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XII. Neurological/Vascular Disorders

A. General

Electrophysiological Studies on Nerve Repair and Regeneration

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—Although modern microsurgical technique makes nerve repair possible, it rarely results in desired nerve functional recovery. In the treatment of nerve injuries, physicians mainly depend on subjective criteria to make clinical decisions regarding the repair method and the type of care in the regeneration process. A quantitative characterization of nerve lesion, repair, and regeneration would offer to physicians an objective tool to measure the degree of lesion, to test the methods available, and to develop better clinical methods.

With the help of an evaluation tool, better methods of nerve repair could be developed such as optimum control of the size and configuration of the scar at the repair site. Better nerve regeneration aids could be developed such as a plastic nerve coupler, external electromagnetic fields, etc. Our goal is to equip physicians with a tool to quantitatively assess an abnormal nerve so that the appropriate clinical treatment can follow.

Progress—A traditional evaluation method is to measure the area ratio of two compound action potentials (CAPs) recorded from stimulating axons both distal and proximal to the repair site. This indicates the fraction of axons functionally connected. Such a method does not give the subpopulation contribution, and requires monophasic recordings that must be obtained intraoperatively. We developed the distribution of added delays (DAD) as a quantitative description of the focal lesion or repair site that can provide detailed information regarding the relative number and health for each fiber group; and we propose two methods for evaluating the DAD, namely, intraoperative and skin surface evaluation methods.

A CAP is conventionally regarded as a linear superposition of Single Fiber Action Potentials (SFAPs). In dealing with the intraoperative evaluation, the area of SFAPs is assumed to be a universal constant that can be estimated from available experimental data. By invoking statistical arguments, the first approximation for the distribution of added delays due to a mechanical lesion is proposed to be the same for all conduction-velocity groups. The DAD is then computed from the recorded CAPs using the intraoperative monophasic SFAP-CAP model. The parameters in the model will also be applied to the skin surface evaluation method. In the latter approach, the peripheral nerve is idealized as existing in a semi-infinite volume conductor. The method of images is used to find the SFAPs on the skin surface. Since there is more uncertainty in the skin surface evaluation method than the intraoperative evaluation method, comparison of results obtained from the two methods will enable optimization of the parameters of the volume conductor model.

Preliminary Results—The animals and equipment are already on-line for data acquisition. For the intraoperative evaluation method: the DCV and DAD have been calculated from previously recorded data from monkeys. Mathematically, the reconstruction technique shows that the numerical results are consistent with the model. Physically, the results agree with expectations. Currently, we are designing an experimental verification of the DAD results.

For the skin surface evaluation method the physical and mathematical analysis is on hand. The numerical computation programs for calculating the DCV and DAD are under development.

Nerve Coupler: Sutureless Peripheral Nerve Repair at the Fascicular Level ---

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Sponsor: *VA Rehabilitation Research and Development Service*

Purpose—Our purpose is to improve the functional results of current methods of peripheral nerve repair. Suture results are often unsatisfactory because of poor coaptation of fascicles, scar tissue at the repair site and neuroma formation. This study continues the development of a new method of sutureless, mono-fascicular, peripheral nerve repair.

Progress—The coupler consists of three parts: proximal and distal cuffs and a central coupler. The ends of a transected nerve (fascicle) are pulled snugly into the proximal and distal cuffs with the aid of a fine hook. The cuffs are then fitted tightly into the central coupler. Twenty-five rats were used to compare the nerve coupler to standard suture repair. The animals were evaluated after 1, 2, and 3 months for the short-term study and from 9–15 months for the long-term study. The short-term animals were evaluated by qualitative histology. The long-term animals were evaluated by qualitative histology, and, in addition, quantitative histology and physiology to determine axonal regeneration.

Preliminary Results—Short-term animals showed fewer adhesions in the coupler repairs than in the suture repairs. Neuromas were absent in all coupler repairs and minimally present in the suture repairs. Alignment was slightly better in the coupler repairs than in the suture repairs. In the long-term animals, there were increased adhesions in the suture repairs, compared to the coupler repairs. Repair site organization appeared slightly better in the coupler repairs than in the suture repairs. The quantitative histology showed the suture repairs to have slightly greater mean diameters than the coupler repairs. The electrophysiological evaluation showed coupler repairs to be better than the suture repairs in six of the ten animals, but this was not statistically significant.

Future Plans/Implications—Further refinements of the nerve coupler are being planned. The coupler is also being used to introduce adjuncts to improve nerve regeneration.

Factors Limiting the Tactile Perception of Form ---

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Sponsor: *National Institutes of Health*

Purpose—The proposed work will continue a program of empirical and theoretical research that seeks to understand the sensory and non-sensory factors that limit the perception of tactile spatiotemporal patterns. The earlier research has led to a model of recognition of static raised characters sensed by the finger. The major thrust of the work will be to further test the model and hopefully extend it to a broader empirical domain (to spatiotemporal patterns presented to different body sites using a variety of

tactile displays). Among the experiments being proposed are: 1) further work on the measurement of cutaneous spatial sensitivity using sinewave gratings; 2) a comparison of pattern perception at different body loci; 3) an attempt to disentangle sensory and nonsensory factors that account for the large individual differences in tactile pattern perception; and, 4) tactile (and visual) recognition of characters drawn from various set sizes (e.g., 8, 15, and 26 characters).

Neural Pathways Involved in Tactile Discrimination

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Sponsor: National Institutes of Health

Purpose—The proposed research is part of a project whose long-term goal is to add to our understanding of the tactile information processing capabilities and limitations of the somatosensory system, especially those neural regions and systems responsible for processing tactile information derived from mechanical stimulation of the glabrous surfaces of the hand. Specifically, it is proposed to examine functional properties and stimulus-response relationships of single neurons of three spinal pathways which project, directly or indirectly, to the thalamic ventrobasal complex: the spinocervical tract, the postsynaptic dorsal column system, and the spinothalamic tract.

Microelectrodes will be used to record extracellular activity of cell bodies or fibers in response to controlled mechanical stimulation of the glabrous skin of the raccoon's forepaw. Neurons will be identified as belonging to one of these three systems by antidromic electrical stimulation of the appropriate region of spinal cord or brain stem. Specific parameters to be examined include modality and adaptive properties, absolute thresholds, and receptive field areas, as well as effects of controlled

mechanical stimulus velocity, displacement, and force on both dynamic and static discharge. Additionally, neurons will be sought which display properties suggesting excitatory or inhibitory convergences, and which display properties of feature detectors (e.g., preferential response to edges or laterally moving stimuli). Properties of neurons of the three spinal pathways will be compared with each other, as well as with properties of both primary afferents and neurons of the cuneate nucleus and thalamic ventrobasal complex, previously studied in this laboratory.

These studies should contribute to our knowledge of the differential contribution of three major somatosensory pathways to the processing of tactile information acquired by a behaviorally salient tactile organ system, the forepaw or hand, especially its glabrous surfaces. This, in turn, should provide information relevant to the design of devices for the utilization of tactile information by individuals handicapped in other sensory modalities. Findings should also have neurological relevance to the differential diagnosis of spinal cord injury or disease.

A New Approach in the Relief of Pain of Leprous Neuritis

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Sponsor: Poona District Leprosy Committee

Purpose—Leprosy neuritis is known for its associated excruciating pain. A search of the literature, however, did not reveal a reference to the use of transcutaneous nerve stimulation (TNS) for relief of the pain of leprosy neuritis. It is the use of electrical stimulation for the relief of pain in leprosy that led to the present investigation with the following goals: 1) to demonstrate the effectiveness of TNS; and 2) to develop a suitable method of application.

Progress—The instrument of stimulation used in this study was a compact device working on dry cells which could be operated by the patient. Out of 40

patients studied, 33 had ulnar nerve involvement, 5 had median nerve involvement, and 2 had lateral popliteal nerve involvement. All the patients had severe pain and no sustained relief was obtained by pain-killing drugs or splints. Subjective parameter used to measure the pain were: a) 4+ severe intolerable pain making patients extremely restless with much hyperaesthesia and no relief with long-term drugs and splints; b) 3+ pain less than 4+ with less hyperaesthesia; c) 2+ pain only on light touch and movement of the limbs; and, d) 1+ pain only on tapping the nerve.

