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* This is only a summary of what this Progress Report contains; it is not intended to be a guide. This summary contains only a few subject matters throughout the Progress Report.*

VETERANS ADMINISTRATION REHABILITATIVE ENGINEERING RESEARCH and DEVELOPMENT SERVICE PROGRAMS

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The Effect of Partial Versus Full Weightbearing on Late Loosening After Total Joint Replacements in the Lower Extremities

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The objective of our study is to measure and document in vivo motion of the interface between cement and bone in total hip and total knee replacements. Four spherical (1.6 mm) markers are inserted in cortical bone near each component of the implant and used as references. From three to six markers (2.39 mm) are embedded in cement. A biplane radiographic technique (1) is used to measure the distance from cement markers to the bone reference markers. Simultaneous biplane X-rays in non-weightbearing (20 kg force or less) and full-weightbearing conditions are taken on the affected side. These are taken postop, before discharge, and 2, 4, 6, 12, 18, and 24 months postoperatively.

To date, there have been 43 patients in our study. Seventeen of these have been total knee replacements (TKR's) and 26 total hip replacements (THR's). There are two bilateral TKR's and one bilateral THR.

Since our last report, we have

constructed equipment which will control the amount of leg rotation at X-ray and which will show the amount of force and the ground reaction torque exerted by the patient. Also, our data reduction methods have been modified to speed the process and to indicate bone intermarker distances as well as the distances from bone marker to cement marker.

Intermarker distances are now routinely measured for the bone markers at each study and compared to previous distances. In checking our patients we found that five TKR's and in one THR there had been significant (0.02 cm) bone marker motion relative to one another. Since the relationship of the bone marker coordinates to the frame reference coordinate system changes with each study, we can only infer the direction of the motion. In at least two of the TKR's, significant motion of cement markers had to be qualified by known motion of the bone reference system. Nevertheless, the magnitudes of the cement marker motion and the previously noted trends were sufficient evidence that indeed cement motion was being measured, but precise magnitudes and directions cannot be reported. In the other patient a bone marker was located in the periosteum rather than cortical bone. Intermarker distances give us the ability to know whether apparently poorly fixed markers can be used.

We have had six patients with measured cement loosening (range: 0.4 to 6.3 mm) and clinical evidence of loosening (radiolucent line on X-ray and symptoms) who have gone to surgery for revision or fusion (in one case of septic loosening). In all cases the prosthesis was found to be grossly loose at surgery, thus supporting our biplane radiography findings. In only 15 patients, out of the total of 43 studied, has no loosening been detected.

Our laboratory is now equipped to generate a report on the biplane analysis for each film set taken including 3-D coordinates for bone and cement markers, intermarker distances for bone and cement markers, and relative motion of

the cement markers with respect to bone (i.e., loosening and migration). Additionally, we generate an updated two-dimensional plot of cement marker motion with respect to time, as well as a clinical correlation report that is placed in the patient's chart for permanent reference.

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Electrical Assessment of Incomplete Spinal Cord Injury and Recovery

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The aim of this research is to study an animal model and human incomplete cervical spinal cord injuries with a spinal cord monitoring system utilizing computer averaged cortical evoked potentials.

We have developed two separate animal models, a contusion injury by the weight-drop method and an anterior cord compression injury by insertion of a pressure transducer. Twenty-four animals have been studied with the

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contusion injury utilizing energies of 250 gm·cm to 1000 gm·cm. The most standard and reproducible incomplete spinal cord injury has occurred with 800–900 gm·cm of energy, and these animals do not completely recover. Twenty-six incomplete spinal cord injuries have been produced by compression utilizing 10–15 pounds per square inch of externally applied pressure. Most of the animals will not completely recover from this cord compression unless they are decompressed surgically.

Results to date indicate that incomplete cord injuries of both types will recover depending on the amount of initial force or energy applied and the length of time compression is applied as well as whether anterior decompression is performed in the compression model.

Spinal cord neurophysiologic function as measured by cortical evoked potentials (CEPs) was studied in 6 animals with compression injury and in 11 animals with contusion injury. Evoked potentials (Fig. 1) showed a characteristic "W" shaped response with two negative and one positive spike in the first 100 milliseconds. The amplitude (measured in microvolts) of the first

negative response was termed A_1 ; the first positive response A_2 ; the second negative response A_3 . The time (measured in milliseconds) from stimulus until the peak of the first negative response (A_1) was termed N_1 ; the time to the peak of the first positive response (A_2) was termed P_1 ; and, the time to the peak of the second negative response (A_3) was designated N_2 .

The only significant CEP difference (at the .01 level) between normal and the compressed cord was an increase in the latency (P_1) of the first positive spike (A_2) in the proximal limbs and a decrease in the amplitude of the second negative spike (A_3).

Testing at a .01 level of significance, the following groups showed statistical differences before and after cord contusion.

1. In the proximal limbs—the amplitude of the first negative spike (A_1) was decreased between normal versus intra-operative contusion, and was increased from contusion to partial recovery phase, but, there was no significant difference between the normal cord and the partial recovery phase. The same was true for the second negative spike (A_3). There was no statistically signifi-

cant difference between the groups for the positive spike (A_2), or any of the latencies (N_1 , N_2 , P_1).

2. In the distal limbs—significant differences occurred between normal versus contused cords, contused versus partially recovered cords (for both negative spikes A_1 and A_3), but none between normal cords and the partial recovery phase. (Fig. 2). Both negative spikes were diminished after weight drop but were restored to their original amplitudes before the dogs were completely recovered from paralysis. Latencies and the amplitudes of the positive spikes were not affected.

The weight-drop experiments do support the potential value of CEP monitoring for use in quantitatively evaluating the neurologic state of the spinal cord, but larger numbers of the compression injury will have to be evaluated by CEP before a definite statement can be made.

An alternative system for determining the CEPs was conceived and studied during the past year. This alternative method has the potential for reducing costs, accepting complexity and the skills needed for obtaining

MEASUREMENTS OF CEP WAVE FORM

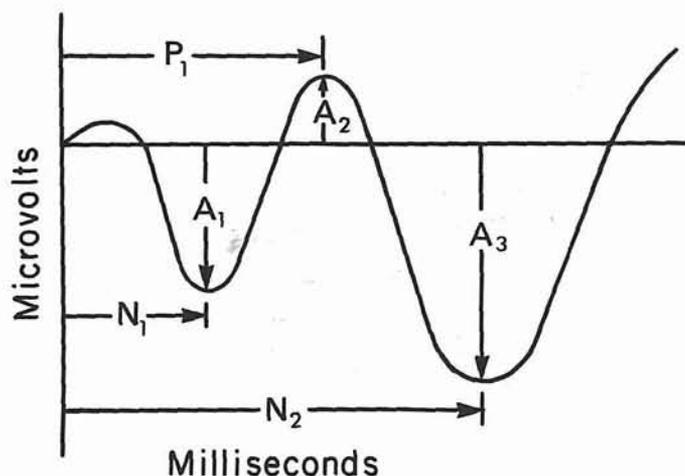


FIGURE 1. Schematic drawing of characteristic "W" shaped wave form produced in the first 100 milliseconds following peripheral nerve stimulus.

CEP summary for weight drop experiments. Data summarizes CEP before weight drop in both proximal and distal limbs, in comparison to the summarized CEP following anterior cord contusion. Note the decrease in amplitude of A_1 and A_3 but no significant change in A_2 , N_1 , N_2 , or P_1 .

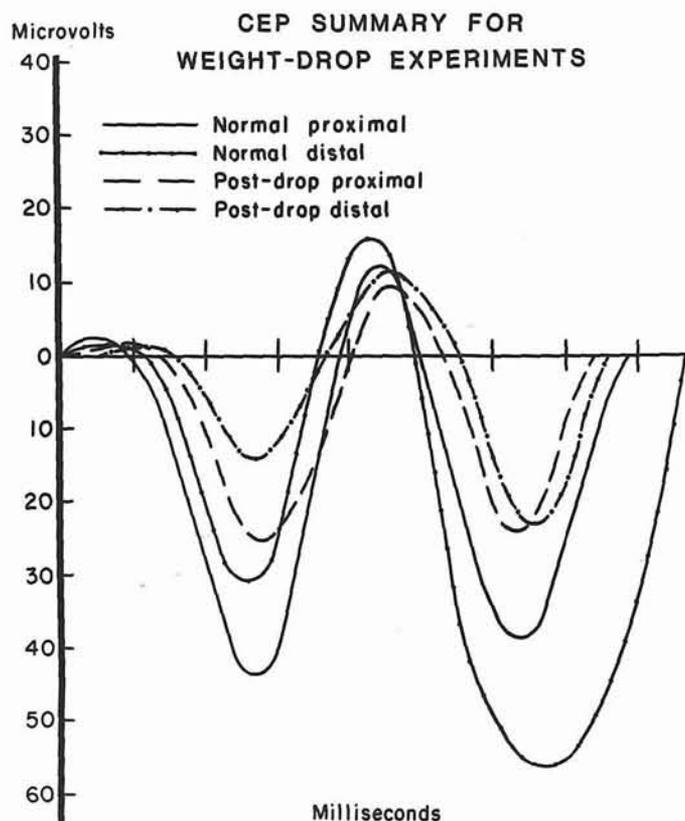


FIGURE 2.

CEPs, and in addition, produces results in a faster time. The present digital technique requires from 5 to 10 minutes for CEP assessment for the four extremities. The alternative method uses analog filters while our present method uses digital techniques. It has been shown that the correlation between cortical evoked potentials and visual and/or oral stimuli can be demonstrated by analog techniques. Because of the potential benefits of the analog method we conducted a study during the past year to determine if the analog method can effectively measure CEPs when the extremities are stimulated.

During the last year, analog circuits were designed, constructed and tested. Tests were conducted on beagles and humans. A correlation was found between the amplitude of the analog filter output and the absence or presence of stimulus to an extremity, but this correlation was not found to be useful in evaluation of the condition of the spinal cord.

Our tests were conducted by comparing the filter output (filtered CEP) amplitudes for the case when an extremity was stimulated, to the amplitude when that extremity was not stimulated. It was found that stimulation increased the filter output amplitude, but that the change in the amplitude was so small that normal variations (noise) of the amplitude were nearly of the same magnitude. For the tests as we conducted them the signal-to-noise ratio was too small for the method to be used.

It is possible that the analogue technique as tried can be modified to improve the signal-to-noise ratio. Thus it is not our conclusion that the technique is without merit or that the investigation should not be conducted, but because of limitations of our program we cannot now plan to conduct such studies during the next year.

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Total Knee Implant—Biotelemetry

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Relief of pain and restoration of function are the primary goals associated with total knee arthroplasty. Although improved motion and relief of pain are often achieved in the short term, mechanical problems often manifest themselves in the long-term follow-up. Radiographic evidence of fibrous membrane formation around the tibial component has been reported to be in excess of 20 percent in some series, with many patients requiring revision of one or both components. It is well recognized that the knee joint is vastly more complicated in geometry and function than the hip, and that the forces and motions are not well understood. This lack of understanding is evident when one considers the 200 to 300 total knee designs currently available, and the trial-and-error approach which has been pursued, often involving only limited clinical trial before general commercial release.

Current techniques for measuring joint loads with instrumental prostheses utilize miniature batteries (1,2) or transcutaneous power supply cables (3). Both of these techniques impose limitations on the amount of time available for data acquisition. The present project endeavors to initiate an effort to apply the knowledge gained in hip-joint biotelemetry (4) to the vastly more complex knee joint, utilizing power induction with telemetered output.

Although this represents the ultimate long-term goal, it is well beyond the scope of the present project.

This project has been initiated in the current report period, and a review of the total knee replacement field is underway. This review encompasses biomechanical studies, commercial implant literature, and published clinical results.

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Evaluative and Corrective Techniques for Neuromuscular Deficits

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The majority of effort during this time period has been committed to improving the laboratory and its measurement capabilities. A new laboratory site has been located. Its size permits a forty-

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There is no report for this period. The reader is referred to the report in the previous issue, BPR 10-34, (Vol. 17, No. 2) Fall 1980.

two foot walkway and placement of two video cameras for measurement of sagittal and coronal plane motions.

Motions will be recorded with two solid-state cameras which easily interface to a digital computer. All motion measurements will be accomplished on-line. A raised walkway incorporating an Advanced Mechanical Technology (AMTI) biomechanics platform is also being constructed. Detailed information on the motion measurement system will be available when it is fully operational.

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

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During the past 18 months, we have treated 13 upper-extremity amputees with immediate or rapid postoperative prostheses. The amputation levels have included 8 above-elbow, 4 below-elbow, and 1 shoulder disarticulation. Eight of the 13 amputations were the result of trauma, 3 were performed electively for neurologic dysfunction due to stroke or brachial plexus injury, 1 above-elbow amputation was performed for tumor, and 1 above-elbow amputation was performed for ischemia. There was one failure (above-elbow amputation) in the group and that failure was the result of poor patient selection, in that we attempted to fit an immediate postoperative prosthesis in a patient dying from a complex medical problem. All remaining patients (12/12) have achieved immediate function with their prostheses and all surviving patients (11/12) have continued to use their prosthetic devices for periods ranging from 1-18 months. (The 1 death in our series was due to an automobile accident in an individual 6 months after amputation and 3 months after his return to work.) Four of six of our patients who were employed at the time of their injury have returned to their same jobs and the two remaining patients are undergoing job training for

a different skill. Three of our patients were students at the time of their injuries and all have returned to school. Four of our patients were retired at the time of amputation and have returned to their prior activities.

During the same time period we have fitted seven amputees who are prior wearers of conventional prosthetic devices with externally powered prosthetic components. All seven patients are currently employed, and all preferentially use their externally powered devices for work, recreation, and activities of daily living.

During the past 6 months we have concentrated on trying to make our electric and myoelectric components interchangeable and to improve the reliability of some of the specific prosthetic devices.

We are continuing our investigation of new types of prosthetic components, both powered and unpowered, for upper-extremity amputees. In addition, we are trying to enlarge our referral base in order to increase our patient population, which will then allow more accurate evaluation of both the immediate postoperative use of powered components for upper-extremity patients and provide more patients for longitudinal followup with respect to eventual rehabilitation.

**Lower Extremity Amputation:
Immediate Postoperative Fitting
of Prostheses**

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We are continuing to evaluate the use of Xenon 133 for prospective amputation-level selection and immediate postoperative prosthetic devices at all levels of lower-extremity amputation. In addition, we are beginning to evaluate a variety of materials to be used in place of plastic as temporary prosthetic devices during the interval between removing the final immediate postoperative prosthetic cast and fitting the definitive prosthesis. Our data continues to support the concept that amputation rehabilitation, when organ-

ized around a team approach, maximizes patient rehabilitation and minimizes surgical complications.

During the last 6 months, we have analyzed our program with an eye toward the geriatric patient population (>70 years of age). In general, success of amputation rehabilitation in geriatric patients is inversely proportional to the age of the patient at the time of surgery. We analyzed the results of geriatric amputation within our own institution before and after the establishment of a dedicated amputation-rehabilitation center. Although there was no significant difference for geriatric amputation rehabilitation before and after the establishment of a dedicated center with respect to age, incidence of diabetes, or operative mortality, there were striking statistically significant differences found in the rate of amputation healing and length of rehabilitation time, as follows:

1. The incidence of primary healing in those geriatric patients who underwent amputation in the confines of an amputation rehabilitation center was 96 percent, compared to 63 percent for those geriatric patients treated prior to establishment of a center.

2. Mean rehabilitation time for geriatric patients treated in the center was 25 days while the rehabilitation time for geriatric patients treated in a nondedicated center averaged 60 days.

3. One hundred percent of our geriatric patients who were ambulatory prior to surgery continued to successfully ambulate after surgery, compared to only 66 percent of those geriatric patients treated in a nondedicated amputation center.

Our data clearly suggest that geriatric patients undergoing lower extremity amputation can be successfully rehabilitated if they are ambulatory prior to surgery and if they are treated in a dedicated amputation center irrespective of the level of lower extremity amputation.

Finally, we are continuing our trial of a pilot program in order to study the feasibility of a regional referral amputation center in our own local VA region.

**Evaluation of
Peripheral Vascular Disease by a
Real-Time Multispectral Imaging
System**

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This project was conceived to meet the growing involvement of the VA Rehabilitative Engineering R&D Service in the serious and widespread problems of veterans suffering from inadequate limb circulation, primarily attributable to arteriosclerosis, and occurring often in association with microvascular disease of diabetes mellitus. Of 15,000 amputations performed annually in this country in management of the terminal stages of these diseases, more than 4,500 are carried out in VA medical centers. The high morbidity and mortality associated with the management of these cases, particularly in patients over the age of 50 years, have been dramatically described in previous issues of the Bulletin.

Diagnostic and prognostic evaluations of these patients now involve sophisticated instrumentation, including laser Doppler flow measurements, radioactive xenon clearance techniques, and a variety of angiographic and skin temperature measurements. These methods suffer in varying degrees from problems relating to their invasive character in some instances, to lack of reliability or repeatability in others, or to persisting difficulty in securing highly reliable correlates with key diagnostic or prognostic criteria that would determine the nature and extent of surgical intervention. Above all, there has been the underlying problem of clinical acceptance of these methods for general use, and thus in the development of a basis for comparison of studies conducted under the same research rubric

in different centers. The criteria of repeatability and clinical acceptance are expected to guide the system under development here.

The multispectral imaging system proposed here is a further development of the system developed by Anselmo and Zawacki (1978) with the support of the National Aeronautics and Space Administration and the California Institute of Technology/Jet Propulsion Laboratory. This system utilizes image-processing technology developed for use in planetary, lunar, and earth surface analysis. The system has been successfully used in early diagnosis of the extent of thermal burn injury. In seeking a method for the early determination of deep coagulation and therefore of full-

thickness burns, infrared photography was considered as a potential method to indicate the devascularization and thermal denaturation associated with the full-thickness burn. The investigators proceeded on the rationale that deoxygenated blood has a moderate absorption in the very near infrared. They reasoned that venous thrombosis would be visible in infrared patterns as an index of stasis or coagulation associated with full-thickness burns, because infrared photography can detect venous structures 2-5 mm from the surface. These infrared techniques can thus display venous plexuses which are deep in the dermis and thus fundamentally concerned with normal skin nutrition. Integrity in their circulatory patterns

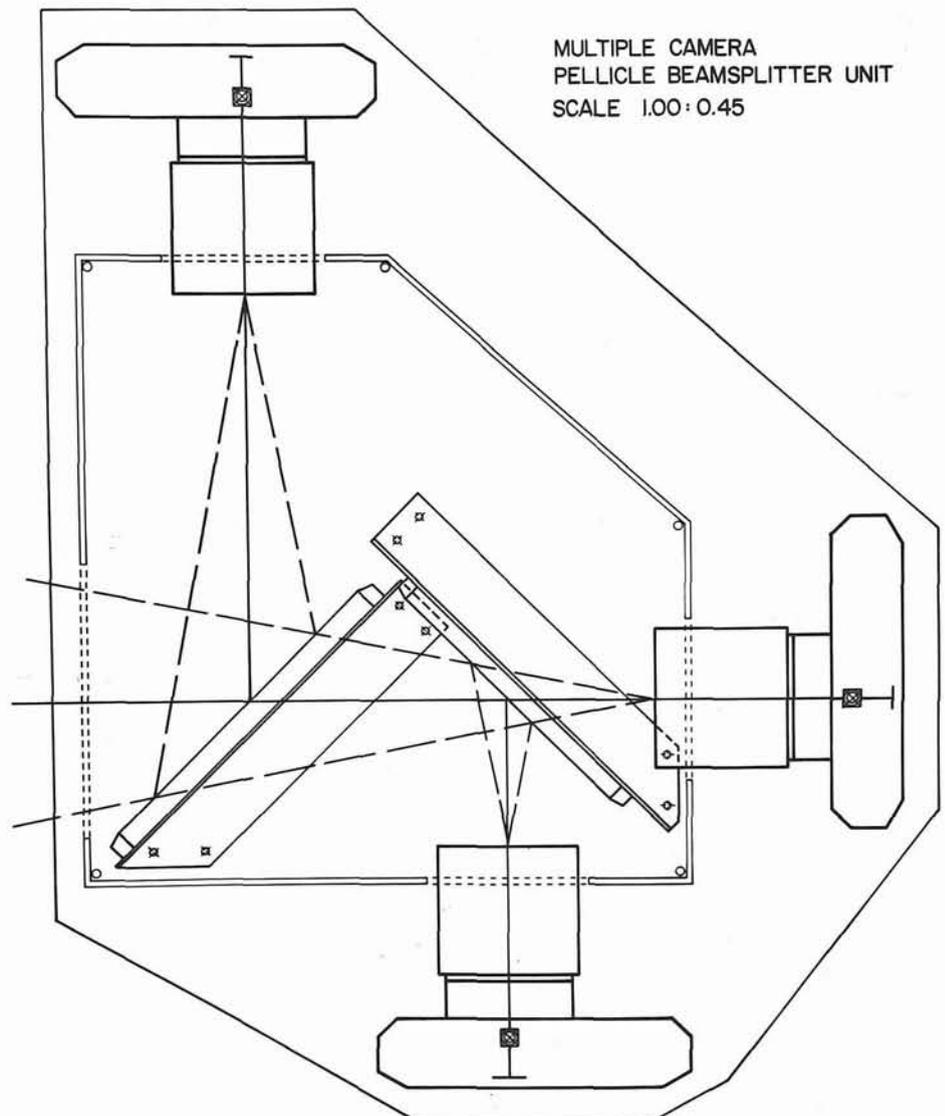


FIGURE 1.

System for simultaneous acquisition of red, green, and infrared images by the use of two beamsplitters and three single-lens reflex cameras mounted on an aluminum plate.

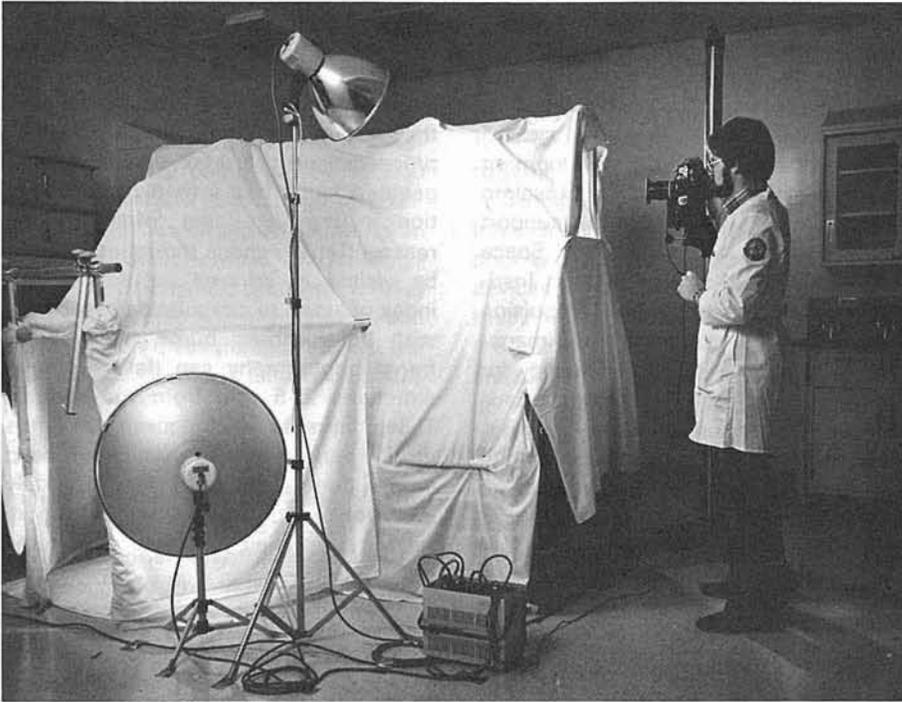


FIGURE 2.

Photographic "tents" of white muslin are used in conjunction with strobe light sources to produce shadowless images of limbs. A front-surface mirror is positioned over the leg for supine images.

would therefore appear to offer means of developing highly reliable indices of skin status in evaluating the progress and prognosis of peripheral vascular disease. This evaluation can be made with very high spatial resolution, a feature unique to this method and not readily available with other widely accepted techniques.

It should be emphasized that the infrared component of the Anselmo and Zawacki imaging system does not detect temperature patterns, but indicates the absorption or reflection of light in this invisible portion of the spectrum.

Two other spectral zones entered into the burns-imaging system of Anselmo and Zawacki. They noted that hyperaemic skin appeared bright red, suggesting use of a region with the red spectrum. By contrast, zones of stasis appeared "parchment white," and suggested use of a color not normally appearing on healthy or thermally injured skin, since a highly spectral reflectance would occur in the zone of stasis. Based on these considerations, red and green filters were added to the infrared sensor. Thus, for evaluation of burned surfaces, their analytical approach used infrared light, which penetrates deepest, to investigate thermal

injury to superficial arterioles and venules located in the dermis; and used red light (which does not penetrate as deeply as infrared) to characterize the zones of hyperaemia associated with dilatation of the capillary bed in the dermal papillae; and used green light (which is the least penetrating) to differentiate the zones of stasis from those of coagulation and hyperaemia, as well as from normal skins. Relevance of these spectral considerations to the proposed imaging system for vascular disease is reviewed below.

The final design objective of this new system for peripheral vascular imaging will utilize a color TV display similar to that now used in the burns system. However, much preliminary work is being conducted with black and white photography through appropriate spectral filters. Both photography and TV display will allow virtually any desired level of spatial resolution. It is probable that useful data on skin circulation in peripheral vascular disease will require resolution down to 1 mm in certain applications, with a concomitant display of only 1 or 2 cm². This requirement, as for example in examinations of small areas of skin around nail beds of fingers and toes, or in evaluation of drug-

induced blanching of facial skin, substantially transcends spatial resolution accepted in the existing burns system. It would be expected that this higher resolution would give useful data on venule and arteriolar physiology not available in less intimate images of skin organization.

A high degree of temporal resolution will be a valuable characteristic of the new system. Hitherto, less emphasis has been placed on the temporal evolution of a response to external or internal stimuli to limb vascular control mechanisms than on "spot" aspects of "before" and "after" data. Preliminary tests with the burns system by Anselmo and Zawacki have emphasized the highly multiphasic nature of peripheral vascular responses to simple external stimuli, such as mild heating. These pilot data have shown distinguishing features between normal subjects and those with peripheral vascular disease, including diabetes. Distinguishing features include spectral reflectance characteristics measured over 60–90 minute periods, with useful differentials between green, red, and infrared reflectance characteristics.

It is expected that, with appropriate modifications which would optimize regions of spectral sensitivity of a two- or three-sensor system, the method would offer advantages over any existing systems in evaluation of peripheral vascular disease. The proposed system would evaluate three interrelated factors:

1. The perfusion density or the amount of oxygenated hemoglobin in the skin would be measured by the "redness" of the skin and would increase along a continuum from unperfused tissue to a state of hyperaemia;
2. Decreasing the oxygen concentration of the cutaneous blood increases the "blueness" of the skin, and can be detected by appropriate filters in the blue-green range;
3. Deeper venous elements in the skin can be visualized in the near infrared.

Initial studies are now proceeding in normal subjects and those with diseased states. To provide design data for an electronic imaging system, all these initial data are acquired as black and white photographic images. Three cameras have been used to produce a rapid succession of images with red, green, and infrared filters (Fig. 1). This tech-

nique is now being replaced with a system of multiple beam splitters to allow simultaneous acquisition of the three images in three cameras. The experimental photographic techniques are correlated with established Doppler blood pressure measurements. To eliminate unacceptable shadows in the photographs, a system of cloth tents has been developed, and three large strobes provide suitable shadowless lighting within these tents.

Subjects are placed supine in the photographic tent for 30 minutes prior to photography. Investigations so far have been confined to the lower limb. After photography in the supine position, a reactive hyperaemia test is performed. Circulation is occluded by a blood pressure cuff on the distal thigh for 5 minutes, then the cuff is deflated and a series of photographs are taken for 30 minutes. The patient is then placed in sitting position with the legs dependent, and the same photographic sequence is followed. To avoid camera movement between the supine and dependent photographic series, a front-surfaced mirror is located over the bed for the supine pictures (Fig. 2).

Since commencement of the studies 5 months ago, 25 photographic sessions have been conducted on 13 patients, suffering from preoperative atherosclerotic occlusion, postoperative atherosclerotic occlusion, preoperative lower-extremity gangrene prior to amputation, diabetic vascular disease, angiospasm prior to sympathectomy, venous stasis ulcer, and paired skin graft healing. All these abnormalities were in the lower extremity (Fig. 3).

Upon completion of administrative arrangements, image processing techniques will be evaluated at the California Institute of Technology / Jet Propulsion Laboratory. Black and white photographs prepared from these investigations are currently under review by JPL staff for suitable processing strategies.

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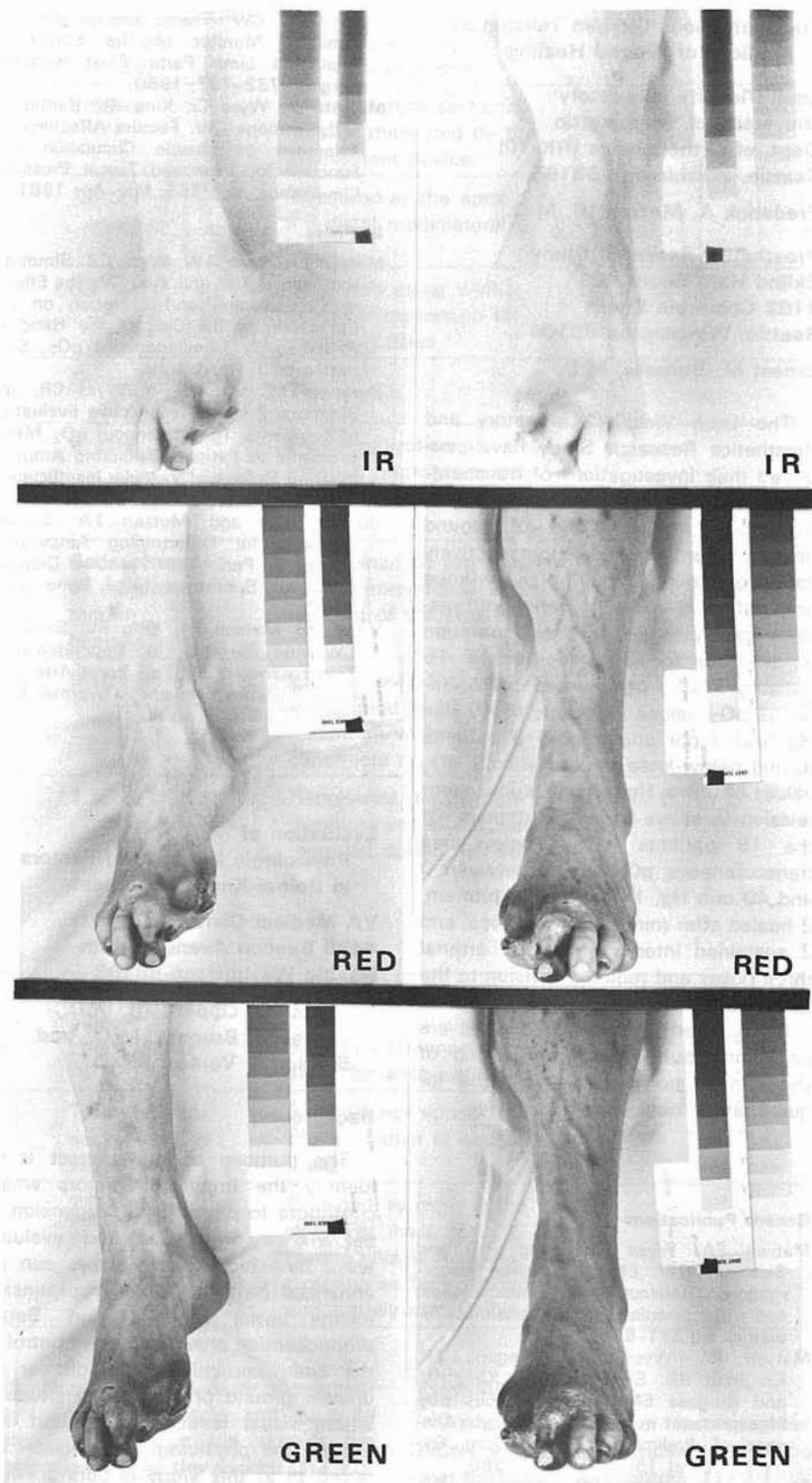


FIGURE 3.

A comparison of infra-red, red, and green filtered images of legs of patients with advanced bilateral arterial disease. For computer processing, the image must be essentially shadowless, and a reference gray scale must be included in each photograph.

Transcutaneous Oxygen Tension as Predictor of Wound Healing

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The Limb Viability Laboratory and Prosthetics Research Study have continued their investigations of transcutaneous pO_2 as an indicator of local cutaneous perfusion and of wound healing potential. We are prospectively studying patients requiring below-knee amputation because of peripheral vascular insufficiency. The final correlation is available for 37 patients. All 15 patients having below-knee transcutaneous pO_2 values in excess of 40 mm Hg healed per primam. All 3 patients having below-knee transcutaneous pO_2 values of 0 mm Hg required subsequent revision to above-knee amputations. Of the 19 patients having below-knee transcutaneous pO_2 values between 0 and 40 mm Hg, 15 healed per primam, 2 healed after minor local revisions, and 2 sustained intercurrent major arterial thromboses and required revision to the above-knee level.

Encouraged by these results, we are continuing our active investigation of this simple, noninvasive technique for quantitating local oxygen delivery.

Recent Publications

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In Press

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Evaluation of Physiologic Suspension Factors in Below-Knee Amputees

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Background

The purpose of this project is to identify the important factors which contribute to physiologic suspension of below-knee prostheses and evaluate ways by which these factors can be enhanced. Better physiologic suspension means better proprioception. Better proprioception provides better control of the limb, particularly at night or on uneven ground or during any situation where visual feedback is limited. Although the physiologic suspension referred to in this study is during swing phase, we feel that enhanced proprioception should result in better control during both swing and stance phases. The goal is not necessarily to produce suspension without any auxiliary support but to increase proprioception through

a sustained intimacy of fit. During the course of this project we have identified the following variables which affect physiologic suspension and have measured their effects by load-displacement tests on six patients.

Measurement of Suspension

1. Volume—Loss or gain in the stump-socket volume relationship affects fit and suspension. A volume testing device has been developed which determines the stump-socket volume relationship and whether it changes with time. Residual limb volume was assumed constant during this study. Socket cross sectional area was found to average 10 percent less than that of the stump, producing a snug fit. If the average cross sectional area of the residual limb is too large then ejection tends to occur. If the average cross sectional area is too small then suspension may be diminished.

2. Interference factor—The interference factor is related to the force per unit area exerted by the stump against the socket wall. This is a function of the degree of expansion of the stump when the patient contracts his muscles and the firmness of the contracted stump tissues to compression. The degree of stump expansion has been measured in the M-L and A-P planes but found to be typically greatest in the distal M-L plane. Calipers are used to measure the M-L diameter of both socket and stump at comparable sites during the contracted and relaxed states. VAPC spring loaded calipers are applied to the stump in the relaxed and contracted position. The degree of contracted stump compression by the calipers then reflects the stump firmness. A stump exhibiting potential for a good interference factor would show maximal expansion and minimal compression, i.e., maximal firmness.

3. Surface factors—Surface factors such as the type of socket liner, number and type of socks, etc., affect the interface friction. During this study we have attempted to maintain these factors constant. These factors are most significant at greater degrees of pistoning and are less significant than other factors here.

4. Contour factors—Contouring provides the anti-gravity component of physiologic suspension. In previous reports we have attempted to quantify

TABLE 1.
Comparison of Physiologic Suspension Factors in Two Below-Knee Amputees:

Factor	Patient ABC	Patient DEF	Implication and Process Comments
1. Stump size	Larger (40%)	Smaller	Average cross sectional area as measured by the assessment device.
2. Expansion in the mediolateral plane	3.1 cm	1.6 cm	Measured at the apex of the distal mediolateral bulge.
3. Firmness	6.3 mm	6.4 mm	Measured using VAPC caliper compression of stump muscles.
4. Contouring by eye	Less	Greater	
5. Contouring by polynomial analysis and profile overlay	Less	Greater	From digitization of external photogrammetry data.
6. Pressure Distribution (weight-bearing)	Uniform	Concentrated at the patellar tendon bearing area	Determined by inspection of skin immediately after removal of the prosthesis.
7. Traction force developed at 2 cm of socket displacement	2.1 kg	9 kg	2 cm socket displacement is assumed to be maximum within the constructs of this study.
8. Displacement of stump out of socket while walking without cuff suspension in definitive socket	3 cm	1.5 cm	Represents the average displacement which was recorded during five steps.
9. Stump and socket volume	Constant 10 percent compression	Constant 11 percent compression	The socket is always slightly smaller than stump but this difference was the same for each patient.
10. Surface factors	P-lite liner	Textured hard socket no liner	Skin did not appear to move relative to socket wall.
11. Skin movement	3 cm	1.5 cm	Obtained by moving the skin over the anterior medial tibia in an axial direction as far proximally and distally as possible.

contour by preparing profiles of the stump in the relaxed and contracted position and profiles of the inside of the socket using external photogrammetry. By superimposing comparable stump and socket profiles the contour overlap or degree of stump expansion can be qualitatively determined. We are now evaluating stump contour using a polynomial analysis of the profile slope.

5. Skin mobility—Skin movement may allow the muscle and tibia to piston even though the skin is not moving relative to the socket.

6. Personal factors—Motivation and the ability to contract the muscles effectively can affect suspension performance. This potential bias has been minimized in this study by multiple test runs.

Previous Work

At the time of our last progress report, we presented evidence indicating that the best socket contour for maximal physiologic suspension might be one made around a stump in which the muscles were contracted. The rationale was that a socket which allowed for muscle expansion would increase con-

tour suspension. We measured seven patients using a load displacement testing device described earlier. Each was tested in plaster sockets made upon the relaxed and the contracted stump. The results showed that suspension was actually better in the relaxed socket. Our interpretation of these results is that suspension is dependent upon several factors including contour and interference factors. With the contracted sockets, the increased contour factors achieved so much at the expense of the interference factor that the net result was a decrease in the efficiency of the suspension.

At the time of this progress report we now have the protocol and instrumentation to measure the above factors. In order to test the use of these factors in identifying the reasons for better physiologic suspension we compared two patients, demonstrating different degrees of physiologic suspension (see Table 1).

Discussion

From Table I it is apparent that, RM's suspension performance was clearly superior to that of BH. RM developed higher traction forces for a given socket displacement on the testing device, demonstrated less socket displacement while walking without auxiliary suspension and appeared more confident in his gait. This finding was somewhat of a surprise, since BH shows greater stump expansion and a larger stump, which should aid suspension. Observation revealed that the displacement was taking place in the soft tissues without skin-socket movement. Thus, suspension is not necessarily dependent only on lack of slippage at the interface. Longitudinal skin mobility was 3 cm for BH compared to only 1.5 cm for RM, indicating that some of the difference could be accounted for by motions occurring within the skin envelope. These results show that socket retention is affected by other factors in addition to contouring and interference fit. BH had a better interference fit factor but a lower contour factor and greater skin mobility—the net result of which was a greater axial movement of the bone and muscle tissues inside the skin. Better contouring may be the best way to compensate for excessive skin mobility.

The foregoing analysis demonstrates the way in which some of the stump-

socket factors can be used in comparing suspension performance. We feel that the ideal socket for any specific patient should take into account all of these factors. We think surgical contouring of the musculature during amputation, and socket fabrication techniques which take into account the above factor, are the most significant steps toward improving below-knee physiologic suspension.

Several new directions have emerged as a result of our studies. The first is the use of the load displacement testing device as a clinic measuring tool to follow axial suspension performance of amputees, especially during the post-operative period. This would be used until a stable situation was achieved or over a longer period of time if patients have suspension problems. Secondly, this device could be used for training amputees to "grasp" their sockets isometrically. The device would not only help the patient develop maximum muscle contraction and gripping of the socket, but would also serve as a record for comparison if socket adjustments are made.

Summary

This study, so far, has attempted to identify the major factors contributing to physiologic suspension. We have developed methods for quantifying these factors in individual patients. As a result, we are now able to compare suspension performances over time and with socket modifications on the same patient or between a series of below-knee amputees. We have found that socket shape (sockets made upon relaxed vs. contracted stumps) can make a substantial difference in the degree of suspension performance. Sockets made upon contracted stumps do not suspend as well as those made upon relaxed stumps, indicating to us that an ideal balance must exist between stump contour and expansion factors. The combination of all stump-socket factors present determines the ideal socket shape. Future directions will include enhancing the contour of the stump surgically, below-knee amputee suspension training during the postoperative period using the load-displacement testing device, and development of socket fabrication techniques which will complement positive suspension factors already present in the stump.

A Grommet Bone Liner for Flexible Implant Arthroplasty

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Alfred B. Swanson, M.D.

History

Since 1962, Dr. Swanson has designed, tested, and used flexible silicone implants for small joint replacement. These implants have been used in treating destroyed joints within the hand, wrist, elbow, and foot. The flexible implant resection arthroplasty method allows nature to build a new joint through a concept in which the implant acts as a dynamic spacer. This spacer maintains the internal alignment and spacing of the joint while supporting the capsuloligamentous system that develops around the implant.

However, with some types of silicone implants surgeons have experienced a small percentage of fractures to the silicone implants. It is theorized that sharp bone edges can lacerate the abutting silicone material, which can eventually lead to tear propagation and implant failure. A current review indicates an approximate failure rate of 4 percent.

The flexible implant arthroplasty has been judged to be a very successful, efficacious, safe, and when necessary, salvageable method of reconstruction of the small arthritic joint. For that reason, this research project is aimed at the development of a protective grommet to be used to eliminate the cutting and eventual tearing of the silicone implant.

Materials

Over the last two years, test results have caused a grommet evolution with respect to material composition, configuration, bioadhesive, and biocompatibility properties. Six different designs of grommets have been tested:

1. A self-fabricated grommet of Proplast, a polytetrafluoroethylene and carbon fiber composite, exhibited an 80 percent porosity with pore size averaging about 200 microns (Fig. 1);

2. A molded high density polyethylene grommet yielded a material with pore size ranging approximately from 100 to 135 microns (Fig. 2);

3. Testing was also done on a nonporous molded grommet of pyrolytic carbon (Fig.3);

4. NASA Lewis Research Center provided a fabricated type 316 stainless steel grommet with an ion diffusion bonded screen surface (Fig. 4).

Dow Corning, in conjunction with Davis Laboratories and NASA, have provided the final two grommet types.

5. A full grommet (Fig. 5), cast molded of cobalt and chromium (Co-Cr) alloy, and

6. A half grommet or shim (Fig. 6) of the same alloy.

These two latter types have both been textured by the use of an ion sputtering technique, innovated by NASA. This provides a surface which may be conducive to bioadhesion (Fig. 7).

Surgical Implantation

The surgical implantation procedures are performed within the Veterinary Clinical Center, Michigan State University, by Dr. James A. McGehee. The stifle arthroplasties and implantations are done on mature Dutch White rabbits. As of Dec. 31, 1980, 138 individual grommets (4 Proplast, 55 carbon Pyrolyte, 26 polyethylene, 13 type 316 stainless steel bonded screen, 20 Co-Cr textured full, and 20 Co-Cr textured shim), have been surgically implanted in 73 separate procedures (Table 1). In addition, 16 flexible Silastic joints only, as controls, have been implanted in 16 separate procedures.

Sample Harvesting

Sample harvesting has been performed at varying time increments up to a year postimplantation for the first four grommet types. For the final study of the controls, Co-Cr full grommet, and the Co-Cr shim, harvesting and testing will be done at 8, 16, and 24 weeks postimplantation (Table 2).

Grommet Evolution

The self-fabricated Proplast grommets proved to be unsatisfactory in their handleability and manipulative qualities. A slight infection rate in humans was reported by Dr. Swanson. The use of this material is being reviewed.

The porous high-density polyethylene grommet became extremely malleable when immersed in tissue fluids. Corners of the protective flanges were

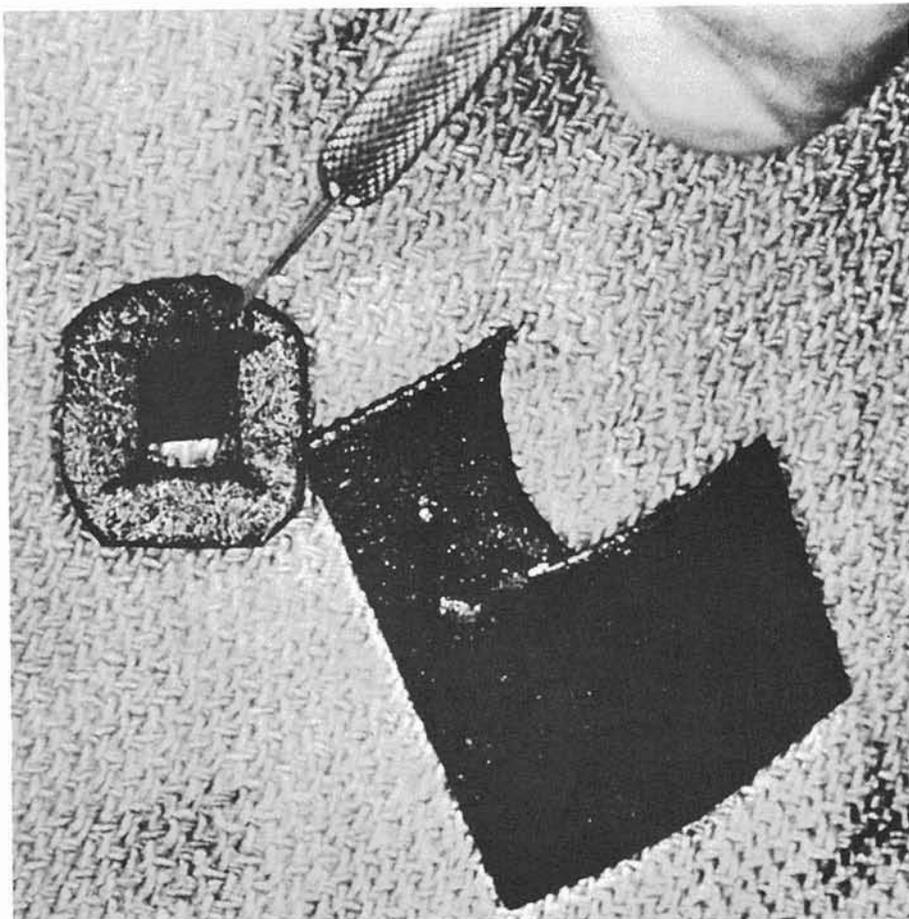


FIGURE 1.
Self prepared grommet of Proplast® material.

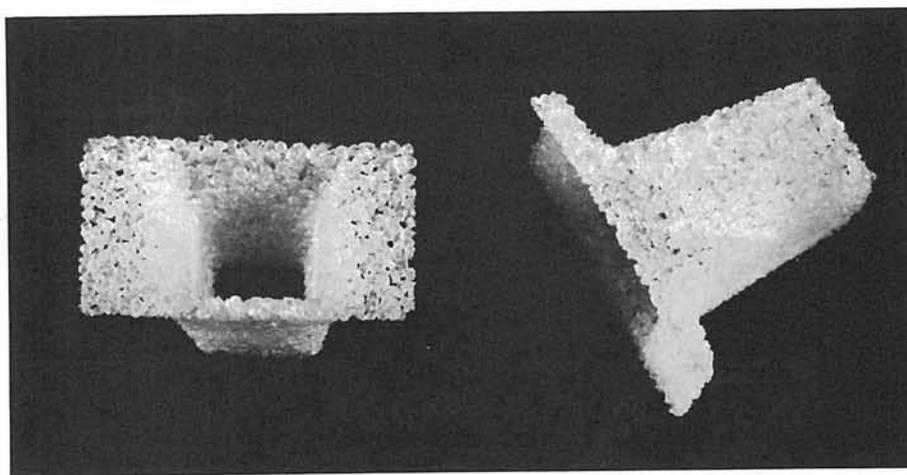


FIGURE 2.
Molded high density porous polyethylene grommet.

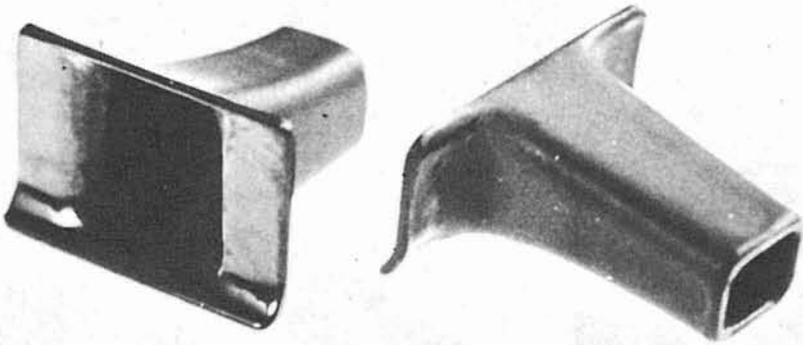


FIGURE 3.
Molded non-porous carbon pyrolytic carbon grommet.

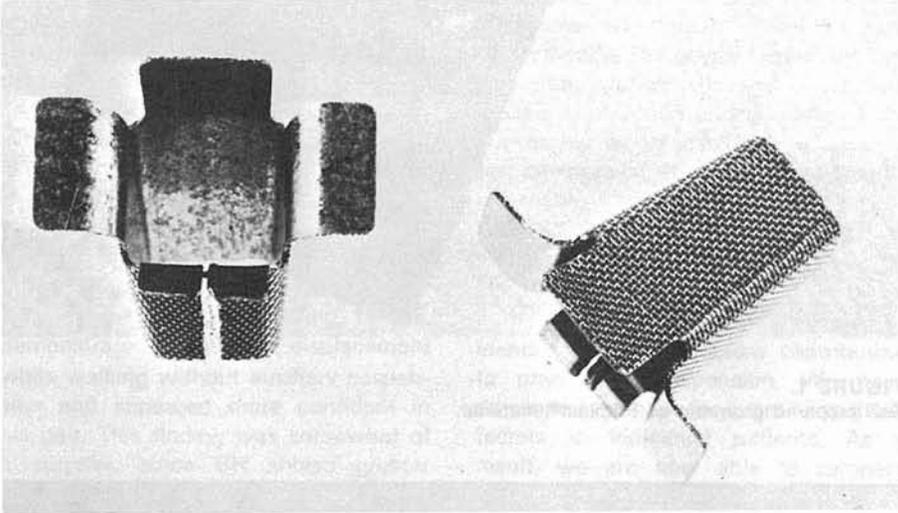


FIGURE 4.
NASA fabricated 316 stainless steel grommet with diffusion bonded screen surface.

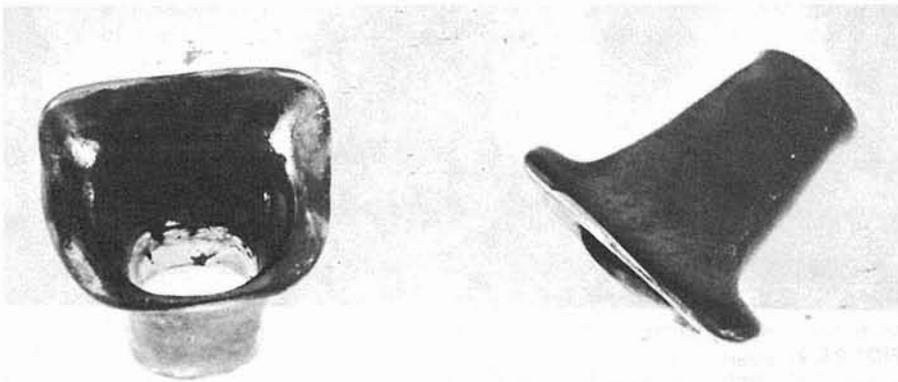


FIGURE 5. Dow Corning molded alloy grommet.

prone to fracture. Upon harvesting, several free-floating pieces of the flange were actually found within the joint. Histological examinations at 8 and 11 weeks postimplantation showed that collagen fibers had penetrated through the entire wall of the grommet, suggesting adequate anchorage. Trabecular bone was also observed beginning to penetrate the pores of the grommet. Samples harvested 6 and 12 months postimplantation will be submitted to the histopathology laboratory for examination in Jan. 1981. In biomechanical tests a 7.5-lb test pull-out load was applied before there was failure between the clamp device and the grommet. The limited structural strength of this porous material may prohibit any further testing at increased loads.

The pyrolytic carbon grommets, although very nice to handle surgically during implantation, proved to have poor durability. Almost every sample harvested has shown multiple fractures of the grommet flange and shaft, with many free-floating fragments within the joint. The sharp edges of the remaining grommets easily cause cutting of the silicone implant (Fig. 8). Recently, histology has been able to embed the bone samples, with the grommet in place, in plastic. Thin slices were then made with a circular saw blade yielding a full cross-section of the bone and grommet in place. Carborundum paper was used to grind down the section for the light microscope. Histologically, at 6 months postimplantation, trabecular bone was identified in close proximity (300 microns) to the carbon grommet with a layer of fibrous connective tissue sandwiched in between. Grommet samples 12 months post-implantation will be submitted to histopathology in Jan. 1981. Biomechanically, the majority of the carbon grommets exceeded the 10-lb. pull-out load originally deemed satisfactory. Several tests exceeded 30-lb., and actually represented a grommet-to-clamp failure rather than a pull-out failure.

The 316 stainless steel, with the bonded screen, had satisfactory handleability. The thin material made it rather malleable. All samples harvested showed deformation of the malleable flanges with subsequent cutting of the silicone implant. Fragments of screen, disassociated from the main grommet,

were found free-floating within the joint in all samples harvested. One sample, 5 months postimplantation, was submitted to histopathology to be prepared with the grommet in place as was done with the carbon Pyrolyte grommet. Biomechanically, the tests exceeded the 10-lb pull-out load and represented a clamp-to-grommet failure rather than a disassociation of the grommet from the bone.

The Co-Cr full grommet had satisfactory handleability during the surgical implantation. Like the other full grommets, however, it does require a large amount of bone stock to be removed to accommodate the grommet shaft. Samples will be submitted to both histopathology and biomechanics for processing as previously described.

The Co-Cr shim grommet showed a real advantage during implantation. The veterinary surgeon was able to step the removal of the bone stock to accommodate the grommet and Silastic implant individually (Fig. 9). A significantly increased amount of bone stock remained after implantation because of the smaller size of the shim (Fig. 10). The Department of Biomechanics at Michigan State University is now developing a method of testing pull-out strength for the new configuration of

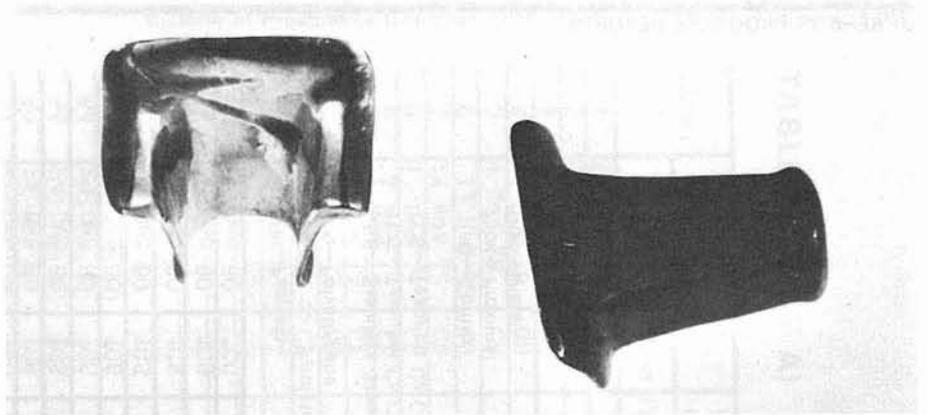


FIGURE 6. Half grommet or shim of alloy.

