VETERANS ADMINISTRATION REHABILITATIVE ENGINEERING RESEARCH and DEVELOPMENT SERVICE PROGRAMS

Vernon L. Nickel, M.D., Director

Interdisciplinary Development and Evaluation of Externally Powered Upper-Limb Prostheses and Orthoses

Applied Physics Laboratory
The Johns Hopkins University
Johns Hopkins Road
Laurel, Maryland 20810

Woodrow Seamone and Gerhard Schmeisser, Jr., M.D.

The research program at Johns Hopkins for the Veterans Administration continues to be focused on the development and evaluation of assistive devices for high-spinal-cord-injured persons. Wheelchair control techniques and continued evaluation of the robotic-arm/workable system were the principal activities of this project during the reporting period. In order to be certain of addressing the real and significant needs of quadriplegic veterans, individual veterans with high level spinal cord injuries have been recruited and enlisted in the program to assess the practicality of these devices in an everyday home or institutional environment. Progress and accomplishments during the January–June 1980 period are summarized as follows:

Chin Controller for Wheelchairs

A new low-profile chin controller has been designed to be compatible with E&J model 3P wheelchair. It provides steering control with chin motions, is compact, and can easily be moved out of the way by the user when not in use. It is for the quadriplegic with no useful hand motion. A technical description of this chin controller is available (1).

A thorough clinical test program on the low-profile chin controller has been in progress for over a year and evaluation is being conducted at this time by five C3–5 quadriplegics. Their relevant circumstances are briefly summarized as follows:

C.R., a 32-year-old veteran with spinal stenosis (producing quadriplegia eight years ago) is living in a state hospital and commutes daily by van to a community college. He received his test wheelchair and control system in early January 1980. He is active in it all day and evening. He has also utilized the wheelchair controller in combination with the robotic-arm/work table system for self-feeding evaluation, for approximately 6 weeks during the reporting period.

M.S., a 23-year-old veteran injured 3 years ago, is living in a suburban nursing home and commutes daily by van to a rehabilitation center for vocational testing and training. The test control system was attached to his existing wheelchair in early April 1980. He is active in it all morning.

B.J., an 18-year-old injured 2 years ago, is living in an apartment attached to his parent's house, and commutes by van daily to a local college. He received his test wheelchair and control system in January 1979. Usually, he is active in it most of the day and evening.

M.C., a 35-year-old injured 17 years ago, lives with his wife in a small suburban house. He received his test wheelchair and control system approximately April 1979. Usually, he is active in it all day and evening.

J.C., a 42-year-old, injured 9 years ago, lives in a rural nursing home. He received two different early models of the test wheelchair and control system approximately 2 years ago. He is active in one of them for highly variable periods of variable frequency.

With the exception of J.C. (who spends substantially more time in bed than the others) all of these quadriplegics are using the APL chin controller on a daily basis, are enthusiastic about its performance, and have experienced no significant failures.

Solo Products, Inc., a manufacturing firm in West Sacramento, California, is bringing the chin controller to the marketplace; initial prototype units are expected to be completed mid-summer 1980. Several individuals and rehabilitation centers have inquired relative to purchasing this control interface for control of the wheelchair by high-spinal-cord-injured persons. No equivalent device exists with comparable cosmetic and functional features.

Computer-Aided Robotic Arm/Worktable System

A modified computer-aided robotic-arm/worktable system has been completed and clinical evaluation begun. This robotic arm is controlled by the dual purpose wheelchair chin controller via an infrared link. The infrared connection permits the user to make the interface and then control any of the robotic arm functions with little or no assistance from an attendant.

The robotic arm assembly unit has been mounted on a small table as part of a modular table concept. One to three of these interlocking tables may be grouped appropriately to provide each quadriplegic his desired functional needs. Each table may be arranged with appropriate components providing vocational and personal needs capability. The robotic arm is microprocessor controlled, and includes a programming keyboard which allows the programmed motions to be readily changed. The user has full manual control of each of the degrees-of-freedom of the robotic arm, as well as capability to call up programs with fixed motion trajectories. This unit has now undergone self-feeding evaluation at the Western Maryland Medical Center by C.R., who is currently eating some of his meals with this system (Fig. 1). A total of 38 meals have been eaten by C.R. with this system during this portion of the evaluation. The selected meal for evaluation has usually been the noon meal which required the following preparation for self-feeding: (i) Meat or fish—had to be cut up in bite-sized portions; (ii) Salad—could be eaten as received from the kitchen; (iii) Mashed potatoes—sticky and difficult to pick up in acceptable portions, but manageable; (iv) Cranberry juice—placed in a cup holder with a straw, totally compatible with self-feeding mode; (v) Vegetables—could be eaten as received from the kitchen; (vi)

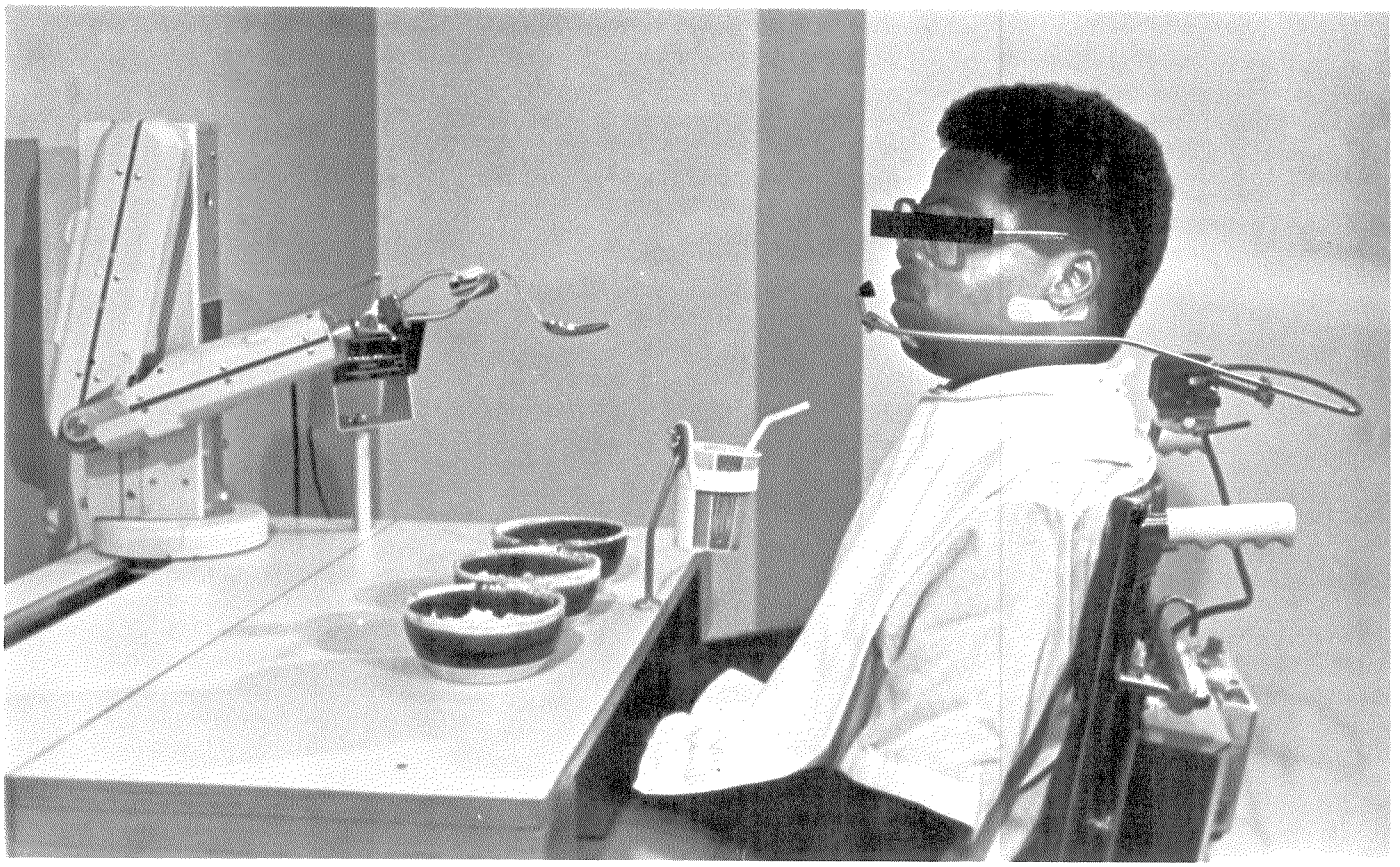


FIGURE 1. Robotic arm used for self-feeding.

Bread—had to be cut up in bite-sized portions, and (vii) Desserts—most, including ice cream and jello, worked well.

C.R. could eat his complete meal in 15–20 minutes if left alone; however, he likes to engage in conversation during lunch and typically took longer. He commented that he liked to use the machine for self-feeding, since he could now independently choose his order of eating various foods. The effort required for self-feeding was minimal and totally acceptable. He suggested that the programmed time cycle for each bite was too long and should be shortened. It is expected that this will be accomplished in a subsequent robotic arm model (now being completed) which will use combined multiaxis motions during programmed modes such as self-feeding.

In spite of a couple of machine breakdowns during the six week evaluation period, C. R. specifically requested that he be able to use the robotic arm system for self-feeding on a longer term basis.

Comments from the Occupational Therapist working with C.R. were very favorable. He sees this device as worthwhile since it gives the user some independence he would not have otherwise. He felt the effort in food preparation, which consists of cutting some food into bite-sized portions and placing in the bowls, requires less effort on the part of the staff than hand-feeding each quadriplegic. He requested that the machine be returned for additional self-feeding evaluation, to include the breakfast meal.

Two additional robotic-arm/worktable systems are in the process of completion of fabrication and assembly. These units are expected to be ready for clinical evaluation by Fall 1980. All units include the dual-purpose wheelchair chin controller which controls either wheelchair mobility, or robotic arm functions through an infrared link, without attendant assistance.

Closed Loop Velocity Controller for Wheelchair Control

Better wheelchair controllers were acknowledged as one of the important needs of the handicapped during the Wheelchair II conference sponsored by the Veterans Administration and Rehabilitation Services Administration, held in December 1978. Improved controllability, more safety features, and less sensitivity to spasticity were noted as some of the parameters which need further refinement. A small amount of research effort has been applied to this problem at APL in FY 81 in order to determine the value and practicality of closed-loop velocity control in the solution of some of these problems. Both a chin control unit and hand control unit (joystick) have been modified to

operate in this mode in order to gain some performance data.

Some of the basic features of this closed-loop control system are as follows:

1. Tachometers are used to sense wheelchair velocity and feedback in closed loop to provide wheelchair velocity-control as a function of input joystick position or chin controller depression. Most conventional wheelchair controllers provide motor torque as a function of joystick motion and thus require more effort to maintain a desired velocity.

2. The two-axis joystick potentiometer arrangement is arranged in the "+" configuration as opposed to the conventional "X" orientation in open-loop torque-controlled wheelchairs. This permits electronic filtering of speed (fore and aft motion of the joystick) without introducing significant filtering in the steering axis (lateral motion of the joystick). This electronic filtering minimizes effects of hand tremors or feedback-induced oscillations. (This feature is essential to avoid feedback from inertial motion of the hand or chin on rough terrain.) The addition of filtering results in slightly longer coast periods, which is probably tolerable in most cases.

3. Use of closed-loop velocity control permits flexibility in setting electronic velocity limits without compromising maximum torque capability. This system has a settable velocity limit in reverse, independent of forward speed limits, to limit reverse motions to a safe and comfortable low speed. The hand controller has a toggle switch to allow the forward velocity limit to have one value (low velocity limit) for indoor use and a high velocity limit for outdoor use. These limits are settable to suit the needs of the individual user.

The demonstration model has been designed and evaluated on the Everest & Jennings Model 3P powered wheelchair. The interface has been designed to provide a totally compatible system with the conventional open-loop torque-controlled wheelchair. The APL-developed system utilizes the original two-axis joystick rotated 45 deg, and adds an electronic card mounted inside the joystick box. This yields 100 percent mechanical and electrical interchangeability with the standard Model 3P controller.

Clinical testing has been conducted primarily by two quadriplegic volunteers with this experimental closed loop joystick controller, as described below.

A closed-loop controller for a joystick-operated wheelchair has been made available to W.S., a high-level quadriplegic (C4-5) veteran possessing very limited functional control with a joystick. Results of over 150 hours of testing in both open and closed loop modes indicate that, while the closed-loop controller has some desirable features in terms of its filtering capability and velocity limtis, it results in less-precise control capability for an individual like W.S. who does not possess the capability for fine motor control of the joystick. He generally found the open loop controller to be superior indoors—while the closed loop controller is superior outdoors, particularly in irregular terrain. A selector switch allows their user to select open or closed loop control, and choice of high or low speed limits. These evaluation tests are continuing.

A second individual, L.E., has conducted limited evaluation of the closed-loop velocity controlled wheelchair in a home environment. This individual, suffering Friedreich's ataxia, has good hand control but suffers early fatigue. For comparison purposes, L.E. utilized the conventional open-loop torque-controlled wheelchair for 3 days in her home, utilizing the chair for 6–8 hours per day. She found it difficult to maneuver in tight quarters, particularly on carpeted areas. It required special attention in going up or down ramps to avoid overspeed. Small loose rugs were hard to manage at low speeds.

For the next 15 days this individual was furnished the APL closed-loop velocity controlled wheelchair. She utilized this chair for approximately 6–8 hours per day. L.E. found the controllability of this model to be vastly superior to open-loop control. It performed smoothly on and off carpets, over sills, up and down ramps, and in tight quarters. It provided smooth acceleration and deceleration. Safety is improved by limiting reverse velocity, and automatic braking is provided when going down steep ramps. Her overall comment was that it took a lot less mental effort to go from place to

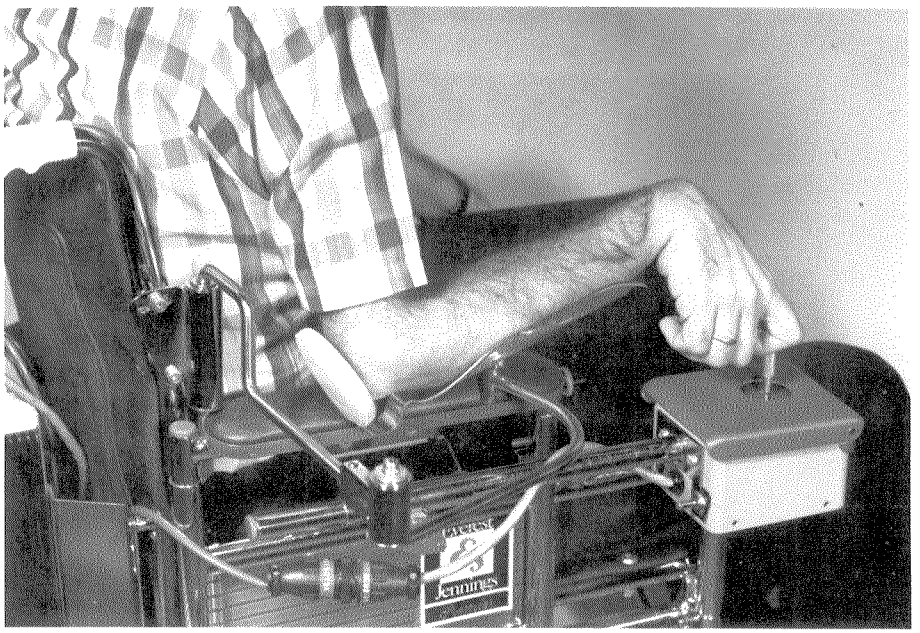


FIGURE 2.
Closed-loop controller test arrangement to study inertial coupling into controller

place, and she would like to procure such a system when it becomes commercially available.

Another feature of the closed-loop controller which has yet to be clinically evaluated is the effect of the filtering in the speed-control loop to minimize unwanted wheelchair excursions due to oscillatory hand motions such as those characteristic of cerebral palsy patients. This controller minimizes inertial feedback to the joystick. A special test arrangement (Fig. 2) was utilized to study these characteristics. The use of the ball-bearing feeder support simulates operating the controller from the shoulder, and comparison testing with a conventional open loop controller has demonstrated a clear superiority of the closed loop control in rough terrain and on hilly surfaces. Maximum torque is available at all times but the system is velocity limited. This controller may permit certain handicapped persons to drive an electric wheelchair who otherwise could not possibly control a standard wheelchair joystick.

Still another inherent feature of the closed-loop controller is its capability of being controlled with an elastic coupling to the joystick. This permits an able bodied person to guide the wheelchair with precision—via a piece of elastic hose slipped over the joystick handle. This reduces the effort required to move the wheelchair to a negligible force level, and still gives good control such as may be required in a crowd or in close quarters for a handicapped individual who does not possess good control of the wheelchair.

This closed-loop controller works equally well on a chin-controlled unit as well as in a joystick mode. Several manufacturers have expressed interest in manufacturing a kit to adapt existing Everest & Jennings 3P wheelchairs to closed loop control.

Reference

1. Schmeisser G, Seamone W: An Assistive Equipment Controller for Quadriplegics. The Johns Hopkins Med J 145:84–88, 1979.

Stimulation of Repair of Cortical Bone Transplants by Implantation of Piezoelectric Materials: A Pilot Study

VA Medical Center
Castle Point, N.Y. 12511

Helen Hayes Hospital
Route 9W, West Haverstraw, N.Y. 10993

George Van B. Cochran, M.D., Sc.D., Bok Y. Lee, M.D., and Wendell Williams, Ph. D.

In the initial phase of this project, the effects of Osteostim™ implantable bone stimulators are being evaluated as to their effect on remodeling of a 1.5-cm segment of distal canine ulna. The segment first is removed, cleaned, and placed in distilled water to lyse the cells. Then the segment is replaced as a graft, after being threaded axially on the titanium cathode of the Osteostim d.c. unit. A similar (sham) operation is carried out on the other side of the dog. After several preliminary experiments, an experimental group of 8–10 animals is now in process and implantations will be complete by September 1980. Animals are sacrificed and results assessed histologically after an 8-week implant period.

Aside from providing an evaluation of these commercially available bone-stimulating units, these experiments are providing a background for the main focus of this project in which miniature bone plates of a piezoelectric material are being utilized to fix the 1.5-cm bone segments in place. The intent of the study is to assess the effect of piezoelectric materials in providing an internally generated electrical stimulus to graft incorporation and remodeling. Preliminary tests with plates fabricated by the Department of Ceramics at the University of Illinois at Urbana-Champaign now are in progress.

Analysis of Wear Particles in Human and Arthroplastic Joints

VA Medical Center
University Drive C
Pittsburgh, Pennsylvania 15240

University of Pittsburgh
Pittsburgh, Pennsylvania 15213

Dana C. Mears, B.M., B. Ch., Ph. D., M.R.C.P., F.R.C.S. (C), Director, Orthopedic Research

Ferrographic Analysis of Wear Particles—Having developed the necessary techniques for making ferrograms from synovial fluids (1), we have now completed our first thorough studies of its applicability. Examination of over 50 specimens in this manner confirmed the existence of distinctive wear particles in human joints. The spectrum of particles varied from one patient group to another, encouraging confidence in its ultimate use in the diagnosis, prediction, and assessment of joint disease (2).

We have now started a third phase of the project, an attempt to ascertain the precise relationship between the cartilaginous particles and an arthritic process. To do this, it is necessary to minimize the number of clinical variables. In collaboration with Dr. Carl Stanitski, we are limiting ourselves to ferrographic analyses of saline washings from knee joints that were obtained at the time of arthroscopic inspection. We restricted the analysis to the knee joint compromised by one of a small variety of arthritides, including chondromalacia patella, torn meniscus and early osteoarthritis. (Some of the examinations reveal no damage to symptomatic joints, and thereby provide valuable normal specimens which otherwise are difficult to obtain.)

Furthermore, arthroscopy permits close visual examination of the articulating surfaces, and provides a complementary detailed clinical assessment of the joints from which ferrographic analyses were performed.

Preliminary data reveal that ferrography is at least as sensitive as

arthroscopy in detecting early damage to the articulating surfaces of a joint (3). (It should be self-evident that ferrography requires minimal surgical intervention.) The data also confirm our earlier conclusions that the numbers and sizes of particles increase with the severity of damage, and that different types of particles are produced. The present emphasis is on ascribing individual particles to particular intra-articular events.

Tissue Response to Wear Particles

Earlier, it was shown that wear particles stimulate the secretion of various neutral proteinases by cultures of macrophages and synoviocytes (4). Since then, we have determined which characteristics of the particles are responsible for this effect.

The importance of particle size and chemistry has been investigated using powdered meniscus particles and commercially available particles of latex. The overall conclusion is that both large (i.e., too big for endocytosis) and small (i.e., endocytosable) wear particles stimulate cells. Practical limitations do not permit a direct comparison of these two classes of particles. Cartilaginous particles produced a greater release of enzyme than equivalent particles of latex, indicating that chemical as well as physical factors are operative (5). Preliminary data suggest that chondroitin sulphate is one such chemical.

References

1. Evans CH, Bowen ER, Bower J, Tew WP, and Westcott VC: J Biochem Biophys Meth 2:11—18, 1980.
2. Evans CH, Mears DC, and McKnight JL: Arthritis Rheum (in press) 1981.
3. Evans CH, Mears DC, and Stanitski C: Transact Orthop Res Soc (in press) 1981.
4. Evans CH, Mears DC, and Cosgrove JL: Biochem J (in press) 1981.
5. Evans CH: Sem Arth Rheum (in press) 1981.

A Grommet Bone Liner for Flexible Implant Arthroplasty

Director of Orthopaedic Research
Blodgett Memorial Medical Center
1900 Wealthy Street, S.E.
Grand Rapids, Michigan 49506

Alfred B. Swanson, M.D., F.A.C.S.

Surgical Implanting and Sample Harvesting—As of June 30, 1980, 89 individual grommets (53 carbon Pyrolite®, four Proplast®, 24 polyethylene, and 8 of 316 stainless steel with bonded screen), have been surgically implanted in 47 separate procedures. The surgical technique has changed due to the carbon Pyrolite grommet fracturing. To accommodate the extreme flexion range of the rabbit stifle which allows the grommets' flanges to come into contact, it was decided to implant only one grommet per stifle. Several were implanted with only one grommet in either the distal femur or the proximal tibia side of the joint. One animal was sacrificed which had the 316 stainless steel bonded screen grommets in the right proximal and distal stifle and the carbon Pyrolite grommet in the left proximal end only. The carbon was fractured after approximately one month implantation. In the right stifle, after 3½ months, a small piece of screen had separated from the grommet's surface and was incorporated in the joint capsule. Rabbit 15 was sacrificed and the carbon grommet samples were submitted to histopathological examination. These implants had been in place for nearly 6 months. The carbon grommets were fractured and there was failure of the silicone implant in both stifles. It was highly suspicious that the sharp edge of the fractured grommet had cut the silicone implant. No samples have been harvested yet that were implanted only in the distal joint.

The other two types of grommets, polyethylene and Proplast®, are still being implanted on each side of the joint in each stifle.

Two rabbits have died during this reporting period from pneumonia. This problem was discussed with the anesthesia faculty and no primary cause could be theorized. The anesthesia procedures had been exactly the same for the other 45 implantations. Therefore, no changes in the protocol will be implemented unless further problems are encountered.

Biomechanical Testing

The mechanical testing to determine the failure load for the grommet-bone union, being conducted by the Department of Biomechanics, is proceeding very well. The original testing procedure and method of clamping the test specimen have proven to be more than adequate for the grommet tests being performed.

Two of the more recent carbon-type grommets tested showed a significant increase in the amount of load that the grommet-bone union would withstand before failure occurred. These particular grommets had been implanted for 116 and 164 days before they were harvested for testing. The loads generated by the tests of these two grommets were 30.9 lbs. and 46.8 lbs., respectively. These tests were run to such high levels of load strictly to establish the higher limits to which both the clamps and the carbon-type grommets could be subjected. Neither of the test loads represent a true grommet-bone union failure, but rather a clamp and grommet material failure. In both cases, the grommets fractured badly and the clamping device was bent at these high load levels. Future load levels will be limited to near the 10 lb. level originally specified for this project. These two tests were informative in determining the levels of loads that the carbon grommets and the grommet-bone union can withstand.

The most recent tests performed were the first tests of the formed stainless steel grommets supplied by NASA. A pair of one proximal and one distal insertion were tested with the resulting loads being 11 lb on the proximal and approximately 20 lb on the distal grommet. These

tests were not established as actual grommet-bone union failure levels, but rather as levels where the clamp slipped free of the grommet cavity. In both cases the grommet material was pulled or bent inward (by the clamp) at the inserted end, showing a material and/or clamp failure to the load imposed on them. This slippage is considered to be of no real significance—as the load levels which were recorded before the slippage exceeded the level considered to constitute a satisfactory grommet-bone union.

Histopathology

The plastic-embedded undecalcified specimens from the right stifle joint preparation were successfully cut on the microtome.

In addition, a cross-section of the left femur was taken so that the plastic grommet was included. This bone was decalcified, embedded in paraffin and cut at 10μ. Sections were stained in Gormori's trichrome, H&E, and hematoxylin-phloxine-metaniyellow stains.

Examination of the plastic and paraffin sections revealed that collagen fibers had penetrated the spaces between the plastic spheres which formed the wall of the grommet and had reached the inner surface. This suggests the grommet was well anchored in the bone end. Tissue reactions, inflammatory cells, giant cells, necrosis, and collagen formation indicate that the body treated this apparatus as foreign material.

Additional plans in progress include repeating this entire procedure but with the carbon grommet in place. To cut sections of the plastic embedded calcic bone-carbon grommet, high carbon steel circular saw blades have been ordered. To cut paraffin-embedded sections, the carbon grommet will have to be removed and the bone decalcified.

Metal Grommets

Recently Dow Corning has determined a method of casting a grommet that may be thin enough to be used. Prototypes of cast-molded grommets are being fabricated by Dow Corning. These will be the same shape as the carbon Pyrolite. We expect to review these in the next few weeks for use in this project.

Seating Systems for Body Support and Prevention of Tissue Trauma

VA Medical Center
3801 Miranda Avenue
Palo Alto, California 94304
Inder Perkash, M.D.

Rehabilitation Engineering Center
Children's Hospital at Stanford
Palo Alto, California 94304
Wallace Motloch, C.O.,
Richard Pasillas, C.O., and
Maurice LeBlanc, M.S.M.E., C.P.

With three full years behind us, our investigation of a seating system that effectively redistributes and diffuses ischemic-producing forces (compression and shear) has resulted in a cushion design with an external profile which, among other features, represents the sitting surface after the application of body weight. Within this profile we have selectively reinforced the areas corresponding to the posterior thighs and the buttocks, peripheral to the ischii and coccyx regions.

Putting the seat cushion to actual user testing over this 6-month period has resulted in the following findings:

1. The subjective responses of the test subjects for our latest model (7th generation) VASIO–P* expressed almost unanimous appreciation for the increase in both pelvic and truncal stability as well as the overall enhancement of postural attitude for wheelchair manipulation and table top activities. Also high on the list of favorable responses was the effect upon sitting tolerance and transfers. Most felt that the present model performed as well or better than the cushion they were using prior to the study.

2. The low-level nonambulator, limited ambulator, and incomplete-lesion subjects' responses to the question of comfort and practicality were somewhat negative. The "static" convoluted features, which were regarded as extremely functional to the higher-level injuries, were looked upon as too restricting, somewhat hotter because of the intimate relationship between buttocks and cushion, and generally less favorable than the unsculptured cushion systems they were accustomed to.

3. The term "static" in itself is a contradiction to what is usually displayed by the low-level spinal cord injured. Having a mean age of 23 yrs., being typically male and highly active, athletic type of person prior to the injury (that possibly being the very cause of the injury), it would be asking too much for such an individual to be content to sit in a "static" posture for the purpose of achieving good pressure readings. Finally, considering that the very act of postural change will provide pressure relief, pressure redistribution, promotion of blood flow as well as nutritional and waste-product transfers, then the profile of the cushion need only be general and construction resistant to bottoming-out upon loading.

4. The increase in skin temperature was to be expected since the heat-dissipating qualities of foam are considerably less than gel, water, or air. By contrast, however, foam has been shown to have a greater potential for humidity control because of its open-cell construction (1).

5. For the above-stated reasons, the protocol for subject selection of the present model of the VASIO-P will now designate "complete paraplegic level injuries T1 through T12."

6. The VASIO-Q (Quadriplegic design) is still being evaluated empirically. Designing into the cushion profile those characteristics which would normally be found after the application of body weight will increase the contact surface area and encourage "static" forces to act

*Veterans Administration Seating Interface Orthosis-Paraplegic.

perpendicular to the body surface. Doing so will reduce shear and soft-tissue distortion which play a considerable role in tissue ischemia.

7. Positional changes and periodic reliefs from pressure are quite difficult to achieve, if not impossible, for individuals with lesions above the level of C5. However, dependent upon the distribution of spinal innervation, the level of performance is best determined by an assessment of remaining function rather than the level of injury. Nonetheless, the demands posed are greater than can be achieved by our present model VASIO–Q and for these reasons our test-subject-selection protocol will designate "complete injuries C5 through C8."

8. It has become apparent that we must better define the total prophylactic and orthopedic needs of the wheelchair-dependent SCI individual, before we can completely formulate the prescription protocol and structural profile of a modular seating system. Armed with this delineation of needs, further investigation can be embarked upon with a clearer understanding of the demands set forth. Its use by clinical evaluators will help to quantify the projected cost involvement, success potential and difficulties of use so that all concerned parties can understand them and recommend provision of a Seating Interface Orthosis or a presently available commercial cushion.

References

1. Stewart SFC et al: Wheelchair Cushion Effect on Skin Temperature, Heat Flux, and Relative Humidity. Arch Phys Med Rehabil 61, May 1980.

Development and Evaluation of a New Artificial Larynx

VA Medical Center
Gainesville, Florida 32602

Lewis P. Goldstein, Ph.D., Howard B. Rothman, Ph.D., and Calvin C. Oliver, Ph.D.

Continuation and modification of the prototype artificial larynx is still underway. There are no new developments to report at this time.

Studies of Normal and Abnormal Motion

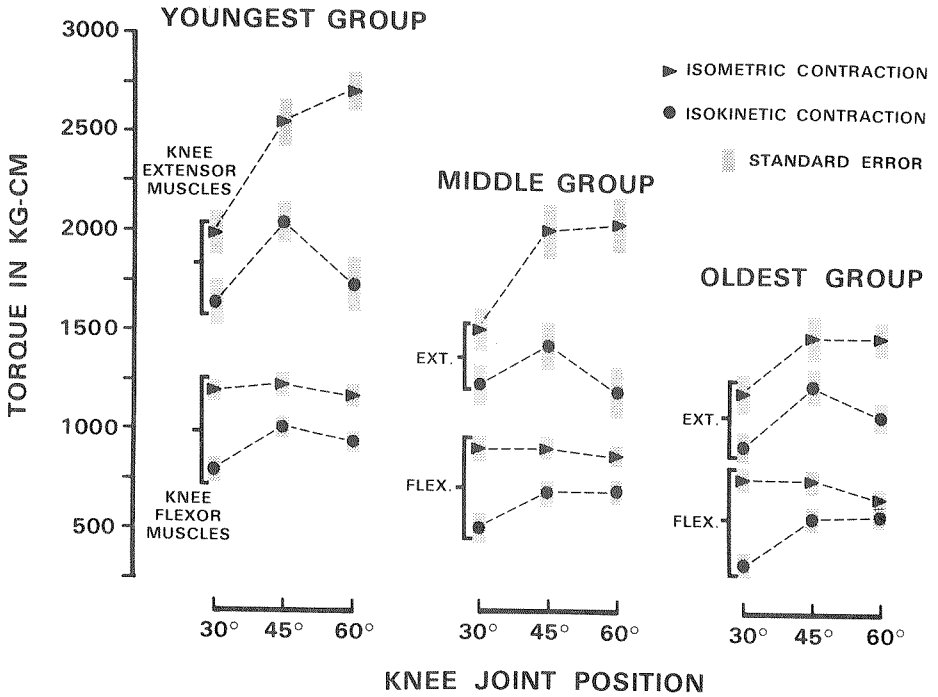
Kinesiology Research Laboratory
VA Medical Center
Wood, Wisconsin 53193

Mary Patricia Murray, Ph. D.

One of the goals of the Kinesiology Research Laboratory is the development of standards of normal functional performance to serve as baselines for assessing the disordered performance of disabled patients. Initial efforts to assess the extent of the deficits in strength of the knee flexor and extensor muscles in patients with knee-joint disabilities were hampered by the fact that no comprehensive standards of normal variability had been established for maximum isokinetic and isometric contractions for older men. Accordingly, a study was undertaken to measure knee muscle strength in 72 normal healthy men in three age groups (20 to 35 years, 50 to 65 years, and 70 to 86 years). Their flexor and extensor muscles were tested during maximum isokinetic contractions at 36 degrees per second and during 5-second maximum isometric contractions at knee-joint positions of 30, 45 and 60 degrees of knee flexion. Measurements of torque were made using a modified Cybex II dynamometer (sitting with 15 degrees inclination of the backrest), and measurements of the knee position were made using an electrogoniometer. Both types of information were recorded simultaneously on a polygraph.

The findings of this study were published in April 1980 in Physical Therapy (1). Strength of the men in the older age groups was significantly less than that of the youngest group (Fig. 1). The strength of the middle-age group averaged 65

FIGURE 1.
Torque versus knee-joint position for isometric and isokinetic contractions of the knee flexor and extensor muscles in three groups of healthy men. For each type of contraction and joint position, the mean maximum torque values shown represent the strongest of two successive trials during the first test week. The shaded areas represent one standard error above and below the mean values. Isokinetic contractions were performed at a speed of 36 degrees per second. (Full knee extension was considered zero degrees.) Reprinted from Physical Therapy (Vol. 60, page 415, 1980) with the permission of the American Physical Therapy Association.



to 80 percent (depending on the knee joint position and type of contraction) of that of the youngest group. The strength of the oldest age group averaged 45 to 65 percent of that of the youngest group. The strength differences between age groups were more pronounced for isokinetic than for isometric contractions. The strength of the isokinetic contractions was significantly less than that of the isometric contractions for all joint positions for both muscle groups. An interesting finding was that the men in the oldest age group generally took longer than the men in the other two groups to reach peak torque during the isometric contractions. Another interesting finding related to the response to repeated testing:

For isometric contractions, differences in torque between repeated trials on the same day **were not** significant, but differences in strength measurements from one week to the next **were** significant.

For isokinetic contractions, however, differences between repeated trials on the same day **were** significant, but differences in strength measurements from one week to the next **were not** significant.

The findings of this study quantify the pronounced extent of the decline in strength of the knee flexor and extensor muscles in men with advanced age, and emphasize the importance of using age-related standards of strength for evaluating the performance of disabled patients.

Studies aimed at evaluating groups of patients before and after different types of hip and knee surgery are continuing. These studies evaluate quantitatively range of motion, strength of muscles spanning the involved joints, multiple components of free-speed and fast walking performance, forces applied to canes or crutches during walking, and weight distribution between the feet during standing. A study evaluating the functional performance of 72 patients 4 years after Charnley and Müller total hip replacement is in final stages of manuscript preparation.

Publications not previously reported

1. Murray MP, Gardner GM, Mollinger LA, and Sepic SB: Strength of Isometric and Isokinetic Contractions. Knee Muscles of Men Aged 20 to 86. Phys Ther 60:412–419, 1980.

Residual Bladder Volume Determination for Spinal Cord Injury Patients

Department of Mechanical and Environmental Engineering, Department of Electrical and Computer Engineering, and Memorial Rehabilitation Foundation
University of California, Santa Barbara
Santa Barbara, California 93106

R. Roemer, Ph. D., R. Wood, Ph. D., and H. Meisel, M.D.

Post voiding residual bladder volume determinations are frequently performed on spinal cord injury patients. This examination involves the utilization of a catheter which introduces the possibility of an infection. Since urinary tract infections and the concomitant frequent kidney involvement are one of the most serious medical problems of these patients, the development of a noninvasive technique for measuring bladder volume on a daily basis at bedside would be a significant contribution to their medical treatment. Thus the long-range goal of this project is to develop a low cost, clinically useful system for non-invasively measuring bladder volume, with particular emphasis on determining the small volumes of residual urine in the bladder of spinal-cord-injury patients. The eventual hardware implementation of such a device will involve an ultrasonic pulse echo system and a microprocessor for data pattern recognition and volume calculations.

The following steps are involved in the research plan:

1. Investigate the accuracy of several volume determination algorithms using a computer simulation of the ultrasonic system;
2. Determine the characteristics of the ultrasonic pulse echo signals from bladders, and develop a simple and accurate method of processing the echoes;
3. Develop a prototype system for laboratory testing, and after testing and any necessary redesign; and
4. Clinically test and evaluate the system.

At present, the computer simulation of the ultrasonic system is being developed. Three integration algorithms are being investigated; (i) a combination of Simpson's rule and trapezoidal integration, (ii) dividing the interior of the region circumscribed by the discrete bladder wall locations into a series of adjacent irregular prisms and octahedrons, and (iii) use of parametric bicubic splines.

The accuracy of these algorithms will be determined for a variety of simple bladder shapes: ellipsoids with and without additional convex and/or concave sections. The sensitivity of the algorithms' accuracies will be determined in the presence of simulated measurement noise.

Prosthetics Research

Prosthetics Research Laboratory
Northwestern University
Room 1441, 345 East Superior St.
Chicago, Illinois 60611

Robert G. Thompson, M.D., and Dudley S. Childress, Ph. D.

Hip-Disarticulation Prosthesis—Efforts have continued toward simulating the effects that changing limb segment parameters and swing-phase controls have on the walking cycle of wearers of the Canadian-type hip-disarticulation prosthesis. A mathematical model of the prosthesis during swing phase has been established and additional gait data are being taken to verify this model. Gait data and computer simulations have been obtained which document the prosthetic motions resulting when either a constant-friction device or a hydralic unit is used with the knee during ambulation. Further simulations are planned to

observe the range of effects that changes in these swing-phase controls as well as others have on the resulting gait.

Synergetic Hook—Design work continues on the electrical current cutoff device.

Below-Knee Preparatory Prostheses

Work continues on the development of a preparatory BK prosthesis, which consists of an interface (socket), a PVC (polyvinylchloride) pylon, and a standard SACH foot. Current investigation is being conducted on the development of interface design including material choice, fabrication techniques, alignment principles, cost, efficiency and adaptation to residual limb volume changes.

Interface design is currently that of the PTB type which is directly applied to the patient's residual limb, thus eliminating the need to take a plaster impression and modify it. The current interface design does not allow the use of a "soft liner": a system is being developed to directly apply a soft liner to the patient prior to forming the interface.

Materials being evaluated in socket design are Aquaplast® (a low-temperature-forming plastic), Lightcast II® (a knitted glass fiber fabric impregnated with a polyurethane resin which hardens when exposed to ultraviolet light) and Scotchcast® casting tape (has the same characteristics as Lightcast II except it hardens when exposed to water). Thermovac® (a co-polymer) and other low-temperature-forming plastic will be evaluated in the future, for possible use in interface fabrication.