Electrodes were placed above and below the site

of pain. For ulnar nerve therapy, they were placed above and below the medial epicondyle. For the median at wrist, both electrodes were placed on the flexor surface of the forearm. For the lateral popliteal nerve at the neck of the fibula, both electrodes were placed on the anterior surface of the leg. By turning the output and rate control knobs, the maximum tolerable sensation to the patient was adjusted. A minimum of one-half hour duration for each test was set. Additional tests were given, depending on the severity of pain.

Results—There was a total relief of pain in 29 patients; 8 patients showed partial relief; and 3 patients had no relief at all. TNS works on the following hypothesis: when nociceptive impulses reach the posterior horn of the spinal cord a “gating”

or control mechanism determines which signals ascend the spinothalamic tract to the brain, where pain is perceived. The “gate” is facilitated or inhibited by peripheral afferents. Increased C fiber action inhibits the gate, allowing passage of impulses, while a relative increase in large myelinated A fiber activity closes the gate, blocking pain.

The results indicate a positive role of TNS in the treatment of leprosy neuritis, as most patients obtained a remarkable degree of relief from pain. It is not possible to predict beforehand whether a particular patient will be benefitted by TNS. But, as TNS is such a simple procedure, the authors feel that it should be tried in all cases of nerve pain. In cases where deformity is threatening, other measures like steroids, etc., should be implemented immediately, without waiting to observe the results of TNS.

Treatment of Leprosy Neuritis by Perineurial Steroid Injection

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Purpose—Leprosy is the single cause of peripheral neuritis in the world today and, if left untreated, can lead to muscular paralysis and consequent deformities such as claw hand, foot drop, lagophthalmos, etc. Early treatment of leprosy neuritis can totally prevent the occurrence of deformities. Leprosy neuritis is also known for associated excruciating pain. Hence, the treatment aims at relief of pain and prevention of muscular paralysis.

The nerve damage in leprosy occurs for two reasons: 1) raised intraneural pressure due to inflammation with resultant ischaemia; and, 2) when the nerve is thickened due to the intraneural changes, extraneural compression and sometimes traction trauma occur at specific sites of nerve involvement, adding to the severity. Depending on the severity of neuritis and nerve damage, it can be treated medically and/or surgically with the aid of physiotherapy. Medical treatment usually involves the use of oral steroids. The role of steroids as an anti-inflammatory agent that diminishes the nerve edema and controls the accentuated response of cell mediated immunity is well known. However, oral steroids for prolonged periods produce side effects such as water retention, G.I.T., etc. This led us to

the concept of perineurial steroid injections, which produce a safer and local effect.

Progress—The procedure consists of injecting a steroid depot preparation along the nerve, either diluted with distilled water and with or without plain Xylocaine (for instant pain relief). The study involved use of triamcinolone acetamide 10 mg. or 40 mg/ml. The study was conducted on 50 cases and included 27 ulnar nerves, 12 median nerves, and 11 lateral popliteal nerves. The injection was given for two purposes: 1) relief of pain; and, 2) as an aid to motor recovery by physiotherapy.

Use of distilled water as a diluent which is hypotonic to body tissues may help to extract the edema fluid from the nerve into the paraneural tissues. The relief of pain by steroid injection takes 1 to 2 hours. The patient gets instant pain relief by injection of 2cc plain 2 percent Xylocaine. Physiotherapy should be started immediately, if the injection is given with an aim at the motor recovery.

Results—Of 50 nerves injected, 26 were treated for relief of pain and 24 of these responded positively. In 24 cases where injection was aimed at motor

recovery, 20 responded favorably. It was observed that nerves treated for relief of pain included predominantly ulnar nerves and, on the whole, motor recovery in ulnar nerves was poor. However, the median and lateral popliteal nerves showed good motor recovery. Factors such as disease and passage through the rigid fibro-osseous tunnel, which increases the extraneural compression and traction trauma, attribute to the poor recovery of the ulnar

nerve.

It was observed that the majority of patients in the tuberculoid spectrum of the disease showed a good response and those with borderline lepromatous showed a poor or a temporary response. During therapy a close watch was kept on nerve function deterioration and, if so observed, prompt surgical intervention was sought.

Inhibitive Casting as an Adjunct to Therapy in Children with Cerebral Palsy

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Purpose—The objective of this study is to examine the benefits of inhibitive casting as an adjunct to therapy for young children with cerebral palsy.

The specific goals of the project are as follows:

1) to determine the effects of inhibitive casts on gross motor function and range of motion in the lower extremity; and, 2) to determine the effects of inhibitive casts on the alignment of joints in standing, on the width of the base of support in standing and walking, and on the pressure points under the feet in standing.

Progress—This project is being carried out jointly between the Therapy Departments at the Hugh MacMillan Medical Centre and Bloorview Children's Hospital, and the Gait Laboratory in the Rehabilitation Engineering Department at the Hugh MacMillan Medical Centre.

Four children are participating in this study, two in a casted group, and two in a control group. Clinical and gait laboratory assessments are performed at 0, 4, 8 and 12 months. The children in the casted group were assessed both with and

without casts at 4 and 8 months, that is, at the beginning and end of the casting period. All four children are undergoing neurodevelopmental therapy throughout the study.

Clinical assessments include Gross Motor Function Assessment, assessment of reflexes and range-of-motion in the lower extremity joints. Gait laboratory assessments include measurement of alignment of joints, width of base of support during walking, stride length, and speed of walking.

Preliminary Results—To date, all four children have undergone three assessments, at 0, 4 and 8 months. Preliminary results indicate positive trends while wearing the casts, including a decrease in forward tilt of the pelvis, a decreased hyper-extension of the knee, increased dorsiflexion, and decreased valgus at the ankle in standing. The same changes are noted when the casts are not being worn, but to a lesser degree. Results from the final gait assessment will be used to determine the carry-over effect of wearing the casts.

B. Arthritis

Evaluation of Osteoporosis by Ultrasound and CAT-Scan

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Purpose—The diagnosis of advanced osteoporosis may be based on changes in the bone density and/or by measuring cortical bone thickness, both of which are generally determined from roentgenological examination of bone. However, the roentgenological evaluation of osteoporosis is qualitative in nature and it requires a minimum bone loss of 30 percent before an unequivocal roentgenological diagnosis of osteoporosis can be made. The aim of this study was to determine if cortical bone thickness and bone density can be measured accurately by ultrasound and CT.

Progress—Three embalmed human femurs were used in this study. The cortical bone thicknesses and bone densities were measured at 16 locations of each femur using a CT unit (Ohio - 2020, Technicare). Thicknesses at the same locations were then measured by ultrasound using the pulse-echo technique. An immersion-type transducer (Dapco, S1H5) was used at a frequency of 5 MHz with a pulse-repetition frequency of 100 Hz. Both the specimen and the transducer were immersed in a water tank. Once these ultrasonic measurements were completed, the bones were sectioned and the actual thicknesses at the same locations were measured with a micrometer. The bone densities at each location were also determined.

Preliminary Results—The individual micrometer measurements made on 48 locations were compared with the corresponding ultrasound and CT data. The correlation coefficients between the actual thickness with the ultrasonically measured thickness was 0.95 and with the CT 0.62. We attribute the error in the CT data partly to the technique involved in the measurement (it can read only integral numbers) as

well as to the subjective nature in selecting bone edges and thus in positioning the electronic cursors. Variations between the actual bone densities for these samples were minimal and it did not show significant correlations with the attenuation of ultrasound.

The results of the *in vitro* study suggest that ultrasonic measurement of cortical thickness is more accurate than similar measurement by CT. Moreover, ultrasound does not use ionizing radiation, and it is significantly cheaper to use than the CT. Thus, ultrasound technique, when fully developed, may be more suitable for large scale screening for osteoporosis.

Future Plans/Implications—This study is being continued in order to compare the relative accuracy of ultrasound, CT, and photon absorptiometry methods in evaluating osteoporosis.

