VETERANS ADMINISTRATION REHABILITATIVE ENGINEERING RESEARCH AND DEVELOPMENT SERVICE PROGRAMS

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Development and Evaluation of a New Artificial Larynx

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

Development of a Communication Control Aid Using Electromagnetic Tracking Technology

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Polhemus Navigation Sciences, Inc. (PNSI) of Vermont, a subsidiary of The Austin Company, has continually been developing SPASYN (SPAce SYNchronization), a company-patented electromagnetic position and orientation measurement technique. The SPASYN concept has been successfully employed as a head-tracking device which is used by military pilots as a helmet-mounted sight system. PNSI has begun to design and develop a new application of this technology: a communication aid for the handicapped called SPA-SYN-COM. Originally conceived by James Krieg, a PNSI systems engineer, SPA-SYN-COM is envisioned to be a portable direct-selection device enabling even the more severely disabled person to communicate by either small natural movements of the head or by some other controllable part of the body.

When fully developed, SPA-SYN-COM would offer disabled persons the possibility of operating a number of useful devices, ranging from electric typewriters and voice synthesizers to telephonic communication systems and environmental controls.

In practice, the user points a head-mounted sighting device at an adjacent target board that contains blocks of letters, numbers and symbols for various control functions. The user's line-of-sight to the target board is measured through the spatial relationship between two electromagnetic dipole antennas: a fixed source mounted behind the head and a sensor mounted on an eyeglass frame. Measurements of the position and orientation of the user's head-mounted sensor can thus be converted into locations on a passive target board.

SPA-SYN-COM was successfully demonstrated at the DeGoesbriand Unit of the Medical Center Hospital of Vermont in Burlington the week of May 19, 1980.

Based partially on the results obtained in that demonstration, the Rehabilitative Engineering Research and Development Service of the Veterans Administration, operating through its Medical and Regional Office in White River Junction, Vermont, decided to support the PNSI proposal to develop the communication aid. A three-phase program was proposed: in the first phase a research-grade instrument is being configured; the second phase will involve the clinical evaluation of the instrument at Trace Research and Development Center at the University of Wisconsin; and the third phase will provide for the prototype development and testing.

At present, the VA views successful completion of the first phase of the program as a requirement for additional funding authorizations. Work on Phase I began in earnest at PNSI on June 29, 1981 and will continue for one year, at which time the clinical instrument will be available for evaluation and testing.

The Phase I technical plan calls for the development of a clinical evaluation instrument, which will not reflect the final prototype configuration in appearance, power consumption, portability or size. Functionally, however, the SPA-SYN-COM instrument will perform in an identical manner to the envisioned prototype.

Essentially, a straight-forward engineering approach is planned to develop the research-grade communication aid. There are four major steps to the approach: System Design, Hardware/Software Design, Unit Testing and System Integration and Test. The System Design process defines the functional elements of the instrument in terms of their input, output, transfer, and interface parameters. This effort will result in specification documentation sufficient to design the exact hardware and soft-modules for system implementation. The modules will be integrated and the resulting instrument tested for compliance with the specifications.

In conjunction with the design process, equal attention will also be given to the Cost Benefit Analysis segment of the program. Any areas of design that represent cost trade-offs will be noted and justified. For example, the size requirement of the microprocessor memory for the research instrument is a function of software development rather than of the computational and/or operational requirements. Notation and justification of such cost trade-offs will enable a more accurate assessment of the cost of a final configuration. Other critical areas which will be carefully assessed for cost versus benefit will include: manufacturing techniques, power consumption, component availability and future interface requirements such as environmental controls, telephone modems, speech modules, etc.

Documentation of the total engineering effort and the Cost Benefit Analysis will be included in the final report for Phase I of the program.

Studies of Normal and Abnormal Motion

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During the period from January 1 to June 30, 1981, the Kinesiology Research Laboratory continued its investigations into the nature, rate, and extent of change in functional performance in patients with total joint and other reconstructive procedures in the lower extremities.

To help determine the duration of benefits in functional performance resulting from total hip arthroplasty, kinesiologic testing was completed over a 4-year period on 58 patients with 72 Charnley and Müller total hip replacements (1). The patients, who averaged 62 years of age with a range from 22 to 78 years, were tested before surgery and 2 and 4 years after surgery. None of these patients had complications related to the total hip replacement, such as loosening or infection, and none of the patients had any neurological disease or major problems with other joints in the lower extremities.

The study showed that, on the average, men and women with these replacements were significantly improved 2 years after as compared to before surgery. Improvement was measured in almost all of the components of function tested, including range of hip motion, hip abductor and adductor muscle strength, weight distribution between the feet during standing, and multiple components of walking performance. During the period from 2 to 4 years after surgery, the patients tended to maintain the 2-year level of performance, particularly as regards range of hip motion and walking performance measurements (Fig. 1). Average hip muscle strength measurements in the men showed slight, but not statistically significant, declines from 2 to 4 years after surgery (Fig. 2). For most patients, the 2 and 4 year levels of performance were still below the normal limits of variability for comparable age and sex groups.

Preoperatively, we had tested 110 patients. Of this original sample, 52 did not meet the criteria for this long-term study, either because of inability to follow-up, complications related to the hip replacement, or severe arthritis of other joints. From information gathered on these patients, an estimate was made that approximately 70 percent of the patients in the original sample of 110 were still functioning better 4 years after surgery than before surgery.

Two studies to assess the effect of different surgical procedures in groups

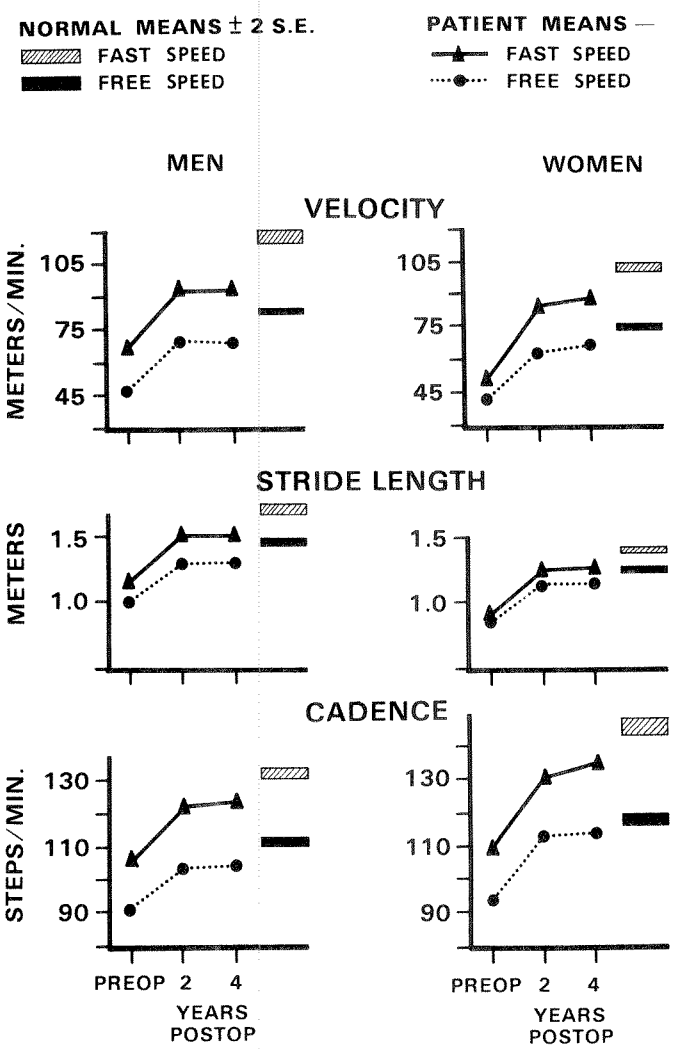

FIGURE 1.
Mean free-speed and fast-walking velocity, stride length (2 successive steps) and cadence for 25 men and 33 women before total hip replacement and 2 and 4 years afterward. All patients were walking without support. Range of normal variability defined by 2 standard errors above and below the mean is indicated by shaded horizontal bars for free-speed walking and diagonally striped horizontal bars for fast walking for men and women. Reprinted with permission from Clinical Orthopaedics and Related Research, No. 147, June 1981, p. 122.

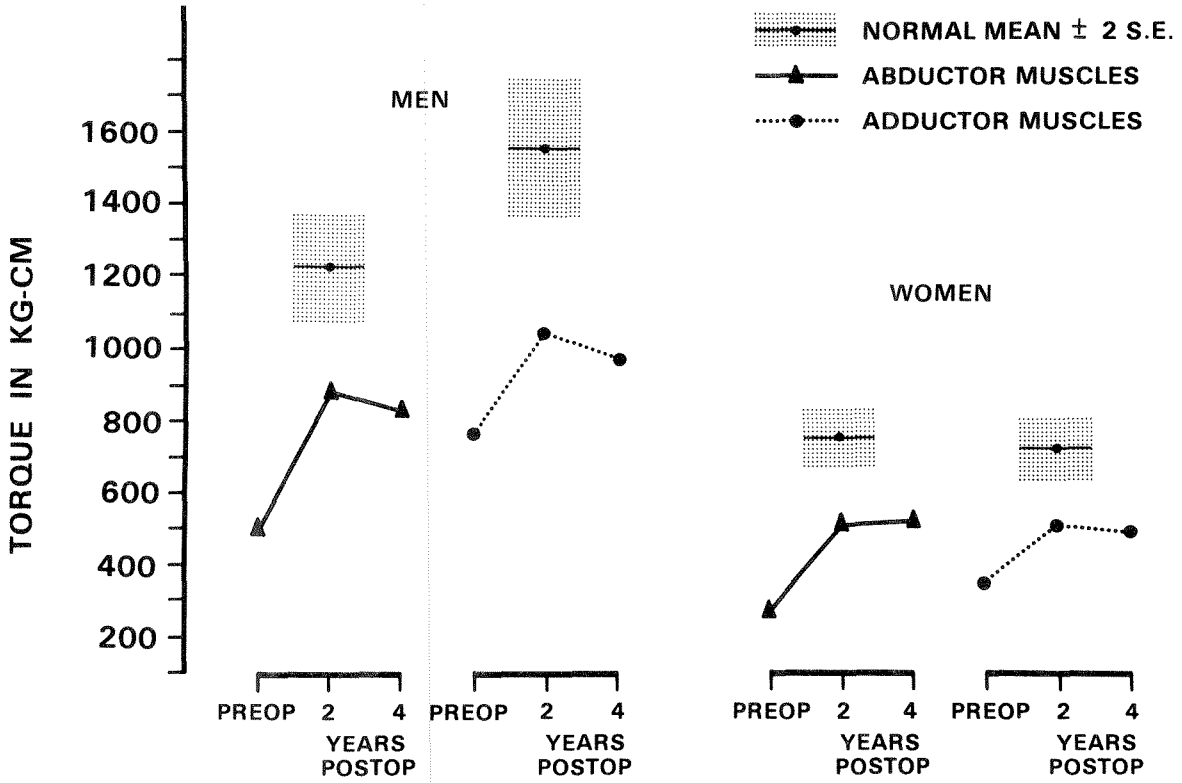

FIGURE 2.
Mean maximum isometric hip abductor and adductor muscle strength before surgery and 2 and 4 years afterward for 30 hips replaced in men and 42 hips replaced in women. The shaded area bisected by the horizontal line represents the normal mean and 2 standard errors above and below the mean for normal men and women. Reprinted with permission from Clinical Orthopaedics and Related Research, No. 147, June 1981, p. 121.

of patients with the same type of hip replacement are near completion. These include a study comparing functional performance of patients with and without osteotomy of the greater trochanter, and a study comparing functional performance of patients operated through an anterolateral as opposed to a posterior approach to the hip.

During the period covered by this report, the Laboratory also published a book chapter in a text, Clinical Biomechanics: A Case History Approach (2). This book chapter, written on request, combined information from two previous works done at the Kinesiology Research Laboratory on the antalgic maneuvers in the gait of patients with hip pain and the compensatory maneuvers in the gait of patients with hip fusion. In the text, gait information from these two studies was synthesized with biomechanical principles in order to elucidate the relationships between gait deviations, hip-joint loading, and the mechanical energy cost of walking.

The Laboratory also collaborated with Dr. Gore in analyzing and interpreting data and publishing a manuscript on a project in which 7642 girls and 751 boys were screened for spinal deformity in a Wisconsin county of approximately 100,000 persons (3). Two hundred forty-three girls and 13 boys had scoliotic curves of ten degrees or greater. Determination of curves which would progress was found to be unpredictable. Identification of progression was possible only by repeated examinations.

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Remote Control Writing

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This is a pilot study to assess the feasibility of generating "handwriting" by inputting the motion with the chin. This may be of particular value to the quadriplegic, whose only other method of written communication is by mouthstick or typewriter or video with special keyboard controls. The advantages of the system would be speed, versatility, simplicity and the satisfaction of producing script. Funding sources for this work, in addition to the VA, are the Paralyzed Veterans of America, and Howmedica, Inc.

Both mechanical and electronic systems have been made for the evaluation process. The former employs a system of linkages and has been used for on-site tests where the individual is asked

to trace standard shapes representing script, as well as make script which is compared with a pre-injury sample. A computer program is now being written to evaluate tests in terms of accuracy and speed at the time of the test. A joystick into an a/d converter will be used. The other electronic tests are to measure the frequencies and accuracy of up and down and side to side motions, based on the coupled oscillation model of handwriting. A sample of "chin writing" from a patient is shown (Fig. 1).

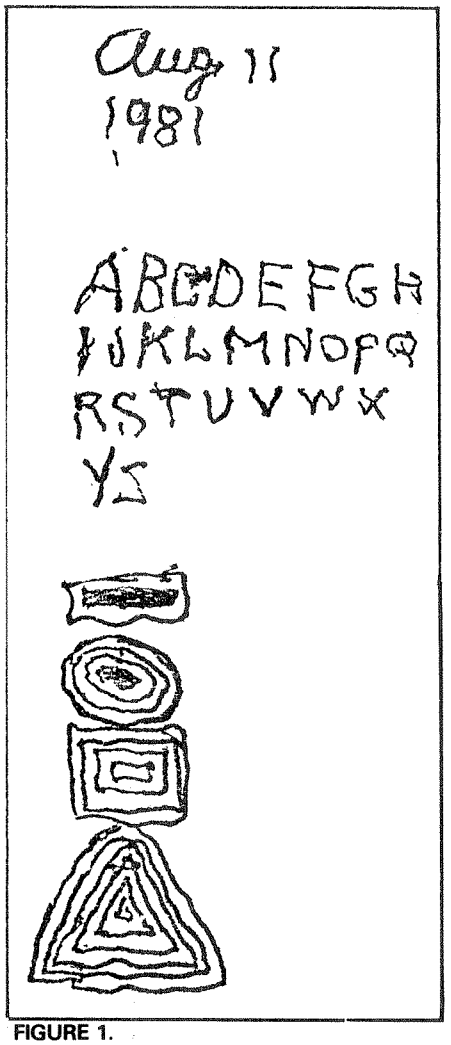

FIGURE 1.
This "handwriting" was generated by a patient who input the motion with his chin. The possibilities of both mechanical and electronic systems are being evaluated.

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

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The present project is a continuation of an earlier study (1) investigating the changes in the strain field in the human pelvis after implantation of the acetabular component of a total hip arthroplasty. The previous investigation utilized three strain gage rosettes (with three gage elements each) glued to a hemipelvis which was loaded to simulate conditions during stance phase of gait while pelvic strain data were recorded on a strip chart recorder. Comparative results using an Austin Moore hemiprosthesis and subsequent implantation of a conventional acetabular component load with matching Charnley type prosthesis were obtained. Processing of the data from 12 such tests required a minimum of three weeks due to the complexity of the computations involved.

In order to expand the scope of the project and allow for consideration of many variables inherent in the placement of acetabular components, a microcomputer-based data acquisition system is being developed to increase the number of strain gage readings that can be made from each specimen and to provide for real-time analysis of the acquired data. This system is described schematically in the flow chart of Figure 1.

Cadaveric hemipelves and their matched proximal femurs are being procured. Each hemipelvis will be instrumented with five strain gage rosettes, for a total of 15 gage elements on each hemipelvis. Corresponding gage elements for each hemipelvis will be connected into a half-bridge in the "bridge completion and calibration" box, which will also contain the resistors necessary to complete the 15 Wheatstone Bridges. The signals generated by each of the 15 strain gage bridges, as well as the load cell used to monitor the ac-

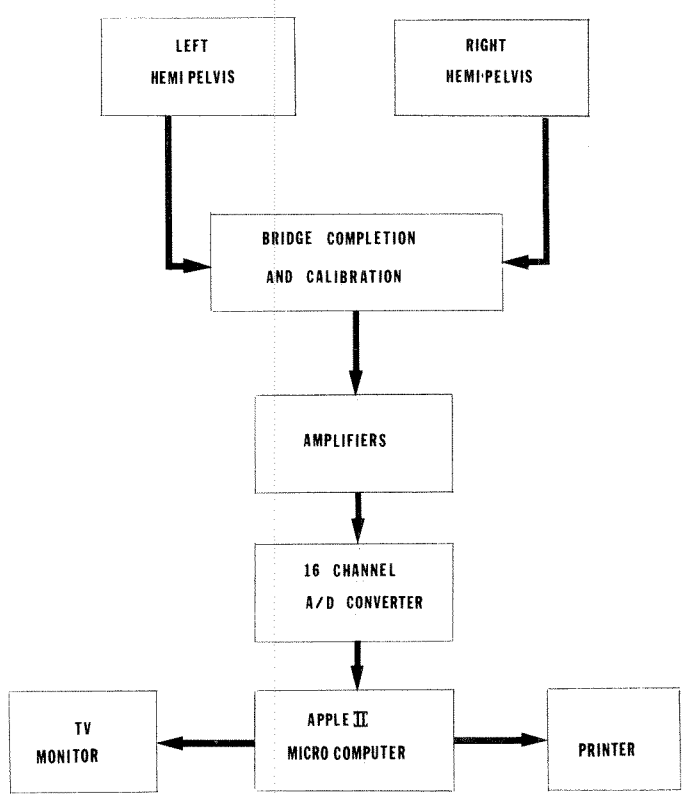

FIGURE 1.
Schematic of microcomputer-based data acquisition system developed to provide real-time data processing and display.

quired load, are amplified by a bank of amplifiers which have been especially designed and custom-built for this application. The amplifier outputs are fed into a 16-channel, eight-bit A/D converter, which feeds the digital representation of the strain gage signals into the Apple II/Plus microcomputer in real time. In order to accelerate execution time and provide real time representation of the strain fields, software is being written in PASCAL rather than the more customary BASIC language used on most microcomputers. The specially designed program allows calibration and scaling of all the data channels. Offset and scaling will be handled by the software rather than by manual adjustment. The program provides for scanning all channels periodically, translating the strain readings from each rosette into the principal strain values and their orientation, and displaying these strain data on a TV monitor as the test is being run. Hard copy of the acquired data will be available via a printer. As of this writing, all computer hardware has been acquired and/or constructed. Software designs have been initiated.

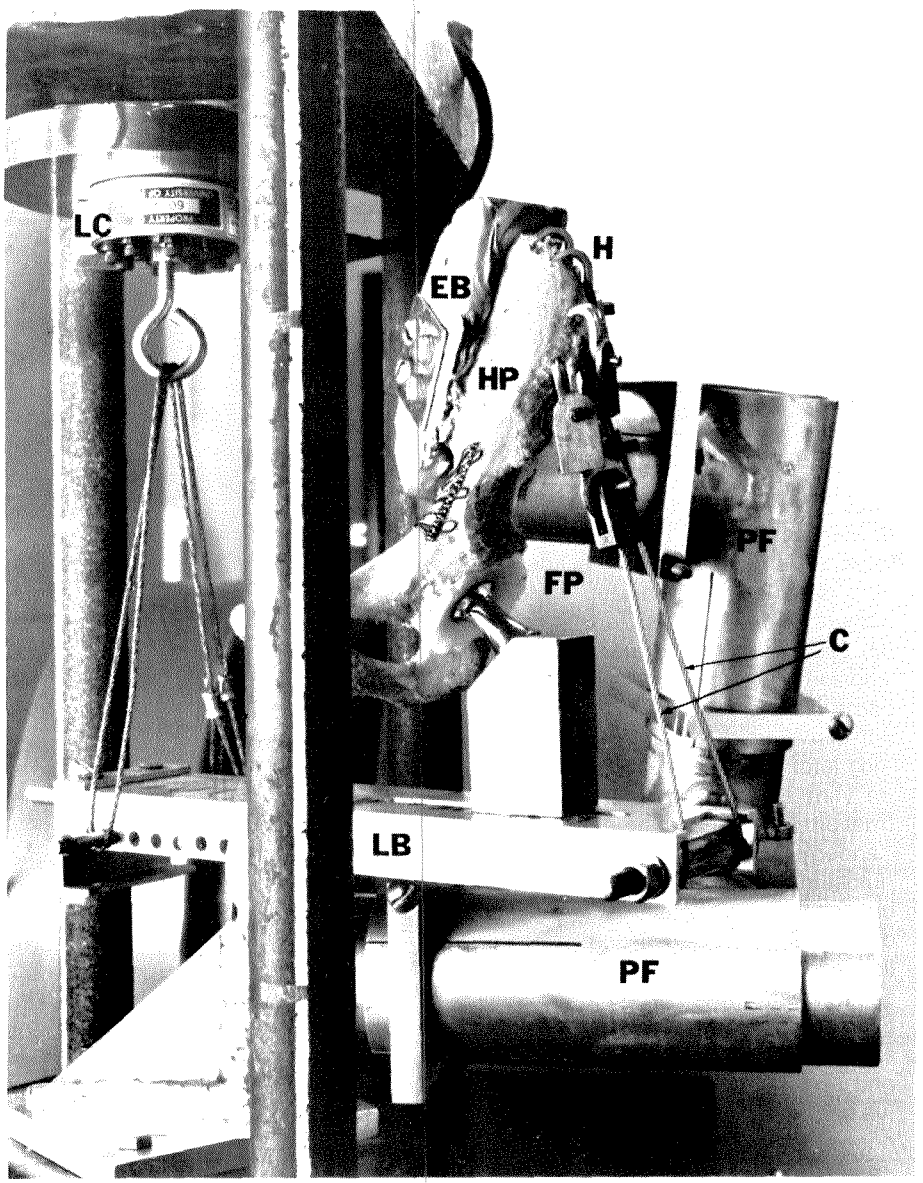

FIGURE 2
Lateral view of hemipelvis (HP) bolted, through epoxy block (EB), to the positioning fixture (PF). A Charnley femoral head prosthesis (FP) is mounted on the loading bar (LB), along with cables (C) and hooks (H) which simulate the abductor muscle pull. The load cell (LC) monitors the simulated ground reaction, applied to the other end of the loading bar.

Redesign and fabrication of the loading arm assembly (Fig. 2) is being carried out to allow for more efficient control of loading parameters. Development of the system described above is intended to allow the evaluation of the strength and stiffness of the bony pelvis-acetabular complex under various situations. These include observation of strain readings:

1. When there has been no cortical reaming as compared to reaming through the outer cortex of the acetabulum—leaving the inner or medial pelvic cortex intact.
2. Comparison of the use of three large keying holes as opposed to the use of no keying holes, and also comparing these techniques to the use of multiple small keying holes.
3. Determination of the effectiveness of a uniform mantle of cement, established by spacers, between the bone and prosthetic acetabulum in improving the strength and stiffness of the bone-prosthesis complex.
4. Comparison of the use of pressure injection techniques for insertion of acetabular cement to that of hand insertion of cement.
5. Comparison of the use of surface replacement acetabular components which have a larger diameter and thinner wall to the smaller diameter, thicker wall, conventional acetabular components.
6. Comparison of the use of metal-encased polyethylene acetabular components to the standard acetabular component.
7. Determination of the effect of various reinforcing techniques used to enhance support of the acetabular components, when there is a deficient medial wall (these include the use of protrusio ring, protrusio ring with femoral head bone graft, and wire mesh reinforcement).

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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 cement-bone interface 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 are taken on the affected side. These are taken post-operatively, before discharge, and 2, 4, 6, 12, 18, and 24 months postoperatively. We generate, by computer, a report on the Biplane Analysis for each film set taken. Reported data are the coordinates for bone and cement markers, intermarker distances for bone and cement markers, and any relative motion of the cement markers with respect to bone (i.e., loosening and migration). Additionally, we generate a 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.

To date, there have been 50 patients in our study; of these 17 have been Total Knee Replacements (TKR's) and 33 Total Hip Replacements (THR's). There are two bilateral TKR's and two bilateral THR's.

We have had 14 patients with measured cement loosening (range: 0.4 to 6.3 mm) and clinical evidence of loosening (radiolucent line on x-ray and symptoms); 6 of these have gone to surgery for revision or fusion (one case of septic loosening). In all cases the prosthesis was found to be grossly loose at surgery, thus supporting our Biplane Radiography findings. To date, 13 of the patients studied (out of a total of 50) have shown no loosening on all studies conducted. Thus approximately ⅔ of all patients studied have shown some motion at the bone-cement interface at some time during our study.

Conclusions

Cement-bone interface motion is more common than not, even in those patients who do not present with clinical symptoms.

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Evaluative and Corrective Techniques for Neuromuscular Deficits

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and

Biofeedback in Rehabilitation for Hemiplegia

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The same facilities are utilized for locomotion studies in both projects. Computer software has been recently developed which enables on-line data acqusition and subsequent compilation, averaging, and plotting of information. This report briefly outlines the functioning of the data measurement, acquisition, and processing systems.

The data handling system is a Digital Equipment Co. PDP 11/23 central processing unit (CPU) with 32K memory, 16 channel A/D converter, 16 bit parallel line unit, 2 RLO1 5Mb discs, high-speed printer, and digital plotter.

Data Measurement and Acquisition—Data are measured using standard commercial equipment and conditioned with filters and integrators designed and fabricated locally. Electromyograms (EMG) are measured using a Biosentry telemetry system incorporating surface or wire electrodes. Bandpass filters eliminate noise and motion artifacts. They have a fourth order, one-half dB ripple, Chebyshev high-pass section with a cutoff frequency of 40 Hz and a second-order Butterworth low-pass section with a cutoff frequency of 400 Hz. They are a state variable realization (1). Integrated EMGs are formed from the filtered EMG with linear integrators. An integrator consists of an active rectifier and a third order Paynter integrator with a 6-ms time constant (2). Canes or devices requiring force measurement are instrumented with a strain-gage bridge. The bridges are powered and forces measured by the telemetry system. All other analog signals, such as goniometric measurements, are hardwired. All analog signals are acquired by the computer via the A/D converter.

Foot contact patterns are measured using a B&L Engineering telemetry system incorporating sensitive switches that can be taped to feet or footwear. This system senses the contact of the heel, fifth and first metatarsals and large toe of both feet. A special interface has been built which encodes the on-off contact information into 8 bits of 16-bit computer word. This pattern is acquired by the computer via the parallel line unit.

The data acquisition program samples all of the data at 250 Hz during the measurement session and stores this on a disc file. The start and end of a measurement run are triggered by electronic eyes which demarcate a 5-meter section of walkway. Immediately after a run, the data are displayed on an oscilloscope and scanned for accuracy. The measurements may be remade if necessary.

Averaging and Plotting—A second program forms an average gait pattern from the sampled data file in several stages. First, the foot channels are scanned and the onset and offset times detected. These channels are displayed on a video terminal with cursors indicating the detected foot events. An optional editing mode is available to correct any detection or recording errors. The average foot patterns and stride information such as speed, etc. are then calculated. The average patterns of all analog channels are calculated by first demarcating the interval of activity in a full stride, second,

interpolating this single stride data at 256 points, and third, averaging it with other interpolated data from that channel (3). The averaged data are then stored.

A third program plots the signals and prints the information from the averaged data file. Figure 1 shows an average gait pattern from a postoperative gait study of a patient who underwent a split posterior tibial tendon transfer: the stride information is included in the legend of Figure 1.

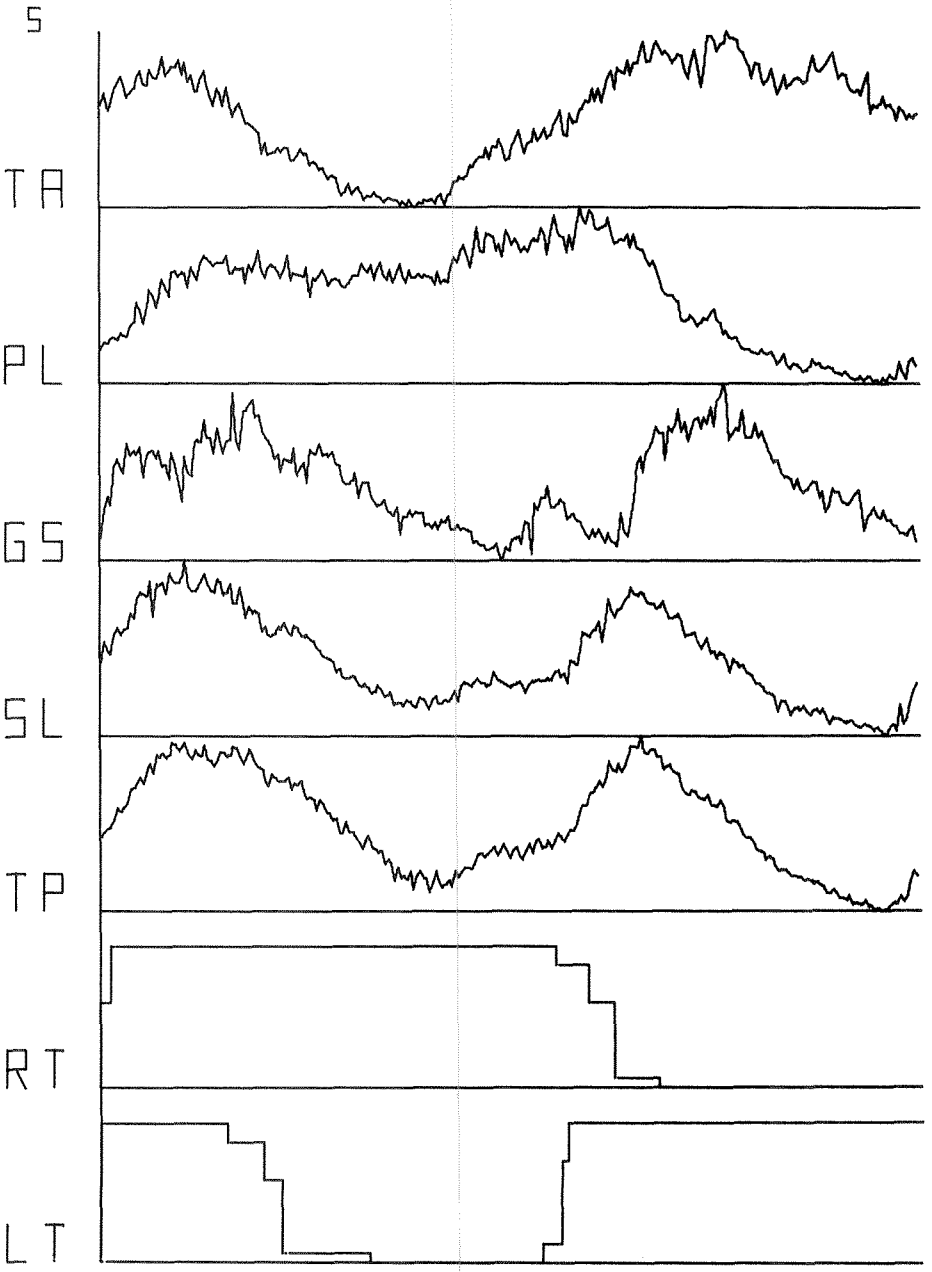

FIGURE 1.
Average integrated EMG from the tibialis anterior (TA), peroneus longus (PL), gastrocnemius (GS), soleus (SL), and tibialis posterior (TP). Right (RT) and left (LT) foot contact patterns. The step sizes are: 1 unit = large toe contact; 2, heel; 4, fifth metatarsal; 8, first metatarsal.
Stride information for Figure 1.
STRIDE TIME=1.1760S: STANCE PHASE=68 percent.
SINGLE LEG SUPPORT PHASE= 21 percent: number of strides=9.
STRIDE LENGTH=0.4113 METERS, VELOCITY=0.3497 m/s.

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Development of Upper Extremity Orthoses Employing Electrical Stimulation

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Introduction—The purpose of this project is to develop and evaluate an upper-extremity orthotic system, employing functional electrical stimulation of paralyzed muscle, to provide control of grasp and release. Palmar prehension-release or lateral pinch-release is elicited by electrical excitation of forearm and hand muscles. Eight C5 or C6 quadriplegic outpatient subjects are currently evaluating this system. Various aspects of these studies are carried out in conjunction with the Applied Neural Control Laboratory, the Engineering Design Center, and the Rehabilitation Engineering Center at Case Western Reserve University.

Laboratory Development—A flexible laboratory stimulation system has been developed to provide versatility in stimulation and control functions. This system allows us to specify stimulus parameters and the type of controller for a specific patient to be used with the present portable stimulation hardware. The system is capable of processing patient-generated input commands from a number of sources, and of regulating the output stimuli to provide the desired coordinated movement in the electrically stimulated muscle. Ongoing studies of these techniques employing the computer to furnish the laboratory with greater flexibility will allow us to design, model, and specify the criteria for future stimulation units. This system is in routine usage in our FES laboratory for establishing proper stimulation parameters

and coordination algorithms, described below. This aspect of the project is supported in part by NIH–NINCDS Neural Prosthesis Program for software development and the VA RER&D program and NIHR for aspects of the hardware development.

Wrist-Hand Orthosis Development—Orthoses are under development to stabilize wrist position for the C5 quadriplegic to use in conjunction with the FES system. The objective is to fabricate a cosmetic appliance which serves the function of conventional devices, but does not encumber the subject during movement generated by FES. Designs of two alternative devices have been completed and are being evaluated. They are fabricated from polypropylene and utilize either a spiral design or a more conventional structure positioned along the radius.

Electrode Evaluation—The percutaneous wire electrode is used exclusively in these studies for excitation of paralyzed muscle. This electrode is fabricated from 10 strand Teflon-insulated wire, as described in previous reports.

Over the period of the past 28 months, 75 multistrand wire (MSW) electrodes have been implanted, and previous to that 103 of a single strand configuration. Of the MSW electrodes, 72 percent are still intact. Of the remaining 28 percent, only eight electrodes were broken (three in one subject after less than 100 days); the remainder were removed intact because of a change in the contractile response which rendered them nonfunctional. Of 24 implanted for at least eighteen months, 17 (71%) were operational, 3 (13%) broken, and 4(17%) removed intact.

The use of percutaneous electrodes has been a safe, reasonably reliable, and extremely valuable technique for excitation of paralyzed muscle for periods of up to several years. This technique enables one to develop functional stimulation systems for subjects to utilize outside the hospital, and for research and development of new concepts of functional electrical stimulation. In the future, we anticipate that the percutaneous electrode will continue to play an important role: (i) in the investigation of new systems, which can be implemented in human subjects without surgery; and (ii) for enabling subjects to utilize functional systems as outpatients to insure that they are candidates for a totally implanted system. Ultimately, in an appropriate subject, the percutaneous system will be replaced by a totally implanted stimulator, as described below.

Electrode Connector Development—A new electrode connector has been developed for covering the site at which the electrodes enter the skin. The connector serves a dual purpose of protecting the area where electrodes pass through the skin and for electrical connection to external apparatus (see previous reports).

The new connector has been in use for the last year with all of our subjects. The new design enables the patient's attendant to maintain the electrode site without technical supervision. Changing the connector at 2 to 3 week intervals results in a clean, long-lasting site, which can now be accomplished without need for the patient to return to the hospital for routine connector maintenance.

Outpatient Evaluation of Functional Systems—Functional electrical stimulation systems have been developed to supply functional control of grasp and release in nine C5 and C6 quadriplegic subjects. The type of grasp provided was either lateral pinch (key grip) or palmar prehension (three jaw chuck grip). The patient obtained proportional control of grasp/release via one of the several available sources. Eight of nine subjects who have been fitted with this system continue to utilize it on an outpatient basis.

