are fooled into believing that the tissue or their processes have been removed. This phenomenon can be called "chemical denervation."

In the group of rats with hemisected cords given the antibody to NGF, only the hemisected side of the cord was surgically denervated, and both sides were chemically denervated. Dorsal root axons, chemically denervated on the control side, sprouted more vigorously than those on the surgically denervated side. (The trauma of surgery may inhibit some of the sprouting potential.) More recent experiments support that exposing rats to the antibodies to NGF with no surgical manipulation will produce vigorous sensory neuron sprouting.

Axonal Regeneration in the Adult Spinal Cord

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Progress—HRP anterograde injury-filling has been used to study the regeneration of axons into and within the adult spinal cord. These studies have examined the use of frog spinal cord as a model to look at axonal regeneration within the central nervous system (CNS). It is possible to introduce three different kinds of axons into the spinal cord: 1) the central branch of dorsal root ganglion cells; 2) the peripheral branch of dorsal root ganglion cells;

and 3) axons of ventral motoneurons. This experimental model can be used to compare the regeneration of three very different populations of axons within the same region of the CNS, and may provide information about the intrinsic differences between the growth potential.

Future Plans—The study will: 1) further define the regions of the frog spinal cord that support or do not support axonal growth, by completing electron microscopic analyses of the regeneration of dorsal root axons; 2) determine, at the electron microscopic level, what cellular elements act as a substrate to axonal growth; and 3) compare the regeneration of the three populations of axons within the white and gray matter of the spinal cord in frogs.

The second goal of this project is to study, at the light and electron microscopic level, the regeneration of dorsal root axons in the rat. The objectives are to: 1) determine the percentage of dorsal root axons that regenerate into the rat spinal cord; 2) define the regions of the rat spinal cord that support or do not support axonal growth by carefully mapping the growth of the axons; 3) determine, at the electron microscopic level, what cellular elements act as a substrate for axonal growth in the rat spinal cord by identifying those cellular elements that are most frequently contacted by axons that have regenerated well; and 4) examine, at the electron microscopic level, the reactive glia barrier at the root transitional zone.

Immunohistochemical studies of the astrocytes in the frog and rat spinal cords will define the types of astrocytes in the normal spinal cords of the two species and determine the identity of the astrocytes that become reactive after dorsal root trauma in the two species. The long-term goal of this research is to use the frog spinal cord as a model of spinal cord regeneration in which to define whether neuronal and environmetal factors sustain or constrain regeneration.

Furthermore, this research will identify similarities and differences in the regeneration of axons in the frog and rat spinal cord.

Recovery of Function and Anatomical Repair After Spinal Cord Transections in Newborn and Adult Rats

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Purpose—The goal of this project is to determine whether neural tissue transplants of fetal spinal cord tissue can promote anatomical repair and mediate recovery of function after spinal cord transections in newborn and adult rats. Neural tissue may be able to restore motor function after spinal cord lesions, either by providing a bridge for axons to cross the gap created by the lesion, or by providing a pool of neurons that can serve as a relay for descending supraspinal input to reach caudal spinal levels. Neuroanatomical tracing techniques are being used to assess the anatomical repair of the injured spinal cord and quantitative behavioral analysis of locomotion, postural reflexes, and bladder reflexes to assess the effect of transplants in recovery of function.

Progress—Segments of immature spinal cord tissue from rat fetuses are being implanted into the lesion sites of adult rat spinal cords at a mid-thoracic level. Anatomical examination of the tissue by light and electron microscopy 1 month to 1 year later indicates that the transplants survive, grow, and mature. There are many areas in which the host spinal cord and the transplants are in direct opposition without any intervening gap or barrier. The transplants contain many mature nerve cells, fibers, and synapses. Experiments indicate that some nerve cells located within the transplants send their axons into the host spinal cord and conversely, some nerve cells in the host spinal cord, send axons into the transplant. The growth of axons appears to be greater after le-

sions made in young animals than in the adult animals. It is known that there is substantial recovery of function and anatomical reorganization following partial spinal cord lesions in newborn and adult mammals. Even following complete spinal cord lesions, the spinal cord possesses some innate capacity for eliciting locomotor patterns (spinal pattern generator for locomotion). However, this motor function of the isolated spinal cord is sufficient to allow stereotyped movement only.

The older the animal is at the time of transection, the poorer the quality of the spinal motor function. Indicative is a decline in autonomous spinal motor function occurring during normal development. During post-natal development, locomotor behavior becomes dependent upon supraspinal control. Spinal cord transection permanently removes that supraspinal control, and spinal motor function reemerges. A similar decline in the innate capacity of the spinal cord to elicit movement occurs during phylogenetic development, since spinal monkeys and humans do not display spinal locomotion, but rats, cats, and dogs do display considerable spinal locomotion. Similarly, bladder function is mediated at a spinal cord level early during post-natal development, but later becomes dependent upon supraspinal control, which is characteristic of the adult. Spinal cord transection results in the permanent loss of this supraspinal control of micturition, and the spinal reflex reemerges.

The aim of this research is to determine whether neural tissue transplants of fetal spinal cord tissue can reestablish anatomical pathways that allow recovery of supraspinal control of locomotor and bladder function. Neural tissue transplantation techniques are being used as tools to better understand the response of the immature and mature central nervous system in terms of damaging and identifying the anatomical and functional processes involved in the repair of the injured spinal cord. The pattern of growth of fibers in newborn and adult, and the pattern and density of innervation in the host spinal cord caudal to the transplant, seen normally, will be compared. In the normal animal, the spinal locomotor generator can be modified by descending supraspinal control.

Development and Regeneration of Afferent Motoneuron Contacts in Rat Embryos

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Purpose—This project will study the inductive interaction between sensory and motor neurons and the specificity of their initial interactions. Some of the experiments will be carried out in organ culture where the environment of the developing neuronal circuits can be controlled. Segments of body wall, including intercostal muscles, ribs, and spinal cord will be explanted from 14-day to 18-day embryonic rats (birth is at 22 days of gestation) and maintained in organ culture for up to 6 days. In this preparation the normal geometric and mechanical relationships of spinal cord and muscle can be retained during the culturing procedure. The intercostal nerve-muscle contacts develop in organ culture with a pattern and time course similar to their development in a living rat.

Our investigation will also: 1) record electrical signals in motoneurons and determine the changes in these signals during the formation of sensory contacts with them and record sensory inputs on the pharmacological properties of immature motoneurons; 2) study the effects of peripheral nerve cut close to the muscle and the effects of lesions of sensory nerves on the electrical and pharmacological properties of motoneurons; 3) investigate the regenerative ability of lesioned sensory axons to contact their target motoneurons (using both morphological and electrophysiological techniques); and 4) study the regrowth of sensory nerves using a dye that is carried in axons and marks their lo-

cation in the spinal cord. Mature mammalian-cut axons in the central nervous system regenerate to only short distances, and, unlike peripheral nerves, do not grow back to innervate their appropriate target. Functional regeneration of sensory nerves will be assessed by stimulating them and recording electrical signals in the motoneurons that they innervate. Our understanding of the functional development of neuronal circuits and their inductive relationships is essential for approaching the important goal of manipulating the regenerative abilities of the adult central nervous system.

Evaluation of a Novel Spinal Cord Injury Model

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Progress—This research was first designed to test the innate capacity of spinal cord fibers to regrow when left with a matrix of viable central nervous system tissue connecting cut segments of the cord, and second, to stimulate nerve fiber regrowth using low-level electrical current applied to the injury.

Progress—To accomplish the first, a spinal cord injury model was developed in which separate cuts were made in opposite sides of the cord at two different levels at midspine. All long fiber tracts extending between the brain and the spinal cord were interrupted, but an undisturbed mass of spinal cord tissue was preserved between lesions. This arrangement induces a paraplegic condition while maintaining a CNS connection between damaged cord ends that act as a conduit for regrowing nerve fibers.

The next step will be to stimulate the regenerative process by electricity, by implanting fine multi-stranded platinum electrodes near the damaged region. The electrodes will be connected to a small, battery-powered cell placed under the skin of the lower back. Results from these studies will provide important clues to answering two questions: 1) What is the potential for nerve fiber growth? 2) Can electrical intervention support a regenerative effort?

Spinal Cord Explants Cultured on Carbon Filaments and Stimulated with Direct Current

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Purpose—Following complete spinal cord transection in mammals, nerve fibers above the transection begin to regrow. It has been thought that the environment at the site of the injury was unfavorable to growing and regenerating axons. Many investigators have attempted to modify the microenvironment to make it more favorable to nerve fiber regrowth. One of the methods has been to stimulate regrowth with minute electric currents. However, the process of axonal regeneration alone is not sufficient for functional recovery. The growing axons must be guided and directed to their proper destination.

A few laboratories have reported successful implants of carbon filaments as substitutes for injured ligaments and tendons, in both experimental and clinical studies. Carbon filaments provide mechanical strength and act as a scaffold for the development of new aligned fibrous tissue. The filaments eventually degrade as the new tissue matures. This study was designed to evaluate the influence of carbon filaments on the growth and orientation of nerve fibers from

spinal cord explants *in vitro*. For this study we designed a petri dish in which we attached approximately 3000 carbon filaments (8-10 mm diameter) to the bottom of the dish with their free ends extending through and beyond the dish. We then sterilized the entire assembly. We placed spinal cord explants on the carbon filaments, with the free ends of the filaments attached to a 0.2-milliampere direct-current source. We prepared spinal cord explants consisting of 1-2-mm-thick thoracolumbar cord segments from 15-day to 17-day-old rat embryos under sterile conditions. All explants were grown for 3 weeks in Dulbecco's modification of Eagles' medium, supplemented with fetal calf serum, glucose, and penicillin-streptomycin at 37 degrees C in a humidified 95 percent air and 5 percent CO_2 atmosphere. At the end of 3 weeks, we rinsed all culture dishes with physiolgical saline. Using an ocular micrometer, we measured fibrous outgrowth from the edge of the explant to its most distal point. We observed healthy explants after 3 weeks in culture. A scanning electron microscope (SEM) showed us that outgrowth from explants was parallel to the longitudinal axis of the carbon filaments. Neurites from the explants were growing on and in between the carbon filaments. The outgrowth we observed with SEM appeared to be both nerve fibers (when stained with silver protargol method) and glial fibers (when stained with immunoperoxidase method). In electrically stimulated explants, neurite length was greater towards the negative pole. We believe that the carbon filaments provide support and guidance for the growing fibers from the spinal cord explants in tissue culture. A 0.2-milliampere constant current, when passed through the carbon filaments, enhanced fiber growth.

Influence of Continuous Electrical Stimulation On the Spinal Cord Motor Neurons

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Progress—Applied electric fields have been reported to facilitate regeneration or regrowth of injured peripheral nerves and severed spinal cord axons. We are conducting this study to evaluate what stimulation parameters might be best. For the study we anesthetized female Wistar rats, 200-250 gm in weight, with 6 percent chloral hydrate, then performed laminectomies to expose T10-T13 levels of the spinal cord. We inserted tantalum electrodes into the cords at a depth of 1 mm and spaced 2 cm apart, with the current traveling in a head-to-foot direction. The stimulator was sutured subcutaneously. For stimulation we used monophasic pulses of 130 mV, 0.3 millisecond duration 120 milliseconds apart. After 3 months of continuous stimulation, we sacrificed all animals by perfusion with Karnovsky's fixative, then removed the spinal cords, cut them into small pieces, and processed them for the electron microscopic examination. After 3 months of continuous electrical stimulation, the animals did not exhibit any motor deficits upon gross observation; they appeared normal in all respects. However, when they were allowed to walk on a smooth surface, such as X-ray film, their hind limbs showed a slight deficit in grabbing as compared to non-stimulated animals. We also noted some tissue disruption of the spinal cord at the site of anodal electrode insertion. Our electron microscopic examination of motor neurons located between the two electrodes and below the cathode showed typical-appearing neurons, glia, and synaptic structures. However, upon further observation, we noted an alteration in the stacking of individual strands of rough endoplasmic reticulum and the distribution and quantity of Nissl substance of the motor neurons.

D. Independent Living for the Severely Disabled

Parameters of Independent Living Programs: A Longitudinal Study

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Purpose—This study builds on three previous comprehensive descriptive studies of independent living programs conducted by ILRU over the past nine years. The purpose is to maintain a database on the status of independent living programs nationally and through analysis, identify trends in their development, the emergence of new problems and new solutions for the delivery of independent living services, and changes in the characteristics of consumers of these services.

Progress—The survey used in previous studies by ILRU has been revised and refined using input received from senior project consultants. It has been pilot tested and further refined. The survey instrument is being mailed to each of the more than 300 programs listed in the ILRU Directory of Independent Living Programs, and to directors of state vocational rehabilitation agencies and the 10 regional offices of the Rehabilitation Services Administration for referral to programs not included in the ILRU list. Information will be solicited concerning populations served, services provided, characteristics of persons providing services, methods by which services are provided and program is administered, sources of funding, and relationships between programs and their community. Data will be coded and entered into the computer for univariate and multivariate analyses. Results will be presented and discussed in a new edition of the ILRU Registry of Independent Living Programs. The survey will be repeated annually.

The existing database is being updated as new information is obtained. A directory listing all identified independent living programs is revised on an on-going basis and is disseminated widely. The registry of independent living programs developed from the previous survey is also available. The ILRU Research and Training Center on Independent Living at TIRR is continuing its networking, training, and technical assistance activities using these data for the benefit of any independent living program or individual interested in independent living.

Independent Living in Rural Areas: A Longitudinal Study

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Purpose—Under a 3-year grant from NIHR, ILRU recently completed a project to expand independent living opportunities for disabled residents of rural areas. Six demonstration sites were established and given ongoing support until the project was completed in April of 1986. The current Research and Training Center project is designed to examine the long-term effects of these interventions in terms of quality and quantity of ongoing activities and outcomes for the community.

Progress—The first component of this evaluation project has involved an initial assessment of three demonstration sites at the time that ILRU funding through the rural demonstration

grant was discontinued. This initial assessment allowed for the collection of baseline data to be used for comparison purposes following assessments in subsequent years. The second component will be followup interviews of selected individuals living in the demonstration site areas. The third component will involve two followup examinations of these demonstration sites at 18-month and 36-month intervals.

To date, three demonstration sites have been chosen from among those previously established by ILRU. Consultants at each site have conducted the Community Needs and Resource Survey developed by ILRU during its rural demonstration project, thus establishing baseline data.

Staff will develop the content and format for personal interviews of residents at each demonstration site. This protocol will be pilot tested on a sample of ten individuals at one site, refined appropriately, and administered at all three sites. All data gathered through the Community Needs and Resource Survey and individual interviews will be coded and computer-entered in preparation for comparativeanalysis after the collection and entry of the data collected at the 18-month interval.

An Operational Definition of Independence

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Purpose—This project is designed to develop an operational definition of independence that spans four uses of the term: in a behavioral sense, as a psychological trait, in connection with functional abilities, and with respect to individual social performance. The objective is to develop an assessment battery to quantify an individual's independence in each of the above specified domains.

Progress—With appropriate expert consultation, a refined conceptual definition of independence is being generated covering each of the four usage areas. Measurement operations (rating scales, standardized tests, the content analyses of direct observations) will be identified which represent the state of the art in each area. Those measurement operations will be applied to a carefully comprised sample of persons eligible for independent living program services. Multivariate analytic techniques will be applied to the resulting data to identify the factorial structure of those measures, and using the factor analytic results, a practical means will be developed to profile quantitatively an individual's 'independence' and generate a single score or profile of scores that reflects the individual's independence relative to others. Subsequent projects then will be undertaken to demonstrate utility of this operational definition in evaluating outcomes of independent living programs.

A thorough literature search has been conducted. The results of this search and an analysis of issues surrounding outcome assessment in independent living were prepared for publication as a chapter in *Rehabilitation Outcomes: Analysis and Measurement*, edited by Marcus Fuhrer, to be published in 1987 by Brookes Publishers.

Common characteristics among definitions of independence were extracted from literature dealing with this construct as a psychological trait, a behavior, an indicator of functional abilities, and an indicator of social status. A listing was compiled of psychometric instruments and tools used in independent living program evaluation to assess the level of an individual's independence.

From existing literature and discussions with senior project consultants, a provisional operational definition of independence has been developed. From this, a preliminary assessment battery will be constructed.

E. Communication Methods and Systems for the Severely Disabled

Capuchin Monkeys as Aides for the Severely Disabled

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Progress—This project is an ongoing attempt to refine the procedures by which capuchin monkeys are trained to serve as aides for high-level quadriplegics. Progress has been made in meeting the following objectives. 1) Approximately 90 percent of the training procedures used in teaching a basic repertoire of skills have been standardized and described in a 100-page illustrated training manual as well as instructional videotapes. 2) Eight high-level quadriplegics are now using simian aides, with feedback from these placements continuing to allow refinement of our profile of desirable candidates. 3) A breeding colony was established in 1985 at the Mannheimer Primatological Foundation in Florida to produce 20-40 infant Cebus per year. A colony has been located in Argentina, and 16 female infants have been purchased. 4) A nonprofit organization has been established, with financial support provided by a corporate sponsor, to apply the knowledge gained from the simian aide research and to place simian aides as mature animals become available, beginning in late 1987 with 15-20 placements per year. 5) An evaluation of the simian aide research is currently being conducted by the evaluation unit of the Department of Rehabilitation Research and Development. A second unrelated evaluation by the New York University Spinal Cord Injury Research Unit is also planned. 6) Data from a market survey testing the preferences of high-level quadriplegics for simian aides versus robotic arm work tables has been collected. 7) An experimental program for teaching college students how to train monkeys initiated in September of 1985 will be evaluated over the next 2 years for efficiency and cost-effectiveness. 8) Canada, Argentina, and Israel are now beginning their own simian aide programs; training material and primate selection information are being provided to them at no charge. 9) Modifications to the wheelchair mounted laser system, food dispenser, and shock/tone unit are being made to make this equipment more reliable and unobtrusive.

An Optimal, Inexpensive Text Entry System for the Orthopaedically and Neurologically Disabled

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Sponsor *None Listed*

Purpose—The goal of this project is to devise software that makes it possible to customize a text-producing system for an individual who is unable to use the standard keyboard effectively and comfortably, because of neuromotor or orthopaedic disability.

Progress—Our approach makes use of inexpensive, off-the-shelf hardware and thedevelopment of software that can allow nonprogrammers to customize a device to a user. Software development falls into two broad areas: field specifiable keyboards, and keyboard optimization.

Two basic techniques may be identified for

field specifiable keyboards: 1) direct input keyboards, for which software is being developed to allow the interfacing of digitizing tablets as specifiable keyboards with a personal computer; and 2) indirect input keyboards, for which software is being developed to display a specifiable keyboard on a personal computer screen and to interface with a number of key selection devices such as joysticks, mice, and trackballs. Each of these techniques utilizes the computer screen to display the text being constructed.

Keyboard optimization approaches under development are: 1) arrangement of keys, for which software has been developed to utilize a user model (user-specific time-dependence on physical parameters of devices), and statistical properties of English to arrange the keyboard items so as to maximize the text entry rate; 2) coding, for which software is being developed to optimize jointly the coding of characters into several keystrokes and the arrangement of the resultant keys so as to maximize text entry rate; and 3) software has been developed to disambiguate text entered from multiple-character keys; the assignment of characters to keys is optimized with regard to minimizing inherent ambiguity.

A variety of low-cost input interfaces have been evaluated as text production control modes. A pilot assessment of a subject's ability to use a joystick for menu selection has been carried out. Work is in progress to refine this assessment and devise assessments for the other inexpensive control modes. Studies of learnability are planned.

Software Development of Alternate Inputs to IBM PC

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Sponsor: *National Institute of Handicapped Research*

Purpose—The purpose of this project is to enable individuals with disabilities to access an IBM PC computer using a variety of devices and communication techniques. Current work includes researching scanning techniques that can be used within a window environment, the development of software, and the completion of the transfer of the LROP (Long Range Optical Pointing) System to a manufacturer for distribution. Each product will be defined and designed, implemented, tested, documented, field tested, and moved to commercial distribution.

PACA—Portable Anticipatory Communication Aid

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Purpose—The PACA was a research and development project to design a portable computer communication aid which would enhance the communication abilities of nonvocal persons who also have physical impairments that preclude the use of direct selection techniques. The project had two primary objectives: 1) to augment the utility of traditional scanning communication aids by adding message element anticipation; and 2) to make this scanning communication aid cost-effective to the user by capitalizing on the benefits of the innovative technology and competitive marketing of an available commercial portable computer.

Progress—The PACA communication aid has been completed. It has been realized as a program, stored in EEPROMs, running on the Epson HX-20 portable computer. The program and Epson have features that support person-

to-person (conversational) communication, note taking, writing, and math calculations. Two operational versions of the program are available: a single-switch automatic scanning version and a two-switch step-scanning version. Neither version requires any hardware modifications to the Epson, other than insertion of the program PROMs. The switch for the single-switch version is connected, through an adapter cable, to the HX-20's bar code reader port. The switches for the two-switch version are connected to a simple low-power electronic circuit plugged into the bar code port.

A significant feature of the PACA program is the use of anticipatory (predictive) algorithms, based on frequency of use, to improve the efficiency of letter and word selection. Letters and words with greater probability of being selected are arranged in their selection arrays in positions that require fewer scanning steps to select. By ordering letters and words dynamically, in this fashion, it is possible to reduce, on the average, the number of scanning steps and switch activations needed to create a message. The improved efficiency of message creation can result in an improved rate of message generation for persons afflicted with severe motoric involvement.

The PACA program was developed with the support of clinical and field evaluations by persons who are both nonvocal and physically disabled.