Publications Resulting from This Research

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- Wave Propagation Characteristics in Long Bone Reflecting Structural Changes Due to Aging.** Chen IH, Saha S, *Biomedical Engineering V: Recent Developments* (S. Saha, Ed.), Pergamon Press, 388-391 (abstract in *Biomaterials, Medical Devices and Artificial Organs*, 14(1 & 2):121, 1986).
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Arthritis Rehabilitation Unit

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Purpose—The purpose of the Arthritis Rehabilitation Unit (ARU), which consists of five beds in a 22-bed general rehabilitation unit, is to identify methods of managing arthritis patients and define protocols for rehabilitation professionals working with this patient population. The staff consists of a rheumatologist, orthopaedic surgeon, psychiatrist, rehabilitation nurses, occupational and physical therapists, social worker, psychologist, a vocational rehabilitation counselor and therapeutic recreation counselor.

Progress—To date, more than 180 patients have been admitted to the inpatient rehabilitation program. The primary diagnosis is rheumatoid arthritis, although patients with other diagnoses such as osteoarthritis and ankylosing spondylitis are admitted.

During the grant period (1983-1987), the staff of the ARU has been collecting demographic data on patients participating in the program. In addition, the staff is using the Arthritis Impact Measurement Scale, an outcome measure developed at the Boston University Multipurpose Arthritis Center, to assess patients on nine scales: mobility, physical activity, dexterity, household activity, social activity, activities of daily living (ADL), pain, depression, and anxiety. Three-month, 6-month, 12-month, and 18-month follow-up data are collected on all the patients at the rehabilitation unit to help determine the long-term benefits of the rehabilitation program. In addition, psychological testing has been completed, on admission, for more than half of the patients with rheumatoid arthritis.

Training efforts have included a program in arthritis for the rehabilitation nurses on the unit, a physical therapy consultant to discuss management of musculoskeletal problems in arthritis for the entire staff, a statewide program for public health nurses in the rehabilitation of patients with arthritis, and a nationwide video conference on management of arthritis using the multidisciplinary team approach.

Results—The staff has completed a survey of more than 500 rehabilitation units to help determine the scope of arthritis rehabilitation in the United States and the need for staff training in management of arthritis patients.

The ARU staff has been engaged in a cooperative effort with the Virginia Department of Rehabilitation Services (DRS) to examine the nature and extent of services for clients with arthritis. DRS data on arthritis clients in 1985 has been reviewed. A sample of 52 arthritis clients referred to DRS in 1986-87 participated in a project to maintain their employment. Project strategies included job site visits and job site modifications using rehabilitation engineering and the resources of DRS.

The staff has completed two research projects. One project was an investigation of sleep problems in patients with rheumatoid arthritis. A second project was an outcome study of equipment use following discharge of 50 patients from the inpatient rehabilitation program. A third study—validation of a self-report activity analysis instrument—is an ongoing project.

Impact of Arthritis Self-Care for Rural Persons

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Purpose—The purpose of the Arthritis Self-Care (ASC) Project is to develop and evaluate the impact of arthritis self-care programs for rural persons. The

independent variable is a type of self-care program, home study/correspondence course or small group; the dependent variables are knowledge, self-care

behavior, helplessness, pain, depression, disability, and social support. The extent of participation in the self-care program, assessed by the number of lessons completed and extent to which behavioral contracts are made and fulfilled, is controlled for statistical purposes.

Progress—We completed the curriculum, developed instructional packages for both the home study and small group programs, and began community entry in 1983 and 1984. In 1985 and 1986 we completed training programs for the 55 community members who implemented the self-care programs in the counties designated as the research setting and offered the intervention, collected data, and began data analysis. Throughout the 5 years we have presented the work of the Project at professional meetings: we have begun to publish our findings.

Preliminary Results—Our self-care programs reached about 500 rural Virginians. Most of the participants

were older, white females with diagnoses of osteoarthritis (85 percent) and rheumatoid arthritis (15 percent). Most (95 percent) completed at least five of the six lessons comprising the programs.

Although all follow-up data have been collected, we have not completed data entry and analysis. Initial analyses suggest that our self-care programs have: 1) increased participants' knowledge and practice of self-care behaviors and decreased their feelings of helplessness to manage their diseases; and, 2) had no effect on participants' pain, disability, and depression. Finally, the home study and small group programs appear to have similar impacts. Further analyses, to clarify the meaning of these initial findings, are in progress.

Future Plans—More ambitious projects to explain the processes by which self-care education has an impact on key clinical parameters and to identify the types of persons most likely to benefit from self-care education are planned.

Endurance Training with Management of Fatigue in Rheumatic Arthritis and Systemic Lupus Erythematosus

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Purpose—The goals and objectives of this study are threefold: 1) to evaluate the long-term costs and effectiveness of aerobic training in improving fatigue, work capacity, and quality of life in rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE); 2) to use aerobic conditioning in SLE and RA as a probe and define the physiologic and metabolic parameters of fatigue and their changes after conditioning; and, 3) to define work ability and performance in patients with SLE and RA.

Progress—This project has been funded since October 21, 1986. As of July 1, 1987, 73 of the 400 potential subjects have been sent recruitment letters.

Of this number, 22 subjects have agreed to participate over the phone, 11 declined participation, 5 have been excluded, 11 cannot be reached, and 24 are presently being telephoned. The first participant will finish the 12-week aerobic training in the middle of August. One subject is being entered into the study each week.

Future Plans/Implications—Fatigue is a disabling symptom in many chronic diseases and causes considerable loss of productivity and impaired quality of life. Aerobic exercise, if effective, could provide an economic rehabilitation intervention.

Multipurpose Arthritis Center: Community Component—Coping Responses to Rheumatoid Arthritis

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Progress—The NIH Multipurpose Arthritis Center is currently funding four major educational efforts. The computer assisted patient education project has successfully completed a program for patients and families of patients with rheumatoid arthritis. This has been well received by patients and is currently undergoing testing by both patients and their families. Editing of the program will proceed along with the evaluation process. The physician assisted program has completed a longitudinal study in which physicians are in contact with a patient with rheumatoid arthritis (the computer) over a period of seven years. This is being evaluated by various types of physicians and by medical students and editing of the program will continue as the evaluation proceeds. The third program involves developing

methods for teaching Family Medicine Residents and is continuing during the next year in which more data will be available and the testing methodology improved. The fourth program involves teaching methodology and content development in the area of physical therapy. Undergraduate teaching of rheumatology by our NIH Multipurpose Center funded physical therapist-educator is now in progress and efficacy will be evaluated during the coming year.

Results—The research project on C3 phenotypes has led to interesting findings in that juvenile onset systemic lupus erythematosus patients have a higher incidence of one phenotype than adult onset patients. Patients with other rheumatic diseases are currently being evaluated.

General Clinical Research Center: “Riadura” and NSAID in Rheumatoid Arthritis Treatment

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Sponsor: National Institutes of Health

Progress—The Clinical Research Center at the University of Oregon Health Sciences Center provides inpatient, outpatient, and Core laboratory facilities for use by faculty investigators conducting a series of studies on the etiology, pathophysiology, and treatment of a variety of human diseases. The Center serves as a unique institutional resource for bringing together scientists from a variety of preclinical and

clinical disciplines for multidepartmental cooperative investigative efforts. Important programs of research currently underway in the Clinical Research Center include oncology, vasospastic and atherosclerotic vascular disease, immunology, endocrinology, narcotic addiction, cardiology, nephrology, and hypertension.

Multipurpose Arthritis Center: Professional Education in Sexual Rehabilitation of Arthritis Patients

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Progress—The Multipurpose Arthritis Center (MAC) of the University of Alabama in Birmingham (UAB)

is a multidisciplinary effort by faculty and staff of the Schools of Medicine, Dentistry, Nursing, Public

Health, and Community and Allied Health, and the University Hospitals and Clinics. A broad spectrum of ongoing and proposed activities is focused on basic and clinical research, education, community activities, and health services research.

Research in MAC includes studies in the areas of immunology, virology, mycoplasmaology, molecular biology, genetics, connective tissue biochemistry, and clinical rheumatology. The Education Component spans the spectrum of professional, allied health, postgraduate and public and patient educational activities. The Community and Health Services Research Component highlights socioeconomic factors that influence the well-being of patients with rheumatic disease.