The systems that we have developed for control of hand function utilize a single proportional command signal, generated by the patient, to grade the coordinated movement of four electrically stimulated muscles. In our systems, we have developed a special purpose controller/stimulator which receives external inputs from one of a variety of sources and delegates appropriate strength stimuli to the muscles at the appropriate time. The controller/stimulator is configured modularly to provide for versatile use of the basic system with minimal hardware variations to tailor it specifically to individual subjects (see previous reports).

Six C5 and three C6 quadriplegic patients have been supplied with this system. Only three systems have exactly the same control figuration, demonstrating the individuality, based on the subject's performance and/or preference, that must be provided. To produce the same general type of grasp in different subjects, different muscles frequently were used. These differences enabled us to correct for problems such as unstable joints and denervated muscles.

C5 subjects were required to wear an external orthosis. For lateral prehension, this orthosis stabilized the wrist only. For palmar prehension, the splint was used for wrist stabilization only in one subject, with finger and thumb coordination supplied by the stimulated muscle; in two different subjects the splint stabilized the thumb and finger interphalangeal joints as well. C6 subjects required no orthosis. This enabled them to use the grasp generated by muscle stimulation as an adjunct to their tenodesis grasp, which generally is weak.

Our subjects have been involved in evaluation of the systems, primarily on an outpatient basis, for up to 2½ years. We have a total of 146 patient months of experience with the system. Of the nine subjects fitted with the system, eight are still in the evaluation program. Three use their system regularly; three use it irregularly, primarily for special functions; two are less than four months with the system; one was discontinued. Generally the most active subjects utilize their system more frequently.

Donning of the systems requires less than two minutes if put on while dressing; otherwise lead wires must be threaded beneath the clothing. The patient must have assistance in putting on the system.

The primary problems encountered generally have not been technical in origin. In response to patient suggestions, new command sources have been modified or generated to solve specific problems. Generally the electrodes produce sufficiently reproducible response so that modification of stimulation parameters is rarely required. Thus, no adjustments of any kind are available externally on the patient stimulator. Battery lifetime (approximately two months) is generally sufficient for intervals be-

tween visits by users to the hospital; batteries are not changeable by the user.

Implantable Stimulator Development—The purpose of this study is to develop and evaluate a multi-channel implantable stimulator for electrical stimulation of paralyzed muscle. The implantable unit has been specified to be sufficiently versatile for use in applications in the upper or lower extremity. The implant is a slave receiver/stimulator which processes information received from an external transmitter and directs the appropriate strength stimulus to the proper electrode at the desired time. Two models of the implant have been developed. Both models are totally powered and controlled by an externally induced radio-frequency (RF) signal. This design provides for long life expectancy, since no battery is utilized. The original model of the stimulator is a four-channel device which generates stimuli in a format identical to the present generation patient stimulator (see previous reports). This stimulator has been fabricated using thick-film hybrid circuit technology. A packaging technique utilizing a glass-ceramic material (Macor) has been developed. The package consists of Parylene coating of the circuit, hermetic feedthrough connections provided by a solder/glass seal, and an epoxy seal between the capsule lid and body. Three stimulators have been implanted in animals to evaluate circuitry, packaging, and electrode performance.

The implant circuitry has been redesigned to increase its versatility of operation and its reliability. The second generation has been designed and implemented in a semi-custom CMOS integrated circuit (Monochip-Interdesign). This revision has doubled the number of output channels to eight and allows independent activation of each channel, while substantially reducing the component count. A pulse-coded RF signal provides the implant with (i) power for circuit operation and stimulation; and (ii) coded information regarding channel selection and stimulator output parameters.

Major support for this aspect of the project has been through the NIH-NIGMS, and work is performed in conjunction with the Engineering Design Center at Case Western Reserve University.

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A Single Unit Study of Muscle Afferents in Human Movement

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In the past 6 months, a laboratory at the McGuire V.A. Medical Center has been established with electrophysiological capabilities to monitor and record single unit afferent nerve potentials from muscle receptors in the awake, unanesthetized human. The major receptor presently recorded is the muscle spindle, most specifically the primary sensory receptor, although cutaneous receptors such as touch and pressure, and joint receptors, are readily recorded. Potentials are recorded from the median nerve at the elbow and mid-upper arm and the posterior tibial nerve in the popliteal space.

Electrical stimulation through the recording electrode allows for muscle afferent nerve fascicle isolation, which results in a more rapid muscle spindle nerve fiber location.

Single unit action potential activity is recorded using manually inserted electrodes of insulated tungsten wire, electrolytically tipped and impedance measured at 35–50 kΩ at 1.0 kH. These electrodes are superior to electrodes with an impedance of 100–150 kΩ as originally reported. Electrodes are fabricated by Frederick Haer and Co., Brunswick, Maine.

Preliminary recordings in normal subjects allow criteria to be developed for receptor identification and basic unit activity during rest, passive stretch, muscle twitch, reflex activity and voluntary movement. Techniques for recording and quantitation of range and velocity of movement are being developed, as is a system for computer evaluation of results. Recording devices are being custom designed in cooperation with the Bioengineering and Orthotics Departments.

Monitoring muscle afferent activity in patients with hyperactive syndromes and phasic movements (especially cerebral vascular accident and Parkinsonian patients) is projected for the immediate future. The overall objective of the program is to study the role of the alpha motor-fusimotor system in human normal and pathological movement.

Functional Spinal Cord Regeneration

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In order to investigate the capacity of the adult mammalian spinal cord to recover function after injury, it is imperative that an understanding of the central segmental (spinal cord) synaptic organization of motor control is accomplished. Since the last progress report (BPR 10-35) substantial progress in this laboratory has been made in understanding the organizational principles of the monosynaptic projections of spindle 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. Since the introduction of the powerful technique termed spike-triggered computer averaging (STA), the central synaptic actions of single group Ia and group II spindle afferents have been the subjects of considerable experimental interest (11, 13–16, 18–20, 22, 25, 26). However, few studies have directly examined the general principles of organization observed

by these two muscle spindle afferent systems. In recent studies of this laboratory, the synaptic actions of single medial gastrocnemius (MG) group Ia and spindle group II afferents in triceps surae motoneurons have been compared in great detail leading to new hypothesis regarding the organization principles of the spindle afferent system (17, 24).

Using STA methods and intracellular micropipette electrodes, the monosynaptic excitatory actions of 67 MG Ia and spindle group II afferent fibers on 1,027 triceps surae motoneurons were investigated in cat lumbar spinal cord. The results of these studies allowed comparisons of both Ia versus spindle group II afferents, and rapidly versus slowly conducting fibers, within each spindle afferent group with respect to conduction velocity in the dorsal funiculus, projection of major collateral branches to triceps surae motoneuron pool, ramification of major collateral branches within the pool, functional connectivity with triceps surae motoneurons, and parameters of monosynaptic excitatory postsynaptic potentials (EPSPs) elicited in triceps surae motoneurons.

Based on these data, the functional organization of the MG groups Ia and II spindle afferent projections to the triceps surae motoneuron pool is summarized in the schematic diagram of Figure 1. The stem axons in the dorsal funiculus (including the caudally directed branches) of both groups Ia and II spindle afferent fibers give up to nine major collateral branches into the triceps surae motoneuron pool (13, 14). These major collateral branches descend from the stem axon into the motoneuron pool at about 1.0 to 1.5 mm intervals. Within the motoneuron pool, terminal branches extend both rostally and caudally (13, 14). These rostro-caudal terminal arborizations are much more extensive for group Ia afferents than for group II afferents. Moreover, our evidence indicates that the spindle group II afferents with faster conduction velocities have more extensive terminal arborizations than spindle group II afferents with slower conduction velocities.

The samples of group Ia and spindle group II single fiber EPSPs were each divided into a fast conducting subgroup and a slow conducting subgroup using the observed mean conduction velocities of the respective spindle fiber groups: fast group Ia afferents ($\geqslant$ 98 m/s); slow group Ia afferents ($<$ 98 m/s); fast spindle group II afferents ($>$ 52 m/s); slow spindle group II afferents ($<$ 52 m/s). Functional connectivity was found to be greater with homonymous than heteronymous motoneurons (group Ia; 86% vs. 57%; group II: 50% vs. 17%); greater for the combined Ia sample than the combined group II sample (78% vs. 42%); and greater for fast than for slow afferents of each type (group Ia: 84% vs. 75%; group II: 57% vs. 23%). The mean amplitude of single fiber EPSPs elicited by spindle afferent fibers was also found to be greater in homonymous than heteronymous motoneurons (group Ia: 88 μv vs. 67 μv; group II: 24 μv vs. 17 μv, not significantly different at the 0.01 level); greater for the combined group Ia sample than the combined group II sample (82 μv vs. 23 μv); and greater for fast spindle afferents than slow spindle afferents (group Ia: 97 μv vs. 74 μv; group II: 24 μv vs. 21 μv, not significantly different). The 10–90% rise time and half-width of single fiber EPSPs elicited by group Ia afferents were not significantly different from those elicited by spindle group II afferents. These data are taken as evidence that the distribution of active terminals of single spindle afferent fibers on the surface of the motoneuron is largely unrelated to the type or size of the afferents. The mean EPSP latencies (measured from the terminal potential) were significantly longer for single fiber EPSPs elicited by spindle group II fibers (0.57 ms) than group Ia fibers (0.50 ms). However, amplitude-matched subsamples of single fiber EPSPs elicited by Ia and group II spindle afferents demonstrated no significant difference in EPSP latency. Rise time and half-width also did not differ between these subsamples. These data lend further support to the hypothesis that Ia and spindle group II afferent fibers have similar distributions of active terminals on the motoneuron soma-dendritic membrane. Overall, these findings indicate a similarity in the central organization of Ia and spindle group II afferents.

Of the variables studied which may discriminate between the central actions of spindle groups Ia and II afferents, single fiber EPSP amplitude may be the most significant, since virtually all spindle group II single fiber EPSPs are less than 70 μv whereas only about one-half of group Ia single fiber EPSPs are less than 70 μv. The differences between the actions of the two spindle afferent systems appear to be largely quantitative (peripheral conduction velocity, functional connectivity and single fiber terminal potential (TP) and EPSP amplitude). Based on our analysis of the central actions of slowly and rapidly conducting fibers of the two spindle afferent groups, it appears that these measured differences are strongly related to peripheral afferent conduction velocity and, hence, to the diameter (size) of the afferent fiber.

Identification of abiding general principles of organization in the central nervous system has been exceedingly difficult. Henneman and colleagues (3, 4, 10, 21, 27) have found evidence that the neural "energy" necessary to discharge a cat lumbar motoneuron, the energy the motoneuron transmits and releases through the muscle cells it innervates, the motoneuron's mean firing rate, and its excitability and inhibitability are all correlated with the motoneuron's size. Based on such correlations, Henneman and colleagues (3) developed the concept of "the size principle" to describe the influence of cell size on the functional properties of motoneurons. More recently, Lüscher et al. (7) have extended the application of the size principle to the Ia and spindle group II afferent systems. Our data lend strong support to the hypothesis that the distribution and density of functional connections of both groups Ia and II spindle afferents are dictated, in part, by afferent size. The larger the spindle afferent fiber, the greater the functional connectivity and the magnitude of the monosynaptic excitatory effect on spinal motoneurons. Contrary to the conclusions of Lüscher et al., however, our data indicate that the size of the sensory neuron bears no relation to the location of its active synaptic terminals on the soma-dendritic membrane of spinal motoneurons.

Relationship of M and S boutons to group Ia and spindle group II terminals:—The present data indicate that the two central actions that best distinguish between group Ia and spindle group II afferents are single fiber EPSP ampli-

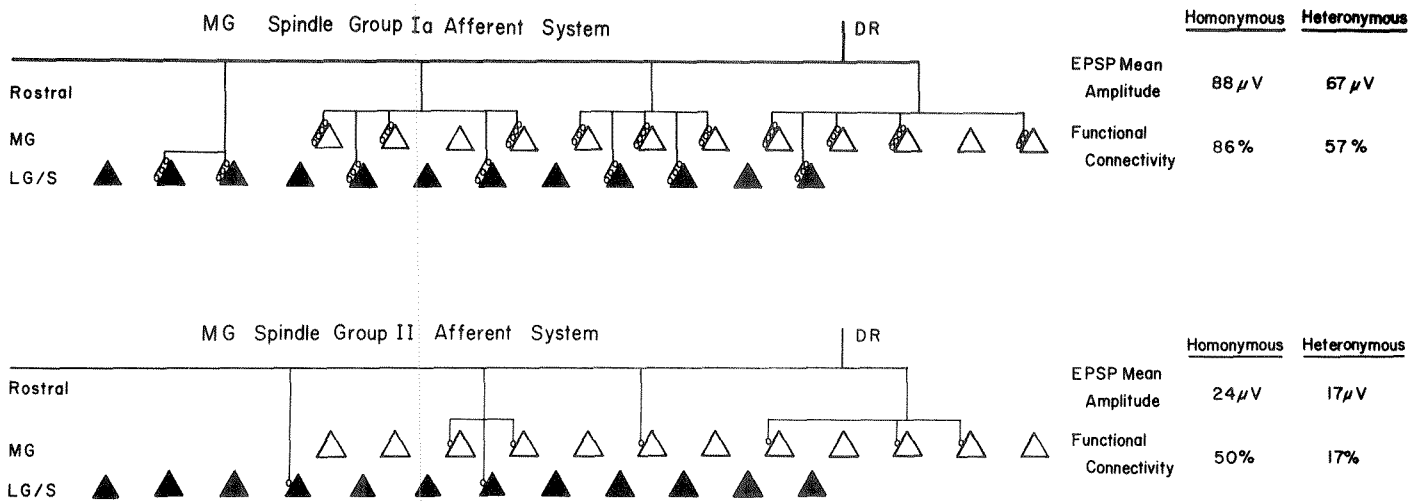

FIGURE 1.
A schematic model of the functional organization of the overall projection of single medial gastrocnemius (MG) group Ia fibers (above) and single MG spindle group II fibers (below) to homonymous and heteronymous motoneurons. Open triangles represent homonymous motoneurons, and filled triangles represent heteronymous motoneurons. The relative density of active terminals (open circles) is estimated, based on the mean amplitude of single fiber EPSPs. DR refers to dorsal root. (Reproduced from ref. 24; copyright 1980 J. Neurophysiol., The American Physiological Society.)

tude and single fiber TP amplitude. Single fiber EPSP and TP amplitudes of group Ia and spindle group II fibers are significantly different. The mean group Ia EPSP amplitude is about three times as large as the mean spindle group II EPSP amplitude and the mean group Ia TP amplitude is about twice as large as the mean spindle group II TP amplitude. Only group Ia fibers appear to be capable of generating large amplitude single fiber EPSPs (> 150 μv) and large amplitude single fiber TPs (> 20 μv) (14, 16). In contrast, spindle group II afferents appear to elicit many more small amplitude single fiber EPSPs (< 10 μv) and TPs (< 5 μv) than do group Ia afferents (13). Furthermore, in single fiber EPSP amplitude-matched samples, a significant difference persisted in the mean amplitude of single fiber TPs of the two spindle afferent types (13). In fact, the amplitude difference between group Ia and group II-elicited TPs in the matched samples was almost as great as in the parent samples. It is possible that these physiological differences may reflect anatomical differences in the central terminations of group Ia and spindle group II afferent fibers.

Conradi (1) has shown that two types of presynaptic boutons terminating on spinal motoneurons disappear following dorsal rhizotomy in cats: type M boutons and a subclass of S boutons which are characterized by their relatively large size and by the apposition of P boutons. Certain evidence is consistent with the hypothesis that group Ia fibers may terminate as M boutons and spindle group II fibers may terminate as S boutons. Firstly, the rapid disappearance of both bouton types following dorsal rhizotomy indicates that both are primary afferent terminals that monosynaptically contact motoneurons. Secondly, these large S boutons are smaller than M boutons. Although there are no anatomical data on the relative number of terminals ending on motoneurons from Ia and spindle group II fibers, this difference in bouton size is consistent with our findings that spindle group II single fiber EPSPs and TPs are generally smaller than those of group Ia fibers. Finally, the majority of both M and S boutons are located on the proximal parts of the motoneuron dendrites often close to the cell body (1). This anatomical finding predicts that M and S boutons should elicit EPSPs with similar temporal parameters. Our observations for group Ia and spindle group II afferent single fiber EPSPs are consistent with this prediction. Critical testing of this hypothesis must ultimately depend on ultrastructural examination of labelled (e.g. horseradish peroxidase) and physiologically identified group Ia and group II spindle afferent terminals in contact with alpha motoneurons.

Spindle afferents: One system or two?—In working with these data on the central actions of spindle afferent fibers, one is struck more by the unity of the two spindle afferent systems than by their divisibility. Peripherally, the anatomical and functional properties of the primary and secondary spindle afferent endings are clearly distinguishable (2, 5, 8, 9, 12, 23). Both receptors are sensitive to tonic stretch of the host muscle, but primary and secondary spindle afferents are differentially responsive to the dynamic aspect of muscle stretch. Even dynamic sensitivity, however, has been found under certain experimental conditions to exist as a continuum, progressively increasing from fast group II through slow Ia spindle afferents (8). Interestingly, Loeb and Duysens (6) have characterized one spindle afferent conducting at 70 m/s as a group Ia, and another conducting at 85 m/s as a spindle group II. Like Matthews (9), these authors consider conduction velocity unreliable for spindle afferent classification in the range from about 65 m/s to 85 m/s.

Single-fiber EPSP amplitude and functional connectivity for the spindle afferent systems decrease according to afferent conduction velocity, from fast group Ia through slow group II afferents. There are no systematic differences in the location of afferent terminals on the motoneuron that are related to the major spindle afferent

classification. Since both afferent systems observe a number of common organizational principles in their monosynaptic excitatory connections with motoneurons, differing in the number of motoneurons contacted and the amplitude of the EPSPs generated, group Ia and II spindle afferents may comprise one continuous functional system that is organized in adherence to a size principle (17).

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Studies for the Design of a New System for Stabilization of the Cervical Spine

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The initial aim was to determine the forces and moments acting in the currently used halo-vest systems. As a preliminary study, to determine the upper bounds of linear forces, an apparatus was constructed to immobilize the torso of a seated subject. Force transducers were used to measure maximum head forces. Normals produced 177 Newtons (N) to the right, 161 N to the left, 126 N forwards and 148 N backwards.

An axis system was defined in the halo-vest, which specified the three forces and three moments acting on each side at the halo vertical rod connections (Fig. 1). To determine some of these forces and moments, clip-on inductance type strain gages (Hottinger-Baldwin) were used. Use of a clip-on system allowed versatility in dealing with the various designs of halo-vest, and avoided permanent attachment. The gages were connected to carrier demodulator units (Celesco), thence to a chart recorder (Gould) for recording and amplification, and finally through an a/d converter to an Apple Plus II computer. An intrumented halo device is shown in Figure 2.

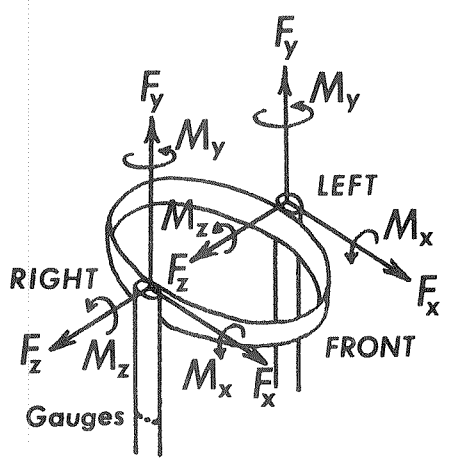

FIGURE 1.
Axis system defined in the halo-vest, specifying the three forces and three moments acting on each side at the halo vertical rod connections.

Equations were written to relate the strains, at points on the various metal rods connecting the halo and the vest, with the forces and moments and with various dimensional constants and materials properties.

Computer programs were produced for various locations of the four gages on the rods of the different halo-vest designs. (The designs included the Ace MKI, MKII and MKIII and the Pope). At the start of each test session, the gages were attached, their locations measured and keyed into the computer, along with the material (steel or aluminum). The test subject then relaxed and the gages were balanced.

The particular activity was then carried out while the computer continuously sampled and stored the strain data. The program computed the forces and moments for each set of data, and determined the maximum values. (The maxima did not necessarily occur at maximum strains). These maximum values were then displayed and printed. When they were satisfactory, the next activity was carried out.

A selection of the maximum values obtained from three normals (using rubber pads between the head and the halo ring instead of pins into the skull) and four patients is shown in Table 1. Note that the values obtained are for one side of the apparatus. Assuming symmetry, the total F_y would be double, while F_x would be double, or plus and minus in turning activities. The limited data available show patients to be similar to normals. Activities not shown in the table, such as walking up and down steps, gave generally lower forces. The force values are all relative to the relaxed position and do not necessarily represent absolute forces relative to zero frame loading. Forces in the horizontal direction F_x were significant as well as the vertical forces F_y.

It appeared that the most important factors in generating large forces were gravity (the weight of the head) and geometrical changes of the body such as when pushing upwards from seated, or shrugging. Muscle forces and inertia forces were probably contributory but apparently to a lesser degree.

Our studies are providing the data to enable an analysis of new design configurations, which will be the next phase of the work.

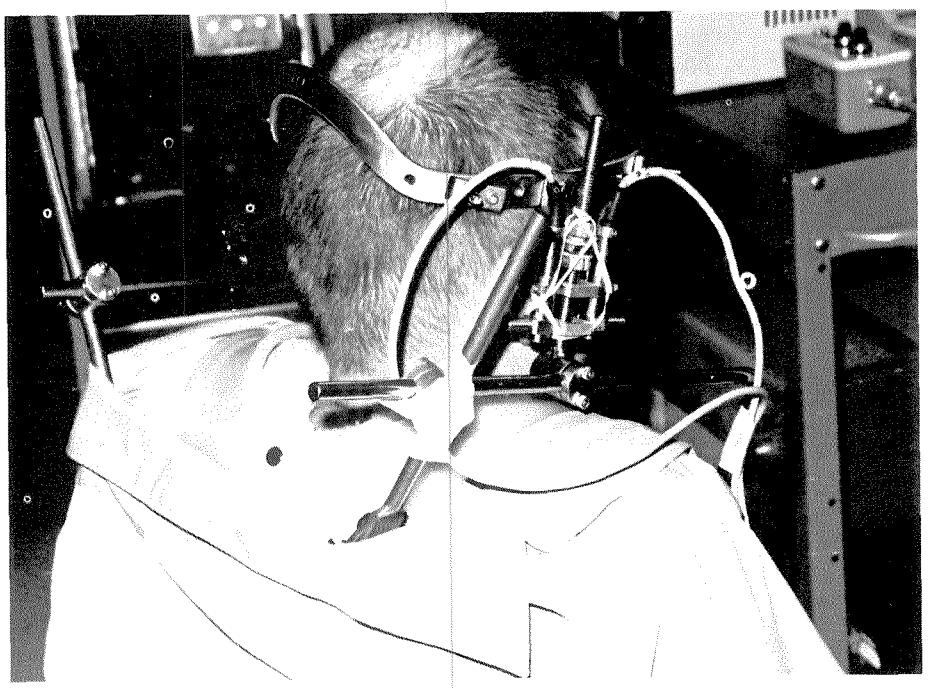

FIGURE 2.
Clip-on strain gages in use. These allowed versatility in dealing with various designs. Computer programs were produced for the differing locations of the four gages on the rods of the various halo-vest designs tested.

TABLE 1.
Maximum forces (in Newtons) obtained from 3 normals and 4 patients for various activities. Forces, shown for one side of the halo-vest, are not absolute relative to zero frame loading, but are relative to those at the "relaxed" position.

Activity	Normals		Patients	
	F_x	F_y	F_x	F_y
Reaching forwards or upwards	40	10	26	—
Reaching arms across chest	43	46	—	51
Bending to floor from seated	28	17	18	93
From lying to seated or vice versa	80	45	40	—
Looking left to right	—	—	25	60
Looking up and down	47	14	18	—
Crouching down	42	—	19	—
Pushing up from seat	60	—	—	79

Development of a Wheelchair Using a Myoelectric Control System

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Progress has been made in both: (i) the investigation of the rate at which information can be transferred over a single myoelectrical channel with temporal patterns of minute all-or-nothing pulses, and (ii) the development of a myoelectric command code for wheelchair control. The requirement for automated experimental facilities to perform the myoelectric information rate investigation was presented in the last progress

report (BPR 10-35). This equipment is now fully functional. It monitors the temporal pattern of myoelectric activity and provides on-line feedback that displays the different types of errors made by an experimental subject when attempting to generate specific myolectric patterns. The two patterns currently used are a single myoelectric pulse (P1) and two distinct sequential pulses (P2). This equipment makes possible attempts to train subjects to generate such patterns in time frames that are too short for conscious attention to the generation of the fine structure of the patterns. For example, P2 is to be generated in a time duration that is too short for two distinct attention states, one corresponding to the generation of the first pulse and the other corresponding to the generation of the second pulse. Initially a pulse-pair spacing of 500 milliseconds (easily generated with conscious attention to each of the distinct pulses) is used to familiarize the subject with the feedback for different types of errors and then the pulse spacing is decreased in steps to 50 milliseconds. Experimentation to obtain data pertaining to human error rate when generating such pulse pairs in a short time frame is currently underway. The ability to use either P1 or P2 in a time frame that is less than twice the time that is normally required for a simple myoelectric response will increase the rate of information flow over a single myolectric channel.

The myoelectric command code for wheelchair control that was described in the last progress report (BPR 10-35) has been implemented. A microprocessor program has been written to provide the required decoding for the experimental myoelectric wheelchair in operation at the West Roxbury VA Medical Center. The program resides in an EPROM, an integrated-circuit memory that is capable of storing computer programs. The EPROM is installed in the microcomputer that has been especially designed for operating the wheelchair. This decoding system is in operation and performs well. The decoded myoelectric signals activate relays that perform functions identical to the functions performed by the microswitches in the joystick assembly of the Everest and Jennings type 34 control unit.

Experience with myolectric wheelchair control has led to the conception of a technique for upgrading the myoelectric system from switched control (E&J type 34) to proportional control. This technique will be implemented before extensive testing of the current system with patients. Two myoelectric channels will be used. The right and left occipitofrontalis muscles have been chosen for the initial experimentation. In high level quadriplegics these muscles are both fully innervated and not spastic. They can be used conveniently with electrodes that are built into a headband.

Right occipitofrontalis muscle myolectric activity will operate the right wheelchair drive motor. The speed of this motor will increase with the firing rate of motor units of the muscle. The left occipitofrontalis muscle will be used for similar control of the left drive motor. A specific combination of activity levels in the two occipitofrontalis muscles will map into the coordinates of a corresponding position for the joystick of a proportional control system. This mapping covers all possible joystick locations that correspond to various forward speeds for the two drive motors.

Provisions are also made to cover all joystick locations that correspond to various reverse speeds for the two drive motors. A rapid twitch of the right occipitofrontalis muscle will change the state of the right motor reversing relay. A rapid twitch of the left muscle will reverse the direction of the left drive motor. The reversal mechanism will be automatically disabled during operation at moderate and high speeds to avoid accidental whiplash. The wheelchair can be rotated in place by reversing only one of the motors.

Preliminary experimentation has been performed to assess the practicality of using the occipitofrontalis muscles for the proportional control technique described above. Both myoelectric activity of the right occipitofrontalis muscle and myoelectric activity of the left occipitofrontalis muscle were simultaneously observed on a two-channel oscilloscope. It is apparent that a large percentage of wheelchair operators will require practice in order to directly control their right and left occipitofrontalis muscles with adequate selectivity to make sharp turns. A technique has been found to achieve the desired control indirectly, eliminating the need for such practice. This technique is based upon the neural interconnection that results in activation of the occipitofrontalis muscle when the eye is closed tightly. Closing the right or left eye independently activates the corresponding occipitofrontalis muscle.

The following example illustrates the use of this indirect but independent control. An operator is initially traveling forward. He desires to make a very sharp left turn. He transfers control of the right occipitofrontalis muscle to the indirect mode by closing his right eye. This allows him to keep the right wheel turning at any desired speed while reducing or eliminating left wheel drive in order to execute the sharp left turn. Note that the code is structured in such a way that the left eye is open when making the sharp left turn. If the code had been structured so that the left occipitofrontalis muscle controlled the right wheel, this sharp left turn would have been made with the left eye closed.

Rotating in place represents another case where the high right-left selectivity that is easily achievable with eye closure can be used. Rotating in place, with the wheels turning in opposite directions, corresponds to a sidward movement of the joystick of a manually operated wheelchair. A rapid closure of one eye will result in reversal of only one drive motor. As a result, an operator not proficient at independently activating his right and left occipitofrontalis muscles could rotate in place. It has been observed that normal automatic eye blinks do not produce significant occipitofrontalis activity, thus they will not interfere with this mode of myoelectric wheelchair control.

Seat Cushions for the Paralyzed

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An evaluation of the skin loads during sitting, and corresponding blood flows as measured in geriatric hospitalized patients, has been published in the Ar-

chives of Physical Medicine and Rehabilitation.

A similar evaluation of paraplegic subjects is currently in progress. Results to date suggest that the paraplegic sitter resembles the geriatric. Sitting loads can be far higher than those developed by the normal, and associated skin blood flows (in the vicinity of the ischial tuberosity) can be considerably smaller. Thus we conjecture that the high rate of pressure sore incidence in paraplegic and geriatric patients reflects not only lessened mobility and insensitivity to load, but also a decreased perfusion capability.

Foot Biomechanics: Force and Pressure Distribution in Health and Disease

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We have submitted our study on the stress distribution on the plantar aspects of the foot for publication. The study used a finite element analysis of the foot within the shoe to determine the effects of shoe sole elastic properties upon pressure. This revealed a significant dependence of the stress on the stiffness of shoe sole material. Shoe soles of intermediate stiffnesses lowered stresses.

We have calibrated thin pressure transducers and are starting to apply them to the feet of healthy subjects and those with foot diseases and disorders.

We have developed a lighted walkway in the floor to record pressure images during gait, and this is ready to use on patients with a variety of foot disorders both before and after treatment.

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

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The research program at Johns Hopkins for the Veterans Administration continues to be focused on the development and evaluation of assistive devices for the high spinal-cord-injured person. Improvement of interface devices, and clinical evaluation of the robotic arm/worktable system and chin controlled wheelchair, were the principal activities of the project during the reporting period. Progress and accomplishments during the January–June 1981 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. Seven E&J wheelchairs equipped with this system are currently being evaluated by volunteer quadriplegics. Testing periods range from a few months to over 3 years in daily living environment. Test models include both open-loop torque control and closed-loop velocity control. Overall results to date indicate that, while closed-loop control with its self-braking characteristics and adjustable velocity limits contributes to wheelchair safety, such features are important only in an outdoor environment. The features do not appear to be required in indoor or institutional environments.

The latest volunteer to receive a chin-controlled wheelchair is a well-educated 35-year-old quadriplegic with neuromyelitis optica of 16 years duration. His only useful upper-limb function derives from a small unilateral remnant of active shoulder musculature. This musculature produces a very weak and limited motion of the hand when appropriately supported. Residual head-neck motion is about ⅔ of normal and is also weak and poorly coordinated.

Prior to participation in this project, this individual had been provided with an E&J non-proportional electric wheelchair with a conventional hand-operated joystick controller and a wrist-hand orthosis designed to assist joystick contact and manipulation. With this equipment he was able to travel independently about the unobstructed corridors of the nursing home in which he resided. His wheelchair control was jerky and erratic. He was obliged to travel very slowly. He could not negotiate narrow places or back up without risk of collision. He could not handle elevators, inclines, irregular surfaces or outdoor terrain. Due to these problems, a non-motorized wheelchair propelled by an attendant was frequently used in preference to the motorized one in order to move him about.

This individual was invited to participate in this program in order to compare his performance using the older wheelchair, manual joystick and control system with that using the new wheelchair with advanced chin controller and closed loop velocity control system. Following equipment delivery and patient orientation, he used the new equipment exclusively for several weeks.

At the end of the test period it was felt by the operator and various knowledgeable observers that his performance with the new system approximated that with the old one and offered no significant advantages. Due to his poorly coordinated head and neck motions, he operated the new proportional wheelchair in a non-proportional mode. He had difficulty switching between reverse and forward. He could not use the high-speed capability or handle the wheelchair safely on ramps or outdoors, regardless of the closed-loop velocity control feature.

It was felt that evaluation by this quadriplegic had enabled better identification of the limits of usefulness of a high technology wheelchair controller. With due consideration of this operator's limited cervical spine range of motion and his poor coordination, it was decided that further testing by him would be unproductive. The test equipment was therefore withdrawn for further evaluation by other types of quadriplegics.

In contrast, during 3 years of evaluation of the chin controller in which the majority of instances have yielded highly successful results, most of the users have possessed better cervical spine range of motion and reasonably good coordination of head and chin motion (see BPR 10-34). Accordingly, discus-

sions are being held with potential manufacturers to try to bring these wheelchair controllers to the market place.

Robotic Arm/Worktable System

Research on the robotic arm/worktable system during the reporting period was primarily concentrated on evaluation testing by a quadriplegic volunteer in his home environment which is also used for the family-owned business. This individual was furnished a complete system which consisted of a dual-purpose chin controlled wheelchair and a robotic arm/worktable system. For a detailed description of each of the subsystems, see BPR 10-35, 10-34 and earlier issues.

The worktable was configured with a low-cost personal computer system located in the main work area of the table and a self feeding arrangement at one end of the table. This quadriplegic volunteer is shown in the self feeding location in Figure 1. Food is placed in three bowls and the robotic arm is programmed to allow self feeding capability with minimal assistance. A typical meal required 30 to 40 minutes to complete.

On the left side of the worktable, a personal computer system is set up to allow handicapped individuals to use a computer with minimal additional help. One feature of this equipment arrangement is the tilted keyboard to allow good mouthstick accessibility. The robotic arm is utilized to insert into and remove the program diskettes from the disk drive. A reading stand permits use of written materials (mouthstick used for page turning) when working with the computer. A telephone located on the table is manipulated with the robotic arm. Figures 2 and 3 show the quadriplegic volunteer in his wheelchair located in the normal work position in front of the computer.

The worktable is designed to permit self docking so that the individual may come to or leave this work area without assistance from an attendant. This feature has worked very well. All control inputs to the robotic arm are via the wheelchair chin controller inputs. Shown in Figure 2 is the robotic arm placing a diskette into the disk drive under robotic arm program control. Provisions are made to store four diskettes in the rack above the disk drive. Figure 3 shows the telephone held in position for conversation.

In the 6 months of evaluation in this environment, this volunteer has verified the capabilities of this system to perform the designated functions in a reliable manner. The chin controller interface was easy to learn to use and it worked reliably. The combination of robotic arm capability and mouthstick capability gives the user flexibility to carry out many tasks on his own. The system has exhibited excellent reliability with only one failure (broken wire) during the 6 months continuous test period. The one attribute which appears to need improvement is speed of response in the use of the telephone and of the self feeding modes. A second advanced model robotic arm, now being completed, operates with simultaneous motion in three axes and is expected to reduce the time to accomplish these tasks to acceptable levels. This individual has taken full advantage of the opportunity over the past 6 months to learn how to use a personal computer, including learning BASIC language and use of some disk programs, and plans to continue working with a computer when these tests are completed during the summer of 1981.

Pseudo Morse Code Interface for Computers

During the course of the evaluation of this robotic arm/worktable system, the mouthstick was found to be generally adequate for keyboard entry except for the multiple key input requirement for key shift and for some word processing programs. Fatigue is also another problem if continuous inputting with the keyboard is required (more than one-half hour at a time). In order to solve these problems, a new technique was evolved as an alternative to keyboard entry to the computer. The requirements for this alternative to the keyboard were that it had to provide standard computer keyboard functions, including upper and lower case, multiple key entry, as well as the capability to operate at an input rate of 10–20 words per minute, and it should permit sustained work at the computer without fatigue. The new system evolved from this program makes use of a standard Morse code high-speed paddle mounted on an adjustable bracket. Minute (less than 1/16 inch) chin motion is required to generate the code. A series of dots or a series of dashes are generated by depressing and holding down one side or the other of the paddle, thus minimizing chin motion input.