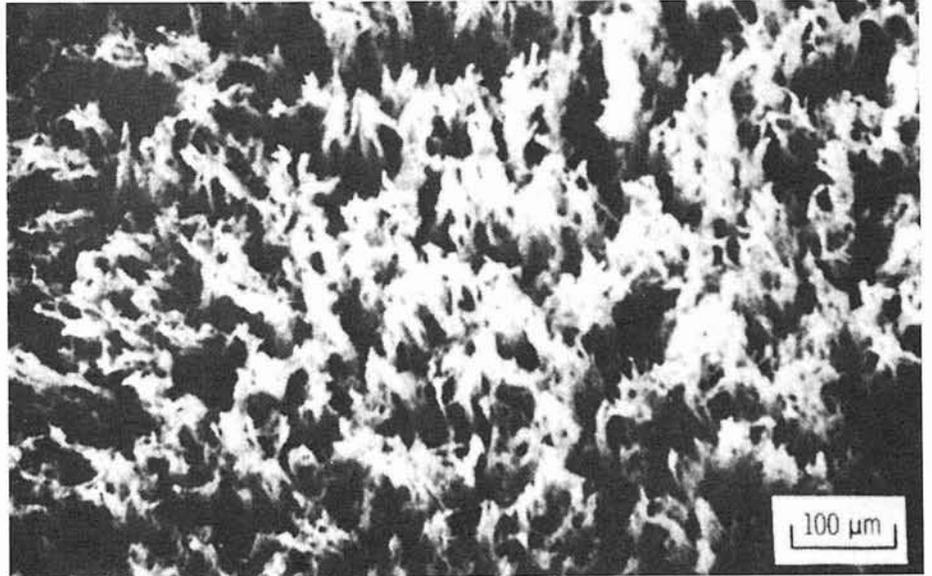
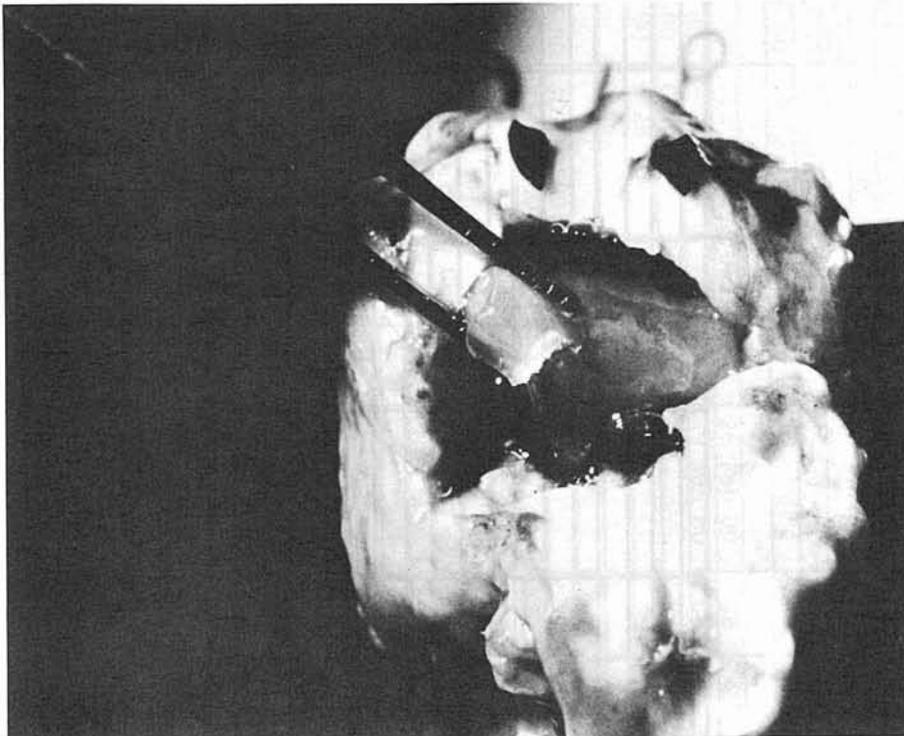


FIGURE 7. Microscopic view of NASA ion sputtered surface.



the shim. Histopathology will receive samples for processing in an effort to demonstrate a bone-to-grommet interface and in-growth.

The development of the ideal grommet should offer new hope to patients with thin bone stock to have the advantage of a durable implant arthroplasty.

NOTE: Following pages contain Figures 9 and 10, and Tables 1 and 2.

FIGURE 8. Silicone implant which has been cut by pyrolytic carbon sharp edge of broken grommet.

TABLE 1 (PART B)

RABBIT #	Rt. Stifle Surgery		Number of Grommets		Lt. Stifle Surgery		Number of Grommets		Proposed EUTHANASIA	Actual EUTHANASIA	Samples Submitted to Biomechanics			Samples Submitted to Histopathology		
	Date	Type	Prox	Dist	Date	Type	Prox	Dist	DATE	DATE	Date	Type	#	Date	Type	#
41	26 Aug 80	C			20 Oct 80	C			4 May 81							
42	17 Nov 80	TCG	1	1					4 May 81							
43	22 Dec 80	TCG	1	1					8 Jun 81							
44	22 Dec 80	TCG	1	1					8 Jun 81							
45	22 Dec 80	TCG	1	1					13 Apr 81							
46	22 Dec 80	TCG	1	1					13 Apr 81							
47	23 Dec 80	TCG	1	1					14 Apr 81							
48	23 Dec 80	TCG	1	1					14 Apr 81							
49	24 Dec 80	TCS	1	1					10 Jun 81							
50	24 Dec 80	TCS	1	1					10 Jun 81							
51	29 Dec 80	TCS	1	1					15 Jun 81							
52	24 Dec 80	TCS	1	1					10 Jun 81							
53	24 Dec 80	TCS	1	1					DIED 25 DEC 80							
54	29 Dec 80	TCS	1	1					20 Apr 81							
55	29 Dec 80	TCS	1	1					20 Apr 81							
56	30 Dec 80	TCS	1	1					21 Apr 81							
57	30 Dec 80	TCS	1	1					21 Apr 81							
58	30 Dec 80	TCS	1	1					21 Apr 81							
59	30 Dec 80	TCG	1	1					21 Apr 81							

Symbol key: PP—Proplast
 CB—Carbon Pyrolyte
 PY—Polyethylene

SSS—Stainless Steel & Screen
 TCG—Textured Co-Cr Grommet
 TCS—Textured Co-Cr Shim

C—Control
 Prox—Proximal
 Dist—Distal

TABLE 1 (PART A)

RABBIT #	Rt. Stifle Surgery		Number of Grommets		Lt. Stifle Surgery		Number of Grommets		Proposed EUTHANASIA DATE	Actual EUTHANASIA DATE	Samples Submitted to Biomechanics			Samples Submitted to Histopathology		
	Date	Type	Prox	Dist	Date	Type	Prox	Dist			Date	Type	#	Date	Type	#
1	24 Oct 79	CB	1	1						DIED 28 OCT 79						
2	24 Oct 79	PP	1	1	16 Jan 80	PP	1	1								
3	24 Oct 79	CB	1	1	21 Nov 79	CB	1	1		10 Jan 80	10 Jan 80	CB	4			
4	24 Oct 79	CB	1	1	21 Nov 79	CB	1	1		16 Jan 80	16 Jan 80	CB	4			
5	4 Nov 79	CB	1	1	9 Jan 80	CB	1	1		6 Feb 80	6 Feb 80	CB	4			
6	13 Nov 79	CB	1	1	11 Jan 80	CB	1	1		7 May 80	7 May 80	CB	4			
7	14 Nov 79	CB	1	1	17 Dec 79	CB	1	1								
8	7 Dec 79	CB	1	1	9 Jan 80	CB	1	1		28 Feb 80	28 Feb 80	CB	4			
9	7 Dec 79	PY	1	1	11 Jan 80	PY	1	1	DIED 24 JAN 80		24 Jan 80	PY	2			
10	8 Dec 79	PY	1	1	16 Jan 80	PY	1	1		22 Feb 80				22 Feb 80	PY	4
11	8 Dec 79	CB	1	1	14 Jan 80	CB	1	1		13 Feb 80	13 Feb 80	CB	4			
12	28 Jan 80	CB	1	1	26 Feb 80	CB	1	1		2 Apr 80	2 Apr 80	CB	4			
13	8 Feb 80	PY	1	1	10 Mar 80	PY	1	1								
14	29 Jan 80	CB	1	1					DIED 26 FEB 80					26 Feb 80	CB	2
15	30 Jan 80	CB	1	1	25 Feb 80	CB	1	1		19 Jun 80				19 Jun 80	CB	4
16	1 Feb 80	CB	1	1	10 Mar 80	CB	1	1		6 Aug 80	6 Aug 80	CB	4			
17	1 Feb 80	CB	1	1	10 Mar 80	CB	1	1		6 Aug 80	6 Aug 80	CB	4			
18	6 Feb 80	PY	1	1	11 Mar 80	PY	1	1								
19	29 Jan 80	SSS	1	1	6 Feb 80	PY	1	1								
20	29 Feb 80	SSS	1	1	9 May 80	SSS	1	1		10 Jul 80	10 Jul 80	SSS	4			
21	29 Feb 80	SSS	1	1	9 May 80	CB	1	1		11 Jun 80	11 Jun 80	SSS	3			
22	14 Mar 80	SSS	1	1	9 May 80	CB		1								
23	16 May 80	CB		1					DIED 18 MAY 80							
24	24 May 80	CB	1		11 Jun 80	CB		1	DIED 13 JUN 80		13 Jun 80	CB	1			
25	16 Jun 80	PY	1	1	1 Jul 80	PY	1	1								
26	18 Jun 80	PY	1	1												
27	8 Jul 80	SSS	1							28 Aug 80	28 Aug 80	SSS	1			
28	11 Jul 80	SSS	1													
29	15 Jul 80	SSS	1													
30	14 Jul 80	SSS	1													
31	15 Jul 80	SSS	1													
32	15 Jul 80	SSS	1													
33	17 Nov 80	TCG	1	1	9 Jan 81	TCG	1	1								
34	14 Aug 80	C			22 Sep 80	C				1 Dec 80	1 Dec 80	C	2			
35	20 Aug 80	C			7 Oct 80	C				3 Dec 80	3 Dec 80	C	2			
36	12 Aug 80	C			29 Sep 80	C				1 Dec 80	1 Dec 80	C	2			
37	13 Aug 80	C			29 Sep 80	C				3 Dec 80				3 Dec 80	C	2
38	20 Aug 80	C			6 Nov 80	C			4 Feb 81							
39	25 Aug 80	C			6 Nov 80	C			9 Feb 81							
40	25 Aug 80	C			20 Oct 80	C			9 Feb 81							

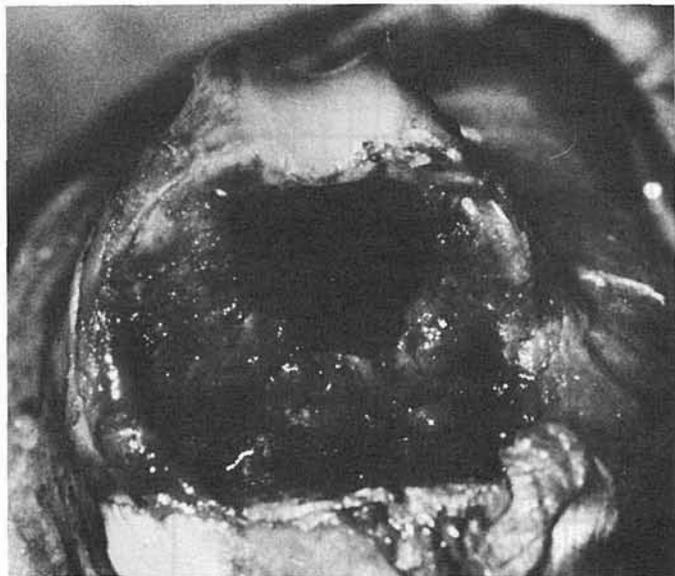


FIGURE 9.
Stepped removal of bone stock in a joint to receive the shim.

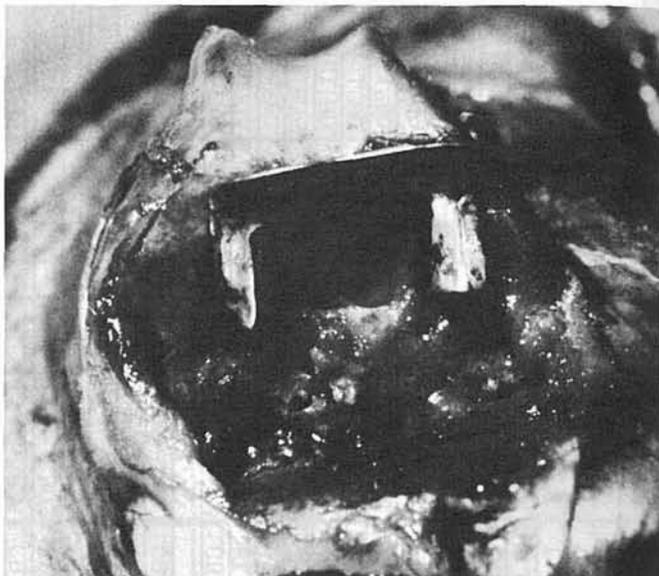


FIGURE 10.
The shim seated in the bone, ready to receive the silicone implant.

TABLE 2

DISTRIBUTION OF SAMPLES FOR EVALUATION

PROCEDURE	POST IMPLANT EVALUATION PERIOD		
	8 WEEKS	16 WEEKS	24 WEEKS
CONTROLS	4	8	4
GROMMETS	8	16	8
SHIMS	8	16	8
GROMMETS TO HISTOLOGY	2	4	2
GROMMETS TO BIOMECHANICS	6	12	6
SHIMS TO HISTOLOGY	2	4	2
SHIMS TO BIOMECHANICS	6	12	6

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

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Wendell Williams, Ph. D.

To date in this project, work has been completed on implantation of Teletronics Bone Growth Stimulation® in thirteen dogs. The purpose of this pilot experiment has been to assess the effect of these d.c. current stimulators on healing of a standard 1.6-cm defect in the distal ulna. In one type of experiment, the 1.6-cm segment of bone is removed from the site; in another type the bone segment is replaced as a bone graft. In each case, one side of the animal serves as a control with a dummy stimulator and

grafts; on the other side an active stimulator is employed with a negative electrode wire running through the defect.

In the first four dogs, wires leading from the stimulator broke because adequate protection was not provided as they crossed the elbow joint from the stimulator implantation site to the stimulation site. After modifications to suit these mechanical demands, no further difficulties were encountered and all stimulators functioned satisfactorily throughout the 8-week implantation period. In all 13 dogs, the stimulators and electrodes were well tolerated and there were no surgical complications (with the exception of one low-grade infection) in the 26 forelimbs involved. Qualitative radiographic and histological assessment of results is now complete and results will be reported at a later date.

In addition, preliminary work is in progress on the second and major phase of the project involving an assessment of the effect of certain piezoelectric materials on the incorporation of the bone transplants in the distal ulna. The necessary implants have been fabricated and initial trials in dogs successfully completed. Results of the work with the d.c. current stimulators will be utilized as a basis for the comparison for effects of the piezoelectric implants.

Evaluation of

Electrical Techniques for Stimulation of Hard Tissue Growth

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Spadaro, Ph. D., and Andrew A.
Marino, Ph. D.

Special Note—This is the final report of this project, since funding is expected to be discontinued in early 1981. With the retirement, in June 1980, of Dr. Robert Becker from the clinical service, Dwight A. Webster, M.D., has served as director of the clinical phases of the program. The other members of the Orthopedic Research Laboratory affected are: Andrew A. Marino, Ph. D., Joseph A. Spadaro, Ph. D., Sharon E. Chapin-Chase, B.S., Maria Reichmanis, Ph. D., and Dawn Doviak, MLT. We are

proud of the innovative contributions of this laboratory to orthopedic research, bioelectricity, and regeneration, which have resulted in over 150 publications and international recognition.

Electrical Osteogenesis—Clinical Study

To date 31 patients have been treated for non-union using the low-current silver electrode (cathode) implant. A publication is being prepared to summarize our experience with this method. Final evaluation will be made using functional and radiological evidence with the assistance of members of the Department of Radiology, State University of N.Y.

Electrical Osteogenesis—Laboratory Studies

A preliminary study of the efficacy of various cathodes for stimulating bone growth has been completed and a manuscript is being prepared. Indications are that a change in operating current on these electrodes changes the relative amount of osteogenic response. Stainless steel electrodes seem to be active at higher currents and platinum at lower currents, for example. A more extensive study of the influence of the electrode and its operating conditions (current, potential) is needed, to learn more about the bone stimulation process.

The rabbit medullary model, which has been used for this study, seems to be a good one. It is straightforward, reproducible and quantifiable. In this model, an electrode is introduced into a long bone via a small drill hole near the metaphysis and advanced into the medullary canal. Surgical injury and spontaneous reaction to it are minimized, and new bone growth is readily observed in histological cross sections of the bone at sacrifice [BPR 10-32, pg 359 (1979)]. A final report is in preparation (J.A. Spadaro, R.O. Becker).

Another preliminary study, which will be completed shortly, was designed to test the effect of Teflon electrets on stimulating osteogenesis on the periosteal surface of the long bones of the rat. An electret is an insulating material which has been heated and cooled in a strong electric field and which maintains a polarized charge within it. An implanted electret will leak this charge slowly to the electrolyte, resulting in a weak electric current. It has

been reported by Suzuki et al. in Japan that such electrets can be osteogenic. A report of this experiment will be prepared for publication in the near future (A.A. Marino, D.A. Webster).

A third study has been completed in which silver-platinum bimetallic current sources have been tested for their competence in stimulating osteogenesis, again using the rabbit medullary canal model. These devices, which are small and relatively inexpensive, do not require an external or implanted power source and only function when actually implanted. In this initial experiment, several variations of these devices were implanted in rabbit femora and tibiae for 3 weeks with sham controls in the contralateral limbs in each case (36 implants in all). Results from histological analysis showed small rings of bone around the active units in 60 percent of cases, and around controls (no bimetallic current) in 17 percent. The results suggest that development of this concept may be fruitful. The implications for possible electronic and electrochemical mechanisms as playing important roles in electrical osteogenesis may even be more important, since these are, so far, the lowest-current devices known to stimulate bone growth. A report of this experiment is being given at the annual meeting of the Orthopedic Research Society in February, 1981 (J.A. Spadaro).

Use of Silver in the Treatment of Chronic Osteomyelitis—Clinical Study

Due to the decision to discontinue funding, this study will terminate and development of this clinical tool will be retarded. The method, developed in this laboratory, involves the application of anodically charged silver-coated mesh to the infected bone and surrounding tissue following surgical debridement and during the healing process. The method offers the possibility of salvaging a limb for many patients after traditional techniques have failed. It appears to provide an alternative for the treatment of stubborn bone infections without extensive use of system antibiotics, caustic germicidal agents, or troublesome suction-irrigation procedures.

To date, 36 patients have been treated and a report on the first 25 is in press in *Clinical Orthopedics and Related Research*. A scientific exhibit on this subject has also been accepted

and will be shown at the annual meeting of the American Academy of Orthopaedic Surgeons in February/March, 1981. (D.A. Webster, J.A. Spadaro, R.O. Becker and S.E. Chapin).

Laboratory Studies on Silver

An experiment has been conducted to study the effect of silver in vitro on demineralized bone morphogenetic matrix (BMP bone). The BMP material, prepared according to Urist, induces bone growth when implanted in muscle in animals. The biological process involves the transformation of non-osseous tissue into bone in and around the implant. We have found, so far, that exposure of this material to moderate-to-high concentrations of silver salts in aqueous solution seems to impede the induction process as measured by the amount of mineralization (by ashing). A report is being prepared for publication (J.A. Spadaro, D.A. Webster and S. Kramer).

Some work has already been completed in relating the electrochemistry of silver electrodes to their antibacterial qualities. In particular, the inhibitory effects at such electrodes is relatively independent of current level, but sharply dependent on electrode potential. Further studies seem warranted in view of the clinical usefulness that has been observed. A report on this will be given at the Annual Meeting of the Society for Biomaterials in Troy, N.Y. in May, 1981 (J.A. Spadaro).

Foot Biomechanics: Force and Pressure Distribution in Health and Disease

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Reginald R. Cooper, M.D.

A modeling study of the stress distribution on the plantar aspect of the foot has been completed. This study involved the finite element representation of the foot and shoe incorporating aspects of the bones of the foot, thick plantar aspect skin, and shoe sole material. The prediction of stress within the skin was performed during a variety of foot loading conditions and shoe sole elastic properties. Optimal shoe sole elastic properties, i.e., shoe soles that minimize stresses within the skin, were explored. A Master's Degree thesis has been completed on this subject and the

material has been presented before the American Society of Biomechanics. A manuscript on this subject has been accepted for publication by the Bulletin of Prosthetics Research.

A study of force distribution during weightbearing on the equinovarus foot has been concluded. That study attempted to correlate the characteristics of the path of the resultant force on the foot through gait with the clinical rating of the foot. The path of the resultant force on the foot during gait was clearly abnormal. The nature of this abnormality did not correlate with the clinical rating of the patient.

An undergraduate engineering student is now calibrating a glass plate measuring system. This device provides photographic images of weightbearing on the sole of the foot. We plan to use this on patients with various foot disorders.

Studies of Normal and Abnormal Motion

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Mary Patricia Murray, Ph. D.

One of our major areas of emphasis continues to be the quantitative evaluation of multiple components of functional performance in patients with arthritis, before and at multiple intervals after various types of total hip and knee joint replacements. These evaluations include not only data on locomotion, but also measurements of strength of muscles spanning the diseased joint, forces applied to canes or crutches during walking, weight distribution between the feet during quiet standing, and range of joint motion.

We are pleased to report that the manuscripts of two of our total hip replacement studies were completed during the period covered by this report. We finished a 4-year followup of 72 cases with Müller and Charnley replacement (1) and we finished a comparative study of the function of patients with and without trochanteric osteotomy in Müller hip replacement (2). Results of these studies will be summarized in a future issue of BPR after these studies are published.

In a separate study, we incorporated electromyography and the use of our force plate for monitoring ground reac-

tions into the gait evaluation of a patient with painful unilateral hip arthropathy. The kinematic, ground reaction, and cane force data of the patient were sent to Dr. Seireg, a co-investigator at the University of Wisconsin-Madison, who developed a unique mathematical model for estimating muscle forces and joint reactions in the lower extremities of the musculoskeletal system during various dynamic activities. Dr. Seireg used his model with a comprehensive interactive computing / graphical display technique to investigate the extent to which joint reaction forces are reduced from normal by the use of pain-avoidance maneuvers or use of a cane during walking (3). The vertical hip joint load of a normal man of 77 kg (the same weight as that of the patient) walking under normal conditions, was estimated at 240 kg. The patient's typical gait was characterized by, among other things, a marked lateral lurch toward the painful side during the stance phase on the painful side when he walked without support. With his antalgic maneuvers, his vertical hip joint load was calculated to be 107 kg. Using a cane in the hand on the side of the painful hip had no effect on further reducing the hip joint load (105 kg). In contrast, use of a cane in the hand opposite the side of the pain was calculated to reduce the hip joint load to 86 kg. The EMG data obtained from the major muscle groups of the lower limb during walking was in agreement with the model's predicted muscle load sharing.

The Fall 1980 issue of BPR contained a study of the gait patterns of 10 above-knee amputees walking with prostheses with constant-friction knee components (4).

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4. Murray MP, Sepic SB, Gardner GM, Mollinger LA: Gait Patterns of Above-Knee Amputees Using Constant-Friction Knee Components. Bull Pros Res, BPR 10-34, 17(2):35-45, Fall 1980.

Quantitative Analysis of the Effect of Total Hip Arthroplasty on Stress and Strain in the Human Pelvis

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The objectives of the proposed research are to quantitatively evaluate the effect of different techniques for implantation of acetabular components of total hip prostheses on the strain and stress patterns of the human pelvis. Paired cadaver pelvises will be used to determine these effects. Each pelvis will be instrumented with strain gages and loaded through its femur to determine the strain pattern prior to surgical treatment of the acetabulum. The acetabular component will then be implanted using one of several different techniques, loaded through a femoral component, and the strain pattern again measured. This will allow objective evaluation of the effect of various techniques for implanting a prosthetic acetabulum in the bony pelvis on the strain pattern in the human pelvis.

Funding for this project was received in November, 1980. We have ordered the appropriate materials to begin the research and are presently planning the early development of the project, but no experimental work has been accomplished to date.

Microsurgical Techniques Applied to Orthopaedic and Hand Surgery

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We continue to apply microsurgical techniques to our experimental models of vein graft patency in rats and the new model of the vascularized ulna. During the past several months we

have completed two projects which will be described.

We have investigated the adverse effect of redundancy, tension, and motion on interposed vein grafts. We are aware that functional results after replantation surgery at no man's land could be improved by early finger motion. However, we have been concerned about motion with resultant tension on vessel patency. This study was designed to provide information about the effect of early motion, tension, and vessel redundancy on vessel patency in one millimeter diameter interposed vein grafts in rats. We use the ipsilateral epigastric vein as a graft source and interpose it into the femoral artery. The anastomosis of each end of the vein graft was accomplished using a 10 suture technique of 10-0 Ethilon on a BV-7 needle. An Ackland frame was used for stabilization of the vessel.

There were 5 groups of animals with 10 animals per group. Group 1 had a 2-cm vein graft with no excision of the recipient femoral artery. Group 2 had a 1-cm vein graft with no excision of the artery. Groups 3 through 5 had a 1-cm vein graft with excision of 1, 1.25, and 1.5 cm of femoral artery, respectively.

The animals were re-explored at 14 days and vessel patency was verified as well as observations regarding aneurysm formation and vessel kinking. The immediate patency was 100 percent in all groups studied. The 2 week patency results for Groups 1 through 5 was 80, 100, 90, 83, and 70 percent, respectively. A linear increase in aneurysm formation was noted and was directly proportional to the vein graft tension. From the results of our study, it appears that mild redundancy is preferable in microvascular anastomoses of vein grafts because of the late patency rate and low incidence of aneurysm formation. Increasing tension in vein graft anastomosis appears to have a linear adverse effect on both vessel patency and aneurysm formation in our experimental model.

We have initiated a pilot study of vascularized canine forelimb ulnar transplants in 19 dogs. We do have some preliminary data to report which demonstrates our technical ability to perform this difficult experiment. To date we have removed 4 cm of ulna with its vascular pedicle and returned the ulna to its tissue bed after cutting its pedicle artery and vein. These vessels have

been reanastomosed using microsurgical technique. Each dog has acted as its own control as we have performed the same procedure on the contralateral ulna without reanastomosis of the vascular pedicle. All 19 vascularized ulnas have bled following release of the vascular clamp. We have re-explored the 19 dogs according to the following schedule: 4 at one week, 5 at 6 weeks, 4 at 3 months, and 6 at 6 months. The vascular pedicle has remained patent in greater than 75 percent of the dogs. We have submitted a grant proposal to permit us to expand this research project over the next 3 years by studying the biological nature of the vascularized graft as well as its mechanical characteristics.

Analysis of Wear Particles in Human and Arthroplastic Joints

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As described in previous reports, a technique called Ferrography has been adapted for the analysis of wear debris found in human joints. Wear particles are retrieved from synovial fluid aspirates, magnetized, and then separated under the influence of a strong, highly divergent, external magnetic field. The resultant Ferrogram can then be examined by a variety of microscopic techniques. A number of different types of wear particles have been identified by this method.

In recent studies, Ferrograms have been made from saline washings of knee joints which had been examined by arthroscopy. Arthroscopic examination yields the kind of detailed information necessary for a thorough characterization and evaluation of the Ferrographic analysis. In particular, it is highly sensitive to changes in the articulating surfaces and the surrounding intra-articular tissues. Concentrating on this group of patients has the further advantage of restricting the number of variables in the system; only one joint, the knee, is studied and the range of

different abnormalities is limited. So far, 35 such samples have been examined.

A preliminary comparison of the arthroscopic examination and the corresponding Ferrographic analyses reveals that Ferrography is at least as sensitive as arthroscopy in detecting damage to the articular surfaces. In four cases, arthroscopy revealed no damage to the articular surfaces, and few particles were retrieved on the Ferrograms. Progressively more severe articular destruction produced more numerous particles of larger size and altered morphology, including fibres. Fibres seem to be more prevalent with meniscal and patellar degeneration than with erosion of the articular cartilage.

Continuing our studies of the cellular reactions to wear particles, we have established the following. Wear particles provoke the release from macrophages and synovial cells of neutral proteinases having the capacity to degrade cartilage. The particles need not necessarily be internalized by the cells to produce this effect. Chemical as well as physical stimuli are involved in this response. Chondroitin sulphate, a component of cartilage, when added to cultures of macrophages at concentrations ranging from 5-500 μ M, greatly enhances the release of both neutral and acidic lysosomal hydrolases.

Foreign Body Reaction in the Lung to Intravenously Injected Biomaterials

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Work during this period has been aimed at defining the role of surface area in granuloma formation in response to the presence of divinyl copolymer beads (Biobeads SX-8) in the lung.

The beads used in this study range in size from 30 to 70 μ m in diameter with a mean diameter of 44 μ m. Four size populations of beads (Schoen et al., 1980; Fitzgerald et al., 1981) were

used: the whole population (30 to 70 μ m) defined as the Standard Bead Model; and three sieved populations, small (30 to 45 μ m), medium (45 to 53 μ m) and large (53 to 70 μ m). 10,000 beads (gas sterilized) contained in 0.5 ml of saline are injected into the tail vein of female Swiss albino mice weighing approximately 30 g. The beads embolize to the lungs where granulomas are formed around the beads which lodge in the arterioles. The basic model with the plastic divinyl beads was developed by von Lichtenberg (1962), and by Kellermeyer and Warren (1970).

The purpose of these experiments for the last 6 months has been to determine the effect of surface area on the rate

and extent of granuloma formation in the foreign body response in mouse lung.

Figure 1 is a scanning electron micrograph of the whole population of copolymer beads used previously in the Standard Bead Model (30 to 70 μ m). The mean diameter of this population is 44 μ m as shown in the histogram in Figure 2.

Figure 3 is a scanning electron micrograph of the small population of beads (30 to 45 μ m) with a mean (Fig. 4) of 37 μ m. Similarly, Figure 5 is a scanning electron micrograph of the larger beads (53 to 70 μ m) which have a mean diameter of 52 μ m (Fig. 6). The smaller mean diameter is due to a few of the smaller beads being retained

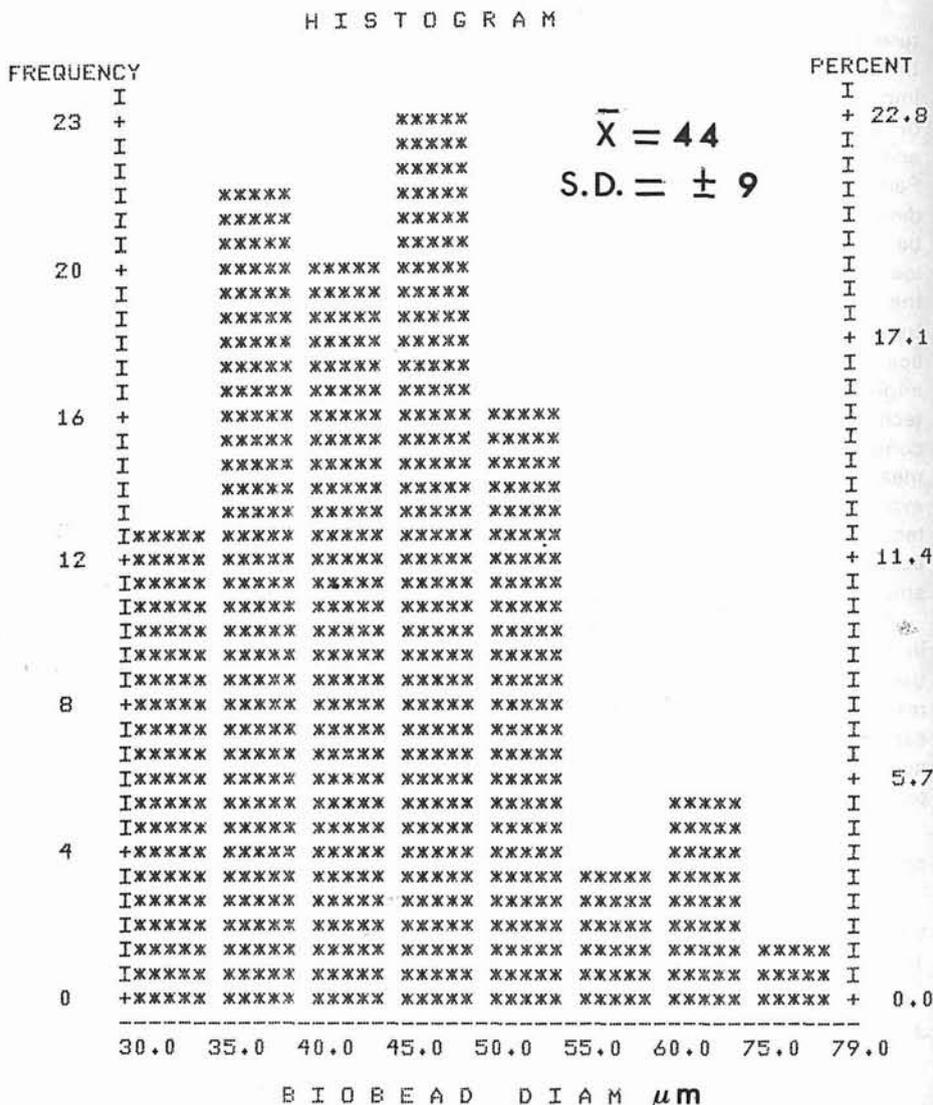


FIGURE 2.

Computer-derived histogram of the size distribution of the divinyl copolymer beads used in the Standard Bead Model (30-70 μ m).

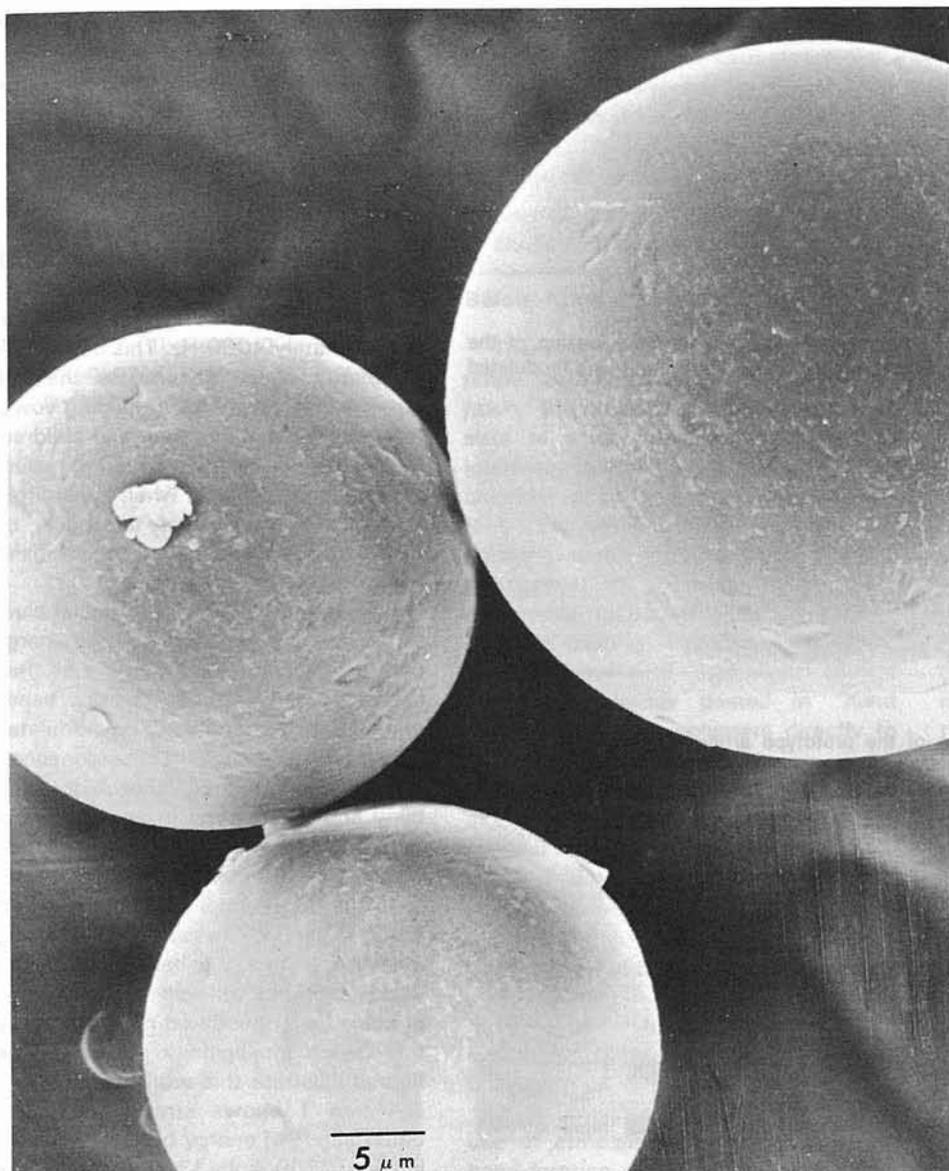
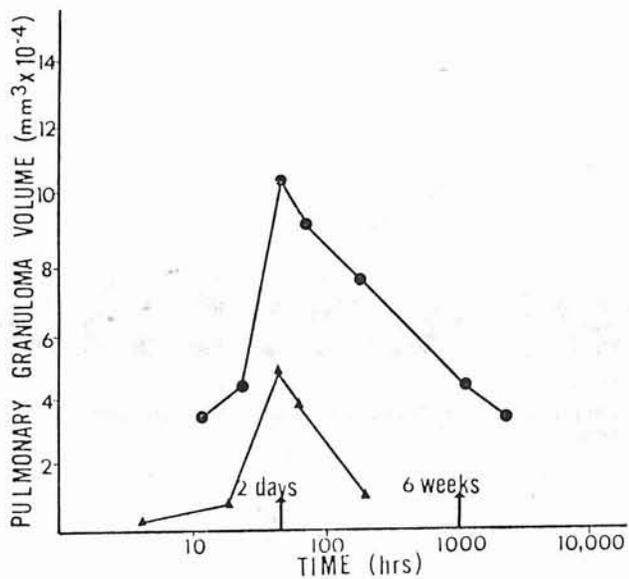


FIGURE 5. Scanning electron micrograph of large, sieved (53–70 μm) divinyl copolymer beads.

FIGURE 7.

Comparison of the plots of changes in volume of granulomas which formed in the mouse lung at various periods after intravenous injection of 10,000 copolymer beads. The circled points represent the Standard Bead Model (30–70 μm). The triangled points represent the beads used in this experiment (30–45 μm). Note the similarity of the two.



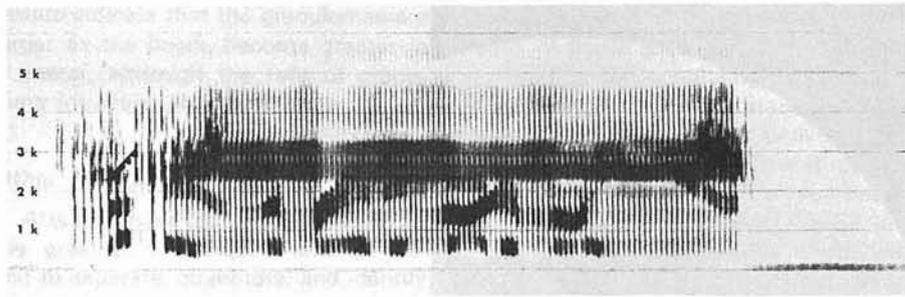


FIGURE 1.

Speech spectrogram (frequency vs. time) of speech produced with an early version of the prototype artificial larynx. Illustrated are intense bands of energy that are not being modulated by the vocal tract transfer function.

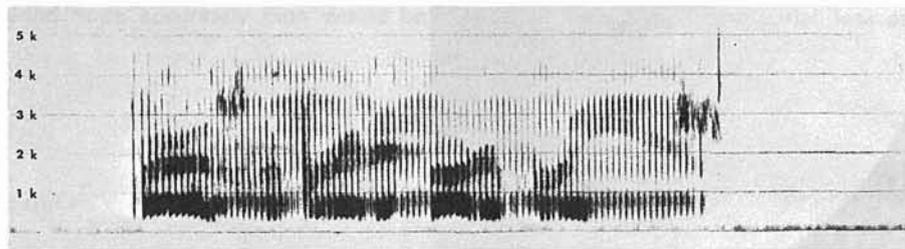


FIGURE 2.

Speech produced with an improved version of the prototype artificial larynx, where some extraneous energy has been effectively attenuated.

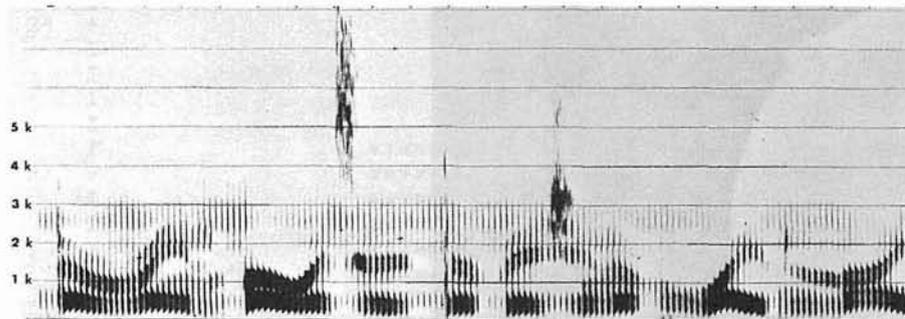


FIGURE 3.

Speech produced with the current version of the prototype artificial larynx while worn on the neck.

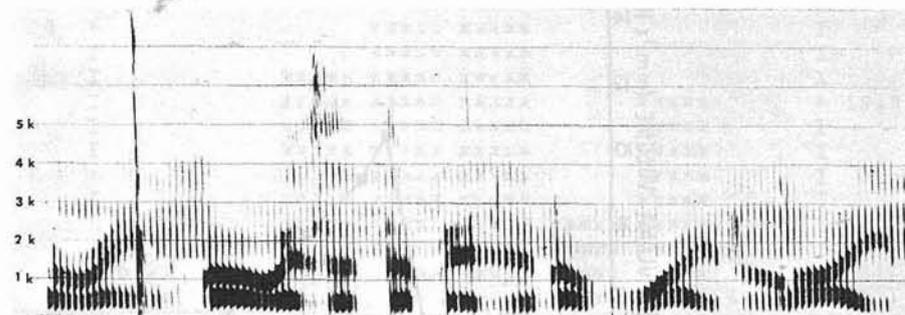


FIGURE 4.

Speech produced with the current version of the prototype artificial larynx hand-held against the neck.

Development and Evaluation of a New Artificial Larynx

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The artificial electronic larynx should, at the least, provide periodic energy throughout the speech range, i.e., up to approximately 4000 Hz. This bandwidth of energy would encompass the frequencies necessary for producing vowel formants for men, women and children. Ideally, the energy produced by electronic larynges should, when transmitted through the tissues of the neck, be modulated according to the transfer function of the vocal tract.

The currently available artificial electronic larynges produce periodic energy over a wider range of frequencies than necessary. Unfortunately, certain bands of energy do not appear to be modulated by the changing vocal tract resonances. This is detrimental to speech intelligibility and also results in an unpleasant mechanical sound being transmitted along with the speech wave.

In the developmental work on a new artificial larynx, an attempt is being made to restrict the bandwidth of the device's output as well as having the produced energy utilized most efficiently for speech intelligibility purposes. The figures illustrate this work to date.

Figure 1 shows strong undifferentiated bands of energy between approximately 2300 and 3300 Hz, and less intense bands of energy at approximately 300 to 850 Hz and 1150 to 2000 Hz. The upper bands of energy, in addition to contributing to an unpleasant sound quality, obscure some second and most third formant energy. The 300 to 850 Hz band falls within the range of the first formant.

Figure 2 illustrates a marked improvement in that the strong bands of energy found in the example illustrated in Figure 1 have been greatly attenuated. However, there is still too much energy between 300 and 1000 Hz.

Figures 3 and 4 provide examples of speech produced with the current model. Figure 3 illustrates speech produced with the prototype neck-mounted. Figure 4 illustrates speech produced with the prototype hand-held. In both figures it is evident that the

most intense energy (indicated by the darkness of the trace) represents the changing vocal tract resonances as speech is being produced. That is, most of the periodic output of the device is being modulated by the vocal tract transfer function. Further, periodic energy above 4000 Hz has been eliminated.

The prototype is pictured in Figure 5.

Further research involves further improvement in sound quality output, greater energy efficiency, and increasing the device's fundamental frequency.

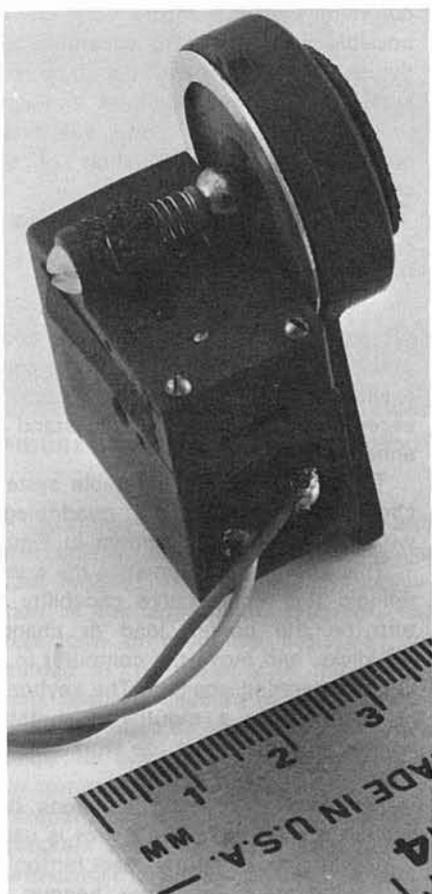


FIGURE 5.
Illustration, to scale, of the current version of the prototype artificial larynx.

Prosthetics Research

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Below-Knee Preparatory Prostheses

There have been continued efforts to refine techniques in the use of preparatory BK prostheses. The design consists of three basic components: an interface (socket); a PVC (Polyvinylchloride) pylon and a standard SACH foot. Emphasis has been given to finishing techniques (converting these prostheses to a more cosmetically acceptable appearance) and durability.

Direct-casting methods are under investigation, with significant clinical experience already gained in "hand forming" different polymers directly to the patient's residual limb.

Investigation is being conducted along two phases of direct socket forming techniques. One particular problem is finding a material which can be directly applied to bony prominences on the limb in preparation for direct forming of the interface. Cotton padding and polyurethane foams have been used and are under further investigation. A search for other materials is currently underway.

The other concept being studied is the use of atmospheric pressure to assist hand-forming of low-temperature plastics directly to the patient's limb. This technique has potential for increasing the accuracy of the impression taken of the limb, and also for using the "total contact" concept of weight distribution to its maximum advantage. Materials being considered for this technique are Aquaplast® and Thermovac®. (Aquaplast is a polycaprolactone modified by a process patented by W.F.R. Corp., 68 Birch St., Ramsey, N.J. 07446. Thermo-Vac is an FDA-approved ethylene copolymer made from an ionomer resin. The sole supplier is U.S. Manufacturing Co.)

Materials currently undergoing evaluation at the time are Aquaplast® (a low-temperature-forming thermoplastic), Scotchcast® casting tape (a knitted fiberglass fabric impregnated with a polyurethane resin which hardens when exposed to water) and Thermovac® (a

co-polymer).

Past interface designs have not allowed utilization of "soft" liners. Current techniques, however, have allowed us to use full or partial liners. These liners have been fitted directly to the patients prior to forming the interface.

We anticipate a higher volume of clinical use and further information regarding direct forming and vacuum forming techniques.

Live Lift-Lock

After several clinical trials, the live lift-lock has been shown to meet its design criterion: to allow the above-elbow amputee with a body-powered, dual-control system to flex the elbow without opening the terminal device when lifting a load.

During clinical use, two design changes were indicated to improve the reliability of the system: (i) counterbore the case and cover to retain the pulley bushing, and (ii) tighten the pawl mounting. These changes have been made and incorporated into two new units which will be fitted to subjects for clinical evaluation.

synergetic Hook

All the hooks not in clinical use are being modified to accommodate the current cut-off device. The device consists of a ring magnet attached to the "fast" motor gearhead and a reed switch mounted on the base of the hook. When zero speed is detected by this device the current is electronically diverted from the "fast" motor to the "slow" motor. This electronic circuitry is now undergoing debugging.

Powered Arm for Shoulder Disarticulation Levels

Work is continuing on a total arm prosthesis for shoulder disarticulation amputees which utilizes unbeatable position-servo control effected by shoulder motion. A system measuring shoulder motion with respect to the sternum, and angles related to the orientation of the sterno-clavicular joint, has been built. A study is currently being performed analyzing the potential effectiveness of using shoulder elevation-depression and protraction-retraction to control prosthetic elbow flexion and wrist rotation, respectively. Preliminary results

of one- and two-dimensional random tracking and blind positioning experiments, in which an ideal prosthesis mechanism operating under no-load conditions was assumed, have indicated the viability of this approach.

At the present time a system is being designed for achieving unbeatable position-servo control by directly coupling prosthesis position to shoulder position. This system will be used in analyzing and comparing the prosthesis performance realizable with currently available powered components.

A Study of the Hip-Disarticulation Prosthesis

A preliminary study of ambulation by a hip-disarticulation amputee has been completed. The ambulation of a "good walker" fitted with the Canadian prosthesis and SACH foot was studied with (i) a constant-friction knee, and (ii) a hydraulic knee for swing-phase control (Dupaco). Hip and knee velocity were measured directly with tachometers and joint position was determined by integration. Photographs made with strobe lights initiated by switches at the foot, knee, and hip were used to determine absolute position of the limb segments at important times in the gait cycle. Socket orientation with respect to the sagittal plane was also determined. A summary of results follows.

1. The hydraulic unit produced a more anthropomorphic kind of gait. Hip flexion and knee flexion occurred simultaneously (with the constant-friction knee the knee flexed and extended and this was followed in time by hip flexion; hip flexion was mainly the result of the collision occurring when the knee came into full extension). The hydraulic unit seemed to permit somewhat faster ambulation.

2. Hip flexion concurrent with knee flexion, as occurred with the hydraulic knees, did not result in effective shortening of the limb during swing through.

3. Analysis showed that changing the natural frequency of the limb segments by altering mass distribution in the segments is difficult. Likewise, knee flexion during gait does not significantly alter the natural frequency of the prosthesis. Limb natural frequency is proportional to the inverse square root of the equivalent simple pendulum length. This is not very sensitive to

modest changes in mass distribution.

4. Passive models of the prostheses during swing phase were developed. Comparisons with actual swing phase data showed the swing phase is significantly influenced by the amputee through forces exerted through the hip joint and hip extension stop, and by the step-length control mechanism.

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

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**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. Improvement and evaluation of powered wheelchair control systems and preparations for continued clinical evaluation of the robotic arm / worktable system were the principal activities of this project during the reporting period. Progress and accomplishments during the July-December 1980 period are summarized below.

Chin Controller for Wheelchairs

Evaluation is continuing on the low profile chin controller compatible with the E&J Model 3P wheelchair. Five E&J wheelchairs equipped with this system are currently being evaluated by volunteer quadriplegics. Four of these individuals have been utilizing this controller for periods of from 9 months to 2 years in daily living environments and were previously discussed in BPR 10-34. The most recent quadriplegic evaluator added to this program was D.W., a 33-year-old male injured 3½ years ago. He is a C4-5 with no significant voluntary muscle power below his shoulders. This individual was fitted with the wheelchair controller in November 1980 for preliminary testing prior to his testing of the composite robotic arm / worktable system scheduled to commence in January 1981.

This wheelchair controller, contrasted to previous models, employs closed-

loop velocity control. This permits the velocity limit to be set low without compromising maximum torque capability for climbing up ramps and over door sills. It also provides self-braking downhill for more controllability on hilly terrain. This individual quickly developed excellent control, has been testing the device for two months, and is continuing the evaluation.

Robotic Arm / Worktable System

Research on the robotic arm / worktable system during the reporting period was concentrated on completion of a computer interface on the worktable for possible applications to vocational activities by severely handicapped persons such as the one described above. A preliminary testing protocol was developed for clinical evaluation of the composite system.

A representative low-cost personal computer was selected in order to study the interface problems related to its practical usage in the physically handicapped vocational situation. The computer and its associated commercially available components were not modified except for tabs and mounting stand to enhance task performance.

The robotic arm / worktable system chosen to interface the quadriplegic with the computer is shown in Figure 1. This arrangement provides the quadriplegic the manipulative capability to turn on the power, load or change minidisks, and move the computer in or out of operating position. The keyboard is operated by a mouthstick suitably located in a holder on the worktable as shown in the photograph.

In addition to basic functions described above, the robotic arm is used to operate the computer reset button in the event of a computer hangup, a significant function in avoiding inadvertent loss of data from a disk. The robotic arm is also used for manipulating a telephone and for bringing reading materials to and from the reading stand. The goal is a total stand-alone system with minimal attendant assistance. To ease the user workload, the robotic arm has been preprogrammed with stored trajectories to perform all of the desired functions upon command from the operator. The user may interrupt or stop the motion at any time or revert to manual control of any of the six degrees of freedom.

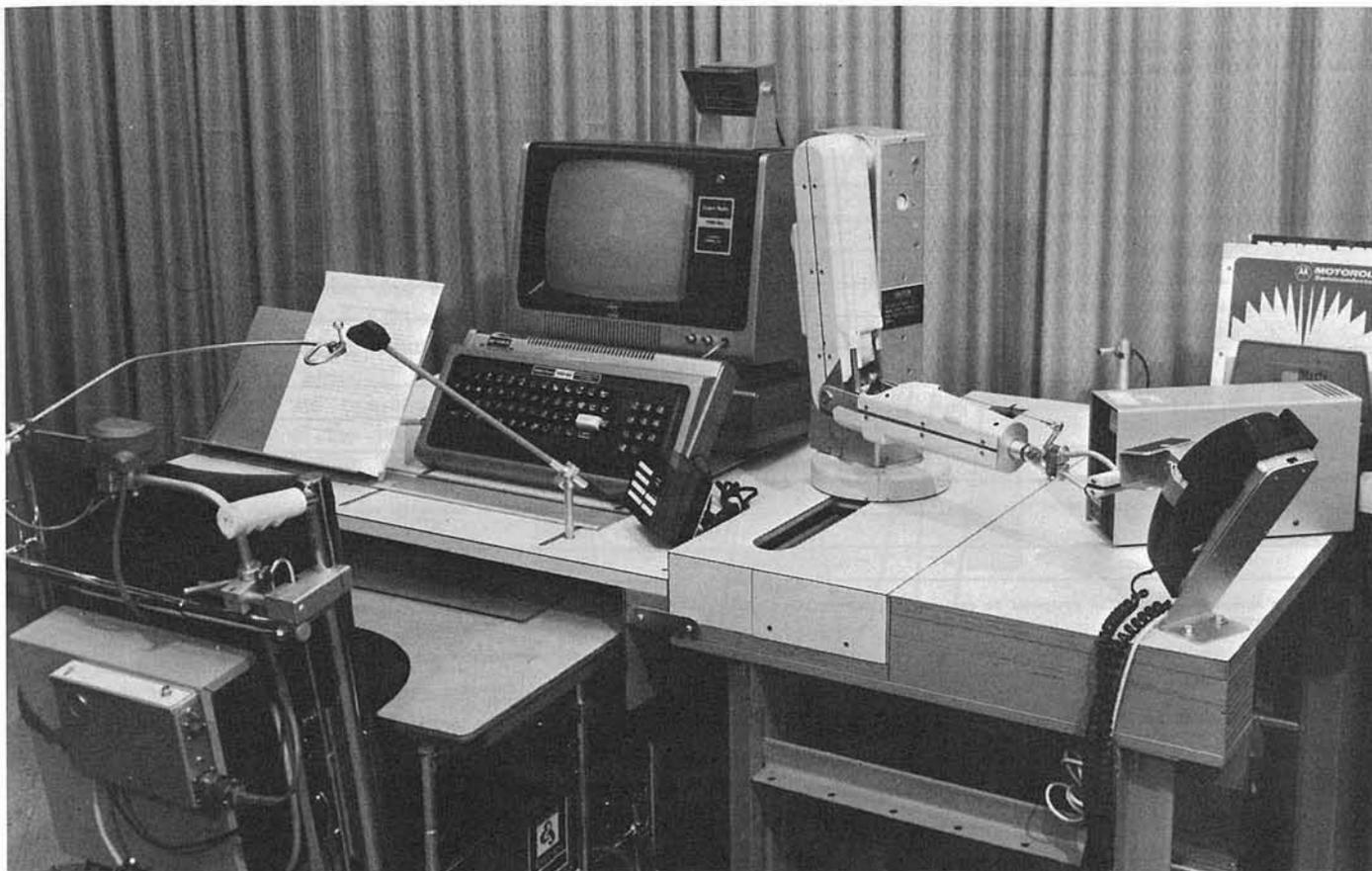


FIGURE 1.—APL/JHU Robotic Arm/Worktable System with personal computer interface.

Selection of the correct robotic-arm manipulative sequence for any particular task requires identification and activation of the appropriate program. The repertoire of programs has been recorded in the memory of the robotic arm. Memory capacity is 40 programs. They are listed by name, five names per page, for eight pages. Operating input to command readout of titles, to enable program selection, and to achieve program activation is achieved via the wheelchair chin controller described earlier in this report and in BPR 10-34. Termination of any program at any time may also be achieved by the chin controller.

