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IV. Spinal Cord Injury

A. General Rehabilitation

A Research and Demonstration Project for Rehabilitation of Paraplegics in Madras

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Sponsor: National Institute of Handicapped Research

Background—In developing nations such as India, the management of (SCI) patients is replete with difficulties at every stage of care because of the paucity of trained personnel and the meager facilities.

The proposal for this project was mooted in 1969 and finally started in 1978.

Aims and Objectives

1. The main aim of "Paraplegia Project, Madras" has been to develop simple methods of care of SCI patients in a general hospital setting without reliance on expensive equipment. While the need for and importance of centers exclusively devoted to a SCI population is recognized, establishment of such centers is unattainable in vast tracts of the world for several decades to come. In contrast, the methods of care at Government Hospital, Madras, if found effective and useful, have the merit that they can be immediately transferred as appropriate technology to other parts of India, and to other developing nations as well.

2. The Paraplegia Project was established for total care of SCI patients in Madras and adjoining districts within a radius of 200 miles. The multidisciplinary care of the patients, highlighted by a monthly Ward Rounds of all specialists, brought rich dividends by decreasing the mortality and morbidity. It increased function in terms of independence of SCI patients, and it decreased the duration and cost of acute and rehabilitation care.

Findings

1. Three hundred system cases and 200 non-system cases have been treated at the project. The final report is in preparation. It is hoped that the findings will highlight the place of "the art of the possible" in

the care of SCI patients in developing nations.

2. SCI patients at Madras were mostly males in their second to fourth decades of life. The injuries were sustained mostly in villages; manual and agricultural laborers were affected mostly. Falls from trees or falls into wells have been the commonest causes of injury; road accidents have accounted for fewer than 10 percent of cases. Cervical spine has been involved in about 50 percent of cases.

3. Most of the patients were treated by conservative methods; operative treatment was done in a few cases where indicated.

4. Over the years there has been a significant reduction of complications, with gratifying results in the care of skin and bladder.

5. Psychiatric workup and counseling have added a new dimension to the care of SCI patients in the last year.

6. Mobility aids were given to nearly all needy patients through the help of governmental and social welfare agencies.

7. Vocational rehabilitation for self-employment with the aid of bank loans has enabled many patients to start anew.

The Madras Method of Acute Care of Flexion Injuries of Dorsal and Lumbar Spine.

The "Madras Method" of postural reduction with two pillows behind the apex of the gibbus has been found to be eminently suited for acute care of flexion injuries of the spine below the level of the fourth dorsal vertebra. The merits of the method are the reduction of the fracture or fracture dislocation, prevention of skin and lung complications, the fact that turning can be done by a single person, and, above all, its simplicity.

Two pillows as wide as the bed are arranged as a wedge at the level of the gibbus. The level of the gibbus is identified and a circumferential line is marked with gentian violet over the middle of the upper of the two pillows. The patient is positioned over the pillows so that the two lines, i.e., those on the patient and on the upper pillow, coincide. With the patient supine, the wedge of the pillows reduces the fracture and, in the course of a few hours, restores the alignment to an acceptable degree. The patient is turned every 2 hours by an attendant using the upper of the two pillows as a lever. No specially qualified person is required for such turning; anyone can be taught to do it. While the patient is in lateral recumbency, a large sandbag is laid over the back to restore the curvature of the spine.

Summary—When viewed in the context of the enormity of the problem, with practically no facilities available for the care of SCI patients, the achievements of the Paraplegia Project in Madras have been praiseworthy. ■

Demographic and Economic Studies

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Detailed statistical data on the incidence and prevalence of spinal cord injury in the United States will be collected and evaluated to determine the direct and indirect costs of SCI, both to the paralyzed individual and the general public (through government expenditures). Cost effective approaches to reducing the incidence of injury will be highlighted. It is hoped that such data will provide an effective economic argument, demonstrating the urgent need for increasing current research expenditures devoted to the cure of spinal cord related injuries. ■

Interactive Video Education System for Rehabilitation

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Problem—In order to facilitate a return to active and fulfilling lives, spinal cord injured patients, and those associated with their care, need to learn a wealth of information. Rehabilitation is largely an educational process where routine issues in life are re-examined and new approaches learned. Information about activities of daily living, vocational opportunities, and recreation are just a few of the important concerns of an effective rehabilitation program. This information should be available to disabled users so that they can independently access it when they need it or are ready to learn it.

Ideally, a rehabilitation program should be flexible enough to accommodate the variety of needs and learning rates among the patients. Such flexibility could also allow individuals to govern their own pace

through the rehabilitation process, further encouraging their independence and personal initiative.

For the physically disabled, however, their ability to interact with conventional educational aids may be impaired. This constraint indicates the need for an interface which brings the material within their range of perceptual and motor abilities. This interface needs to be incorporated into a system that effectively presents the educational information to the user population.

Significance—This system promises to be cost effective while providing greater access to information. Successful learning is an experience in which one gains information and an enhanced sense of ability to deal with new situations. A spinal cord injury rehabilitation program using this system could provide patients with information, a model for coping with new situations, and the positive experience of living independently through learning. This system also has potential applications in educational and industrial training environments.

Background—Classroom instruction and one-on-one sessions with the health care staff are the traditional rehabilitation learning experiences in a spinal cord injury unit. However, limitations of time, facilities, and personnel may make needed information and instruction unavailable just when the patient is most ready to learn. Video is a convenient and effective medium for instructional rehabilitation that is currently widely used. However, many disabled patients are unable to independently operate video playback equipment, placing them in a position of dependence on the health care staff. The need to address this problem was initially identified by a clinical nurse specialist in the Spinal Cord Injury Center (SCIC). The development effort in this project has involved RR&D, SCIC, and graduate mechanical engineering students at Stanford.

Hypothesis—We hypothesize that a combination of interactive video technology and computer-aided instruction methods can be used to supplement and enhance the learning experience of the patients in a rehabilitation program. Further, we believe that the rehabilitation process is significantly augmented by giving patients the opportunity for independent self-instruction and the use of sophisticated assistive aids which encourage independence.

Approach—Our objective is to provide the disabled community with 24-hour independent access to video

information. This involves identifying and consolidating relevant video educational material and enabling all users to interact with this information resource. The user population includes high-level quadriplegics, who have no use of their hands but normal head and vocal control. Able-bodied users, such as family members and health care staff, should also be able to interact naturally with the system. The system will be concurrently developed and evaluated in order to design it to best serve the needs of its users.

Status—A prototype system has been constructed to demonstrate the concept and undergo preliminary evaluation. In order to make the system accessible to persons with high-level spinal cord injuries, it is designed to be automatically activated by the approach of a user. Voice input is used, since disabled and able-bodied users can operate this interface with equal ease.

The system is designed to be functionally flexible and easily reprogrammable, allowing us to modify, add, and experiment with different features. It also monitors its own use and stores pertinent data. For example, for each learning session, the computer records the date and time that the system is activated, elapsed time spent with the system, sequence of video programs viewed, and performance characteristics of the voice interface. This information provides a quantitative measure of how the system is performing and being used and will help us better understand the needs of the users. The system is assembled in a self-contained package that can be readily transported to different sites for demonstration and clinical evaluation.

We plan to continue to evaluate and develop this prototype system. Information gathered from the evaluation of this prototype will be used to design a more comprehensive system. This system might incorporate interactive videodisc technology to provide faster access to more video material. We plan to add more interfaces (joystick, touch screen, etc.) in order to allow users to choose the most efficient mode of input for them. Providing this selection of interfaces would also enable us to compare and evaluate their performance. We also hope to include new interactive video programs which would be relevant to the needs of the users. ■

Outcome Studies Pertinent to the National Spinal Cord Injury System

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This project encompasses four studies, three 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 NIHR.

The three retrospective studies capitalize upon existence of the common data base 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 U.S.A. The second study is concerned with documenting post-rehabilitation outcomes for quadriplegic patients who, at discharge from inpatient rehabilitation, require ventilatory assistance. The third study attempts to clarify effects on patient outcomes of delaying patients' transfer from an acute care setting to a rehabilitation setting.

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 of 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 Applications 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.

Status to Date—During the project's first year, the U.S.-Australian systems study was completed, and an article has been submitted for publication. One data set reflected experience with 65 consecutively admitted patients whose care during 1979 and 1980 occurred in the spinal cord unit at the Royal Perth

Rehabilitation Hospital in Perth, Western Australia. The second data set pertained to 1606 U.S. patients who had been cared for in one of the regional systems during the same 2 years. The results indicate that decubitus ulcers, atelectasis, pneumonia, pulmonary emboli, ulcers of the gastrointestinal tract, and heterotopic ossification all occurred more frequently in the U.S. group. This was especially true of 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 they will develop complications that slow rehabilitation progress.

The studies concerned with post-rehabilitation outcomes for ventilatory dependent quadriplegics will continue during the second year, as will the prospective study comparing outcomes for system and non-system patients.

Development of a Reconditioning Exercise Program for Patients with Paraplegia

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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 that 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 initially will be 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 exercises 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 days per week for 8 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.

Status to Date—This first year has been directed at achieving a series of tasks that include: testing of an arm ergometer developed by the TIRR Rehabilitation Engineering Center, testing of an expired gas collecting system, evaluating methods of ECG recording during arm exercise in the laboratory and in the outdoors gamefield, developing a procedure for measuring leg blood pressure during exercise with the arm, establishing a baseline of biochemical measurements relating to exercise, and developing historical documents for recording clinical/socioeconomic historical data and a computer data file system for storing data for subsequent analyses. These tasks have been successfully accomplished with two exceptions: (i) telemetry of ECG under outdoor gamefield conditions, which is subject to interference from citizen band radio transmissions; and, (ii) measurements of blood lactate during arm ergometry, which was impractical on a cost/effort basis with equipment available at the beginning of the project. Solutions to these problems are being sought.

The methodology for assessing the cardiovascular tolerance to physical work with arm exercise has been well established. It has been successfully applied to 16 untrained paraplegic males, some more than one time, and to six healthy male subjects tested in the same manner to obtain comparative data. One well trained paraplegic male also has been tested. The healthy subjects are currently being trained in the use of the wheelchair in the gamefield events for subsequent determinations of the energy requirements of such events.

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

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There are three major project objectives: (i) to assess current strategies employed after discharge to achieve psychosocial adjustment and productive lives for spinal cord injured persons, (ii) to develop and test new strategies or refine current strategies to enhance outcomes postdischarge, and (iii) to 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 over 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 so that compounding problems can be avoided, utilizing resources efficiently by tailoring programs to meet the actual needs of clients, and improving rehabilitation outcomes by providing appropriate services.

Status to Date—A protocol was developed for interviewing rehabilitation professionals. Eight professionals from six rehabilitation disciplines were asked to describe the needs of spinal cord injured 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, how they found out about resources,

satisfaction with resources, and special difficulties encountered in meeting their needs. A list of approximately 600 spinal cord injured clients eligible to participate in the study was obtained.

The protocol for interviewing clients currently is being refined to ensure that all essential information can be obtained in an efficient manner. The protocol is being thoroughly pilot-tested with a number of subjects. During 1984, client interviews will be conducted, and arrangements have been made to work collaboratively with the National Spinal Cord Data Base and the Research and Training Center project on Outcome Studies Pertinent to the National Model Spinal Cord Injury System.

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

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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 between individuals operating these programs, and to provide access to a dependable source of technical assistance related to these programs.

Non-experimental survey methodology is being used. The data are summarized in frequencies according to specified categories of interest, and some correlational studies are being done to determine trends in independent living program development. Data from project surveys are used to assess the types of services being provided for persons with spinal cord injury.

In order to facilitate use of the information developed, the project maintains 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, consumers, and supplementary

reviews by additional experts, both in and out of the independent living field.

Status to Date—A survey instrument has been designed and distributed, a computerized data base management system has been designed, and a tentative report format has been developed. Work on all tasks is underway as scheduled. Project staff have responded to several hundred mail and telephone inquiries. On site training has been provided in Houston and Dallas, and a series of additional training programs are being planned. One book chapter has been published and two articles have been prepared for professional journals. Presentations have been made at meetings in Houston, Dallas, Denver, and Charlotte, North Carolina. Efforts have been made to coordinate training with the Houston Center for Independent Living, and feedback has been obtained relating to the effectiveness of project efforts.

The work plan for the next grant period emphasizes analysis of the survey data. Other effort will be devoted to data base updates, information dissemination, training, and networking.

Vocational Evaluation for Quadriplegics with a High School Education or Less

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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: (i) identifying and documenting jobs that can be performed by the described population group; (ii) conducting a comprehensive review of existing vocational assessment tools and determining relevance of tools to assess potential of quadriplegics; (iii) selecting and organizing a meaningful process; (iv) incorporating the model vocational process into the Vocational Department's service delivery program; and, (v) evaluating the effectiveness of the model evaluation process.

The expected outcome of this project is the estab-

lishment 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 disability groups with severe physical impairments.

Status to Date—This project is continuing in the developmental phase. Of 6050 jobs that have been reviewed, 162 have been judged by the project staff to be options for quadriplegics with a high school education or less as follows:

Occupational Category	No. of Job Options
Clerical	78
Service	20
Agricultural and related	0
Processing	18
Machine Trades	46

A total of 334 vocational assessment tools have been reviewed. Of this total, 55 commercial work samples, 18 noncommercial work samples, and 15 psychometric tests were determined by the project staff to be within the physical capabilities to be performed by quadriplegics.

Activities planned for the forthcoming year include: (i) identification and documentation of job options in bench work, structural, and miscellaneous occupations; (ii) continuation of review of assessment tools; (iii) selection of assessment tools that are applicable to measuring potential for identified job options; and (iv) organization of vocational evaluation process.

B. Medical Treatment

Determinants of Renal Function Alterations During Long-Term Follow-Up in Patients with Spinal Cord Dysfunction Using Radionuclide Procedures

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Background—The relationship between spinal cord injury (SCI) and urological disorders is well established. No other group compares with SCI patients in terms of severity and morbidity of urinary tract infections (UTI). The UTI and the other complications associated with a neurogenic bladder, such as vesicoureteral reflux, bladder cellules, diverticuli and trabeculae, urethral strictures and abcess, calculi, etc., often result in renal disease and the ultimate renal failure which is a leading cause of death among SCI patients. Thus, continual long-term follow-up of these patients is necessary. Most SCI centers utilize excretory urography (EXU) coupled with blood urea nitrogen or serum creatinine measurements for this purpose.

Earlier studies from this laboratory have shown that measurement of effective renal plasma flow (ERPF) with a comprehensive renal scintigraphy procedure (CRSP) is preferable to EXU for several reasons. However, there were several discrepancies between EXU and CRSP results in some patients. This study was designed to explore these discrepancies and evaluate the clinical significance of minimal CRSP and EXU changes after SCI.

Hypotheses

1. Anatomic changes of the kidney demonstrated by excretory urography (EXU) are clinically useful in the long-term management of the urinary tract, even if unaccompanied by functional alterations.

2. Functional alterations in the kidney demonstrated by comprehensive renal scintigraphy procedures are clinically useful in the long-term management of the urinary tract, even if unaccompanied by anatomic changes.

3. Normal CRSP parameters differ significantly in spinal cord injury patients and other types of patients.

4. Measurement of the glomerular filtration rate (GFR) or filtration fraction provides clinically useful information about SCI patients having discordant EXU and CRSP findings.

Methodology—All SCI patients with neurogenic bladders are evaluated with renal scintigraphy during their initial hospitalization and at their annual follow-up examinations. Those with a significant decrease in ERPF are evaluated with EXU as well. KUB X-rays are taken of each patient to detect renal or bladder calculi. Blood chemistries and urine analysis are performed as deemed necessary by the attending physician. GFRs are measured by renal scintigraphy. Those patients who receive both EXUs and CRSPs have these tests graded as normal or abnormal, and the concordance of these test results are determined. In the case of discrepancies, other test measurements, such as GFR or serum creatinine levels, are used to determine the validity of CRSP and EXU findings. The mean and standard deviation for ERPF and other scintigraphic parameters in SCI patients are compared on an age- and sex-adjusted basis with results from renal transplant donors prior to nephrectomy.

Preliminary Findings—We have performed over 2000 CRSPs. Most (1839) were on patients entered into the study. Although no new patients are being entered at this time, we are continuing to follow those patients already entered.

Since the last report, we have measured GFRs in 20 patients using the 5-minute camera/computer technique combined with a single blood sample collected at 180 minutes. In addition, we have refined the computer program used in the study, making it more automatic, and revised background correction methods. We also have revised slightly the formula for calculating GFR from the single 180-minute sample, and developed an algorithm for use when blood samples are not drawn at exactly 180 minutes, but rather in the interval ranging from 146 to 235 minutes. Comparisons have been made between differential and total GFR values and differential and total ERPF values, with much better agreement than in the previous group of patients. We have performed duplicate GFR measurements in three patients at 1-week intervals and found no statistically significant differences in total GFR, relative function on either side, or differential GFR values.

Because we have refined the limits of expected values for CRSP parameters in spinal cord injury patients, we have found fewer and fewer discrepan-

cies between CRSP results and EXU results. Moreover, we are performing fewer EXUs than originally expected, since we are seeing fewer people whose renal status requires, or even allows, excretory urography to be performed. We will, in the coming year, focus our attention on those patients who have discordant CRSP and EXU results, possibly even paying their expenses to return for follow-up examination, if they have not returned since the initial discordance was discovered. At this point, our distinct impressions are that past discordances resulted from inadequate information on expected limits for CRSP parameters in spinal cord injured patients. The study will be completed in May 1985. ■

Effectiveness of Prophylactic Antimicrobial Therapy in Patients with Spinal Cord Injury

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Background—Bacteriuria is the most common complication of spinal cord injury (SCI). Patients with indwelling catheters may all be safely assumed to have continued bacteriuria. The advent of intermittent catheterization programs (ICPs) has resulted in a dramatic decrease in the incidence of bacteriuria in these patients, but even successful ICP graduates are at very high risk for contracting bacteriuria. The present study was designed to determine whether any of several prophylactic antimicrobial treatments could reduce the incidence of bacteriuria in SCI patients who were free of indwelling catheters.

Hypothesis—Bactrim, Macrochantin, Hiprex, Neg-Gram, and ascorbic acid given at prophylactic levels are superior to no treatment in preventing urinary tract infections in SCI patients without indwelling catheters.

Methodology—SCI patients with neurogenic bladder constitute the study population. Neurologic level and extent of lesion are documented. Upon entering the study, a urine culture, colony count, and sensitivity are obtained and appropriate antibiotic therapy initiated. After sterile urine is achieved, subjects are assigned by ordered sequence to one of five prophylactic

treatment regimens. Cultures, colony counts, and sensitivities are obtained weekly while the subject is hospitalized. The study is discontinued if and when it becomes necessary to replace the indwelling catheter, if the patient becomes reinfected, or if continued follow-up becomes impractical. The average number of weeks each patient remains infection-free is being calculated, and the differences between each drug's ability to maintain a sterile urine is being determined.

Preliminary Findings—Bactrim was the drug found to be most effective for prophylactic treatment of urinary tract infection in spinal cord injury patients; ascorbic acid was the least effective. However, it should be noted that the median infection-free period was only 11 days for Bactrim. Current evidence suggests that none of the drugs tested, including Bactrim, was particularly useful in preventing urinary tract infections in these patients at the doses studied. It should also be noted that patients given ascorbic acid generally had fewer infection-free days than control patients. The study concluded on July 1, 1984. ■

Urinary LDH Fractions for Localizing Site of Urinary Infections in Patients with Spinal Cord Dysfunction

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Background—There is a marked difference between the clinical significance of cystitis and pyelonephritis. Several procedures have been proposed to distinguish between the two. One common method, ureteral catheterization, is expensive, highly invasive, and not without attendant risk. It is generally acknowledged that there is a need for a simple laboratory test capable of distinguishing between upper and lower urinary tract infections. This project has examined lactate dehydrogenase (LDH) isoenzyme patterns of ureteral urine in an attempt to determine whether alterations in them can be used to differentiate between upper and lower urinary tract infection (UTIs) in spinal cord injury (SCI) patients.

Hypothesis—The urinary LDH isoenzyme patterns of SCI patients with upper tract infections are signifi-

cantly different from urinary LDH patterns of SCI patients whose urinary tract infections are confined to the bladder.

Methodology—Ureteral urine specimens, bladder urine specimens, and prostatic secretions have been obtained from a series of male SCI patients. Colony counts, culture identification, and antibiotic sensitivities have been performed on all specimens. Total LDH and the relative proportion of each of the five LDH isoenzymes have been determined. Ultimately, total LDH and relative LDH isoenzyme concentrations will be compared statistically in patients with (a) bladder infection only, (b) kidney and bladder infections, (c) prostate and bladder infections, and (d) kidney, bladder, and prostate infections.

Preliminary Findings—To date, we have studied a total of 20 patients, 15 of whom have had total LDH assays. In these patients, bladder urine, urine from the right and left ureters (separately), and prostatic secretions were analyzed for total LDH and relative amount of LDH in each of five subfractions.

Our results to date suggest that neither the level of total LDH nor the relative proportions of the LDH subfractions in bladder or ureteral urine or prostatic secretions are diagnostic of an upper tract infection. In practical terms, even if total LDH levels or subfraction proportions in ureteral urine were diagnostic for an upper tract infection, current practice of culturing this urine for bacterial growth and antibiotic sensitivity would be less expensive, more direct, and therefore preferable to measuring total LDH levels or subfraction proportions. Increasing the number of patients studied is very unlikely to alter these provisional conclusions, since we have encountered both false positive and false negative results, and these must be considered even in the light of studies on additional patients. ■

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

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Background—The surprisingly high incidence of heterotopic ossification (H.O.) following spinal cord injury (SCI) and/or other severe neurologic injuries or diseases suggests that it is a frequent complication of patients admitted to rehabilitation programs. When its severity limits joint motion and exacerbates the disability, impaired function may be of such degree that it limits ambulation or wheelchair independence, or it may even impair mobility to the extent that the patient must remain bedfast. Protracted periods of confinement in bed or in abnormal sitting postures in wheelchairs may cause the formation of pressure sores. A drug, Didronel (etidronate disodium), has been shown effective in preventing H.O. when administered prophylactically after spinal cord injury. Since the occurrence of H.O. frequently leads to extensive and costly hospitalizations, as well as to interruption of the vocational rehabilitation process, it is warranted to pursue studies that directly impact on prevention of H.O. rather than to study the complication after it has occurred.

Hypotheses—(i) There is an optimal time post-injury when Didronel therapy should be initiated to achieve the maximal prophylactic effect; (ii) there is an optimal duration of Didronel therapy that will yield a maximal prophylactic effect; and (iii) there is an optimal dosage of Didronel that will yield a maximal prophylactic effect.

Methodology—The study population is being made up of patients admitted to the UAB-Spinal Cord Injury Care System between 0 and 120 days post-injury, whose lesions are neurologically complete (or neurologically incomplete with residual function less than a Frankel Classification of "motor non-functional"), 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 1 year post-injury.

Preliminary Findings—One hundred thirty-eight subjects have been entered into the study. Substantially more subjects have been entered into the Early Treatment Group (15 to 44 days post-injury) than into the Late Treatment Group (45 to 120 days post-injury). The reason for this is that most SCI patients are admitted to this center well within 44 days of injury, since our Spinal Cord Injury Care System emphasizes early admission. It is imprudent to delay transfer admissions solely for the purpose of being able to enter a prospective patient into any clinical study. In this case, it would be considered particularly imprudent, since the agent, disodium etidronate, has been proved effective in the early prevention of heterotopic bone formation. However, if patients are admitted to our center 45 or more days after injury, they are entered into the Late Treatment Group routinely, if they meet all other selection criteria.

A total of 85 patients/subjects have been assigned to the Early Treatment Group. The remaining 53 patients/subjects met Late Treatment Group entry criteria and have been thus assigned. Those patients/subjects in the Early Treatment Group were further subdivided into comparably sized sub-categories with approximately half receiving drug therapy for 90 days and the remaining half receiving the drug for 180 days. A similar sub-categorization process was utilized for patients/subjects in the Late Treatment Group.

Of the 138 patients/subjects entered into the study, 58 have been dropped from the protocol for reasons beyond our control. These included voluntary withdrawals and, in some instances, our inability to follow these patients after discharge.