More patients are expected to be fitted with the preparatory prostheses so that evaluation and modification may continue.

Powered Arm for Shoulder Disarticulation Levels

We are continuing work on a total arm prosthesis for shoulder disarticulation amputees that utilizes unbeatable position-servo control effected by shoulder motion. As part of this work, an analysis of the dynamic characteristics of physiological control of the elbow and wrist has been performed. The results of this analysis provide a set of functional parameters that will serve as design goals during the development of the prosthesis mechanism and control system.

At the present time we are designing a shoulder motion transduction system that will be used in analyzing the effectiveness of unbeatable position-servo control, and may also be used in the actual prosthesis. An initial study will be performed to determine the optimal performance that can be realized assuming an ideal prosthesis mechanism operating under no-load conditions. Then a study will be performed comparing system performance realizable with different, currently available, powered components. The results of these studies will be used to derive the optimal system configuration.

Engineering Applications in Orthotic and Prosthetic Treatment of Musculoskeletal Defects

Motion Study Laboratory
Rehabilitation Medicine Service
VA Medical Center
10701 East Boulevard
Wade Park, Cleveland, Ohio 44106

E. Byron Marsolais, M.D., Ph. D.

The clinical gait laboratory evaluated 347 subjects between May of 1979 and May of 1980. The following breakdown of cases were seen: total hip replacement 63, hip pain 23, hip fracture 5, total knee replacement 36, knee pain 46, knee arthrotomy 33, patellectomy 3, knee fusion 2, femoral shaft fracture 5, ankle fusion 6, bunionectomy 12, ankle pain 13, low back pain 40, cerebral palsy 17, multiple sclerosis 4, below knee amputation 9, above knee amputation 3, cerebral vascular accident 18, polio 1, normals 8.

Some patients had multiple evaluations. All orthopaedic patients and some others are regularly scheduled for a preoperative evaluation and have regularly scheduled postoperative followup evaluations. The concept of a gait analysis prior to undertaking a potentially gait-altering treatment or surgical procedure is becomng routine. Currently, a major revision of the clinical laboratory report form is underway. The new form will provide knee, hip, and ankle angle, EMG, and force plate data in addition to the previously supplied foot contact data. Following completion of the new form, we will begin our proposed statistical study on the effect of the laboratory on the operation of the Medical Center.

Kinematic data acquisition problems—Another revision of the SELSPOT hardware is currently underway. We continue to believe that the potential for a satisfactory three-dimensional kinematic system is present in SELSPOT, but the current equipment does not provide a satisfactory signal. (A discussion of SELSPOT is published elsewhere in this issue of BPR).

The three-dimensional stroboscopic photographic system has been our major method of kinematic data acquisition. The slow progress with the SELSPOT system has mandated major updating and streamlining of the strobe system. Automation was achieved through design and construction of a hardware stroboscopic controller and use of the LPS-11 peripheral device on the PDP 11/45 minicomputer. Software was written and tested which acquires force plate, EMG, and synchronization data while simultaneously communicating with the strobe controller. A new calibration board for the strobe system was constructed and calibration software was written and tested. A new procedure for anatomical measurements which defines a principal axis system for the limb segments has been designed and marker panels which contain four non-coplanar targets have been developed and tested for the pelvis, thigh, shank, and foot. New software for driving, testing, and calibrating the Graf/Pen (Science Accessories Corp.) sonic digitizer has

been written and tested. Major changes have also occurred in the preprocessing of the kinematic data. Subroutines have been written and tested which minimize the errors in the measured attitude matrices, correct the reconstructed three-dimensional positions of the segment landmarks based on known interpoint distances, provide three-dimensional reconstruction from our stereo photographs, and calculate the four by four homogeneous transformation of a limb segment. Additionally, software which allows an interactive graphical analysis of the EMG data utilizing the Tektronix graphics terminal has been written and tested. General graphics software for the Xerox Versatec electrostatic hardcopy graphics system has been written and tested to facilitate the final output of the analysis.

A concurrent re-evaluation of our total data collection system is underway with development of a new real time system which allows concurrent sampling of 16 channels of analog data at an individual rate of greater than 250 Hz. User interface with the sampling routines is provided through a special purpose command line interpreter and intelligent user software. Final data storage is provided by a powerful data base management system. This SSF (structured sequential file) allows the experimenter to set up skeleton files identifying the patient and containing calibration data. The software provides for automatic merging of that information with the raw experimental data into a composite result file.

Clinical Applications—In cooperation with the Rehabilitation Engineering Center (REC) of Case Western Reserve University, the possibility of "carry-over", or prolonged therapeutic effect, of functional electrical stimulation of the peroneal nerve is being studied in the correction of drop foot in cerebral palsy children. For the six children and one young adult who have been examined thus far, the dorsiflexion produced during gait by the use of electrical stimulation is not sustained when the stimulator is turned off.

Software has been developed by the REC to quantify and to document specific abnormal foot placement patterns during the stance phase of gait, such as equinus, varus, or valgus posturing. Additionally, software to perform ensemble averaging of dynamic EMG activity during gait has been developed. Aside from its use in the present functional electrical stimulation research, this software should significantly extend the utility of gait analysis as a diagnostic tool in planning treatment for patients havng abnormal muscle activity and in monitoring their performance.

Preliminary results of a study done in cooperation with the Division of Orthopedics at Cleveland VA Medical Center and the Department of Orthopedics of Case Western Reserve University indicate that Gait Laboratory evaluation of patients with asymptomatic loosening of total knee joints has excellent correlation with loosening as demonstrated by precision X-ray measurement of the displacement of small stainless steel balls strategically placed at the time of total joint surgery. Six patients have currently been evaluated by both techniques. A statistical discriminant analysis indicates that, using Gait Lab criteria of duration of double support and of footflat of the affected limb, a correct decision can be made 100 percent of the time as to whether the patient fits into the "loose" or "tight" group. There are currently 3 patients in each group. The double support phase is defined as the configuration when the heel of the leg with the prosthesis and the toe of the normal leg are both in contact with the ground.

A similar relationship has not been found for the total hip patients.

Electrical Assessment of Incomplete Spinal Cord Injury and Recovery

VA Medical Center
10701 East Boulevard
Cleveland, Ohio 44106

Case Western Reserve University
2065 Adelbert Road
Cleveland, Ohio 44106

Henry H. Bohlman, M.D., Eugene Bahniuk, Ph. D., and George Raskulinecz[a]

Introduction—Incomplete spinal cord injuries have the potential to recover function to varying degrees, depending upon the amount of initial spinal cord damage as well as on mechanical factors producing compression of neural tissue. The objective of this research is to measure, in animals and man, the degree of spinal cord damage noninvasively and the effect of various factors on recovery of the injured spinal cord—and thereby predict which spinal cord injury will and which will not recover.

The current method of spinal cord monitoring utilizes computer-averaged Cortical Evoked Potentials (CEP) which travel through the ascending posterior column after stimulation of the peripheral nerve. The investigators wish to demonstrate spinal cord dysfunction caused by anterior spinal cord compression or damage by monitoring posteriorly mediated electrical conduction, since anterior cord function can only be monitored by invasive techniques.

Plans are to program and computer-analyze the CEP wave forms from the standpoints of amplitude and latency, to determine the patterns of alteration of various types of

[a]Henry H. Bohlman, M.D., is Associate Professor of Department of Orthopaedic Surgery, School of Medicine, Case Western Reserve University, and Chief, Spinal Cord Injury Service, Veterans Administration Medical Center, Cleveland, Ohio. Eugene Bahniuk, Ph.D., is Associate Professor of Solid Mechanics, Structures and Mechanical Engineering, Case Western Reserve University, Cleveland, Ohio. George Raskulinecz is an Engineer at the Veterans Administration Medical Center, Cleveland, Ohio.

spinal cord injuries. It would be important to correlate specific wave forms with specific spinal cord pathology, and standardize cortical evoked responses with incomplete cord injury.

A further goal of this program will be to develop a less-expensive, simplified monitoring system, utilizing real-time filtering rather than a computer average system. A less complicated system would have wide use for gross monitoring of spinal cord function under the various pathologic and surgical conditions of spinal cord dysfunction, and in preventing spinal cord damage during many types of spine surgery.

Background and Work Accomplished

Clinically, the pathology of cervical spine and partial cord injuries appears to be a combination of incomplete cord contusion and cord compression by anterior mechanical factors, such as protruding discs and bone fragments (1,2,3,4,5). Removal of these mechanical factors by the anterior approach has aided recovery of the patient's spinal cord function. If the spinal cord is incompletely damaged or contused during injury, varying degrees of functioning cord tissue remain. Mechanical factors which anteriorly compress this remaining viable cord tissue may prevent optimal recovery of spinal cord function. The compressive elements may physiologically block spinal cord function and recovery for extended periods of time without totally destroying neural tissue; the spinal cord remains ischemic and deformed as long as compression remains. When neurologic recovery has plateaued clinically, the spinal cord may still recover if the compression is removed.

The problems are: (i) how to measure the degree of spinal cord damage noninvasively, (ii) a lack of knowledge of the effect of various factors on recovery of the injured spinal cord which precludes prediction which spinal cord injuries will eventually recover, and (iii) the problem of assessing spinal cord function in the anesthetized patient during spinal surgery.

Hypothesis—The hypothesis is that immediate anterior compression of the spinal cord will cause an incomplete paralysis which will not recover if maintained chronically, and that removal of chronic compression will allow recovery of the spinal cord to varying degrees. The spinal cord monitoring system utilizing average CEP over the scalp resulting from stimulation of peripheral nerves may be able to predict the extent of spinal cord injury and prognosis for recovery.

Many authors have studied incomplete spinal cord trauma in experimental animals. The original animal model was produced by Allen (6) in 1911 utilizing a weight dropped on exposed posterior spinal cord through a vertical tube. Incomplete spinal cord contusion could be produced by 400 gm-cm of energy applied posteriorly through a laminectomy exposing the midthoracic spinal cord. Tarlov and Gelfam (7,8) produced incomplete thoracic spinal cord injury by compression. The spinal cord compression was produced by a balloon inserted anterior to the thoracic cord via a laminectomy or posterior approach. Tarlov's method of inserting various sized balloons gave no accurate assessment of the exact amount of pressure being applied to the spinal cord. His neurologic grading system was based on motor assessment of the hind limb as follows: (0) no voluntary movement, (1) perceptible movement, (2) good movement but unable to stand, (3) ability to stand, and (4) ability to walk.

In the clinical injury situation, mechanical factors that compress the spinal cord are most frequently located anterior to the spinal cord itself. Therefore, experimental protocol should compress the spinal cord via the anterior approach. An animal model was developed which allows production of an incomplete spinal cord lesion by the application of controlled mechanical pressure against the anterior spinal cord. Provisions have been made to selectively introduce controlled anterior spinal cord contusion. Since anterior cord compression is a prime mode of cord damage in many cervical spine injuries, this model more closely simulates the clinical pathology (9). It is hoped to establish that this model will allow for discrimination of irreversible from reversible spinal cord lesion and that the information will be transferable to spinal cord injury patients for evaluation. Our model allows for the standardization of each factor contributing to the cord lesion; that is, the individual effects of compression and contusion as well as combined effects of both. The mechanical pressure in the animals is relieved and recovery of function is recorded. Animals are killed after spinal cord injury and the spinal cords are studied histologically. We are attempting to correlate the degree of histologic spinal cord damage with the clinical degree of paralysis and recovery.

Specific Objectives—Short-term objectives will be to correlate the degree of incomplete spinal cord injury in animals and man with the changes occurring in the CEP. Another objective will be to determine, on the basis of CEP monitoring, which patients are irreversibly damaged and cannot recover, and which will recover from anterior decompressive surgery. The long-term objective is to standardize the wave form created by CEP during the monitoring of spinal cord injuries to correlate more accurately the degree and types of incomplete injury and to predict the amount of neurologic recovery to be expected (10).

No other investigators have produced an animal model of incomplete cord compression and contusion utilizing the anterior cervical approach, nor has there been any study of the length of time the spinal cord injury model may tolerate pressure and still recover after pressure is relieved (11). This model would also resolve the questions of which cord lesions would benefit from anterior surgical decompression as well as how soon postinjury this de-

compression should or must take place.

Status of Research

Current research at the Veterans Administration Medical Center Spinal Cord Injury Laboratory has involved development of an animal model of predictable incomplete cervical cord injury by utilizing a pressure device to create anterior cervical cord compression. The pressure transducer after implantation between the fifth and sixth cervical vertebrae was remotely monitored during a period of constant compression (4–6 weeks). The animals were fitted with a backpack carrying a spring-loaded fluid reservoir to maintain a predetermined constant pressure. Technical problems with the transducer have been corrosion about the plunger with sticking as well as leaking-out of the closed fluid system. (Special O rings have solved the leakage problem and the current design includes a polyethylene plunger to prevent corrosion and sticking.)

Of eight animals who lived, incomplete quadriparesis was produced in all eight with pressure continuously applied. Central cord paralysis (major forepaw weakness) was noted in seven and anterior cord syndrome was noted in one (hindpaws weaker). All eight animals were paralyzed within 12–72 hours of applied anterior spinal cord compression with varying grades of paralysis. The Tarlov grading system was utilized with an additional grade added to indicate when the animal was able to climb a 20 degree inclined plane (grade 5). Severely quadriplegic animals were cared for by twice-daily turns, emptying the bladder by Credé compression, and by hand feeding.

In all eight of the animals studied, pressure was continuously applied to the anterior cervical spinal cord (commonly from one to six weeks) and then in six cases, when no further spontaneous recovery of motor function occurred, the transducers were removed and retracted. Two animals recovered without retracting the transducer. Significant motor recovery occurred in all eight animals, some within 48 hours of removing the pressure from the spinal cord. The chronically compressed cord can recover if the pressure is relieved even though decompression is carried out later after injury. All eight animals were able to walk up a 20 degree inclined plane prior to killing (9).

Incomplete cervical spinal cord injury by contusion has been produced in 15 animals by the weight-drop method of Allen. A range of 270 gm·cm to 970 gm·cm of kinetic energy was applied through the same anterior cervical approach. All drops were from a height of 20 cm. One animal was unaffected and one died. Of the remaining thirteen animals the paralysis pattern was a central cord syndrome (foreleg paralysis greater than hindleg), which was also produced by anterior cord compression. This has never been reported in the literature, however, most investigators have not utilized the anterior cervical spinal cord for investigation even though cervical injuries are the most common in humans. In general the degree of paralysis paralleled the amount of energy applied to the spinal cord. Twelve of the animals who were paralyzed recovered but one injured with 970 gm·cm did not fully recover. The amount of energy required to produce severe paralysis in the cervical cord was significantly higher than other investigators have reported in the thoracic cord (12, 13, 14).

The pathologic findings in the cervical cord of both the compression and the contusion model range from no change to central grey matter necrosis or laceration of the white matter—depending upon the amount of energy applied at the time of injury.

It has been established that to produce an incomplete spinal cord injury by extradural anterior cervical cord compression, 15–20 pounds per square inch (103–138 kPa) of external pressure must be applied to the transducer device. This injury will not fully recover unless the pressure is relieved, but even with decompression after 4 to 8 weeks of paralysis the animals can recover neurologic function.

In collaboration with Richard Brown, Ph. D., from the Engineering Department, Case Western Reserve University; and Clyde Nash, M.D., Department of Orthopaedic Surgery, Case Western Reserve University, a mobile, selfcontained spinal cord monitoring system was constructed; currently it is being used to analyze the animal models of incomplete spinal cord injury. The purpose of the spinal cord monitoring is to find the relationship between the CEP and physiologic insult to the spinal cord of beagle hounds. In addition, the CEP techniques are being applied to monitoring human patients after acute spinal cord injury, during spinal surgery, and in long-term followup of these patients (10,15,16,17,18).

Work Proposed and Methods of Procedure

The remainder of 1980 will be spent completing standardization of an incomplete spinal cord injury (cervical) by individually utilizing anterior cord compression and by anterior cord contusion. Ten adult 14-kg beagle hounds will be subjected to the standard anterior operative procedure for anterior cord compression by inserting the extradural pressure transducer, fitted with a mini pressure sensor, and placed through a hole in the disc space between the fifth and sixth cervical vertebrae. This transducer is instrumented with a strain gage pressure-sensing element to measure the magnitude of the compressive force applied to the anterior cord by the transducer.

External control of the transducer is accomplished by passing all necessary connections from the ventral aspect of the dog's neck to the dorsal region subcutaneously, with a polyethylene tube. The tube is fixed to the skin by sutures. The beagles are fitted with a special harness with pockets which hold the spring-loaded fluid reservoir to apply continuous pressure. Transducer placement is checked during surgery with

anteroposterior and lateral roentgenograms. The day following surgery, after it has been determined that there is no spinal cord damage from the operative procedure, a predetermined amount of pressure is applied to the spinal cord.

It is now recognized that paralysis ensues within 48 hours of pressure application and becomes most severe by 4 days. Pressure is maintained at a constant level for 4 to 8 weeks until further spontaneous neurologic recovery no longer occurs. Daily neurologic examinations are recorded by the modified Tarlov grading system. Recordings of CEP are carried out before and during surgery and the immediately following day, and at weekly intervals thereafter. The CEP is expected to decrease in amplitude following spinal cord injury but to return to normal if the animal recovers function.

At the four-week postoperative interval, if the animal has stopped recovering function, the transducer is removed or retracted and observation of recovery is recorded again until all possible recovery occurs (4–8 weeks). The animals are then killed and the spinal cords serially sectioned and stained with hematoxylin-eosin as well as Luxol fast blue with PAS counter stain.

Five control animals have had spinal cord compression of 20 lb/in^2 (103.40 cmHg), were not decompressed, and did not recover neurologic function.

Also in the remainder of FY 1980, ten adult beagles will be subjected to anterior cervical spine cord contusions by the following method. A metal tube has been constructed 20 cm in height with a level attached to maintain absolute vertical direction. A specific weight will be dropped through the tube to contuse the spinal cord extradurally through an anterior drill hole. The purpose of the weight drop is to produce a consistent incomplete cervical spinal cord injury which will not totally recover. To date the most consistent energy applied to produce severe quadriparesis has been in the range of 700 to 900 gm·cm.

Following production of the individual models of incomplete spinal cord injury by compression and by contusion, there will be a combination of the two problems in each animal; i.e., first contusing the cord by dropping a measured weight and then applying compression by inserting the pressure transducer, still producing an incomplete spinal cord injury. The cord compression will be maintained for 4 to 6 weeks (or until the neurologic recovery becomes static) then the transducer will be removed to allow for further spinal cord regeneration or recovery. It is believed that this combined model most closely simulates what occurs pathologically in human incomplete spinal cord injuries, and that it will define the role of mechanical compressive factors affecting spinal cord recovery. In FY 80, 40 pure-bred adult beagles will be tested with this model. Twenty animals will be subjected to contusion and compression without surgical decompression and 20 to contusion and compression with late anterior decompression by removal of the transducer after neurologic recovery has ceased. Comparing the two groups will provide a measure of the effectiveness of anterior decompression surgery. All of these animals will be monitored with CEP.

For the experiment described, the CEP will be a means (i) to ensure that cord trauma is not due to the operation, (ii) to indicate when the spinal cord is disturbed, and (iii) to measure the changes in the spinal cord with time.

In FY 81, 40 animals will be subjected to the contusion-compression injury, but during that year complete cord injury will be produced as manifested by cessation of CEP for 48 hours and grade 0 paralysis. Complete cord injury will be produced by a constant weight drop and increased compression. Twenty animals will be treated without surgical decompression and 20 by anterior decompression 48 hours following injury. We will attempt to determine the effect of early decompression on clinically and physiologically complete spinal cord injuries. Appropriate histologic studies will be performed on the spinal cords after killing.

In addition, in FY 81 and 82, a plan to develop a computer program for comparisons and analysis of the CEP waveform produced from the first 100 milliseconds recorded with an animal model and patients sustaining incomplete spinal cord injury will be introduced. We will measure and analyze the abnormal wave form from the standpoint of amplitude (peak to peak) and latency (time of occurrence). All data to be analyzed will be stored in the large capacity PDP 11/45 computer available at the VA Medical Center. Analysis will include the type and degree of spinal cord injury, the effect of anterior surgical decompression, and final results of treatment.

Approximately 75 new spinal cord injuries are admitted to the Cleveland VA Medical Center Spinal Cord Injury Service per year. The mobile spinal cord monitoring system is being utilized to carry out postinjury, intraoperative, and followup recordings of CEP on these new admissions. The monitoring system may help diagnose more accurately those patients who are incomplete cord injuries and those who may be helped by anterior decompression surgery.

In addition, there will be a correlation of serial monthly recordings in the postoperative period with recovery of neurologic function by clinical examination.

Development of a Real-Time Filtering Unit for Clinical Monitoring (RTFU)—The method now being used for monitoring CEP involves collection of 64 digitally averaged CEP in a small computer and storing of this data in a larger digital computer. This is probably the most powerful and appropriate method for this research. The advantage is that there is a minimum of lost information, and information can be recalled at any time for analysis.

For routine clinical monitoring on

a large scale, the disadvantages of the current system are the initial capital cost ($50,000), large size, the need for technical personnel knowledgeable in computers and electronics, and dependency on a computer company contract for repairs ($400/month).

Therefore, in parallel with our current research, an alternative method for monitoring spinal function is being constructed which utilizes techniques of real-time filtering of CEP developed by Dr. T. F. Collura at the Department of Bioengineering, Case Western Reserve University. The circuitry sums the output from two electronic filters which filter the raw CEP at the stimulus frequency and its first harmonic. For visual stimuli, the RTFU reasonably approximates CEP obtained by the conventional averaging technique.

Limited testing on Dr. Collura's apparatus indicates real-time monitoring of CEP from peripheral nerve stimulation is a viable technique. For this reason the RTFU is being constructed for use in our animal studies.

This RTFU will be composed of real-time filters, stimulators, and EMG amplifiers now in use with the existing digital computers.

The output of the RTFU will be continuously recorded on our existing Honeywell Multichannel Visicorder. The CEP will be simultaneously recorded with animal blood pressure, temperature, respiration; additional information can be recorded as necessary.

The distinct advantages of the RTFU are the cost, which is approximately one-tenth that of the digital computer averaging system, and its simplicity, which should make it more reliable and cheaper to maintain. There is a continuous real-time display of the CEP, whereas the computer-averaging technique provides a single reading every 2 minutes. The RTFU can be operated by non-technical personnel normally on the staff of hospitals.

For this program, it is proposed to monitor the CEP of the spinal cord by both methods (real-time filtering and digital computer-averaging). The computer-averaged data will serve as a data base for our studies. The two monitoring methods will be compared to determine the viability of the RTFU and to make improvements if necessary. For instance, our initial RTFU will use only the fundamental and first harmonic of the peripheral nerve stimuli. More accurate data may be obtained if additional harmonics are used; these can be added to the RTFU if needed. The optimal stimulus frequency and duration for the RTFU must be determined.

If the RTFU method is shown to give a reliable and reproducible measure of spinal cord function, it has the potential to be used as widely as an electrocardiogram; it would be applicable to a wide variety of spinal disorders and to the monitoring of operative procedures on a large scale.

Resources—The facility being used is the new research building at the VA Medical Center, Cleveland, Ohio. A shielded room of 400 ft^2 (37.16 m^2) is being used for the monitoring equipment, transducer design, and construction, and for testing animals for neurologic function. An additional 400 ft^2 (37.16 m^2) operating room is utilized for the surgery and intraoperative monitoring. The research rooms are located on the second floor, easily accessible to the Spinal Cord Injury Service (an acute care unit comprising 80 patients) also on the same floor of the Medical Center. Animal facilities are located within the new research building.

The VA Medical Center of Cleveland is affiliated with Case Western Reserve University. The University currently has a large medically oriented engineering school as well as a medical school. This arrangement allows access to both medical and engineering resources to support research. In addition, the Department of Orthopaedic Surgery at Case Western Reserve University currently has an identical spinal cord monitoring unit, well established, with which to collaborate—the CWRU unit has monitored over 250 normal patients and will help serve as a baseline for normal controls in humans. Additionally, spinal cord injury patients are being monitored at the University Hospital with the same unit.

The VA Medical Center presently has a funded computer center and there is a large, powerful, central digital computer installation in the research building specifically designed to meet the needs of the Center's growing research. There is a full-time computer programmer at this center, who will help design programs for analysis of the CEP.

A Model 1858 Honeywell Multichannel Visicorder to measure the effects of blood pressure, heart and respiratory rates, temperature and other variables which may affect the spinal cord injury will be utilized. This unit is in use now with the animal model.

The spinal cord monitoring unit utilizing computer averaged CEP is built and in use. It is hoped to build an additional RTFU for monitoring CEP.

References:

1. Bohlman HH: The Pathology and Current Treatment Concepts of Cervical Spine Injuries (Instructional Course Lectures). American Academy of Orthopaedic Surgeons. C.V. Mosby Co., vol. 31, pp 108–115, 1972.
2. Bohlman HH: Cervical Spondylosis with Moderate to Severe Myelopathy: A Report of 17 Cases Treated by Robinson Anterior Discectomy and Fusion. Spine 2:151–162, June 1977.
3. Bohlman HH: Cervical Spine Injuries, A Critical Review of 300 Hospitalized Cases. J Bone Joint Surg, 61A: 123–152, Dec. 1979.
4. Bohlman HH: Late Anterior Decompression of Spinal Cord Injuries—A Preliminary Report of 36 Cases. J Bone Joint Surg Sept 1975
5. Davis DD, Bohlman HH, Walker AE, Robinson RA, Fisher F: The Pathological Findings in Fatal Craniospinal Injuries. J Neurosurg 34:603–613, May 1971.
6. Allen AR: Surgery of Experimental Lesion of Spinal Cord Equivalent to Crush Injury of Fracture Dislocation of Spinal Column. A preliminary report. J Am Med Assoc 57:878–880, 1911.

7. Gelfam S and Tarlov IM: Physiology of Spinal Cord, Nerve Root and Peripheral Nerve Compression. Am Physiol 185:217–229, 1956.
8. Tarlov IM: Spinal Cord Compression: Mechanism of Paralysis and Treatment. Springfield, Ill. Charles C Thomas 1957.
9. Bohlman HH, Bahniuk E, Raskulinecz G, Field G: Mechanical Factors Affecting Recovery of Incomplete Cervical Spinal Cord Injury, A Preliminary Report. The Johns Hopkins Medical Journal, 145:115–125, Sept 1979.
10. Bohlman HH, Bahniuk E, Raskulinecz G, Field G: Spinal Cord Monitoring of Experimental Incomplete Cervical Spinal Cord Injury. Spine: In press, March 1980.
11. Hukuda S, Wilson CB: Experimental Cervical Myelopathy: Effects of Compression and Ischemia on the Canine Cervical Cord. J Neurosurg 37:631–653, December 1972.
12. Ducker TB: Experimental Injury of the Spinal Cord. Handbook of Clinical Neurology, Vol. 25 Injuries of the Spine and Spinal Cord, Chap. 2:9–26 (Vinken P.J. and Bruyn G.W. ed.), New York, American Elsevier Publ., 1976
13. Assenmacher DR and Ducker TB: Experimental Traumatic Paraplegia: the Vascular and Pathological Changes Seen in Reversible and Irreversible Spinal Cord Lesions. J Bone Joint Surg 53A:671–680, 1971.
14. Brodkey JS, Richards EE, Blasingame JP, Nulsen FE: Reversible Spinal Cord Trauma in Cats—Additive Effects of Direct Pressure and Ischemia. J Neurosurg 37(5):591–593, November 1972.
15. Croft TJ, Brodkey JS, Nulsen FE: Reversible Spinal Cord Trauma. J Neurosurg 36:402–406, April 1972.
16. D'Angelo CM, VanGilder JC, Taub A: Evoked Cortical Potentials in Experimental Spinal Cord Trauma. J Neurosurg 38:332–336, March 1973.
17. Nash CL, Lorig RA, Schatzinger LA, Brown RH: Spinal Cord Monitoring During Operative Treatment of the Spine. Clin Ortho & Rel Res 126:100–105, July–August 1977.
18. Perot PL: The Clinical Use of Somatosensory Evoked Potentials in Spinal Cord Injury. Clin Neurosurg 20:367–381, 1973.

Development of Improved Grouting Materials for Artificial Joint Replacement

VA Medical Center
50 Irving Street, NW
Washington, D.C. 20422

Office of the Associate Dean for Research
George Washington University Medical Center
2300 Eye Street, N.W.
Washington, D.C. 20037

William P. Fortune, M.D., and Fred Leonard, Ph.D.

The purpose of this work is to develop new methods for stabilization of artificial joints. In the model proposed the prosthesis is a "standard" femoral hip component whose stem is coated with a low modulus porous polyethylene. At various places on the stem will be inset sections of an anhydrous, biodegradable polymer hydrogel whose surface is flush with the surface of the porous polyethylene.

In use the prosthesis will be set in the intramedullary canal. It is hoped the following hypothesized series of events will occur. Swelling of the polymeric material against the bone will provide initial stabilization of the prosthesis while the body's contiguous tissue grows into the porous polyethylene to provide further stabilization. Subsequently, the biodegradable polymer will be resorbed and replaced by additional bony ingrowth. The result will be a femoral hip prosthesis stabilized initially by the swollen polymer and ultimately by bony ingrowth. The low modulus porous polyethylene interposed between the metal prosthesis and the bone will help distribute the stress over the area of the bone/prosthesis interface and thereby minimize bony necrosis and metal fatigue due to high local stress. During this period, work has been continued along the following lines:

1. Evaluation of collagen as a biodegradable hydrogel
2. Synthetic attempts to impart greater hydrophilicity to well tolerated biodegradable synthetic polymers
3. Preparation of polymeric compositions consisting of biodegradable synthetic polymers and hydrophilic fillers.

Of the three approaches, the preparation of polymeric compositions consisting of biodegradable polymers and hydrophilic fillers appear to give greatest promise. Compositions have been obtained which swell in Ringers solution up to 50% and generate swelling pressures of 100 psi. The observed volume increase is greater than can be attributed to hydration of the filler alone and may be due in addition to an osmotic effect whch may be substantial, depending upon the aqueous solubility of the filler. Rings of the composition have been molded to a stainless steel rod, inserted into cancellous bovine bone and immersed in Ringers solution at 37 deg C for a period of 1 week. The ultimate shear stress to pull out the rods after swelling had occurred was 169 psi. and 189 psi. These values are considerably higher than those obtained for gelatin and collagen and may be compared to 181 psi. found for polymethyl methacylate.

For the future we plan to further evaluate and optimize these types of compositions and undertake in vivo evaluation in laboratory animals.

Program for the Study of Disabilities Due to Vascular Disease: Thromboembolism

VA Medical Center
Castle Point, New York 12551

Bok Y. Lee, M.D., Frieda S. Trainor, Ph. D., David Kavner, D. Eng., and William R. Thoden, M.A.

This program is designed to determine the physiological mechanisms, clinical effectiveness, and optimal parameters for the prophylaxis of deep venous thrombosis using external intermittent pneumatic

compression. Using native whole blood thromboelastography (a method for measuring coagulation dynamics), a technique has been developed for quantitating percent fibrinolysis. This technique has been applied in a clinical study where the percent fibrinolysis was monitored using native whole blood thromboelastography before and after 2 hours of external intermittent pneumatic compression applied to one arm of the patient.

The influence of fibrinolytic activity on thromboelastography is detected as a decrease in amplitude following the point of maximum amplitude. To quantitate fibrinolytic activity, one measures the maximum amplitude and then the amplitude at 10 mm, 20 mm, 30 mm, and 40 mm below the maximum amplitude. These values are placed in the following equation to obtain a value of percent fibrinolysis:

$$\%F = 1 - \left[\frac{Ma + 2a_1 + 2a_2 + 2a_3 + a_4}{8\,Ma}\right] \times 100$$

A series of 50 patients received external intermittent pneumatic compression applied to one arm for 2 hours. Of these 50 patients, 31 (62 percent) showed a quantitative increase in percent fibrinolysis following 2 hours compression. Precompression, percent fibrinolysis averaged 3.9 ± 4.0; postcompression, percent fibrinolysis averaged 6.2 ± 8.1. The average increase in percent fibrinolysis was 245 ± 286% with a range of increase of 8 percent to 1167 percent; no patient decreased.

Enhanced fibrinolytic activity secondary to external intermittent pneumatic compression was detected in the systemic circulation by blood drawn from the contralateral arm and analyzed by thomboelastography. It appears that the naturally occurring fibrinolytic activity is enhanced by external intermittent pneumatic compression. This activity, in addition to preventing stasis, is essential in its role in the prevention of postoperative deep venous thrombosis.

Evaluation of Electrical Techniques for Stimulation of Hard Tissue Growth

VA Medical Center
Irving Avenue and University Place
Syracuse, New York 13210

J.A. Spadaro, Ph. D., Dwight A. Webster, M.D., and A.A. Marino, Ph. D.

We are pleased to note that Dwight A. Webster, M.D, has become part of the Orthopedic Research team at this station, as well as Chief of the Orthopedic Service. Dr. Webster will be working on both clinical and laboratory phases of our research program, notably electrical osteogenesis and silver bacteriostasis.

Use of Silver in Treatment of Chronic Osteomyelitis

The clinical research program for the silver mesh treatment of chronic osteomyelitis is progressing. To date 32 patients have been treated. Silver ions are electrically injected into a surgically debrided infected bone by daily application of anodically activated silver-coated conductive dressings, making use of the antibiotic effect of the silver to eliminate residual bacteria. An in-depth review of the first 25 patients treated with this method shows about 75 percent have an improvement in their clinical situation. Because of the indolent nature of osteomyelitis, only long term followup will indicate the real effect of this treatment. The application of the dressing is shown in Figure 1 and is described more fully in the literature (J. Bone Joint Surg. 60-A, pg. 871-881, 1978).

Electrical Osteogenesis—Clinical Trials

To date 30 patients have been treated for non-united fractures using the low-current silver cathode implant method. This technique continues to show approximately 75 percent success in patients with established non-union of 2 years median duration. We are now beginning a thorough analysis of the experience and data acquired thus far, in order to project the future course of this application. At the same time, new laboratory experiments are being designed to extend the electrical osteogenesis method to problems of large segmental loss of bone, an area for which there is no present adequate remedy. A particular advantage of the silver electrode is its ability to be rendered bacteriostatic by being operated anodically for a short period of time, prior to or during the 6-week cathodic osteogenic period.

Limb Regeneration Experiments

The pursuit of the limits of mammalian regenerative capacity has been carried one step further with the observation that surgically induced contact between peripheral nerve and the epidermis can lead to a regenerative response. An experiment has been completed using 80 Sprague-Dawley rats with unilateral amputations through the distal third of the femur. In half of the animals, the sciatic nerve was dissected free and its terminal branches fed through a hole in the epidermis directly over the cut femur and sutured to the skin. In the remaining animals (controls) the same hole in the epidermis was made, but the nerve was left in situ.

After 2 weeks the experimental group showed a blastemal-like cell mass and later active osteogenesis, myogenesis and epimorphic reconstruction of the lost structures. The maximum response (6 weeks) showed a bony outgrowth, an organized epiphyseal plate, capped by articular-like cartilage. In addition, 2 weeks after amputation, individual nerve fibres had grown out from the cut nerve and ramified throughout the wound epithelium. Healing in the control group was dominated by fibrous connective tissue proliferation and moderate amounts of chondrogenesis and, later, bone.

The results thus far indicate an important contribution of the neural-epidermal contact in triggering regeneration. They also confirm the

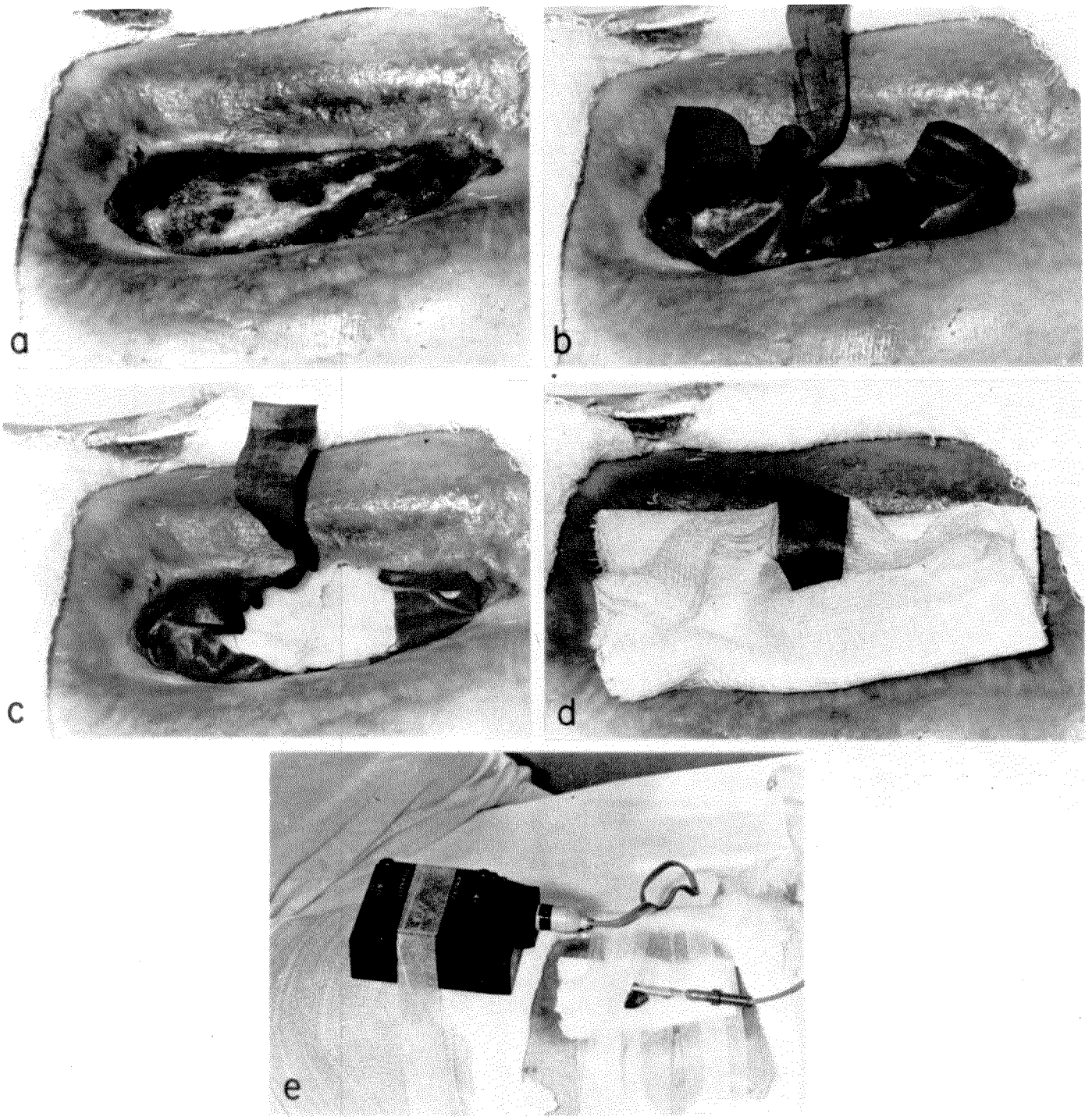


FIGURE 1.
Application of conductive silver-nylon anode material to saucerized, infected, tibial non-union: (a) the wound itself in cast window (case T.W.); (b) saline wetted silver-nylon placed in contact with all wound surfaces below skin level; (a "tail" is left out for electrical contact.); (c) a gauze stent moistened with normal saline packed over nylon; (d) dry sterile gauze placed over entire wound with "tail" protruding; (e) constant voltage source and positive lead connected to silver-nylon. Return electrode (not shown) is placed on intact skin with electrode paste and its position selected to enhance silver ion mobility into infected regions of the wound bed.