Incorporation of a personal computer system as part of the worktable has several desirable features. First, it provides a low-cost total computer system with 48K memory; secondly, the BASIC language is very easy to learn and could be mastered by the majority of potential handicapped users; and finally, the capability to manipulate minidisks in and out of the disk drive with the robotic arm provides fast access to data. A large selection of

computer programs is available on the market at low cost for computers of this type.

In a sample computer problem planned for inclusion in the initial clinical evaluation, the composite system provides the user with easy access to name, address and phone listing, and technical and pricing data on selected product lines. The system enables writing, editing, and printout to hard copy of appropriate data. The data are formatted in simple BASIC language which allows page changing and data management with minimal keyboard entries

A preliminary protocol for clinical evaluation of the JHU/APL Robotic Arm/Worktable system has been written. The evaluation protocol has as its primary objective the examination of the practical utility of this system concept to carry out realistic tasks related to vocational, educational, and personal needs of the high-level quadriplegic. The functional capabilities to be evaluated under this protocol include the following specific areas of tasks activities:

1. Wheelchair chin controller characteristics for general mobility;
2. Functional worktable activity for handling various reading materials and using the typewriter and telephone for written and oral communications;
3. Functional worktable activity utilizing a personal computer for vocational and educational purposes;
4. Self-feeding.

The evaluation protocol assumes that the quadriplegic can perform the required chin motions to serve as inputs to the chin controller and can utilize a mouthstick for keyboard and page-turning activities. It must be recognized that while some attendant assistance is required to place basic reading materials into the storage area, food into bowls, etc., this system is designed to minimize attendant assistance during actual conduct of specific tasks.

Conduct of the proposed evaluation program requires participation of the handicapped individual for approximately 4 hours per day over a period of 7 to 8 weeks. In order to provide a qualitative and quantitative measure of system performance, the user will be

PHASE II
ROBOTIC ARM/WORK TABLE SYSTEM

READING/TYPING TASK

User's Name _____ Period Covered _____

How many times were reading materials utilized? _____

How many times was the typewriter utilized? _____

Problems encountered in handling reading materials _____

Problems encountered in handling typewriter/typing paper, etc. _____

Alternative Method(s) of Accomplishment of this Task _____

User rating on acceptability of this equipment to carry out the prescribed task relative to alternative method(s):

1. Completely adequate and acceptable _____
2. Satisfactory but needing minor improvements _____
3. Minimally acceptable (needs redesign or major changes) _____
4. Unacceptable for the task _____

User Comments _____

FIGURE 2. (Questionnaire No. 2)

asked to fill out questionnaires on a weekly basis, evaluating his performance on each specified task. Important factors to be evaluated include reliability, ease of operation, functional practicality, and possible future improvements and changes. Total robotic arm "on" time is automatically recorded with an electronic elapsed-time indicator built on the computer electronics circuit board.

Sample questionnaires on two selected tasks are shown in Figures 2 and 3.

Closed-Loop Velocity Controller for Wheelchair Control

A new item reported in the JHU progress report in BPR 10-34 was the closed-loop velocity controller for electric wheelchairs. This concept appears particularly applicable for limited velocity wheelchairs for individuals with poor hand-control of a joystick. Closed-loop control also provides an effective braking technique for steep grades, and effec-

tively filters unwanted high-frequency hand motions.

This concept has been applied to a chin-controlled wheelchair as well as a joystick-operated wheelchair. The chin-controlled application is being evaluated clinically and is described elsewhere in this progress report. The joystick-operated model has undergone limited clinical evaluation and general testing in indoor and outdoor environments.

One manufacturer, Medical Equipment Distributors, Inc. (MED), has expressed interest in manufacturing this controller as an interchangeable module for joystick-operated E&J Model 3P wheelchairs. They have conducted limited performance evaluation with one APL unit and in personal communications have reported favorably on its performance capabilities, particularly in downhill braking situations. MED, Inc., is currently building six prototype units for field testing in various parts of the country. Upon satisfactory completion

PHASE III
ROBOTIC ARM/WORK TABLE SYSTEM

PERSONAL COMPUTER FILE MANAGEMENT TASK

User's Name _____ Period Covered _____

Approximately how many hours have been spent with this task? _____

Good features of this task _____

Bad features of this task _____

Alternative Method(s) of Accomplishment of this Task _____

User rating on acceptability of this equipment to carry out the prescribed task relative to alternative method(s):

1. Completely adequate and acceptable _____
2. Satisfactory but needing minor improvements _____
3. Minimally acceptable (needs redesign or major changes) _____
4. Unacceptable for the task _____

User Comments _____

FIGURE 3. (Questionnaire No. 5)

of the evaluation of these test models, they hope to make this closed-loop control model commercially available throughout their dealership.

Seating Systems for Body Support and Prevention of Tissue Trauma

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The following is an abstract of the complete progress report, copies of which are available upon request.

The single most important interface for the wheelchair dependent, spinal-cord-injured person is between the

buttocks and the seat. Without sensory feedback, an unaccommodating interface in this area will create a number of problems that will have a direct impact upon the quality of life for those dependent upon the wheelchair for mobility and function. In addition to pressure sores, there exists the potential for biomechanical malalignment of the spine, pelvis, and lower limbs, and a reduction in sitting tolerance. For those who operate shoulder, head, or mouth switches, there is also potential for incongruity between the operation and the static position of the switch during and after negotiating rough terrain.

The Veterans Administration Seating Interface Orthosis (VASIO) is the centerpiece of a total body support system that not only acts as a prophylactic against pressure sores but will enhance the orthopedic management of the entire body of high-level quadriplegics. In the preliminary clinical evaluations the VASIO-P (the suffix P identifies the model for paraplegic use) has not only enhanced the wheelchair environment but has also had a considerable impact on a number of aspects of daily living, such as wheelchair manipulation, table top activities, sitting time, and postural attitude. Detailed data on these and other points are available in the full text of the progress report.

The unique design of the VASIO-P encourages selective repartitioning of weightbearing away from bony prominences to the muscle-covered areas of the proximal posterior thighs and lateral flanks of the buttocks (Fig. 1). Pressure relief under the ischial tuberosities and coccyx is effected by reduction in the amount of foam under the entire perineal and peri-ischial region. The increase in femoral and lateral gluteal support is provided by intracushion inserts of high density foam. Hip abduction is maintained by the elevated foam pommel and recessed thigh contours. This feature is desired to promote aeration of the groin, reduce urethral blockage, and maintain the height of the trochanter in relation to the ischium at a desirable constant. Other desirable characteristics of the VASIO-P cushion, supported by data in the full report, are as follows:

1. Increases sitting time to allow for an increase in activities of daily living.

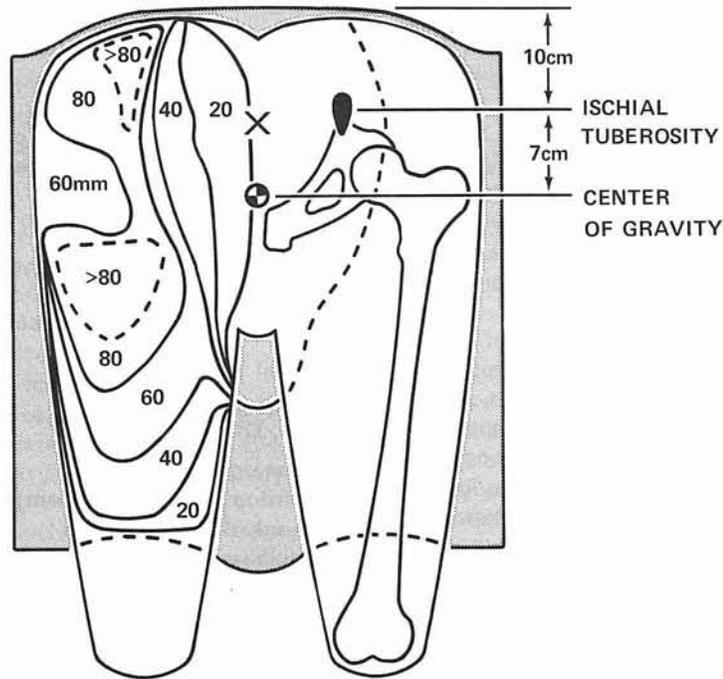


FIGURE 1.

Approximate anatomical and pressure distribution of person with lower-limb atrophy sitting on VASIO-P.

2. Suitable for use by both continent and incontinent individuals.
3. Provides a stable base for manual propulsion and for transfers.
4. Deters adductor and extensor spasticity of the hips.
5. Discourages the development of pelvic obliquity and lateral spinal curvature.
6. Failure-resistant and easy to maintain.
7. Radical atmospheric pressure and temperature changes have little effect on performance when compared to inflated or fluid-filled cushions.
8. Minimizes shear when incorporated into a wheelchair with reclining back.
9. Can be used in wheelchair seat widths from 16 in to 20 in.
10. Cost effective for the manufacturer, yet available at minimal cost to the patient.

Great concern has been expressed over the fact that polyurethane foams are subject to deterioration and failure as a result of fatigue of the molecular structure. However, when one considers the findings of the research team at the Texas Institute for Rehabilitation and Research, it can readily be seen that if the foam is first statically pre-stressed,

"subsequent dynamic loading causes no additional ILD (indentation load deflection) loss". We consider this material an essential element for progressive development of soft-tissue tolerance to loadbearing forces.

Our evaluation of the VASIO-P is far from complete. However, the pressure and performance data and subjective responses collated thus far indicate that modular seating is a viable mode for the future because of its ability to meet both the orthopedic and prophylactic needs of the spinal-cord-injured wheelchair dependent person.

Seat Cushions for the Paralyzed

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The evaluation of pressure, shear, and skin bloodflow developed in the vicinity of the ischial tuberosities while sitting, has been completed for a group of 15 paraplegic subjects.

More than one quarter of the paraplegic pressure data far exceeds in

value any corresponding normal (control) group value. Paraplegic shear values are also large (typically several times normal values) and paraplegic blood volume flow rates are much smaller than those associated with sitting normals.

In other words, the sitting paraplegic tends to develop large skin loads and small skin bloodflows, as compared to the normal. In these respects, the paraplegic is similar to the geriatric hospitalized patient.

It would seem possible that the tendency of geriatric and paraplegic patients to develop pressure sores may reflect not only limited motion capabilities, but also the action of neurotrophic factors resulting in less favorable load vs bloodflow trends within loaded tissue.

Residual Bladder Volume

Determination in Spinal Cord Injury Patients

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A computer simulation of the proposed ultrasonic method of non-invasively measuring residual bladder volume has been developed to compare the accuracy of volume calculation algorithms. The simulation uses a model of the geometric relations between the transducer/receiver and the bladder, for the clinical procedure proposed for final use, to generate a discrete series of front and rear bladder wall positions. These positions are used in the algorithms.

Three algorithms have been developed: (i) a linear interpolation scheme using planar surfaces between triads of points to create a faceted surface for the approximated bladder, (ii) a second order interpolation using a modified Simpson's rule, and (iii) a third order interpolation scheme using parametric bi-cubic splines.

These algorithms have been used to calculate the volume of simulated bladders for several shapes and sizes (100-900 ml) for both noisy and noiseless data from the simulations. The results show that the parametric bi-cubic splines give the most accurate results for data without noise, while if noise is present the Simpson's rule approach is significantly more accurate.

Using this algorithm and a reasonable approximation to the expected noise in a clinical situation, the volume can be calculated to an accuracy of close to ± 8 percent. This result is for a situation in which only 20 intersections of the ultrasonic beam and the bladder are used.

Development of Upper-Extremity Orthoses Employing Electrical Stimulation

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Introduction

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 eight 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 is sufficiently general for it to be configured with various command control sources and for stimulation of the appropriate muscles for one of the two grasping modes. Command signals may be generated by head or shoulder position, or by mechanical switches or myoelectric activity. These alternatives allow for 16 basically different system configurations. 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 for both maximum patient safety and low power consumption, and is implemented on miniature high density printed circuit boards.

A major aspect of the progress in this period has been in implementing

engineering modification in the stimulator electronics. These modifications were necessary to extend the capabilities of the present generation stimulator beyond those specified in our design. These changes resulted from newly developed command schemes and stimulation sequences generated over the past 3-year period. Presently we are pursuing two aspects of engineering development in parallel. First, we are completing the engineering to incorporate new command schemes into the present generation stimulator. Second, we are initiating the development of a second generation patient-based stimulator which will be more versatile than the present device in both its command control and its stimulation schemes. The stimulator will enable the patient to control both grasping modes.

Outpatient Evaluation of Functional Systems

Eight subjects are presently involved in the evaluation of functional electrical stimulation orthoses. Seven are outpatients; one an inpatient. Each is quadriplegic secondary to spinal cord injury. Five have C5 function; three have C6 function. None is a candidate for tendon transfer. Each of the subjects fitted with the functional system continues to be active in the program. The results described in the previous 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.

A Program for Upper-Extremity Functional Neuromuscular Stimulation

As a result of our studies, we have evolved a clinical program for implementation of FNS hand assist systems. The program consists of five phases:

1. Evaluation of neurological status of the muscle
2. Electrode implantation
3. Muscle development and physiological evaluation
4. Laboratory development / training
5. Outpatient use / evaluation / follow up.

The first stage of *evaluation of neurological status* consists of identifying whether muscle have normal voluntary control or a lower- or upper-motor neuron paralysis. From this pattern we determine the muscles to be electrically stimulated based on the

voluntary functions absent and those muscles with an UMNL. *Electrode implantation* is then performed. The electrode implantation phase of our program is described in (2). *Muscle development* is accomplished by chronic electrical stimulation of the muscle. "Exercise" stimulators for this purpose have been developed within our project (3). *Physiological evaluation* is performed with external transducers for measurement of the muscle's fatigue properties with maintained stimulation, recruitment (stimulus-input/force-output) properties, and electrode properties such as threshold and impedance. Each electrode is evaluated in this manner. These properties enable the investigator to develop coordinated movement patterns which the subject will ultimately use functionally. When muscles have developed sufficient strength, the electrodes are then considered stable (determined by repeatable response, stable threshold and impedance), and coordinated stimulation of muscles is provided, *laboratory training* of a functional system is begun. This consists of the patient evaluating the various control schemes and integrating them with the hand grasping pattern to perform functional activities. Following discharge from the hospital, *outpatient followup* enables us to evaluate the FNS systems functionally and determine aspects which may limit more regular usage and more widespread deployment.

In the next period we plan to include two additional subjects in this program.

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Functional Neuromuscular Stimulation of Limbs: A Feasibility Study

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Telephone discussions were held with a subcontractor about the content and preliminary results of analytical studies being performed for the project. A report on those studies is awaited. No experiments or other laboratory studies were conducted during the period, since project termination was effective September 30, 1980. The primary emphasis during the period was on writing. A previously drafted manuscript documenting results of a literature survey was extensively revised per review recommendations and was resubmitted for publication.

In summary, this project was directed toward examination of the concept of a field control electrode (FCE). The purpose of the FCE was to selectively activate small subsets of nerve fibers within a peripheral nerve trunk via manipulation of potentials applied to quadrature field elements and circumferential driver elements. Experimental validation of the concept was the project goal. A substantial part of the project effort was devoted to concept implementation using thin-film techniques to produce experimental units for animal testing. When faulty processing procedures delayed availability of experimental thin-film units, alternative validation through measurements on scale models and by theoretical studies was pursued. All three areas of project activities revealed positive features and some restrictive conditions. However, the available time and money was insufficient to permit a definitive answer as to concept validity.

A Single Unit Study of Muscle Afferents in Human Movement

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The project objective is to establish a laboratory at the McGuire V.A. Medical Center to monitor and record

single unit afferent nerve potentials from muscle receptors in the awake unanesthetized human. Activity of the alpha motor—fusimotor system will be investigated in normal and pathological movement mechanisms.

Initially, the subjects will be normal individuals and the results will be used as controls in receptor response at rest, during passive stretch, muscle twitch, reflex activity and voluntary movement. As receptor recording becomes reliable and accurate, patients with cerebral vascular accident, and Parkinsonian patients showing clonus and tremor, will be studied to differentiate between the two types of phasic activity and to compare activity between the normal and the pathological patient.

Single-unit activity from muscle afferents in various peripheral nerves (median, posterior tibial, common peroneal) will be recorded using manually inserted, insulated tungsten wire electrodes electrolytically tipped and measured at 100–150 k Ω at 1.0 kHz. Simultaneously, range of motion and the electromyogram of the receptor-bearing muscle will be recorded.

It is anticipated that the study will help to clarify the role of the alpha motor — fusimotor system in human normal and pathological movement, allowing one to use the results confidently in diagnosis, treatment and rehabilitation of patients where problems of movement activation and coordination are involved.

Engineering Applications in Orthotic and Prosthetic Treatment of Musculoskeletal Defects

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The primary efforts of this laboratory are to provide a meaningful clinical gait analysis, and to improve or create gait by means of functional electrical stimulation (FES).

Automation of the collection and processing of data is considered to be an important step toward providing a meaningful gait analysis. A new automated data collection system is currently available with capability of sampling 16

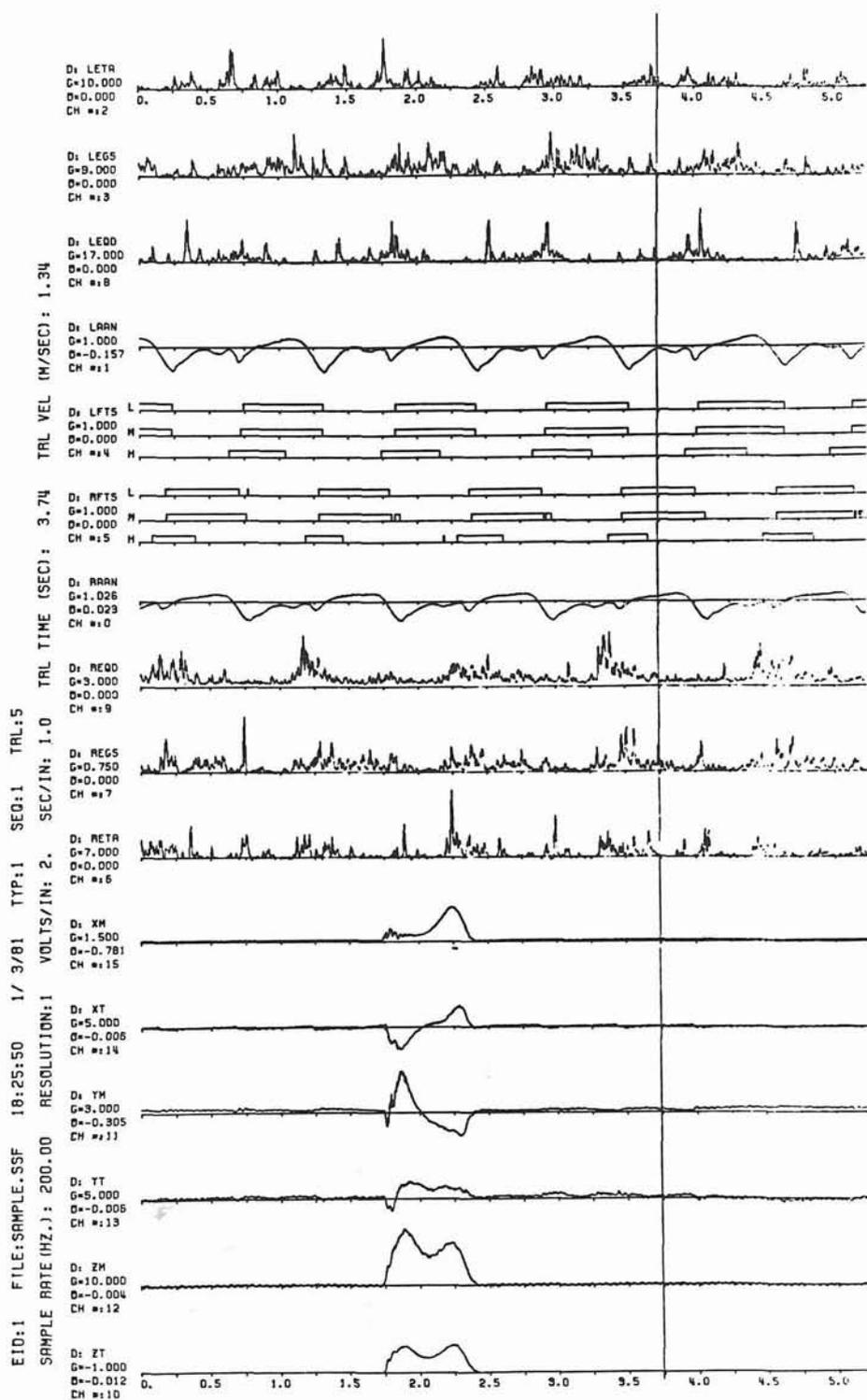


FIGURE 1.

This figure contains raw data recorded from a normal subject. On the left side of the plot are measured parameters with associated gains, offsets, and analog-to-digital channel assignments. Going from the top to the bottom of this figure are EMG's of: Left tibialis anterior (LETA), left gastrocnemius (LEGS), and left quadriceps (LEQD). Next are angle of the left ankle (LAAN) in the sagittal plane with dorsiflexion being positive, and left foot-floor contact data obtained with a three-electrode configuration affixed to the sole of the shoe, (H-heel, M-medial, L-lateral). The data following are for the right leg foot switch, ankle angle, and EMG.

Six channels of unprocessed force plate data are at the bottom of the plot and can be used to reconstruct forces and moments at the foot-floor contact.

channels of analog data at the maximum frequency of 350 Hz. This system was developed with partial support from the Rehabilitation Engineering Center at Case Western Reserve University. At the present time there are no analysis programs compatible with the new data collection system, but a plot of raw data is available (Fig. 1). A more complete gait analysis would require three-dimensional kinematic data which will be provided by the SELSPOT system available from SELCOM AB of Partille, Sweden.

A 16-channel microprocessor-controlled stimulator will be the primary tool for the FES. It consists primarily of large scale integration (LSI) integrated circuits. This custom hardware was integrated with a Cromenco Z80-based Microprocessor Development System for overall program control. The hardware is configured so that, once programmed for a certain waveform pattern, it can operate independently of constant processor handling. A real-time operating system was developed for the stimulation unit which supports an elementary command language allowing the operator to alter the instrument's output waveform with relative ease. Some of the functions provided by the operating system are: the configuration of channels into groups for use with multiple electrodes per muscle when sequential stimulation is desired, real-time data sampling for control application, modulation of the stimulus parameters according to the feedback signal(s) and/or a set-point, and handling of input-output devices and the operator interface (line printer, console). Because the work in FES is still very much in the research stage, the specifications for the stimulation unit were set flexibly so that they could evolve with time. This instrument will be a valuable tool in investigations to solve problems concerning the use of multichannel/multimuscle FES.

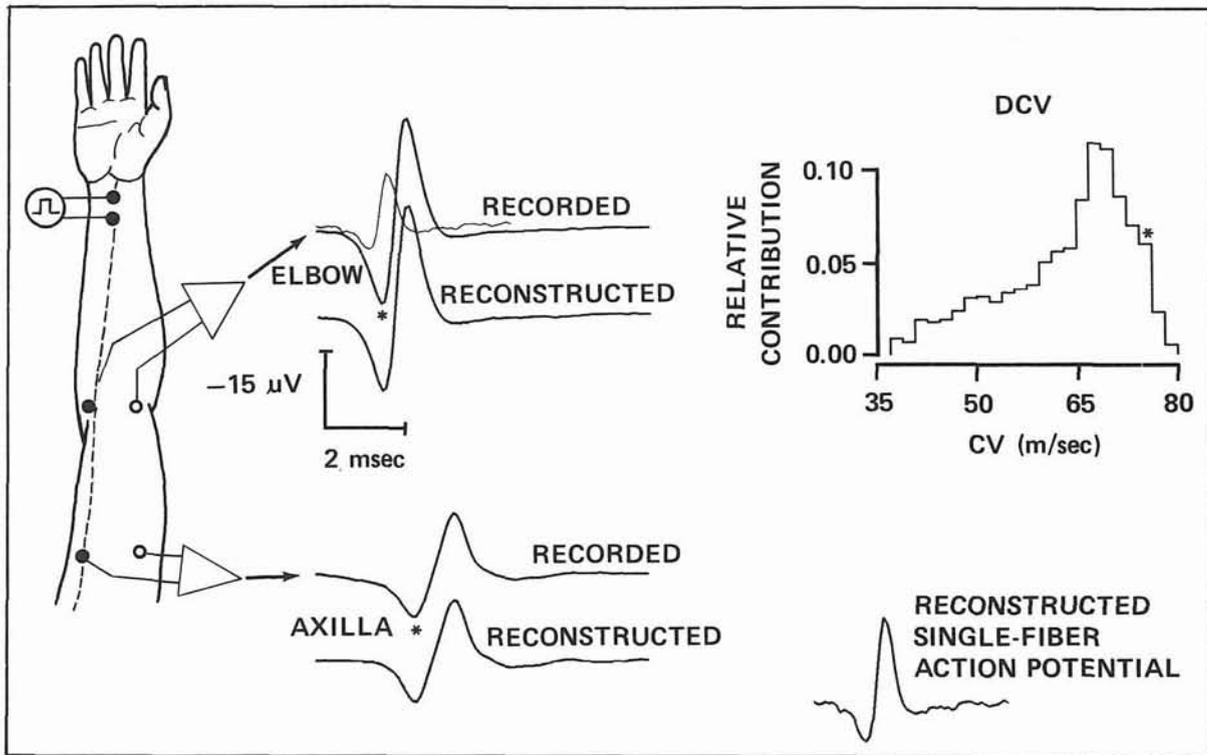


FIGURE 1.

Elements in the derivation of the distribution of conduction velocities (DCVs) in the median nerve of a normal subject. Compound action potentials (CAPs) were recorded referentially at elbow and axilla in response to stimulation at the wrist, and were analyzed to yield the DCV shown. The single-fiber action potential (SFAP) was derived from the DCV and the recorded elbow CAP, and the reconstructed CAPs were computed from the DCV and the SFAP; hence, the reconstructed axilla CAP serves as a check on the estimation procedure. The asterisk (*) on the DCV histogram indicates the conventional maximal CV calculated from the onset latencies of the CAPs (also indicated by asterisks); note that this is less than the true maximal CV of fibers in the nerve bundle, because the onset peak positivity of the CAP is later than the onset peak of the earliest SFAP (the thin line superimposed in the uppermost trace (13)).

Nerve Conduction Velocity Distributions: Clinical Research Applications

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Introduction

Clinical electrophysiologic evaluation of conduction properties of peripheral nerves is typically limited to characterizing small sub-populations of fast and/or slow conducting myelinated fibers (1-4). The standard clinical practice is to study only the fastest fibers, because of previous inability to extract quantitative information about the slower-conducting nerve fibers. Over the past six years, however, several research groups have attempted to extract more information from the compound action potential (CAP) of a nerve bundle (5-11). The approach has been to estimate

the distribution of conduction velocities (DCV) in a nerve bundle using methods derived from analytic models of the nerve and/or muscle CAP. The DCV is similar in concept to the histologic fiber diameter distribution, but may be obtained using non-invasive electrophysiologic methods. It is a measure of the contribution to the CAP made by nerve fibers in a set of conduction-velocity (CV) classes. A complete presentation of DCV techniques may be found in the monograph edited by Dorfman, Cummins and Leifer (12).

An example of the recorded and computed data obtained with the method of Cummins et al. (10,13) is shown in Figure 1, using CAPs obtained from a 20-year-old male. The interval between stimulus onset and CAP onset was measured but not stored. The DCV comprises the relative contributions from classes of nerve fibers conducting in the range of 35-80 m/sec. (Classes were based on 2-m/sec CV intervals within the overall group conducting in the 35-80 m/sec range; refer to Figure

1 where graph envelope at top-right defines relative contributions of these CV classes.) Slower conducting fibers did not contribute sufficient amplitude to the CAP to be above the noise level. The asterisk (*) located at the 75 m/sec bin in the DCV of Figure 1 indicates the conventional "maximal" CV calculated from the difference in latency of the positive peaks of the elbow and axilla CAPs. Note that this does not correspond to the fastest CV in the nerve bundle. The fastest CV is determined from the positive peak of the shortest-latency single-fiber action potential (SFAP—the thin-lined waveform superimposed on the recorded elbow CAP), and is usually 4-8 m/sec faster than the conventional "maximal" CV. The reconstructed waveforms in Figure 1 were obtained as a check on the accuracy of the model variables for the DCV. The SFAP was calculated from the DCV and the recorded elbow CAP; therefore the reconstructed elbow CAP (obtained from the SFAP and the DCV) should always be similar to the recorded

elbow CAP. The best measure of the quality of the DCV estimate is the reconstructed axillary CAP.

The non-invasive nature of DCV methods makes them well suited for studies requiring serial measurements of nerve function. Specifically, DCV analysis may help to clarify some unresolved issues regarding the dynamics of nerve growth, development, damage, healing, and response to treatment.

The more complete characterization of the nerve bundle provided by the DCV, as compared to conventional techniques, makes it a logical tool in the evaluation of many types of neuropathy. One important application is likely to be the early detection of peripheral neuropathy. Also, some diseases—for example, familial amyloidosis and some forms of sensory neuropathy—tend preferentially to affect nerve fibers conducting in specific velocity ranges. These patterns of involvement can be appreciated more readily with a DCV than with conventional nerve conduction techniques.

Project Goals

There are four major objectives in the project whose funding began on October 1, 1980.

The first objective is to complete normative studies on subjects ranging in age between 15 and 80 yrs. The most extensive data will be obtained from the median nerve using surface electrode recordings; however, the sural and peroneal nerves will be studied in some subjects. Some of the subjects will also be studied using near-nerve needle electrodes (3). It is hoped that this recording method will permit the application of DCV techniques to deeper nerves by improving the signal-to-noise ratio of the recordings.

The most clinically-relevant objective is to determine the utility of DCVs in the early detection and discrimination of peripheral neuropathic disorders. This is a key question in determining the advantage of DCV analysis over current methods of maximal CV, latency, and amplitude measurement. This objective will be realized through the time-serial testing of patients early in the disease process (such as subtle diabetic and uremic neuropathy), as well as through attempts to detect neuropathy, via DCV analysis, in patients having normal

conventional electrophysiologic examinations.

The third objective of this research addresses issues of basic neurophysiologic and rehabilitative interest, namely, to determine whether or not peripheral neuropathy occurs in primary lesions of the central nervous system. The sensitivity of DCV analysis may help to uncover peripheral nerve involvement in multiple sclerosis, hemiplegia and spinal cord injury.

The final objective is to design and construct a prototype device which can generate DCVs using the estimation method of Cummins et al. (10). Currently, this technique is implemented on a general-purpose Digital Equipment Corp. PDP-11/34 computer.

Progress to Date

Some of the surface-electrode normative studies have been completed, and progress has been made toward evaluation of the reliability and clinical utility of DCV analysis. Factors studied include test-retest reliability, variance due to changes in temperature and stimulus intensity, and the capacity of DCV analysis to detect subtle electrophysiologic abnormalities in a small population of diabetic patients. This work was completed in the time between submission and funding of the proposal. The findings indicate that DCV analysis, when controlled for stimulus intensity and temperature, provides a reliable measure of nerve-bundle conduction characteristics which can detect subtle peripheral nerve abnormality even when conventional electrophysiologic techniques yield normal results (13).

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Cervical Spine Injuries

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A new program in Clinical Bioengineering, within the Spinal Cord Injury Unit, was begun in the fall of 1980. An initial objective was to determine areas for research effort which were relevant to the patient population of this unit, as well as having broader significance. A problem which had received previous attention was how to devise a mechanical means for applying a reproducible "Closed Injury Lesion of the Spinal Cord" (Principal Investigator, A.B. Rossier, M.D.). The apparatus consisted of

a high velocity impact hammer directed at the spine of cadaveric monkeys. However, due to the complex viscoelastic deformations of the entire body system of the animal and difficulties of exact centering, the method was unsatisfactory. A revised method has now been planned involving the application of a known shear impact or a known shear displacement to one vertebra with respect to those on either side. This will be attempted by attaching clamps to the three vertebrae involved, rigidly fixing the vertebrae at each end and applying the impact to the central vertebra. While not being a true "closed injury" method, the vertebrae are not resected and the mechanical input is to the bone rather than being directly on to the cord. Direct cord impact using a weight dropped from a height is the only "standard" method which has been described. If a reproducible "closed injury" method can be found, this will be the model for studies on the effect of various treatments after injury.

A second project dealing with the patient subsequent to an acute injury is entitled "Studies for the Design of a New System for Stabilization of the Acutely Injured Cervical Spine." It is essential to prevent as much as possible any relative movement between the vertebrae to enable healing to occur and to prevent further injury. The halo-vest is the most widely used device at present, but various other non-invasive orthoses are still used in certain cases. However, the halo-vest is not ideal in several respects. The skull pins produce early and sometimes later discomfort, application of the halo-vest and adjustment in all planes is not easy, distraction forces cannot be determined, and the jacket frequently allows excessive movement. Improvement of the design, or introduction of an alternate design, requires additional knowledge of the mechanics of the system—in particular of the forces and moments acting. To separate the different components of forces and moments, 20 strain gages will be attached on the framework of a halo-vest device on a patient. Readings will be taken at progressive stages of bone healing and for various activities and maneuvers. The data acquisition and processing system, based on a desktop computer, will enable results to be obtained at the time of testing. A computer analysis will then be made of

the response of two systems to combinations of forces and moments. The systems are a halo-vest and an orthotic arrangement with principal support on the occipital and forehead regions. The effect of certain design variables will be studied.

The above studies address the problems of injury in the acute and early stages. Particular attention is to be given to injuries of the cervical spine. While these studies are likely to expand, it is intended to simultaneously pursue practical devices to enhance the independence of individuals with cervical injuries.

Development of a Wheelchair Using a Myoelectric Control System

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Progress has been made in two areas: further development of the command code used for myoelectric wheelchair control, and design and implementation of facilities for investigating the rate at which information can be transferred over a single myoelectric channel where myoelectric activity is limited to temporal patterns of minute all-or-nothing pulses.

Wheelchair Command Coding

Experimentation with the myoelectric wheelchair has resulted in the development of an improved version of the command coding. The code in current use allows the patient to select any one of five motional states: forward (F), forward and toward the right (FR), forward and toward the left (FL), backward (B), and stop (S). The patient can go from any one of the five states to any one of the other four states by the appropriate combination of two sequential myoelectric pulses in two channels. Details of the code are

presented in the progress report for this program in BPR 10-30.

This code has been found to be satisfactory for wheelchair control by high level quadriplegics, but experience with its use indicates that it has a nonessential feature that can be traded off for a more desirable feature. The nonessential feature is the complete freedom to go from any motional state to any one of the other motional states. Specific restrictions on this freedom can be made without corresponding sacrifices in performance. For example, when going forward, it is not essential (or desirable because of whiplash) to be able to go directly to the reverse state. By restricting the possible combinations of state changes as depicted in Figure 1, the degrees of freedom required by the code structure are reduced so that it is no longer necessary to require two sequential myoelectric pulses as mentioned above.

The restriction of state transitions also allows the addition of the two states; backward and to the right (BR), and backward and to the left (BL). To make any one of the state transitions shown in Figure 1 requires only one myoelectric pulse, either in the right channel (R) or the left channel (L) as indicated. Simultaneous activity in both channels will immediately result in a transition from any state to the stop (S) state.

A microprocessor program is currently being written to allow implementation of the code of Figure 1 with the experimental myoelectric wheelchair that is now in operation. The wheelchair control system has been designed so that the code can be changed by simply changing the EPROM (an integrated circuit memory that stores the microprocessor program).

A potential feature of the code (not being programmed at the present) is the ability to provide the operator with the option of being able to break out of the pattern of Figure 1 into a mode where the myoelectric activity is decoded for the execution of other functions. For example, it may be desirable to break out to decoding patterns for such functions as rotating the wheelchair in place or operating from the wheelchair a wireless transmitter that sends coded messages to environmental control equipment. The opportunity for breakout from the control pattern of Figure 1 would be

made to occur during an antiwhiplash pause in the stop state. This pause would be automatically implemented by the microprocessor upon entering the stop state. Either of two additional decoding patterns could be selected during the antiwhiplash pause, one by a right-channel myoelectric pulse and the other by a pulse in the left myoelectric channel.

Information Rate Investigation

A potential technique for increasing the rate of information flow through a single myoelectric channel is being investigated. It is based upon training operators to generate temporal patterns of minute myoelectric pulses that occur in a time frame that is too short for the operator to consciously shift attention to the generation of each of the sequential pulses.

Initially, the set of temporal patterns will have only two members, a single pulse (P), and a double pulse (D) consisting of a pair of pulses with a temporal spacing in the order of 50 milliseconds. If an operator learned (through practice with appropriate feedback) to generate either P or D at will, the code of Figure 1 could be implemented with only one myoelectric channel. Electronic equipment would discriminate between P and D in one channel without requiring two separate channels. Such a single-channel system may be able to produce sequential wheelchair commands at the same rate as the corresponding two-channel system, because the fastest rate of attention shift for the conscious generation of individual wheelchair control commands in a command sequence is in the order of one command every 200 ms (a period much greater than the 50-ms pulse spacing discussed above).

Success with this approach would result in a rate of myoelectric information flow that would also be adequate to allow the development of equipment enabling quadriplegics to compete in the labor force at such tasks as programming computers. Several myoelectric channels and considerable operator training would be required to achieve information transfer rates comparable to those obtained with the use of conventional keyboards.

Preliminary experimentation with two subjects has shown that it is possible

to generate pulse pairs with spacings in the order of 50 ms after practicing with feedback. The subjects were one of the experimenters, and an SCI patient with higher than average technical aptitude and motivation. Both feedback and performance monitoring were implemented by display of the myoelectric signal on a storage oscilloscope that was used in the single trace mode and triggered by the first pulse of a pulse pair. Each of the two subjects learned to generate pulse pairs at will (with approximately a 50 ms spacing between the two pulses in a pair). Less than half an hour of practice was required in each case to be able to successfully generate pulse pairs for approximately 50 percent of the attempts to do so.

Equipment for experimental training of patients is currently being developed. The myoelectric signal will be monitored with a microcomputer. A visual display will be used both to prompt the subject to generate either P or D and to provide on-line feedback pertaining to the results of each trial. In addition to notifying the subject as to whether or not the correct response has been made, the coded visual feedback will display errors in pulse spacing and duration. The feedback format is specifically chosen for effectiveness in assisting the subject to avoid past errors in future trials. The timing requirements for the pulse patterns will be adjustable by the operator, so the subject can start with a large pulse spacing in the order

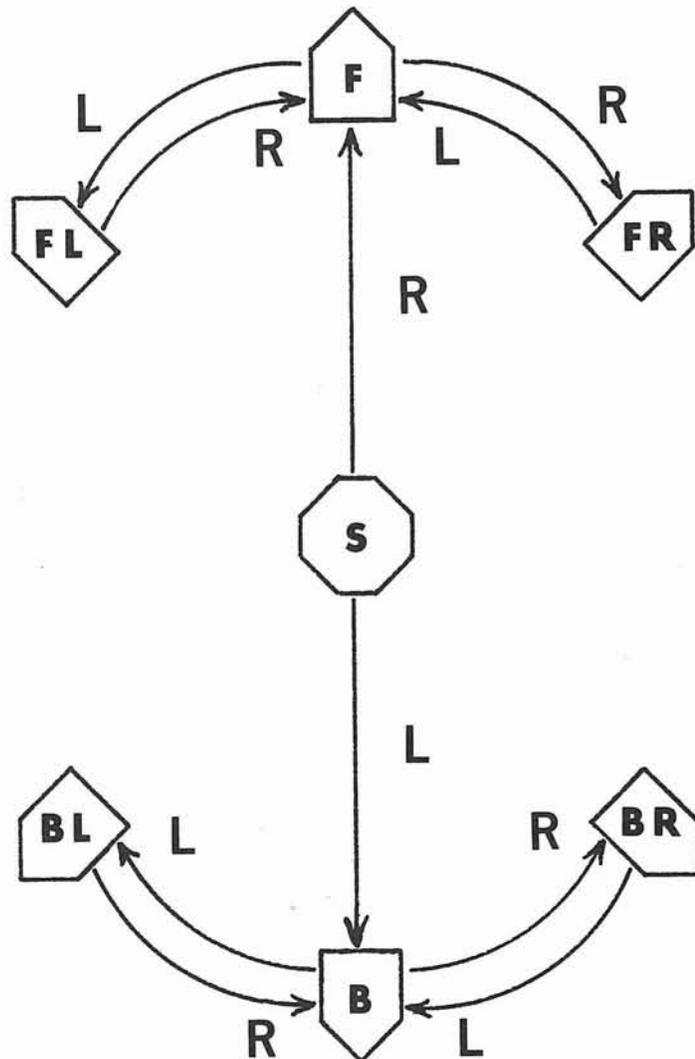


FIGURE 1. Improved wheelchair command code.

of one half-second. The subject will then be gradually led down through the critical threshold spacing in the order of 200 ms to shorter pulse spacing where the ability to perceive the generation of the two pulses as two distinct actions is lost.

At the time of this writing, the hardware facilities for this investigation have been constructed and tested. The software (microcomputer program for experiment control) is nearly completed. The positive results of the limited preliminary experimentation provided the prerequisite for development of the microcomputer-controlled patient training equipment described above.

The microcomputer-controlled equipment will be used for further experimentation to reduce the error rate of the two initial subjects and to train subjects more representative of typical SCI patients. In the preliminary experimentation discussed above, it was found that generation of pulse pairs subjectively bore no similarity to the initiation of two distinct actions. The subjects reported that it simply consisted of doing what made the two appropriately spaced pulses appear on the oscilloscope display. The microcomputer-controlled equipment will be used to assist typical SCI patients to gradually make the transition from wide pulse spacing to spacings that are below the level of conscious resolution. This equipment will allow the training procedure to consist of a sequence of simple and clearly defined steps rather than requiring the use of vague instructions such as telling the patient to do whatever makes an oscilloscope display have certain features. This equipment will be functional in time to obtain more conclusive data for the progress report in the next BPR issue.

Functional Muscle Control by Electrical Stimulation of Afferent Nerves

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Dr. Hussey has no report for this issue. He hopes to obtain substitute funding to continue this project, presently being pursued at a reduced level.

Power Steering for the Mobility Engineering Van-Compatible Wheelchair

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Under a contract with Mobility Engineering and Development, Inc., power steering is being developed for the MED, Inc., van-compatible wheelchair (This wheelchair was developed under an earlier VA contract with MED, Inc.). As a result of this contract, power steering will be installed on three prototype wheelchairs:

1. A MED, Inc., van-compatible wheelchair with a high-back integral-headrest van seat.
2. A MED, Inc., van-compatible wheelchair with E&J type upholstery.
3. A modified E&J wheelchair (21st Century Scientific Model 2C-3P-CP) retrofitted with power steering and electric brakes.

In addition to the power steering, other improvements will be provided on

these chairs to enhance their performance for eventual clinical testing. Most of these improvements were suggested by a short manufacturer-conducted test involving patients at Sepulveda VAMC.

To date, low-RPM motors have been installed on one of the MED, Inc., chairs to reduce noise as well as power consumption. Excellent results were achieved. Poly-V drive belts are also being installed to further reduce the noise.

Fabrication of the first model of control circuitry with power steering is nearing completion. New control boxes have been designed. One has been assembled, but has not yet been evaluated.

The electric braking system for the 2C-3P-CP has been designed and one prototype system is functioning. Minor changes to prevent the brake assemblies from extending beyond the outside edge of the rear wheels are still required. Performance tests are planned for the near future.

A clinical evaluation of the two configurations of MED, Inc., prototypes and the modified E&J chair, with and without power steering, is being planned for the end of FY 1981 and FY 1982.

Development of Hindfoot Joint Resurfacing Prosthesis

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Our first report on this project was contained in the Spring 1980 Bulletin of Prosthetics Research. As mentioned in that report, it was not possible to begin laboratory work until July of 1980

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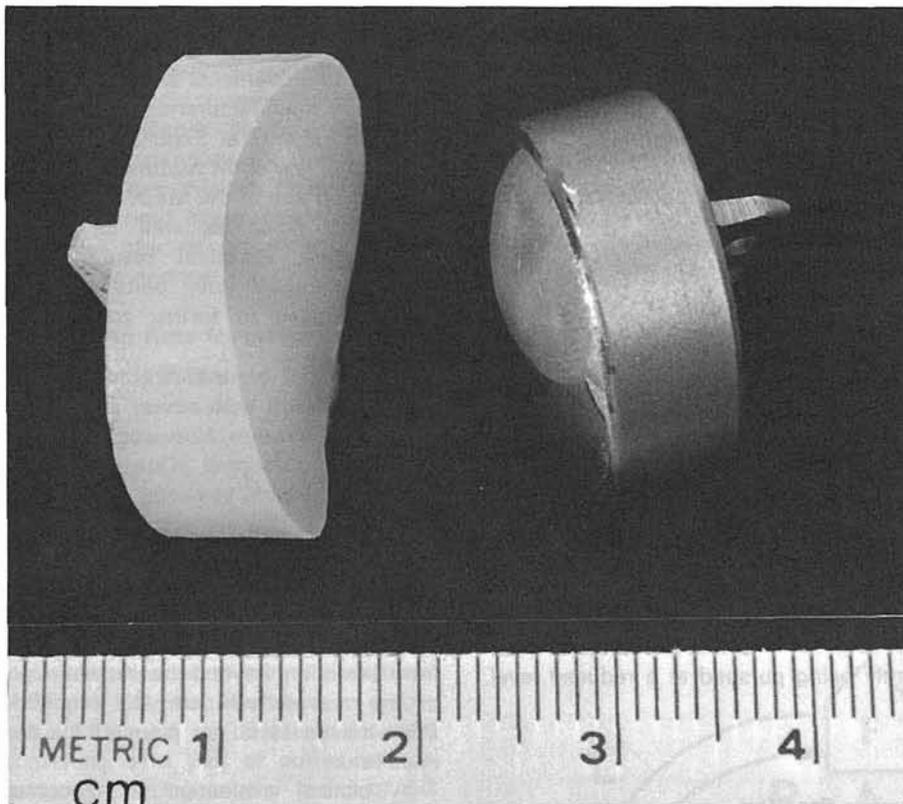


FIGURE 1. Prototype talonavicular resurfacing prosthesis. Talar component is 316L stainless steel, navicular is UHMWPE. Components would be available in various thicknesses to allow proper fit and ligamentous tension.

due to administrative delays in receiving the funding. Therefore, this report covers the first 6 months of actual laboratory work, July through December 1980.

As described previously, the purpose of this project is to develop hindfoot joint resurfacing prostheses for the talonavicular joint, the subtalar joints, and the calcaneocuboid joint. Two initial decisions were made regarding the prostheses to be developed: (i) the design of the prosthetic components would be such that only minimal amounts of bone would have to be removed. The purpose of this was to allow for the possibility that a prosthesis might have to be removed and that there should, therefore, be sufficient remaining bone to allow the performance of an arthrodesis as a salvage procedure. (ii) It was decided that the prostheses would be developed using standard total joint replacement materials (i.e., ultrahigh molecular weight polyethylene [UHMWPE] and wrought stainless steel or cast cobalt alloy). This choice of materials eliminates the need for special consideration to be given to problems of component wear and materials degradation.

Prior to the receipt of funding provided by the Veterans Administration, we had developed a prototype prosthesis for the talonavicular joint (Fig. 1). Therefore, initial tasks in this project were to evaluate this prototype talonavicular joint prosthesis for (i) adequate range and type of motion, (ii) adequate prosthetic component supporting cross-section to prevent subsidence of the components into the talus and the navicular under anticipated tibial loads, and (iii) determination of the effect of the prosthetic components on the distribution of ligament loads in the ankle-hindfoot joint complex.

The articular surfaces of the prototype talonavicular joint prosthesis were designed with only a brief examination of the surfaces of normal joints prior to the beginning of this project. To serve as a baseline for the evaluation of the type and range of motion provided by this prosthesis as determined by surface geometry, it was decided to evaluate carefully the surface geometry of 10 cadaver talonavicular specimens.

These specimens were evaluated for articular radius of curvature and arc length as a function of radial position about the center of the joint surface, for

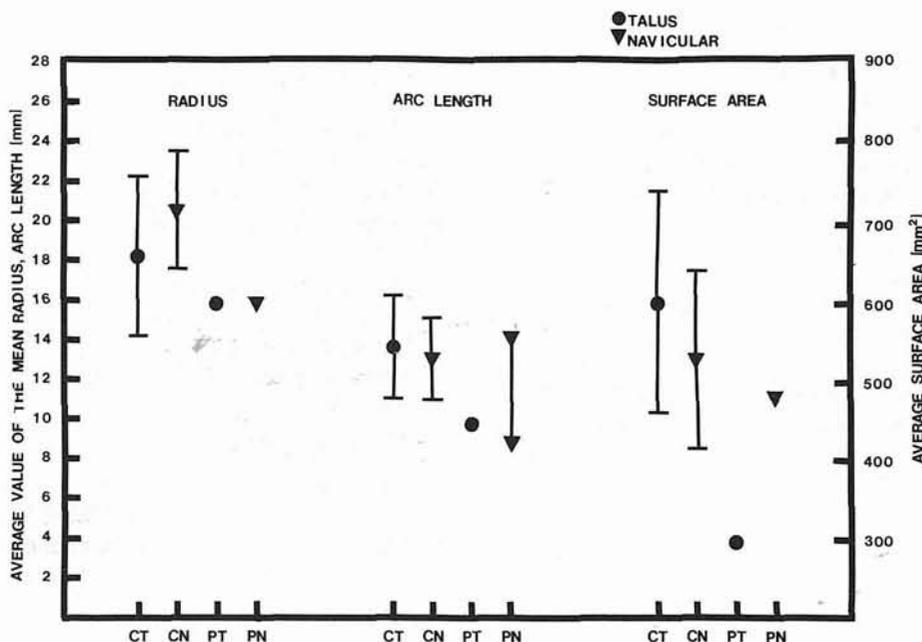


FIGURE 2. Comparison of average articular surface geometry of 10 cadaver talii (CT) and naviculars (CN) with components (PT, PN) of the prototype resurfacing prosthesis.

joint surface area, and for congruency between the talar and the navicular components. Measurements were accomplished by hand using radius gauges and profile gauges. A paper written as a result of this work was submitted to *Foot and Ankle* (the journal of the American Orthopedic Foot Society). It was accepted for publication. The paper contains a detailed description of experimental methods and results. However, some of the results can be summarized here. Figure 2 shows the surface geometry data for the cadaver specimens, and compares them to the surface geometry of the prototype talonavicular prosthesis.

In the cadaver specimens, it was found that in 8 out of 10 cases the navicular mean radius of curvature was larger than the talar mean radius. In contrast, in 8 out of 10 cases the navicular arc length, roughly indicative of the size of the joint surface, was less than the talar arc length. If one compares the data from the cadaver specimens with the data for the prototype prosthesis, two assessments can be made. First, it is apparent that the radius of curvature of the prototype

prosthesis is slightly smaller than is typical for the cadaver specimens as a whole. Secondly, it can be seen that the arc length of the navicular component reflects the arc length of the cadaver specimens rather well. In contrast, however, the talar component had a considerably shorter arc length showing that the small "button" configuration which was used for the talar component provides a noticeably smaller surface than is present in the natural joint.

These results indicate that the prototype does not strictly fulfill the design criteria for a true resurfacing prosthesis. However, no plans have been made to change the surface geometry until other subsequently described tests have been made on the same prosthesis. In that way any changes made can be integrated to respond to the other important design considerations (adequacy of support cross-section and maintenance of normal distribution of ligament loads).

Two types of data must be obtained in order to determine whether prosthetic components will be adequately supported. First, it is necessary to know the compressive strength of the can-

cellous bone plateaus created by removing joint surface material in preparation to receive the prosthetic components. Secondly, it is necessary to know the amount of tibial load which is transferred to the hindfoot in various foot positions. If the force per unit area applied by a joint prosthetic component to the cancellous bone plateau exceeds the compressive strength of the bone, subsidence of the prosthetic component into the bone will occur and the effectiveness of the prosthetic restoration will, of course, be seriously compromised.

Average values of compressive strength and approximate elastic modulus in compression of cancellous supporting bone for 13 fresh and two embalmed tali and naviculars have now been determined in our laboratory. Measurements were made with an Instron mechanical test machine using a 6.35-mm diameter flat-ended steel cylinder at a loading rate of 1.0 mm per minute. The tali and naviculars were prepared with flat surfaces as if to receive prosthetic components, and four measurements were made on each specimen surface.

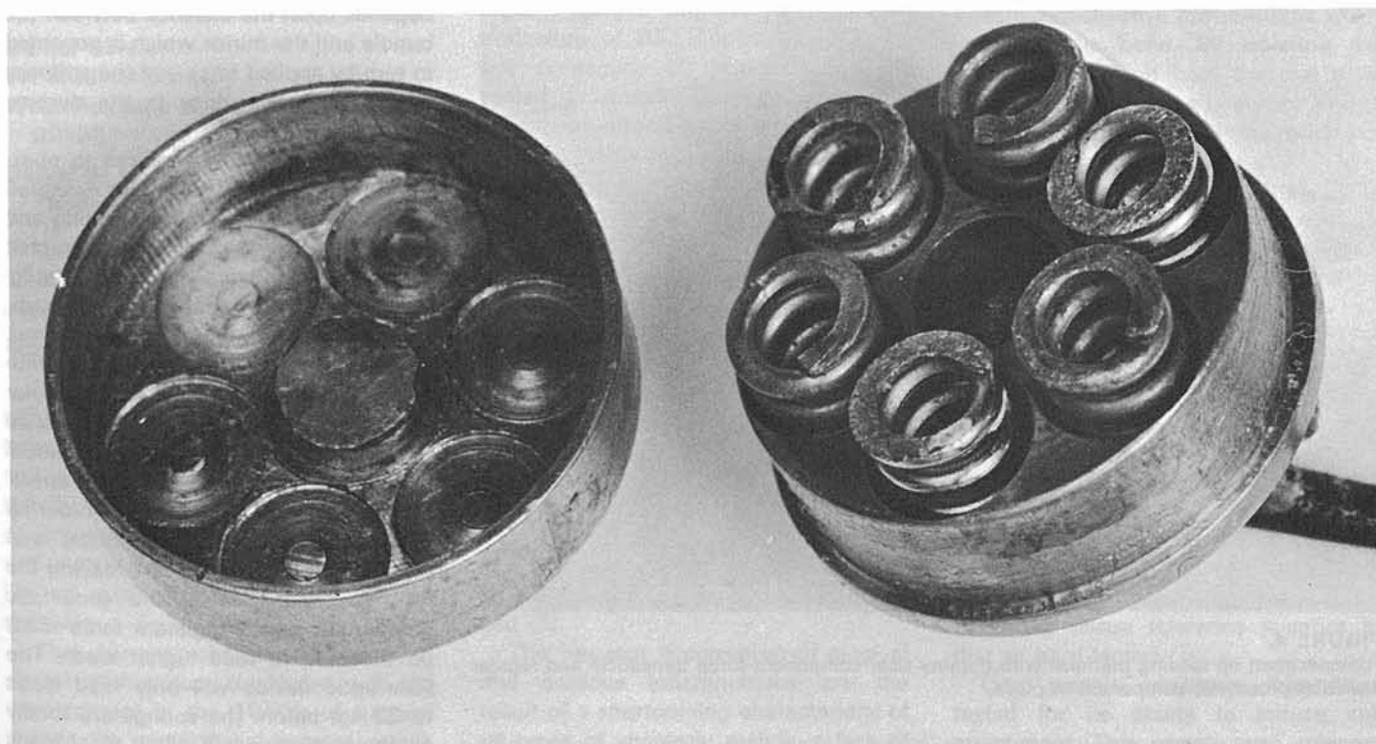


FIGURE 3. Interior of the dummy talar component-force transducer showing the loading springs, fiber bundle and mirror.

As shown in Table 1, the naviculars were less strong than their talar counterparts in 10 out of 15 cases. This seems logical and in keeping with Wolff's Law, since loads are distributed progressively to more bones in the foot as one moves distally from the tibia. Also, more of the dense cancellous bone immediately underlying the cortical bone of the joint surface and the cartilage is left around the periphery of the plateau prepared to receive the talar component than is the case for the

navicular implant site. In contrast to the strength relationship, the naviculars were stiffer in 11 out of 14 cases. The physiological significance of this is not known and there may be none since the data scatter was considerable.

Using these data and the cross-sectional areas of support for the present prototype talus and navicular prosthetic components, it appears possible that intra-articular loads of 207 kgf for the talus and 138 kgf for the navicular might cause cancellous bone

collapse. Since body weight is usually less than 100 kg and the portion of body weight reaching to the talonavicular joint will be less than that applied directly to the tibia, it appears that the prosthetic cross-section is sufficient at least to support the body in a static single foot stance.