Sixty-eight subjects have completed the entire protocol, which includes a 1-year post-injury follow-up examination. At present, the active study population consists of 81 patients who have elected to remain on the protocol and who appear capable of being followed post-discharge and willing to cooperate. Eight patients have completed the drug treatment phase, but still have an annual follow-up examination pending. Five patients are currently completing the drug treatment phase. Follow-up examinations for these patients/subjects will be scheduled subsequent to their completing this phase of the study and being discharged from the center. The study will be terminated and the data analyzed after a minimum of 100 patients have completed the entire protocol. ■

Dermal Fibrosis in Spinal Cord Injury Patients

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Background—Spinal cord injury (SCI) patients with documented episodes of autonomic hyperreflexia have been observed to develop cutaneous changes characteristic of scleroderma, which is a collagen disease of unknown etiology and pathogenesis. The disorder manifests itself primarily in the cutaneous, vascular, musculoskeletal, gastrointestinal, pulmonary, cardiac, and renal systems. Dense fibrosis may appear in the gastrointestinal tracts, a cystic type of fibrosis may develop in the lungs, renal vessels may show signs of accelerated nephrosclerosis, and fibrosis of the myocardium and respiratory structures may result in cardiopulmonary failure. It is believed that the autonomic nervous system is in some way involved, but supportive evidence is lacking for this condition which is, at present, untreatable. Since the cause of collagen disease is still unknown, it is theorized that these changes in spinal cord injury patients with known autonomic dysfunction may help in understanding the cause, and may suggest appropriate treatment for the collagen diseases in general.

Hypothesis—There is a cause-effect relationship between autonomic nervous system dysfunction and dermal fibrosis in SCI patients.

Methodology—A series of chronic SCI patients with scleroderma-like skin changes have been studied retrospectively. Skin changes have been graded according to a previously developed scale. Blood and urine specimens have been analyzed extensively, and skin biopsies have been collagen-typed via indirect immunofluorescence. Other tests, including comprehensive renal scintigraphy procedures (CRSP) and skin temperature gradient studies, have been performed.

Preliminary Findings—Twenty-one retrospective study group patients/subjects have been entered into the protocol. Complete data are not available on all 21 patients due to (i) loss of some tissue specimens in transit between laboratories; and/or (ii) the inability

of the project team to perform all tests on certain patients.

Generally speaking, blood and urine specimen analyses were not consistently abnormal. Serum alkaline phosphatase abnormalities were identified in four patients/subjects. However, these findings may be attributable to other unrelated metabolic changes in the bony skeleton. Although 8 of 19 patients/subjects were found to have abnormal serum serotonin values, it must be stressed that five of the abnormal values were elevated and three were depressed. The known technical difficulties associated with serum serotonin measurements necessitate revalidation of the finding and considerable prudence in interpretation. Among 14 patients/subjects in whom sedimentation rate measurements were acquired, more (n=9) had abnormal findings than had normal findings (n=5). This was not entirely surprising, since sedimentation rate abnormalities are frequently encountered in the spinal cord injured. Six of 20 patients upon whom renal scans were performed showed some evidence of abnormal findings; however, there was no discernable pattern (viz., similarity) in the nature of the scan data.

The biopsy findings suggest a fairly consistent fibrotic change in collagen in patients with injuries above the sixth thoracic segment who have identifiable clinical changes in skin texture. This confirms our impression that autonomic dysfunction resulting from spinal cord lesions at or above T6 may initiate cellular and/or vascular changes or damage capable of inducing primary or secondary fibroproliferative abnormalities. Completion of this study should increase our understanding of collagen disorders, since many of them have characteristic fibroproliferative changes associated with the pathogenesis of a given disease.

In all, 23 skin biopsies have been obtained: 5 from pilot-study subjects, 16 from patients/subjects comprising the retrospective group; and 2 from "old" control subjects. Twenty of 21 patients/subjects demonstrated pathological changes consistent with dermal fibrosis (viz., scleroderma). The characteristic pathology was not demonstrable in the microscopic evaluation of similar skin biopsies performed in the control subjects (both of whom had sustained spinal cord lesions at or below the level of the sixth thoracic segment). Clinically, pathologic skin changes noted in this population are seen only in patients with spinal cord lesions above the sixth thoracic segment. Indirect immunofluorescence of skin biopsy material with anticollagen antibodies against human interstitial collagen Types I and III showed a pattern of diminished

Type III collagen in the upper dermis with accompanying fibroproliferative changes in both the upper and lower dermis. Histochemical studies revealed fairly normal aminergic activity with decreased cholinesterase activity.

Termination of the project 1 year earlier than planned is based, in part, on the fact that biopsy results have been consistent, and it is doubtful the inclusion of additional subjects will provide any new information. ■

H Reflex Changes Following Spinal Cord Injury

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Sponsor: Veterans Administration Rehabilitation
Research and Development Service

This study was undertaken to determine if H/M ratio, as a measure of central synaptic excitability, varies significantly over time in patients with traumatic spinal cord injury, and if so, during what post-injury period.

Methods—We have serially tested the tibial H reflex bilaterally in six patients (mean age 26.2) with complete, traumatic SCI. Testing began in the first week post-injury in 5 of 6 patients; they were all tested serially through the first 6 months. Testing frequency was approximately 1 or 2 sessions per week during the first month, and 1 session per month thereafter for an average 8.7 testing sessions per patient. None of these patients had febrile illnesses, skin breakdown or other known sources of nociceptive input at the time of testing, that might influence H/M ratio. All six patients had complete cord injuries by clinical examination, in that none had regained any voluntary muscle contractions in the lower extremities during the course of the study. Three patients were started on spasmolytic medications during the course of the study; the other three patients were not. The five patients tested during the first 2 weeks after injury manifested clinically a transition from hypoactive ankle jerk reflexes to normally active or hyperactive reflexes by several months.

Six healthy, age-matched control subjects (mean

age 26.8) were tested twice with a mean interval of 65 days between the first and second sessions and were compared with SCI patients.

We measure maximum amplitude (peak-to-peak) of the H reflexes and of muscle (M) evoked potentials using a grid ruled in millimeters. Maximum H reflex amplitude was divided by amplitude of the maximum M response to yield an H/M ratio, to reduce possible variability caused by changes in recording electrode placement and muscle atrophy. One-way analysis of variance was performed comparing mean H/M ratios over time for SCI patients. Two sample t-tests were then used to compare changes in H/M ratio for SCI patients between three periods after injury (1 month, 2 to 3 months, and 4 to 6 months) and with H/M ratio changes for control subjects. Two sample t-tests of serial changes in H reflex and M response amplitude for SCI patients and age-matched controls were performed over time intervals where H/M ratios changed significantly. All statistical procedures are two-tailed tests.

Results—H/M ratios in control subjects had an overall mean of $0.51 \pm .19$ (s.d.). For control subjects, mean H/M ratio for session one was $.51 \pm .15$, and for session two, $0.52 \pm .23$. SCI patients had an overall mean H/M ratio of $0.43 \pm .25$. These values are not statistically different.

Mean H/M ratio for SCI patients at three time periods after cord injury were: (1) $0.39 \pm .18$ for the first month, (2) $0.37 \pm .22$ for the second and third months, and (3) $0.70 \pm .11$ for the fourth to sixth months. Comparing H/M ratio for SCI patients for the first and second time periods with controls, there was no significant difference; however, for the third period (4-6 months), mean H/M ratio was larger for SCI patients than controls, though this difference was borderline significant. SCI patients not treated with spasmolytic medication were significantly larger than control subjects for this third time period (4-6 months); those treated with spasmolytic medication were not significantly different than controls.

Analyzed separately, the three patients treated with spasmolytic medication still manifested significantly larger mean H/M ratios at 4 to 6 months than at 2 to 3 months. Mean H/M ratios also were larger during the late period for the three patients not on spasmolytic medication, but this difference did not achieve statistical significance. Neither group manifested significant differences between the first and second testing periods.

Discussion—The transition from spinal shock of

acute SCI to spasticity of chronic SCI is generally described as a gradual appearance of hyperreflexia. The hyperactive ankle jerk as one clinical manifestation of that spasticity has been said to recover from spinal shock within several weeks to several months in different patients. The SCI patients studied here also showed a transition from depressed tendon reflexes at 1 to 2 weeks post-injury to active tendon reflexes by 6 months.

Temporal Course of H/M Ratio Changes—To assess temporal changes in synaptic excitability of the ankle jerk reflex pathway, maximum H reflexes and M responses were recorded serially and their amplitude ratios calculated.

The five patients tested between 36 hours and 5 days in this study had readily elicitable H reflexes, with significant H/M ratios of .24 to .67. Others also have readily recorded H reflexes between 1 and 4 days after cord injury.

For several weeks tendon reflexes remain depressed or absent, though H reflexes are readily elicited, as we have noted in five cases in the present study. This has been attributed to a persisting fusimotor depression to the muscle spindle, which gradually resolves.

Three to 6 months after SCI, there is a significant increase in H/M ratio and H reflex amplitude, as demonstrated in the present study, suggesting an increase in IA-motoneuron synaptic excitability. This increase was associated with hyperactive ankle jerk reflexes in 4 of 6 patients and was not prevented by the spasmolytic medication, baclofen.

The present study is preliminary. Large fluctuations in H/M ratio were noted during the first month after SCI, though common temporal changes were not present in all patients. Other factors, such as level of injury, corticosteroids, bladder distention, and amount of passive exercise may contribute to the session-to-session variability in SCI patients. Controlling such factors, and performing more frequent serial testing in additional patients, may allow resolution of other common temporal changes.

Introduction of the spasmolytic medication, baclofen, was followed by a decrease in H/M ratio in 2 of 3 patients, though it did not prevent the later increase after 3 months. Baclofen may not be the only explanation for the decrease in H/M ratio at 1 to 2 months, since one non-treated patient showed a decrement over the same interval. Additional studies may be useful to explore the effect of spasmolytic medications on H reflex changes and the evolution of spasticity after spinal cord injury.

Peripheral versus Central Mechanism—The increase in H/M ratio after 3 months could result hypothetically from peripheral muscle atrophy, rather than a central increase in synaptic excitability. Preferential disuse atrophy of muscle fibers belonging to the largest motor-units (i.e., type II atrophy), not participating in the H reflex because of their high threshold, would result in a lower M amplitude but a larger H/M ratio. However, studies have shown that type II, not type I, muscle fibers predominate in chronic SCI patients. Furthermore, we have shown that there is a significant absolute increase in H reflex amplitude contributing to the increase in H/M ratio, but there is not a significant decrement in M response amplitude. Thus, muscle atrophy does not seem to explain this increment in H/M ratio.

These significant increases in H/M ratio and H reflex amplitude, but not M response amplitude, suggest that central synaptic changes underlie at least some of the hyperactivity that develops in phasic stretch reflexes after spinal cord injury. These results do not rule out the possibility that muscle spindle sensitivity increases as well and contributes to the appearance of hyperactive tendon jerk reflexes.

In summary, serial changes in H/M ratio are observed after complete spinal cord injury. A significant increment in H/M ratio is noted after 3 months, largely the result of an increase in H reflex amplitude. Further study of the temporal course of reflex changes after spinal cord injury may yield further understanding of the neurophysiologic mechanisms underlying the appearance of spasticity. ■

Longitudinal Assessment of Physical Therapy Factors that Affect Quality of Life of Persons with Spinal Cord Injury

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Objectives—The objectives of this study are:

1. To determine the importance of the patient's compliance in performing weight-shifts in a wheelchair to prevent breakdown of skin in weight-bearing areas of the body;

2. To improve the criteria and procedures for selecting spinal cord injured patients to be braced and trained to become functional ambulators; and

3. To determine the incidence, characteristics, and outcome of pain complaints in patients with severe spinal cord injury.

Reduction in the level of funding has necessitated reduction in the scope of the study. Considering the resources and expertise available, we elected to defer action on Objective 1 (above) and to concentrate on Objectives 2 and 3. As we complete work on the latter, staff effort will be redirected to pursue Objective 1.

The patients being studied are individuals who received severe injuries to the spinal cord resulting in paraplegia or quadriplegia. A total of 70 patients between ages of 20 and 58 years with paraplegia have been studied in pursuing Objective 2. A list of patient attributes, and the equipment and services associated with gait training, was compiled for each patient. Follow-up evaluations 6 months to several years after bracing are being made to assess brace utilization.

It is expected that the results will improve the criteria for identification of those who will remain brace users.

A total of 113 patients between the ages of 11 and 80 years (58 with quadriplegia and 55 with paraplegia) are already 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. The results are expected to illustrate trends in the etiology and resolution of pain complaints.

Status to Date—During the past year we have analyzed the results of brace utilization by 70 patients who received bilateral knee-ankle-foot (KAF) orthotic devices and have drafted a report on the findings. Pilot studies have begun with an orthotist, T. Engen, to devise a simplified, lightweight, modular orthotic device for early bracing and gait training. Data concerning the pain complaints made by 113 patients with spinal cord injury during their initial hospitalization for comprehensive rehabilitation have been gathered and categorized. The data have been examined for correlations between population variables, etiology of injury, level and neurological completeness of injury, and location and suspected etiology of pain complaint. Therapeutic procedures that patients have identified as most effective in alleviating individual pain states have been identified. The status of each pain complaint at time of the patient's discharge has been documented.

The plan is to continue analyzing these data to identify relationships that could shed additional light on the mechanism responsible for the state of discomfort, and on mechanisms responsible for allevia-

tion of the discomfort. An indication that a significant number of pain complaints in paralyzed patients may be of the mechanical, low-back variety will be pursued. Collaboration with the orthotist to develop improved methods of early bracing will continue. ■

Residual Bladder Volume Determination for Spinal Cord Injury Patients

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Sponsor: Veterans Administration Rehabilitation
Research and Development Service

The goal of this research is to develop a low-cost, portable, clinically useful method of measuring bladder volume noninvasively. Our approach has been to utilize ultrasonic A-scans plus microprocessor-based numerical algorithms to calculate the bladder volumes. To date, we have completed our laboratory studies on simulated bladders and bladder walls, and have developed a complete laboratory system for measuring bladder volume on human subjects. Volunteer subjects are required to lie on a couch, the bladder area is mechanically scanned with a transducer placed on the skin surface, and the computer automatically calculates the bladder volumes between 45 cc and 225 cc as determined by measuring the voided volume. The average error of the calculated volume was approximately 12 percent using our initial algorithms for detecting the bladder walls and for integrating the distance measurements.

These human laboratory trials are continuing in order to obtain a larger data base for testing possible algorithms. Other significant efforts include the continued development of improved algorithms for more accurate volume calculations, the design of a prototype clinical system for initial testing on patients at the Tucson Veterans Administration Hospital, and the design and testing of the final system. ■

Development of Analytical and Laboratory Models of the Bladder and Urinary Tract

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Research and Development Service

The main objectives of this research are:

1. Design and construct a device to be implanted in a dog that will apply pressure to the bladder and force the dog to urinate. It must be possible to activate the device externally without having any part of the device pass through the skin.

2. Develop analytical and laboratory models of the bladder, urethra, and urinary tract.

Implantable Device—A preliminary design has been completed for a device that can squeeze a dog's bladder hard enough to overcome the resting urethral pressure. The device will allow doctors to measure the bladder pressure required to force open the muscular valves in the urethra. The central component consists of a bladder cover and inflatable inserts that can be wrapped around the bladder. A pump placed in the scrotum can be activated externally and moves fluid from a reservoir placed in the belly to the inserts in the cover. The inflated inserts apply pressure to the bladder. In order to relax the bladder after voiding, one can press a release valve in the pump, allowing the fluid to return to the reservoir.

A number of improvements to the current design are being considered. New materials and attachment methods are being investigated, which will allow the device to be installed more quickly and securely. New arrangements for the inflatable inserts, which will apply more uniform pressure, also are being investigated.

Analytical and Physical Models—The objective of this part of the research has been to study the fluid mechanics that occur in the lower urinary tract of a dog—namely, the bladder, the internal sphincter, external sphincter, and the urethra. This objective is being accomplished in two ways. First, a mathematical model is being constructed using the finite element method to model both the flow of urine and the reaction of the tissues to that flow. Second, a physical model is being designed and will be constructed to provide data for comparison to results from the mathematical model.

A preliminary search of the literature has shown that physical modeling has been attempted by var-

ious investigators, and these physical models have been compared and analyzed. Of these models, one presented by Martin and Griffiths in 1976 represents closely the actual mechanics of micturition; however, the circular cell presented by Scott, et al., in 1971, modeled the sphincter quite sufficiently.

A mathematical model of the bladder was presented in 1976 by Beard at the University of Exeter. His results were based upon a theoretical model and were used as a basis for a more accurate mathematical model. Beard considered the longitudinal tension in the urethral wall, and developed various parameters such as "elastic length" and the "spread" of the urethral pressure profile.

It can be concluded from this report that various physical models of the bladder have been developed while very few mathematical models have been completed. Because of this, extra time and effort have been put into the development of the mathematical model, and up to this point in time, that development is being concluded. The bladder neck and the muscles involved in micturition will be modeled using the finite element method. The finite element method is useful in structures and fluid flow because various parameters can be inserted into the elements so as to model that particular element in a more accurate manner, rather than in a sweeping generalization. Furthermore, various points along the bladder wall and within the fluid flow may be checked. This is more convenient than at the boundary conditions. It is the estimate of the investigator that formal studies should be completed by September 1984, and a publication of the results by January 1985. ■

Neural Mechanisms Underlying Bladder Dysfunction After Spinal Trauma

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An enhanced understanding of the neurophysiology and neuropharmacology of bladder function and of dysfunction following spinal trauma requires the development of an animal model where the animal is unanesthetized, and where many of the neural and muscular events underlying bladder function can be simultaneously measured.

We have produced such a model, in which bladder performance can be continually evaluated through a knowledge of cystometric relationship between blad-

der volume and pressure. We implant into the bladder a miniature (4 mm diam) transducer to measure pressure. At selected sites on the bladder surface, pairs of small ultrasonic crystals are placed whose distances apart can be measured and used to determine bladder volume. We also can install leads to measure detrusor and pelvic floor muscle electrical activity. The electromyographic leads for these devices are tunneled under the skin to exit from the back of the animal's neck. So far, we have monitored bladder function before and up to 1 month after instrumentation. This model gives us a tool to monitor bladder function and dysfunction before and after spinal trauma.

The underlying cause for bladder dysfunction after spinal trauma is unknown. Recent evidence suggests that endogenous peptides like enkephalin may play a key role. We hypothesize that a morphine antagonist like naloxone might prove extremely beneficial in helping restore bladder function if applied to the spinal cord just after trauma.

In normal (i.e., uninstrumented and awake) dogs, the bladder volume at which urination began was raised significantly after spinal morphine. This change was reversed by spinal administration of naloxone. Such changes in micturition threshold following spinal morphine injection resembled very closely the changed thresholds that we later saw following spinal transection in these dogs. Further, there was a reduction of micturition thresholds in two of the three acutely transected dogs given spinal naloxone.

While further experimentation is necessary, these preliminary results do highlight a possible role of the endogenous opiates in producing bladder dysfunction after spinal trauma. We are now extending these pharmacological studies to our chronically instrumented animals. ■

The Bio-Feedback Incontinence-Training Program

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Prostatic enlargement and urologic diseases occur often in the elderly and in the veteran population as the average age of Americans rises. Some veterans suffer from urinary incontinence which can have devastating psychologic and social consequences.

Success in the treatment of urinary and fecal incontinence has been demonstrated by researchers using urodynamic techniques to provide clinical biofeedback training.

Hypothesis—Subjects who receive biofeedback training by means of urodynamic monitoring will demonstrate a significant reduction in urinary incontinence and/or urinary retention.

Purpose—The biofeedback incontinence training program is directed at investigating the usefulness of this new and relatively noninvasive treatment of urinary incontinence for the veteran patient.

Methods of Procedure—The treatment/intervention involves the subject being catheterized and monitored by cystometry. Changing bladder pressures and sphincter electromyographic data are recorded on an automatic printout. The subject is positioned to view the readings as they are produced to provide feedback regarding bladder activity. The bladder can be repeatedly inflated with carbon dioxide gas to simulate filling of the bladder. The subject will be provided graphic models of normal micturition patterns to emulate during the biofeedback sessions. The session will last approximately 1 hour and be scheduled every other week. The subjects will undergo a minimum of four sessions, with eight anticipated as a maximum.

Population and Sample—Twenty to 30 veterans, outpatients, or inpatients with a history of urinary incontinence or urinary retention will be the subjects. Excluding criteria will include urinary obstruction and inability to communicate or attend training sessions. Initial screening of subjects will include urologic evaluations and screening for drug use that inhibit or alter normal micturition (phenothiazines, tricyclics, etc.). All subjects will be included in follow-up by phone or by mail. Contact will be made at 30, 60, and 90 days post-termination of treatment.

Special Consultant—Kathryn L. Burgio, Ph.D., Staff Fellow, NIH, NIA, Gerontological Research Center, Baltimore, Maryland.

Effects of Spinal Cord Injury on Drug Metabolism

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The pharmacokinetics of medications administered to spinal cord injured patients have been widely investigated. There are numerous reports regarding alterations of normal physiological, neurological, and biochemical functions in the spinal cord injured 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 spinal cord injured patients.

The first study will focus on the absorption time profile of two drugs, riboflavin and acetaminophen. For purposes of this study, their critical difference is that riboflavin is absorbed by an active transport process, while acetaminophen is passively absorbed from the gastrointestinal tract. A subsequent study will focus on the disposition of two aminoglycosides in hospitalized spinal cord injured patients for whom antibiotics are indicated because of clinical infections. An indication that the pharmacokinetics of these antibiotic agents differ in these people and able-bodied individuals may be important for providing adequate treatment of infections and for minimizing possible adverse reactions to these drugs by spinal cord injured patients.

Status to Date—This study concerned the absorption time profiles of riboflavin and acetaminophen completed. Absorption of riboflavin was assessed by measuring its urinary excretion in 10 spinal cord injured patients and in six normal subjects. The patients had injuries from the first to the seventh cervical level, and they were between 2 and 15 months duration from the time of their injury. A significant difference between fasted and non-fasted conditions was observed for both spinal cord injured and control subjects in time to reach peak excretion and in percentage of dose recovered. However, the results were identical in the two subject populations.

Absorption of a 650 mg fasting dose of acetaminophen was studied in five spinal cord injured patients by measuring serum concentration using a high pressure liquid chromatographic assay. There was no

significant differences for half-life and area under the curve, but a significant decrease was observed in peak serum concentration. There also was a significant increase in the time to peak as compared to values in the literature.

The results indicate that spinal cord injury does not impair absorption of riboflavin from the gastrointestinal tract. However, as compared with normals, there is a difference in the rate of absorption of acetaminophen, but not in the total amount absorbed.

Studies comparing the disposition of aminoglycosides in spinal cord injured and able-bodied subjects will be conducted next. ■

Collagen Dysfunction in Quadriplegia

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This two-part project seeks to elucidate the ways in which collagen metabolism is altered in spinal cord injury by determining what the consequences are of such alteration and what causes that alteration. Part 1 is an effort being made to show that administering the drug diphosphonate within 7 days of injury will ameliorate and perhaps prevent heterotopic ossification, urolithiasis, and osteoporosis. Part 2 will develop a method 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 spinal cord injury.

Adrenergic receptors also are being measured by radioligand binding assays. The objective is to show an abnormality in them which in turn may affect enzyme activity within the cell. By doing radioligand assays for the enzyme lysyl hydroxylase and chemical assays of the skin to determine the degree of hydroxylation, an attempt is being made to demonstrate that spinal cord injury causes an alteration in the activity of one of the most important enzymes of the collagen metabolism. If the specific defects in the collagen metabolism of spinal cord injury can be identified, they may be amenable to pharmacological intervention.

Status to Date—On part 1, followup studies on two of the patients admitted to the study in 1982 have been completed. On part 2, glucosylgalactosyl hydroxylysine (glugal Hyl) and galactosylhydroxylysine (gal Hyl) concentrations were determined in 37 weekly urine pools on spinal cord injury patients at various times since injury. In the group between 6 and 60 months after injury, statistically significant differences are seen between glugal Hyl and gal Hyl excretion and skin and bone related problems, respectively.