CompuTalk

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Sponsor: *Volunteers for Medical Engineering, Inc.*

Progress—A talking keyboard has been designed and a prototype of the system has been developed and field tested. It is presently being used at the National Rehabilitation Hospital. The unit is a low-cost assembly making use of available electronic components. In order to operate the unit, one merely types a message and the CompuTalk assembly speaks the words or sentence as soon as the enter key is depressed. The message can be 256 characters long and is read from a liquid crystal display integral with the keyboard assembly. In addition, each of the keys of the standard keyboard can be programmed by the user to have a stored message, 56 characters long, that is nonvolatile and accessed by pressing the function key and then the message bearing key. The plan is now to configure the electronics for producibility. This includes the development of a printed circuit board for automatic interconnections. Additionally, it is planned to incorporate another liquid crystal display so that the person to whom the user is speaking can see what is being typed while facing the user.

Future Plans—The work on the printed circuit board for the electronics assembly has been submitted to layout for interactive graphics (IAG) creation. When the layout is complete, we will begin the production of the units and assemble a number of prototypes for distribution to the VME Chapters around the country and for use by local institutions dealing with rehabilitation of disabled persons.

We have received a number of constructive comments from client evaluations which we will incorporate into the production version. This will include the second liquid crystal display facing the person to whom the client is trying to communicate and the examination of means for enlarging the keyboard target area for the visually impaired or for those clients who have motor control problems.

Due to the numerous requests we have had for this device, we will be concentrating on making the printed circuit for the electronics packaging and then proceed to manufacture a number of units for distribution to the various chapters and to the rehabilitation facilities for their continual use and evaluation. We will then begin to advertise via the Concepts for Independent Living and other networks to let

people know that it is available. At that time we will have complete documentation and will be well on the way to FDA approval. We will be seeking funding from various sources so that we can make all of the plans happen in a timely fashion by applying some full-time effort to the project.

Electrically Controlled Talking Tracheostomy Systems

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Sponsor: *Rehabilitation Engineering Division, Department of Physical Medicine and Rehabilitation, University of Michigan*

Purpose—An individual can become dependent on mechanical ventilator support because of neuromuscular disease, high level spinal cord injury, or any other condition that seriously reduces respiratory function. For those requiring long-term ventilation, a tracheostomy tube is surgically implanted into the trachea below the larynx. Cuffed tracheostomy tubes are used to protect the inner airways of the lungs and to ensure that adequate ventilation parameters are maintained.

Providing a means of communication to these patients is crucial to their medical as well as psychological well-being. One method of providing verbal expression for a patient using a tracheostomy tube is to partially deflate the cuff, allowing air to flow up across the vocal cords. Another method employs a specially designed talking tracheostomy tube such as the Portex talking tracheostomy tube.

The Portex is a single-cuffed tracheostomy tube with an additional small-gauge air line running along its curved surface and ending just above the cuff. The external end of this air line is connected to a source of compressed air that is regulated to produce audible speech (approximately 5 liters/minute). A "tee" in the air line provides a port to control the airflow to the vocal cords. Air escapes out the control port until the port is covered by a finger, which causes the air to flow through the air line to the vocal cords. It is the quadriplegic patients' inability to close this control port that prevents them from independently actuating a system such as the Portex.

Progress—Several systems for independent actuation of the talking tracheostomy systems have been developed. Different design constraints based on patient needs have resulted in a variety of system configurations. These systems can be categorized into 110-volt AC and 12-volt DC systems.

A 110-volt AC high-pressure solenoid valve can be installed at a compressed-air outlet: either a wall outlet such as those in hospital rooms, or an air tank, or an air compressor. Alternately, a low-pressure 110-volt AC solenoid can be used to open and close the control port on the talking tracheostomy tube, but residual resistance of the valve in the open state causes a small amount of air to flow continuously across the vocal cords, causing dryness and irritation. The air needs to be passed through a humidifier bottle before going to the vocal cords.

A DC relay is used to activate the solenoid valve: DC voltage is obtained from the 110-volt AC line via a simple power supply, which also isolates the patient from the 110-volt AC line current. A momentary, time-latched, or latching switch is used to control the relay and operate the solenoid valve. This system is easily transported with a compressed-air tank cart, but requires a 110-volt AC outlet for operation.

A 12-volt DC high-pressure solenoid valve that is powered by the ventilator battery or a wheelchair battery can also be used. The ventilator and its battery can be mounted on either an electric or manual chair. Pressurized tanks or a battery-operated air compressor are used as the source of compressed air and are also mounted on the chair. A momentary, time-

latched, or latching switch controls the solenoid valve. Occasionally, the ventilator and talking tracheostomy systems do not have a separate battery but use the wheelchair batteries. For that situation an automatic switching relay has been developed to alternate the 12-volt DC drain evenly between two 12-volt wheelchair batteries.

These systems have been extremely successful in allowing patients to independently control their talking tracheostomy systems. This independent voice control has greatly enhanced communication for these individuals.

Future Plans—Future work will include improvements in mounting systems, air compressors, and all other system components. Options for more automatic control of these talking tracheostomy systems are also being considered. Such a control system is difficult to design as it must sense speech initiation.

A Single Switch Keyboard Emulator for the IBM PC

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Purpose—The personal computer has become a primary tool for allowing the severely disabled to communicate with and control their environment. In the past, the most commonly used personal computers were from the Apple II family. The IBM PC and PC-compatible computers have become the standard personal computers in business and science, largely because of their superior processing power and memory capacity. Steady decreases in cost have made them an excellent choice for the handicapped user. A special software keyboard emulator called ALTKEY has been developed as an input driver for IBM PC-compatible computers. It is designed to solve the same problem in software that the Adaptive Firmware Card solves in hardware on the Apple II.

Progress—ALTKEY augments the device driver software already present in the basic input/output system read only memory (BIOS ROM) by adding a scanning system that allows each user to design and edit individualized scan menus. Input generated by this system goes to the regular keyboard buffer where it is treated as actual keyboard data.

ALTKEY presents the user with a series of input choices listed across one line of the video screen. These choices are highlighted one at a time in a repeating pattern. The user makes a specific choice by activating a switch when the desired entry is highlighted. The switch can be one of the shift keys on the keyboard or a momentary switch connected to a game port input. Each selection can display a new set of choices or send key codes to the keyboard or both.

The list of branching menus and entries is called a scan tree. The scan tree is defined in a simple text file called a scan tree definition file. The user can create and edit these files, customizing them for specific application programs. The flexibility of the tree design allows required selections to be minimized by presenting the user with the most likely choices first.

Future Plans—The current version of ALTKEY was designed with the intent to add enhancements on a regular basis. Planned additions include options for two switch scanning schemes and Morse Code entry. There are discussions currently underway throughout the software industry aimed at developing a standard for memory-resident software. When this becomes a reality, ALTKEY will be modified to conform if possible. Until that time, testing with other memory-resident software will continue in an effort to keep ALTKEY current.

Development of a Unified Quantitative Model for Augmentative Communication Systems

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Progress—A conceptual model has been designed to assist in the comparative analysis of all current selection-based augmentative communication techniques. Six tests of the model have been completed and documented. Two by G. C. Vanderheiden are in press: "Overview of Selection-Based Augmentative Communication Systems," and "A Unified Quantitative Modeling Approach for Selection-Based Augmentative Communication Systems." We also are studying the minimum sample lengths required for stable predictions of user performance, and preparing an additional document: "Testing of Predictive Capability of a Quantitative Model for Augmentative Communication Systems," by Vanderheiden.

Comm-Aid

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Purpose—The Volunteers for Medical Engineering Inc. (VME) have developed a software program that is intended for the multiply-handicapped persons who have communicative disorders, exhibiting communication developmental levels of approximately 8 months to 5 years. The complete package is actually an authoring system, allowing a therapist/teacher to create a communication device tailored to a specific individual's needs. The program, which runs on an Apple computer, uses a touch tablet (a PowerPad) as an input device. The surface of the pad may be mapped into any arbitrary arrangement of (up to 144) rectangular areas, and each area may be assigned a high-resolution graphic picture and a string of "voice-text." The program then creates a customized disk; start-up with this disk in the drive turns the computer into a communication device. By sequentially pressing areas of an overlay on the PowerPad, the user can produce the corresponding graphic "sentence" on the screen, and hear the voice-synthesized text (via an Echo™ speech synthesizer) at the same time.

Comparing this package to currently available products, Comm-Aid is unique in combining the following features: The customized touchpad layout allows the therapist to make allowances for an individual's capabilities (in terms of muscular control and cognitive ability). The graphics display may be chosen from a library. By using commercially available software tools, the therapist may modify or add to the library. With speech output provided by the popular Echo synthesizer, vocal feedback can be anything that is meaningful to the intended user. Turnkey operation permits the therapist to appropriately label the disk that the system produces (e.g., "Johnny Jones"). To work with Johnny Jones, the therapist simply turns power on with his disk in the drive.

Progress—All parts of the program are operating: pattern layout editing, graphic selection, and voice-text entry. The automatic package compiler is incomplete; however, a hand-compiled sample disk is being tested with handicapped children to refine the user interface.

Future Plans—First, we will complete the programming of the package as described, and produce the library of graphic symbols under the guidance of a specialist in augmentative communication for the handicapped. Then we

will produce a manual to guide the therapist through the authoring process. Current efforts are proceeding on a "donated spare time" basis by a member of VME. To permit faster completion and fine-tuning of the project's features, proposals for grant funding are being prepared.

Application of Technology to Enhance the Employability of Severely Communicatively Impaired Individuals

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Purpose—One of the major barriers to successful employment for severely disabled clients is lack of adequate communication for the workplace. Although computer technology has been used to augment the communication skills of the nonvocal physically handicapped, little attention has been given to resolving their communication problems related to entering and retaining employment. The purpose of this demonstration project is to develop a multidisciplinary approach for analyzing the communication needs of a client and a particular workplace; for prescribing and customizing an appropriate communication system for that client; and for training that client to have communication competence for the workplace. Removal of the communication barrier to employment is expected to provide greater independence for the disabled with subsequent economic and psychosocial benefits.

Progress—*Assessment Phase.* A very important feature of this project has been the development of rapid, targeted assessment procedures. Utilizing this approach, it has been possible to identify the type of augmentative communication device needed by a client after two or three two-hour visits to the Clinical Training Center on campus. This not only maximizes use of valuable facilities and staff time, but also reduces the stress of the assessment process for clients whose severe physical disabilities make travel difficult.

Greater efficiency has been made possible due to the comprehensive preassessment evaluation carried out by the multidisciplinary Assistive Device Assessment Program (ADAP) team. The crucial elements of this are: a screening interview with the referring individual, and a detailed application form and written reports from the potential client's physician and all agencies from which he/she has received service. Based on this information, the team decides whether to accept the client and, if so, what additional information is needed. The ADAP social worker gathers the needed information through additional collateral contacts, one or more visits to the client's home, and, if relevant, visits to the client's school or sheltered workshop.

The application materials and the social work report enable the speech and language pathologists on the team to plan a cognitive/communication assessment that utilizes parts of various standardized tests as well as a variety of informal measures designed for the particular client being assessed. The results from the cognitive assessment are used to guide subsequent evaluations. For example, sections of tests such as the McCarren-Dial and Perceptual Memory Task are used by the vocational counselor to establish the client's probable vocational readiness and direction. Motor assessment procedures similar to the one used by the Sacramento State Assistive Device Center are used selectively by the rehabilitation engineer based on what is already known about the client's physical capabilities. Of course, a complete assessment is done in areas for which there is any question about capability. Following the motor assessment, clients are tested (either directly or through simulation) on several communication devices that might be suitable based on their cognitive and physical abilities.

Vocational Placement Phase. The project team has encountered unexpected difficulty in

securing funding for the recommended augmentative communication devices. To overcome skepticism and to provide stronger documentation, project team members have trained several clients to use the recommended device on a regular basis. Because most of the project clients are too severely disabled to have been eligible for existing vocational rehabilitation programs, project staff members have been working with representatives of various community agencies in developing new routes to the workplace for them. Some of the more promising avenues include placement in sheltered workshops, individualized vocational training programs, and supported work.

Status of Clients. Of the 18 accepted applicants, 14 have been assessed regarding their cognitive and physical abilities for using a communication device. Currently, seven project clients are undergoing some type of training for improving their communication competence and/or vocational potential. Two of the clients have secured their own suitable electronic communication systems, and three clients are in the vocational phase of the project.

Future Plans—During the remainder of this 3-year project, the assessment procedures will be further refined and specified so that they can be duplicated by other teams of professionals working in the areas of augmentative communication and vocational rehabilitation.

Neuromuscular Assessment for Assistive Communication Device

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Purpose—The number of communication and environmental control devices available to severely motor-handicapped individuals has grown enormously in recent years. However, equipping such patients with these devices requires a complex program of neuromuscular assessment, as each person's available motor resources will determine the type of interface used to connect the human and the device. We have embarked upon such an evaluation program with a severely handicapped nonvocal cerebral palsy patient, with the goal of developing a specialized interface for use with an assistive communciations device.

Progress—Our investigation has focused on myoelectric activity in the head and neck region (primarily the frontalis and sternocleidomastoid muscles), and on left/right head rotation as device control possibilities. To refine the subject's frontalis control, we have implemented a biofeedback training program using a specially modified myoelectric biofeedback device, the Myobeeper. (This device was described in our 1983 Progress Report.) We will continue our efforts by constructing a prototype interface that will translate head rotation into various voltages suitable for device control purposes.

Investigations on a Communication System for the Severely Handicapped

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Sponsor: *None Listed*

Purpose—A particularly severe impairment is the total loss of speech with a simultaneous loss of major motor functions. In such cases at least one residual motor function is an indispensable prerequisite for the maintenance of ability to communicate with other persons. A communication system based on a personal computer has been developed.

Progress—Only slight modifications are re-

quired to adapt the communication system to different types of, and changing, handicaps. This means that the disabled person is not bound by a rigidly fixed system.

To a particular degree, account can be taken of the individual wishes of the handicapped person with respect to the form of the program, the functions employed, special words, and writing speed. The possibility that the handicapped person will be able to communicate whenever he wishes without being dependent upon any direct aid on the part of others, and with no great restrictions on the form of expression, is the major advantage of this system.

The communication system enables the patient, simply by moving a single finger, to display any message he wishes on a monitor screen, or to print it out on a printer, and, in addition, to actuate a number of electrical switching functions. The system is operated by the handicapped person via an input device, which can be adapted to the individual concern.

The advantage of this system is the flexibility of the hardware and software. There are costs for additional hardware only as a result of an individual adaptation of the input part.

Future Plans—To complete the project, the following investigations will be carried out: comparison of different types of communication systems and input devices; efficiency of the systems; and optimization of the interaction of system and adapted man-machine-link.

F. Environmental Control Systems for the Severely Disabled

UHCI: Ultrasonic Head Control Interface

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Purpose—In order to perform some tasks independently, severely disabled individuals must find communication pathways to replace the ones that have been totally lost, or they must amplify those that are impaired. High-level quadriplegics have a particularly difficult time in replacing lost or diminished channels to the outside world, since many of them can control only the muscles at their neck level and above.

Although many interfaces have been developed for use by severely disabled individuals to bridge the gap between body and environment, none has proved to be ideal. Some have sanitation problems (pneumatic puff/sip switches); others intrude physically upon the user (chin-operated joysticks) or are socially objectionable (head wands). In addition, many are limited in their ability to convey the user's will regarding the operation of the device in question.

Recent technological advances have produced eye-tracking and voice-control interfaces, but even these solutions are less than perfect. Eye-tracking interfaces restrict the user's range of vision while communicating. Voice-recognition interfaces have long response times and are limited to a discrete vocabulary, making them unsuitable for real-time control situations involving continuous variables (such as speed and direction).

Successful development of a device that can overcome current interface shortcomings would be of significant value to severely injured individuals who wish to control their mobility, communication, or recreation in a socially acceptable and aesthetically pleasing manner. In particular, the existence of a device that operates at a distance without the necessity of mechanical contact, that uses a control site not required

for normal sensory input, and that is easy to learn and use could be an ideal solution.

An array of ultrasonic distance-ranging sensors can monitor the head position of a severely disabled quadriplegic operator to obtain information for controlling mobility, communications, and robotic devices. Such a device requires no direct physical contact, and is expected to be more socially acceptable and cosmetically pleasing than devices that do.

Progress—An Ultrasonic Head Control Interface (UHCI) that employs two Polaroid ultrasonic distance-ranging sensors to track the user's head position has been developed. As the user tilts his/her head forward and backward, left and right, the UHCI generates control signals as if the user were moving a joystick. These signals can be used to control a wheelchair, a communication aid, a video game, a robotic arm, or any other device that accepts joystick input. Because the sensors require no mechanical contact with the user's head, the user has no reason to feel confined or "wired up" as is often the case with other interfaces.

UHCIs have been installed on two electric wheelchairs. The first, an Everest & Jennings model 3P equipped with a reclining Recaro seat, is in use in France by a quadriplegic woman. The second, an Invacare Rolls IV with a Solo Products Power Pack, is being evaluated at the VA Medical Center in Palo Alto.

Preliminary Results—Both units have been operational since June 1983. User evaluation has been performed with 10 quadriplegic individuals. After a short demonstration and training session, the subjects were transferred into a chair equipped with the units. Most were able to navigate successfully without problem. They stated that they preferred the ultrasonic head control to the chin-controlled joystick wheelchairs they had used previously.

A generalized interface for a robotics application has also been developed. As with the UHCI, it allows the user to select tasks and control the operation of a mobile robotic arm via head position. In particular, it allows the user to "draw" the desired robot trajectory on a cathode-ray tube.

A technical manual for the UHCI, including background material, electronic schematics, computer program listings, explanations, and illustrations, has been compiled and made available to more than 50 investigators around the world who are considering the UHCI for research or commercialization.

Future Plans—Within the Veterans Administration, a Request for Evaluation was submitted to the Evaluation Unit and approved. Action is under way to obtain funds for the commercial production of four units, which will be evaluated at VA Medical Centers throughout the country. A decision will then be forthcoming regarding the prescription of electric wheelchairs using the UHCI technology for appropriate severely disabled veterans.

Interactive Motion and Graphic Environmental Simulation

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Purpose—The Interactive Motion and Graphic Environmental Simulation (IMAGES) project involves developing simulation technology applications to the specific needs of two diverse populations: those individuals with spinal cord injury and those with visual impairments.

For the spinal cord injury population, or those with mobility restrictions, the project will provide the necessary tool for safe, cost-effective, systematic research, development, and evaluation of powered wheelchairs. It will attempt to answer such questions as: Who can use powered wheelchairs safely? Under what operating circumstances can they be expected

to perform satisfactorily? What features limit a chair's effectiveness and acceptance? What key features are needed to make these chairs more accessible?

The same tool can also be used to examine the potential uses of robotic aids, the need for mobility of the robotic aid and how this might best be achieved, and the interaction between the user and the aid. Simulation technology could also be used to gain a better understanding of the functional visual capacity of visually impaired individuals, answering such questions as: What does the person with age-related maculopathy, diabetic retinopathy, or glaucoma actually see? How can individuals be taught to better utilize their residual vision? How can a safer, more efficient environment be produced? What are the critical performance specifications for the next generation of diagnostic, training, reading, and mobility aids?

Progress—The IMAGES project centers around a Digital Image Generator (DIG) display, donated by the Singer Link Company, and three IRIS 2400 graphic workstations. These workstations are located at Stanford (robotic simulations), at the Western Blind Rehabilitation Center (visual impairment simulations), and at the University of Santa Clara (wheelchair simulations). Having three locations of the workstations allows the maximum number of researchers to work on the project while maintaining a common focus around the large DIG display housed at Stanford.

Extensive liaison is maintained with staff at the NASA Ames Research Center because of their extensive experience in the application of simulation technology to aerospace problems. The recently acquired IRIS workstations are in place, and development of appropriate databases has begun. Pilot testing will assess the feasibility of using simulation technology to study wheelchair mobility, the visual needs and abilities of partially sighted travelers, and the application of robotic manipulators to physically disabled users.

Voice-Actuated Control System

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Purpose—The Volunteers for Medical Engineering, Inc. (VME) has designed a low-cost (estimated to be less than $100) voice control system that will have, in the first prototype, 256 separate control commands. The output can activate a voice synthesizer and a message panel for communication and/or any electrically operated appliance.

Progress—The circuit diagram for the Voice-Actuated Control System (VACS) has been completed, and the parts for the prototype have been ordered. The Sensor Design Group of the VME has been asked to review the design and to suggest design improvements so that the least expensive and most reliable design can be built as the prototype. The current parts list for the control unit shows a cost of less than $20.

Future Plans—We plan to build several units for evaluating performance. The potential for this low-cost Voice-Actuated Control System is tremendous and will find commercial applicability as well as direct applicability to the disabled person. We will therefore look to the needs of the disabled persons while developing the commercial applicability. The VME plans to form a nonprofit manufacturing division, with this as one of the products that will be sold to create funds for continuing projects.

Information about VACS will be disseminated throughout the VME chapters. It will be listed on the database of the "Tech Net" division of the Concepts for Independent Living Corporation (CIL) and on other hotlines throughout the country in order to provide the greatest possible accessibility.

Design of Showers and Bathing Fixtures for Disabled and Elderly Veterans

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Purpose—Moderately and severely disabled people are often prevented from adequate independent bathing in their homes because existing bathing fixtures and other assistive devices do not meet the needs of many of these people. Existing fixtures and adaptive devices are often very expensive, not widely available to the disabled consumer, very specialized in design (for a specific disability, etc.), and not well evaluated for use by disabled people. New bathing fixture designs are needed that meet the varying needs of moderately and severely disabled people of all ages and that are capable of being manufactured in a cost-effective manner.