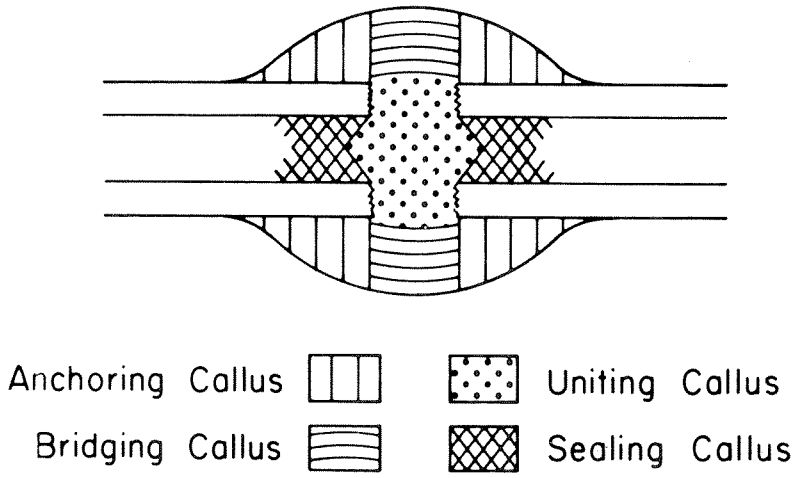


FIGURE 2.
Regional distinctions used in grading the status of fracture healing in the fibula of the rat. For each region the amount and quality of cartilage and bone was graded on a scale from 1-5. This data was combined with general characteristics (union, alignment, callus size) to obtain a final histological grading of the fracture (called the 'healing index'). (See: Marino AA, et al, Clin Orthop Rel Res 145, pg. 239, 1979.)

fact that mammals have more regenerative capacity than is generally believed. We will continue this work in an effort to learn why the neural-epidermal contact is so important, using (among other things) the electron microscope.

Influence of 60 Cycle Electric Fields on Fracture Healing

An experiment was performed to measure the influence of externally applied low-frequency electric fields on the rate of fracture healing in the rat fibula osteotomy model, a model often used in fracture healing studies. Osteotomies were performed on 75 rats, half of which were kept in special cages in which an alternating 60-Hz electric field of 5000 Volts/meter was applied vertically for the entire 14-day post-fracture period. The other half of the animals were kept in identical cages, with both plates grounded (i.e. no electric field). In all cases, the animals were completely insulated from contact with the field plates.

The fractures were graded histologically at 14 days by judging the growth in four regions (Fig. 2). The grading was done without knowledge of the time since fracture or whether the slide was from the control or treatment condition. The grading included determination of new bone, cartilage, alignment, fibrous connective tissue, etc., and formation of a "healing index" for each fracture. In the field-exposed animals, the new bone had thinner trabeculae and large blocks of cartilage in the uniting callus. They appeared at 14 days to be at the 10-day stage of healing for control animals. The overall healing index of exposed animals was significantly lower than controls ($p < 0.001$). This study suggests that low-frequency electric fields act as a systemic stress to the animal, thus retarding the metabolic efficiency of the bone healing process. It emphasizes the need for more knowledge of the results of environmental and therapeutic exposure of large areas of the body to such fields.

Foot Biomechanics: Force and Pressure Distribution in Health and Disease

VA Medical Center
Iowa City, Iowa 52240

Reginald R. Cooper, M.D.[a]

A modeling study of the stress distribution in the plantar aspect of the foot has been completed. This culminated in a Masters' thesis in engineering (Sachio Nakamura). This study included a representation, by finite element analysis, of the foot within a shoe. The finite element model included aspects of the bones of the foot, thick plantar-aspect skin, and shoe sole material. Numerical procedures permitted the prediction of the stress distribution throughout the foot-shoe structure during the activities of weightbearing. The objectives included an investigation of the effects that shoe sole elastic properties have upon the magnitudes of stresses developed within the thick skin of the foot. A systematic search of linearly elastic shoe sole properties revealed a significant dependence of the stress developed within the foot on the stiffness of shoe sole material. Relatively high stresses within the foot occurred when the foot was loaded through extremely soft or hard shoe soles. Shoe soles of intermediate stiffness generally lower the stresses within the foot. An optimum, linearly elastic, shoe sole material that minimizes stresses within the foot during weightbearing should be developed.

A study to measure experimentally the effects of pressure exerted upon the foot from shoes of different elastic properties is currently underway. This study involves the measurement of pressure upon the foot surface using thin pressure transducers within the environment of the shoe. The results of this study will comment upon the validity of the mathematical techniques used to predict stress distribution

[a]Dr. Cooper is Chief, Rehabilitation Medicine, Veterans Administration Medical Center, Iowa City, Iowa 52240.

throughout the foot, will help determine orthotic design, and will help in development of surgical procedures for a variety of foot problems.

A device has been designed and constructed to permit the observation of the foot-floor pressure gradient by subjects walking barefoot over a glass plate. This device is currently being calibrated to permit the quantification of pressure images, and is expected to have application in the evaluation of patients with a variety of foot abnormalities. Upon the completion of calibration and the development of patient protocols, the device will be used to observe the plantar-aspect pressure distribution on patients with various foot disorders, both before and after treatment modalities.

Textured Grommets for Flexible Implant Arthroplasty of Finger Joints

Research and Advanced Concepts Section
NASA—Lewis Research Center
21000 Brookpark Road
Cleveland, Ohio 44135

Bruce A. Banks, Head

Two concepts utilizing ion thruster technology are now being considered for anchorage of finger grommets for flexible implant arthroplasty. They are:

1. Ion sputter texturing of cast cobalt chromium grommets and/or half grommets (shims), and
2. Photochemical texturing of Ti-6 Al-4 V sheet and forming the textured sheet into grommets.

Ion sputtering for concept 1 has been successfully demonstrated. Dies for grommet fabrication for concept 2 have been successfully fabricated and used to form grommets of Ti 6-4. Animal evaluations of both concepts are planned.

Development of a Wheelchair Using a Myoelectric Control System

VA Medical Center
1400 Veterans of Foreign Wars Pkwy.
West Roxbury, Massachusetts 02132
Alain B. Rossier, M.D., and Mehdi Sarkarati, M.D.

Neurocom
Franklin, Massachusetts
George Crawford, Ph. D.

Progress has been made toward the goal of using single motor-unit activity, detected with surface electrodes, for myoelectric control by quadriplegics. Each motor unit activation is converted into a TTL-compatible electrical control pulse with a threshold detector and monostable multivibrator. The high signal-to-noise ratio required to implement this system was achieved by the development of myoelectric amplification equipment having a noise figure of approximately 3 dB (similar to that described in previous BPR progress reports on this program).

The frontalis muscle and the upper portion of the trapezius muscle were used in experimentation with quadriplegics. These muscles were chosen because they are both conveniently accessible, large-surface muscles that can be activated by high level quadriplegics. Preliminary results indicate that the frontalis may be unsatisfactory because of interference from EEG spectral components falling in the frequency band required for sensitive detection of single motor-unit activity. The patient participating in the frontalis investigation (a C4 quadriplegic) could consistently eliminate the electrical interference from the forebrain by intensely concentrating on any subject. Mental fatigue results from the continuous concentration required to keep the interfering EEG activity squelched. The extent to which the electrode spacing can be reduced, to decrease the EEG-to-EMG ratio, without resulting in an unacceptably low EMG-to-noise ratio has not been investigated.

EEG activity did not interfere with the use of the trapezius. From a cosmetic point of view, the trapezius has another advantage: the miniature module at the electrode site is easily concealed with clothing. However, the trapezius was found to have a disadvantage with respect to the frontalis. For cases where a patient can sit erect with no head support, the system sensitivity may be limited by background myoelectric activity that is associated with the maintenance of posture. Preliminary experimentation with one of the investigators as a subject indicates that one can learn to eliminate this interfering myoelectric activity while maintaining an erect posture and while rotating the head to look to the side. An effort is commencing to teach patients this type of control. Without this training, patients are currently being taught to use the experimental myoelectric wheelchair in a few minutes. This is done with the myoelectric detection threshold set above the level of the background postural activity. The object of working towards single motor-unit detection is to achieve effective, effortless wheelchair control with no visible muscular motion—and to open the door to applications requiring continuous high-speed information transfer as computer programming for occupational rehabilitation.

Functional Muscle Control by Electrical Stimulation of Afferent Nerves

Spinal Cord Injury Service
VA Medical Center
West Roxbury, Massachusetts, 02132

Robert W. Hussey, M.D., and Alain B. Rossier, M.D.

Mechanical Engineering Department
Massachusetts Institute of Technology
77 Massachusetts Avenue
Boston, Massachusetts 02139

Michael J. Rosen, Ph. D., and William K. Durfee

This project is concerned with ways of improving upon the fast-fatiguing muscle contractions that are typically seen in functional electrical stimulation (FES). In particular, it is hypothesized that, since reflex activation of muscles involves the spinal motor neuron pool, it will result in motor unit recruitment that follows the size principle. This contrasts with direct stimulation of the muscle motor nerve which recruits the large, fast-fatiguing motor units first. Our experiments, therefore, are aimed at comparing the properties of muscle contractions produced by direct and reflexive stimulation. We are using 10-day T12 spinal dogs as an experimental model of the human paraplegic.

The first stages of this project were concerned with design of a stimulating electrode. We have developed, and are using, a cuff-style electrode made entirely of silicone rubber with contacts of carbon-conductive elastomer. This electrode is radially symmetrical and presents a soft, smooth surface to the nerve.

The first reflex recruitment tested was excitation via synergistic muscle loops. Force was recruited in the medial gastrocnemius muscle reflexively by stimulating the nerve branch to the lateral gastrocnemius, and directly by stimulating its own nerve branch. This method had to be abandoned due to unavoidable passive current spread between the two stimulating sites—which contaminated the data.

We are currently investigating the flexor withdrawal reflex at the ankle. Isometric force is measured in the anterior tibial muscle. The reflex stimulation site is the distal tibial nerve, near the medial malleolus; the direct site is the common peroneal nerve, just after it splits from the sciatic. In six of the seven dogs tested at this combination of sites to date, there has been a consistent reflex response. It appears, however, that the withdrawal reflex will have little application in any practical FES orthosis. The recruited force levels are very low, and decay quickly due to rapid adaptation of the reflex. We plan on testing a few more dogs with this protocol in order to characterize the reflex more completely, and will then move on to investigate other reflex mechanisms that could be potentially useful in FES applications.

Identification of Fatigue by EMG Power Spectrum Analysis

VA Medical Center
4500 S. Lancaster Road
Dallas, Texas 75216

Richard E. Jones, M.D., Vert Mooney, M.D., Timothy Carmichael, MSEE, and Roland Ortengren, Ph. D.[a]

The purpose of this project is to develop clinically useful methods and equipment for identifying localized muscle fatigue by power spectrum analysis of myoelectric signals, and apply these to monitor rehabilitation progress after injury or surgery to the musculoskeletal system.

As previously reported, equipment for obtaining and recording myoelectric signals had been assembled and tested. A reliable technique for acquisition of myoelectric signals picked up by surface electrodes has been developed and data from static-load fatigue tests of quadriceps and biceps muscles have been recorded. The recordings provide a reference for signal characteristics of the myoelectric activity in these muscles and have been used in testing the computer-programmed algorithms for fatigue analysis. The feature to be evaluated is a shift of the myoelectric signal power spectrum which occurs during fatiguing contractions. The analysis procedure is based on the fatigue index method described by Lindstrom et al. (1977).

A software package has been developed for fatigue analysis of static isometric muscle loading. The whole procedure comprises five steps, of which the first is recording the myoelectric signals on magnetic tape. (This step is necessary when the digitization rate of the computer system is lower than the rate required by the signal information flow, which is invariably the case with a small computer system when more than one myoelectric signal channel is desired).

The second step is digitization of the signal and storage in the computer's disc memory after analog anti-alias-filtering to remove high-frequency components, which otherwise would appear as artifacts in the power spectrum to be estimated. The required sampling rate, 2048 Hz, is scaled down by means of the tape recorder to 256 Hz (eight times) which the present computer system can handle.

In the third step the center (centroid) frequency of the power spectrum is estimated for one-second segments: after tapering of the outer one-tenths of the data window, a 512-point Fast Fourier Transform is calculated and then the periodogram, yielding the squared magnitudes (the power) of the complex frequency components; a power spectrum estimate is obtained as the average of four consecutive periodograms; finally, the spectral moments of order one and zero and their ratio are calculated, the ratio yielding the centroid frequency of the power spectrum estimate.

The fourth step in the analysis procedure is estimating the fatigue rate as outlined by Lindstrom et al. (1977).

[a]Dr. Ortengren is the author of this report.

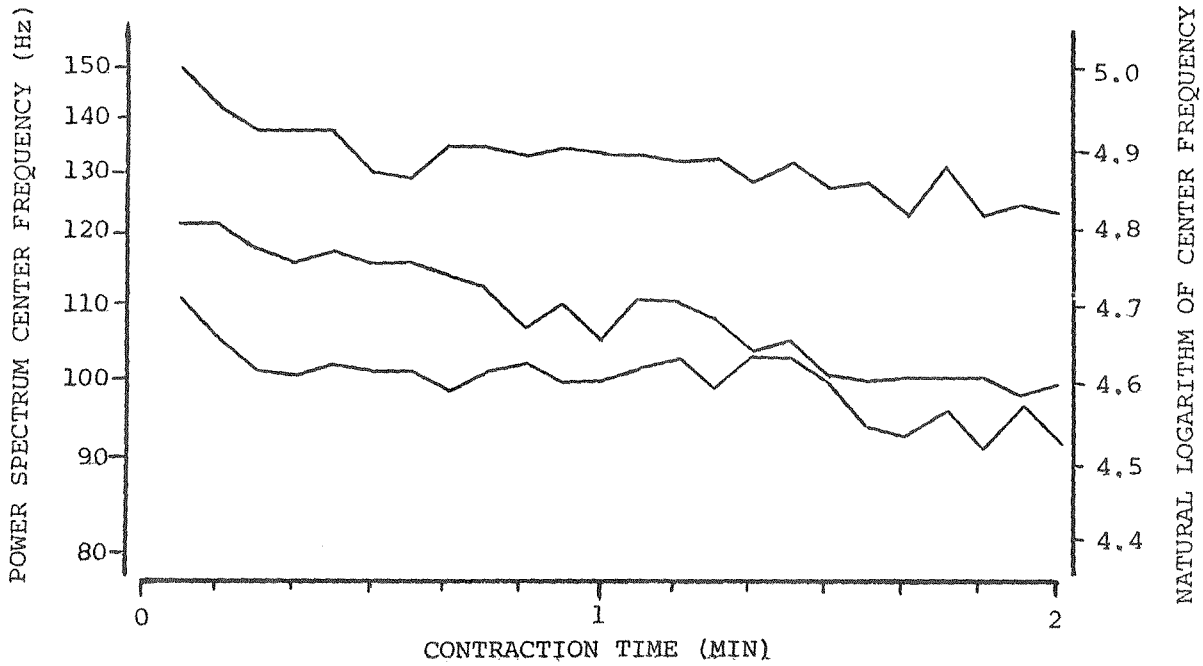


FIGURE 1.
Fatigue curves for m. vastus lateralis (top), m. rectus femoris (middle) and m. vastus medialis (bottom) obtained for resisted knee extension in a subject sitting with straight knee, the leg horizontal and loaded at the ankle with 10 lbs. The signals were picked up by bipolar surface electrodes, interelectrode distance 3 cm. The regression coefficient (the slope) is statistically significant for each curve ($p < 0.01$). The time constants corresponding to the slopes are 16.7, 8.7, and 18.6 minutes, respectively.

The method is based on the experimental finding that the center frequency of the myoelectric signal power spectrum decreases exponentially with time during an isometric forceful contraction. Thus, the fatigue rate is obtained by taking the logarithm of the center frequencies and estimating the slope by applying regression analysis. A probability of fatigue measure can be obtained based on Student's t-distribution by calculating the probability that the slope value deviates from zero. Since the center frequency decreases exponentially with time, the fatiguing process can be described by a time constant of fatigue which is obtained as the inverse value of the fatigue rate. A clear-cut example of fatigue curves from a quadriceps fatigue test is shown in Figure 1.

In the fifth and the last step of the fatigue analysis procedure, the calculated results are stored in a data file together with administrative information about the subject (patient) and the experimental conditions.

The development of the computer programs for the analysis procedure has been possible through use of computer equipment—an LSI-11/2 minicomputer system provided through the courtesy of Dr. A.R. Potvin, chairman of the Biomedical Engineering Program at the University of Texas at Arlington. Delivery of the minicomputer system for this project is expected in September, 1980. At this time, work can begin on an optimization of the computer programs with respect to processing speed and memory requirements, and development of a package for fatigue analysis in the clinical environment.

Until the project computer system is delivered and installed, the present software package and procedures will be used in the studies immediately planned. These will include an investigation of the crosstalk characteristics of the quadriceps musculature, using both surface and wire electrodes, and a study of the fatigue rate of the quadriceps members at different knee angles in normal and atrophied muscle.

Reference

Lindstrom L, Kadefors R, and Petersen I: An Electromyographic Index for Localized Muscle Fatigue. J Appl Physiol REEP, 43:750–754, 1977.

Design of Prosthetic and Orthotic Devices and Biomechanical Studies of Locomotion

VA Medical Center
4150 Clement Street
San Francisco, California 94121

University of California, Berkeley
Biomechanics Laboratory
5144 Etcheverry Hall
Berkeley, California 94720

Franklin T. Hoaglund, M.D., Harry E. Jergesen, M.D., Charles W. Radcliffe, Larry W. Lamoreux, Ph. D., Don M. Cunningham, and Gordon Stout

The Rehabilitative Engineering Research Program (RERP) was established at the San Francisco VA Medical Center during FY 1979. It combines the resources of the Uni-

versity of California Biomechanics Laboratory (UC-BL) with new clinical staff at SFVAMC. The primary purpose of the program is to conduct clinical evaluations of lower-limb external prosthetic devices, in order to expedite the transformation of promising prototype devices into commercially manufactured products, and to improve the standards for application of existing devices to the care of veteran amputees.

The design activities of UC-BL will continue on a reduced scale, and additional clinical research projects may be undertaken in San Francisco as patient needs and staff expertise dictate.

CLINICAL EVALUATION PROJECTS

The initial projects of RERP include a clinical evaluation (on 35 amputees) of the UC-BL Four-Bar-Linkage Polycentric Knee for above-knee (AK) amputees, a mail survey of prosthetic conditions and problems among 200 local amputees, and a study of the causes of loosening in hip joint implants. During this report period (Jan.–June, 1980) all of these projects have been initiated. Renovation of laboratory and office space at San Francisco was completed in June of 1980 and installation of tools and equipment for the Prosthetics Laboratory is nearly complete.

Self-contained measuring instruments from UC-BL that do not require computer support are being used in the initial evaluation project to assess walking-speed ranges and knee stability at both heel contact and toe-off. Questionnaires and forms have been prepared for documenting amputee physical condition, prosthesis characteristics, and amputee locomotor abilities. Components for a Digital Equipment Corp. LSI–11 based laboratory data acquisition and data processing system were ordered by UC-BL during this period, and most have been received. It is anticipated that this system will be assembled and installed at San Francisco by the end of September 1980, to provide more versatility in clinical laboratory gait measurements, as well as a data management system for patient records.

DESIGN OF LOWER-LIMB PROSTHETIC DEVICES

Four-Bar-Linkage Polycentric Pneumatic Knee—Clinical evaluation has begun at San Francisco. Development of more durable skin for polyethylene foam shank covers continues.

Six-Bar-Linkage Knee with Friction Swing Control—This knee-disarticulation unit was revised to increase the capacity of the friction swing-control as described in a previous report (BPR 10-32). Five prototype devices were obtained during the present report period. Initial laboratory tests, and one fitting in cooperation with the Navy Prosthetics Laboratory, indicate that the new swing-control is very smooth and effective. The design automatically provides greater resistance to flexion than extension, a desirable feature.

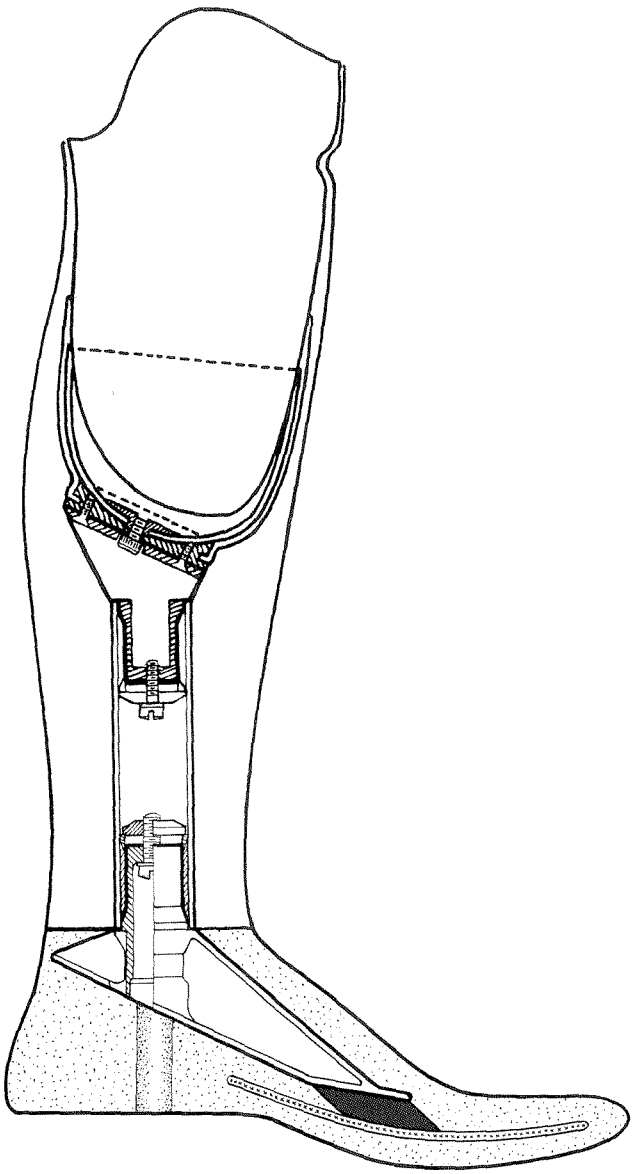


Figure 1
Modular below-knee prothesis, a UC-BL device, currently under evaluation clinical at San Francisco VA Medical Center.

The remaining prototypes will undergo amputee trials at RERP.

Friction Stabilized Knee—A subcontract has been awarded for fabrication of five units of this previously described (BPR 10-32) knee mechanism for the less-active AK amputee. Initial amputee fittings are expected to begin in September 1980.

SACH Foot with Metal Keel—This previously described unit is undergoing further testing of three different methods of toe-break reinforcement. The prosthetics industry has expressed some interest in producing the device commercially.

Modular Below-Knee Prosthesis—This assembly consists of a molded plastic shell that accepts the socket, an aluminum adapter that connects the shell to a tubular aluminum pylon structure, and a UC-BL metal-keel SACH foot with integral pylon coupling. Figure 1 shows the construction of the device. A spherical coupling between the plastic shell and the pylon adapter permits ±5 deg angular alignment adjustments about the distal end of the socket. Cosmetic cover material is polyethylene foam as used on the Four-Bar Polycentric Knee. The assembly allows rapid fabrication of a relatively light prosthesis (2.5 lb or 1.1 kg).

Multi-Input Control of Knee Stability—Computer control of a hydraulic knee damper, in response to kneemoment position and hipmoment sensors on the prosthesis, allows laboratory experimentation with a variety of stability control philosophies. Activities on this previously described project during the current report period include planning of a portable microcomputer controller, preliminary design of a low-power digital valve block, and refinement of the existing prototype rotary damper control valve. The goal of this project is to define stability control philosophies that provide greater safety and comfort to amputees under the varied conditions of daily living.

MOBILITY AIDS FOR THE SEVERELY DISABLED

PC-2 Wheelchair—Further development of this variable-height wheelchair has been suspended in order to focus resources on the completion of the Powered Spring-Suspension Wheelchair, and Solid State Controller. The PC-2 Wheelchair will, however, be included in the daily living evaluations scheduled to start in October 1980.

Powered Spring-Suspension Wheelchair—This wheelchair has a spring suspension, a 6.3 mile-per-hour top speed, good hill-climbing ability, and a 25 mile range in across-town driving. During this report period, the design and drawing package were completed, and the design of a new seat was started. An intensive search for a possible manufacturer was undertaken, and the Clement Corp. of Concord, California, was chosen to build four prototype chairs for delivery in October 1980. The Clement Corp. has expressed a strong interest in producing the chairs commercially after the four prototypes have completed the daily living evaluation planned for October 1980 through March 1981.

Solid State Controller—The Bowman/UC-BL Solid State Controller provides very smooth control, regenerative braking, current limiting, and and adequate power capability to drive the one-quarter horsepower motors typically used on higher performance wheelchairs. Motor voltage feedback has been added to inhibit low speed coasting and improve joystick response, and other circuit refinements and packaging changes have been made to ready the controller for limited-scale production. Bowman Electronics is building five units which will be evaluated in daily use testing from October 1980 to March 1981.

Spring Suspension Caster Forks—20 of the previously reported Spring Suspension Forks are being fabricated for daily use testing starting in October 1980.

Manual Wheelchair Projects—Work on manual wheelchair designs has been temporarily halted in order to concentrate efforts on completing the electric wheelchair projects described above.

Evaluation of Physiologic Suspension Factors in Below-Knee Amputees

VA Medical Center
4435 Beacon Avenue So., Room 402
Seattle, Washington 98108

Frederick G. Lippert, III, M.D., Ernest M. Burgess, M.D., and Sandor A. Veress, Ph. D.

Introduction

This report presents our progress in defining factors which play an important role in physiologic suspension in below knee amputees. We are studying contour suspension factors including the tibial-fibular movements which may occur within the socket during the amputee's attempt to suspend his socket. Our last report presented coronal and sagittal stump contours of four below knee patients and suggested that greater contouring produced greater resistance to prosthetic slippage. We are defining suspension as the amputee's resistance to prosthetic slippage due to an applied tensile force.

Methods

Further modifications of the tensile testing device now have made it possible for the patient to stand in an ambulatory position and apply his own tensile force to the device (which is anchored to the floor). The force-sensing element is an aluminum cross having strain gauges bonded to its surfaces. These strain gauge outputs are summed and amplified in such a manner to yield moment, shear and axial force components. The center of this cross is attached to the heavy aluminum plate and each of its four arms is connected upward through a bearing to one aspect of a smaller plate. The prosthetic socket is attached by means of an adjustable coupling to

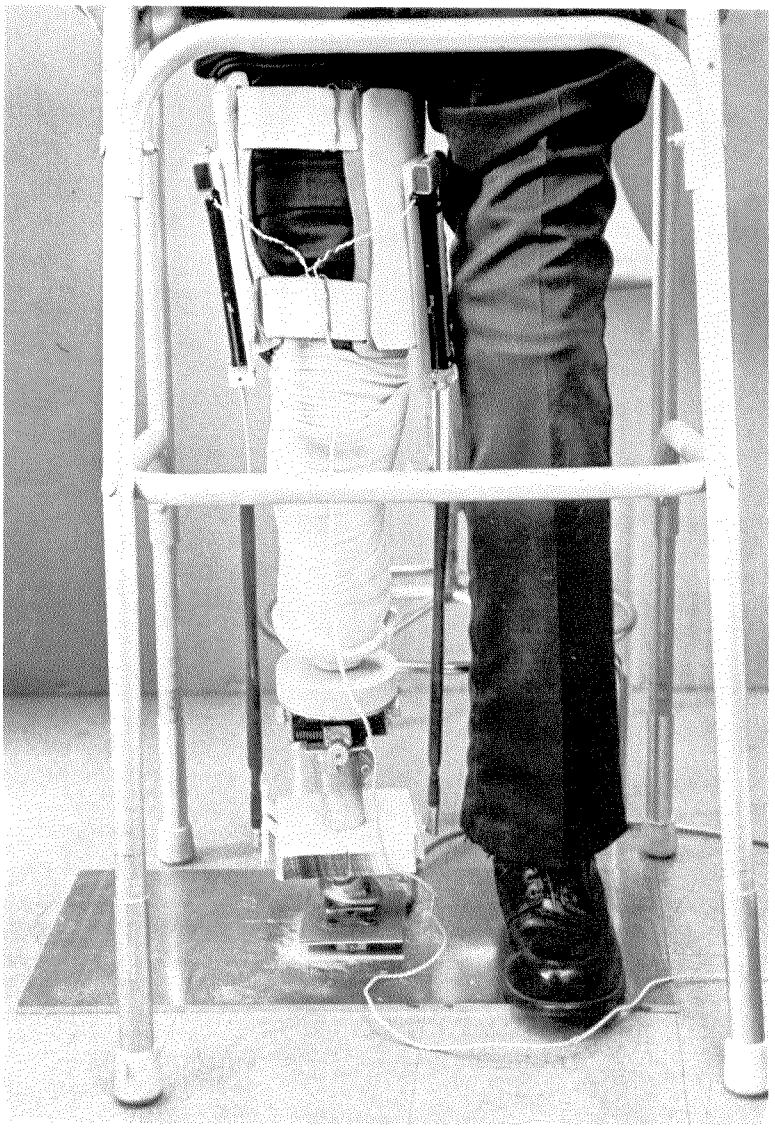


FIGURE 1.
Prosthetic socket testing device

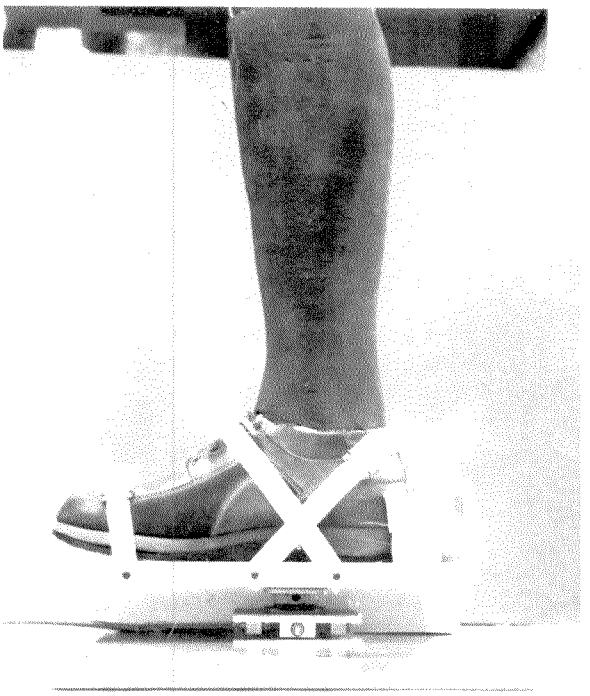


FIGURE 2.
Prosthetic leg tensile testing device

the upper plate of the force measurement module (Fig. 1). Definitive prostheses can be measured by using a different adjustable coupling (Fig. 2). Socket alignment with respect to the measurement fixture is obtained by orienting the socket's volume center directly above the center of the force-measurement fixture and eliminating any relative socket flexion-extension.

Two LVDT's with batteries are attached with Velcro to a thigh cuff. The motion elements of these LVDT's are attached through flexible cables past the medial and lateral sides of the knee joint either to the pylon or to the sides of the prosthesis. The prosthesis remains stationary as the leg is moved up or down. The two (LVDT) signals are summed, amplified, recorded, and calibrated to determine the exact amount of socket stump separation which is occurring in conjunction with the force measurement.

The floor-to-socket height is adjusted to be ½ inch lower than normal to facilitate the patient's application of an upward axial tension. With the prosthesis in place and aligned correctly, the force and displacement apparatus is calibrated. The patient then dons the prosthesis and assures that he is settled fully into the socket. He is asked to pull upwards with his stump while watching two oscilloscope screens which indicate fore-aft and medial-lateral force components (Fig. 3). By keeping the blips approximately in the center of the screens he assures that pure axial force is being applied. When a tensile force of at least 2 Kgs. (the weight of a typical prosthesis) has been reached the run is completed. The patient resettles back into his prosthesis ready to record another run. This is done with the stump musculature alternately contracted and relaxed for a total of 6 to 14 cycles. Calibration of the apparatus is rechecked after the patient removes his stump from the prosthesis. Typical graphs for the measurements are shown in Figure 4.

Force and displacement curves reveal considerable socket displace-

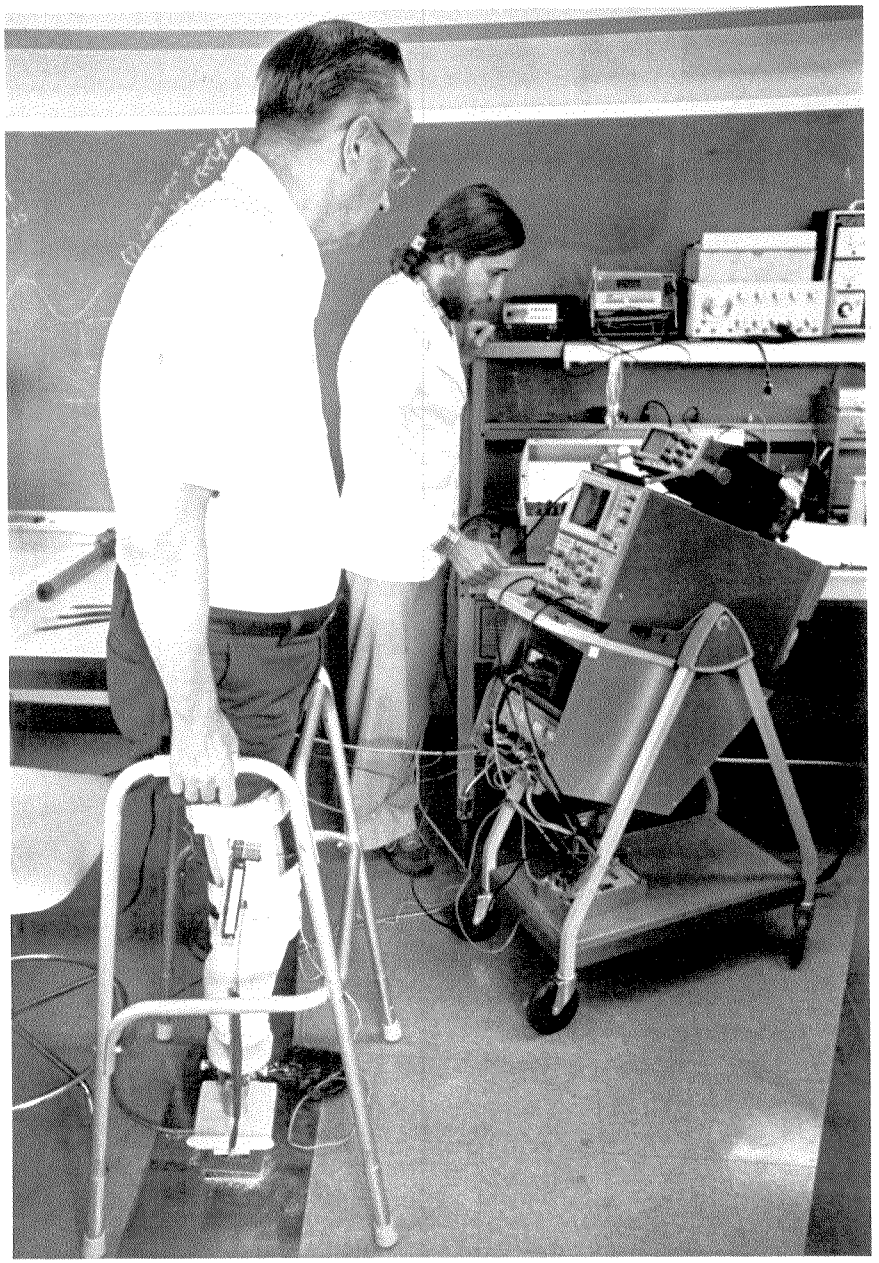


FIGURE 3.

ment before all suspension is lost, as well as a significant amount of displacement between full and zero weightbearing conditions. The present measurement system provides a more realistic description of the dynamic process of socket suspension.

During our studies, it became apparent that stump firmness when contracted is a potentially important factor. Soft, flabby stumps with large contour changes may be as functional as firm-but-flatter stumps. To measure firmness we used spring-loaded (1.5 psi) VAPC prosthetic calipers to measure the width of the stump at the palpable apex of the distal medial-lateral muscle bulge. The firmness measurement was the difference in the width determined by the calipers with and without spring compression. The rationale is that on a contracted stump with firm muscles, the 1.5 psi caliper compression would compress the soft tissues less than on a flabby stump. Figure 5 shows eight patients of differing stump firmness. Patients 7 and 8 with small ranges thus show a greater firmness than patients 3, 4 and 9.

In order to explore the concept of maximizing contour suspension by prosthetic modification we made two test sockets from Polysar, one in which the prosthetic wrap was layed up over relaxed musculature and the other over contracted musculature (Figure 6). Both were made according to standard prosthetic techniques—with the following exceptions:

1. Relaxed wrap

Instead of removing material from the lateral-distal side of the model, light pressures were applied during wrapping so as to achieve the same effect without introducing volumetric irregularities.

2. Contracted wrap

This wrap was taken over contracted stump musculature and required a second set of hands in moulding the area just proximal to the distal M-L muscle bulge to enhance the contour suspension effect without introducing any volumetric irregularities (i.e. constriction).