Insensitive skin morphological studies and hydroxyproline determinations were done in cooperation with the Cullen Eye Institute of Baylor College of Medicine. A manuscript is being prepared for publication. Alpha and beta adrenergic receptors have been measured in 12 additional skin biopsies. The former show a trend towards increasing numbers with increasing time since injury. Work has begun on the skin lysyl hydroxylase activity project. ■

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

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This project is intended to extend the application of spinal cord stimulation (SCS) for treatment of abnormal motor control to spinal cord injury patients with a degree of preserved volitional control through the use of a broader selection of stimulation sites. We have found indications that better results may be obtained in some cases by considering other stimulation sites, and therefore propose to compare alternate sites of stimulation (specifically lower thoracic and lumbar) with currently used upper thoracic and cervical posterior sites in terms of the effectiveness of SCS for treatment of abnormal motor control in paralyzed patients. Finally, in order to understand the mechanisms of action of SCS in these patients, we shall attempt to find neurophysiological correlates to the degree of improvement of motor control in spinal cord injury patients. A variety of neurophysiological tests, including multi-channel EMG recordings, evoked potential recordings, and observation of twitches elicited by spinal cord stimulation will be used in this task. Approximately 10 patients per year will be studied.

Status to Date— From a total of 220 referrals of spinal cord injury patients during the year for evaluation or treatment of pain, spasticity, degree of lesion, problems of bladder function, etc., 13 were selected as appropriate candidates for application of SCS, five primarily for pain, and eight primarily for motor disorders. Several of the patients had multiple trials of SCS, both above and below their lesions, allowing a direct comparison of the relative effectiveness.

These procedures have worked well in general, but attempts to place electrodes in the lower thoracic and lumbar regions have suffered from the tendency for the electrodes to move to the anterior side of the cord in this region.

Work on the definition of electrophysiological correlates of the effects of SCS continues, but no definite conclusions have been reached. It has been noted that there may be an antidromic effect of stimulation via sensory fibers in the dorsal columns, which could account for the potential effects of stimulation below the lesion. Muscle twitch studies and evoked potential studies are underway to attempt to elucidate this point. In addition, recording from the epidural space is being vigorously pursued.

Evoked Potentials Study

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Sponsor: American Paralysis Association

The functional integrity of motor pathways following spinal cord injury is generally assessed by means of clinical examination. However, these methods cannot be used to predict the degree of dysfunction, such as occurs during the acute phases of injury. Such knowledge would be extremely valuable, for it would assist in the application of future treatments which might benefit any motor fibers identified as still intact.

Inferences of spinal cord continuity have been previously attempted by recording somatosensory evoked potentials (SEP's). However, this method provides specific information only on intact fibers in the ascending sensory tracts, while frequently the extent of motor and sensory tract damage differs significantly. Previous studies in Dr. Levy's laboratory have demonstrated that discrete, evoked potentials from spinal cord motor neurons may be elicited by direct stimulation of the spinal cord or by transcranial stimulation of the motor cortex.

The current study will evaluate motor neuron evoked potentials studied at various levels of spinal cord injury using a cat model.

Effects of Low-Power Irradiation on Clonus and Spasticity in Spinal Cord Injured Persons

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Sponsor: American Paralysis Association

The deleterious effects of spasticity resulting from spinal cord injury are well documented. Treatments currently utilized to alleviate this condition have met with limited success. Recent studies suggest that low power irradiation of peripheral nerves may markedly reduce both clonus and spasticity in spinal cord injured individuals.

Dr. Walker will examine the effects of laser versus sham irradiation in 20 human SCI patients. Functional recovery following treatment will be estimated by measuring clonus counts, tissue compliance (a measure of spasticity), changes in range of motion, and somatosensory evoked potentials. All subjects will receive a neurological score based on a standard testing protocol.

The results of these tests will be evaluated to determine if treatment is associated with an improvement in neurological performance.

The Effect of Electrical Stimulation of Muscles on the Cardiovascular System

Jerrold Petrofsky, Ph.D.
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Dayton, Ohio 45435

Sponsor: American Paralysis Association

Dr. Petrofsky has previously demonstrated the ability to stimulate paralyzed muscles with external electrodes so as to rebuild muscle bulk and enable coordinated movements of paralyzed lower limbs. It was observed that such muscle stimulation can cause substantial changes in the cardiovascular system. It can also induce other physiological changes in the subject's thermoregulatory system, where sweating does not occur below the level of injury.

This contract enables the conduct of a series of experiments dealing with cardiac stress during electrically induced bicycling in a thermoregulated environment. Physiologic data will be taken to study

heat adaptation and how well the paralyzed individual can adapt to heat.

In addition, the contract calls for Dr. Petrofsky to document protocols and procedures for establishment and operation of a F.E.S. center, with particular emphasis on all aspects involving patient safety.■

C. Spinal Cord Regeneration

Monitoring of Post-Injury Changes

Jacob Abraham, M.D.

Christian Medical College and Hospital
Department of Neurological Sciences
Tamil-Nadu, Vellore, India

Sponsor: American Paralysis Association

Ischemia and edema are critical factors influencing the amount of nervous tissue damage that may develop following physical injury. Physiological responses at the cellular level also are initiated by trauma and elicit a series of metabolic responses which appear to further aggravate neuronal integrity. Using a primate model, Dr. Abraham's laboratory will document these vascular and cellular changes at various stages post-injury.

Later studies are anticipated in which several therapeutic regimens, including omental transposition and correction of metabolic abnormalities, will be applied in hopes that such intervention will neutralize the harmful effects normally accompanying spinal cord injury.■

Tissue Implant Studies

Carl Cotman, Ph.D.

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Sponsor: American Paralysis Association

Recent studies indicate that tissue implants may restore functions lost after brain injury in rats. Such implants appear to promote the growth of injured axons and may possibly replace the components of damaged axonal circuits.

The current study has been established to determine the effectiveness of tissue implantation techniques for the restoration of function in the injured spinal cord. The growth properties of embryonic tissue implants inserted at various intervals following injury will be examined to test the hypothesis that implants develop better if insertion is delayed follow-

ing injury (delay paradigm). Additionally, growth promoting and inhibitory factors, previously isolated from central nervous system wound fluids, will be collected, assayed, and evaluated for their usefulness in enhancing the growth of the spinal cord implants and/or other damaged spinal cord tissue.■

Collagen Matrix Implant Studies

Jack de la Torre, Ph.D., M.D.

Ottawa General Hospital
Ottawa, Ontario, Canada

Sponsor: American Paralysis Association

Previous studies have attempted to use tissue bridge implants to serve as a matrix for the regeneration of neuronal tissue but have met with limited success. Vascularization of such bridges is generally slow and the bridge itself may form a barrier to regenerating axons.

Dr. de la Torre is studying the regeneration of spinal cord axons using a cell-free collagen matrix of fibers which has previously been shown to support rapid vascularization in host tissues. It is hoped that the loose, cell-free components of the matrix will provide less of a barrier to growth than is usually encountered. The study will also examine the efficacy of in situ drug therapy applied at the site of the tissue bridge implant.■

Omentum Transposition Study

Harry Goldsmith, M.D.

Boston University Medical School and University Hospital
Boston, Massachusetts 02215

Sponsor: American Paralysis Association

Dr. Goldsmith pioneered the technique of surgical transposition of the omentum to reduce edema (accumulated tissue fluid) and restore circulation following brain trauma. This surgery is now being performed at a number of medical centers worldwide. The application of this treatment to spinal cord injured patients was believed to be of primary value only during the acute phases of injury. Recent data suggest, however, that chronically injured patients also may derive benefits from this procedure. Studies in cats have revealed that neuroelectric activity is partially restored across the traumatized area of the spinal cord following omental transposition, although functional recovery has not been observed.

The current project will study the cat model to

analyze and compare the potential effectiveness of omental transposition used in conjunction with a variety of proposed therapeutic regimens (Naloxone, Diapulse, DMSO) to promote regeneration and functional recovery in cases of chronic injury.■

Cortico Spinal Neuron Studies

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Sponsor: American Paralysis Association

The cell bodies of corticospinal tract motor neurons may be dependent on target cell (muscle fiber) input for continued maintenance following spinal cord injury.

This project will test the hypothesis that corticospinal neuron degeneration may be minimized by directly applied administration of a central nervous system derived neurotrophic factor. Dr. Manthorpe's laboratory will attempt to purify one such factor from the bovine cerebral cortex.

Later studies will be aimed at developing a methodology for therapeutic presentation of putative trophic factors to corticospinal cell bodies and/or axon processes using a catheterization infusion system.

The final stage of the study will evaluate the effects of such therapy on the functional recovery of corticospinal neurons following complete spinal cord transection.■

Effects of Application of Direct Current on Regeneration of Nerve Cells

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Texas Technical University
Health Science Center
School of Medicine
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Sponsor: American Paralysis Association

Constant low intensity direct currents (LIDC) have been shown to enhance cellular growth, both within the body and in tissue culture. Prior application of this technique has been limited to the treatment of bone fractures and decubitus ulcers.

The current study will apply this procedure to explore its potential effect on nerve cell regeneration. Initially, the effects of constant LIDC will be studied in sectioned rat sciatic nerve and regeneration will be

estimated using electron microscopy and histological techniques.

Later studies will attempt to document the changes induced by LIDC on different neuronal cell types. The technical data obtained from these studies will eventually be used to examine and describe the electrical, neurophysiological, and biochemical changes that occur in spinal cord injured animals from the moment of injury throughout later stages of recovery.■

Use of PF in Stimulation of Spinal Cord Neuron Development

James Turner, Ph.D.
Bowman Gray School of Medicine
Wake Forest University
Winston-Salem, North Carolina 27109

Sponsor: American Paralysis Association

Dr. Turner's study will attempt to characterize the activity of a new central-nervous-system-derived neurotrophic factor (PF) that has been previously shown to stimulate axonal outgrowth in fetal rat retinal explants.

The initial phases of the study will focus on determining the optimum conditions for stimulating spinal cord neuron development with PF in a tissue culture environment. The second phase of the study will examine the stimulatory effects of PF in spinal cord transected rats who have received tissue implants, with animals evaluated for evidence of functional recovery.■

D. Independent Living for the Severely Disabled

Conducting a State Policy Study to Help Develop New Options for Independent Living

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Sponsor: National Institute of Handicapped Research

Objectives—This project's goal is to establish an agenda for state executive and legislative initiatives based on concerns of persons with disabilities. In collaboration with the Kansas Advisory Committee for the Employment of the Handicapped (KACEH),

researchers conducted the first statewide survey of concerns of persons with disabilities in Kansas.

Progress—Over 1,400 Kansas citizens with disabilities responded, and dozens of interested parties participated in planning conferences to create the survey, discuss its findings, and plan subsequent actions. Collaborators included state legislators, consumer groups, service providers in ILCs, and rehabilitation centers. The KACEH will address a crucial area of concern: accessibility of public buildings through cooperations from the state attorney general's office and the governor. ■

Human Concerns of Disabled Persons: Developing New Methods for Addressing Common Community Concerns, and Developing a Human Concerns National Data Base

S.B. Fawcett, Ph.D.

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Sponsor: National Institute of Handicapped Research

Objectives—This project is intended to teach disabled consumers constructive ways to improve their community. A unique self-help method, the Concerns Report Method, has been developed to allow disabled consumers to assess, prioritize, and convey their concerns and ideas for improvement to decision makers. Specific project objectives include providing technical assistance to users of the Concerns Report Method, developing a common data base of concerns, and creating and evaluating new methods for solving identified problems.

Progress—Over 500 disabled citizens have participated in nine different applications of the Concerns Report Method. Reports of major strengths, problems, and ideas for improvement were prepared at the request of ILCs, consumer organizations, and mayors' councils on disabilities in 11 counties in Kansas and Missouri. New projects are underway in Washington, D.C.; Helena, Montana; and, Los Angeles, California.

In the past year, this project also has conducted the only reported research on a specific problem common to many local communities—violations of handicapped parking spaces by nondisabled persons. Experimental research demonstrated the effects of upright posted signs and police crackdowns on violations. ■

Effects of the Family on Independence

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Sponsor: National Institute of Handicapped Research

Objectives—This research will seek to determine the most crucial elements of intervention to help families plan a successful transition for their adult children who are disabled. The study's aim is to explore the relationship between how much and what kind of future planning families use, and how much stress and satisfaction they experience.

Progress—Over 50 percent of the 60-family sample has been interviewed, and trends suggest high degrees of stress, little available information or family support, and a crucial need for residential options for young, disabled adults. This project has grown out of previous RTC/IL research that has resulted in four book chapters, two chapters in NIHR-sponsored symposia, one training manual, and over 20 workshops and presentations reaching over 1,300 consumers, service providers, and family members. ■

Utilizing the Concerns of Disabled Consumers to Assess the Impact of Independent Living Programs

R.M. Mathews, Ph.D.

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Sponsor: National Institute of Handicapped Research

Objectives—This project is designed to determine the impacts of ILCs on the needs and concerns of disabled citizens. The assessment will be based on repeated statewide use of the Concerns Report Method, as reported in RTC/IL Project R-16 ("Conducting a State Policy Study to Help Develop New Options for Independent Living"). This project also will seek to promote consumer involvement, increase consumer awareness, and provide a new method to determine if overall need is being met.

Progress—The first statewide survey using the Concerns Report Method was completed this year (R-16) and the results of that project will serve as the baseline. This project will conduct two additional surveys and analyze differences between communities with ILCs and those without ILCs. ■

Systematic Approaches to Consumer Involvement: Training Citizens with Disabilities in Community Leadership

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Sponsor: National Institute of Handicapped Research

Objectives—Although consumer involvement is a hallmark of independent living, ILCs have found it difficult to organize effective and continuing consumer leadership. This project is designed to develop techniques to promote consumer involvement and leadership.

Progress—A unique conceptual framework for consumer involvement has evolved from an extensive review of literature, detailed observations from field studies, and surveys of experts in consumer involvement. As a result, over 200 competencies and strategies involved in consumer leadership have been identified. Three self-help guides for consumers have been developed and disseminated nationally, and procedures are in process for implementing a comprehensive consumer leadership training program.

Training has been provided to over 60 consumers and to 35 students in a university course. ■

Support for Families: Family Problem Solving

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Sponsor: National Institute of Handicapped Research

Objectives—This research is intended to help families identify a systematic method to solve shared problems related to disability in the family, and to resolve conflicts that impede independence of the disabled member. The study's aim is to develop a problem-solving guide that families can use either independently or with the guidance of an ILC counselor.

Progress—Project staff have collected resources and conducted interviews with a sample of families to identify examples of key issues to be addressed. Materials development is now in progress, and field testing will occur in late summer. ■

Management Procedures in Attendant Care: A Training Model for Disabled Consumers

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Sponsor: National Institute of Handicapped Research

Objectives—Attendant care is a vital service for many disabled people who live independently, but many lack the skills necessary to train and manage their own care attendant. This project involves developing empirically-based techniques for disabled people to use in training and managing attendants.

Progress—An attendant-care training and management model has been formulated to address two important problems: lack of job specification for attendants, and the consumer's inability to provide objective feedback on attendant's work performance. This model uses performance checklists, which are developed by the consumers, to allow consumers to monitor, evaluate, and provide feedback to caregivers. As a result, the consumer's control is maximized.

A draft of an attendant-care procedures manual has been developed. It includes a directory of generic checklists and instructions for tailoring them to individual needs. The manual is now being used and evaluated by several consumers, and aspects of the model have been disseminated via a research article and a regional training seminar for 45 trainees. ■

Human Dignity Project

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Sponsor: National Institute of Handicapped Research

Objectives—Despite progress achieved by the independent living movement, disabled persons continue to report unacceptable treatment by some staff of community service organizations. Poor treatment may range from unjustified assumptions about a certain disability's limitations to offensive comments. This project is designed to develop and evaluate a method that consumer organizations can use to help local service providers improve the way they treat disabled consumers.

Progress—Although this is a proposed project, preliminary interviews have been conducted with con-

sumer organizations in three cities, ILC staff, and a number of community service providers. These interviews have identified dimensions of acceptable service in specific service situations. Tentative intervention techniques have been developed to help consumers encourage more acceptable service delivery. ■

An Analysis and Review of Peer Counseling Provided by ILCs

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Sponsor: National Institute of Handicapped Research

Objectives—According to a national survey conducted by the project, although 58 percent of 120 programs surveyed offer peer counseling, there is no uniform goal or common service technique across ILCs. This project's goal was to prepare a directory to serve as the basis of a network for peer-counseling programs so they can contact each other, avail themselves of existing materials, and consider ways to resolve common problems.

Progress—The survey of ILC peer-counseling programs was completed, and results have been summarized in two research articles submitted for publication. The directory was completed: it covers peer-counseling programs offered by 112 ILCs. More than 350 copies have been disseminated. ■

Development of an Impact Evaluation Package for Independent Living Centers

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Sponsor: National Institute of Handicapped Research

Objectives—The overall objective is to develop and test an evaluation package that ILCs can use to evaluate their impact on consumers and the community. Because the ILC model is based on a new and novel philosophy, traditional evaluation approaches have not worked.

Progress—A package has been developed and its validity tested. Current work includes testing for reliability, determining error rates for retro-fitting

data, and developing effective data presentation methods.

The demand for the package has been very large. As the package is being refined, over 400 manuals were disseminated and 300 professionals and administrators trained to use them. Training has been conducted in three federal regions, and two more regions are scheduled. ILCs in seven states are using part or all of the package. Two articles about the system are being prepared. ■

Encouraging Private-Sector Initiatives to Improve Community Accessibility

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Sponsor: National Institute of Handicapped Research

Objectives—Architectural barriers still pose major obstacles to independence for people with disabilities. Since few financial incentives exist for private owners of public facilities to remove barriers, strategies must be developed to encourage their voluntary removal. This project is investigating many strategies for reducing barriers, including information prompts, feedback on facility accessibility, and low-cost incentives, such as publicity.

Progress—The first of several intervention studies was begun last fall. Over 350 businesses in Kansas City participated. Results are being used to refine and package the most cost-effective interventions into a set of guidelines for use in other communities. These will describe how to develop accessibility checklists, survey settings, summarize survey information, and complete an accessibility guide. Two research articles are being prepared, and a workshop was presented to 30 participants. ■

Nongovernmental Funding Alternatives

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Sponsor: National Institute of Handicapped Research

Objectives—Because ILCs cannot rely on continuing federal support, they must have new ways to identify nongovernmental funding sources. This project's goal is to develop ways to help ILCs establish revenue-

based planning procedures, including private foundations, for fund-raising.

Progress—Using results of a 1983 needs assessment survey and working with a local ILC, RTC/IL developed a procedures manual for planning and conducting fund-raising activities. The manual has been widely disseminated, used in workshops by over 30 ILC and rehabilitation program administrators, and used to assist one ILC in creating a private fund-raising foundation. ■

Promoting Community Support for Independent Living

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Sponsor: National Institute of Handicapped Research

Objectives—This project will seek to increase the general public's understanding of independent living, promote community support for independent living programs, and increase involvement with and acceptance of disabled persons. Model informational packages and self-help guides will be prepared. The impacts of these materials on community awareness and public support for independent living will be evaluated.

Progress—A national survey of ILCs was conducted to obtain information about outreach and community awareness. Survey results indicate the clear need for assistance in promoting community support for independent living and suggest several potentially effective communication techniques, important messages to be communicated, and appropriate audiences to be addressed. ■

[See also **IV. Spinal Cord Injury, A. General Rehabilitation**, Documenting and Utilizing Programs to Provide Community Adjustment and Independent Living Services for Persons with Spinal Cord Injury]

E. Communication Methods and Systems for the Severely Disabled

Development of a Unified Quantitative Model for Augmentative Communication Systems

Gregg Vanderheiden

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Sponsor: National Institute for Handicapped Research

A conceptual model has been designed to assist in the comparative analysis of all current selection-based augmentative communication techniques. Predictive validity testing using the model is also planned. The model has been fully specified, and a computer program is being written for testing it with actual subjects using augmentative communication techniques. Subsequent extensions of the model will incorporate refinements dealing with the implications of perceptual and motor interaction, and cognitive and language factors. Testing of the model is scheduled for completion by December 1984. ■

Study of Dominant Single Speech Motor Subsystem Dysfunctions

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Sponsor: National Institute of Handicapped Research

The purpose of this project is to quantify motoric abilities for the assessment and treatment of severe motor speech disorders in individuals who are considered candidates for augmentative communication systems. Instrumental measures have been used, including analysis of the lip, jaw, and tongue motor impairments. A jaw fixation prosthesis was utilized, and acoustical, perceptual, and physiological analysis of subjects' speech with and without the prosthesis was conducted. A group of congenital spastic subjects have been compared along the dimensions of fine force and position control in the lips, tongue, jaw, and upper limbs.

The study is scheduled for completion in September 1984. Three publications incorporating the results of the study thus far are currently in press: (i) Barlow

and Abbs: Orofacial fine motor control impairments in congenital spastics: Evidence against spindle-related performance deficits. *Neurology*, in press; (ii) Barlow and Abbs: Force transducers for the evaluation of labial, lingual, and mandibular function in dysarthria. *Journal of Speech and Hearing Research*, in press; (iii) DePaul, Abbs, and Barlow: Physiologic and acoustic analyses of the effect of a bite-block prosthesis in a spastic dysarthric. In C. Linebaugh (ed.), *Clinical Dysarthria*. San Diego: College-Hill Press, in press. ■

Cooperative and Commercial Facilitation Projects

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The Trace Center conducts cooperative research and development activities with manufacturers and individuals designing software and adaptive devices for handicapped persons. Among those involved in such cooperative tasks during the last year have been: Prentke Romich Company, Shreve, Ohio; Senti-ent Systems Technology, Pittsburgh, Pennsylvania; Adaptive Communication Systems, Pittsburgh, Pennsylvania; Adaptive Peripherals Company, Seattle, Washington; and Smith-Kettlewell Institute, San Francisco, California.

The activities involved development of a hybrid optical headpointer, conceptual work on a communication acceleration algorithm (Minspeak and Speedkey), an adaptive firmware card for the Apple IIe, an eye-tracking system for use by the severely physically handicapped, and development of an oculoencephalographic system for those with minimal motor control. ■

Developing International Aids Compatibility Standards

Barry Rodgers

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Sponsor: National Institute of Handicapped Research

Over the last several years, the Trace Center has worked with individuals and groups both in the United States and internationally to develop a stan-

dard for interconnection between user-operated switches and electrical communication aids. Two years ago, a Common Interconnection Format for Type 1 interconnections was proposed. Four separate standards now have been developed that cover almost all of the compatibility issues included in the original single standard proposal. The four standards (SET, ISA, SBC, and KEI) have been developed with the assistance of consultants from six countries throughout the field of augmentative communication and computer access. Current work was reported at the RESNA Conference, Ottawa, Canada, June 1984. ■

Portable Simple Electronic Transducer and Morse Code Decoder to Serial RS232 Converter

David Kelso

Trace Research and Development Center
Waisman Center on Mental Retardation and Human Development
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Sponsor: National Institute of Handicapped Research

This project addresses one of the main problems restricting the wider use of portable computers—their limited input capability for switches and joysticks, which are commonly used as input transducers for handicapped individuals. This problem is being addressed through development of a standard input method and standard Morse code keying pattern to decode switch closures and joystick position and convert them into serial information readable by the computer through the serial RS232 port. This is being done in conjunction with development of a portable writing, communication, and computer-access aid under other funding. The project is scheduled for completion by summer 1985. ■

Information Resources

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Sponsor: National Institute of Handicapped Research

The Trace Center has published an updated version of the International Hardware/Software Registry, containing 70 new entries in addition to 100 original entries that have now been updated. A Telecommunications Resource Book, listing alarm, call, and monitoring systems, as well as telecommunication devices

for the deaf, also is expected to be published in 1984. Cooperation with Tools for Living in the Community and with the Rehabilitation Engineering Society of North America has resulted in publication of a new sourcebook guide on technology for independent living. This sourcebook is now available through the Rehabilitation Engineering Society of North America. ■

Access to Computer-Based Services for Persons Unable to Use Current Systems Due to Physical Impairments

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Sponsor: National Institute of Handicapped Research

An investigation was undertaken to determine the types of access problems involved in computer-based services such as those being found in libraries. A technical report has been produced (University of Wisconsin, Department of Computer Sciences—Computer Sciences Technical Report #516, October 1983). This report examines the situation at the University of Wisconsin-Madison campus, and analyzes the general computer access problem in libraries as it impacts upon severely handicapped patrons. ■

Keyboard Emulators

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Sponsor: National Institute of Handicapped Research

Devices taking input from any special communication aid or interface, and translating those signals to the electrical configuration required by a particular computer keyboard, have been designed for the Apple II and IIe, and the IBM PC. They are now commercially available, and work is progressing on development of a multi-computer keyboard emulator that can be reconfigured (by the manufacturer) to work with the IBM PC, the PCjr, the Macintosh, and the Lisa. ■

CRT-Based Headpointing Input Device

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Sponsor: National Institute of Handicapped Research

Transfer of a long-range optical pointer that is CRT-based (stationary workstation) from the research and development prototype stage to commercial dissemination is in progress. ■

Comparing Complex Position Averaging Techniques

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Sponsor: National Institute of Handicapped Research

A computer program has been developed for capturing position and movement patterns of individuals using the long-range optical headpointer. The program was tested with 20 subjects, one-third of whom had cerebral palsy, one-third degenerative neuromuscular diseases, and one-third spinal cord injury. Hypotheses tested implementation of a particular hysteresis algorithm, among other things. Data analysis has failed to support the notion that this particular implementation of position averaging is useful across the three subject categories tested, or within any of the three categories. Other findings of the current study include observational data regarding skill acquisition time and mastery of the technique by those with extremely erratic headpointing capability.