This application includes feasibility proposals in fundamental research from seven investigators to study basic mechanisms involved in the pathogen-

esis of the rheumatic diseases. Five new projects are proposed in patient and professional education. Six projects are proposed in the Community and Health Services Research Component, and include critical evaluation analyses applicable to this important area. In addition, three Core Units are proposed: continuation of the Hybridoma Core Facility, and development of a new Immunogenetics Core and a new Evaluation, Biostatistics, and Data Management Core Unit.

The overall goals are to coordinate existing arthritis programs and initiate new programs in arthritis so that we can achieve: 1) greater knowledge of the etiologies, pathogeneses and therapies of the rheumatic diseases; 2) better systems of health education; 3) documentation of current and improvement of future patient services; and, 4) a more enlightened community attitude toward arthritis.

Multipurpose Arthritis Center: Education Component—Arthritis Patient Education Model

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Progress—The UNC-CH Multipurpose Arthritis Center (MAC) represents a broadly-based, coordinated effort by faculty and staff in the Schools of Medicine, Nursing, and Public Health toward development of new basic knowledge, enhanced education, and improved mechanisms for health care delivery in arthritis. Providing special impetus and support in this regard are the following: Area Health Education Centers Program; N.C. Rehabilitation Network; UNC Rehabilitation Program; the ongoing Arthritis Rehabilitation in Industry Program; and the N.C. State Arthritis Act and its legislated planning committee. Certain new directions in an already well-established immunology research program will be pursued, e.g., study of the idio-*type*/anti-*idiot*ype network in human autoimmune disease, analysis of tissue deposited immune complex function in SLE, and the establishment of an Immunoreagent/Immunoassay Core Facility.

The major thrust of MAC proposed activities, however, concerns a series of innovative projects

in the Education and Community Components. These include: 1) study of a new psychosocial model for patient education; 2) development of educational models in arthritis for occupational and physical therapists, both as part of a core undergraduate curriculum, and also in the community for those already in practice; 3) development of a health care model for ambulatory elderly patients with arthritis to be conducted jointly by nurse practitioners and occupational therapists; 4) analysis of the Social Security Administration disability determination process for arthritis; 5) development of a model training program in arthritis and rehabilitation for industrial managers with applicability to the general problem of the worker with arthritis; and, 6) an epidemiologic study of patterns of arthritis care in Eastern North Carolina. In all of these projects, particular emphasis has been placed upon effective evaluation, which will be aided by an Evaluation Core.

A National Arthritis Data Source (ARAMIS)

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Sponsor: *National Institutes of Health*

Purpose—The American Rheumatism Association Medical Information System (ARAMIS) is a rheumatic disease computer data bank system containing longitudinal clinical data for approximately 19,000 patients and 120,000 patient encounters, and representing more than 100,000 patient-years of observation. The system operates from an IBM 370/3081 computer at Stanford University and is accessed nationally through TYMNET or TELENET communications networks using the Time-Oriented Data Bank (TOD) data management system.

The program is based upon the premises that chronic diseases have become the most prevalent health problems, that study of such diseases requires observation of occurrences over prolonged time periods, that the expense of longitudinal study requires use of economies of scale, that patient outcome in chronic disease results from a complex interplay between multiple factors, and that many important questions need to be studied with observational, in addition to experimental, techniques. This program has the goal of improving knowledge, management, and patient outcome in arthritis by providing long-term information relating to disease severity, patient characteristics, social factors, and treatment to patient outcome. The program has two

major aims: first to continue to develop a national data resource of high quality, longitudinal, accessible clinical data, and second, to employ these data in a systematic, multicenter investigative program of major clinical questions in the rheumatic diseases.

Progress—Program priorities include the classification and definition of diseases, the systematic study of long-term (6 to 20 years) outcomes, the economic impact of illness and treatment, and study of regional and national differences. Thirty clinical investigators and epidemiologists at 12 institutions undertake over 50 projects annually. The present proposal includes classification studies of osteoarthritis, rheumatoid arthritis, vasculitis, and systemic lupus erythematosus, economic impact studies in each major disease, comparative studies of arthritis at different sites, population-based studies of incidence and prevalence, and long-term studies of outcome in rheumatoid arthritis, juvenile arthritis, scleroderma, systemic lupus, osteoarthritis, and following joint surgery. With this project, 15 years of data development at numerous institutions are brought to bear upon major clinical questions, and very large and detailed longitudinal patient data sets are made nationally available.

Multipurpose Arthritis Center: Stanford, CA

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Sponsor: *National Institutes of Health*

Purpose—The Stanford Arthritis Center (SAC) conducts research, educational, and patient care programs to improve health outcomes of arthritic patients. In particular, SAC designs and implements new educational and community programs and gauges their success by outcomes experienced by patients. To do so, SAC draws upon multi-faceted research activities, large numbers of patients and community physicians, cooperating hospitals and health services, a major system for managing data (ARAMIS),

and skills of economists, epidemiologists, educators, and health professionals in assessing new programs.

Central to SAC activities is development of reliable methods to evaluate health outcomes. SAC has developed instruments measuring functional status, symptoms, adverse effects of drugs and costs of health care for arthritic persons; other instruments, particularly concerning psychological variables and quality of life, are in developmental phases. This work depends upon a Core Unit which assists in

experimental design, instrument development, data management and computational issues, biostatistics and data analysis.

Progress—Seven successful programs will continue concerning: long-term outcomes for rheumatoid arthritis, juvenile arthritis and joint replacement; self-management education for patients; comparison of osteoarthritis outcomes in 3 different health services; comparison of team versus individual physician care of chronic arthritis of the elderly; and, treatment of refractory lupus nephritis with total lymphoid irradiation. Six new projects are added, all related

to chronic arthritis: identification of influential psychological factors; analysis of incidence by population characteristics; a new method for estimating indirect costs; the impact of exercise on incidence of osteoarthritis; distinction between seronegative and seropositive arthropathies; and, search for a pathogenic antigen in cartilage of rheumatoid joints.

Improved outcomes for arthritic patients nationally must occur within limits of financial resources. This Center develops and/or evaluates care programs for large groups of arthritic patients with the objective of improving the effectiveness, efficiency and satisfaction achieved by health services.

Northeast Ohio Arthritis Center Support: Legal Aspects of Chronic Illness: A Study of Arthritis Patients

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Sponsor: National Institutes of Health

Purpose—The long-term objectives of this proposal are: 1) to expand efforts directed towards the education of health professionals, patients, families, and the general public; 2) to develop, implement, and evaluate prototype community/health services programs at a high level of scientific endeavor; and, 3) to expand clinical and basic research efforts. New programs in education include 1) an evaluation of use of the education-influential in teaching rheumatology to family practice training units; 2) studies of continuing graduate medical education in arthritis with emphasis upon involvement of the learner in the identification of objectives; and, 3) augmentation of an audiovisual library as an umbrella educational resource. Specific new community programs include 1) a systems analysis of arthritis health care delivery in Northeast Ohio; 2) identification of the legal needs of arthritis (chronically ill) patients; 3) studies of the perceived needs of arthritis patients, and available

resources to meet those needs as viewed by the patient and community health nurses; 4) the establishment of an industrial database pertaining to arthritis problems and management in Northeast Ohio; and, 5) an evaluation of NEOMAC/community organizational behavioral interrelationships.

Research programs are targeted to study cartilage metabolism and osteoarthritis, mediators of inflammation, acute phase reactants, the immune response in arthritis, genetic/clinical interplays in ankylosing spondylitis, and myopathic disorders. Core programs include a cell/tissue culture unit, and an evaluation/education core as an overall resource to the center's project components. Administration includes administrative policy, executive, steering (operations), and community advisory committees to fully interdigitate center/University/community interface.

Multipurpose Arthritis Center: Community Component—Arthritis Impact Measurement Scales

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Sponsor: National Institutes of Health

Purpose—This proposal describes in detail a plan to expand and strengthen the Boston University Multipurpose Arthritis Center. A program of activities and specific projects will be pursued in three major components: research, education, and community/health services research. The proposal also describes a plan to support areas of special research interest by means of two core units, and to continue an effective administration component.