Previously, stump, sagittal, and coronal section overlays were made from alginate models and then measured by a carpenter's copycat. This technique introduced potential motion errors. In order to eliminate these possible errors, stereophotogrammetry is used to obtain the coronal and sagittal sections. Using this system, the patient's stump profile in the sagittal and coronal planes is obtained instantly using a close range, stereometric camera system and a Balplex stereo plotting instrument (Fig. 7). Stereo photographs, in a diapositive form, are used directly on the Balplex plotting instrument to create calibrated stereoscopic images. The profiles are

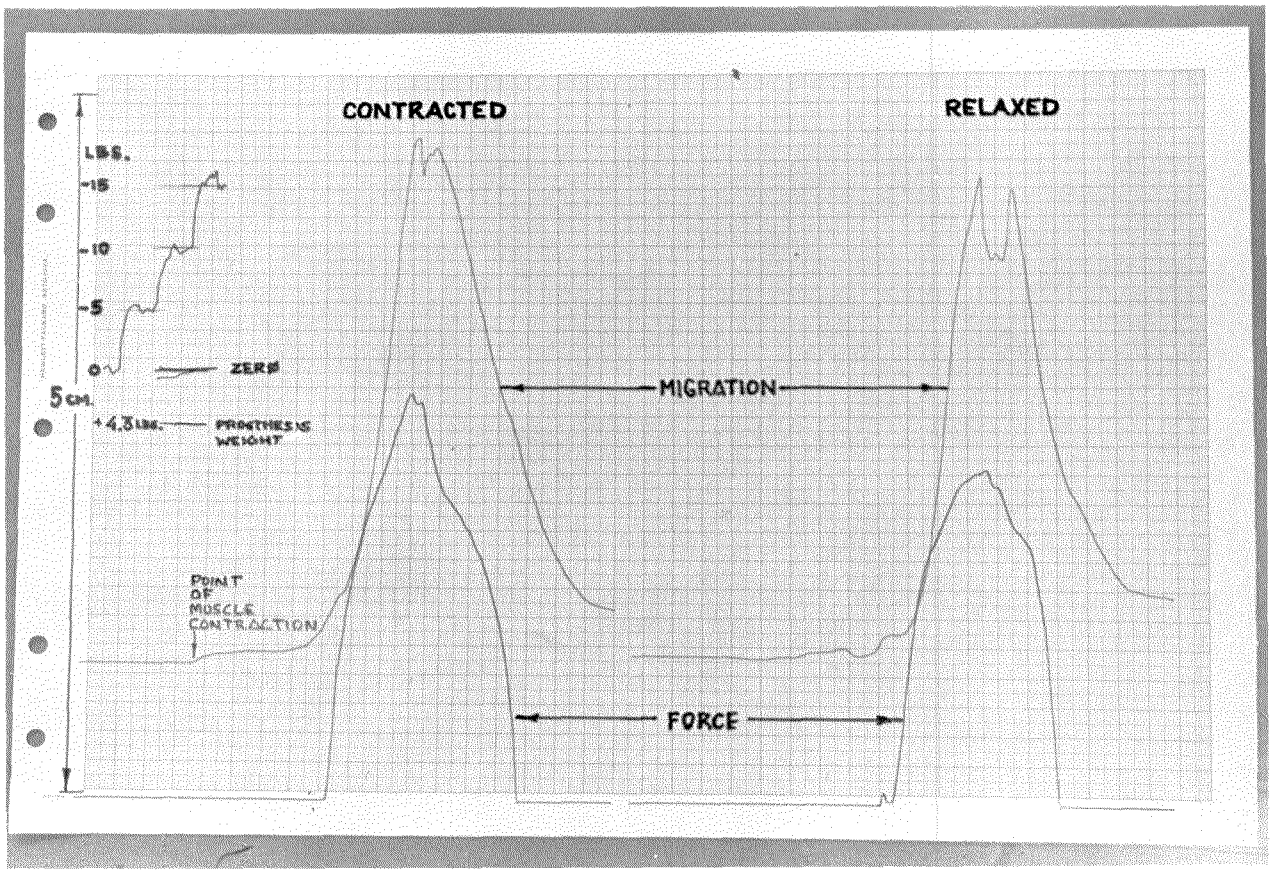


FIGURE 4.
Note: Force calibration data displaced by approximately 15 lbs.

generated by plotting the lowest possible contour elevation around the perimeter of the stump image (Fig. 8). This technique was compared to that of the alginate method and found to be more accurate and easier to do with less chance of error. Contours presented in this report are those obtained using the stereophotogrammetry techniques.

The relative motion between the tibia and fibula is obtained using X-ray photogrammetry. Stereo X-rays are taken in a variety of loading modes in and out of the socket. Each X-ray contains the necessary calibration and bone markers to accurately determine the three dimensional motion between fibula and tibia. (Fig. 9, Table 1). We are assuming that tibial and fibular motion when present, may play a role in suspension due to the effect of internal structural displacements within a non-compressible fluid medium. Figures 10 and 11 show the vectorial motion of the fibula with respect to the tibia under a variety of conditions.

Tibial-fibular motion appears to be decreased by the presence of the prosthetic socket.

Conclusions

Two patients were measured for retention ability using Polysar sockets made over relaxed and contracted stumps and definitive prostheses. Force vs. displacement data revealed that the ability to resist tensile forces was higher with the "contracted" sockets than the "relaxed" sockets (Fig. 12). This further substantiates our feeling that contour suspension factors are important to physiologic suspension, and that sockets moulded to fit the dynamically contracted musculature may provide better suspension. Future studies will continue to explore this concept, the idea being that amputees requiring better physiologic suspension while engaging in more vigorous work or athletic activities may need a socket that is a compromise between the contracted and relaxed stump position.

FIGURE 5.

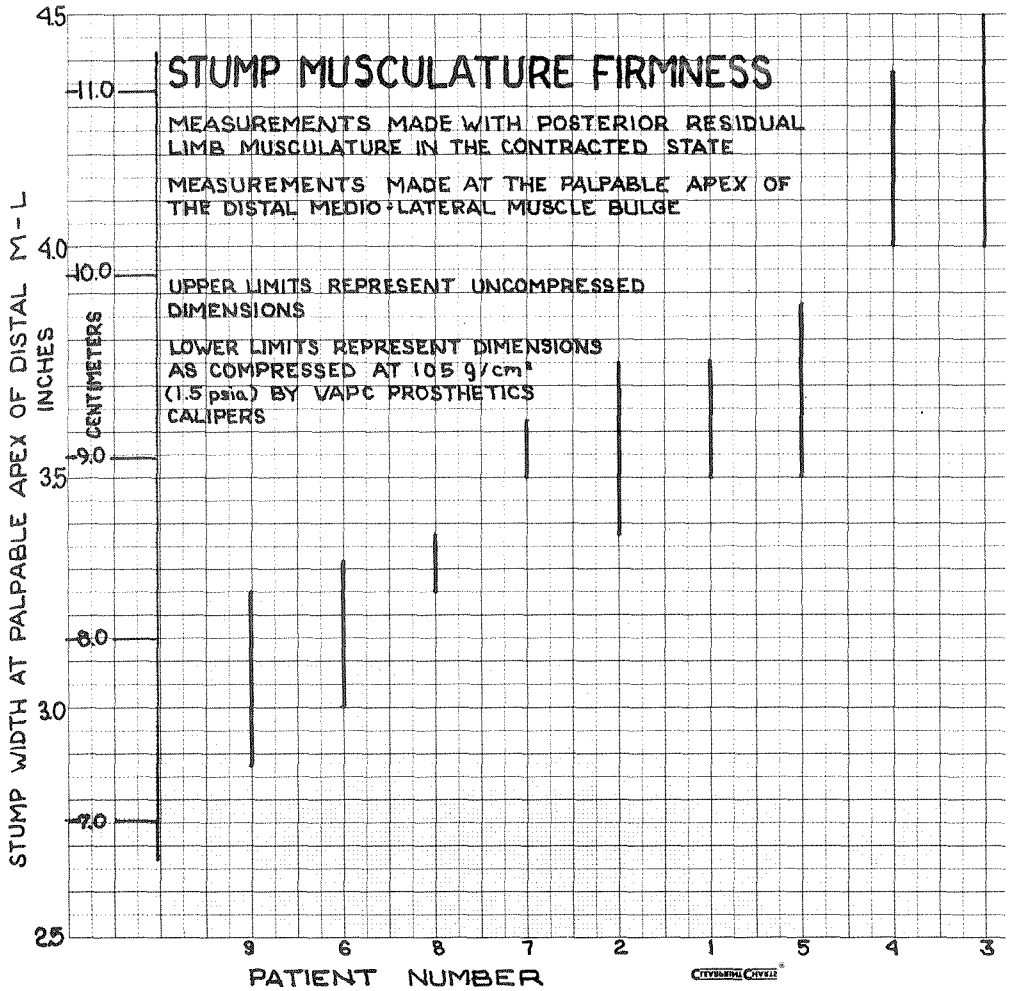


FIGURE 6.
Two test sockets, that on the left layed up over relaxed musculature and that on the right over contracted musculature.

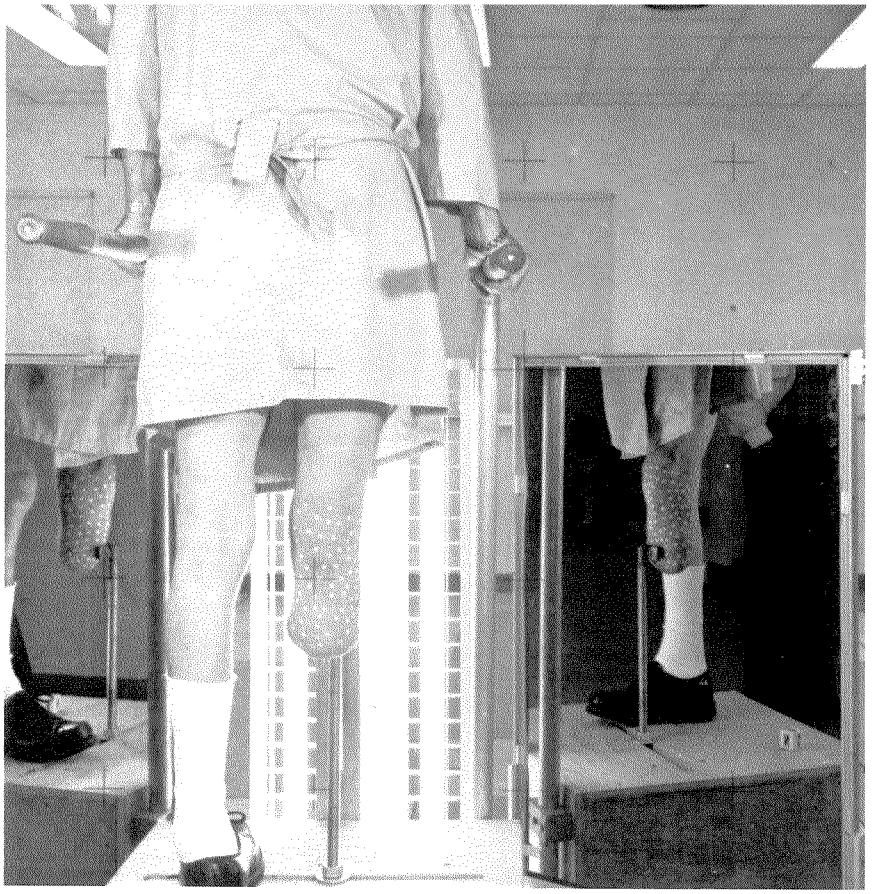


FIGURE 7.

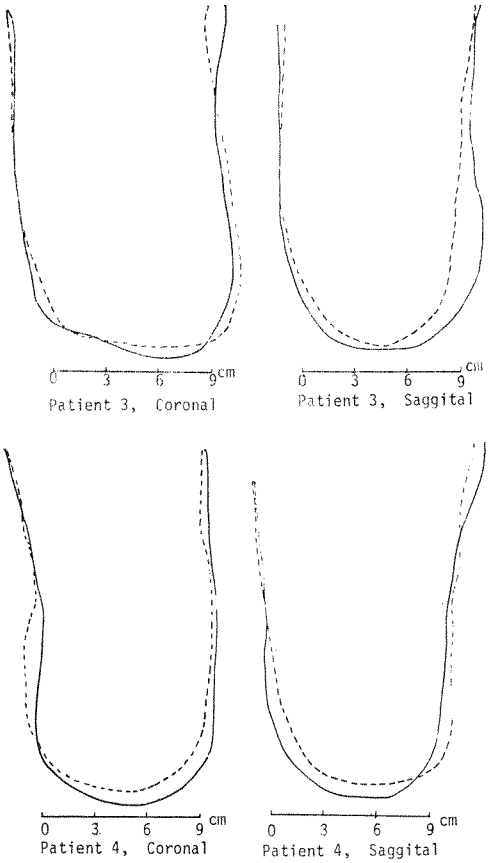
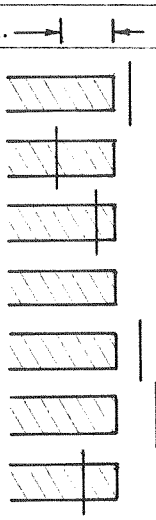


FIGURE 8.
Overlay of relaxed and contracted stump profiles. Solid lines indicate relaxed state; dotted lines contracted state.

PATIENT NUMBER	STUMP FIRMNESS	STUMP EXPANSION	DISTAL M-L STUMP-SOCKET RELATIONSHIP	PISTONING DUE TO 2 Kg. AXIAL TENSION R (MUSCLE STATE)	C
	(mm.)	(mm.)	1 cm.	(mm.)	(mm.)
			DS	17	12
3	12.7	3.2	RS	27	24
			CS	20	21
			DS	40	38
9	9.5	6.3	RS	75	44
			CS	30	31
1	6.3	1.6	DS	31	33



KEY: RELATIVE STUMP WIDTH (RELAXED)
RELATIVE SOCKET WIDTH

FIGURE 12.
Residual limb and comparative prosthetic socket dimensions with relevant retention measurements. NOTE: All width measurements made at palpable apex of distal M-L.

Abbreviations:
- DS Definitive prosthesis
- RS Relaxed type Polysar socket
- CS Contracted type Polysar socket
- R Stump musculature relaxed
- C Stump musculature contracted

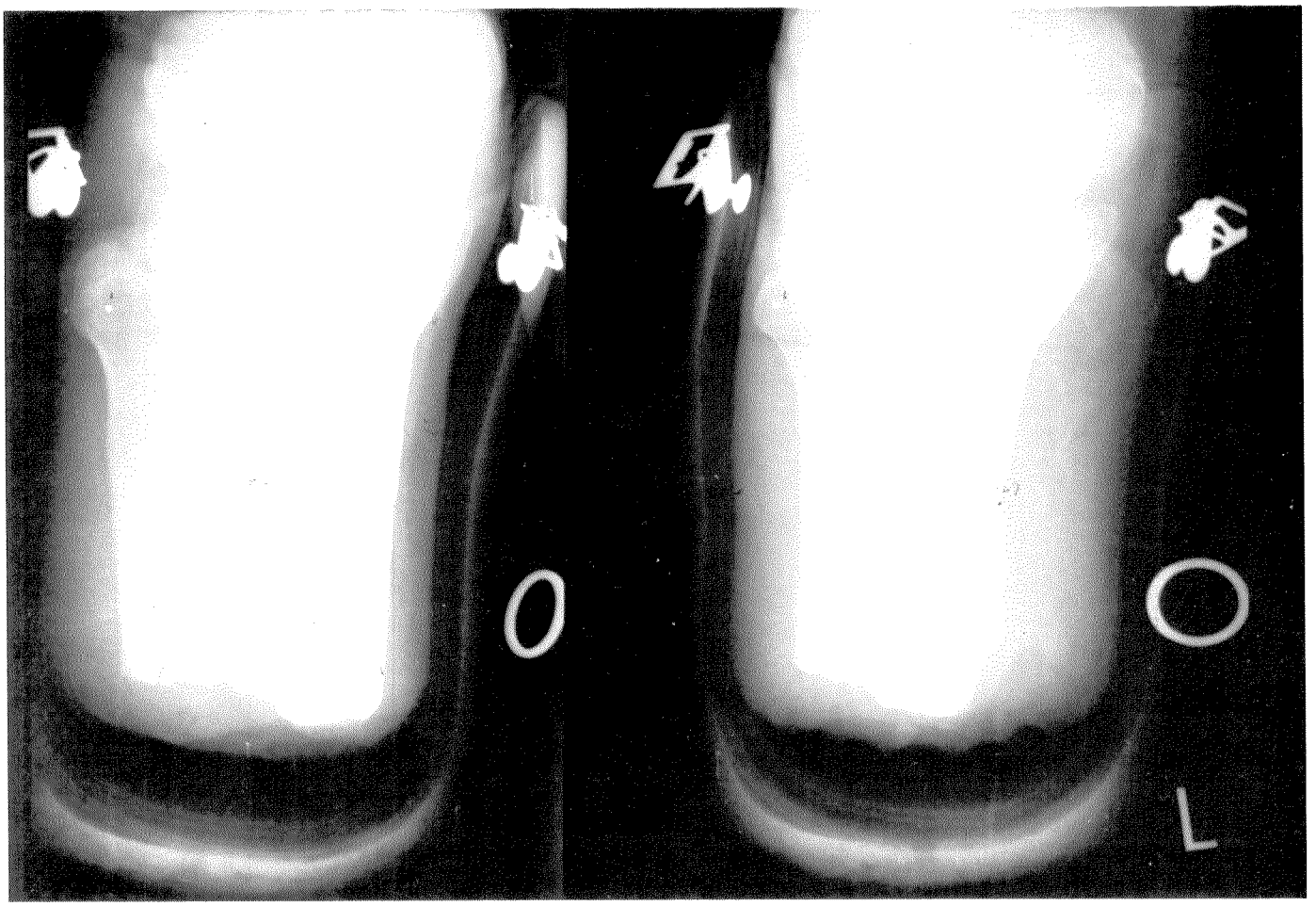


FIGURE 9.

TABLE 1.
Motion Components (mm) estimated from measurements of the fibula with respect to the tibia during relaxed and contracted conditions. (Values indicate movement of fibula markers 3 and 4 with respect to tibia markers 1 and 2.)

	Motion Between Markers												
*Patient	1 - 3			1 - 4			2 - 3			2 - 4			2 X RMSE
	X	Y	Z	X	Y	Z	X	Y	Z	X	Y	Z	
1_a	no marker 3			3.649	2.003	.614	no marker 3			3.192	1.334	-2.101	±.180
1_b	"	"	"	1.785	2.308	1.860	"	"	"	-9.061	2.719	-3.061	"
1_c	"	"	"	4.731	3.584	1.247	"	"	"	6.279	1.801	.545	±.162
2_c	-.379	.094	-3.059	.709	.449	-3.938	-.881	.747	-.255	.207	1.260	-1.134	±.144
3_c	.077	-2.251	3.498	2.133	-2.494	-5.143	.044	-1.514	7.312	2.100	-7.757	-.868	±.154
4_c	3.885	-5.381	.615	.874	-3.801	2.767	3.482	-5.003	3.525	.471	-3.423	5.677	±.146
5_c	-3.622	-3.418	7.447	-2.971	-3.651	-3.470	-3.901	-3.675	8.306	-3.258	-3.908	-2.611	±.128
5_d	-.777	-2.072	6.337	-4.353	-3.016	-1.412	.025	-1.209	5.456	-3.551	-2.153	-2.293	"

*. Patient 1-4 residual limb - right leg; Patient 5 residual limb - left leg.
a. Residual limb in Prosthesis with no extra loading during both relaxed and contracted conditions.
b. Residual limb in Prosthesis with a 15 lb load added during the contracted condition.
c. Residual limb was free during all x-rays.
d. Relaxed limb was free of Prosthesis during x-ray. Contracted limb was wearing the Prosthesis + a 15 lb. load during x-ray.

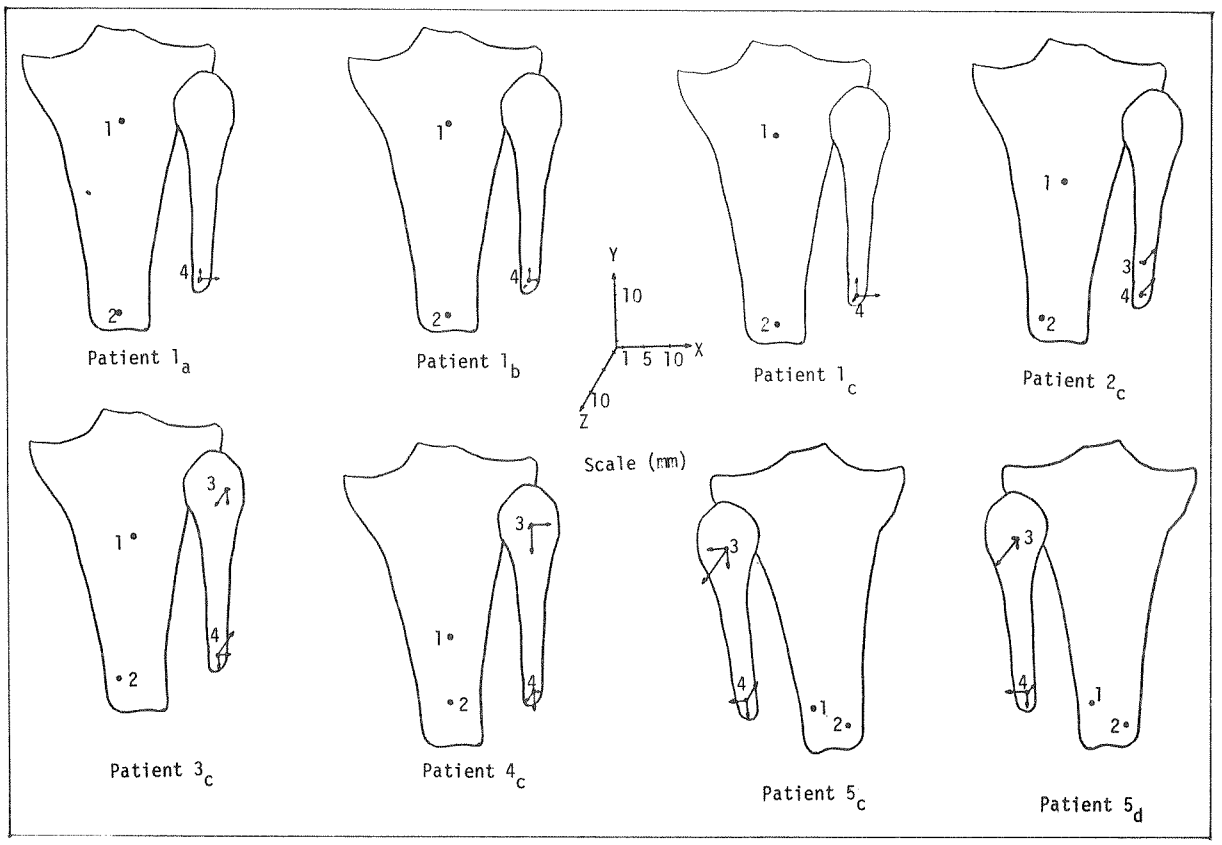


FIGURE 10.
Posterior Profiles of the right (Patient 1–4) and left (Patient 5) residual tibia and fibula showing motion vector components of fibula markers 3 and 4 with respect to tibia marker 1.

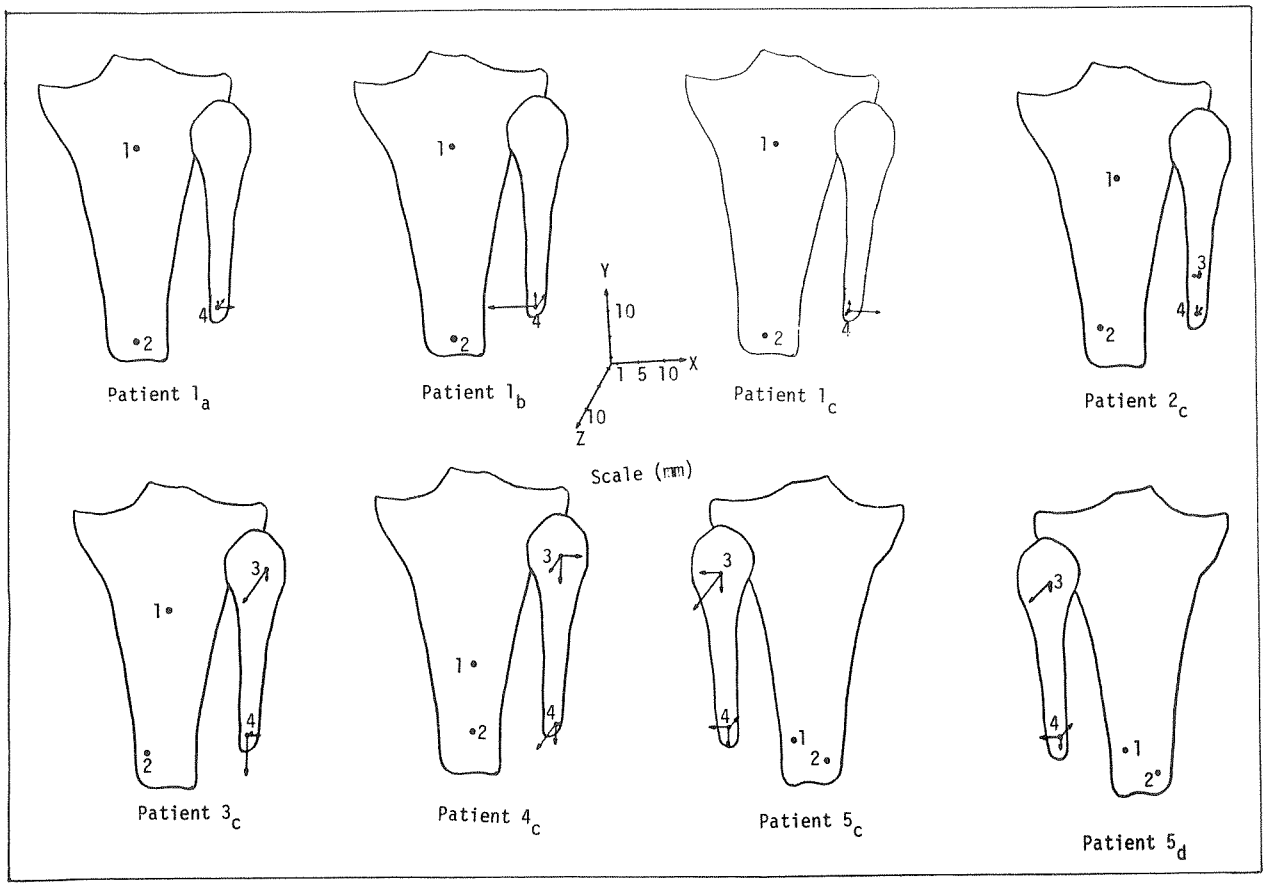


FIGURE 11
Posterior Profiles of the right (Patient 1–4) and left (Patient 5) residual tibia and fibula showing motion vector components of fibula markers 3 and 4 with respect to tibia marker 2.

Orthopedic Implant Device Retrieval and Analysis

VA Medical Center
New Orleans, Louisiana 70146

Allan M. Weinstein, Ph. D.

Investigation of Total Knee Prosthesis—An investigation has been started to study the clinical performance of total knee replacement prostheses. This is currently being conducted in three parts:

1. A survey of all Louisiana orthopaedic surgeons to determine the type and frequency of knee arthroplasties. In addition, data concerning previously used designs of knee prostheses is being collected, to enable problems to be identified.

2. A total of 51 patients having polycentric total knee prostheses are being examined for both clinical and biomechanical improvements. This series of patients has the advantage of having all been operated upon by a single surgeon thereby removing one important variable.

3. A series of explanted total knee prostheses are being examined. These have been obtained, usually, as a result of above-knee amputation and offer the opportunity to study the histology around both successful and unsuccessful prostheses.

Biocompatability of Stainless Steel Orthopaedic Implants—A study is being conducted to determine the extent to which the histology of tissue adjacent to stainless steel orthopaedic implants may be related to the occurrence of any corrosion of that implant. In this way, the biocompatibility of these implants may be examined in detail.

To date, a total of seven internal fixation devices have been retrieved at the time of surgery. Four of these were removed routinely and the other three for clinical symptoms associated with the implant, most noticeably pain. At the same time that the devices were removed, the strip of tissue overlaying the plate was dissected away and stored in formalin. This was later photographed, embedded in paraffin and serially sectioned for histological examination. In general, hematoxylin and eosin (H and E) stain was used to reveal the salient features, however selected sections were stained also with Perl's, Gomion's trichioure and baltrophenathroline (BPA). The extent of any tissue reaction was graded on a scale of 0–5, where 0 indicated only a thin fibrous membrane having formed adjacent to the metal surface, and 5 indicated a very heavy inflammatory reaction having occurred (Table 1).

TABLE 1. Tissue Index

0 Thin fibrous membrane containing lipid cells.
1 Thin acellular fibrous membrane.
2 Mild chronic inflammatory response.
3 Moderate chronic inflammatory response without giant cells.
4 Heavy chronic inflammatory response with giant cells and a few granulomas.
5 Severe inflammatory response with giant cells, granulomas and necrosis.

The internal fixation plates were cleaned, photographed and examined for evidence of any corrosion. If this was found to have occurred, the severity was graded on a scale of 0–5, according to the scheme listed in Table 2.

The results from these tests revealed that, associated with all of the implants, was the formation of a fibrous "pseudomembrane" However, in certain of the screw holes, inflammatory reactions with many giant cells, granulation and localized areas of necrosis were observed. In addition, plate-like particles, similar in appearance to hemosiderin, were found in many of the sections. The tissue reaction indices were compared with the equivalent corrosion indices for each screw hole and the result is shown in Figure 1. This indicates that although there existed a considerable degree of scatter, a relationship could be drawn between the severity of the tissue reaction and the extent of corrosion in that screw hole. It was interesting to note that although the scatter of results was large, certain cases were observed

TABLE 2. Corrosion Index

0 No surface degradation visible at 60X magnification.
1 Very mild surface degradation visible at 60X magnification.
2 Mild surface degradation easily visible at 60X magnification.
3 Moderate surface degradation visible without magnification.
4 Heavy degradation visible without magnification.
5 Very severe surface degradation.

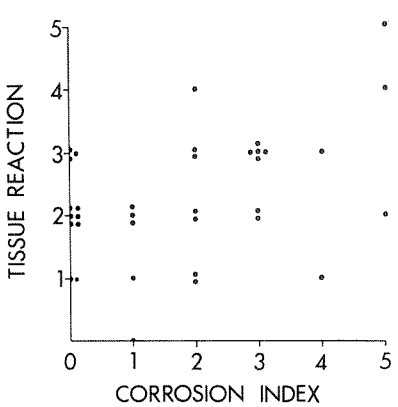


FIGURE 1.
Tissue reaction index compared with equivalent corrosion index for each screw hole.

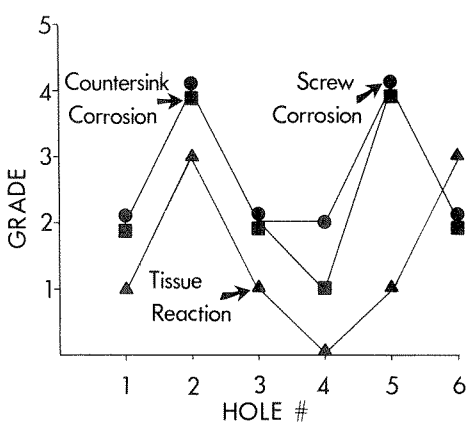


FIGURE 2.
Corrosion and tissue-reaction grading plotted to reveal extent of correlation. Triangles indicate level of tissue reaction; circles indicate screw corrosion and squares, countersink corrosion.

with excellent correlation between tissue reaction and corrosion index (Fig. 2).

This work is continuing in order that a larger number of cases may be obtained and thereby improve the validity of any conclusions, the results from this to be presented in a later issue of the Bulletin.

The Use of Gait Analysis to Study Gait Patterns of the Lower-Limb Amputee

VA Medical Center
3350 La Jolla Village Drive
San Diego, California 92161

Frank L. Golbranson, M.D.

Progress Report for Period January 1 through June 30, 1980

Initially it had been our hope that we would be able to identify unique patterns associated with specific clinical problems, i.e., for stump ulcer, improper dynamic or static alignment of the prosthesis or improper stump-socket fit. This has been proven not to be the case. However, what mathematical analyses have revealed is that specific signatures can be assigned to a given amputee. These analyses included work, f/L ratio, velocity, stride length and frequency, single support and double support. These mathematical findings, although not clinically useful directly, do shed light on many characteristics of amputee gait. We hope also that these findings will serve as a nidus for further investigational endeavors in this field.

Efforts to identify features of locomotory performance which characterize the gaits of the unilateral BK and AK amputees, with and without problems, are resulting in some degree of success. Selected combinations of variables distinguish the performance of the with-problems from that of the without-problems categories, while other combinations distinguish between the AK and BK amputees. Moreover, the introduction of additional variables such as the ratio of stride frequency to stride length (f/L), helps to explain or to improve the precision of some derived measures characterizing the gait of individuals having locomotory impairments.

A criterion, using two variables, was found to distinguish the difference between AKs and BKs. The two variables were:

a. The sum duration of the double support periods of the gait cycle (tds) in seconds, and

b. The average velocity V, in meters per second. Using the expression tds = C/V, the coefficient C was found to differ between the two groups, namely, 0.416 ± 0.047 for BKs and 0.362 ± 0.034 for AKs. Letting the threshold between the two be C = 0.384, the degree of successful classification was 26 of 33 BKs and 9 of 11 AKs.

A criterion, using two variables, was derived which distinguishes differences in performance between the BK with-problem and without-problem categories. The two variables were: (i) the efficiency (eff) of external work and (ii) the root mean square (RMS) value of the deviation in the flexion-extension movement of the prosthetic-side hip. The efficiency in reference is the completness of the transfer between potential and kinetic energies during a gait cycle as measured with force plates. The RMS measure is derived from the magnitude of departure from normal joint movement expected at a given velocity of walking. The criterion relation is RMS + 15.3 eff = 11.7. Values calculated in this manner show that results less than 11.7 are associated with the with-problem category and results greater than 11.7 are associated with the without-problem category. The degree of successful classification was 10 of 13 BKs without problems and 10 of 12 BKs with problems.

Investigation of the single support period, which is also the swing period of the contralateral limb, revealed that the precision of the expression characterizing duration could be markedly improved by introducing the ratio of stride frequency to stride length (f/L). The sum of the left and right swing periods (tsw) in seconds may be expressed by the following: (tsw = 1.76 − 0.264 $\sqrt{V}$ − f/L, where V is the average velocity of walking in meters per second, and f/L is strides per second divided by stride length in meters. The relative accuracy of this expression was tested by determining the difference between the computed and measured values (tc-tm). The mean error and standard deviations in seconds are listed below by categories:

Category	N	Mean error	Std. Dev.
BK w/o Prob	18	+0.044	0.035
BK w Prob	15	+0.009	0.070
AK w/o Prob	6	−0.068	0.063
AK w Prob	5	−0.018	0.087

The measurement error is estimated to be between 0.020 and 0.040 seconds as derived from cinematographic records obtained at 50 frames per second.

A mathematical model has been derived to characterize the work done against the external environment. The method of measurement is the same as the technique pioneered by Cavagna in the early 1960's and utilizes the ground reaction forces as registered by force plates. The sample consisted of 13 BKs without problems, 13 BKs with problems, 5 AKs without problems, 4 AKs with problems, 8 normals walking at own choice of speed, and 3 normals walking at three different speeds. The mathematical model best fitting through the total sample is as follows:

$$W = 1.10(1.4 - V)^2 + 4.74\,V\,(0.7 - f/L)^2 + 0.22$$

where W = work (joules per meter per kg, J/m/kg)
V = average velocity (meters per second)
f/L = ratio strides per second to stride length (in meters)

The relative accuracy of the model was tested by determining the difference between the measured and computed values (Wc − Wm). The

mean error and standard deviation in J/m/kg are listed below by categories:

Category	N	Mean error	Std. Dev.
BK w/o Prob	13	+0.017	0.139
BK w Prob	13	−0.029	0.107
AK w/o Prob	5	−0.004	0.089
AK w Prob	4	−0.147	0.029
Normals	8	+0.035	0.079

The range in work for the sample was from 0.15 J/(kg•m) for one of the eight normals to 0.94 J/(kg•m) for an AK with a 4-inch long stump. The mathematical model has offered additional use for correlation with other variables by introducing measured values of work, velocity and f/L ratio to calculate a work factor adjusted for the velocity and f/L ratio.

Functional Spinal Cord Regeneration

Gainesville VA Medical Center
Gainesville, Florida 32602

University of Florida
College of Medicine, Departments of Neuroscience and Neurosurgery
Gainesville, Florida 32610

George W. Sypert, M.D., and John B. Munson, Ph. D.

In order to study the capacity of the adult mammalian spinal cord to accomplish recovery of function after injury, possibly by the mechanisms of regeneration and synaptic plasticity, it is necessary to understand some of the fundamental mechanisms that control synaptic function (the sites of neuron-to-neuron connection and communication). Since the report in the previous issue of the Bulletin, BPR 10-33, 1980, this laboratory has made substantial progress in the understanding of one of the important mechanisms that control synaptic activity and, hence, information processing in the mammalian spinal cord. The mechanism is "presynaptic inhibition".

Reduction in the amplitude of monosynaptic excitatory postsynaptic potentials (EPSPs) in cat lumbar spinal motoneurons by conditioning volleys in another muscle nerve was first reported by Frank and Fourtes (1). Since there was no change in membrane potential or excitability measured by intracellular current injection or in antidromic action potential invasion, they used the term "presynaptic inhibition" for this phenomenon. Later, Frank (2) suggested that this EPSP depression could result from either (i) interaction between excitatory and inhibitory postsynaptic potentials generated in dendritic membrane remote from the site of microelectrode recording such that the inhibitory effect could not be detected or (ii) presynaptic inhibitory mechanisms exerted on the afferent fibers or terminals mediating the EPSP.

Subsequent studies by Eccles and associates, as summarized by Eccles, (3) and Schmidt (4), supported a presynaptic inhibitory mechanism. These studies demonstrated that the time course of the measured inhibition of monosynaptic reflexes was accurately correlated with the negative dorsal root potential. It was further shown that the magnitude and time course of depolarization of primary afferent fibers correlated closely with the depression of monosynaptic Ia EPSPs and the negative dorsal root potentials. These investigations led to the hypothesis that presynaptic depolarization of primary afferent fibers by the activation of axo-axonic synapses is responsible for the EPSP depression because it decreases the size of the presynaptic action potential and hence reduces the release of excitatory transmitter. Other investigators have suggested that increases in extracellular potassium may be the main course of primary afferent depolarization and hence account for the phenomenon of presynaptic inhibition.

In view of the questions raised by the various studies on presynaptic inhibition, the present study was performed to further elucidate the mechanisms involved in this phenomenon (3,4).

Electrical test stimulation (just suprathreshold for group I nerve fibers) of medial gastrocnemius muscle (MG) Ia afferent fibers, produces terminal potentials (TPs), focal synaptic potentials (FSPs), and excitatory postsynaptic potentials (EPSPs) in feline L_7 spinal cord laminae VI (interneuronal pool), XII (inhibitory interneuronal pool), and IX (triceps surae motoneuron pool), and axonal potentials (APs) dorsal to these neuronal pools (6). Conditioning stimuli (CS) that are classically associated with presynaptic inhibition of extensor monosynaptic reflex transmission were used in this study to produce presynaptic inhibition. Reliable alterations in the latency and amplitude of MG-Ia-elicited APs, TPs, FSPs, and EPSPs following CS were observed when the data were averaged and digitized using a laboratory computer. The results of this study (5,6) provide the strongest evidence to date that presynaptic inhibition in the mammalian spinal cord is the result of axo-axonic synapses that mediate a depolarizing ionic conductance change in the terminal boutons of primary afferent fibers. Such a system provides a powerful mechanism for controlling sensory information from peripheral body parts at the earliest possible sites in the central nervous system, and may also serve to limit and sharpen incoming sensory signals.