Findings of the study were reported at the 1984 Rehabilitation Engineering Society of North America Annual Meeting in Ottawa, Canada, June 17-22. ■

Adaptation of Standard Tests of Aphasia for Computer-Assisted Administration

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Sponsor: National Institute of Handicapped Research

The Token Test (Derenzi and Vignolo, 1962), the Revised Token Test (McNeil and Prescott, 1978), and the Colored Progressive Matrices (Raven, 1962) are being adapted for computer-assisted administration.

Use of alternative inputs, such as a touch-sensitive screen and a touch-tone telephone interface, are also being explored. Software has been written that provides the necessary graphics capabilities, and initial testing of components with subjects is scheduled. A subsequent project investigating computer strategies for recognizing perseveration and self-correction attempts by aphasic individuals will incorporate these techniques.

A Unique Comprehensive Communication System for Speech-Impaired Persons

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Sponsor: Veterans Administration Rehabilitation
Research and Development Service

Description—The Comprehensive Communications System for Speech-Impaired Persons evolved from a previous project published as the "Electronic Communicator for Speech-Impaired Persons." The previous unit utilized Morse Code entered by joystick or other two-axis controller and featured user programmable messages, all in a portable microprocessor-based device.

The present system resulted from the field testing of the previous unit in which it was determined that the Morse Code system, while usable, required a definite training time for any speed and was probably not necessary with the advancement of microprocessor technology. The new system, implemented first on the Apple II family computer, uses a joystick to select letters directly. The letters are arranged in a square around the perimeter of the joystick with essential punctuation and a "shift" key for numbers and special functions. The system is easily learned, has capability for user-defined message strings, allows for printing and saving of text to diskette, and presents the letters in a large type font for many who have visual perception involvement along with other motor impairments.

The joystick is used to select each character the user wants to print on the screen. The standard joystick is bounded by a four-sided square. Starting at a predetermined corner of this square, the joystick slides in a clockwise direction along each side. As the joystick moves, its X and Y coordinates change. The program has a table written into it. As the coordinates of the joystick change, the program selects a corresponding character—a letter or number.

That character is displayed in the top left-hand

corner of the screen. It is 2 inches high, (on a 12-inch monitor) and may be made larger or smaller as necessary.

When the user slides the joystick to a point where the required character is displayed in the top left corner of the screen, the user presses push button one, PB 1, on the joystick unit. The character is printed on the screen. The joystick is then moved to select the next required character. This mode is called the Writing Mode of the program.

A	B	C	D	E	F	G	H	I
<								J
\$								K
HI								L
>								M
Z								N
Y								O
X	W	V	U	T	S	R	Q	P

- Note:**
1. > is a space key.
 2. < is a backspace/correction key.
 3. HI is a prewritten work, viz., "HI."
 4. · at the center of the square is a period. Other syntax symbols can be added at the particular patient's request.
 5. \$ is also a prewritten word, of the patient's choice. For the demonstration disk, the patient chose to print the word "FANTASTIC" whenever he selected \$.

The present program is available on diskette and requires an Apple II family computer with 64K of memory and a joystick or other two-axis input device. A monitor and disk drive are also required.

Future Plans—Future plans are to reduce the system into a dedicated microprocessor-based device utilizing the Intel 8748 microprocessor, a vacuum fluorescent display, EEPROM memory, and RS-232 serial interface, as well as a special interface to the Apple II family keyboard input. This portable "Joywriter," as it is named, will permit the user to have a comprehensive communication system that is easily learned, may be an independent portable device, and may have a keyboard emulator for the Apple II family of computers.

Efficacy of Remote Delivery of Aphasia Treatment by TEL-Communicology

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Sponsor: Veterans Administration Rehabilitation
Research and Development Service

Background—There are many travel barriers that inhibit subjects with aphasia from receiving treatment. The remote location of speech-language pathology treatment centers often impedes continued treatment after the acute phase. Because of travel barriers, treatment programs may be based on factors other than the rehabilitative needs of the patient. Considering the large numbers of veterans with aphasia, this comparative study of TEL-Communicology and clinic delivery systems for treatment of aphasic subjects should be of great significance in the areas of service delivery and cost control.

Purpose—The purpose of the project is to compare the efficacy of two methods of delivery of an aphasia treatment program by (i) remote delivery by TEL-Communicology, involving both clinician and computer-assisted delivery, and (ii) face-to-face delivery in the clinic. The comparison of the achievement levels of the subjects in each group is based on:

1. Pre-treatment interim and post-treatment evaluation of patient changes in communication ability, and
2. Statistical analyses of certain health care delivery criteria that measure: (i) availability, (ii) accessibility, (iii) acceptability, and (iv) cost-effectiveness. The long-term objective of the project is to determine (i) if TEL-Communicology is efficacious and cost-effective, and (ii) if it makes quality health care more available and more accessible.

Subject Selection—Subject selection is based on the following criteria:

1. Veteran,
2. Male,
3. Eighty years of age or younger,
4. First left hemisphere thromboembolic cerebral vascular accident,
5. Neurological stability,
6. No other history of brain injury,
7. Between 2 and 52 weeks post-onset at entry,
8. Premorbid ability to read and write English,
9. No more than 12 sessions of language treatment prior to entry,

10. Language severity between 10th and 80th Overall Percentile on the Porce Index of Communicative Ability (PICA),

11. Corrected vision no worse than 20/100 in the better eye,

12. Binaural hearing acuity no worse than 40 dB SRT, unaided, in the better ear,

13. Adequate sensory and motor ability in one upper extremity for pointing, gesturing, and writing,

14. Agreement to participate in the study, and

15. The ability to utilize the telephone and any additional telephonic equipment, or a competent person available to assist in setting up the devices and treatment materials at the subject's residence.

Subjects meeting criteria are assigned to (i) a control group that receives 5 hours of face-to-face treatment, and (ii) an experimental group that receives 5 hours of treatment by telephone. The same stimulus variables are used in both groups. The results of the pre-evaluation, interim evaluation, and post-evaluation determine the rate and amount of improvement in each of the two groups.

Accomplishments—During a 17-month period, 38 aphasic subjects met criteria and entered the study. By May 31, 1984, 15 subjects had completed the 24-week treatment period. The charts of 2,934 neurologically impaired patients were reviewed. Of those, 2,315 patients were rejected because they were not aphasic. Of the patients diagnosed as aphasic, 278 were not accepted because of localization. Ninety-eight potential subjects were rejected because of etiology, and 45 did not meet the criteria of weeks post-onset. The remaining 160 were not accepted because they did not meet the criteria of age, PICA (Porch Index of Communicative Ability), visual acuity, or amount of previous treatment.

Location of Study—The Veterans Administration Medical Centers in New Orleans, Little Rock, Miami, and Birmingham serve as treatment centers. Birmingham VAMC is the project center. ■

Bliss Symbol-to-Speech Conversion: "Blisstalk"

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The Bank of Sweden Tercentenary Foundation
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The Swedish Council for Planning and
Coordination of Research

"Blisstalk" includes an electronic communication board on which Bliss symbols are selected by a magnet or by scanning; their corresponding linguistic expressions are spoken by a built-in speech synthesizer (or written as text) in the chosen language.

The Bliss symbols themselves were developed by the Austrian, Karl Blitz, in the 1940s. He was deeply impressed by difficulties in communication among people who spoke different languages, or even the same language with different intentions. While in China, Blitz—now calling himself Charles Bliss—was inspired by the Chinese ideographs to develop his own set of characters. He hoped they could be used as the basis of a system of world-wide commonality of expression and understanding. This system was set forth in his nearly 1,000-page work, *Semantography*, published in 1965.

In 1971, a special education teacher at the Ontario Crippled Children's Centre found a description of *Semantography*, and obtained a copy for a symbol communication project which had been instituted for nonvocal pre-reading children. The project staff, with consultation from Charles Bliss, developed vocabularies and procedures for use of the symbols which are now called Blissymbols. An institute for the purpose of developing the Bliss system was established in 1975. Located in Toronto, Ontario, Canada, it is called the Blissymbolics Communication Institute.

The use of Blissymbols in Sweden began in 1976 at two regional rehabilitation centers, one in Gothenburg and one in Linköping. In 1977, the Swedish Blissymbolics Resource Center was formed. Interest in Blissymbolics grew rapidly in all of Scandinavia, and the formation of the Nordic Bliss Communication Committee came about a year later, in 1978. According to the Swedish Institute for the Handicapped, there are about 800 children in Sweden who use Blissymbolics in some form; with many of them, it is their primary means of communication.

The groups concerned with speech synthesis and

vocal aids for handicapped at the Royal Institute of Technology in Stockholm have, for some years, been interested in implementing a "talking Bliss system." This interest has been encouraged by the Blissymbolics Communication Institute and others concerned with voice-output communication aids. This system was realized for Swedish in early 1981, and has since been developed for English and French. Bliss users interact with a 500-symbol Bliss board which includes a (multi-language) text-to-speech system developed by our speech synthesis group. The system presently contains a formant speech synthesizer implemented on a programmed signal processing chip and a powerful microcomputer. The Bliss-to-speech program transforms the symbol string indicated by the Bliss user to the corresponding well-formed sentence. Bliss-to-text programs have been developed as well, which perform a similar transformation to well-formed written sentences. The user may intermix Bliss symbols and spelled words to produce the spoken or written message.

Linguistic knowledge has been applied in a variety of ways in the realization of this device. An algorithm for producing well-formed sentences employs a lexicon for pronunciation, part-of-speech and special feature information, a grammar to mark clauses and phrases, and morphological rules to produce correct inflectional endings. Words that are spelled using the board's alphabet squares are pronounced by the speech synthesizer according to grapheme-to-phoneme rules or an accompanying "exceptions" lexicon in the chosen language. A set of phonetic rules control the language-dependent sound inventory, adjusting the realization of phonemes in quality, duration, and pitch according to the linguistic context.

Linguistic knowledge has been applied in a variety of ways in the realization of this device. A special phrase structure grammar has been written which marks clauses and phrases, referring to parts-of-speech information in a lexicon containing words corresponding to Bliss symbols. Phrase order is then inspected to determine sentence type. The speech synthesizer incorporates rules for pronunciation and prosody. Bliss-to-speech and Bliss-to-text programs have been developed for Swedish, English, and French languages.

This brief report has been abstracted from a 16-page illustrated paper which appeared in the Speech Transmission Laboratory's Quarterly Progress and Status Report. The paper discusses the development of Blisstalk, its structure, and its modes of operation. The choice of natural language grammar is motivated and differences between this grammar and "Bliss

grammar" explained and exemplified. An Appendix is included which lists possible verb phrase types in English and indicates their availability to Blisstalk users.

[See also **IV. Spinal Cord Injury, F. Environmental Control Systems for the Severely Disabled**, Ocular Controlled Communication and Environmental Control for Severely Disabled Veterans, Interactive Voice Studies and the Design of Command Vocabularies for Voice-Controlled Systems, and Ultrasonic Head Control Unit]

F. Environmental Control Systems for the Severely Disabled

Capuchin Monkeys as Aides for Quadriplegics

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Research has shown that capuchin monkeys have the potential to be as valuable to high-level quadriplegics as guide dogs are to the blind. Current goals include:

1. The standardization of training procedures used in teaching capuchins a basic repertoire of skills. Training procedures for approximately two-thirds of the basic behaviors have been standardized and are described in a training manual. These same behaviors are in the process of being videotaped. Footage will be edited and narrated to produce instructional videotapes.

2. The redesign of equipment that allows the disabled user to direct, reward, and punish his animal helper. The shock/buzz remote control unit used to discipline the monkey has been reduced in size and weight and the harness which holds it, redesigned. Powder and liquid reward dispensers are being replaced by a dispenser that allows a quadriplegic to deliver a variety of food rewards.

3. Redesign and standardization of training equipment. The ease with which monkeys learn specific tasks is partly a function of the design of the training equipment. Equipment continues to undergo modification as improvements in design are discovered.

4. Placement of monkeys. Six quadriplegics are currently using simian aides with an additional two placements expected during the summer of 1984. The number of tame female *Cebus apella* available to this program is very small. It has limited the number of research placements made. Capuchins placed in the future will probably come from a group now being raised specifically for this project.

5. Exploration of sources of *Cebus apella*. Young *Cebus apella* have been obtained from private centers, universities, pharmaceutical laboratories, and zoos. These sources are unpredictable, however, and unlikely to yield more than 5 to 10 monkeys per year. Breeding stock for a Florida-based colony is being sought from Argentina, Brazil, and Peru. This colony should eventually produce 30 to 50 infants per year.

6. Evaluation of all placements. An evaluation of each placement is conducted by project staff. In addition, an independent evaluation of several of the placements will be made within the next year by the Veterans Administration research evaluation unit.

7. An analysis of the type of organization that can train and place simian aides on a larger scale. Such an organization has been described and established. It is Helping Hands: Simian Aides for the Disabled, incorporated in 1982 as a nonprofit organization. Its eventual goal is to train a larger number of simian aides and place them with quadriplegics throughout the United States.

Headwand with Grasp and Release Capabilities

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The objective of this project was to design and fabricate one or more suitable devices that would give the headwand user controllable grasp and release capabilities.

Two devices were designed and fabricated. The first was one that provided for grasping and releasing of objects, with control by puffing and sipping through a plastic tube by the user. The grasp/release mechanism was activated by a sheathed cable which was attached to the diaphragm of a power-brake assist unit that had been salvaged from an automobile. The plastic puff-sip tube was connected to the chamber side of

the diaphragm in the unit and the diaphragm was then moved by the evacuation of air (by sipping), or by pressurizing (by puffing), when the user chose to do so.

The diaphragm in the unit used in this project had a diameter of approximately 9 inches, yielding a surface area of 63 square inches. Since an individual with adequate pulmonary function is capable of sipping and puffing 12 to 14 pounds per square inch, forces in the sheathed cable of the magnitude of 760 pounds are possible (less friction in the cable and mechanism). This was more than adequate to operate the mechanism of the grasp/release function which was developed for this model. Cable forces at the grasping mechanism of 16 to 20 pounds were all that were required to provide for 3 to 4 pounds gripping force, which is adequate to lift most objects that are reasonable in size and weight. The cable did provide some hindrance to the user due to its routing and added weight to the wand itself.

The second design provided for the grasp/release mechanism to be manipulated by a small air cylinder which is mounted at the tip of the wand and is essentially part of the mechanism itself. The wand is lightweight aluminum tubing and supplies air which is pressurized or evacuated from the air cylinder. Supply air pressure is provided by an air tank which can be charged from any supply of air pressure (such as service stations or plant air sources). Very small volumes of air are required for each activation of the mechanism. Therefore, the air tank provides for use of the device for relatively long periods of time between charges.

Control of the mechanism is accomplished by manipulating an electric switch that operates a solenoid air valve. The electric switch is of the micro-switch variety and can be easily activated by jaw manipulation, tongue movement, etc., depending on the choice of the user.

A disabled individual was hired as a consultant to help the researchers evaluate the devices. This young man, who has cerebral palsy, has no use of his hands, and has used a headwand for typing, etc., for several years. He was given the first of the two devices (with puff/sip control of the manipulator) in October 1983, with the goal of performing independent daily living tasks for which he had been formerly dependent. No vocational tasks, as such, were attempted using that design. The young man was shown the second device in January 1984, and the evaluation of some simple vocational tasks was carried out in February 1984.

The first tasks attempted by the client in his home using the first device were simple. Such things as

picking up pencils, small bolts and nuts, peanuts, etc., and placing these objects at various levels were performed. The first purposeful task that he attempted was to play the game of Monopoly with some friends. He has long enjoyed playing the game, but had to have fellow players move the pieces and toss the dice for him. In his first attempt to do so, he was able to toss the dice one-at-a-time, and then to pick up his playing piece, move it, and place it on the board accordingly.

The second of the two designs was the preferred one to evaluate in a vocational setting. The work station chosen is one that requires the manipulation of small, light objects.

Further research is to be carried out to determine the potential effectiveness of such a device to enhance vocational productivity. ■

Ocular Controlled Communication and Environmental Control for Severely Disabled Veterans

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The purpose of this project is to further develop and refine an existing ocular-controlled communication system and to explore the feasibility of using this system for environmental control for severely disabled patients, particularly those with brainstem dysfunction. The Ocular Controller, developed by Denver Research Institute, University of Denver, consists of an infrared-light-emitting diode reflecting off the patient's cornea into a sensing unit that translates eye movements into electronic signals. The signals are averaged and encoded by a microprocessor-based device which is programmable to effect written communication, synthesized speech, and control of a number of switches used for environmental control (EC).

A device was developed, fabricated, and tested with a second patient at the Denver VA Medical Center. Preliminary evaluation showed the patient, a 55-year-old veteran who had sustained a severe brainstem infarct 5 years previously, to have excellent horizontal and fair vertical eye control with minimal nystagmus. There was no motor control of extremities, lips, or tongue. Head control was fair when supported in the semi-recumbent position, but fatigued easily. There

was moderate to severe generalized extensor spasticity. Both verbal intelligence and functional physiological state tested within normal limits, and receptive language and vocabulary were excellent.

For this patient, a three-position Morse code system was used to maximize accuracy of encoding. Modification of the eyeglass-mounted light source and camera produced improved stability and less need for ongoing adjustment of the glasses. However, this continues to be the weakest component of the system, too unstable for prolonged use with this spastic patient in the sitting position, and is still most functionally used by the patient in bed. Modification and reprogramming of the encoding system was successfully accomplished to reduce set-up time to less than 1 minute, enable any caregiver or friend to easily do it, and minimize attendant error.

The communicator was interfaced with a video terminal with memory and dot matrix printer. This allowed the patient to edit and print complex communications. Communication speed with this device averaged 18 to 22 characters per minute. In addition, an orthographic vocal encoder was interfaced with the system. Preliminary experience with this device has been good, although complete evaluation has not yet been done. EC devices were found so far to have little practical application with this patient. In particular, movement of the patient's bed position often caused him to become poorly positioned due to his spasticity and inability to reposition himself. For this reason, it is suspected that independent bed control may not be feasible for patients such as these.

Since the video display and eyeglass component must be precisely positioned and occupy much of the patient's visual field, television tuning was also considered by the patient and treatment team not to be a reasonable goal. Control of room light level has been developed, and is presently being tested. More complicated EC functions, such as telephoning and robotic manipulation, are not considered within the scope of this project.

Further work is planned to include improving the mechanical stability, simplicity, and reliability of the eyeglass system; further simplifying and standardizing the encoder/control system; and exploring the feasibility of simple EC functions with a third patient. The goal remains of more closely approaching a simple, reliable, inexpensive unit suitable for production and delivery to patients in need of this system. ■

MicroDEC II—Environmental Control System for Computer Access Aid

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The MicroDEC II assistive device was designed to provide a person who has a severe physical disability with control over electrical devices within the living or working environment and the equivalent of keyboard access to an Apple II+ or Apple IIe computer.

Developed as an upgrade and extension of the commercially available MicroDEC environmental control system, the MicroDEC II retains all of the original unit's device control features. Through a two-switch scan-and-select technique, the user can control power to lamps and electrical appliances, and with optional interfaces can control a call alarm, electric bed, and television. The MicroDEC II, like the original MicroDEC, also provides the user with complete control of a standard handset or a speaker telephone. Phone calls can be received or placed, and up to six phone numbers can be programmed by the user and dialed automatically.

In the computer access mode, the MicroDEC II presents the user with appropriate selection groups on an auxiliary alphanumeric display. Characters, words, and commands selected by the user are transferred to the Apple computer through an interface board and appear to the Apple, electrically and logically, as if they had been typed at the keyboard. This arrangement, referred to as keyboard emulation, gives the MicroDEC II user access to any standard off-the-shelf software written for keyboard input.

Beyond simple emulation of the Apple II+ or Apple IIe keyboards, the MicroDEC II enhances text entry for word processing by arranging letters and words within the displayed groups according to their statistical probability of selection. Thus, more likely letters or words require fewer actions to select than less likely items. The MicroDEC II's word resource includes a core group of the 500 most frequently used words and a learning element of approximately 150 words that dynamically reflect the user's topical word usage.

The development phase of the MicroDEC II project has been completed. Our laboratory is now working with a manufacturer to transfer this device to the commercial sector. ■

Wheelchair Control and Robot Arm/Work Table System for High Spinal Cord Injured Persons

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The objective of the project during this period (June 1983 through May 1984) has been improvement in performance, versatility, and reliability of the Robot Arm/Work Table System (RA/WT) to enable eventual selection of a functionally optimal design as a model for a commercial or production prototype. Prior to this period it was proposed that 2 RA/WT units be rotated between the Spinal Cord Injury Services of the Richmond and Cleveland VA Medical Centers (for clinical evaluation by quadriplegic volunteers associated with these centers) and the Johns Hopkins University Applied Physics Laboratory (for equipment modifications in response to recommendations by these quadriplegics). Collaborative research proposals were submitted to RERADS by the chiefs of these SCI services to cover the clinical evaluation phases conducted in these VAMCs. This report summarizes the equipment modifications carried out in response to recommendations received either before or during the report period from the users at the two participating VAMCs.

Modification of the arrangement of telephone components during the previous period was so favorably received during the current period that no need for further modification is anticipated. A variety of relatively minor modifications of the self-feeding components was carried out. This function is now well received by most users. The general problem of space congestion in front of the user's face was improved both by modification of the telephone and introduction of a puff-operated computer keyer. The Robot Arm can be used to change floppy discs in a personal computer, but its lift and grasp force limits, the extent of wrist rotation, and its precision limits restrict its handling of reading materials to sorting and manipulating only the thinnest magazines and pamphlets. The resolution of these problems could substantially enhance quadriplegic productivity with a personal computer or typewriter. It also could permit or enhance user self-grooming. It is believed that the current design of the Robot Arm will accept modifications intended to satisfy these functional goals.

A new microprocessor, a 6809, was chosen and integrated into the Robot Arm controller to increase

operational reliability and flexibility. Software design for the old F-8 microprocessor was translated. A computer board was assembled with the 6809. Single axis capability was verified. To shorten task performance time, work was begun on the multiaxial mode capability to control three axes of motion to allow simultaneous operation in a non-coordinated fashion.

A problem was encountered and a solution found to enable more than one person to use the same RA/WT. Each user requires somewhat different end points of the terminal device about his head. A means of quickly changing the motion-file for each user was achieved by using the disc storage capability of a personal computer. In the absence of a personal computer, a wafer drive was found suitable. This unit fits on the support column of the RA/WT. Each data cartridge can hold motion files for at least ten persons.

To enable respirator-dependent and other quadriplegics with limited head and neck motion to use the RA/WT, a new controller was designed and fabricated that uses the jaw muscles (bite) and tongue for control inputs.

Development and Evaluation of a Robotic Aid for the Severely Disabled Individual

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Problem—Persons with physical disabilities such as quadriplegia and severe arthritis have a greatly reduced capacity for manipulating their environments, a condition often exacerbated by reduced mobility. The importance of access to, and control of, one's environment has long been recognized by disabled people and rehabilitation professionals. To date, the need could be addressed only by human attendants and occasionally by trained animals.

Significance—Unlike special-purpose devices and environment controllers, a robotic aid is a general-purpose tool, capable of manipulating a wide variety of objects and performing useful tasks in a changing and unpredictable environment. As a cost-effective alternative and/or adjunct to personal assistance in certain situations, a successful robotic manipulation aid can be expected to enhance the disabled individu-

al's sense of self-worth, functional independence, and productive capacity.