Progress—Four shower prototypes have been developed using participatory design methods and structured evaluations of the use of each fixture by disabled subjects. The design and development process uses full-size prototypes made of fiberglass that are modified and then evaluated using an evaluation protocol consisting of pretrial and posttrial interviews, photographic and video documentation of subject trials, and documentation of user comments and suggestions. Disabled subjects are recruited from the Atlanta VA Medical Center and from other Atlanta centers providing rehabilitation, independent living services, and support for disabled people.

Preliminary Results—Four shower prototypes were developed initially and then evaluated during 1984 and 1985. They included: 1) a cushioned shower designed primarily for people who are capable of transferring to and from a wheelchair with little or no assistance; 2) a fiberglass shower with two integral seats designed primarily as a test prototype for evaluation of the bathing abilities of right and left hemiplegics; 3) a roll-in shower with seat designed for people who can transfer; and 4) a two-piece roll-in shower designed for people who shower in their wheelchair, which permits independent use when possible and accommodates assistance by an attendant.

Based on the results of the evaluations, the basic design of three of the showers (1, 3, and 4) was found to be appropriate. Minor modifications to improve usability of the prototypes and to develop the designs for future manufacture are now being completed.

The two-piece roll-in shower has been modified to increase the depth of the unit, improve the design of the floor, and develop a shower curtain system capable of being operated manually or with a power operator. The new version of the roll-in shower is now being evaluated at the Atlanta VA Medical Center. The seat and the grab bars provided with the roll-in shower have been modified and this new design also is being evaluated by the investigators. Another seat is currently under development that will feature a cushioned surface and a specially contoured seat area. This design will be based on the design of the fiberglass seat but will require some detail changes due to the use of the cushioning material.

The design of the cushion shower is being modified to correct a problem with the fixture size and with the positioning of users in the fixture during bathing. The current design of this fixture provides very good lateral trunk support and body stability. This is accomplished by the use of a contoured seat and back area combined with a raised floor under the user's feet that acts to push the user back into the seat.

Unfortunately, many subjects experienced pain and discomfort caused by the raised floor and by inadequate space in the seat and back areas. The current design does not accommodate users who are moderately overweight although this type of fixture would be very useful for this type of user. Modifications to the current design are planned that will continue to provide good body support while increasing the

dimensions of the seat area and lowering the floor height.

Future Plans—Modifications to the two-piece roll-in shower and to the roll-in shower with seat (both fiberglass and cushioned versions) are being completed. The cushioned shower that is being redesigned will be fabricated and then evaluated. A new shower seat is being developed and will be evaluated for use in existing bathtubs. This design will use the seat design from the roll-in shower with seat and will add a tubular frame designed for use in a bathtub. Following the completion of the fixture modifications and the evaluation of the improved fixtures, the investigators will complete the work on an illustrated applications workbook that explains how to select the correct fixture based on user need, how to install that fixture, and how to use the fixture safely.

Development of a Robotic Arm for Use by the Physically Disabled

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Sponsor: *TRIUMF, National Research Council of Canada and Health and Welfare Canada*

Purpose—The objective is to develop a reliable robotic appliance that will provide severely physically disabled persons with the capability of manipulating selected items in their environment in such a manner that these users will continue to use the appliance on an everyday basis. Based on an extensive survey of previous work in this area, interviews with potential users who are severely disabled, occupational and physical therapists, and service delivery specialists, a design criteria and "wish list" of reasonable tasks were established. The final product price will be comparable to that of an electric wheelchair.

Progress—Development work on a robotic manipulator to meet these specifications has been carried out by the authors during the past 3 years. The manipulator geometry, which is human size in scope, was initially designed to perform tasks in the workstation environment. The arm geometry is horizontal axis-cylindrical coordinate and consists of 3-degrees-of-freedom for object positioning and 3 degrees for orientation plus 1 degree for gripper actuation. The versatility of the arm is enhanced by an end effector exchange, which will provide special-purpose grippers for program tasks. The manipulator is lightweight and portable. All degrees of freedom may operate simultaneously under digital P.I.D. control. The working envelope is defined using software boundary limits.

Any computer with an RS-232 serial port, typically an Apple or IBM PC, can be used for supervisory control. It is through this computer, using various input techniques such as Morse code keyboard emulators, keyboard scanning systems, or voice input systems, that the disabled user will be able to control the arm.

As much as possible, the tasks are carried out under program control to minimize the need for user input. However, the user has the ability to interrupt these programmed tasks to make spatial adjustments if required. The programming of a task is based on a lead-through-teach concept that is performed by a friend/attendant, or by a set of manual move commands that will allow the user to single-step through a desired routine. At present, the manipulator is capable of performing such tasks as picking up a manual from a bookshelf and placing it in front of the user; turning pages; picking up, serving (with a straw), and replacing a drink; serving a mouthstick; loading a diskette; picking up an electric razor and shaving a person; brushing hair; and brushing teeth using an electric toothbrush.

Future Plans—The Neil Squire Foundation currently has two third-generation prototype robotic arms. The future development of these arms will be based on field testing in hospital and group home situations conducted in the fall of 1986. Safety precautions will continue to be a

high priority. One of the safety features that will be included is hardware redundancy employing a separate CPU and power supply to monitor the operation of both the low-level and supervisory controllers. In addition, a direct user panic stop system will be implemented in hardware. Software precautions will include a self-test on system start-up, monitoring controller error and output signals for appropriate behavior, and reducing critical trajectory torque in zones that could possibly result in injury. Gripper development and refinement will also be an ongoing concern. A later version of the manipulator will be a bedside unit mounted so that the arm will swing over the bed to face the user when called into service.

Investigation of the Utilization of a Robotic Arm by Disabled Persons in the Workplace

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Purpose—Persons who have disabilities that limit arm and hand functions cannot perform manipulative tasks that are often required on the job. In recent years, robots of various designs have been developed for use in industry. The researchers of this project felt that the robotic arm has potential as a manipulative tool that would allow physically disabled individuals to perform workstation tasks currently beyond their capability.

The objectives are to investigate the feasibility of the utilization of industrial robots, specifically robotic arms, to complement the existing available motions of a disabled worker, and to validate their effectiveness using disabled workers performing industrial tasks.

Progress—The originally proposed methodology called for the purchase of two robotic arm devices and assigning them to workers at two different workstations at Center Industries Corporation (CIC) in Wichita. Subsequently, a third workstation was developed at CIC in which a robotic device would be designed and installed on a machine that would provide for continual adjustment previously performed manually by the machine operator. These adjustments were the only barrier that prevented a severely disabled worker from operating the machine. A suitable device has been designed, fabricated, and installed on this machine and is currently in use.

Two small robotic arms, complete with microprocessors, and manufactured and marketed by Microbot, Inc., were purchased. They are of the type that maintains a base position but have all of the motions that the human arm is capable of performing. To the "hand" of the device must be added an end effector or gripper to facilitate the handling of parts or materials.

One workstation at CIC in the Boeing tinning room was selected to utilize one of the robots. A worker who is quadriplegic from cerebral palsy has operated this workstation with success, maintaining production and quality standards.

The robot grasps, one at a time, small electrical resistors having wire leads from a holding fixture. It then dips the wire leads into a liquid flux, then in molten solder, and deposits the part in an alcohol bath. The worker ensures that the next part to be manipulated is in the holding fixture by the time the robot is ready to grasp it during the normal cycle. The worker observes the operation to ensure quality and uses a special tool for periodically skimming dross from the surface of the molten solder. The proper depth of solder is maintained by the worker dropping small beads of solder into the pot. Using the teach pendant, the programmer manually operates the robot through the positions required in the cycle of operation. The microprocessor remembers the steps and repeats the cycle automatically when asked by the operator to do so (i.e., pressing "RUN" button on the teach pendant).

The robot, after grasping the part, moves to immerse its wire lead in the liquid flux and then to the molten solder that is contained in an electrically heated pot. The part is then turned end-for-end and the dripping process is repeated before depositing the finished part in the alcohol bath.

A third robotic arm, called the Armatrol, marketed by Feedback, Inc., was investigated. The Armatrol offers all the operating functions of the Microbot unit except for "roll" of the "wrist." The significant difference between the Microbot unit and the one by Feedback is that the Feedback unit operates with servomotors, whereas the Microbot unit operates with stepper motors. Programming of the Feedback unit is accomplished by a computer keyboard and is more difficult to understand by persons who are not knowledgeable of robotic language. It is felt, however, that servomotor technology provides for more dependable positioning of the "hand" because the position feedback system is located on the output shafts of the drive motors.

Staff members were able to set up the Armatrol in the tinning workstation. The type of electrical components handled was limited due to the inability of the "wrist" to rotate. The unit operated quite satisfactorily until contract requirements for that particular component diminished. Efforts are under way to find another suitable task for this device.

More recently, an industrially rated robotic arm was purchased. This is the Alpha, manufactured by Microbot, Inc. The manipulations of the arm are the same as the models purchased earlier in the project. Drive motors and the electronic controls are of a quality to ensure dependable operation on a continuous basis in a rigorous production environment. Project staff are currently learning its sophisticated capabilities and programming procedures. It is anticipated that a workstation will be chosen in the near future for operation of this robotic arm.

Preliminary Results—Results of the operation of the first two workstations by a robotic arm to assist a severely disabled worker have shown the concept to be a viable one. During the time of consistent behavior by the robots, production rates and quality were comparable to those of manual operation by able-bodied workers. Additional workstations are being sought for robot implementation at CIC.

Members of the staff continue to be extremely encouraged at the prospect of the use of small robotic arms to provide the manipulative tasks required at workstations that physically disabled persons could not otherwise accomplish. Costs of new devices are being continuously monitored. If a reliable, low-cost, robotic arm can be found, it is obvious that it can provide a cost-effective means for severely disabled workers to work at a pace that is both quantitatively and qualitatively productive.

One major conclusion can now be made. It is not currently feasible to assume that anyone, disabled or nondisabled, can be expected to perform manufacturing operations that are not highly repetitive in nature. The operation of a robotic arm in a manually controlled mode is not fast enough to satisfy production requirements performed by an able-bodied arm or hand for jobs that require random movement and choices. Robots work best when activity is repetitive and accomplished in the same sphere of operation.

Machine Vision

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Purpose—The objective of this project is to design a machine vision system for use with our microprocessor-controlled electric feeder and with other manipulative aids for handicapped persons. Aids for handicapped persons that involve manipulation (e.g., electric feeders)

We feel that development and testing time associated with the Unimation PUMA 560 arm will be reduced by the ability to focus all of the work into a physically defined yet flexible environment. Additionally, we feel that safety to the user and the arm will be enhanced by the features of the described structure.

Progress—The laboratory environment for the testing of the PUMA 560 robot arm consists of an 8-foot-diameter table fabricated out of three similar 120-degree sections. The top of each of these sections provides a rectangular cavity (approximately 20 x 36 x 3 inches) into which can be placed any desired type of testing module. Typical module options are: a light-table for vision systems work, a cushioned surface for ultrasonic proximity sensor testing, a grid surface for coordinate system testing, and a "Lego"-like surface for pick-and-place applications.

One of the three cavities provides a platform that is actually a dropaway surface into which a plug-in module can also be placed. The user dials in a maximum force level (from 2 to 50 pounds) and the dropaway platform, sensing the amount of force the robot arm (or any other item) is impressing upon its module surface, will drop out of harm's way when the limit is exceeded. The purpose of the dropaway section is to provide a redundant safety feature that is out of the robot-software control loop. It is designed to provide an immediate reduction in resistance. However, it cannot withstand very-high-velocity shocks.

The remaining two cavities are static, though they may be upgraded to dropaway status if necessary. Under the table are cabinets for storage of the plug-in modules, the PUMA controller, the workings of the dropaway section, and various power supplies and random storage items. The cabinets house all of the dropaway controls, as well as highly visible panic buttons that are capable of cutting power to the robot, dropping the dropaway surface, or both.

Future Plans—The design of the PUMA 560 table, including electronics and control displays, has been completed. After the table has been constructed, the dropaway surface will be evaluated. Design changes will be implemented when necessary to support unforseen testing needs.

Development of a Training and Reference Manual for a Robotic Manipulation Aid

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Purpose—The first-generation Veterans Adminstration/Stanford University Robotic Aid was developed to give individuals with high-level spinal cord injuries increased control through the ability to better manipulate their environment.

As part of the clinical evaluation of the Robotic Aid, a training and reference manual was developed to provide trainers and users of the device with standardized instruction and to communicate the features and intent of the system.

The need for directed training on this system is pronounced. The Robotic Aid is an interactive system requiring both a human operator and machine intelligence and is intended for use in an unstructured human living environment. Since this system does not operate in the same context as a programmed industrial robot, more responsibility is placed on the user who must first decide what task is to be carried out and then guide the robot's motion explicitly, using his or her own sensory and decision-making capabilities. This necessitates a certain level of control expertise; not only must the user be familiar with the commands to which the robot responds, but he or she must also be able to anticipate the motions evoked by those commands.

Progress—The training and reference manual has evolved with the Robotic Aid Project. It began as a small set of training exercises and grew to include instructions ranging from how to start up the system hardware and improve command recognition, to suggestions for troubleshooting and information on the technical aspects of the system. The many different versions of the manual reflect the changes that have occurred in the 5 years of first-generation development. Its readers include technical and clinical researchers as well as experienced and first-time users of the Robotic Aid.

Preliminary Results—Various versions of this manual have been used in the training of more than 100 individuals. The tasks covered in the manual are designed to test an individual's mastery of particular command sequences. Many are based on needs expressed by the initial users of the system, e.g., the ability to get a drink of water. Other direct results of user feedback include a voice management program with options for training, updating, and saving a vocabulary and on-line instruction for recovery from error conditions. In both cases, user autonomy has been increased, permitting greater interaction with the robot while lessening intervention by a supervisor or attendant.

Future Plans—Work on the training and reference manual for the first-generation Robotic Aid was suspended in 1984 with the funding of the second-generation proposal, Development and Evaluation of an Advanced Manipulation Aid for the Severely Disabled. The current (first-generation) edition of the manual will be used as a foundation for instructions and guidelines for the new system.

One format under consideration is a computerized version of the manual integrated into the human interface, such as an on-line "help" facility. Another would use interactive video technology. A master copy of the manual would be updated regularly so that a state-of-the-project report would always be available and a user could submit a request for a hard copy simply by saying, "PRINT." This option might include a perforated "cheat sheet" that would serve as a quick reference for experienced users and eliminate the need for the printed manual as an encyclopedia.

Evaluation of Robotic Aids for the Severely Physically Disabled

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Purpose—The concept of using robotics to provide increased functional independence for the disabled is not new, but to date little data have been published showing that specific tasks can be performed satisfactorily within a reasonable period of time. At present, no robotic aid for the disabled has made it from the laboratory to the marketplace.

It is hypothesized that repeated evaluation by disabled users and continued improvement of present technology based on these users' feedback will make robotic devices and interface controls for the disabled practical, cost-effective, and generally available.

This project is an expansion of a study that investigated the use of the robotic aid for eating and hygiene tasks. The robotic aid being evaluated is a Unimation PUMA 260 industrial arm, augmented by an IBM PC/AT and a Keytronics Voice-Input Keyboard Emulator. A workstation surrounding the robot arm makes accessible the materials needed for functional tasks. Within reach of the arm are a computer terminal, a microwave oven, a refrigerator, disk drives, and a two-way speaker phone.

A freestanding kiosk on a rotating base holds supplies for activities of daily living (hygiene and grooming), for vocational and recreational activities, and for feeding. One of the four sides of the kiosk is exposed at a time, the others being concealed by the casing.

Individuals with high-level quadriplegia

(neurological levels C3 and C4) and no arm or hand function are learning to operate the robotic arm by means of voice commands to complete tasks such as brushing hair, washing the face, brushing teeth, eating a meal, preparing food, playing boardgames, retrieving objects, shaving, and word processing. Subjective and objective measures of user satisfaction include time to complete task, thoroughness, ease, and other outcome measures specific to each task.

Preliminary Results—A self-instruction manual on the use of the robotic arm has been written. Functional tasks have been evaluated subjectively by various user groups. Improvements have been made to the system based on user feedback; for example, a new command program is being written on the PC/AT to allow more flexibility in user interface strategies.

The workstation and kiosk are presently being assembled for a more comprehensive, objective evaluation and an improved level of utility for the robotic aid.

Eating and Hygiene Tasks for the Robotic Aid

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Purpose—Central to the goal of enabling people with quadriplegia to control their surroundings independently is the challenge of assisting them in fulfilling their needs in everyday living. Two areas are of particular importance: eating and hygiene. Persons with quadriplegia should be able to perform these tasks by themselves with the help of the Stanford/VA's Robotic Aid.

The problem addressed here is to design the environment and write the needed application software to accomplish this goal. Methods used to develop these particular applications for the Robotic Aid are themselves generic. Other tasks, particularly in the vocational and entertainment areas, can be modeled after concepts developed here.

Over the past 3 years the Robotic Aid has been programmed for a variety of food preparation and personal clerical tasks. However, none of these demonstration programs were refined to the extent needed for routine usage in a daily living format. The Robotic Aid has always been "interactive" in the sense that the user can change the movement, pattern, and objective of the manipulator at any time, but these capabilities have not been fully explored in the context of allowing direct contact between the user and the robotic arm.

Progress—By making full use of both the clinical and engineering expertise available in the Stanford/VA environment, several key eating and hygiene tasks were defined. After producing full scenarios of each eating and hygiene task, a team of engineers, therapists, and users programmed the Robotic Aid to perform the desired subtasks. Special emphasis was given to having actual quadriplegic persons involved at all stages of programming and development.

The VAL programming environment was used to write the robotic arm routines, while the VOTERM was used for voice recognition and ARMC was used to implement the voice commands.

Preliminary Results—The original scope of this work was successfully completed in the summer of 1985, and the results demonstrate that the Robotic Aid can be used effectively by individuals with quadriplegia to groom and feed themselves in a routine manner. Such individuals are now able to use voice commands to direct the Robotic Aid to wash their face, brush their hair, feed themselves a three-course meal, and brush their teeth.

Videotapes are available to show these tasks being performed by an individual who does not have functional use of his arms and legs because of quadriplegia.

The Role of Choreographic Exploration in the Design of the Robotic Aid

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Purpose—A robot intended for human service applications faces challenges that differ from those of its industrial counterparts. A machine that must share a living space with its human user needs to account for the quality of its character as well as its capabilities. In a robot, character arises from its form, scale, finish, sound, and other elements.

A particular feature of the robot is the way that it moves, and the quality of that movement is a very distinctive part of its character. Any comprehensive approach to the design of the Robotic Aid must also include the design of its movement.

To support this approach, more information is needed about how quality of movement affects the overall character of the robot and how this quality bears on the user's acceptance of the robot as an assistive device. Much of the functional effectiveness to be delivered by the Robotic Aid will depend on the positive attitude of the user and the user's willingness to learn and explore with the machine. Could not a machine that is awkward, or intimidating to use, needlessly discourage a person in a real living situation?

Progress—Exploration in the expressive, aesthetic use of the robot arm began in 1978, with "Ballet for One Arm." In that work, the PUMA 250 was programmed to move with graceful precision in synchronization with a piano composition. Audiences still respond enthusiastically to videotapes of the piece, and their enthusiasm has encouraged more exploration.

Work begun in 1982 and continuing over a period of 3 years developed a robot choreography that demonstrates the machine's expressive potential.

To encourage an extensive further exploration into the design of aesthetic movement and the varieties of movement character, the Robotic Aid Project has now participated in a collaboration to mount a full-scale performance of computer-music, dance, and robot choreography. A liaison was formed with composer Michael McNabb, Stanford's Center for Computer Research in Music and Acoustics, and Brenda Way, artistic director of the dance company, ODC/San Francisco.

For this performance a large robot arm, the PUMA 560, was selected because it promised a more effective stage presence than the smaller PUMA 250. Over a period of 4 months, four individuals worked intensively to design and program choreographic sequences for the robot. Dance professionals Brenda Way and Julie Kanter were trained in the use of the robot teach-box and the VAL programming language. Each person worked to explore the expressive capabilities of the arm, keeping in mind the musical score being written and the overall concept of the piece. In many cases, the robot's movement was designed to relate closely to the movement of a single dancer.

A theme was developed around the notion of a "dialog" between the robot and a human dancer. The robot, as a character in the performance, was called upon to show recognizably different "moods." This naturally led to exploration of the range of expression that the machine could be programmed to display.

More than 1 hour of choreographic material was developed, of which approximately 40 minutes were finally selected for the performance. The work comprises five distinct movements and demonstrates a wide range of expression. The finished work, "Invisible Cities," was performed with 13 dancers, 2 musicians, and a robot programmer. The premier performance was at Stanford University on December 6 and 7, 1985. Critical reviews were favorable.

Future Plans—Two lines of future work are indicated. The first is to continue the assessment of the influence of perceived aesthetic move-

ment on the user's acceptance of the robot. The second is to develop a series of utilitarian tasks to be performed by the robot using distinctly different movement styles: Might a Martha Graham fetch a glass of water in a way different from that of a Charlie Chaplin? Is there a value in giving the user a choice as to the kind of character his or her own robotic aid might have?

Once a fluency in the expressive ability of the robot can be demonstrated, access to that ability could be extended to the user. How often do we show emotion or intention by the way we set down a plate or pick up a cup? Those simple expressive gestures may be denied, today, to an individual with limited motor or manipulative abilities. But, with access to a choreographic vocabulary in the robot, the user might gain a rich medium for gestural expression.

Aesthetic Implications of Robotic Movement: A Case Study

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Purpose—User acceptance of assistive devices has been a chronic, significant problem in the introduction of new technology for the disabled community. In the case of the Stanford/VA Robotic Aid, the character and the aesthetics of motion could be a factor in user acceptance. This study addresses that problem.