References

1. Frank, Karl, and Fuortes, Michelangelo G.F.: Presynaptic and Postsynaptic Inhibition of Monosynaptic Reflexes. Federation Proc 16:39–40, 1957.
2. Frank, Karl: Basic Mechanisms of Synaptic Transmission in the Central Nervous System. Inst. Radio Eng. Trans. Med. Electron. ME-6:85–88, 1959.
3. Eccles, John C: The Physiology of Synapses: New York, Academic Press, 1964.
4. Schmidt, Robert F: Presynaptic Inhibition in the Vertebrate Central Nervous System. Ergebn. Physiol. 63:20–101, 1971.

5. Sypert, George W., Munson, John B., and Fleshman, James W.: Effect of Presynaptic Inhibition on Axonal Potentials, Terminal Potentials, Focal Synaptic Potentials, and EPSPs in Cat Spinal Cord. Neurosci Abstr 5:730, 1979.
6. Sypert, George W., Munson, John B., and Fleshman, James W.: Effect of Presynaptic Inhibition on Axonal Potentials, Terminal Potentials, Focal Synaptic Potentials, and EPSPs in Cat Spinal Cord. J. Neurophysiol. (in press), 1980.

Permanently Attached Artificial Limbs

Southwest Research Institute
8500 Culebra Road
San Antonio, Texas 78284

C. William Hall, M.D. and William Rostoker, Ph. D.

Sintered Titanium Fiber as Bone Interfacing Material—Stabilizing the intramedullary rod portion of the percutaneous load-bearing skeletal extension (PLSE) has always presented a problem. Our greatest success had, in the past, incorporated bone cement as the anchoring mechanism. However, tissue reaction caused a fibrous layer to develop between cement and bone. This effected a loosening of the cementing properties of the bond and allowed the entire device to evulse under certain types of stress.

We have, for the past few months, tried sintered titanium-fiber-coated intramedullary rods prepared by Dr. William Rostoker, University of Illinois, Chicago Circle. The success of Galante, Rostoker, et. al., using sintered titanium fiber as a lattice for bone ingrowth (1,2), prompted our trying this method of bone stabilization.

It was necessary to design and fabricate all metal parts used in the device from titanium, 6 aluminum, 4 vanadium. Dies were first machined to form the titanium fiber rings and compress these onto the solid core rod prior to sintering. The pedestal was later covered with nylon velour to complete the device.

After implantation, the skin flap was brought into apposition with its counterpart using a running subcutaneous $\overline{0000}$ catgut suture. The lugs were left buried beneath the skin so that none of the device was exteriorized at that time. The amputated stump containing the implant was bandaged with a sterile dry dressing compressed slightly with an elastic outer bandage. A Thomas leg splint was applied to the leg as a protective device. At the end of four weeks, the dressing and splint were removed and the lugs exteriorized by sharp dissection using a bistoury blade. After removing the lug screws, the external trifurcated yoke was connected to the implant and the animal returned to pasture.

The six original prototypes had a tendency to shear the titanium fiber from the solid rod during implantation (Fig. 1). This was caused by forcing the device into an undersized intramedullary canal. Two animals developed longtudinal fractures of the tibia because of the wedging effect, and they had to be sacrificed. A later model (Fig. 2) incorporated a solid titanium pilot on the tip that protected the fiber coating from shear forces. The last model (Fig. 3) added concentric broaching rings to the pilot and also a semicircular step in the pedestal that matches a mortice cut into the distal end of the tibia. These two additions should allow for a close fit within the bony canal, protect the sintered titanium fiber from shearing from the shaft, and prevent rotation of the device during healing.

Of 12 sintered titanium fiber implants, three animals remain free-roaming in the pasture and have received no medication since their immediate postoperative period. Two animals have yet to receive the external attachment. One animal kidded 6 weeks post-implantation and developed osteomalacia of

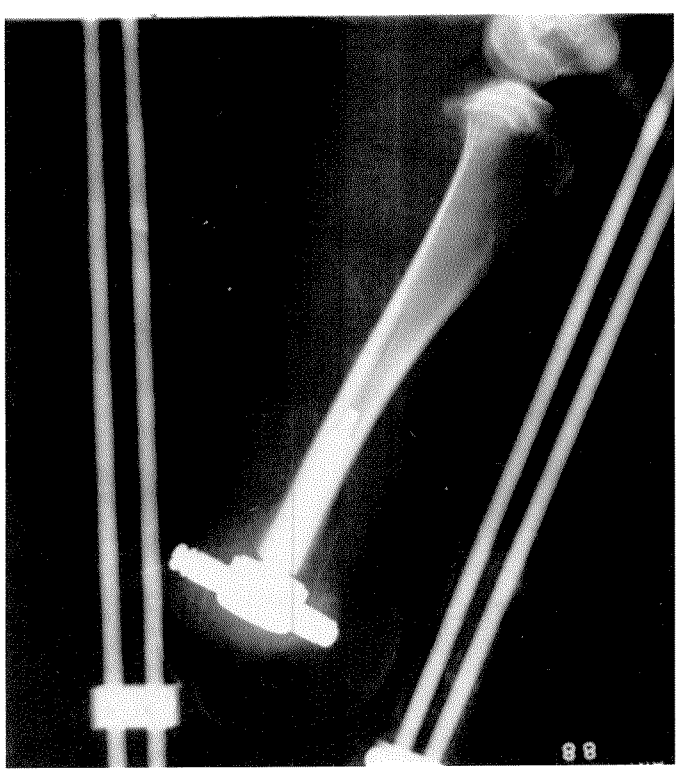


FIGURE 1.
Radiograph of PLSE whose fiber coating has sheared during implantation. Note protrusin of rod beyond the sintered titanium fiber. A linear fracture of tibia caused by the wedging of the fiber coating is also visible.

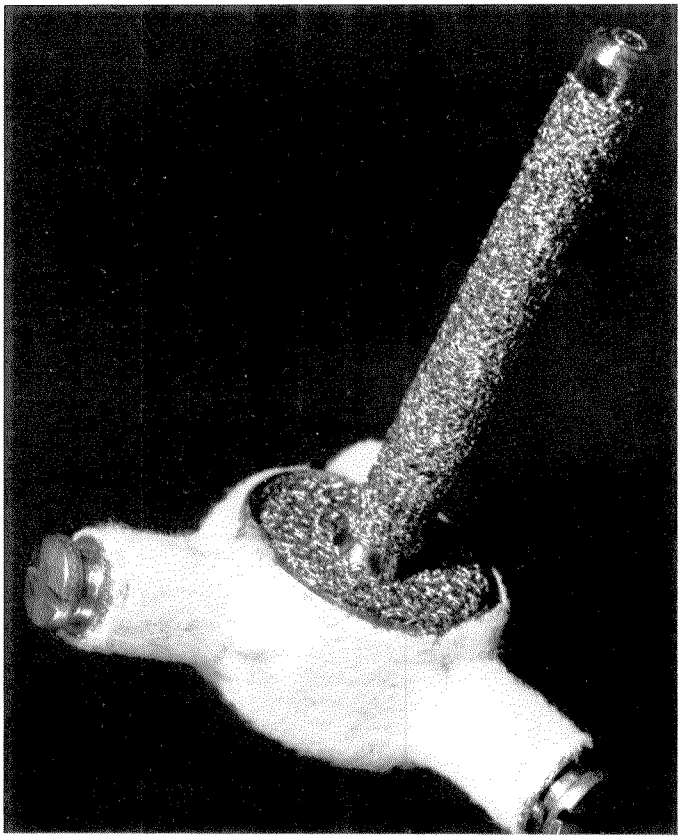


FIGURE 2.
The second model of this device incorporated a solid pilot on the tip that protects the leading edge of the titanium fiber from shear forces during implantation.

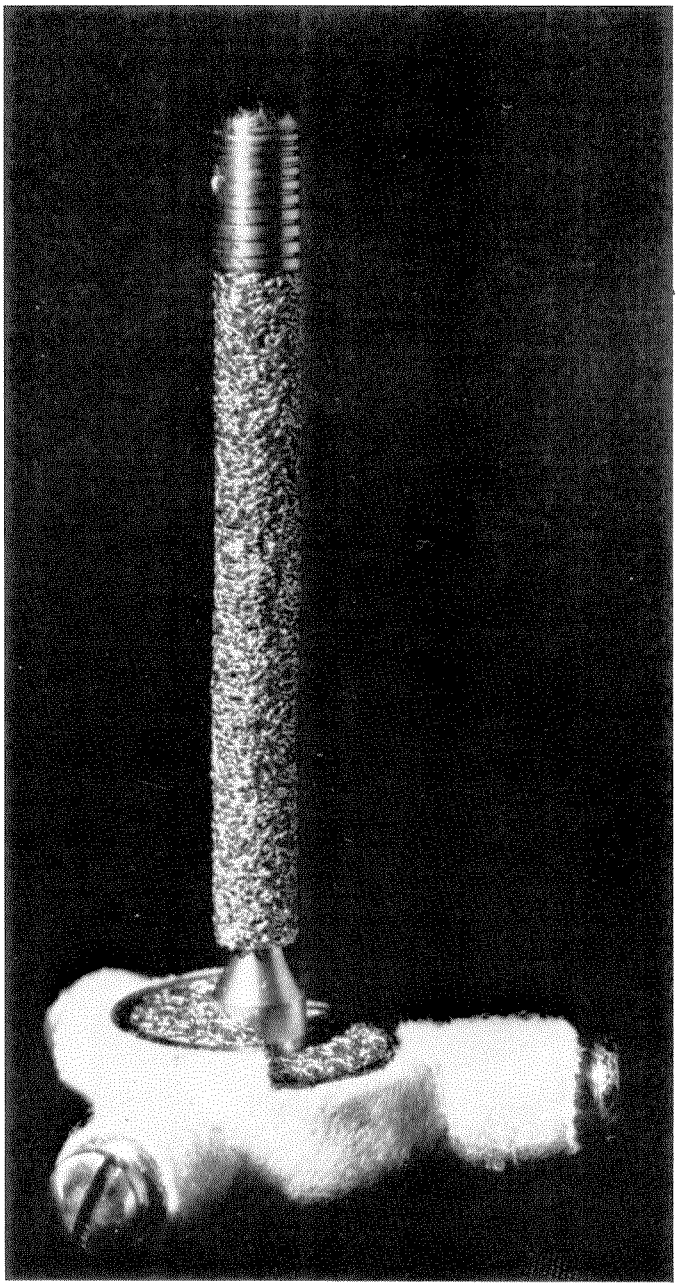


FIGURE 3.
The third model differs from the second in that the pilot has grooves that serve as a broach and the base pedestal is stepped to mate a mortice cut into the distal end of the tibia. This prevents rotation of the device during healing.

pregnancy. Even though supplemental vitamins and minerals were given, the prosthesis never stabilized. This animal was sacrificed after weaning of the kid.

Two of the implants fractured due to stress concentrations at the site of tool marks. This had been a problem with previous models (Fig. 4) but presumably has been eliminated by careful polishing the surface of the rod before applying the fiber coating.

One animal developed gangrene of the skin flap that evidently resulted from a compromised blood supply. Two animals developed sinus tract formation around one or more of the percutaneous lugs. These types of infections have been treated by daily irrigation using Dakin's Solution and intramuscular Combiotic®. The response to this treatment has, however, been poor.

During Hurricane Allen, one animal evidently mired the pylon in the rain-soaked pasture and evulsed the entire prosthesis. The animal was found the following day hobbling around without the device and was therefore sacrificed without benefit of a histological conclusion. The prosthesis itself was never located.

Although the statistical results remain dubious, we are encouraged by the excellent bone-anchoring capabilities offered by the sintered titanium fiber interface. The last model (Fig. 3) seems to include everything that we have been seeking in a PLSE, and represents what must be the ultimate that can be attained using state-of-the-art tech-

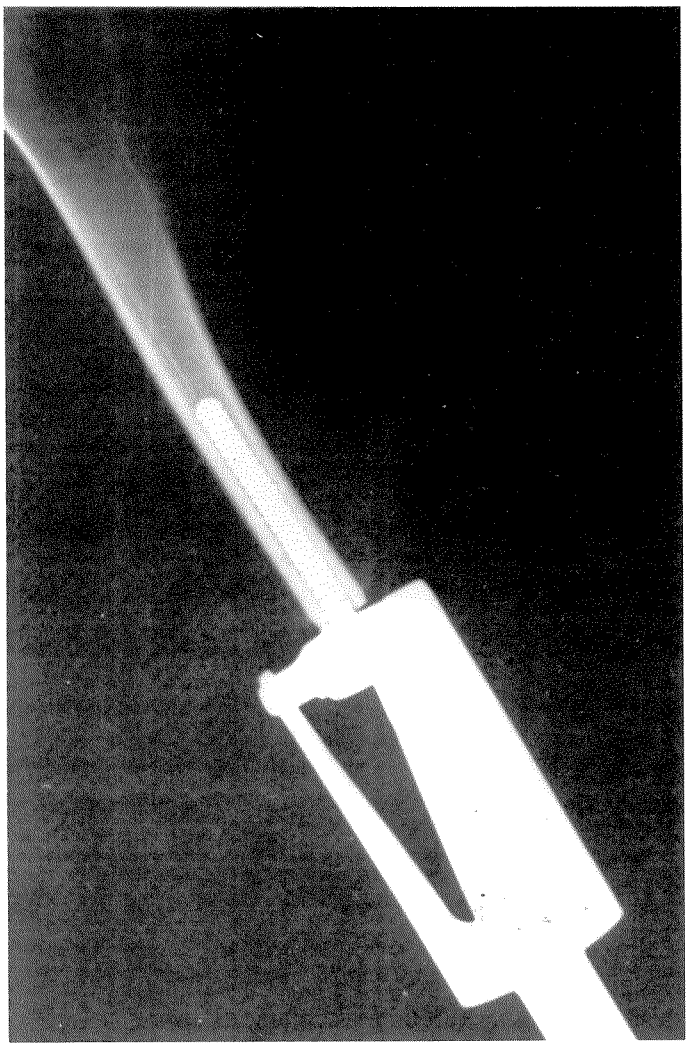


FIGURE 4.
A fracture of the intramedullary rod is visible on this radiograph. It is obvious on this model that stresses were concentrated in the grooves. Similar stress concentrations occur when tool marks are not removed by polishing.

nology. Only one of this design has been fabricated and implanted—because the program was not approved for continued funding, no further implants are contemplated.

References

1. Rostoker W, Galante JO and Shen G: Some Mechanical Properties of Sintered Fiber Metal Composites. J Test & Eval 2:107–112, 1974.
2. Anderson GBJ, Gaechter A, Galante JO and Rostoker W: Segmental Replacement of Long Bones on Baboons Using a Fiber Titanium Implant. J Bone & Joint Surg 60-A:31–40, January 1978.

Clinical and Laboratory Study of Amputation

Prosthetics Research Study
Eklind Hall, Room 409
1102 Columbia Street
Seattle, Washington 98104

Ernest M. Burgess, M.D.

The Prosthetics Research staff performed 50 amputations at the VAH, Seattle, during the Jan. 1–June 30, 1980, period. Of these, 50 were amputations for peripheral vascular disease. These patients formed the base for our continuing limb viability research. We have added multispectral photographic analysis (MSA) of skin circulation as an additional investigative technique. Martin Afromowicz, Ph. D., Research Associate Professor, Department of Electrical Engineering, University of Washington, is collaborating with us, together with the NASA Health Sciences team, University of Wisconsin. Presently, ischemic limbs are studied by accepted techniques and, in addition, transcutaneous PO_2, Laser Doppler measurement, and multispectral analysis. All of these systems are noninvasive, painless, and inexpensive at the clinical level.

Our preliminary report of 75 amputations, performed for ischemia with double blind study using multiple-site transcutaneous PO_2 measurements, will be submitted for publication August 1, 1980. We now plan to calibrate for routine clinical use. This limb viability research is an on-going and expanding project.

The Boeing Engineering Consultation Services have cooperated with us in developing a new ankle-foot prosthesis designed to provide higher functional performance than those presently available. It is now being field-tested under our supervision. We have extended our relationship with the Department of Kinesiology, University of Washington, and are continuing to evaluate certain performance patterns of amputees, including running. These studies have been used to develop the new PRS-VAH ankle. Dr. Motohiro Nagai, Associate Professor, Kanagawa Rehabilitation Center, has joined us for one year as a Research Fellow.

Investigation of Viability of the Neuromuscular Structures of the Extremities

University of Washington
School of Medicine, Dept. of Orthopaedics (RK-10)
Seattle, Washington 98195

Frederick Matsen III, M.D.

This project has carried out an early evaluation of our data, so far with 37 patients, on preoperative

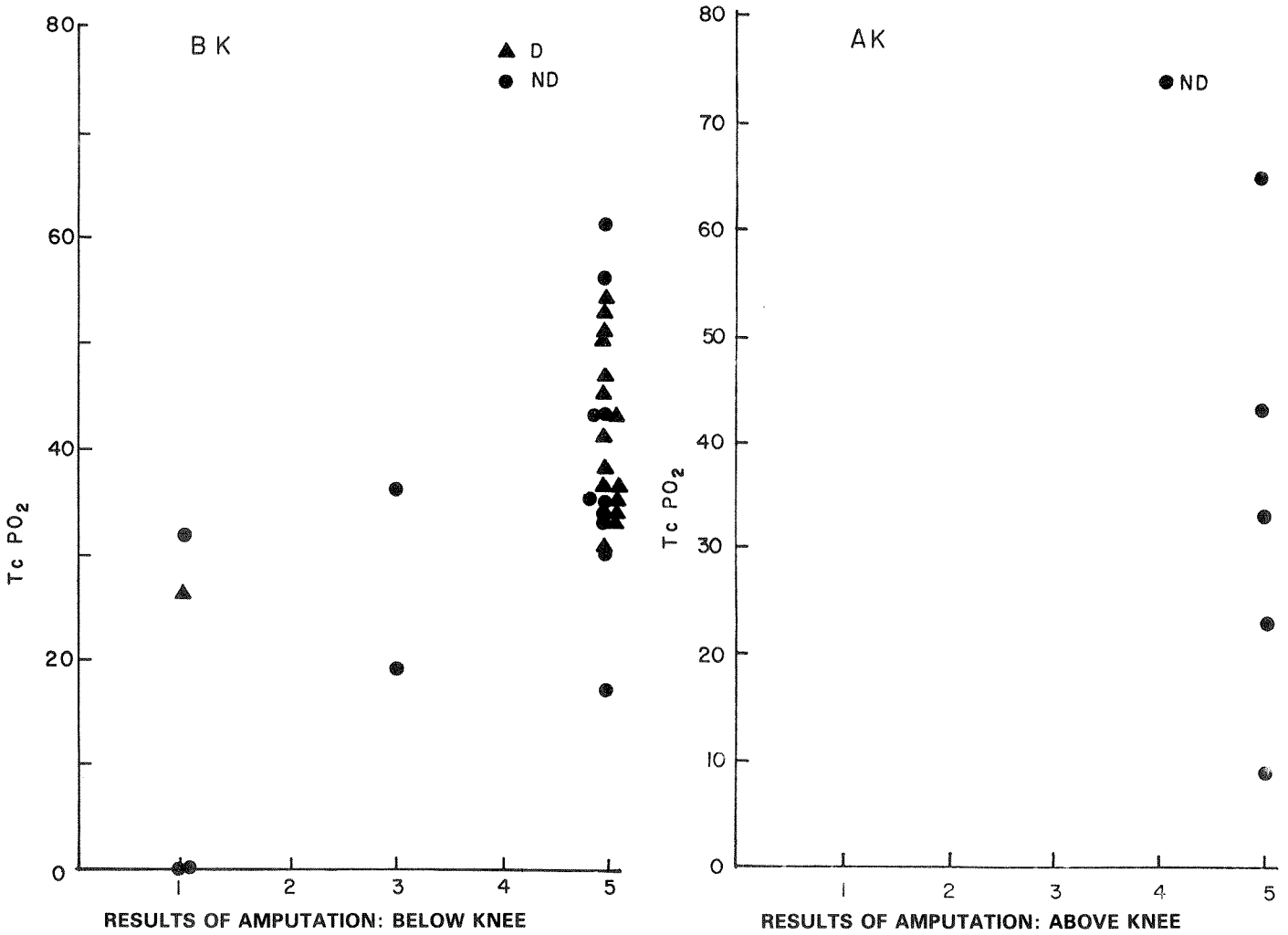


FIGURE 1.
Results categories range from #1 (failed with revision to higher level) to #5 (primary healing). Preoperative transcutaneous measurement of oxygen concentration is plotted using the scale at left.

transcutaneous measurement of oxygen concentration ($TcPO_2$) in relation to end-results after amputation for ischemia. Figure 1 shows that analysis. The results of the amputation are plotted on the abscissa, where #1 represents failed with revision to higher level; #2, failed after unsuccessful local revision; #3, healed only after local revision; #4, secondary healing; and #5 represents primary healing. Thus, category #3, #4, and #5 resulted in healing at the original level of amputation, while category #1 did not. We had no cases that fell in category #2.

In this series, there were 31 below-knee amputations of which 27 were successful (#3, 4 or 5), and six above-knee amputations of which five were successful. That indicates not only a high success rate of amputation, but also a very high incidence of below-knee amputations saving the knee joint in these patients with peripheral vascular disease (including a large number of diabetics).

If we look at the BK results (Fig. 1), we note that when $TcPO_2$ at the level of amputation was zero there was a 100 percent incidence of failure (only two patients fell in this category). When $TcPO_2$ was above zero, amputation was successful in 27 of the 29 cases. We will study the two cases of failure in detail to discover whether postamputation thrombosis or infection may have played a role in those failures. In any event, the results would lead us to the preliminary conclusion that below-knee amputation is likely to succeed with segmental transcutaneous PO_2 in excess of 15 mmHg and very likely to succeed with transcutaneous PO_2 of 40 mmHg and above.

Preliminary study of the multispectral analyzer—Two experimental models of ischemia were used; first was limb elevation and the second was tourniquet application about the calf. Initially, the multispectral analyzer was used on unheated skin of a normal male sub-

ject's right and left feet. Blood flow was measured by laser Doppler in heated skin of the left, and transcutaneous PO_2 was measured at four sites (two on the left and two on the right).

Both transcutaneous PO_2 and laser Doppler showed a definitive and reproducible response both to the ischemia induced by limb elevation and to that induced by tourniquet inflation. The results from the multispectral analysis did not initially show significant change with either of these perturbations, although the final data analysis is yet to be completed.

The MSA was then tried on heated skin, using a hair dryer to warm the skin to about 40 deg C. The change was heartwarming as well as footwarming: the multispectral analysis instrument then revealed a significant change between normal heated skin and the heated skin of the foot rendered ischemic by inflation of the tourniquet.

Our hypothesis so far is that normal exposed skin in a normally cool room is quite vasoconstricted and that there is not much change in superficial skin blood—with or without ischemia. This corresponds to burned skin that has been rendered hyperemic by immersing in a Hubbard tank and vigorous scrubbing, which are the circumstances surrounding the use of the MSA in the Burn Unit.

The idea of incorporating a miniaturized MSA probe into the attachment ring for the $TcPO_2$ probe was discussed. That would provide a constant amount of heating for the skin, which should increase the sensitivity of the MSA in intact skin. The concept of an implantable MSA probe which could look at thermal and muscular perfusion was also discussed.

Maxillofacial Restorative Materials and Techniques

Temple University School of Dentistry
Broad Street and Montgomery Avenue
Philadelphia, Pennsylvania 19122

Wilmington VA Medical Center
1601 Kirkwood Highway
Wilmington, Delaware 19805

John F. Lontz, Ph. D., James W. Schweiger, D.D.S., M.S., and Ernest B. Mingledorff, D.D.S.

Introduction—Polydimethylsiloxane (PDM siloxane for short) continues to serve in devising novel polymer matrices with extended networks of cross-linking and chain branching for innovative combinations of elastic, tensile constants with prepolymer-oligomer-catalyst composition variants (1). Most notable illustration in this regard is the combinative and interactive role of the oligomer chain length and catalyst concentration depicted schematically in Figure 1, wherein the maximization of the characteristic strength-to-modulus (S/M) ratio is used as an index of product improvements and innovations for unexplored intrinsic properties for biocompatibility and for practical merits as prosthetic affixtures to human tissues.

It is thus in this regard that the polymer-oligomer-catalyst composition variants are being extended to various oligomers other than

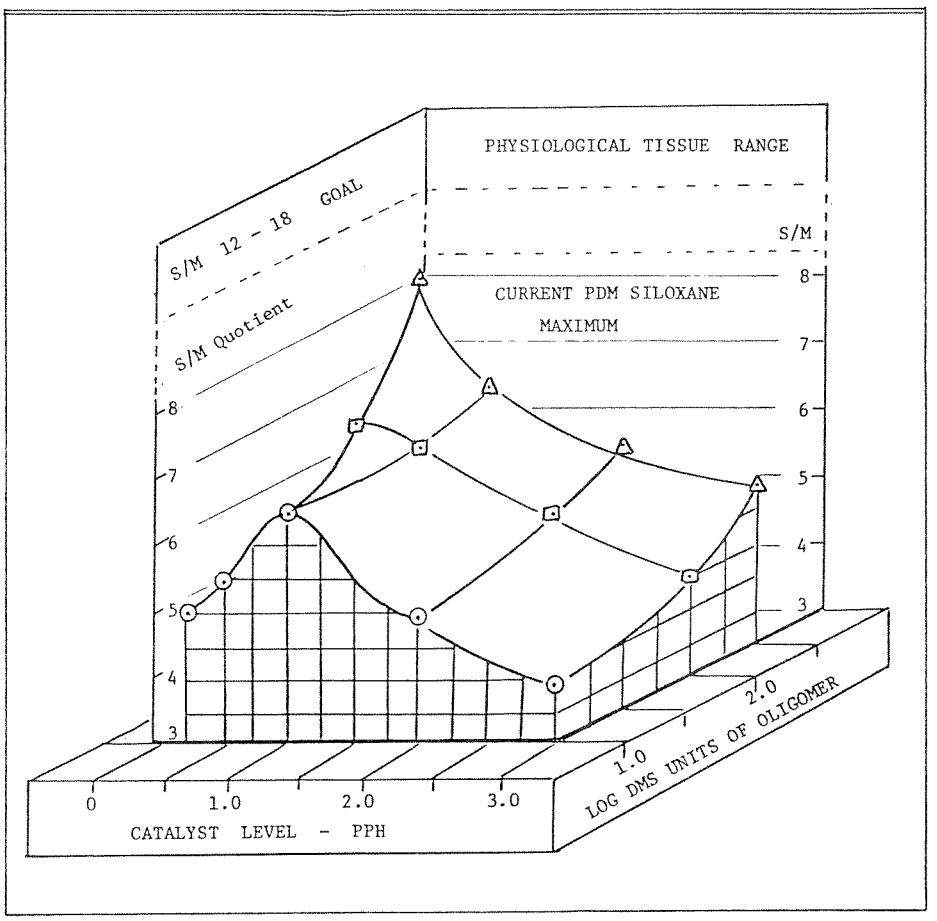


FIGURE 1.
Variations in polydimethylsiloxane oligomer units and catalysts levels as a means for approaching the physiological range of the tensile strength (S) to tensile modulus (M) in terms of a (S)/(M) quotient. (Presented at the World Biomaterials Congress, Baden, Austria, April 8–12, 1980 (Reference (1)).

PDM siloxane that might contribute significantly to enhanced adherence of the prosthesis, to longer-lasting adhesion, or to a new set of dermal adhesives more easily managed by the wearer. To this end, this report covers a new series of oligomers in the product development phase that are known to have some specific attribute, notably tackiness in some cases, or hydrophylic quality that would be favorable in contact with sensitive human skin and tissues. The first of these oligomer variants, as recounted in the ensuing section, is polyisobutylene (PIB) the molecular architecture of which is endowed with extraordinary adhesive quality.

In the meantime the human excised donor (HED) tissue culture testing for toxicity and potential tumorigenicity continues with greater intensity on cell development kinetics, tissue regeneration, and corollary assessment of the course of biochemical activity during tissue growth. In this effort the HED tissue types for study have been expanded to include mandibular bone regeneration which can be a significant contribution to anatomical reconstruction of maxillofacial cases.

The work during this 6-month period continues along the lines of six projects integrated into a Comprehensive Development Plan described in previous BPR reports (2,3,4 and 5). Emphasis during this period has been on product innovation (Project I), toxicity testing (Project IV), and Field Participation (Project V) which are being recounted in this report.

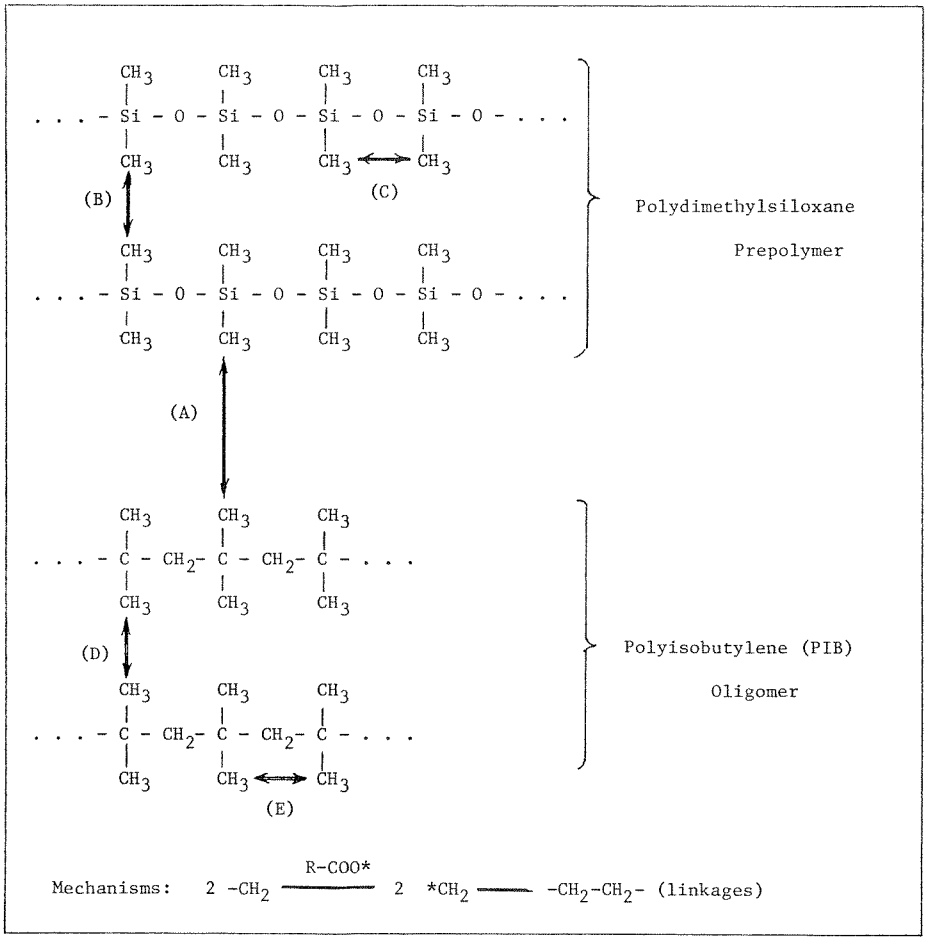


FIGURE 2.
Copolymerization (A) and chance intrachain polymerizations (B, C, D and E) of polydimethylsiloxane prepolymer (PDM) and polyisobutylene (PIB) oligomer in the course of the free radical methylene-dimethylene reactions to attain integral product tackiness for "built-in" adhesiveness of prosthesis. Studies are in progress on variations of oligomer structures and reaction modifications to achieve optimum adhesiveness.

Product Development (Project I)

Polydimethylsiloxane as a single chemical product developed in this Contract, as recounted in the previous BPR reports, is unique on two accounts.

Firstly, it is derived from two distinct molecular size components of polydimethylsiloxane, namely (i) prepolymer, serving as main chain length or backbone which by proper milling is extended so as to replicate the physiological collagen, as it were, by increased polymerization and extensive thermal cross-linking, and (ii) polydimethylsiloxane oligomer, serving to provide extensive chain branches to replicate the lipoidal, as it were, component of human tissue.

Secondly, the processing technique combining these two components by intense milling establishes a means now for exploring other, alternate, oligomers of dissimilar chemical configuration to modify the net prosthesis-to-tissue intersurface or interfacial characteristics, notably for longer adhesive retention—or for built-in cohesion to human skin without use of applied adhesives.

The first of a series of these alternate oligomers, suggested from a proprietary source, is polyisobutylene (PIB) commonly known in industry as Vistanex, a product of Exxon Chemical Corp., with well-defined, uniform chemical specifications and a long history and track record in the adhesive industry. Figure 2 depicts the oligomer structural array of PIB which, like polydimethylsiloxane (PDM), is endowed with two methyl ($-CH_3$) groups. As speculated in Figure 2, the potential free radical activity initiated by the conventional benzoyl peroxide thermal activation can provide a diversity of dimethylene ($-CH_2CH_2-$) linkages from the methylene ($*CH_2$)

Table 1. Summary of Tensile Characteristics and Tear Strengths of PDM-PIB Prepolymer-Oligomer Compositions

PDM/PIB Ratio	Catalyst Level (pph)	Tensile Strength (ASTM D638m)				Tear Strength (ASTM D1938) Lb/in
		Modulus Lb/sq in (M)	Strength Lb/sq in (S)	Elong'n Percent	(S)/(M) Quotient	
95/05	0.05	104	578	1640	5.6	183
90/10	0.05	97.1	487	1600	5.0	133
85/15	0.05	62.4	327	1700	5.2	86.9
Catalyst level variation series:						
80/20	0.05	58.1	240	1420	4.1	88.1
80/20	0.10	75.9	323	1200	4.3	69.3
80/20	0.20	92.6	363	1300	3.9	68.3
Compared with all PDM prepolymer-oligomer variations (Reference (1)):						
80/20 (Ranges)	(0.05) (to) (0.20)	(38) (to) (148)	(245) (to) (440)	(1200) (to) (1700)	(2.9) (to) (8.7)	(180) (to) (230)

radicals, a common feature of elastomer technology. Accordingly, it is deemed appropriate at this time to explore this new PDM-PIB siloxane composition inasmuch as PDM is now well-established as prosthesis stock material disseminated throughout over 40 VA and non-VA participants in its clinical usage, and in the interim it is appropriate to explore innovations and product improvements.

(Moreover, polyisobutylene is primarily a aliphatic hydrocarbon, having no aromatic, amino, or oxy structure that would be prone to biological activity and, such being the case, should be non-toxic and non-tumorigenic, a feature affirmed by no indicated literature citation to the contrary.)

Table 1 summarizes the first of a series of milled PDM-PIB compositions and the resulting tensile and tear properties. The data indicate reasonably equivalent duplication of the range obtained by the PDM-PDM prepolymer-oligomer combination in so far as the tensile constants are concerned, but with lessened tear strength as the PIB oligomer replaces the PDM siloxane oligomer. Preliminary adherence tests, devised by lap shear pulling, confirm the expected greater adherence of the PIB oligomer at all composition ratios indicated in Table 1. The merit of increased adhesibility constitutes an attractive trade-off for the lessened tear strength, and thus warrants further studies to optimize the PDM-PIB methylene linkage. A sequel series of durability, exposure and maintenance performance standards tests (4) are to be carried out along with practical tests on pigmented prostheses for adherence to tissue and the obligatory HED tissue culture tests for toxicity and potential tumorigenicity.

Toxicity and Potential Tumorigenicity Testing (Project IV)

The widespread criticism against use of animal testing systems in adjudicating toxicity to humans (6) constitutes the principal thrust of this project; that is, to circumvent this criticism by means of the human excised donor (HED) tissue-culture system—and further replacing the ubiquitous fetal calf serum by human serum.

The HED tissue testing system is set up with specific, clearly targetted groups of tissues, namely **orofacial** (Group I), pertinent to maxillofacial and related head and neck prosthetic reconstructions as implants and devices, **internal mucosal and organs** (Group II) and **skeletal** (Group III) as depicted in previous report (5). However, the transition to human sera, despite its replacement of the animal sera, could be criticized as involving unmatched serology or complications of antigenicity to the proper qualification of the HED tissue testing system. In this regard, the progressive series of alternates that are being explored to attain a universal standard of human protein component for cell growth and maintenance are as follows: (i) pooled-sources human sera, (ii) specific single-type human sera, (iii) separated, purified human albumin, and (iv) alpha growth factor (human). As the control, synthetic (non-serum) medium is employed. The ultimate goal is to propose a biocompatibility test that would be adopted for A.S.T.M. test standards (7) and included in Performance Standards for registration with FDA (8).

The range of the HED tissue accumulated pool currently under study for biocompatibility of PDM siloxane utilizing human sera includes the following:

Group I Orofacial (maxillofacial)—skin, lip, gingiva, palate, and nasal.

Group II Internal (mucosal, etc.)—tracheal, esophageal, prostate, etc.

Group III Skeletal (bone)—mandible, patella, tibia, etc.

Of particular note at this time is the successful culturing of bone (mandible and spinal) cells using pooled human serum (PHS) and specific type (single, non-pooled) serum (STS) along with controls having no sera in which each of

these cases were successfully cultured—usually after prolonged periods, up to 60 and more days. The testing system is to be extended to use of human α-protein growth factor (9) which is expected to accelerate the confluent growth to possibly 3 to 6 days, a more acceptable time period for a standard test as is desired by A.S.T.M. (7). The successes here demonstrate clearly the choice of human over animal (fetal calf serum) which at this writing also happens to be in critical short supply and expensive (10). (The previous tests on toxicity and potential tumorigenicity that utilized fetal calf serum in initial and in maintenance nutrient are now being repeated with selected PHS and STS along with corollary biochemical and biophysical monitoring, as described in previous report (Figure 48, Reference (2)).

Field Participation (Project V)

Since the formalized inception of this program in February 1979 among VA and non-VA participants (Table 8 in Reference (4)) in the controlled clinical usage, only one production lot (stock L-125-76-1 (SY-1)) of the 435 lots was returned for quality recheck. The reported deficiency was the presence of "scaly surface" of a molded orbital. The procedure in such a case is to conduct specification durability tests on returned stock material with inspection of molded prosthesis made from it, for a possible fabrication problem. The problem was traced (see below) to a molding detail and the return stock proved to be within specification and highly satisfactory (11).

Molding (Fabrication) Check—The scaly structure of a participant's molded orbital, mentioned above, was traced to the incomplete film drying of the foiling layer on the dental stone mold, which left a soft gel mass. When PDM siloxane stock material is implaced into a mold and pressured to full closure, such incompletely dried foiling gel mass intermixes with the stock and on curing (100°C for 1 to 2 hours) forms scaly separations, which are readily seen after removal of the fabricated prosthesis. An equivalent orbital molding (P-1497), made from that return stock using carefully dried foiling, eliminated the gel-formed scaly problem as had been expected, and the perfect orbital molding was sent to the participant for quality assurance.