The research component will build on a strong base of work funded from other sources. In addition, four developmental and feasibility studies are proposed: 1) a study of vitamin A metabolism in prealbumin forms of amyloid disease; 2) the isolation of cDNA clones for serum amyloid A; 3) an investigation of stair climbing in arthritis; and, 4) a study of the difficulty dimension in functional assessments.

MAC education efforts will continue to be aimed at a broad spectrum of arthritis health professionals in conjunction with the Schools of Medicine, Nursing and Allied Health Professions of Boston University. Specific projects in the education component will include an evaluation of the current status of house officer education in rheumatology at internal medicine and family practice residency programs, a study of the effects of a targeted training program on interpersonal skills of physical therapy

students and an investigation of coping in chronic arthritis.

Activities in the community/HSR component of the MAC will continue to focus on the inner-city community in conjunction with the Department of Health and Hospitals of the City of Boston. Seven specific community/health services research projects are proposed: 1) a project to modify the Arthritis Impact Measurement Scales for use in clinical practice; 2) a project to develop a computer-based community network for clinical rheumatology trials; 3) an inner-city nursing home project combining outreach and data collection for this important population; 4) a study of the rheumatology referral behavior of general internists and family practitioners; 5) an epidemiologic study of osteoarthritis in conjunction with the Framingham Heart Study; 6) an epidemiologic study of oral contraceptives and rheumatoid arthritis in conjunction with an established drug epidemiology group; and, 7) an investigation of the relationship between stressful life events and disease activity in rheumatoid arthritis.

Two core units are proposed: an Amyloid Studies Core Unit and a Research and Evaluation Support Core Unit. These core units will support numerous investigations in areas of special interest to this center.

Occupational Role Dysfunction in Illness: Comparisons with Normative Data

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Sponsor: National Institutes of Health

Progress—The Role Checklist is currently used by the Occupational Therapy Service. The purpose of this project is to determine if the Role Checklist can discriminate among subjects with various diagnoses. The data generated from this project will also be examined against pre-existing data from a normal population to determine if the Role Checklist can discriminate between this sample and a normal

population. The subject population will include inpatients and outpatients between the ages of 18 and 90, who have been referred to the Department of Rehabilitation Medicine, Occupational Therapy Service.

To date, data on 80 subjects has been gathered. A total of 400 subjects is required with 50 from each of the following diagnostic categories: cancer, cystic

fibrosis, eating disorders, major affective disorders, neuromuscular disorders, rheumatoid arthritis, schizophrenia, and systemic lupus erythematosus.

Thus far, approximately 57 subjects have come from the NIMH units with the remainder from the other seven categories.

Multipurpose Arthritis Center: Problem-Oriented Educational Program for Arthritis Using Aerobic-Type Exercise

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Sponsor: National Institutes of Health

Purpose—This Multipurpose Arthritis center (MAC) proposal engages scholars and scientists from various schools and departments of Northwestern University and from the community in a comprehensive arthritis program. Five feasibility projects are proposed: cell cytotoxicity in rheumatoid arthritis; phenytoin modulation of collagen and collagenase synthesis in synovial cells and effect on macrophages; connective tissue constituent immunogenicity in juvenile chronic arthritis; synovial pathology in early osteoarthritis; and analysis of osteoarthritic and rheumatoid bone for use in prosthesis design. These projects will support new young scientists as well as allow three senior scientists to extend or redirect their work.

The second area of focus is an interdisciplinary educational program, utilizing a problem solving approach, aimed at both professionals and patients. The three projects proposed are: train and evaluate rheumatology fellows as teachers of medical residents using a new curriculum to be developed in outpatient musculoskeletal disease; evaluation of a problem-oriented, aerobic-like exercise program for arthritics; and the use of a discussion group format to enhance problem solving skills in the older os-

teoarthritic. The interdisciplinary team includes professional educators, a medical education evaluator and health professionals at the medical school.

The third area of focus, community and health services research, draws upon a strong base of community involvement combined with the research excellence of Northwestern's Center for Health Service and Policy Research (CHSPR). Three interrelated projects explore various aspects of knee pathology. The first will develop and validate a measure of outcome for a subsequent comparative study. The second will examine the costs of treatments for osteoarthritis of the knee. The third builds upon the work of the earlier two to compare costs and efficacy of arthroscopic surgery and alternatives. Three additional projects add breadth to the research agenda focusing upon musculoskeletal impairment in the elderly, status of families with juvenile arthritic children and a multi-center study of Social Security payment allocation systems.

The Biostatistics and Data Management Core will provide individual project technical assistance as well as database management for a computerized case-finding patient index.

Study of Behavioral Aspects of Rheumatoid Arthritis

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Sponsor: National Institutes of Health

Progress—The long-term objective of this project is to gain a fuller understanding of the behavioral aspects of rheumatoid arthritis (RA), a chronic condition which affects over 5 million persons in the U.S. and is a leading cause of disability. The

major question to be explored is why and how do some persons with RA manage to cope very effectively with this disease, while others appear to become helpless in the face of it? Specifically, this investigation aims to investigate longitudinally the

health and illness behaviors of a sample (panel) of persons with RA to determine the extent and developmental course of learned helplessness and active coping in persons with this condition. This investigation will lay the groundwork for future interventions aimed at helping persons with RA cope with their illness.

A panel of 360 patients with RA ranging from those newly-diagnosed to those who have had the condition from 5-6 years will be studied at 6-month intervals over a 3 to 3-and-a-half year period via mailed questionnaires and/or telephone interviews. Among the instruments already developed for this project are measures of arthritis-specific attitudes, locus of control beliefs, depressive effect, values,

health and illness behaviors, and functional capacity. These measures will be administered repeatedly over the course of the study to ascertain changes in behavior and its psychological concomitants. This design was chosen to provide data over the first 10 years of a person's history with RA. Multiple regression analyses are planned to test theoretical models linking arthritis history and experience variables to indicators of learned helplessness or coping which, in turn, will be regressed upon health and illness behaviors and health outcomes. In addition to testing models, these data will provide a wealth of systematically gathered descriptive information to greatly expand our knowledge of RA.

UCSF Multipurpose Arthritis Center: Community Component—Studies Using a Panel of Rheumatoid Arthritis Patients

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Sponsor: National Institutes of Health

Purpose—The major objectives of the Multipurpose Arthritis Center at the University of California, San Francisco are: 1) to conduct basic research in areas related to the etiology and pathogenesis of rheumatic diseases (e.g., mechanisms of immunoregulation, heterogeneity of lymphocytes and monocytes, genetic control of immune responses, molecular mechanisms of lymphocyte activation, regulation of natural killer cell activity, cell biology and chemistry of inflammation); 2) to develop and evaluate new methods for the prevention, diagnosis, and treatment of rheumatic diseases (e.g., lung disease and altered susceptibility to infection in patients with systemic lupus erythematosus); 3) to conduct research into the health care of patients with rheumatic diseases (e.g., health care costs, disability, utilization of medical services); 4) to train biomedical scientists, physicians, and other health professionals; 5) to

conduct education programs for physicians, allied health professionals, and patients; 6) to devise and test more effective ways to educate health professionals and patients (e.g., staff of home health agencies, arthritis care and education in nursing homes, teaching methods in joint protection); and, 7) to work with local, state, and national organizations for the purpose of developing and applying new knowledge.

Progress—To meet these objectives, comprehensive programs in Research, Education, and Community/Health Services Research have been developed at the three major teaching hospitals of the University of California, San Francisco (i.e., Moffitt-Long Hospital, San Francisco Veterans Administration Hospital, San Francisco General Hospital) as well as in the Schools of Medicine and Nursing.

Benefit and Cost Comparison Between a Coordinated Team Care Approach and a Traditional Office Based Approach to Outpatient Management of Rheumatoid Arthritis

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Although many advocate a multidisciplinary team approach to the care of rheumatoid arthritis patients, there are few studies on the relative efficacy or costs of such an approach. This project is a controlled study of a coordinated team care program for ambulatory rheumatoid arthritis (RA) patients at the Rehabilitation Institute of Chicago. This program will be compared to a matched (age, sex, ARA functional class) sample of patients drawn from the Northwestern Medical Facility Foundation Arthritis Section's practice, an example of a traditional office-based program. Functional status and costs, both direct and indirect, are the primary outcomes of this 5-year study of a least 60 patients.