Work was also begun during this reporting period on methods to determine the actual loads borne by talonavicular prosthetic components for a given static tibial load. A number of methods for determining loads on the talonavicular joint components were examined. We were not able to find any commercially available force transducers which could be interposed successfully between the prosthetic articular surfaces. Instead, the approach we have taken has been to construct a "dummy" talar component, internally instrumented to register force. Our initial effort in this direction is shown in Figure 3. This dummy talar prosthesis contains six stiff springs as shown, plus a centrally located fiber-optics bundle and a centrally located mirror. Half of the fiber optics bundle is used to transmit light to the mirror and the other half to receive the light reflected from the mirror. The amount of light returned to the fiber optics bundle depends upon the distance between the bundle and the mirror which is governed in turn by applied force and the stiffness of the internal springs in the dummy prosthesis.

Electronic circuitry required to operate the fiber-optic system was designed and constructed; a foot positioning and loading platform was also constructed as shown in Figure 4. Initial results with this experimental approach indicated that, as might be expected, talonavicular loads were maximal with the foot in plantarflexion. Talonavicular loads of up to 50 percent of applied tibial loads were recorded. The initial results revealed, however, that considerable work must be done in order to provide a means for adequately and reproducibly positioning and loading the foot specimens. Also, the prosthetic component which registers force must be modified to read higher loads. The fiber-optic device will only read loads to 33 kgf before the springs are totally compressed: this will allow tibial loads only up to about body weight, and it is desirable to test the forces across the

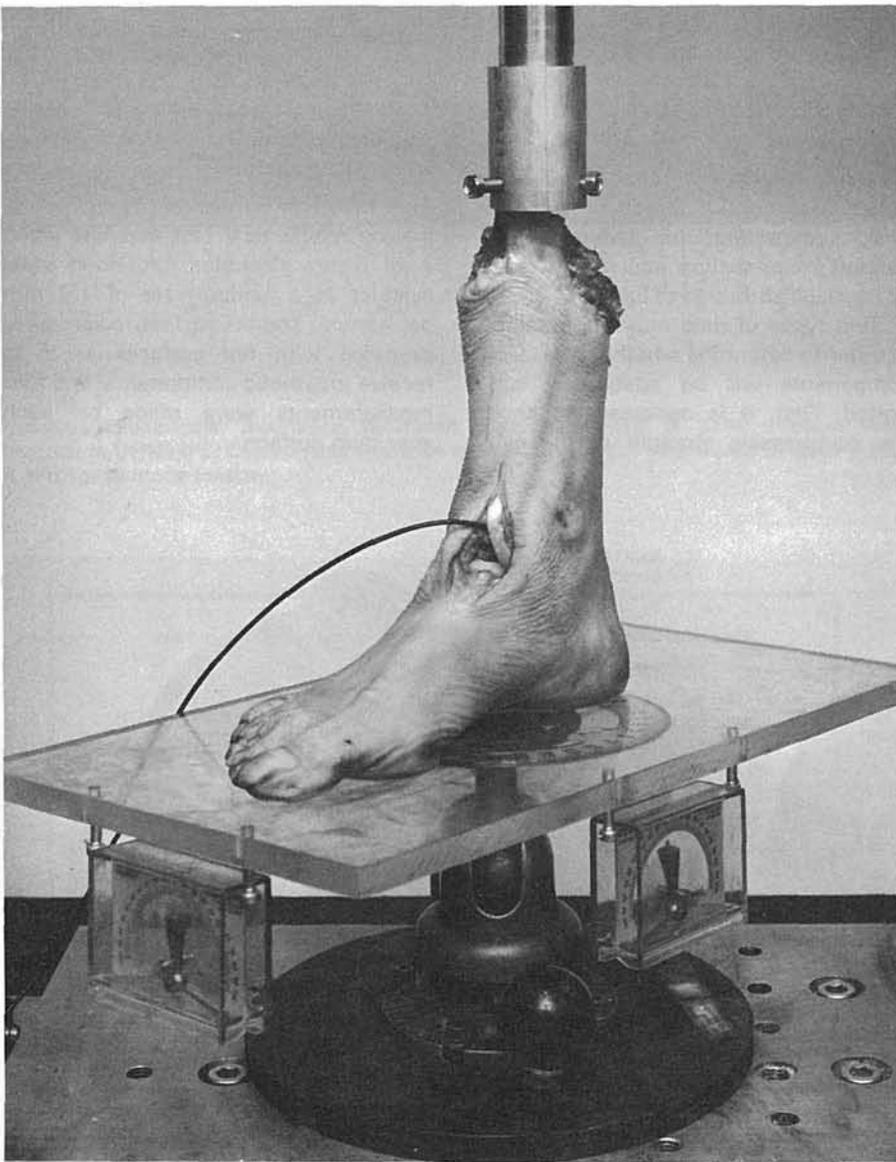


FIGURE 4. Footspecimen on loading platform with dummy talar component-force transducer and regular navicular prosthetic component in place.

talonavicular joint under somewhat higher tibial loads. Work is underway both to improve the foot loading and positioning platform, and to produce a

dummy prosthetic component instrumented with straingages to read higher loads.

TABLE 1.
Compressive Strength and Elastic Modulus of Talus and Navicular Specimens

Specimen No.	Compressive Strength (MN / m ²)		Elastic Modulus (GN / m ²)	
	Talus	Navicular	Talus	Navicular
1	9.58	6.31	0.758	0.202
2	15.40	33.60	0.102	0.694
3	114.00	28.60	4.770	0.388
4	27.40	11.30	12.200	0.316
5	55.40	15.60	7.180	0.823
6	46.40	4.96	2.390	0.155
7	22.90	20.90	1.430	1.010
8	25.80	14.20	9.770	0.163
9	11.80	3.86	1.860	0.044
10	30.30	71.30	2.590	2.930
11	65.80	45.60	3.060	1.790
12	36.20	64.80	0.944	1.240
13	11.80	18.80	2.610	0.744
14	5.08	12.70	0.760	0.439
15	—	30.80	—	—
Mean and Standard Deviation	34.1 ±29.2	25.6 ±20.8	3.60 ±3.65	0.781 ±0.786

Development of Hydrogel Surfaces for Dental and Orthopedic Implants

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This is the first report of a newly-funded research program with a starting date of October 1, 1980.

Introduction

Full denture wearers chew with an efficiency which at best is only 35 percent that of persons with intact natural dentitions (1). For this reason, the dental profession has long sought an implant to provide the anchorage and stability necessary to improve the limited masticatory capabilities of full dentures.

The current clinical discipline of dental implantology originated with the development in the 1940's of surgical metals for maxillofacial reconstruction. The subsequent availability of thermoplastic materials (particularly polymethyl

methacrylate) and the bioceramics resulted in a further proliferation of implant designs and techniques. A recent evaluation of 952 implants by Cranin and colleagues (2) however, has revealed an overall success rate of only 49 percent after 6 years in situ. Reports have led the Council on Dental Materials and Devices and the Council on Dental Research to recommend the curtailment of the clinical practice of endosseous implants for the present (3,4).

The typical dental implant is "semi-buried" in that portions extend into the oral cavity to serve as support for prosthetic replacements of the missing dentition. The clinical features which herald implant failure include hyperemia and circumferential hyperplasia of gingival tissues adjacent to the protruding implant, a seropurulent exudate expressed with moderate pressure, and mobility of the device within its osseous bed (5).

The frequent occurrences of gingival and osseous inflammations are the result of a shortcoming characteristic of all types of implants; mainly, a lack of attachment of gingival tissues to the implant at the point of emergence from

the jaw. Regardless of design or composition, all endosteal implants are encapsulated by fibrous connective tissue which effectively separates the device from host tissues and creates a potential space for the entry of oral micro-organisms (6).

Attachment of the natural tooth to both gingiva and bone is facilitated by the incorporation of collagen fibrils into the cemental layer of the tooth root (7). The tooth implant in use at the present time contain no surfaces or components capable of promoting a physiologic attachment with either gingivae or bone to achieve retention. Rather, the problem of retention has been addressed from a purely mechanical viewpoint.

Hypothesis

In the present study, a biological approach to the retention of dental implants is proposed. Several biological substances have been identified recently which are capable of promoting cell attachment and stimulating the formation of specific connective tissues through the transformation of cells. It is hypothesized that by incorporating such substances into implants with their biological properties intact, a prosthetic device can be fabricated which will actively promote the synthesis of an attached connective tissue matrix when embedded in bone. By isolating the submerged portion from the oral environment, the attached matrix would prevent inflammation of the bone-implant interface.

Preliminary Findings

The overall approach to the problem of cell attachment is to develop a protein-containing hydrogel which will ultimately serve as a surface coating for conventional implants. The hydrogel under investigation is the crosslinked polymer poly [2-hydroxyethyl methacrylate] or PHEMA.

Among the many applications of this material (8), the most important usage by far is in the fabrication of soft contact lenses (9). The principal advantage of hydrogel lenses are the ease of fit and a tissue tolerance superior to that of hard lenses.

One protein, collagen, has been tested for its ability to induce cell attachment. This protein was selected on the basis of its reported ability to promote cell differentiation (10,11) and

cell attachment to a substratum (12), *in vitro*.

Type I collagen was obtained from acid soluble pepsin digests of rabbit bone matrix by salt precipitation (13). PHEMA hydrogels were prepared as described by Refojo (14). The ingredi-

ents are HEMA, ethylene glycol, water, 12 percent sodium metabisulfite and 6 percent ammonium persulfate in volume proportions of 6:0.6:3:0.2:0.2, respectively. The mixture is pipetted to siliconized glass tubes and polymerized 4 to 6 hours at 37 degrees C. The

resulting flexible rods are dialyzed exhaustively against saline to remove unbound ingredients. Collagen solutions are added as the aqueous component of the formulation.

Hydrogel rods, 3 mm in diameter by 5 mm in length, with and without collagen, were implanted intramuscularly in adult albino rabbits. After 4 weeks *in situ*, the hydrogels and encapsulating tissues were removed for histologic examination. The specimens were collected in formalin and embedded in methacrylate. Four-micron thick sections were stained with hematoxylin and paragon trichrome.

Figures 1 and 2 are cross-sectional views of hydrogels without and with, respectively, type I collagen after 4 weeks *in situ*. The regular alignment of fibroblasts and dense connective tissue encapsulating the hydrogel without collagen (Fig. 1) is typical of the interface formed in response to bone-embedded dental implants. In contrast, a composite interface was formed in tissues surrounding a collagen-containing hydrogel. Figure 2 shows that a looser connective tissue containing cells morphologically different from fibroblasts was formed adjacent to the hydrogel surface, separating it from the nearby fibrous capsule.

The use of micropores to enhance cell contact and attachment to the added protein has also been studied. Porous hydrogels were prepared by adding particles of NaCl or sucrose, 100 to 250 microns in size, during polymerization. Pores are created by the dissolution of the embedded particles during dialysis of the polymerized plastic. When transplanted to rabbit muscles, an ingrowth of cell processes occurred at hydrogel surfaces with (Fig. 3) and without (Fig. 4) added collagen. The most notable difference was an increased cellularity in the presence of collagen. Tentative histologic evidence of tissue adhesion was obtained in analyses of hydrogel plugs intentionally withdrawn from encapsulating tissues *in situ*. A thin layer of cells (two to three cells thick) was detected on some surfaces of porous hydrogels with collagen.

Proposed Work

A second protein, the serum glycoprotein fibronectin, will be incorporated into PHEMA hydrogels. The binding of

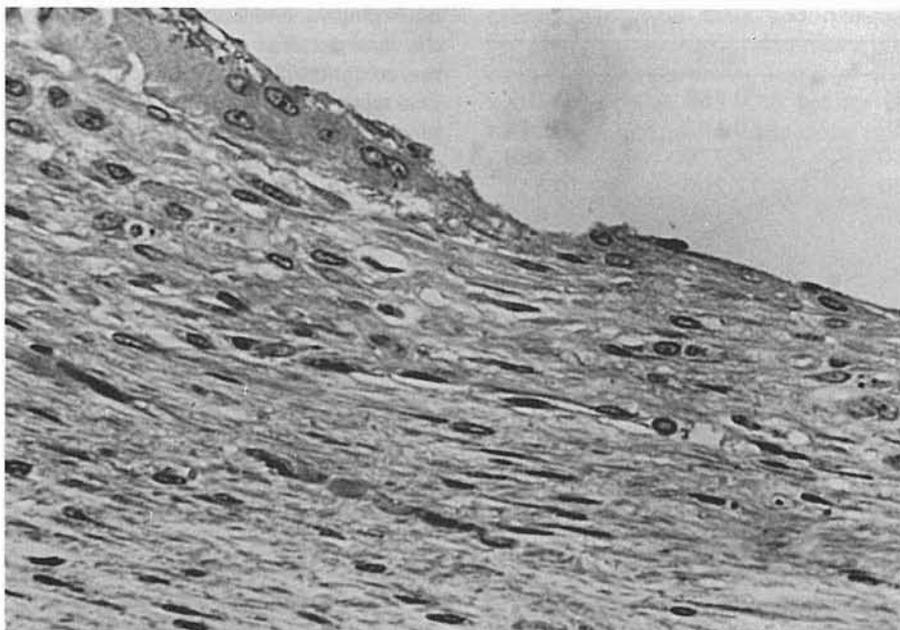


FIGURE 1.

Four-micron-thick crosssection of a hydrogel transplant (clear area) and its tissue bed after 4 weeks in a rabbit muscle pouch. The hydrogel, which contained no proteins, was encapsulated by dense fibrovascular connective tissue. A multinucleated giant cell can be seen at the hydrogel surface.

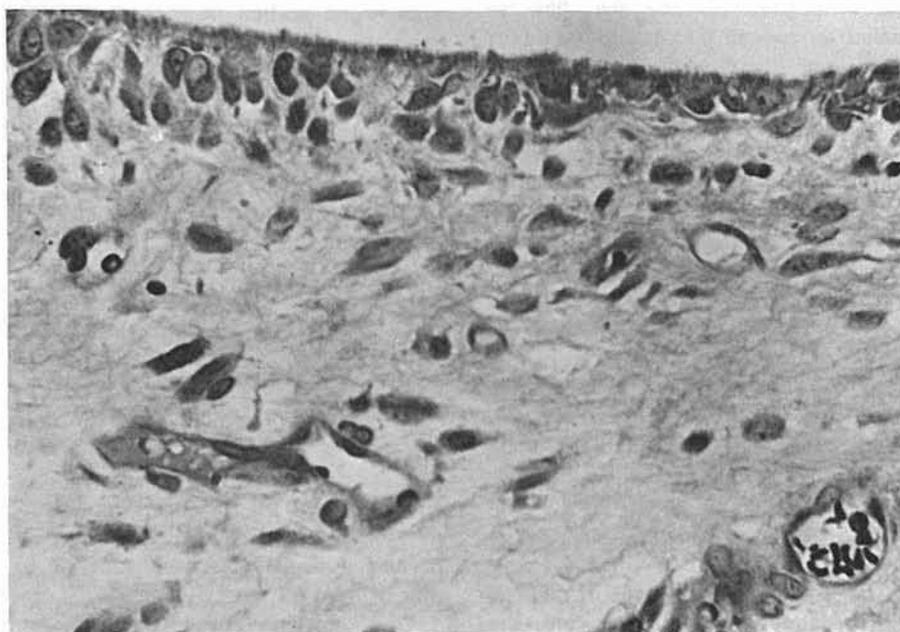


FIGURE 2.

A hydrogel transplant, from the same rabbit as Figure 1, containing type I native collagen from rabbit bone at 30 µg/ml of copolymer mixture. The tissue reaction consisted of loose connective tissue with a highly cellular layer at the hydrogel surface.

fibronectin to cells' surfaces, demonstrable by immunofluorescence (15), restores certain normal surface properties to transformed cells such as adhesiveness and contact inhibition of movement (16). Of particular interest to the present study are the observations that the addition of fibronectin to cells in culture induces the formation of actin bundles and a flattened cellular morphology, suggesting a close association between cytoskeletal actin and membrane-associated fibronectin (16, 17). A transmembrane linkage between actin and fibronectin during cell attachment has recently been proposed on the basis of immunofluorescence and ultrastructural findings (18, 19).

Under laboratory conditions, fibronectin binds readily to collagen, alpha chains and to the cyanogen bromide peptide alpha-1(I)-CB-7 (20). A collagen-fibronectin meshwork has been demonstrated on the external surfaces of attached cultured fibroblasts which disappears after dissociation with trypsin and reappears after reattachment (21).

In view of these findings, pre-formed collagen-fibronectin complexes are to be incorporated in hydrogels to promote cell and tissue attachment. All of the research is conducted in rabbits and dogs. Protein-containing hydrogels, prepared as described previously, are tested intramuscularly and intraosseously for morphologic evidence of cell attachment. Hydrogels are prepared with autologous proteins to reduce immunological phenomena.

1. Isolation of plasma fibronectin—Affinity chromatography as described by Engvall and Ruoslahti (22) will be used to obtain fibronectin. Briefly, gelatin is coupled to cyanogen bromide-activated sepharose 4B. Plasma from 50 ml of freshly drawn blood is chromatographed at room temperature on a 1.5 X 7.5 cm column in phosphate-buffered saline (pH 7.2, .01 M sodium citrate). Adsorbed fibronectin is eluted with 8 M urea and recovered from the urea eluate by dialysis against acetate buffer, pH 3.4.

2. Extraction of type I skin collagen—A 1 X 10 cm strip of dorsal skin is trimmed of epidermis and subcutaneous fat, minced, homogenized and pepsin digested in .5 M acetic acid for 18 hours at 4 degrees C. Digestion is

terminated by the addition of 3 M tris and the supernatant digest, collected by centrifugation, is dialyzed against 1.7 M NaCl (.05 M tris, pH, 7.5) to precipitate type III collagen. The 1.7 M supernatant, collected by centrifugation, is made 2.4 M in NaCl to precipitate type I

collagen. Type I collagen is reprecipitated at 2.4 M NaCl three additional times. The final precipitate is purified by suspending in 0.2 M NaCl-.05 M tris (pH 7.6), dialyzing against the same buffer for 24 hours at 4 degrees C, and applying to a DEAE-cellulose column



FIGURE 3. 4- μ thick cross-section of a hydrogel transplant containing 30 μ g collagen / ml of copolymer mixture with micropores produced by the dissolution of embedded sucrose particles measuring 100 to 250 microns. The transplant and its tissue bed were removed after 4 weeks in a rabbit muscle pouch. Cytoplasmic extensions into the plastic and a highly cellular connective tissue characterized the tissue response.

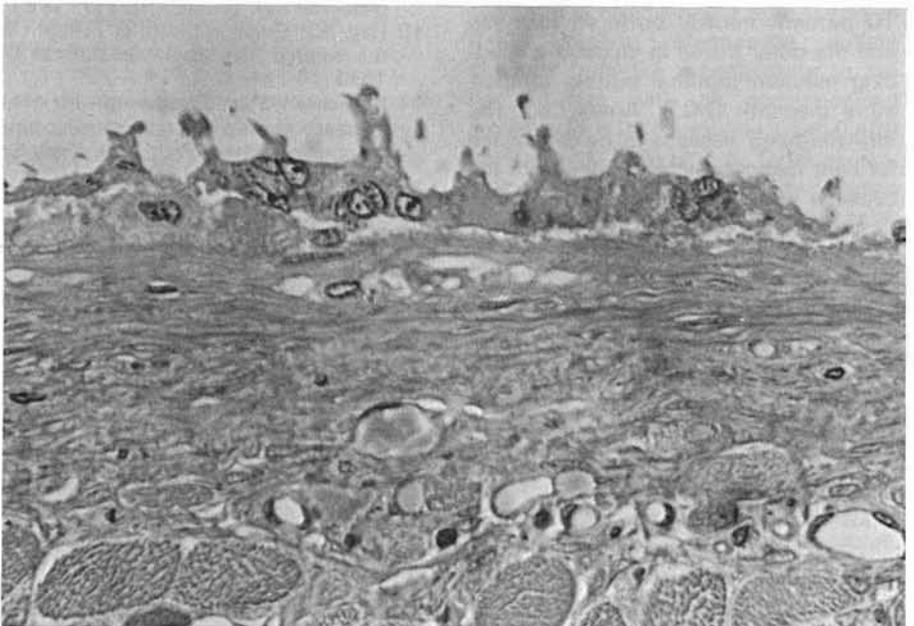


FIGURE 4. This transplant, removed from the same rabbit as that of Figure 3, was prepared in the same manner but without added collagen. The tissue reaction was similar with respect to cytoplasmic extensions but differed in that a thinner, less cellular and more fibrous connective tissue encapsulated the hydrogel.

equilibrated with the NaCl-tris buffer. Type I collagen is eluted from the column with the same buffer at 4 degrees C, while proteoglycans are retained by the column.

3. Collagen-fibronectin complexes: binding studies.—The proteins added to hydrogels will be in the form of Type I collagen-fibronectin complexes. This part of the research will determine the proportions of each protein necessary for complete binding. The methods are a modification of the inhibition assay of Kleinman et al (20). Briefly, I-125-labelled fibronectin and I-131-labelled collagen (by the chloramine T method) are combined in different proportions and the mixtures are chromatographed on a gelatin-sepharose column. Uncomplexed I-125-fibronectin is retained by the column, while collagen-fibronectin complexes are eluted with column buffer.

4. Morphologic assay for cell attachment—Intramuscularly implanted hydrogels will be removed 4 to 8 weeks after placement and examined microscopically for evidence of cell attachment.

Each implant will be harvested with a small amount of surrounding muscle tissue and cut cross-sectionally into equal halves. One-half will be fixed in 10 percent neutral buffered formalin and the other frozen in cryostat embedding medium (optimal cutting temperature medium; O.C.T., Ames Co.). The formalin-fixed tissue will be processed for light microscopic examination of the capsular tissues and cell populations as described previously.

The frozen tissue specimens will be examined by fluorescent technics for evidence of cytoskeletal actin bundles indicative of cell attachment to the hydrogel. Actin will be labeled by the addition to thin cryostat sections of heavy meromyosin (HMM), a subfragment of myosin, conjugated with fluorescein isothiocyanate (FITC). HMM binds specifically to actin filaments.

5. Dental implants—The reaction of healing bone to protein-containing hydrogels will be observed for a period of up to one year. Hydrogels are to be polymerized as coatings of metallic tooth replicas. The optimal protein concentrations and porosity character-

istics will have been determined in the previous phase of experiments. The coated replicas will be inserted into fresh dog tooth extraction sites and the gingiva sutured to close the sockets.

Future research programs will examine protruding dental implants.

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Bone Strength: In Vivo Stress and Strain

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The Orthopaedic Bone Biomechanics Laboratory at the Seattle Veterans Administration Hospital is continuing to examine in vivo strain and stress data as well as continuing to assess the in vitro mechanical properties of bone tissue. Preliminary experience has shown that in vivo strain measurements can be reliably monitored from the cortical surface of large animals such as the dog. Additional work is progressing at present so that in vivo strains can be monitored from rats. Although the histology of rat cortical bone is different from canine and human bone, preliminary measurements suggest strain measurements are surprisingly similar. Results of our initial studies are summarized in the manuscripts listed and additional papers submitted but not yet in press.

The Orthopaedic Bone Biomechanics Laboratory has also continued to analyze the effects of alteration in bone composition on mechanical properties. An analysis of the effect of fluoride and dichloromethylene diphosphonic acid (Cl₂MDP) on bone turnover and bone

strength has been completed and submitted for publication. Growing rats were given 100 ppm of fluoride as sodium fluoride (NaF) in the drinking water, 0.5 mg. per kg. body weight of phosphorus as dichloromethylene diphosphonic acid (Cl_2MDP) injected subcutaneously, or both.

Fluoride treatment increased periosteal bone formation and endosteal bone resorption while the Cl_2MDP decreased endosteal resorption. When given together Cl_2MDP counteracted the fluoride effect on both bone formation and resorption, yet the bone resorption in the combined group was still increased. Fluoride did not alter the mechanical properties of bone. Cl_2MDP treatment caused an increase in bone stiffness but a decrease in ultimate torque, angular deformation, and energy absorption. When given together fluoride treatment could only partially overcome the Cl_2MDP effect.

In addition to the above studies, we continued investigation of the uniaxial fatigue properties of human cortical bone. Monotonic tensile tests and uniaxial fatigue tests were conducted on devitalized human cortical bone specimens. Fatigue testing was conducted with strain ranges ($\Delta\epsilon$) from 0.005 to 0.010 and mean strains of either -0.002, 0.0, or +0.002. Stress range of the first loading cycle (Δ stress₀) was documented for each specimen.

The results showed that the number of cycles to failure (N_F) was independent of mean strain, and that fatigue is more strongly controlled by strain range than stress range. The data also demonstrated that the fatigue resistance of bone is much lower than indicated by previous bending fatigue tests. The results suggest that the fatigue strength of cortical bone at 10^7 cycles may be closer to 7 MPa than 40 MPa as indicated by previous bending fatigue tests.

Implications of these findings are quite significant. Extremely low value for fatigue strength would indicate that human cortical bone may be constantly accumulating fatigue damage during normal daily activities. The normal process of bone remodeling would thus be a prerequisite to the long-term structural integrity of the skeletal system. Details of this work are listed in the bibliography. Dr. Dennis Carter and William Caler of the Orthopaedic Research Laboratories, Massachusetts

General Hospital, directed this phase of the investigation, initially performed at the University of Washington and finished at Massachusetts General Hospital.

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Development of Improved Grouting Materials for Artificial Joint Replacement

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In an attempt to overcome the acute and chronic shortcomings associated with the use of acrylic cement in the fixation of artificial joints (and concurrently to achieve early postoperative joint stabilization) a new method of stabilization is being investigated.

In the model proposed, the prosthesis is to consist of a "standard femoral artificial hip" whose stem is to be coated with a porous material, e.g., metal, ceramic, or polymer of pore size 120-400 microns. At appropriate places along the stem are to be inset sections of a swellable, biodegradable, hydrophilic material whose surface is to be flush with the surface of the porous coating. In use, the artificial hip will be placed in the close-fitting cavity in the femoral intramedullary canal and the following hypothesized series of events are expected to occur: swelling of the hydrophilic material against the bone

will provide initial stabilization of the prosthesis; bony ingrowth into the porous coatings on the prosthesis stem will then occur to provide additional stabilization; subsequently the swollen biodegradable material will be resorbed and replaced by additional bony ingrowth. The result would be a femoral hip prosthesis stabilized initially by the swollen material and ultimately by bony ingrowth.

During this period, work has been concentrated on the development of hydrophilic materials consisting of composites of poly-epsilon caprolactone (PCL) and inorganic salts which form hydrates.

The composites are prepared by milling the inorganic salts into the polymer on a two-roll rubber mill at a roll surface temperature of 40 degrees C. The milled sheets which form are then chopped up and may be molded to any desired shape. Three of the polymer salt composites were produced:

- Composite I—
50.3% $\text{CaSO}_4 \cdot \frac{1}{2} \text{H}_2\text{O}$ /49.7% PCL
Composite II—
71.5% $\text{CaSO}_4 \cdot \frac{1}{2} \text{H}_2\text{O}$ /28.5% PCL
Composite III—
50.3% MgSO_4 /49.7% PCL

On exposure to water, calcium sulfate changes from the hemihydrate to the dihydrate with an accompanying increase in specific volume from 0.383 to 0.431 cm^3/g . Magnesium sulfate changes from the monohydrate to the heptahydrate with an accompanying increase in specific volume from 0.409 cm^3/g to 0.595 cm^3/g . Calcium sulphate has a low water solubility whereas magnesium sulfate a high water solubility and the latter may have limited usefulness in the implant. It was originally selected because of its large specific volume increase upon hydration and its high osmotic activity. This provided the possibility of enhancing implant swelling rates to allow more rapid stabilization.

The composites were evaluated with respect to swellability and swelling rates in Ringers solution, swelling pressures, and shear stresses withstood when simulated prosthesis were implanted in bovine bone.

In the free swelling experiments, molded discs of the composite were immersed in Ringers solution. The greatest volume swelling was obtained

with the Composite II, containing 71.5 percent CaSO_4 . The swelling was 49 percent compared to 4 percent for Composite I and 24 percent for Composite III. These values compare to 0.2 percent swelling for unfilled polymer. The rate of swelling was highest for Composite III, the composite containing magnesium sulfate.

The swelling pressure measurements were carried out on molded discs of the material immersed in Ringers solution, and which were restrained from swelling. Such measurements are of importance in this work because in stabilizing a prosthesis, the pressure exerted by the swollen polymer against bone determines the magnitude of the frictional force holding the prosthesis in place. In this instance Composite II, gave a swelling pressure of 100 psi, and Composite III, a swelling pressure of 49 psi. The initial portions of the swelling pressure curves for both Composites are linear and the slopes may be taken as first order, initial swelling rate constants. The rate constant for Composite III is 0.723 psi/hr which is three times as large as the rate constant for Composite I, 0.240 psi/hr. This faster rate would be expected from the higher osmotic activity of magnesium sulfate.

Simulated prostheses consisting of stainless steel rods with molded insets of Composite I were prepared and implanted in bovine bone which was immersed in Ringers solution for various time periods up to 20 days immersion. Shear stresses were then measured. The shear stresses increased from 6 psi to 47.8 to 135 psi, in from 3 to 20 days.

The polymer salt composites appear to have useful properties as implant stabilization materials. The one significant drawback is the relatively slow swelling rate—a desirable time for adequate stabilization of a hip prosthesis for partial weightbearing would be within 24 hours after surgery.

Two apparent ways of achieving higher swelling rates would be the use of polymers more hydrophilic than PCL and/or exploitation of the osmotic effect. A more hydrophilic polymer such as polylactic acid would provide faster diffusion of water throughout the material. This should result in faster swelling. It has been shown that magnesium sulfate with high osmotic activity produces a much faster initial swelling rate

than calcium sulfate. The problem is that salts of high osmotic activity are also highly soluble so that no longterm implant stability may be expected. The solution may be to compound a material with an insoluble filler like calcium sulfate and a small amount of magnesium sulfate. The magnesium sulfate would provide a higher initial swelling rate and the hydrated calcium sulfate would maintain the swollen state after the magnesium sulfate was dissolved away.

Also to be studied is the use of other salts in the composite. Two possibilities are dibasic calcium phosphate and tetra sodium pyrophosphate. Dibasic calcium phosphate forms a dihydrate and should behave similarly to calcium sulfate. Its use is suggested by the fact that it is a precursor of hydroxyapatite, the primary mineral in bone. Tetrasodium pyrophosphate forms a decahydrate with a 40 percent volume increase, yet it is less soluble than magnesium sulfate.

Functional Spinal Cord Regeneration

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In order to study the mechanisms involved in recovery of function in the mammalian spinal cord after injury, it is requisite that an understanding of the basic synaptic organization of segmental motor control is achieved. Since the report in the previous issue of the Bulletin (BPR 10-34, 1980) this laboratory has made substantial progress in the understanding of the synaptic projection of spindle group II afferent fibers onto spinal motoneurons.

Mammalian muscle spindles (muscle stretch receptors) give rise to two groups of afferent fibers, both activated by muscle stretch: (i) rapidly conducting group Ia fibers and (ii) slowly conducting spindle group II fibers. Central actions of group Ia fibers are known in great

detail (1, 2, 3, 4). The central actions of spindle group II afferent fibers, however, are poorly understood, primarily because of the difficulty in activating them selectively using electrical stimulation and blocking techniques (5).

The introduction of the spike-triggered computer averaging (STA) technique by Mendell and Henneman (6) has permitted study of the actions of individual afferent fibers on their target motoneurons. Using this technique, Kirkwood and Sears (7) and Stauffer et al. (8) reported the presence of a monosynaptic projection of spindle group II afferents to spinal motoneurons.

Recent studies in this laboratory have provided the first rigorous examination of the properties of the medial gastrocnemius (MG) spindle group II projection to cat triceps surae motoneurons in a sample containing a large number of motoneurons and a wide spectrum of afferent fiber conduction velocities (9, 10). These studies demonstrated that functional connectivity is closely related to afferent conduction velocity. Spindle group II afferent fibers were divided into two functional connectivity groups based on the proportion of homonymous motoneurons receiving a monosynaptic projection. Fast afferents (greater than 52 m/s) had high connectivity (69 percent) whereas slow afferents (less than 52 m/s) had low connectivity (27 percent).

Maps of the location of homonymous (MG) and heteronymous (lateral gastrocnemius and soleus (LGS)) motoneurons connected with single MG spindle group II fibers were constructed (Fig. 1). Major collateral branches of fast and slow spindle group II afferent fibers were found to descend into the triceps surae motoneuron pool at 1–1.5 mm intervals. The terminal ramifications were shown to be much greater for fast than for slow spindle group fibers.

The amplitude of spindle group II single-fiber excitatory postsynaptic potentials (EPSPs) bore no significant relationship to afferent or motoneuron conduction velocity, to motoneuron species (i.e., homonymous or heteronymous), to terminal potential amplitude, or to location of the synapse on the motoneuron. The mean amplitude of single-fiber spindle group II EPSPs was 24.3 μV in homonymous motoneurons and 17.0 μV in heteronymous moto-

neurons. Measurements of spindle group II EPSP rise time and half-width indicated that spindle group II EPSPs may be generated in multiple electrotonic compartments of the target motoneuron's somadendritic membrane.

Based on these data, it was possible to obtain the first reasonable estimates of spindle group II aggregate EPSP amplitude (the aggregate EPSP is the postsynaptic potential generated by action potentials arriving more or less synchronously in all given presynaptic fibers from a defined source, e.g., all spindle group II afferent fibers from the MG muscle). A computed aggregate EPSP amplitude was obtained by multiplying the mean single-fiber EPSP amplitude by the mean number of fibers connecting with a target cell. Computations of aggregate EPSP amplitudes for the projection of MG spindle group II afferents to MG and LGS motoneurons, however, is complicated by the findings that fast and slowly conducting group II afferents exist in unequal numbers in the MG muscle nerve. Approximately two thirds of the 71 MG group II fibers which have axonal diameters of 4–12 μm are less than 9 μm in diameter, placing them in the slow afferent category. Accordingly, aggregate EPSPs were computed separately for fast and slow spindle group II afferent projections to homonymous and heteronymous motoneurons. The aggregate EPSP amplitude computed for fast

spindle group II afferents projecting to MG motoneurons was 0.4 mV. Calculations for the remaining afferent-motoneuron connections revealed the following aggregate EPSP amplitudes: fast group II to LGS motoneurons, 0.1 mV; slow group II to MG motoneurons, 0.28 mV; slow group II to LGS motoneurons, 0.06 mV.

Analysis of single traces of spindle group II motoneuron single fiber EPSPs showed a limited and continuous range of EPSP amplitudes. Moreover, a mean synaptic latency of 0.57 ms was found to exist at the spindle group II – motoneuron synapse. These data indicate that the nature of spindle group II – motoneuron synaptic transmission is monosynaptic and chemically mediated.

The functional role of this segmental spindle group II excitatory pathway to motoneurons may include tonic excitation of antigravity musculature, maintenance of an excitatory level in motoneurons, minimizing oscillations in the muscle feedback control system, production of the tonic stretch reflex, and the generation of shivering. These recent studies on the monosynaptic projections of spindle group II afferent fibers to spinal motoneurons most certainly provide a wealth of new information on this important system, and should lead to an improved understanding of the mechanisms involved in spinal cord motor control, as well as furnishing an important normative data base for this

laboratory's investigations of the mechanisms of regeneration and synaptic plasticity in the spinal cord after injury.

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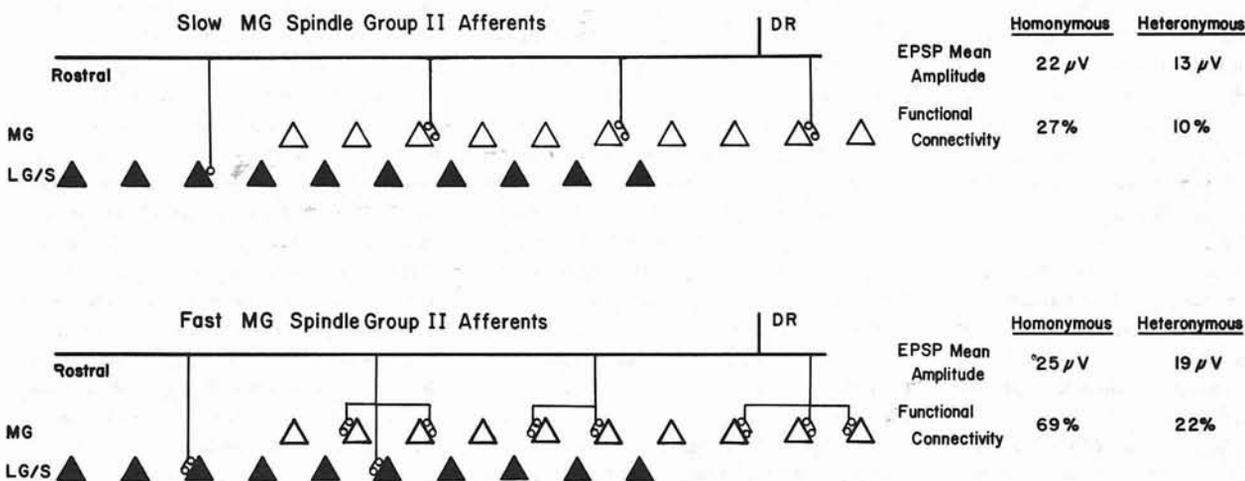


FIGURE 1.

Summary of homonymous and heteronymous monosynaptic actions of fast and slow MG spindle group II afferents. Major collateral branches of group II afferents probably occur at 1- to 1.5-mm intervals along the length of the triceps surae motoneuronal pool. Branches of slow group II fibers ramify little; branches of fast group II fibers ramify extensively to contact motoneurons throughout most of the same pool. EPSPs are similar except that rise times and EPSP latencies of slow group II EPSPs are briefer. On the average, group II afferents make monosynaptic contact with half of homonymous motoneurons. (DR, dorsal root.)

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Program for Evaluating and Monitoring the Dysvascular Patient

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This newly initiated "Program for Evaluating and Monitoring the Dysvascular Patient" is composed of two projects: (i) assessing the role of myocutaneous perfusion measurements in the rehabilitation of the amputee, and (ii) an experimental-clinical study of the effects of lumbar sympathectomy in the management of atherosclerotic occlusive disease. This initial report presents the goals of the projects and the proposed methods to meet these goals.

Role of Myocutaneous Perfusion Measurements

This proposed study is designed to apply two methods of determining local perfusion rates to clinical problems having to do with the rehabilitation of amputees. The plan of work can be roughly divided into three broad categories. They are: development of instrumentation package, controlled animal experimentation, and clinical verification. It is hoped that upon completion of this study, the rehabilitation of amputees (both prospective and existant) will benefit from a straightforward application of these quantitative perfusion analysis methods.

Developmental work will be concerned with electrode fabrication and investigating techniques of insertion that are clinically suitable. We will also use commercially available photoplethysmographic sensors. The fitting of the photo probe with a suitable pressure registering device will involve some technical innovation and development, but we do have similar experience and have performed preliminary clinical trials in our vascular laboratory. The set of data is referred to as myocutaneous perfusion analysis. The development of

this integrated measurement system will be the first task we will address. The general criteria that will be applied to the instrumentation system includes consideration of patient safety, stability and accuracy of sensors, ease of use in clinical environment, and cost of equipment and testing.

A series of animal experiments will be performed to relate the myocutaneous perfusion measurement derived from the hydrogen and pressure photoplethysmograph to direct electromagnetic flow probe and analysis of tissue metabolism. The procedure will involve exposure of the femoral artery in anesthetized canines (beagles) and primates (*Macaca mulatta*). An electromagnetic flow probe will be placed around the vessel distal to a controlled graduated stenosis. Sterilized hydrogen electrodes will be embedded in the muscle and the overlying skin. The photoplethysmograph probe with the attached applied pressure sensor will be positioned on the skin of the ipsilateral medial thigh. A run will consist of the animal breathing an O₂ enriched air mixture with no more than 2 percent hydrogen added (explosive limit $\geq 3.84\%$ H₂). After the output of the H₂ electrodes stabilizes, the hydrogen in the breathing gas is reduced to zero and the two washout curves are recorded. Recordings from the photoplethysmograph probe are also taken. This data will include the pulsatile component indicative of the quality of flow, the absolute changes of reflectivity, and the perfusion pressure determined by recording the applied pressure required for cessation of pulsations or to blanch the area.

This series of data will be acquired as the limb gradually becomes more ischemic by increasing the controlled stenosis on the femoral artery. Arterial blood samples along with blood drawn from the femoral vein will be analyzed to obtain limb oxygen consumption, pH, lactic acid levels, and other biochemical parameters associated with tissue ischemia.

Following this series of canine and primate experiments, which will quantitatively relate the myocutaneous measurements with overall limb perfusion and ischemia, a series of 10 canines will be employed in a preliminary investigation of chronic ischemia and the ultimate limits of tissue viability.

Baseline measurements of myocutaneous flow will be performed prior to surgical ligation of the femoral artery. Follow-up measurements will be taken at one week intervals. Symptomatic indications of ischemia will be noted. After a period of time which will be determined by the severity of symptoms or level of myocutaneous flow, an attempt will be made to bypass the occluded segment with a vascular graft to restore flow. If this does not succeed, an amputation will be performed using data from the perfusion probes as a guide. This part of the study is not expected to be definitive but should provide important physiological data relevant to ultimate limb salvageability and to indicate the direction of future studies.

Myocutaneous perfusion analysis using hydrogen clearance and pressure photoplethysmographic techniques will be applied to patients undergoing amputation for ischemic vascular disease. The site of amputation will have been previously determined by conventional clinical methods. After the patient is in the operating room, a series of perfusion measurements will be performed at increasingly distal sites from the chosen level of amputation as well as at a few proximal sites.

After these intraoperative studies have been completed on five amputees, the set of measurements will be applied to prospective amputees to assist in the determinations of optimal amputation level. This is defined as the most distal site compatible with wound healing and eventual rehabilitation of the patient. The myocutaneous perfusion measurements will be performed at a series of locations down the leg of these prospective amputees. The results will be plotted against a horizontal axis of distance down the leg. The recommended site of amputation (or salvageability recommendations) will be determined by noting an abrupt change in the perfusion rate (discontinuity of perfusion gradient) or by using previously obtained data to establish a minimal level of perfusion to maintain tissue viability and wound healing.

After amputation and healing of the wound has occurred, the myocutaneous perfusion measurements will be performed on the distal stump. These data will be correlated with the eventual rehabilitation of the patient and evalu-

ation of the stump as a load bearing surface. As experience and appreciation for these physiological measurements is accrued, we will evaluate those existent amputees whose prosthesis appears to be causing soreness of the stump or tissue breakdown. It is possible that by assessing stump perfusion, other skin areas might be better employed to distribute loading or recommendations for a revision be made.

Lumbar Sympathectomy

The experimental procedure calls for use of 20 subhuman primates (*Macaca mulatta*). Each primate will undergo unilateral sympathectomy with the contralateral lower limb serving as a control. The 20 primates will be divided into two groups: 10 animals having lumbar sympathectomy in the absence of a stenosis and the second group of 10 animals will have lumbar sympathectomy in the presence of an arterial stenosis created using a previously described technique.

Anesthesia shall be induced using sodium pentobarbital and maintained using gas (Halothane) anesthesia. Mean arterial pressure and ECG and lower limb digital temperature will be continuously monitored. Cardiac output will be monitored using thermal dilution techniques at regular intervals. After induction of anesthesia, baseline measurements of femoral artery flow using standard electromagnetic flowmetry and hydrogen washout in calf muscle and subcutaneous tissue will be done bilaterally. Total peripheral resistance shall be calculated as mean arterial pressure divided by mean femoral artery flow. After baseline measurements are obtained, laparotomy in preparation for lumbar sympathectomy shall be done and measurements repeated. Lumbar sympathectomy shall then be carried out from the L-2 to L-4 level and measurements repeated at prescribed intervals. Histological examination shall be done to confirm the presence of sympathetic ganglion. The operative procedure shall be concluded after 6 measurements are taken, a period of 3 hours. These measurements shall be taken immediately post-sympathectomy.

In the second group of primates, lumbar sympathectomy done in the presence of an arterial stenosis, the stenosis shall be created prior to laparotomy after baseline measurements

are obtained. Measurements of flow and hydrogen washout shall be taken after the stenosis is created, after laparotomy, after sympathectomy, and at similar intervals as those described for the group of primates where lumbar sympathectomy was done in the absence of an arterial stenosis.

The subhuman primates in each of the two groups shall be followed up at prescribed monthly intervals for 3 years post-sympathectomy. At each followup examination, measurements of flow, peripheral resistance, hydrogen washout, and digital temperature shall be carried out. Obtained results shall be tested for significance using the two-tailed t test for paired data.

The clinical portion of this study shall entail the use of 100 patients from the VA Medical Center, Castle Point Surgical Service. All participants in the study shall be properly informed of the requirements of their participation and the value of their participation and shall give their informed consent prior to admission into the study.

After informed consent is obtained, each patient shall undergo a battery of noninvasive vascular testing to obtain baseline data as to the extent of the disease process. The testing shall include external magnetic flowmetry measurements of peak pulsatile flow in the thigh and calf segments, segmental Doppler systolic pressures (brachial, high thigh, above-knee, below-knee, calf, ankle), photoplethysmographic determination of ankle and metatarsal pressures and flow waveforms, digital thermistor thermometry, reactive hyperemia, treadmill exercise testing, and hydrogen clearance determination of calf muscle and subcutaneous tissues. Patients shall also undergo arteriography

Based on these data, patients with well matched atherosclerotic occlusive disease shall be randomly assigned to one of two groups. One group shall be treated with lumbar sympathectomy and the other group shall be treated with the appropriate reconstructive arterial procedure. Lumbar sympathectomy shall be done from L-2 to L-4 and operative specimens shall be examined histologically. Intraoperatively, standard electromagnetic flowmetry shall be used to assess total limb blood flow before and after sympathectomy or reconstruction. Hydrogen clearance by calf muscle and subcutaneous tissue shall also be

measured before and after procedure, as shall total peripheral resistance and femoral vascular resistance and digital temperatures. During the postoperative period, completeness of lumbar sympathectomy shall be determined by use of the sweat test and the patient's clinical progress shall be monitored at prescribed intervals until discharge using the same techniques as preoperatively save arteriography. At discharge, the patient shall be enrolled in a followup program at prescribed intervals. Patients who were treated by sympathectomy alone shall be eligible for direct arterial surgery at any one time it appears to be clinically warranted. The efficacy of lumbar sympathectomy in the management of atherosclerotic occlusive disease shall be judged on the quantitative and qualitative improvement of noninvasive vascular test results following lumbar sympathectomy versus reconstructive arterial surgery. Obtained inter- and intra-group data before and after operations shall be tested for significance using the Student two tailed t test for paired data.

Rehabilitative Engineering Research Program

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The Rehabilitative Engineering Research Program (RERP) was established at the San Francisco VA Medical Center with the primary goal of improving the quality of prosthetics care for the lower-limb veteran amputee. The program draws upon the resources of the VA Medical Center (VAMC), the University of California Medical Center in San Francisco (UCSF), and the University of California Biomechanics Laboratory in Berkeley (UC-BL). Permanent staff

members of the core program include orthopaedic surgeons plus research prosthetist, physical therapist, and biomedical engineer.

Objectives

1. To determine which aspects of prosthetics care are perceived as problems by the amputees who receive services through the VA Medical Center Prosthetics Treatment Center.

2. To assess, for each recognized problem area, both the number of amputees experiencing the problem, and the degree to which the problem interferes with activities of daily living.

3. To rank the identified problems in order of priority for attention by the program. (Simple numbers are not necessarily the prime criterion. For example, the great majority of new amputations currently are below the knee, but one continues to hear the claim that the most serious unsolved problems are still faced by the above-knee amputee.)

4. To propose technological, administrative, and/or educational solutions to those problems that have been identified.

5. To implement proposed solutions and evaluate their effectiveness.

6. To plan for the eventual expansion of program activities to include a more comprehensive evaluation of locomotor disabilities among patients other than amputees.

In addition, the program continues to support the VA project on Mobility Aids for the Severely Disabled that was administratively linked to UC-BL in FY 74.

Progress toward these objectives during the period 1-July-80 to 31-Dec-80 is summarized below.

Problem Identification

The first three objectives require information about the amputee population that is being served. To gain such information, a mail survey was undertaken to contact all of the amputees who have received prostheses through the VAMC Prosthetics Treatment Centers in San Francisco and Martinez, California during the years 1978 and 1979. An initial mailing of 251 inquiries yielded 113 responses from amputees. A followup mailing 8 weeks later to 114 amputees produced 26 more responses. Preliminary analysis of the

first 96 responses reveals the figures shown in Table 1.

TABLE 1.
Analysis of first 96 responses.

Type of Amputation	Number	Percent
Below-knee	54	56
Above-knee	29	30
Knee disarticulation	1	1
Syme	1	1
Bilateral	11	12
BK / BK	6	
BK / AK	4	
AK / AK	1	
Cause of Amputation		
Injury		
Gunshot	32	33
Explosion	20	21
Traffic	6	6
Recreation	1	1
Other	8	8
Vascular		
With diabetes mellitus	11	11
Without diabetes	14	15
Tumor	3	3
No response	1	1

More detailed analysis of the data is currently underway.

Followup interviews with those amputees who appear to be most dissatisfied with their care will be used to assess the exact nature and severity of the problems encountered.

Additional surveys are underway to assess the value of suction suspension for the BK amputee, and to estimate the size of the local population of kneedisarticulation amputees.

Even without detailed analysis, it is evident from the survey responses, from comments of amputees attending the local amputee clinic, and from experience with the fitting of prototype devices, that amputees are facing significant problems in obtaining comfortable socket fit and convenient service. Several factors appear to be involved in their difficulties, including limitations in prosthetics technology, the lack of availability of current prosthetics technology in many limb shops, inadequate followup by the VA on prescribed devices, frustrations with the operation of the VA system for amputee care,

and expanded aspirations for more active participation in athletic activities.

Because of the many factors involved in these problems, implementation of solutions will require the cooperation of many different groups of people, both within the VA and outside of it. Individual limb-shops must certainly be involved, as well as their regional and national professional organizations. Within the VA, procedures must be worked out for cooperation between those departments responsible for research, patient care, and education. All of these departments must be involved in any comprehensive solution, but prosthetics research tends to fall into the spaces between them. In other words, the tasks that prosthetics research seeks to accomplish involve activities in research, patient care, and education. If it is to be effective, prosthetics research cannot be confined to any one of these three areas.

Subcontracts with the University of California have been established to make available to the RERP the resources of UC-BL and the Department of Mechanical Engineering in Berkeley for engineering support and prototype development, and the Department of Radiology at UCSF for application of modern CAT Scan techniques to problems in prosthetics.

Clinical Evaluation

The VA provides amputees with prostheses as part of an effort to return them to as normal a life as possible following their loss of a limb. The ability to walk, go up or down stairs and ramps, avoid or surmount obstacles, and move quickly out of the way of danger are all elements of normal locomotion which the amputee may find difficult, and which the prosthesis is intended to facilitate. The ability to evaluate how well an amputee can accomplish these tasks with a particular prosthesis is a fundamental part of prosthetics research. Consequently, the development of a facility for routine clinical evaluation of the gait and mobility of amputees has been a primary goal of the RERP. Such a facility would also be ideally suited for future expansion of the program to include patients with other locomotor disabilities.

As previously reported, the renovation of space for such a mobility laboratory was completed in June of 1980. In

July, 1980 the first device evaluation project began with the fitting of the first of an eventual 25 to 30 UC-BL Four-Bar-Linkage Polycentric Knee units to veteran amputees. Fittings are being made by local limb-shops with instruction and guidance by the research staff. Amputee subjects are volunteers contacted through the amputee clinic of the VA Medical Center Prosthetics Treatment Center. By December 31, 1980, 22 subjects had undergone an initial physical, prosthetic, and gait examination in the mobility laboratory, 15 of these had been fitted with new prostheses, and 6 had returned for followup examinations 6 weeks after receiving their prostheses.

The objectives of this type of device evaluation project are:

1. To develop a complete, practical set of instructions to the prosthetist for alignment and fabrication of a prosthesis incorporating the new device;
2. To identify prescription criteria for selection of appropriate candidates to be fitted with the device, with a summary of indications and contraindications;
3. To assess the structural integrity, functional performance, and safety of the device, with consideration of any claimed advantages—in the case of the Four-Bar knee, improved voluntary control of knee stability; and
4. To facilitate progress from prototype to commercial product by assembling all of the information that would be needed by a prospective manufacturer to make the device, including engineering drawings and materials specifications in addition to the information from 1 through 3 above.

The goal of the Four-Bar Knee project is to assemble the above information, based on six month or longer followup of 25 subjects, by June 30, 1981.

Evaluation of other devices is in the planning stages. During this report period, additional prototypes for evaluation have been fabricated, including 5 friction-stabilized knee units, 5 six-bar-linkage knee units for knee-disarticulation amputees, 25 modular below-knee prosthesis components, and 6 metal-keel SACH feet. Prosthetics manufacturing firms have demonstrated an active interest in the Four-Bar Knee unit, the modular components for BK prosthesis assembly, and in the metal-keel SACH foot.

Mobility Aids for the Severely Disabled

Powered Spring Suspension Wheelchair—Components for six Powered Spring Suspension Wheelchairs were fabricated during this report period, and one unit was assembled. Like an earlier prototype, the chair has lively outdoor performance, long range, comfortable spring suspension, and good indoor maneuverability. Numerous minor changes have been made, both to improve function and to simplify production of the chair. After some modifications, the electric fail-safe brakes perform well, consuming only 3 watts per side and providing about 50 pounds (223 N) of braking force at each rear wheel when the controller is turned off. Seats and footrests for the chairs are still under construction. Durability and daily use testing beginning in February 1981 are expected to continue through October 1981.

Solid state controller—Five prototype Bowman / UC-BL solid state controllers were delivered by Bowman Electronics, with printed circuit boards and packaging suitable for rugged daily use. The controllers have smooth, precise control, efficient drive, regenerative braking, current limiting, and capacity for continuous 50 ampere currents to the motors. The controllers will be tested as components of the Spring Suspension Wheelchairs.

Spring Suspension Caster Forks—Parts for 20 spring suspension forks were fabricated, and the first pair assembled performs well. The forks will be tested both as components of the Spring Suspension Wheelchairs and as retrofit forks for conventional wheelchairs.

Feedback control project—A computer model of a wheelchair with feedback controller has been developed. The model simulates the behavior of a powered wheelchair on different ascending and descending grades as well as variable side slopes. Different feedback control schemes will be simulated with a view to improving control response.

Design of Bathrooms, Bathroom Fixtures, and Controls for the Able-Bodied, Disabled and Elderly

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Project Goals**

This research seeks to develop bathrooms, bathroom fixtures and controls that are safely and independently usable by disabled and elderly people. The intent of the research is not to develop special fixtures for special people, but rather to interface the usage capabilities of diverse groups of disabled individuals into products that are capable of eventual manufacture. Research activities will endeavor to develop bathroom and fixture prototypes that remain sensitive to the ever-changing requirements resulting from aging and disability.

The major emphasis of the research will be to provide a means for safe, independent attention to personal hygiene by the severely disabled. Specific usage requirements of these individuals possessing characteristics of spinal cord injury (especially quadriplegia), severe cerebral vascular accident (CVA), multiple sclerosis, arthritis, and other medical conditions will be provided for in the design of all prototypes. Research and development will focus on the characteristics of two generalized groups of users: those capable of transfer to and from a wheelchair with little or no assistance, and those whose disability precludes unnecessary transfers, even with assistance. All fixtures will satisfy the needs of one of these two groups while still providing for the needs of the less-disabled and the able-bodied.

Background

This project is a continuation of previous research sponsored by The National Institute of Handicapped Research and The Rehabilitation Services Administration from 1976-1979, conducted at Virginia Polytechnic Institute and State University. Both project

principal investigators have moved to Georgia Tech, assuring continuity of this new research.

Project Collaboration

The major component of this research will be conducted by the co-principal investigators and staff of the College of Architecture at Georgia Tech. Extensive testing, evaluation and design activities will occur at the Decatur Veterans Administration Medical Center. Additional collaboration will occur between the research staff and Emory University, Shepard Spinal Center, The Augusta Veterans Administration Medical Center, and The Georgia Tech Center for Rehabilitation Technology.

Representatives of plumbing fixture industries will participate in all phases of design, development and evaluation. Current involvement with industry includes The Crane Corp., The Bradley Corp., and Facet-Glas Corp. Other manufacturers will be encouraged to participate, to increase the potential for manufacture of the research product.