Table 2. Quality Recheck on Tensile and Tear Resistance Properties in Support of Field Participation Project V

Property	Units	L-125-76-1 Quality Recheck	Performance Standards
Tensile Constantss			
Modulus	lb/sq in	52.7	40—80
Strength	lb/sq in	336	250 min
Elongation	percent	1400	800 min
S/M	(index)	6.4	4.2
Tear Resistance			
Tear Strength ASTM D1938	lb/in	125	80
Tear energy	grams	1600	1200
Tear propagation from 100% Stretch		None	None
Competitive RTV Reference SILASTIC 382			
Tear Strength	lb/in	28	(80)
Tear energy	grams	120	(1200)
Tear propagation from 100% Stretch		Instant	(None)

Specification Test Check—The most critical quality check relates to tensile (extensile) quality and tear resistance. Table 2 summarizes these principal quality features measured on flat test mold of the returned lot of stock material, (L-125-76-1 (SY-1)). The quality recheck tests showed no deviation from specification standards of tensile and tear resistance properties. The tear resistance of a maxillofacial prosthesis is the most crucial feature for the practical aspect of durability in handling by the wearer. Tear resistance is an outstanding, even unique merit of PDM siloxane developed in this Contract compared to competitive prosthetic materials (for example, RTV Silastic 382 often used for medical applications) (12). Figure 3 illustrates the unique tear resistance of milled PDM siloxane, a milled and thermally polymerized elastomer prosthesis with its eventual tear induced only by continued extension lasting up to 900 percent stretch compared to less than 50 percent for RTV Silastic, like most non-milled competitive candidates for maxillofacial prosthetics with poor tear resistance.

This single instance of a quality recheck emphasizes the obligatory technical backup that has to be provided by the Contract in furthering the competent availability of stock material, a technical service not available with other competitive prosthetic materials—notably plasticized polyvinyl chloride (13) and polyurethanes (14).

Acknowledgement

The recent, full-time participation of Dr. Mary D. Nadijcka, Research

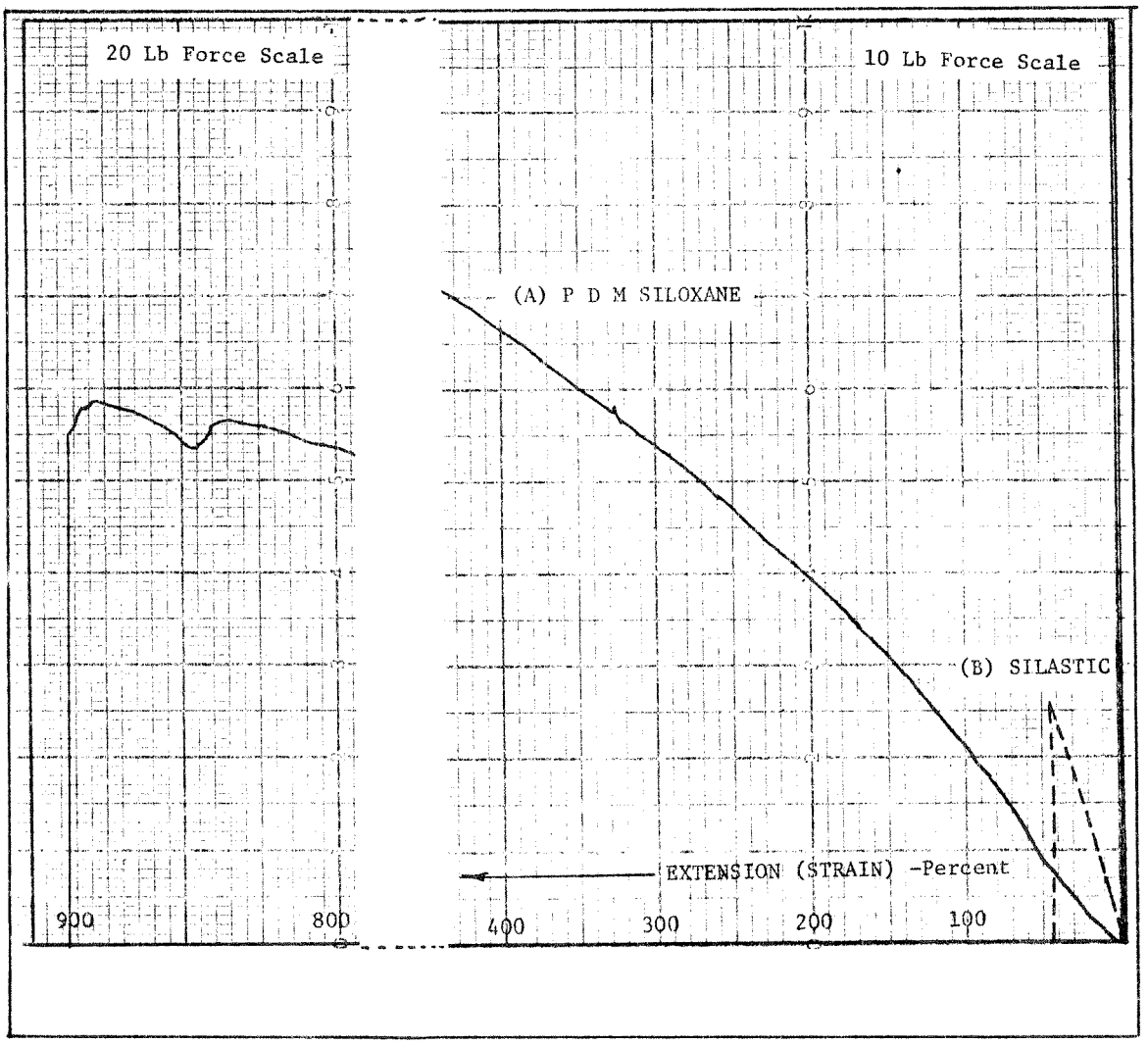


FIGURE 3.
Tear strength determination for a quality re-check (Instron Tensiometer, A.S.T.M. D1938).

Materials	Force to tear	Strength Lb/in
(A) PDM Siloxane Lot L-125-76-1	11.7	216
(B) RTV Silastic 382	2.6	28

Cell Development Biologist, heretofore as Consultant, is most timely to the Contract, serving to impart her expertise in providing competent assessment of the immensely multivariant and complex morphological and cellular structures.

References

1. Lontz, John F. and Schweiger, James W.: Polydimethylsiloxane for Safe and Effective Orofacial Prosthetics. IV. Replicating Tissue Elasticity with Prepolymer-Oligomer-Catalyst Variants. Presentation and manuscript for the World Biomaterials Congress, Baden (Austria), April, 1980, Page 1.41.
2. Lontz, John F. and Schweiger, James W.: Maxillofacial Restorative Materials and Techniques. Bull. Prosth. Res. BPR 10-32, Fall 1979, pp. 376–404. A fuller account of each of the six projects of this Contract V 101(134)P-337 is presented in this published report.
3. Lontz, John F. and Schweiger, James W.: Maxillofacial Restorative Materials and Techniques. Bull. Prosth. Res., BPR 10-31, Spring 1979, pp. 119–136. This published progress report explains the significance of the differences in the molecular architecture between the low (hence inadequate) tear resistance of RTV silicones compared to the milled and high temperature (HTV) polymerized polydimethylsiloxanes with their high and highly favorable tear resistance.
4. Lontz, John F. and Schweiger, James W.: Maxillofacial Restorative Materials and Techniques. Bull. Prosth. Res., BPR 10-30, Fall 1978, pp.223–244. This progress report introduces the end-use, practical testing of polydimethylsiloxane for durability and effectiveness for Performance Standards under the provisions of the Medical Devices Act Amendment of

1976 which will be included in the HED tissue culture testing to demonstrate safety to human tissues.
5. Lontz, John F. and Schweiger, James W.: Maxillofacial Restorative Materials and Techniques. Bull. Prosth. Res., BPR 10-29, Spring 1978, pp.145–155. This published report introduces the concept and biometric system for the HED tissue culture testing to provide proof of safety in terms of demonstrated non-toxicity and potential non-tumorigenicity coupled with concommittant clinical follow-up.
6. Bicking, Charles A., Editor: Report of the Workshop on Biological Screening Tests, Las Vegas, Nevada, September 12–14, 1977, EPA 600/9-79-004. This report, covering a broad area of testing systems, favors utilization of cytotoxicity employing certain target cells for information on cellular toxicity and metabolism. During the workshop session which the writer attended there was off-the-record concern about the over-use of animal testing for correlation, even in extreme cases to human risk.
7. Brown, S.A.: Biocompatibility Activities of the ASTM Committee F–4. World Biomaterials Congress, April 8–12, 1980. Abstracts, page 5.1.4. The test methods include the following: extraction of plastics (published as F-619), cell culture testing for toxicity hemolysis, thrombogenesis, etc. A major activity of ASTM is the development of a protocol for biological testing divided into classification for particular end-use. The ASTM system, according to a spokesman for FDA (Dr. Robert S. Kennedy, Bureau of Medical Devices), will be a prominent candidate as the agency to set up Performance Standards.
8. Federal Register, July 25, 1978, Part V, FDA, Medical Devices, Proposed Procedures for Development of Performance Standards.
9. Holmes, R., Mercer, G. and Mohamed, N.: Studies of Alpha-Protein in Human Cell Cultures. In Vitro, 15: 522–530, 1979.
10. Miles Research Products, Kankakee, IL. This supplier advised that fetal calf serum is in worldwide shortage and that the unit (100 ml) prices have increased from $16–20 to $60–70 which becomes substantially prohibitive and so requiring modifying completely the test nutrient system.
11. Lontz, John F., letter, May 22, 1980, to a Field Participant (ML) The quality of L-125-76-1 (SY-1) was rechecked at participant's request for source of problem, which turned out to be not the material but the molding procedure.
12. Dow Corning Corp., Medical Products Division. Silastic 328 is their RTV medical grade elastomer for use in minor prosthetic reconstructions, but lacking for orofacial reconstruction (with on-and-off handling, disinfecting, and so on) the tear-resistance especially in thin edges.
13. Sweeny, W.T. and co-authors: Evaluation of Improved Maxillofacial Prosthetic Materials. The polyvinyl chloride compositions described in this published report contain plasticizer additives with no chemical description of ingredients that can be checked in the Toxic Substances List.
14. Gonzalez, Juan B.: Polyurethane Elastomers for Facial Prosthetics. J. Prosth. Dent. 39:179–187 1978.

Development of Upper Extremity Orthoses Employing Electrical Stimulation

VA Medical Center
10701 East Boulevard
Cleveland, Ohio 44106

Case Western Reserve University
Rehabilitation Engineering Center
Department of Orthopaedics
2040 Adelbert Road
Cleveland, Ohio 44106

P. Hunter Peckham, Ph.D.

The purpose of this project is to develop and evaluate upper extremity orthotic systems employing functional electrical stimulation of paralyzed muscle. The systems are designed to provide control of either palmar prehension-release of the fingers (1), or lateral pinch-release of the thumb (2). These systems are currently being utilized by seven outpatient subjects. These studies are carried out in conjunction with the Rehabilitation Engineering Center at Case Western Reserve University.

System Design

The design of the stimulation system allows the subject to perform either of the two grasping tasks, depending upon which muscles are electrically stimulated. Command control information is derived from the subject's head position, shoulder position, or level of myoelectric activity in a muscle with voluntary control. These command signals allow proportional control of the contractile force of the stimulated muscles. (Each of the systems for control and stimulation has been detailed in previous BPR reports.) The hand control systems have been implemented as lightweight units designed and fabricated for patient usage. The circuitry provides both for maximum patient safety and low power consumption, and is implemented on miniature high-density printed circuit boards.

Electrodes and Connectors—Chronically indwelling percutaneous wire electrodes fabricated from 10-strand type 304 stainless steel (Cooner, Inc.) are used for stimulation (3). The percutaneous interface is covered with a surface skin connector, which has been redesigned in the past period to enable the subject's attendant to change it at home. This new design will eliminate the need for the subject to return to the hospital for routine connector maintenance which formerly was performed at approximately monthly intervals.

Patient Control of Functional System—The strength of contraction is regulated by the command signal generated by the subject. (The use of three command sources, shoulder position, head position, and a myoelectric signal, have been described in previous reports.) The shoulder-position scheme has been developed further in the past period, and a control scheme which was demonstrated to be feasible in studies performed in conjunction with the Applied Neural Control Laboratory at C.W.R.U. has been implemented in the functional system. The shoulder-position command source which is used measures movement in two axes; horizontal (protraction-retraction) and vertical (elevation-depression). In this control scheme, horizontal movement is used as the proportional command to regulate the stimulus output, and the velocity of movement in the vertical axis is used to provide a logic signal which results in the command signal being fixed regardless of the shoulder position. This relieves the subject from having to exert continuous control over the system, particularly during tonic (maintained grasp) type activities. Figure 1 shows the sequence of events in a control task.

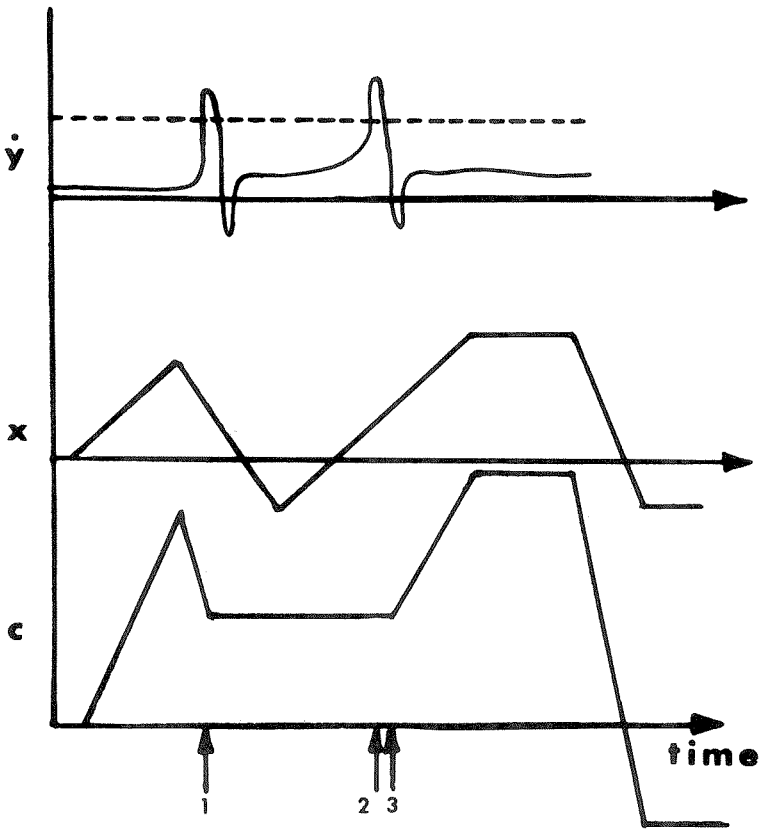


FIGURE 1.
Control scheme utilizing horizontal axis (X) of shoulder position transducer to supply proportional command, and exceeding a threshold velocity in the vertical axis (Y) to supply logical "hold" command.

Outpatient Evaluation of Functional Systems

Seven outpatient subjects are presently involved in the evaluation of functional electrical stimulation orthoses. Each is quadriplegic secondary to spinal cord injury of at least 1 year duration and is totally paralyzed below the level of injury. The system fitted and the patient's functional level are given in Table 1. Each of the subjects fitted with the functional system continues to be active in the program. The results described in the previous issue of BPR continue to be valid in demonstrating that those subjects utilizing the systems on the most regular basis are those who are most independent and who incorporate it into their daily activities.

An additional subject (WHK) was fitted with a functional system during this past period. This subject is quadriplegic at the C6 level, and was referred to us from outside of the immediate Cleveland vicinity. In 3 days, this subject was completely evaluated, implanted with electrodes, and set up with a functional system. Although the subject found the function very useful and learned its operation rapidly, it was mutually decided not to pursue further use of the FES system at that time, primarily because of potential maintenance problems that could develop. This experience demonstrated that a functional system could be implemented within a short hospital visit, suggesting that the state of development is moving closer to more widespread clinical development.

In the next period, we plan to include three additional subjects in this program, and work to remove those aspects of the system which are impeding more widespread usage of this technique.

Exercise Stimulator Development

Electrically induced exercise is used to increase muscle strength and reduce fatigue in the electrically stimulated muscle. A more versatile general-purpose stimulator is being developed to replace that presently in use. The new unit will provide exercise for greater numbers of muscles. The exercise stimulator currently being designed is a six-channel unit delivering simultaneous biphasic stimulus pulses. The following is a short description of the operation of the system.

The stimulator operates in two modes which are arbitrarily termed the flexor and extensor modes. Each output can be assigned to either mode and the stimulator can be set up to operate as (i) flexor only, (ii) extensor only, or (iii) alternating flexor and extensor. Consequently, if the stimulator is set up to operate as flexor only, each channel that is assigned to be an extensor channel would be inoperative whereas each channel that is designated a flexor channel, and is active, would stimulate. When the stimulator is set up to operate alternately between flexor and extensor, each flexor channel is on for a predetermined amount of time as is each extensor channel. The time period that each is on is programmable in 1-second increments from 2 to 30 seconds.

The exerciser provides for timing of the exercise sequence, detection circuitry to sense broken or disconnected electrodes, and a timer to detect the amount of exercise that a muscle has received. The latter information will be used to correlate muscle physiological data with exercise time.

The exerciser at this time is nearing completion of the prototyping stage; in the next period it will be completed and units will be provided to the patients currently in the program to replace older, less versatile units. It is anticipated that these new units may also be used outside of the FES program as general purpose stimulators.

Reference

1. Peckham PH, Mortimer JT, Marsolais EB: Control Prehension and Release in the C5 Quadriplegic Elicited by Functional Electrical Stimulation of the Paralyzed

LEVEL OF INJURY	FUNCTIONAL SYSTEM: LATERAL PREHENSION-RELEASE	FUNCTIONAL SYSTEM: PALMAR PREHENSION-RELEASE
C5	2	2
C6	3	-

TABLE I. FUNCTIONAL SYSTEMS FITTED TO OUTPATIENTS

Forearm Musculature. Submitted for publication.
2. Peckham PH, Marsolais EB, Mortimer JT: Restoration of Key Grip and Release in the C6 Tetraplegic through Functional Electrical Stimulation. In press, J Hand Surg. 1980.
3. Peckham PH, Mortimer JT, Marsolais EB: Percutaneous Intramuscular Excitation of Paralyzed Skeletal Muscle: Electrode Performance. Submitted for publication.

Lower Extremity Amputation: Immediate Postoperative Fitting of Prostheses

Vascular Surgery Section
Tucson VA Medical Center
Tucson, Arizona 85723

James M. Malone, M.D.
Wesley S. Moore, M.D.
Joseph M. Leal, C.P.

Phase I of our program to evaluate the feasibility of a regional amputation center within the VA has been completed. At the present time, the clinical and research facilities including a dedicated prosthetics laboratory are fully functional. As part of our initial effort, the results of lower extremity amputation rehabilitation at the Tucson VA were analysed before and after the establishment of our amputation center, in order to assess the impact of the center concept. Prior to the establishment of a dedicated amputation center, 53 lower extremity amputations and seven revisions for amputation failure were performed in 52 patients (July 1, 1975—June 30, 1977).

After the establishment of a dedicated amputation team and amputation center, 73 primary amputations, 15 preparatory guillotine debridement amputations, and 2 amputation revisions for failure were performed in 67 patients (July 1, 1977—July 30, 1979).

The establishment of a dedicated amputation center included the utilization of immediate postoperative prosthetic techniques on all levels of lower extremity amputation and all types of patients, including both dysvascular and vascular amputees. In fact, over 85 percent of our patients have undergone amputation because of complications of either diabetes mellitus or vascular insufficiency.

In addition, our program utilizes objective amputation level selection with Xenon 133 skin blood flow (1), accelerated immediate postoperative patient rehabilitation (2), and the coordination of surgery, rehabilitation, and patient care through a dedicated identifiable amputation rehabilitation team. Prior to the establishment of our amputation center (July 1, 1977) the amputation healing rate was 63 percent, the mean rehabilitation time was 128 days, the mean hospital time was 68 days, and successful rehabilitation in those patients who were ambulatory prior to amputation was only 69 percent.

After the establishment of an identifiable amputation team and functional amputation center, the amputation healing rate was 97 percent, the average rehabilitation time was 31 days, the average hospitalization time was 38 days, and there was a 100 percent incidence of successful rehabilitation in those patients who were ambulatory prior to amputation. In addition, in no case was there a detrimental effect on wound healing due to the application of immediate postoperative prosthesis.

There was no difference between the two groups with respect to surgical mortality, however, all parameters of

hospitalization and rehabilitation were significantly improved in those patients treated in the amputation center (P=0.01). In addition, life table analysis of those patients who underwent amputation in a dedicated center demonstrated that 100 percent of the patients successfully used their prostheses for followup periods ranging from 1–18 months, and that the incidence of late stump revision was less than 10 percent.

Comparison within the same institution of the results for lower extremity amputation rehabilitation before and after the initiation of a dedicated amputation rehabilitation center clearly demonstrates the superiority of a center concept with respect to both the surgical and the prosthetic results of amputation rehabilitation.

Phase II, the trial of a pilot program which will study the feasibility of a referral regional amputation center within the VA hospital, is now under way. Contact is being made with other VA hospitals in the region to solicit their cooperation in referring their amputation cases to the Tucson VA Hospital for primary care.

References

1. Moore WS: Determination of Amputation Level: Measurement of Skin Blood Flow with Xenon 133. Arch Surg 107:798–802, 1973.
2. Malone JM, Moore WS, Goldstone J, et al: Therapeutic and Economic Impact of a Modern Amputation Program. Ann Surg 189:798–802, 1979.

Upper Extremity Amputation: Immediate Postoperative Conventional, Electric, and Myoelectric Prostheses

Vascular Surgery Section
Tucson VA Medical Center
Tucson, Arizona 85723

James M. Malone, M.D.
Joseph M. Leal, M.D.
Sandra J. Childers, BA

As a natural outgrowth of our expanding lower extremity amputation rehabilitation program at the Tucson VA, patient referrals for individuals who underwent upper extremity amputation have begun to grow. We have approached the upper extremity amputee in much the same way as the lower extremity amputee, choosing to utilize the immediate postoperative application of a prosthesis in the operating room. In addition, in selected patients who have been active users with conventional types of prostheses, we have been actively involved in studying the feasibility of utilizing electric and myoelectric prostheses rather than conventional prosthetic components.

Contemporary surgical and prosthetic treatments for upper extremity amputation provide only 50–60 percent patient rehabilitation, with an average rehabilitation time of 6 months. During the past 18 months our group has fitted all levels of posttraumatic amputation from below-elbow to forequarter with immediate postoperative conventional, electric, myoelectric and combined electric-myoelectric prostheses (Table 1). In addition, we have performed elective above-elbow amputation with the fitting of immediate myoelectric electric prosthesis in selected patients with upper extremity hemiplegia due to stroke or brachial plexus malfunction. One hundred percent of our patients have had complete prosthetic function within 2-12 days after amputation. This prosthetic function can be defined as full control of the terminal device and full control of the elbow for amputation levels at above-elbow or higher. In addition, all of our patients continue to use their prostheses extremely well.

Comparison of data with both conventional prosthetic devices and myoelectric and electric devices in our institution strongly suggest that currently available electric and myoelectric prostheses may provide increased function and cosmesis when compared to standard hook and cable prostheses. We are continuing to expand our program and are now seeing increasing numbers of patients who are being referred for fitting of electric and myoelectric prostheses after long periods of conventional hook and cable usage (Table 2).

Although the number of patients in our series is small, the data contrast markedly with the existing literature, which suggests that the immediate postoperative use of electric and myoelectric prostheses for traumatic and elective upper extremity amputation may provide major improvement in patient rehabilitation when compared with conventional surgical and prosthetic management.

We plan to expand this program with

TABLE 1.
Traumatic and elective upper extremity amputations

Amp. level	#	Immediate postoperative prosthetic techniques			
		Conventional	Electric	Myoelectric	Electric-myoelectric*
Below-elbow	1	–	1	–	–
Above-elbow	5	3	–	2	2
Forequarter	1	–	1	–	–
	7	3	2	2	(2)

*All Myoelectric Elbows Fitted With Electric Hands and Conventional Hook

TABLE 2.
Upper Extremity Prosthetics: Overall experience with immediate postoperative fitting and late fitting

Amp. level	#	IPOP*	Conventional	Electric	Myoelectric**
Below-elbow	3	1	–	2	1
Above-elbow	6	5	3	1	2
Forequarter	1	1	–	1	–
	10	7	3	4	3

*Immediate Postoperative Prosthesis
**All Myoelectric Elbows Fitted with Hook and Electric Hands

analyses of specific prosthetic devices as well as of the feasibility of the immediate postoperative fitting of electric and myoelectric prostheses in patients undergoing upper extremity amputation.

NOTE: Additional non-sensory material follows this section.

SENSORY AIDS IN THE VA RER&D SERVICE PROGRAMS

Edited by **Howard Freiberger, A.M.**
Chief, Rehabilitation Engineering Service
Veterans Administration Prosthetics Center,
252 Seventh Avenue, New York, N.Y. 10001

Development of an Advanced Optical Character Recognition Speech-Output Accessory for Blind People

Telesensory Systems, Inc.
3408 Hillview Avenue
Palo Alto, California 94304

Pat Clark, M.S., and
Robert Savoie, Ph.D.

Telesensory Systems, Inc., is developing a "family" of devices intended to meet the print reading needs of blind people. One of these devices, the Optacon, was introduced in 1971. There are now over 7,000 in use throughout the world. Two additional devices are under development. One is a synthetic-voice accessory for the Optacon, that recognizes printed characters and speaks words intelligibly as the reader scans print by hand. The other is a speech-output reading system that automatically scans print under the control of a blind user. The research and development leading to the new devices is partially supported by an interagency contract with the Veterans Administration, the Bureau of Education for the Handicapped, and the Rehabilitation Services Administration. Over a 30-month period, this project plans to implement low-cost Optical Character Recognition (OCR) techniques suitable for use with an Optacon, low-cost high-quality text-to-speech techniques, and a means for automatically scanning a bound book.

Results of the first 15-month effort (starting September 1978) were reported previously. A series of test units, culminating in one based on LSI-11 microcomputers, was constructed. The test unit was demonstrated at two large conferences during the summer of 1979. At the end of 1979, construction of a breadboard of the hand-scan system was well underway, and the initial designs of the optics system, user controls, and bookholder for the automatic scanning system were complete.

Based on the feedback received from blind consumers at the summer 1979 conferences, extensive software modifications were begun to improve the rsponsiveness of the system. These modifications have been completed, and system dynamics are now much improved, allowing the user to start and stop the speech immediately, and to spell or selectively re-play words conveniently. A method for helping the user in making Optacon optimal adjustments (magnification, threshold) was specified, and work has begun on its implementation. Provision was made for disabling the voice during tactile reading.

The software for Optical Character Recognition has been continually improved, and now works equally well on serif and sans-serif typeset material and typewritten material. The number of type fonts recognized with high accuracy continues to increase.

The breadboard for the hand-scan system was completed except for the custom-designed Programmable Digital Signal Processor (PDSP) integrated circuits, which are still being fabricated. A special emulator was built to allow the rest of the system to operate in the absence of the PDSP chips. The complete breadboard has been in continuous operation for about 3 months at the time of this report.

The major effort on the hand-scan system has been the construction of Field Evaluation prototypes. The design of the prototypes was completed and all electronics parts were ordered and received. The mechanical package for the unit was de-

signed and a first unit was constructed. The prototype units are table-top models, approximately 20 inches on each side and 11 inches tall. The Optacon connects to a prototype unit via a cable attached to its I/O connector. Tooling for the construction of electronic circuit boards is complete. A tracking aid, based on the Colineator from Mauch Laboratories, was designed and parts were ordered. A substantial number of subassemblies were constructed and tested.

Construction of a breadboard of an automatic scanning system is in progress. A bookholding device which will accommodate single sheets of paper as well as hardbound and paperback books has been built. Software algorithms to assist the user in determining the format of a page are being developed. Human factors studies were conducted which resulted in a preliminary set of user controls. Software and hardware to implement these controls have been developed, and further human factors studies will be conducted.

The optical, mechanical, and electronic components needed to collect video images for OCR are being developed. To read printed characters, a very small spot of light from a laser is scanned across the page of text using a mirror scanning system to deflect the laser beam. Video pictures are constructed from the signals from a photodetector using analog circuitry to amplify the signals, to generate the signal timing, and to automatically adjust for varying black/white contrast conditions. Further video processing including automatic magnification adjustment is done using digital hardware, with a microprocessor acting as the control center for the entire scanner system.

In a recent milestone, video data was collected and transmitted through all of the data paths. Work continues to refine all elements of the system.

Clinical Application Study of Reading and Mobility Aids for the Blind

Eastern Blind Rehabilitation Center
VA Medical Center
West Spring Street
West Haven, Connecticut 06516

James J. Acton, William R. De l'Aune, Ph. D., and Patricia D. Gadbaw

As reported in BPR-10-33, the Research and Mobility Departments of the Eastern Blind Rehabilitation Center have been evaluating a prototype cane provided by Dr. Gilbert Elchinger of the Polaroid Corp. A transducer used in the Polaroid sonar-focusing camera is mounted on an aluminum long cane and connected by means of a lightweight cable to a small electronics package worn by the user. Specific circuitry allowed experimentation with different sensing ranges outside of which the device would not respond to the presence of an obstacle.

A major conclusion was that the cane mounting was not acceptable as a head-protection system. This was because of the inability of the sensor to reliably detect objects smaller than half-an-inch in diameter at a distance of 5 feet when the cane was swept from side to side. Other mounting options, such as a chest-worn system or a wheelchair mount, which would not cause the device's field of view to scan rapidly from side to side, appear much more promising. Further studies are underway.

Consultation with research engineers at the American Foundation for the Blind on their many projects is continuing. In particular, the Computerized Travel Aid experiment has been conceptually broadened to include evaluations of various types of sensors and different modes of processed signal presentation. The first devices are expected in the fall of this year. Evaluation of the talking glucose analyzer is also expected to begin at this time.

A nationwide evaluation of the ITT Night Scope, coordinated by the Palo Alto Blind Center, is now underway. Because of the very specific type of visual deficits required of participants in this study, some difficulty has been encountered in filling all of the cells in the experimental design. Other rather mundane (and New England specific) difficulties such as the inclement winter nights and the extreme length of the summer days, have made testing worrisome, but in essence, the cooperative study is proceeding well and will undoubtedly become a model for future studies. Preliminary talks with the New York Association for the Blind concerning an evaluation of the reliability of mobility measures have taken place. The inclusion of private agencies in cooperative projects of this nature will add considerably to the generalizability of the results—and to our ability to obtain reasonable sample sizes in future endeavors.

The ongoing analysis of data from the Beliefs about Blindness Survey (BABS) obtained from clients and staff of the E.B.R.C., and from college students, is providing the researchers with many very provocative findings. Reliability and validity studies are now close to completion. Response consistency over time is being studied in college students unfamiliar with blindness. An examination of the responses of E.B.R.C. clients to the BABS before and after rehabilitation is underway. Clients' responses are also being compared with staff ratings of the clients' rehabilitation progress. Factors underlying the discrete beliefs are being determined. A paper on this subject was published by Drs. Needham and Ehmer in the February, 1980, issue of the Journal of Visual Impairment and Blindness.

The personality and demographic data obtained from congenitally blind persons in cooperation with psychologists from the New York Association for the Blind has undergone preliminary analysis. Means on most of the MMPI and CPI scales have been found to be significantly

different from those obtained from sighted samples. Differences between the adventitiously blinded male sample of E.B.R.C. clients and the congenitally blind group are also highly significant. New standardized scoring charts have been tabulated for the different sample groups, and a computer program has been developed to plot standardized MMPI profiles on the basis of group rather than sighted population norms. Personality factors linked to autonomy and employment success are also being studied.

The monaural auditory impairment simulation device, described in the Spring 1978 issue of the Bulletin of Prosthetics Research, has been received and has obtained a favorable preliminary evaluation. The simulator is currently being tested at the Madison Campus of the University of Wisconsin in a multi-handicapped mobility program. Further use of the device by other groups is anticipated. The delivery of the binaural simulator is expected in the Fall of this year.

A paper by Dr. De l'Aune, "Hearing: Its Evolution and Ways of Compensating for its Loss," was published in the Journal of Visual Impairment and Blindness (74-1, January 1980, pp 19–23). A master's thesis conducted at the E.B.R.C. under the supervision of Dr. De l'Aune was also published in the Journal of Visual Impairment and Blindness (74-5, May, 1980, pp 189–192) under the title, "Effects of Hearing Aids on Localization of White Noise by Blind Subjects."

The E.B.R.C. Research Department was visited by Ms. Phyllis Barnes of Maryland Computer Services, Inc., in April. Demonstrations of the different talking terminals, word processing units, and computers offered by MCS were given at a staff meeting.

Dr. De l'Aune attended an interagency research meeting in VA Central Office in February. He also participated in a special meeting concerned with hearing aid problems during this visit.

Mr. Ernest Matthews visited the E.B.R.C. in April to demonstrate the Beamscope Lens. This system, consisting of a front-mounted Fresnel lens, is used to magnify the screen image of television sets. The device has a magnifying power (approximately 2X) comparable to the systems currently used, but does not cause the problems with fatigue associated with the hand held or eyeglass-mounted lens systems. It does require, however, that the viewer be in a position directly in front of the screen, restricting the number of people able to view the set at any one time. A lens is being purchased for further evaluation by the low vision department.

Development of a Personal Information System for the Visually Impaired

Western Blind Rehabilitation Center, VA Medical Center, Palo Alto, California[a]

Department of Electrical Engineering, Stanford, University, Stanford, Calif.[b]

John G. Linvill, Sc. D., Gregory L. Goodrich, Ph. D., Martin Morf, Ph. D., John Gill, Ph. D., and Gregory A. Fowler, M.S.E.E.

Summary of research activities for the period January 1, 1980 through June 30, 1980.

With only a few exceptions, communication and information processing techniques for the visually impaired (and particularly for the totally blind) have shown little improvement since the invention of Braille over one hundred years ago. One of the most noted exceptions, the Library of Congress Talking Book Program, serves thousands of people each year, but this is a one-way communication system and for that reason leaves much to be desired. The development of the Optacon and Stereotoner were milestones, since they allowed direct access to print and written material. Their limits were relatively low reading speeds even after extensive training and practice, so that many people have been reluctant to begin using these aids.

Recently two converging trends have produced an environment in which better communication can be offered the visually impaired. The first trend has been the increasing dependency of the sighted population upon computers as communication and information media. The second trend has been the increased ability to utilize computer signals to generate outputs in Braille, spelled-speech, and full synthetic-speech.

These converging trends have resulted in the development of computer-assisted sensory aids designed specifically for the visually impaired. Existing computer aids are relatively expensive single-purpose devices functioning as reading machines, terminals or information systems. Despite these limitations, their value as rehabilitation tools have become obvious.

The present project is designed to apply state-of-the-art computer technology and human factors design to the development of a personal information system for the visually impaired. The system will provide easy and efficient writing and retrieving of information related to three primary areas: (i) education and in-class work, (ii) office or job-related work, and (iii) personal documentation. In addition to writing and retrieving, the system will provide information processing capacities to allow entering, oranizing, modifying, and documenting to be done by the blind.

The system envisioned will consist of two units: a portable record/playback unit and a non-portable main processor. Several possible outputs for the system are being considered, including dynamic Braille, synthetic speech, and print. Braille and conventional keyboards

[a]Dr. Goodrich is Research Psychologist, Western Blind Rehabilitation Center.
[b]Dr. Linvill is Professor and Chairman, Dept. of Electrical Engineering, Stanford University.

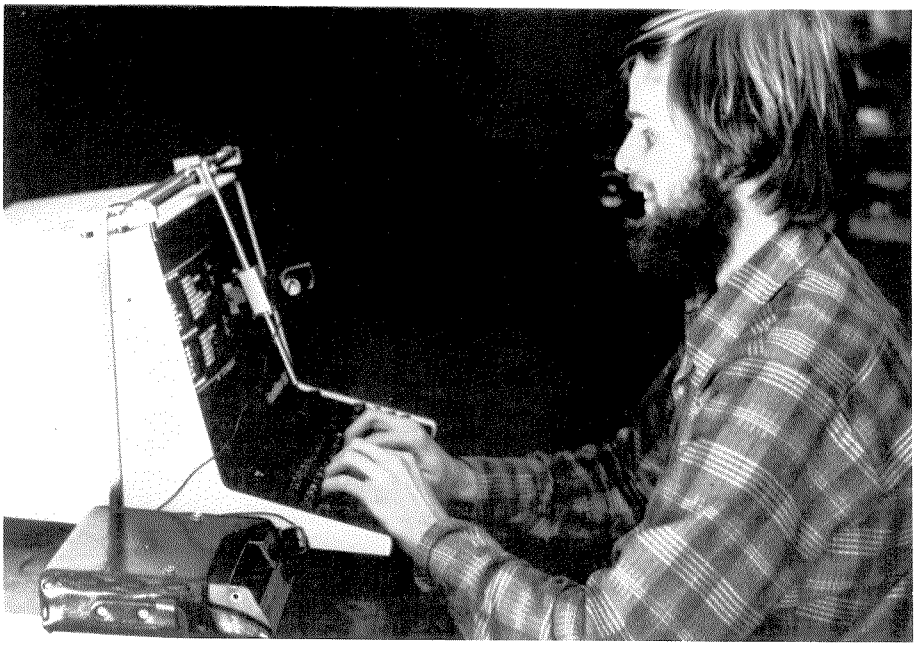


FIGURE 1.
Greg Fowler entering data into the computer system. The terminal is a Hazeltine 1500. Note the Optacon in its case lying on the table to the left of the terminal, and the Optacon camera which is held in place against the CRT by the tracking-aid device.

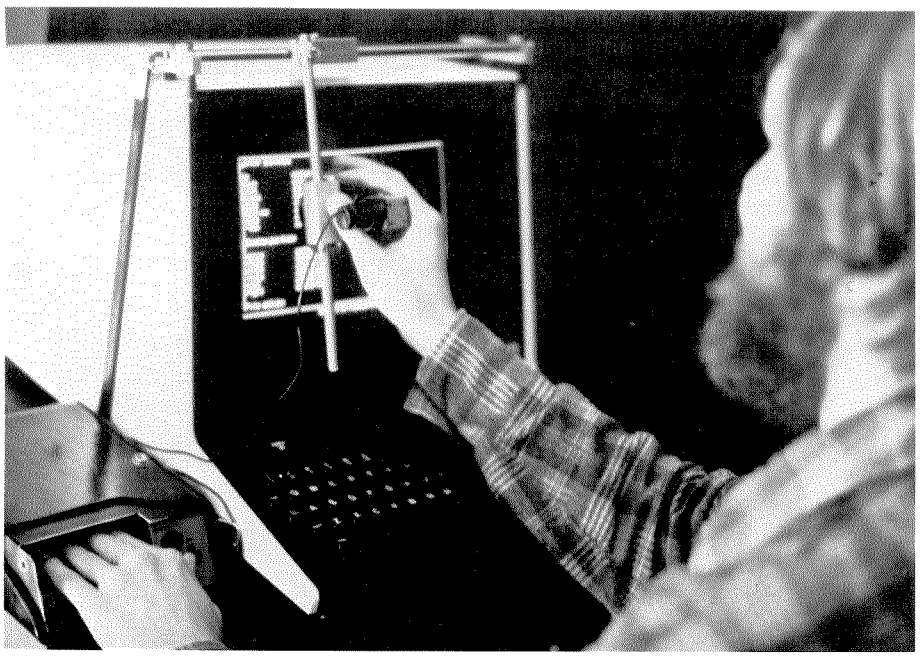


FIGURE 2.
Greg Fowler reading information from the CRT display: his left hand rests with fingers on the active Braille readout, while with his right hand he scans material displayed on the CRT, using the Optacon camera.

are being considered as input modes. A key concept in the design process is allowing for possible combinations of outputs to optimize user choice and control of the system.