Progress—As a part of the Rehabilitation R&D Center's Robotic Aid Project, an industrial robotic arm was programmed for use by quadriplegics as a personal assistant in a rehabilitation setting. During actual use by the research staff and other subjects, it became apparent that some programs resulted in movements that were jerky and awkward, while others resulted in movements that were smooth and graceful. It was perceived that the graceful movements positively influenced the users' feelings about interacting with the robot.

It is proposed that aesthetic (i.e., choreographed) movement of a robotic arm can favorably affect an individual's attitude about accepting and using a robotic aid. It is further hypothesized that the provision of an aesthetic component in the user's orientation to the robot can, of itself, have a very favorable effect on user acceptance.

The focus of the project was an assessment of attitudinal changes shown by selected individuals with quadriplegia, in response to the presentation of two different orientation programs on the use of a robotic arm. One program included a discussion of aesthetic sequences of robotic movement, industrial design, and kinetic art. In contrast, the other program presented the "standard" introduction to the robotic arm, which involved utilitarian sequences of robotic movement.

A questionnaire was administered before and after the orientation sessions. An exploratory follow-up study was conducted on one of the subjects actually trained to use the robotic arm.

Preliminary Results—A doctoral dissertation on this preliminary study of aesthetic training was completed and submitted to Stanford University in December 1984. Results of the study were inconclusive because of the extremely small sample populations, but were suggestive of the proposed effect.

Future Plans—A pilot project has been proposed in which the arm will be programmed for utilitarian tasks utilizing aesthetic movements.

Development of Environmental Control Units for Disabled Veterans

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Progress—This project had two goals: 1) to further develop an environmental control unit (ECU) for use in hospitals and long-term care facilities; and 2) to determine if new developments in home electronic equipment are applicable to disabled individuals. (This project was a continuation of an earlier one conducted by Bresler, "An Environmental Control Unit for Rehabilitation Hospital Use," reported in *Proceedings of the Second International Conference on Rehabilitation Engineering*, Ottawa, Canada, p. 605.)

Using much of the same hardware and software the ECU would be repackaged in a smaller display box and would also use different interface circuits to enhance the data integrity of communications between system subsections. Some standards work at the Electronic Industries Association might be applicable to ECU users. The Electronic Industries Association Consumer Electronic Bus Technical Steering Committee is studying remote controls for in-home applications and monthly Committee reports were reviewed during the project. The Committee is concerned about interference between existing remote control systems and would like to establish standards allowing consumers to control several devices from different manufacturers with one remote control. Although progress has been made in studying existing systems, no control standards have been developed to date.

Development of a standard would greatly simplify ECU design. The ECU developer would need only to design a controller, eliminating the need to modify each controlled device. If these standards are developed, a controller could be developed either by modification of control units for the general population or design of a new unit. In this way an ECU user in a hospital setting could become familiar with consumer items for use after leaving the hospital. At the present time, a hand wired control unit and slave unit have been constructed. Continuation of this research has been left to ECU manufacturers.

Analytic Techniques for Automated Grasp

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Purpose—As the application of robotics in industry and other fields moves towards greater flexibility, the need for systems with enhanced sensory capability and algorithms with greater generality is becoming apparent. One important aspect of automatic manipulation is the establishment of a secure grasp of an object. The ability of robot manipulators to securely grasp objects, without human supervision, shall be essential for the "intelligent" robots of the future.

This thesis first attempts to analyze conditions for which stable grasping occurs. A review of mathematical models for contacts leads to the selection of point contacts (with friction) as the primary model for study, and "soft finger" contacts as a secondary model. Conditions for stable grasping are given for statically determinate systems in which all forces are known for a given load on the object. A more general approach, called quasi-static analysis, is presented which can predict the stability of a large class of statically indeterminate, as well as determinate, systems.

The second part of the thesis explores the possibility of automating grasp by considering

the process of finding secure grasps as an optimization problem. The first step in accomplishing this is the establishment of suitable goal functions which reflect the stability of the grasp. Secondly, constraints are needed to keep the gripper away from undesirable configurations. The resulting constrained, non-linear, optimization problem is then considered for two- and three-dimensional simulations. The results of the simulations indicate that the method is particularly effective when the gripper is initially close to the desired position, although effective grasps can often be found even when this is not the case.

The Application of Continuum Methods to Path Planning

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Purpose—Most algorithms which have been developed to solve the path planning problem are based on a mapping of a given problem into a finite state space. While this *combinatorial* conversion always results in a problem which can ultimately be solved by a computer, the computational complexity of transformed problems which accurately reflect their continuous counterparts can be prohibitively high.

By contrast, certain previously developed algorithms did not follow this approach. These algorithms worked directly with the continuous problem space, and are called *continuum algorithms* in this report. These *continuum* algorithms were relatively unsophisticated when compared to the more popular combinatorial methods, yet their results were good.

This observation served as a motivation for the research reported here, in which it was sought to provide continuum algorithms with a more rigorous theoretical base. The main result of this work is the development of a real-valued function which characterizes the proximal relationship of two non-point convex bodies. This function is different from similar functions reported previously in that it also provides useful information when the sets under consideration intersect.

In this document, the need for such a function is established, and certain computationally useful properties of the developed function are proven. Efficient means for its computation for polyhedral sets are developed, and the algorithms for this are presented. These results are subsequently used in a path-planning algorithm based on numerical relaxation. Results of comparing the performance of this algorithm with that of Brooks' planar free-body path-planning algorithm are presented.

Computer Methods in Manipulator Kinematics, Dynamics, and Control: A Comparative Study

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Purpose—The objectives of this research were:

1) Design and develop efficient algorithms for manipulator kinematics and dynamics, including inverse kinematic solutions, actuator torque computation, and equations of motion for simulation.

2) Investigate the reduction in computation that can be obtained when the manipulator fits the assumptions of a restricted model incorporating simplifications common to most industrial manipulators, and estimate the reduction that can be anticipated when the equations are worked out symbolically by doing so for a model of the Stanford Arm.

3) Analyze the singularities that can arise in inverse kinematic solutions and develop efficient means of dealing with their presence.

4) Present stability proofs for several control schemes, including the conventional joint servo, computed-torque control, resolved-rate control, and resolved-acceleration control.

5) Compare the expected performance of the conventional joint servo and the computed-torque servo in computer simulations of the Stanford Arm.

The principal contributions of this dissertation have been: the development of efficient computer algorithms for inverse velocity/angular velocity solutions, inverse acceleration/angular acceleration solutions, actuator torque computation, and equations of motion for simulation; the introduction of damped least-squares formulations to eliminate singularity problems in inverse kinematic solutions; a comparison of algorithms based on Kane's equations of motion to previous formulations based on Newton-Euler methods; an investigation of the reduction in computation that can be obtained for manipulators meeting certain restrictions; stability proofs for improved versions of the resolved-rate controller and the resolved-acceleration controller that account for singularities; and a comparison via simulation of the conventional joint servo against the computed torque servo.

G. Wheelchairs, Including Seating and Controls

University of Virginia Rehabilitation Engineering Center

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Progress—The Rehabilitation Engineering Center (REC) is in the fourth year of a 5-year program, conducting research on wheelchairs and seating for the disabled. Some of the seating studies are contracted to the University of Tennessee Rehabilitation Engineering Center at Memphis.

The emphasis at REC is to conduct technical studies on all aspects of wheelchair and seating design and function that will lead to a better understanding of the principles involved and hence contribute to improved design, fabrication, and prescription.

Progress—Recent work on specific tasks includes the following:

1) The dynamometer used for wheelchair propulsion studies has been completely rebuilt, allowing greater accuracy and quicker adjustments. The system includes a method for recording arm position in three dimensions by means of wands that are attached to the arm with Velcro straps. The position of the wands is recorded by potentiometers. Speed, power, and instantaneous torque using handrims or levers have been retained. All data are analyzed by computer. Included among the various studies is development of a computer program to predict the most effective seating position and propulsion system for an individual based on a few simple measurements and projected usage.

2) The effect of seat and back angle on pressure patterns and cushion contours has been recorded for a number of persons with spinal cord injury. The information will be used in design and prescription related to seat contours and configurations.

3) The effect of seat and back position on the functional ability of persons with cerebral palsy has been studied by colleagues at the University of Tennessee in Memphis. Anthropometric data collection has continued at Mem-

phis and Charlottesville.

4) The effect of pressure patterns on tissue deformation is being investigated using magnetic resonance imaging.

5) A caster shimmy friction damper has been designed and fitted to a number of wheelchairs for testing before manufacturing.

6) Stress analysis studies have focused on low-frequency fatigue failure, as a suspected mechanism of failure in wheelchair frames.

7) A double drum machine for fatigue testing wheelchairs has been designed and constructed for use in test procedures of the International Standards Organization and the American National Standards Institute.

8) A theory for "wheelies" has been conceived and developed.

9) Battery studies have concentrated on the tubular positive plate design. The technology is available to produce such a battery in gel form that would last four times as long as conventional deep discharge batteries at a cost increase of about 50 percent. This could result in savings of up to $6 million annually.

10) A battery monitor that eliminates the false readings due to power surges has been designed. Work on a microprocessor design to yield accurate energy levels for any type of battery continues.

11) The investigation into fault-tolerant powered wheelchair control systems has been initiated.

12) The adaptive controller has been simplified to a selective controller and installed in an Invacare Rolls powered wheelchair. Testing of algorithm options continues.

13) A wheelchair data logging system has been completed.

14) A motor controller has been designed to convert a 24-V supply to an output varying from 15 to 40 V. Test results are encouraging.

15) Several wheelchair designs are being considered by manufacturers for production. These include the NASA/UVA composite wheelchair, the lever drive, and a new design that folds to a very compact package with the main wheels removed and allows instant adjustment in seat position while seated.

Development of a Linear Synchronous Motor for Wheelchair Use

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Purpose—The Linear Synchronous Motor (LSM) is a wheelchair drive system designed to take advantage of recent high-technology advances in motor controls. The goal is to implement a wheelchair drive system that is less expensive, is more efficient, requires less maintenance, is lighter weight, and will perform with optimum efficiency at any speed on any terrain. This motor will be built into the circumference of the large wheelchair wheel. The wheel becomes the rotating member or rotor of the motor, and the coils that control this rotation or stator will be mounted onto the frame. Thus, the only moving part in this system is the wheel itself. It is intended that this system will eventually become an integral part of an "intelligent" computer-controlled drive train for powered wheelchairs.

The purpose of the current research was to design, build, and bench test a single LSM motor on a wheelchair wheel. In addition, a computer simulation model of the motor was to be developed.

Progress—The computer simulation of this motor was developed on the Hewlett-Packard Model 310 microcomputer. Full computer-aided designs were developed on the HP 9920 CAD system utilizing HP Draft and EGS 200. After preparation of the working drawings, the initial controller was constructed.

The controller was based on the Motorola 6809 microprocessor. A commercially available board was utilized and the power board was added to provide three-phase pulse width modulation current control. The initial control

system tested successfully and work proceeded on the motor itself.

A bench prototype was constructed using a solid aluminum base, bearings, a 20-inch-diameter rotor, and matching stator, which comprised one-half the rotor area. In addition, the rotor shaft extended through the test bed frame and connected to a pneumatic brake. The end of the shaft connected to an optical encoder to send a digitized signal to the microprocessor. This arrangement not only provided the processor with essential information as to the orientation of the rotor with respect to the stator, but also permitted exact monitoring of the motor's rpm under all loading conditions controlled by the brake. The system functioned successfully and fulfilled all expectations in March 1986. The measured efficiency was within 0.45 percent of the projected efficiency based on computer modeling. Projections indicate that a second-generation machine would be able to achieve more than 90 percent efficiency and deliver torque at low rpm to exceed published figures for wheelchair needs.

Designs have been revised and a new proposal submitted. When funded, a 3-year program will begin to develop an optimal LSM, install working units on an existing chair, and after acquiring further test data confirming expected performance, design an initial prototype vehicle of a new conceptual design. The LSM appears to be an ideal motor for vehicle applications, and initial cost estimates are favorable.

Future Plans—Present progress on the LSM has consisted of refinements to the control system and a design for an improved stator having more windings on an iron core. Further test data will be gathered in the time elapsing until further funding can be procured.

When further funds are available, an optimized motor design will be implemented and a pair of such motors using rare earth magnets will be produced. These units will be tested on existing power wheelchairs to determine specific problems in control and motor design for this application. The inherent reliability of LSM and low maintenance combined with the high efficiency and design simplicity offer much freedom in vehicle design. The research team plans to implement a power chassis design as outlined in *Wheelchair III* in the third year.

Developing Safety Standards for Wheelchair Occupants in Vehicles

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Sponsor: *S.A. Department of Transport and Design Arts Board of the Australia Council*

Purpose—Testing of vehicle restraints for wheelchair occupants has revealed that commonly used methods are unsafe. Previous work at Regency Park Centre for Young Disabled led to the development of a crashworthy restraint system for wheelchair occupants. More recently, the issue of safety standards has been addressed.

Progress—The following initiatives were undertaken to overcome these difficulties:

1) An illustrated booklet, *Wheels on Wheels*, was published to inform prospective users and buyers of the need for restraints, the choice of suitable wheelchairs, and related safety issues. (The booklet is available free on request from Rehabilitation Engineering Department, Regency Park Centre for Young Disabled, P.O. Box 209, Kilkenny, S.A. 5009 Australia)

2) An informative videotape, similar to the booklet in content, is available on VHS cassette (PAL System, price $30 Australian).

3) A "Draft Australian Standard: Wheelchair Occupant Restraint Assemblies for Motor Vehicles," was distributed for public comment in May 1986. Copies may be obtained from The Standards Association of Australia, 80 Arthur Street, North Sydney, NSW 2060 Australia.

These developments towards better standards will provide protection for wheelchair occupants traveling in vehicles and facilitate

transport of severely disabled people.

Optimal Biomechanical Design/Development of Arm-Powered Mobility Devices

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Purpose—Individuals with lower limb disorders are looking for more optimal solutions to their mobility and exercise needs. Through such improvements, they could enjoy the quality and degree of independence and societal integration to which they are entitled.

Few alternatives to conventional wheelchair handrim propulsion are currently available and precious little research has been done to fine-tune the rider to his mobility aid. A need exists to design better arm-powered drive systems which are ergonomically optimal, functional, and economically feasible for device development.

Modern control theory, when coupled with human biomechanical performance measurements, could lead to nearly optimal arm-powered drives for use in mobility vehicles and stationary exercise machines for the disabled. This would involve the development of a tractable, computerized, biomechanical model for the upper limb as it applies to a broad spectrum of arm-propulsion tasks. Given specified performance criteria (such as maximum power output or maximum efficiency), this model could then be used to create optimal configuration and dimensions for any proposed drive system and purpose.

In the approach adopted here, experimental results obtained from subjects operating a variety of arm-powered ergometer drive systems will be used to help define and refine the biomechanical model of the upper limb performing optimal ergonometric tasks, applying modern optimal control theory. In order to develop a more universal mathematical model, several drive and load systems will be employed, each with such variable features as crank length for arm-cranking experiments or lever length and pivot position for oscillating lever propulsion. Kinematic and dynamic data will be acquired and analyzed with simultaneously collected electromyograms (EMGs).

Progress—The laboratory arm-powered ergometer has been designed and is under construction. Progress is being made on linear and eccentric-trajectory drive system designs (including application of the Kallander tapered belt drive) for use in subsequent experiments. Design work is carried out using the computer-aided design facilities at the Stanford Center for Design Research.

Mathematical equations of motion describing the dynamics of the arm-cranking task have been developed and are being entered into the computer. Dynamic and MG data acquisition systems are being assembled in preparation for the initial round of experimentation and analysis.

Powered Wheelchair Performance

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Sponsor: *Regency Park Centre for the Young Disabled*

Purpose—Many disabled children need a powered wheelchair to achieve independent mobility. The number of children at this Centre using electric wheelchairs has increased from 2 to 87 in the past 9 years. They need a safe, reliable wheelchair. Currently, however, there are no

standards or laboratories in Australia for testing the performance of wheelchairs, and consequently the incidence of breakdowns is high. An internal report at the Centre indicates that annual maintenance costs on some makes are up to 30 percent of the purchase price. Both the reliability of electric wheelchairs and wheelchair stability for safe outdoor use need to be improved.

This project's goals are to conduct performance measurement studies on electric wheelchairs and to use quantitative procedures to improve client/wheelchair matching, using results from the above.

Future Plans—In the preliminary phase, a data measuring and logging system will be purchased, adapted, and mounted on an electric wheelchair, and an adjustable ramp will be built for testing the static and dynamic stability of wheelchairs. During the experimental phase, the data logger will be used to analyze patterns of wheelchair usage, which will be related to problems experienced in wheelchair use. The results of this study will be made available to the Standards Association of Australia and a professional scientific journal. We will work with wheelchair manufacturers to improve the design of electric wheelchairs and control interfaces.

This project will ultimately result in the establishment of an Australia-wide wheelchair testing facility at the Regency Park Centre for Young Disabled.

Wheelchair Controls

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Sponsor: *Department of Health and Social Security, Great Britain*

Purpose—Development is being carried out on a "proportional" wheelchair control that will provide smooth acceleration and balanced steering. The system is intended to have a range of input control options to suit a wide range of severely disabled people. The system is also intended to be interchangeable with the conventional controls issued with the normal range of wheelchairs.

Progress—A number of head controls for quadriplegics have been investigated, one operating on a positive pressure system in which the tongue is used to block off one of the four sensors. A control switch is triggered by the resulting back pressure. Being investigated is another noncontacting system that utilizes a retroreflector fitted to the patient's head and an infrared emitter-detector fitted to the wheelchair.

Three-Wheeled Vehicle

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Progress—The Volunteers for Medical Engineering, Inc. (VME), working with a basic design from a client, has produced a very powerful and versatile vehicle. It includes in its design features a dual-motor power application selectable by the user and a multiple-speed manual transmission.

The first prototype of the design was fabricated and made ready for its first powered ride in June, 1986. Documentation exists for many of the parts so that the next unit will be more readily fabricated. Efforts are now underway at VME to purchase parts in England for building a second model to test and evaluate.

Future Plans—The team working on the proto-

type will prepare an instruction manual and parts list for the design so that recipients of one of the models will be able to operate and maintain the unit.

The servo mechanism for the operation of this vehicle can be improved by the dedicated effort of the volunteers. However, the VME will be actively pursuing funding to allow the servo electronics engineers to complete the redesign in a timely manner.

The vehicle is expected to out-perform all the three-wheeled electric vehicles on the market. The performance parameters will be documented for such a comparison. The aerodynamics and the aesthetics of the next model will also be given more attention.

Steiner Tractor Modification

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Sponsor: *Volunteers for Medical Engineering, Inc.*

Purpose—The Steiner Tractor, made specifically for a paraplegic, can be used without modification by a person who has good upper body strength. The Volunteers for Medical Engineering, Inc. (VME) has modified the tractor so that a person with little or no upper body strength can operate it. Modifications include powered motion of the steering mechanism, and powered engagement, actuation, and disengagement of the automatic transmission.

Progress—The Steiner Tractor has been adapted with the powered steering actuation and with the powered engagement of the automatic transmission. The controls for the operation of these mechanisms will be client-specific, thus the first to be incorporated in the design is the chin controller developed by the Johns Hopkins Applied Physics Laboratory. VME plans to secure the license for this and other similar applications. Another proportional control device developed by VME for use on a powered wheelchair by a person totally paralyzed from a stroke will also be implemented on the tractor. It operates via Morse code-type inputs using client thumb motion only.

Future Plans—Proposals are being written seeking funds for the timely completion of the total adaptation for the first two control systems and for further development of the addition of sensor controls to allow the tractor to be operated by anyone capable of operating a joystick.

We will develop the means for someone to automatically lock himself into the tractor bed so that he can perform more of the operations of entering and running the tractor, as well as a number of techniques for the emergency deactivation of the drive and power of the tractor as backup for the prototype system.

Seat Cushions for the Paralyzed

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Purpose—This project was undertaken to 1) evaluate the role of shear in pressure sore causation, 2) monitor paraplegic sitting reaction to assess buttocks blood flow characteristics, and 3) develop an instrument capable of sensing buttocks blood flow.

Having determined that seated paraplegics, on average, evidence a smaller amount of cutaneous pulsatile blood flow than do normal subjects, we moved to determine the underlying

reasons. The reduced blood flow may imply unfavorable loading owing to an inappropriate posture, not sensed by the paraplegic, or it may suggest a reduced circulatory capability, possibly resulting from neurotrophic considerations or years of atrophy.

Progress—To study this matter experimentally, the waveform analysis method developed by Strandness has been incorporated into our existing apparatus. Harmonic analysis of plethysmographic waveforms permits a separation of that blood flow reduction owing to externally applied load, from that due to inferior natural circulation.

Twenty-one normal subjects (average age, 47) recruited from staff members and hospital patients with ailments other than paralysis or outer extremity circulation impairment, were tested in the vicinity of the ischial tuberosity while seated. They displayed a second harmonic relative to the fundamental, of mean value 0.34 with a standard deviation of 0.09.

Twenty paraplegic subjects (average age, 47), recruited from outpatients and volunteers and accepted without concern for other ailments, have been divided into two subgroups—those with peripheral arterial deficiency as indicated by conventional Doppler segmental blood pressure testing ($N=7$) and those who have a normal peripheral arterial circulation ($N=10$).

Preliminary Results—Our results indicate the median paralyzed subject in sitting manifests a second harmonic strength roughly 20 percent less than that of the normal. Next, those who are both paralyzed and deficient in peripheral arterial circulation exhibit a wide range of buttocks blood flow characteristics as a function of thigh pressure. High thigh pressure is associated with a well-perfused buttocks, large second harmonic values, and lack of pressure sores. Low thigh pressure is associated with a poorly perfused buttocks, low second harmonic values, and the presence of pressure sores.