The output of the keyer device is sent to a single chip microprocessor which translates the Morse code into ASCII code and serially transmits this signal at 300 baud to the computer terminal via a standard RS-232 input system. Standard Morse code characters are used for the alphabet and numerics and some additional codes are created to complete all keyboard functions including shift, space bar, control, repeat, and other special keys. In order to maximize the character entry rate for a given physical motion capability, a pseudo Morse code is utilized. The code system selected for this purpose utilizes dots and dashes having equal dwell time but distinguishable from each other by utilizing high pitch tones for dots and low pitch tones for dashes. This pseudo Morse code improves the throughput speed by about 30 percent for a given physical capability.

Since this system can contain the full ASCII set and outputs via a standard RS–232 signal, it is compatible with a wide variety of computers, including the Apple II, Radio Shack TRS–80, and many commercial time-sharing terminals. Operation with each of the above models has been demonstrated in the Laboratory. In demonstration testing with an Apple Computer, word processing with Applewriter was shown to be a practical task. Writing programs in BASIC, including use of a disk drive for data storage and retrieval, is readily accomplished. A steady rate of 60 characters per minute for long periods was demonstrated to be feasible.

The system as presently configured is a stand-alone system comprised of a commercial high-speed Morse code paddle mounted on a bracket, a single microprocessor chip to perform the Morse-to-ASCII conversion and tone generation, and a RS–232 connector to the host computer. In application programs such as Applewriter (word processor program), additional special codes were added in the microprocessor to simplify the mechanics of calling up such commands as "delete word, delete paragraph, change the cursor to move to a specified portion of the text, return to BASIC, etc."

It is anticipated that this system may

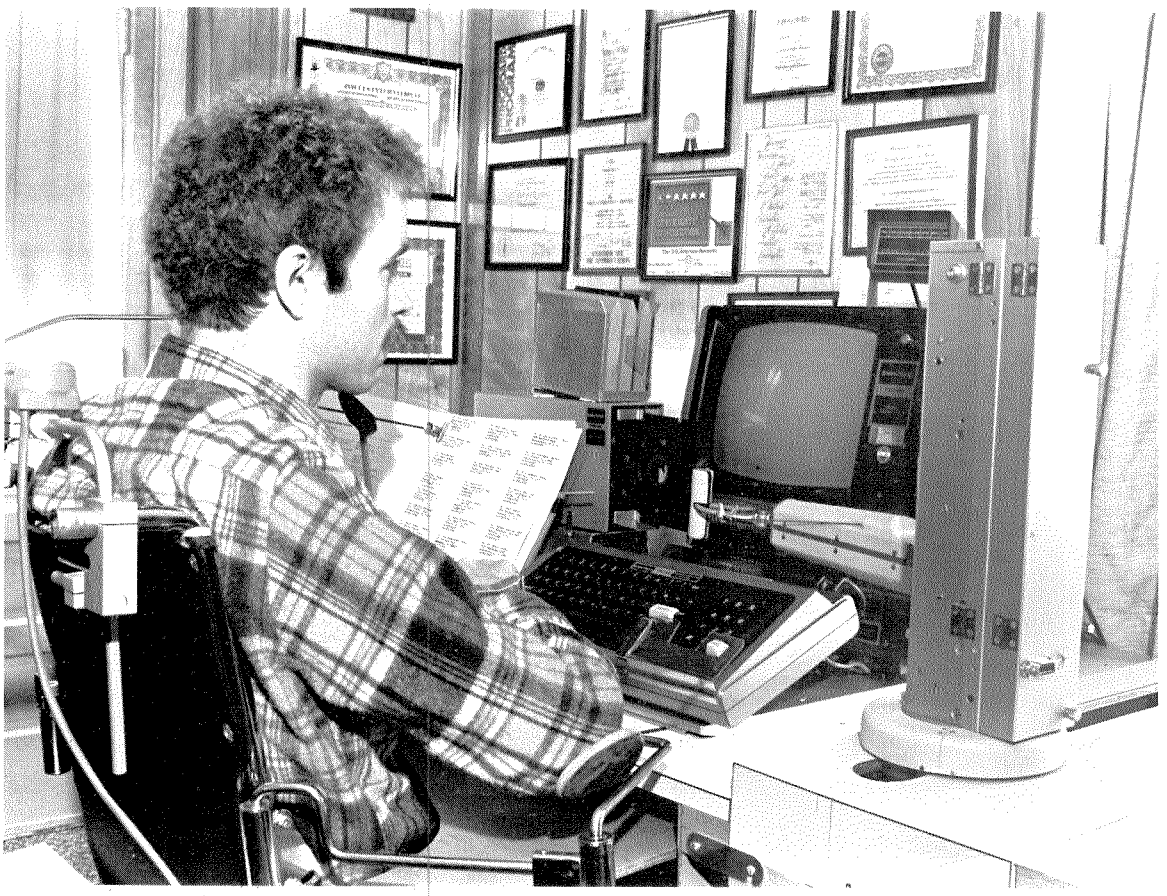

FIGURE 2.
Robotic arm (foreground) is programmed to permit precise tasks, such as placing a diskette into the mini disk drive, to be carried out on command.

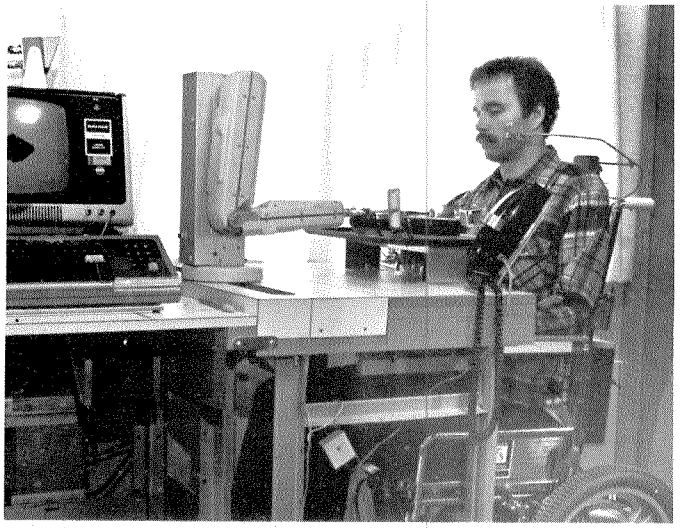

FIGURE 1.
Quadriplegic evaluates self feeding capability of robotic arm system

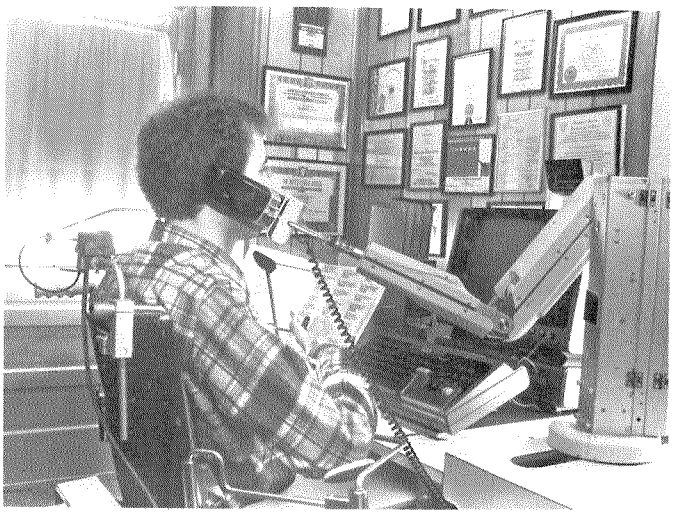

FIGURE 3.
Multiple-task capability is made possible by worktable layout and by the combined use of the robotic arm and a mouthpiece.

have a broad application to a wide class of handicapped persons including quadriplegics, persons with minimal hand or arm function, and certain non-vocal persons who need flexible communication means. It is a low-cost device and we are actively contacting potential manufacturers to try to make the system available to potential users.

Powered Upper Limb Prosthesis

During previous years of research, this project team developed and evaluated motor units and control systems for powered upper-limb prostheses (see various articles in BPR 10-13 through 10-22). This design concept uses a single drive motor and a cable drive system to power a VO Dorrance series 5 hook and/or elbow motion. Although experimental models were highly successful in clinical trials, attempts in previous years to find a manufacturer were unsuccessful.

Dankmeyer Inc., a Baltimore manufacturer of artificial limbs, expressed interest early in 1981 to manufacture and distribute a motor unit and control system for upper-limb prostheses based on this concept. This firm has enlisted an electronics manufacturing company to make the electronics and battery pack. Engineering prototypes are presently being developed. If the prototype models are successful, it is expected that Dankmeyer will make the unit available commercially.

Foreign Body Reaction in the Lung to Intravenously Injected Biomaterials

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Work during this period continues to be devoted largely to defining the role of surface area in granuloma formation in response to the presence of divinyl copolymer beads (Biobeads SX-8, BioRad) in the lung (see BPR 10-35).

The area of the granulomas, formed in mouse lungs perfused with a fixative, was measured by tracing the outline of the granuloma and bead projected on the ground glass of a light microscope, and the total area of the granuloma determined with a Numonics Electronic Graphics Calculator by substracting the area of the bead from the total.

Other studies—Studies are continuing to use the bead model with sieved 45–53 μm beads to measure the effectiveness of anti-inflammatory drugs. We have tested six anti-inflammatory drugs to date (acetyl salicylic acid, ellagic acid, polyanetholsulfonic acid, hydrocortisone, azathiaprine and bacterial levan (prepared with Erwinia herbicola)), and preliminary results indicate that this model bead system provides a consistent and reproducible method for assessing the anti-inflammatory activity of these drugs.

Publications not previously reported

Coleman SE, Hood CI, Schoen FJ, Robinson M: Electron microscopic study of the effect of anti-inflammatory agents on the foreign body response in mouse lung. Absts. of Southeast Electron Microscopy Society, 1980.

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

A Grommet Bone Liner for Flexible Implant Arthroplasty

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Surgical Implantation and Harvesting

As of March 5, 1981, all surgical implantations at the Veterinary Clinical Center at Michigan State University of the textured full grommets and shim grommets were completed. A total of 17 proximal and 17 distal textured full grommets, and 18 proximal and 18 distal textured shims were implanted. Harvesting has been accomplished as close to the proposed dates of sacrifice as possible (See Table 1, pp. 112–113, in BRP 10-35, Spring 1981, Vol. 18, No. 1).

Biomechanics

As of May 31, 1981, fourteen full grommets and twelve shims were submitted to the Biomechanic Department of Michigan State University for testing. Partial results from these tests are included in this report (Table 1).

Histology

As of May 31, 1981, sectioning and microscopy has been done on all samples which were submitted to the Histology Department at Michigan State University. Because of the imminent retirement of the pathologist on this project, another source of the processing and microscopy for the textured samples has been procured. Samples will be processed by Gerry H. Kenner, Ph. D., Associate Professor of Bioengineering, Clemson University, South Carolina.

Specimen retrieval, trimming, and initial fixation in buffered formalin will be done at Michigan State University. After the samples are received at Clemson University, they will be processed through a graded series of daily alcohol changes (once 70%, twice 95%, once 99%) followed by two daily changes of polymerized thin methylmethacrylate resin. Final embedding will be in thick, prepolymerized methlymethacrylate resin.

The polymerized block will be trimmed to approximately a 0.5 in cube. Five or more sections, each 250-500 micrometers thick, will be cut from the block using a diamond saw blade (metal) or a

TABLE 1.
These figures are results from the more recent tests that have been run by the Department of Biomechanics.

	RIGHT SIDE	LEFT SIDE	REMARKS
Rabbit #27 Test 13 tested 8/28/80 Material SSS	Implanted 7/8/80 **Distal Femur** Max. load 10.14 lb.	No implant.	Only one side was implanted (right distal femur). Test went well.
Rabbit #45 Test 14 tested 2/4/81 Material TCG	Implanted 12/22/80 **Prox & Distal** No test results.	No implant.	Animal died from a broken back. Tried test: no results due to grommet falling out during the setup.
Rabbit #42 Test 15 tested 3/11/81 Material TCG	Implanted 11/17/80 **Distal:** Bad angle but the results are Max. load 35.7 lb. **Prox:** Good alignment. Max. load 14.80 lb.	Implanted 1/14/81 **Distal:** Good alignment. Max. load 23.7 lb. **Prox:** Pulled out during setup. Approx. load 2 lb.	Good test series from this specimen. Some trouble with the angle on some femur grommets.
Rabbit #47 Test 16 tested 4/27/81 Material TCG	Implanted 12/23/80 **Distal:** Very little bone around the grommet. Max. load 2.1 lb. **Prox:** Good test. Clamp slipped but grommet did not move. Max. load 16.4 lb.	Implanted 3/2/81 **Distal:** No test result. Fell out during prep. **Prox:** Good test results. Max. load 11.3 lb.	Good tests. Heavy wear on the Silastic implants from both sides.
Rabbit #48 Test 17 tested 4/27/81 Material TCG	Implanted 12/23/80 **Distal:** No test. Fell out during prep. No bone around grommet for support. **Prox:** Good test. Max. load 18.0 lb.	Implanted 3/2/81 **Distal:** Good test results. Max. load 16.0 lb. **Prox:** Good test even though the load is low. Max. load 4.5 lb.	Tests went well.
Rabbit #55 Test 18 tested 4/27/81 Material TCS	Implanted 12/29/80 **Distal:** Good test results. Max. load 8.6 lb. (Clamp slipped. Little bone around grommet.) **Prox:** Test results, Max. load 4.5 lb.	Implanted 3/4/81 **Distal:** Tried a new clamp. Max. load 3.4 lb. **Prox:** No test; bone badly fractured, could not get a grip on it.	Test went well but had some trouble with fractured bones. This was our first test on the new shims. We are trying a new method of clamping and it seems to work.
Rabbit #56 Test 19 tested 4/30/81 Material TCS	Implanted 12/30/80 **Distal:** No test. Load less than .5 lb. **Prox:** Tested at a Max. load of 1.2 lb.	Implanted 3/5/81 **Distal:** Good test. Max. load 10.54 lb. **Prox:** Good test. Max. load 5.6 lb.	Used the new clamps (upper). The test procedure is still the same as before.
Rabbit #57 Test 20 tested 4/30/81 Material TCS	Implanted 12/30/80 **Distal:** Good test. Max. load 6.7 lb. **Prox:** Good test again; Max. load 7.0 lb.	Implanted 3/5/81 **Distal:** Same, very good test. Max. load 10.26 lb. **Prox:** Good. Max. load 11.90 lb.	These tests went very well even though the results seem a little "backwards," in that the grommets that were in the shortest time carried the highest loads.
Rabbit #34 CONTROL ANIMAL No grommets were used.	Implanted 8/14/80 No load. These were tested by a different method and the loads were very low. Max. load 2–4 g.	Implanted 9/22/80 No load. The results were the same on this and all other tests run on Control Animals.	
Rabbit #36 CONTROL ANIMAL	Same	Same	
Rabbits 38, 39, 40 CONTROL ANIMALS	Same	Same	

jeweler's blade (plastics) mounted on a Gillings-Bronwill thin sectioning machine. After the sections are cut they will be labeled according to their position and medial-lateral, dorsal-ventral will be indicated on the specimen. Five specimens from each block will then be finally ground to 200 micrometers or less with graded series of grinding papers using petrographic lapping wheels.

The sections will be microradiographed for 10 minutes at 12 milliamps at 55 kilovolts on a General Electric model XRD–6 X-ray machine using Kodak High Resolution Professional Film type SO-343.

After microradiography, the sections will be stained with Paragon (basic fuchsin and toluidine blue). The sections will be placed on microscope slides on a slide warmer at 50 degrees C. Several drops of Paragon stain will be placed on the sections and allowed to dry. After 20 to 30 minutes, the dried stain will be removed with distilled water, the sections rinsed with alcohol, lightly abraded with a tooth brush and allowed to dry. Finally, a glass coverslip will be mounted with synthetic resin.

Histology will consists of checking the microradiographs and stained sections to determine the tissue apposition at the bone-implant interface. Specifically, the presence or absence of a collagenous membrane and mineralization in the implant-tissue interface will be studied.

During the next quarter, harvesting of the implantations will continue on the proposed dates for sacrifice. Four samples will be harvested and submitted to Clemson University for histology studies. Twenty-four samples will be harvested and submitted to the Biomechanics Department at Michigan State University.

Textured Grommets for Flexible Implant Arthroplasty of Finger Joints

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Grommets made of Co-Cr-Mo alloy (Vitallium) have been ion-textured using a modified 30-centimeter-diameter ion source. The figure (Fig. 1) shows a schematic drawing of the apparatus. The grommets are attached to rods that allow the grommets to be placed inside the discharge chamber. Grommets for the distal and proximal stems of a No. 4 Swanson finger joint have been textured. The sputtering conditions are 1000 volts ion energy and approximately 1.2 mA/cm² current density for 30 minutes. Total grommets, which encircle the stem, and grommet shims, which cover 3 sides of the stem, have been ion-textured. These grommets are presently being evaluated at the Michigan State Small Animal Clinic by Dr. James McGehee.

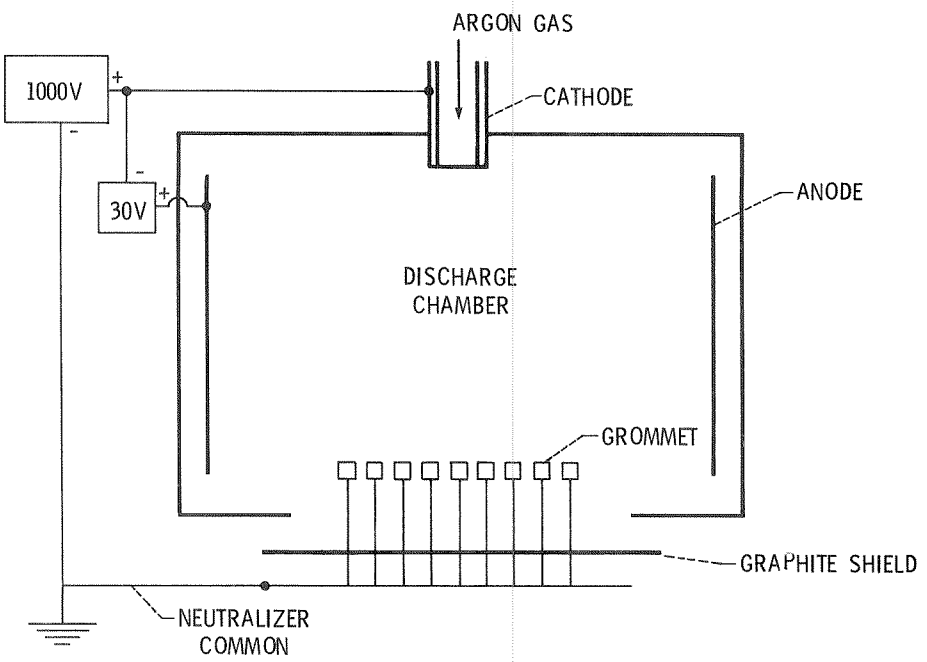

FIGURE 1.
Ion source configuration for grommet texturing is shown in this schematic. Grommets textured by means of this sputtering technique are currently being evaluated.

Microsurgical Techniques Applied to Orthopaedic and Hand Surgery

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Clinical application has demonstrated vascularized diaphyseal bone grafts to be reliable in bridging osseous defects. In theory, the vascularized bone grafts eliminate the need for long-term bone remodeling and creeping substitution of nonviable bony tissue. The vascularized bone grafts retain viable osteocytes which permit the vascular graft to heal to adjoining bone as if it were segmental fracture. We continue to investigate the biological properties of vascularized bone grafts. Our progress report describes in additional detail our findings. Our continuing studies will permit us to correlate the biological healing characteristics of vascularized bone grafts with their mechanical properties.

A segment of diaphyseal canine ulna 4 centimeters long is mobilized, the vascular pedicle cut, and then the vascular pedicle reanastomosed using microsurgical technique. Reanastomosis is accomplished with micro-instruments, the operating microscope with 25 power, and the use of 10–0 nylon suture. The 19 dogs studied to date had undergone bilateral forelimb procedures. A 4 centimeter autograft of ulna has been elevated with its vascular pedicle on one side and a nonvascularized graft on the opposite side. In this way each dog has acted as its control with a vascularized and a nonvascularized 4 centimeter ulna graft. In the vascularized bone graft the ulna was elevated out of its tissue bed

along with its vascular pedicle and then reduced anatomically. Its vascular pedicle was reanastomosed and soft tissue closure was accomplished in the routine manner. The contralateral ulna had a similar procedure without anastomosis of the vascular pedicle and with stripping of the periosteum.

Re-exploration of the dogs was performed according to the following schedule: 4 at one week, 5 at 6 weeks, 4 at 3 months, and 6 at 6 months. In the convalescent period after the initial surgery, animals were periodically labelled with tetracycline to permit, at sacrifice, analysis under the microscope of viable osteocytes. Re-exploration was performed to visualize the vascular pedicle and to determine whether the pedicle was patent. Specimens were then obtained for bone histology including frozen bone, tetracycline labelling, and decalcified bone, H + E labelling. Bone scans were done in the immediate postoperative period in all dogs using technetium labelling. X-rays were done at the time of the original procedure, at the time of the bone scan, and at sacrifice.

All animals survived the experiment and were sacrificed on schedule. Of the 19 vascularized bone grafts at re-exploration, 63 percent were patent. X-rays taken at the time of sacrifice showed healing of both the vascularized and nonvascularized bone grafts at the distal osteotomy but most specimens showed nonunion of the proximal end of the osteotomy. Bone scans were unreliable in permitting us to evaluate in the immediate postoperative period whether the vascularized bone grafts had adequate blood flow. Histologically, the vascularized bone grafts showed preservation of osteocyte in 80 percent of the specimens. In the 20 percent of the vascularized bone grafts where the pedicle was not patent and osteocytes were not present in lacunae, we did see creeping substitution apparent in the subperiosteal section of some specimens. In the nonvascularized bone graft controls, we did see some osteocytes in lacunae but the number of these osteocytes was markedly less than what was seen in the vascularized specimens.

The biological behavior of vascularized canine ulna autografts results in preservation of osteocytes in the vascularized bone graft and supports the theory that bone grafts taken with the vascular pedicle intact can function without the need for long-term creeping substitution. Our subsequent experiments will address the issue of mechanical properties to determine whether these grafts can provide immediate mechanical behavior comparable to adjacent bone upon healing of both ends of the vascularized bone graft to recipient bone.

Student Projects in the Development of Replacement Ligaments and Tendons Using Polylactic Acid/Filamentous Carbon Composites

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This project started April 1, 1981. The work involves two graduate students: one from the Department of Mechanical and Aerospace Engineering, Rutgers University, and the other from the Department of Anatomy, the Graduate School of Biomedical Sciences. Over the past 4 years, the overall objective of a project pursued at the New Jersey Medical School has been to provide a class of synthetic ligaments and tendons for use as long-term implants. This work has resulted in the development of a particular material candidate, a composite of polylactic acid polymer (PLA) and filamentous-carbon. The composite acts as a rate-controlled mechanically degrading scaffold for the development of new tissue. This candidate material is currently in clinical trials. There remain a number of areas that require additional research. The specific projects of the engineering and biomedical students will be to further refine a three-dimensional kinematic model of the human knee in preparation for human patient analysis, and to develop an in-vitro fibroblast cell culture system to study the modes of cell attachment to the implant materials and of extrusion of new collagen, respectively.

It is expected that the first (kinematic model) project will be useful in a number of ways. For example, analytical methods may be used to establish design parameters for a replacement ligament. This is accomplished by analytically and experimentally determining the forces to which the ligament is subjected. In addition, such methods may be used to determine the mechanical response of the knee to replacement of a given ligament. The effect on motion and force distribution of the inevitable change in ligament properties and exact attachment sites introduced by the use of a substitute ligament can be investigated. Finally, such analytical techniques will clearly provide a more detailed understanding of knee mechanics.

The mechanics of the knee joint involves kinematic and force analyses. Prior to kinematic analysis, information on the bony landmarks of the patella, the distal femoral condyle, the tibial plateau, and the tibiofibular joint must be obtained. Likewise, the soft tissue landmarks, attachments of tendons and ligaments to the bony surfaces and the location of muscle groups must be evaluated. Usually this is performed experimentally and the biomechanical information, such as surface contact area, lengths of tendons and ligaments, and strains in tendons and ligaments, can be calculated.

A computer assisted tomography (CAT) scan system was utilized to obtain the geometry of the knee. A cadaver knee was examined and slices of the knee at 5 millimeter distances apart were recorded. These slices were projected in the computer to generate data bases for the tibia and the femur. Computer aided design and three-dimensional graphics programs were utilized to view individual slices and three-dimensional views of the tibia and the femur. The development of the computer programs for the kinematic analysis has been facilitated through the use of a RAMTRAK-PDP 11 minicomputer system provided through the courtesy of Dr. Paul A. Frost, Xybion Corp., Cedar Knolls, New Jersey.

The second project facilitates the study

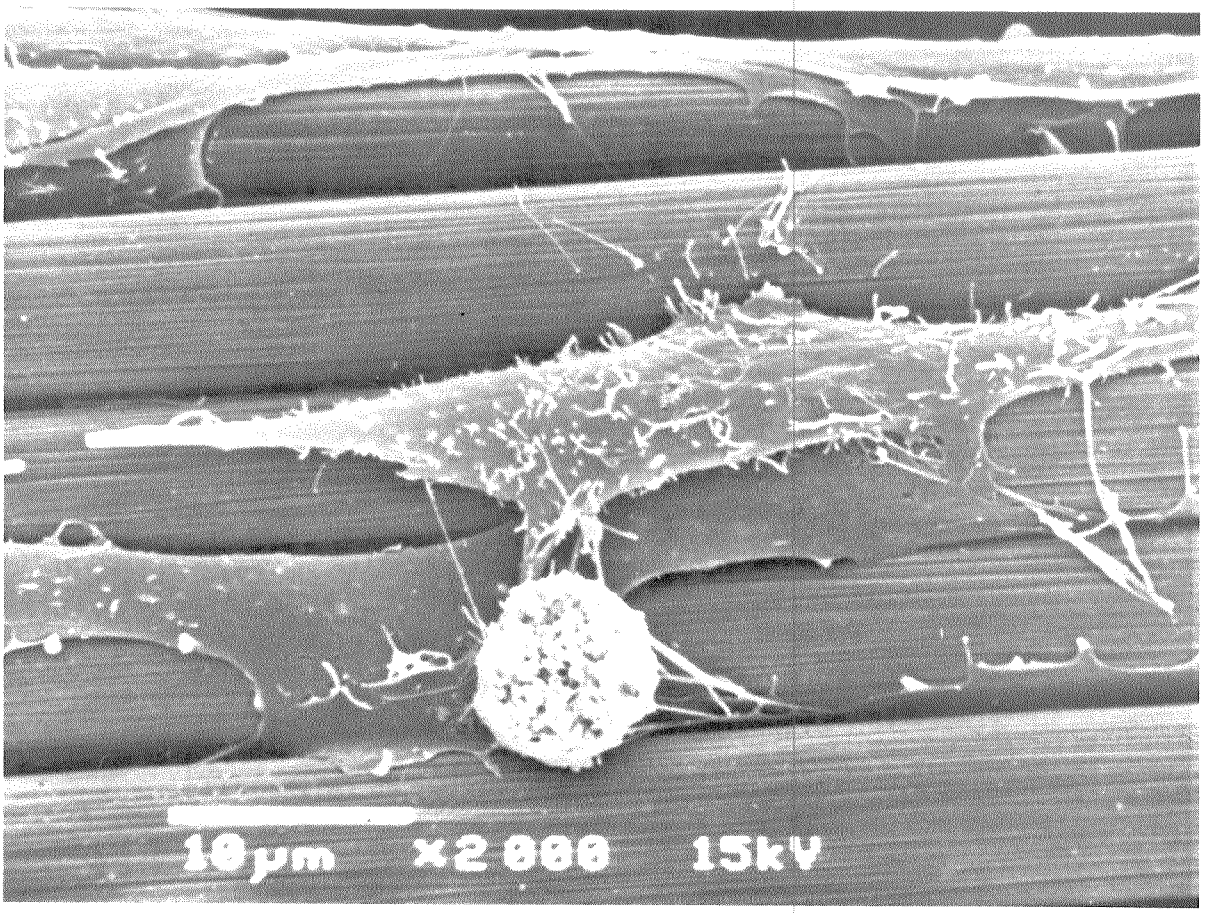

FIGURE 1.
Scanning Electron Micrograph of Fibroblasts attached to carbon fibers in cell culture.

of degradation rate and tissue regrowth rate control. With a fibroblast cell culture system, the degradation of the implant can be quantified and the various methods of acceleration of tissue growth, i.e. growth hormones, Vitamin C, can be studied in an in-vitro model.

The experimental model utilizes 14-day-old Sprague-Dawley rat tendon fibroblasts. The extensor tendons have been removed from the hind legs of the young rats and grown as explants on implant surfaces. To date, cell dynamics alone have been studied. However, in the near future, collagen formation will be stimulated by the addition of ascorbate into culture media.

It has been found that the cells do not adhere to PLA sheets since the surface is continually dissolving away. This property of PLA may become an advantage in gliding tendon repair and replacement. However, when the tendon explants are placed on a sheet of 10 μm carbon fibers, cells rapidly migrate out along the fibers. Within 1–3 days after the start of the explant culture, fibroblasts from the explant begin migrating out of the tissue onto the carbon fiber substrate. These cells migrate away from the explant and along the length of the carbon fibers. They are often seen 1–2 mm away from the explant after 2–4 days in culture.

Tendon cells grown on carbon fiber range in shape from rounded cells about 12 μm in diameter to long, spindle-shaped, 1–2 μm thick cells that align along the length of the fibers. The rounded cells are thought to be undergoing division. The spindle-shaped cells, when viewed with the scanning electron microscope (SEM) (Fig. I), show tooth-like attachments on the carbon substrate. Transmission electron microscope (TEM) pictures are being attempted in order to determine the ultrastructural nature of these attachments. Many of these cells also show microvilli. After 5–7 days in culture, these cells form colonies which may completely envelope individual fibers, form bridges between fibers, or envelope bundles of fibers. Often, one cell is observed to form attachments to several fibers.

This work is continuing during the next quarter with a quantification of the rate of cell migration and an investigation of the effect of fiber type and diameter. A method for determining, in culture, the amounts of DNA, RNA, and total protein is being adapted to this experimental model in order to determine the growth rate of cells on the carbon substrate as opposed to the growth rate of cells on normal culture dishes or on Dacron fibers. By changing certain culture conditions and supplementing the nutrient media with ascorbate, fibroblasts may be stimulated to secrete collagen. Several methods are available for determining the amount and type of collagen produced under these conditions. In the future, the synthesis of col-

lagen, by cells cultured on these substrates, will be investigated to determine the effect of cell-substrate interactions on cell function.

Development of Hydrogel Surfaces for Dental and Orthopedic Implants

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A soft, porous polymer of hydroxyethyl methacrylate (PHEMA), containing connective tissue and plasma proteins is under development as a candidate for eventual use as a surface coating of endosseous dental implants. The implant is an oral prosthesis which is partially submerged in a surgically prepared alveolar bone bed, with the protruding portion serving as an anchor for full or partial dentures. Thousands of these much-needed devices have been placed during the last 30 years, but recent surveys have revealed an overall survival rate of only 49 percent after 6 years in situ (1-3). The major cause of failure is the lack of an attached tissue interface to prevent the entry of oral flora into the bone bed with consequent inflammatory bone destruction (4). The protein-containing polymer under investigation is intended to effect the required tissue attachment, thereby providing a barrier to microbial invasion. What follows is a report of progress of an ongoing animal study to evaluate tissue and cell responses to the polymer.

The proteins being studied are plasma fibronectin and type III collagen. Molecular collagen has been shown to promote cell differentiation (5,6) and cell attachment to a substratum (7) in vitro. Attachment of cultured cells, however, requires the presence of a serum protein, fibronectin. The binding of fibronectin to cell surfaces, demonstrable by immunofluorescence (8), restores certain normal surface properties to transformed cells, such as adhesiveness and contact inhibition of movement (9). 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 (9,10). A transmembrane linkage between actin and fibronectin during cell attachment has recently been proposed on the basis of immunofluorescence and ultrastructural findings (11,12).

Under laboratory conditions, fibronectin binds readily to collagen, alpha chains and to the cyanogen bromide peptide alpha-1(I)-CB-7 (13). 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 (14).

In view of these reported findings, the proteins selected for incorporation into the polymer were complexes of fibronectin and collagen. Tissue reactions were studied in dogs, using autogenous proteins to avoid allergic phenomena. Proteins were obtained as follows.

A skin specimen 1 cm wide and 10 cm long was surgically removed from the shaved midback under intravenous Nembutal anesthesia, and the wound closed with resorbable sutures. During the same intervention, 100 to 120 ml of whole blood was drawn from the jugular vein and collected in anticoagulant citrate dextrose solution. Plasma was obtained by centrifugation of whole blood (1500 × g), and fibronectin (FN) extracted by affinity chromatography with gelatin coupled to CNBr-activated Sepharose 4B (Pharmacia Fine Chemicals, Piscataway, N.J.). Figure 1 contains a typical chromatogram of dog plasma. FN was eluted with 6M urea and the peak eluate was pooled and dialyzed against acetate buffer (pH 3.6) at 4 degrees C. From 175 to 200 μg of FN per ml of whole blood are routinely extracted by this method. Part of the FN was coupled to Sepharose 4B with the intent of selecting, by affinity chromatography, a subpopulation of skin collagen with fibronectin-binding properties.

Skin specimens (1.5 to 2.0 grams, wet weight) were trimmed free of subcutaneous fat and soft tissues, diced, homogenized in 0.5M acetic acid (HAc) and digested at 4 degree C with pepsin (hog stomach mucosa, Sigma Chemical Co., St. Louis, MO.) at final concentrations of 5 mg (wet weight) of skin per ml of 0.5M HAc and 0.02 mg pepsin per ml of di-

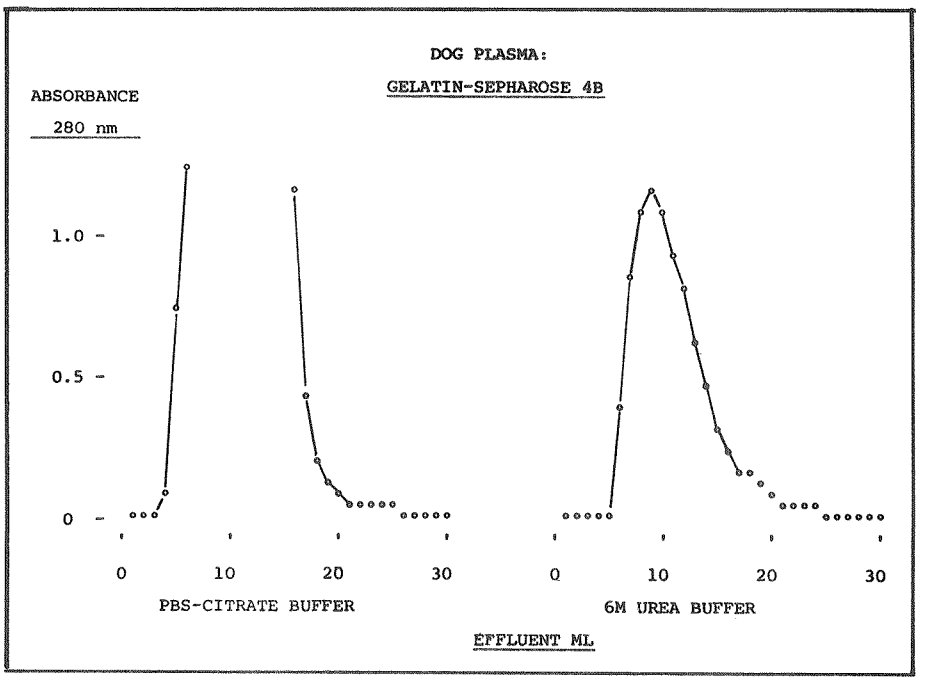

FIGURE 1.
Affinity chromatography at room temperature of fresh dog plasma. The column bed was CNBr-activated Sepharose 4B to which gelatin (Swine skin type I denatured collagen) had been coupled. Plasma fibronectin selectively binds to gelatin while all other plasma proteins are eluted with the column buffer: PBS/.01M sodium citrate, pH 7.2. Fibronectin is eluted with 6M urea/.05M tris, pH 7.5.