The project is currently in the first year of its planned three-stage schedule. The first stage is a simulation of the system using a PDP 11/34 computer. The system can be accessed remotely from diverse locations including the Western Blind Rehabilitation Center, a feature that will avoid costly duplication of equipment while maximizing the evaluation environment.

The second phase of the project is the implementation of experimental systems and their testing at the Western Blind Rehabilitation Center. The systems will be developed at Stanford University where they will have received pre-testing and development input from one of the investigators (G.F.) who is himself blind (Fig. 1 and 2). The third phase of the project will be the application of the experimental results from preceding stages to develop an information system which can meet the needs of the blind user population.

Work to date includes making the PDP 11/34 system accessible to a blind user, both at Stanford and remotely. Access to the system has primarily been through an Optacon using a commercially available Optacon camera and, for a limited time period, using a Votrax voice-output unit. A Telesensory Systems Versabraille® is also being evaluated—but not with the PDP 11/34, since the Versabraille® has not yet been fitted with an ASCII-to-Braille converter.

Remote access to the PDP 11/34 is currently via telephone lines from Mr. Fowler's home to Stanford. The system, even in its current primitive configuration, works well allowing for the preparation of memoranda, reports, class papers, and general information filing. In the coming months, the remote capabilities of the system will be expanded when equipment at the Western Blind Rehabilitation Center is brought on-

line. This will allow for easy communication and development work between sighted and visually impaired investigators, even when it is not physically possible to meet.

Two main classes of software problems have been identified. First, it has been found that elements of the user interface must be especially adapted to the requirements of the visually impaired user. Second, though not specific to a visually impaired user, it has been found that standard multiprocessing operating systems (e.g. UNIX) can be used as a foundation for the personal information system. Modifications can be expected to take into account the design of the system, but the operating systems will be an adequate starting point.

It may become desirable to be able to interface the personal information system with other computer-based devices. Since this enters an area of complex standards, formats and connectors, a meeting was conducted at the Western Blind Rehabilitation Center in February 1980 to document possible requirements for the system. The results of this meeting are documented elsewhere in this issue (see "Standards for Computer Sensory Aids for the Handicapped" in the Standards Section, which is a new department, in this issue of BPR.

The schedule for the remainder of this year includes comparison of existing computer aids, implementing of a document preparation and retrieval system, development of a microcomputer system with specialized I/O capacity, investigation of methods of maintaining reliable file systems, and upgrading of the current microcomputer interface system. Also, during the remainder of the year, evaluation protocols will be developed.

Clinical Application Study of Mobility Aids for the Blind

Central Rehabilitation Section for Visually Impaired and Blinded Veterans
VA Medical Center
Hines, Illinois 60141

John D. Malamazian and Leicester W. Farmer

During this reporting period of Jan. 1–June 30, 1980, five veterans participated in the electronic travel aids (ETAs) program for blinded veterans at the Hines VA Blind Rehabilitation Center. One veteran admitted for training with the Sonicguide program and another one admitted for participation in the Laser Cane program did not complete their training courses. One veteran completed the Laser Cane course and was issued a cane, and a veteran who is a bilateral above-knee amputee was issued a Lindsay Russell Pathsounder to enable him to achieve mobility in his wheelchair. The fifth veteran is currently receiving training with the Laser Cane.

Mr. Nazir Ali, president of Nurion, Inc., manufacturer of the N–6 Laser Cane, visited the Hines Blind Center to introduce and demonstrate an ETA which can be mounted on a wheelchair to detect "down" stairs: the aid is called the Step Sensing Device (SSD). This device will be evaluated by Mr. Leicester W. Farmer and the Orientation and Mobility Specialists at Hines, after which it will be returned to Nurion, Inc., to be evaluated by other agencies and individuals.

The long-awaited orientation and mobility textbook, *"Foundations of Orientation and Mobility,"* published by the American Foundation for the Blind, became available to the public in March, 1980. Mr. Farmer is one of some 22 authors who have contributed a wide range of subject matter to the textbook. This is the first textbook in the area of orientation and mobility, and it should prove to be a valuable resource for all persons involved in consumerism, study or work in blind rehabilitation and orientation and mobility. Mr. Farmer's contribution to the textbook is in Chapter 11, "Mobility Devices".

On March 28, 1980, Mr. Ben Seltzman, manager of The American Foundation for the Blind's Model Shop, visited at Hines and with the research personnel at the Blind Center. He informed the staff about work being done in the Model Shop, and gained some insight into the activities of the Hines research personnel. Some discussion was devoted to mutual problems and concerns about product modification and quality control.

Mr. Hershon Goldman and his wife, Phylis, visited Mr. Farmer at Hines April 4, 1980 to gain some knowledge of the ETAs program and to get information about the travel aids, sensory systems and light probes. Mr. Goldman is a Social Worker with the Jewish Institute for the Blind in Jerusalem, Israel.

Messrs. Farmer and Leonard Mowinski exhibited electronic reading machines and travel aids at the Museum of Science and Industry in Chicago, Illinois on May 4, 1980. The program was sponsored by the Chicago Council for Exceptional Children and the exhibits were part of the activities held for Exceptional Children's Week which Chicago proclaimed from May 1 through May 7, 1980. The program helped to expose the lay public to some of the adaptive equipment that is or could be utilized by handicapped children. The exhibits highlighted the role of technology in educating the exceptional child.

On June 10, 1980, Dr. M. Rifal Saglam, chairman of the Computer Science Department at Bogazici Universitesi in Istanbul, Turkey, visited with the research personnel at the Blind Center. Among the many topics discussed was the part that ETAs can play in overcoming some of the problems of architectural barriers, and some of the factors involved in environmental modifications. Dr. Saglam is an architect as well as a computer scientist, so he

was able to speak with some insight and appreciation of the problems associated with architectural barriers. Mr. Farmer pointed out the continuing role that ETAs can play while our society is still a long way from having a barrier-free environment.

A followup study of the Binaural Sensory Aid (BSA) Sonicguide ETA program since its inception in 1971 was completed during this reporting period. This study parallels a similar study of the Laser Cane Program which was reported earlier (BPR 10-32, Fall 1979, p. 423). The followup was conducted by telephone and all current Sonicguide users were contacted. The results of the Sonicguide study follow—

The BSA/Sonicguide Program since its Inception in 1971

1. 39 candidates have been accepted for training with the BSA/Sonicguide since the program began in May 1971.
2. One veteran did not qualify for participation in the program because of poor cane and travel skills.
3. One veteran decided against participation in the Sonicguide program after having been accepted but chose to take a 6-week refresher course in the basic orientation and mobility (O/M) program.
4. Four veterans did not complete the BSA/Sonicguide program after having started it.
5. 33 individuals have completed the BSA/Sonicguide training course and were issued the travel aids.
6. 10 persons have returned their BSA/Sonicguide travel aids.
7. One veteran lost his Sonicguide when a fire destroyed his home.
8. 22 persons have retained their Sonicguides.
9. The youngest person to be admitted to the program was 22 years of age.
10. The oldest person to be admitted to the program was 66 years of age.
11. The mean age of all persons accepted for the BSA/Sonicguide program was 40 years.
12. The mean age of the 22 persons who currently have Sonicguides is 45 years.
13. Five (22.7 percent) of the current Sonicguide owners use their ETAs on a daily basis.
14. Seven others (31.8 percent) of the Sonicguide owners use their travel aides at least three times a week.
15. Five others (22.7 percent) of the Sonicguide users employ the devices at least one time per week.
16. Five others (22.727%) of the Sonicguide owners use the ETAs occasionally.
17. Thus 17 (77.3 percent) of the 22 Sonicguide owners use their travel aids at least one time per week.

The results of the ETA follow-up study indicates that lifestyles and the opportunity to travel play an important part in the frequency with which certain travelers use their ETAs. Some of the veterans live in rural or remote areas that demand the use of some form of transportation whenever they leave their homes. Some among these users who employ their devices "at least one time per week" and "occasionally," often take their Sonicguides with them when they leave home and would use them more frequently if independent travel opportunities presented themselves. Many of the "occasional" Sonicguide users take their travel aids with them when they anticipate being in unfamiliar environments, when they go to conventions, or if they go shopping with family members or friends and know that they will have the opportunity to spend some time traveling independently.

It is important to note that not one of the 22 Sonicguide owners said that he never used his travel aid; they all used the Sonicguide at least on occasions and did not just put it away in a closest and forget about it. This special area of ETAs is the subject of arguments about the importance or utility of electronic travel aids. This study indicates (as did the review of the Laser Cane program earlier) that when the ultimate question about device usage is asked and the results weighed, the conclusion is that the ETAs are used on a regular basis by a statistically significant number of travelers who have successfully undergone ETA training.

Clinical Trials of Reading Machines for the Blind

Central Rehabilitation Section for Visually Impaired and Blinded Veterans
VA Medical Center
Hines, Illinois 60141

John D. Malamazian, Harvey L. Lauer, and Leonard Mowinski

Communication aids research at the Central Blind Rehabilitation Center is conducted by Harvey Lauer and Leonard Mowinski. Most of the work is clinically-oriented evaluation research.

Evaluation of the Model III desktop Kurzweil Reading Machine continued with the instruction of several veterans and a BRC staff member in its use. Recent updates of the machine's computer program provide suitably intelligible speech, improved accuracy in recognizing typewritten characters, and the implementation of the system as a "talking computer terminal." Though the latter feature lacks editing and "echo" features, it was found suitable for some applications. A talking scientific calculator program for the KRM was also tried and found to be functional.

It is believed that further improvements in handling page formats and in optical character recognition are needed before issuance of the KRM can be recommended for selected veterans.

In June, Mr. Lauer attended the International Conference on Rehabilitation Engineering in Toronto, Canada, where he conferred with developers and researchers and worked with the prototype of the Kurzweil Talking Terminal. The ex-

perimental model proved very functional in communicating with several distant computers. Several other talking and Braille terminals are also appearing in prototype and early production models which warrant evaluation.

Several computers and terminals are being interfaced in the research department to write specifications and evaluate Braille and speech-output terminals. Such instruments are needed by blind professional and clerical workers in environments where video and print terminals are commonly used. Three newly-blind trainees in the BRC had been computer professionals and are contemplating reemployment: by working with these terminals and the Kurzweil machine, they gave valuable input to the department, and at the same time they were able to obtain experience which will be useful in their projected occupations.

The project to examine and improve the audible direct-translation reading code proceeded with the building of the second and third prototypes by Bernard Vecerek of Illinois Institute of Technology. Final details of the design have been established; three more machines are planned. These instruments interface with the Optacon tactile reading aid to provide a bimodal display (touch and hearing). A choice of four tonal codes enables the testing of the value of additional tones in the display, as well as testing the value of a bimodal display. The bimodal display is found to be preferred by reading aid users who have tried it, as well as by Optacon students in the blind center.

Jeff Moyer of Telesensory Systems, Inc. (TSI), spent a day with Mr. Lauer to confer regarding several projects. TSI manufactures the Optacon and is under government contract to build a computerized "talking" version. One of the ITT tonal-code prototypes was loaned to TSI for consideration of the bimodal display as part of the talking Optacon.

The manufacturer of the Kurzweil machine, KCP, is also interested in this project because they need an optimally-intelligible audible code for their hand-scanning option, being designed. Both companies were loaned a Colineator tracking aid designed under a former VA contract by Mauch Laboratories. A modified version of that will be used in the computerized Optacon.

A speech-compression (pitch-correcting) module is being evaluated in cooperation with the Prosthetics Center of New York. Made by the Variable Speech Control Company, it is the LOC 1 module for use with Library of Congress talking book players. Early results are positive.

Electrical engineer Aaron Bauch of the American Foundation for the Blind visited the research department to confer and to demonstrate new designs, including a speech-output glucose analyzer, a talking thermometer, and a talking currency identifier.

Deltak, a producer of educational videotaped courses, taped the work of this research department for inclusion in a course on the effect of computer technology on labor (including the handicapped).

A series of four articles on communication aids for the blind by Lauer and Mowinski was published in the January, February, March and May issues of The Braille Forum. Its publisher is the American Council of the Blind. Updated copies of these articles and other reports are routinely shared with guests and as responses to numerous inquiries of the department.

Clinical Application Study of Reading and Mobility Aids for the Blind

Western Blind Rehabilitation Center
VA Medical Center
3801 Miranda Avenue
Palo Alto, California 94304

Joseph J. Hennessey, Gregory L. Goodrich, Ph. D., Richard R. Bennett, and Diane L. Morrissette

Kurzweil Reading Machine Evaluation—During the period Jan. 1 through June 30, 1980, the Center's evaluation of the KRM 3 continued. Several significant improvements in the KRM's operation were made by Kurzweil Computer Products through implementation of software changes. In January the V–1919 program arrived. This program offers improved "report" and "read item" commands, and a "black mask mode" which improves the KRM's ability to read tabular material. The V–1919 program offers the user greater flexibility to control the characteristics of the synthetic voice by using special command sequences. A further refinement contained in this program is the inclusion of a "typed text" or "printed text" mode key, which allows the user to "tell" the machine whether the material to be read is typed or printed. This information, because it describes letter spacing (e.g. set or proportional spacing) allows greater OCR accuracy from the KRM than was possible with previous programs.

The improved OCR accuracy is important, because the two major limitations of the KRM have been its marginal OCR accuracy (particularly with less-than-ideal print) and the difficulty, for the user, in coping with complex (e.g., multicolumn) page formats. If the KRM's ability to handle multicolumn pages, pictures, and graphics can be improved without adversely affecting OCR accuracy, it will warrant a complete field evaluation of the reading machine.

Two other software improvements were made. The first was the

issuance of the calculator software for the KRM. While this tape increases the versatility of the KRM, the program contained several "bugs" which were detailed and referred to Kurzweil Computer Products for correction. The second was the delivery of the V–2004 program which added the Speech Output System (SOS) to the V–1919 program. The SOS allows the user to send and receive ASCII characters without having to load a separate software program. In addition to making the read and SOS functions easier, the V–2004 also allows the KRM to function as a voice output for a computer, decreases the difficulty in evaluating OCR accuracy, and enables deaf-blind individuals to read with the KRM. The later capability uses the ASCII character string generated when the scanner reads a page to drive a refreshable Braille device (e.g., the Elinfa Digicassette).

A few mechanical problems have occurred with the KRM 3. Two repair visits were required, with both necessitated by damage to a cable connecting the scanner and computer units. The WBRC's KRM 3 was mounted on a steel cart to increase its portability; the cart has a 3-inch lip which created a slight bend in the cables when attached to the scanner. In time, this resulted in damage to the cable and it required replacement. The same cable was later damaged following a demonstration of the KRM by Kurzweil Computer Products personnel at a Blinded Veterans Association meeting in Fresno. In addition to being damaged relatively easily, the cables are difficult to install by a blind individual. It is hoped that consideration will be given to replacing the current system of cables with cables which are easier to install and less susceptible to damage.

In-service training of all communications staff has continued during the current reporting period, as have demonstrations of the KRM and other computer devices to veterans, families, and visitors to the WBRC.

Computer Assisted Sensory Aids

A key question to be resolved in applying computer technology to the benefit of handicapped populations will be the determination of standards for these aids. The standards needing consideration range from the size and shape of the physical connectors, to data-transmission rates and storage format of the device. This subject is not unique to sensory aid research, and it has been a major concern for the computer industry as a whole for many years. While a simple answer to this question is unlikely, a clear understanding of the factors involved may lead to less confusion in the application of computer technology. To this end, a meeting was held at the WBRC to determine the factors needing consideration and to begin the process of recommending an approach to this problem (see "Consideration of Standards for Computer Sensory Aids for the Handicapped," in the Standards Section, which is a new department, in this issue of BPR.)

The WBRC's research effort has also been actively engaged in linking a variety of computers and computer-based aids to document applications. To date these activities have included linking a Tektronix 4051 Graphics System, the Elinfa Digicassette, the KRM (Models 2 & 3) and a variety of printers and peripheral devices. Most recently the use of telephone modems has been employed to demonstrate the capacity for computer aids to interact remotely via telephone connections. This has been done with researchers at the Central Blind Rehabilitation Center and remote computer systems.

The major limitations encountered have been in the area of human factors design of the computers and computer sensory aids when used by the visually impaired. Examples of these limitations include: the use of lights to signal a "ready" state in modems, the need to dismantle parts of the Elinfa Digicassette and KRM to change baud rate and parity, and the need to use numerous control consoles when interfacing various aids.

From this work, several conclusions seem warranted:

First, developers of computer-based aids should ensure that settings such as baud rate, parity, and start and stop bit settings are externally controllable. It may be advantageous to have this control directly from keyboard commands, rather than employing special-purpose knobs or switches (e.g., as is done on some commercial terminals such as the DEC VT–100).

Second, the development of new devices does not warrant the development of special-purpose keyboards: where possible, conventional terminal keyboards should be employed to minimize the need for users to learn special button and key configurations and uses. Ideally, a set of keyboard mnemonic commands could be developed so that a user learning the control of one device could generalize that knowledge (with minor modification) to other devices.

And third, it appears that, to fill the needs of many handicapped individuals, current technological trends will dictate that they have a variety of relatively expensive aids. This results from the development of single-purpose devices (e.g., one for reading, one to function as a terminal, and one to provide data storage and editing and, perhaps, others to provide a choice between output modes). This trend does not seem to be economically sound, and perhaps greater attention should be given to developing multi-purpose devices. Some progress exists along this line, but a greater effort needs to be made. The examples of multiple-use devices include the KRM's ability to function as a voice output for a terminal and as a reading machine, and the Elinfa Digicassette's ability both to control a computer remotely and to provide a refreshable Braille display of the computer's output. Those examples are currently "steps in the right direction", but insufficient to be widely accepted by even a moder-

ately sophisticated user population.

It will be claimed that more versatile devices mean more expensive units, and possible delays in bringing this more complex technology to commercial production. But the idea and the goal should certainly be kept in view.

Elinfa Digicassette Evaluation—Work with the Elinfa Digicassette continued, primarily by testing its ability to interface with other devices. In some respects (e.g., as an alternative output mode for the KRM) it functions satisfactorily; however, this early model does not contain the more sophisticated data storage, retrieval, and editing features of later models. Recently the built-in battery charger appears to be malfunctioning since the rechargeable batteries are not given a full charge, resulting in the frequent inability to accept and store data or, alternatively, to transmit data to other devices (e.g., computer-printer). Replacement of batteries does not remedy the problem, so the Digicassette will be returned for repair.

Night Vision Aid and Wide Angle Mobility Light Evaluation—The Night Vision Aid is a hand-held monocular aid devised to assist night-blind individuals when traveling in scotopic environments. It utilizes a light amplification system and provides a 40-deg field of view. The Wide Angle Mobility Light (WAML) is a modified scuba diving light, designed to provide sufficient illumination for travel by night-blind individuals.

The WBRC is coordinating a cooperative evaluation of these two devices with the Veterans Administration's Blind Rehabilitation Centers at West Haven, Connecticut, and Hines, Illinois. The primary goal of the evaluation is to determine the effectiveness of the devices in reducing the night travel problems of veterans with night blindness. The method employs performance measures (e.g., contact with objects in the environment and time to complete travel of the route) of veterans negotiating a prescribed route. Twenty-four subjects from each of the three Centers will be used in the evaluation. Currently, the WBRC has completed measurements on both devices with nine subjects.

A major problem in this cooperative effort has been the development of comparable routes at the three different locations. The Eastern Blind Rehabilitation Center has located a route, but it appears that a suitable route near the Central Blind Rehabilitation Center does not exist. An alternative route will need to be developed. The data analysis from this project will be limited by the lack of equivalence between the three evaluation routes; however, because each will use a constant scoring method, some comparisons will be possible.

Mowat Sensor Study—The Mowat Sensor is a hand-held, electronic travel aid designed to provide tactile or auditory information regarding the user's travel path and objects in that path. The Mowat uses an ultrasonic beam to probe the environment, and it converts the reflected sound waves into signals of either the tactile or auditory modality.

A preliminary survey was conducted to ascertain the reliability of the Mowat, to determine specific applications, and to estimate the frequency of use by veterans who had been issued the device. The survey included 15 veterans who represent the entire population of veterans issued the Mowat through the three Blind Rehabilitation Centers. The veterans reported that the Mowat was useful, and all reported continuing to use the aid, although reported frequency of use varied among individuals. With normal use, none of the veterans reported malfunctions of the device since completion of training. (A complete report of this survey is in preparation.)

The relatively high useage rate of the Mowat (as estimated from the survey) contrasted markedly with previously reported useage rates for other electronic travel aids, and indicated that a larger, controlled study was warranted. A proposal for such a study has been submitted for review. It would employ control and experimental groups matched on a number of variables, including stated need to travel, age, living condition, and geographic areas traveled. Orientation and mobility training for the two groups would be identical except that only the experimental group will be trained with and issued a Mowat Sensor. Following discharge, telephone surveys will be made at 1, 3, 6, 9, and 12 months to survey frequency of travel, travel techniques, travel problems encountered, travel objectives and changes in travel patterns. In addition, the experimental group would be asked questions specific to their use of the Mowat. It is estimated the project would require 2 years to complete.

Eye Movements and Central Scotomas—In keeping with the WBRC's work in developing eccentric-fixation training programs for veterans with macular scotomas, the Center co$_{\text{r}}$ operated with Dr. Ian Bailey on a project to examine the eye movements of veterans with central field losses. In part, the study was designed to assess the efficacy of prescribing optical magnification above the amount needed to attain the individual's threshold for reading print. (The prescribing of greater-than-threshold magnification for patients with central scotomas is considered by many to be a means of improving reading ability.) The study used a spectacle-mounted eye monitoring system. Threshold print sizes were determined for each subject and each veteran was then asked to read aloud from reading cards of varying print size. The results of the study indicate that patients with macular field losses make many more saccadic eye movements than normally sighted individuals. The reading pattern was fairly constant across all 11 subjects. Increasing print size did not result in improved reading speeds. This result indicates increased magnification (beyond threshold level) may not have a beneficial impact on patients with central scotomas. Some caution in applying this result must be exercised, since the sample population

was not sufficient to control all variables which might have influenced the results: for example, size and shape of the central scotoma could not be controlled.

Low Vision Diagnostic Tests—As described in the WBRC's research report in the Fall 1979 Bulletin of Prosthetics Research, a preliminary study of the Frostig Figure-Ground Test indicated that it might have validity as a predictor of reading performance for veterans with low vision. The test consists of two pages of four figures each. Each figure consists of a geometric pattern(s) embedded in a randomly drawn background. The test can be easily administered and requires between half an hour and two hours to complete. Preliminary results indicated that the test yielded a higher correlation with reading performance than conventional measures (e.g., visual acuity).

A data collection form has been developed and data are being collected. The analysis of the data is scheduled to begin in August 1980.

NOTE: Some sensory-aid material will be found in the following report.

Rehabilitative Engineering Support for the Atlanta (Ga.) VA Medical Center

Georgia Institute of Technology (Georgia Tech)
Office of Interdisciplinary Programs, 225 North Ave. N.W.
Atlanta, Georgia 30332

Gary W. Kelly

Prototype Wheelchair Wheel with Integral Anti-Rollback Capability. (Gary W. Kelly, Research Scientist, and Kenneth S. Morgan, Graduate Research Assistant.)

The goal of this project is to develop a wheelchair wheel with an integral anti-rollback device, which can be substituted for existing wheels without requiring any modifications or additions to the wheelchair frame. The device is intended to aid people who are confined to manual wheelchairs to climb ramps, hills, or other inclines without fear of rolling backwards.

The design of this wheel (two prototypes will be built later this year) has evolved, over the last 6 months, from a rather conventional looking wheel with a hub-mounted clutch unit to a device that more closely resembles a rolling-element bearing.

The centrally located hub/bearing unit and wire spokes have been replaced by a circular track supported by the struts and a mounting bracket that utilizes the existing axle, bolt, and mounting hole in the wheelchair frame. The tire itself will be fitted to a machined rim that will also support three interior-mounted roller modules spaced at 120-deg intervals, which will in turn ride on the outside of the circular track.

These roller modules contain the key elements of the anti-rollback device. Each V-groove roller (which rides on the track) contains a small roller-clutch/bearing unit that rides on a bearing-supported axle mounted to the module housing. The axle also has several regularly spaced radial holes at one end, to accept the tip of a spring-loaded plunger which is mounted to the side of the module housing.

In operation, the tire/rim assembly will rotate freely on the track when moving forward, and will lock if rotated backward. Locking is accomplished by having the roller-clutch lock on the shaft and locking the shaft with the plunger. Should the wheelchair user want to roll backward, the plungers on all three modules may be disengaged simply by pulling back on the pushring, which retracts the plungers through a simple linkage. When the pushring is released, the plungers are automatically re-engaged by spring action.

The advantage of this system (compared to anti-rollback devices currently on the market) is that this device is completely controlled by moving the pushrings forward or backward. Existing devices require the wheelchair user to remove his/her hand from the pushring to manually engage or disengage the device, thereby risking a temporary loss of control of the wheelchair. This new device will also permit the wheelchair user to execute normal turns (by moving wheels in opposite directions) when climbing narrow ramps and inclines.

It is expected that future work using this wheel configuration will result in a wheel with integral anti-rollback and a braking system, as well as the possibility of developing a family of wheels with various degrees of mechanical force reduction. This last concept should be particularly useful to those wheelchair users that have some use of their arms but not enough for a standard manual wheelchair, and require powered wheelchairs as a result.

Advanced Concept Design of a High-Performance Indoor-Outdoor Vehicle for the Physically Handicapped. (Gary W. Kelly, Research Scientist, and Kenneth S. Morgan, Graduate Research Assistant.)

The initial phases of this program have been devoted to studying the current state of the art of powered wheelchair design, and an attempt to gather as much information as possible about wheelchair users, their wheelchairs, and the ways they use them. To this end, an in-depth survey of powered wheelchair users in the Metropolitan Atlanta area is being conducted. The results of that survey will provide a detailed account of what powered wheelchair users like and don't like about their wheelchairs, and what changes and trends they would like to see implemented. The investigators will then attempt to incorporate some of those ideas in a vehicle design of their own.

The design study began with an examination of several generally available powered wheelchairs, as well as some prototype models from U.C. Berkeley's Biomechanics Lab, and two extremely sophisticated production models from Permobile of Sweden. The investigators have also been investigating the feasibility of fully and partially tracked vehicles as well as more conventional three-wheel and four-wheel configurations using either front or rear drive wheels.

Sonic Orientation and Navigation Aid. (G. W. Kelly, Research Scientist, and R.

D. Atkins, Research Engineer.)

Background—The sonic orientation and navigation aid (Sona) is believed to be a new concept in mobility and orientation of the blind. Over the past 20 years there have been several notable attempts to develop electronic mobility aids. The present device does not pretend to be a mobility aid but is intended to be an orientation aid. The transmitter is meant to be carried by the blind user, and the receivers (transponders) are mounted at key places in the environment such as restrooms, entrances, emergency exits, elevator call buttons, and similar important landmarks.

The user enters a code for that location, such as 911 for an emergency exit. The transponder upon recognizing this digital code replies with an audible sound. The traveler may now orient with respect to the sound and use a cane or dog to progress to the exit in a normal manner.

The device is based on existing garage-door-opening devices with a transmitter modified to allow input through a "touch-tone" keypad. The transmitter is approximately the size of a package of cigarettes, and is battery powered. The receivers are permanently mounted and can be run at low cost from exisitng 110-volt electrical supplies.

Hardware—The transmitters and receivers are identical to those used in garage door equipment. Several devices have been purchased and tested for range, coding, power requirements, and reliability. They are highly satisfactory, with ranges of 75 feet (nominally) and as much as 150 feet. Signals do not penetrate between floors in buildings where this has been tested. No antenna is required on the transmitter. The circuits are CMOS low-power circuits and as many as 512 addressable codes are available. This is more than enough for our purposes. We are now developing a variety of tone output circuits from an available synthesizer chip to improve tonal variety which will provide feedback to the user that he is getting a correct response for his entered code. (An example would be a bass note for the men's room and a higher note for the ladies room.)

Software—Fortunately, no software is required. The modification of the transmitter to accept entry from a keypad rather than the setting of switches is entirely a hardware modification.

The transponders require only a voltage and a circuit to turn on or off: there is no electric motor.

Future Research—It is anticipated that several transmitters and as many as 40 transponders will be operational this fall. Initial tests of the utility and reliability of this system will be conducted. It is hoped future tests will be encouraged at other facilities and research conducted into improved packaging. The present projected costs are about $25 (transmitter) and $30 (transponder) for modified units. Units constructed for this purpose should be lower in cost in the larger quantities.

Future research will be based on broader applications for the device, such as voice output from the transponder for utilization in bus systems (the bus could answer the transmitted signal with its destination). Applications in elevator control systems to avoid panel modification to serve those confined to wheelchairs will be explored. The system would allow entry of floor choice by a portable panel. When used by the blind the elevator could signal the proper floor upon arrival when the request for that destination had been received from a blind person's transmitter and not the usual push button panel.

Electronic Typewriter for the Visually Impaired. (G. W. Kelly, Research Scientist, and L. J. Moriarty, Research Engineer)

Background—There are now three different manufacturers of cassette braille machines for the blind, but there is not yet a machine that reproduces large print for visually impaired persons with usable vision.

The present project is to develop a device suitable for use by persons who would normally use large print. Many of these persons now use CCTV systems with limited success and no portability; they are confined to doing their reading in one place and may encounter difficulty in using CCTV for any serious long-term reading. Too many of these persons are forced to rely on recorded materials which have the same limitations for them as the totally blind person.

The electronic typewriter of this project is analagous to cassette braille machines except that the entry method is a normal typewriter keyboard. Material is stored electronically in the machine, and when the memory unit is filled the information is stored on a standard cassette. That material may be recovered at a later time and displayed on the one-line, 40-character, self-scan display. The characters are .2 inches high or approximately the size of 20-point type. The characters fill the screen from right to left and continue scrolling across at a rate determined by the user.

An optional CCTV output is provided to allow coupling to a television monitor such as those used on CCTV's. The format would be 40 characters, 24 lines.

Hardware—The prototype being assembled will consist of a Keytronics keyboard, an American Printing House modified 4-track monaural cassette recorder, a Digital Electronics Corp. vacuum fluorescent display, and an RCA 1902 microprocessor. The device will have 8K bytes of memory for storage of information and a battery pack capable of providing an operation time of 4 hours before charging.

The electronic typewriter is designed to be the size of an attache case and weigh about 10 pounds; this could be even smaller with production packaging.

The device is equipped with RS232C interface for use with a computer or a printer. An additional output will allow interface to a video monitor.

Software—Software consists of programming that allows the device to operate with many of the same functions as cassette braille machines. Additionally, of course, it must control the self-scan display.

The software and hardware does allow the cassette unit to be used independently as a cassette recorder. The American Printing House unit was chosen because it was felt that the consumer would be familiar with the unit.

Future Research—The unit is ex-

pected to be completed this Fall. Short-term evaluation and testing will follow. It is hoped that funding will be available for an in-depth evaluation and the development of improved units.

Additional features that should be added in later models are: a calculator, speech compressor, and BCD inputs for other digital devices. Investigations into multi-line displays, improved software, and better packaging would carry the device closer to a production model.

Research on Micro-Computer/Computer Terminal Character-Tone Output for the Blind. (G. W. Kelly, Research Scientist and D. A. Ross, Graduate Research Assistant.)

An application of character recognition through the use of audible tones was involved in the creation and sale of the Stereotoner a number of years ago. The use of this idea seems to have been all-but-forgotten over the years, but it appears as if it could be a potential inexpensive solution to the problem of "displaying" computer output to the blind.

The purpose of the present research is to develop tone-generating software for a low-cost microcomputer capable of acting as a computer terminal for such a device.

Hardward Choices—A number of microcomputers were looked at in terms of flexibility, ease of software development and support, and cost. The Apple II was found to be very flexible in terms of both hardware adaptability and software development. Also, the entire system needed for the above project costs less than $2500.

The system purchased was an Apple II with 48K of random access memory and a 5-inch floppy disk drive. An Alf music board capable of producing three simultaneous tones was also purchased. This board was designed by Alf Corp. to plug directly into one of the I/O ports on the Apple and produce tones within a six octave range when properly activated by the Apple II processor. The other items purchased were an RS232C interface and a DC Hayes modem, which enable the Apple II to be hooked by phone or cable to a main computer.

Software Development—The basic software whch has been developed assigns from one to three pitches to each of the possible 128 ASCII characters. Each letter of the alphabet is assigned a single discrete tone, and significant effort was made in the assignment of these tones to assure that they would be musically pleasing to the ear for a large number of commonly used letter and word combinations. Each of the other ASCII characters has been assigned a combination of two or three tones, which give them unique and easily recognized sounds.

In addition to the above basic software, the playback, list, and search software is also in its completion stages. This software will allow the user to get an "instant replay" of the information he has just received from the main computer. The played-back material may be listened to at any chosen speed, with speed selected by turning a game paddle potentiometer attached to the Apple II. The search feature will allow the user to find and list (with tone output) any part of his transaction with the main computer and the main computer's responses.

Future Developments—It is conceivable that this software could become the basis of a new "musical language" for the blind. The software could be translated into simple hardware which would be independent of the Apple II. This hardware, then, could be interfaced to a number of possible electronic readouts such as digital voltmeters, digital clocks, etc.

It is also possible to use this new "language" to store and retrieve "talking books" directly from computer storage. Finally, in conjunction with a print recognition program, it could be used to directly translate the printed page into a "musical language" for the blind at an affordable cost.

Electronic Communicator for the Speech Impaired. (G. W. Kelly, Research Scientist, and J. Wallace, Electrical Engineer.)

Background—The purpose of the electronic communicator is to enable the speech-impaired person to manually key-in information to a device which will then display it for someone else. There are some devices of this general type on the market, but there are a number of problems with them. There are some that have voice output, but they are expensive and not very portable. There are less-expensive devices which are small and quite portable, but their alphabetic keyboard is small and awkward and may be impossible to use for the many speech-impaired persons who also have other physical impairments.

The communicator being designed in our current project is small, portable, low in cost, and has single-key entry. This single key allows even those who have only gross hand control to enter and display their messages. The only drawback is that the user must know Morse code, which requires some training, but the training of Morse code has over the years been reduced to a simple routine for anyone with the motivation to learn it. Also, the key used for entry is semi-automatic, making the entry of a dot or dash dependent only on the direction in which the key is pushed (either left, or right), rather than requiring fairly precise control of dwell-time.

Hardware Used—The device has basically three parts: a two-way key for entering the Morse code, a microprocessor which interprets the entered code and places the entered code on the display, scrolling the characters across the screen as they are entered and a 16-character alphanumeric display.

In addition to the above, there will be a small speaker in the device to provide audio feedback to the user. Also there will be switches allowing the user to select automatic repeat and speed control if the user has the dexterity to use it.

The micro-processor is an Intel 8748 which has its own programmable read-only memory on board. The device will operate for 4 to 6 hours from a pack of rechargeable nickel-cadmium batteries. The display has 16 half-inch LED characters.

Software—The software written for the processor updates the display every 80 microseconds, scrolling it as each character is decoded and adding the decoded character to the display. Between updates, it decodes the key en-

tries as the user enters them. It also looks for key closure and outputs a 1000-Hz tone while the key is closed. If the device is switched to the repeat mode, the software will automatically repeat whatever key entry the user has made until the key is released. For each repeat, the tone is also repeated. The repeat rate may be either fast or slow, depending on the setting of a "repeat rate" switch.

The software described above has been completely developed, but has not been tested on the actual hardware to be used. A primitive prototype has been assembled, using other hardware, and it functions properly.

Continued Development—The final prototype will be finished in the summer of 1980 and will be subject-tested beginning in late summer. There seem to be possibilities for continued development of the device for the manually impaired. The single key could replace keyboard entry on computer terminals, enabling easy use of those terminals by the manually impaired.

End of Sensory-Aid Section

Power Steering for the Mobility Engineering Van-Compatible Wheelchair

VA Medical Center
Sepulveda, Calif. 91343

Fred J. Weibell, Ph.D.

Mobility Engineering and Development, Inc.
Canoga Park, California 91306

Charles M. Scott, B.S.M.E., and Ronald E. Prior, Ph.D.[a]

Under a VA-sponsored project at VA Medical Center, Sepulveda, California, a local supporting contract will develop and test power-steering for a van-compatible wheelchair designed for the VA under a previous contract with Mobility Engineering and Development, Inc.

Power steering, if properly implemented, should improve the stability of powered wheelchairs in rough or hilly terrain. The objective of this project is to design, evaluate, and refine a system that will eventually make available to disabled veterans wheelchairs with selectable power or differential steering. The original wheelchair was designed to be compatible with the Scott Van, a specially equipped van for use by quadriplegics and others with limited motor function. As a result of this contract, three of the six van-compatible wheelchairs delivered to the VA under the previous contract will be equipped with power steering. Clinical tests will be performed as a separate project.

[a]C. M. Scott is president of Mobility Engineering and Develompent, Inc., and R. E. Prior is director of electronics and data processing for the firm.

Pressure Sores: Etiology and Prevention

VA Medical Center
3801 Miranda Avenue
Palo Alto, California 94304

Stanford University Medical Center, Stanford University
Stanford, California 94305

Lars M. Vistnes, M.D.[a]

Background—There is little if any dispute over the fact that pressure in excess of mean capillary pressure is one of the most significant factors in the causation of pressure sores.

A great deal of significant experimental work has been done in an attempt to delineate the relationship between the degree of pressure and tissue injury and the relationship between high and low pressures. Some of the earlier work on this problem was achieved by fairly crude instrumentation, and some by pure clinical intuition. More recent work has been more sophisticated, using modern electronic transducers. Until the present time, with the exception of two somewhat peripheral studies, all of those findings relate to pressure alone as measured under the bony prominence at skin level and with the subject at complete rest. This is an artificial situation since, on movement, tremendous forces, far in excess of those measured at rest, are generated, as in the case of the paraplegic patient moving himself into a wheelchair, shifting in bed, using an overhead trapeze, etc.