These results are presented as work-in-being. The indicated trends are supported by limited and even fragmentary data.

Future Plans—Our plans are to fully document those tentative trends given above.

Remote Monitoring of Pressure Relief Activity and Sitting Asymmetry in the Wheelchair User

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Purpose—Regimens for pressure-relieving activities (PRA) such as pushups and weight shifts to prevent pressure sores among wheelchair users are widely prescribed, but compliance is thought to vary considerably among individuals. Objective studies confirming that pressure sores are prevented by PRA have not been undertaken and the frequencies of movements prescribed are simply clinical rules of thumb of unknown origin.

Progress—Previous studies monitoring PRA have been undertaken in the hospital environment due to the limited memory and power capacity of the instrumentation used. Most pressure sores caused by prolonged sitting in a wheelchair occur, however, in the home and workplace. In this study, we developed an instrumented seat-board that functions as a force plate and is connected to a purpose-built low-power signal conditioning and microcomputer package. This battery-driven system will operate for well in excess of 30 days without the need for any user or operator interaction. The device detects full weight relief and lateral and forward weight transfers. In addition, the position of the client's center of pressure is sampled periodically to detect asymmetric sitting behavior causing excessive loading of tissue on one side of the body. We anticipate that the causes

of asymmetry in many clients can be attributed to environmental factors (e.g., ergonomics of home and workplace) rather than musculoskeletal deformities alone. The force plate replaces the sling seat of the wheelchair and is mounted on adjustable drop-hooks providing the user with a normal sitting height. The force plate is readily removed to allow the chair to be folded and stored. The total weight of the system is 4.1 kg.

Display software has been developed to allow raw data that are stored on the portable unit to be transferred to a personal computer and displayed for clinical interpretation and evaluation.

Future Plans—The next phase of this study will employ ten units to: 1) determine the frequency and variation of PRA in spinal cord injured wheelchair users; 2) establish whether sitting asymmetry is frequently encountered and attributable to ergonomic factors; and 3) allow comparison of PRA and sitting asymmetry between two groups of spinal cord injured wheelchair users—one group with a history of ischial breakdown and a group with no history of breakdown attributable to prolonged sitting.

Wheelchair Seating Effectiveness

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Purpose—Many disabled children spend a large part of each day seated in a wheelchair, and need comfortable, supportive seating that meets their functional requirements. Inappropriate seating is a major contributor to the problems they experience in balance and comfort. Widely accepted seat guidelines in cerebral palsy have not been scientifically validated. New seating systems have become available, but their effectiveness has not been objectively assessed.

Our goals are to develop a standardized fitting protocol and outcome evaluation procedures for wheelchair seating systems in terms of cost, comfort, cosmesis, and function, and to evaluate six new special seating systems using the protocol established.

This project will result in improved seating for disabled children, at this Centre and elsewhere in the world.

Progress—In the preliminary phase, protocols have been developed for the fitting of seating and the comparison of alternative special seating systems. Several new seating systems, such as matrix supports and foam-in-place methods, have been obtained.

In the experimental phase, cerebral-palsied children have been fitted with special seating systems, and each will be evaluated over a 3-month period from the date of fitting.

The results of the project evaluation, which will include prescription criteria, will be published in a professional scientific journal, and an instructional course on modern seating techniques for cerebral-palsied children will be conducted.

CUSHFIT: An Expert System for Wheelchair Cushion Prescription

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Purpose—Correct prescription of a wheelchair cushion is an important requirement for many wheelchair users, especially those vulnerable to pressure sores. Careful matching of clinical characteristics, personal preference, and cushion properties is required for a successful out-

come. This is a skillful process requiring a systematic selection of candidate cushions based on a set of observations and measurements. The number of centers employing advanced cushion-fitting procedures is limited because of difficulties in transferring expertise and the specialization needed to provide these services. Cushion fitting is, however, ideally suited to an expert systems approach whereby a computer program allows a person with average expertise to function as effectively as a specialist.

Progress—The program CUSHFIT has been developed. The clinician uses the program to collect clinical information and feedback from the patient as the fitting process proceeds. Measurements of pressure are made by the therapists and input to the program. Goal pressures for each body site are established based on the existing skin condition and the clinical status of the patient. A satisfactory cushion is one that meets the patient's subjective needs, the clinician's goals, and the goals established by the expert system. If the first cushion recommended by the program proves to be unsatisfactory, further suggestion is made based on observations and measurements made with previous cushions. Computer recommendations can be overruled at any time by the clinician as can any goals proposed by the program. Full control of the fitting process is retained by the clinician. CUSHFIT provides the structure needed to complete it efficiently.

Advantages of using this approach are numerous, including automatic documentation of observations and measurements; automatic database generation within and between collaborating centers; consistent evaluation procedures to assist with third-party payer reimbursements, and service continuity less vulnerable to specialist staff turnover. CUSHFIT has been in routine use for 2 years at Helen Hayes Hospital and is now undergoing evaluation at three other centers. Data will be shared by the collaborating centers, forming a database to study in-field performance of different cushion types and prescription practices using the program. Results will identify necessary modifications to the program following which CUSHFIT will be distributed more widely.

A Computer Interface for the TIPE Seating Pressure Evaluator

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Purpose—Pressure sores are a major problem for individuals who are wheelchair-dependent, particularly those with sensory losses. Many researchers have investigated the causes of these pressure sores and have sought methods of preventing them. A project at the University of Michigan is investigating the use of electrical muscle stimulation as a means of preventing pressure sores (see Electrical Muscle Stimulation for the Prevention of Pressure Sores: 1 and 2). Part of this research involves measuring and recording the dynamic forces exerted at the seating interface.

The pressure transducer system being used is the Texas Interface Pressure Evaluator (TIPE) pad. The pad consists of a 12 x 12 array of switches within an inflatable pad. Wherever the interface pressure exceeds pad pressure the corresponding switch is activated (closed). The TIPE pad is normally connected to a separate display unit which produces a transient visual picture of the pad switch conditions.

No provision for permanent recording of observed data is provided. Many experiments require information about pressure behavior to be recorded over an extended period. This recorded data must also be converted to a form which prepares it for computer analysis. An interface has been developed to meet these needs.

Progress—The electronic interface was constructed to replace the TIPE display unit and to act as a direct link between the TIPE sensor pad and a computer. The interface converts the state of pad switches to a digital format that can be read and recorded by any general-purpose microcomputer. The digitization and transmission of all switches occurs 30 times per second.

The interface is based on a Hitachi HD6803 microcomputer unit. This is a single-chip microcomputer that includes 128 bytes of random access memory, a programmable time, a serial communication interface, and 13 programmable input/output lines in one 40-pin package. A special algorithm has been developed for switch matrix decoding to prevent false positive switch closure detection.

The TIPE pad and interface are connected to the main serial port of a Zenith Z-150 computer. The Zenith is both software and hardware compatible with the IBM PC. Data acquisition software written for the Zenith receives switch matrix sample sets from the interface and stores them for later analysis. Information can be recorded at rates from 0.01 to 30 samples per second. Parameters such as sampling rate and duration are defined by the experimenter using a configuration file. This is a text file that can be edited to easily accommodate changes in experimental design.

During sampling the computer continuously updates a console screen display. This display includes time information in numeric form, pad pressure (from a pressure transducer connected through an analog/digital converter), and a 12 x 12 array of ¼-inch squares that mimic the condition of each switch (on=red and off=blue). All data can be stored on floppy disk for offline analysis. Data can be replayed over a range of speeds from ⅕ to five times real time.

Seating Systems for Body Support and Prevention of Tissue Trauma

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Purpose—Pressure sores continue to be a problem for individuals with spinal cord injuries (SCI) due to long periods of unrelieved sitting in inadequately designed wheelchairs. In addition, neurologically impaired trunk and hip musculature results in decreased trunk stability and an increased tendency to develop spinal deformities. Certain spinal deformities, such as lateral scoliosis, can increase an individual's risk of developing pressure sores by forcing one area of the buttocks to bear a greater than normal percentage of the weight. However, although most patients are aware of the need to prevent pressure sores, their primary concern is maximizing their trunk stability to enable them to be as functional as possible.

This project has two primary goals to approach the overall problem: 1) to design a universal seat cushion that will be usable by a large percentage of the SCI patient population; and 2) to determine how various sitting postures affect the distribution of pressure beneath the buttocks, and the extent to which these postures enhance or compromise trunk stability. This information will permit the development of seat cushions and other components that together promote a stable, symmetric sitting posture and help to control the magnitude and distribution of pressure beneath the buttocks.

The primary benefit to be derived from this investigation is a reduction in the incidence of pressure sores among the VA SCI population.

It has been shown by other investigators that certain areas of the buttocks are better able to tolerate pressure without developing a pressure sore than are other areas. A number of seat cushion designs have therefore been developed to transfer the load away from the more susceptible areas and redistribute it to the more tolerant weightbearing areas. Most of these cushions required custom fitting for each individual. A primary goal of this project has

therefore been to develop a seat cushion and other postural support components that could be commercially produced and would be usable by most of the SCI population without the need for custom modifications.

Progress—A cushion was designed based upon measurements taken from plaster casts of the buttocks of VA SCI patients bent over a table in a simulated seating position. The resulting design consisted of a contoured cushion of several materials, including an imbedded polyethylene stiffener under the trochanters. This design underwent eight revisions, taking into account resulting measured pressures at the ischial tuberosities, before clinical trials were conducted on more than 80 patients. The results showed the cushion to be effective in reducing interface pressures to levels well tolerated by over 79 percent of the subjects tested.

The effect of various postures on the magnitude and distribution of pressures beneath the buttocks is being investigated with subjects drawn from the inpatient and outpatient populations of the VA Medical Center Spinal Cord Injury Center. Pressure is measured at the buttocks-to-cushion interface while the subject is seated in his typical posture. Various positioning devices are then utilized to support the posture under study, and new pressure measurements are taken. Subjects are also given a questionnaire on subjective factors such as perception of trunk stability and comfort.

The seat cushion discussed above has been completed and is now being marketed commercially as the Veterans Administration Seating Interface Orthosis (VASIO).

Preliminary Results—Initial tests on the effect of a 2-inch-thick foam lumbar cushion on buttocks-to-cushion interface pressure distribution have been completed. Forty subjects were selected who did not have any fixed spinal deformities and who exhibited asymmetric sitting posture. When using the lumbar cushion, 27 of the subjects (68 percent) revealed a change in pressure beneath the ischial tuberosity of greater than 5 mmHg (mean, 12.2 mmHg). Four of the subjects showed an increase in pressure, and 23 showed a decrease in pressure. Data are being gathered on the subjective responses to short- and long-term use of the lumbar cushion relative to comfort, trunk stability, upper extremity function, and overall desirability.

Future Plans—The next phase is to investigate the effect of posture on respiratory function and to refine the specifications for the lumbar pad relative to size, shape, and materials.

Seating Systems Analysis

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Progress—The researchers at the seating clinic have been aware of the wide variety of solutions for seating problems, and the difficulties of matching these to the disability. A survey is being undertaken of the clinical problems, and monitoring the effects of the solutions. Solutions are being analyzed in terms of suitability and cost-effectiveness.

There is a problem in simply recording the disability. We plan to provide information on how to match seating solutions to the disabilities of wheelchair users.

Wheelchair Control and Robot Arm/Worktable Systems for High Spinal Cord Injured Persons

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Purpose—The goal of this continuing research is to complete the basic development of a working model of the robotic arm/worktable system to permit manufacturing of a limited number of units at low cost so that they may be placed in selected VA Spinal Cord Injury Centers.

Progress—In order to obtain realistic data on quadriplegic users, the latest upgraded JHU/APL system was delivered to the VA Medical Center in Hines, Illinois, in August 1985. Selected quadriplegic patients have been evaluating the system to determine the usefulness of this system for tasks such as self-feeding, reading, using a phone, and performing other tasks of daily living. Such evaluation is very useful to provide information on patients who would best benefit from the system and to develop procedures for usage of the system.

These tests are proceeding. The workstation has been designed with the specific goal of meeting total task accomplishments in complete safety and with little or no attendant assistance. The system, totally operable by the user from his wheelchair, is an integrated system that considers some of the important needs of a high spinal cord injured patient. APL's role during the past year has been primarily that of performing design modifications on these experimental systems in response to recommendations received from the Hines VAMC or previously from VA centers in Richmond, Virginia, and Cleveland, Ohio. This report summarizes some of the major equipment modifications made during the reporting period.

Multi-Axis Robot Controller: The robot arm is a six-degree-of-freedom, computer-controlled anthropomorphic limb. The individual degree of freedom may (if the user so selects) be directly controlled by selection of the desired joint to be moved. Alternatively, the user may select preprogrammed motions to perform a task where such structured trajectories can accomplish the task. During 1984, a nev microprocessor- a 6809, was chosen and integrated into the robot arm controller to increase operational reliability and flexibility. The unit can now control up to three axes of motion simultaneously in a noncoordinated fashion, resulting in reduced time to perform certain work functions. This development is now completed and all three APL units, including the model at Hines, have been updated. Instructions have been provided to the evaluators to make use of the expanded programming capability.

Interface Devices: Previous models of the workstation utilized a dual-purpose input controller mounted on the wheelchair, which can either control the wheelchair or the robot arm. This design worked well for certain patients who could utilize an E&J wheelchair compatible with this controller, but the concept lacked flexibility for patients with other models of wheelchairs. A new table-mounted chin-controller was subsequently developed, which provides an alternative to the APL-developed chin-operated wheelchair controller. One unit was delivered to the Hines VAMC and is currently being evaluated. This alternative allows the user to select the best input approach for his specific needs.

An important task on the workstation is the use of a personal computer. The user may choose between a mouthstick input system or a chin-operated Morse code keyer. Earlier workstation designs used a separate controller for robot control and a different mechanism for inputting Morse code for use on a personal computer. Such an arrangement causes undue clutter in front of the user's face. To overcome this problem, the Morse code keyer was integrated into the chin-controller, and the robot arm program selection mode was modified to allow a

single mechanical device in front of the user's face on the worktable. Preliminary testing in the laboratory indicates this system shows great promise of performing both functions and minimizes the equipment in front of the user's face.

One of the important needs of quadriplegics is the means to perform, with minimum attendant assistance, certain personal or hygiene functions. The function of tooth brushing is currently being addressed. To accomplish this function, wrist motion capability is being modified to allow 180-degree rotation. It is expected that preprogrammed modes coupled with this extended geometry capability will allow this function to be accomplished with minimum user effort.

Manufacturing and Producibility: The APL robot arm worktable system was selected by the VA for transition to a manufacturing prototype model. Such a model has been designed and constructed, and is undergoing acceptance evaluation testing. APL has provided assistance to the manufacturer in technical problems and in the checkout procedure. Upon completion of these tests, it is expected that a small number of units will be ordered and placed in VA Medical Centers for long-term utilization by quadriplegic patients.

Wheelchairs: On-Line Measurement and Storage of the Load During a Field Trial

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Sponsor: *Ortopedia GmbH/Kiel, E&J/Camarillo, CA*

Purpose—Fatigue-life predictions, lightweight designs, and the determination of relevant test criteria for hand-driven wheelchairs have led to this industry-sponsored project. The purpose of the investigation is to acquire extensive information about the wheelchair user's behavior, including the frequency and manner of its use, and the kind and amount of load exerted upon the wheelchair in daily use. A group of about 20 wheelchair-dependent subjects will be observed continuously for 7 to 10 days.

Progress—The entire measuring apparatus is composed of a sensor-equipped handrim wheelchair, a portable (CMOS) microprocessor-controlled measuring and storage device, and a PC/plotter unit for evaluation of the data.

The electrical signals evoked by the strain-gauge sensors in the front and rear right axle of the wheelchair (assuming a load distribution not significantly deviant from symmetrical) are in some way proportional to the three Cartesian forces (F_x, F_y, F_z) at the touching points between wheels and ground. Fed into the microprocessor, they are explicitly calculated and then for the reason of data condensation stored in a load-time history using a modified peak-to-peak counting method.

To regain a certain time correlation of the occurrences, the histograms are built up in a two-dimensional form. For example, the F_x-peak value in the front is stored with the simultaneous F_x-value in the rear, thus creating a stored pair.

Comprehensive analog experiments are carried out in the moment to better understand and interpret the future "time-missing" frequency distributions, whereby emphasis is laid on the phase among the measured values.

Laboratory work was accomplished by July 1986, with field trials from August through October, then evaluation. The project's deadline is March 1987.

A New Wheelchair Bumper

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Sponsor: *Royal Ottawa Hospital*

Purpose—The purpose of this project is to redesign our wheelchair bumper so that it can be made available at a considerably reduced cost. The new bumper provides the same protection and performs the same functions as the original bumper.

Progress—The new bumper is made from plastic ABS tubing. It is attached to the wheelchair footrests by two metal connectors especially made for this purpose. If the bumper is to be used for competitive sports involving other wheelchair users also with bumpers, we recommend that it be equipped with overriders made by inserting two wooden dowels in the ABS tubing. These overriders will prevent one bumper riding over another bumper in a head-on collision.

The only feature absent in the new bumper, which was present in the original unit, is the ability to adjust for any distance between the footrests. With the new bumper, the distance between the centers of the two rubber tips of the footrests must be determined, or specified, prior to its construction.

The bumper protects the feet of users during accidental collisions in activities of daily living and in sports. It also protects furniture from being scraped by the metal wheelchair footrests.

Bicycle-Type Brakes for Wheelchairs

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Purpose—The purpose of this project is to design a new braking system which can be used to slow down a moving wheelchair and control its direction. Conventional wheelchair brakes are not useful for this purpose since their function is just to lock the wheels.

The two brakes are independently controlled by levers placed behind the arm rest. Independent control enables the user to steer the wheelchair and vary the speed by applying appropriate pressures to the left and right brake levers. The brakes are adapted from standard bicycle brakes by adding special mounts and control handles.

The benefits of these new wheelchair brakes include: 1) Daily Use—Wheelchair users finding themselves rolling down an incline and who wish to slow down or stop the wheelchair, can use the bicycle-type brakes rather than their hands. This greatly improves the effectiveness and safety of wheelchair braking; 2) Involvement in Wheelchair Sports—proper speed control is essential to many wheelchair sports, including track racing, basketball, etc.

Bioengineering Research and Development at IMA: Rehabilitation Engineering. Economic Cushion Seat of Variable Configuration for Cerebral Palsy Children

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Sponsor: *Consejo Nacional de Investigaciones Cientificas y Técnias, Argentina*

Purpose—The fundamental design parameters of the cushion seat of variable configuration for cerebral palsy children are: 1) low cost; 2) usablility by a large population of disabled children;

3) simplicity in construction so that it may be fabricated by disabled workers or even members of the family of the children affected by cerebral palsy; and 4) versatility of the system so that it allows for manual transportation of the disabled child. It is also attachable to an automobile seat and can be mounted on a standard wheelchair.

The cushion seat is fabricated with materials easily available in a developing country. High ductility aluminum plate, polyurethane foam, and a non-toxic paint is applied in several coatings.

Mini Litters: A Specialized Mobility Construction for Spinal Cord Injured Patients with Bilateral Lower Limb Amputations and Diminished Seating Capacity

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Purpose—The spinal cord injured patient has many problems inherent in and associated with his/her acquired disability. One of the problems is a diminished circulatory function and associated absence of skin sensitivity below the spinal cord level of injury. This frequently results in superficial skin and deep tissue ulcers, primarily over ishial tuberosities and over the femoral heads through pressure due to immobility while being confined to bed, trauma secondary to transferring, or shear forces during sitting or ambulation in mobility systems, wheelchairs, or litters. If these ulcers are severe, conditions often develop necessitating the amputation of the affected limb or limbs.

SCI patients having bilateral above-knee amputations, bilateral hip disarticulations, or a combination of the two types, pose a challenging problem concerning their daily ambulation in a home, institutional, or medical environment. After such amputations, sitting capacity is severely reduced or eliminated completely as a direct result of the majority of pressure-bearing areas required for sitting having been removed by the amputation. Where previously the posterior thigh had borne weight, now the residual limb simply flexes when the patient sits, leaving the ischial tuberosities and the sacrococcygeal area to bear the total body weight. This also results in a change in center of gravity of the wheelchair-bound patient and affects the force vectors of posteriorly directed shear forces.

The therapeutic value of independent mobility can reduce the hospital stay of a patient with these problems, which results in financial savings to the patient or public facility while freeing bed space for other patients.

Progress—The Orthotics and Prosthetics Laboratory at the Veterans Hospital in Memphis, in dealing with this problem, has created a device that is simplistic in design yet functional in operation. Originating from the idea of the manually propelled full-sized litter, a manual and electric-powered short litter was designed from a standard manual or motorized wheelchair frame. This accomplishes several purposes. The mini litter is not cost prohibitive; it is safe to operate at home and in a controlled institutional environment; it is suitable for indoor and outdoor use; it is transportable and will collapse like a regular wheelchair for shipment; it increases the patient's mobility and creates a greater degree of independence.

The type of wheelchair used for the manual powered mini litter was an Everest & Jennings Premier Model with amputee frame, reclining back, full-length arms, 20 x 2.125 pneumatic tires for comfort and traction, and 8″ x 1″ hard rubber front tires for ease of turning and proper torso angulation. Standard armrests were chosen over adjustable height armrest for strength and stability in removing and attaching the mattress frame.

Design and fabrication of such a vehicle focused on three concerns. First, safety considerations were paramount with regard to changes

in the center of gravity of a high level SCI patient with bilateral above-knee amputation and the propensity of a vehicle such as this to tip over forwards and backwards while being operated. Second, the vehicle had to be easily mounted and dismounted by the patient, be comfortable, and provide for maximum use by the patient. For this, many factors were considered, such as the eye level of the patient during vehicle operation, the ability and the range of motion of the upper extremities of the patient to propel a selection of available wheels, and the respective individual motivation level of each patient. Third, practical considerations in fabrication included initial cost, future repairs, maintenance cost, parts accessibility, and access to repair centers.