Development of two distinctly different types of fixtures are planned. One is for usage with existing buildings equipped with standard bathroom fixtures and the other type is for new installations. Fixtures developed for use in existing bathrooms will be a retrofit type, designed for a specific type of user. A number of possible solutions will be investigated, since part of solving the problem of safe and independent hygiene for the disabled and elderly is to improve the potential for usage of existing fixtures already in the home.

Fixtures designed to be installed in new bathrooms (or added to existing homes as part of a renovation) will be capable of change from time to time. This capability should assist in meeting the changing physical needs of the user. This adaptability is important, since it allows for usage by a wide range of individuals; disabled, elderly, or able-bodied. With this potentially wide usage, the mass production of the fixtures, resulting in low unit cost to the consumer, appears likely.

Three types of prototypical fixtures are envisioned; the first will provide for total body cleansing (bathtub, shower type fixture); the second will allow cleansing of the upper extremities (sink type fixtures); and the third will be used for defecation (commode type fixture).

Final prototypical design will reflect the means that best answers the requirement for safe independent usage for the disabled and elderly.

In order to improve the potentials for technology transfer through eventual marketing of the research product, bathroom fixture manufacturers will participate at all stages of the research and development. This collaboration will help insure the practicality of the final products, and also provide the plumbing fixture industry with a better understanding of the hygiene needs of the disabled and the elderly.

Methodology

The methodology used for development of the prototypical bathrooms, bathroom fixtures and controls will emphasize direct interaction between disabled individuals of varying functional capabilities and the research team. Disabled volunteers will be involved at every stage of research, from compilation of design criteria through final evaluation of the finished prototypes. Their participation will consist of volunteering the following: pertinent information on activities of daily living; demonstrating full or partial transfer capabilities in bathroom simulations; demonstrating upper extremity range of motion and manipulatory skills; general evaluation of prototypes through partial or complete usage at various stages of development; and offering generalized information relating to user acceptance, aesthetics, and means for product improvement. While generalization of such subjective information may be impossible, the value of such diverse information will be significant. Key transfer usage sequences will be videotaped and compared as prototypical development progresses. Individual hygiene requirements will be compared to assure that the range of user needs are met in the final prototypes.

Very careful examination and documentation of physical characteristics prevalent in the disabled and elderly populations will occur. Conditions such as trunk and lower-limb spasticity, limitations of arm and hand function, tendency to develop decubitus ulcers, loss of tactile sensation, trunk instability while seated or transferring, poor balance, and perceptual and interpretative deficiencies will be considered during prototypical development. Extensive in-

teraction will occur between three groups: (i) the disabled and elderly individuals at Decatur; (ii) medical professionals comprised of M.D.'s, occupational therapists, physical therapists, corrective therapists, and (iii) design members of the research team. Criteria for development of the prototypes will be derived from this multidisciplinary relationship and will be biased toward functional potentials exhibited by disabled volunteers.

This project is expected to start in February, 1981 and continue for three years.

In Vivo Loading of Knee Joint Replacements

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Background

At the inception of the current project, three specific goals were set: (i) To expand our previous implant telemetry capability to nine channels to allow all six degrees of joint loading to be defined, (ii) To design a new telemetrized prosthesis using the tibia rather than the femur as the instrumented side to allow different types of new prostheses to be investigated, and (iii) To use the new system in a combined program of evaluation using both telemetry and gait analyses in the Cleveland VA Medical Center Gait Laboratory.

Progress

Our implant telemetry has been successfully expanded to a nine-channel capability through a complete system redesign. The transmitter circuitry has been modified to increase individual channel subcarrier stability and decrease harmonic distortion. The demodulation (receiving) circuitry has been totally redesigned, using state-of-the-art demodulation techniques. Tests conducted on a three-channel subsystem have shown the new system to be capable of the necessary channel discrimination to separate successfully up to nine

channels. The remaining channels of demodulation are currently being assembled.

A total condylar-type telemetrized knee joint in which the tibial portion is instrumented has been designed and built as a prototype, using 6 percent aluminum, 4 percent vanadium, extra-low-interstitial titanium alloy.

Specialized assembly techniques including electron beam welding and coating with parylene have been developed in conjunction with NASA-Lewis in Cleveland. A new procedure has been used to increase the reliability of the bond of the semiconductor strain gages to 6A1-4V ELI titanium substrate.

Initial evaluation of the present design, with a standard ultrahigh molecular weight (UHMW) polyethylene total condylar tibial insert as the bearing surface, has demonstrated that this design is capable of resolving all six degrees of loading. Mechanical testing of this design under maximum cyclic loading demonstrated a functional telemetry life in excess of five million cycles using an acceptable evaluation mode for continued functional implant service. A final prototype, currently being assembled, incorporates modifications based on the previous testing to increase the functional telemetry life even further.

Collaboration is currently well under way with the Cleveland VA Medical Center Gait Laboratory to insure the successful completion of the combined analyses portion of this project.

Summary

Based on work already completed, no serious impediment to the successful completion of this project is envisioned. The present design will allow not only the standard total-condylar design, but also new unconstrained and semi-constrained designs to be evaluated as well.

Orthopaedic Implant Device Retrieval and Analysis

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This report covers the period of June through December 1980.

An interactive computer system for the storage, retrieval, and analysis of clinical and materials-characterization data associated with orthopaedic implants has been put on line. The system consists, basically, of four independent modules. The essence of the system centers on cross-referencing capabilities which are basically unlimited. The system has been designed for use by essentially non-computer-trained personnel.

The implant retrieval and analysis system was written in standard computer languages and contains no computer-installation-dependent subsystems. It is currently being used in the interactive mode on a Digital Equipment Corp. System 2060 digital computer. However, it was also designed to be used in a batch environment where all data input and cross-referencing information is entered from data cards. The four separate, independent modules are (i) initial clinical and material data entry, (ii) cross-referencing to allow manipulation and statistical treatment of data, (iii) printing to provide hard copy, and (iv) editing and updating to allow entry of followup or missing data to a case that was previously entered.

The module for input of clinical history and material characterization data associated with each implant device corresponds closely to the information contained on ASTM F-561 standard forms. It should be noted that these forms were modified so that data entry would extend beyond the limits suggested in F-561, and so as to be more compatible for computer entry and analysis. Among the features of this module are the ability it provides to review a clinical or material examination form before proceeding to the next form, the use of a question mark response which prompts the computer to giving the user additional user information, and warnings to the user

that no data was entered in a particular item when that item has been left blank.

The cross-referencing module is actually the heart of the system. A user may cross-reference as few or as many variables at one time as he chooses. There are a total of 54 possible variables to cross-reference. These span from single criteria, such as hospital or particular device, to ranges in values of

TABLE 1. Patient Gender.^a

	Overall	VA
Female	296	1
Male	664	414

^aA specific individual may be counted several times in this table if he or she received several implants.

variables such as patient weight, dates in situ, etc. In addition, and/or logic has been included in multi-answer possibilities. Individual patient files may be retrieved by using either patient case number, name, or identification number.

The print and update modules are relatively self-explanatory. A detailed description of the system may be found in reference (1).

As of the end of this reporting period, 960 implant numbers have been entered into the system. A summary of some of

TABLE 2.

Age distribution as of December 31, 1980 of all those patients for whom birthdates are recorded.^b

Age	Male	Female
20-25 yrs.	28	3
25-30	38	6
30-35	40	4
35-40	17	3
40-45	22	3
45-50	31	5
50-55	62	5
55-60	72	5
60-65	72	10
65-70	31	8
75-80	0	16
80-85	57	12
	470	80

^bIn addition, a significant number of patients were under 20 years of age.

the information currently on hand with regard to these 960 implants will be presented in the tables below. It should be pointed out that the system is currently being used not only for this VA project, but also to monitor orthopaedic implants from other sources. Thus, the tables will have data presented for the overall system and for the VA Medical Center in New Orleans.

Gender of patients into whom implants were inserted is shown in Table 1. Of the 960 total implants inserted, 295 have been removed, including 112 of these that were removed at the VA Medical Center in New Orleans. During the 5-year period of January 1976 through December 1980, 697 implants were inserted overall, including 339 at the VA Medical Center. During that

TABLE 3.
Implant distribution by generic code.^c

Overall	Implant Type	VA
0	Ankle	0
326	Hip	106
68	Rod	31
99	Knee	61
3	Elbow	0
33	Pin	21
100	Screw (used alone)	57
95	Plate	42
179	Hip nail plate	73
7	Staple	7
5	Shoulder	4
2	Wrist	2
3	Finger	3
40	Other	8
960	Total:	415

^c Screws used in conjunction with a major appliance, e.g., hip nail plate, are not counted separately.

same time period, 117 implants were removed, or expressing that as a percent of the total, 16.8 percent were removed. Similarly, for the VA system, 69 implants or 20 percent were removed.

The age distribution for 550 patients for whom birthdates are entered (in 5-year intervals) as of December 31, 1980, is shown in Table 2.

The types of implants in the study,

listed by generic implant names, are shown in Table 3. For the hip implants, which refer to both total hip and hemiarthroplasties, 326 insertions and 69 removals have been entered into the system. The reasons for removal of each implant are shown in Table 4. The

TABLE 4.
Reasons for removing hip arthroplasties (multiple answers permitted).

Overall	Reason	VA
3	Early infection	1
8	Late infection	1
3	Breakage of implant	0
40	Pain	11
36	Loosening	10
15	Malposition	4
15	Other	4

reasons will naturally add up to more than 69 because this is a multi-answer variable. It is interesting to note, however, that in more than 50 percent of the cases, pain and/or loosening was indicated. Similar data are shown for 40 bone plate removals and for 48 hip nail removals in Tables 5 and 6, respectively. It is interesting to note that only approximately 50 percent of the bone plates and only approximately 10 percent of the hip nails are being removed routinely.

The tables mentioned illustrate only a small sample of the type of information that can be withdrawn from the system. We are currently analyzing the information that we have on our system and this will be the subject of future reports.

TABLE 5.
Reasons for removal of bone plates (multiple answers permitted).

Overall	Reason	VA
23	Routine	8
5	Early infection	4
2	Late infection	0
0	Break	0
14	Pain	8
5	Loosening	3
2	Malposition	0
9	Nonunion	5
3	Unknown	0
2	Other	0

TABLE 6.
Reasons for removal of hip nails (multiple answers permitted).

Overall	Reason	VA
5	Routine	1
4	Early infection	0
6	Late infection	2
7	Break	3
16	Pain	9
11	Loosening	5
9	Malposition	5
11	Nonunion	5
1	Unknown	0
13	Other	5

Identification of Fatigue by EMG Power Spectrum Analysis

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As previously reported (BPR 10-34), equipment for obtaining and recording myoelectric signals has been assembled and tested. An instrumented exercise chair has been constructed for investigations of quadriceps muscle fatigue at various angles of knee extension. A force transducer is used to monitor loads applied at the ankle. Reliable techniques for acquisition of myoelectric signals picked up by surface and wire electrodes have been developed, and data from static-load fatigue tests of quadriceps and biceps muscles have been recorded and analyzed. The project minicomputer system (DEC LSI-11/23) has arrived and is being used to analyze data. The feature to be evaluated is a shift of the myoelectric signal frequency power spectrum which occurs during fatiguing contractions. The analysis procedure is based on the fatigue index method described by Lindstrom et al. (1977).

Results to date indicate that cross-talk signals from muscles adjacent to the muscle monitored by a surface electrode are relatively insignificant in the quadriceps, if electrodes are properly located. Quantification of the exact degree and source of cross-talk signals has yet to be determined.

Both bipolar and monopolar wire

electrode characteristics are being investigated. Calculated fatigue curves for wire electrode signals show fatigue indexes approximately twice as large as those for surface electrode signals.

Current investigations of quadriceps muscle fatigue include monitoring of heart rate and blood pressure. Other physiological parameters which will soon be monitored are cardiac output, oxygen consumption, and local metabolic state (by venous blood samples and muscle biopsy). Contributions to the total myoelectric signal and to the calculated fatigue index from fast-twitch and slow-twitch muscle fibers will be investigated by monitoring fatiguing muscles which are predominantly composed of one or the other fiber type.

Reference

1. Lindstrom, L., Kadefors, R., Petersen, I.: An electromyographic index for localized muscle fatigue. *J Appl Physiol REEP* 43:750-754, 1977.

Pressure Sores: Etiology and Prevention

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During the early summer and fall, many loose ends were tied together on this project. The finalization of the bench model completed the funded program ending October 1. With Dr. Vistnes' pending move from the VA to Stanford as Chief, Division of Plastic and Reconstructive Surgery, he did not apply for a continuation of the program.

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

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A study was concluded which treated and analyzed selected variables in amputee and normal gait. The salient findings from the study are presented; a final report is in preparation. The objective of the study was to delineate differences in locomotory performance (i) between amputees and normals, (ii) between below and above knee amputees and (iii) between amputees with and without problems. The study included 44 unilateral lower-limb amputees able to ambulate without walking aids; it was conducted at the Gait Analysis Laboratory at the Children's Hospital and Health Center in San Diego. Cinematography was used to obtain kinematic data and force plate measurements to obtain kinetic data. Empirical equations were developed to relate various observations, but no attempt was made to develop basic principles or to provide dimensional consistency.

Cycle Time—The cycle time t was analyzed for durations of the single and double support periods, the relation of these components to velocity, and comparison of the prosthetic limb to the sound limb in performance. The total double-support period empirically showed a strong inverse relation with velocity of walking:

$$\sum t_{ds} = \frac{0.4}{V}$$

where $\sum t_{ds}$ = duration of double support, seconds
 V = average velocity, m / s

A difference in coefficient was noted which discriminated BK from AK amputees. The mean coefficient was 0.415 for BKs and 0.362 for AKs. By careful choice of a threshold value (0.384) 23 of 33 BK were above threshold and 9 of 11 AK were below threshold. Surprising was the pronounced influence of the stride-frequency / stride-length

(f/l) ratio upon the sum durations of the swing periods:

$$\sum t_{sw} = 1.76 - 0.264 \sqrt{V - f/l}$$

where $\sum t_{sw}$ = sum of the left and right limb swing periods, seconds

V = average velocity, m/s
 f/l = ratio of stride frequency in strides per second divided by stride length in meters.

The mean error (t measured - t calculated) and the standard deviation of the error for the sample of 44 amputees was less than 0.090 second. Combining the durations of single and double support yielded the following expression for duration of the gait cycle in seconds:

$$T = 1.76 + \frac{0.4}{V} - 0.264 \sqrt{V - f/l}$$

The mean error (T measured - T calculated) for the sample was less than 0.02 second with a standard deviation of 0.052. This magnitude of error was approximately 2 percent and was comparable to the estimated instrumentation error.

External Work—Mechanical work done against the external environment was included in the amputee gait study to provide an additional set of variables by which to assess the biomechanical behavior among the different categories in the test protocol. The external work was calculated from the vertical component and the longitudinal shear component of the ground reaction forces registered by force plate measurements. Included in this investigation were 8 normals walking at free choice of speed, and 3 normals walking at three different speeds in two separate test bouts. And there were 13 BK without problems, 14 BK with problems, 5 AK without problems, and 4 AK with problems—all walking at free choice of speed. The resulting values were normalized into joules per meter per kilogram body mass ($J / m \cdot kg$). Analysis of the composite results showed work to vary parabolically with both average forward velocity V , in meters /second, and with the f/l ratio, strides /second

divided by stride length in meters. The mathematical relation is the following:

$$W = 1.1 (1.4 - V)^2 + 4.74V \\ (0.7 - f/l)^2 + 0.216$$

The value 1.4 in the first term was chosen from literature as the approximate preferred walking speed of a large sample of adults; likewise, the value 0.7 in the second term was chosen from literature as the mean f/l ratio demonstrated by a large sample of adult men and women (1,2,3). The velocity range represented by the expression is from 0.5 to 1.6 meters per second and the f/l ratio range is from 0.44 to 0.90.

The mathematical model represents the composite of both normals and

amputees, with and without problems, and does not distinguish between them. Moreover, the physical health status among the 36 amputees is not differentiated; included among the amputees were seven whose amputations were necessitated by vascular problems. The relative accuracy of the mathematical expression was tested by calculation of mean error. For each subject, the difference between measured and calculated work was derived. These differences were treated by categories to develop mean errors and the standard deviations (Table 1).

Joint Movement Deviation—A technique for detecting and displaying deviations in joint movements was employed to analyze locomotory per-

formance of the amputees. The technique consisted of comparing actual with synthetic joint movement waveforms and is described in the Spring 1980 issue of the Bulletin of Prosthetics Research: "A Technique for the Display of Joint Movement Deviations" BPR 10-33 pp 73-79.

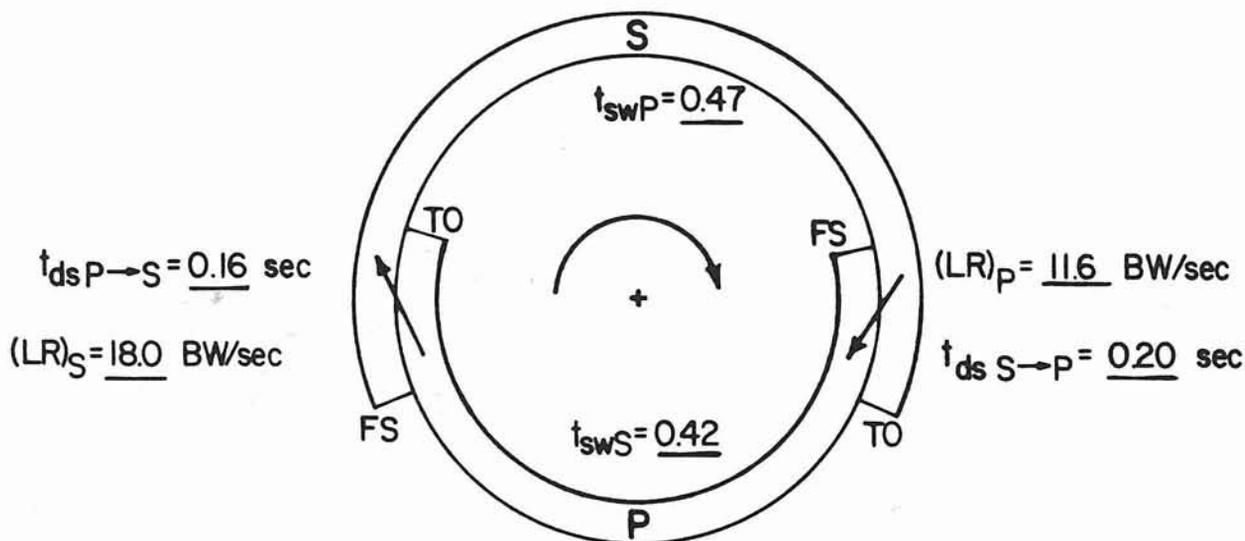
Gait Cycle Diagram—A circular gait cycle diagram for unilateral amputee performance (Fig. 1) was found useful to help understand bilateral test results and to compare test results among subjects. The diagram was simply the conventional linear gait cycle event scale depicted in a circle. Magnitudes of temporal, displacement and force variables were marked at appropriate locations on the circle to aid in understanding bilateral relations such as the durations of double support during transition from prosthetic to sound limb and from sound limb to prosthetic limb, and how these relate to loading rates in body weights per second, and subsequent swing or single-support periods. Note that Figure 1 is plotted clockwise in compass fashion with zero degrees at the top. Appropriate changes

TABLE 1.

Category	Mean Error, J / m · kg	Std. Dev.
8 normals	-0.035	0.079
13 BK w / o problems	-0.017	0.139
14 BK w / problems	+0.029	0.107
5 AK w / o problems	+0.004	0.089
4 AK w / problems	+0.147	0.029

The magnitudes of mean error are in the order of expected instrumentation error.

GAIT CYCLE DIAGRAM



SUBJECT: F.P. RBK w/o problem

$v = \underline{1.15}$ m/sec

$f/L = \underline{0.57}$

$f = \underline{0.81}$ str/sec

$T = \underline{1.23}$ sec

$L = \underline{1.43}$ meters

$W = \underline{0.385}$ J/m/kg

Eff. = 64.7 %

FIGURE 1. Gait cycle diagram in circular form was among the innovative or novel treatments deployed.

in signs and numerical values would be needed for the mathematical convention of moving counterclockwise from zero degrees at the right side of the horizontal axis.

Ground Reaction Forces—The analysis of ground reaction forces was delimited to two aspects: (i) weight acceptance on the basis of loading rate in body weights per second and (ii) special treatment of the peak values of the longitudinal shear forces.

The loading rates were loosely related to the average velocity of walking and were almost without exception lower for the prosthetic than for the sound limb in all four categories of amputees. Two AK-without-problems amputees demonstrated slightly higher loading rates on their prosthetic side.

The analysis of peak accelerative and decelerative components of the longitudinal shear forces for both the prosthetic and sound limbs were treated in a manner intended to help understand how the amputee used each limb in the parasagittal plane. The peak values were used to derive a two-component description, a magnitude and an angle:

$$R = \left[\left(\frac{ds+as}{2} \right)^2 + \left(\frac{dp+ap}{2} \right)^2 \right]^{1/2}$$

$$\theta = \tan^{-1} \left[\frac{dp-ap}{ds-as} \right]$$

where dp = peak decelerative force, prosthetic side
 ap = peak accelerative force, prosthetic side
 ds = peak decelerative force, sound side
 as = peak accelerative force, sound side

This technique permitted results to be plotted in polar coordinates with prosthesis on one axis, sound leg on the other. The data segregated principally into two opposite quadrants of central angles of 135 degrees and 315 degrees, respectively, which allowed each subject to be evaluated as to relative effectiveness of each limb in "brake" and "thrust" capability. Eight of a total of eleven AK amputees demonstrated good braking and poor thrust on the prosthetic side and, conversely, low braking and high thrust on the sound side (angle about 315 degrees—or 135 degrees

using the mathematical convention). Nine of a total of 12 BK with problems showed characteristics similar to the AK's described above. The BK's without problems distributed almost equally in the two opposite quadrants with central tendencies at 135° and 315°, respectively

Asymmetries—Bilateral asymmetries were quantitated in five variables: (i) loading rates, (ii) peak shear forces, (iii) step lengths, (iv) single support, and (v) double support. Loading rate asymmetry was the most consistent and step length asymmetry the least. No relation was found to exist among the asymmetries nor were they found to correlate systematically with other variables of gait.

Malignment—Gross effects in BK prosthesis malalignment produced pronounced effects on performance. However, among three subjects tested, no "signatures" were identified which could be considered a predictable result of misalignment. Each subject chose an individual strategy to accommodate for the effect of a given malignment.

Summary and Conclusions

Innovative, and perhaps novel, treatment of commonplace gait variables were deployed to increase awareness regarding interrelations among selected gait variables. In some instances, methods emerged which may offer to enlarge the armamentarium for investigators who analyze and evaluate locomotor performance. In other areas, notably external work, further study and refinement are needed before a measurement can become a reliable tool for comparing performances.

In general, there was no single variable, or combination of variables, which clearly distinguished the performances of one category from another among the amputees. This finding was not totally unexpected considering the complex impact of amputation and the use of a prosthetic limb upon the biomechanics of walking.

Trends, on the other hand, were evident. Furthermore, comparison of prosthetic limb with sound limb performance revealed characteristics attributable to constraint imposed on the body by the amputation and the prosthetic limb and elaboration of

bilateral compensatory behavior by the presence of a (maybe) painful stump. While relations among variables, deviations in performance, and certain trends were observed it is not altogether clear that, as yet, cause can be deduced from effect. Two factors tend to obscure the issue. One is that this study was deliberately delimited to keep it manageable within the resources. The other factor, more difficult to isolate, is the possible existence of residue of previous gait problems, which a currently problem-free amputee might have had, resulting in a permanent gait pattern resembling one with problems.

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Maxillofacial Restorative Materials and Techniques

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Summary Highlights of On-Going Research and Development—During the period of this semi-annual report, intensive efforts have been devoted toward qualifying polydimethyl (PDM) siloxane as a safe and effective prosthesis under the provisions of the Medical Devices Act (1). Such qualification involves well-spelled-out, scientifically documented procedural details in the form of formal testing with formalized specifications. In other words, investigative research and development for the legal criteria of "safe and effective" takes on an intense definitive prescribing of material properties of

PDM siloxane under most severe and replicative conditions in the conceivable physiological conditions of prosthetic service.

Thus, among the six project phases outlined in past semiannual reports in the Bulletin for Prosthetics Research (2), major emphasis has been accorded to (i) property changes of PDM siloxane when exposed to approximated physiological metabolites and (ii) demonstrated safety, in terms of biocompatibility of PDM siloxane with actual human excised donor (HED) tissues. In both of these respects, the principal goal has been to prepare detailed draft specifications for testing and standards, for review and approbation by the American Society for Testing and Materials in conformance with the regulations of the Food and Drug Administration under the provisions of the Medical Devices Act.

In summary, the specifications for testing and standards, which require extensive formal approval by interested reviewers from various laboratories, are in the process of draft proposals and are expected to place PDM siloxane within the obligatory requirements of being demonstrated safe and effective to prolonged exposure to human tissues. In the meantime, the remaining phases of research and development are being continued on fabrication, production, and the technical service which is being provided for the extensive extramural, VA and non-VA, nationwide use of PDM siloxane developed specifically for maxillofacial and orofacial reconstructive devices. The material is attracting considerable interest for other biomaterial applications.

Product Development

A critical end-use requirement for effective, long-lasting prostheses is that of tear resistance. In orofacial reconstructions, the prosthetic devices are subjected to repeated handling, often with considerable stretching, in some cases with repeated hygienic maintenance, and generally continued exposure to physiological adventitia with concomitant absorption of lipids, notably glycerides, and organic acid-derived metabolites. These features of exposure with predictable retention of tear resistance constitute the principal requirement of effectiveness, in terms of durability in accordance with the regu-

latory provisions of the Medical Devices Act (1) on safe and effective medical devices. The companion requirement of safety, with which this project is also concerned in its entirety, is reported under Toxicity Testing and Standards discussed in another section of this report.

Resistance to tearing is a standard criterion of effectiveness, with implied durability, applied generally in the trade to rubber materials because of their well-known sensitivity to organic solvents and compounds (3) especially on prolonged exposure. This project is obliged to test and rate the tear resistance under expected environmental (particularly physiological and hygienic maintenance) conditions. Some of these chemical exposures have been published in a previous report (4). The present effort has been directed toward assessing the effective durability in prolonged contact with selected physiological entities of organic chemical type. This assessment in turn is intended

for devising a standard test procedure and product specification for submittal for review and adoption by the American Society for Testing and Materials (ASTM), an agency recognized by the Food and Drug Administration (FDA), for details of exposure tests affirming PDM siloxane to be safe and effective (5).

Selection of Replicating Physiological Exposure Conditions—In devising a testing procedure and hence the specifications for test resistance, two aspects are essential. The first of these relate to selection of the chemical entities that would in part replicate those in the physiological contact by the PDM siloxane. The second relates to the exposure condition to be specified to provide a test protocol; that is, of specified exposure time and temperature that would accelerate the rate of deterioration and thus compress the prosthesis-wearing time, presumably 3 to 5 years, for sustained effective durability.

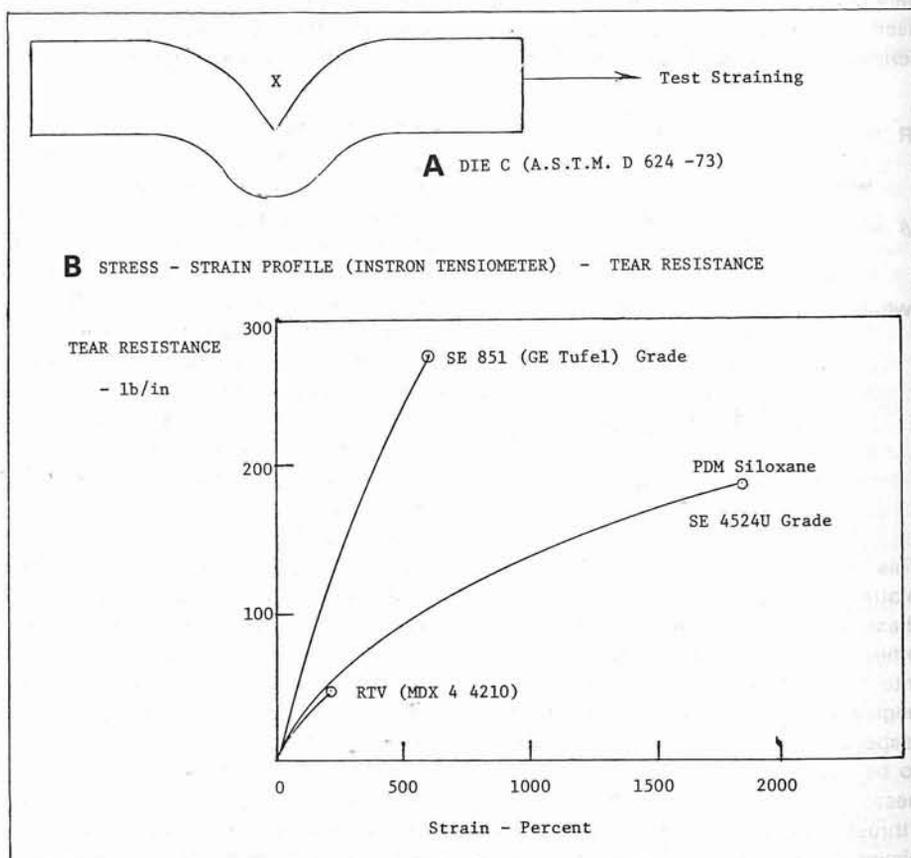


FIGURE 1.

Comparisons of tear resistance of PDM siloxane derived from standard SE 4524U grade and new, high tear resistant SE 851 grade along with that of an RTV silicone of a competitive proprietary source.

Selection of Physiological, Chemical Exposure—In the scope or rationale of an official test and specification for effective durability, it is necessary to take into account the fact that external, internal (insertive), and implant forms of the prosthetic devices come in contact with a wide variety of physiological chemical entities in the course of contact with skin, mucosal surfaces, and internal tissues. The assault or impact on the polymer elastomer molecular structure can be physical absorption with distension of the molecular chain, or chemical with subtle ester and other interchanges. Since some replication of the physiological chemistry entities has to be specified, the present study provides two chemical types, namely:

1. glyceride interaction, using corn oil (5) (Mazola) replicating potential lipid reactivity; and

2. organic acid interaction, using lactic acid, replicating obvious common metabolite.

Specified Test Procedure and Form—The official ASTM tear resistance test form is specified in procedure D-624. Of the three specified dies in D-624, the form known as Die C, as shown in Figure 1(A), was chosen mainly because of the V-notch which intensifies or concentrates the potential weak point in design of prostheses, especially with recessive overcap (6). The V-notched test sample is elongated in a tensiometer (Instron) at a specified rate, 20 inches/minute, from which the elongation (strain) versus reactive force (stress) is recorded in a profile as shown in Figure 1(B). From the profile or force-strain curve the tear resistance is determined at the ultimate transverse rupture (x) and calculated in unit of force (pound or kilogram) per unit of thickness (inch or centimeter).

Accelerated Test Conditions—Once the specification test procedure, in this case the D-624, is selected for whatever end-use qualification, the choice of the exposure conditions can be arbitrarily imposed as would be suited to the end-use. Obviously, the 3-to-5-year ex vivo exposure is impractical, particularly in this project, as new forms and sources of the component prepolymer (gum stock) and oligomer are subject to change, a not uncommon situation in the history of biomaterials for medical devices (7). Hence, an accelerated

TABLE 1:

Summary of Tear Resistance of PDM siloxane from Accelerated Exposures with Glyceride and Lactic Acid.

Glyceride Source: Corn oil (Mazola).

Lactic Acid: 85% Analytical Grade.

Exposure Conditions: 100° C. for 24 hours.

Tear Resistance Testing: A.S.T.M. D 624-73.

Catalyst level (pph)	Fabrication P-Code (a)	Tear Resistance (lb/inch)	Elongation to Ultimate tear (percent)	Exposure Medium
0.50	1589	69.8	868	Control
	1582	74.0	1150	Glyceride
	1581	70.0	838	Lactic acid
1.0	1590	173	1526	Control
	1584	174	1422	Glyceride
	1583	171	1043	Lactic acid
2.0	1591	140	637	Control
	1586	175	673	Glyceride
	1585	145	466	Lactic acid
3.0	1592	160	578	Control
	1588	160	527	Glyceride
	1587	141	403	Lactic acid
Compared with RTV silicone (MDX 4 4210)				
	Control	38.6	148	(L-125-94 3C)
	Glyceride	28.1	95	"
	Lactic acid	33.2	123	"

(a) Fabricated by curing in dental stone mold just as carried out in fabricating prostheses.

temperature-time of 100 degrees C for 24 hours has been applied, to insure likely physiological assault. The inordinately high temperature, much beyond the 37.4 degrees C physiological temperature, with the two physiologic model metabolites, is presumed to impose several orders of acceleration of the service time (estimated up to 5 years) interaction.

The accelerated exposure (100 degrees C for 24 hours) is carried out by placing triplicate Die C cut test samples in 20-cm diameter Petri dishes containing, in one instance, the triglyceride oil (Mazola) and in the other, concentrated lactic acid (85 percent). The test samples are cut from flat moldings of

PDM siloxane, taken from one of the production campaigns (XI) fabricated in dental stone molds under thermal profiles identical to that used in fabricating orofacial prostheses. The test range includes a series of catalyst levels, bracketing the conventional, industry-wide formulation 99:1, designating 1 part catalyst per hundred (pph) weight part of composition. (Included is a deficient or half (0.5 pph) as a titer of possible loss of catalyst activity during aging.)

The results on tear resistance are summarized in Table 1 and depicted by bar graphs in Figure 2 for a range of catalyst levels (pph) resulting from accelerated exposure to the triglyceride

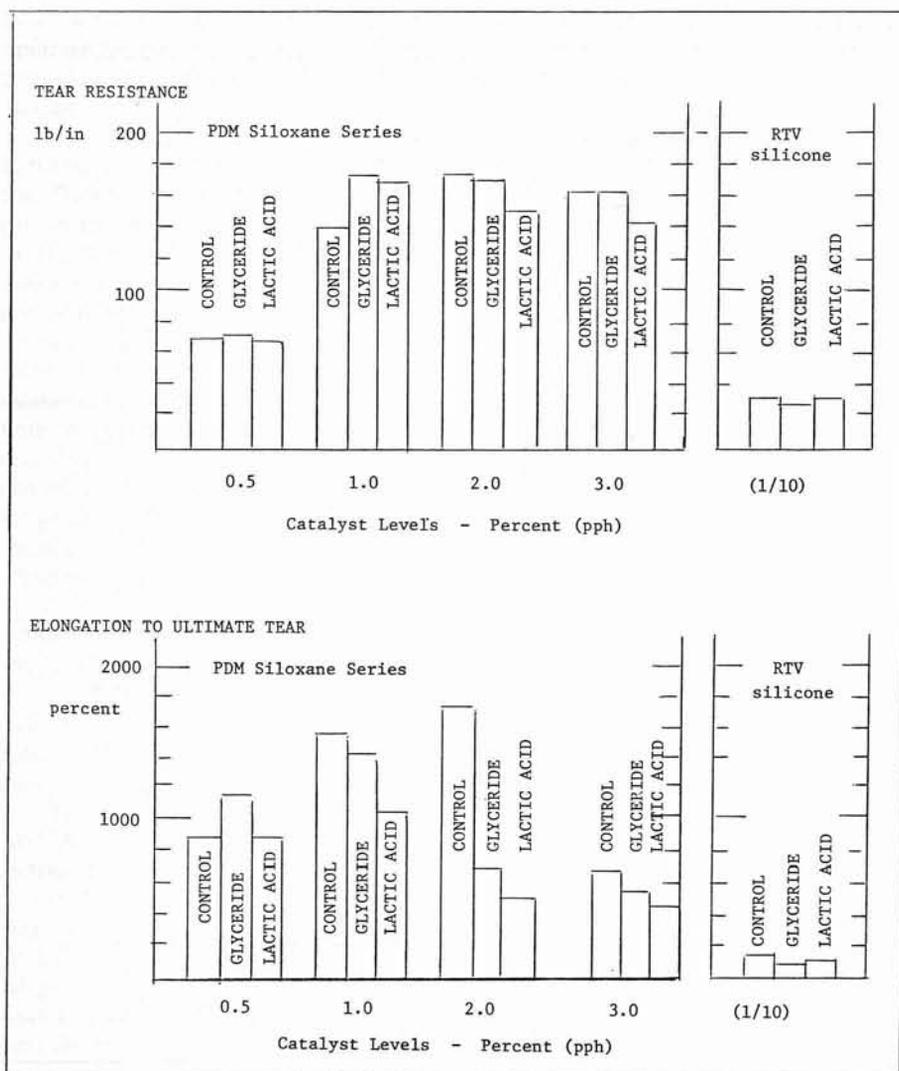


FIGURE 2.

Effect of accelerated glyceride (corn oil) and lactic acid exposure of PDM siloxane from current standard grade SE 4524U polymerized at a range of catalyst levels.

(corn oil) and in lactic acid, replicating the intensified physiologic chemistry to which PDM siloxane would be exposed. Included in the summary and bar graphs is a proprietary competitive RTV (room temperature curing) silicone (MDX 4-4210, Dow Corning). These summaries reveal several salient features, namely,

1. Tear resistance in control series reaches a maximum at the 1 pph catalyst level,

2. Glyceride exposure does not significantly affect the initial (control) tear resistance value of PDM siloxane,

3. Lactic acid exposure likewise does not significantly affect the initial (control) tear resistance of PDM siloxane,

4. The competitive RTV form of siloxane (MDX 4-4210) is markedly inferior to PDM siloxane in tear resist-

ance and significantly affected by glyceride exposure.

Although elongation to ultimate tear is not generally considered in specification tests and standards, the effect of the chemical exposure of the two physiological chemical entities can be seen in the tabulation for the elongation (percent) data. In general, there appear to be instances of enhanced elongation, presumably due to continued thermal chain kinetics (8) on the one hand, but decreased elongation on the other. The PDM siloxane series, however, maintains as much as ten-fold improvement in extensibility over the competitive proprietary RTV siloxane.

The salient significance of retention of improved tear resistance and the corresponding elongation to rupture by

as much as 10 fold (1000 percent, see P-1583 and P-1584) means that suturing of PDM siloxane to skin or muscle tissue for suture-stabilized surgical implantation is thus accorded a high safety factor unmatched by any available biomaterial.

New High Tear Strength Silicone Elastomer—This project maintains constant review of new candidate silicones or siloxane elastomer with improved properties for effective durability. Recently, the General Electric Company has introduced a new proprietary silicone, Tufel® (registered GE trademark) as High Tear Strength Translucent Silicone Rubber (Prepolymer gum stock) compounds (9, 10), with tear strength up to 250 lb./in. compared to the 173 lb./in. level attained with the current PDM siloxane prepolymer (SE 4-524U). Often such proprietary improvements presage a gradual and ultimate displacement of long-established prepolymers which could include the project's SE 4-524U stocks. To anticipate this eventuality, the product-development phase has embarked upon the routine of ascertaining the tensile constants and tear resistance at a range of catalyst concentration (pph) levels.

Tensile Constants—Based on the project's established 80/20 (prepolymer/oligomer) formulation, the tensile constants obtained with General Electric Tufel® prepolymer grade SE 851 and their SF 96-1000 centistoke viscosity grade oligomer are summarized in Table 2 along with the tensile constants of the SE 4524 grade developed in this project. Comparisons of the modulus (M) values with varying catalyst levels, indicate that the new SE 851 prepolymer is substantially equivalent to current standard SE 4-524U for the tactile (feel) flexibility. However, comparisons of the strength (S), elongation, and the dimensionless S/M quotient indicate subtle molecular differences that affirm the vendor's (GE) innovative feature of SE 851 to be high tear resistance.

Tear Resistance—Table 3 summarizes the comparison of the tear resistance values of the new Tufel SE 851 with that of the project standard SE 4-524U prepolymer. The data affirm the vendor's assertion of high tear strength with the SE 851 grade of prepolymer (gum stock). Although the molecular siloxane chemistry is the same for both the SE 851 and SE 4-

524U, there is a marked difference in the molecular chain structures such as intrachain linkage, cyclic structure, cross-linkage, chain branching, etc., (8) so common with proprietary variants in competitive silicone technology.

Physiologic Accelerated Testing—

The same accelerated (100 degrees C for 24 hours) exposure testing in presence of triglyceride (corn oil, Mazola) and lactic acid has been applied to SE 851 with results summarized in Table 4 and in bar graph form shown in Figure 3. As was the case with SE 4-524U, the accelerated exposures imposed no deleterious effect as loss in tear resistance. The evident variability in the force (lb./in.) and the ultimate elongation is provisionally ascribed to possible solvation of the physiologic (replicating) glyceride and the lactic acid on the siloxane molecular segments along with the additional 24-hour thermal (100 degrees C) exposure. In effect, some fundamental combinative or conflicting solvating-temperature kinetics are presumed to be involved. However, the test data per se are believed to be adequate to exemplify the effective durability against possible physiologic assault on the PDM siloxane molecular configuration.

Significance of the Tear Resistance

Testing—The test method applied in this product development places the PDM siloxane in good stance to demonstrate that the fabricated prostheses are endowed with a high order of tear resistance, substantially unaffected by key physiologic chemical entities. Such being the case, orofacial prostheses can be designed as composites with hard, high-modulus prostheses—especially as removable soft liners for hard obturators, dentures, and other internal anatomical reconstructions. The design principle is one in which the PDM siloxane is a soft, elastic, mechanically retained enclosure over a hard (usually acrylic) structure. Especially intriguing is the unique combination of high tear strength and high elongation, which opens up possibilities of surgical reconstitution through sutured implantation in orthopedics, cerebral, and gastrointestinal ventures hitherto avoided because of risk of failure by ever-potent physiological assault coupled with extensile stressing.

TABLE 2.

Comparison of Tensile Characteristics of GE Prepolymer (Gum Stock) Grades for PDM Siloxane Prostheses. Composition: 80 / 20 Standard Prepolymer / Oligomer Ratio. Fabrication (Test Sample Moldings): 100 ± 5° C for 2 hours.

Comments: Oligomer sources General Electric Company SF96-1000 for SE851 and Dow Corning silicone fluid for SE4524, both substantially equivalent. P-Codes identify the recorded thermal profiles in polymerization. S / M Ratio (dimensionless) serves as a measure (gage) of living tissue replication (See BPR 10-26 Fall 1976, page 324)

Identification Molding P-Code	Prepolymer Grade	Catalyst level (pph)	Tensile Constants			
			Modulus (M) lb/sq in	Strength (S) lb/sq in	Elongation percent	S/M Ratio
1654	SE851	0.5	76	228	642	3.0
1609	SE4524U	0.5	56	281	775	5.0
1663	SE851	1.0	116	537	1007	4.6
1610	SE4524U	1.0	104	487	780	4.7
1656	SE851	2.0	162	618	778	3.8
1611	SE4524U	2.0	159	455	443	2.9
1665	SE851	3.0	128	548	805	4.3
1612	SE4524U	3.0	139	524	421	3.8

TABLE 3.

Comparison of Tear Resistance Value of SE Prepolymer (Gum Stock) Grades for PDM Siloxane. Composition: 80 / 20 Prepolymer / Oligomer Ratio. Fabrication (Test Sample Molding): 100 ± 5 degrees C for 2 hours.

Comments: Oligomer sources: GE silicone fluid for SE 851 and Dow silicone fluid for SE 4524U, both fluids are substantially equivalent per ASTM specifications. Molding P-Code identifies the fabricating recorded thermal profile.

Identification Molding P-Code	Prepolymer Grade	Catalyst level (pph)	Tear Resistance (A.S.T.M.)	
			Tear Force lb/in	Ultimate Elongation percent
1662	SE 851	0.5	125	540
1587	SE 4524U	0.5	70	868
1665	SE 851	1.0	185	519
1590	SE 4524U	1.0	173	1210
1664	SE 851	2.0	278	472
1591	SE 4524U	2.0	140	637
1657	SE 851	3.0	229	477
1592	SE 4524U	3.0	160	578
RTV Reference (MDX 4-4210)				
(L-125-94-C)	--	10	39	148

Fabrication in Larger Sizes

A new phase of this project has come into prominence as a result of numerous requests emanating from the Field Participation Project IV with over 40 clinical participants, a number of whom have requested assistance to mold PDM siloxane into prosthesis larger than the usual maxillofacial sizes used for noses, orbits, ears, obturators, and so on. The larger sizes include foot and hand extremities, breast forms, and the more devastating facial losses in the areas of the chin and chin-throat regions.

The fabrication of maxillofacial prosthesis moldings, generally serviced by the dental profession, is limited to the dimensions of the two standard brass dental molding flasks, namely:

1. Regular Hanau flask, 3 inches wide X 2½ inches deep, and
2. Giant Hanau flask, 4 inches wide X 3½ inches deep.

For prosthesis dimensions larger than these two, there are no commercially available brass flask molds. The flask form (in matched half-sections) serves to contain the compression-strong but fragile dental stone in a balanced, even, planar force of compression with no flexure. The minutest flexure or point pressure causes unrestrained multi-fragmented cracking. For this reason, the more extended fabrication required to accommodate hundreds of needed prosthetic reconstructions is simply not attempted, except with RTV elastomers pressed at low pressures using fluid RTV silicones—with results that are seriously lacking in tear resistance, as described previously (Table 3), and which are especially sensitive to deterioration by organic solvation. Under prevailing regulatory requirements for effective and safe medical devices, the RTV silicone derived prostheses, some using toxic metallic catalysts, do not and cannot properly accommodate the criteria of safety and especially of effective durability.

The low, inadequate tear resistance of RTV silicone is well known throughout the prostheses art and technology. The participants using PDM siloxane in the Field Participation program have had sufficient experience with the high tear resistance and extension of PDM siloxane to adopt it in non-pigmented form to internal prosthetic reconstructions beyond the presently limited

TABLE 4.

Effect of Accelerated Glyceride and Lactic Acid Exposures on Tear Resistance—SE 851 Prepolymer. Composition: 80/20 Prepolymer/Oligomer. Fabrication: 100 degrees C, 2 hours. Dental Stone Mold. Exposure: 100 degrees C, 24 hours.

Identification Molding P-Code	Catalyst level pph	Exposure Medium	(Tear Resistance (A.S.T.M.))	
			Tear Force lb/in	Ultimate Elongation %
1662	0.5	None - control	125	540
1648	0.5	Glyceride	152	1288
1650	0.5	Lactic acid	94	890
1655	1.0	None - control	185	519
1646	1.0	Glyceride	192	1243
1649	1.0	Lactic acid	165	968
1664	2.0	None - Control	278	472
1644	2.0	Glyceride	224	1090
1651	2.0	Lactic acid		
1657	3.0	None - control	229	477
1647	3.0	Glyceride	222	878
1652	3.0	Lactic acid	230	815

maxillofacial or orofacial range. This project has therefore been obliged to undertake the task of devising a simplified, inexpensive stone mold with internal and external metal reinforcing components. The first case undertaken was for the molding of missing extremities of a club foot, to serve as an engineering (fabricating) model with inexpensive standard hardware items that could be used with no more complicated hand tools than a hacksaw and electric drill. (In contrast, a brass flask would cost \$750 based on a quotation obtained several years ago.)

A Shoe-like Prosthesis—A right-foot defect of a young 26-year-old female technician required a molded prosthesis, for obvious cosmetic reasons, depicted schematically in Figure 4 with overall dimensions of 8-inch length X 3-inch width X 2-inch height. The prosthetic specialist (JK) made a slipper-like prostheses using a three-part gypsum cast molding from a proprietary RTV silicone which requires less than 100 pound force of compression to form.

The shoe-like prosthesis, weighing approximately one-half pound (225 grams) was designed to slip over the stump pedal with elastic tension. The prosthesis lasted only a few weeks of wear, failing because of extensive tearing. The prosthetic technician referred the problem to this project to devise a box mold that would withstand the forming pressure for PDM siloxane and the required thermal schedule for the mold mass to assure proper curing (polymerization). The three-part gypsum mold was shipped to the VA research laboratory and the following fabrication tasks were carried out.

Box Mold Restructuring—The hard-cast gypsum mold, received in broken pieces, was repaired by encasing with a dental-stone skirting enclosure as shown in top and side view in Figure 5, followed by bracing with iron flat bars (1 inch wide X a quarter of an inch thick) joined at the ends with 6-inch bolts, and a second application of dental-stone skirting such as depicted in Figure 5. The dental-stone skirting is

applied to both halves of the gypsum cast, using the powder-water slurry which sets in 10-15 minutes to a hard stone. The skirting of dental stone with enclosed iron braces is kept to a minimum, so that the width does not exceed the lateral spacing (7¼ inches) in the Carver press as shown in Figure 6.

Filling the Mold with PDM Siloxane—Lacking fluidity, the PDM siloxane has to be emplaced by pressing slips or strips of sections into the cavities of

both mold halves. A charge of 250 grams was required to assure full replication of the prosthetic form. When the filling is completed, the mold halves are put into proper registration for the next step, pressuring.

Mold Pressing—As depicted in Figure 6, the filled mold is pressed in a Carver press progressively to 10,000 pounds for a planar area of approximately 250 square inches, or approximately 400 lb/in² and held at this compressive force for 2 hours. These

factors have been arrived at by trial-and-error and need to be taken into account because of the inherent time-dependent viscoelastic rheology of the PDM siloxane. Additionally, vent sprues need to be placed at the far reaches of the mold cavities to ensure complete filling. When the pressing is accomplished, the entire mold is taken off the press and two or more thermocouples are placed in pre-drilled holes or vent sprues to contact the PDM siloxane and/or the stone mold. The compres-

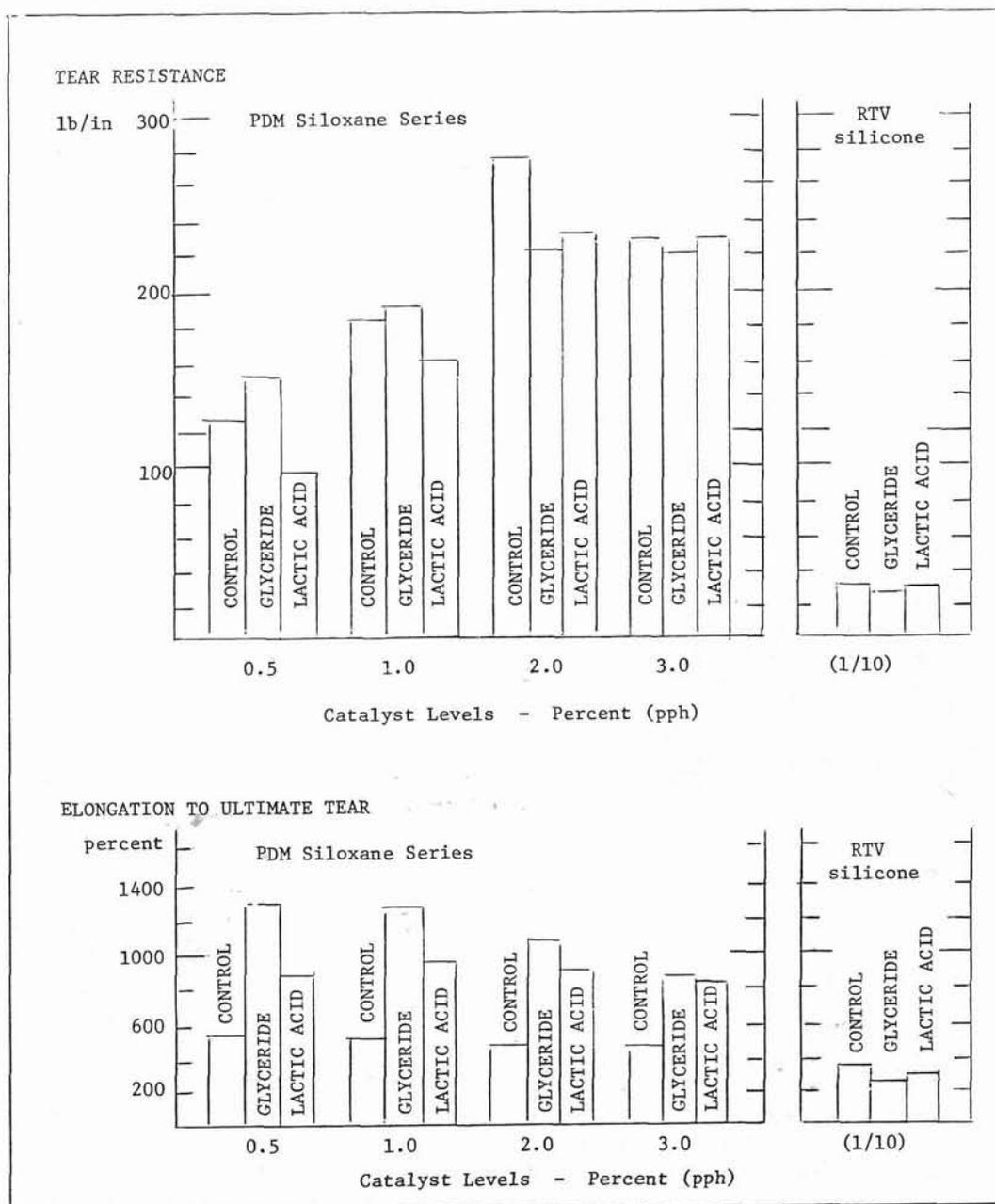


FIGURE 3.

Effect of accelerated glyceride (corn oil) and lactic acid exposure of PDM siloxane from new, high-tear-resistant SE 851 (Tufel) polymerized at a range of catalyst levels.

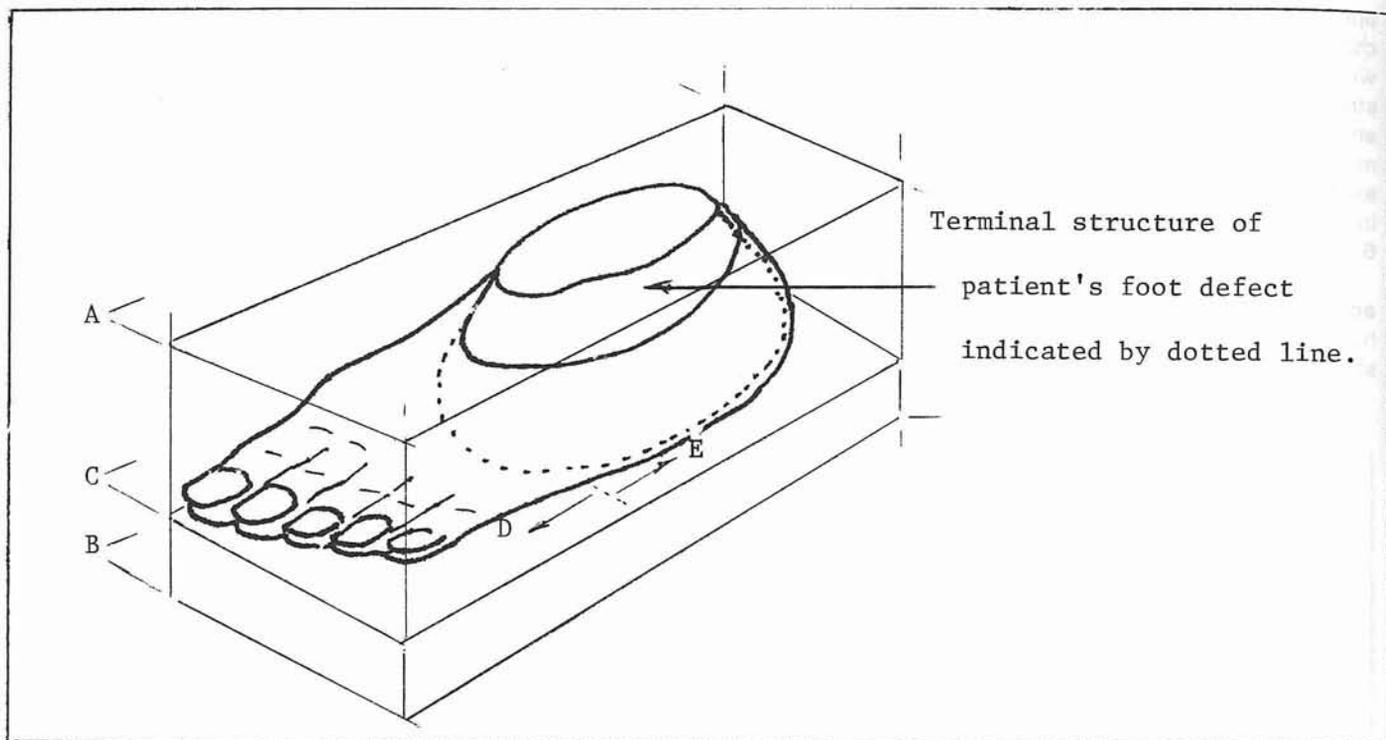


FIGURE 4.