Previous studies have noted some improvement in groups of RA patients who have participated in team-care programs involving various combinations of rehabilitation specialists. One methodologic difficulty that has been noted is the relatively short follow-up time of the previous studies. That has limited the assessment of efficacy to only the short term, with no opportunity to examine long-term benefits. This study will follow patients for at least 2 years (some as long as 4 years) to better assess the long term effects and costs of an interdisciplinary team care program.

Progress—The Rehabilitation Institute of Chicago's Arthritis Team has representation from Rheumatology, Physiatry, Orthopedic Surgery, Nursing, Social

Work, Physical Therapy, Occupational Therapy, Clinical Psychology, and Vocational Rehabilitation. Patients are initially screened by a physician, a nurse, a social worker, and jointly by a physical and occupational therapist. A team meeting is held to generate a care plan and to implement any other appropriate referral. Team meetings are then held on a quarterly basis to update team members on progress and problems and to make revisions of the care plan as needed.

Measured outcomes of this comparative study include portions of the Arthritis Impact Measurement Scales, the Sickness Impact Profile, the Jebsen Hand Function Tests, the fifty-foot-walk time, and subjective assessments by the patient and a blinded rheumatologist. Economic outcomes include direct and indirect costs aggregated using a variety of modern methodologies.

Publications Resulting from This Research

A Controlled Trial of Rehabilitation Team Care for Outpatients with Rheumatoid Arthritis: Methodologic Issues. Chang RW, Falconer J, Ross C, Sutin JA, Dyer AR, Manheim L, Schmid FR, *Arthritis Rheum* 29:S62, 1986.

Observed Versus Self-Report Measures of Functional Status in Arthritis Rehabilitation Research. Chang RW, Falconer J, Ross C, Sutin J, *Arch Phys Med Rehab* 67:693, 1986.

A Controlled Trial of Rehabilitation Team Care for Outpatients with Rheumatoid Arthritis: Preliminary Analysis. Chang RW, Falconer J, Ross CK, Sutin JA, Dyer AR, Carpino C, Siegel ME, Tran N, Schmid FR, *Arthritis Rheum* 30(4S):S45, 1987.

C. Low Back Pain

Myoelectric Analysis of Human Spine Function: Myoelectric Measurement of Human Muscle Endurance

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Sponsor: VA Rehabilitation Research and Development Service; Division of Orthopedics, University of Texas Health Sciences Center at Dallas

Purpose—Stimulated by a number of reports which have shown changes in the spectral moments (mean and median power frequency) properties of EMG signals during sustained isometric contractions, we have, for the past 6 years, been investigating such changes in several muscle groups with special attention to clinical applications. A primary interest is in the use of the technique to obtain information about low-back pain patients which would otherwise be unavailable. Our initial work progressed to the point where a prime objective was to characterize the changes in spectral moments which can be observed with a single measurand (for example, a time-constant or slope measure). We believe this is an essential step for clinical applicability of the methodology. Thus, much like a strength measurement or blood pressure measurement, norms could be established and an individual's results could be compared to appropriate norms to determine physiologic integrity.

Progress—To date our work leads us to the following conclusions: 1) measurands which would appear to be useful based on implications of previous reports (such as percent change in spectral moment, absolute change, or time-constant derived from curve fitting with a simple exponential model) show considerable variability in normal populations when test administration procedures are tightly controlled; 2) these measurands derived in populations where different fatigue characteristics might be expected (orthopedic patients, highly trained athletes) exhibit behavior which is not significantly different from established norms; and, 3) based on results from

collective studies in which the monitored change in spectral moments are quantified, clinically usable discriminating power is minimal.

Results—Clearly, spectral moment changes do reflect important physiologic processes. Our results suggest that more accurate models of these processes are required in order to be able to define measurands which would be clinically sensitive indicators of muscle endurance. These conclusions temper the initial optimism which is raised upon connection of electrodes to a muscle and observation of the spectral moment changes during sustained contractions (i.e., an activity which appears to be fatiguing). In fact, we find that the quantitated change in spectral moment characteristics is a more predictable indicator of load level across different subject populations than it is an indicator of endurance. We emphasize that we do not recommend discarding the technique, as changes in the spectral moment are reliable and must reflect important underlying processes. Rather, attention must be focused to understand exactly what spectral moment changes reflect relationships to other experimental variables, definition of quantitative characterization of the changes based on conceptual models, and the acquisition of evidence in support of clinical discriminating power based on defined quantitative measures.

Implications—These findings suggest that a cautiously optimistic perspective be placed on the use of myoelectric spectral analysis methods in clinical rehabilitation applications at the present time.

Evaluation of Psychophysiological Ways to Assess Chronic Low Back Pain

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Sponsor: VA Rehabilitation Research and Development Service; Department of Clinical Investigation of the US Army

Purpose—The goal of this project is to evaluate the effectiveness of psychophysiological ways to assess low back pain.

Progress—Subjects with low back pain are given a complete physical examination and other objective medical tests. They are then interviewed by a psychologist and given both a standard and a specially modified Minnesota Multiple Personality Inventory (MMPI). They then participate in 4 weekly muscle tension and heat pattern recordings while experiencing various intensities of low back pain.

Preliminary Results—This study is still in its early stages. We have already found that subjects with low back pain do not change many of their MMPI responses depending on whether or not they are in

pain when answering the questions. Too few subjects have completed participation for firm conclusions. To date, we have not found clear relationships between low back or leg thermograms and intensity or diagnosis of low back pain. Paraspinal muscle tension correlates well with pain intensity regardless of diagnosis.

Future Plans/Implications—We will continue the study until sufficient subjects are completed to permit us to draw clear conclusions from the data.

Publication Resulting from This Research

Thermographic Correlates of Chronic Pain: Analysis of 125 Sequential Subjects Incorporating Evaluations by a Blind Panel. Sherman R, Barja R, Bruno G, *Archives of Physical Medicine and Rehabilitation* 68:273-279, 1987.

Low Back Pain Studies

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Sponsor: National Institute on Disability and Rehabilitation Research

Progress—Currently under way are several research projects, each comprising several studies, in the following areas.

1) **Epidemiologic Analyses, Prediction of Disability and Assessment of Rehabilitation.** These studies involve the assessment of a wide range of back pain-related risk factors (e.g., occupational, psychological, recreational, environmental, anthropometric, and radiographic) and the development of a reliable information-gathering system in order to improve diagnosis and treatment. Both organic and functional correlates of low back pain are considered in developing a multi-attribute utility model for predicting low back pain impairment and disability. This project has led to the creation of a questionnaire for predicting disability early in the course of the disease. This is a crucial step in developing early, definitive treatment programs to prevent chronic disability

which accounts for 85 percent of the total costs associated with low back pain in this country. Other areas of investigation are assessment of costs associated with low back pain and relative cost-benefit ratios for various rehabilitation techniques.

2) **Mechanical and Electrical Rehabilitation.** Research on spinal orthoses has led to the development of a new internal fixation device, the Vermont Spinal Fixator, which offers numerous advantages over previous stabilization systems. Thorough studies of various mechanical and electrical outcome measures have been completed. Further biomechanical characterization of several external orthoses and clinical assessment of electrical stimulation, bracing, and other treatment modalities are now underway and should lead to advances in effective treatment and pain reduction.

3) **Seating.** The aim of improved seating in both

static and vibration environments has led to studies of relationships among types of seating, spinal support structures and seated postures. Recommendations arising from studies of vibration in cars, trucks and buses are being incorporated in various vehicular designs. The Center has also recently established a Seating Research Center, which supports research on the mechanics of office seating and offers research and development consultation to chair and office environment manufacturers. The application of new technologies can be expected to reduce low back pain among office and other seated workers.

4) **Vocational Rehabilitation.** To improve the rate of successful return to work after a back injury or period of disability, rehabilitation engineers are investigating workers' functional physical capacities, job task requirements, and the effect (and cost effectiveness) of matching workers and jobs through job selection and modification. Research engineers at the REC also work with industry representatives toward incorporating human factors in worksite and equipment design, in order to minimize the risk of back injuries and to assist the back-injured or handicapped worker in an early and safe return to work.