There is also an economic incentive to put robots to work for the more than 7,000 severely disabled veterans. Their labor-intensive attendant care can exceed \$50,000 per year. The total cost of human services in industry averages \$17 per hour and is rising—the cost of robots averages \$6 per hour and is dropping.

Background—The application of robotics to rehabilitation has few precedents. Over the past two decades, perhaps 10 projects can be identified that relate in some way to this human/technology endeavor. Historically, projects were outgrowths of relatively low technology prosthetics research or were (at the other extreme) efforts to apply the type of large remote manipulators associated with nuclear reactor maintenance.

More recently, industrial robotics and artificial intelligence have been making significant progress in developing utilitarian systems that improve industrial productivity and product quality in a cost-effective manner. While these developments have important implications for rehabilitation, their emphasis is on excluding humans rather than working with them. Telemanipulation, on the other hand, seeks to produce a mechanical extension of a human being, exploiting the operator's full range of perceptual, intellectual, and especially manipulative abilities.

Between the extremes of human involvement in the manipulation process lies interactive robotics, of which rehabilitative robotics is a part. The human, exercising a primarily supervisory role, directs the computer system to perform the desired task. A task is as simple as directing a move left action or as complex as serving a meal. The interactive nature of the process implies that the user has, at all times, complete control of the system.

Hypothesis—Based on our expectations that the development of a single general-purpose manipulation system is a more cogent answer to the manipulation needs of the severely disabled than is the design of a multitude of special-purpose aids, our current work is directed towards testing the following hypotheses:

1. The utility of a robotic aid is primarily dependent on the user being able to interact naturally with a machine that is capable of performing a variety of generic tasks autonomously.
2. Natural human-machine interaction is possible if the interface is managed by intelligent programs.
3. Autonomous machines must be able to sense

their environment, make plans, and control their actions.

Approach—The VA/SU Robotic Aid has been the first project to be based on a commercially available human-scale, 6-axis, industrial manipulator, driven by high-level software, using totally digital, multi-micro-processor-based control algorithms.

Status—The Robotic Aid Project embodies a clinical system and a laboratory development system. The design of the clinical system has been stabilized to a degree that allows us to pursue intensive evaluation trials with severely disabled individuals at the Palo Alto VA Medical Center's Spinal Cord Injury Service. Over 90 users have been trained to use the clinical system, of whom more than 20 were quadriplegics. The feedback from this user involvement has driven the development effort and defined specific goals in terms of the most desirable (and feasible) tasks. Actual use has pinpointed areas of needed improvement, including planning and control algorithms, environmental layout, command semantics, command phonetics, and procedures for training new users (an important consideration)■

Design of a Six-Axis Joystick for a Robotic Manipulation Aid

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Problem—The utility of a robotic manipulation aid depends largely on the interface between the user and the machine. "Commanding" a system to perform a task can be done through keyboard entry or spoken commands, but "piloting" the mechanical arm is best accomplished by a joystick-like device or some other control interface that uses the motoric capabilities of the user.

Hypothesis—It is our hypothesis that a general joystick-like device allowing control of the robot arm will significantly enhance the performance of the voice-commanded manipulation aid currently in use. The joystick will take over the true "piloting" functions

while freeing the voice communication for supervisory roles.

Further, it is hypothesized that a design allowing simultaneous control of all six axes of the robot will permit the joystick to be a natural interface device, encouraging pointing in any direction. Such a general pointing capability should be combined with a facility to restrict motion to only one axis at a time, thereby eliminating drift in undesired directions.

Status—Three prototype versions of VIDOF, the six-axis joystick, have been designed.

The VIDOF has undergone a preliminary phase of parameter adjustment for able-bodied users. Qualitative feedback from about 20 users indicates that the device requires a training stage before confidence is attained in making complex, high-speed maneuvers of the arm that VIDOF allows.

Future plans include quantitative performance testing, investigating various operating modes, and comparing the range of robot control devices currently available. Finally, the most important goal is extending the design process for the specific need of evolving robot controllers for the disabled users of the VA robotic aid.

Sensor and Gripper Development for the Robotic Aid Project

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Problem—The utility of any robotic system is limited to a great extent by its ability to sense its environment and to adjust to unforeseen situations it encounters. Three primary goals are obstacle avoidance, object recognition, and force or position ranging feedback during piloting maneuvers. These goals can only be achieved through the extensive use of sensors on or near the extremity of the robot arm, the gripper.

Development must thus proceed on three fronts: mechanical design (including gripper mechanisms and transducer technology), electronic interfacing (to preprocess the transduced signals for the main computer), and software algorithms (to make optimal use of the sensor information in the attainment of the goals mentioned above).

Significance—The first generation VA/Stanford robotic aid for the severely disabled was primarily designed to be a voice-controlled manipulation aid, with the user responsible for all of the decision making. While feasibility of voice-controlled manipulation was demonstrated, a performance plateau was reached due to the inability of the machine to absorb some of the burden of control. Without gripper-based sensors, the robot's performance and application were consciously limited for reasons of safety—primarily for the user, but also for the environment and the robot itself.

Hypothesis—It is postulated that performance of any robotic system can be enhanced by sensory aids. With a robotic system under constant supervision of a user, as is the case for the VA/Stanford robotic manipulation aid, the user is always in complete control of the arm's motions. For safe and fast action, the limiting factor is the bandwidth of the communication channel between user and system. For some operations, neither voice nor joystick control may be adequate, and feedback from sensors to the system and to the user is seen as the only reasonable means of correction or redirection of movement.

Status

- A. Gripper Design: a third-generation gripper has been developed which incorporates several major design enhancements: higher frame rigidity, greater gripping force, better transmission, and less mechanical backlash than previous versions.
- B. Optical Sensors: more robust, sensitive, and compact optical sensors are being used in the current development system gripper finger pads, permitting more sensors to be used in the same space, and better closed-loop algorithms to be developed.
- C. Tactile Sensors: whisker sensors have been developed to the single-unit prototype stage, but have not been implemented on the gripper.
- D. Microswitch Sensors: the clinical system gripper has been fitted with microswitch pressure plates on the gripping, forward, and lower touch surfaces for elementary obstacle avoidance and alignment to a surface.
- E. Conditioning Electronics and Preprocessor Units: a standardized transducer electronics and preprocessor unit has been developed, allowing any multi-sensor system to be incorporated into the general control scheme with a minimum of spe-

cialized interfacing. Both the six-axis force sensor and the new gripper have been interfaced using this procedure.

- F. **Algorithm Development:** the design of a real-time control framework in the main computer for the second-generation development system is complete. Work is proceeding on interfacing the gripper control processor and the force-wrist processor to the main computer. Algorithms have been written to implement closed-loop control from these sensor sources, and are currently being tested. Projects include hovering, aligning, peg-in-hole insertions, centering-and-grasping, object contour following and identification, and obstacle avoidance techniques.

The above elements will be part of the second generation robotic aid development system, presently in its initial stage of full control implementation. The enhancements mentioned will be the first step to endowing the development system with sensory and manipulation capabilities the first generation robotic aid does not have.

Interactive Voice Studies and the Design of Command Vocabularies for Voice-Controlled Systems

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Problem—The state of the art in voice recognition technology has made it possible to use voice as a viable communications link to computer systems in some situations. One case in which feasibility has been demonstrated is a voice-controlled robotic manipulator system for the severely disabled.

Limiting factors of the human/machine interaction center on human performance given machine characteristics and machine performance given human attributes. Errors can result from the incapability of the recognition unit to distinguish between two words with a high level of confidence. Problems also arise from errors that users make in the use or pronunciation of the allowable commands. There is a need,

then, to develop tools to construct command vocabularies so that the phonetic differentiability among all words is high, while semantic and syntactic clarity is retained.

Significance—Speech may be one of their only remaining means of communication for people disabled by high-level spinal-cord injury or neurological disorders. This suggests that voice recognition units are potentially very powerful devices for communication with computer systems. The utility of such devices has been demonstrated in the case of the VA/Stanford Robotic Aid Project.

A key component to successful human/machine integration is the voice command recognition rate. If this rate can be increased from the measured overall 85 percent to the theoretically attainable 99 percent, then acceptance, performance, ease of use, and confidence are expected to rise accordingly.

Background—When the first generation of the robotic aid system was assembled 5 years ago, the state of the art in voice recognition technology centered on the digital coding of time histories of band-pass-filtered speech samples. Templates thus created could be stored economically. The Interstate Electronics VOTERM unit was selected because it was one of the better systems of that generation, and because it had extensive diagnostic features.

The voice recognition system cannot monitor or correct its own misrecognitions. A technique was thus developed to systematically tally them manually in order to establish the user's as well as the VOTERM's performance during actual use of the robotic aid.

A pilot study was conducted using five able-bodied and five quadriplegic users prior to their using the VOTERM as an input device for controlling the robotic aid. Once voice training was completed, most of the users achieved recognition rates of 100 percent. However, when the same vocabulary was used in the context of controlling the robotic aid, frequent recognition errors occurred. It appeared, therefore, that further study was required on variables that affect voice recognition during actual use.

It has been shown that training techniques are crucial to establish user confidence and competence in the operation of a complex system. Special attention, therefore, had to be paid in the development of voice training techniques, concentrating on speech consistency, user attitudes, stress factors, and environmental variables.

Hypothesis—It is postulated that a combination of error tallying, template comparison, and user training will remove the most frustrating sources of error for voice control of the robotic aid. By coordinating these efforts, a set of vocabulary design/modification tools can be constructed. More importantly, the utility of voice as a viable means of controlling advanced assistive devices such as the robotic aid can be assessed.

Approach—The general methodology involved the design and development of quantitative analytical tools as well as the evolution of techniques and procedures based on experience and observation of user interaction with the robot system.

The voice command tallying techniques provide information on the commands a robot user employs during a typical 1 to 2 hour training session. To test prospective command words for compatibility with the existing vocabulary, a computer program (VDEL-TA) was written to perform template comparisons, indicating differentiability in matrix form. Words too phonetically similar could then be removed from consideration.

Training procedures include specific directives on how to provide the speech quality that the voice recognition unit requires. These guidelines began as the manufacturer's suggestions and evolved to include observations by the trainers on the best techniques and most frequent causes of recognition errors. Factors concerning voice consistency and the emotional content of the spoken commands, i.e., those involving the quality of the interaction between the user and the system, are of prime importance in this context.

Status—The robot command vocabulary currently consists of 58 words, and is in its fourth generation (V-4). The first version V-1 was constructed mainly on the basis of functional capabilities. The subsequent version, V-2, was made to incorporate several new command features. No evaluation methodologies were brought to bear at this stage. The evolution from V-2 to V-3, necessitated by user frustration at the quality of the voice recognition, was guided primarily by observations and suggestions by the trainers. Overall recognition rates, as measured by the tally method, dropped from 84 percent to 80 percent overall, due in part to experimentation with 15 new command words.

The evolution from V-3 to V-4 was guided by our experience with previous versions, utilizing all of the tools and methodologies mentioned in the preceding

section. The overall recognition rate increased from 80 percent to 86 percent, with a significant shift to types of errors that less seriously affect performance.

Future plans include special-purpose vocabularies for specific applications and the inclusion of several new functional modes requiring new command words. Based on the success of the previous methods, these changes will be made in a systematic way to optimize user acceptance through careful choice and comparison. ■

The Study of Manipulator Motion Under Constraint

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Problem—Research in hybrid man-machine manipulation systems has identified the need for automatic trajectory generation of manipulator motions. The principle of such hybrid systems is that an operator always has the option of guiding a manipulator through a motion under manual control. However, if a task is easier to describe to the dedicated assistive computer, which makes these systems possible, than it is for the operator to carry it out manually, the operator may ask for a motion to be completed under computer control.

A number of hybrid man-machine manipulation systems have been built and evaluated (Brooks, Buckley). The device described in Buckley is currently being evaluated in other research at RR&D. While it cannot be disputed that such devices increase the manipulative capabilities of the operator that they serve, the degree of useful computer assistance available from these systems has been minimal. This is due mainly to the high complexity required to describe manipulator motions in sufficient detail for them to be executed under computer control.

If such systems are ever to become more than laboratory curiosities, the burden of making implicit information about motions explicit enough for execution must be shifted from the human operator to the assistive computer of the system. Along with the development of an effective human interface, this is a fundamental problem in this field.

Approach—The primary difficulty in manipulator trajectory generation is that of characterizations of collisions. Given an adequate model of the world in which a manipulator operates, it is very easy to determine on a yes or no basis if a manipulator may be placed in a given position. It is not as easy to numerically characterize the relative badness of two manipulator positions in terms of some performance index. Such a characterization is useful in determining how to modify a manipulator position so as to eliminate possible collisions.

It is therefore sought to develop a strong, mathematically consistent numeric characterization of a manipulator moving among obstacles. Having done this, it is sought to apply previous results in numerical analysis to the computer generation of valid trajectories.

Status—The formulation of the trajectory generation problem as a nonlinear programming problem has been accomplished. This includes the development of a piecewise-differentiable constraint function which characterizes collisions that are valid for the entire problem domain. As far as is known, this work is original.

Algorithms have been developed for efficiently calculating these functions for polyhedral sets. Implementation of these algorithms is near completion.

The investigation of numerical algorithms for computing trajectories that take advantage of this formulation is currently in process. ■

Evaluation of the Human/Machine/ Environment Triad: An Interactive Model Applied to the Robotics Aid Project

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Problem—There is a critical need for user evaluation of rehabilitation research and development products at the prototype stage. There are no established protocols for prototype evaluation, nor are sufficient resources being allocated to carry out this crucial facet of the development process. The government regulates safety and efficacy of market-ready products through the FDA, but has no standardized pro-

ocols for evaluation of prototypic rehabilitation products. An environment to facilitate user and applied health professionals' input at all stages of the development process is needed to assure that the products generated are useful to people with disabilities.

The Office of Technology Assessment's Report, *Technology & Handicapped People* (1982), concluded that: "Evaluation is—or should be—an ongoing and integral part of the entire lifecycle . . . A coherent, and well-focused program of evaluation is necessary at all levels of technology diffusion and adoption. Such a program does not currently exist in the disability-related technology sector." (OTA, 1982) Research must also be conducted to determine what training procedures should be used to introduce people of all ages to new, sometimes sophisticated, products.

Background—There are often communication gaps when professionals trained in medicine, the social sciences, and engineering attempt to explain their differing approaches to solving a problem. Yet the evaluation of complex interactions between intelligent systems and intelligent beings demands an attempt at synthesizing the jargon, styles, and research methodologies of these various fields. The rapidly expanding technological advances, and their unexplored human/machine complexities require an interdisciplinary synthesis of medical, social scientific, and engineering methodologies in order to properly evaluate this class of sophisticated devices. An underlying premise is that intergenerational interaction will also facilitate the development of higher quality products better suited to the varied needs of all segments of our aging population.

A team composed of individuals from a variety of disciplines has been organized to develop research protocols and a working model for prototype evaluation.

Status—This clinical research has generated over 25 professional presentations over the past 2 years. Abstracts are available in the Robotics Information Package. Over 100 users have been trained to use the robotic aid using the interactive evaluation model (Engelhardt, Leifer, et al, 1983) approach. They range in age from 5 to 72 years and include over 22 high-level spinal cord injury patients. A 200-page manual has been developed and utilized by people of varying levels of formal education, from those without high school degrees to those possessing the Ph.D. Training methods are currently being researched in our locus of control study which hypothesizes that successful use of the robotic aid can be enhanced if training style

is matched to user characteristics. Voice studies are ongoing to better illuminate the research questions related to using voice as a control mechanism for a sophisticated assistive device.

Issues in technology transfer are also being actively examined from the theoretical diffusion of innovation perspective, the health services research perspective, and the manufacturer's production perspective. ■

Ultrasonic Head Control Unit

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Sponsor: Veterans Administration Rehabilitation
Research and Development Service
Paralyzed Veterans of America
Invacare, Solo Products, Jib Ray, and Polaroid, Inc.

Problem—Quadriplegics and others lacking control of upper and lower limbs have a need for improved communication and control of their environment. While many interfaces have been developed for use by severely disabled individuals, none are ideal: some have sanitation problems (pneumatic puff/sip switches), while others may physically intrude upon the user (chin operated joysticks) or may be socially objectionable (head wands). Some technologically advanced approaches have drawbacks of their own: eye control units restrict the user's gaze unduly, while voice control provides inadequate system responsiveness and behavior discrimination. Each is limited in its ability to convey the will of the user to operate the device to which it is attached. Trade-offs are frequently involved in their design and use.

Significance—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 or communication in a socially acceptable and aesthetically pleasing manner. Desired characteristics would include operation of a device from a distance without the necessity of mechanical contact, use of a part of the body that will not interfere with sensory input, and easy training and use. Other features, such as modular construction, low cost, the ability to accommodate many users, and self-calibration, would contribute to the appeal of the interface, and thereby stimulate its widespread use.

Background—Several methods have been developed to allow a user to communicate with a device to control it. Demonstrated techniques include magnetic induction coils, light emitter/detector pairs, radio transmission, EMG signal detection, EEG signal detection, eye movement detectors, and light reflectance. While the feasibility of each has been demonstrated, each approach fails one or more of the performance criteria defined above. Inherent in many of these potential solutions is the requirement that the user wear a portion of the interface.

Hypothesis—Ultrasonic distance ranging requires no physical contact with the object of interest. A person would not feel encumbered using a device that incorporates this technology. The investigators hypothesize that an array of distance-ranging sensors can monitor the head position of a severely disabled quadriplegic operator to obtain command and control information for the operation of mobility and communication devices.

Approach—In this project, two Polaroid ultrasonic distance-ranging sensors are employed. They emit inaudible sound waves that propagate through the air until reflected by an object. A portion of the echo signal returns to the transmitting sensor and is detected by the associated electronics. The measured time from transmission to the reception of the echo is proportional to twice the distance between the sensor and the object.

In this rehabilitation application, two separate sensors are directed at the user's head. The two distance ranges, one from each sensor to the head, and the fixed separation of the sensors describe a triangle whose vertices are the two stationary sensors and the user's moving head. A geometric relationship allows the offset from the base line and center line of the two sensors to be calculated. This information is then used to map the user's head position onto a two dimensional control space.

In operation, users of the Ultrasonic Head Control Unit (UHCU) merely tilt their head off the vertical axis in the forward/backward or left/right directions. Their changing head positions produce the same effects as a joystick. Thus, the UHCU can be used to control any device usually controlled by a joystick (wheelchair, communication aid, video game, etc.).

The main advantage of this type of interface is that no mechanical contact between the sensors and user's head is required. Users should not feel confined, as frequently occurs with other interfaces. The use of the remote sensing ability of the UHCU should

result in rehabilitation devices that are socially acceptable and cosmetically pleasing.

Status—UHCUs have been installed on two electric wheelchairs. The first is an E&J Model 3P equipped with a reclining Recaro seat and is in use in France by a quadriplegic woman. The second is mounted on an Invacare Rolls IV with a Solo Products Power Pack and is being evaluated by spinal cord injury patients at the VA facility.

Both units have been operational since June 1983. After a short demonstration and training session, quadriplegic users were transferred into the chair and were able to successfully navigate the chair without a problem. Users state that they preferred the ultrasonic head control to the chin-controlled joystick wheelchairs.

Several other applications of the UHCU are being pursued. Used in conjunction with a robotic arm, the UHCU will provide control of the robot's hand position. The user's head position will be used to control two degrees of robotic-arm freedom. Compared to the current voice recognition method, a faster and more interactive manipulation of the hand is anticipated.

In a communications application, the UHCU will monitor the user's head position and control a moving light cursor in an X-Y matrix of letters and words. Selection is then accomplished by pausing on the desired square. A commercial joystick-operated aid has been donated for this work.

A technical manual documenting the work on the UHCU, including background material, electronic schematics, computer program listings, explanations, and illustrations, has been compiled. Its intended purpose is to provide information that would allow a technically knowledgeable and adequately equipped person to construct a UHCU and apply it to the control of devices such as powered wheelchairs. This manual has been made available to interested parties who are considering the UHCU for research or commercialization.

International Texas Industries (Intex), of San Antonio, Texas, has made initial commitments in pursuit of production of a wheelchair controlled by the UHCU. They anticipate the first units will be ready by the end of 1984.

[See also **IV. Spinal Cord Injury, E. Communication Methods and Systems for the Severely Disabled, Bliss Symbol-to-Speech Conversion "Blisstalk"**]

Design of Evaluation of Showers and Bathing Fixtures for Disabled and Elderly Veterans

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

The purpose of this project is to finalize the design of four showering and bathing fixtures designed to meet the needs of disabled and elderly veterans. This is being done by conducting an evaluation of the fixtures as part of the ongoing design process. The evaluation is done with several groups of disabled people. The results will determine the validity of each design in terms of access, usage, and safety. The evaluation will also indicate if design modifications are necessary prior to introduction to consumers.

Evaluation Procedure

Testing of Three Fixtures with Subjects Capable of Transferring from a Wheelchair—Due to space limitations, only three fixtures are able to be tested simultaneously.

A. Description of the Fixtures

1. A cushioned shower designed primarily for people who transfer to and from the fixture with or without assistance.
2. A fiberglass shower, with two seats, designed primarily for testing usage by right and left hemiplegics. Other subjects (arthritics, amputees, and paraplegics) also will be tested on this fixture.
3. A fiberglass roll-in shower with seat, designed for people who can transfer.

B. Subjects and Selection Procedure—The investigators have selected over 400 former patients of the Atlanta VAMC with conditions of quadriplegia, paraplegia, hemiplegia, amputation, and arthritis to be considered potential subjects. Occupational therapists and the investigators are selecting the subjects from this group of 400 people.

C. Testing and Videotaping—Testing evaluation activities are conducted in the outpatient clinic of the Atlanta VAMC. The following procedure is used: The occupational therapist trains the subjects in the proper usage of each fixture, then the subject transfers to the fixture and begins to bathe. During all testing, the occupational therapist supervises the subject's activities to insure safety. The testing is videotaped to allow

future analysis of movements and task accomplishment.

D. Post-trial Interview—Following the completion of bathing in each fixture, the occupational therapist administers a post-trial interview. The interview deals with success or failure in transferring and the usage of the fixture, as well as a user appraisal of the fixture. The occupational therapist records both her own observations and those of the subject to avoid inaccurate responses.

Future Activities—After completion of the testing evaluation of the first three fixtures, the investigators will test a two-piece, roll-in shower designed for subjects who cannot transfer from a wheelchair.

Following all testing activities, the investigators plan to analyze the data gathered during the interim evaluation procedure to determine if modifications of the fixtures are necessary. After completion of the redesign and modification, the investigators will undertake another testing/evaluation cycle to insure design adequacy of each fixture. It is anticipated that the Veterans Administration will then undertake a formal evaluation of the fixtures at various locations, prior to their commercialization.

[See also **I. Amputations and Limb Protheses**, **C. Upper Limb**, **I. General**, Long-Term Recording of Voluntary Elicited Nerve Signals and **XIII. Sensory Aids**, **A. Blindness and Low Vision**, **2. Mobility Aids**, SONA/SONA ECS]

G. Wheelchairs, Including Seating and Controls

Wheelchair Research and Development

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The activities of the Rehabilitation Engineering Center during the past year have centered around wheelchairs and seating for the disabled. The seating aspect of the program is relatively new, and as in wheelchairs, the studies are tailored to develop the background information necessary for the effective design of seating systems on either a custom or production basis. The work is shared with colleagues at the University of Tennessee Rehabilitation Engineering Center in Memphis. Four tasks have been actively pursued: tissue physiology, posture studies, anthropometric data collection, and fitting and measuring techniques. An instrument has been developed for recording the shapes of body support while under load which, together with pressure profile measurements, will provide data for the design of modular support components. At the Memphis center, a study of spinal muscle activity in various sitting positions at rest and during activity is yielding information on appropriate postural support. This, with the anthropometric data on disabled persons and the modular components, will provide the envelope of data for effective seat design.