Nevertheless, sufficient evidence regarding the damaging effect of pressure has been accumulated to make medical and paramedical personnel aware of the need for frequent positional change. The standard nursing procedure of turning these patients every 2 hours is based on intuition rather than fact, and is more than often not followed due to lack of personnel. The attempt to distribute pressures from smaller to larger areas by various means, such as flotation, goes back to Paget who in 1851 described the first water bed. The efficacy of that device has been reported both clinically and scientifically. Similarly, the clinical application of other useful devices has been reported, as in the case of the "mud bed", camping mattresses filled with air and/or water, and various cushions made from or filled with different materials. The periodic relief of the effects of pressure by intermittent change of the pressure within the support was reported as early as 1948, when Gardner described his alternating pressure air mattress. Early technical problems resulted in this device failing to gain wide acceptance, although later modifications have been reported to be satisfactory from a clinical point of view.

In all of the above, only pressure at rest measured at skin level has been referred to with the exception of three articles that deal with deep pressure and other forces during movement. Clinical observations, both personal and coupled with that of others, combined with evidence from rubber mechanics, would indicate that there are two areas of maximum pressure; one under the bony prominence at the interface of skin and support device (as traditionally measured)—and another one deep in the tissue just at the bony prominence. This is partly substantiated in an earlier experiment by Husain, who observed deformation of foam rubber, but did not make any actual measurements. If that is the case, the amount of tissue between the skin and bony prominence becomes critical as it is known that tissue will

[a]Dr. Vistnes is Chief, Surgical Service, at the VA Medical Center, Palo Alto, and Associate Prof. of Surgery (Plastic and Reconstructive), at Stanford University Medical Center.

diffuse pressure. This has been recognized intuitively for a long time by clinical plastic surgeons, but not substantiated.

It is necessary, at this time, to establish these facts by actual scientific measurements in order to substantiate or refute the new trend in reconstructive surgery of closing pressure sores with large masses of tissue in the form of myocutaneous flaps.

Up to this point in the discussion, other causative etiological factors in the formation of pressure sores have been alluded to with the mention of *forces* and *movement.* These forces are the tremendous shearing forces which are generated in tissues by directional pressure, as when the patient in bed has his head or torso partly elevated thereby creating shearing in the sacral area, or gradually slips forward in a wheelchair, thereby creating shearing in the ischial area. A prototype wheelchair designed in 1976, using NASA technology, shows beyond a doubt that exceptional peaks of forces of this nature are generated both at rest and during activity. Such shear forces may cause deformation of tissue and thereby of blood vessels by extension, rotation, wrinkling or buckling.

As has been pointed out by Reswick and Rogers, there is a definite time relationship between pressures and tissue injury both microscopically and grossly. This relationship has been determined for pressure but not for shearing forces. Similarly, the question of the effect of repeated minor injury, not in itself sufficient to cause permanent damage, must be answered in the case of paraplegia. Allied information (from insensitive tissue due to denervation by leprosy) indicates that such repeated minor trauma will accumulate and eventually cause, first, tissue inflammation and later, breakdown.

Whereas it is both possible and practical to gather information as to pressure, shear forces, and their temporal relationship to tissue breakdown in the experimental animal (by both serial biopsy and actual observation) that method is not practical in man. In order to take effective preventive measures, early detection of tissue damage is essential. It is not enough to look for red spots on the skin indicating that the damage has taken place. Such red spots are evidence of inflammation, the healing of which is by scar—a tissue notoriously poorly equipped to deal with repeated stresses. On the other hand, an early sign of inflammation both in skin and muscle which can be detected is an increase in local temperature. Areas that have been subjected to repetitive stress may show temperatures 5 deg centigrade or more higher than similar unstressed areas, and differences in temperature of as little as one degree centigrade have been found to be significant. Thus, armed with proper data as to forces in time relationship, and a suitable microtransducer to detect temperature changes, a flexible pad can be constructed incorporating a series of these devices with a minicomputer to produce the feedback signal warning of impending tissue disaster. All this technology exists at the present time.

Methods

Short-term objectives consist of the development of a bench model simulating skin and soft tissue, with a metal or plastic device simulating a bony prominence capable of producing both pressure and lateral force (shear), and with incorporated miniaturized pressure and force transducers to produce, via hookup to mini-computers, a real picture of what happens three-dimensionally under given conditions. At a later date, this information will be transferred to the animal model, introducing temperature measurements and correlation with histological biopsy data. In the longer term, the data accumulated will be stored in minicomputers which, in combination with a pad incorporating the transducers used for detection of significant parameters, can be used as a feedback device in the cushion of a wheelchair or in a bed.

Concurrently in the small-animal model, the effects of pressure on other tissue (such as muscle now incorporated in myocutaneous flaps for pressure sore repair) will be studied. Using Kosiak's model, rats will be subjected to various degrees and times of pressure and the tissues thus subjected will be studied microscopically.

Goals

The final long-term objective of these studies is to create a device which can be used to (i) study problem cases (why breakdown occurs in the same area consistently). (ii) Study various cushion devices made, (iii) suggest improvement in seating devices, and (iv) incorporate these devices in wheelchairs of newly injured patients for their education and prevention of breakdown, as well as in old spinal injuries to prevent breakdown after surgery and (in the case of geriatric patients) to provide warning to nursing staff of impending disaster.

Progress through June 1980

To date, the study on pressure effects in the animal model have been completed. Using the rat as the experimental animal, it has been shown that there is differential sensitivity of skin and muscle to long-term and short-term pressure. Thus, the muscle incorporated in a myocutaneous flap is not equipped to tolerate long-term pressure, as is the skin. There is consistent evidence of tissue necrosis in the muscle underlying a pressure point when there is no histological evidence of the same breakdown in the overlying skin where the pressure was presumably greater. This work has been submitted and accepted for publication in the Journal of Plastic and Reconstructive Surgery (1).

Similarly, a wheelchair seat has been constructed on the principles of optical barography in conjunction with a hookup to a video tape recorder and a device translating light intensity to color ranges, each color range being associated with a given pressure range. With this device it has become possible for the first time to measure and record, on a permanent basis, the dynamic changes in pressures that occur and shift from place to place with the patient in motion. This work has been presented at the Annual Meeting of the American Association for Plastic Surgeons back in Scottsdale, Arizona, June 1980, and has been accepted for publication in the Journal of Plastic

and Reconstructive Surgery (2).

The bench model for the study of three-dimensional distribution of pressure and shearing is nearly completed. Reliable microtransducers have been created and tested for reliability and are in the process of being assembled in an array to minicomputers for sequential display and analysis of data.

References

1. Nola G and Vistnes LM: Differential Response of Skin and Muscle to Pressure. Plast & Reconst Surg (in press).
2. Springhorn ME, Vistnes LM, and Leifer LJ: The Use of Optical Barography for the Study of Some Aspects of Pressure Sore Etiology. Plast & Reconst Surg (in press).

Foreign Body Reaction in the Lung to Intravenously Injected Biomaterials

VA Medical Center
Gainesville, Florida 32602

Department of Pathology
School of Medicine
University of Florida
Gainesville, Florida 32611

C. Ian Hood, M.D., Ch.B., and Frederick J. Schoen, Ph.D., M.D.[a]

Work on this project from January 1, 1980 through June 30, 1980, has been aimed at defining a standard bead model (SBM) for the foreign body reaction in the mouse lung. This model is being used as a basis for studying the interaction between various foreign materials and host tissue, and for determining the effectiveness of anti-inflammatory drugs.

The beads used in this model (von Lichenberg, 1962; Kellermeyer and Warren, 1970) are divinyl benzene copolymer (Biobeads, SX-8) that range from 30 to 70 μm in diameter with a mean of 44 μm; 10,000 of the sterile beads (gas sterilized) are injected into the tail vein of female Swiss albino mice weighing approximately 30 g. The beads embolize to the lungs and lodge in the arterioles, apparently impairing neither cardiac nor pulmonary function. Figure 1 is a scanning electron micrograph of the copolymer beads, and Fig. 2 is a computer-derived histogram of the size distribution of the beads.

To establish the model, at least 6 mice were sacrificed at each time period of 5 min; 3, 6, 12, 24, 48, 72, 96 hr; 8 days, 6 weeks, and 96 days. The lungs were inflated by inserting a blunt needle into a small hole in the trachea and injecting 1 ml of a paraformaldehyde-glutaraldehyde fixative. The lungs were then removed from the chest, small samples taken for electron microscopy and the rest fixed overnight in 10% formaldehyde for preparation of paraffin sections which were stained with hematoxylin and eosin and observed by light microscopy. The earliest reaction, which was observable only with the electron microscope, occurred at 3 hrs. At this time, an initial attachment of a few polymorphonuclear leucocytes could be observed (Fig. 3) and the wall of the arteriole in which the bead lodged was still intact. The maximum reaction occurred at 48 hrs (Fig. 4) when a large granuloma had formed consisting of both polymorphonuclear and mononuclear leucocytes, and the blood vessel was obliterated. Following this, the granuloma decreased in size and by 8 days consisted entirely of mononuclear cells. Table I shows the average diameter of granulomas formed around the copolymer beads after each time period. Measurements were made with the light microscope using a Filar micrometer. A plot of the changes in volume of the granulomas with time is shown in Fig. 5 where the maximum volume is at 48 hrs.

Use of Standard Bead Model to measure effectiveness of anti-inflammatory drugs.

The Standard Bead Model was found to be a sensitive and quantitative tool for measuring the effects of various anti-inflammatory drugs including ellagic acid, polyanetholsulfonate (Liquoid), hydrocortisone acetate and bacterial levan which was prepared by culturing *Erwinia herbicola* in 5% sucrose in Trypticase Soy Broth and isolating the levan produced by the method of Davies et al., 1955.

Table II shows the relative effectiveness of these drugs in reducing the mean diameter of the granulomas formed at 48 hours. Ellagic acid re-

TABLE I

Mean diameter and volume of granulomas at each time period after intravenous injection of copolymer beads[a]

Time	Mean Diameter (μm)	Mean Lesion Volume (mm^3)
3 hr.	57 ± 10[b]	0.3×10^{-4}
6 hr.	58 ± 13	0.3×10^{-4}
12 hr.	72 ± 22	1.4×10^{-4}
24 hr.	97 ± 22	4.3×10^{-4}
48 hr.	143 ± 33	14.7×10^{-4}
8 d.	102 ± 27	4.7×10^{-4}
6 wk.	93 ± 23	4.4×10^{-4}
96 d.	84 ± 24	2.9×10^{-4}

[a]At least 100 granulomas were measured for each time interval.
[b]Standard Deviation

NOTE: This model is highly reproducible and the 48 hr. period at which the largest granuloma volume was observed is being used to measure the inflammatory response to other types of materials useful in surgically implanted biomedical devices, such as Bioglasses and polylactide beads which are being tested for delivery of drugs to specific sites in the body.

[a]Dr. Hood is Chief, Laboratory Service at VAMC, Gainesville, and Professor, Department of Pathology, University of Florida. Dr. Schoen is Resident, Department of Pathology, University of Florida

duced the mean diameter by only about 10 percent, but there was a great deal of variation in the size of the granulomas with a large standard deviation, indicating an inconsistent response. The other three drugs were more effective, with barely any inflammatory response after 48 hours following treatment with bacterial levan. By comparing the reduction in the volume of the granulomas, the effect of the anti-inflammatory agents is even more marked (Table II). An electron micrograph of a granuloma 48 hours after treatment with polyanetholsulfonate (Liquoid) is shown in Fig. 6 where only a few polymorphonuclear leucocytes are attached to the bead, comparable to the normal response after 3 hours.

Other studies in initial stages.

As part of the characterization of the Standard Bead Model, experiments have been initiated to isolate the granulomas at each time period, and to separate, identify, and quantitate the types of cells present in the granulomas using the method of Moore et al., 1977. This will enable us to have a quantitative measure of the cell types present at each period in granuloma formation, and to compare this with the types of cells present after treatment with anti-inflammatory drugs.

The initial studies that have been reported in this progress report were performed using a population of copolymer beads ranging from 30 to 75 microns as shown in Figure 2. There seemed to be a considerable amount of variation in granuloma size depending upon the diameter of the bead. To define the relationship of bead size to granuloma formation, the beads were sieved into 3 size populations: 30-to-45 microns; 45-to-53 microns; and 53-to-75 microns. Experiments underway indicate that beads 45 to 53 microns in diameter produce larger and more uniform granulomas than those from the mixed population. The smaller beads (30 to 45 microns) and the larger beads (53 to 75 microns) are now being tested for comparison.

Another type of bead that has been tested is a poly d, l-lactide bead designed for carrying drugs. The reaction

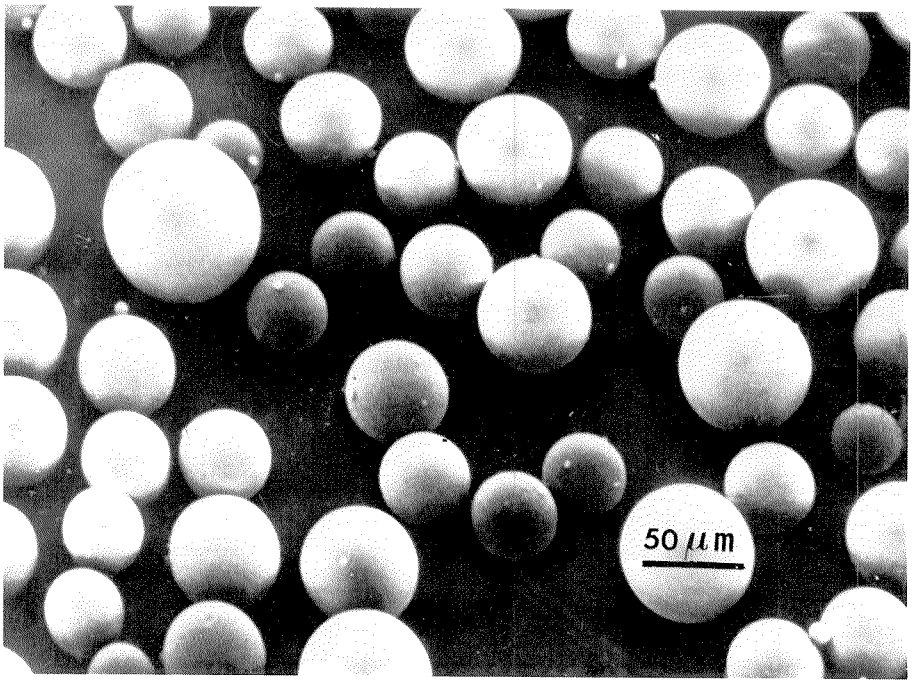


FIGURE 1.
Scanning electron micrograph of the divinyl copolymer beads (Biobeads SX-8) used in the Standard Bead Model.

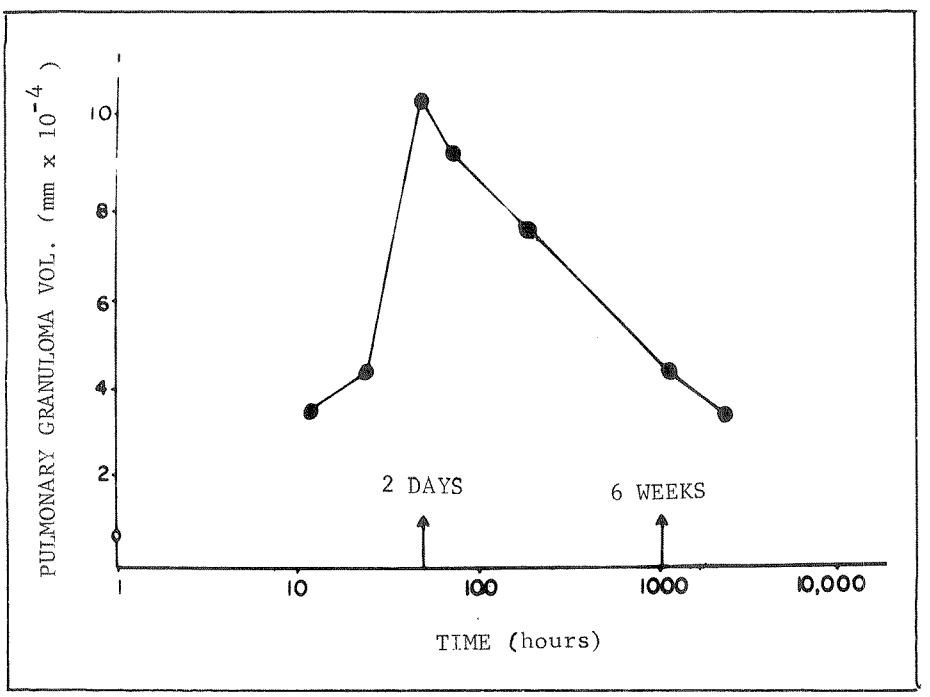


FIGURE 5.
Plot of the changes in volume of granulomas which formed in the mouse lung at various periods after intravenous injection of 10,000 copolymer beads. The maximum granuloma volume occurs at 48 hours.

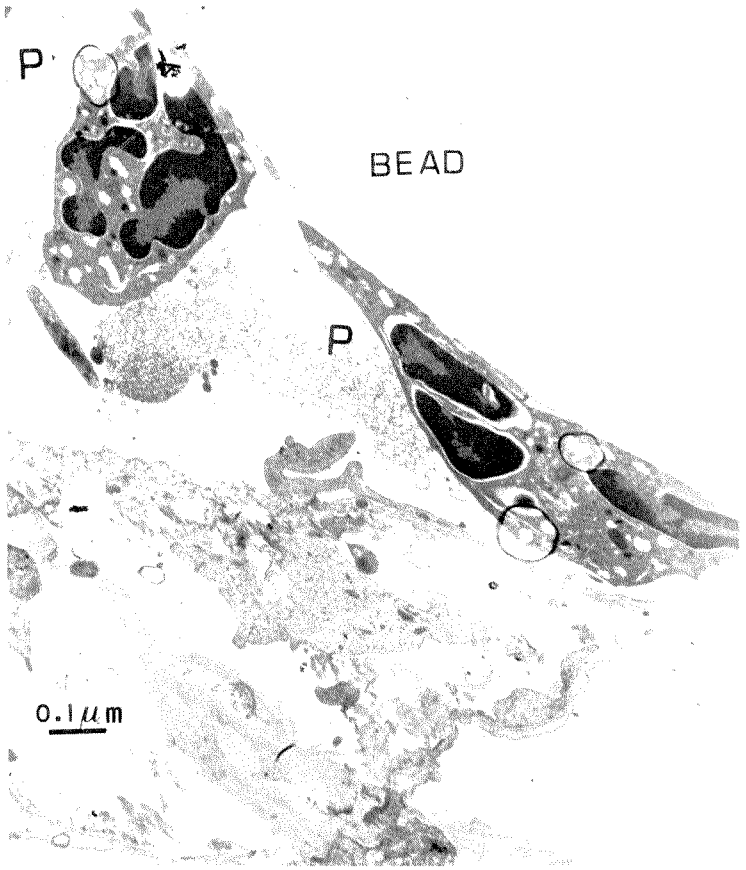


FIGURE 3. (above)
Electron micrograph showing the inflammatory response in the mouse lung 3 hours after IV injection of 10,000 divinyl copolymer beads. This reaction could be detected only by EM. A few polymorphonuclear leucocytes (P) are attached to the bead.

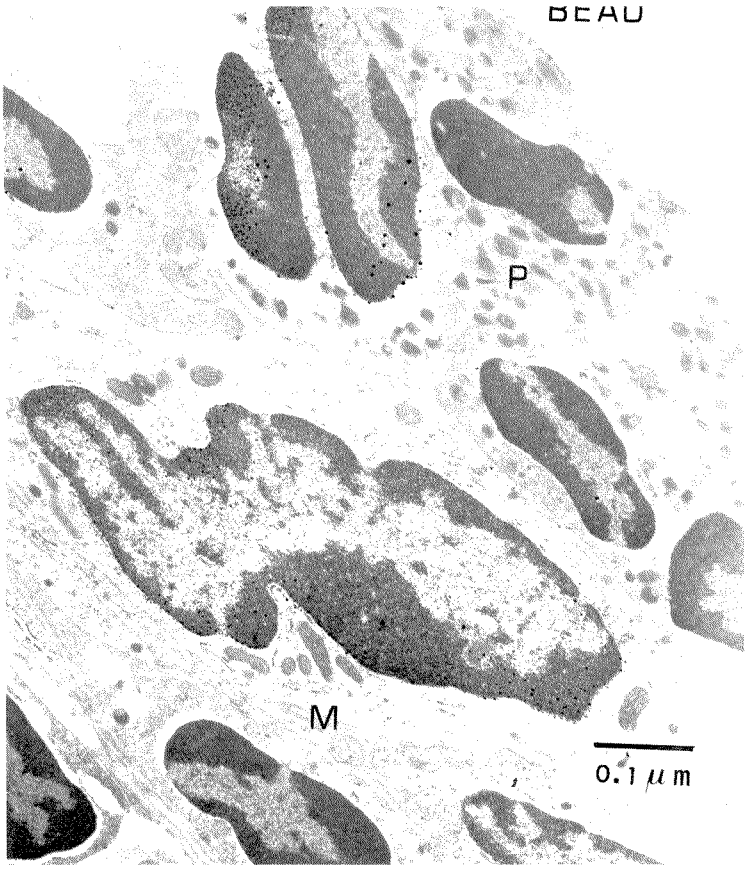


FIGURE 4. (above)
After 48 hours, a large granuloma has formed in the lung around the bead and is composed of polymorphonuclear (P) and mononuclear (M) leucocytes. 10,000 beads were injected intravenously.

FIGURE 6. (below)
Electron micrograph of reaction to copolymer bead 48 hours after intravenous injection and treatment with the anti-inflammatory agent polyanetholsulfonate (Liquoid). The response is greatly reduced from the control and is equivalent to what would be expected after only three hours in control lungs.

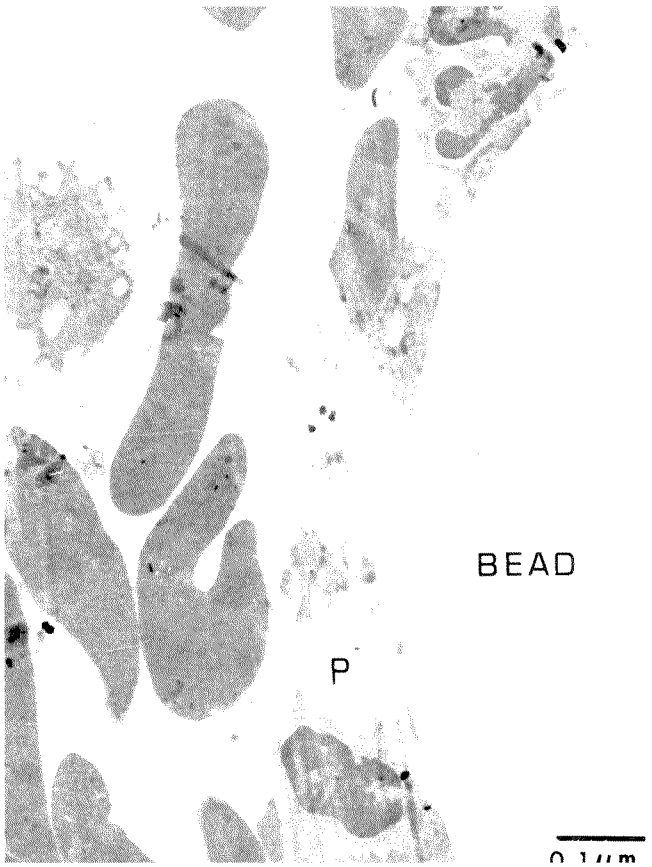
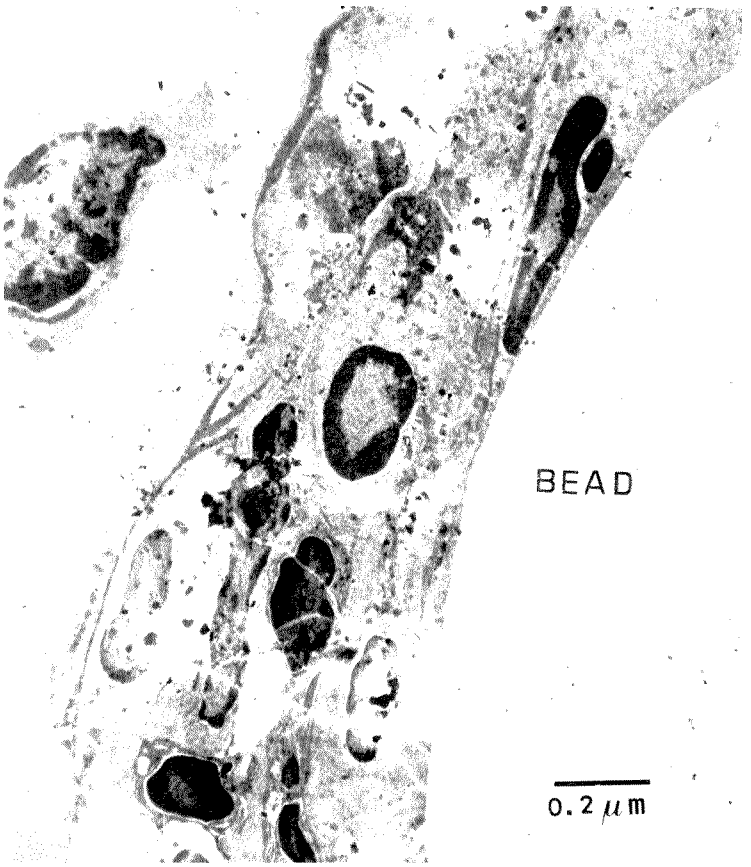


FIGURE 7. (below)
48 hours after injection of poly d, 1-lactide beads, a thin rim of polymor phonuclear cells has formed around the bead. The granuloma is mucl smaller and less compact than one formed 48 hours after injection of diviny benzene copolymer beads.



was less at all times than with the divinyl benzene copolymer beads, and at 48 hours the granuloma was smaller and much less dense than in the standard bead model (Fig. 7). These studies are continuing.

TABLE II

Effect of anti-inflammatory drugs on mean diameter and volume of granulomas after 48 hours[a]

Drug[b]	Mean Diameter (μm)	%Reduction in Diameter	Mean Volume (mm^3)	%Reduction in Volume
Control	143 ± 33	—	14.7×10^{-4}	—
Ellagic Acid	129 ± 44	10	10.6×10^{-4}	28
Polyanethol-sulfonate (Liquoid)	76 ± 33	47	1.7×10^{-4}	88
Hydrocortisone acetate	69 ± 15	52	1.1×10^{-4}	93
Levan (bacterial)[c]	62 ± 11	57	0.67×10^{-4}	96

[a]At least 100 granulomas measured/drug.
[b]Experimental procedures:
Ellagic acid—(2×10^{-4} M), 0.5 ml IV 2 hr prior to bead injection, followed by twice daily IP injection of 0.5 ml until sacrifice.
Polyanetholsulfonate—(8mg/ml)—0.05 ml IV and IP 2 hours prior to injection of beads followed by IP injection of 0.1 ml three times daily until sacrifice.
Hydrocortisone acetate—(25 mg/ml), 0.2 ml SC followed 3 days later by 0.2 ml SC 2 hrs. prior to bead injection.
Levan—(25 mg/ml), 0.01 ml/g wt (0.25 mg/g wt) given 2 hours prior to bead injection SC or IP and then daily until sacrifice.
[c]Bacterial levan from *Erwinia herbicola*

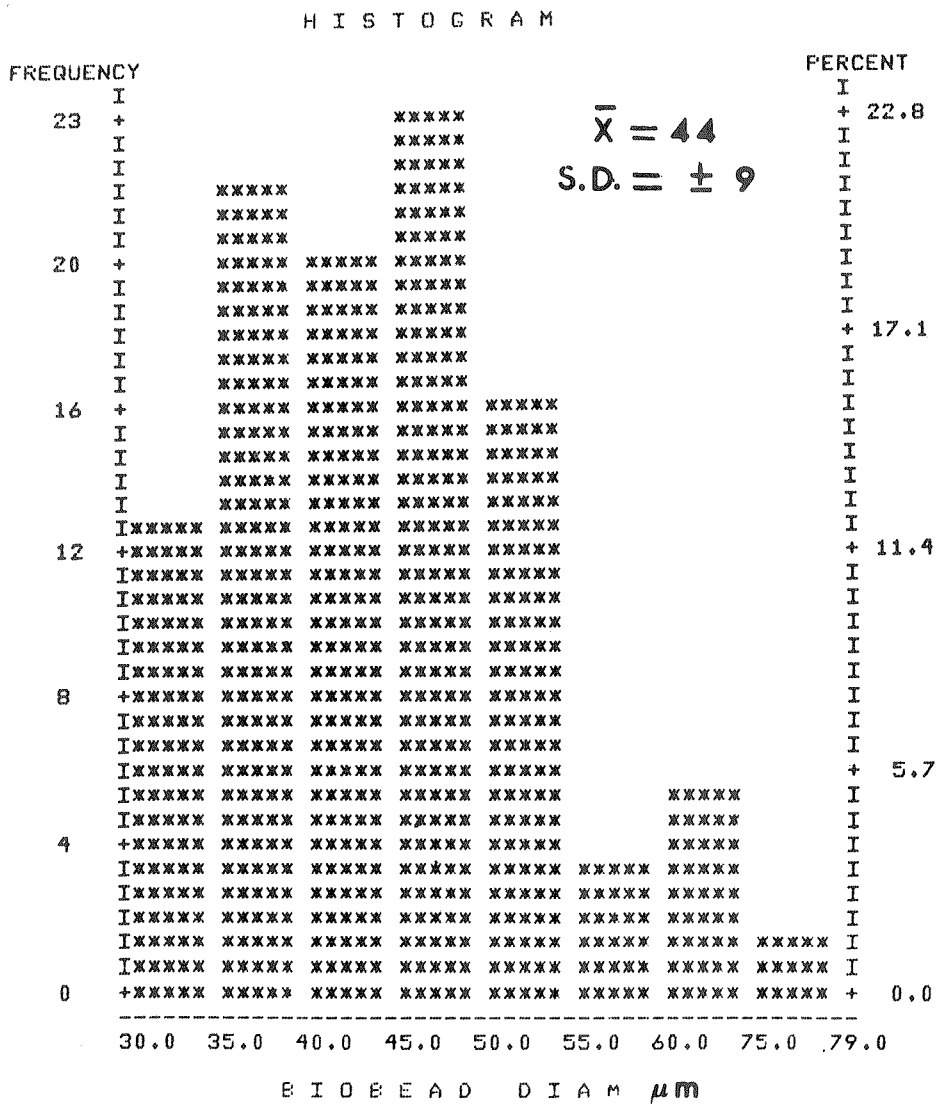


FIGURE 2.
Computer-derived histogram of the size distribution of the divinyl copolymer beads used in the Standard Bead Model.

References

Davies AM, Shilo M, and Hestrin M: The Influence of *Aerobacter* Levan on the Permeability of the Blood Vessels of the Skin: Studies with Antibody Globulins and Trypan Blue. Br J Exper Pathol 36:500–506, 1955.

Kellerman RW and Warren KS: The Role of Chemical Mediators in the Inflammatory Response Induced by Foreign Bodies: A Comparison with the Schistosome Egg Granuloma. J Exp Med 131:21. 1970.

Moore DL, Grove DI, and Warren KS: The *Schistoma Mansoni* Egg Granuloma: Quantitation of Cell Populations. J. Pathol 121:41–50, 1977.

Von Lichtenberg F: Host Response to Eggs of *S. Mansoni:* Granuloma Formation in the Unsensitized Laboratory Mouse. Am J Pathol 41:711, 1962.

Publications (Abstracts)

Coleman SE, Hood CI, Schoen FJ, and Robinson M: Ultrastructure of the Inflammatory Response to Injected Foreign Particles in the Mouse Lung. Florida Scientist 43:48, 1980.

Schoen FJ, Hood CI, Coleman SE, and Robinson M: Pulmonary Interaction with Intravenously Injected Foreign Body Particulates. Am Rev Resp Dis 121:257, 1980.

Wilson J, Pigott GH, Schoen FJ, and Hench LL: Toxicity Testing of Bioglass. World Congress on Biomaterials, Vienna, Austria, 1980.

Coleman SE, Hood CI, Schoen FJ, and Robinson M: Early Foreign Body Reaction in the Mouse Lung to Intravenously Injected Polymer Beads. Proc Electron Microscopy Soc Amer (in press).

Coleman SE, Hood CI, Schoen FJ, and Robinson M: Electron Microscopic Study of the Effect of Anti-Inflammatory Agents on the Foreign Body Response in Mouse Lung. Abstracts of the Southeast Electron Microscopy Society, 1980.

Papers

Wilson J, Schoen FJ, Pigott GH, and Hench LL: Toxicology of Bioglass. J Biomed Mater Res (submitted).

Evaluative and Corrective Techniques for Neuromuscular Deficits

Engineering Building
Vanderbilt University
Nashville, Tennessee 37240

VA Medical Center
1310-24th Avenue, South
Nashville, Tennessee 37203

Paul Griffin, M.D., and
Richard Shiavi, Ph.D.

Electromyographic Gait Pattern Analysis—The evaluation of pathological gait patterns from patients having the same spastic pathology is difficult because of the large quantity of multichannel data required and interpatient variability. Because of this problem, a project was initiated to develop a methodology to describe concisely, and classify, gait patterns. A concise description of the progress made during the last year follows.

Review and Theory

Published reports of kinesiological investigations of the muscular synergy patterns of normal subjects during level walking have been studied (1,2,3). Compilation and comparison of these results show much interindividual variability (3). Detailed normative data is required for understanding normal gait and providing a comparative base for assessing gait disabilities (4). Thus, it is necessary to develop techniques for concisely describing locomotor patterns.

Bekey, et al., have addressed this problem (5). Their method represents each EMG channel by a two-dimensional binary vector whose value depends upon the duration of activity during stance and swing phases. An improvement in the detail of representing the EMG pattern can be accomplished by using the entire data set and expanding it in a Karhunen-Loeve (K-L) expansion.

Methodology

The myoelectric (EMG) and foot-fall patterns from 25 normal subjects who were asked to walk at free speed were measured in the middle 5 meters of an 8-meter walkway, using Biosentry and B & L Engineering telemetry systems, respectively. The EMG patterns were recorded from the tibialis anterior (TA), peroneus longus (PL), gastrocnemius (GAS), and soleus (SOL) muscles, using Beckman silver/silver-chloride-surfaced electrodes and differential amplifiers. Since there was very little cycle-to-cycle variation, a representative cycle was chosen as a subject's pattern.

The gait cycle was divided into 16 segments of equal duration, starting at foot (heel) contact. Each EMG pattern was encoded in a 16-element vector. The value of each element was the proportion of time that the muscle was active (10 percent above noise level) during that segment. A typical monophasic TA pattern is represented by $x^1=(1,1,.8,0,0,0,0,0,0,0,.88,1,1,1,1,1,1)$.

A Karhunen-Loeve expansion (6) was performed on the 25 vectors on each of the 4 EMG channels using an IBM scientific subroutine package implemented on a PDP-11 computer.

The K-L expansion is essentially a covariance analysis, with the eigenvectors becoming the new basis vectors and the eigenvalues stating the amount of variance accounted for by their respective vectors. The new coordinates are calculated using the eigenvector matrix as a transformation matrix. Sixteen new coordinates and basis functions were produced. In effecting a dimensionality reduction, only a few will be used. The number of coordinates acceptable will be the minimum number which produce an error free grouping of different patterns.

Cluster analysis was performed using a one-way split algorithm (7) and the average pattern was calculated for each group. The cluster analysis was repeated for two, three and four coordinates in order to determine the minimum number.

Results and Discussion

Since the eigenvectors are from a covariance matrix, each element emphasizers specific variable portions of the gait cycle and as such are physically interpretable. Table 1 shows the first five eigenvectors from channel TA. Vector 1 emphasizes differences in late stance and midswing among these normal subjects. The eigenvector set for the other channels were different but similarly interpretable. The new coordinates for each pattern indicate how much of the vector properties are contained in its pattern. The vector x^1 has new coordinates:

$$y^1 = [-.5, .57, -.14, \ldots].$$

This is consistent for a monophasic pattern.

The eigenvalues calculated from the K-L expansion showed that 68 percent, 75 percent, and 80 percent of the total variance were accounted for by 2, 3, and 4 of the new basis vectors. The results of the cluster analysis show that the clusters produced using two coordinates always had one group pos-

EIGENVECTORS IN COLUMN

1	0.016	0.032	-0.013	-0.032	-0.109
2	0.221	0.143	-0.569	-0.082	-0.348
3	0.193	0.374	-0.381	0.113	0.027
4	0.241	0.352	-0.104	0.295	0.007
5	0.368	0.141	0.046	0.432	-0.093
6	0.420	-0.035	0.295	0.034	-0.018
7	0.441	-0.041	0.330	-0.084	0.018
8	0.339	-0.110	0.261	-0.155	-0.107
9	0.251	0.158	0.114	-0.245	0.167
10	0.126	0.426	-0.035	-0.400	0.343
11	-0.084	0.238	0.065	-0.203	0.405
12	-0.088	0.165	-0.055	-0.246	0.066
13	-0.124	0.259	0.145	-0.389	-0.438
14	-0.248	0.464	0.398	0.089	-0.490
15	-0.252	0.327	0.228	0.439	0.314
16	0.001	0.011	0.015	0.004	0.038

TABLE 1
Eigenvectors for channel TA.

sessing a mixture of monophasic and biphasic patterns. The clusters produced using three coordinates always produced groups whose members had similar patterns and thus three coordinates were sufficient.

Once the clusters were determined, the average patterns for each group was calculated. The group patterns for all four EMG channels are shown in Table 2. The group patterns show definite differentiation among patterns with different phasicity and with different duration of phases.

References

1. Basmajian J: Muscles Alive. Williams and Wilkins, 1974.
2. Perry J: Kinesiology of Lower Extremity Bracing. Clin Orth Rel Res 102:18–31, 1974.
3. Paul J: Comparison of EMG Signals from Leg Muscles with the Corresponding Force Actions Calculated from Walkpath Measurements. In Human Locomotion Engineering. Proc Inst Mech Eng, London, 1974.
4. Grillner S: Locomotion in Vertebrates. Physiol Rev 55:247–304, 1975.
5. Bekey G, Chang Chi-wu, Perry J, and Hoffer MM: Pattern Recognition of Multiple EMG Signals Applied to the Description of Human Gait. Proc IEEE 65:674–681, 1977.
6. Glaser E and Ruchkin D: Principles of Neurobiological Signal Analysis. Academic Press, 1976.
7. Hartigan J: Clustering Algorithms. Wiley, 1975.

```
PATTERNS FOR    TA: %SUB
|**          ***  *|   36
|*           ******|   40
|************ **|      8
|**  ****  **   *|      8
|*    ********  *|      8

PATTERNS FOR    PL: %SUB
| *******         |   28
|********      **|   20
|     ***         |   16
|********  ***  *|   24
|**   ***  ****  |    4
|*         *******|    8

PATTERNS FOR   GAS: %SUB
|     ***         |   28
|   *****         |   20
|********         |   40
|***  *****    **|    4
|***  *******   *|    4
| ****** ****     |    4

PATTERNS FOR   SOL: %SUB
| *********       |   16
|*********      *|   12
| *******         |   44
|   *****         |   16
|     ***         |   12
```

TABLE 2.
Activity pattern for four EMG channels. The column farthest to the right indicates the percentage of subjects having a particular pattern.