D. Vascular Disorders

Blood Velocity and Spectra Estimations from Doppler Ultrasound

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—Doppler ultrasound is in widespread use as a noninvasive diagnostic modality for cardiac and peripheral vascular disease. Prompt diagnosis and treatment, including follow-up evaluations, are crucial to the middle aged and elderly. Surgical and pharmacological treatment can be effective in returning the patient to reasonably normal and productive function if diagnosis of vessel disease is made prior to a catastrophic episode, such as myocardial infarction or stroke. Present methods of determining blood velocity and Doppler spectra, two vital diagnostic indicators, often suffer from poor resolution and inaccuracies. The present research uses modern methods of signal analysis to provide optimum accuracy in velocity and spectral estimates. The results will improve Doppler diagnostic techniques with existing equipment, and will be applicable to improvements in the new generation of flow color Doppler instruments recently introduced to the noninvasive laboratory. Following the validation of the signal analysis methods, a study will be proposed to implement the techniques in a clinical research program.

Progress—Computer programs that employ autore-

gressive methods of velocity and spectral estimation from pulsed Doppler data have been developed and implemented on the Georgia Tech CYBER computer. These programs have also been installed in the MASSCOMP data acquisition system in the School of Mechanical Engineering. Measurements have been performed on a moving string target device, which provides a constant velocity for calibration of results, and on several flows in laboratory models using an 8-megahertz pulsed Doppler ultrasound instrument. Graphics routines for displaying the results have also been developed. Data processing is in progress in order to determine optimum parameters to improve the analysis methods. The research is on schedule with respect to the proposed protocol.

Preliminary Results—A series of new computer programs for autoregressive data analysis have been developed and checked out. We have also worked on the development of a mathematical model for synthesized Doppler, which can be used to vary parameters more readily and under better control than is possible with experimental data. This synthesized model is approximately 50 percent com-

pleted. Additionally, experiments with the string target device and with several flow systems have provided actual data for analysis. Our results to date indicate that autoregressive estimates of velocity are significantly better than estimates obtained via the usual Fourier methods. Further, estimates of Doppler spectra obtained by autoregressive techniques have considerably less variance than those calculated by FFT algorithms. Thus, the results at this stage are very promising and are providing the improvements we hypothesized.

Future Plans—We plan some further validation studies with the synthesized Doppler model and with flow model experiments in order to establish firmly the improvements and limitations of our techniques. Next, we will make Doppler ultrasound measure-

ments in a compliant model of the human carotid bifurcation and compare our velocity estimation results with those obtained by laser Doppler anemometry, a very accurate instrument but one that cannot be used in noninvasive vascular diagnosis. The carotid models will include simulated plaques so that we may study the flow disturbances created by mild to severe arterial disease. The results of these studies will then serve as a basis for developing a protocol for a clinical research program involving early detection of early carotid arterial disease.

Presentation Resulting from This Research

Fluid Mechanics of Large Arteries. Don P. Giddens et al., presentation at the *New England Doppler Conference*, Durham, NH, May 1986.

A Program for Evaluating the Dysvascular Patient

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Sponsor: VA Rehabilitation Research and Development Service

The Role of Lumbar Sympathectomy to Manage Lower Limb Arteriosclerotic Occlusive Disease—This is an ongoing program in the evaluation of the dysvascular patient with atherosclerotic occlusive disease (ASOD), for purposes of rehabilitation.

Purpose—The program supports the development of quantitative measures for improved assessment of subcutaneous tissue viability when ischemia and/or edema are present. The measures are intended to provide clinically usable criteria to guide the preoperative and intraoperative selection of interventions and to follow the clinical course of the patient during rehabilitation. The proposed studies are to assess the efficacy of measures resulting from three test procedures: orally administered fluorescein as a perfusion indicator, inhaled hydrogen measurement of perfusion, and measurement of mechanical pressure-displacement relationships in tissue.

Progress—The use of orally ingested fluorescein is a new approach which substantially reduces the risk of allergic reaction over that when the dye is ad-

ministered intravenously. The test permits rapid measurements of skin perfusion in localized limb areas. Inert hydrogen gas washout at open sites without skin covering, intra-operatively or following tissue debridement, is possible, since the outer layer is missing which otherwise would inhibit transport of hydrogen from tissue to probe. The advantage of hydrogen for this purpose is that the measurement area can be small, and the hydrogen gas is physiologically inert so that there are no side effects. During the third year of the current program, instrumentation for multiprobe analysis is being designed and assembled. In the proposed study, surface probes are to be developed, extending to a multiprobe arrangement so as to obtain a distribution of readings over a surface. The tissue mechanical measurements are based on instrumentation which is being developed in the current program. Quantitative data is obtained to monitor changes in tissue property associated with edema and with the revascularization compartment syndrome.

With each test, the objective is a convenient instrument package which will permit easy measurement in the clinical environment. Development

and evaluation will proceed in laboratory studies of responses to ischemic and edematous processes, and in some instances to the sequelae of lumbar sympathectomy. Test results will be evaluated for potential in predicting tissue viability in studies of patients with ASOD in the lower extremities. Clinical outcomes will be represented as (Category I) failure due to inconclusive healing or failed healing evidenced by surgical intervention or death; and (Category II) healing, or non-healing but without progression of disease. Testing is done pre- or intraoperatively and postoperatively, and according to schedule in the follow-up period. Results will be compiled for each of the tests in the study to determine the relation of test criteria to sensitivity and specificity in predicting Category I or Category II results. From this information, it is intended to further expand knowledge on the use of the instrumentation and quantitative methods being studied so as to minimize the need for amputation and other loss of mobility and function. The ultimate goal is improved rehabilitation, freedom from pain, reduced healing time and hospital time, while minimizing expense.

Measurement of Edematous Changes During the Revascularization Compartment Syndrome—Edema in the lower limb may occur following revascularization. The edema can lead to the revascularization compartment syndrome, a serious problem in which fluid accumulates in a compartment of the leg. When this occurs, pressures increase within the compartment and blood flow is reduced, leading to ischemia and necrosis. The pressure must be monitored to know when therapeutic intervention is required. The present approach is invasive in which pressure is measured through needle and catheter insertion. We are developing a noninvasive approach to follow the patient during the edematous changes. This approach is based on external tissue mechanical measurement.

Preliminary Results—Preliminary studies in animals show good correlation between pressure changes within the compartment and the external mechanical tissue compliance over the compartment. Preliminary studies in humans show good correlation with the clinical course and good repeatability of results. The new approach promises to be a useful alternative to direct pressure measurement. Since the approach is noninvasive, it reduces risk to the limb.

Use of Cutaneous Pressure Photoplethysmography in Managing Peripheral Vascular Occlusive Disease—A technique for local measurement of cutaneous perfusion pressure (CPP) has been developed. This method provides measurements at multiple points on the limb in the patient with occlusive disease and a variety of symptomatology including claudication, rest pain, gangrene and ulcers. As previously reported, results indicate that the technique can successfully identify the presence of peripheral vascular disease, distinguish among different levels of severity, and aid in determining the optimal level of amputation consistent with wound healing. The technique can also assist in following the patient's course of recovery after reconstructive vascular surgery.

Presently, we are developing quantitative methods for incorporating multiple measurements into a prognostic index. This development will accomplish two purposes. First, it provides a quantitative approach to incorporating multiple measurements. Second, it improves sensitivity and specificity over that which would otherwise be possible with a single measurement.

Fluorometry in Assessing Tissue Viability—The quantitative use of fluorescein dye indicator in predicting tissue viability is being examined in a surgical flap model. Perfusion fluorometry is a method which quantifies tissue fluorescence and replaces subjective visual observation. A light source in the blue wavelengths of 450 to 500 nm is transmitted via a fiber optics pathway to illuminate a selected area of tissue, of 1 cm diameter. The light excites the fluorescein in tissue which emits light in the range from 520 to 660 nm. This light is transmitted via a second fiberoptic bundle to a photomultiplier tube which, with the aid of electronics, provides a direct readout of dye fluorescence. Fluorescence at the skin surface is measured following flap formation and is correlated with viability of the flap tissue at seven days. The perfusion fluorometry technique is expected to prove helpful in the intra-operative assessment of flap viability and in the treatment of pressure sores.