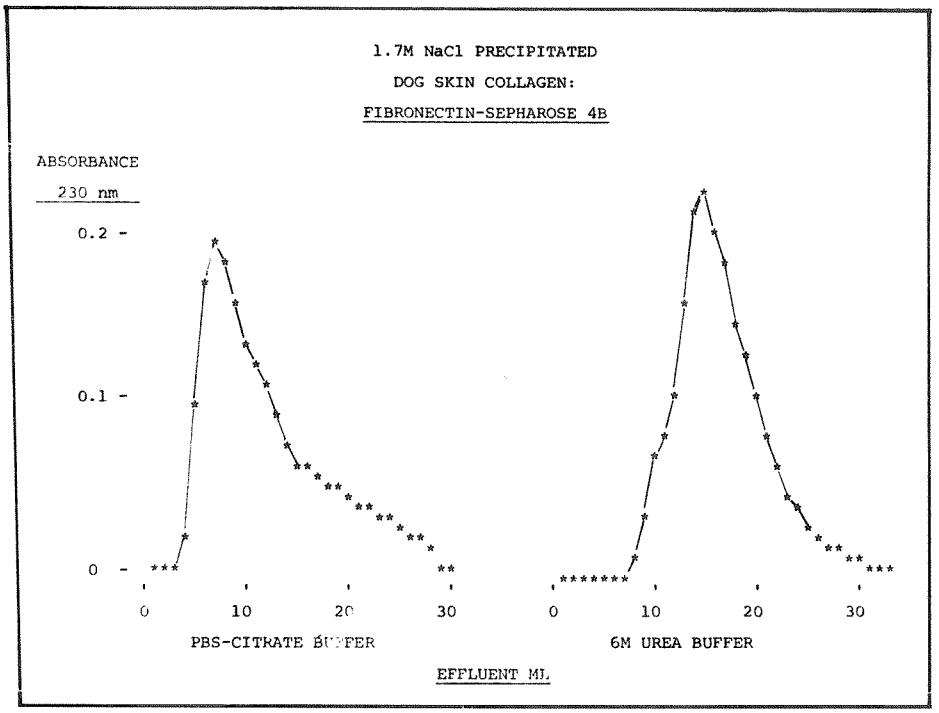

FIGURE 2.
Affinity chromatography at room temperature of acid soluble, pepsin digested, salt precipitated (1.7 M NaCl) type III dog skin collagen. The column bed was CNBr-activated Sepharose 4B to which dog plasma fibronectin had been coupled. Approximately one half of the salt precipitated collagen was eluted with column buffer (PBS-citrate). 6M urea eluted the remaining collagen with fibronectin-binding properties.

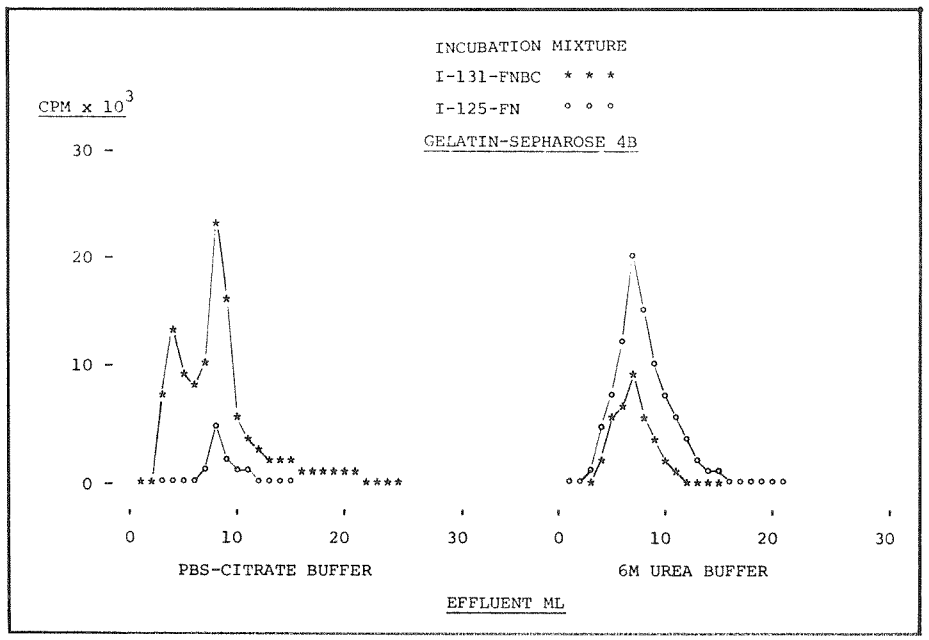

FIGURE 3.
Affinity chromatography with gelatin-sepharose 4B of an incubation mixture containing 50μg I-131-labelled fibronectin-binding collagen (FNBC) and 10μg I-125-labelled fibronectin (FN). The proteins were incubated for one hour at 37 degree C prior to chromatography.

gest. Digestion was stopped after 18 hours by elevation of the digest pH with 3M tris-base, after which type III collagen was precipitated by the addition of NaCl to 1.7 molar. The precipitated collagen was collected by centrifugation (48,000 $\times$ g), resuspended in 0.5M HAc, reprecipitated and washed two more times. The final washed precipitate was resuspended in 0.5M HAc, desalted by dialysis versus 0.1 percent HAc and lyophilized. A portion of the lyophilized collagen was solubilized and further purified by affinity chromatography with FN-Sepharose 4B. A collagen affinity chromatogram is plotted in Figure 2 showing the elution with 6M urea of a subpopulation of type III skin collagen with fibronectin-binding properties, comprising roughly one half of the crude salt precipitated preparation.

The formation and composition of complexes were studied with I-125-labelled FN and I-131-labelled fibronectin-binding collagen (FNBC) as follows. Radioiodination was by the chloramine-T method (15). Mixtures of various weight proportions of the labelled proteins were incubated for 1 hour at 37 degrees C and then chromatographed on gelatin-sepharose 4B. Figure 3 is a chromatogram of a mixture containing 50 μg FNCB and 10 μg FN. The plot showed that a portion of the I-125-FN did not bind to gelatin and was eluted with column buffer (PBS-citrate) together with I-131-FNBC. These eluates were presumed to represent complexes in which FN binding sites were totally saturated with FNBC. The urea buffer eluted several fractions containing both radionuclides at differing proportions. These were presumed to contain complexes of partially saturated FN with some sites available for binding to gelatin.

The presumptive complexes were examined by polyacrylamide gel electrophoresis analysis of selected elution fractions containing both I-125 and I-131 activity. Two aliquots each from elution fractions containing both isotopes were electrophoresed on 5 percent phosphate gels, with and without pretreatment with 2 mercaptoethanol (2ME). Thereafter the gels were cut into 2-mm slices and each slice counted for both radionuclide activities.

The results of one such analysis are plotted in Figure 4. The data for the ali-

quot not treated with 2ME show that the highest concentrations of either radionuclide are associated with molecular species greater than 200,000 molecular weight. Pretreatment with 2ME resulted in a decrease of high molecular weight radioactivity and the reappearance of I-125 activity at the molecular weight of FN (200,000). The decrease in I-125 and I-131 activity resulting from 2ME treatment was presumed to represent the disassociation of FN-FNBC complexes. Estimates of FNBC:FN weight ratios were calculated from the differences, due to 2ME, in high molecular weight radioactivity.

The results indicated that complexes eluted with PBS-citrate buffer consisted of from 19 to 23 parts FNBC to 1 part of FN, by weight. Complexes eluted with 6M urea produced a range of proportions from 9 to 0.6 parts FNBC to 1 part FN. Overall, the data showed that regardless of the starting proportions in an incubation mixture, a family of complexes was formed varying in the proportions of the two proteins.

Radiolabelled proteins were also used to determine whether collagen and fibronectin were firmly bound to the polymerized hydrogels. The polymers were prepared in the usual volume proportions of 6 parts hydroxyethyl methacrylate, 0.6 parts ethylene glycol, 0.2 parts each of ammonium persulfate and sodium metabisulfite, and 3 parts protein solution. Sucrose powder, sized from 100–250 micrometers (μm), was added after 10 minutes of initial polymerization and dispersed by vortexing. Fifty mg of sucrose was added per ml of PHEMA formulation.

After polymerization in siliconized glass test tubes was complete, the hydrogels were removed, sliced into several small wedges, counted for radioactivity and then dialyzed for three days versus 200 volumes of saline, with daily changes of dialysate. At the end of dialysis, the wedges and aliquots of the three dialysates were counted. Dissolution of the sucrose by dialysis produced porosity throughout the polymer. The amounts of labelled protein added ranged from 5 to 100μg/ml of hydrogel mixture. The results revealed that regardless of the amounts added, the percent protein retained by the polymer remained constant for each type of protein. The average percents retained were, I-125-FN: 92.5 percent, and I-131-FNBC: 80.7 percent.

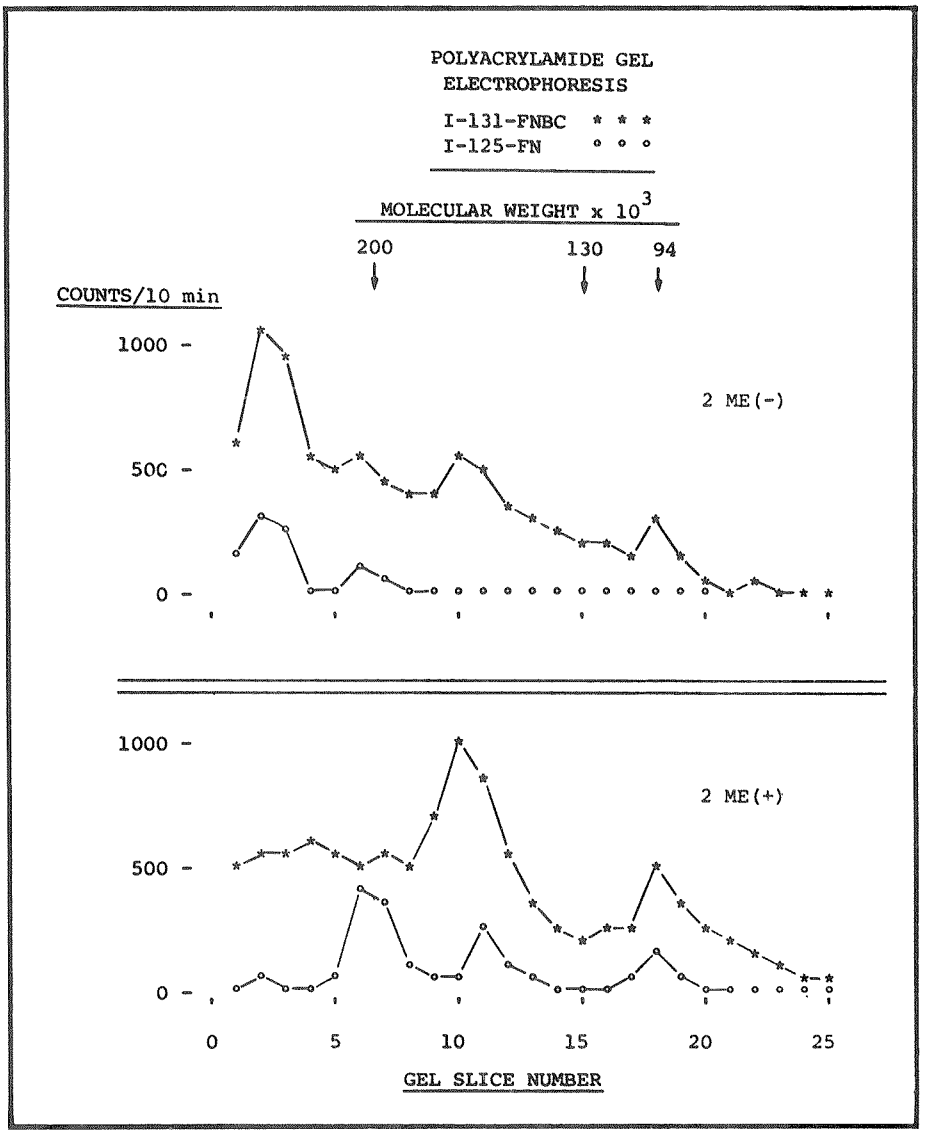

FIGURE 4.
Polyacrylamide gel electrophoresis on 5% phosphate gels of a 6M urea eluate from the affinity chromatogram of Figure 3. The gels were cut into 2mm slices and each slice was counted for 10 minutes. Simultaenously electrophoresed molecular weight standards are indicated. An aliquot of the eluate not pretreated with 2-mercaptoethanol (2ME –) contained a molecular species greater than 200,000 with high count rates of both radionuclides. Pretreatment with mercaptoethanol (2ME +) reduced the high molecular weight associated radioactivity, presumably through disassociation of FN-FNBC complexes. The increase in I-125 activity with 2ME treatment at the molecular weight of FN (200,000) supports this presumption.

Based on the above findings, hydrogels were prepared for in vivo assessment in dog jaws. Porous hydrogels with and without protein were cut into several discs measuring 4 mm in diameter by 2 mm in thickness. These were placed in bone beds prepared as follows. Vertical incisisions were made of the mandibular buccal gingiva and mucosa and full thickness flaps retracted to expose the buccal alveolar bone plate of right and left posterior teeth. Circular beds were prepared with rotary carbide instruments approximately 5 mm inferior to the alveolar crest. The bed dimensions were made comparable to those of the discs to produce a relatively snug fit. The buccal tissues were replaced and the incisions closed with resorbable sutures.

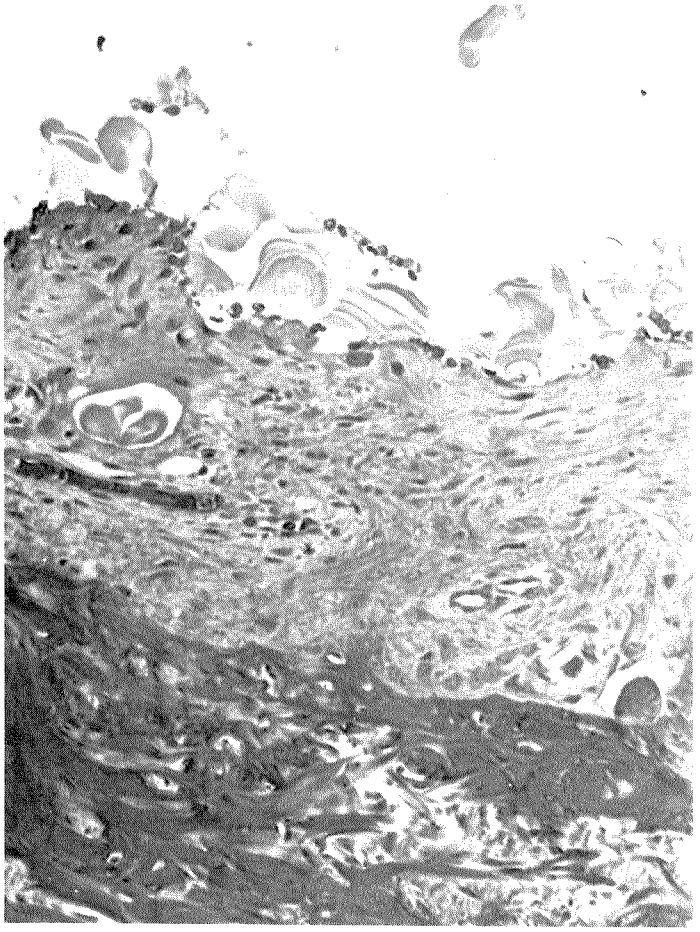

FIGURE 5.
Four micron thick cross-section of a polymer disc (clear area) and its alveolar bone bed. The porous polymer contained no proteins and was encapsulated by a thick layer of fibrovascular connective tissue.

A total of 40 discs were placed in 2 dogs, 20 per dog. During a 2 month period of observation only three discs produced chronic inflammatory responses with fistula formation. Four groups of porous hydrogels were tested, containing the following μg of protein/ml of hydrogel:

1. No protein, control.
2. 100 μg FN.
3. 100 μg FNBC.
4. 10 μg FN and 50 μg FNBC, incubated for one hour at 37 degrees C.

The discs were removed after 2 months as follows. Vertical incisions were made as before and the soft tissues were retracted. Teeth within the area were extracted and the interradicular septa removed. Block sections of buccal bone, each containing one disc, were cut, fixed in formalin, decalcified, and prepared for light microscopy.

Figures 5 to 7 are representative micrographs of the specimens. The major observations were:

1. Discs without proteins (Fig. 5) were encapsulated with fibrous connective tissue which separated them from the healing bone bed.

2. Discs with either protein alone (fibronectin, Fig. 6) had little or no inter-

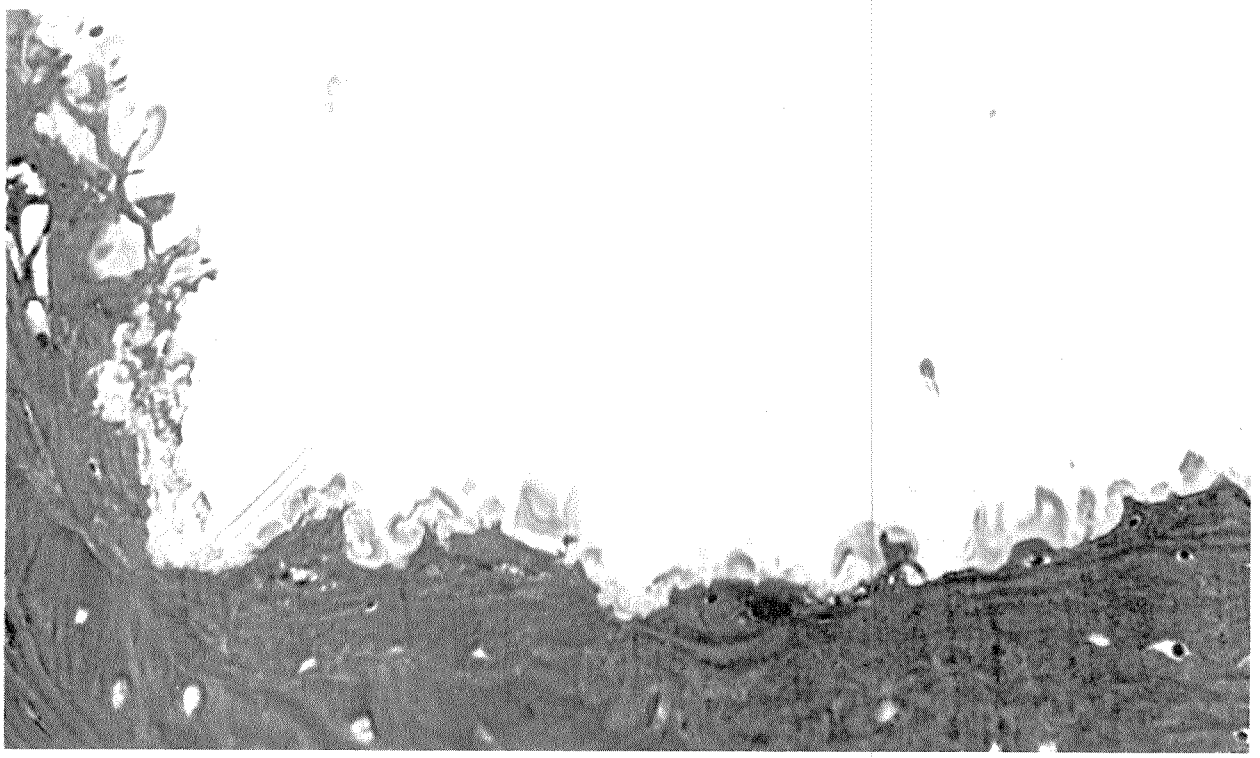

FIGURE 6.
Discs containing either fibronectin alone, as in this figure, or collagen alone, had little or no fibrous connective tissue separating the discs from healing bone beds.

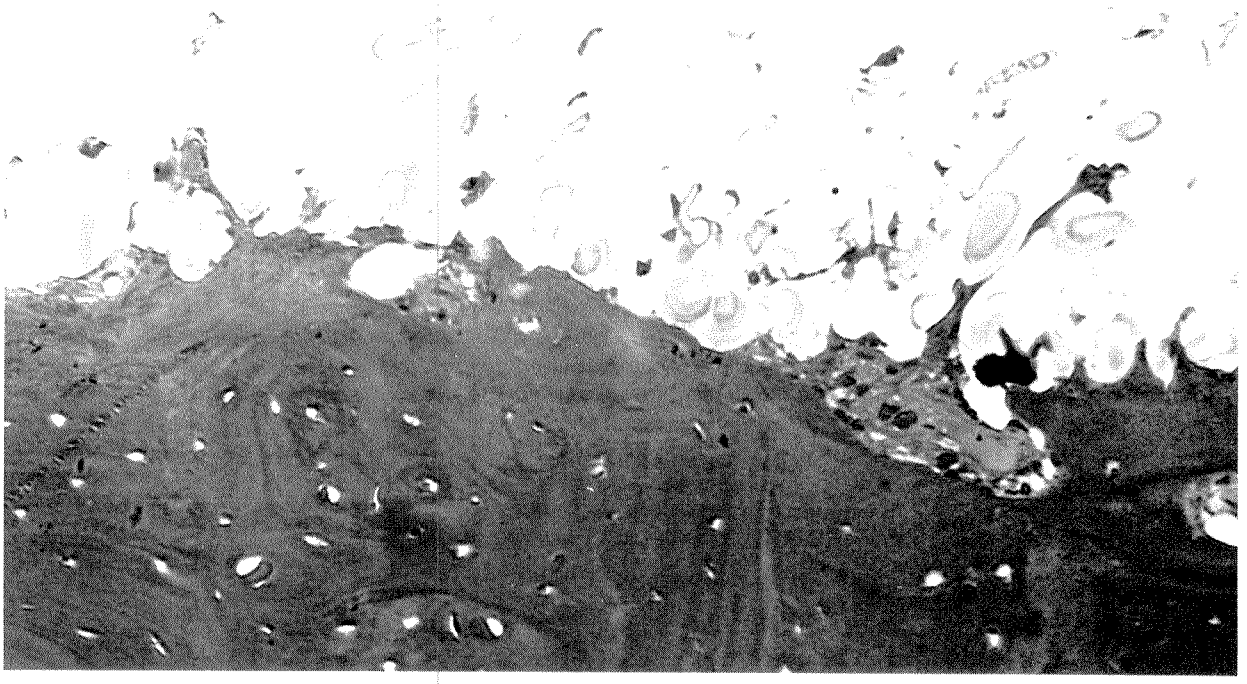

FIGURE 7.
Discs containing incubation mixtures of FN and FNBC contained numerous penetrations of cells and tissues from adjacent healing bone beds.

posed fibrous connective tissue between healing bone and the polymer.

3. Discs with the incubation mixture (Fig. 7) were also without fibrous capsules, but the disc-bone interfaces showed numerous deep penetrations of cellular elements into the polymer.

The results to date support the concept that attachment of a tissue bed to an implanted prosthesis can be obtained through the incorporation of connective tissue proteins whose normal biological function is to provide a substratum for cell attachment. Studies are in progress to test this concept in the form of polymer-coated dental implants inserted in fresh dog molar extraction sites.

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Bone Strength: In Vivo Stress and Strain

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MICROMINIATURE STRAIN GAGE PREPARATION, IN VIVO IMPLANTATION, AND IN VITRO MATERIAL PROPERTY EVALUATION

Introduction

During the past 10 years, foil and semiconductor strain gages have been used to analyze the mechanical responses of bone during normal skeletal locomotion, enabling biomechanics researchers to make correlations with simplified static models. Many authors (1,2,3) have described "state of the art" techniques for fabrication, implantation and insulation of foil and semiconductor type strain gages in large experimental animals, but there appear to be no published reports on the use of microminiature strain gages for investigating the in vivo response of small laboratory animals with rapid bone turnover.

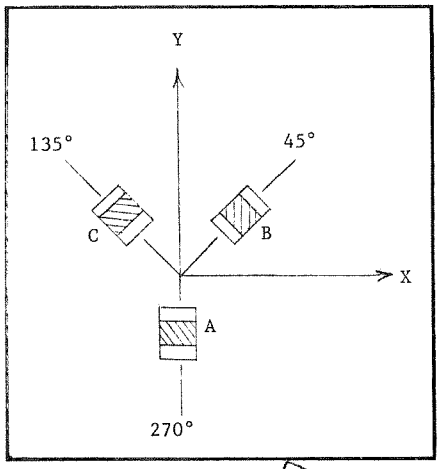


FIGURE 1.
Rosette gage configuration.

This report will present a technique for the preparation of microminiature rosette strain gages that can be installed in laboratory animals as small as 150 grams. One such animal, the rat, has undergone extensive biochemical, histological and metabolic research, but there have been no reports on the mechanical behavior of rat bone in vivo and very little in vitro information is available. Such information is invaluable in assessing the mechanical response of bone, and can provide new insight into the link between changes in the function of bone and bone architecture—the adaptive remodeling response of bone (Wolff's Law).

Gage Description

Male Holtzman albino rats ranging from 150 to 650 grams were instrumented with microminiature three-element 45-degree rosette strain gages (Micro-Measurements EA-06-015RJ-120). The gages were the electrical resistance type consisting of a grid of constantan foil on a thin polyimide backing. Figure 1 shows schematically the configuration of the three-element rosette, which when implanted is oriented so that the abscissa is along the long axis of the bone. Each gage is 120±1% ohms, with a gage factor of 2.00±1%, and self-temperature compensation of 6 ppm/deg F.

The gages were employed in a quarter bridge with excitation from a constant current source. Constant current was used to minimize noise from poor or faulty electrical connections. An excitation voltage of 0.25 volts (2.1 milliamperes) was chosen for each gage element. This excitation level was based on a power density for bone of 0.5 watts/in^2 and a gage grid area of 0.0003 in^2. A total of six bridges and current sources enabled recordings from six single gages or two rosette gages. The constant-current source and bridge circuitry for one channel are shown in Figure 2.

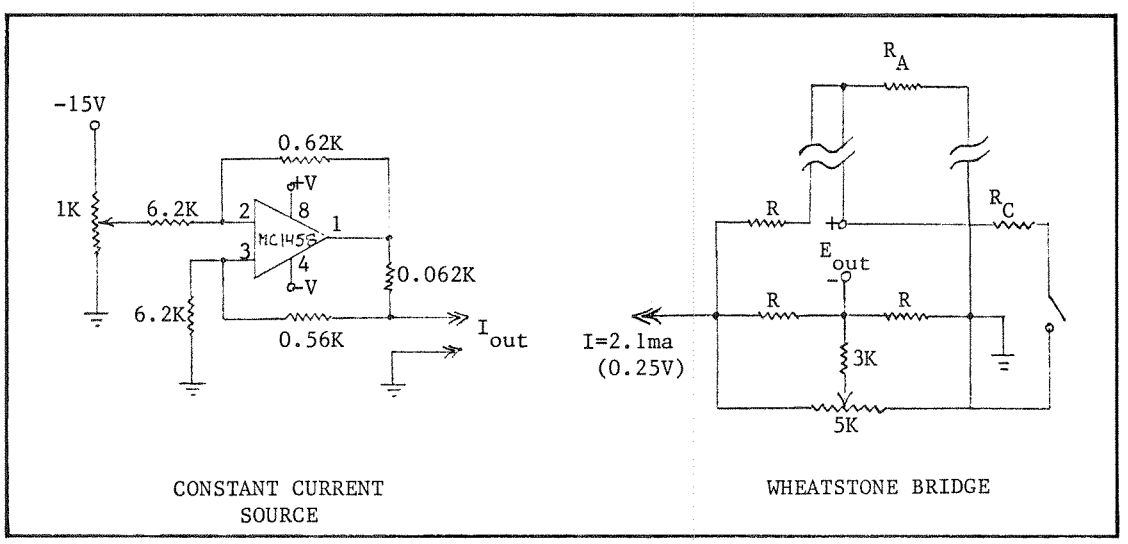


FIGURE 2.
Circuit diagrams of constant current source (left) and Wheatstone bridge (right). Circuitry at left supplies 0 to 20 milliamps excitation. Circuitry at right consists of three precision (0.02%) resistors (R) and a gage or active resistor (R_A) forming a full bridge. Note that a three lead-wire system is used to compensate for differences in pathway resistance. Resistor, R_C, provides a known strain level for calibration, while the 5K potentiometer initially balances the bridge.

Gage Preparation

The gage units were constructed using 38-gage polytetrafluorethylene (PTFE) insulated lead wires soldered directly to the grid solder tabs. Strain relief tabs at the gage were not used owing to the small size of the gage and implantation site. Waterproofing and mechanical protection were achieved by applying a thin base coat of toluene-thinned acrylic (Micro-Measurements, M-Coat D) followed by a coating of polysulfide/epoxy waterproofing compound (Micro-Measurements, M-Coat G). A 2.5 mm section of the lead wires was also potted using the Type G coating. The gage unit was then trimmed resulting in a prefabricated, encapsulated, wired unit with a maximum overall area of 10 mm^2 (2.5 × 4.0 mm) and overall thickness of 0.5 mm. A miniature multipin connector (Amphenol, 222–11N07) interfaced with a three-wire resistance compensation system to the Wheatstone bridge. Figure 3 shows the completed gage unit with attached lead wires, connector, and jacket support.

Surgical Implantation

Femurs of anesthesized rats were exposed and then isolated with cotton-tipped wood applicators. The exposed bone surface was scraped free of periosteum and alternately degreased-dryed with xylene-cotton tipped applicators until a clean dry surface was obtained. After neutralizing the surface with ammonium solution and drying, the gage was introduced subcutaneously from the dorsum to the bone site and methyl 2-cyanoacrylate (Permabond 101) was applied to the back of the gage (Fig. 4). A pre-shaped implement that contoured to the bone surface was then used to bond the gage to the bone. The portion of the lead wires encapsulated with M-Coat G was bonded to the bone in a similar fashion (Fig. 5). The gage and a portion of the surrounding bone was then covered with a very thin layer of fast-drying epoxy for additional mechanical and electrical insulation. A loop was introduced in the lead wires and sutured into the subcutaneous tissue for added stress relief (Fig. 6). The wound was then sutured closed and the plug assembly taped to the rat's back (Fig. 7).

Verification of Strain Gage Readings

During the course of development of this technique, 18 healthy male rats were instrumented. Following a recovery period of 4 to 6 days, the in vivo strains of the rats were recorded during normal locomotion on exercising wheels.

At sacrifice, the gages were visually examined for insulation failure and/or debonding and both femurs were removed. Of the 18 instrumented rats, in vivo recordings were obtained from all but 4 rats that had chewed off their jackets before recordings could be made. In every case, however, visual examination confirmed insulation and gage adhesion integrity. Two rats were kept instrumented until debonding occurred (as evidenced by erratic readings) and the gages were found to give good readings for 12 days.

In order to quantitatively assess the in vivo performance of the gages, in vitro tests were performed on three freshly excised rat femurs. The proximal end of each bone was embedded in methyl methacrylate and securely anchored. To the free or distal end a series of static loads were attached and recordings made of each of the three gages (Fig. 8). The original gage was then removed, with care taken to mark its exact location, and a new gage was installed in exactly the same manner as the original gage. The replacement gages agreed closely (6–10%) with the original gages.

Material Property Evaluation

In vitro static, non-failure cantilever beam and dynamic failure torsion tests were performed on eight freshly excised femurs from health "normal" rats ranging in age from 43 days to 122 days (166 to 490 grams). With respect to the cantilever beam tests, the proximal end of each bone was embedded in methyl methacrylate and anchored and loaded as in the procedure for gage verification described previously (Fig. 8). For these experiments the gage was bonded to the anterior or tensile surface of the bone. A simple state of stress was assumed and the axial Modulus of Elasticity (E_{xx}) was determined by the following equation:

$$E_{xx} = \frac{WLd}{I_x \epsilon_{xx}}, \text{ where}$$

W is the load in Newtons,
L is the distance from the load to the center of the gage in meters,
d is the distance from the bone surface to the centroid in meters,
I_{xx} is the moment of inertia about the X-axis in m^4, and
ϵ_{xx} is the axial strain from the gage readings.

Several different loads (W) were used and the slope of the plot of W vs. ϵ_{xx} was calculated using a linear regression by the least squares method. These tests yielded values for the axial modulus of 15.3 GPa (43 days) to 32.6 GPa (122 days) or an overall mean of 26.8±7.7 GPa. In addition, an average value of 0.41±0.11 for Poisson's ratio (transverse strain/axial strain) was obtained.

A torsion device developed by Burstein and Frankel (5) and shown schematically in Figure 9 was used to calculate the shear modulus, G. In this case both ends of the rat femur were potted in methyl methacrylate and the bone then held by the small grips (F and H) shown in Figure 9. A rosette strain gage was bonded to the center of the unpotted portion of the femur in order to record the strain of failure. A typical torque (T) vs. angle of twist (θ) curve is shown in Figure 10. Based on the formula:

$$T = GK\theta \text{ where}$$

G is the shear modulus in Newtons/m^2,
K is a property of the bone cross-section in m^4, and
θ is the maximum angle of twist per unit length in radians/m,

the following information was determined. Shear modulus ranged from 1.1 GPa (69 days) to 3.3 GPa (122 days) or an overall mean of 2.5±0.8 GPa. Furthermore, the in vivo shear strain ($\gamma_{xy} \approx 500\mu\epsilon$) was 6.5% of the shear strain at failure for 74-day-old rats in contrast to 3.4% for 122-day-old rats. These results indicate that the mechanical properties of rat bone vary with age and/or maturity and hence remodeling is occurring. The trend is toward an increase in strength as evident by both mechanical properties and in vivo shear strain vs. in vitro shear strain at failure.

Discussion

In vivo recordings for a typical rat are shown in Figure 11 along with the cor-

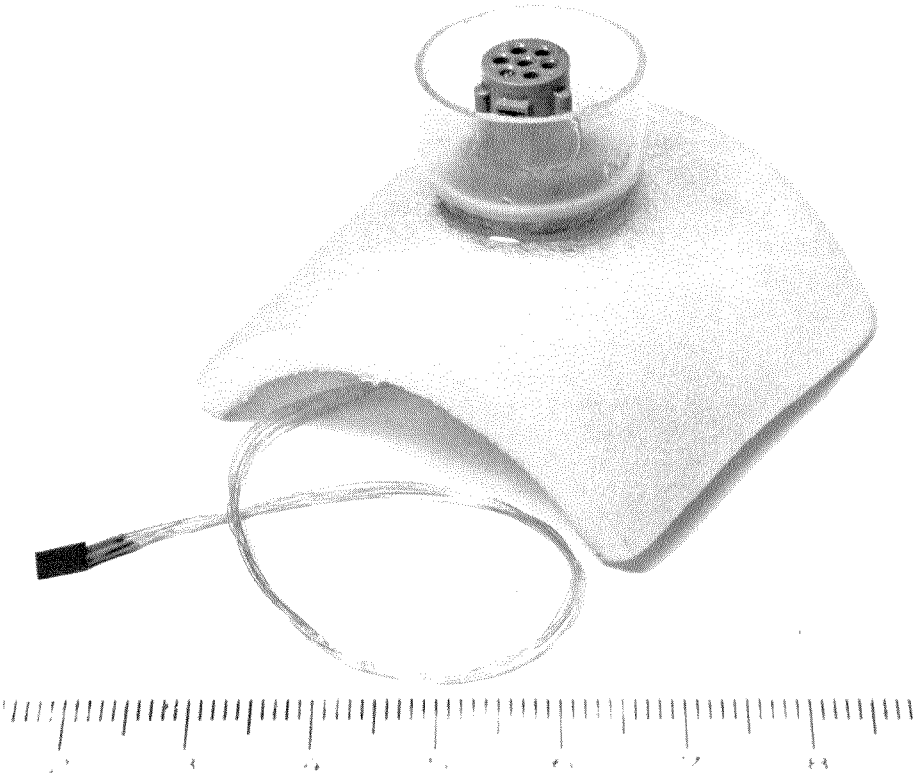


FIGURE 3.
Micro-miniature rosette strain gage unit. Gage with attached lead wires interface to recording apparatus via miniature multi-pin connector. Connector is protected by syringe container, both of which are bonded to moldable expanded polyethylene jacket support to provide strain relief for wires.

responding axial (ϵ_{xx}), transverse (ϵ_{yy}), and shear (γ_{xy}) strains. Axial strain magnitudes of 250–300 microstrain ($\mu\epsilon$) were characteristic of most of the recordings. This strain level is in agreement with other authors (1,4). The techniques presented in this paper, however, differ somewhat from classical strain gage preparation and implantation as reported by (1,2,3). Some changes resulted from the miniature nature of the gage unit and test animal, but others such as the final epoxy insulation are unique. Basically, though, a strain gage unit for in vivo implantation should meet the following requirements: (i) durability (mechanical, chemical and electrical), (ii) size—small enough to permit placement on the bone surface of at least three gages or one rosette, and (iii) sterilizability (autoclave or gas).