Box mold design for fabricating prosthetic cosmetic appendage to replace missing region of foot, utilizing slipper concept. For a two-part split mold the partition plane C, between end planes A and B, would be located at some intermediate plane. The missing bulk (D) is made of PDM siloxane to replicate the instep and toes and the design continues as a cup-like casing E around the heel for firm retention. The design demands exceptional tear strength and resistance because of repeated stretching each time the prosthesis is taken off and put on.

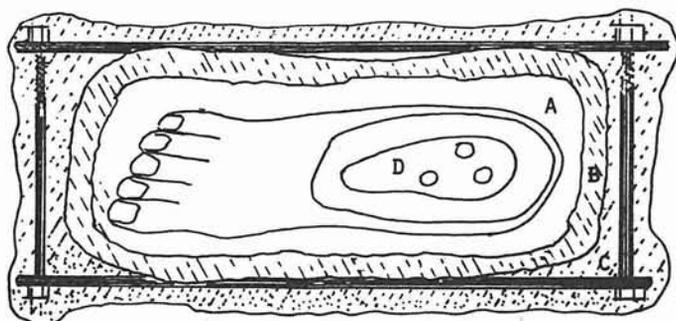
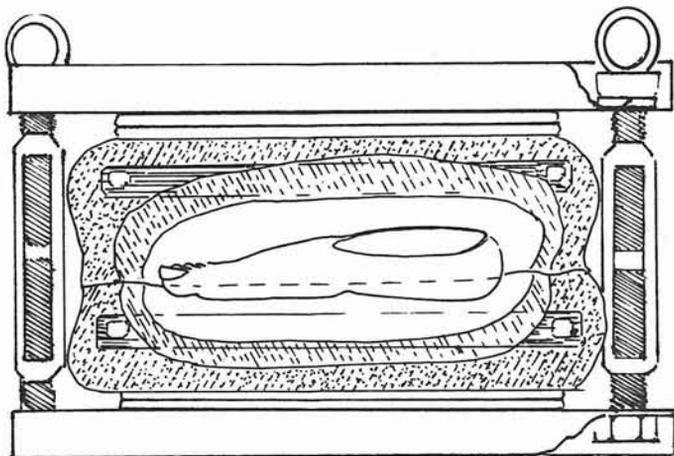


FIGURE 5.

Drawings describe the engineering of box mold reinforced with embedded iron flat stock and bolts serving as structural reinforcement of the first gypsum form for prosthesis, further encased with dental stone skirting. With appropriate sprues or vent outlets at distant recesses, this arrangement extends the fabrication of PDM siloxane into a variety of much-needed prosthetic reconstructions in sizes not presently attainable with current sizes of standard maxillofacial molds.

In the plan view at left, above is shown (A) the first gypsum casting of the patient's foot defect, and dental stone skirting (B) used to repair or restrain the original casting. Iron flat stock (C) and bolts are shown emplaced for reinforcement, while more dental stone skirting encases the metal reinforcement. In the elevation view (at left, below) heavy-duty aluminum or iron U-stock with double draw-bolts are in place to clamp the mold halves. (Note: drawing fails to show reversed pitch of draw bolts.) Total hardware cost for this mold was \$18.00 and total craft time was 2 hours, reflecting the successful transfer of a highly developed but inherently simple technique to the production of larger prostheses.



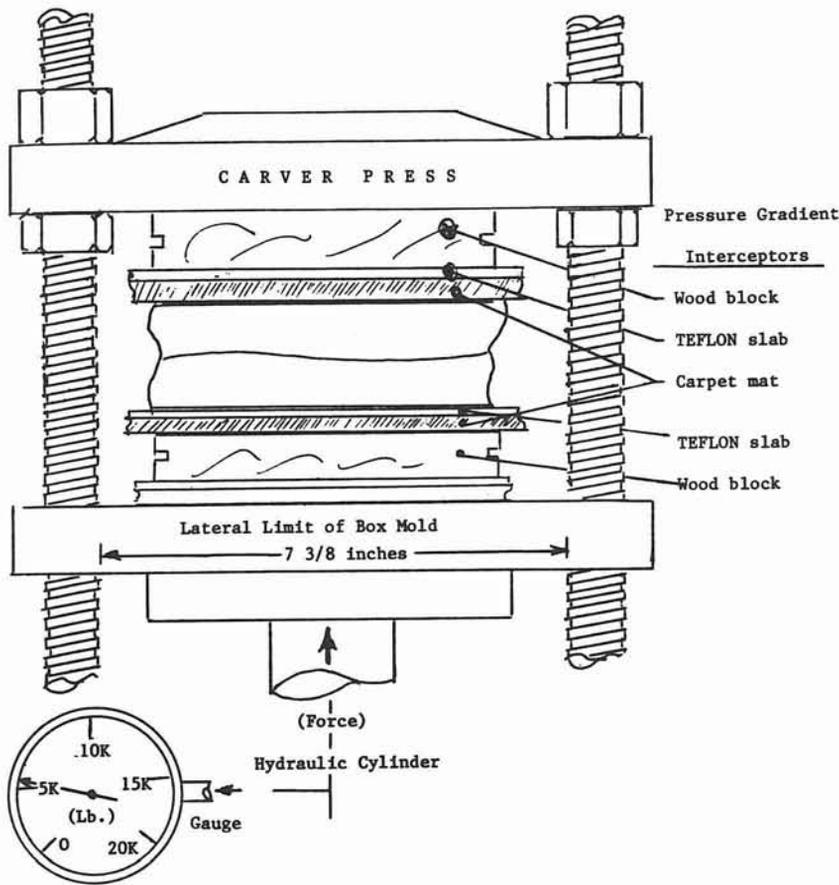


FIGURE 6.

Pressure application in Carver press using an array of pressure gradient interceptors to redistribute the force on the compression-sensitive stone mold. The range of decreasing material stiffness from wood to plastic (in this case a handy piece of 1/4-inch-thick Teflon sheet stock, to carpet mat) serves to allow the two mold halves to adjust for any off-plane slanting. The PDM siloxane, because of its high viscoelasticity, requires a prolonged flow time to reach the remote recesses of the mold.

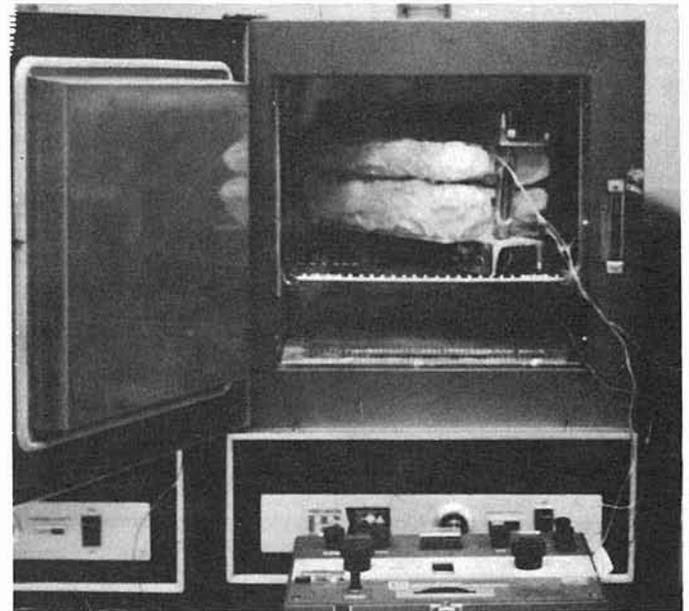


FIGURE 7.

Polymerization by oven curing of PDM siloxane in dental stone mold in an electrically heated, thermally controlled and monitored oven. (In this case the foot prosthesis depicted in Figure 4 is preformed as depicted in Figure 5.) **At left, above,** assembled stone mold for fabricating foot prosthesis of PDM siloxane, pressed and clamped for polymerization (curing) with thermocouples (2) emplaced deep in the mold for temperature monitoring. **At right, above,** insertion of the assembled stone mold in an electrically heated laboratory oven for polymerizing the PDM siloxane at 100 ± 5 degrees C for 2 hours monitored by potentiometer for the thermal profile shown in Figure 8.

sion of the two mold halves is restored by clamping the filled mold between two aluminum angular U-beams (2 X 2 X 2 inches) with draw bolts at each end.

Thermal (Curing) Schedule—To effect the necessary curing or polymerization, the PDM siloxane must be heated at $100 \pm 5^\circ\text{C}$. for 2 hours in a heat mass comprising:

1. stone component 8575 grams
2. iron bracing 1060
3. aluminum clamp-
ing beams 1890
4. PDM siloxane . . . 250

for a total weight of 11,775 grams, a sizeable mass to be heated, especially with a major section of low-heat-conductive stone.

The thermal schedule shown in Figure 7 involves regulating the power input from an initially high-temperature

environment (A), usually the maximum of the oven, which is then programed downward as the internal mold temperature equilibrates (B) to specified $100 \pm 5^\circ\text{C}$. for 2 hours. Figure 7 shows the placement of the mold in a typical laboratory heated-air oven, while the respective temperatures are recorded from a potentiometer, as depicted in Figure 8.

Significance of the Expedient Forming Mold—The curing of the foot prostheses had to be repeated twice to patch up deficiencies or incomplete filling. This made the first significant contribution to the art of fabricating large prostheses—the patch sections were found to be firmly, chemically bound to the precedent molding. This expedient technique has also shown the importance of using sprues at distant

cavities into which the PDM siloxane, or equivalent prepolymer stock, must be forced. Finally and most importantly—this effort opens up for PDM siloxane entry into larger-dimensioned medical sculpturing of prosthetic devices needed in artificial limbs, where its exceptional tear resistance, in combination with chemical durability and biological safety that outrank current flexible prosthetic materials, will be of great value.

Pigmentation

The current standard six-shade internal pigmentation, SY to SR range (3), is applicable to all races by the simple expedient of applying external pigmentation with brown-black manganese dioxide as required. The fine precipitated powder form of manganese dioxide is especially useful for cosmetic matching

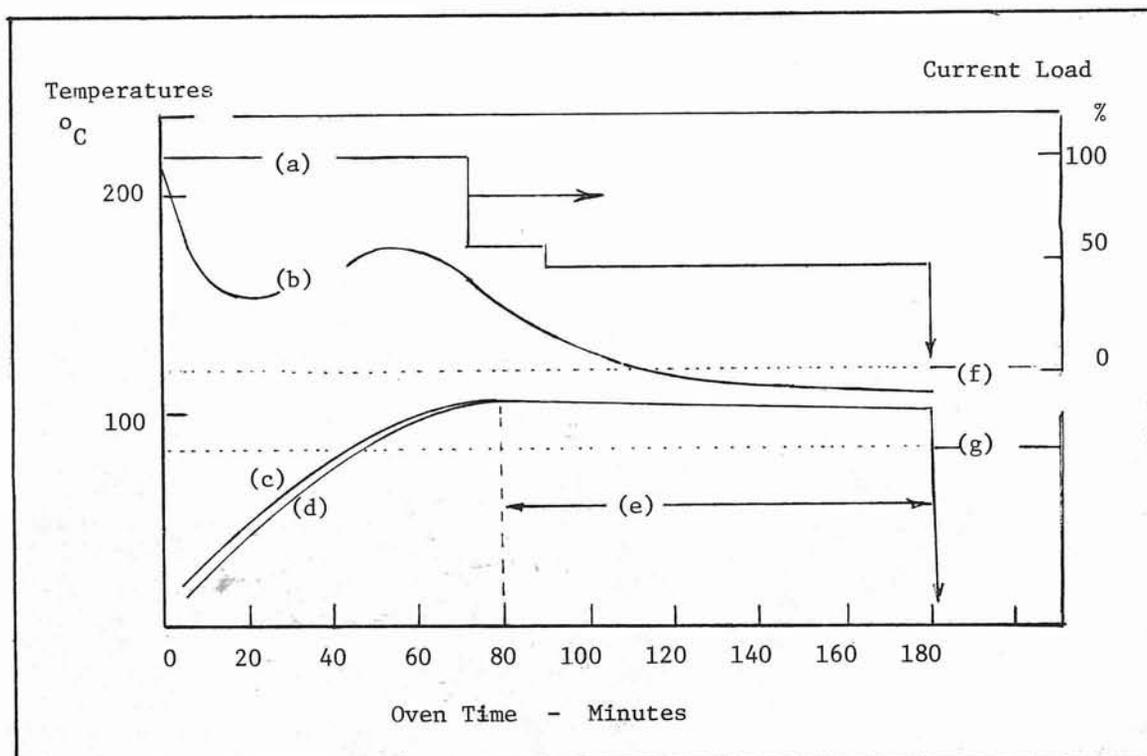


FIGURE 8.

Thermal profile for controlling and monitoring the polymerization (curing) of PDM siloxane to assure attaining the specified tensile (tactile) quality and tear resistance.

Control and Monitoring Details

- (a) Oven setting from high (100 percent current load) oven temperature lowered to thermal exchange equilibrium between oven and molding.
- (b) Oven temperature external to the molding assembly.
- (c) Temperature in stone mold, thermocouple #1.
- (d) Temperature in stone mold, thermocouple #2.
- (e) 2-Hour time span at 100 ± 5 degrees C for standardized polymerization.
- (f) Thermal limit (120 degrees C) of stone mold.
- (g) Initiating temperature (80 degrees) for catalyst activity in polymerization.

for the summer suntan shade, as it is highly replicative of the physiological melanin pigments existing at the skin surface. There have been several isolated requests to augment the current SY and SR shades, which replicate the color variation from the predominantly carotene yellow (SY) to predominantly hemoglobin red (SR) described previously (11), to accommodate darker skin with internal pigmentation.

In response to these requests, this phase of the project has initiated the preparation of an augmenting series of intrinsic Afro pigmentation with added manganese dioxide involving covariant effect of particulate form, incremental level of pigmentation, and degree of mill dispersion. Preliminary data based on the digital color difference (DCD) indices (see previous BPR progress reports) currently being generated in this phase of the project, indicate that the mere internal inclusion in depth of the dispersed melanoid replication imposes an inordinate loss of the internal red-yellow color esthetics. External topical pigmentation, as is the case with human skin, remains the preferred means for attaining the Afro pigmentation which most skilled prosthetists apparently follow as the general practice in cosmetic matching. Subjectively, internal dispersion of the melanoid-like pigment absorbs excessively the internal reflections and even cancels out the highly reflective performance of the titania pigment used to replicate lipid reflectances.

Further efforts are continuing in this effort to develop a balance of effects to attain a satisfactory internal darker, melanoid pigmentation.

Toxicity and Tumorigenicity by HED Tissue Culture Testing

The major thrust of this project phase has been toward developing critical laboratory procedures and materials specifications for a draft HED toxicity test standard to be submitted for review and ultimate standardization by the American Society for Testing and Materials (ASTM). The ASTM has a special Committee F-4, dealing with standard tests and specifications for safe and effective medical and surgical materials and devices. The senior author (JFL) is a member of this committee.

ASTM Processing to Approval—To attain formal approval as an official

TABLE 5.

Summary of Proposed ASTM Standard Practices for Biocompatibility of Polymeric Materials by Tissue Culture Procedures

Cell Type (designation)	Medium	Serum type	Growth Period (Days)	Criteria of toxicity	ASTM designation
Mouse (L929)	MEM ^a in agar	Bovine (calf)	1	Morphological, cell classifications ^b	F4.20.06.50B (Draft Form)
Human lung, embryonic (WI 38)	MEM	Bovine	1	Morphological, cell classifications ^c	F4.20.06.50 (Draft Form)
Human skin, embryonic (HFS 15,HR 218)	MEM	Bovine	1	Morphological, cell classifications ^d	F4.20.06.50 (Draft Form)

Comments: ^aMEM—Minimum essential medium.

^bNumerical grading specified in terms of malformation and degeneration.

^cDescriptive—sloughing, granulation, lysis and rounding.

Note: None of these test standards preempt or approximate the human relevance criteria of the HED tissue culture test system. Moreover, the growth period of only one (1) day will always be suspect of delayed toxicity because of insufficient period of culture.

ASTM designation, the draft test standards and specifications are reviewed by task study groups, subcommittees, and the executive committee, by as many as 40 panelists in as many as a dozen draft revisions in sessions that take place twice each year. The proposed draft involves detailed descriptions and subsidiary specifications that require scrupulous, unequivocal and confirmable results, generally much more involved than what is normally pursued in investigative research. Each draft and revision is subject to ballot approval by panel reviewers having an interest in the proposed standards. As a consequence, this phase of the project has pursued two distinct paths on about the same level of priority, namely,

1. Devising definitive laboratory protocol test standards and specifications with HED cells for biocompatibility of PDM siloxane; and

2. Supporting the HED tissue culture test development with biochemical and biophysical markers to affirm the morphological assessment of safety to human tissues.

These are distinct endeavors but nonetheless highly interdependent.

Status of Test Standards for Biocompatibility of Polymers (Elastomers) by Tissue Culture Techniques. Table 5 presents a summary of the current status of recommended practices

for biocompatibility on the basis of cytotoxicity under review by the ASTM Committee F-4 on Medical and Surgical Materials and Devices. The most commonly cited test systems are the agar plate culturing with an established mouse (connective tissue source) cell line (11) with bovine serum and established human embryonic WI-38 cell line (12) also with bovine serum. Presumably, if and when adopted into official standard, either test could conceivably be required to qualify PDM siloxane. While there has been considerable investigative background and published literature on these heterogeneous or mixed cell-serum systems, their promulgation for responsible assessing of biocompatibility on PDM siloxane poses questions about relevance and validity using established cell lines, long removed from the human primary tissue cells, and grown with foreign serum. In other words, it is important to emphasize that the WI-38 "human" cell albeit originally derived from intact human origin, is not a primary human cell endowed with all genetic predisposition, but rather a cloned fibroblast gradually or completely degeneticized so as to lose relevance to its primordial characteristics. There will always remain valid doubt about toxicity (or tumorigenicity) when using fibroblasts of established cell lines since it is not known if they

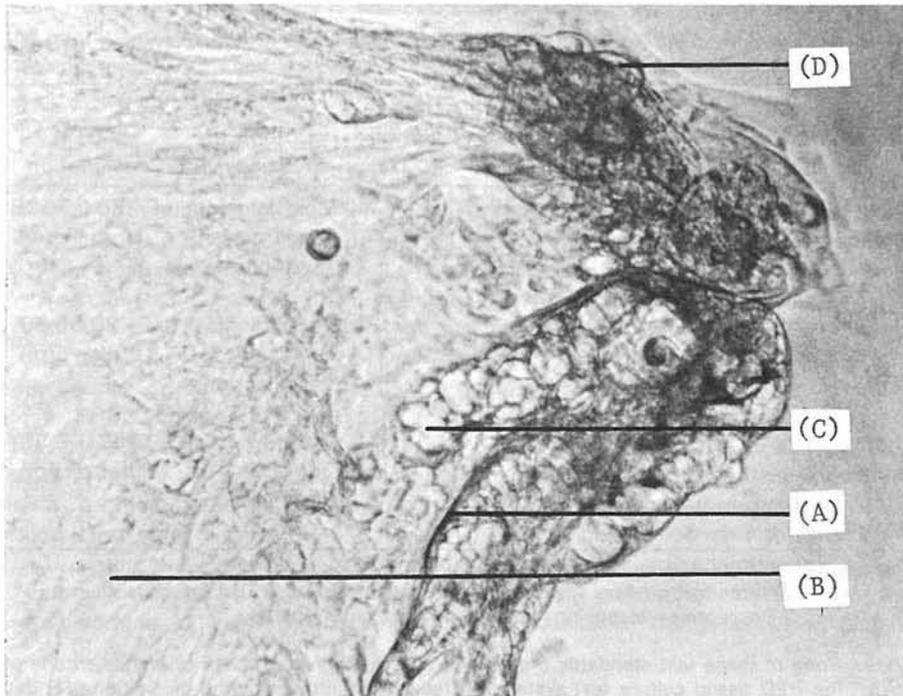


FIGURE 9.

HED nasopharynx tissue grown (14 days and still in progress) in presence of PDM siloxane using slightly modified A3 medium with 10 percent human serum (dialyzed O-positive). Marked outgrowth is evident displaying tissue with several layers thick of mucosal epithelium (A), fibroblasts (B), and other undefined cell formations (C and D).

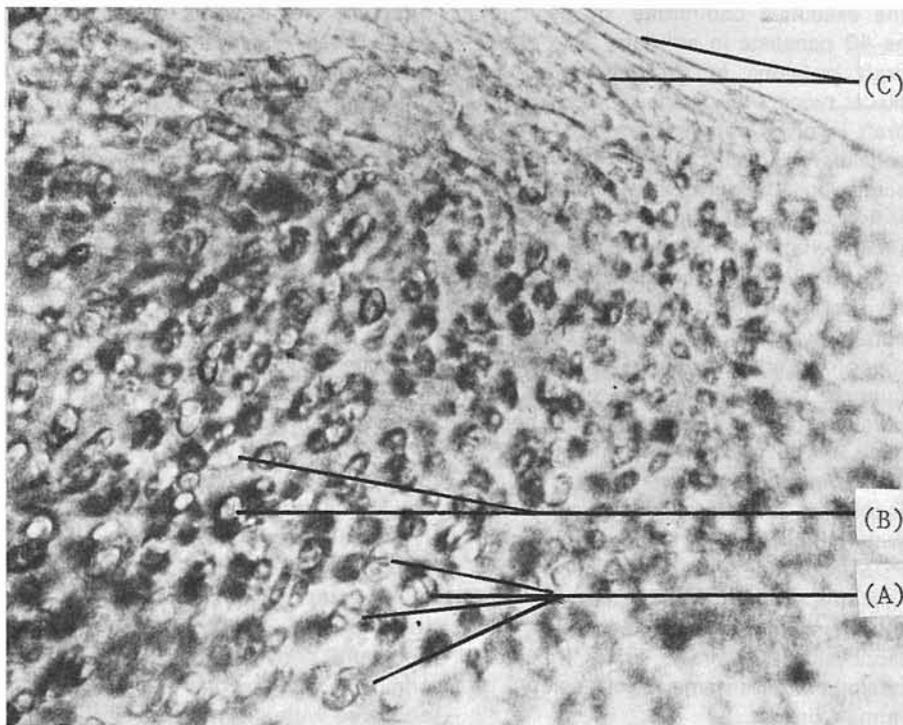


FIGURE 10.

HED cartilage (toe) tissue grown (14 days and still in progress) using slightly modified A3 medium with 10 percent dialyzed human serum (O-positive). Marked tissue regeneration is evident displaying new cells (A) in groups of at least two growing in the lacunae (B) with new matrix or laminate (C) being formed during this tissue growth process. This piece of tissue increased in size during this culture. This type of outgrowth with organized regeneration constitutes the thrust of the HED tissue culture system in contrast to the seemingly restricted conventional cell culturing using solely fibroblasts and undifferentiated cells.

are comparable in all ways to primary cells. Indeed, the equivalency of established cell lines to their *in vivo* characteristics has never been established or ventured experimentally.

As to the relevancy of the tissue testing for safety of PDM siloxane on the basis of the currently proposed ASTM draft biocompatibility using WI-38 established cell-line, the reference literature (12) cited 20 out of 24 silicone rubber specimens from diverse manufacturing sources as being cytotoxic in this cell culture. Thus, this adverse citation against any polydimethylsiloxane needs to be dealt with. It is on this point that the ensuing (i) test development for ASTM review and (ii) supplementary investigative studies on the HED tissue culture system are of necessity predicated.

Experimental Approach for ASTM Draft Standard.

The approach is now predicated upon using:

1. Primary HED cells taken from orofacial, skin, and bone tissues;
2. Synthetic medium with completely defined growth hormones and factors; and
3. Defined human serum fraction separated from potentially toxic or inhibitive components.

The importance of using defined growth hormones and especially growth factors has given a new widespread impetus to continuous modifications in tissue culture technique. A number of growth factors specific to various cells have been isolated from various sources and are gradually becoming commercially available. Of particular relevance to this effort is the ongoing separation and use of alpha-1-protein discovered by Holmes (13, 14) with representative orofacial tissues (pertinent to maxillofacial prosthetics) in the form of primary excised tissue cells, which comprise a diversity of symbiotic cell types that are coexistent in the total physiologic and anatomic state. These cultures should arise as outgrowths from the excised tissue. Figure 9 illustrates the first of a series of experimental efforts to affirm the feasibility of symbiotic tissue culture with prominent concurrent outgrowth of mature cells, fibroblasts, and other as yet unclassified cell structures, using synthetic A3 medium (13) augmented with specially processed human serum.

Another example of prominent symbiotic tissue growth is shown in Figure 10 of an HED cartilage (toe) section similarly cultured in synthetic A-3 medium with the specially processed human serum.

The significance of these two examples of tissue growth, as distinct from the conventional cell cultures with only undifferentiated or matured fibroblast growth, as prevalent in current ASTM biocompatibility testing, is that an all-human-tissue/human-serum test is being devised for a more relevant and meaningful ASTM test standard. Moreover, this tissue growth system is intended to contravene the citation (12) of cytotoxicity against silicones generally by applying an all human-tissue/human-serum testing system. This implies (as the next requirement) the production of a specification-defined human serum with a prescribed titer of growth factor and stripped free of growth inhibitors or toxic factors so common in any serum.

Separation and Standardization of Human Growth Factor—As mentioned previously, specific growth factors are coming into prominence in tissue culture; the one of particular interest to this project is the alpha-1-protein, termed AGF for short and isolated from human serum by a specified procedure (14). The AGF eliminates the usual 60–90 day adaptive phase required to establish actively growing cultures of established cell lines in serum-free chemically defined medium (15). Eliminating or shortening the cell adaptation stage has been the first requirement for a biocompatibility test standard, not only for the saving in time but also to eliminate the risks of contamination during repeated medium maintenance (which is also an important economy factor in cutting down on use of expensive nutrient medium).

Since the activity or titer of AGF in human serum is variable, as is expected due to genetic factors and type of diet, an important task in this phase has been to separate the AGF factor on each lot of serum and to assay its biological activity or titer with an established human heart cell (Girardi) line. This is evident in Figure 11 which illustrates the differential separation of numerous fractions of human serum on inexpensive commercially available glass microbeads (16). The activity of AGF is monitored by its effective activity in culturing an established human heart

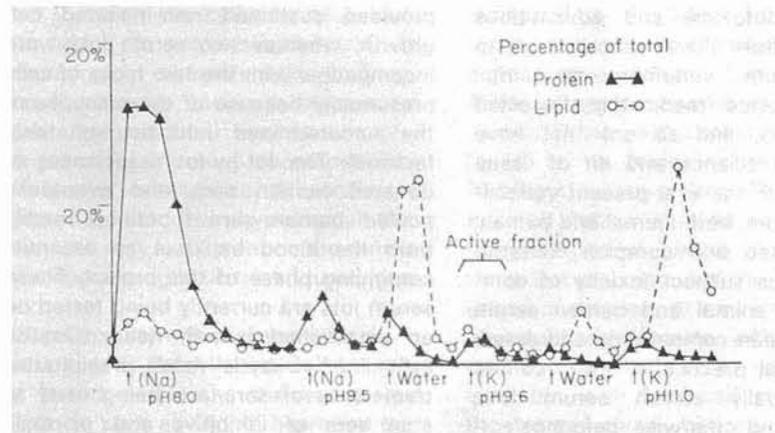


FIGURE 11.

Separation of human serum on glass microbeads at 25 degrees C showing the percentage of total protein and lipid material found in each fraction. All fractions were tested for biological, tissue culture activity. Activity was located in Fractions 23 to 27 inclusive. After Holmes (13).

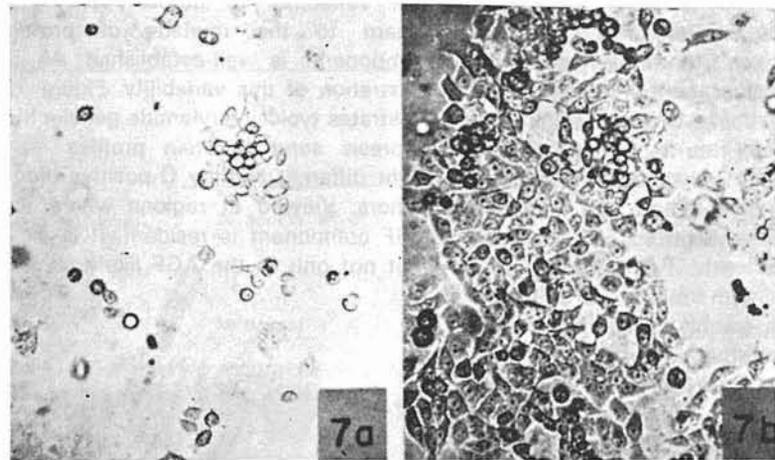


FIGURE 12.

Effect of AGF (alpha-1-protein) on replicate cultures of unadapted human heart cells placed in chemically defined medium: 7a, 24-hour-old culture with no AGF added; 7b, 24-hour-old culture with 8 µg/ml AGF added to the medium. After Holmes (13).

cell line in serum-free A3 synthetic medium (16). The latter replaces whole or modified human sera. As indicated in subsequent discussion all sera, human or animal, contain factors that are deleterious to cell culturing (16). Figure 12 illustrates the high potency of AGF, used in serum-free A3 synthetic medium, in the rapid adaptation of an established heart cell line in a matter of 24 hours, compared to normal adaptation in conventional medium that require 60 to 90 days to attain the equivalent confluency of cell growth. In any standardized test, this time

compression provides significant cost benefit along with lessened errors due to the change of medium and risk of adventitious, compromising contamination.

Importance of AGF to Biocompatibility Testing—The focus on the single, isolated human growth factor (and there may be others as the human sera fractions are currently being studied) provides the first definitive specification feature for developing and standardizing a reconstituted human serum nutrient that would be (i) specified with definitive titer of the AGF, and (ii) be stripped of deleterious inhibitive or toxic

factors, endotoxins, and adventitious chemicals (from therapeutic sources in human serum, veterinary in animal serum, ingested medication, ingested agrichemicals, and so on) that have plagued the science and art of tissue culturing with the ever-present variability of all serum, both animal and human. The undefined and complex contamination versus suspect toxicity of components of animal and human serum has never been competently addressed. The universal practice in tissue culture is to actually screen serum lots, purchased and otherwise, before selecting a particular one for the assay of cell growth, discarding those which give inhibitive or contradictory results; it is viewed as a matter of quality variability.

Typical of the commonplace variability of serum activity to which this project is frankly addressed, are the data indicated in Reference 17. These data were taken from published studies (17) on tissue culturing of rabbit chondrocytes using DNA content analyses as the cell titer for cell growth and multiplication. The data in Reference (17) clearly demonstrate the presence of seemingly uncontrollable factors of cell growth with both homologous (rabbit-cells with rabbit serum) and heterologous (rabbit cells with foreign sera) combinations, in some cases with markedly lowered cell growth to the point of complete inhibition that could be regarded as indication of toxicity. Data such as these underscore the compelling restriction to the use of homologous sera, appropriately processed to remove the toxicant(s). This has been the concept and intent of the HED tissue culture system to provide a standard criterion of biocompatibility of PDM siloxane with prescribed homologous human cell-serum system in order to vacate the adverse literature citation (12) of silicones as being cytotoxic. It is thus clear that human sera need to be stripped of the inhibitive or toxic factors therein contained.

Similar cell growth variability with marked inhibited or toxic effects have been experienced in the present, ongoing HED tissue culture tests with primary tissue cells and with reference established human cell lines using human serum of different donors. Of the five lots tested in an incoming regular series of serum donated by the Blood Bank of Delaware, only three

provided sustained non-inhibited cell growth, whereas two serum lots were incompatible with the two types of cells presumably because of the presence of the undetermined inhibitive or toxic factor(s). The lot-by-lot assessment of donated human sera and eventually pooled human sera (obtained readily from the blood bank) is an essential continuing phase of this project. These serum lots are currently being tested on an established human heart (Girardi) cell line. Dialytic and precipitative treatments of sera are being used to strip sera of inhibitive and/or toxic factors. Such treated human sera or serum proteins will be an important part of the specifications for submittal to the ASTM F4 standards review committee.

Stripping Cell Growth Inhibitive (Toxic) Factors from Human Sera—

The variability of human sera with regard to the myriads of protein components is well-established. As an illustration of this variability, Figure 13 illustrates typical acrylamide gel electrophoresis serum protein profiles from eight different healthy O-positive blood donors. Viewed at regions where the AGF component is resident, it is clear that not only is the AGF likely to vary

in content or probably in activity, but some of the other components may be complexing or serving as carriers of adventitious toxicants or inactivated complexes (lipoprotein) of AGF. This raises several questions regarding the molecular attributes of the serum proteins: (i) are they low molecular weight (up to 1000 more or less), (ii) intermediate or middle molecular weight (5000 more or less), and (iii) can they be stripped from the serum by dialysis, selective precipitation, sedimentation, or any other biophysical or biochemical method, as a means to provide compatible human-derived serum or serum component? The project includes a program to set up separatory techniques applying cell growth assessment, by DNA analyses, and with the rapid screening with established cell lines, the preparatory or process specifications will be provided as an essential specification item for the biocompatibility testing.

Figure 14 depicts the first of the preparatory techniques now in progress utilizing dialysis to remove suspect low and intermediate molecular weight inhibitors and/or toxicants from reconstituted serum proteins with natively

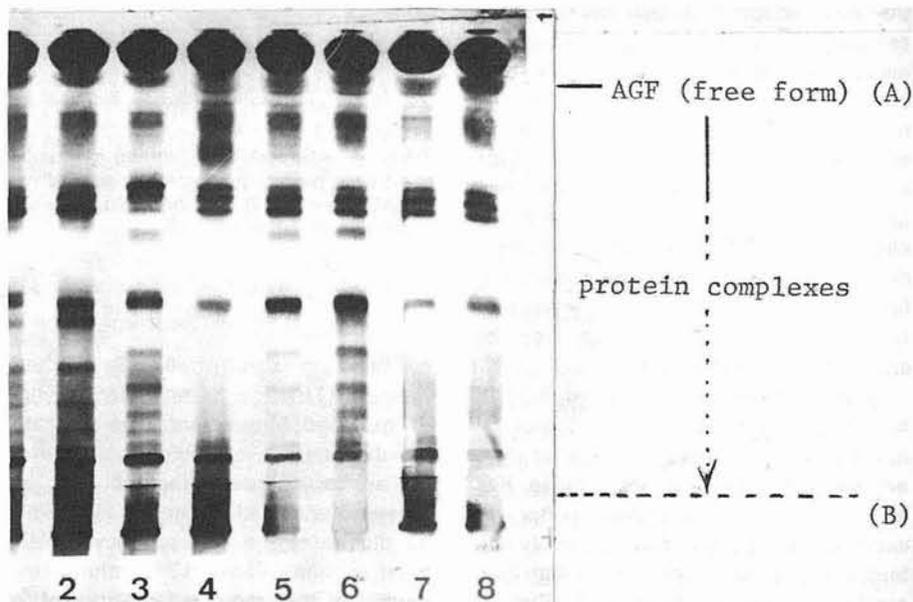


FIGURE 13.

Human serum patterns by gel permeation (acrylamide) obtained from eight healthy donors, indicating inordinate variability of component serum proteins and other factors and adventitiae. AGF used in this project is characteristically located in free form at position A, but can be found spread throughout the permeation range to position B presumably in innumerable protein complexes. It is thus understandable that serum, human and otherwise, for tissue and cell culturing requires reconstituting, such as depicted in Figure 14, by well-defined procedures and assays of growth effects in actual cultures.

retained AGF, thereby providing an inexpensive, process-standardization nutrient serum. This effort is most compelling with both types of cells. Thus, whereas AGF with serum-free A3 medium promotes cell growth with established cell lines within a 24-hour period (and for this reason established cell lines are used as an activity titer for AGF), the primary HED tissues and/or cells require serum proteins and will not grow with AGF and A3 medium solely. The ultimate biocompatibility test for the ASTM standards is to grow primary HED tissues and cells which retain their mature morphological states, e.g., mucosal, epithelial, etc. These cells will in fact be in direct contact with the prosthetic form of PDM siloxane. Culturing undifferentiated fibroblasts which are characteristic of established cell

lines (or even the culturing of primary cells which do not retain their specific morphological characteristics and appear fibroblastic, due in most cases to inadequate nutrition) may be too presumptuous for affirming biocompatibility. The lack of coexistence of specific cell types may alter the physiological relevancy and may lead to erroneous conclusions concerning toxicity and tumorigenicity.

Cytotoxicity—Biocompatibility

Testing with Established Cell Lines—As stated previously, the established cell lines, such as Girardi heart and that derived from HED tissues, are being utilized in subsidiary tests for qualification of AGF lots and for specifying the dialysis cut-off of human serum lots to remove and identify adventitious toxicants and growth inhibitive factor(s).

Incidental to this effort has been the testing (using the established heart cell with human serum (O-positive)) of PDM siloxane against a non-toxic control Teflon, and a toxic RTV silicone found to be toxic in previous nasal fibroblast culture testing. The results of a 7-day culture showed no significant manifestation of toxicity in any of the three test materials, but the 30-day test is still in progress at this writing. In an earlier series of tests with HED oral mucosal tissue (primary cell) culture tests but with fetal calf serum, using the same three biomaterials, PDM siloxane and Teflon showed no toxic or inhibitive effects whereas RTV (MDX) siloxane imposed either growth inhibition or cell degradation of some sort. These inconsistent results are presumed to delineate differences in test sensitivity, that is between the presumably refractive established cell lines and the more sensitive primary orofacial tissue cells. This clearly indicate the compelling reason to specify biocompatibility testing in an all-human cell-serum system to assure scrupulously close approximation to the normal tissue morphogenesis and its specific symbiosis. Cell lines artificially derived generations ago are being utilized for ancillary quality checks enumerated above, but not for the assessment or arbitration of toxicity with implied or expressly stated human relevance.

Nutrient Standards and Cell Growth Titrers—As was evident in the serum variability noted previously (17), DNA analyses and other biochemical markers are being applied toward specifying quality standards (ASTM) for (i) AGF titer, (ii) quality of processed human serum, and (iii) assessment of the severity of toxicity imposed by the prosthesis material. Ongoing procedural experiments in this regard are illustrated by the interim summary shown in Table 8 wherein the cell growth is collaterally monitored by the biochemical markers which are to be components of the proposed biocompatibility test standard, (ASTM). Culturing schedules of 7 and 30 days are contemplated on the presumption that these two time ranges would provide a gradient of severity of the imposed growth inhibition or toxicity. The results as indicated in Table 8 are to be considered as listing of the component assessment in a more comprehensive interpretation of biocom-

- 20b -

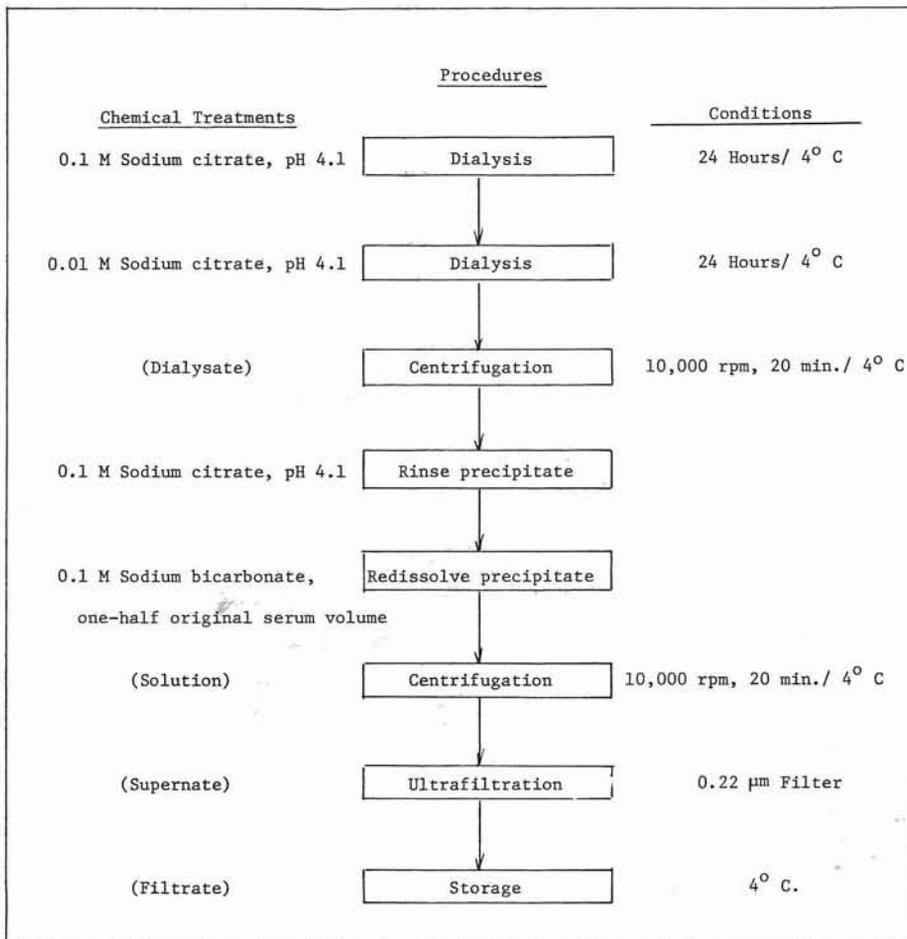


FIGURE 14.

Preparation of precipitated protein from human serum by dialysis against sodium citrate to remove low and intermediate molecular weight components as suspect (but to be determined) toxic or growth inhibitive adventitia in source lots. The protein precipitate is reconstituted by redissolving for use in medium in which primary cultures are grown. (This constitutes effort to narrow down the ever-present variability of serum in tissue culturing generally.)

patibility test results, a feature lacking in present competitive specification tests.

The results shown in Table 8 are not intended at this time to suggest a qualitative rating of biocompatibility, but rather to indicate expected variability in the given time periods, namely 0-7 and 7-21 days with the now displaced fibroblast cell line. The time period 7-21 days of culturing indicates, from the cell count, lowering of cell growth for each of the imposed materials in contrast to positive increase in the case of the control. There is however a uniform lowering of the DNA titer and LDH activity for all experimental sets for this time period. For whatever may be inferred, the DNA decreases are least with the control and imposed Teflon, the highest with RTV (MDX) with that of PDM siloxane intermediate to Teflon and RTV (MDX). In the case of the LDH activity, the least being with the control, there is approximate replication with the imposed test materials. This illustrated experimental set or matrix is being adapted to the already discussed specifics of processed human serum in combination with specified AGF in the synthetic medium A3 to ensure more vigorous tissue cell growth. As stated previously, the ultimate objective is to provide a detailed specification testing procedure for ASTM acceptability on biocompatibility in order to clear PDM siloxane from the adverse cytotoxic citation (12) imposed on silicones.

Production

The level of production of PDM siloxane in the standard 6 internally-pigmented shades continues at 60 one-pound units per year to support the some 360 pounds furnished to over 40 centers in the previous years, starting in 1977, for the VA-wide needs. This level of production, estimated at a demand level of about one eighth of the clinical requirement hardly justifies economically any commercial takeover (20). Thus, the VA source represents the only one that persists with on-going technical support for the regulatory requirement of "safe and effective." The reasons why the demand level is so low are elaborated-on in the ensuing section on Field Participation.

The process of compounding the 80 / 20 composition of prepolymer (gum

TABLE 6.

Summary of Selected Biochemical Markers during Extended Tissue Culturing for Biocompatibility Assessment

HED Tissue Type: Gingival ^a		Medium : NCTC 133 Zn ^b		Serum : Pooled Human Serum ^c	
Test Material	Days of growth	Cell Density (cell / ml) 10 ⁻³ % Change	DNA (intracellular) mg / flask % Change	LDH Activity ^d (intracellular) 10 ⁻¹⁴ units / ml % Change	
None— Control	7	11	—	1.8	—
	30	22 90	+	0.8	-52
Teflon® FEP ^e	7	20	—	2.3	—
	30	12 38	-	1.1	-52
PDM Siloxane	7	18	—	2.5	—
	30	12 30	-	0.6	-77
RTV Silicone (MDX 4 4210)	7	6.1	—	2.9	—
	30	5.6 8	-	0.5	-84

^a Predominantly fibroblasts from several passages.

^b Precursor medium to Holmes A3 (13).

^c For comparison with pre-processed serum.

^d Lactose dehydrogenase (total) as cell growth marker.

^e Transparent tetrafluoroethylene-hexafluoroethylene (Du Pont Co.) as negative cytotoxicity control.

stock) and oligomer (silicone fluid) as described in previous BPR reports is based on intense milling in a three-roll mill. The milling serves three functions, namely (i) decyclize the stiff stock with molecular stretch-out into which (ii) the oligomer is intimately incorporated, and (iii) the six pigment components are uniformly dispersed. For reasons of safety, two operators are required, one checking on the other to trip the stop-safety switch, as the 6-inch rolls could draw in operator's finger with a crushing force from the 2-HP driving system. The process for producing one-pound lots in campaigns of 24 to 30 lots in one working day takes approximately 12 to 20 minutes, exclusive of times for weighing ingredients and clean-up of the mill from the highly tackified form of the milled PDM siloxane stock.

In conformity with the FDA regulatory provisions, the production details for the PDM siloxane stock materials, and the fabrication or molding procedures, must

be detailed into a Good Manufacturing Process (GMP) form of documentation (21), a task that is the obligation of this project. The GMP is subject to inspection and review by the FDA and serves to assure to the user-consumer, the patient, a consistently reproducible safe and effective quality of the prosthetic device, uncompromised by any changes in source materials, production milling, shelf life, and attending physical testing. The GMP in finished documented form must be comparable to industrial engineering process standards, complete with materials specifications, equipment descriptions, and involvement of facilities including compliance with OSHA regulations. As can be surmised from the preceding discussions of this report, the product development and fabrication efforts are intended to develop the detailed GMP, a task tentatively scheduled for completion in FY 1982.

A companion conformity with the GMP is the requirement for a Good

Laboratory Procedure (GLP) documentation (22), which is also planned as an obligatory task of the overall project. The GLP is required to describe and specify testing details for the principal features of "safe and effective," with chemical specifications for the source materials and the fabricated form. The current efforts in the tissue culture program are intended to lay the groundwork for the GLP concurrently with a draft of a standard practice for biocompatibility tests.

It is expected that the preparation and completion of these three documentations will place the PDM siloxane in a favorable, attractive position for some commercial takeover serving not only maxillofacial consumer markets, which is an inadequate market by itself, but also the entire field of insertive and implanted prosthetic devices for soft tissue reconstructions that have a much greater potential market. Meanwhile, as the present profit outlook is too small (12), the continued production of PDM siloxane for the maxillofacial prosthetics field is completely vested into this project for which all the procedural documentation must be at hand for regulatory compliance, inasmuch as the Veterans Administration is indeed the sole manufacturer. On the presumption that adequate research staffing is provided, the completion of this task is planned for FY 1983.

Field Participation (Technical Service)

This project continues to supply the materials and technical information to VA and non-VA clinics (some of the latter making prostheses for veterans) engaged in or commencing maxillofacial prosthetic reconstructions. Table 7 provides a general summary of the clinics to which the complete starter sets of the six SY and SR internally pigmented one-pound stocks have been furnished since the start of the field participation program in 1977. Supplemental, repeat stocks of pigmented (and more recently non-pigmented) production lots are being sent to participants on request. A survey is planned for this year covering all recipients to ascertain the scope of the utilization of PDM siloxane—and to determine why the clinical adoption is far below the expected patient input and replacement.

The field participation program is in

addition to supplying the stock and ancillary pigmenting materials for cosmetic matching, a means for providing on-going technical service. Unlike the regimens of dental prosthetic technology, the technology and skill of maxillofacial prosthetics are completely lacking a structure base based on formalized training that involves its own particular molding technology, understanding of the material's properties, concepts of color replication with pigmentation, and anatomical sculpturing of prostheses not only for comfortable accommodation but also for the minimal use—or even avoidance—of adhesives. The task of fabricating maxillofacial prosthetics is therefore taken on as an "extra" activity by dentists, dental technicians, artists, and some medical illustrators, none of whom have the full complement of needed understanding and required skills. As a result, this project has responded to an average of four inquiries per week relating to these three cited expertise areas, one of which has been made a subject of the previous section of this report on fabrication.

In addition to the extant deficiency in the profession or technology of prosthetics engineering for the maxillofacial reconstruction, the inquiries from the field participation disclose a number of major shortcomings in the fullest accommodation of clinical needs, not only for service-connected facial disfigurement but especially with regard to the prominent statistics of surgical ventures in head and neck cancer. Another prominent deficiency is the lack of a salary range that would induce a

prosthetic technician to continue working in maxillofacial prosthetics, and as a result there is loss of such personnel to other jobs. A third deficiency is inadequate refurbishing of maxillofacial studio and even insufficient funding for flasks, presses, and ovens as permanent items, and for the expendable materials, such as dental stone powder, waxes, hydrogels, and simple bench tools. In this field-participation program a variety of miscellaneous items were furnished to encourage clinical interest, some being as simple as pigments, painting adhesive, mold separators, brass flasks on loan, thermocouples, and so on.

The mainstay of the field participation information support include color videotapes on fabrication and cosmetic painting, and quality evaluation of the participant's fabrication based on specification measurements and color measurements from cosmetic matching. Needed for this part of the project is the preparation of a complete manual (presently available in abbreviated draft form) to serve as VA approved or endorsed procedures for the fitting, fabricating, and hygienic maintenance of safe and effective prosthetic devices fabricated from PDM siloxane. That is a task planned for completion in FY 1982.

Acknowledgment

This project is supported by the Veterans Administration Contract V101 (134) P-337 to Temple University, School of Dentistry, Philadelphia, Pennsylvania. Our special thanks and credit are gratefully accorded to Dr. Vernon L.

TABLE 7.

VA and Non-VA Participants Provided PDM Siloxane Maxillofacial Prosthetics

Clinical Centers	Participants	
	Current	Expected
Veterans Administration	15	26
Armed Services	2	4
Medical Schools	12	24
Hospitals and private clinics	9	24
Total in U.S.A.	38	78
Foreign countries total	8	24
Combined totals (a) and (b)	46	102

Comments: The numbers are based on formal requests responded to by shipment of one-pound lots of PDM siloxane.

A survey of usage by the participants is planned this FY with a questionnaire to ascertain intensified effort to accommodate the estimated statistical need (1000 to 3000 new cases each year, amounting to 50–150 pounds of PDM siloxane production per year.)

Nickel, former Director of the Rehabilitative Engineering Research and Development Service, Veterans Administration Central Office, for his counsel and encouragement. Our thanks and appreciation are also extended to Dr. Ernest B. Mingledorff, School of Dentistry, Temple University, for his sustained counsel and interest from the initiation of this Contract. The timely services of Dr. Richard Holmes as research consultant are gratefully acknowledged for his counsel and especially for the introduction of his unique A3 synthetic medium and the AGF human growth factor to the project.

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Rehabilitative Engineering Research and Development Center Palo Alto Veterans Administration Medical Center Palo Alto, California 94304

Larry J. Leifer, Ph. D., Director; Franklin G. Ebaugh, Jr., M.D., Acting Medical Director.

There is a continuing need to identify, understand and ameliorate the handicaps encountered by physically disabled veterans. The Rehabilitative Engineering Research and Development Center at Palo Alto, in cooperation with the Stanford University School of Engineering, is charged with bringing state-of-the-art engineering science, design, and technology to the direct benefit of disabled veterans and others. This is being done through an array of projects which involve VA medical center physicians, staff, students, faculty and veterans. Most projects are undertaken in cooperation with industry to accelerate the transition from laboratory prototype to commercial availability.

This Center will be 3 years old in May 1981. Phase I of a three-phase facility development plan was dedicated on September 20, 1980. That 6,400-sq.-ft. modular building contains office space for a RER&D staff of 23, a nerve / muscle systems laboratory, a laboratory computer facility, a micro-computer applications laboratory, and the beginnings of a mechanical systems development laboratory. A major portion of the technical work is performed, under contract, at Stanford.

Center staff are principal investigators and / or co-investigators, with VA physicians, in five major merit-reviewed projects. There are 12 pilot project studies in progress at this time and 5 in review. Ten grant proposals are currently being reviewed by the Veterans Administration, the National Institutes of Health, the National Science Foundation, and the Paralyzed Veterans of America.

Brief reviews of most active projects are available in the following pages. You are encouraged to make direct contact with the personnel on any project. CBS television network produced a good 7-minute videotape program covering RER&D Center activities as of September 1980; you

are welcome to borrow a copy of that tape.

In contrast to our last 2 years of rapid expansion, we anticipate a reduced rate of growth during the coming year. The availability of grant funding will be a major determinant of any real expansion. However, together with the mounting realization that rehabilitation is a primary concern of the Veterans Administration and the health care system at large, our Center expects to continue playing an increasingly vital role in the field of Rehabilitative Engineering.

Development and Evaluation of a Robotic Aid for the Severely Disabled

Personnel involved with this continuing project, and their institutional affiliations, are: **Larry J. Leifer, Ph. D.** (VA, Stanford); **Inder Perakash, M.D.** (VA, Stanford); **Bernard Roth, Ph. D.** (Stanford); and the following research assistants (Stanford): **Charles Buckley, Charles Wampler, John Jameson, Mitchel Weintraub, and Michael Van der Loos.**

Support for this project is provided under the VA merit-reviewed research program.

Need & Approach—It is hypothesized that individuals with severe disability need physical control of their personal space. They are expected to benefit from such control in relationship to self-esteem and in personal and financial independence.

It is proposed that industrial-grade electromechanical manipulators can be used effectively by severely disabled individuals to satisfy a significant portion of this need. Basic design studies focus on the development of new man-machine command and control strategies required for the rehabilitative

application of these manipulators. A sensate hand for the mechanical arm is also under development. The project is dedicated to in-depth exploration of the technical feasibility and psychosocial desirability of robotic manipulation aids.

Results

The project has been underway for 1 year. Year-one procurement tasks have been completed. All procured items have been delivered and Version One system integration has been completed on schedule.

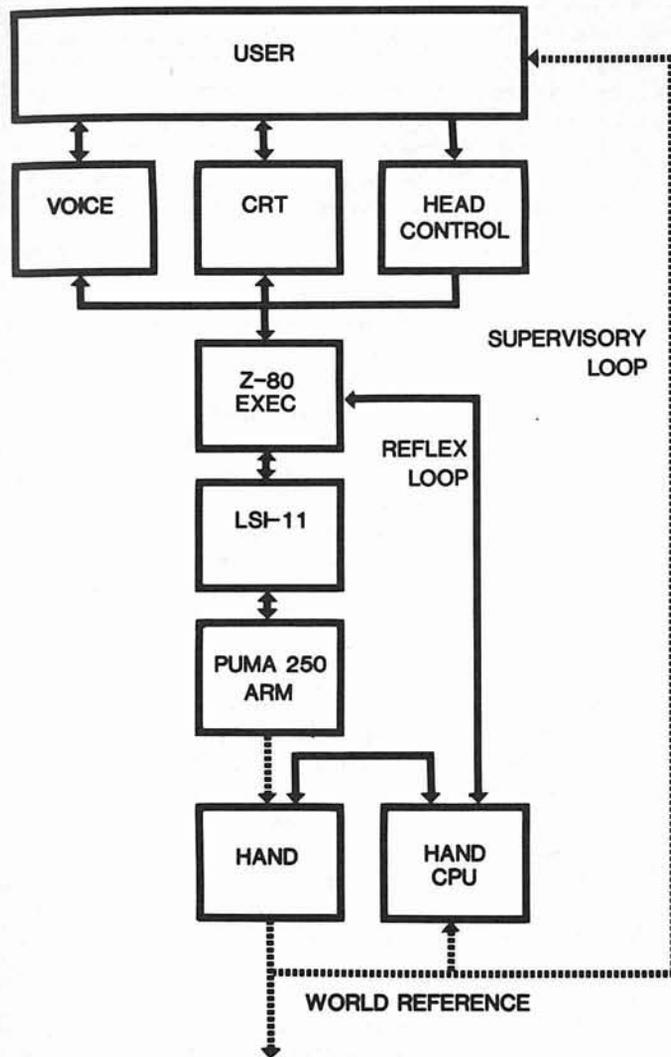
An overview of the system is presented schematically in Figure 3 and photographically in Figures 4a and 4b.

Software development for the sensate hand (Fig. 1 and 2) is proceeding more slowly than anticipated. A non-contact head control unit has been designed, fabricated, and used to drive a "Smart Wheelchair". Adaptation to manipulator control is pending release, by Unimation, of a new manipulator operating system which accepts direct motion vector updates. A new Voice Command Language (Version 2) has been written and tested with the Unimation PUMA-250 Arm. Preliminary tests indicate that unreliable voice-recognition unit performance may seriously degrade man / machine interaction in voice-command modes. Pretesting of a Robotic Aid User Training Course has been performed by members of the "Disability Seminar". This group includes psychologists, sociologists, psychiatrists, physicians, engineers and consumers (spinal-cord-injury patients) from the Palo Alto VA. Preliminary programs have been written for Wiener adaptive filter modeling of the man / machine system. No describing function models of system performance have been written to date.