Publications Resulting from This Research

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A Program for Evaluating the Dysvascular Patient (Project Extension)

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Sponsor: VA Rehabilitation Research and Development Service (Project #XA086-ARA)

Purpose—This is an ongoing program in the evaluation of the dysvascular patient with atherosclerotic occlusive disease (ASOD), for purposes of rehabilitation. The program supports the development of quantitative measures for improved assessment of subcutaneous tissue viability when ischemia and/or edema are present. The measures are intended to provide clinically usable criteria to guide the preoperative and intraoperative selection of interventions and to follow the clinical course of the patient during rehabilitation. The proposed studies are to assess the efficacy of measures resulting from three test procedures: orally administered fluorescein as a perfusion indicator, inhaled hydrogen measurement of perfusion, and measurement of mechanical pressure-displacement relationships in tissue.

The use of orally ingested fluorescein is a new approach which substantially reduces the risk of allergic reaction as opposed to when the dye is administered intravenously. The test permits rapid measurements of skin perfusion in localized limb areas. Inert hydrogen gas washout at open sites without skin covering, intraoperatively or following tissue debridement, is possible since the outer layer is missing which otherwise would inhibit transport of hydrogen from tissue to probe. The advantage of hydrogen for this purpose is that the measurement

area can be small, and the hydrogen gas is physiologically inert so that there are no side effects. During the third year of the current program, instrumentation for multiprobe analysis is being designed and assembled. In the proposed study, surface probes are to be developed, extending to a multiprobe arrangement so as to obtain a distribution of readings over a surface. The tissue mechanical measurements are based on instrumentation which is being developed in the current program. Quantitative data is obtained to monitor changes in tissue property associated with edema and with the revascularization compartment syndrome.

With each test, the objective is a convenient instrument package which will permit easy measurement in the clinical environment. Development and evaluation will proceed in laboratory studies of responses to ischemic and edematous processes, and in some instances to the sequelae of lumbar sympathectomy. Test results will be evaluated for potential in predicting tissue viability in studies of patients with ASOD in the lower extremities. Clinical outcomes will be represented as (Category I) failure due to inconclusive healing or failed healing evidenced by surgical intervention or death; and (Category II) healing, or nonhealing but without progression of disease. Testing is done pre- or

intraoperatively and postoperatively, and according to schedule in the follow-up period.

Results will be compiled for each of the tests in the study to determine the relation of test criteria to sensitivity and specificity in predicting Category I or Category II results. From this information, it is intended to further expand knowledge on the use

of the instrumentation and quantitative methods being studied so as to minimize the need for amputation and other loss of mobility and function. The ultimate goal is improved rehabilitation, freedom from pain, reduced healing time and hospital time, while minimizing expense.

Evaluation of Pressures Applied by Elastic Dressings

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Sponsor: Chesebrough-Pond's Inc.

Purpose—Elastic stockings are often used to treat edema and swelling and varicose veins, as well as to control hypertrophic scar in burn patients. Recently it has been suggested that compression stockings may also be effective in preventing thromboembolism following surgery. In most applications, the stockings need to apply a graduated compression on the limb to facilitate the venous and lymphatic flow. However, the therapists often use various compression dressings without any direct measurement of the applied pressure. The objective of this study is to compare the pressures applied by different sizes and types of dressings on lower limbs of different diameters. The change in pressure with time was also measured. The effectiveness of pressure dressings in reducing swelling and edema in patients is also being evaluated.

Progress—In our laboratory study, we compared the pressures applied by ProSorb (Chesebrough-Pond's Inc.) and Tubigrip (Seaton Products) dressings on cylinders of various diameters. The pressure was monitored by a specially designed flexible pressure transducer consisting of a pressure switch, a solid state pressure transducer, and a digital readout in mm of Hg (Clinical Technology Corp).

Pressure readings were also taken on a limited number of patients with post fracture edema and lacerations. The reduction in swellings was measured by using a liquid displacement method (Volumeters Unlimited), as well as measuring the change in circumference.

Results—Our results clearly show that the applied pressure depended on the geometry of the limb and it was highest (measured at lateral malleolus) at the ankle. As expected, the pressure also was a function of the type and size of the elastic stocking. When we monitored the pressure applied by a stocking on a cylinder of fixed diameter, we found that the pressure decreased slightly with time, indicating stress relaxation of the stocking material. The drop in pressure was higher during the first few hours and then it slowly stabilized with time.

If the same size elastic stocking was applied on cylinders of increasing diameters, the applied pressure increased more rapidly than predicted by theoretical calculation, assuming a linear elastic behavior of the fabric material. This suggests that the stress-strain behavior of the stocking material is highly nonlinear due to the woven nature of the fabric.

Based on our study on a limited number of patients, we found the pressure dressings to be efficacious in controlling edema and swelling. We also found the volume change as measured by the displaced liquid to be a more reliable indicator of the reduction in swelling than the commonly used clinical method of measuring the circumference of the limb. The patients found the ProSorb dressing to be more comfortable and to apply more uniform pressure compared to other types of dressings.

Future Plans/Implications—This study is being continued to determine the optimum pressure levels necessary for various types of clinical problems.

Publications Resulting from This Research

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Postoperative Thromboembolism in Surgical Patients

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Sponsor: *National Institutes of Health*

Purpose—A series of controlled prospective clinical trials with supporting laboratory investigations in the pathophysiology of thrombotic states and related conditions, and the pharmacology of new antithrombotic and hemostatic drugs will be conducted.

Progress—The principal clinical trials, which are already in progress, include: 1) study of a hemodynamically optimized system for external pneumatic compression of the lower limbs to prevent venous thrombosis in patients undergoing neurosurgical operations; 2) investigation of the effective-

ness and safety of therapy of established venous or arterial thromboembolism with a heparin preparation of low molecular weight and high antithrombin affinity; 3) trial of the prevention of venous thromboembolism in patients with fractures of the hip by administration of a heparin-like compound (Organon 10172); and, 4) administration of DDAVP to improve hemostasis in patients undergoing cardiopulmonary bypass and exploration of the role of von Willebrand's factor in the hemostatic defect in such patients.

Characterizing Atherosclerotic Lesions by Proton Spectroscopy

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Sponsor: *None Listed*

Purpose—There have been reports of *in vivo* imaging from atherosclerotic lesions in which image intensities are brighter in the plaque when compared with the surrounding uninvolved vessel wall tissue, presumably due to the presence of lipids in the plaque. The purpose of the present study has been to obtain proton spectra characteristic of atherosclerotic lesions in order to eventually predict imaging characteristics as related to pathology.

Progress—Work to date has focused on: 1) determining sample handling procedures and pulse sequences; 2) identifying characteristics of spectra associated with atherosclerotic lesions, in contrast to uninvolved tissues; 3) relating spectral peaks to analyzed chemical constituents of the vessel wall and lesion; and, 4) considering the implications of

results for *in vivo* studies.

Data are being collected on a Varian XL-200 system (200 MHz) for 90 degree pulses and for spin echo sequences. Tetramethylsilane diluted in deuterated chloroform is used as a reference. Spectra were obtained from post-mortem aorta wall and serum. Changes with time and temperature, effects of storage in saline, and of storage by freezing have been observed. Spectra in these studies to date show relatively little dependence on the aforementioned handling conditions over the range of parameters investigated. All samples show the characteristic peaks which are generally described as the methylene and methyl groups of lipids. Other peaks are clearly present and values for T1 and T2 have been obtained.

We anticipate that an optimal differentiation be-

tween lesion and nonlesion can be determined for the *in vivo* mode, once relaxation and spectral characteristics are known and once pulse sequences are selected to match these characteristics.

Publications Resulting from This Research

Characterizing Atherosclerotic Lesions by Proton Spectroscopy.

Ostrander LE, Frank AS, Daoud A, Darcy K, Lee B (abstract), *Fifth Annual Meeting of the Society of Magnetic Resonance*, Montreal, 1986.

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