The wheelchair studies, which began several years ago, are continuing with the generation of basic technical information. Comprehensive experiments and analysis have lead to an understanding of caster flutter and a formula to predict the critical speed based on trial, moment of inertia, and tire profile. Tire studies have shown that the roll-off problem associated with no-flat tires can be overcome by increasing the modulus of elasticity of the inner structure. Although the ride characteristics may be impaired, another study has indicated the effect of using springing on the main wheels, and current experiments compare the characteristics of available spring forks for the caster wheels. The study also is associated with frame stresses that are measured experimentally and calculated with computer analysis. A program compatible with small computers has been developed and made available to industry.

Previous work at the University of Virginia developed performance profiles for powered wheelchairs that indicated rather low efficiencies in the normal operating range. Followup studies on motors and controllers have pinpointed certain problems, and a simple choke coil has been introduced to improve motor efficiency impaired by pulse width modulation controls. Work on an adaptive controller to provide user-friendly operation of a wheelchair is progressing and a battery monitoring system is nearly ready for trial. This microprocessor based device monitors charging and discharging, and with a built-in learning capacity will serve as a fuel gage for the wheelchair user.

An investigation into available and experimental batteries continues and a report has been written to assist the purchaser in choosing a battery. A similar study has assessed battery chargers. For the future, a new NICAD battery with non-sintered plates promises improved power density and much longer life.

In product design, the NASA composite wheelchair has undergone testing and modification and a prototype for evaluation is being readied at this time. A lever drive wheelchair has been built that allows the user to move from forward to neutral to brake to reverse by lateral movement of the lever—a function compatible with the ability of most quadraplegics. This design, which uses a 3 to 1 gear ratio was based on ergometric studies that clearly showed propulsion efficiency could be doubled or tripled by using levers and an appropriate gear ratio. The ergometric laboratory recently has been fitted with a three-dimensional arm position recorder and analyzer. With the torque recording and EMG this will yield previously unavailable data on the biomechanics of wheelchair propulsion.

The Rehabilitation Engineering Center has become increasingly active in wheelchair standards, developing and verifying test procedures for use by ANSI (American National Standards Institute) and ISO (International Organization for Standards). A recent contribution resulting from this work has been a method for determining rolling resistance using three light beams and an accurate timer. ■

Manual Wheelchair with Anti-Rollback Wheel

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Sponsor: Veterans Administration Rehabilitation
Research and Development Service

Purpose—This ongoing project involves the further development and commercialization of a novel anti-rollback wheel for manual wheelchairs. The system is transparent to the user; i.e., it is controlled entirely through natural movements in using the wheelchair.

Progress—A patent is pending on the initial and advanced designs of the system. Efforts have continued to commercialize the final designs, and equipment has now been purchased that will permit the Atlanta Veterans Administration Medical Center to produce a limited number of units for testing.

Future Plans—As efforts develop to establish a national center for evaluation and testing, this work can proceed. Until national guidelines have been established and funds made available for evaluation and testing, the final phase cannot be completed. ■

Alternate Transit Vehicle for the Physically Disabled Person

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Sponsor: Veterans Administration Rehabilitation
Research and Development Service

Purpose—To design systems and subsystems as an alternate to present powered wheelchairs.

Progress—This project began as a graduate feasibility study examining conceptual designs of a transit vehicle for physically disabled persons. It became apparent that the major obstacle to any conceptual design was the fact that the control electronics did not exist. In addition, semistructured interviews with powered wheelchair users revealed possibilities for improvement in present wheelchair controllers. The logical direction for this project then became to examine the electronics of wheelchair control, with a goal of designing a controller that was flexible enough to serve as a retrofit item for present chairs or that could be incorporated in future conceptual designs.

The first prototype has been constructed and is undergoing initial field testing. The controller is microprocessor-based with optical encoder feedback and is an original design in power processing. As a retrofit item for present powered wheelchairs, it offers several advantages in addition to a projected consumer cost below that of present controllers. One advantage is that costly hardware modifications, which customize the controller to special needs, are not needed because the design is implemented in software instead of hardware. All controller characteristics are set in software and are user/therapist programmable. The controller is silent in operation with no audible relay chatter or motor hum. Closed-loop control provides the classical advantages in addition to a "path memory" feature that allows the chair to automatically back out of a confined area along the same path it entered. A degree of self-diagnostics is presently functional and is presented to the user through an eight-character display. The processing power of the controller remains virtually untapped, with much of the signal processing handled by support devices. This allows the controller to assume additional functions in addition to driving the wheelchair.

Future Plans—With the basic hardware design finalized, future work will be concentrated in software development. This involves addressing the human factor questions of wheelchair control. Control strategies to be examined include logarithmic velocity control, proportional acceleration control, deadband limits, and a variety of digital filtering techniques. Additional self-diagnostics are to be incorporated, including current monitoring on each motor.

One of the most promising features of this controller is that it would solve a substantial and growing problem for powered wheelchair users: the congestion of assistive devices on their chair. Each new aid typically requires special attention to make the device accessible to each individual. The joystick or other interface used to drive the chair can also access a variety of other functions. Future plans include incorporating several devices in this manner, including remote environmental control and other aids through the RS232C interface. ■

Integrated Wheelchair Technology Tested

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Problem—Wheelchairs traditionally have used a relatively narrow range of potentially applicable technologies. Newer technologies (such as synthetic composite structural materials and digital motor control) used in isolation lead to incremental improvements, but are often limited in their potential effectiveness when used in an otherwise conventional configuration. Other issues, such as styling, have not been previously effectively addressed. Wheelchair manufacturers are unable to commit resources to develop designs significantly different from those already tooled and in production.

Significance—Improvements in the mobility of disabled veterans resulting from the use of more sophisticated power wheelchair configurations can improve their ability to access a variety of indoor and outdoor environments, enhancing their integration in society and the economy. New material technologies can yield improved wheelchair durability and convenience, as well as lowered purchase cost, while more attractive styling can ease social integration.

Background—The RR&D Omnichair project resulted in a proof of concept vehicle that is capable of moving forward and backward, moving directly sideways without turning, turning in place, or any combination of simultaneous motions. This novel mobility device became the object of a variety of industrial design studies by interested professionals and students. A graduate student project group developed a programmable digital controller for the Omnichair at Stanford in 1982. It was desired to integrate the experiential results of this work in a working wheelchair technology testbed.

Approach—It was decided that RR&D would undertake the design and fabrication of a wheelchair technology testbed that would embody a variety of new technologies used to their best advantage. The technologies targeted included synthetic composite materials, power MOSFET electronics, nickel-cadmium batteries, and microprocessor-based digital control electronics. It was further intended that the

resulting design would also represent the state-of-the-art in reliability, ease of manufacture, and ease of owner servicing.

The costs involved in building this device were borne by a combination of Base funds (for chassis and mechanical constructions), Merit Review funds (digital feedback controller and power electronics), and industrial cooperation (seating system, motors, and assorted components). The expertise of a large number of center personnel from all three organizational groups was recruited to assist in programming, physical modeling for design of the composite components, styling conceptualization and housing realization, and team support. The physical vehicle was completed in early June in time for the annual meeting of the Rehabilitation Engineering Society of North America, though it was not operational due to software development problems. The vehicle, nicknamed Alexis by the development team, was functionally complete in August.

Status—Substantial industrial interest was generated by the development and completion of this vehicle, and in September of 1983, a venture capital company (International Texas Industries) signed a licensing agreement with the holder of the omnidirectional drive patent. The Alexis is now in an industrial design phase and is expected to be in production by the end of calendar 1984. Work on the vehicle prototype ceased at RR&D upon consummation of the patent agreement. The technologies and designs developed for the prototype (power electronics, digital controller and proportional-integral feedback algorithms, synthetic composite chassis/suspension) are freely available to any interested parties.■

Wheelchair Feedback Controllers

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Problem—Users of electric wheelchairs often have difficulty controlling their mobility device due to its poor response. Most current electric wheelchair controllers operate in an open-loop mode, providing no compensation for disturbances affecting the wheel speeds. Electric wheelchair users frequently encoun-

ter situations that cause unwanted variations in both the velocity and the direction of their wheelchair. Traveling on hills and sides of slopes, and maneuvering on carpet and across bumps, are examples of situations that impose a heavy control burden upon the wheelchair user.

Significance—Improvements in the handling of electric wheelchairs both indoors and outdoors will be facilitated by this research. The development of a broad-based digital controller will provide people having minimal muscular control the means of controlling a wheelchair, thereby making wheelchairs useable by a greater portion of the disabled population. It will also enable the new generation of omnidirectional wheelchairs to be practical and controllable. Evaluation of controller performance will provide a more accurate understanding of the ergonomic aspects of wheelchair control and the effectiveness of various control schemes.

Background—Invacare Corp. is marketing an electric wheelchair with feedback control using motor voltage and current information processed by electronic circuitry based on discrete components. A number of research groups are studying microprocessor-based feedback controllers with wheel-velocity sensors. Work has been done at the University of California at Berkeley on the modeling and computer simulation of a conventional electric wheelchair with conventional control system and with a closed-loop controller.

Concurrent with the design of microprocessor-based controllers and control schemes for wheelchairs, the present project seeks to develop good dynamic models of two types of wheelchairs: the three-wheel-drive omnidirectional vehicle developed at the RR&D Center, and the conventional two-wheel-drive power wheelchair.

Hypothesis—A velocity-feedback controller should provide greatly improved response compared to that of an open-loop controller. The questions are (i) what feedback algorithm should be used? (ii) what parameters should be sensed to achieve the desired control? (iii) is a microprocessor the indicated hardware?, and (iv) how can the effectiveness of individual schemes be measured?

Approach—The VA controller project uses the technologies and methodologies of electric motor control, power electronics, digital control theory, ergonomics, and system evaluation. The project's specific objectives include: (i) design and development of solid-state power bridges suitable for providing pow-

er from wheelchair batteries to DC motors; (ii) design and development of microprocessor-based controller hardware suitable for an omnidirectional wheelchair; (iii) development of control software for an omnidirectional wheelchair; (iv) implementation of power bridges, controller hardware, and controller software on Alexis, an omnidirectional wheelchair; (v) design and development of a microprocessor-based controller module suitable for use on the spectrum of conventional two-wheel-drive electric wheelchairs; (vi) development of controller software for conventional wheelchairs; (vii) packaging of power bridges and controller hardware into a stand-alone module; (viii) implementation of power bridge/controller module on a conventional electric wheelchair; (ix) evaluation of controller performance for omnidirectional and conventional wheelchair applications; and (x) documentation of results in form suitable for manufacturers' use.

Status (in commercial development)—The controller development for the omnidirectional wheelchair has been completed; the design is serving as the basis of a controller now being developed commercially. Evaluation of the Alexis controller will proceed as prototypes become available. Current emphasis is upon determining the relevancy of various factors to wheelchair control, as well as the development of the controller for conventional electric wheelchairs. Evaluation of this controller will follow soon after its implementation. ■

Images Project

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Problem

A. Externally Powered Mobility—While general specifications for a personal vehicle can be stated, there has been little effort to develop the tools needed for a systematic research, development, and evaluation program. This problem is encountered when one attempts to increase user access to existing powered wheelchairs and/or improve wheelchair performance for current users.

1. Who can use existing powered wheelchairs safely?

2. Under what operating circumstances can they be expected to perform satisfactorily?

3. What are the key features of existing wheelchairs which facilitate or limit their effectiveness?

4. What percent of the potential users elect to remain immobile because they don't like existing wheelchairs?

5. What are the key features needed to make powered wheelchairs more accessible?

B. Low Vision—While general specifications for a personal vehicle can be stated, there is no equivalent knowledge base for research and development related to low vision aids. This is particularly true for applications involving mobility and orientation. And, while the situation is better with respect to reading aids, there is profound need for new tools to study low-vision phenomena, and a systematic development program to utilize the knowledge gained. The performance of the rehabilitation community in bringing new technology to bear on this class of problems is particularly notable as the field of robotics moves towards the realization of general purpose machine vision systems—while we waste the chance to help low-vision individuals effectively use the vision they already have.

1. What does the individual with macular degeneration, retinitis pigmentosa, or a cataract really see?

2. How could the visual world best be "enhanced" for presentation to a specific individual's retina?

3. What training procedure will maximize performance while taking individual preference into account? and

4. What are the critical performance specifications for the next generation of diagnostic, training, mobility, and reading aids?

Significance—It is uniquely possible in simulation studies to simultaneously measure performance and preference. This unique capability facilitates the maintenance of a balanced R&D program. Typically, technical members of the development team are biased in their consideration of the technical aspects of system performance. Medical members of the team are biased to evaluate the physiological performance of the patient. Only the patient/user is biased in favor of his/her own preference. And, it is preference which determines what devices will and will not be used after the patient goes home.

Hypothesis—It is hypothesized that simulation science and technology should play a central role in rehabilitation. There are three key levels of implementation:

1. General purpose high performance simulation is needed to define the limits of human and machine performance and to define the necessary and sufficient conditions for solving specific problems. Such systems are powerful, complex, and require highly skilled operators.

2. Task-specific simulation is needed for clinical diagnostics, treatment, and professional training. Moderate operator skill is required. The specifications for such systems may be derived from basic studies.

3. Personal (single user) simulators are needed for extended therapy and performance maintenance. They would be used at home, user owned and user operated. Their specification would be derived from basic studies and confirmed in the clinical setting.

Approach—Using the simulator gift from Singer Link Co., the following three-part effort will be undertaken:

1. A graphic data base will be constructed and developed that can be used for both low vision and wheelchair studies. A single setting, that of the Stanford Shopping Center, has been chosen for both studies.

2. A pilot study will be performed to assess the feasibility of using Digital Image Generator (DIG) technology in the study of wheelchair mobility. The dynamic equations of motion for an existing wheelchair have already been derived in the course of our ongoing work on wheelchair controls. With minor parametric changes, our initial wheelchair pilot study can be based on existing software. The driving environment will be that of the Stanford Shopping Center data base indicated above.

3. A pilot study will be performed to assess the feasibility of using DIG technology to study the impact of low vision perception on mobility. It is believed that this study can (for now) best be done in the context of wheelchair use by persons with low vision.

Status—A high-resolution, real-time, color Digital Image Generator has been donated to Stanford University and is on permanent loan to the VA. A preliminary version of the Stanford Shopping Center data base has been developed and a pilot demonstration videotape has been produced which demonstrates the capability of our system. ■

Seating System for Body Support and Prevention of Tissue Trauma

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

The purpose of this project is to investigate the factors that influence the development of pressure sores and postural deformities in the seated spinal cord injured individual and to develop seating system components that help to reduce the incidence of such problems. A universal contoured foam wheelchair cushion (VASIO-PARA) has been developed and clinically evaluated with 81 subjects. The cushion was found to be successful in reducing the pressure applied to the tissues of the buttocks to levels well tolerated by 79 percent of the subjects. The cushion was transferred to commercial production after incorporating design improvements based upon the findings from the clinical study.

Present efforts on the project are directed toward developing a better understanding of the interrelationships between cushion materials, design geometry, and subject's body build and the resulting pressure distribution over the sitting surface. Investigations also are being conducted on how variations in sitting posture alter the pressure distribution and pelvic orientation and how the cushion and trunk support components can be designed to accommodate and/or promote an optimal sitting posture.

To date, over 200 patients have been tested on the commercial version of the cushion and several design variations. The commercial cushion incorporates a waterproof coating that is washable to improve hygiene and help reduce bacterial growth. In order to determine if the coating alters the pressure distribution characteristics of the cushion, subjects were tested on a cushion with the coating and on one without it. No statistically significant difference was found between the two cushions.

Inserts of firmer foam are imbedded in the cushion beneath the trochanters in order to increase weight bearing in this area and decrease the load applied to the ischial tuberosities. The importance of the spacing between the inserts was investigated by comparing subjects on two cushions, one with a 7 inch spacing and one with an 8 inch spacing. The mean ischial pressure (mean \pm standard deviation) on the right side was 85 ± 27 mmHg for the 7 inch cushion and 66 ± 16 mmHg for the 8 inch cushion.

Similar results were seen beneath the left ischium, while no significant change was recorded at the trochanters. The manufacturer has been informed of these findings. Design variations for the inserts are currently being tested to develop an insert that distributes the pressure more evenly over the trochanters.

Preliminary work has been initiated to investigate the response of skin blood flow under conditions of applied mechanical loading. A laser doppler capillary perfusion monitor is being used to noninvasively monitor the skin blood flow. This may eventually lead to criteria for identifying patients at risk for decubitus ulceration.

Modular Seating for Children

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Sponsor: Scottish Home and Health Department

A survey carried out by Dundee Limb Fitting Centre to determine the seating problems of the disabled population in Dundee found that there was a particularly important group of children with moderate seating problems who do not have adequate seating. The principal characteristic of this group of children is inadequate head and/or trunk control. Their prevalence was estimated to be 250 per million of the total population. Cerebral palsy is the main diagnosis while spina bifida and a variety of myopathies contribute smaller proportions. It is considered that a suitable seating system would help these children to develop head and trunk control and encourage a symmetrical seating posture.

A number of commercially available seating systems partially satisfy this requirement, and a number of these currently are being fitted to evaluate their effectiveness. It is anticipated that a modular approach will be employed in the development of a new system. A series of seat and back modules will be designed to accommodate the large age and size range of the children. The modules will be located in a standardized metal framework by a series of clamps that allow some adjustment. The complete chair will be designed either as freestanding or to fit into a standard-type wheelchair.

The functional performance of the chair will be assessed during clinical trials. These will involve controlled subjective assessment by staff, attendants, and children using the chairs.

The final stages of the project have as their goal ensuring that the system becomes generally available as a commercial product.

Modular Seating for the Elderly

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Sponsor: Scottish Home and Health Department

A survey of the numbers and types of seating problems was carried out some years ago in Dundee District. The elderly were found to account for more than 75 percent of those identified as having inadequate seating or requiring special seating. The severity of problems among the elderly ranged from minor problems (such as some difficulty rising) to extremely severe problems such as skeletal deformity, pain, and no postural stability. The deficiencies in current seating fell into the following general categories:

1. Physical size—the dimensions of the chair do not match those of the person using it.
2. Postural support—the chair does not give support to compensate for loss of postural stability of the user.
3. Discomfort—this is most commonly a result of the deficiencies in 1. and 2.
4. Transferring—the height of the chair, position of the armrests, etc., are not the optimum to assist transfer to and from the chair.
5. Mobility—attendant-propelled hospital chairs are generally hard to push and difficult to steer.

A modular system, with a variety of seating components available to mount in an adjustable framework, appeared to offer the best opportunity of catering for the range of physical dimensions. A range of modules have now been developed that may be assembled together to make a chair to suit the requirements of the individual patient. Four sizes each of seat and backrest modules have been constructed, with one style of headrest and one style of armrest at present. The system was evaluated initially with the modules mounted in a static frame. Each chair was adjusted to suit the individual using it. This showed that great improvement could be obtained in fit, comfort, and postural stability over the furniture available in the hospital in which the evaluation was conducted. Ambulant patients generally found that transferring was improved as well because the armrests protruding beyond the seat front were useful points of support.

A further evaluation with chairs preset to give four sizes in a standard configuration suggests that between 70 percent and 80 percent of the target population could be accommodated in a small range of chair sizes with adjustments reduced to height, headrest position, and, possibly, armrest position. The armrest design is important to facilitating transfer to and from the chair and also is being investigated at Dundee Limb Fitting Centre. When the mechanics of rising from a chair are more fully understood, it is hoped that it will be possible to devise a simple system of prescribing the optimum armrest characteristics for an individual with difficulties in transferring.

A number of mobile chairs now also have been produced, and mobility is immediately improved compared with most hospital chairs by using larger wheels. However, the optimum wheel size, tire construction, and push handle and wheel positions are still to be finalized. ■

H. Personal Licensed Vehicles

Building a Data Base for Standards for Personal Licensed Vehicles

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The Rehabilitation Engineering Center for Personal Licensed Vehicles (PLV) was established at Louisiana Tech University in September 1983. It will continue, and expand, research and development already in progress at the University's Department of Biomedical Engineering.

Data gathered at this facility will provide the basis for further development of the center's driving simulators as (i) a testbed for evaluating the adequacy of various control devices relevant to severely disabled clients; (ii) a training simulator with expanded tracking, braking, and acceleration tasks, randomly generated on the computer screen; (iii) further expansion of the growing data base of disabled drivers; performances from referred driver assessment and training clients (via the State Division of Vocational Rehabilitation), with (iv) statistical correlations between simulator performance and in-vehicle performance during training.

Mathematical modeling of the driver's in-vehicle environment will analyze critical demands such as

range-of-motion and strength and control variables applied to a specific vehicle such as the Scott Van. Quantitative assessments of a client's capabilities, using the Available Motions Inventory (AMI) approach, will be computer-linked to allow graphic display and analysis.

Psychological and cognitive functioning will be assessed using computer-based testing procedures (developed from validated tests such as Wais Picture Completion Test). Current microcomputer-based assessment will be applied and expanded to measure client needs related to secondary control devices.

A system analysis of available devices will develop standards for the marketing and application of assistive driving devices. Guidelines will be developed for the integration of the system's components into a workable, reliable solution to the client's driving needs.

Information dissemination of project results and outcomes will include videotaped programs, slide presentations, journal and textbook publications, technical-scientific conferences, newsletters, Tech Briefs, and satellite-linked training.

An extended van will be converted to a mobile testing and driver training vehicle. The van will include a driving simulator; testing equipment—to measure vision, hearing, range of motion, and strength of the disabled driver; and, a small computer for processing test data. A local hook-up will supply power.

The van will travel to vocational rehabilitation centers, other rehabilitation facilities, and possible testing sites within a 500 mile radius of the center. This area includes Shreveport, Baton Rouge, New Orleans, Louisiana; Houston, Dallas, Texas; Little Rock, Arkansas; Jackson, Mississippi, Birmingham and Mobile, Alabama; and, Memphis, Tennessee. ■

A Driving Simulator for the Physically Handicapped Person

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Purpose—The Handicapped Driver Simulator is a system designed to facilitate therapeutic evaluation of the hardware to be retrofitted to a handicapped driver's vehicle. It consists of a full-scale mock-up of the necessary portion of a van interior, including

steering wheel, dashboard, seat, and other items necessary for driving. In front of this dashboard is a large screen monitor, driven by a modified Apple IIe microcomputer on which the simulation takes place. This system is designed to allow easy changing of hardware configurations and thus allow an individual to be evaluated for many different retrofit systems.

Progress Report—In September 1983, the initial design for the Handicapped Driver Simulator was completed. A summary report was written and the engineering drawings were prepared. This led to the ordering of the components that were unobtainable locally. Bolts, nuts, screws, etc., were not ordered at the time because of their widespread availability. Space for the construction of the project was arranged, but no construction has started due to shipping delays in the arrival of the components.

The software for this system is still under development. The electronic modifications for the driving microcomputer have not yet arrived, but are expected by the middle of June. These consist of a Motorola 68000 coprocessor board and a Supersprite board. The coprocessor will greatly increase the computational speed of the Apple by virtue of its 32-bit MPU. The Supersprite board will give the Apple the ability to display up to 32 Movable Object Blocks (MOBs) on the large screen monitor at one time. This should easily facilitate real-time driving simulation on the system.

Future Plans—The system will be constructed in the mechanics lab at the Atlanta VAMC. Materials for the frame have arrived, and the remainder of the parts are expected within several weeks.

There also are other uses for this system. Not only can it be used for evaluation and to familiarize drivers with the equipment to be installed in their vehicle, but in the future it may assist in the training of handicapped drivers. The system also may be used as a testbed for development of new handicapped driving aids. ■

I. Functional Electrical Stimulation

1. General

Development and Evaluation of Safe Methods of Intracortical and Peripheral Nerve Stimulation

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Functional electrical stimulation (FES) is a means of replacement or augmentation of lost or impaired neural activity. Important considerations in potential therapeutic applications of FES are the design of biocompatible electrodes and the selection of stimulus parameters that will safely and effectively activate target neuronal populations or peripheral nerves.

Work in this laboratory has included the design, fabrication, and in vivo evaluation of surface and penetrating electrodes for activation of cortical neurons and of various types of electrodes for stimulation of peripheral nerves. During the past 3 years this laboratory has developed stimulating intracortical microelectrodes (STIM) for activation of discrete populations of neurons of the cat's sensorimotor cortex. The STIM are fabricated from Pt30%Ir, or pure iridium, and implanted in the precruciate gyrus of adult cats under general anesthesia. The electrodes have smooth, beveled tips with geometric surface areas of approximately $20 \times 10^{-6} \text{cm}^2$. Three weeks after implantation of an array of three STIM electrodes, a recording electrode is inserted stereotaxically into the ipsilateral medullary pyramidal tract to monitor the compound action potential (CAP) reflecting the neural activity evoked by the STIM during continuous stimulation for periods of from 24 to 160 hours. The stimulations are conducted using charge balanced, symmetrical, constant current, cathodic-first pulse pairs, 200 μsec /phase in duration at 20 pulses per second, at charge densities ranging from 150 to 3200 $\mu\text{C}/\text{cm}^2 \cdot \text{ph}$.