Modifications and changes to this chair consisted of attaching two sets of amputee adaptors on the existing offset wheels to lengthen the wheel base. The upholstery was completely removed. Anti-tipping devices were installed on the rear posts and two 6-pound counterweights were placed for more effective stabilization. Measurements were taken of the patient from axilla to the end of the torso to determine necessary length of the mattress frame that would position the patient's shoulders directly over the drive wheels for proper excursion to achieve maximum results for energy/effort expended. When associated with the length and weight of the patient, this helps determine the length of the wheel base and the center of gravity of the vehicle. It enabled us to relate the two within safety limits for the propulsion. In addition to length determination, we also decided to increase the safety aspect by ensuring that the alignment of the frame would be on a descending angle from the head of the patient to the rear of the vehicle or from the large drive wheels to the smaller directional wheels. The center of gravity was moved even further, which immensely decreased the possibility of the vehicle turning over as a result of a sudden stop or hard bump on an irregular surface.

Once the size of the mattress frame was determined, its length, width, and height were fabricated from ½″ plywood and lined with naugahyde. Metal reinforcements were added for safety and structural stability. A second frame was formed from lightweight aluminum conduit and formed in such a way as to be attached to the plywood mattress frame and to be attached also to the full length non-adjustable armrests of the chair. The frames were attached to the armrests with bolts and nuts. The armrests were then welded with a crossbrace consisting of ½″ steel flat bar stock to make the two armrests one removable unit. The mattress, a 4″ thick 65-percent density foam rubber covered in washable naugahyde, was then added to the frame. Measurements were taken to determine the length of the wheel lock extensions which were fabricated and attached. A safety belt was attached along with a luggage tray and utility pouches.

An Everest & Jennings 3P motorized chair was also adapted and with the additional weight of batteries and the different design of the motorized frame, the only modifications required were the wheel lock extensions, anti-tipping devices and attaching the hand control to the mattress frame.

These carts are not designed for primary vehicles. They are used as a secondary vehicle to allow time off pressure-affected areas of the body.

H. Personal Licensed Vehicles

Unistik Vehicle Controller: Reliability, Applications, and Secondary Controls

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Sponsor: *VA Rehabilitation Research and Development Service*

Progress—The Unistik Vehicle Controller (UVC) has been developed under a joint interagency agreement by the National Aeronautics and Space Administration (NASA) and the Veterans Administration (VA) for the purpose of providing a means for enabling severely handicapped individuals to drive a motor vehicle. Work to date has included development of primary (acceleration, steering, braking) controls and installation in a 1981 Ford van, conversion to a programmable microprocessor-based feedback system, and development of simple electromechanical secondary controls. The device consists of the following components:

Driver Interface: This includes a high-resolution, low-effort joystick that may be modified to be used with or without orthoses. The control box and forearm support are brought into proper position for the driver by an electric positioning mechanism. The joystick controls acceleration, steering, and braking. Gear selection and starter switches are situated on the primary control box and may be operated with pushbuttons or toggles. A high brake bias is incorporated into the joystick mechanism, which maintains braking when the hand is moved to change gears. The parking brake is also set by joystick position.

Signal Controller: This is an analog electronic system that processes signals from the driver interface, integrating and modifying them according to feedback from tachometer signals and other variables. Steering control uses a high-gain mode for maneuvers at slow speed, and a low-gain mode to enable the system to operate smoothly at highway speeds. The signal controller may be modified in various ways according to the needs of the individual driver.

Vehicle Interface: The actuators are servomotors that can very rapidly provide the necessary force to move conventional high-effort driving controls. All vital functions have redundant actuation, which automatically becomes functional in the event of failure of any of the primary actuators. Modification of the vehicle electrical system was carried out, and backup batteries were added in order to provide constant, reliable power to the signal controller and actuators. Servos were chosen to maintain function well within operating limits, and temperature control was carefully addressed.

Microprocessor-Based Monitoring System: This provides vehicle security, a self-diagnostic startup system, and continuous monitoring of control function, activating redundant systems and alerting the driver in case of malfunction. The monitoring system cues the driver in the startup sequence and will not allow the engine to be started unless the correct driver access code is entered and the vehicle control system is demonstrated to be functioning properly.

Secondary Control System: An electromechanical secondary control system has been developed that localizes parallel secondary controls (horn, lights, wipers, CB radio, turn signals, hazard lights) and some sequential functions (automatic wheelchair tiedown, parking brake release) in a second movable control box that may be located in any position convenient to the driver. Operation of this secondary control system requires a second functional extremity at present.

The Unistik is presently undergoing exhaustive component life-cycle and system safety and reliability testing, as well as extensive clinical evaluation to better define target population and training requirements. Preliminary

evaluation suggests that quadriplegic drivers at the C5 level and triplegics can safely and effectively operate the system. Ongoing plans include development and adaptation of a voice-actuated secondary control system, using NASA technology that is already available and well-developed in this area.

The Unistik represents a unique, cost-effective, and reliable system for enabling individuals with severe physical disabilities to drive a motor vehicle. It is wholly contained within the passenger compartment, is easily installed, and retains the integrity of the normal vehicle control system. Since the device is a 'bolt-on' system, it can be moved to a new vehicle with ease and is expected to last the lifetime of the user. The expected relative low cost and wide availability of the system will make driving available to a significant number of disabled people who would otherwise be dependent on public transportation.

I. Functional Electrical Stimulation

1. General

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

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Purpose—The purpose of this project is to develop a closed-loop functional neuromuscular stimulation (FNS) system to improve dynamic force and position control of paralyzed limbs. If stimulation systems can be made more functional, they should receive greater acceptance.

The cat ankle joint, including the gastrocnemius and tibialis anterior muscles, serves as the model for developing closed-loop FNS control. The gastrocnemius muscle is electrically stimulated by intramuscular (IM) and nerve cuff (NC) electrodes while the force (F) and stimulated motor unit responses (SMUR) are recorded in order to determine the relationship between these variables and stimulation (S) parameters, electrode configurations, and muscle length. Variable amplitude, biphasic bipolar rectangular 100 microsecond stimulus pulses with a 5-second interpulse interval were used.

Preliminary Results—In intramuscular stimulation (IMS), muscle tension as a function of stimulus amplitude follows a monotonic curve (as expected). However, IMS was sometimes found to be highly nonlinear, exhibiting a plateau, possibly due to recruitment of a distant nerve branch within the muscle. Using decreasing versus increasing amplitude pulse series had little effect on the tension versus pulse amplitude (PA), whereas reversing the polarity of the bipolar IM electrodes shifted the curve (i.e., response threshold) significantly without changing the shape.

Bipolar nerve cuff stimulation (NCS) generally resulted in monotonic tension curves similar in shape to IMS curves. However, changing electrode polarity of the NCS electrodes in some cases changed the shape of the curve as well as shifting it, introducing an intermediate plateau. Stimulus thresholds for NCS were between 0.2 and 0.6 ma versus 1 to 5 ma for IMS. F versus PA curves at several lengths under NCS showed increasing tension with length. Δforce/ΔPA increased with length, particularly at mid-range values. The SMUR peak-to-peak amplitudes were independent of muscle length.

At all lengths, force was monotonically related to SMUR. These F versus PA curves can be described with a third-order polynomial with a correlation coefficient $r^2 \approx 0.99$.

The relationship between force and SMUR is sensitive to the location of the EMG electrodes. Monotonic curves were most often obtained with electrodes spaced <5 mm apart and axial with the muscle fibers. We have found that 1) increasing versus decreasing pulse amplitude series generate nearly identical forces; 2) comparison of F versus SMUR curves resulting from IMS at sites several millimeters apart were similar in shape only; 3) SMUR is consistently saturating before force saturated; and 4) the correlation between peak-to-peak SMUR and F or PA was better than for integrated SMUR versus F or PA.

With increasing electrode separation (especially >1 cm) and/or orientations perpendicular to the muscle fibers, F versus SMUR curves were often nonmonotonic. The nonmonotonicity in these curves originates in the SMUR responses. When electrodes were widely separated, the probability of recruiting different motor units with much different thresholds increases, resulting in polarity reversal as first one and then another motor unit is recruited.

The force produced by IMS and NCS depends both on electrode location and stimulus polarity. There is little evidence of hysteresis with increasing versus decreasing stimulus series. The relationship between peak-to-peak SMUR and peak tension was often quite linear when electrodes were positioned axially and close together, but SMUR were not found to be affected by length, limiting their use as a force-feedback signal primarily to onset of tension ane saturation.

Implantable Systems for Stimulation of Skeletal Muscle

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Purpose—The object of this project is to develop and evaluate, in animals, an implantable stimulator for electrical excitation of paralyzed muscle. The implant is an 8-channel externally powered and controlled device.

Progress—Progress on implantable stimulators has been made in three areas: circuitry development, packaging, and evaluation. Circuitry development has focused on modification and reintegration of the CMOS semi-custom integrated circuit. The circuit has been redesigned to provide external amplitude regulation, as well as pulse width and interpulse interval control available in!the present implant circuitry. The design provides 5-bit amplitude regulation over 0-20 ma, 8-bit pulse width regulation over 0-255 microseconds, and 1 millisecond interpulse interval regulation over 0-50 Hz for each of eight channels. Reintegration is under way at present.

Packaging development has focused on improvement of packaging materials to provide a high quality device. The package utilized is a titanium with epoxy/silicone elastomer for stabilization of interface junctions between the package and the leads and antenna. Packaging protocols have been detailed to provide quality assurance throughout assembly.

Evaluation has focused on monitoring, in a dog model, the performance of the device during both passive (no stimulation) and active periods. These studies have been carried out *in vitro* and *in vivo* in four animals, each of which have been operational for more than 6 months (longest, 16 months).

Future Plans—Future studies will focus on continued *in vitro* and *in vivo* monitoring in the dog animal of the implantable stimulator and its subcomponent assemblies (i.e., electronics, package, connector, leads, electrodes). The purpose of these studies is to determine the reliability and stability of implant function and to

determine a means of analysis of system malfunction. In addition, we expect to incorporate this device in studies utilizing human subjects in the project entitled "Functional Neuromuscular System for Upper Extremity Control," reported elsewhere in this issue.

Recruitment Properties of Nerve Cuff and Epimysial Electrodes

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Progress—A preliminary investigation of the recruitment properties of nerve cuff and epimysial electrodes has been performed. Monopolar cuff electrodes were chronically implanted in the left posterior tibial nerve in two cats. In two other cats, cuff electrodes were implanted on the left tibial nerve and epimysial electrodes were implanted on the right lateral gastrocnemius. After 3 to 4 months, the electrode wires were explanted and the nerves stimulated to determine recruitment data at various pulse durations for all electrodes. No other stimulation was applied during the study.

Electrodes used in this study were manufactured by Avery Laboratories, Farmingdale, NY. The nerve electrode had a 1x2 mm platinum disk placed inside a 3 mm diameter silicone rubber cuff. The epimysial electrode had a 1x2 mm platinum disk placed on a 1 cm diameter sheet of silicone rubber reinforced with Dacron. During testing, a 2 cm diameter stainless steel disk was placed in the leg opposite to that being tested and was used as the ground electrode.

In the first two animals, stimulation values at threshold and maximal levels of contraction were determined by simply palpating the muscle. Histological studies of the nerves were then performed. In the second two animals, recruitment data were collected over a wide range of pulse amplitudes and pulse durations using a monophasic waveform. The procedure followed was to fix pulse duration at 10, 20, 50, 100, 200, or 350 microseconds and then vary pulse amplitude to generate ankle plantarflexion torque in small steps between threshold and maximal values. A torque transducer built in our prototype shop was used for this purpose. To prevent excessive fatigue, only twitches were produced and the peak value of the twitch response was recorded.

It was found that thresholds for the monopolar cuff electrode were between 0.1-0.2 mA while the maximal stimulation values were approximately twice the threshold value. Pulse modulation with nerve cuff electrodes requires a step size no greater than 1 microsecond for adequate regulation of muscle force. Stimulation levels for the epimysial electrodes were 30-100 times higher than those obtained with nerve cuff electrodes. Controllability is not a problem with epimysial electrodes, but there is a high cost in energy expenditure. Additional studies are planned to yield sufficient data for statistical analysis.

Ljubljana Rehabilitation Engineering Center—Core Area: Functional Electrical Stimulation

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Purpose—In functional electrical stimulation (FES) of extremities, electric current is applied to neuromuscular systems of the limbs to cause functional movement of a paralyzed extremity. Electronic stimulators have functional and therapeutic properties that cannot be attained

by any other orthosis. The development of such FES systems is the primary goal of the Ljubljana Rehabilitation Engineering Center, which is made up of the following institutions: the University Rehabilitation Institute, Faculty of Electrical Engineering, J. Stefan Institute, and University Medical Center.

Progress—During the past 3 years (1983-1985), FES research was divided into five areas. The following were the major achievements.

1) *Enhancement of applicability of FES devices and therapies for paretic patients* (Uros Stanic, D.Sc., Dipl.Eng., J. Stefan Institute). A dual-channel stimulator for gait correction in paretic patients was developed. A multichannel EMG recording system was introduced and neuromuscular control of gait studied. Design of 3-channel implantable stimulators was also begun.

2) *FES of spinal cord injured patients* (Alojz Kralj, D.Sc., Dipl.Eng., Edvard Kardelj Univerisity Ljubljana). A posture-switching technique prolonging standing time was introduced. Stair climbing by a completely paralyzed person was achieved. Percutaneous femoral stimulation and flexor reflex triggering with an implant was started.

3) *Electrotherapy of spastic and paretic extremities* (Lojze Vodovnik, D.Sc., Dipl.Eng., Edvard Kardelj University Ljubljana). Various therapeutic approaches (passive joint ranging, cooling, afferent nerve stimulation, TENS, epidural stimulation) were examined together with optimization of stimulation parameters and sites for treatment of spasticity.

4) *Microcomputer-aided diagnosis and rehabilitation of the neurogenic bladder using electrical stimulation* (Peter Suhel, D.Sc., Dipl.Eng., Edvard Kardelj University Ljubljana). In this connection, FES treatment of urinary incontinence in elderly women was started, and a microcomputer-controlled catheter puller was developed to assist in treatment.

5) *Quantification of effects of electrical stimulation in patients with urinary disorders* (Stanislav Plevnik, D.Sc., Dipl.Eng., Edvard Kardelj University Ljubljana). An intensive electrical stimulator for everyday short-term self-stimulation at home was developed together with an electrical fluid bridge-testing device.

The researchers of the Ljubljana Rehabilitation Engineering Center have been invited speakers at international meetings and conferences and have published in scientific journals. The stimulators are manufactured by two Yugoslav factories, and patients from all over the world are coming to the University Rehabilitation Institute because of the unique FES rehabilitation approach.

Implantable Multichannel Implant Systems

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Progress—A comprehensive R&D program for the development and application of implantable multichannel stimulation units and associated hardware is in progress. Our immediate clinical objectives are 1) gait enhancement in patients with unilateral impairment, and 2) long-term therapeutic exercise for patients with bilateral involvement. The status of several projects within this program are described below.

Clinical Laboratory for FES Research (P. Meadows, D. Kannenberg, J. Campbell, N. Su). A clinical laboratory is being developed to support research with an implantable stimulation system. The laboratory will house all of the equipment and personnel required to train implant candidates before and after surgical implantation as well as to determine stimulation patterns used by an external controller to control the implant devices in all modes of operation. The laboratory equipment directly involved with the implant operation can be divided into three categories: the laboratory computer system, the gait walkway, and the implant/external controller/physical therapist control-

ler system.

Laboratory Computer. Before an experimental run, a computer will be used to formulate control sequences for each of 16 possible channels and to transfer stimulation data table information to/from the external controller. During the run, the computer will collect goniometric, electromyographic, and force data from the patient as he/she proceeds along the gait walkway. These data will then be analyzed and results presented to the clinicians using the laboratory. In this way, parameters for gait stimulation may be quickly determined and analyzed for modification by the clinicians.

To present the results of data analysis in an easily interpreted manner, and to facilitate the modification of data tables corresponding to gait stimulation parameters, a high-speed, high-resolution, color graphics workstation will be used. Data table information that corresponds to pulse widths for individual pulses within a channel sequence may be quickly reviewed and modified using a mouse and sent back to the laboratory computer for processing and transmission to the external controller.

Gait Walkway. The gait walkway will be approximately 8 m long and will have color video recording equipment and a gait stride analyzer available for patient performance measurement. Force measurements will be available from instrumented shoes and canes.

Implantable Stimulator. The implantable stimulator utilizes a 3-chip set of integrated circuits developed at Stanford University Integrated Circuits Laboratory. The chips and their associated electronics are enclosed inside a titanium, hermetically sealed can, with tantalum feedthroughs for eight electrode and three antenna connections. The implantable stimulator receives its information and power from a 20-MHz transmitter modulated with an external timing control code, composed of two words, a "Transition" word, and an "Amplitude" word. The Transition word is used to change the state of any of the eight channels. The Amplitude word selects the current amplitude of the state sequence of a given channel. It has three bits to individually address tie eight channelr, four bits to adjust the current magnitude, plus one more bit to set the current polarity.

The implant is approximately 1.75 inches in diameter and 0.375 inches thick. Protruding from the edge of the package are connectors. Attached to these connectors are up to eight electrode leads, terminating in monopolar nerve cuff electrodes. The implant will be placed over each device.

The implant delivers variable pulse width biphasic pulses, with amplitudes from 200 microamperes to 2.25 microamperes. Pulse width control spans the range from 26 to 300 microseconds with a step size of 156 nanoseconds.

External Controller. Supplying information and power to the implant units is a microprocessor-based external controller worn on the patient's belt. The controller uses a CMOS microprocessor for low-power portable operation, and contains circuitry needed to convert stimulation parameter information into the control words and then to implement the transmission process.

The controller has sufficient memory to contain pulse information for 16 channels in several modes of operation in the form of data tables. The elements of these tables correspond directly to the pulse widths required for a particular muscle group to produce a desired amount of force. In this manner, a modulated sequence of muscle forces may be defined to realize the desired trajectory of the patient's lower extremities. The controller device is able to control two implant stimulators for a total of 16 channels.

Therapist Control Unit. Communicating to the external controller worn by the patient will be a therapist control unit. This device is carried by the physical therapist or another clinician walking with the patient during gait runs. With this device, the therapist is able to locally adjust scale factors for any of the channels of the implanted stimulators, to interrogate the status of the implant system, to trigger or modify the operation of the external controller, and to generally assist the external controller in implant system operation. The device has a two-line, 16-character alphanumeric liquid crystal display and a number of controls that allow extensive interaction between the therapist and

the implant/controller system.

Neuroaugmentive Procedures for Modification of Abnormal Motor Control in Patients with Spinal Cord Injury

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Progress—Sixty patients with muscle hypertonia after spinal cord injury have undergone spinal cord stimulation (SCS). These patients had spinal cord injuries ranging from C2 to T12. Electrodes were placed above, below, or above and below the lesion in the posterior epidural space for a period of at least 3 days during which time stimulation pulses, typically of 3 to 5 mA amplitude and of 0.2-millisecond duration at 30 Hz were applied. The effects of spinal cord stimulation were monitored by recording motor unit activity with surface electrodes over leg muscles during an examination of segmental and suprasegmental spinal cord activity, in addition to patient reports and neurological evaluations.

Preliminary Results—The results of SCS can be divided into four distinct categories. In Group I, consisting of 17 patients or 28 percent of the entire group, the effect was characterized by marked suppression of muscle hypertonia and so-called spontaneous spasms. In Group II, the effect of spinal cord stimulation on muscle hypertonia was moderate as evidenced by the suppression of the tonic but not phasic features of spasticity. This was observed in 20 patients, or 33 percent of the total. In Group III, neurological and neurophysiological evaluations revealed only a marginal effect. The condition of this group of nine patients (15 percent) did not improve significantly. In Group IV, consisting of 14 patients (23 percent), there was no effect.

SCS was markedly or moderately effective in reducing spasticity in 63 percent of the patients. We found that control of spasticity by SCS was not correlated with the severity of spasticity, the type of spasticity (flexor or extensor), or the ability to ambulate. However, stimulation in incomplete cervical lesion patients was 90 percent effective, compared to 14 percent effectiveness in complete cervical lesions, and stimulation below the lesion was more effective than above. We concluded that SCS is effective when electrodes are properly positioned below the lesion over the posterior aspect of the spinal cord in patients with some residual spinal cord function. We hypothesize that SCS controls spasticity by modification of activity of the spinal-brainstem-spinal loop and also by suppression of segmental excitation through antidromic activation the of propriospinal pathways.

Evaluation of the Effectiveness of Electrical Stimulation of the Leg Muscle in Cerebral-Palsied Patients

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Progress—The previous phase of the project clearly indicated that FES of the quadriceps muscles of cerebral-palsied patients substantially increased muscle bulk, tone, strength, and endurance. The evaluation, performed on the Cybex II system, had large standard deviations when the statistical analysis was performed due to human factors associated with patient collaboration, level of associated mental retardation, attitude, etc.

A myoelectric recording and processing system, designed to be used as a fatigue monitor during isometric knee extension loading, is simple and easy to use with this group of patients. The EMG activity at the end of 30 seconds is compared to the initial level and its ratio derived as an index for muscle progress.