In vitro mechanical testing can evaluate material properties of bone using relatively simple models, although in the future more complex models will be used to fully characterize rat bone with respect to properties in all directions, since bone is really an anisotropic material. Average or mean values for Modulus of Elasticity and Shear Modulus should be limited to groups of rats of similar age and maturity, since the material properties of the bone change significantly with time. Average values or

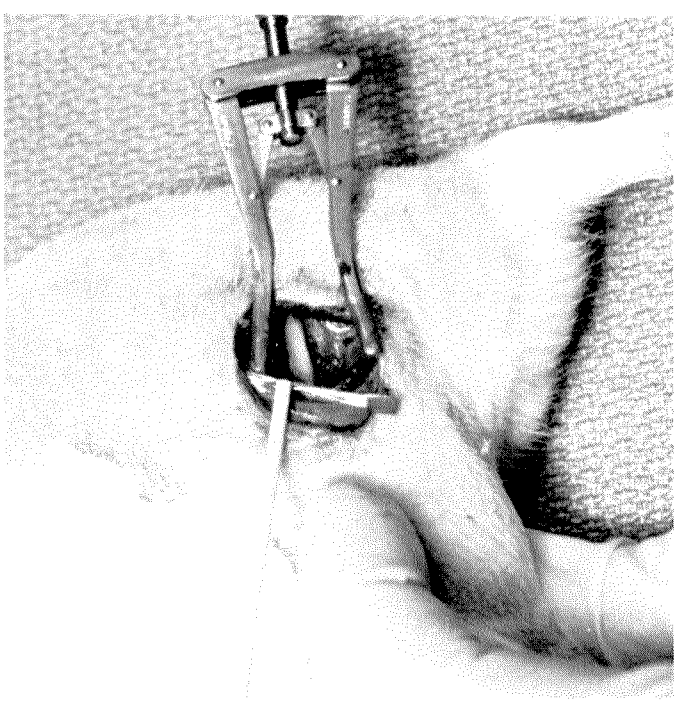


FIGURE 4.
Left femur of rat exposed, isolated, and cleaned; gage ready for implantation.

FIGURE 5.
Gage bonded to anterolateral surface of rat femur.

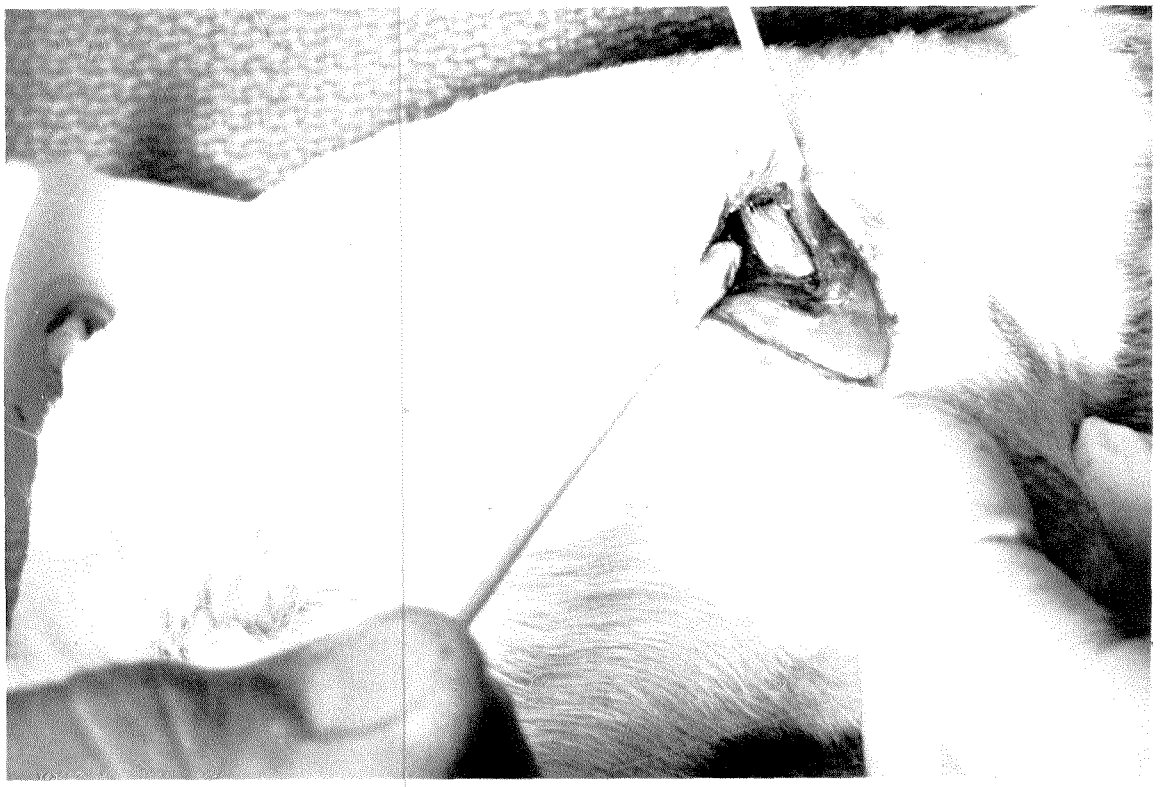


FIGURE 6.
Close-up of implantation site with fast drying epoxy encapsulation.

magnitudes, however, are useful in comparing rat-bone material properties with other animal models as well as with humans, and therefore have been included in this report. Mechanical testing techniques such as those presented in this report, used to investigate the physiological and pathological actions of vitamins and hormones on skeletal tissue, will prove invaluable in assessing bone remodeling and bone disease. Experiments of this nature are currently under investigation, as well as histological studies.

Conclusions

Micro-miniature rosette strain gages are available that can be fabricated into units capable of in vivo implantation on very small test animals. These units are rugged and permitted strain recordings for up to 12 days. Other authors (1,2,3) have reported obtaining readings for 3 to 5 weeks, but were not dealing with an animal model with rapid bone turnover such as the rat. Experimental stress analysis techniques applied in vivo represent a step forward for the biomechanics researcher, who until recently was limited to in vitro studies of bone behavior. In vitro mechanical testing,

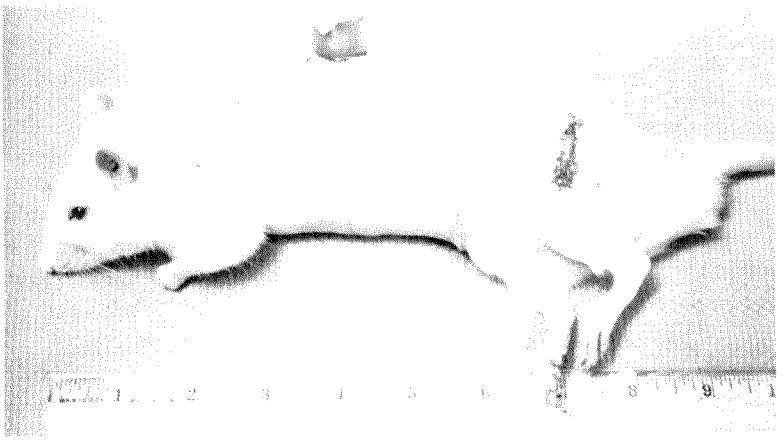
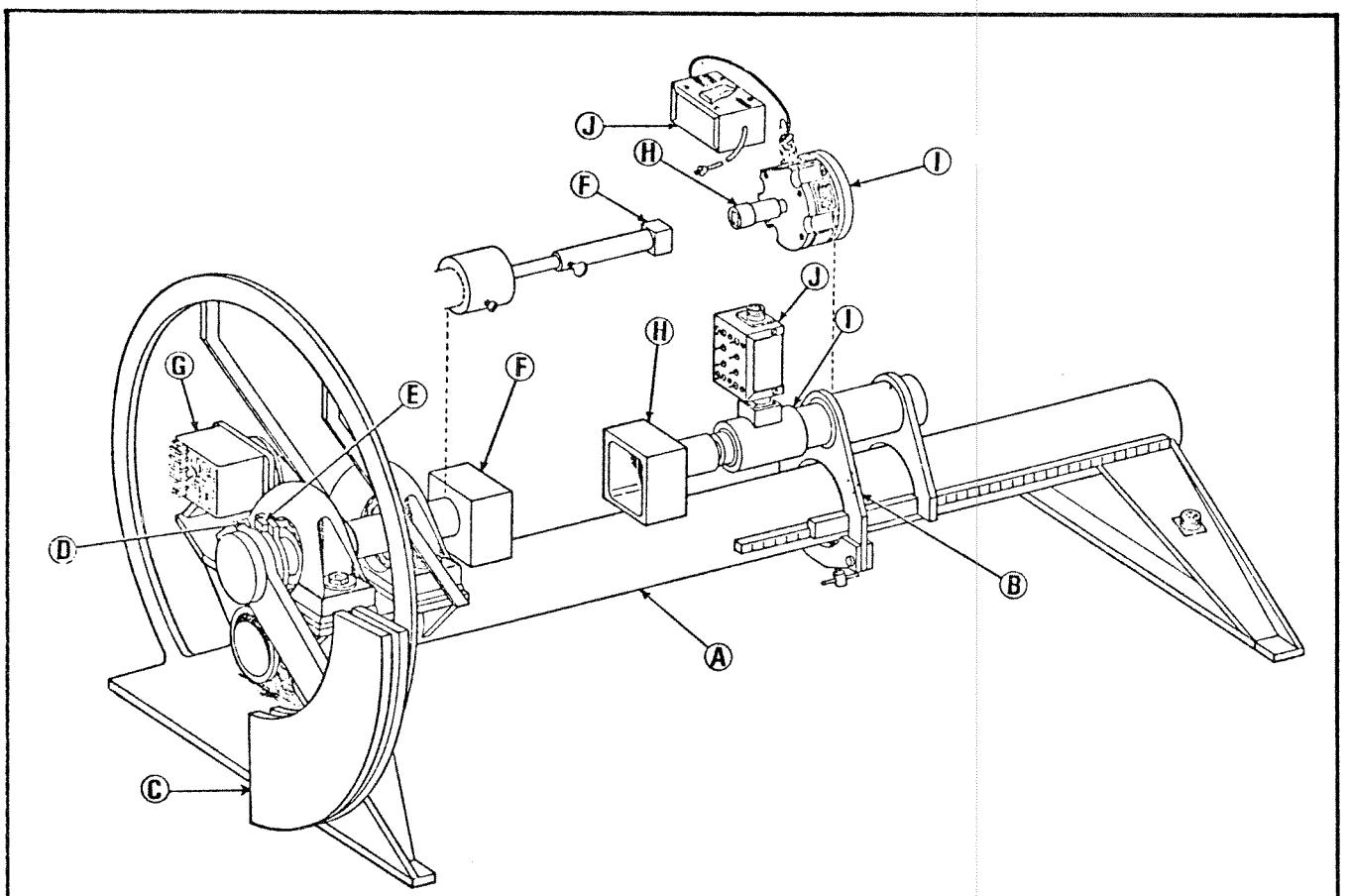


FIGURE 7.
Gage installation complete; plug assembly secured to rat; wound sutured closed and coated with sterile surgical dressing.



The components of a Standard Torsion Testing machine are: A. Frame; B. Tail stock; C. Pendulum; D. Dog clutch in pendulum; E. Dog clutch on rotating shaft; F.* Rotating grips; G. Angular deformation transducer; H.* Stationary grips; I.* Torque transducers; J.* Self calibration system;. *Two sizes shown.

FIGURE 9.

however, is an important aspect of bone biomechanics research, but should be interpreted carefully. In addition, using rats as a model could prove invaluable in assessing the factors responsible for bone remodeling and bone disease, since the biochemical, histological, morphological and metabolic information on rats is extremely well documented.

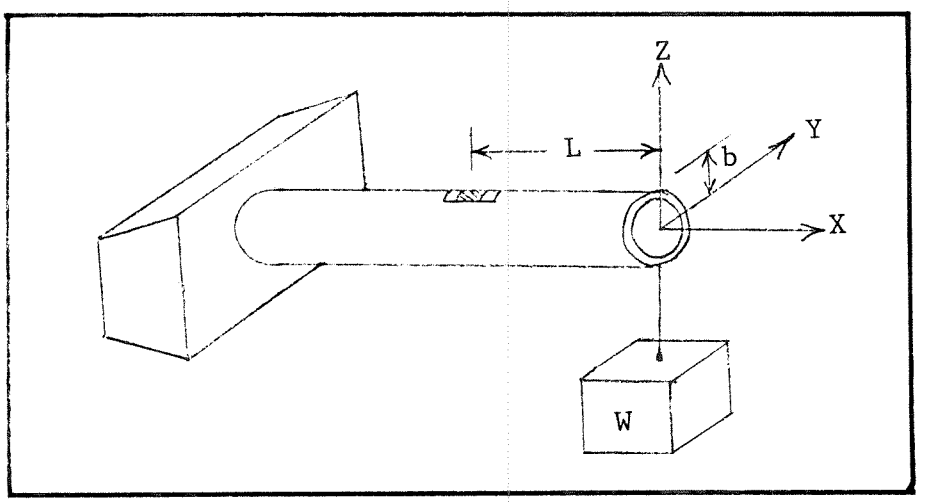


FIGURE 8.
Loading geometry for gage function verification and cantilever beam tests, with bone represented as a hollow elliptical tube.

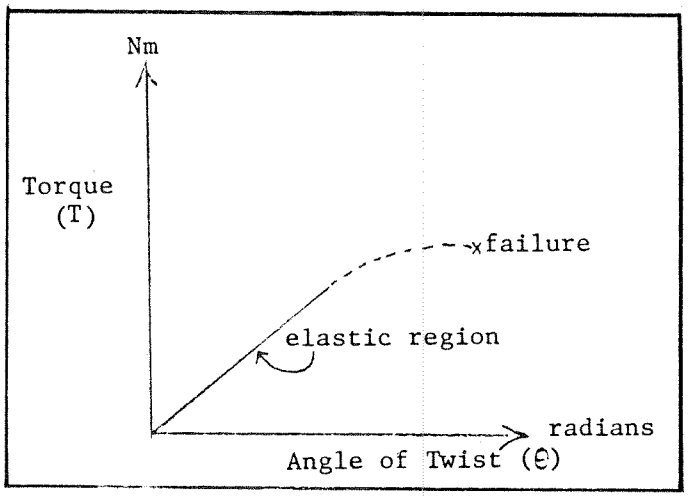


FIGURE 10.
Torque (ordinate) vs. Angle of Twist (abscissa) for a typical normal rat femur obtained from the loading device illustrated in Figure 10.

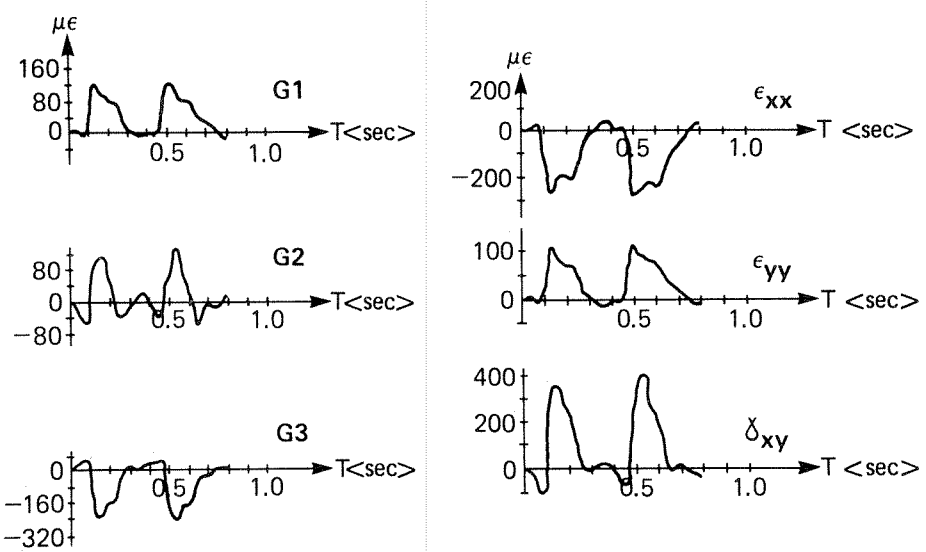


FIGURE 11.
In vivo strain recordings from gages A, B, and C and corresponding axial (ϵ_{xx}), transverse (ϵ_{yy}), and shear (γ_{xy}) strains for two gait cycles.

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In Vivo Loading of Knee Joint Replacements

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Background

Since our previous report, work has proceeded well in the two required areas: the development of a suitable mechanical telemeterizable total-knee joint, and the development of the necessary telemetry electronics. Although, as in any applied research project, many unanticipated problems have arisen in the course of this development, no insurmountable problems have been encountered.

Mechanical Development

As previously reported, it is the goal of this project to instrument the tibial portion of a total knee joint replacement to determine the loads and forces borne by such devices in-vivo. The commercial design chosen as the basis for our development is the total condylar total knee joint replacement. Development of such a device allows standard femoral components to be employed, and the entire telemeterized total knee assembly can be installed using standard clinical surgical procedures. That is, our goal is to reproduce as closely as possible the overall geometry of commercially available total condylar total knee joints systems. An exploded view of our basic instrumented tibial design is again shown in Figure 1 for reference.

With the exception of the actual plateau assembly, the entire device is fabricated using 6 Aluminum – 4 Vanadium extra-low iron (ELI) titanium alloy, and fabricated in the University's precision machine shop. The tibial plateau articulating surface is a standard ultra-high-molecular-weight polyethylene tibia plateau, which is machined for us by Howmedica Corp. from their standard tibial component blanks. Therefore, when implanted this device will be mated with a standard Howmedica femoral component.

Load Cell Design—Reference to Figure 1 shows that the actual load path in

this design is from the tibia plateau through the plateau tray, then through the load cell which resolves the three forces and three moments. In order to resolve all force and moment components with seven data channels, the tray is pinned to only two arms of the load cell. On the other two arms it rests on titanium stems with polyethylene film interfaces. The pins are pressfit into the arms of the load cell. The tray is placed on top and then electron-beam (EB) welded to the pins. The load cell, in turn, is attached to the housing by means of a central stud which is passed through the housing and then also EB welded. Because of this load path, the stems of the pins inserted into the load-cell arms are subjected to bending moments which are difficult to specify for the purposes of analysis. Furthermore, as the beams with the welded pins undergo bending, they try to warp the floor of the tray locally. This loading induces a stress state which is very difficult to predict theoretically.

Because of the inability to define completely the constraints and loading on the ends of the pins that are inserted into the beams, classical beam analysis was accepted as being inadequate, but at least it provided a starting point for the design. This analysis predicted that there would not be any problems from fatigue due to bending. This was substantiated by subsequent axisymmetric finite element analysis. Fatigue testing of the assembled unit has shown that compressive loading of the assembled implant should result in no failures of the pins. Classical analysis also indicates that there should be no failures in fatigue due to shear loads on the implant, especially at the load range that we expect to encounter in the knee. However, fatigue testing in pure shear, or pure shear combined with compression, have not been performed to date. Although it is our belief that the shear loading on the pins (induced by bending deformation in both the load cell beams and tray due to compression loading) is a sufficient test of the pin strength in fatigue, we plan to perform a number of fatigue tests which emphasize the effects of shear loads. Our laboratory has a Model 1230 Instron Dynamic Test Machine which is capable of producing the desired compressive and shear loads at any frequency up to 100 cycles per second.

Mechanical Testing—The fatigue testing that was performed on the implant was carried out with a load that varied in magnitude from 100 to 900 lbs. in compression at a frequency of 65 cycles per second. We had set a limit of five million cycles as an acceptable life in fatigue at those loads. This criterion is somewhat harsh, since the 900 lb. maximum limit is six times the body weight of an average male. Fatigue testing of the implants has shown that the pins, load cells and housing would withstand this five million cycle limit. However, the tray was developing a small fracture in the wall section in the region of the pin at or just slightly beyond the five million cycle limit. To find the solution to this problem, a series of tests were conducted where 4 different pin collar profiles were used in 2 different diameters with 2 trays of different floor thicknesses, which led to a total of 16 possible combinations. Each tray had rosette strain gages located over the areas where the fractures had been occurring. They were loaded to their maximum level and the strains recorded. The results of these tests indicated that by increasing the floor thickness of the tray and using a slightly different collar profile than had been originally used, stresses could be reduced by a factor of two in the regions where the fractures had occurred originally.

The next best possible combination was to keep the same floor thickness as originally used and increase the collar diameter by .075 inches. This, likewise, reduced the stresses by almost a factor of two. A subsequent finite element analysis also showed very comparable results and predicted that there should be no fatigue failures in the trays in the regions of the walls where they had been occurring. At the conclusion of these tests, a new tray design was fabricated. A series of fatigue tests were run on the revised implant and it succeeded in surviving more than 11.7 million cycles before the test was concluded. Although this was in excess of our criterion of five million cycles for an acceptable implant, it was decided to see if any fractures could be produced in either the tray, the pins or the load cell. At the 11.7 million mark the test was concluded and a careful examination of these three critical components showed no signs of excessive wear or any microfractures.

This last implant prototype subjected to fatigue testing was uninstrumented except that a fully wired load cell was used. At the end of the test there was no indication that any of the strain gauges had debonded from the titanium substrate or had failed from fatigue. The current plans for further testing include the shear fatigue test previously mentioned, as well as taking a fully instrumented telemetering implant prototype and installing it in a knee simulator to which we have recently obtained access. By means of this knee simulator, known loads in compression and shear in both the AP and lateral directions, as well as axial torques, can be applied at any level desired. The output from the device will be reduced using the full data acquisition system and then compared with the known simulator inputs for accuracy.

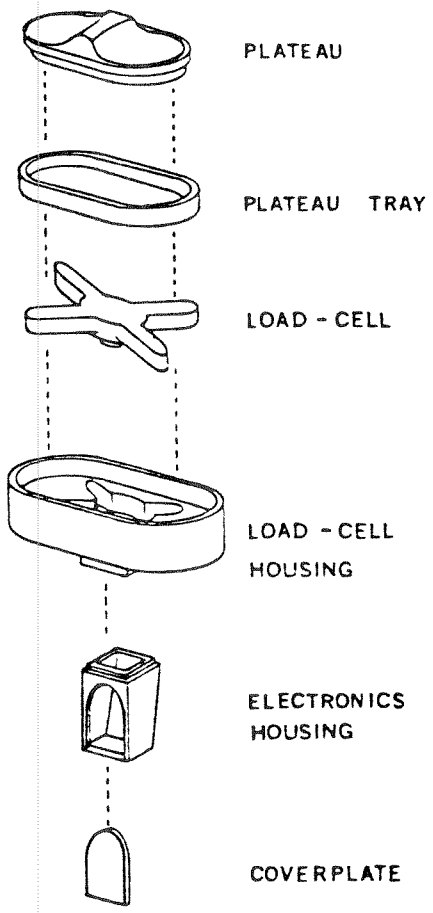

FIGURE 1.
Exploded view of telemeterizable total knee tibial system

Telemetry Development

Strain Gage Bonding—One of the unanticipated technical problems that has arisen relative to this project was the

difficulty associated with getting a good strong bond between the strain gages and the titanium. Because the titanium oxide formed so rapidly on any processed implant, we found it was not possible, using standard techniques, to reliably bond the strain gages to the titanium load cell. Therefore, a new technique for bonding strain gages to 6-4 ELI titanium was developed in our laboratory in conjunction with the Lord Corp. to improve the bonding reliability of the strain gages to this metal by eliminating the titanium oxide coating prior to bonding. The technique utilizes a special etching protocol, then a pre-treatment with a biocompatible conditioner (Chemlock 205) from Hughson Chemical Division of Lord Corp., which is then set after the gages are mounted. Use of this procedure has resulted in much better strain gage bonding and should prevent any problem in this area.

The steps in this procedure start with the machined part receiving a sandblasting. This is followed by a methyl ethyl ketone (MEK) ultrasonic 3-bath cleaning, followed by 10 minutes at 77 deg C in a mild alkaline solution, with stir agitation. After a water rinse, the MEK 3-bath ultrasonic cleaning is repeated, followed by an acid etch for 2 minutes at 45 deg C, with stir agitation. After a water rinse, the part is blown with dry air and when dry is given a spray-on coat of Chemloc 205.

Transmitter Circuitry—During the previous project period, two separate telemetry circuits (a single and a dual transmitter version) suitable for incorporation in the stem of this device have been assembled and tested. To insure against the possibility of intermodulation due to the housing of two separate micro-transmitters in the same stem, a series of laboratory tests were performed. These tests consisted of physically encapsulating two separate micro-transmitters with associated subcarriers into the actual stem geometry and receiving and analyzing the output from each on a Tektronix spectrum analyzer. Results showed no difference between a received pattern from a single transmitter or from that same transmitter when a second transmitter was active in the same housing. While the single transmitter version is lower in power, it employs more tightly spaced information channels. In contrast, the dual transmitter version, although consuming slightly more power, allows for greater channel separation and, therefore, greater sensitivity per channel. For this reason, our current plan is to use the dual transmitter version, since the increased current drain is acceptable for the batteries now used and the possibility of using some of the new high-energy density batteries would more than compensate for the power loss with this version.

Telemetry Reception—As part of this evaluation, two McIntosh Laboratories FM tuners were aligned, matched and tested in our laboratory and found to be in agreement within plus or minus 1 db over the full range of frequencies projected for use in this project. These tuners are utilized because they have a fixed-gain output which emanates prior to the standard stereo de-emphasis circuitry found in all modern FM tuners. This capability is essential, since the de-emphasis circuitry would, of itself, serve to decrease the received signal as a function of the subcarrier frequencies. It was these matched tuners that were utilized in conducting the above dual transmitter tests.

Also, as part of this telemetry receiver evaluation, the fidelity of the tape recorder (Technics Model 1500) being utilized in this project was analyzed. To this end, a number of record/playback tests were conducted at different frequencies using different types of recording tapes. As a result of this testing and evaluation, it was found that adequate fidelity and accuracy (tape drop-out and distortion due to flutter, wow, and tape tension) could only be guaranteed if the dual-channel tape system was aligned specifically to a high-quality instrumentation-grade tape on precision reels. Therefore, the tape system that is currently committed to this project has been aligned by an audio laboratory in Cleveland and matched to 3M–301 instrumentation tape. As a result of this procedure, the tape recorder is now capable of accurately recording the output of the dual McIntoshes without any perceptable loss in sensitivity.

Telemetry Demodulation—Since early in the project, when the very real possibility of having to utilize a single transmitter to broadcast all seven channels of data from the implant had to be considered, it was decided that a demodulator system based on the utilization of phaselock loop techniques would give the best possible channel separation. For this reason, a major portion of the electronic development in the early project period was devoted to developing the necessary phaselock loop demodulators. While these original demodulators were found to work reliably under the controlled conditions of the laboratory, they were also found to have a significant temperature instability compensation problem when moved from location to location. This was primarily due to our inability, in the early stages of the project, to obtain commercially a stable voltage-controlled oscillator which not only covered the audio range of our subcarriers, but also supplied the highly accurate quadrature output required for good phaselock loop AM demodulation. As a result, the original design utilized a heterodyning technique and a hybrid voltage-controlled oscillator circuit operating an order of magnitude higher than the subcarrier frequencies. Empirical analysis of the operational circuit showed that this heterodyning technique, although theoretically sound, tended to amplify any thermal non-linearities in the circuitry.

For this reason, commercial manufacturers were again queried, and a suitable low-frequency, high-precision voltage-controlled oscillator (VCO) with quadrature output was found to be on the market now at a reasonable cost. The demodulation circuitry has since been re-designed, based on this new VCO. With the use of this new voltage-controlled oscillator circuitry and its associated balanced multipliers, the required phaselock loop now operates in the same frequency range as the subcarriers, allowing direct lock onto the desired channel. It also allows for more accurate alignment of the tuning range of the individual demodulating units. In fact, this new design also has the additional bonus of increasing the overall reliability of the demodulation system because it actually results in fewer components necessary for implementation of the circuitry. Re-design of this system also greatly improved its ability to track the individual subcarrier channels over a much wider range.

Telemetry Packaging—As can be seen from Figure 1, the implant contains a

stem of standard external geometry which is in fact a hollow cavity accessible through a mating dovetailed sliding coverplate. It is this compartment which contains the actual energy cells and microcircuitry necessary to telemeter out the loading data.

Since our assembly protocol calls for pre-sterilization of the electronic circuitry prior to final assembly, our first investigation concerned itself with the effect of ethylene oxide sterilization on the microcircuitry components. To this end, a microcircuit consisting of an FM transmitter, three subcarrier oscillators, and a set of energy cells was assembled and tested in our laboratory. This initial testing documented the basic transmission parameters of subcarrier amplitude, center frequency and spectral purity as analyzed on a spectrum analyzer, the transmitter sensitivity and transmitter center carrier frequency, as well as the transmitter's signal strength. Following this test, the microcircuitry was then double wrapped and sent over for standard gas sterilization at University Hospitals. The circuitry was then retested in the laboratory. As a result of this testing, it was determined that the temperatures and gas utilized in the sterilization procedure did indeed have a slight effect on almost all the abovementioned circuit parameters. Therefore, following the second documented test, the circuitry was again sent to the hospital for a second sterilization. Following this second sterilization, retesting demonstrated that no further changes had occurred from the parameters documented following the first sterilization. For this reason, prior to final setting of the implant microcircuitry parameters, all associated components are first cycled through a gas sterilization procedure at least once. However, similar testing of the strain gages utilized on the load cell showed them to be essentially impervious to any effects of the sterilization procedure.

Summary

As stated previously, we currently anticipate no insurmountable technical problems in the successful completion of this project. The required telemetry capability is fully developed and tested. The basic mechanical design has also been extensively tested and shown to meet the mechanical requirements for a fully functioning total knee joint replacement. The only remaining aspect of this project currently under development is the finalization of the packaging of the whole implant system. This aspect of the project is being given considerable attention, since implantation of a total joint replacement gives long-term biocompatibility a whole new meaning. That is, anything that is implanted as a total joint replacement must be considered a permanent implantation. Therefore, the packaging and sealing techniques utilized in this device must be adequate to function for the anticipated long-term period.

Orthopaedic Implant Device Retrieval and Analysis

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This report covers the period 1 January 1981 through 30 June 1981. Two aspects of our retrieval and analysis effort dealing with total knee replacements are being reported.

The first aspect is the results of a surgeon survey, conducted in Louisiana, to provide more specific information concerning the selection and use of total knee arthroplasty.

The second aspect is the results of a continuing followup study of the polycentric knee arthroplasty.

Surgeon Survey

Purpose—The survey of orthopaedic surgeons in Louisiana was conducted in order to determine both the type and frequency of total-knee prostheses currently being inserted. It was further intended that this survey would examine the sentiments of practicing surgeons toward this procedure and possibly identify any common problems being encountered.

Method—A list of orthopaedic surgeons in Louisiana was compiled, using records obtained from the Louisiana Orthopaedic Society supplemented with a check of the telephone directories of the seven largest metropolitan areas of the state. A total of 159 orthopaedic surgeons were identified as practicing in Louisiana, and each was mailed a questionnaire in July of 1979. In December 1979, a revised questionnaire was prepared, which could be completed more easily, and those surgeons not replying to the initial mailing were contacted a second time. The requested information included the number of total knee replacement procedures performed, the types or designs of prostheses for total knee replacement (TKR) utilized, designs which had been abandoned, and comments about TKR.

Results—31 replies to the initial questionnaire and 48 replies to the second questionnaire were received for a final response rate of 50 percent. Of the surgeons who replied, 48 (61 percent) stated that they were currently using total knee arthroplasty as a treatment for rheumatoid and degenerative arthritis. These 48 surgeons claimed a total annual insertion of 487 devices.

In Table 1, the different designs of total knee prostheses have been characterized by their frequency of insertion according to the replying surgeons. Clearly,

TABLE 1.
Number of Each Total Knee Design Being Inserted in Louisiana in 1979.

Device	No. Surgeons* Using Each Device	Total No. Used Annually
Total condylar	35	302
UCI	11	59
Noiles	8	48
Townley Anatomical	5	21
Marmor Modular	2	19
GUEPAR	7	16
Polycentric	1	8
Stabilo-Condylar	2	6
Spherocentric	3	5
Cruciate condylar	1	1
Gustillo	1	1
Zimmer Offset Hinge	1	1
Annual Total		487

*Number of surgeons does not total to 79 because some surgeons do not perform total knee arthroplasty and some surgeons use more than one design.

the total condylar design has been most frequently inserted by this group, with 62 percent of all insertions and 73 percent of the replying surgeons who performed total knee arthroplasty using this design.

Also included in the questionnaire was a request for information concerning the reason why a particular device was chosen. The result clearly illustrated that the surgeon considered the design to be the most important. Other criteria noted as important were a device's usefulness in varied diagnoses, instrumentation associated with the prosthesis, availability, and finally previous training with a specific device (Table 2). The number of total-knee replacements performed each year per surgeon ranged from one to forty, with the average being ten.

TABLE 2.
Selection criteria used by Louisiana orthopaedic surgeons in choosing a prosthesis

Criterion	Number Noting
Design of prosthesis	12
Usefulness in varied diagnosis	9
Instrumentation	7
Availability of the device	6
Received specific training	4

The responses concerning devices no longer utilized by a surgeon, and the reasons for changing, were also investigated. The reason most often noted referred to the design of the prosthesis. Several surgeons noted that a newer design appeared to offer an advantage over an earlier design. Complaints concerning particular devices appeared consistent with those reported in the literature, such as the inadequate range of motion with a Geometric (1), and the loosening and disintegration of the UCI tibial component (2). Individual Louisiana orthopaedic surgeons also reported discontinuing use of the GUEPAR, ICLH, Noiles, total condylar, and the cruciate condylar prostheses.

Discussion

For the reporting year 1979, the survey revealed a general lack of enthusiasm with total-knee prostheses among Louisiana orthopaedic surgeons. Although several surgeons expressed apparent satisfaction with the knee arthroplasty, most did not. Several commented that they discouraged total-knee arthroplasty for fear of "disaster," while three surgeons noted that they had ceased using the procedure entirely. These reactions are very similar to the sense of dissatisfaction noted by Hori (3) in his study of orthopaedic surgeons at the major joint centers in Illinois in 1976. Hori further inquired as to how many additional patients would have been treated with TKR if reliable designs were available and found that an additional 60 percent more procedures would probably have been performed if a better system had been available.

On the basis of the 50 reply rate, it is possible to estimate that the total number of knee prostheses inserted in Louisiana in 1979 was between 489 and 987. The lower of these figures would apply where none of those surgeons who did not reply inserted any total knees, while the higher figure would apply if the surgeons who did reply were fully representative of the whole—obviously, a situation, somewhere between the two extremes may be expected. In order to examine the validity of the survey, all of the manufacturers of these devices were contacted to obtain their sales data in Louisiana in 1979 for both total condylar and other designs. These figures indicate that the sales of all total-knee prostheses were 610, of which 306 (50 percent) were total condylar designs. These figures for total sales are in broad agreement with the survey. While the somewhat low percentage of total condylar knees is surprising, this may reflect an over-generalized use of the term by the replying orthopaedic surgeons.