A computerized data acquisition and control system for conducting stimulation and recording procedures has been developed for freely moving animals. Early components of the CAP remain quite stable during continuous stimulation at 20 to 40 μamp ,

although some diminution is observed over 24 hours. Late (transsynaptic) components of the CAP undergo greater attenuation. However, cortical stimulation at 320 μamp (3200 $\mu\text{C}/\text{cm}^2 \cdot \text{ph}$) for 24 hours produced profound elevation of the threshold of early and late components of the CAP that is not reserved 7 days poststimulation. This is consistent with histological findings of neuronal damage and loss within tissue surrounding these electrodes. However, neurons adjacent to these electrodes were activated by charge densities as low as 100 $\mu\text{C}/\text{cm}^2 \cdot \text{ph}$ as indicated by CAP recordings.

In vivo dissolution of surface platinum and STIM Pt30%Ir electrodes has been observed. With surface (subdural) platinum disc electrodes, erosion of platinum occurred at charge densities exceeding 20 $\mu\text{C}/\text{cm}^2$. At 100 $\mu\text{C}/\text{cm}^2$, 50-339 ng Pt/site was observed after 9 hours of stimulation. The rate of platinum dissolution gradually decreased during stimulation in vivo, probably due to protein inhibition of the dissolution process, which has been shown to occur in vitro. Pt30%Ir STIM electrodes also undergo dissolution of the uninsulated tip when pulsed in vivo. Scanning electron microscopy observations indicated erosion of the tips after pulsing for 24 hours at charge densities of 200 to 3200 $\mu\text{C}/\text{cm}^2 \cdot \text{ph}$ or 1 week at 200 $\mu\text{C}/\text{cm}^2 \cdot \text{ph}$. However, STIM electrodes fabricated with pure iridium, and whose uninsulated surface is activated by the deposition of a high valence oxide film, appear superior to STIM fabricated from Pt-Ir alloy; the activated surface does not undergo dissolution nor cause neural damage when pulsed with geometric charge densities up to 3200 $\mu\text{C}/\text{cm}^2 \cdot \text{ph}$.

We also have begun assessment of metabolic changes in the neuronal micro-environment with prolonged electrical stimulation. Ion-selective micro-electrodes were used to monitor changes in the concentration of potassium $[\text{K}^+]_o$ and calcium $[\text{Ca}^{2+}]_o$ in the extracellular compartment of the cerebral cortex of anesthetized cats during as long as 4 hours of continuous stimulation of the cortical surface. At stimulus charge densities shown to induce only minimal localized histologic changes (20 $\mu\text{C}/\text{cm}^2 \cdot \text{ph}$ at 50 pulses per second), $[\text{K}^+]_o$ at a depth of about 750 μm underwent only a transient increase at the beginning of stimulation, followed by a rapid return to the prestimulus concentration, while $[\text{Ca}^{2+}]_o$ was unaffected. At a higher charge density (100 $\mu\text{C}/\text{cm}^2 \cdot \text{ph}$ at 20 pulses per second) there was a rapid transient increase in $[\text{K}^+]_o$, followed by a more gradual return to a plateau about 1 mM above the prestimulus value. $[\text{Ca}^{2+}]_o$ usually underwent an initial increase followed by a slow decrease to a plateau value above 0.5 mM. At a charge density of 100 $\mu\text{C}/\text{cm}^2 \cdot \text{ph}$ and 50 pulses

per second (shown in histological studies to induce significant neural damage), $[\text{Ca}^{2+}]_o$ slowly decreased to near or below 0.5 mM in the middle layers of the cortex. After 30 to 40 minutes of stimulation, $[\text{K}^+]_o$ underwent episodic fluctuations about a plateau value 0.5 to 1 mM above the prestimulus concentration. Simultaneous recordings of the compound action potential in the ipsilateral pyramidal tract indicated that these fluctuations were due to local changes in the excitability of intracortical circuitry conditioned by the intense stimulation. The results have implications for the possible interrelation of the changes in extracellular ionic concentration and the early stages of stimulation-induced neural damage.

Histologic evaluations carried out on the same animals in which the ion-selective electrode measurements were made indicated a positive correlation of neural damage with both charge density and total charge. With electrical stimulation of low charge density (20 $\mu\text{C}/\text{cm}^2 \cdot \text{ph}$, 50 pulses per second) a transient increase in $[\text{K}^+]_o$ was observed with no histologically demonstrable neural damage. The most intense electrical stimulation (100 $\mu\text{C}/\text{cm}^2 \cdot \text{ph}$, 50 pulses per second) resulted in a tonic increase and episodic fluctuations of $[\text{K}^+]_o$ and a marked decrease in $[\text{Ca}^{2+}]_o$ —accompanied by moderate neural damage in the form of shrunken neurons, widespread extracellular edema, and swollen axons and dendrites.

These findings indicate at least a rough correlation between the threshold of neural damage due to electrical stimulation and the capacity of the brain's homeostatic mechanisms to maintain the extracellular concentration of K^+ and Ca^{++} at their prestimulus values.

Studies on stimulation of peripheral nerve also have been conducted. Histological evaluations of dog sacral nerves were carried out following stimulation to produce electromyoturbation. Two cuff-type electrodes and one spiral-type electrode were implanted chronically. A marked buildup of connective tissue around the nerve and filling the lumen of the array of both types of cuff electrodes was noted 1 to 6 months after implantation. The nerves were extruded from the lips of one type of cuff electrode by the buildup of connective tissue. The silastic spiral electrode appeared to be most promising for peripheral nerve stimulation, due to its ease of implantation, self-sizing properties, and lack of induction of excessive connective tissue formation. The minimal neural damage observed in these studies was attributed to surgical trauma or mechanical factors rather than electrical stimulation per se. The spiral electrode is currently being tested in further experiments in which it has been implanted on the common peroneal nerve of

cats. Neural activity is monitored by recording CAP from the cauda equina during 16 hour continuous stimulation of the anesthetized cat at stimulus currents two times the threshold for A beta fibers; no neural damage attributable to electrical stimulation has been detected. ■

Development of Neural Stimulating Electrodes and Evaluation of Their Electrochemical Reactions

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Sponsor: National Institutes of Health
(National Institute of Neurological and Communicative Disorders and Stroke)

Ongoing research is aimed at developing electrode materials which might be capable of safely delivering up to 50 amps/cm² of geom. electrode area in 0.2 ms (10 mC/cm² geom. area), with biphasic charge-balanced pulses. Safe stimulation of the nervous system implies the avoidance of chemically irreversible faradaic reactions such as water electrolysis, saline oxidation, and metal dissolution. With Pt and Pt:Ir alloys, up to 0.4mC/cm² area (approx. 0.8 mC/cm² geom. area) can be injected without the occurrence of water electrolysis or saline oxidation, but a small amount of charge is lost to metal dissolution.

The anodically formed oxide on the surface of activated Ir metal was demonstrated to be exceptional in its charge injection capacity and corrosion resistance. Charge injection limits before gassing were as high as 5 mC/cm² geom. area for cathodic pulses, and 25 mC/cm² geom. area for anodic pulses. Metal dissolution was not detected.

Ir oxide films have also been deposited onto the surface of Ti and Pt:Ir electrodes by the thermal decomposition of IrCl₃. These thermally prepared Ir oxide films have the same electrochemical properties, mechanical stability, and corrosion resistance as the anodically formed oxide on Ir metal. Electrodes prepared with a thermal Ir oxide film on Pt:Ir or Ti had charge injection limits before gassing up to 10 mC/cm² geom. area for anodic pulses. Charge injection limits for cathodic pulses are currently under investigation. The electrochemical properties and stability of the thermal Ir oxide films indicate that these films would be useful for electrode applications where the physical properties of pure Ir might limit its fabrication into a practical electrode, e.g., electrodes for cochlear stimulation or muscular stimulation. Experi-

ments are in progress to apply the technology of preparing thermal Ir oxide films to Pt:Ir electrodes currently under development for use in a cochlear prosthesis. Ir oxide coated Pt:Ir electrodes are expected to have an increased charge carrying capacity and an increased resistance to metal dissolution.

Other studies have determined that the response of the open circuit potential of thermal Ir oxide films on Ti is linear over the pH range of 2 to 10. These results indicate that electrodes prepared with a thermal Ir oxide coating may be useful for monitoring in vivo pH changes during electrical stimulation. ■

Artificial Sensory Transducers

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The goal of the contract is the development of force and position sensors for use on the paralyzed hand. These sensors will be used to provide sensory information to evaluate hand function in individuals for whom the hand muscles are electrically stimulated, and to provide sensory feedback to control systems for these electrical stimulators so that closed-loop control of the stimulators can eventually be achieved.

Single-element and multiple-element variable-capacitance force sensors to be located on the thumb and fingertips are currently under development. These sensors consist of metal foil parallel plates separated by a compliant polymer dielectric. The square metal foil plates range in size from 2 to 20 mm on a side, and dielectrics range from 1 to 2 mm in thickness. When aluminum foil plates are used, a dielectric consisting of silicone rubber dissolved in silicone oil gives the best results. Ratios of elastomer to oil of 1 : 1 or 1 : 2 gave the best linearity, reproducibility, and lack of hysteresis.

The capacitance of the sensor is measured by an electronic sampling circuit. A fixed charge is applied to the capacitor as a current pulse, and the voltage at the end of the pulse is sampled and held. This voltage is proportional to the reciprocal of the capacitance, but since the capacitance is proportional to the reciprocal of the plate separation and hence the force, the output voltage should be linearly related to the applied force. Experimental evaluation of sensors constructed in this manner has shown them to have

highly linear characteristics over the range of forces from 0 to 9×10^6 dynes.

Using the structure described above or a new thick film printing technique, 64-element array sensors have been constructed. In the thick-film case, a flexible 125-micronthick Kapton film is used as the substrate and silver electrodes are printed on its surface using screen printing technology and a silver epoxy ink. The electrodes consisted of eight parallel strips 2 mm wide by 20 mm long with electrical contact pads brought out at one end. An array of 0.75-mm-square silicone rubber and silicone oil dielectric pads is then printed over the electrodes on the substrate using the same technology. As the silicone rubber begins to cure, two of these structures are pressed together with an orientation such that the long axes of the electrodes on one substrate is at right angles to those on the other. The dielectric pads bond to one another as the structure cures, and curing is completed at elevated temperatures. A multiplexing circuit to address each of the 64 capacitance elements thus formed has been designed and tested, and the sensors presently are being evaluated in the laboratory. Preliminary results show the output voltage as a function of applied force to be similar to that for the individual sensors, but the linearity is not quite as good, and there is a greater tendency toward drift in the signal.

Future plans for this work include analyzing the thick film sensors in an attempt to improve stability and linearity characteristics. Additional dielectric materials will be investigated along with variations in dielectric shape. In addition, the contract calls for investigation of thin and thick film strain gages for position sensing at the finger joints, and methods of electrotactile feedback of sensor information to the individual wearing the sensor. In the final year of the contract, sensors for temperatures and texture will also be investigated. ■

Adhesion Studies Program

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The Adhesion Studies Program to improve and evaluate the performance and reliability of biocompatible insulating materials used in neural prosthetic

implant devices is underway at Hughes Aircraft Company, El Segundo, California.

The general objective of this program is to provide the National Institutes of Health (NIH) and the manufacturers of neural prostheses with usable and practical materials and process specifications for electrical insulation and substrate materials systems. Materials for use in the Neural Prosthesis Program must satisfy the following requirements when used in implants: the insulation shall remain bonded to the substrate, electrical continuity and function shall be maintained, and the entire system shall remain biocompatible for the functional life of the implant device.

To achieve these goals, a systematic evaluation of various dielectric materials and substrates is in progress. Specifically, four inorganic and four organic coatings were chosen for investigation. Based on initial screening studies, two polyimides (DuPont's PI-2555 and Hughes Aircraft Co.'s HR605P) and a chlorinated hydrocarbon (Union Carbide's Parylene C) were selected for further study. The three were applied on interdigitated metallized test patterns for long-term aging studies. The initial electrical stress screening under immersion in water and salt solution was performed on gold metallizations. Subsequently, test fixtures were fabricated using titanium, platinum, and iridium metallizations. Adhesion to the various metals was tested both before and after surface treatments. Biocompatibility testing (in vivo) of the three coatings is underway at Huntington Medical Research Institute.

Results from long-term testing at 40 deg C in deionized water and 0.9 percent aqueous NaCl solution, with a continuous 9 volts d.c. electrical stress, have shown no deterioration of insulating properties for the PI-2555 (gold metal) after 1.6 years. This test is still in progress.

Adhesion testing on iridium, platinum, and titanium using a tape test method (ASTM D3359) after immersion at 65 deg C in 0.9 percent NaCl gave the best results with PI-2555 and HR605P on iridium and titanium metallization. PI-2555 and HR605P on platinum did not adhere as well. Parylene C adhered poorly to platinum and titanium.

There were no observable tissue reactions after 16 weeks of implantation of the three coatings on passive platinum electrodes in the subdural cavity of cats. The biocompatibility studies are continuing at the Huntington Medical Research Institute. Effects of sterilization by autoclave and by ethylene oxide on the adhesion strength and electrical insulation properties of the coatings are being evaluated. ■

Ion-Exchange Stimulation Electrodes

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Sponsor: National Institutes of Health
(National Institute of Neurological and Communicative Disorders and Stroke)

The broad goal of this program is to develop neural stimulating electrodes with large current density and charge density that utilize faradaic reactions with solid insoluble electrode products. Because such electrodes may have some toxic ionic by-products, coating with ion-specific transfer membrane to exclude contact of these ions with body tissue is being evaluated.

At the time this work was begun in 1979, only platinum electrodes employing electrical double-layer charging and tantalum oxide capacitor electrodes were viable for stimulation. Both had insufficient charge capacity for advanced types of stimulation applications. Overdriving platinum results in corrosion, generation of hydrogen and oxygen, and electrolysis of constituents of body fluid, all of which are harmful.

The first faradaic electrode chosen was silver/silver chloride since it has a known high capacity and an insoluble product. An ion transfer membrane with a high transference number for chloride ion was needed to exclude the low-solubility silver ion from contact with body tissue. A highly specific membrane was developed that could be applied in thin layers to small electrodes. An electrode was prepared that looked very promising when cycled for over 3000 hours at a current density of about 0.1 A/cm² in a 200 μ s-per-phase biphasic pulse at 67 Hz. Unfortunately, at higher current densities a layer of porous silver grows and cracks off the membrane.

Present development is focused on avoiding the shape-change problem. One approach is to grow the porous silver layer to a steady-state thickness on the active electrode surface by pulsing, prior to coating with the membrane. Another approach is to develop more pliable membranes less subject to cracking. Development is still in progress to solve the shape-change problem. Other electrodes also are being considered, such as iridium oxide which has recently come into prominence.

Mathematical modeling calculations of temperature rise and pH change were made to gain a better understanding of limitations to use of stimulating electrodes. Temperature rise by joule heating and other irreversible effects does not appear to be a problem now, but could be a limitation for future,

micrometer-size electrodes operated at greater than 10 A/cm². Calculations show that pH changes can be very large at oxide electrodes during biphasic pulses, but the pH excursions extend only a few micrometers away from the surface. The practical significance of such pH excursions is as yet unknown.

A possible side benefit of the membrane-coated Ag/AgCl electrodes is that they may be useful as in vivo microelectrodes for chloride sensing. Some effort is continuing on the preparation of microelectrodes for evaluation.

Capacitor Stimulating Electrodes for Activation of Neural Tissue

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Sponsor: National Institutes of Health
(National Institute of Neurological and Communicative Disorders and Stroke)

The overall goal of this program is to develop highly miniaturized capacitor-type intracortical stimulating electrodes suitable for the chronic electrical stimulation of highly selective neural elements, thus contributing to the development of advanced neural prosthetic devices for the treatment of various disorders. Ideally, these electrodes should be mechanically stable, biologically compatible as implants, and useful over a long period of time. The latter two conditions also imply absence of corrosion and toxic species formation over a long, useful life.

An initial short-term objective was to develop cylindrical shaped and conically tipped microstimulating electrodes (100 microns in diameter and 200 microns in active length) capable of storing at least 20 nanocoulombs within 0.1 milliseconds without exceeding 4 volts (corresponding to a minimum charge injection density of 2.3 nC/cm²). Ultimately, for single neuron stimulation, the electrode will have to be further miniaturized to approximately 5 microns in diameter and 7 microns in active length. The electrical requirements in terms of current and charge densities are 50A/cm² and 20 mC/cm², respectively.

During the course of this program, high-surface-area tantalum capacitor electrodes were prepared by either a slurry dip or electrochemical etching process. In the 100-micron-diameter configuration, the charge injection density was found to exceed 6.4 nC/cm², which effectively ensured a higher safety margin in neural stimulation. The leakage current at 4 V was of the order of 0.1 nA/nF, which is quite acceptable for neural stimulation. Furthermore, a series of fabrica-

tion procedures also was developed in order to prepare complete microelectrode assemblies with insulation and electrical leads ready for implantation. A number of such complete stimulating electrode assemblies were prepared, characterized, and delivered to NIH-NINCDS for in vivo testing.

In addition to tantalum, other potentially attractive metal/metal oxide systems, including titanium, niobium, hafnium, and zirconium also were studied. The most promising system discovered to date is the titanium/titanium dioxide system. A novel oxide formation method, developed in this program, permits titanium electrodes to operate in a hybrid capacitor/faradaic mode. Essentially, a reversible redox reaction of the oxide film thus formed would enable the electrode to handle safely a charge density of the order of 20 mC/cm² per pulse, which meets the ultimate goal of the program.

The present effort is focused on the optimization of this oxide-forming technique and evaluation of the performance of these electrodes over long periods of time in vitro. Specific electrode fabrication techniques also are under development in order to produce smaller microelectrode assemblies suitable for in vivo testing in the near future. ■

Capacitor Stimulating Electrodes for Activation of Neural Tissue

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Sponsor: National Institutes of Health
(National Institute of Neurological and Communicative Disorders and Stroke)

Introduction—A common concern of any neural prosthetic device, whatever its application, is the operation of the stimulation electrode. For intracortical neural stimulation, the electrode must be able to inject substantial quantities of charge without deleterious irreversible faradaic reactions occurring across the electrolyte-tissue interface. With a capacitor electrode, an insulating dielectric layer on the surface of the electrode allows charging of the electrode while preventing the passage of the electronic current necessary for the faradaic reactions. Ta/Ta₂O₅ capacitor electrodes on high surface area substrates have been used successfully for neural stimulation where moderate charge densities are required.

In this program, we have attempted to make a smooth, high-charge-density electrode by using films of barium titanate (BaTiO₃) which can have a dielectric

constant of up to a hundred times that of tantalum oxide. Because of the inverse dependence of the capacitance on the film thickness, however, the films must be made as thin as possible without causing excessive leakage current during their operation. We have deposited BaTiO₃ films by sputtering onto Pt substrates, and tested their electrical properties in phosphate-buffered saline.

Methodology—The films were deposited onto planar Pt substrates by rf sputtering in an Ar/O₂ atmosphere. Films were made with thicknesses from 1 to 2.5 μm. The substrate temperatures ranged from ambient to 940 deg C. After the deposition some of the films were annealed in air at temperatures from 900 deg to 1200 deg C for periods up to 6 hours. The structure of the films was determined by X-ray crystallography; the morphology and coherence by electron microscopy.

The electrical properties of the films were measured using diluted phosphate-buffered saline as the top contact. The AC capacitance was measured with a capacitance bridge at frequencies from 0.5 to 10 kHz. The DC leakage current was measured for positive biases with an electrometer or picoammeter.

Results—The films had to be annealed above 1000 deg C in air before the pure, crystalline BaTiO₃ phase was formed. This annealing, however, led to formation of large crystallites and a porous structure. For films of 1.2 μm or less, areas of the exposed Pt substrate were observed by electron microscopy. The capacitance of the 2.5 μm films was 2.5 μF/cm² when measured in the liquid electrolyte. This high capacitance, which corresponds to an effective dielectric constant of 7000, resulted from the large surface area associated with the porous structure. Unfortunately, the high capacitance was accompanied by a high DC leakage current due to the contact of the electrolyte directly with exposed areas of the Pt substrate. The as-deposited, unannealed films had an amorphous structure and a much lower leakage current, but their dielectric constant was less than 100.

Conclusions—As a result of our work on BaTiO₃ and anodic oxide dielectric thin films, we do not view as very promising the ultimate success of making useful capacitor electrodes with the smaller dimensions necessary for single neuron stimulation. A more fruitful direction of research is the investigation of thin film materials that use surface redox reactions to accomplish charge transfer without permanent altera-

tion of the solution composition. One material of this type currently under investigation in our laboratory is iridium oxide.■

Multichannel Multiplexed Intracortical Recording Arrays

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This project seeks to develop multielectrode recording arrays that can be implanted directly in the cortex and that are capable of recording the electrical activity of single neurons over long periods of time (months to years). By allowing neuronal activity to be recorded simultaneously from many cells spaced in depth through the cortex, these probes should constitute a major advance in instrumentation for studying the central nervous system. Significant progress in understanding the information-processing techniques active in neural structures should occur, and understanding these will, it is hoped, lead to improved understanding of a variety of neurological disorders. The ability to record the signature activity from neurons at many points through the cortex for external processing by a microcomputer also offers the hope of being able to close the control loop in a variety of neural prostheses, allowing stimulation to be conditioned on responses (or command signals) from the body itself.

In the probe structure under development, the supporting substrate for the electrode array is silicon, formed from a wafer by selective chemical etching. Typical dimensions include an overall length of 3 mm, a shank width of 60 μm , and a substrate thickness of 15 μm . The upper surface of the probe is insulated with silicon dioxide and silicon nitride dielectrics on which are deposited thin-film interconnect leads of polysilicon or tantalum. These leads are insulated with overlayers of silicon dioxide and silicon nitride, which are selectively removed over the recording sites to permit lead contact to the extracellular fluid. At the rear of the probe, integrated circuitry is formed to allow the very small neural signals to be amplified and then multiplexed to the outside world on a single wire. This circuitry allows the number of wires which must be attached to the probe to be limited to only 3 for as many as 40 recording channels.

A batch process has been developed for producing these probes with high yields. A prototype integrated circuit for amplifying and multiplexing up to 12 recording channels has been fabricated and tested successfully. The required chip area is 1.75 mm² in 6 μm /feature NMOS technology. Passive probes (without on-chip circuitry) having as many as 10 channels have been fabricated and are now being tested using short-term experiments in animals. Neural activity has been recorded from both tip-mounted and side-mounted recording sites, with signal-to-noise ratios exceeding 5:1. These results are very encouraging in regard to the eventual successful application of the fully integrated probe structure.

During the next phase of this project, primary effort is being directed at the further study and optimization of probe/recording-site geometries to best recording characteristics, and at the successful integration of the signal-processing circuitry directly on the probe. Efforts also are directed at the development and evaluation of long-term implantable probe assemblies, including improved insulating materials capable of preserving their electrical integrity in the face of long exposure to saline.■

2. Upper Limb Applications

Restoration of Upper Limb Function Using Functional Electrical Stimulation (FES)

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Research and Development Service

The focus of research activities in the Case-Western Reserve University Rehabilitation Engineering Center is directed toward restoration of upper limb function. Projects at this time include restoration of motor function through functional electrical stimulation, closed-loop control of electrically stimulated muscles, and electrotactile stimulation for sensory augmentation.

These studies are the core area of research in the program. The purpose of the project is to develop and evaluate systems employing functional electrical stimulation to provide control of hand movement.■

Closed-Loop Control of Electrically Stimulated Muscles

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The objectives of this research project are to design and evaluate closed-loop control systems for the regulation of grasp and release in functional neuromuscular stimulation orthoses. Systems will be implemented for lateral pinch and palmar prehension in C5 and C6 quadriplegic patients to provide repeatable input/output properties, regulation of grasp stiffness, and coordination of multiple channels of stimulation with a single command signal.