Adaptive Neuromuscular Stimulator

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Sponsor: *LSU Bioengineering Foundation*

Purpose—Different skeletal muscles are controlled with different firing rates and recruitment control strategies. The biceps, for example, utilize motor unit recruitment to derive 80 percent of its maximal force, and firing rate increase to obtain the final 20 percent. The FDI muscle, however, utilizes recruitment to obtain its initi'l 35 percent of uhe maximal force and to obtain the remaining 65 percent by firing rate increase.

In order to restore function to paralyzed muscles using electrical stimulation with a natural physiological control strategy, a new system was designed and tested.

Preliminary Results—The system is based on computer-controlled dual-channel stimulators, one modifying the muscles' firing rate and the second its motor units recruitment range. Testing clearly showed that control of recruitment in the force range of 20 to 100 percent of the maximal force is possible with concurrent increase in firing rate. Pure firing rate is possible once the full recruitment is obtained. The system, therefore, can control any skeletal muscle according to its natural control strategy with substantial increase in force accuracy and fatigue reduction.

Fitness Improvements and Physiological Responses to FES Exercise

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

Progress—To accomplish these studies, specialized instrumentation have been designed and constructed including: closed-loop and open-loop stimulator systems utilizing either digital or analog circuitry; FES knee extension exercise devices; and arm ergometers (arm crank and wheelchair) for voluntary exercise.

Several studies, which have been performed, or are currently in progress, include: development of standardized FES knee extension exercise protocols to provide safe and effective means of evaluating performance, and to enhance the capacity of paralyzed muscles for this form of exercise; determination of metabolic and cardiopulmonary responses for FES exercise in comparison to these responses obtained

for the same exercise performed voluntarily by able-bodied individuals; determination of metabolic and cardiopulmonary responses for combined FES leg and voluntary arm exercise; and evaluation of central hemodynamic responses (ventricular stroke volume and cardiac output) for various forms (dynamic and static) of FES exercise.

Results—Chronic FES knee extension exercise (3 times a week for 12 weeks), using a progressive intensity load weight protocol, had resulted in marked improvements in quadriceps muscle strength and endurance. No known damage to the muscles, bones, or skin had occurred. Linear increases in oxygen uptake (VO_2) and pulmonary ventilation (VE) with exercise intensity were observed. However, heart rate (HR) did not increase above resting values. The maximal VO_2 achieved (20 lb-load) was nearly twice the rest value. These relatively low maximal VO_2 and VE values and the lack of HR response cast doubt upon the efficacy of this exercise mode to provide a cardiopulmonary training effect. FES exercise also appeared to be inefficient in comparison to voluntary exercise. This was indicated by higher VO_2 for FES exercise than for voluntary exercise (performed by able-bodied individuals) at each intensity level. The inefficiency may be due to histochemical characteristics of the paralyzed muscles, inappropriate stimulation patterns and stimulation of inappropriate muscle fibers.

One factor which probably limits FES exercise capability is inadequate blood flow to and from active muscles. It appears that cardiovascular adjustments during voluntary exercise (e.g., increased cardiac output and redistribution of blood from inactive to active skeletal muscles), which are normally mediated through autonomic sympathetic pathways, may not occur to the same extent with FES exercise. This is because FES bypasses the central nervous system by peripherally inducing contractions, and many patients with impaired neuromuscular function (e.g. spinal cord injury) also have impaired autonomic function.

In another study, spinal cord injured subjects performed maximal effort voluntary arm crank ergometry (ACE) and FES-induced knee extension exercise separately and simultaneously. We found additive VO_2 and VE responses during the hybrid FES-ACE exercise, whereas the marked increase in HR was completely an effect of the voluntary ACE exercise. Knee extension performance, as indicated by resistance to fatigue, was significantly better during hybrid FES-ACE exercise than during FES alone. This may be due to enhanced sympathetic stimulation induced by the voluntary ACE exercise. These findings suggest that hybrid FES-ACE exercise may be used to increase active muscle mass and the maximal VO_2 achieved. This may improve the aerobic training capability of paralyzed individuals.

Preliminary results of an ongoing study suggest that simultaneous combinations of voluntary and FES-induced contractions of paretic muscle enhances training capability for strength and endurance. This form of hybrid exercise can permit significantly stronger contractions than those elicited by voluntary effort alone, and enables exercise to continue for longer periods of time. Such training may ultimately result in greater and more rapid restoration of voluntary function.

In an effort to promote blood flow in the lower extremities via FES, we performed a pilot study on able-bodied subjects. A multichannel stimulator was used to elicit appropriate pulsatile contractions of the calf and thigh muscles, and in effect create a venous muscle pump. During FES, we found significant increases in central hemodynamic responses above rest values suggesting reduced blood pooling in the legs. Applications of this "pump" may include deep venous thrombosis and decubitus ulcer prophylaxis in immobilized patients.

Future Plans—Our future research will focus on the implementation of long-term exercise training programs using advantageous FES techniques. We will also continue our physiologic evaluations to determine mechanisms for any improvements of muscular and cardiopulmonary functions, as well as to provide a better understanding of the limiting factors for FES exercise.

2. Upper Limb Applications

Sensory Augmentation for FES Upper Extremity Prostheses

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Purpose—The purpose of this project is to provide substitute and augmentative sensory feedback to enhance the utility of FES upper extremity prostheses.

Progress—An electrocutaneous communication system has been designed that provides feedback information about prehensile force, the output of the shoulder position command transducer, and stimulator status. Efforts to date in our laboratory have led to the development of a six-level frequency coding paradigm to input grasp force information to the subject. Electrical stimulation parameters have been selected that attempt to optimize signal discriminability and minimize accommodation effect. The frequency modulation grasp force information is provided by activating one or the other spatially discrete elements of a multi-element electrocutaneous display.

The particular element of the electrode array (display) that is active at any given moment provides a spatially encoded correlate of the output of the subject's shoulder position command transducer. An array that consists of five electrodes, placed on one side of the upper back skin, scales the subject's command feedback signal into five equal parts. During the past year the efficacy of this spatial position electrocutaneous feedback scheme was demonstrated by having subjects perform shoulder position tracking tasks with and without the feedback display turned on.

The final aspect of the composite sensory augmentation system consists of furnishing machine state information to the FES system user. A scheme to do this was developed over the past year and is now being evaluated in one quadriplegic individual. The machine state feedback includes coded electrocutaneous messages that assist the FES system user in: 1) selection of the mode of grasp; 2) specification of the position of the shoulder that corresponds to the start or "zero" point of the command signal; and 3) realignment of the shoulder before reentry into the state of voluntary active control after the system has been put into a "Lock Grasp" state. (The Lock Grasp state refers to the condition during which the user can set the muscle stimulation parameters at any arbitrary level of command and then disengage the shoulder position controller and have the FES system automatically maintain the muscle stimulation parameters at the selected level.

Future Plans—Future work will concentrate on performing functional evaluations of the composite sensory feedback system in selected quadriplegic individuals. The functional tests will be laboratory-based and consist of simulated activities of daily living as well as more abstract assessments that involve the manipulation of instrumented objects.

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

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Purpose—The purpose of this project is to design, develop, and evaluate an implantable device that will provide two independent (degrees-of-freedom) signals for use as command control and feedback source in upper extremity assistive systems for the high level spinal cord injured population. The implanted device will measure relative skeletal position changes of opposing bony segments. The movement will be generated by voluntary movement of the body over which the user retains voluntary control (e.g., shoulder in C4 injury or lower, wrist in C6 or lower). This information will provide the means for the user to control his hand position and force in a functional neuromuscular stimulation (FNS) hand assist system. Alternatively, the signal may be used in a position feedback loop, such as for control of wrist position by FNS in a C5-level quadriplegic subject. It will also have application to control upper extremity prostheses and a powered wheelchair.

Functional Neuromuscular Systems for Upper Extremity Control

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Purpose—The objectives of this project are to develop implantable systems for functional neuromuscular stimulation and to implement and evaluate their effectiveness in providing restoration of upper extremity function in the high level spinal cord injured subject. The studies performed in the past year have focused on the development of the system hardware and software for implementation of implantable stimulator systems into human subjects.

Progress—Progress in the past year has been made in both development of the implantable stimulation system and in the clinical studies. The implantable system has been completed and is ready for human implantation. The implantable system consists of the external command control sensor, the portable processor-transmitter, and the implanted stimulator. The external command controller is a two-degree-of-freedom position sensor for shoulder-sternum measurement. The sensor has been redesigned so that it now utilizes linear Hall effect devices as the sensor elements. The entire unit is cast in acrylic for ease of fabrication and greater reliability.

The external processor has also undergone redesign to provide for more versatile processing of input commands and enhanced generation of more complex stimulation sequences. The unit is based on two CMOS microprocessors (RCA CDP6805E3) and has the capacity to control up to four implantable stimulators. Software has also been enhanced to simplify programming of the stimulation and command sequences. Implantable stimulator development has focused on aspects that are central to human implementation, specifically for leads, connectors, and electrodes. A new in-line connector has been implemented and tested. A connector is essential for human implants to allow for serviceability in the event of failures. The connector is small and flexible, and thus keeps stress distributed along the lead.

The fabrication procedures of the epimyseal electrodes have been improved to provide better adhesion between components and more secure surfaces for suturing. Implantable components have been fabricated with at least double redundancy in stimulator devices, connectors, leads, antennae, etc., to ensure that backup support and repair components are

available. All of the procedures for human implantation have been developed and all instrumentation for surgical installation have been completed.

Clinical studies have focused on development of surgical and evaluation protocols and selection and preparation of human subjects. The protocols are complete, and institution review has been obtained. Surgical implantation is a two-stage process, the first stage of which has been completed in two tetraplegic subjects and involves surgical restoration of the hand involving tenodeses, tendon transfers, and arthrodeses. The second stage is implantation of the stimulator-receiver. This is to be undertaken after performance of grasping function is stabilized using percutaneous electrodes. This level of performance has been reached with both subjects.

Functional Electrical Stimulation in Upper Extremity Muscles of Spinal Cord Injured Patients

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Purpose—A study is being undertaken on the effect of electrical stimulation in upper extremity muscle strengthening of spinal cord injured patients. The aim of the project is to introduce functional electrical stimulation to the treatment program in the spinal injuries unit, in a controlled manner in which physiological benefits are monitored. The significance of the project is that this new treatment modality offers potential for increased independence of spinal cord injured patients through muscle strengthening. The hypothesis to be tested is that FES-assisted exercising of partially paralyzed upper extremity muscles results in significantly greater muscle strengthening in the arms of spinal cord injured patients than equal periods of conventional exercises.

Progress—Four subjects have now entered the project, and it is intended to study approximately six subjects throughout a 12-month period. Baseline measures have been taken of strength of the affected muscles (as measured by a Penny & Giles Myometer), muscle bulk (as measured by CAT scans), range of movement of the appropriate joint, functional skills, and body image.

Future Plans—During a 3-month period of training, using FES or active exercise (to be randomly decided), monthly strength and range of movement measures will be taken. Retests will then be taken of all the baseline measures.

During a subsequent 3-month training period of active exercise or FES (whichever was not undertaken during the first 3-month period), monthly strength and range of movement measures will again be taken. At the end, retests will be conducted on all the variables measured at baseline. The FES-assisted exercise is to be conducted on as many days each week as each subject can manage. Stimulation is to be 10 seconds on and 50 seconds off at 30 Hz, with sufficient current to cause a full range of movement without the subject's active assistance. Duration is to be for 15 minutes per day on each muscle group during week one, 30 minutes per day in week two, 45 minutes per day in week three, and 60 minutes per day in week four. During months two and three this duration of training is to be maintained, with the subject augmenting the effect of the FES by actively assisting movement.

The active exercise sessions are to consist of an appropriate set of isotonic or isometric exercises selected by the physiotherapist. The duration of exercises is to be the same as for FES, that is, work up to 60 minutes per day for each muscle group.

3. Lower Limb Applications

Walking Restored in Paralyzed Man Using Electronic Orthotics

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Purpose—Research activities in this program are directed toward further development of a neuromuscular orthotics system to provide paralyzed persons with specific functional activity, performed smoothly and repeatedly with minimal fatigue.

Progress—Approximately 125 electrodes of a new design were implanted, and found to behave essentially the same as those of the original design. Both portable and laboratory stimulators were modified to allow surface stimulation of the trunk muscles in addition to percutaneous stimulation of the hip, leg, and foot muscles. Predetermined stimulation patterns of the portable sensors can be triggered now with both hand switches and a combination of foot switches; the stimuli are both pulse-width and frequency modulated. Addition of trunk muscle stimulation has allowed better posture, reduced weight borne on the arms, and increased duration of walking.

Closed-loop control of muscles controlling transverse hip motion has been shown to improve stability and resistance to perturbations; it permits both reduced levels of stimulation during standing and reduced arm support. Computer simulations of the double limb support phase of gait have been developed and will be used in improving walking patterns and developing closed-loop control algorithms for walking. Analysis of force, kinematics, and muscle EMG signals has lead to development of new functional activities, such as stepping sideways and walking up and down stairs.

An ankle-foot orthosis and a knee-ankle-foot orthosis have been designed and fabricated (all active subjects have the AFOs) for protection of joints now and for incorporation of sensors in the future. A variable capacitance joint-angle sensor is being tested for use with closed-loop control.

Future Plans—Work is directed toward continued improvement in electrode design and implantation, investigation of the causes of muscle fatigue during FNS use, development of an adaptive controller to obtain longer duration standing and to provide closed-loop control for walking, evaluation of sensor needs, and design of those necessary for the closed-loop system.

Electrical Stimulation of Paralyzed Muscle After Spinal Injury

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Purpose—Individuals with spinal cord injury have absent or diminished control over muscles that are innervated below the level of their injury. Many of the paralyzed muscles can be activated by electrical stimulation of the nerves leading to these muscles.

This study attempts to identify the therapeutic benefits of a regular program of electrically induced leg reconditioning and exercise in a general population of veterans whose legs

have been paralyzed by spinal cord injury. The study group consists of individuals with paraplegia and quadriplegia who are patients of the Spinal Cord Injury Service of the VA Hospital at Hines, IL. This predominantly male population provides a diverse mix in terms of level and completeness of injury; actual age and years post-injury; height and weight; and the extent of cardiovascular, renal, urinary, skeletal, neuromuscular, peripheral vascular, cutaneous, and psychological complications brought on as a result of spinal injury. We did not consider individuals with damage to their spinal cord below T11, with severe peripheral vascular or cardiovascular problems, or with pressure sores in areas affected by stimulation, for this protocol.

Progress—To date, we have completed baseline evaluations on 21 qualifying individuals. We screen an additional three or four potential candidates each month. For the most part, the qualifying individuals had incomplete quadriplegia ($N=10$) or complete paraplegia at T11 or above ($N=7$). For this study we first measured torque and fatigue characteristics produced by a 100-mA stimulus (a 20 Hz train of 0.5-msec compensated monophasic pulses) delivered to the knee extensors via large (2x4 cm) water-soaked surface electrodes in alternating fashion (2.5 sec ON, 2.5 sec OFF). We then placed 18 of the individuals in a twice-daily, 6-day-a-week, 20-minute exercise protocol, with weekly assessment of progress. After four to eight weeks of electrically induced exercise, some participants exhibited large increases in muscle force and fatigue resistance, while others showed little change. We are now attempting to correlate the extent of increases seen (if any) with our other observations.

Sensory Prosthetic Feedback and Application to the FES—Orthosis Systems

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Purpose—The concept of a total neural prosthesis (i.e., simultaneous electronic substitution for both motor efferent and sensory afferent activity) has been proposed. A sensory feedback prosthesis was developed with footload transducers, a "balanced" (carrier-suppressed) modulator, and a vibrocutaneous interface at the subject's skin.

Progress—The system has been reported to provide prolonged balance and upright posture assist in a T4 (complete) paraplegic in whom tactile feedback of feet position was substituted for visual feedback. This sensory feedback prosthesis can also be combined with an FES orthosis, i.e., FES combined with long leg braces. Currently, the total neural prosthesis (TNP) system performs standup and sit-down as well as prolonged maintenance of upright posture and balance.

Future Plans—Future applications of the TNP are planned which will include walking and optimizing the human operator-system interaction control strategies.

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

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Purpose—Persons with spinal cord injury resulting in paraplegia need to regain functional use of their legs. Functional electrical stimulation (FES) of paralyzed muscles is a potentially useful method for restoring standing and walking functions in paraplegics, but several problems must be solved before FES becomes clinically acceptable. These problems include unreliable stimulating electrodes, insufficient muscle strength, fatigue resistance of the paralyzed muscles, and unavailability of a totally implantable stimulation system. Another problem is the lack of suitable engineering models to study the tradeoffs among alternative FES schemes proposed for controlling paraplegic standing and walking.

We hypothesize that the use of large-scale computer models based on engineering principles is essential to the systematic development of FES systems, just as such models are necessary in controlling aircraft, satellites, and robots, and in planning economic policy.

Our project has three objectives. The first is to formulate a control problem of standing and walking, implement it on a computer, and study the tradeoffs among alternative control schemes. The computer implementation consists of a model of the musculoskeletal system, a model of the feedback sensors, and a feedback controller whose properties can be chosen to optimize a performance criterion. The second objective is to understand the functional significance of individual muscles in maintaining upright posture, with emphasis on identifying functional muscular synergies. To accomplish this objective we are using a computer model of the musculoskeletal system and focusing on the mechanics and geometry associated with posture and the imposition of various physical constraints, such as keeping one's knees fully extended or feet flat on the ground. The third objective is to program a graphics workstation to display a real-time animation-like simulation of the human body under FES control.

Progress—In formulating the control problem of paraplegic posture induced by FES, we realized that muscle fatigue is a property of the musculotendon actuator that must be modeled before fruitful FES control studies can be conducted. Emphasis is therefore now directed toward modification of our current musculotendon actuator model. The model of musculotendon actuator dynamics has been amended, however, to account for muscle that is electrically activated by pulse trains, as with FES.

We also realized that it would be desirable to base our model of the knee on a mechanism that more closely resembles patello-femoral-tibial mechanics than our current model does. An engineering model of the musculoskeletal system for use in studies of the geometrical properties associated with postural mechanics has been completed and computer optimization techniques implemented to identify functional muscular synergies.

Open-Loop Control of the Paralyzed Human Knee

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Purpose—Regulation of electrically stimulated paralyzed muscle is being investigated to improve impaired gait in humans. Developing a reliable control system is essential to the even-

tual success of these neuroprosthetic systems. Clinical systems generally use open-loop control of muscle activation, but have limitations. Muscle properties are nonstationary; they depend on muscle kinematics, muscle energetics, and stimulation history. Moreover, electrode characteristics can also be nonstationary. While the natural solution to compensate for these variables is to use closed-loop control, success can still be achieved with open-loop systems. Open-loop systems are demonstrably successful and relatively easy to implement.

Progress—As a first step in developing a reliable open-loop control system, muscle response repeatability has been investigated. Dynamic responses have been matched to a target trajectory by specifying open-loop stimulation sequences to paralyzed muscle. Surface stimulation of the quadriceps muscles of four complete paraplegics permitted dynamic knee responses in a controlled laboratory situation. Response repeatability was assessed before and after a two-month electrical exercise program. Additionally, the effect of the exercise on muscle strength and endurance was measured weekly.

During an experiment, stimulation sequences were specified by an iterative, trial-and-error procedure such that the knee angle response matched the target trajectory as closely as possible. The target trajectory consisted of extending the knee then returning to a rest flexed position during two seconds of a three-second period. Single period trials were repeated five times before and after a continuous 50 period endurance trial.

Before the exercise program, peak extension typically decreased to less than 70 percent of initial extension by the end of the endurance trial. Following the exercise program, peak extension was maintained, decreasing to only 95 percent of the initial value. Despite maintenance of the peak, the leading and trailing segments of the response demonstrated significant degradation. From these studies, a limited conclusion can be made regarding FES-assisted gait. Our exercise protocol does improve muscle endurance, although muscle responses will degrade nonuniformly during repeated trials.

A hardware and software system are being developed to evaluate various control schemes to regulate the swing phase of gait in paraplegics. Studies of open-loop control will be continued with stimulation of antagonist muscles. In addition, various closed-loop control schemes will be evaluated.

Triggers for Control of Implantable Gait-Assist Systems

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Purpose—A microprocessor-controlled, implantable gait-assist system is being developed at our center. In this system, triggers will initiate and terminate preprogrammed stimulating sequences. Initial systems will be radio-frequency coupled, but the ultimate goal is to implant all hardware inside the body. Reliable triggers should occur approximately every 25 percent of the gait cycle. Initial systems will use unobtrusive external triggers; later systems will use implantable triggers.

Progress—External trigger sources tested were footswitches under the heel, first and fifth metatarsals, and the great toe, and pressure sensors in the crutches. Potentially implantable triggers tested were vertical accelerometers (mounted on the upper thigh), the onset and offset of EMG activity of the latissimus dorsi, erector spinae, posterior deltoid and lateral head of the triceps.

The subjects were seven incomplete spinal cord injured persons with walking speeds of at least 30 meters per minute and a four-point reciprocating gait. These criteria were goals for our implant subjects to determine if, at this

level, there are reliable triggers.

Footswitches, vertical acceleration, and the pressure sensors in the crutches were reliable in all subjects. A small standard deviation in trigger timing indicated reliability. The EMG activity of the latissimus dorsi and erector spinae were reliable in five out of seven subjects. The posterior deltoid and triceps were reliable in only two subjects. At least one external trigger occurred every 25 percent of the gait cycle. However, reliable potentially implantable triggers occurred only at 0 percent and 50 percent of the gait cycle (left and right foot strike). We will look for other potentially implantable triggers whose timing occurs at 25 percent and 75 percent of the gait cycle.

Computer-Controlled 22-Channel Stimulator for Limb Movement

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Purpose—The aim has been to modify and test the Nucleus Multi-channel Implantable Hearing Prosthesis as a portable computer-controlled 22-channel neural stimulator. Its new purpose is pattern activation of individual motor nerves in the lower extremities of paraplegic subjects to form functional movements such as exercise, standing, and gait.