Review

Progress on the Smart Sensate Hand hand has been reported in Leifer et al (1980a,b). Sensation is based entirely

BLOCK DIAGRAM OF SYSTEM

**FIGURE 3.**

A block diagram of the Robotic Aid shows the logical relationships among its major elements. It is emphasized that the USER is in command and control of the manipulator. VOICE commands are used to specify operating modes and the general features of successive movements. A HEAD CONTROL UNIT allows the user to make fine adjustments to voice-selected motion and is important to real-time flexibility within unstructured manipulation environments. The CRT display is used for advisory information and command/control verification status displays. The Z-80 EXECUTIVE Microcomputer integrates the function of all other subsystems and maintains a file system for data and programs. The LSI-11 microcomputer is dedicated to controlling the electromechanical ARM (Unimation PUMA-250). A sensate hand will be capable of "feeling" the environment without mechanical contact. This is based upon photoelectric proximity detectors.

The HAND CPU is a Z-80 microcomputer dedicated to processing sensory data in a REFLEX loop which controls hand motion without user intervention. In the SUPERVISORY loop the user assures that his/her commands are being performed correctly by the manipulator.

**FIGURE 4.**

This is the assembled Robotic Aid as it appeared in September of 1980. No attempt has been made to miniaturize the electronics. It is reasonable to expect that they will be placed below the arm on its mobile platform.

Apparatus arranged on shelves of the equipment stand is as follows: bottom shelf holds LSI-11 microcomputer dedicated to controlling the Unimation PUMA-250 arm. Center shelf holds a Z-80 EXECUTIVE microcomputer which integrates the function of all other subsystems and maintains file system for data and programs. Third shelf contains the hand CPU (hidden in shadow) which is a Z-80 microcomputer dedicated to processing sensory data in a reflex loop. To the left of the hand CPU may be seen voice command processing apparatus. (Voice command not shown.)

executed synchronously. Stored program sequences can be used at any time with simple "RUNname" commands. Further evolution of the language is planned pending results from user evaluations scheduled during the second half of 1981. The following is one clear result of our work with manipulation and voice command/control:

ROBOTICS RULE-1

If you speak to a machine,
the machine must speak back.

Summary

The project is on schedule. One Version One Robotic Aid has been designed and assembled. The manipulator subsystem has been reliable. However, the Centigram voice-recognition unit proves to be unacceptable and we are now evaluating alternative commercially available units. A user training program is under development, with non-technical-user pretesting underway prior to formal clinical investigations.

Pending

Technical activity in the coming 6 months will be dominated by assembly of a second Robotic Aid needed to pursue fundamental issues related to command and control of manipulation (including terminal device centered control). Clinical evaluation of the first Robotic Aid will begin shortly, with full-time evaluation studies beginning when the second Version One system becomes available.

Publications

Leifer L, Sun R, Van der Loos M: A Smart Sensate Hand for Terminal Device Control of a Rehabilitative Manipulator. In *Advances in Bioengineering*, V.C. Mow, editor, ASME, New York, pp. 69-72, 1980.

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Analytical Modeling of the Human Lumbar Spine

Personnel involved with this continuing project, and their institutional affiliations, are: **Robert L. Piziali, Ph.**

D. (VA, Stanford); Lyle W. Swenson, Jr., Ph. D. (VA); and Timothy A. Koogle, Eng. D. (VA).

Support for this project comes from the RER&D Center's core budget.

Need and Approach—A detailed understanding of the mechanics of the human lumbar spine is a major contribution to the scientific description of the human musculoskeletal system. Approximately 7000 spinal-cord injuries occur each year in the United States alone. By carefully analyzing injury mechanisms and reducing their occurrence, highly significant savings in human suffering and medical expenditures would be made.

The rationale for this project maintains that the lumbar spine is a complex structure, but that advanced experimental and analytical techniques can be formulated which will determine the mechanical properties of the vertebrae and intervertebral joints, and simulate the static and dynamic response of the spine subjected to loading. It is our desire that development of these capabilities will allow for efficient and inexpensive evaluation of the mechanics of spinal problems such as reduction of trauma-produced dislocations, diagnosis of instabilities, appropriate clinical stabilization of the fractured or fracture-dislocated spine, and mechanical aspects of low-back pain.

Status

A number of analytical models simulating the response of the human spine have recently been developed. These models can be categorized according to whether they simulate static or dynamic situations, and each category can be further differentiated according to whether two- or three-dimensional motions can be analyzed, whether small or large displacements can be accommodated, whether the vertebral bodies are modeled as rigid or elastic, and finally, according to the techniques which are used to model the nonlinear intervertebral discs and ligamentous structures. This abstract reports on a combined analytical-experimental program that has produced a general computer code that features all of the capabilities mentioned above.

In developing our computer methods for analysis of the lumbar spine, we have attempted to characterize the

anatomical and mechanical features as completely as possible. To accomplish these goals the vertebral bodies have been modeled using finite element techniques as three-dimensional elastic structures possessing all relevant anatomy allowing for contact interaction between neighboring articulating elements. The bodies can possess arbitrary inertia properties. This is required, since inertial off-set loading and related inertia distributions must be appropriately accounted for in studies involving trauma producing failures of the vertebrae, such as automobile impact situations.

The elastic properties of the vertebral bodies, as have been shown in our static analyses, would seem to be important in the overall deformation of the spine and contribute significantly to the disc-vertebrae stiffness.

Modeling of vertebral elasticity properties has been achieved using the technique of structural modal analysis. Using the general three-dimensional finite element model of a vertebral body, several of its unconstrained elastic natural frequencies and normal modes of vibration are determined using the method of subspace iteration. These data along with the governing modal equations of motion allow the elastic deformations of the vertebrae to be calculated, and permit an assessment of the elastic contributions to the calculated dynamic behavior of spine segments. (This represents an important contribution, since previous work using distributed parameter models have considered the vertebral bodies as rigid or part of a homogenous continuum. Consequently, the importance of dynamic stresses developed within the bodies could not be calculated, and their importance has yet to be fully evaluated.)

Ligamentous and intervertebral disc interactions between vertebrae are accounted for using nonlinear spring force-deflection data. (The use of general nonlinear data is an improvement over similar modeling techniques since most previous models have used linear or bilinear force-deflection data in the form of simple extensional and rotational springs. Similarly, previous models of the disc have been represented by simple linear beam elements.)

Pending

The overall objectives are to develop an understanding of the mechanical characteristics of the lumbar spine as a means for identifying and reducing spinal trauma, for evaluating techniques of diagnosis and treatment of fractures, and for studies on the mechanical aspects of low back pain. This project continues to conduct an extensive basic science study by determining the geometric and load-displacement characteristics of the vertebrae and all elements of the intervertebral joints. The analytical models will be used to predict both the motion of the vertebrae due to external or muscle forces and the resulting forces and strains throughout the lumbar vertebrae and intervertebral joint. This is a long-term development, but its completion should produce a valuable clinical tool.

Publications

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A large displacement dynamic model of the lumbar spine with experimentally determined material properties. Trans 26th Ann Meeting of the Orthop Res Soc, Atlanta, Georgia, February 1980.
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Experimental and Theoretical Study of Mammalian Movement

Personnel involved with this continuing project, and their institutional affiliations, are: **F. E. Zajac, Ph. D.** (VA), and **W. S. Levine, Ph. D.** (University of Maryland.)

Support for this project comes from the RER&D Center's Core Budget, and from NIH NS 11971.

Need and Approach—The interplay of forces acting on a limb that are produced by contracting muscles, by gravity, and by objects external to but touching the body is very complex. Nevertheless, our understanding of such interactions is crucial to the study of neural mechanisms controlling movement.

To achieve insight into such interactions we have initially chosen to study animals and humans jumping to maximum heights and distances. The main reasons are that, first, jumping is amenable to both analytical, computer-

simulation, and experimental investigation and, second (and perhaps more importantly), the techniques developed for that investigation are useful in the study of other movements.

Status

We have found that the solution to achieving best performance is two-part. During the first propulsion phase, the optimal control is non-unique, is a consequence of biomechanics alone, arises from active biomechanical or externally-imposed limits (such as those arising from contact of one limb segment with another), and is implemented by sub-maximal muscular activation patterns. During the second phase, optimal control is unique and results in the full activations of single-joint extensor muscles and inactivation of single-joint flexor muscles. Specific future goals are to understand the role of double-joint muscles in the second phase of the jump, and to develop techniques to compute the optimal control when various combinations of limits are active.

Pending

With the development of the techniques as a basis, it will be possible to study patients with motor deficits that result from neurological and musculoskeletal disorders. Using the same basic approach of experimental and theoretical interaction, our intent will be to model the biomechanics, the neuromuscular system, and the neural control mechanisms in these patients during well-defined motor tasks. With this model we would hope to quantitatively assess and predict the motor ability of a given patient and to develop strategies for rehabilitation and treatment commensurate with the patient's specific skeletal, muscular and neurological deficiencies.

Publications

Levine WS, Zajac FE and Zomlefer MR:
Experimental, analytical and computational study of maximum height jumps. Proc. Joint Auto. Control Conf, Vol. 1: paper TA10-D, 1980.

Nerve Conduction Velocity Distributions: Clinical Research Applications

Personnel involved with this continuing project, and their institutional affiliations, are: **Kenneth L. Cummins, Ph. D.** (VA); **Leslie J. Dorfman, M.D.** (VA, Stanford); and **Larry J. Leifer, Ph. D.** (VA, Stanford).

Support for this project comes from the Muscular Dystrophy Association, the RER&D Center's core budget, and from the VA merit-reviewed research program.

The progress report for this period will be found with reports of the latter program elsewhere in this issue of BPR: look for "VA RER&DS Progress Reports" in the Index.

Development of a Camera for Application in Sensory Aids for the Blind

Personnel: **Sally L. Wood, Ph. D.** (VA). This new VA merit-reviewed project was funded in Fiscal Year 1981.

The initial report will be found elsewhere in this issue of BPR, in the "Sensory Aids" section of the VA RER&DS Progress Reports.

Patterns of Conduction of Impulse Trains in Myelinated Fibers

Personnel involved with this new project, and their institutional affiliations, are: **Sally L. Wood, Ph. D.** (VA); **Stephen G. Waxman, M. D.** (VA, Stanford); and **Jeffrey D. Kocsis, Ph. D.** (Stanford).

Support for this research is provided by the RER&D Center's core budget.

Need and Approach—Computer simulations of impulse conduction in myelinated fibers can lead to increased understanding of mechanisms of conduction. Such simulations have been used by Waxman and Brill to investigate the effect of short internodes in the facilitation of conduction through demyelinated segments of axon which are typical of multiple sclerosis. A more general examination of conditions which promote conduction into and through demyelinated regions is needed. In particular, the effect of reduced diameter of the demyelinated segment should be

examined. If such mechanisms can be modeled, the results may be relevant to mechanisms of remission in multiple sclerosis. Further, new empirical data on ionic channel properties of mammalian CNS fibers have become available during the past year and should be incorporated into the simulation program.

A simulation program was written which uses the Hodgkin-Huxley model equations modified for myelinated fibers. This computer program allows variation of physiological parameters and axon structure. For example, a region of demyelination with short proximal internodes can be simulated in the middle of an otherwise uniform myelinated fiber. In addition, a wide variety of stimulus patterns is allowed in order to test a fiber's ability to carry information under the particular simulation conditions of interest. The program runs on a PDP-11/34 digital computer.

Status

The simulation program developed has been used to investigate the relative refractory period as a function of axon parameters. In addition, patterns of conduction during the subnormal or relative refractory period were examined for a uniform myelinated axon. A stimulus sequence of regularly spaced pulses was applied, and the resulting train of action potentials was observed both close to the stimulation site and distant from it. The spacing between stimulus pulses was varied between 1.6 msec and 16 msec. Close to the stimulation site, there was a great variability in the response to the stimuli depending on the recent history of the fiber. However, at the distant site the pattern on action potentials was much more uniform. This study will be used as a basis for comparison with the ability of a partially demyelinated fiber to carry stimuli patterns.

Evidence of entrainment was observed for a two- and three-pulse stimulation sequence. (Fig. 5) The amount of variability between the first and second impulse decreased as the distance from the stimulation site increased. These simulation results were consistent with and also extend results obtained from recent electrophysiological recordings from mammalian cortical axons. However, entrainment was not maintained for later impulses in the

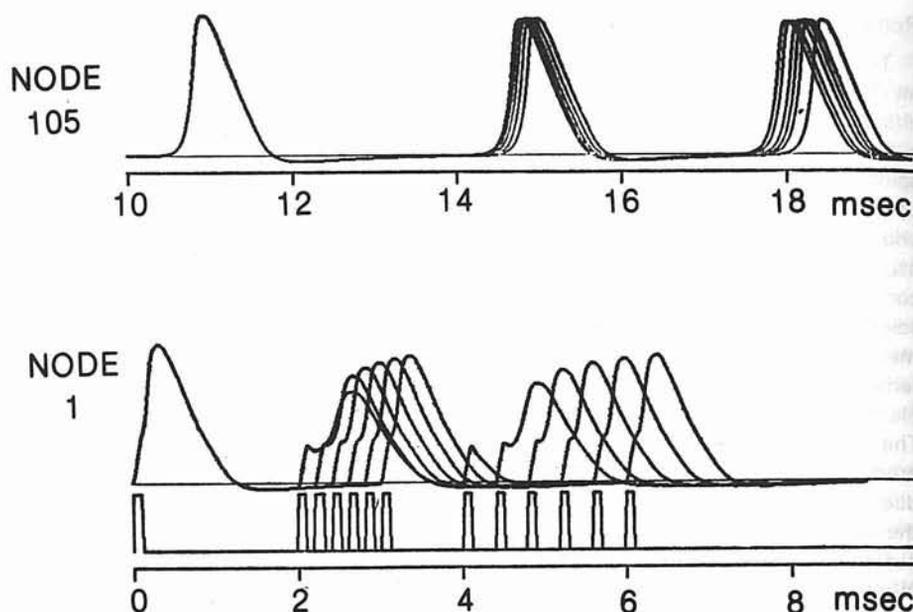


FIGURE 5

This figure shows the superposition of action potentials from a train of three stimuli with Interstimulus Intervals (ISI) between 2.0 and 3.0 msec. Computed results are shown at node 1 and node 105 for a stimulation site at node 0. At node 1 the intervals between impulses (IBI) are variable and depend on the initial ISI's. However at node 105 there is strong evidence of entrainment. The interval between the first and second impulse at node 105 varied by only 0.2 msec over the six stimuli presented. This is in contrast to a variation of 1.0 msec at the stimulation site.

train, and these later impulses tended to remain at the original average frequency of propagating stimuli (1). In general, distant intervals between impulses (IBI) were relatively insensitive to temporal patterning of the stimulus and tended toward regular intervals corresponding to the average interstimulus interval (ISI) of propagated stimuli. The effect of demyelinated segments on this behavior will be examined.

Pending

The simulation program is being modified to include recently available empirical data on ionic channels in mammalian CNS. The new program will be used to study the effects of reduced diameter in demyelinated segments of a myelinated axon. The amount of reduction required in order to promote conduction into and through a demyelinated region will be examined under a variety of conditions. The effect of the demyelinated segment on the conduction characteristics of the total fiber will be investigated with respect to relative refractory period and entrainment. The effects of the absence of potassium conductance will also be simulated.

Publications

Wood SL, Waxman SG, Kocsis JD: Conduction of trains of impulses in uniform myelinated fibers: computed dependence on stimulus frequency. In preparation.

Nerve Repair and Evaluation

Personnel: Vincent R. Hentz, M.D. (VA, Stanford); and Gordon S. Abraham (Stanford).

This continuing project is supported through a VA contract to Stanford University.

Need and Approach—Following peripheral nerve transection, the surgeon's goal is to repair the nerve so that the individual axons regenerate and eventually reach their original muscle or sensory end organs. The extent of functional recovery depends on many factors, the most marked being axonal alignment and tissue reaction both to the injury and the repair process (scar formation). Due to the large number and minute size of axons in the nerve bundle, the alignment can at best only be approximated.

Conventional nerve-repair techniques employ sutures placed either through

the epineurium or through the perineurium to approximate the nerve ends. The inflammatory reaction to suture, and injury incident with placing them, are principal causes of scar formation. Scar formation is the primary barrier to axon regeneration. To circumvent these drawbacks, a new technique termed tubulization utilizes a wrap or tube of hypo-antigenic collagen to approximate nerve ends.

In several small animal nerve models (rat saphenous and cat median and ulnar) tubulization techniques have demonstrated superiority to standard suture repair methods by both histologic and physiologic measurements.

The continuing goal of this project is to develop methods for evaluating the extent of recovery following repair by either suture or tubulization techniques in an animal model evolutionarily closer to man. The project will compare and correlate several methods of histological and electrophysiological evaluation techniques. Histological techniques including axon counts and axon diameter distributions are fairly common methods of determining the extent of regeneration and maturity across the repair site, but tell nothing of the extent of functional recovery of the regenerated axons. Conventional conduction velocities (CVs) of the compound action potential (CAP) waveform onset indicate the state of only the fastest fibers. Recently developed methods for evaluating nerves utilize the distribution of CVs from every axon, CV being the electrophysiologic correlate to axon diameter. Most importantly these methods give some measure of functional reconnection.

Status

Two nerve conduction velocity distribution (NCVD) techniques exist, the Motor NCVD and Mixed NCVD. The Motor NCVD utilizes the EMG evoked by colliding two carefully timed CAPs. The Mixed NCVD estimates a delay distribution utilizing a minimum sum-squared error criterion for solving an over-specified system of linear equations to analyze the CAP based on superposition of the single fiber action potential (SFAP). The latter method requires explicit knowledge of the SFAP waveform or the analysis of two CAPs.

The computer and software controlling the delivery of the timed stimuli, input and analysis of the evoked EMG

or CAPs exists in clinical space at the Stanford University Hospital. Due to the restriction on animal experimentation in clinical space, a method for delivering the stimuli and recording the evoked response off-line of the computer was developed. The off-line method uses Frederick Haer Pulsar stimulators to deliver the timed stimuli. The response is amplified by a Tektronix AM502 differential amplifier and recorded on a Hewlett-Packard FM instrumentation tape recorder. The tape is then brought to the computer lab and played back into a modified version of either the Motor NCVD or Mixed NCVD.

Both off-line techniques and modifications to the data collection software have been implemented, but due to the short conduction distances of the nerve model (here utilizing the Crab-Eating Macaque monkey (*M. Fascicularis*)) further refinements in the procedure and analysis software must be made.

Pending

With the refinements made in the software and procedure, controlled nerve transections and repairs will be performed and their regeneration monitored by the electrophysiologic techniques described. At various times histological evaluations will be made and compared to the electrophysiologic results.

External and Internal Stabilization of the Disrupted Lumbo-Dorsal Spine

Personnel involved with this continuing research, and their institutional affiliations, are: **Inder Perakash, M.D.** (VA); **Donald A. Nagel, M.D.** (Stanford); **Timothy A. Koogle, Eng. D.** (VA); and **Robert L. Piziali, Ph. D.** (VA, Stanford).

Support for this project is provided by VA Grant No. 564766249.

Need and Approach—There are presently over 125,000 people with spinal cord injuries living in the United States. A means for evaluating devices used in stabilizing the injured spine would be extremely useful in allowing the spinal injured patient to become active and self-sufficient as soon as possible after injury. Long-term deformity could also be reduced thereby, adding substantially

to the patient's physical and psychological well-being.

This research project is aimed at studying the various techniques for stabilizing the disrupted lumbar spine in order to ensure that the spine will remain stable and will heal without deformity while the patient is allowed early mobilization. A method was developed to measure accurately the motion between vertebral bodies thereby allowing the objective evaluation of various internal and external stabilization devices. Work on an instrumented implantable fixation device with telemetry has also been initiated.

Status

An electromechanical transducer which allows the accurate measurement of complete spatial motion between vertebral bodies in the human spine was developed and reported in the literature (1, 2). We have used the transducer to complete a series of studies on the effectiveness of various individual internal and external spinal-stabilization devices. Devices which were studied include external stabilization in the form of the Taylor-Knight Brace, the three-point hyperextension brace and the body cast. Internal devices include stainless steel wire loops and Harrington distraction rods. Whole unembalmed cadavers were used in the studies. We have found that patient motion might be very restricted if only wire loops are implanted. A greater degree of patient mobility is possible using Harrington rods; however, some restriction of motion through braces, etc., is still necessary. For the motions studied, the Taylor-Knight Brace produced a greater degree of immobilization than the three point hyperextension brace. While body casts were clearly the most cumbersome of the fixation devices, these were found to be the most effective in reducing the motion in the disrupted spine.

Additional studies have been initiated to determine the effectiveness of combinations of internal and external devices, i.e., Harrington distraction rods with Taylor-Knight brace, etc. In addition, experiments with other fixation devices have begun. In particular, we are evaluating the new Luque instrumentation as well as the large diameter Harrington compression rods applied to the laminae.

We have also begun developing an instrumented Harrington distraction rod with telemetry. Semiconductor strain gauges are mounted on the rod in a manner which allows the determination of the forces being applied to the rod after implantation. The rod is connected to a multichannel telemetry package which is implanted near the rod thereby allowing remote sensing of the force data. Considerable work has been completed in developing the sealing methods required to isolate the electronic instrumentation from the body and two preliminary experiments have been conducted using prototype instrumented rods in whole cadavers. It is hoped that this portion of the project will result not only in the measurement of forces being applied to the Harrington rods, but also in valuable information regarding bone graft incorporation at the spinal injury site.

Pending

Studies regarding the effectiveness of combinations of internal and external stabilization devices are currently in progress. In addition, the Luque instrumentation and Harrington compression systems are being tested for their ability to immobilize the fracture dislocated spine. Further work is also underway in developing the instrumented Harrington distraction rod with telemetry.

Publications

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2. Nagel DA, Koogle TA, Piziali RL, and Perkasch I: Stability of upper lumbar spine following progressive disruption and the application of individual internal and external fixation devices. J Bone and Joint Surg, 63-A/1:62-70, January 1981.

Development and Evaluation of A Downhill Ski-Sledding System for Persons with Disabilities

Personnel involved with this continuing research, and their institutional affiliations, are: **Peter W. Axelson, B.S.** (VA); **Larry J. Leifer, Ph. D.** (VA, Stanford); **John J. Csongradi, M.D.** (VA); and **William G. Winter, M.D.** (VA-Denver).

Support for this research has come from the RER&D Center's core budget. Merit review was pending in Spring 1981.

Need and Approach—The field of rehabilitation engineering has generally ignored the recreational needs of disabled individuals. There is a need for equipment that will enable persons with disabilities to participate in an able-bodied manner in a variety of sports.

Downhill snow skiing is ideal to begin the integration of disabled individuals into the mainstream of able-bodied recreational enthusiasts. A new downhill ski-sled for the disabled has been developed by Peter Axelson and has received preliminary field testing by paraplegics and instructors in several handicapped ski programs. This sled has proved to be safe, controllable, and compatible with 97 percent of all ski chairlifts.

Status

During the 1979-80 ski season, prototype ski-sled Arroya IV was field-tested at nine ski areas including Winter Park Ski Area, Winter Park, Colorado and Snoqualamie Ski Summit near Seattle, Washington. Instructor clinics were also held at each of the nine ski areas where ski programs for the disabled are utilizing a total of 15 ARROYA IV downhill ski-sleds. These clinics provide instructors, disabled ski programs, and users with knowledge about the safe operation of the ski-sled.

Information gathered from instructor and user questionnaires will allow development of better manuals for future use by instructors and users. The information will also be used to develop future ski-sleds, incorporating user feedback and suggested modifications.

Demonstrations of the Arroya IV ski-sled at various instructor clinics throughout the United States and in Norway generated very positive publicity. Each clinic received local newspaper coverage and some received television coverage. The objective of this publicity was to make individuals aware of the available opportunity for paraplegics to use the Arroya IV ski-sled.

The ARROYA ski-sled is unique. It has many downhill advantages over the Norwegian "Pulk", the "Smith Sled" and other sled-like devices that are available for skiers with disabilities.

Most of these other devices can be used for cross country skiing. However, none of the other devices satisfy the many requirements necessary for a device to be safe and compatible with existing downhill ski area facilities. The advantages of the Arroya ski-sled are (i) chairlift compatibility, with regard to chairlift loading, unloading, and evacuation procedures, (ii) user controlability in a variety of snow conditions and terrain, (iii) secure and comfortable skier-sled interface by means of contour molded cushions which allow the skier to become a "part" of the sled, and (iv) integration of the disabled skier with other skiers, unlike many other sports and recreational activities available to persons with disabilities.

Arroya IV downhill ski-sleds were used in competition at the 4th Annual National Handicapped Ski Championships in Colorado, where 40 percent of the male competitors were disabled veterans. The ski-sled was also demonstrated at the Winter Olympics for the Disabled in Geilo, Norway, where it was proposed that the ski-sled be integrated into international sports competition for the disabled.

Conclusion

This work has benefits for both society and the individual. Because of the low-pressure situation associated with recreation, integration of the disabled into the able-bodied population is facilitated. Able and disabled individuals benefit mentally and physically from skiing activities, and these effects can carry over into all aspects of life. We expect to demonstrate that anyone on the ski slopes is an able-bodied skier.

Pending

To keep the ski-sled program going during the 1980-81 ski season, the RER&D Center in Palo Alto has allocated funds for 10 Arroya V ski-sleds to be fabricated at a projected cost of \$1,000 each. The redesign and development of the ski-sled prototype, ARROYA VI must await further funding.

Publications

- Axelson, Peter W. and McCann, Robert E.: The Arroya. Sports n Spokes, January-February 1980.
Axelson, Peter W.: Arroya. Paraplegia News. January 1980.

Axelsson, Peter W.: Arroya. A Final Report to the Stanford University Design Division, June 1979.

Improved Predictive Filtering Techniques for the Non-Invasive Analysis of Neuromuscular Systems

Personnel: **C.C. Boylls, Ph. D.** (VA).

Support for this new research project is provided by the RER&D Center's core budget.

Need To understand the emergence of behavior from collections of neurons and muscles inevitably requires an in situ description of how those elements influence each other. Recent work by various authors has been directed toward obtaining the transfer functions of, in particular, individual motoneurons and motor units by the technique of so-called "spike-triggered averaging." This entails the prediction of motoneuron/unit behavior from simple cross-correlations computed between the input to, and output of, the system under study, very often in the alert animal or human subject. Unfortunately, however, the method is suited primarily to linear, time-invariant processes driven by Gaussian white noise. It is the aim of the present work to develop predictors of neural and muscular behavior which remain accurate outside such constraints.

Approach and status

Computer simulations were constructed of the monosynaptic pathway connecting primary and secondary spindle receptors of a typical mammalian muscle to the alpha-motoneurons of that muscle. The model represents a common experimental situation wherein the discharges of a spindle ending are recorded in concert with motoneuron discharge, the aim being to describe the reflex influence of that ending upon the neuron. In initial work (1) the simulations were used to obtain "intracellular" records of motoneuron polarization fluctuations in response to stochastic inputs emulating spindle receptor discharge statistics. Applying a traditional spike-triggered averaging algorithm to those data revealed serious errors in the estimation of latency, time-course, and sign (excitatory, inhibitory) of the reflex effects upon the motoneu-

ron. The bulk of these errors proved attributable to the nonuniform representation of frequencies within the signal generated by the spindle receptor; such receptors do not produce "white noise." However, the problem of nonuniform frequency representation was alleviated by constructing a least-squares linear (Wiener) predictor of motoneuron polarization dynamics which, for the simulated data, yielded substantial improvements in the estimation of reflex effects.

A second stage in the analysis has been to produce estimates of motoneuron response to spindle inputs using purely "extracellular" measurements; i.e., simulated recordings of motoneuron action potentials. Although this process is inherently nonlinear, the Wiener predictor can provide a remarkable estimate of the polarization changes within the motoneuron, even when the spike train generated by that neuron appears to be a poor encoding (in either frequency or interspike interval) of potential.

Pending

In the immediate future, studies will be aimed at assessing the effects of statistical nonstationarity and of exogenous correlated motoneuron inputs in the model described above. Additionally, the effects of strong nonlinearities in the motoneuron spike-generator will be assessed. It seems likely that the Wiener estimator as a corrector for spike-triggered averages will break down in such situations—and an approach based upon model-referenced adaptive filtering will be explored. Along a different line, the application of these methods to the estimation of twitch-contraction properties in mammalian motor units will be treated, this in collaboration with students from Stanford University.

Publications

1. Boylls CC, Spiked-triggered averages, artifacts, and artifices. *Neurosci. Abstr.* 6: 158, 1980.

Study of Upper-Limb Bio-Mechanics Using Ultrasound Transmission Imaging

Personnel involved with this new research project, and their institutional affiliations, are: **Vincent R. Høntz, M.D.** (VA, Stanford); **Parvati Dev, Ph. D.**

(VA); and **Kenneth W. Marich, M.B.A.** (S.R.I. International). Support for this research is provided by the RER&D Center's core budget.

Need and Approach—Modern functional and especially biomechanical analysis of living hands have been restricted because, until now, no safe non-invasive method for studying bone and soft tissue relationships has existed. A new technique, ultrasonic transmission imaging, combines the advantages of X-ray laminography and fluoroscopy and allows risk-free visualization of soft tissues and bone in real time.

One major objective of this study is to extend the capabilities provided by ultrasonic transmission imaging to the study of upper limb function. Anatomical standards will be developed to guide the interpretation of the ultrasonic images of the hand. Data obtained from this technique will augment standardly derived biomechanical data, to better understand normal upper-limb functional anatomy. To achieve these objectives, a stabilization platform will be constructed that will lead to the development of a series of standardized imaging positions that will maximize the available anatomic and diagnostic information. The image will be evaluated for resolution and definition of the internal structures of the upper limb at various ultrasonic frequencies.

Another major objective is to develop mathematical models of hand biomechanics, for the eventual evaluation of specific abnormalities and for the selection of optimal rehabilitative measures, including reconstructive surgery. Anatomical data from ultrasonic images and from cadaver dissection will be used to formulate a kinematic model of the finger for simulation on the computer. The performance of the model, in terms of joint angles, will be compared with that of the cadaver with tension on flexor and extensor tendons. A model of the index finger will be compared with that of the human subject with all except flexor and extensor muscles paralyzed using localized nerve and muscle blocks. The model will be extended to include other finger muscles through continued use of the technique of selective blocks. The performance of the model will be compared with that of selected finger-function abnormalities.

Status

Proposals to perform the above research have been submitted to the VA and to NSF. Preliminary experiments have shown the importance of preparation stabilization for imaging purposes and for the performing of anatomical measurements. *Images from fresh and frozen cadavers were compared and it was determined that extremely fresh cadavers were required for imaging of internal structures. Ultrasound transmission and reflection images were compared. Reflection images were found to be useful for making precise measurements at a few locations on the finger. Transmission images were more useful for obtaining the overall geometry of the internal structures of the finger, and for observing the change in geometry during movement.*

Pending

A pilot project will be developed in which anatomical measurements will be made around a single joint. The joint to be studied is the wrist, because of the considerable body of information on its kinematics. A mathematical model will be developed and a force analysis performed on the model and on a corresponding cadaver preparation.

Smart Wheelchair

Personnel: **David L. Jaffe, M.S.** (VA).

Support for this new research is provided by the RER&D Center's core budget.

Need and Approach—It was the aim of five graduate Mechanical Engineering students at Stanford University's "Smart Product Development Laboratory" to develop ideas that would enable quadriplegics to more efficiently maneuver wheelchairs in their life-space. With funding and electronic expertise from the Palo Alto Veterans Administration Rehabilitative Engineering Research and Development Center, the concept of a "smart" electric wheelchair came into being.

A totally different means of user chair control has been implemented. The current prototype model utilizes Polaroid Ultrasonic Sensor technology. On the Polaroid camera, this sensor provides the subject-to-camera distance

required for focusing. On the 'smart' wheelchair (a modified Everest and Jennings model 3P—Fig. 6), a pair of these sensors triangulate the user's head position. Two additional forward-facing sensors detect the presence of obstacles in the path of the chair. Side sensors serve to detect walls at the right and left of the chair. Two optical shaft encoders obtain wheel speed data from the two driven wheels. A micro-processor is employed to obtain sensor data, implement control algorithms, and provide motor speed drive signals.

Status

In operation, a center or rest head-position is defined. Deviations from this "origin" in both the forward-back and left-right planes can be calculated from the ranging of the two sensors. This information is then used to control the speed of the two motors that propel the chair. From the user's point of view, he directs the motion of the chair with his head. To move the chair forward, he would position his head forward of the 'rest' position. Similar operations per-

form motion in the remaining three directions; left pivot, right pivot, and backwards. Since combinations of these directions are allowed, a smooth right turn can be accomplished by positioning the head forward and to the right. In effect, the user's head has become a proportionally controlled joystick. Since very minimal motion is required to use this system, this unique non-contacting scheme seems to have potential as an ideal solution for quadriplegic control of an electric wheelchair.

Several operational modes are currently implemented. Aside from the head control mode described above, the chair can slow and subsequently stop for obstacles in the direction of motion. A "follow-that-wall" mode enables the chair to travel parallel to a chosen wall without constant operator intervention. (Open doorways are detected and ignored, but a discontinuity of more than a few feet disables this mode and returns control to the user.) A "cruise-control" mode utilizes wheel-speed data obtained from the shaft encoders, which are friction-coupled to the driven wheels.

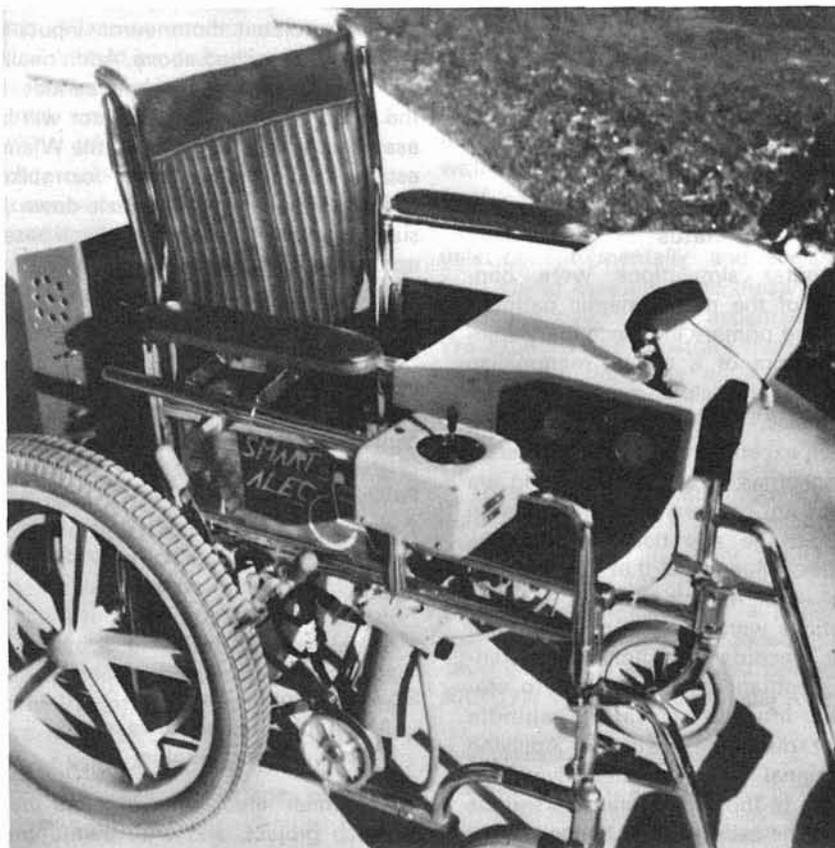


FIGURE 6.
The Smart Wheelchair.

This data is then used to maintain a constant chair speed and heading, despite terrain changes. Necessarily, there is also a mode that allows the user to freely move his head without activating any chair movement.

In actual operation, the prototype chair performs quite satisfactorily. After a minimum amount of practice, controlling it can apparently be mastered by anyone. The system's ability to accomplish fine maneuvers is limited only by the geometry of the chair and its caster wheel system. A slight "oversteering" instability has been noted in straight-line travel, but it is believed that a modification of the head-position algorithm should cure this minor problem.

Pending

The current design phase is addressing the reduction of system physical size and memory requirements. New EPROM-based software is being developed, and recent hardware advances are being incorporated to accomplish this goal. The final design will attempt to capture the head-control features on a single circuit board.

Publications

Smart Wheelchair, David L. Jaffe, Proceedings of the Sixth West Coast Faire, San Francisco, California, April 3-5, 1981.

Development and Evaluation of an Omnidirectional Electric Wheelchair

Personnel involved with this new research project, and their institutional affiliations, are: **William H. T. La, Ph. D.** (VA); **Timothy A. Koogle, Eng. D.** (VA); and **David L. Jaffe, M.S.** (VA).

Support for this research is provided by the RER&D Center's core budget.

Need and Approach—Current electric wheelchairs have limited maneuverability, which makes them difficult to control in tight spaces such as through narrow doorways, in and out of elevators, and around household furniture. This limitation stems from the fact that they possess only two out of the possible three degrees of freedom of motion in the plane; i.e., they cannot go sideways at the same time as moving forward, backward, or rotating.

In the subject design, omnidirectional mobility is achieved by using three independent drive wheels. Each wheel is provided with peripheral rollers that allow it to move passively along the direction of its axis, while retaining the ability to exert traction in its direction of conventional travel (Fig. 7). The collective actions of the three wheels, disposed so as to provide traction in three different directions, enable the system to go in any direction while simultaneously rotating on itself. Operation of this wheelchair in confined spaces is devoid of maneuvering constraints other than the physical size of the chair and its rider, thereby approaching the freedom of human locomotion.

Status

This is a new project dealing with a radical departure from conventional wheelchair or automobile design. Only a radio-controlled scale model is presently available for demonstration and study. Proposals have been submitted to the VA and the PVA for a 2-year development and evaluation effort. Work initiated on VA core budget has consisted of preliminary theoretical kinematic and dynamic studies, as well as design of an experimental full-scale prototype. Parts are being acquired for the first model, expected to be operational this summer.

The major areas of investigation at present are the stability of the system, the design of the omnidirectional

wheels, and the design of the electronic controller. Because the wheelchair is supported on three drive wheels, some stabilizing means such as casters or anti-tipping skids will be needed. The omnidirectional wheels present a clear dilemma about the size of the rollers: using larger rollers helps the vehicle overcome small obstacles on the ground, but roughens the ride due to the larger gap between rollers. Moreover, the actual configuration and fabrication of a wheel with peripheral rollers having skew axes are new problems in the field of vehicle design. The complexity of the drive system, together with the general need for corrective and safeguarding measures such as joystick input averaging, torque and acceleration limiting, course maintenance on a side slope, etc., apparently require the use of a microprocessor-based controller.

The main criteria governing the design of the wheelchair will be safety, cost-effectiveness, and usefulness. Modular construction will facilitate maintenance and repair. The 3-wheel-drive arrangement is inherently more reliable than the conventional design, since the wheelchair can still operate after failure of any one of the drive systems, albeit with limited mobility. Modularity will take the fullest possible advantage of this characteristic.

Pending

Theoretical studies, and prototype development and design, will continue

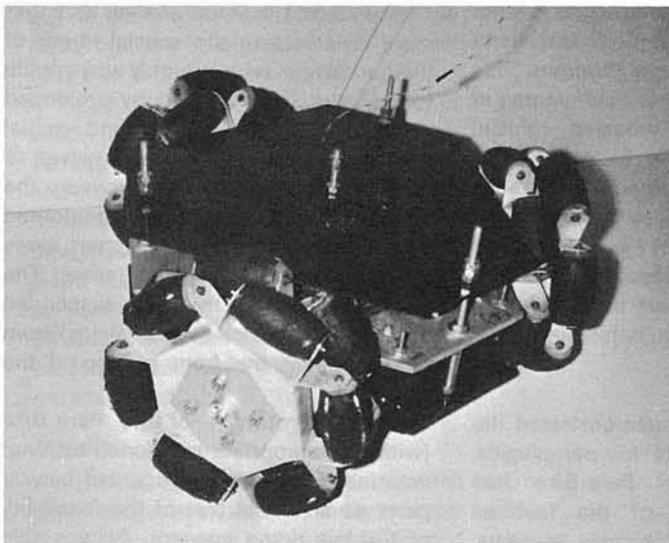


FIGURE 7. Scale model of omnidirectional mobility base.

for the next two quarters. Some user evaluation will be performed thereafter, paralleling the construction of a second version which will constitute the next design iteration. This work is also expected to enjoy a mutually beneficial technological exchange with a student design project at the Department of Mechanical Engineering, Stanford University, aimed at providing an omnidirectional mobile base for an industrial manipulator based on the same design.

Publications

La HT: Omnidirectional Vehicle, U.S. Patent No. 4,237,990, 1980.

Development / Evaluation of a Recreational Bicycle for Paraplegics

Personnel involved with this continuing project, and their institutional affiliations, are: **Larry Leifer, Ph. D.** (VA, Stanford); **Peter Axelson, BSME** (VA); **Candy Mintz, BSME** (Stanford); and **Douglas Schwand, MSME** (VA).

Support for this project is supplied by the RER&D Center's core budget.

Need and Approach—Individuals without the use of their legs have been excluded from the physical and emotional benefits of recreational bicycling, due to the lack of a bicycle design responsive to their special propulsion, seating, and balance needs.

Our approach has been to start by designing and building a working prototype of a bicycle for paraplegics, within the context of the Stanford University Design Division Masters Program. This phase of the development culminated in a hand-pedaled two-wheeled vehicle, called the Para-Bike (Fig. 8).

Our continuing approach focuses on improving the Para-Bike concept, with prototype development/evaluation and identification of appropriate manufacturers, in order to assure the availability of a quality bicycle for paraplegics.

Status

The Para-Bike has demonstrated the feasibility of a bicycle for paraplegics. The design of the Para-Bike has repositioned several of the features found on standard bicycle designs, including the drive mechanism and the position of the cyclist. A hand-cranked



FIGURE 8.
Peter Axelson, a T-10 paraplegic, easily rides the parabike.

chain wheel and chain linkage to the front wheel replace handlebars, combining the propulsion and steering mechanisms. The pedaling axis is offset from the steering axis to enhance steering control. Back-pedaling activates a caliper brake on the rear wheel.

The natural tendency of a bicycle to balance and self-steer diminish at slower speeds. Whereas people who have the use of their legs may drop a foot to help balance when coming to a stop, on the Para-Bike the rider wears protective wrist and hand guards, and the proximity to the ground allows the rider to comfortably use a hand as a support when starting or stopping. (As a precaution, a spherically shaped rollerskate wheel is mounted on the frame to either side of the rider to be used in training.)

A web and cushion seating arrangement responds to the special needs of the paraplegic, who is highly susceptible to pressure sores caused by prolonged pressure over the coccyx and ischial tuberosities. Elastic straps are woven to form a mesh stretched between the tubes of the box-like frame. A contoured cushion redistributes the support away from the pressure problem areas. The rider sits upright, the legs suspended (in cushioned, quick-release slings) from either side of the front portion of the frame.

A first prototype of the Para-Bike (without appropriate cushioned seating) was fashioned out of discarded bicycle parts as an initial test of the feasibility of the low-riding concept. An unstable steering tendency, resulting from the coupled steering and pedaling, led to

the incorporation of adjustable steering geometry on the current prototype. By fine tuning of the variables influencing steering, it is expected that the optimal arrangement can be selected experimentally. This experimentation will be underway following the completion of the adjustable front fork.

A temporary front fork has allowed the initial evaluation of the Para-Bike. The performance is characterized by a learning phase similar to that experienced by individuals on standard bicycles. The initial awkwardness gives way as the rider becomes proficient in balance and directional control.

Pending

Plans call for the completion of the adjustable steering geometry on the current version of the Para-Bike and the selection of a preferred steering configuration to be completed by May 1981.

A grant proposal has been submitted to the Paralyzed Veterans of America's Technology and Research Foundation for the subsequent Para-Bike prototype development/evaluation and the identification of appropriate manufacturers.

Publications

Schwandt, D., "Para-Bike", *Sports 'n Spokes*, Phoenix, Arizona, November / December 1980, pp. 18-19, 21.

Spinal Injury Patient Transport System

Personnel involved with this new project, and their institutional affiliations, are: **Eric E. Sabelman, Ph. D.** (VA);

Timothy A. Koogle, Eng. D. (VA); and Robert L. Piziali, Ph. D. (VA, Stanford).

Support for this project is provided by the RER&D Center's core budget.

Need and Approach—Existing equipment for moving spinal-injury patients from emergency room to specialized centers is cumbersome, does not provide reliable cervical traction, and is incompatible with new diagnosis and treatment facilities. Variations in traction force during transport, and necessity for removing traction during CAT scanning and hyperbaric O₂ treatment, can exacerbate the injury.

Examination of existing devices and consideration of needed improvements has led to the following design criteria:

1. Application of fail-safe cervical traction at known constant force and angle;
2. Head and torso immobilization without compromising respiration;
3. Compatibility with helicopter, ambulance and intra-hospital transport;
4. Compatibility with CAT scanner;
5. Compatibility with hyperbaric O₂ chamber;
6. Permit tilting without change in patient position or traction; and
7. Diminishment of bedsores during stay time up to 7 days. Cost, cleaning, maintenance, and useful life are additional considerations.

Status

A prototype has been constructed, consisting of (i) plywood mock-up backboard, (ii) traction device, and (iii) lateral head, axial shoulder and torso-strap restraints (Fig. 9).

The baseline backboard is a cylindrical section of 30 inch radius, 18 inches wide from hip to shoulder and eight inches wide from shoulder to four inches above the top of the head. Eventually, a clamp-on section supporting the legs and a detachable folding wheeled trolley will be included. Features include: (i) ease of fabrication, (ii) partial conformation to body contour (minimizing depth of padding and pressure on spine), (iii) conformation to curvature of CAT scanner carriage and gantry openings, and (iv) geometric rigidity. Materials are to be laminae of graphite fiber in an epoxy matrix on upper and lower surfaces with a syntactic foam core, for a total thickness of about one centimeter. Materials are

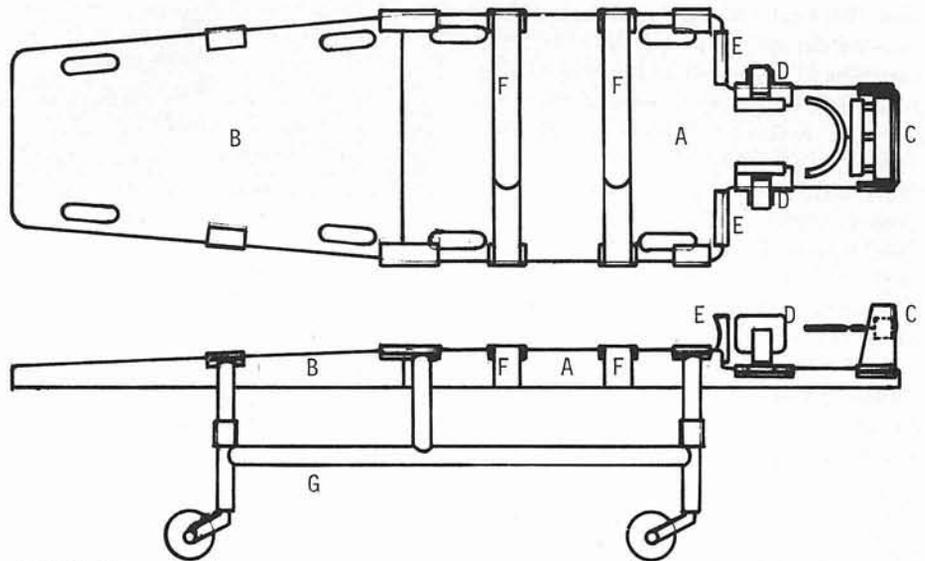


FIGURE 9.

Spinal-injury-patient transport system. "A" identifies the backboard and "B" the leg-support. Backboard is described as a cylindrical section of 30 degrees radius. Traction device is at "C", and lateral head restraint units are at "D" locations. Axial shoulder restraints are at "E", torso straps at "F". Trolley "G" and the leg-support section are not included with the first-generation systems currently being fabricated and put to use, but will be added later.

self-extinguishing and non-sparking. Padding is to be a cylindrical segment of conformal Flow-lite material which distributes skin pressure and increases lateral support. Back and head pads are attached with "Velcro" strips.

Traction force is provided by nine Negator constant-tension springs on a common axle held in brackets about the head. Selected springs are attached (using captive screws) to a bar supporting the tongs, providing increments of 2.6 lbs. force. The traction device is presently compatible with tongs extending no more than two inches above the head, but can be equipped with integral tongs of X-ray-transparent material.

Head restraints are adjustable in width and height above the board; various designs have been fabricated and are under test to determine minimum interference with CAT scanning, hearing, and possible head injuries. Head and torso restraints are positioned on the edge of the board by detent pins. Shoulder restraints are hinged, to be folded flat while placing the patient on the board.

Pending

A final design will be determined after clinical evaluation of the prototype, mechanical test of board materials, and modification of attachments (if required). Up to 12 of these first-generation

systems will be fabricated and put to use by the Santa Clara Valley Medical Center and Ralph K. Davies Medical Center spinal-injury units. Leg support and trolley attachments will be added later. Operation and maintenance manuals will be prepared and supplied to users. Results will be published and designs submitted to potential large-scale manufacturers and users.

Two-Handled Spoon for Independent Eating with Cerebral Palsy

Personnel involved with this terminating project, and their institutional affiliations, are: **Christine Wright, Staff Therapist**, Fremont Older School for the Orthopedically Handicapped, Cupertino, Calif., and **Greg Shaw, M.S. Product Design**, Children's Hospital at Stanford REC, Palo Alto, Calif.

Support for this project was provided by RER&D Center core funds.

Need and Approach—A two-handed spoon is intended for use by individuals who cannot eat independently without spilling because of motor incoordination. Such a device offers the opportunity for increased independence in eating.

Eighteen individuals with cerebral palsy were tested from September, 1978 to June, 1980 at 16 rehabilitation facilities. Each individual received a test kit which included a two-handed spoon, test manual and questionnaire. The manual provided instructions and illustrations of bowl or plate to be used, use of the spoon, adjustments of the spoon which might solve individual problems, and a variety of foods to use during the evaluation. The questionnaire was used to collect data regarding an individual's performance using a standard spoon and the two-handed spoon.

Status

Results indicated that 2 of the 18 subjects using the two-handed spoon were able to eat spoon foods independently for the first time. For nine subjects, the spoon improved some aspects of eating performance such as posture, but it did not significantly improve their ability to eat independently.

Successful use of the spoon was not possible for seven of the subjects. One of the two subjects indicating successful use of the spoon did so while assuming a "fixating" posture to stabilize movements. While that is usually an undesirable posture for individuals with cerebral palsy, this particular subject exhibited such gains in eating independence and self-esteem that the evaluator recommended continued use of the two-handed spoon.

Individuals demonstrating the great-

est progress in independent eating while using the spoon were those afflicted with athetoid/spastic and ataxic/spastic cerebral palsy with little evident symmetry. Their movement disorder did not prevent them from eating finger foods, using a sandwich holder or using a cup with two handles. The results of this field study indicate that persons with similar disabilities as these two successful subjects could achieve greater independence in eating by using a two-handed spoon.

A population large enough to justify manufacturing and distribution of a two-handed spoon was not identified in this study.

Pending

No future work is anticipated on this project. However, a custom-made two-handed spoon can be fabricated by clinicians incorporating many features of the spoon used in this study. Further information may be obtained by writing the RERanD Center (153), Veterans Administration Medical Center, Palo Alto, CA 94304.

The Mechanics of Human Cancellous Bone

Personnel involved with this continuing research project, and their institutional affiliations, are: **Lyle W. Swenson, Jr., Ph. D** (VA); **Robert L. Piziali, Ph. D.** (VA, Stanford); and **Kil-Soo Kim, M.S.** (Stanford).

Support for this research is provided by RER&D Center core funds.

Need and Approach—In any mathematical simulation of physical systems or processes, it is desirable to describe the fundamental features of the system or process as realistically and accurately as possible. Extensive research in modeling biomechanical systems involving cancellous bone have considered an appropriate model for the material to be described by the classical elastic materials. This approach yields a questionable representation for cancellous bone, since an important aspect of the tissue constitution is neglected.

The method used to model the three-dimensional geometrical behavior of human cancellous bone considers the trabecular structure as a network of columnar members where the actual bony structure is replaced by a gridwork

of flexible beam-columns possessing individual material and geometrical properties.

Status

In order to suggest physical experiments to evaluate the mechanical behavior of cancellous bone, and to effectively represent the cancellous structure in finite element analyses, a lattice theory leading to continuum representation of cancellous bone is being developed.

The fundamental concepts are facilitated by considering cancellous bone as a network of columnar members where the actual bony structure is replaced by a gridwork of flexible beams possessing individual material and geometrical properties. By introducing elastic beams to represent the trabecular structure one provides rotational degrees of freedom that account for non-central forces and couples. The model proposed here, therefore, encompasses certain physical phenomena not present in the classical elastic model.

The equations of motion were obtained by considering the deformation of members attached to a representative joint. The potential and kinetic energies stored in representative elements were expressed in terms of the discrete displacements and rotations of the adjacent joints. Using Taylor expansions about the representative joint, and passing from discrete variables to continuous variables, expressions for potential and kinetic energy densities were obtained. Boundary conditions as well as equations of motion were obtained by applying Hamilton's variational principle.

Using this technique to achieve a continuum representation of cancellous bone leads to an extremely useful model for several reasons. First, the nature of the load-carrying mechanism of the cancellous structure is properly represented. The constitutive equations show that the cancellous bone supports internal couple stresses. This capability is not present in the classical elastic material. Support of couple stresses is a result of the moment-carrying ability of individual trabecular members. Therefore, this representation provides a means of obtaining insight into the basic deformational response characteristics of cancellous bone.

Second, the constitutive equations

indicate explicitly and clearly the necessary data required from physical experiments to complete the continuum theory. Effectiveness of these constitutive equations is indicated by comparing the predicted trabecular elastic modulus with values reported in the literature. Assuming the Young's modulus for an individual trabecula is the same as for cortical bone, about $1.5 \times 10^4 \cdot \text{MN/m}^2$, and that the trabecula thickness and length are $150 \mu\text{m}$ and $800 \mu\text{m}$ respectively, the continuum Young's modulus is calculated to be $4.2 \times 10^2 \cdot \text{MN/m}^2$. Values measured by Evans range between $1.4 \times 10^2 \cdot \text{MN/m}^2$ and $6.2 \times 10^2 \cdot \text{MN/m}^2$. This result is encouraging and lends support to the modeling technique. Finally, when using the finite element method to model and analyze joint behavior under mechanical loads, the discrete approach quickly becomes uneconomical and a continuum method is the sole alternative.

Pending

Further progress in the development of the model for human cancellous bone includes the determination of cancellous bone morphological parameters such as trabeculae length, width, cross-sectional area, and spatial orientation. Following this, experimental validation of the theoretical model will proceed by mechanically testing specimens of human cancellous bone by standard tension, compression, torsion, and bending programs. Long-term areas of applicability of the new cancellous bone model are in the analytical investigations of degenerative joint disease processes, prosthesis implantation and failure analysis, biomechanical studies of bone structures such as the spine, knee, and whole limb response, and finally in basic science investigations such as bone remodeling processes and Wolff's law.

Publications

Swenson (Jr) LW, Schurman DJ and Piziali RL (1978). A lattice theory for a continuum representation of cancellous bone. Trans 24th Ann Meeting of the Orthop Res Soc, 1978.

Pressure Sore Instrumentation

Personnel involved with this new research project, and their institutional

affiliations, are: **Lars M. Vistnes, M.D.** (VA, Stanford); **Gordon S. Abraham** (VA, Stanford); and **Diane Riker** (Stanford).

Support for this research comes from the RER&DS Center's core budget.

Need and Approach—An estimated 125,000 Americans are paralyzed by spinal cord injuries. Each year a large number (7,000–10,000) of persons are added to this population. 50–60 percent of these individuals develop pressure sores which require large amounts of time and money to repair (\$13,000 per sore).

Surface pressure is the usual measured variable investigated when dealing with pressure sores. How surface pressure relates to deep pressures within the tissue, (e.g. under a bony prominence), and how these pressures, along with temperature and shear forces, relate to the formation of pressure sores is not well delineated.

Using a three-dimensional array of miniature pressure transducers, this project will correlate surface pressure to deep pressures in a bench model. The array will then be implanted into a biological model (pig) to correlate these pressures (including additional factors such as time and temperature) to histologic tissue changes. This information will allow a logical program of pressure-sore prevention to be developed, involving development of better wheelchair seating devices, and bio-feedback or warning devices.