The stiffness regulation system consists of two feedback loops; one is an internal force regulation loop that modulates stimulus pulse width and interpulse interval; the other is an external position feedback loop with a stiffness controller that regulates the relationship between force and position. All elements of the stiffness regulation system have been (and are being) tested in animal experiments. The results of those tests are being applied in the design of the hand-grasp regulation systems.

In the initial part of this study, we have concentrated on systems identification of the stimulated muscles and evaluation of the response properties of the closed-loop force feedback system. In these tests, the subject's hand is held stationary with the appropriate digit resting against a stationary force transducer. The control systems are implemented by software in a laboratory microcomputer.

Systems identification of the force modulation of electrically stimulated muscles consists of three phases: (i) estimation of the muscle fusion frequency (i.e., the frequency, at which there is 10 percent ripple in the force), (ii) measuring the recruitment characteristic (steady-state relationship between pulse width and force, measured at the fusion frequency), and (iii) estimation of the muscle dynamic properties. The muscle dynamic properties are modeled by a discrete time difference equation relating the force output at each stimulus instant to the two previous force outputs and the previous recruitment modulation parameter. When static recruitment nonlinearities are removed, the linear model predicts the actual force output with an error less than 10 percent. These

results are in agreement with our results from animal studies.

The stability, rise time, overshoot, and settling time of the closed-loop force regulation system are measured from responses to step changes in command. Responses are also evaluated for ramp command inputs, since ramps are more representative of the types of inputs generated by patients. The criteria for acceptable step responses are (i) rise time (0 to 90 percent) less than 1 second, (ii) overshoot less than 20 percent, (iii) settling time (± 5 percent of steady state value) less than 2 seconds, and (iv) no sustained oscillations in the output at the stimulus instants.

It was possible to meet these criteria with a wide range of controller parameters (e.g., a gain range of 5 to 10) indicating that the system was robust (insensitive to controller or muscle parameters). These results are also in agreement with previous animal studies.

Future plans include similar evaluation of the complete stiffness regulation system, which has been implemented in software. Testing will be expanded to include evaluation of the patient's ability to control the closed-loop systems.

3. Lower Limb Applications

Walking Restored in Paralyzed Man Using Electronic Orthotics

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This is a 3-year research program which began in September 1983; it is a continuation of earlier work of functional electrical stimulation of paralyzed muscles. The goal of the work is the development of a neuromuscular orthotics system to provide paralyzed persons with specific functional activity. As compared with the existing prototype system the new one should yield smoother performance, improved stability, reduced fatigue, and be adaptable to an implantable form.

Nine paraplegic patients with complete lesions ranging from T-4 to T-11 have participated in the study. Seven of these are currently active subjects. They are implanted with percutaneous intramuscular electrodes in major muscles of the legs and pelvis which deliver stimuli for flexion and extension of the hip, knee, and ankle. Either a laboratory computer or a portable microprocessor-controlled stimulator pro-

vides programmed, sequential electrical stimuli to produce desired combinations of movements for standing up, level walking with either right or left leg, and going up or down stairs.

With this instrumentation all patients have developed clinically usable muscle forces. Their exercise program includes using electrical stimulation for an hour a day and walking for half an hour three times a week. Quadriceps muscle force and girth of the thigh increased over a period of several months of exercise. The patient's aerobic capacity is monitored using an arm-ergometer. All patients are able to tolerate a 50 to 100 percent increase in workload with lower heart rate and lower blood pressure than that recorded for the same workloads at the start of the exercise program.

Among the six patients who have been able to walk with electrical stimulation, the total number of electrodes implanted ranged from 36 to 108. The electrodes, made of 76 μ , multistranded stainless steel, were generally well tolerated; over the course of 9 months, electrode failure varied among the patients from 25 percent to 50 percent. The failure was either mechanical or due to physical movement where response to stimulations was no longer functional. At the time of this communication, four patients were able to walk with a standard walker for distances ranging from 3 m to 50 m, and two were able to walk only in parallel bars. The major problems encountered were poor balance due to lack of functional hip muscles, high energy requirements, and non-related medical complications.

During the past year three major improvements in the neuro-orthotic system have been developed. In almost all patients the capability for dorsi and plantar flexion has been added through implantation of peroneus longus, tibialis anterior, and soleus muscles of the lower leg, eliminating the earlier need for an ankle-foot orthosis. In two patients postural control has been improved by the implantation of hip extension muscles. One patient is able to climb and descend stairs holding onto rails. A closed-loop, or feedback, control has been implemented, allowing the computer to adjust the levels of stimulation according to the knee angle during standing, thus minimizing the amount of stimulation delivered to the muscles and reducing fatigue.

Future work is directed toward (i) improvement in electrode design and implantation technique, (ii) improvement in stability and smoothness of motion through the implementation of closed-loop controllers of electrical stimulation using an improved mathematical model of human gait, and (iii) evaluation of sensor needs and design of those necessary for the closed-loop system. ■

[See also **II. Orthotics, A. Lower Limb**, An Investigation into the Mobility of the Cerebral Palsied Child]

4. Other

Active Physical Therapy: Application of FES to Rehabilitation Medicine

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This pilot project has begun to examine in detail the effects of isokinetic and dynamic exercise on paralyzed skeletal muscle and on the cardiorespiratory and skeletal systems. The overall goal of the studies will be to train a large number of paraplegic and quadriplegic subjects (with injuries at various levels of the spinal cord) by each of the two exercise modalities, and then to study the responses of the cardiovascular, respiratory, and skeletal systems.

Isokinetic exercise is often used to condition muscular strength. Isokinetic exercise involves lifting weights very slowly up and very slowly down with sufficient load applied to a muscle to fatigue it fairly rapidly. This type of exercise, while conditioning muscular strength, has historically been very poor in terms of developing cardiorespiratory fitness. To condition the cardiorespiratory system physically, training such as aerobic exercise must be used. In contrast to isokinetic exercise, aerobic exercise involves the rapid movement of muscle against a light load at a sufficient level so that the muscle can produce energy (through the utilization of oxygen-consuming pathways in the muscle). While applying to nonparalyzed individuals, such responses may or may not apply to the paralyzed because of the possible disruption of many autonomic pathways resulting from the spinal cord injury.

The purpose of the current series of experiments has been to examine various training protocols involving isokinetic and dynamic training of skeletal muscle and other body systems. Included in the parameters examined have been the effect of various exercise training programs on muscular strength, muscular endurance, muscle size, limb size, limb blood flow, bone mineral density, cortical bone thickness, blood pressure at rest, blood pressure during

exercise, heart rate at rest, heart rate during exercise, orthostatic tolerance at rest, drug tolerance, pulmonary function at rest, ventilation and ventilatory equivalent during exercise, lactic acid production in the blood during exercise, acid base balance at rest and during exercise, and exercise efficiency as assessed by oxygen uptake for a given exercise regime. Further studies also will be performed to examine the thermoregulatory stresses induced by these forms of exertion.

Electrical stimulation is delivered sequentially to skeletal muscle by three electrodes placed on the surface of the skin. Using carbonized rubber electrodes, stimulation is applied with a pulse width of 300 microseconds and a frequency of between 20 and 40 hertz. The amplitude of the signal is modulated to control the degree of recruitment in the underlying skeletal muscle below the electrodes. The degree of recruitment (and therefore the strength development) of the skeletal muscle was then controlled according to the computer program adjusted for the desired position of the leg during isokinetic or dynamic exercise (closed-loop control). The closed-loop control system employed throughout these experiments used the position of the limb as feedback.

During the first 9 months of the work (which is projected to extend over a number of years), experiments were conducted to collect baseline data on the cardiorespiratory responses during isokinetic and dynamic exercise.

Closed-loop electrical stimulation was used to induce isokinetic contractions in skeletal muscle of eight paralyzed individuals and to examine their cardiorespiratory responses to that form of exercise. (Four nonparalyzed subjects also were evaluated during similar but voluntary exercise as a basis of comparison with the paralyzed subjects.)

After 6 weeks of training, an experimental session was conducted during which cardiovascular and respiratory parameters were recorded during 4-minute periods of exercise at progressively increasing intensities for all subjects. Results indicated that the training program has caused an average increase in the circumference of the thigh of the eight spinal cord injury (SCI) subjects of 2.7 cm (± 0.6 cm). This was paralleled by an increase in strength of the quadriceps muscle group, which averaged 4.9 kg (± 2.8 kg). When the cardiovascular responses during 4-minute bouts of exercise were measured, it was shown that even during the most fatiguing bouts of exercise, the average cardiovascular responses were small. Heart rate increased from 83 beats per minute at rest to 101 beats per minute at the end of exercise, while blood pressure increased from a mean resting

pressure of 96 mm Hg at rest to 115 mm Hg at the end of exercise in the paralyzed subjects. There were significant differences (in the heart rate and blood pressure responses to exercise) of the paraplegic and quadriplegic subject.

Another four paraplegic, four quadriplegic, and four control subjects participated in a second series of experiments on a modified Monark bicycle ergometer to examine the effects of electrical stimulation on the cardiorespiratory responses that occur during dynamic exercise. The cardiorespiratory responses during exercise were then examined in these same subjects and compared to those of nonparalyzed controls in an additional exercise session. Both groups of subjects had similar responses to exercise. However, the magnitude of the heart rate and blood pressure responses to the exercise were different in the three groups of subjects. The differences were apparently related to the degree of damage in the autonomic nervous system associated with the spinal cord lesion that initially resulted in the paralysis. However, aerobic exercise had many beneficial effects on paralyzed individuals that may help them attain better health.

Finally, during this period of time, pilot experiments were started to assess the effect of physical training on drug tolerance of the body. Also, the initial thermoregulation experiments were started, with subjects doing armcrank ergometry in a heat chamber, to assess thermoregulatory tolerance during exercise. As the work continues these areas will be expanded until the full objectives of the study can be realized.

Influence of Sural Nerve Stimulation on Motor Unit Control in Normal Subjects and Those with Spastic Paresis

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Introduction—Stimulation of touch and pain afferents can modify muscular activity in a manner appropriate to the stimulus; i.e., the foot withdraws on painful stimulation. Spinal-polysynaptic reflexes are modifiable by supraspinal influences. Anticipation can enhance responses, while repetitive stimulation will lead to habituation and attenuation of response. In patients with lesions of the spinal cord causing impairment of conduction in descending motor pathways, spinal-polysynaptic reflexes are disinhibited.

The most commonly observed response in the lower extremities is the flexion reflex. This reflex can occur spontaneously or on very minimal mechanical stimulation of the limb. On the other hand, pressure applied to the sole of the foot may elicit forceful plantar flexion.

Partial involvement of descending motor pathways may permit the patient to extend the lower extremities and even to stand. The antigravity posture of plantar flexion and lower extremity extension can be voluntarily increased. Muscle activity tends to persist for seconds after voluntary activation ceases. It is very difficult or impossible for such patients to voluntarily flex the lower extremity in order to step. At the same time, flexor spasms occur frequently in response to nociceptive and other skin stimulation.

While recording from single motor units in first dorsal interosseous, extensor digitorum indicis, and flexor digitorum profundus, electrical stimuli delivered to the flexor and extensor surfaces of the fingers produced transient inhibition of motor unit firing. Cutaneous afferents have been demonstrated to modify excitability of motor neurons.

Some patients with spastic paresis have discovered that transcutaneous nerve stimulation applied to the involved extremity (sural nerve) improves muscular strength and control. This observation suggests that appropriate stimulation of sensory nerves might result in facilitation of motor neurons, making them more accessible to residual corticospinal innervation. Such stimulation might also increase activity in polysynaptic flexor reflexes, making it easier to oppose voluntarily the antigravity posture. Intermittent extension and flexion of the lower extremities could be induced by appropriate activation of spinal reflexes.

Methodology—The subjects were seven normal adults, two females and five males. Five patients with multiple sclerosis resulting in spastic paraparesis preventing ambulation or ambulation only with bilateral support and two patients with corticospinal tract disease resulting from amyotrophic lateral sclerosis were studied.

In this preliminary study, the influence of electrical stimulation of the sural nerve upon voluntary control of the tibialis anterior muscle was investigated. Tonic stimulation at a nonpainful level insufficient for activation of the flexor nociceptive reflex was used. The influence of stimulation upon single motor unit control and the force of maximum dorsiflexion of the foot was investigated. Normal subjects and those with weakness resulting from involvement of descending spinal motor pathways were studied.

Biomechanical Measurements—The patient was placed in a supine position with the right leg supported on a 1-inch styrofoam pad. The heel of the foot was free of the support surface. The foot was allowed to assume a slightly plantar-flexed rest position. It was then attached to a Grass strain gauge by means of a lightly padded leather strap and cable. The loop of the strap circled the foot just proximal to the metatarsal-phalangeal joint, so that toe movement would not interfere with the measurement of force of dorsiflexion. The strain gauge was connected to a DC amplifier set to produce an approximately 0.5 kg/cm deflection.

Sensory Nerve Stimulation—Two silver disc electrodes set in plastic and 2.5 cm apart were placed over the sural nerve at the level of the malleolus, with the cathode proximal. Square wave pulses of 0.05 to 0.1 msec duration at an intensity of approximately 50 to 100 V were applied at a level just sufficient to produce a "tingling-warm" paresthesia. For patients with spastic paresis, the level of stimulation was kept below that sufficient to produce dorsiflexion of the great toe or a flexion reflex, even upon stimulation lasting several minutes. Stimulus frequency and intensity were kept constant throughout the experiment.

Recording of Tibialis Anterior Motor Unit Activity—A 26-gauge monopolar needle electrode was inserted into the tibialis anterior muscle, and a single motor unit was isolated during minimal voluntary muscle contraction. Using auditory feedback of the motor unit potential to establish control, the subject became familiar with the level of effort required to activate a single motor unit and sustain its firing. During dorsiflexion of the foot and single motor unit activation, the force was measured simultaneously. The subject was then requested to dorsiflex the foot repeatedly to a level just sufficient to activate a single motor unit.

Experiment 1—Single Motor Unit Control—The subject was instructed to maintain steady firing of a tibialis anterior single motor unit during measurement of force. Following 1 minute of steady firing, audio feedback was discontinued for a period of 30 seconds. Sural nerve stimulation was then begun and continued for 30 seconds to 1 minute. Additional experiments in which the audio feedback was discontinued for periods up to 2 minutes also were performed on the same subjects.

Experiment 2—Maximal Effort—The subject was instructed to dorsiflex the foot maximally in three

trials. He/she was then told that during the next trial there would be concomitant stimulation of the sural nerve. Finally, three additional trials of maximal effort were made immediately following those accompanied by sural nerve stimulation.

Experiment 3—Following three maximal dorsiflexions the sural nerve was stimulated for a period of 5 minutes. Three maximal dorsiflexions were then repeated.

Results

Normal Subjects—Single Motor Unit Control—All subjects were able to maintain stable firing of tibialis anterior motor units in the absence of audio feedback for 30 seconds or more. Sural nerve stimulation (SNS) uniformly resulted in increased firing rate and often recruitment of additional motor units. The corresponding increase (greater than 20 percent) in force of dorsiflexion was also recorded. A two-fold to three-fold increase in force was not unusual. In several trials one subject habituated to the stimulus and did not increase tibialis anterior motor unit firing rate. All subjects experienced a definite increase in the level of effort required to maintain a stable level of tibialis anterior activation. SNS was experienced as a weight or force promoting plantar flexion.

Maximal Effort—In the two female subjects, it was possible to assess the influence of SNS upon maximal effort. In each of three trials the force of dorsiflexion was reduced.

Multiple Sclerosis Patients—Single Motor Unit (SMU) Control—SMU control in the absence of audio feedback was unstable or impersistent in three-fifths of the multiple sclerosis (MS) patients. SNS causes SMU firing and force to decrease in three-fifths and increase in two-fifths of the patients. All patients reported an awareness of increased effort required to maintain stable activity in tibialis anterior.

Maximal Effort—Maximal effort was tested in three patients. In all three, the force of dorsiflexion increased by 50 percent or more following sensory nerve stimulation. The effect was followed for up to 20 minutes. In two subjects, a period of 5 minutes of SNS without muscle contraction resulted in a progressive increase in force or dorsiflexion over a period of 10 to 15 minutes. In two patients, SNS during maximal contraction caused a decrease in force, and in one subject, an increase.

Patients with Corticospinal Tract Disease—Amyotrophic Lateral Sclerosis—In the small sample of two patients, SMU firing was stable in one subject but unstable in the other, in whom a progressive increase in firing was noticed in the absence of audio feedback. SNS caused a decrease and an increase respectively in the subjects. The sense of effort was increased in both subjects during SNS.

Maximal Effort—In both subjects the force of maximal contraction decreased with SNS, but increased following stimulation.

Discussion—Results from this small number of subjects are not conclusive. However, some consistencies are present. All subjects experienced an interaction with the stimulus, the net effect of which was an awareness of increased effort required to maintain tibialis anterior contraction at a stable level. Variability in force output during SNS can be explained in part by varying degrees of voluntary effort applied to counter the apparent resistance to dorsiflexion. Even in normal subjects, maximum dorsiflexion may be decreased by simultaneous sensory nerve stimulation.

In MS patients the influence of SNS upon single motor unit control was more variable. The ability to counteract the resistance to dorsiflexion was compromised. Also, in these patients, the increased force of dorsiflexion seen with SNS might result from the simultaneous activation of flex or reflex afferents. All subjects manifested an increased force of dorsiflexion following SNS. Some subjects reported that the experience was similar to exercising against a weight.

The final effect of increased force of dorsiflexion following SNS may be similar to post-exercise facilitation. Inhibition of dorsiflexion produced by SNS may result in greater levels of excitatory transmitter in the spinal cord during voluntary attempts at dorsiflexion. When the inhibition stops, then enhanced excitability persists.

SNS may find practical use, since the patient may not need to dorsiflex against resistance in order to improve the strength of dorsiflexion.

Further experiments will examine the effect of SNS upon maximal effort and SNS without muscle contraction upon the maximal strength of dorsiflexion following stimulation. The duration of this interesting effect also will be examined. Additional subjects must be tested using the above protocol. ■

Effect of Electrical Stimulation and Passive Stretch on Peripheral Nerve Disorders

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The loss of innervation to skeletal muscles of patients with peripheral nerve injuries can lead to complete degeneration of the muscles. The goal of this study is to establish the significance of specific treatment modalities (electrical stimulation and passive exercise) employed to overcome the state of muscle inactivity, retard muscle atrophy, improve the microvascular system, and enhance reinnervation and functional recovery.

The specific objectives of this study are to critically determine by histochemistry, light and electron microscopy, and by electrophysiology, if the above two treatment modalities are beneficial in (a) the short-term and long-term management of peripheral nerve injuries as well as (b) enhancing subsequent reinnervation. These parameters will be determined in the extensor digitorum longus muscle of rat.

This study has immediate relevance to rehabilitation of neuromuscular dysfunction. Considerable effort is expended by therapists to overcome the degenerating effects of skeletal muscles due to loss of innervation. Loss of innervation may be incurred by denervating diseases, some myopathies, accidental or purposeful nerve injuries, and limb reimplantation. The usefulness of some treatment modalities (electrical stimulation and passive exercise) currently employed to treat these conditions have not been established or are controversial. Questions as to their precise benefit to the recuperating patient are still largely unanswered. The present study addresses these problems and is designed to define the benefits and increase our understanding of the above two therapeutic modalities.

It is anticipated that therapy programs involving the use of electrical stimulation and passive exercise will be based on the results of our project. A more efficient protocol may then be established to aid the disabled to gain functional recovery in the shortest possible time, and to improve their employment chances, as well as independent living prospects. ■

Fitness Improvements and Physiological Responses to FES Exercise

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Our several years of research in upper body exercise for the disabled (wheelchair/armcrank ergometry), and more recently in functional electrical stimulation (FES) exercise of paralyzed leg muscles, suggests that higher levels of physical fitness may be achieved with combinations of these exercise modes. FES exercise can result in marked increases in strength and endurance capability. It also may improve the integrity of the bones.

However, little data are available concerning metabolic, cardiovascular, and pulmonary responses to this form of exercise and how these responses differ from those for able-bodied individuals performing the identical exercise task voluntarily. Because autonomic sympathetic nervous system control in many of these patients may be limited or absent during this peripherally induced exercise, organ system responses may be inadequate for the metabolic demands of the contracting muscles, which would severely limit performance. It is particularly important to determine whether blood flow to the electrically stimulated muscles is sufficient and whether critical variables such as arterial blood pressure and muscle temperature are within safe limits. Thus, further understanding of physiological responses to FES exercise seems necessary to reduce potential risks to patients using FES for exercise therapy and for locomotive activities.

In contrast to FES exercise, voluntarily performed arm exercise in paraplegics appears to elicit similar metabolic, cardiovascular, and pulmonary response patterns as for able-bodied individuals performing the same exercise. Thus, sympathetic influence of organ system control appears to be functional with this form of exercise. Conditioning protocols utilizing wheelchair and armcrank ergometry have been shown to be effective in improving the performance of the upper body musculature, and potentially promoting some degree of cardiovascular and pulmonary fitness. However, high levels of aerobic conditioning cannot be expected with arm exercise because the relatively small skeletal muscle mass employed usually tends to fatigue prior to the cardiovascular and pulmonary systems receiving exercise of sufficient intensity and duration to cause training effects.

Ideally, aerobic conditioning requires an exercise mode that utilizes a large skeletal muscle mass. In this way, greater demands can be placed upon the cardiovascular and pulmonary systems while reducing the effects of local muscle fatigue. Applying this principle to paraplegic patients, greater skeletal muscle mass for exercise may be incorporated by simultaneously exercising the arms (voluntarily) and the paralyzed legs (FES). This complex mode of exercise may promote upper body and lower body fitness as well as cardiovascular fitness. It also seems possible that this complex mode of exercise will permit better performance of the electrically stimulated legs (than for FES leg exercise alone) because sympathetic nervous system adjustments to exercise would be stimulated by the voluntary arm exercise.

Because of the potential for improving the physical fitness of paralyzed individuals, more research needs to be performed in: developing protocols for FES exercise; evaluating physiological response to FES exercise; and evaluating the combination of FES and voluntary exercise for aerobic conditioning.

The goal of our research project is to improve rehabilitation of individuals with lower limb paralysis or paresis resulting from spinal cord injury or stroke. A primary need for individuals is the improvement of their physical fitness. To accomplish this goal, two specific long-term objectives (with their short-term objectives) are proposed:

1. To evaluate the effectiveness of exercise programs incorporating electrical stimulation of paralyzed muscle for their potential in improving muscle strength and endurance, bone mineralization, and general physiological fitness.

- a. Develop standardized exercise protocols utilizing electrical stimulation of paralyzed muscles to provide safe and effective means of evaluating muscle performance.

- b. Develop exercise conditioning protocols for enhancing the capacity for aerobic and anaerobic exercise in electrically stimulated paralyzed muscles.

- c. Compare metabolic, cardiovascular, and pulmonary responses to electrically induced exercise of paralyzed muscles with the same exercise tasks being performed voluntarily by able-bodied individuals.

2. To evaluate the effectiveness for aerobic conditioning of exercise protocols that incorporate simultaneous electrically induced exercise of paralyzed legs and voluntary exercise of the arms.

- a. Determine peak oxygen uptake and cardiopulmonary responses for electrically induced leg extension exercise and armcrank/wheelchair ergometer exercise performed separately and in combination.

- b. Determine changes in the capacity of paraplegic individuals to propel manual wheelchairs following upper and lower body exercise programs.

Weight Transfer Training Using Biofeedback and Electrical Stimulation in Strokes and Incomplete Spinal Cord Transections

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Hypothesis—Patterned electrical stimulation of lower extremity muscles will facilitate patient awareness of the involved leg, transfer of weight to the leg, and assist therapists in teaching standing balance and weight transfer.

Method—Design and construct a weight-bearing test device, weight transfer apparatus, force feedback display and electrical stimulators. Study and control groups will be observed to determine if weight-bearing, gait, endurance, energy expenditure, and ambulation level are altered by patterned electrical stimulation.

Goal—Improved gait training program for patients recovering from certain neurological conditions, shortening hospitalization time, and an improved level of ambulation.

[See also **IV. Spinal Cord Injury, B. Medical Treatment**, The Effect of Electrical Stimulation of Muscles on the Cardiovascular System and **C. Spinal Cord Regeneration**, The Effects of Application of Direct Current on Regeneration of Nerve Cells]