If the 609 figure for the manufacturers' sales is accepted as accurate and complete, then it becomes possible to estimate more accurately the overall usage of total knee arthroplasty. If the 79 surgeons who replied are inserting 489 protheses, then those 80 surgeons who did not reply should be inserting only 121 prostheses. This lowers the average number of insertions per surgeon from the figure of 10 (per surgeon replying and inserting) to 3 (per surgeon in the state)—while implying that a large percentage of all insertions are being performed by a comparatively small number of orthopaedic surgeons.

It would be of great interest to compare these findings with a similar study for total hip prostheses if one were available; certainly a more even distribution of insertions would be expected. It is intended, however, that a similar study be conducted in future years for total knee prosthesis in order to examine any changes which occur with time.

Polycentric Total-Knee Arthroplasty Followup

Purpose—A continuing followup of the polycentric knee affords the longest experience of any non-constrained total knee replacement. In this particular study, a maximum followup period of 93 months was available, with more than one-half of the 56 devices in use for at least 48 months. Although the polycentric total knee is no longer widely used, continuing accumulation of long-term results of its application provides valuable information in the continuing development of a more reliable arthroplasty.

Methods—A questionnaire containing 103 items regarding the preoperative, operative, and immediate postoperative condition of each patient was completed (Table 3). Each patient was contacted, those available were examined, and a form (Table 4) was completed describing each patient's current condition. The questionnaire and followup data form, Tables 3 and 4, are not shown; the two tables which occupy seven pages are available on request to Dr. Weinstein or to this publication. If the patient was not available for re-examination, the followup data form was completed from records of the latest available examination. A thorough radiographic analysis was performed regarding device placement, wire marker migration, and evidence of device settling for all radiographs available throughout the period of implantation, along with weightbearing anterior-posterior and lateral views taken at the time of the followup visit.

In order to define the outcome for the patient population, two knee rating scales were utilized. The first was the modified Larson Knee Score (4) (Table 5) which is a complex, multiple entry rating scale with a 0 to 100 point range of scores. The second was a simpler function rating scale, Table 6 (5) in which the

TABLE 5.
Modified Larson Knee Score

Function (40 points)		Anatomy (10 points)	
Limp:		**Genu Valgum or varum:**	
none	12	0-10	4
slight	8	10-25	2
moderate	6	over 25	0
severe	2	**Flexion contracture:**	
not walking	0	none	2
Support:		over 10	0
none	12	**Patellar abnormality:**	
cane, occas.	8	none	1
cane, always	6	lateral pos	0
crutch	4	high riding	0
2 canes	1	inc. mobility	0
2 crutches	1		
not walking	0		
Distance walked:		**Swelling:**	
unlimited	12	none	3
6 blocks	8	slight	2
2-3 blocks	6	moderate	1
indoors only	2	marked	0
bed, chair	0	**Pain (40 points)**	
Stairs:		none	40
normally	4	slight	35
use bannister	2	mild	25
any method	1	moderate	20
not able	0	severe	10
		disabled	0

Range of motion (10 points)
0 to 45 degrees
Deduct 1 for each 10 of loss. Max. 5 points.
45 to 90 degrees
Deduct 1 for each 15 of loss. Max. 3 points.
90 to 130 degrees
Deduct 1 for each 20 of loss. Max. 2 points.

TABLE 6.
Simplified point system for assessment of function

		Points
Pain	None	50
	Mild	40
	Moderate	15
	Severe	0
Walking ability	Outdoors, 30+ minutes	20
	Outdoors, 0-30 minutes	15
	Indoors	5
	Unable	0
Range of movement	80 +	30
	60-79	20
	30-59	5
	0-29	0
Acceptable Function	Pain	40-50
	Walking	15-20
	Movement	30

If acceptable in all 3 Add 10

TABLE 7.
Summary of patients

Patients Reviewed	51	
Total number of knees	56	
Age	mean:	58 years (range: 41–81)
Males	46	
Females	3	
Weight	mean:	178 pounds (range: 128–260)
Diagnosis		
Rheumatoid	9	
Osteoarthritis	32	
Post-Traumatic	14	
Other	1	
Followup	mean:	50 months. (range: 0–93)

TABLE 8.
Operative data

Tourniquet Time	1.5-2.0 hours	(range: 1 to 4)
Blood Loss	150 cc.	(range 100 to 500)
Hospital Stay	23 days	(range 7 to 60)
Healing Time	2 weeks	(range 1 to 6)

Operative Occurrences

Procedure	No. of Patients	% of Population
Patellectomy	0	0
Medial Facetectomy	5	9.6
Lateral Facetectomy	7	13.5
Patellar Shaving	11	21.2
Osteotomy of Posterior Femoral Condyle	26	50.0

Early Complications

Intraoperative deaths	0
Pulmonary embolism	1
Myocardial Infarction	1
Delayed wound healing	1
Infection	0

individual was evaluated using only three parameters. A bonus was provided if an individual were acceptable for all three measurements. The simplified rating scheme has a range of values from 0 to 110.

Overall evaluation to determine the success rate for the arthroplasty utilized the simplified rating scheme and the degree of satisfaction as reported by the patient during the interview. Additionally, any individual who underwent reoperation was classified as a failure.

Anterior-posterior radiographs from patients in the study were subjected to a more detailed analysis than called for in the general study, in order to determine the degree and significance of any settling that had occurred. Only the tibial components were evaluated in this manner, with the lateral and medial components studied separately.

Radiographs of an individual were examined in the following manner (Fig. 1):

1. A line (L1) was drawn determined to be the joint line using bone tissue not removed by the procedure as the landmark.
2. Another line parallel to L1 was drawn tangent to the most distal region of the bone cement for the medial component (L2).
3. A similar line was drawn for the lateral component (L3). (Not shown in figure)
4. The distance between the lines L1 and L2, and between lines L3 and L4, were measured and recorded as the distances (H1 or H2).
5. The width of the joint was measured at its widest point (W).
6. A length-width ratio was calculated and recorded for each component (Settling ratio - R).

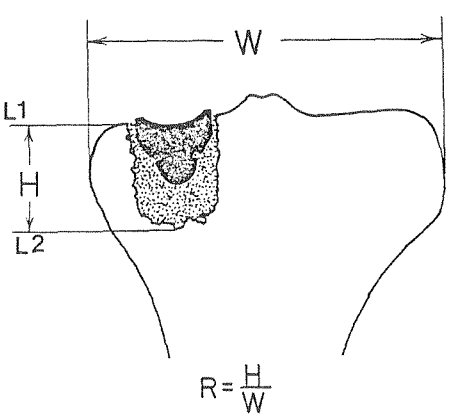

FIGURE 1.
Settling Ratio Determination.

The width measurement was utilized in order to compensate for any magnification variation between the different radiographs of a particular individual. When any region was unclear, several radiographs from the same individual were examined to insure that the same landmarks were chosen. No attempt was made to analyze the data as the measurements were being taken.

The calculated settling ratio was plotted versus time from implantation and a linear regression was performed in order to determine the slope of the best fit line. This slope for the time rate of change of the settling ratio was recorded as the settling indices for the medial and lateral components.

In order to determine the actual number of individuals present in the study during a given time interval, and to determine the probability for failure during any given interval, survival analysis was performed on the data. The 93-month interval for the study was subdivided into 10 periods. Survivorship of the arthroplasty was measured from the date of insertion. Although individuals entered the study at different times, for the purpose of these calculations, every participant entered the first interval and continued through all intervals until the time of followup for a given individual was reached. Individuals removed from the study were then marked as either "failed" or "withdrawn." An individual was marked as withdrawn if the study ended or the patient was lost to observation. This technique allows the use of data from cases for which the response (failure) had not yet occurred by the end of the study. The major restriction is the assumption that withdrawals occur randomly, not in anticipation of failure (6).

Results—The patients who were followed represent 58 consecutive polycentric arthroplasties (Table 7). Two arthroplasties were lost to followup because of unobtainable medical records—therefore 56 of the arthroplasties are included in the study. Of the knees included in the study, 33 were evaluated during an examination which occurred during March, 1980, through May, 1980. The remaining 23 knees were evaluated using the most recently available medical records.

The earliest arthroplasty was performed in April 1972; the most recent included in the study was performed in March, 1979. Approximately 10 arthroplasties per year were performed from 1972 through 1976 when the rate dropped to 2 per year through 1979.

Unique to this population is the male-to-female ratio. Other published studies of total knee arthroplasty involve predominately females, but only three arthroplasties of this study were performed on females, because the majority of the patients were treated at the Veterans Administration Medical Center, New Orleans.

The patient population represents a carefully selected group with the following preoperative indications identified as necessary for success:

1. minimal deformity,
2. minimal ligamentous laxity, and
3. good bone quality

Overall, the preoperative complaint common to all individuals was pain, with every individual complaining of moderate to severe pain on weightbearing. Additionally, 60 percent complained of moderate to severe night pain. The average range of motion for the group was 106 degrees (range 30 to 140) with 37 percent of the individuals demonstrating a flexion contracture of 5 degrees or greater. Disability severe enough to prevent an individual from working was claimed by 46 percent of the population.

Preoperative radiographs indicated only two individuals with normal joint spacing of the medial compartment, with 45 percent of the population rated as having severe loss of medial joint spacing. Only 15 percent of the population demonstrated severe loss of lateral joint space. Irregularities of the tibial surface were noted for 60 percent of the population with 86 percent demonstrating femoral surface irregularities.

The data obtained from the operative reports are given in Table 8.

Prophylactic antibiotics were administered intravenously to all patients with approximately 50 percent of the population receiving Cephalosporin (used prior to 1976) and 50 percent receiving Methicillin (used exclusively in 1976 and later). Cultures were recorded for 52 procedures with 6 (11.5 percent) identified as positive. In five of the six cultures the organism encountered was Staphylococcus epidermidus, with anaerobic diphtheroid in the other. The individual whose arthroplasty cultured the anaerobe had been treated with Cleocin. Three of the individuals with cultures

positive for the Staphylococcus had been treated with Cephalosporin and two with Methicillin.

Anticoagulant therapy was not routinely utilized with aspirin administered to ten individuals (19.2 percent) and Warfarin for one.

Early complications following the surgical procedure resulted in the deaths of two individuals. A 57-year-old male died from a pulmonary embolism on the second post-operative day. An 89-year-old female died during the second post-operative day following a myocardial infarction. No further complications developed during the immediate postoperative period except for one individual who suffered delayed wound-healing. That problem resolved without a skin graft.

Examination of the operative radiographs of 44 knees (12 unavailable) disclosed lucent lines present in nine knees (20 percent) immediately after implantation. Valgus placement was noted for one medial and one lateral tibial component. Twelve knees (27 percent) were noted as having an anterior tilt (anteroversion) of the tibial component with one individual demonstrating a posterior tilt (retroversion). Valgus placement was noted in two medial femoral and two lateral femoral components with two lateral femoral components placed in varus orientation. One individual was noted as having a flexion placement of the femoral components.

Six individuals underwent manipulation under anesthesia following surgery. The mean time for manipulation was 24 days postsurgery (range 14 to 35). The individuals underwent manipulation because they demonstrated a limited range of motion (mean value 50 degrees.) With one exception, all manipulations were performed prior to 1975. (The surgeon in charge became convinced that individuals would gain adequate range of motion in time without the added trauma of additional anesthesia.)

The results of this review are presented initially as tables showing the state of each case before surgery and at followup for various parameters. A cross-tabulation grid was formed with possible preoperative values of a given parameter marked on the vertical axis and possible followup values on the horizontal axis. Any block within the grid corresponds to a unique pairing going from a given preoperative to a certain followup condition as listed in each particular block of the table. In Table 9, Pain Rating, the horizontal row labeled "severe" includes the 25 individuals who suffered severe pain preoperatively. Of those individuals, one suffered disabling pain at followup, and four suffered severe pain. Thirteen individuals went from severe preoperative pain to mild pain at followup, with seven individuals demonstrating no pain at followup after having severe preoperative pain. Presentation of data in this manner indicates both the final quality of results and the degree of change between the two periods. A diagonal line is drawn intersecting cases showing no change in value from the preoperative to the follow-up condition (four knees in Table 9). Cases lying above the diagonal correspond to those that have improved following surgery; those lying below it have deteriorated. The general quality of the results in a group of knees can be seen by their distribution about the diagonal "no change" line. In order to simplify the presentation, a chosen value is defined as "acceptable" for each parameter, and a vertical line is drawn at this point crossing the horizontal axis. Only cases falling to the right of the vertical line are considered acceptable at followup. Further, a summary expressed as percentages is presented below each table. Each table includes every individual from the study for whom both preoperative and postoperative values for the indicated parameter were available.

Referring to Table 9, pain relief at followup represented the most dramatic improvement offered by the procedure, with only one individual worsened and four unchanged. The lower rate of improvement in walking ability (Table 10) resulted from the general condition of the participants of this study; no attempt was made to alter or exclude the rating of an individual whose limited walking ability was unrelated to the arthroplasty.

Three individuals demonstrated a passive range of motion (Table 11) of less than 70 degrees at followup. Two of the individuals with reduced range of motion were short-term, with the device in place for 16 months or less. One died of gunshot wounds 3 months after surgery, and the other died 16 months after surgery following a pulmonary embolism. The third individual continues as a marginal success after 56 months. The average range of motion for the population was 106 degrees with 37 percent of the population demonstrating 110 degrees of motion or greater. Extension contracture of greater than 5 degrees was present in seven individuals, with one individual demonstrating an extension deformity of 30 degrees.

Medial/lateral instability was not a major problem for this patient population, with moderate medial instability more prevalent than lateral instability, and no individual suffering from severe instability in either compartment.

The radiographs of 46 arthroplasties were available at followup and examined for the presence of lucency. Nineteen knees demonstrated slight lucency associated with at least one component of the arthroplasty. The most common site of the lucency was the medial tibial component (in 16 arthroplasties) with the lateral tibial component suggesting slight lucency in 13 arthroplasties. Lucency around femoral components was much less common, present in only four medial and three lateral components.

Moderate lucency was noted in a total of three arthroplasties, in two medial tibial components and one medial femoral component.

Sclerosis beneath one or more tibial components was identified radiographically in 51 percent of those reviewed. Breakage of the wire marker was identified in the radiographs of six individuals. This breakage was thought to follow a loss of bony support beneath the central portion of the component, which permitted a flexing of the polyethylene and the encased wire.

The number of items necessary for completion of the Larson Knee Rating Scale left many individuals with an incomplete rating. Of the 54 knees in the study, only 36 could be rated with the Larson rating. Utilizing the simpler scale suggested by Freeman, 45 knees were rated postoperatively but only 44 could be rated preoperatively.

The minimum rating considered acceptable, using the Freeman scale, was 75. In order to attain an acceptable rating an individual could have no worse than mild pain on weightbearing, 80 degrees of motion, and the ability to walk indoors. (The cross-tabulation of the Freeman rating is presented in Table 12.) One individual demonstrated a drop in rating following the surgery, with seven individuals identified with unacceptable knee ratings at followup.

In order to check the effect of time on

TABLE 9.

PAIN RATING

Pre-op	FOLLOW-UP: Disabled	Severe	Moderate	Mild	Slight	None
Disabled	0	4	0	12	0	8
Severe	1	4	0	13	0	7
Moderate	0	0	0	0	0	0
Mild	0	0	0	0	0	0
Slight	0	0	0	0	0	0
None	0	0	0	0	0	0
	Unacceptable			Acceptable		

SUMMARY

Acceptable	81.6%
Unacceptable, improved	8.2
Unacceptable, unchanged	8.2
Unacceptable, worsened	2.0
Total reviewed	49

TABLE 10.

WALKRATE

Pre-op	FOLLOW-UP: Unable	Severe df.	Mod. dif.	No limit
Unable	0	1	1	0
Severe diff.	1	3	4	3
Moderate df.	1	2	9	9
No limit	0	0	0	0
	Unacceptable		Acceptable	

SUMMARY

Acceptable	76.0%
Unacceptable, improved	3.0
Unacceptable, unchanged	9.0
Unacceptable, worsened	12.0
Total reviewed	34

RANGE OF MOTION (degrees)

Pre-op	FOLLOW-UP: <70	70-90	90-100	>100
<70	1	0	0	2
70-90	1	3	3	4
90-100	0	3	2	0
>100	1	6	4	21
	Unacceptable		Acceptable	

SUMMARY

Acceptable	71.0
Unacceptable, improved	0.0
Unacceptable, unchanged	7.0
Unacceptable, worsened	21.0
Total reviewed	52

TABLE 11.

SIMPLIFIED KNEE RATING SCALE

Pre-op	FOLLOW-UP: Disab	Severe	Prob	Fair	Ok	Excel
Disabled	0	1	0	6	0	0
Severe	0	1	4	13	6	9
Problem	0	1	0	2	1	0
Fair	0	0	0	0	0	0
OK	0	0	0	0	0	0
Excellent	0	0	0	0	0	0
	Unacceptable			Acceptable		

SUMMARY

Acceptable	84%
Unacceptable, improved	14
Unacceptable, unchanged	22
Unacceptable, worsened	0
Total reviewed	44

TABLE 12.

knee-rating value, a plot with linear regression was performed (figure 2). It should be noted that, twice, two knees had identical ratings and times of followup (rating = 60, followup = 51 months; rating = 95, followup = 84 months).

Although the rating of individuals with a followup of 60 months or greater is somewhat lower than that for short-term arthroplasties, the trend is slight. The average knee rating at different followup periods is almost constant.

A total of 11 knee prostheses were identified as failures. Six knees have undergone reoperation. Three of these knees were revised to a more constrained device, while revision for the others involved replacement of one or more of the polycentric components, leaving the patient with a polycentric arthroplasty. One of the polycentric revisions was subsequently fused. The five remaining were classed as failures based on functional result (knee rating and patient assessment) but have not at this date undergone reoperation. Moderate to severe pain on weightbearing was associated with every failure.

Analysis for settling was performed on 27 individuals from the study. This sub-group represents those individuals on whom three or more readable radiographs were available covering the implantation time of the device. This population contains most of the failures (10 of 11). This was not a conscious choice, but a result of the higher frequency of examination for individuals having difficulty.

The average number of radiographs

read per individual was 6 (range 3 to 13) covering an average period of 50 months (range 18 to 93).

The time rate of change of the settling ratio was determined for both the medial and lateral tibial components. Table 13 reports the values for each individual in the analysis, arranged for medial and lateral compartments. Each set is subdivided into three categories, based on a sharp break in the settling index value. The group labeled "definite" demonstrates what is felt to be definite settling, the second group is identified as "questionable" for settling, with the third having no evidence of settling. Thus, for the medial component, a slope of 0.085 or greater is taken as definite evidence of settling, a range of 0.030 to 0.084 is questionable, and less than 0.030 is classed as not settling. (A negative slope probably represents an indeterminant value rather than actual rising of the device, and is most likely a result of measurement inaccuracies.)

The trends in the settling index values for lateral compartment (Table 14) are less clear than for the medial, with three numerically large negative values well beyond the assumed "indeterminant" range. Whether or not such values represent rising of the prosthesis is not clear.

Table 15 describes the settling ratio for the 10 of the 11 knees described clinically as failures. Every individual classed as a failure demonstrated at least questionable settling on radiographic analysis, with 50 percent of the failures

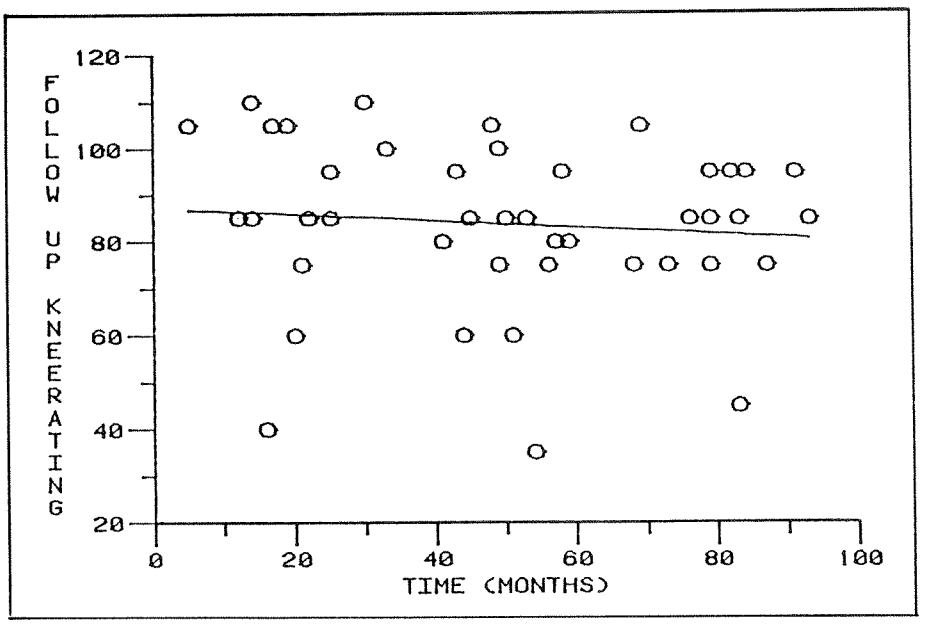

FIGURE 2.
Knee Rating versus Time at followup.

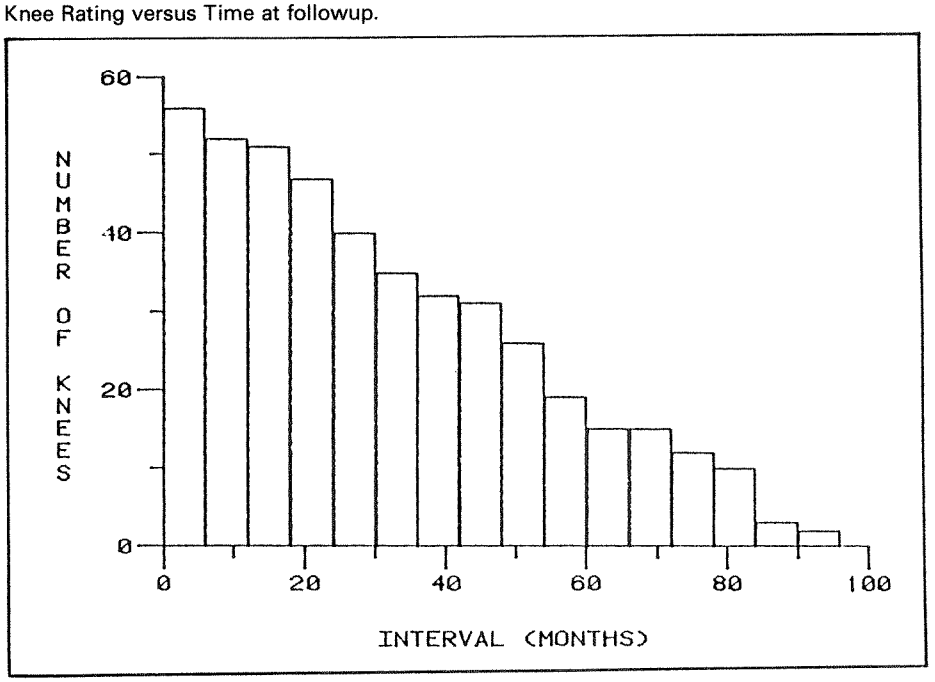

FIGURE 3.
Number of knees exposed versus Time.

MEDIAL SLOPE VALUES

ID	SLOPE	TIME (months)
DEFINITE SETTLING		
366L	0.583	26
401L	0.290	37
698R	0.146	45
828L	0.143	28
443L	0.113	23
924R	0.094	44
210L	0.087	55
434L	0.086	35
QUESTIONABLE SETTLING		
633L	0.068	35
083L	0.052	23
635R	0.047	62
504R	0.041	35
551R	0.034	68
337R	0.030	53
NO SETTLING		
698L	0.027	43
147L	0.024	49
265R	0.018	57
510L	0.011	18
720L	0.006	50
874R	0.004	77
701R	-0.002	60
930R	-0.004	72
044L	-0.020	89
266L	-0.027	59
269L	-0.043	93
038L	-0.085	67
965R	-0.093	36

TABLE 13.

demonstrating definite signs of settling. Also listed are the values of the settling ratio for the 17 non-failures. Of this group, eight (47 percent) demonstrated a suggestion of settling with four (24 percent) of these individuals having definite settling.

Of the four individuals who demonstrated definite settling, two are short term (23 months or less) and warrant a close examination. It is felt that these two individuals are at risk, and some conservative response by the clinician may be called for. One of the remaining is marginally successful; the individual has a rating of 75 (minimally acceptable) after 55 months. The rate of settling and current quality of result suggests that clinical failure may occur shortly. The remaining individual rates 105 on the Freeman scale (excellent) with only slight pain; this individual does demonstrate moderate medial ligamentous laxity and is currently in twenty degrees of varus, which would be consistent with medial settling.

The life table for survival analysis is presented in Table 16. It is important to note that, during the later intervals of the study, the number of arthroplasties exposed or "at risk" is drastically reduced as individuals are withdrawn. With a mean followup period of 50 months for this study, only 15 arthroplasties are exposed to 5 years or longer use. Thus, even with this study, only a small portion of the population has an exposure time suitable for a long-term study. The number of knee arthroplasties exposed is plotted versus the interval of the study, in Figure 3.

LATERAL SLOPE VALUES

ID	SLOPE	TIME
DEFINITE SETTLING		
510L	0.377	18
434L	0.272	35
366L	0.103	26
828L	0.098	28
QUESTIONABLE SETTLING		
698R	0.060	45
720L	0.058	50
265R	0.052	57
266L	0.042	59
NO SETTLING		
337R	0.017	53
701R	0.014	60
965R	0.010	36
210L	0.087	55
874R	0.010	77
504R	0.010	35
635R	0.001	62
147L	0.001	49
038L	0.001	67
924R	-0.012	44
698L	-0.015	43
551R	-0.017	68
044L	-0.020	89
083L	-0.028	23
633L	-0.047	35
269L	-0.068	93
443L	-0.185	23
401L	-0.270	37
930R	-0.628	72

TABLE 14.

FAILURES

ID	Medial Settling Index	Lateral Settling Index	Status or Knee Rating
266L	-0.027	0.042	45
337R	0.030	0.017	Reoperation
366L	0.583	0.103	60
401L	0.290	-0.270	Reoperation
434L	0.086	0.272	Reoperation
504R	0.041	0.010	45
551R	0.034	-0.017	Reoperation
720L	0.006	0.058	60
828L	0.143	0.098	Reoperation
924R	0.094	-0.012	60

NON-FAILURES

ID	Medial Settling Index	Lateral Settling Index	Status or Knee Rating
038L	-0.085	0.001	85
044L	-0.020	-0.023	75
083L	0.052	-0.028	?
147L	0.024	0.001	75
210L	0.087	0.010	75
265R	0.018	0.052	95
269L	-0.043	-0.068	95
443L	0.113	-0.185	110
510L	0.011	0.377	?
633L	0.068	-0.047	95
635R	0.047	0.001	85
698L	0.027	-0.015	95
698R	0.146	0.060	105
701R	-0.002	0.014	85
874R	0.004	0.010	85
930R	-0.004	-0.628	?
965R	-0.093	0.010	110

TABLE 15.

Figure 4 presents a plot of the proportion of the population failing versus time in situ. In this study the time of greatest danger of failure occurred between the 48th and 54th months, with 12.5 percent of the exposed population failing. The interval of highest proportion of failing was immediately preceded by the interval with the second highest failure proportion (6.8 percent). An earlier interval of elevated failure occurred between months 18 and 24, with 6.7 percent of the individuals at risk during the interval failing.

A plot of the overall probability of survival versus time is presented in Figure 5. The final level of survival was 0.705. The estimated time at which 25 percent of the population would fail was 51.3 months.

The population was subdivided into two groups according to preoperative weight of the individual, with 200 pounds at the cut-off value. The probability of failure versus time for the two subgroups is plotted in Figure 6.

In comparing the two groups, the cumulative probability of survival at 96 months was 0.80 for the knees in individuals weighing less than 200 pounds, and 0.50 for individuals weighing more than 200 pounds.

Discussion—With no consensus in the literature on what constitutes a success, assessing the results of total-knee arthroplasty is difficult. A procedure may be said to have failed if it does not meet the goals established for it. A successful total-knee arthroplasty must provide stability, mobility, and freedom from pain. The simplified knee-rating scale utilized for this study provides a semi-quantitative measure rating level-of-pain, range-of-motion, and the ability of the patient to ambulate, with 50 percent of the rating weighted toward pain, 30 percent toward range of motion, and 20 percent toward walking ability.

During the patient interview, the most common expression of satisfaction was about freedom from pain, the most common complaint was about the presence of pain associated with the knee. Thus the 50 percent weighting of the scale for pain is probably justified. The large drop in rating between mild pain (40 points) and moderate pain (15 points) made that single observation determine whether the rating was a success or failure. An "acceptable" rating (75 points) was unobtainable if the observer noted moderate pain at followup. The distinction between mild and moderate pain is not clear; the necessity for such distinctions limit the usefulness of this and other semi-quantitative rating schemes. The Larson knee score assigns 40 percent to pain rating, with an additional category which reduces the abrupt drop in points but requires distinction between slight, mild and moderate pain—thus making the subjective decision more difficult.

The multiple factors influencing the walking ability of an individual limit its usefulness in a rating system. The simplified rating scale utilizes only the distance the individual can walk. The Larson scale rates, in addition to the distance walked, the presence of a limp, use of aides, and the ability to maneuver on stairs. Again, none of the additional parameters identify knee function problems alone. The 20 percent weight of the simplified scale assigned to walking ability is justified.

As described earlier, the minimally acceptable rating of 75 represented an individual with mild pain, greater than 80 degrees of flexion-extension motion, and the ability to walk indoors. When asked how they would rate their knee, of the individuals who subsequently were rated as minimally acceptable (75 points) two felt their knee was very good, two felt

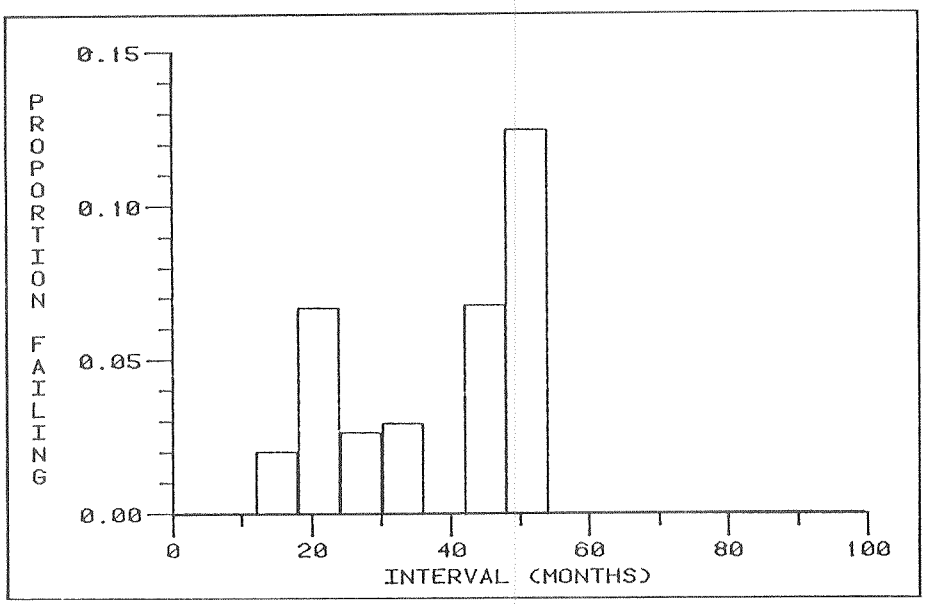

FIGURE 4.
Proportion Failing versus Time.

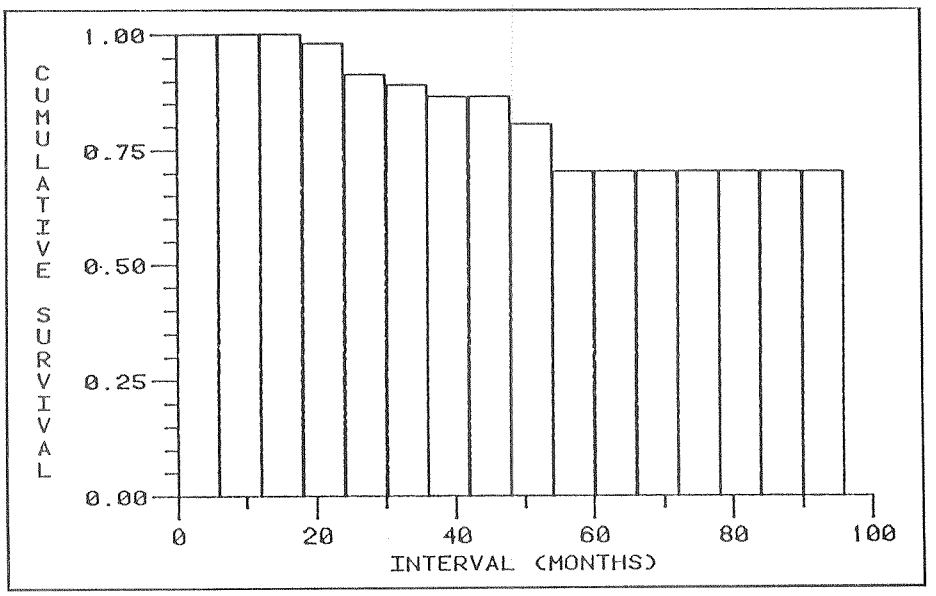

FIGURE 5.
Cumulative Survival.

Life Table

Interval (months)	Entered	Left	Failed	Proportion failed	Cumulative survival
0 - 6	56	4	0	0.00	1.00
6 - 12	52	1	0	0.00	1.00
12 - 18	51	3	1	0.020	1.00
18 - 24	47	4	3	0.067	0.980
24 - 30	40	4	1	0.026	0.914
30 - 36	35	2	1	0.029	0.890
36 - 42	32	1	0	0.000	0.864
42 - 48	31	3	2	0.068	0.864
48 - 54	26	4	3	0.125	0.806
54 - 60	19	4	0	0.000	0.705
60 - 66	15	0	0	0.000	0.705
66 - 72	15	3	0	0.000	0.705
72 - 78	12	2	0	0.000	0.705
78 - 84	10	7	0	0.000	0.705
84 - 90	3	1	0	0.000	0.705
90 - 96	2	2	0	0.000	0.705

TABLE 16

the knee was good and two felt that it was fair. Of the individuals rating 95 points or greater, all identified the results as good (3 individuals) or very good (14 individuals).

The knee rating serves to distinguish a "success" from a "failure" by the independent evaluation of selected parameters rather than a single subjective decision. Marginal scores are the least dependable, and the single step of the pain evaluation from mild to moderate essentially selects the failures.

The eleven individuals identified as failure either because of reoperation (6 patients) or knee rating (5 patients) were grouped for separate analysis to identify factors associated with the failure.

With such a small total number of failures, statistically significant inferences concerning factors predisposing an individual to failure were not possible. Ten of the 11 failures occurred in individuals with a diagnosis of primary (eight failures) or secondary (two) osteoarthritis, with one rheumatoid individual classed as a failure. The individual with rheumatoid arthritis complained of moderate pain on weightbearing, but had an excellent range of motion and was able to ambulate four to six blocks.

The population was examined to determine if any individual failed to meet the preoperative indications. In checking preoperative deformity, six individuals exhibited 10 degrees of varus and one had failed. Of the 6 individuals with 15 degrees of varus preoperatively, also one had failed. Two knees had 20 degrees of varus preoperatively, one could not be rated as the patient died shortly after surgery, and the other failed. One individual demonstrated 10 degrees of valgus preoperatively, and failed. One individual began with 28 degrees of valgus, is currently classed as a success, but has reverted to 20 degrees of valgus at last followup. Though no clear conclusions can be drawn, there appears to be the suggestion that greater than 15 degrees of varus or valgus may predispose a knee to failure.