Progress—In late 1984 the modified Nucleus Stimulator was completed and delivered. It consisted of the Sanyo MBC-1000 microcomputer with a special interface printed circuit board for its connection to the speech processor interface (SPI): Z80-A processor, programming and erasure circuit. The speech processor (SP) connects into the SPI unit; the SP has an antenna that overlies the receiver stimulator unit (RSU). A Nucleus-adapted connector allowed the use of any or all of the 22 channels at one time. New computer software programs were developed. The Nucleus Radio Stimulator Unit output was calibrated at various temperatures (21.8-39.8 degrees Celsius) over a 6-month period showing no variation in seven tests and slight variation at the lowest temperatures.

Using four barbiturate-anesthetized adult rabbits, it was shown that individual or multiple channels could be computer-controlled in their pulse amplitude, width, and frequency to activate single or multiple nerves resulting in single, co-contractions, and simultaneous bilateral joint movements. To determine the threshold and maximum currents required to produce muscle contractions in human lower extremities, amplitude recordings and nerve diameter measurements were taken during lower extremity amputations in nine patients. Stimulation was carried out at 0.2 msec and 20 pps using a portable, battery-operated, calibrated, constant current stimulator (Cordis Corp., Miami, FL, model 910A). The currents necessary to produce maximum contractions fell consistently below the maximum output capabilities (3.5 mA, 0.4 msec) of the 22-channel stimulator. There was a close correlation between nerve diameter measurements taken at surgery and those obtained from the *Color Atlas of Human Anatomy* (McMinn and Hutchings, Year Book Medical Publishers, Chicago, 1977). These measurements are necessary in planning the size of the spiral electrodes to use in the clinical trials planned in this study.

Future Plans—The microcomputer and interface equipment are being modified into one unit that is a battery-operated, belt-worn microprocessor with the capability of carrying the paraplegic subject's own individual programs for controlling limb movement. Also planned is the production of a totally implantable array of leads, connectors, and electrodes to deliver stimulation to selected motor nerves.

In collaboration with the West Roxbury VA Spinal Cord Injury Service, we will locate five 20- to 30-year-old, healthy, mid to lower

thoracic paraplegics to participate in the clinical trials. It is anticipated that the first subject will receive the implant in late 1986 and will begin the program to first exercise individual and groups of muscles to increase strength and overcome fatigue. We hope to complete the study having all five subjects using the stimulators within three years.

Lower Limb Function with FES

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Progress—Research is based on stimulation of the quadriceps, hamstrings, and common peroneal nerves with a view to achieving standing position and walking. Two groups of patients are used. In the first group are paraplegic patients suffering from a complete upper motor neuron lesion ranging from T4 to T12. In the second group, paraplegic patients suffering from incomplete lesions receive the stimulation starting 4 to 6 weeks after injury.

Future Plans—Future development in this study involves production of feedback mechanism for foot position and knee angulation. A fully implantable system is also being investigated for improved muscular contraction following nerve stimulation.

A Computer Model for Control of Paraplegic Posture

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Purpose—Suitable engineering and computer models need to be developed to study paraplegic posture controlled by functional electrical stimulation (FES).

Computer models, once developed, can be used to design FES-control systems specific to individual paraplegics enabling them to regain their mobility.

Although much is known regarding automatic control system design, the design of FES-control systems is still hampered by such factors as the nonlinearity of physiological characteristics. One of the most important considerations in FES-control system design is the determination of the relationship between FES input (pulse trains) and corresponding limb movement. Another important consideration to control system design is muscle fatigue, which significantly affects paraplegic posture induced by external stimulation.

We hypothesize that development of suitable models for activation dynamics and muscle fatigue is critical to FES-control system design of user-specific systems and to computer studies of tradeoffs among alternative systems based on different design criteria.

Progress—Our current approach is to model musculoskeletal dynamics, which we decompose into three parts: skeletal dynamics (influenced by external forces such as the ground), musculotendon dynamics, and musculoskeletal geometry. Two planar motions in the sagittal plane are being considered for study: free-standing and crutch-assistive standing. In the skeletal model for free-standing, five body segments including the feet are modeled as rigid bodies assuming bilateral symmetry. The musculotendon dynamics are made up of activation dynamics and contraction dynamics. Since muscle fatigue plays an extremely important role in postural control induced by FES, once muscle fatigue is modeled, we will focus on minimization of muscle fatigue to regulate posture and move-

ment of the lower extremities. Movement of the upper extremities is modeled as an external disturbance. The disturbance rejection control schemes will thus be emphasized.

We have developed reasonably complex models for activation dynamics, contraction dynamics, and skeletal dynamics of the human lower extremities. By using a simplified double-inverted pendulum skeletal model, several open-loop control laws were applied and found to function well even under small external disturbances (i.e., where the disturbances model movement of the upper extremities). In order to improve system performance, closed-loop control and state estimation are needed. Currently, efforts are being made to model and embody muscle fatigue into the overall system for studies on controllability and observability.

Functional Electrical Stimulation in Dropped-Foot Conditions

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Purpose—This study will evaluate the effectiveness of functional electrical stimulation in dropped-foot conditions. Improvement of gait by selective stimulation of a child's own muscles would seem to be of considerable benefit if it can be shown to be effective and lasting.

A preliminary study on two children with cerebral palsy was encouraging. Both children had weakness of the extensors of the ankle and walked with a dropped-foot gait. The use of FES resulted in increased ankle dorsiflexion during the swing phase of gait and a more normal heel-toe gait.

We propose to use functional electrical stimulation in ten children with various neurological conditions. The aim will be to assess the effect on gait of stimulation of the peroneal nerve to activate the extensors of the foot. The stimulation will be used on a daily basis for a period of one year. Assessments of the effects of FES will be made at the beginning of the trial, at 6 months, 12 months, and 6 months after cessation of FES.

The following assessments and measurements will be carried out on the children:

1) Muscle bulk of the calf will be measured by direct measurement of girth and by computed tomography to accurately measure muscle bulk and density of the calf extensors.

2) Assessment of the strength of the ankle dorsiflexors will be carried out using a Penny & Giles Myometer.

3) Gait measurements and a video recording will be made with the subject walking along a straight line. Markers will be placed on bony landmarks. Measurements will be made using a transparent goniometer.

The instrument used will be the Gorenje Mikrofes Electrical Stimulator, which incorporates a heel switch so that electrical stimulation only occurs when the heel is off the ground. The electrodes will be applied to the skin over the peroneal nerve below the head of the fibula. Initially a low voltage will be applied for ten minutes. The voltage will be gradually increased to the limit of comfort and tolerance, and time will be incrementally increased up to four to six hours a day and switched off whenever the child is sitting down. Regular checks of progress, of the skin below the electrode, and of the equipment will be made.

Restoration of Locomotion in Paraplegics Using Functional Electrical Stimulation

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Sponsor: *None listed*

Purpose—Functional electrical stimulation (FES) for the restoration of locomotion in paraplegics is studied. The research of the two participating institutes is focused on 1) fundamental and clinical problems to achieve an implantable system for the selective artificial stimulation of peripheral nerve fibers, and 2) the optimization of the current possibilities for clinical use of FES.

Progress—Some of the current research projects are:

Nerve stimulation. Multi-electrode configurations for nerve stimulation are studied in rats with the electrodes placed around the nerve and intrafascicular. Recruitment stability and overlap in recruited groups of motor units for different electrodes are investigated. Further, we are investigating the production and use of a platinum electrode array made on a silicon substrate using chip technology for multichannel intrafascicular stimulation.

Stimulation control. In order to achieve reproducible movements we study open- and closed-loop control in animal experiments and in men. In rat experiments the muscle has been loaded with a servo-controlled mechanical load. In human subjects the transfer sit-to-stance is studied using specially developed equipment. The subject is in a supine postion on a bench, while his legs exercise against an adjustable resistance force. The equipment is used to study open-loop stimulation, system identification, and closed-loop adjustment of the open-loop stimulation pattern.

Assessment of kinematic information. The control of functional movements by artificial stimulation can be improved by feedback of kinematic information. We therefore studied the use of accelerometers because they offer the potential for future implantation and whether the subject is lying, sitting, or standing can easily be detected. We developed a theory for assessment of the leg segment angles without integration for two-dimensional rotations. We validated the theory by measurements on a pendulum and with two-dimensional movements of the lower extremities during stance phase.

Clinical application of test and training equipment. In clinical applications, surface electrodes are still most important. The electrode configuration and electrode position are important for optimizing the reproducibility in muscle recruitment. Therefore methods are developed and tested.

The active training of paralyzed muscles to work needs special equipment. The training for strength of the muscles involved in the sit-to-stance transfer is studied using the apparatus described previously.

Muscle endurance is trained on a bicycle ergometer, in which the stimulation patterns are synchronized with the angle of the pedals. The angular velocity is controlled by a feedback control loop.

The cardiac condition of the subject is estimated from the response to graded exercise testing using a specially developed arm ergometer. This exercise may be combined with leg exercise induced by electrical stimulation.

4. Other

Fitness Improvements and Physiological Responses to FES Exercise

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Purpose—The purpose of this project is to compare the acute and chronic exercise responses of functional electrical stimulation (FES) of the lower limbs to standard arm crank ergometry (ACE) and "hybrid" exercise (i.e., FES plus ACE) in elderly VA subjects versus their young able-bodied and disabled counterparts.

The study will be completed in two phases. Investigations of the metabolic and cardiorespiratory responses to FES, ACE, and "hybrid" exercise will be completed on young able-bodied males and wheelchair users at the Laboratory of Applied Physiology, Wright State University. Subsequently, the acute responses to FES, ACE, and hybrid exercise as well as longitudinal training studies will be initiated with the elderly VA population, domiciled at the VAMC in Dayton, OH, for comparison to the younger men.

Cardiorespiratory and metabolic assessments will be made by well established techniques. The optimal exercise protocols using FES, ACE, and hybrid exercise will be developed in the younger population for application to the older men. Peripheral responses to acute and chronic treatments will be assessed via a modification of impedance plethysmography for estimation of limb blood flows. Central hemodynamics will be assessed using impedance cardiography and CO_2-rebreathing cardiac outputs.

Progress—We have studied 20 younger able-bodied subjects and wheelchair users. Optimal exercise protocols have been developed and both acute and chronic responses are now under study in the younger population. Portions of this work have been recently presented at the Fifth International Symposia on Adapted Physical Activity, in Toronto, Ontario, Canada, and data have been published in *Clinical Research, Federation Proceedings,* and by IEEE.

Predictive Factors for Restrengthening Paralyzed Muscle by Electrical Stimulation

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Purpose—Electrical stimulation of paralyzed muscle could be potentially useful for many persons with spinal cord injuries, however little work has been done to document this assumption. Furthermore, electrical stimulation is not presently being used on a large scale for persons with spinal cord injuries, because physicians cannot predict how various patients will respond to electrical stimulation. The goal of this project is to develop a set of tests that will help physicians to predict the responses of muscles to electrical stimulation.

Progress—We have begun preliminary studies on determining predictive factors with 18 patients of the Hines VA Spinal Cord Injury Service. All patients have given their informed consent to the research protocol. This predominantly male population provides a diverse mix in terms of level and completeness of injury, actual age and years post injury, height, weight, and medical and psychological compli-

cations brought on as a result of spinal injury. We have not considered individuals with damage to their spinal cord below T11, with severe peripheral vascular or cardiovascular problems or with pressure sores in areas affected by stimulation, for this protocol.

Preliminary Results—We completed initial evaluation on these patients using electromyographic radiographic (CT scan), and neuromuscular techniques, before entering them in a 4-to-8-week protocol. In this protocol we are stimulating their thigh muscle force and fatigue during 20-minute exercise sessions, tracking changes in thigh muscle force and fatigue characteristics from week to week. Preliminary results suggest a possible correlation between muscle mass (as determined by the CT scan) and initial response to electrical stimulation.

Electrical Stimulation of Osteogenesis Using Selected Techniques

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

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

Progress—Originally, restraint and anesthesia of the animals, used by others in previous similar experiments, were to be employed in this research to permit daily placement of electrical devices as well as the stimulation treatment. However, the excessive restraint, prolonged anesthesia, and consequent inactivity of the animals usually result in a loss of weight, health, and not infrequently, life. To avoid these complications, a system of jacket, tether, and electrical swivel was developed to permit routine electrical stimulation treatment of animals with any stimulation technique. It was believed that such a system would help to establish a more accurate index of the biological response to electrical stimulation with *in vivo* animals.

The jacket-tether-swivel system allows the animal to have freedom of movement within its cage with access to both food and water *ad libitum.* A group of 12 animals has recently completed treatment with electromagnetic stimulation by a sinusoidal waveform of three different amplitudes using the above system. The group sustained the treatment without restraint or anesthesia and with no loss of weight, health, or life. The biological response to the electromagnetic stimulation described above is currently being evaluated by histomorphometric

analysis. The development of the jacket-tether-swivel system permits electrical stimulation treatment of animals in a humane and comfortable manner.

Future Plans—With the system now reduced to routine practice, treatment of the additional animal groups necessary to achieve the specific aims of this project are scheduled for completion over the next year.

Value of Electrical Stimulation on Fertility in Male Patients with Spinal Cord Dysfunction

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

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

Preliminary Results—Six patients have been entered in the study. All six were caused to ejaculate via rectal stimulation. All of the patients had adequate sperm counts but none had more than 10 percent motile sperm. Therefore, artificial insemination was not performed. Only one patient was able to ejaculate with the assistance of a vibrator.

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

Cardiovascular Circulatory Dynamics in Quadriplegics With and Without Functional Electrical Exercise (Active Physical Therapy)

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Purpose—The purpose of this study was to demonstrate selected cardiovascular training effects secondary to functional electrical exercise for quadriplegics.

Progress—Eight quadriplegic subjects engaged in 12 weeks of exercise bicycle ergometry that utilized closed-loop control of movement of the paralyzed skeletal muscle. Baseline evaluation of cardiovascular status (including response to supine and head-up tilt) were initially performed. Post-training period (after 12 weeks) of the cardiovascular status of the quadriplegics indicated a statistically significant increase in resting systolic blood pressure, heart rate, and cardiac index. Efforts are directed toward understanding fundamental material properties of cardiac muscle in quadriplegics and potential changes in functional electrical exercise.

Electrical Muscle Stimulation for the Prevention of Pressure Sores: 1) Pressure Studies

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Purpose—Pressure sores (decubitus ulcers, ischemic ulcers, etc.) represent a severe and costly problem for many disabled individuals. This is particularly true for those who are wheelchair-dependent and have sensory loss. A research program has been implemented to determine whether electrical muscle stimulation (EMS) can be used to prevent the formation of pressure sores.

It is generally accepted that the primary cause for the development of pressure sores is the local restriction of blood and lymph vessels due to external forces exerted on the tissue. There are a number of mechanisms through which EMS can possibly help prevent pressure sores: 1) tissue undulation and variations of seating interface pressures permitting increased blood and lymph flow; 2) increased local blood flow to muscle and surrounding tissue in response to muscle contraction; 3) increased blood and lymph flow due to muscle pump activity; and 4) long-term effects of chronic stimulation, including increased muscle bulk and strength, increased vascularization, and changes in tissue properties such as metabolic and muscle twitch characteristics.

These positive effects must be weighted against possible negative effects to develop stimulation parameters that are effective in preventing pressure sores. Possible negative effects include increased intramuscular pressure, muscle oxygen requirements, metabolite production, fatigue, heat, and sweat.

Progress—Pilot studies have been performed to study the tissue undulation and seating interface pressure variations produced as immediate and dynamic effects of EMS. Bilateral surface stimulation of the gluteus maximus has been performed on able-bodied and spinal cord injured subjects while seated in a wheelchair. Varying stimulation frequencies and intensities have been used but have been limited to those that produce at most a 1-inch medial lateral movement at the knee while seated. Seating cushions used in these studies have included a sling seat, 1-inch gel pad, temper foam, polyurethane foam, and a ROHO cushion.

Interface pressure measurements have been made using two different pressure measurement pads. Pressure measurements made using a Scimedics pressure pad evaluator have shown seating interface pressure variations as great as 15 mm Hg even with these relatively low stimulation intensities. Pressure measurements made using a TIPE pressure pad have shown a redistribution of seating interface pressures during stimulation. (A specialized computer interface for the TIPE pad is reported elsewhere in this publication.)

Future Plans—Results of ultrasonic imaging of the buttocks during stimulation are reported separately in this publication. Blood flow measurements using radioactive tracers are currently underway with both able-bodied and paralyzed subjects. Clinical trials to determine prac-

tical efficacy of using electrical muscle stimulation to prevent pressure sores is planned for the near future. Both short-term, dynamic effects and chronic effects as well as their interactions will be studied.

Electrical Muscle Stimulation for the Prevention of Pressure Sores: 2) Ultrasonic Shape Imaging Studies

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Purpose—The rationale for using electrical muscle stimulation (EMS) for preventing pressure sores is presented above (Electrical Muscle Stimulation for the Prevention of Pressure Sores: 1) Pressure Studies). This report covers work on ultrasonic imaging of the buttocks both with and without stimulation. The purpose of this study is to determine buttock shape and tissue reconfiguration that occurs with stimulation. The value of this type of investigation stems from a conceptual model of pressure sore formation based on tissue distortion.

Distortion of tissue results mostly from the application of uniaxial forces. Body tissue, which is essentially incompressible, must laterally expand when subjected to uniaxial forces in order to maintain constant volume. This tissue distortion tends to collapse blood and lymph vessels and thus promote ulcer formation. Hydrostatic loading, on the other hand, avoids tissue distortion and its associated restrictions of blood and lymph flow.

Progress—An ultrasonic pulse echo image acquisition system (U.I. Octoson-Ausonics Corp.) has been used to image the buttocks of five able-bodied subjects under various seating conditions. The Octoson has a large water bath that can be covered with a plastic membrane and was used to produce a transverse plane image of the buttocks. Ultrasonic images have been generated under three conditions:

A) Buttocks suspended in water with no external load and no stimulation. The subjects supported themselves by their arms with hips flexed at approximately 90 degrees and buttocks suspended in the Octoson water bath.

B) Subject seated on plastic membrane with no electrical stimulation simulating the standard seating interface condition.

C) Subject seated on a membrane with electrical stimulation applied. This shows the effect of stimulation on the buttock tissue configuration during sitting. Bilateral stimulation at 50 Hz was used with intensity set as described in the pressure study.

Preliminary Results—Noticeable distortion of the buttocks was observed in trial B compared to trial A as would be expected. In trial C, the effects of the evoked buttock contraction were clearly visible. The shape of the buttocks was significantly changed from trial B toward that of the suspended buttocks as observed in trial A. Similar results have been obtained for all five subjects tested so far. These results of the trials show that low level stimulation can produce a significant change in buttock shape and configuration.

Future Plans—Arising from this work will be blood flow studies with radioactive tracers and clinical trials to test two hypotheses: 1) dynamic undulation produced with electrical stimulation can increase blood and lymph flow and help prevent pressure sore formation; and 2) reconfiguration of the buttocks through stimulation can help reduce tissue distortion and blood and lymph vessel occlusion to help prevent pressure sores.

Rehabilitation of Fast and Slow Skeletal Muscle

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Purpose—The purpose of this project is to document the response of "fast" and "slow" skeletal muscle to transcutaneous electrical stimulation. The experimental model used in the m. tibialis anterior (TA, fast) or m. soleus (SOL, slow) from the New Zealand white rabbit. Muscles are cast immobilized and stimulated at either 10 Hz or 50 Hz for 1 hour per day, 5 days per week for 4 weeks. Following the treatment period, muscle contractile and histochemical properties are measured.

Progress—Initial studies were directed toward measuring the baseline properties of the atrophied TA and SOL. It was demonstrated that casting angle had a profound effect on the muscular response. For example, when the TA was cast at about 10 degrees plantarflexion, hypertrophy, not atrophy, resulted. In addition, the SOL, a predominantly slow muscle, atrophied to a much greater extent and demonstrated a partial slow-to-fast fiber type transformation during the immobilization period.

With this baseline information in hand, present studies are directed toward measuring the muscular changes induced by either 10 Hz or 50 Hz transcutaneous stimulation. Initial studies demonstrated that 50 Hz intracast stimulation results in increased intramuscular pressure to the extent that muscle necrosis occurs. Also, because the TA fatigues quickly in response to 50 Hz stimulation, 10 Hz stimulation actually has a greater strengthening effect over the 4-week treatment period. We are now experimenting with different stimulation protocols in order to minimize TA fatigue during stimulation.

Treatment of Spastic and Paretic Muscles in CP Children

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Purpose—The aim of this study is the improvement of present treatment procedures used for therapy of spastic and/or paretic legs in cerebral-palsied children. The main therapy is afferent and efferent electrical stimulation with various stimulation modalities. An additional therapeutic procedure machine ranging at all three joints (ankle, knee, and hip) is proposed.

Progress—Since the project started we have succeeded in introducing this kind of therapy only for the ankle joint. Completion of the necessary equipment will enable intensive therapy of all three joints on both legs. The main goal of all therapeutic procedures is prevention or at least postponement of surgical intervention at an early age. According to specific neurological and biomechanical deficits of each child, both kinds of therapy will be combined.

The progress of each patient is estimated through various objective tests, which are divided into two groups: functional tests and hyperexcitability tests. In the first group are gait measurements and posture stability tests; in the second group are tendon reflex tests and biomechanical measurements such as a pendulum test and resistance to passive movement. Through these various tests possible neurophysiological mechanisms responsible for biomechanical deficit are also studied.

Since the study is mostly oriented to long-term effects we are not able to present definitive results at this time.