The pressure transducers, developed at the Stanford University Integrated Circuits Lab, are batch-produced by integrated circuits techniques allowing for extremely small size and low cost. The transducers have high sensitivity ($30 \mu\text{V/V/torr}$) and excellent long-term stability (1 torr/month). They are biologically implantable.

Status

Due to the large amount of data needed to be monitored and processed, a microcomputer system is being developed. This system will be capable of driving the transducers and conditioning the signals for the computer, and of displaying the various parameters of interest in real-time.

One channel of the transducer circuitry has been constructed as a test device. This device gained immediate

attention and interest from physical therapists at the VA spinal-cord unit. Since the transducer is small and produces a continuous pressure readout, it is simple to reposition the sensor and adjust wheelchair cushions. Even without the quantitative data from the two tissue models, such a device (in a "two-dimensional" array) would be of great use in adjusting seat cushions to give the best pressure distribution.

The dimensions of the actual pressure transducer are only 1.3 mm by 1.0 mm by .4 mm, but it is mounted on a rectangular ceramic package with dimensions roughly eight times that of the actual transducer. The packaging is necessary for lead attachment—but the large size and sharp corners of the package make it a poor choice for implantation. A new transducer with recessed lead-bonding pads is being developed.

Pending

At this time we are still awaiting the arrival of the computer system and transducer circuitry components for use in the three-dimensional models (a prototype cushion pressure monitor is being constructed for use by the physical therapists for wheelchair cushion adjustment) ■

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

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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 salient features of the design were described in BPR 10-34.)

Evaluation—A set of prototype wheels were fabricated and mounted on an Everest & Jennings Universal wheelchair frame. After a short debugging period the device was tested on a number of ramps and hills on the Georgia Tech campus. The wheels performed as designed and the tests were considered successful. However, a number of shortcomings were detected and noted. To verify these findings the wheelchair was tested by a number of patients at the Warm Springs Rehabilitation Facility in Warm Springs, Georgia. The wheelchair received generally positive comments, but several other shortcomings were found and noted.

The deficiencies centered on three basic themes:

1. The wheels were excessively heavy;
2. The anti-rollback device caused a 2-inch increase in the overall width of the wheelchair; and
3. The anti-rollback device could not be locked out to allow the wheels to free-wheel in both directions.

Conclusions and Recommendations—This set of prototype wheels was intended to prove the viability of the "roller bearing" concept and for this reason, the majority of the design effort was devoted to the anti-rollback mechanism. A preliminary follow-on study just completed has shown that the weight of a single wheel unit can be reduced to less than 10 pounds. While this is heavier than the standard 6-pound pneumatic wheel, the authors feel that it is still an acceptable figure. That study has also suggested several changes in the anti-rollback modules that may reduce their width by as much as 50 percent and thereby reduce the width on this prototype wheel to the same dimensions found on standard wheels. The lack of a lock-out device has not yet been addressed at this time.

The authors intend to continue testing the current set of prototypes, and hope to apply the information gained to the design of a second-generation prototype that will eliminate most, if not all, of the deficiencies found in the originals.

An Alternate Vehicle for the Physically Handicapped. (Gary W. Kelly, Research Scientist, and Kenneth S. Morgan, Graduate Research Assistant.)

This project was initially reported in BPR 10-34 under the title: Advanced Concept Design of A High-Performance Indoor-Outdoor Vehicle for the Physically Handicapped.

The purpose of this study has been to determine the mobility requirements of college students confined to powered wheelchairs and develop a vehicle design capable of meeting them. It was felt that a study of these requirements was sufficiently broad enough to have applications to a number of other environments (such as industrial areas, office complexes, shopping malls, and the like), yet specific enough to be thoroughly investigated in the allotted time.

After collating the results of a short survey, in-depth interviews with a number of physically handicapped students, and discussions with several rehabilitation therapists, the following criteria were established:

1. The vehicle must be capable of being easily operated by a C-5/6 quadriplegic^a.
2. The vehicle must be capable of being easily maneuvered through indoor obstacles like doors, elevators, and corridors as specified by the American National Standards Institute Publication ANSI A117.1-1980.
3. The vehicle must be capable of being easily and safely maneuvered over outdoor obstacles like irregular terrain, a standard 8-inch high road curb, steep hills, and capable of being driven on campus roads.
4. The propulsion system must be compatible with the needs of both indoor and outdoor operation.
5. The steering and speed control mechanisms must be compatible with a variety of add-on adaptors and assistance devices.
6. The vehicle must be capable of carrying a variety of student accessories (i.e. books, tape recorder, fold-away

table, etc.) without interfering with the performance or operation of the driver or vehicle.

In addition to the above criteria, a significant number of wheelchair users expressed a strong desire for a wheelchair capable of higher speeds, and one that could raise and lower its seat.

Although there have been a number of "high-performance" wheelchairs developed in the last few years (including one with an advertised speed of over 18 miles/hour), little if anything has been done to determine experimentally how fast a wheelchair user really needs to go. In the case of the proposed vehicle, its size, mobility, and available power constraints resulted in a two-speed control system with a range of 0-3 miles/hour for indoor use and 0-15 for outdoor use.

The problem of variable seat height was resolved by determining that the vehicle should have the capability to position a seated 50th percentile male at approximately the same eye level as a standing male of the same size.

Current Hardware, Capabilities and Limitations—After the foregoing design parameters were established, an attempt was made to compare them with the capabilities and limitations of current wheelchairs and similar vehicles, to determine whether an existing vehicle could be modified to meet them or if a new design would have to be developed. Sales literature and technical reports covering most American and European wheelchair manufacturers were studied, as well as reports on experimental models being developed at rehabilitation research facilities in the U.S.

While there have been a number of noteworthy designs developed in the past few years, no single design or design variation was found capable of meeting all of the design requirements. As a result, it was decided to develop an original vehicle design specifically addressing the established criteria.

Vehicle Design—A wide assortment of mobility systems were studied to determine their applicability to the design parameters. These included: military tracked vehicles; forestry and materials-handling vehicles; snow-mobiles; all-terrain wheeled and tracked vehicles; and remote controlled vehicles for NASA's planetary exploration program. The vehicle concepts that evolved

^a A C-5/6 quadriplegic was recommended by several rehabilitation therapists as the highest level generally capable of handling an adapted van and/or a high-performance wheelchair, although higher-level quadriplegics do operate suitably adapted powered wheelchairs.

from the study fell into three broad categories: (i) fully tracked vehicles, (ii) half-tracked/wheeled vehicles, and (iii) multi-wheeled vehicles. At the same time, a parallel study was made of available power sources (i.e., liquid and gas fuel for internal combustion engines, battery and fuel cell power for electric motors) to determine their compatibility with the design parameters.

After deliberation, it was decided to base the vehicle design on a concept consisting of four drive modules, each mounted on a separate leg assembly. These leg assemblies are in turn fixed to a central structure (supporting the seat, batteries, controls, and accessories) and are raised and lowered by electro-mechanical linear actuators. System modularity was a prime criterion during vehicle development, since it greatly simplifies the replacement of damaged or defective components (thus potentially reducing vehicle down-time) and permits the greatest possible flexibility for the user and rehabilitation therapist to adapt the vehicle to the user's particular requirements.

The use of four drive modules and a microprocessor control system could give this vehicle some unique mobility characteristics. Since each module would be capable of independently powering and steering its drive-wheel, it would be possible to steer this vehicle using either the front or rear set of wheels, or both could be used when particularly tight maneuvering is required. In that mode the vehicle would be capable of translating from side to side and turning about a vertical axis through its midpoint. In addition, the use of articulated legs would permit the user to vary his/her seat height and (using a relatively simple "lift and roll" sequence) might permit the vehicle to "step" over obstacles such as street curbs.

The vehicle as currently conceived would be approximately 52 inches long, 27 inches wide and would weigh between 400 and 450 pounds (with batteries). It is designed to have a top speed of 15 miles/hour carrying a 200-pound driver, the capability of climbing a 15-degree slope (27 percent grade), and a projected maximum range of 20 miles.

Conclusion—At this time the authors are completing an analysis of the proposed vehicle's stability and other

operating parameters. All studies to date indicate that the proposed vehicle will successfully meet all of the established design criteria. Some preliminary hardware designs have already been generated. It is hoped that a complete set of drawings and specifications will be finished within a year.

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Sonic Orientation and Navigational Aid (Sona)—(Gary Wynn Kelly, Principle Investigator, Robert D. Atkins, Research Scientist, and Theresa Schaber, Research Technologist.)

As initially described in BPR 10-34, this is a project to develop an orientation and navigational aid for visually impaired persons to assist them in the location of certain major landmarks in the environment. It consists of a transmitter carried by the visually impaired user and receivers (transponders) mounted at key locations in the environment such as above restroom doors, entrances, emergency exits, elevator call buttons, etc. Entering a code number into the transmitter transmits a digital code. The receiver set for this specific code then activates an audio oscillator which can be heard by the visually impaired traveler.

Statement of the Problem—The visually impaired traveler is confronted with two main tasks in moving through the environment. One basic task is actual mobility, accomplished through the use of residual vision, long cane, or guide dog. The second task is orientation within and to the environment. Most electronic travel aids developed to date have addressed the mobility problem of "wayfinding" through an environment rather than orientation within the environment. This device provides a means of orientation to the visually impaired traveler that allows him to identify and locate specific kinds of known elements

within his environment.

Configuration—The transmitter now in use is slightly larger than a package of cigarettes, while future models may be somewhat smaller. It has a touch keyboard, an on-off switch, and a transmit button. These may be combined to lessen the number of switches in future models. No antenna is required on the transmitter.

The receiver is larger, and is readily mounted with the tone generator output.

The transmitter is battery powered, and preliminary tests demonstrate that the batteries last for 2 to 3 months. The receivers are powered from normal house current; their power consumption is less than one watt on standby and less than three while generating a tone.

Present Evaluation—The present evaluation demonstrates that the tone generators need to be improved to produce more pleasing signals that are still distinctive. The transmitter requires improved packaging to reduce its dimensions as much as possible. The present transmitter is slightly larger than the original design had called for. The range of the device is approximately 75 feet indoors with a maximum range of 150 feet. It does not carry between floors in any building yet tested.

Future Planning—As funding permits, more evaluations will be conducted and improvements made in the transmitter design and packaging. The costs are approximately \$35.00 per receiver and \$30.00 for the transmitter, in limited production. We believe this can be improved to \$25.00 per transmitter and \$5.00 to \$10.00 per receiver with design improvements and higher production. That would be necessary for mass installation, and would compete with the manufacturing costs of braille labels of far less utility.

Electronic Typewriter for the Visually Impaired—(Gary Wynn Kelly, Principle Investigator, Lawrence Moriarty, Research Scientist, and Theresa Schaber, Research Technologist.)

The electronic typewriter for the visually impaired is designed to meet the needs of persons with usable residual vision who can utilize large print if it is available. This is an electronic device based on word processor technology, and consists of a keyboard, a processor with memory, cassette storage of information, and a large-character display.

Characters may be typed into memory on the keyboard, at the same time appearing on the display from right to left in a self-scan mode. They are stored in the internal memory until recorded on cassette for long-term storage. They may be recovered from cassette storage later and read on the display at a rate selected by the user. Editing and search features are available.

The number of persons capable of using large print is at least five or six times as great as those presently using braille. This would indicate a short-sighted concentration on the severely visually impaired person, leaving others to muddle through by themselves with the use of low vision aids. This is unrealistic and ignores many of the problems of this large population. Low vision aids, while they have improved enormously in recent years, are not a panacea and do not eliminate the necessity or desirability of large print. Low cost accessibility to large print is not a reality at this time. The present device addresses this problem and offers potential cost beneficial solution.

Hardware—The device is based on an RCA 1802 microprocessor with 12K RAM memory. There is additional ROM memory for handling display, editing, and cassette interface instructions.

The display is a vacuum fluorescent, 40 character unit with a character height of .2 inches. This is slightly larger than 18-point type used in large print publications. Filters are provided to change the color according to user preference and ability.

The cassette unit is an American Printing House four-track variable speed recorder used widely in the production and reproduction of cassette material for the blind. It is a modular part of the unit, capable of being used for electronic storage of information and as a conventional cassette unit. Information is stored and played back into the main typewriter unit at 800 Baud. This is a standard cassette interface used widely in the microcomputer industry.

The typewriter keyboard is a standard keyboard with a numeric keypad to the right. That may be used to control some machine functions or as a numeric keypad—programming has not yet been established to decide this. Further user testing will demonstrate which would be more desirable. The RS232 serial interface is a standard interface and is

compatible with others of the same type. It allows easy interface to acoustic couplers or printers equipped with such an interface.

The video interface provides a character generator for video output to any standard monitor such as those used with a CCTV. In addition, hardware may be purchased at most microcomputer stores to allow interface with a standard television.

Projected hardware costs for production units appear to be approximately \$1200.00 to \$1400.00 for limited production and less than half that amount for large production. These costs are dropping quickly with competition in the display market, CMOS microprocessor market, and the cost of CMOS RAM memory.

Software—The software now consists of all the necessary control and interface software and the editing package. The control software controls the display rate of the self-scan display, the manipulation of information in memory, and the input versus output features. The interface software primarily controls the cassette interface. It will be expanded to include the video display and the RS232 serial interface. The editing package is elementary at this time allowing "screen" editing, some search and replace capability, cursor control, normal backspace, forward space, delete character, return, etc.

The editor is expandable and will continue to expand to allow more thorough editing. This device is not a word processor, however, and will never have a capability as great as the sophisticated devices on the market for that purpose. It provides a text editor package only.

Present and Future Plans—At present one unit exists for initial evaluation and modification. When packaging is completed it will be tested with several visually impaired persons to determine its utility and to correct obvious problems. These users will have some input into the expansion of the editing capabilities and other software functions. As funding permits, a second improved unit will be built and an iterative evaluation process will be pursued.

It is hoped that eventual funding will allow the evaluation of multiple units in cooperation with other centers.

A Music-Tone Terminal for the Visually Impaired. (Gary W. Kelly, Principal Researcher, and David Ross, Graduate Research Assistant.) This project was initially reported in BPR 10-34 under the title: Research on Micro-Computer / Computer Terminal Character-Tone Output for the Blind.

To date, four main programs have been written using the basic tone-producing subroutines. One program was written to be used with the RS-232C interface, and a second was written for the d.c. Hayes Modem. Each of these first two programs enabled the APPLE II to be used as a musical terminal which could "play back" incoming data repeatedly for the programmer at whatever playback rate he chose.

A third program was written for the purpose of teaching the newly implemented musical language to the blind. This program teaches the student by presenting him with a limited vocabulary of words and phrases, letting the student experiment with the keyboard and attempt to match the sounds listened to with ones he himself makes on the keyboard. The program gives immediate feedback to the student along with hints when necessary. A fourth program was written which enabled the APPLE II to be used as a self-contained musical computer. A fifth, and yet-to-be-written program for the APPLE II, will allow it to be used as a musical text editor.

System Evaluation—There has been time for only a limited evaluation of the system to date. However, of the few blind students who have used it in connection with a computer training program, all have worked with it enthusiastically, and one was able to reach a reading rate of 100 words per minute after only 6 weeks of working with the system.

Future Developments—Plans have been made to use this software with a word processing system, allowing the blind person to edit his own work by "listening" to what he has written.

This software may also be easily translated into simple hardware which could function independently of the APPLE and have the capability of interfacing to any digital device.

Finally, in conjunction with the development of 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.

Communication for the Speech Impaired (Gary Wynn Kelly, Principal Investigator, and Theresa Schaber, Research Technologist.) (This project was initially reported in BPR 10-34 under the title: Electronic Communication for the Speech Impaired.)

This report summarizes the development of a communication aid for the speech impaired. The device consists of a Morse code entry system, a microprocessor, memory, and a display. It is intended to be a portable device designed to be primarily battery-operated.

The Problem—Many persons with a speech impairment encounter difficulty when communicating with the general public. This is partially due to the severity of the individual impairment, and partially due to the inexperience of the listener in understanding a speech impaired person.

Many aids have been developed that address this problem. The present investigators are only concerned with the more recent electronic aids. Most depend on the user's manual ability to write, enter with keys, or touch selectively specific areas of a "keyboard." A fundamental problem with such devices is the inability of many speech impaired persons to successfully utilize any system requiring what is for them a high level of manual dexterity. Thus many of the aids are useless to this part of the population, which consists largely of persons with histories of stroke, brain damage, or cerebral palsy. There is a need for a device that will provide effective and efficient communication for persons with a speech impairment and still address potential manual limitations.

A newly developed device (designed in the Rehabilitative Engineering Program at the Georgia Institute of Technology) addresses the problem of manual ability in communication in addition to providing a substitute for speech. The device consists of a joystick input into an automatic Morse Code key. Moving the joystick left produces dots and to the right, dashes. The incoming code is translated by an Intel 8748 microprocessor and is displayed as text on a 16-character LED display.

Audio feedback of each transmitted dot or dash is provided since the user cannot see the display. The configuration is such that the joystick is nearer the user, and the display is facing away from the user, and the device is "aimed" at the person with whom communication is desired.

The Intel 8748 has 4K of on-board ROM memory. This permits space for all code translation, multiplexing the display, and storing eight preprogrammed messages.

The newest model now under construction has additional memory permitting the storage of other messages which will be selected by users, health service delivery personnel, and from samples utilized on existing devices.

Two prototypes have been built to date and have been tested in a laboratory setting. Information gained from this experience has been incorporated into the third device now under construction.

The Software—The software is relatively simple in the present devices, consisting of a machine language program controlling the self-scan display, code translation, and stored messages.

The software is expected to remain approximately the same through future devices, increasing in complexity with modifications in hardware. The new model will feature 64 messages and a 2-line self-scan display. The software to drive this more complex system will be an expanded version of the existing program.

Future Planning—As funding permits, the new communicator will be completed and undergo an initial evaluation to determine its utility as compared to other techniques. Disabled users will be urged to participate in the evaluation and redesigning of this model. It is expected that the data will allow another improved version to be constructed.

Considerable work will be required to provide improved housing for the model as it is designed. The present version is too bulky and awkward to carry and store.

The communicator is designed to be used in a variety of situations, from communications with family members to requesting information of persons such as bus drivers, waiters, skycaps, and department store clerks. The latter

are persons who might find it difficult to understand those attempting speech, or who work in places where the slowness of writing and other techniques may prove awkward or even hazardous.

The system requires that the potential user learn to transmit (not receive) Morse Code successfully. The predicted speeds with this device should be fifteen to twenty words per minute with reasonable practice. Much higher speeds may be obtained by those not too severely limited in coordination.

A good redesign for an optimal shape and size is needed. This is expected to be completed during the following 12 months. In the process of obtaining an optimal shape and size, the electronics may undergo some revision. The display is extremely legible under a wide variety of lighting conditions, but is larger than necessary and contributes to the packaging problems of the present model.

Initial evaluation with the Atlanta Veterans Administration Medical Center will begin in early 1981. This will be an on-going process through the rest of the program.

*Sensory Aids
Section follows*

SENSORY AIDS IN THE VA RER&D SERVICE PROGRAMS

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Clinical Application Study of Reading and Mobility Aids for the Blind

**Western Blind Rehabilitation Center
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**Joseph J. Hennessey, Gregory L.
 Goodrich, Ph. D., Diane L.
 Morrisette, and Sue Melrose**

The death of Richard R. Bennett was a deep personal and professional loss to his friends and colleagues at the Center, and indeed to all who knew him. He taught us many things about blindness, technology, and people, and made this learning easy. We cannot repay our debt to him for these lessons; we can only pass them along.

Kurzweil Reading Machine Evaluation

During the current reporting period no substantive changes have been made to the Kurzweil Desktop Reading Machine's hardware or software. The WBRC's research has shown it to be capable of reading many type fonts and single-column materials such as books, letters and other documents of simple format. It has been largely unable to read many magazines, telephone directories, and other materials containing graphs, pictures, mixed type fonts and complex page formats (e.g. legal texts, Newsweek, the Bible, federal job application and other forms, and some professional journals).

Purchases (to date) reported by Kurzweil Computer Products, Inc. confirm this utilization of the machine. These purchases, with few exceptions, have been made by libraries which contain a great deal of information of the type easily read on the machine. Of course, the price of the machine may also be a factor in the very low number of machines purchased by individuals. Usage rates by visually impaired users of libraries have not been reported and it is to be hoped that these data will be collected and made available in the future, as they constitute a valuable source of evaluative material.

Computer-Based Braille Systems

Recently, several paperless or refreshable Braille systems (Elinfa Digicassette, Telesensory Systems, Inc., Versabaille, the Clarke and Smith Brailink, and the German Braillocord) have entered the commercial market. The WBRC has had experience only with the early model Digicassette (reported in previous issues of this publication), but funding has been approved for the purchase of a Versabaille. Future work will evaluate the Versabaille as a stand-alone system and as a peripheral or terminal for other computer systems.

Spatial Contrast Sensitivity

Spatial contrast sensitivity (the ability to detect visually sine wave gratings of varying frequency and contrast) has been shown to be of promise in the early detection of some pathologies and in documenting changes in the visual system during the aging process. Research conducted at the WBRC by the Center's research staff and Drs. James Marron and Ian Bailey (School of Optometry, University of California, Berkeley) indicated that it may also be an effective screening procedure in determining functional visual performance in orientation and mobility.

Spatial contrast sensitivity was measured in 22 veterans. Each veteran's mobility performance was measured in both an outdoor and indoor mobility route and the results correlated with the results of the contrast sensitivity function (CSF). The correlation between CSF and mobility performance was +0.57. The correlation between mobility performance and visual field was +0.55, and between visual acuity and mobility performance the correlation was +0.07. Thus, both CSF and visual field appeared to be moderate predictors of mobility performance, while visual acuity appeared unrelated to mobility performance with the subjects tested.

A multiple correlation technique was used with the variables of visual field and CSF to determine their combined relationship to mobility performance. This yielded a correlation of +0.73,

accounting for 53 percent of the variance in subjects' performance.

A more detailed description of the study is contained in Dr. Marron's Master's Thesis which was based upon this study. It is available through Dissertation Abstracts International (James A. Marron, "Visual Skills and Orientation-Mobility Performance in Low Vision", School of Optometry, University of California, Berkeley, December 1980).

More work will be needed before CSF can be clinically applied in low vision work; however, the magnitude of correlations obtained in this study strongly suggests that spatial contrast sensitivity is a fruitful area for investigation. Research at the WBRC will continue in this area.

Frostig Figure-Ground Test

As previously reported in the Bulletin of Prosthetics Research, the Center has been actively investigating the use of the Frostig Figure-Ground Test for the assessment of near-vision performance of partially sighted individuals. A preliminary report on the current investigation was presented at the Annual Meeting of the American Academy of Optometry in Chicago (December 1980). The data indicated that the Frostig test correlated +0.63 with reading speed on the CCTV and +0.71 with reading speed using optical aids. The data also indicated a moderate correlation with reading duration using optical aids, although there was no significant correlation with reading duration using the CCTV.

The Frostig Figure-Ground Test, like the contrast sensitivity function (reported above), appears to have substantial utility in the functional assessment of low vision, and will remain an active part of the WBRC's research efforts. It is hoped that the test will be useful in comparing the progress of a partially sighted veteran during training and in assessing the adequacy of prescribed low vision aids.

Written Communications

At the request of staff in the Center's Interpersonal and Communications Section, research personnel began working on the development of a screening test to aid in establishing criteria for the issuance of typewriters. In many cases the need for a typewriter and the veteran's ability to use it can be easily assessed. In other cases, the need may

be clear, but the veteran's ability to use the device might be questionable. This clearly leaves a difficult situation: the recommendation to provide a typewriter which might not be used, or not recommending one which might be useful. These can be described as false positive and false negative cases.

A two-part strategy has been adopted in order to minimize the number of false positives and false negatives. First, an easily administered three-part test has been developed and is being administered to students instructed in the use of a typewriter. This procedure will provide normative data on speed and accuracy in various aspects of typing. The second part of the study will be a follow-up on the actual usage rates of these veterans, and an attempt will be made to correlate testing results with actual and reported use of the typewriter. A pilot followup project within the Medical Center's immediate geographic area is being planned.

Night Vision Aid and Wide Angle Mobility Light Evaluation

The Night Vision Aid is a hand-held monocular device designed to intensify available light under scotopic or dim photopic conditions. The system was designed by IT&T to assist night-blind individuals when traveling in areas of reduced illumination.

The Wide Angle Mobility Light (WAML) is a modified scuba diving light which produces a bright, wide beam of light. The size of the beam and the level of illumination were selected in order to reduce night travel difficulties of people with night blindness.

The WBRC, the Central Blind Rehabilitation Center (CBRC) in Hines, Illinois, and the Eastern Blind Rehabilitation Center (EBRC) in West Haven, Connecticut, are conducting a cooperative study to evaluate the effectiveness of these devices to enhance the night mobility of night-blind individuals. The project consists of performance evaluations during the day, at night unaided and at night with each device. A minimum of 24 subjects per Center will be studied. The CBRC has had two subjects complete the evaluation, the EBRC has had four subjects participate in a pilot study, and the WBRC has completed evaluation of 20 subjects. Inclement weather has delayed progress at the CBRC and EBRC. Additionally, the Night Vision Aid at the EBRC has

malfunctioned and requires repair.

In addition to the evaluative information gained on these two devices, the project will also compare the adequacy of the methodology which uses an identical protocol at the three Centers, but only similar (not identical) mobility routes. If the methodology provides useful information, it may facilitate future investigations of mobility aids.

Mowat Sensor Study

A follow-up study will be conducted on the Mowat Sensor, an electronic travel aid for the visually handicapped. The device uses reflected high frequency sound to provide the user with tactual or auditory information regarding the presence or absence of objects within the device's range of approximately 4 meters (about 13 feet). The study will utilize both an experimental and a control population to determine if use of the Mowat affects the user's mobility. The variables to be examined include frequency of travel, type of travel, travel techniques, problems encountered in travel, and the user's confidence in travel situations.

Subjects in the two groups will each receive a complete orientation and mobility program at the WBRC, but only the experimental group will receive training with the Mowat. Training with the Mowat will be integrated into the normal mobility training schedule.

All orientation and mobility instructors at the WBRC have completed a two day Mowat Sensor Teacher Training Workshop conducted at the Center, and teaching guidelines have been established to ensure that each subject will receive a defined training program.

Upon completion of training and return to the home community, each subject will be surveyed by telephone at intervals of 1, 3, 6, 9 and 12 months to assess the effects of the training program and / or Mowat usage. Due to the difficulties in matching subjects for the control and experimental groups it is expected that this study will continue for approximately two years, including time to complete the one-year follow-up.

Wide Angle Mobility Light Follow-up Study

The WAML (described earlier) has been available and marketed since July 1979. A telephone followup of veteran

and non-veteran users of the WAML will be conducted. Information sought includes effectiveness of the device, maintenance and reliability information, user applications, and suggested modifications.

The study is being carried out in conjunction with Michael Marmor, M.D., (Chief of Ophthalmology, VA Medical Center, Palo Alto) who was one of the developers of the aid. Results of the study, including consumer input regarding possible modifications to the device, will be shared with (and considered by) the manufacturer, Farallon-Oceanic, as the basis for possible future modification of the device.

Clinical Application Study of Reading and Mobility Aids for the Blind

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**James J. Acton, William R.
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Roman**

An administrative shift of Blind Center Research from the research to the psychology department of the Medical Center took place in October, 1980. Although this is viewed as a positive change, an extensive amount of time was spent during this reporting period developing and defining the new relationships and research priorities which have resulted from this change.

Mrs. Evelyn Roman was hired as a research assistant in August. Mrs. Roman will assume responsibility for the personal evaluation and coordination of new communicative devices intended primarily for the totally blind. In this capacity she has been evaluating an experimental update program for the Kurzweil Reading Machine, Model II, and has been familiarizing herself with the other devices currently under study at the E.B.R.C. She will form the cornerstone of future evaluations of talking terminals and paperless braille systems.

The computer coding of Low Vision Data from 1969 to 1979 has been completed. A study of field restrictions and acuity limitations as they relate to instructor-perceived functional loss in mobility and communicative areas is underway. Ms. Patricia Gadbaw is

coordinating this research effort.

A meeting with Dr. Robert Adriene and Dr. Richard Miller from the Psychology Department of the New York Association for the Blind was held in September. Analysis of MMPI and CPI scale scores of congenitally blind clients has been completed and a preliminary report of the research has been prepared. Comparisons of personality characteristics of the congenitally and adventitiously blinded clients are now in progress.

A meeting with Dr. Henry Dove, Coordinator, Health Services Research Program at West Haven VAMC, was held in October 1980. HSR&D's interest in program evaluation has opened up possible areas of interaction with Blind Center Research. In November, Ms. Karen Schneider of HSR&D met with the Chief of the Blind Center and Dr. De l'Aune to discuss possible projects.

Ms. Adrienne Karp, Audiologist from the New York Association for the Blind, visited the Research Department in November. Recent developments in hearing aid design and the resulting impact on the blind were discussed. The recently received Binaural Auditory Impairment Simulator was also examined. Serious problems were encountered because of the inability of the earphones to occlude the undistorted natural acoustic signals present in real time simulations. Standardized Speech Discrimination Test Tapes were provided to the Research Department by Ms. Karp for further evaluation of the system.

The New York City Mayor's Office for the Handicapped requested consultation with Dr. De l'Aune concerning the work of Bernard Leitner. Mr. Leitner is an architect noted for his use of "sound architecture." A meeting exploring the use of his designs by the blind is expected in 1981.

In December, several meetings were held with Mr. Tim English, President of EXIT-US, Inc. EXIT-US, which is developing talking emergency signs, desired information concerning our experiences with synthetic speech. The signs, while designed primarily for the sighted who are deprived of vision during smoky situations, would obviously be a boon to the blind. The signs would not only provide an audible, easily localized cue as to the location of the exits, but would be capable of providing the

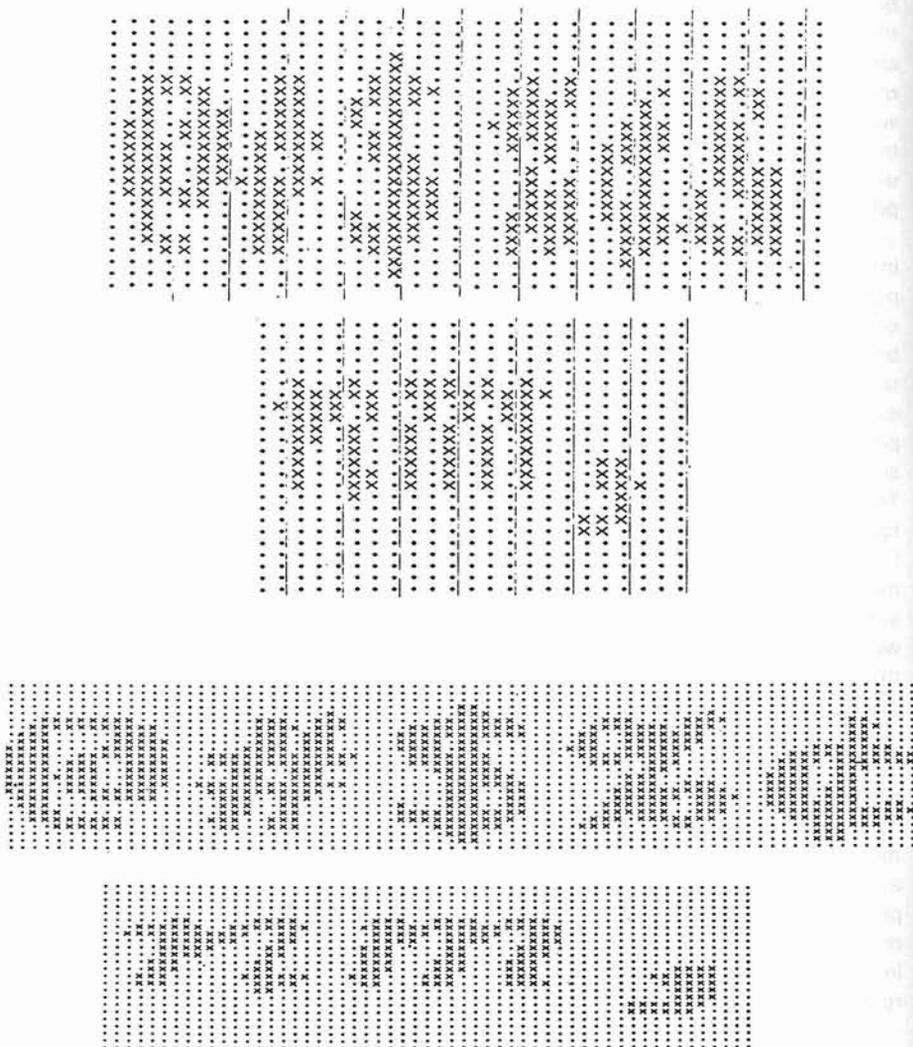


FIGURE 1 Wood
The upper half of this figure shows a normal Optacon image of some commonly used symbols and two letters printed in italics. The lower half shows these same symbols with approximately a threefold increase in horizontal resolution. This increase in horizontal resolution can be obtained from the Optacon camera at the expense of reducing the scanning speed (1). Both the vertical field of view and the vertical resolution, which are the same for all images shown here, cannot be increased with the current Optacon camera.

public with information concerning the nature of the emergency and the best escape route.

Ms. Georgette Nielson returned to the E.B.R.C. with the final production model of her Low Vision Reading Stand. The stand, which is to be distributed by the American Foundation for the Blind, incorporates a number of features recommended by the E.B.R.C.'s Low Vision Staff. The Low Vision Staff was quite pleased with the final product, which is being evaluated.

The Beamscope Lens, a Fresnel Lens designed to be placed in front of a television screen to magnify its image,

has been under evaluation by the Low Vision Department. At this point it is felt that the device is comparable both in price and performance with the currently issued telescopic aids. While it does not have the problems of weight and awkwardness associated with the telescopic devices, it can be used only for TV viewing and requires that the viewer be positioned directly in front of the set, problems not shared by the telescopes. Veteran reaction has been generally unenthusiastic. A new model designed for smaller screened TV sets has been received for evaluation.

Development of a Camera for Application in Sensory Aids for the Blind

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Introduction

The purpose of this project is to develop an improved hand-held camera for use in a reading machine for the blind. This machine will allow a user to scan printed material with a hand-held camera and hear spoken English output. The camera will provide images for a character-recognition module which generates a stream of identified characters. These characters serve as input to a text-to-speech module which produces the spoken output heard by the user. The camera will have high-enough resolution and a large-enough field of view to allow the reading of print sizes between 6-point and 20-point type, which corresponds roughly to type with capital letters between .05 in and .2 in tall and thus includes most common reading material. The camera will be compatible with the Optacon, a tactile-output reading device, and the Voice Output Reading System, HS-2 both of which are products of Telesensory Systems, Inc. (TSI), of Palo Alto, California.

Background

The camera currently used by the Optacon has a 6X24 point retina. In order to tactually read varying sizes of print, magnification is adjusted manually by the user with the aid of tactile feedback. There is also a manually controlled threshold adjustment to compensate for some variations in contrast and reflectivity of the material being read. This camera was originally designed to provide images for tactile reading, and several improvements are desired for use as a camera which provides input for machine recognition of characters.

The field of view of the Optacon is too small to allow very much tolerance for errors in hand tracking. The character image can be at most 24 points high, and almost all of that is needed in order to have vertical resolution adequate for character recognition algo-

rithms. Small errors in hand tracking could easily cause characters to be cut off at the top or bottom. Tactile reading of characters is often possible when pieces are missing due to inaccurate tracking, because human pattern-recognition makes extensive use of context. However, machine recognition algorithms are rarely so tolerant or sophisticated.

The resolution of the Optacon retina is restricted by the small size of the retina, the fixed ratio of horizontal and vertical resolution in the absence of motion, the fixed image-sampling rate, and the limits of the manually controlled magnification setting. Increased vertical resolution cannot be obtained because the total height of a printed line must fit within the 24 points of the retina. Some increase in horizontal resolution can be obtained (Fig. 1) at the expense of lowering the scanning speed [1], but even with no motion, improved two-point discrimination is desired in order to help determine intercharacter boundaries.

Automatic control of magnification and threshold is not possible with the Optacon camera. Such automatic control with manual override is desired so that less training is required before the reading machine can be used.

An experimental camera with a 1024-point linear array was built and evaluated by TSI. The images from this camera were superior to the images obtained from the currently used Optacon camera. It is expected that the improved quality of the images as well as the larger field of view for each character will increase the accuracy of the character recognition software, which will in turn improve the quality of speech output.

Motion detection software, which uses cross-correlation of sequential 6X24 Optacon images, was written and tested. It was determined that this technique could be used to encode the camera position accurately enough for the recognition software [1].

Design Goals

The new camera is intended to offer improved performance over the current Optacon camera which is used in both the Optacon and the Voice Output Reading System, HS-1. It will contain a moderately high resolution solid state retina which will allow automatic control

of magnification and line tracking. These improvements will make camera positioning much less critical, and will therefore require much less skill and effort from the user. The larger images and improved signal-to-noise ratio are expected to improve the performance of the character recognition software. In addition, the new camera will allow increased reading speeds because the new retina can be sampled at a faster rate than the Optacon retina. The new camera will also contain a 6 X 24 Optacon retina for motion detection and tactile feedback. Camera motion will be detected by image cross correlation, and no external encoders which might hamper camera movement will be used.

Three prototype cameras will be designed and built, and blind subjects will test and evaluate the Voice Output Reading System, HS-2, using the new camera. A substantial amount of work on this project will be performed by TSI. This work will begin upon completion of contract negotiations.

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An Auditory Prosthesis for Sensorineural Hearing Loss

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Hearing loss is conventionally classified into two main categories—conductive and sensorineural. In the first, the hearing loss (as measured by elevation in threshold of detectability) can be attributed exclusively to a lowered efficiency in the transmission of acoustical energy to the cochlea. The use of hearing-aid amplifiers to compensate for such conductive hearing losses has proven of great value. The second category—"sensorineural" hearing loss (SNHL)—represents what might be called "all other" forms of hearing loss. Although threshold elevations are usually present, amplification of the acoustic energy is often not of any

significant benefit to such patients and, even worse, frequently results in further deterioration of the patient's ability to process acoustic information—particularly speech information. It would be fair to say that at the present time most patients with a significant degree of sensorineural impairment will derive limited or no benefit from contemporary hearing-aids(1).

The central idea of this research project is the analysis of SNHL in individual patients not in terms of physiological causes, but rather in terms of the consequences to the patient's ability to process spectral or pitch information. From this point of view, the more peripheral stages of the neural auditory pathways become a system that introduces spectral and/or intensity distortion into the signals it transmits to higher auditory centers. Recent research in this laboratory as well as others indicates that it may be possible to characterize the distortion produced in an SNHL patient by means of simultaneous dichotic pure tone stimuli. Within the context of a theoretical model of pitch processing (2) the SNHL distortion can not only be characterized but it is also possible to compute a compensatory signal distortion for each patient which, when combined with his SNHL distortion, will tend to normalize the neural signals reaching the higher auditory centers. To the extent that these central neural signals are normalized, the patients' ability to deal with auditory stimuli, especially with spectrally complex ones like speech, should be greatly improved. The overall goal of this research is to specify the design of a signal-distorting hearing aid which compensates for the hearing deficits produced by damage to the sensorineural mechanism.

Because this project was only recently approved and was first funded in fiscal year 1981, little experimental progress can be reported at this time. A PDP 11/44 computer system has been ordered; the special purpose auditory stimulus generators are under construction. The initial screening of SNHL subjects is beginning. Each subject will receive a complete audiological battery to determine degree, slope, and site of lesion of hearing impairment. Next, selected SNHL subjects will have to complete an extensive series of tests of monaural and dichotic

pitch perception. The results of these tests will be studied in relation to the audiological results and will be used in conjunction with the theoretical model of pitch processing to further characterize each subject's hearing loss. This theoretical analysis should determine the type of external signal processing which would enhance each subject's ability to properly perceive complex auditory stimuli like speech. Later reports will present data obtained from SNHL subjects and will discuss the theoretical analysis in detail.

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A Tactile Aid for the Treatment of Sensorineural Hearing Loss and Aphasia

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Treatment for severe speech discrimination deficits resulting from sensorineural hearing loss and severe auditory comprehension deficits in patients with Wernicke's or global aphasia is limited. What does exist is not very effective. The patient with marked problems in discriminating speech subsequent to an acquired sensorineural hearing loss receives little help from amplification or aural rehabilitation. Similarly, the patient suffering marked auditory comprehension problems as part of the language deficits found in Wernicke's or global aphasia shows little improvement when treated with traditional aphasia therapy.

Recent advances in the development of sensory substitution aids, specifically transmission of information through tactile sensation, provide a potential treatment method for the two groups of patients discussed above. To date, tactile sensory substitution of auditory information has been utilized with deaf patients. The limited initial results are

promising. No attempt has been made to treat aphasic patients with tactile sensory substitution of acoustic information.

Patients with acquired sensorineural hearing loss appear to be excellent candidates for treatment with tactile substitution of auditory information, because, unlike the congenitally deaf, patients with acquired hearing loss typically have intact language. Thus, treatment can focus on improving speech discrimination and avoid the need to teach language. Patients suffering aphasia typically have no significant hearing loss, but their language deficits make it difficult for them to comprehend what they hear. Some aphasic patients have improved their verbal expression through intersystemic reorganization therapy which utilizes an intact performance system, (e.g., gesture) to improve performance in a deficient performance system (e.g., oral expression). Similar pairing of an intact input system (e.g., tactile), with an impaired input system (e.g., auditory), has the potential of improving performance in the impaired system.

Our investigation is designed to test the efficacy of TeleTACTOR, a wearable electrotactile sensory aid, as a treatment for speech discrimination deficit in severe sensorineural hearing loss, and for auditory comprehension deficit in severe aphasia. Worn as a belt across the abdomen, TeleTACTOR presents acoustic frequency, intensity and temporal information through 32 pulse generators which provide electrotactile stimulus patterns on the skin. A controlled 16-week treatment trial will compare performance with and without TeleTACTOR. Secondary purposes include: (i) determining whether improvement, if obtained, while wearing TeleTACTOR generalizes to continued improved performance when not wearing the device or whether it must be worn continuously as a prosthetic aid, and (ii) identifying patient characteristics that predict favorable or unfavorable response to the treatment method.

Communication Aids Research for the Blind

Central Rehabilitation Section for Visually Impaired and Blinded Veterans

Hines VA Hospital
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John D. Malamazian, Harvey L.
Lauer, and Leonard Mowinski

Communication aids research at Hines Blind Rehabilitation Center is conducted by Harvey Lauer and Leonard Mowinski. Recently, administration of the program has been transferred from the Rehabilitative Engineering R&D Center at Hines Hospital to the Blind Center. Mr. Mowinski is on the Research payroll and will divide his time between the two areas.

Kurzweil Reading Machine

The Kurzweil Reading Machine Evaluation is currently not funded separately as was the case for 3 years from 1978 through 1980. However, reading machine research at this center proceeds in four areas: (i) test use of the KRM by the staff and the veterans as improvements are made; (ii) testing of tonal reading codes refined at this center and adopted for the proposed hand scanning option of the KRM; (iii) testing the value of bimodal reading using tactile and auditory presentations of letter shapes; (iv) interfacing the KRM and other instruments to provide and test talking and braille outputs, communication terminals, and typewriters. (For a detailed report, see "The Kurzweil Reading Machine" in the Technical Notes section of this issue.)

Tonal Output

The project to improve the tonal code as a supplement for the Optacon direct-translation reading machine was continued with the delivery of eight prototype units to the Central Blind Rehabilitation Center. The units measure 6X6X2 inches and are equipped with rechargeable batteries. Features include separate volume controls, 2 headphone jacks, 2 RCA jacks, stereo-mono mode, invert-normal for reading reverse print and switchable outputs of 12, 20, and 24 tones.

One Optacon student has been taught to use the bimodal display (pins and tones), and will be issued a tonal

output upon completion of the training course. Progress was good and letter recognition improved, as did reading speed. Also, because of the pitch variation, the ability to correct skewing and off-center tracking was made easier.

The Blind Center and the RER&D Center will collaborate in evaluating the tonal output under the new RER&D Device Evaluation Program. The evaluation team will study: (i) Definition of characteristics and size of the population which the device was designed to serve, and the assessment of the needs of the population. (ii) The technical and engineering features. (iii) Human factors. (iv) Quantification of the changes in the patient's life state afforded by the use of the device as opposed to either existing devices or no device at all. (v) An analysis of the potential benefits accrued from the use of the device as compared to cost of development.

An instruction manual for the tonal output was prepared by Messrs. Lauer and Mowinski and is available upon request.

Evaluation of the Talking Optacon

The Central Blind Rehabilitation Center has been chosen as one of several sites at which to evaluate the prototype model of the talking Optacon. A staff member will be sent to Telesensory Systems, Inc., for training and briefing in February of 1981.

Other Devices Evaluated

During the reporting period, several devices were evaluated by the staff and the veterans of the CBRC. The Elsi Quartz Digital Clock from Sharp Corp. has a visual liquid crystal display (LCD) and a speech output. The speech output is clear and easy to understand. Other features include alarm, timer, and stopwatch functions. The unit is powered by two Type AA batteries which provide several months of service. This clock received a favorable review from the staff and veterans, and is found to be an excellent substitute for those who cannot read a braille watch due to conditions which affect tactile sensitivity. The device retails for \$90.00.

The Casio ML-81 was evaluated by the research staff. This musical calculator has four functions in addition to square root, percent and memory. Other features include two alarms, timer, stopwatch, date and time. The interest-

ing feature of this unit is the musical output: for the timer and alarm features, a 20-second musical selection is played. For numerals, the decimal point, and the equals sign there is a graduated scale starting with the low note "La" representing the decimal point, and the high note "Re" for the number 9. When the equals key is depressed, a musical output for the answer is sounded and the number is displayed on the visual display. The musical output may be hard to understand when the answer contains several digits. However, depressing the stopwatch key will cause the answer to be repeated, one note (digit) at a time. With keyboard familiarization and practice with the tones, some blind people can use this calculator. The retail price is \$50.00. There are several companies which sell musical calculators, some of which may not be suitable. The research team has evaluated the ML-81 and ML-82 and found them to be satisfactory. Other musical calculators examined would not be suitable for this application.

The Canon Co. has recently introduced the Canon Canola SP 1260-D talking calculator. This 12-digit desktop unit provides the user with a large blue visual display, a paper-tape display for record keeping, and a synthetic speech output for keyboard and answers. One unique feature is the 128-item memory which stores function signs and numbers. This feature allows the user to call out all entries and results for verification, approximating an audible paper tape. The speech board successfully used in the Speech Plus talking calculator is used in the Canon Sp-1260-D. The unit retails for \$400.00.

While at a technology conference in Harrisburg, Pennsylvania, Mr. Lauer learned of the VOXCOM Card Reader System. The manufacturer sent a unit to the CBRC for evaluation and use by blinded veterans. The VOXCOM is a system for recording voice messages on flat surfaces such as cards and photographs. The unit consists of a Panasonic recorder / player, and a card-reader that, when placed in the cassette well opening, can record and play back the flat cards. The cards are 10 inches long and have 25 seconds of recording tape on each side. The system was designed as a teaching aid utilizing the oral-visual-aural approach.

This system would provide an excel-

lent alternative to a braille address file, especially for those with reduced tactile perception, who could not utilize the braille code. The user could use jumbodot braille to label the card, recording the desired information on the tape. The CBRC is investigating the possibility of converting the GE recorder from the American Printing House for the Blind to accommodate the card reader of the VOXCOM. The VOXCOM system sells for \$200.00 and the card-reader sells for \$85.00. It can be purchased from VOXCOM, 100 Clover Green, Peachtree, GA., 30269.

OTHER ACTIVITIES

1. In July, Mr. Lauer attended the annual conference of the Visually Impaired Data Processors International in Louisville, Kentucky. Most of the presenters demonstrated and discussed new equipment for the blind. After the conference he and Mr. Farmer gave lectures and demonstrations on aids for the blind in Nashville, Tennessee at an in-service conference of state rehabilitation workers. While in Nashville they visited the laboratory of Dr. S. C. Ashcroft at Vanderbilt University. He is investigating the application of talking and braille computers and terminals.

2. In September Mr. Lauer was the keynote speaker at the conference on communication aids for the blind sponsored by the Pennsylvania-Delaware chapter of the American Association of Workers for the Blind.

3. Mr. Lauer was a member of a panel on technological aids for the blind sponsored by the National Federation of the Blind of Illinois (NFBI).

4. Mr. Lauer attended the conference of the Prairie State Chapter of the NFBI and presented a paper on communication aids for the blind.

5. An article entitled "Personal Type Speech Compressors—An Article for Teachers and Consumers" was submitted to the Aids and Appliances Review, a publication from the Carroll Center for the Blind. This paper along with articles from Dr. Emerson Foulke and Dr. Hadi Magid will comprise the upcoming issue on Speech Compression.

Clinical Application Study of Mobility Aids for the Blind

Central Rehabilitation Section for Visually Impaired and Blinded Veterans

VA Medical Center
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John D. Malamazian and Leicester W. Farmer

Electronic Travel Aids Training Activities

The Hines Blind Rehabilitation Center admitted seven veterans for participation in the Electronic Travel Aids (ETAs) Program for Blinded Veterans. Six have completed their training and received their respective travel aids; the seventh veteran will complete his training course during the next reporting period. Three of the trainees were issued Mowat Sensors, two received Laser Canes, and one veteran was issued a Sonicguide. Another veteran who was admitted during the previous reporting period completed his training and was issued a Laser Cane; thus seven ETAs were issued to veterans between July 1, 1980 and December 31, 1980.

The Preliminary Evaluation of the Nurion Step Sensing Device (SSD)

For a detailed report on the Step Sensing Device, see the report in the Technical Notes section of the Bulletin.

Visits and Presentations

Mr. Omar Miran, Vocational Rehabilitation Counselor from Wisconsin, visited Mr. Leicester W. Farmer October 27, 1980, to get first-hand information about the Hines ETA program and to discuss availability of ETAs and applicability to clients in the field.

October 30, 1980, Dr. and Mrs. Y. W. Yang from the Lincoln Achievement Center in Gary, Indiana, and Mr. Bashier Masoodi, member of the Indiana Rehabilitation Services Board, visited Mr. Farmer to get information concerning ETAs and light probes and to discuss appropriate electronic devices for various grades in public school systems.

Mr. James Haager, graduate student in industrial design at the University of Illinois in Urbana-Champaign, journeyed to Hines November 5, 1980, to discuss the general area of ETAs, information transfer, and the research he is doing

in the area of sonic aids for the visually impaired. Mr. Haager is trying to develop objective measures for determining the most efficient methods of translating the signals received from ETAs and to reduce the cost of sonic devices through the evaluation of the various basic components.

November 18-19, 1980, Mr. Gunnar Jansson, Associate Professor, Department of Psychology, University of Uppsala, Uppsala, Sweden, visited Mr. Farmer for wideranging discussions about ETAs, light probes, new ETAs on the European market, developing and evaluating ETA programs and devices, training formats, device deployment, followup studies, and consumer usage after the "halo effect" has worn off. The two men expressed the desire that in the future the Hines O / M research specialist and appropriate Uppsala University staff personnel might engage in some cooperative efforts involving some of the above areas, along with research relative to some unexplored areas in orientation and mobility.

July 17, 1980, Messrs. Farmer and Harvey Lauer made presentations on ETAs, light probes, and electronic reading machines at the Seminar on Aging and Low Vision at the Howard Johnson Motor Lodge in Nashville, Tennessee. The Seminar was sponsored by the Tennessee Commission on Aging, and AAWB.

October 15, 1980, Mr. Farmer made a presentation at the Roosevelt Grade School in Maywood, Illinois. The presentation was made as part of an effort to acquaint the students with the occupations and careers of various persons in the Metropolitan area of Chicago. The audience was made up of 4th to 6th graders.

Mr. Farmer made a presentation, "Technology and the Blind Consumer", at the Annual Fall Orientation and Mobility Non-Conference which was held at the Milwaukee Area Technical College on October 25, 1980.

On December 10, 1980, Mr. Farmer was invited to give a lecture on basic O / M techniques, ETAs, and light probes to the kindergarten class at the Wilson Primary School in Bellwood, Illinois. The experience showed that these small children have great capacity for understanding and appreciating modern technology.

**The Clinical and Acoustic
Parameters of Hearing Aid
Effectiveness**

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Increased emphasis on the low-frequency information contained in speech processed by hearing aids produced the following effects: First, the quality of speech was enhanced substantially, both in quiet and in the presence of speech babble. Second, phonemic identification in quiet appeared to benefit from the addition of a relatively mild degree of low-frequency emphasis. Finally, phonemic identification in the presence of babble did not appear to be degraded to any substantial extent when low-frequency information was increased in amounts typical of contemporary hearing aids. This conclusion is applicable to the case of listeners who (i) have gradually-sloping sensorineural hearing loss of moderate degree, (ii) who are fitted with conventional hearing aids, (iii) who are listening at comfortable listening levels, and (iv) who are subjected to competitive speech babble at typical signal-to-noise ratios.

This work places in doubt the practice of arbitrarily reducing low-frequency amplification in the determination of satisfactory hearing aid characteristics for the hearing-impaired veteran. That is ordinarily done because clinicians have tried to guard against upward spread of masking wherein, theoretically, the presence of low-frequency amplification interferes with the intelligibility of speech in the presence of competing messages and sometimes even in quiet.

In another study, the performance of hearing impaired subjects on three speech intelligibility tests was compared. The scores on the Northwestern University Auditory Test No. 6 and the CNC Test of Lehiste and Peterson were similar to each other, but markedly different from the CID W-22 Test. The latter test has been used by the VA for the past 25 years for compensation and hearing aid evaluations. It has proven to be insensitive to degrees of hearing impairment, generally providing intelli-

gibility scores higher than the impairment would warrant. Sufficient data have now been gathered on the NU-6 and CNC Tests to permit their use in research and hearing aid evaluations. These tests are reliable, sensitive to degrees of hearing impairment, and the equivalency of certain lists within each test has been established.

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

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**Pat Clark, M.S., and
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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. Additional devices are under development. One will be a companion or accessory for the Optacon that will recognize printed characters, assemble words, and speak these words intelligibly as the blind user scans print by hand. The other will be 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 inter-agency contract from the Veterans Administration, the Bureau of Education for the Handicapped, and the Rehabilitation Services Administration (now NIHR). 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 21-month effort (starting September, 1978) were previously reported. By the middle of 1980, a breadboard of the hand-scan system had been complete for about three months, and construction of field evaluation prototypes was well under way. Major components of an automatic laser scanner had been assembled, and video data had been collected and transmitted through all the data paths.

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. The portion of the contract dealing with an Optacon-based, OCR speech-output reading system has been completed. Five units have been constructed for the inter-agencies contract, and a formal field evaluation of these units was scheduled to begin in the first quarter of calendar year 1981. The evaluation is expected to be one year in duration. An additional three units will be separately evaluated. Informal evaluations were performed at TSI by blind employees and visitors during the latter half of 1980, and many useful suggestions have been incorporated into the units.

Hardware and software development for the automatic scanning system is continuing. The system is capable of making a low-resolution scan of an entire page for the purpose of determining page format. It can also track single lines at higher resolution for the purpose of reading. The optical/mechanical system has been redesigned to eliminate one galvanometer and thereby reduce the cost and complexity of the system. Circuitry to provide adaptive black/white contrast thresholding has been installed and is being evaluated. Refinements in the clocking circuitry and the drive system have been incorporated.

An architecture for the microprocessor portion of the scanner has been selected. The testbed now includes a single-board microcomputer, a terminal, and a video display. The scanner can be directed to perform a variety of functions in response to commands issued from the terminal. These functions include collection of video data from either a format or a read pass. The data can then be viewed locally by the designer or collected on diskette for processing on a central computer.

Data collected during the format pass must be processed to determine the exact location of lines of text as well as the presence of features such as columns or non-text elements. Algorithms to perform location, classification, and ordering of text elements have been developed on the PDP 11/34. Data collected from the scanner breadboard have been transferred to the 11/

34 and used to refine the algorithms.

Data collected during the read pass are processed into a format suitable for OCR. This processing includes image enhancement and computation of status information. Scanner data have been collected and transferred to the 11 / 34, where successful recognition was performed.

A preliminary set of user controls has been identified and implemented. The software was written in a higher-level language and was developed on the PDP 11 / 34 and then transmitted (downloaded) to the breadboard hardware. A special keyboard which connects to the breadboard through an RS-232 interface has been constructed. Demonstrations of the user controls package have resulted in suggestions for refinements which will be incorporated into the system.

**Rehabilitative Engineering
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John Trimble, Ph. D., Engineering Director

Dr. Trimble hopes to present a progress report of several projects in the Fall 1981 issue, BPR 10-36.