Evaluation of preoperative instabilities (an indication of ligamentous laxity) revealed 17 individuals with moderate medial instability and one failed. Among the two knees with severe medial instability, none had failed. Only one knee demonstrated moderate lateral instability, and it was not a failure. Three knees demonstrated moderate to severe bilateral instabilities and none of these have failed.

A qualitative estimate of bone quality was determined using preoperative radiographs. Four individuals were rated as having severe loss of bone density, or osteopenia, with no failures among them. One failure was recorded among the two knees rated with moderate osteopenia.

Though not mentioned as a preoperative contraindication, 6 failures occurred among the 24 individuals who had undergone knee surgery prior to the arthroplasty. The types of previous surgery in the failed knees demonstrated no pattern, with one patellectomy, one tibial plateau prosthesis, and one each with osteotomy and synovectomy.

Excess weight has been implicated in the failure of total knee arthroplasty. The mean preoperative weight of the entire population was 174 pounds; of

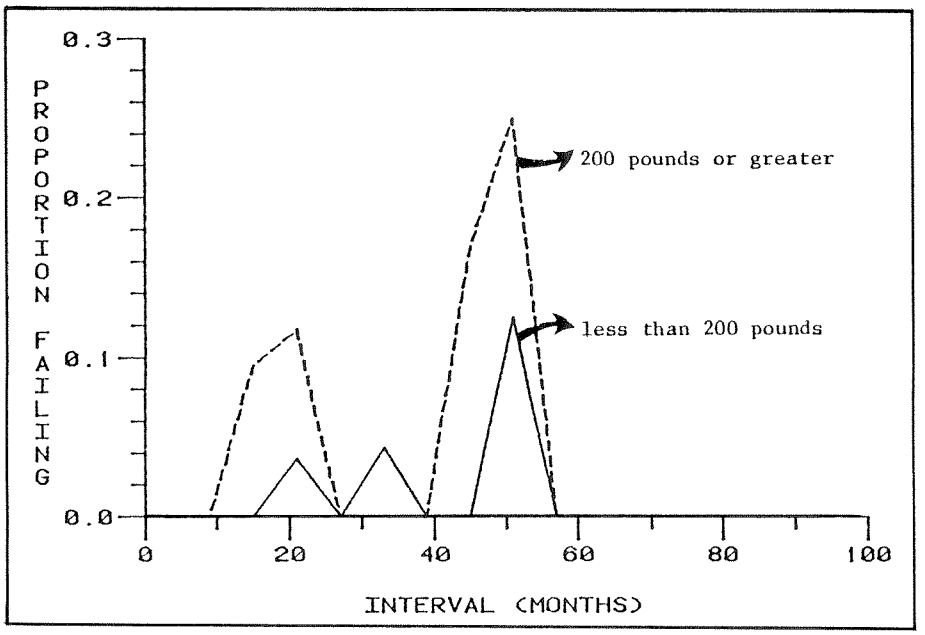

FIGURE 6.
Proportion Failing versus Time.

the non-failures, 172 pounds, and of the failures, 190 pounds. The difference was not statistically significant ($p < 0.20$). Twenty-seven percent of the individuals 190 pounds or greater (4 of 15) failed, while 14 percent (4 of 28) of those individuals weighing less than 190 pounds failed.

No relationship was noted between the presence of lucent lines postoperatively (in nine cases) and later failure. Of the three individuals displaying marked lucent lines at followup, two were classed as failures. The large number of individuals (19) with only slight lucency demonstrated no tendency toward failure.

The effect of individual component placement as noted in the operative radiographs was evaluated. The one individual with retroversion placement of the tibial components, and the one individual with a flexion placement of the femoral components, each failed and underwent revision. No association was noted between varus or valgus placement of the components and subsequent failure.

The relationship between device placement and success of the arthroplasty could not be verified with this population. In his evaluation of Geometric total knee arthroplasty, Lotke (7) noted varus positioning in four of the five instances of mechanical failure of the prothesis. Illstrup (8) suggested that a common sequence of failure for the Polycentric knee involved a good initial result with slight residual varus which would be followed by a gradual sinking of the medial tibial block increasing the varus. At followup, 5 knees of the 56 were in varus with one failure—and 5 were in valgus with 1 failure.

The settling index was the evaluated parameter most closely associated with failure, suggesting settling as the primary mode of failure. Bryan (9) mentioned failure due to settling as an infrequent occurrence. Lax ligaments and unexplained pain which were reported as causes of failure in the Bryan study could have been caused by implant settling.

The initial attempts at identifying settling using a qualitative impression of radiographic changes was not adequate. The quantitative measurement procedure provided a strong indication of the presence or absence of settling and the rate of settling, for most cases. The difficulty in evaluating certain cases could be eliminated if a standardized radiographic technique were utilized.

Because of the increased risk to the device associated with individuals weighing 200 pounds or more, a linear regression was performed between the values for the settling index (once for medial and once for lateral) and the weight of the individual. No trend was present between weight and either of the index values. The slope of the regression line in each case was near zero. The results are not unexpected; time in situ of the device should alter the influence of the individual's weight on the settling index.

The method for determining the settling ratio as described would be applicable only to Polycentric arthroplasty. Other knee arthroplasty procedures require the removal of the entire surface of the tibial condyles, and no bony landmarks remain to identify the joint line. For such devices, another landmark would have to be selected, possibly the head of the fibula.

Actuarial methods (life tables) are commonly used when measuring the time to occurrence of some event or response. They have been used in epidemiological studies and in the engineering analysis of the failure of manufactured components. Dobbs (10) suggested the use of actuarial methods to compensate for the differences in length of followup between different studies of hip arthroplasty, one factor which limits the comparison of such studies. The method can be applied with little difficulty, allowing periodic and overall failure rates to be determined for a group of patients with varying followup.

Survival analysis generates a more conservative estimate of survivorship than the conventional method of reporting the proportion failing within a given population. With 11 failures identified among the 56 knees that underwent Polycentric total knee arthroplasty in the present study, the simple failure rate would be 19.6 percent. The cumulative survival as determined by survivorship methods for the same population was 70 percent, or a failure rate of 30 percent. The computations produce a higher and more realistic failure rate because the probability of failure is calculated for successive intervals by dividing the number of failures by the number of devices at risk during the interval. Successive multiplication of the probability of survival produced the cumulative probability of survival.

The effect of weight on the probability of survival is profound, with a drop from 0.8 to 0.5 as preoperative weight exceeds 200 pounds. The curves of the proportion failing appear similar for both groups displaying only a difference in magnitude. (Figure 6) In both curves there appear two periods of peak failure, with no failures after the 55th month. In his study of long-term followup of Polycentric arthroplasties, Bryan (11) noted a continuing incidence of failure between the 5th and 7th years. At present, no such failure has occurred in the population under study, and a 5-year survival at present appears to insure a 7-year survival. As the number of individuals exposed during the 5 to 7 year period increases, failures may and probably will occur.

Dobbs suggested extrapolation of the survival probability to predict failure at some future time. Such a prediction would be valid only if the future behavior could be defined by the past. In the current study, if the first 30-month interval had been used to predict failure in the second 30-month interval, the high incidence of failure at 50 months would not have appeared. The causes of failure of a joint arthroplasty are not constant in time; for example, infection can occur early, while wearing out of the prosthesis usually occurs late. Extrapolations of survival data, especially when the patterns of failure are irregular and of varying causes, are not valid. Actuarial methods provide many advantages in analyzing the effects of time on a population. They serve to limit the influences of differing followup periods when two or more studies are compared. They do not however, provide a view of the future.

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Development of Hindfoot Joint Resurfacing Prosthesis

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Introduction and Background

This project is based on the hypothesis that established total joint replacement technology can be employed for implants for acquired deformities of the hindfoot joints (subtalar, talonavicular and calcaneocuboid). If properly designed, these implants will restore normal hindfoot position and allow hindfoot joint motion, thus providing nearly normal function. It is planned to develop implant components which resurface the joint with the need to remove only minimal amounts of bone. This strategy will make it possible to remove the implants to perform an arthrodesis if necessary for any reason. Outside of reports of the work being performed in this laboratory (and previously by one of the investigators with M.A.R. Freeman and M. A. Tuke in England) there are no publications in English describing such prostheses.

Initial project tasks have been to establish methods for determining whether prototype prostheses (i) provide adequate range and type of motion, (ii) maintain normal forces in surrounding ligaments and (iii) provide adequate component base cross-sectional areas to prevent collapse of supporting bone. Other design considerations such as articular wear resistance are not being investigated, but will be satisfied by using materials with proven clinical performance. It is necessary to use human cadaver specimens to perform the types of tests described.

This report covers the second half of the first project year. During this year, efforts have been directed chiefly at establishing test methods and performing tests to assess the adequacy of a prototype talonavicular prosthesis already available at the beginning of this project.

Talonavicular Joint Surface Geometry

Determining the surface geometry of the normal talonavicular joint was among the first project activities and was described in this Bulletin (BPR 10-35, Spring 1981). As mentioned at that time, the report was submitted for publication in Foot and Ankle, the journal of the American Orthopaedic Foot Society. During the present reporting period the article was published (1). Specimens are now being gathered for similar assessments of joint surface geometry for the subtalar joints and the calcaneocuboid joint.

Talonavicular Compressive Force Measurements

It is necessary to determine forces transmitted across prosthetic joint components under anticipated tibial loads for two purposes. First, it is possible (especially in the case of polymeric components) that the force per unit area on one of the components will be sufficient to cause damage to the component or alteration in its shape, thus impairing its function. In addition, the intra-articular force results in a compressive stress (force per unit area) in the supporting bone. The magnitude of the stress depends both on the force transmitted across the joint and the cross-sectional area of the base of each of the supporting, articulating components. If the compressive stress under normal joint loads exceeds the compressive strength of the supporting bone, it is possible that the joint components will subside into the bone and thus change their function. In this regard, measurements were made of the compressive strengths of the supporting bone in both the talus and navicular (reported in the immediately previous issue of BPR).

Determining the actual force transmitted across the prosthetic talonavicular joint under applied tibial loads in cadaver specimens has been a more difficult task. This is because it is necessary to incorporate force measurement elements in one of the talonavicular joint components, thus effectively turning it into a force transducer.

Initial efforts to produce a talonavicular prosthesis instrumented to read intra-articular force were documented in the immediately previous issue of BPR. February 1981 marked the completion and utilization of a special talonavicular joint prosthesis, incorporating a fiber optics force transducer, into the talar component. This prototype device was capable of reading moderate (up to 30 kgf) talonavicular loads over a normal range of foot positions relative to the tibia in human cadaver specimens. A complete description of the transducer and its performance was published (2) as a project report in completion of the research project requirement for the degree of Master of Engineering in Bioengineering at the University of Utah.

Subsequent to the development of that prototype force-reading talar component, various methods were explored to allow the component to respond to a higher range (over 100 kgf) of talonavicular force. Essentially, it was necessary to develop or obtain a small, but extremely stiff, low-hysteresis spring which would fit inside the talar component of the joint prosthesis. The prototype configuration of six small coil springs could not be reworked to obtain the required stiffness. A number of spring materials and spring-type devices were explored and evaluated. Finally we were able to incorporate a pair of Belleville springs into the device, as

shown in Figure 1. Belleville or disc springs are essentially precision-made washers which, instead of being flat, have a raised inner rim relative to the outer rim. A wide variety of these springs is available (National Disk Spring Division, Rolex Company, Hillside, New Jersey). In addition, these springs may be stacked in series, parallel or combinations of series and parallel configurations to give a broad spectrum of spring performance. Two springs in series configuration are now used in the talar component, providing a useful force range up to 200 kgf. Figure 2 shows a calibration curve for the prosthesis with the new spring components.

Ankle Ligament Tension Measurements

Little work has been reported in the field of laboratory determination of ligament forces, and most ligament function studies of any type have been concerned with the knee. Other investigators in this laboratory recently developed a novel method for simultaneous determination of the forces in ligaments in statically loaded cadaver specimens, and have applied this technique to biomechanical studies of the knee (3). The technique is now being applied to the ligaments surrounding the ankle-hindfoot joint complex in this project (Fig. 3).

In the technique under development, stress in **intact** ligaments is sensed by utilizing strain gage transducers placed on the surface of the bone near ligamentous attachments. The strain readings can be converted to force by subsequently severing the ligaments and applying a series of known loads to develop calibration curves. Multiple gage sites with sequential recording of data allow simultaneous static measurements of resultant ligament forces at known positions under known external loads, before and after introducing prosthetic ankle, talonavicular joint, or other hindfoot implants.

Ligamentous function in the ankle region is varied and complex, since some of the ligaments stabilize both the ankle joint and the hindfoot joints. The purpose of this initial study was to define further these anatomical interactions in the deltoid, anterior talofibular, and calcaneofibular ligaments in normal specimens. Embalmed cadaver ankle specimens are being used for protocol development. As techniques are refined, fresh specimens will be studied as they become available. A test platform has been designed and built which allows the specimens to be positioned with known amounts of dorsiflexion/plantarflexion, varus/valgus, and rotation relative to the vertically held tibia. Known loads are then applied to the tibia with an Instron testing machine.

Three specimens have been tested to date, following a detailed protocol involving three tibial force levels (4, 40 and 70 kgf), five positions of varus/valgus, and seven positions of flexion. Data obtained showed reproducible trends in strain patterns. Initial observations are as follows:

1. The anterior portion of the **deltoid**

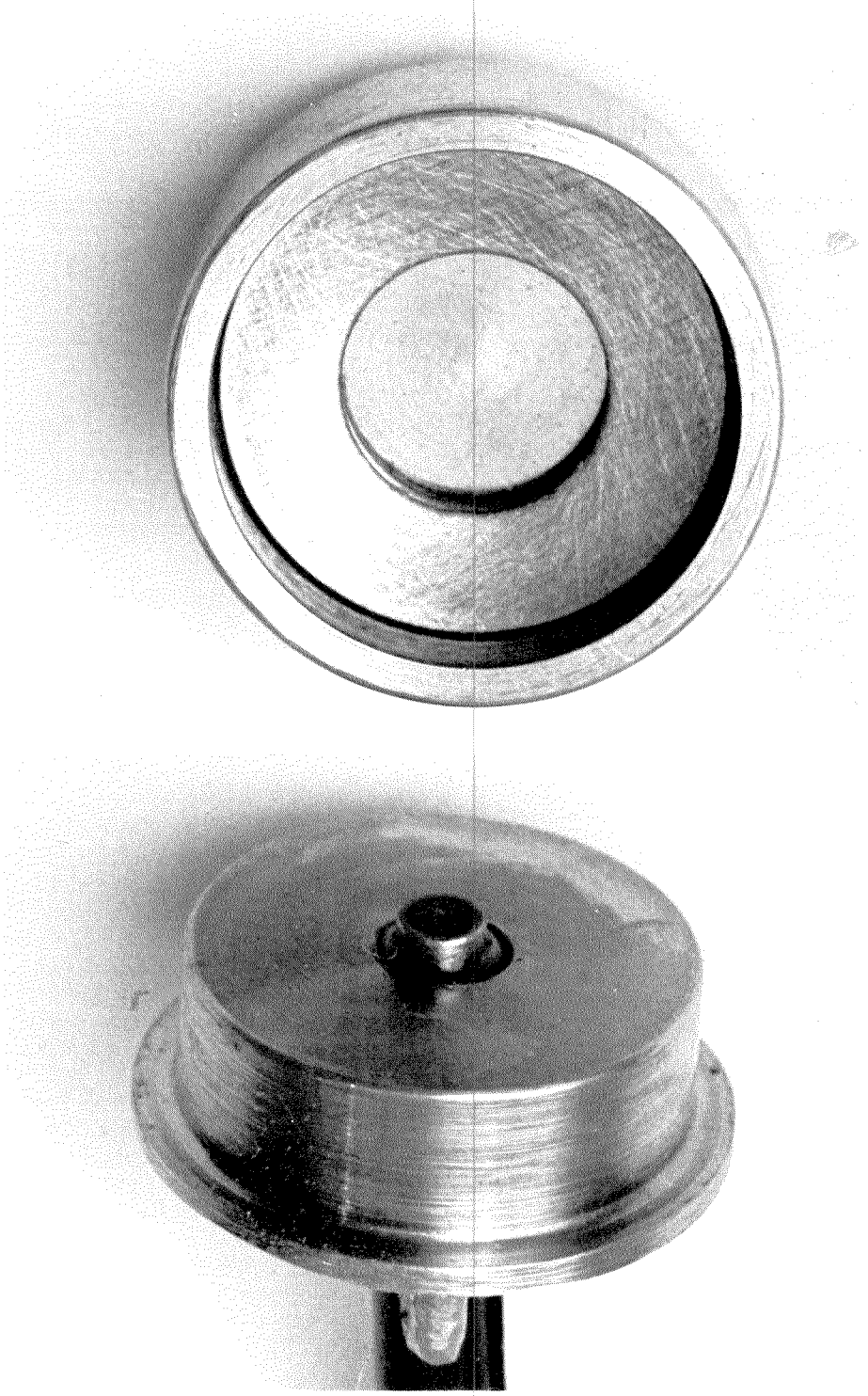

FIGURE 1.
Interior view of improved talar component force transducer showing location of Belleville (disc) springs. Scale is approximately 4 2/3 X life size.

ligament becomes more taut as the ankle goes from dorsiflexion to plantarflexion. Ligament tensions as high as 14 kgf were recorded in a neutral varus/valgus position with 70 kgf tibial axial load applied. Trends were reversed for the posterior portion of the deltoid ligament. Force measurements of 23 kgf were obtained at the maximum dorsiflexion level studied (30 degrees) for this ligament. This was the highest ligament force recorded in our initial studies. Both portions of this ligament were stressed in valgus positions. However, the posterior portion of the deltoid ligament showed increased tension with varying degrees of varus combined with dorsiflexion. This is thought to be secondary to the subtalar motion causing tightening of this ligament in the aforementioned position.

2. Progressing from dorsiflexion to plantarflexion, the **anterior talofibular ligament** showed steadily increasing tension. Varus/valgus positioning had little effect on forces observed.

3. As the ankles were placed in dorsiflexion, the tension on the **calcaneofibular ligament** increased. This occurred with varus positioning also. The forces were small compared to those seen on the medial side of the ankle.

4. In general, as tibial loads were increased a general increase in ligament tension was seen. However, ligament tensions at 4 kgf of tibial force were already 80 to 90 percent of the values observed at 70 kgf.

This initial study has shown that the technique described appears useful in determining the relative tensions in the ankle ligaments. The findings emphasize the need for critical evaluation of these functional interactions. For example, the contribution of subtalar joint movement to ligament tension, especially in causing the posterior portion of the deltoid to be under increased load, is contrary to previously accepted descriptions of ligament function. This work should provide a baseline which will allow evaluation of changes in ligament function related to prosthetic replacement of the ankle and/or hindfoot joints.

Quantifiable and reproducible positioning of the foot relative to the tibia is important in producing and understanding both ankle ligament tension measurements and talonavicular compressive force measurements. A device of simple but unique design, al-

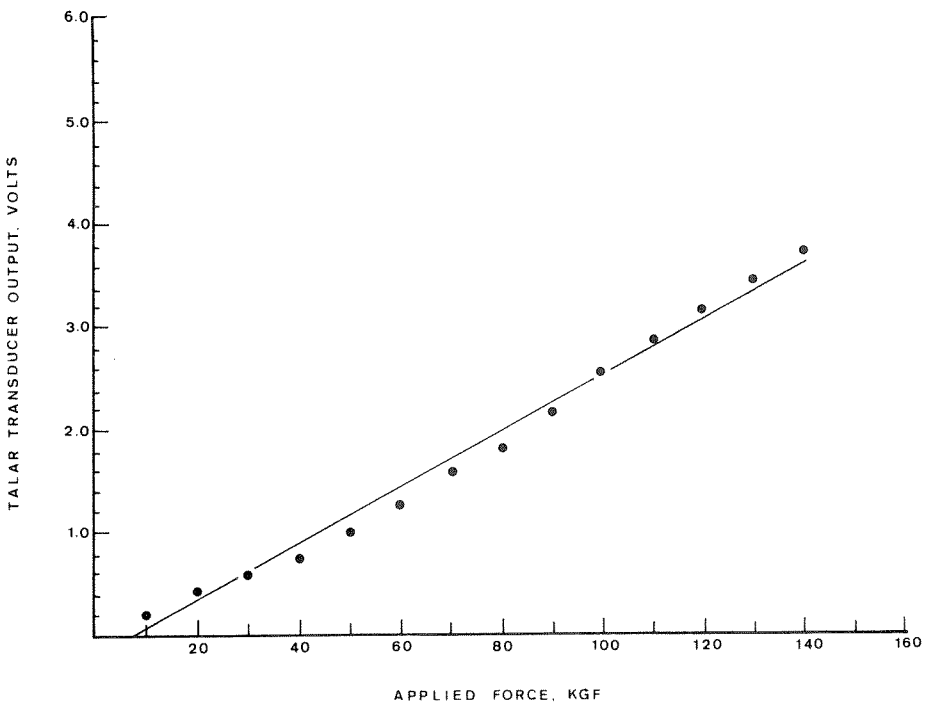

FIGURE 2.
Voltage output of improved talar component force transducer as a function of applied load.

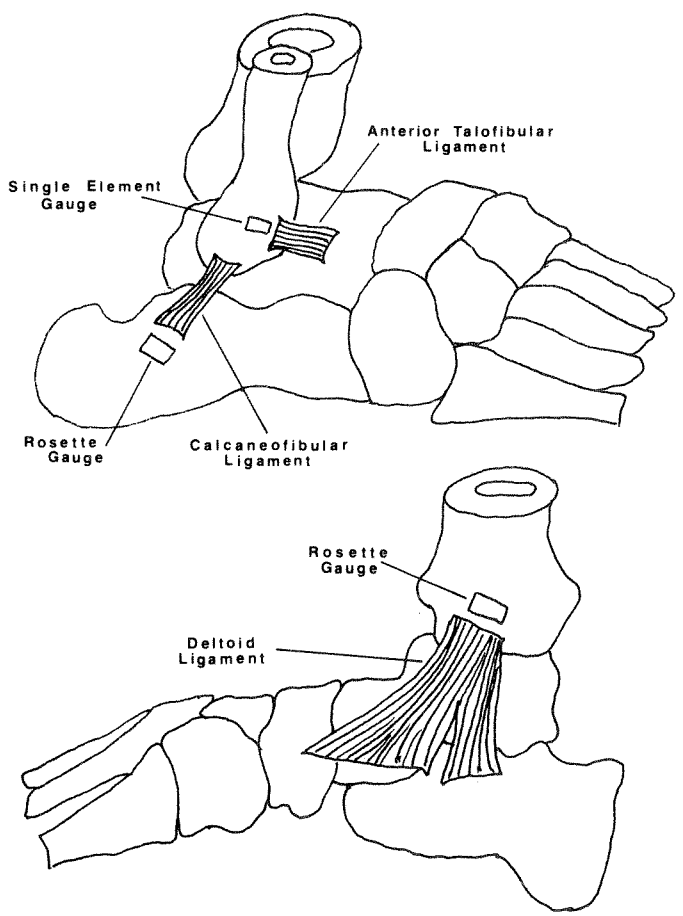

FIGURE 3.
Location of strain gauges for measurement of ligament tension in the ankle-hindfoot joint complex.

lowing positioning of the foot relative to the tibia in any combination of dorsiflexion/plantarflexion, rotation and pronation/supination, is under construction. It will be described in subsequent reports.

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

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Work is continuing in dogs with several types of implants, and evaluation of an initial series of implantation at 20 sites in 5 dogs is currently underway. In the coming year, the effect of the implants on graft incorporation will be studied using quantitative histological techniques with the aid of an Optomax (semiautomatic image analyzer). The project is complicated by the fact that the large specimens of radius and ulna require in vivo fixation techniques to adequately preserve the tissue.

Engineering Applications in Orthotic and Prosthetic Treatment of Musculoskeletal Defects

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In a major development for the Motion Study Laboratory, a 57-year-old nonwalker, for whom all conventional means of ambulation assist had been tried at a major rehabilitation center, became a walker through the use of functional electrical stimulation. A pharmacist who suffered a bilateral stroke approximately 3 years ago, he was paralyzed from the neck down and for 6 months was unable to move at all. He gradually regained function of most of his body. Presently he is able to use his left hand well, his right hand to some degree. There is decided weakness in the left leg, and in the right leg he has no function of the hip flexors or the lateral trunk muscles to "hike" the hip. This limitation interferes with his forward progress in walking, because he is unable to bring his foot through. The patient has a double upright ankle-foot orthosis on the right, but he says it doesn't help much. He does have some selective control of the extension of the right knee, though very little at the ankle. He has some control at the hip on the right but it is not as good as the knee. The patient can stand independently—but can only walk backwards. With the assistance of a therapist who advances his right leg for him, he is able to walk forward.

The patient was implanted with intramuscular electrodes in the right iliopsoas and the rectus femoris. A stimulator was made which is turned on with a heel switch. A timer then activates the rectus after an appropriate delay (Figs. 1 and 2). The patient has been given a stimulator for his personal use at home and is clearly able to walk unassisted with the stimulator and a walker frame, though he is totally unable to walk without the stimulator. We believe that this is a type of patient who may greatly improve with electrical stimulation.

Two other patients are currently in the program. Work is continuing in conjunction with Case Western Reserve University and Dr. Hunter Peckham on an implanted version of the stimulator.

A Master's Thesis (1) resulted in the demonstration of ankle, knee, and hip

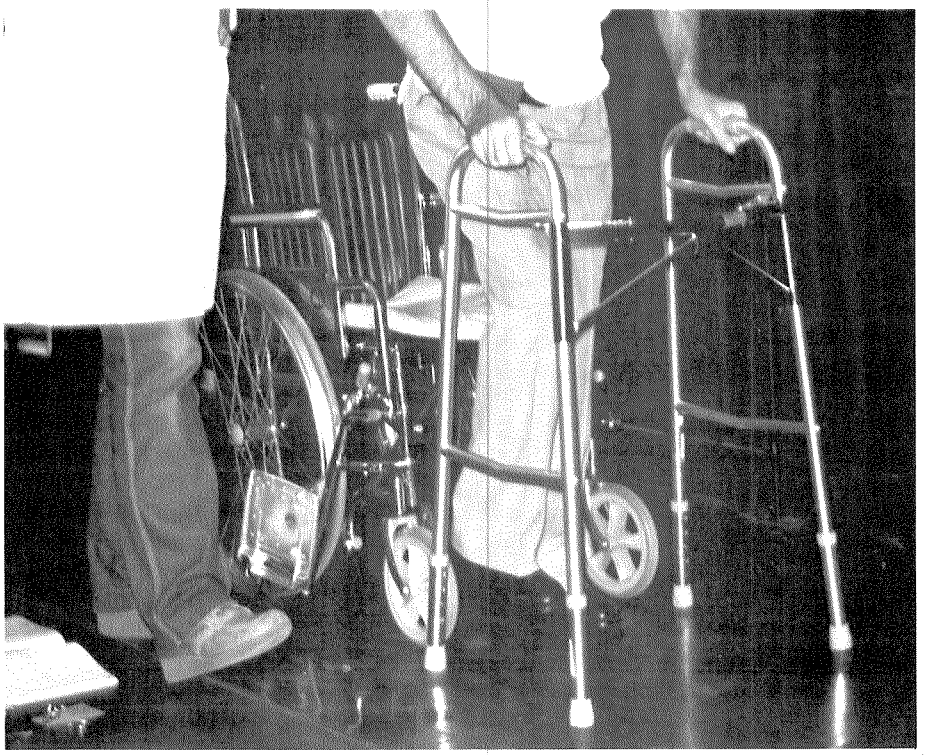

FIGURE 1.
Patient walking with Functional Electrical Stimulator. Right iliopsoas stimulated (hip flexed; knee remains flexed).

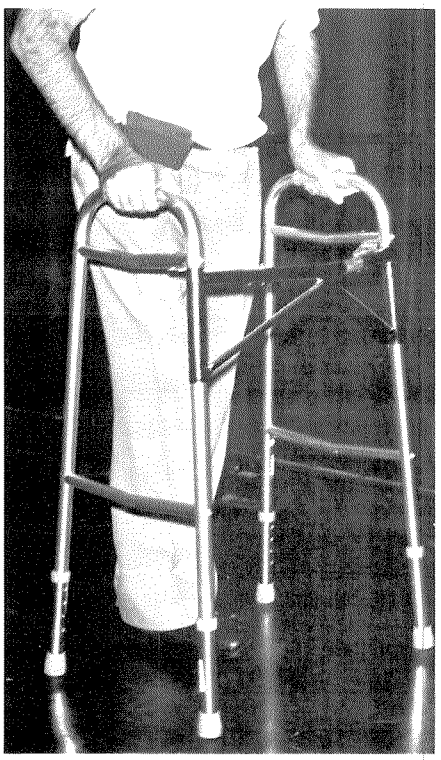

FIGURE 2.
Patient walking with Functional Electrical Stimulator. Right rectus femoris stimulated (hip flexed and knee extended).

kinematics by Selspot with acceptable accuracy. A second Master's Thesis (2) resulted in the upgrading of the joint force estimation capability of the laboratory.

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Prosthetics Research

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Below-Knee Preparatory Prostheses

Direct-casting methods are still being investigated, with continuing experience gained through clinical use of preparatory below-knee prostheses.

Interesting observations are coming to our attention in the comparison of direct-formed (on the patient) socket shape with sockets which have been refined from a number of check socket fittings.

Socket shape and cast modifications are now among the main areas which are under investigation regarding the concept of "total contact" fit.

Clinical use of preparatory below-knee prostheses is progressing. Modifications for Syme's amputation levels have been developed and look promising.

Powered Arm for Shoulder Disarticulation Levels

Work is continuing on a total arm prosthesis for shoulder-disarticulation amputees that utilizes unbeatable position-servo control effected by shoulder motion. A preliminary investigation, analyzing the ability of the normal subject to control the physiological arm and shoulder, has been completed. The results of this investigation have indicated the viability of using shoulder elevation/depression and protraction/retraction to control prosthesis elbow flexion and wrist rotation.

An experimental prosthesis has been built to allow further evaluation of unbeatable position-servo control of prosthesis function. In this system, unbeatable position-servo relationships have been effected by implementing direct cable linkages between the prosthesis activators and a shoulder motion transduction system. The activators incorporated in the prosthesis are the Northwestern University wrist rotator and Liberty Mutual/Boston elbow. Actuator control signals are derived from strain gage force transducers, attached to the linkage cables, that are sensitive to forces derived from shoulder motion. Evaluation of this system is currently in progress.

Hip-Disarticulation Ambulation

A master's thesis has been completed entitled "Pendular Models of the Swing Phase During Gait: The Canadian-type Total Limb Prosthesis." Ambulation data was collected from a vigorous amputee who walked on a Canadian-type prosthesis with a hydraulic knee and on a similar prosthesis with a constant friction knee. Comparisons showed substantial differences in the kinematics of walking with these two prostheses. The amputee under study walked about 10 percent faster on the prosthesis with the hydraulic knee than with the constant friction unit. Angle-angle diagrams (hip angle vs. knee angle) were determined for both conditions.

Pendular models (mathematical) were made of the limbs, and the model response under gravitational influence was compared with walking responses. The results indicated that the swing time of the prosthesis as used by the amputee was much shorter than the swing-time of the model under gravitational influence. This result is consistent with conventional wisdom which states that the prosthesis is forced considerably during gait by the hip flexion stop and by accelerations in the hip region.

Redistribution of prosthetic mass in the models indicated that such attempts in prostheses would probably not be practical for reducing natural oscillation periods.

Models showed that the knee flexion achieved during swing-through by the amputee during gait was not sufficient to produce toe clearance of the floor. Consequently, compensatory floor clearance actions were necessary during gait.

Lower-Extremity Amputation: Immediate Postoperative Fitting of Prostheses

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Due to funding changes and hiring freezes, there was a large lag time for active research productivity in our project. We have just recently recruited a new research prosthetist and have added several new areas of investigation to our prior work. In addition to continuing to evaluate use of Xenon isotope to measure skin blood flow for amputation level selection, and the use of immediate postoperative prostheses for amputation rehabilitation, we are also beginning to evaluate (i) skin temperature as it relates to prosthetic design and environmental factors, and (ii) new prosthetic materials which may contribute to more durable lightweight prostheses, especially needed by geriatric amputees.

We have begun preliminary evaluation of Scotch-cast® (water-activated

polyurethane on fiberglass) for construction of immediate postoperative and temporary lower-extremity prostheses. This material has a large amount of promise, both with respect to prosthetic costs and for rehabilitation of patients with limited physical strength.

We are beginning our evaluation of the feasibility of a regional referral amputation center within the VA system of medical centers.

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

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Since our last report, we have tripled the number of amputees treated with immediate postoperative prosthetic devices after traumatic or elective upper-extremity amputation. Although our group of patients is still small, our initial conclusions would suggest significant improvement in patient prosthesis use and two-handed function, and a decrease in pain and phantom limb problems. In addition, for those patients who were working prior to their injury, we have been extremely successful in returning them to a working environment.

We have been working with manufacturers of various powered prosthetic devices in order to incorporate changes which will allow many of the components to be interchangeable.

Due to funding changes and hiring freezes there was a lag in our program; however, we have just hired a new research prosthetist and expect to be back in full swing very shortly. At the present time, we are making plans to formulate a prospective randomized study which will compare conventional and externally powered components when applied as immediate postoperative prostheses after upper-extremity amputation.

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

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Scope and Goals

The goal of this research is the development of an imaging system for diagnostic and prognostic evaluation of peripheral vascular disease associated with inadequate limb circulation. As described in our previous report, we are developing a television display technique that utilizes up to three separate simultaneous images of the affected limb, each taken through a photographic filter selected to optimize display of specific deficiencies in selected elements of the cutaneous and subcutaneous vascular arborizations.

At this point, we are approaching completion of photographic data that will provide a baseline suited to the selection of these filters, and at the same time, engineering specifications are being prepared for the electronic data acquisition and image processing system. Final specifications of the electronic processing will be based upon analyses of the baseline data acquired in normal subjects and patients with vascular disease.

Accomplishments in Reporting

Two photographic protocols have been tested. In each case, black-and-white film images have been subjected to initial computer evaluation. Enlarged prints of each negative have been prepared to provide a complete library of the negatives taken with green, red, and infrared filters. These prints are useful in preliminary data evaluation and in controlling lighting parameters.

Photographic Protocol A—This protocol has been used for the study of eight normal subjects and nine patients with vascular disease. It involves the following sequence:

1. Sphygmomanometer cuff placed at midthigh (deflated).
2. Patient rests for 15 minutes.
3. Reference photos taken with green, red, and infrared filters.
4. Cuff pressurized to 50 mm Hg above systolic blood pressure. Pressure maintained for 5 minutes.
5. Reference photos taken before release of cuff.
6. Upon release of cuff, photographic sequence started with pictures at 0, 5, 10, 15, 30, 45, 60, 90, 120, 150, 180 . . . to 300 sec; 1 picture/min to 10 min; 1 picture every two minutes from 10 to 20 minutes.
7. Take Doppler records of systolic pressure and wave from recordings at knee and ankle (elapsed time 5 min).
8. Take photographs of dependent leg at 30, 45, and 60 sec after sitting up.

This sequence demanded excellent coordination on the part of the photographer to secure three images with three cameras at short intervals in the first 5 minutes of the sequence after deflation of the cuff.

Photographic Protocol B—Following preliminary data analyses, it became apparent that vascular changes following the ischemic challenge were periodic in character, with a solitary change in the optical density (reflectance) as a fraction of time over the 20 minutes of the photographic sequence. These first analyses have suggested that a faster photographic sequence would be desirable, and a modification of Photographic Protocol A has now been tested. In most aspects, the sequence is the same as in Protocol A, but the photography is confined to the green filtered image. After the reference sequences preceding and following the cuff inflation for 5 min, photographs are taken every 10 sec for 20 min. To accommodate all the picture frames (totaling approximately 140) on a single roll of film, a motorized camera back is used. There have been four subjects in the initial group using this protocol, two controls and two patients.

Preliminary data analyses of records from Protocol A, using reflectance from the region of the knee and from the lower portion of the leg, shows strong

periodicities that decrease in amplitude and frequency with the passage of time to the completion of recording at 20 min. However, the large changes in sampling intervals between the beginning and the end of these records under Protocol A carry a major risk of aliasing of high frequency data, particularly for sequences between 10 and 20 min. We are therefore making a major effort to complete similar analyses from film sequences under Protocol B, where the 10-sec sample interval will be adequate to evaluate high and low frequency components of these reflectance records from the beginning to the end of the recording epoch.

Plans and Goals

Spectrophotometry and correlated photography through special filters will be performed on blood samples transillumined with light identical with sources to be used in operating the TV data acquisition system. These blood samples will first be equilibrated with a series of gas mixtures having progressively lower oxygen tensions within the expected physiological tissue oxygenation range. This study is necessary in the selection of the vidicon tube to be used in the video converters.

A further baseline of normal subjects and patients with arterial disease will now be established using Photographic Protocol B, extended to a trispectral photographic imaging already tested under Photographic Protocol A.

Progress in baseline data acquisition is now approaching a point where adequate information will be available for the implementation of the electronic engineering phase of the project. This will require a substantially higher level of scientific effort in coordination of biochemical, biophysical, and engineering phases of the project. This expanded commitment will be the subject of a further research proposal in the next 90 days.

Instrumentation for Clinical Investigative Engineering Center

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Work was started to design and construct instrumentation for the Clinical Investigative Engineering Center. The laboratory will be used to conduct clinical investigations, the immediate technical focus of which will be in the area of locomotor impairments. The primary goal is to enable clinicians to employ objective techniques to (i) help make choices in prosthetics and orthotics treatment and methods, (ii) measure progress and efficacy of therapy, and (iii) evaluate new and untested components, appliances, and treatment techniques. The secondary and longer-range goal is to enable development of clinically deployable instrumentation to measure variables associated with gait and having an impact on improvements in locomotory function. To reach these goals, engineering objectives include the provision of instrumentation which (i) is reliable and relatively trouble free, (ii) is convenient to use, and (iii) presents data derived from measurements shortly after testing, formatted in a manner easy to interpret and understand.

The first phase instrumentation is modest in scope and is patterned after successful designs employed at various facilities engaged in locomotion studies. Four categories of gait variables were chosen. They include: (i) detection and indentification of joint movement deviations occurring bilaterally, using electrogoniometry, (ii) limb loads and loading rates using load-sensing sandals, (iii) instantaneous forward velocity using a tachograph, and (iv) mechanical work done during walking using accelerometers. Signal processing and data display will be done using a Commodore Business Machine "PET" microcomputer.

Substantial progress has been made. An electronics technician was hired after certain restrictions from the Federal hiring freeze were eased. Mechanical designs were prepared and fabrication of the mechanical components is about 70 percent complete. Orders were processed for electrical supplies and for equipment; received to date are about half of the supplies but none of the equipment. The construction of a barograph was completed. Experience is being gained in the acquisition of plantarbarograms of patients having foot disorders secondary to diabetes.

Evaluation of Physiologic Suspension Factors in Below-Knee Amputees

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Our work to date has identified physiologic suspension factors at the below-knee level of prosthetic substitution, has established protocols for their measurement, and has begun to investigate their significance. (See our progress reports in BPR 10-33, 10-34, 10-35.) Muscle activity properly captured in this socket design can enhance the physiological components of suspension and stability. Physiologic suspension, between the residual limb and the prosthetic socket, results directly in improved 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. The goal is not necessarily to produce suspension by the physiologic factors alone but to improve the existing suspension and proprioception through a sustained intimateness of fit.

We are studying below-knee amputees in order to determine the statistical significance of the various suspension factors. A multiple regression analysis has been performed to establish the relationship between the measured suspension factors and the suspension performance. These analyses will enable us to identify which factors are most important to suspension performance, which factors are improved by training, and finally, what final suspension performance can be predicted for an amputee based on measurements of his suspension factors before training.

Methods

At this time we are measuring all below-knee amputee patients who are ambulatory in their prostheses without skin

problems, in conjunction with the prosthetics clinic at the Seattle VA Hospital. Using our protocol, we have evaluated both conventional and myoplastic residual limbs.

Our evaluations consist of an activity profile questionnaire to establish the level of activity available to each individual (Appendix A), a series of measurements of socket and residual limb suspension factors, and measurement of the suspension performance of the prosthesis. Selected patients are also measured stereophotogrammetrically for limb and socket contours.

The socket and residual limb suspension factor measurements are as follows:

1. Limb length, L in centimeters, from the distal aspect of the patella to the distal tip of the residual limb.
2. Gastrocnemius circumference, G in centimeters, measured at the apex of the distal medio-lateral muscle bulge.
3. Medio-lateral expansion, E in centimeters, measured in the distal stump, upon contraction of the residual gastrocnemius muscle mass.

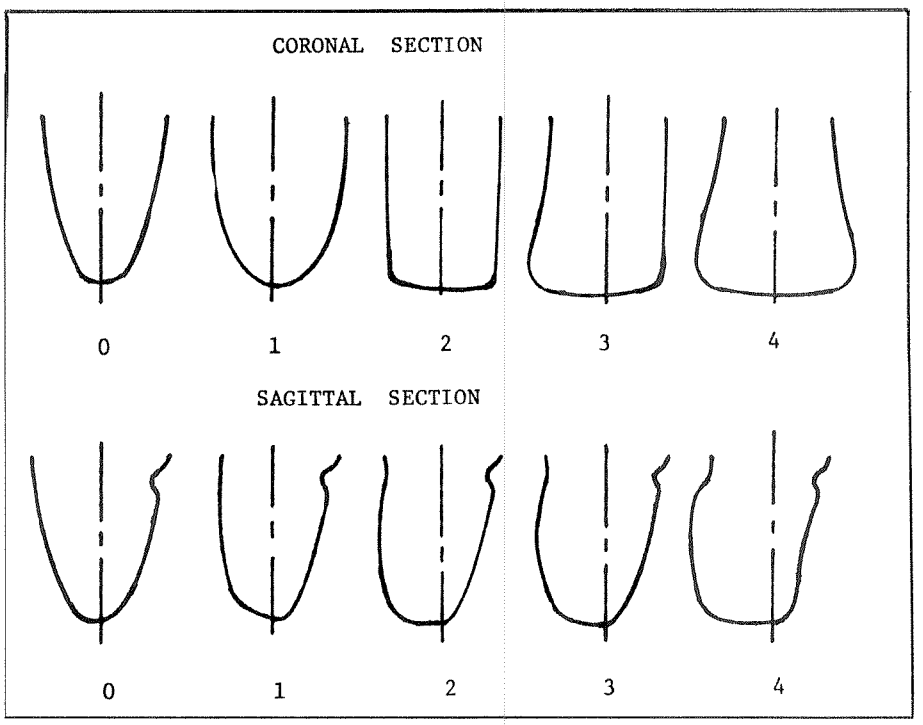

FIGURE 1.
Limb contour factor subjective rating scale.

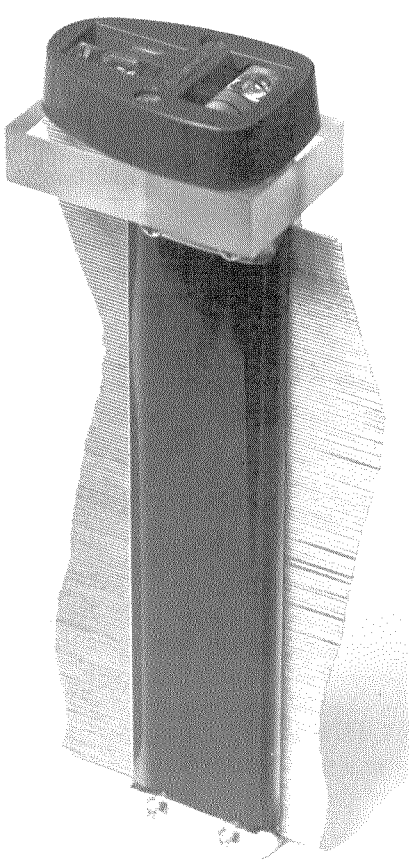

FIGURE 2.
Socket contour replication device.

4. Compliance (the amount of compression), F in centimeters, induced when the contracted muscles at the point of the expansion measurement are subjected to a compressive force. The amount of compression is inversely proportional to the firmness of the contracted musculature.
5. Skin motion, M in centimeters, the maximum amount of vertical motion possible between the skin and the bony structure of the residual limb. It is measured by palpation of the anterior medial face of the tibia.
6. Limb contour (the degree of taper or bulbousness in the shape of the residual limb). Two methods are used for the evaluation of this parameter. One approach matches contour tracings of the limb to weighted cases, and sums the resulting scores to produce a contour factor C_1 (Fig. 1). The other approach fits a third-order polynomial curve to photogrammetrically derived contours of each aspect of the residual limb, and produces a contour index C_3 from the sums of the resulting slopes.
7. Socket contour, similarly to the limb contour index, the qualitative judgement C_2 is based on tracings of the socket made with a special tool adapted for that purpose (Fig. 2). A mathematical description is fitted to the contours of a positive model of the socket to produce contour index C_4.
8. Interference D (a measure of the relative fit in the distal medio-lateral dimension between the residual limb and the prosthetic socket). It is expressed in centimeters, with a plus value indicating tightness.
9. Interference P, similar to above except that it relates to the narrowest place existing in the socket, usually between the levels of the distal muscle bulge and the fibular head.

The suspension performance of the prosthesis is evaluated from measurements of pull-off force versus displacement as the subject pulls straight up. The device used to make these measurements was previously reported in BPR 10-33. Figure 3 illustrates the following characteristics:

1. Suspension stiffness, S in Newtons/cm., is a measure of the effectiveness of the interface between residual limb and prosthesis. This factor is measured at the point where the force passes from weightbearing to tensile in nature.
2. Maximum retention force, P in Newtons, is an indication of how the muscle contours interact with the contours of the socket in their most advantageous position. This force occurs at an average slippage of 3 cm.

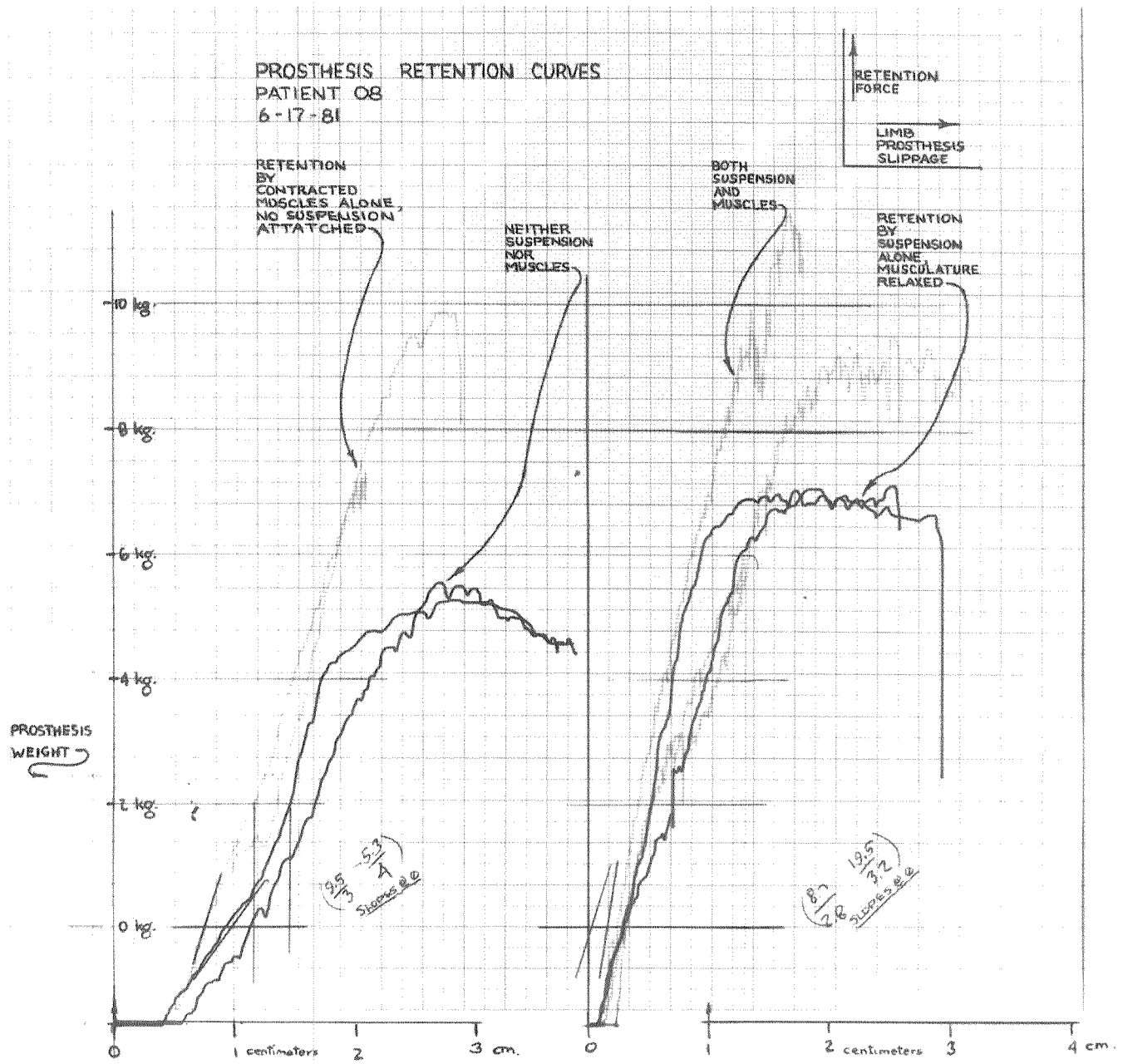

FIGURE 3.
Retention-testing device, data output curves.

Figures 4 and 5 illustrate a subject's suspension performance being evaluated. The device on which his foot rests measures the forces, and the linear displacement transducer is strapped to his leg.

Results

Data collected on 17 subjects are presented in Table 1. These subjects were randomly selected from the prosthetics clinic and received no special training or prosthesis modifications in order to maximize their physiologic suspension. The purpose was to develop methods for evaluating suspension factors and performance, and to fit preliminary multiple linear regression equations to the data. The blanks in the table indicate subjects who were measured early in the program and were unavailable for re-evaluation as more suspension factors were added to the study.

In the statistical treatment of the data, the measured suspension performance (i.e., the stiffness or maximum force values) is assumed to be a dependent variable which is a function of the independent variables (the suspension factors). A computer program generates the coefficients for an equation of the form:

$$S = A_0 + A_1 L + A_2 G + A_3 E + A_4 F + A_5 M + A_6 C_1 + A_7 C_2 \quad [1]$$

(where S, L, C, etc. are as defined in Table 1.)

This is a linear equation because none of the suspension factors are raised to a higher power. The coefficients A_0, A_1, etc. are determined so as to give the smallest difference between the value for suspension stiffness predicted by the equation and the actual measured value. The magnitude of this difference is indicated by the standard error of the estimate, s, which is calculated for each equation. The degree to which suspension performance is linearly related to the suspension factors is called the coefficient of multiple correlation, R^2. This term has a value of 0 if there is no linear correlation at all, and a value of 1 if there is perfect linear correlation. A low value indicates that possibly a non-linear relationship exists between the variables.

Using patients 1–11 the following

equations were determined:

$$S=(-316.5 + 3.47\,L + 9.22G - 8.06\,E + 89.5\,F - 15.96\,M + 1.4.02C_1 - 5.40\,C_2)\ \text{N/cm} \quad [2]$$

$$s = \pm 29.4\ \text{N/cm},\ R^2 = .887$$

and,

$$P= (83.9 + 1.29L - .27G - 24.0\,E - 53.2F - 11.57\,M - 12.84C_1 + 20.58\,C_2)\ \text{Newtons} \quad [3]$$

$$s = \pm\ 23.4\ \text{N},\ R^2 = .873$$

Equations [2] and [3] indicate some interesting facts about the sample population. Limb length correlates positively with both suspension stiffness, S, and maximum axial force, P. Gastrocnemius circumference has a large positive correlation with stiffness and a small negative correlation with maximum force. Expansion correlates negatively with performance, with a larger reduction to the maximum axial force. We feel this is due to the prosthetic sockets' lack of modification to take advantage of the muscle expansion, causing an "ejection socket" effect. Compliance contributed positively to suspension stiffness, but correlates negatively to maximum force. Skin motion has a negative correlation with performance (the less, the better). Finally the contour factors apparently have contradictory effects on performance. We feel this is because the socket

SUBJECT NUMBER	L Limb Length cm.	G Gastroc. Circum. cm.	E Expansion cm.	F Compliance cm.	M Skin Motion cm.	ID Interference D - cm.	IP Interference P - cm.	C_1 Limb Contour Subj.	C_2 Socket Contour Subj.	C_3 Limb Slope Photo-gram cm/m	C_4 Socket Slope Photo-gram cm/m	P Max. Axial Force N	S Suspension Stiffness N/cm
1	15	28	.5	.3	2.0	-	-	5	5	-	-	80	52
2	22	26	-.3	.6	3.5	-	-	5	5	- 1.8	-5.0	60	34
3L	12	29	.3	.8	1.5	-	-	4	7	1.5	-	110	50
3R	17	25	0	.3	1.5	-	-	4	7	.6	-	110	63
4	19	32	.6	.6	3.8	-.2	-.5	5	5	2.2	-3.1	50	78
5	14	34	0	.9	5.0	-.2	-.2	4	4	4.8	-	30	83
6	18	26	.2	.5	1.4	.3	.3	5	6	-	-	150	52
7	15	27	.3	.5	3.0	1.3	.9	4	3	-	-	30	11
8	16	29	.6	.5	1.0	-.2	-.1	4	5	-	-	90	35
9	16	23	.4	1.0	2.3	2.6	.4	1	1	-	-	20	15
10	21	31	.6	.7	0.5	-.8	-.5	5	5	1.0	-	80	142
11	13	28	.9	.6	2.0	.9	1.9	6	5	-	-	40	52
12L	14	28	.7	.2	2.4	-	-	-	-	4.9	-	120	162
12R	22	25	.4	.4	2.5	-	-	-	-	2.6	-	160	131
13L	11	27	0	.2	2.4	-	-	-	-	-13.7	-	55	18
13R	16	27	.4	.6	2.7	-	-	-	-	- .8	-	55	13
14	-	-	-	-	-	-	-	-	-	9.0	.6	-	120
15	-	-	-	-	-	-	-	-	-	8.6	-.3	-	95
16	-	-	-	-	-	-	-	-	-	2.4	4.6	-	50
17	-	-	-	-	-	-	-	-	-	1.1	9.7	-	45

TABLE 1.
Master Data Record

contours have not been designed to optimize either suspension stiffness or maximum force.

Patients 2–5, 10, 12 and 17 were used to investigate the relationship between suspension stiffness and the photogrammetric limb contour factor;

$$S=(90.3-20.0\,E - 56.4\,F + 5.77\,C_3)\ \text{N/cm} \qquad [4]$$
$$s = \pm\ 22.0\ \text{N/cm}$$

In considering equations 2–4 one should appreciate that they reflect correlations of each factor, not cause and effect relationships, and do not account for other possible factors which might have had an effect. Because each factor in the equation is derived from a different set of dimensions, the magnitude of the coefficients cannot be compared directly. The large standard error is assumed to be caused by the lack of specificity in patient selection and prosthetic modification.

Discussion

The results thus far, even though they lack large numbers, seem to indicate that the initial hypotheses regarding important stump and socket factors are correct. On the basis of the regression analysis, skin motion and socket and stump contour correlate highest with the socket retention factors. This situation suggests that special attention to surgical and prosthetic contouring might further enhance an amputee's physiologic suspension capability. We have referred to this concept previously. Still to be tested is the effect of the specific retention training, using the testing devices described in this report. Later, we

FIGURE 4.
Retention-testing device, front view.

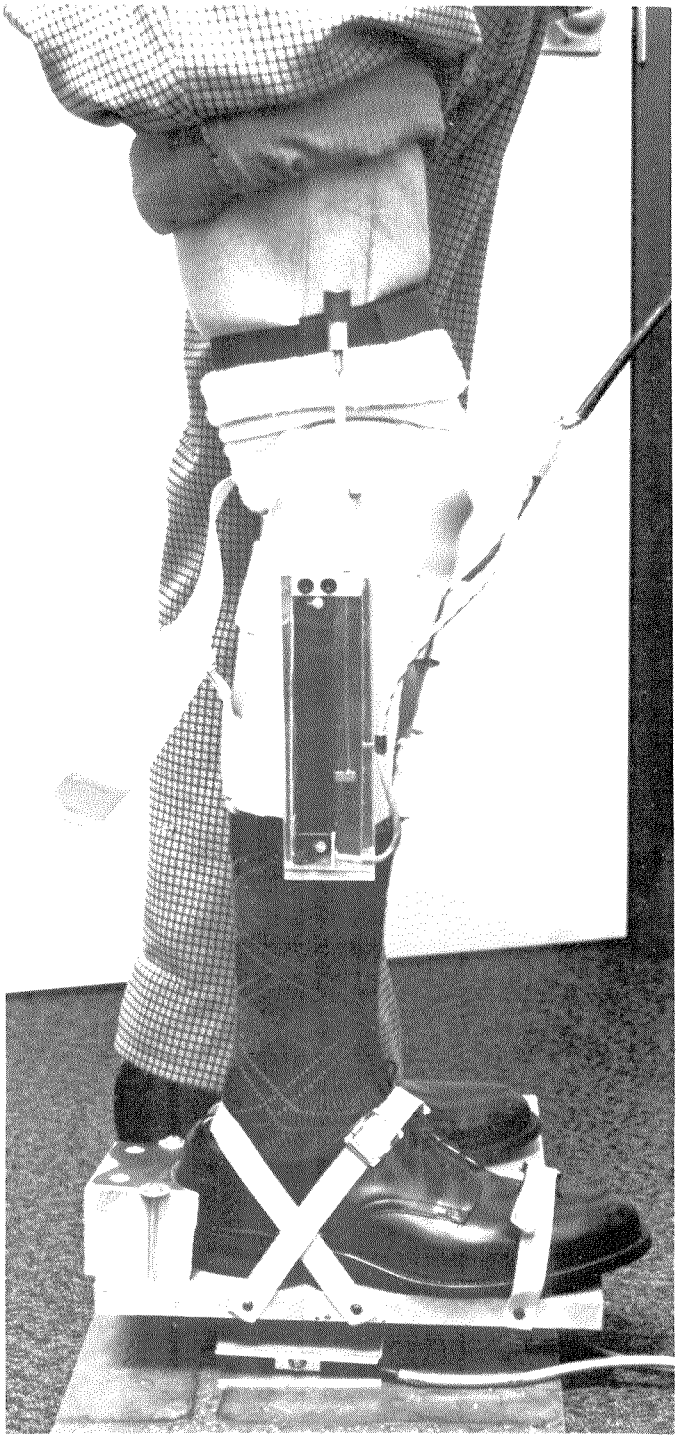

FIGURE 5.
Retention-testing device, side view.

will also explore surgical and prosthetic modifications. Meanwhile, we plan to continue the present study using the protocol described, to gain a larger number of patients and a greater statistical validity. In addition, the activity questionnaire (Appendix A) combined with assessment of gait in the clinic, will establish the relationship of measured suspension performance to real-life performance.

The practical application of these studies is in pinpointing the key suspension factors, especially those that are controllable, which are contributing to physiologic suspension, and in providing a performance protocol which can be used during clinic to follow the amputee's progress.

Summary and Conclusions

1. Suspension factors in below knee amputees have been defined, measured and correlated with suspension performance.
2. The data collection protocol is feasible for outpatient clinic evaluation.
3. Continued refinement of existing data-gathering techniques, and specific attention toward the effects of training and of surgical and prosthetic modification, would appear to be promising.

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APPENDIX: Questionnaire and Consent Form.

UNIVERSITY OF WASHINGTON
Consent Form
Evaluation of Physical Characteristics of Below Knee Residual Limbs to Study Prosthetic Suspension

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Sandor A. Veress, Ph.D., Department of Civil Engineering—206-543-7613

The purpose of this study is to determine those factors which contribute to better prosthesis suspension and thus improved function to you as an amputee. Suspension refers to the attachment of your prosthesis and includes belts, cuffs, wedges, lacers and the action of your residual limb against the walls of the socket. Your participation in this study will be of direct benefit to you in that it will provide an analysis of the function of your own suspension and thus reveal possible ways of improvement.

To obtain this information we use several techniques and types of measurement apparatus. First, you will be asked to complete a questionnaire which provides us with a profile of the activity level, comfort and stability provided to you by your prosthesis. Second, we will measure both your stump and your prosthesis. All measurements cause no discomfort beyond standing on crutches and contracting the musculature in your residual limb. The first measurement utilizes a device which traces the contour of your residual limb to obtain its profile. The second measurement consists of immersing your limb in a water bath to determine its volume. The third measurement requires you to pull upward while wearing your prosthesis which is attached to a force plate to determine the effectiveness of your suspension. The other measurements of your stump and socket will be made with tape measure and calipers to check your fit.

The overall time involved will be about one hour plus, if it is convenient for you, fifteen minutes to stop at the University of Washington so that we can take a three dimensional photograph of your residual limb. (See map attached)

You may decide to omit any questions or any part of this study or not, at your own discretion.

In order to participate, you should be able to keep your balance while standing on your opposite leg, using a walker support, for short periods of time. The risks of the study are possible discomfort and fatigue, and the possibility of a fall. You will be able to rest any time you feel necessary during the course of the measurements. In the unlikely event that a physical injury occurs as a direct result of a study procedure, you will be treated at no cost at the V.A. Hospital.

All information provided by you will remain confidential and you may withdraw from participation at any time without penalty and without jeopardizing your future care. Subjects who drive to the hospital or clinic for the purpose of participating in this study will be compensated on a mileage basis.

_____ _____
Signature of Investigator Date

Copies: Subject
File

SUBJECT'S STATEMENT:

I voluntarily consent to participate in this activity. I have had an opportunity to ask questions. The study as described above has been explained to me.

_____ _____
Signature of Subject Date

VAMC PROSTHETICS RESEARCH
FUNCTIONAL CAPABILITIES QUESTIONNAIRE
PLEASE COMPLETE

NAME_____
SOCIAL SECURITY NUMBER _____ DATE_____
SIDE AMPUTATED?:_____

1. Do you have any medical complications of which we should be aware? (Those which affect your balance, stability, or sensation would be of significance)_____

2. **What is your occupation?**_____

3. **How many hours per day are you on your feet?**_____

4. **How far would you say you walk on an average day?**_____
   Blocks/Miles/Kilometers

5. **What percent of your walking is done on smooth surfaces?**
   None Very Little Some A lot All

   On uneven terrain?
   None Very Little Some A lot All

   On rough terrain?
   None Very Little Some A lot All

   In the dark?
   None Very Little Some A lot All

6. **How much do you use a cane?**
   None Very Little Some Frequently Always

   How much do you use crutches?
   None Very Little Some Frequently Always

   How much do you use a walker?
   None Very Little Some Frequently Always

   How much do you use a wheelchair?
   None Very Little Some Frequently Always

7. **How much difficulty would you say you encountered going up curbs?**
   None Very Little Some A lot

   How much difficulty would you say you encounter going up stairs?
   None Very Little Some A lot

   How much difficulty would you say you encounter going up ramps?
   None Very Little Some A lot

   How much difficulty would you say you encounter going down curbs?
   None Very Little Some A lot

   How much difficulty would you say you encounter going down stairs?
   None Very Little Some A lot

   How much difficulty would you say you encounter going down ramps?
   None Very Little Some A lot

8. Please assign an **approximate value in hours per week** that you engage in the following activities (if zero, leave blank):
   A. RECREATIONAL WALKING_____
   B. RUNNING_____
   C. SWIMMING_____
   D. DANCING_____
   E. GOLF_____
   F. FISHING_____
   G. HUNTING_____
   H. SKATING_____
   I. ROLLER SKATING_____
   J. SKIING_____
   K. VOLLEYBALL_____
   L. BASKETBALL_____
   M. FOOTBALL_____
   N. BOWLING_____
   O. HORSEBACK_____
   P. HIKING_____
   Q. OTHER_____

9. **Do you use ladders?**_____ **Do they pose a problem going up?**_____ **Going down?**_____

10. **Do you experience phantom sensations in your amputated leg(s)?**_____ **Do you use these sensations when you walk?**_____

11. **Are any areas of your stump(s) usually tender to touch?**_____ **How about right now?**_____

12. **What is the condition of your other leg?**
    Normal_____
    Some Cramping_____
    Limits Activity?_____
    Open sores?_____
    Any pain?_____
    Amputated also?_____

13. **On a scale of 1 to 10 where 10 is best, how would you rate:**

	Left	Right
A. Your prosthesis	____	____
B. The weight of your prosthesis	____	____
C. The suspension of your prosthesis (Can you walk with your prosthesis unattached? _____)	____	____
D. The intimateness of the fit of your prosthesis	____	____
E. The comfort of your prosthesis	____	____
F. The stability of your prosthesis	____	____
G. The ease of walking with your prosthesis	____	____
H. Your ability to tell where your prosthesis is without looking	____	____

14. **Do you ever contract the muscles in your stump itself:**
    A. To help hold the prosthesis on?_____
    B. To make yourself more stable in difficult situations?_____
    C. When on stairs?_____
    D. When landing on the prosthesis?_____
    E. Any other time?_____ Describe_____

15. **Which of the following descriptions best describe your feelings about the foot of your prosthesis?**
    A. It is very good
    B. It is not as stable as it should be
    C. It doesn't walk very smoothly
    D. It's not good on uneven terrain
    E. It's too heavy
    F. It is not very versatile
    G. Other

For each of the following areas, select the category or categories which **best** describe **your** personal experience.

1. **With regard to my suspension, when wearing my prosthesis, I feel:**
   A. Very Secure—as if the prosthesis were always a part of me. Even on stairs.
   B. Moderately Secure—The prosthesis feels firmly attached except when walking fast or using stairs.
   C. Somewhat Insecure—Although the prosthesis feels poorly attached, sometimes I can compensate for it.
   D. Quite Insecure—As if I lose contact with the prosthesis, whenever I lift it off the ground, the suspension never gives me a sense of security.

2. **When I bear weight on my prosthesis, I feel that it is:**
   A. Very Stable—It feels stable even on stairs, on uneven terrain, and walking in the dark.
   B. Moderately Stable—It feels stable except on uneven terrain or in darkness.
   C. Slightly Unstable—The leg never gives me a real feeling of stability, even indoors.
   D. Very Unstable—The leg is only moderately stable on smooth surfaces and is very unstable on uneven terrain so that it wobbles and makes balance difficult.

3. **I have the feeling that the prosthesis is a part of me:**
   A. All of the time—I always know where the prosthesis is and rarely if ever have to look at it.
   B. With only some exceptions—I find that in some activities I must watch the foot to avoid tripping.
   C. Sometimes—I find that I frequently look at the foot for safety and would probably not want to walk in the dark.
   D. Not at all—I find myself constantly watching where I put the foot for safety, to avoid tripping, and because there is no other way to judge where it is.

4. **Due to the fact that I wear a prosthesis, I find that in my activities I experience:**
   A. No increase in difficulty, I even feel confident at night and on uneven ground.
   B. Slightly increased difficulty, depending on the situation but nothing that I can't cope with.
   C. Moderate increase in difficulty, the prosthesis requires a significant increase in attention and energy expenditure.
   D. Decidedly more difficulty, the prosthesis causes wobbling, tripping, knee buckling, and/or problems in balance which makes many activities too difficult to consider.

5. **In your own words, please say anything which you would have done differently about your own prosthesis.**_____

_____

_____

_____

_____

A Program to Improve Efficiency and Reduce Risks for Wheelchair Locomotion

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We have recently completed three studies which relate to the physiological stresses of wheelchair locomotion and wheelchair design. One study compared the metabolic and cardiopulmonary responses of eight geriatric ($\bar{x}$ = 62 yr) wheelchair-dependent (WD) and 10 geriatric ($\bar{x}$ = 58 yr) ambulatory (AMB) patients during locomotion (1). WD subjects propelled their wheelchairs, and AMB subjects walked, on a level tiled surface for 5 minutes at their preferred velocities. During the last minute of each locomotive bout, oxygen uptake ($\dot{V}O_2$), pulmonary ventilation ($\dot{V}E$), and heart rate (HR) were determined (2). These procedures were repeated twice for a total of three trials.

Mean results for the two groups of patients were as follows: velocity = 2.0 and 3.1 km•hr^{-1}; $\dot{V}O_2$ = 0.535 and 0.814 l•min^{-1}; $\dot{V}E$ = 19.4 and 26.2 l•min^{-1}; and HR = 95 and 92 bpm during wheelchair locomotion and walking, respectively. Similar HR values for wheelchair locomotion and walking tend to suggest comparable relative stress for these activities. When taking into consideration that wheelchair locomotion (arm exercise) elicits peak $\dot{V}O_2$ values that are approximately 30 percent lower than those for walking (leg exercise), it appears that both groups performed at a similar percentage of their peak aerobic power. The 37 percent lower velocity for wheelchair locomotion as compared to walking should be taken into consideration when scheduling activities for these patients.

The second study compared metabolic and cardiopulmonary responses of geriatric patients during wheelchair propulsion utilizing conventional handrim stroking and arm cranking (3). Seven volunteers ($\bar{x}$ = 61 yr) each operated their own conventional handrim wheelchair as well as a wheelchair incorporating an arm-crank propulsion system. During three 5-minute test bouts on a level tiled surface, their preferred velocities were determined by an electronic speedometer. $\dot{V}O_2$, $\dot{V}E$, and HR were determined during the final minute of each test (2). Mean preferred velocity was found to be 2.1 and 2.8 km•hr^{-1} for the conventional and arm-crank wheelchairs, respectively. During locomotion at these velocities, respective $\dot{V}O_2$ was 0.555 and 0.560 l•min^{-1}; $\dot{V}E$ was 20.3 and 20.8 l•min^{-1} and HR was 94 and 90 bpm. When the arm-crank wheelchair was operated at the same velocity as the conventional wheelchair (2.1 km•hr^{-1}), $\dot{V}O_2$ and $\dot{V}E$ were 11 percent lower and HR was 8 percent lower. The equality of $\dot{V}O_2$ for operating these wheelchairs at the preferred velocities suggests that the selection of velocity was based upon absolute metabolic demands. The 33 percent higher velocity for the arm-crank wheelchair and the lower HR values at this velocity indicate that this form of locomotion is more efficient. This is further supported by the lower physiological responses observed during operation of the arm-crank wheelchair at the same velocity as the conventional wheelchair.

It is also interesting to note that the WD subjects using the arm-crank wheelchair had preferred velocities that were similar to the AMB subjects during walking in the above study.

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The third study compared the physiological responses of 9 AMB and 7 WD volunteers to conventional and arm-crank wheelchair propulsion (4). Both wheelchairs were operated for 5 minutes at 3.0 km•hr^{-1} on level tiled and carpeted surfaces. The arm-crank-propelled wheelchair was operated in 3 gear ratios—low, medium and high. During the final minutes of each test $\dot{V}O_2$, $\dot{V}E$ and HR were monitored (2). These physiological responses were significantly lower during arm-crank wheelchair propulsion for all gear drive ratios on each surface. Average percent differences were as follows: 30 percent and 33 percent for $\dot{V}O_2$; 27 percent and 34 percent for $\dot{V}E$; and 16 percent and 19 percent for HR, on the tiled and carpeted surfaces, respectively. In absolute terms, these responses were lower for the arm-crank wheelchair on the carpeted surface than for the conventional handrim wheelchair on the tiled surface. As with the aforementioned study, these results indicate that arm-crank wheelchair propulsion is less stressful than conventional handrim wheelchair propulsion at given velocities. Both of these studies suggest that arm-crank propulsion systems could be used to improve wheelchair design and thereby improve patient rehabilitation.

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The Mechanical Properties of Porous Coated Orthopaedic Alloy

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Objectives

Although existing designs of total joint replacement have proved extremely successful, it is generally recognized that the chances of failure increase with time. Foremost among the causes is a loosening of the prosthesis, causing pain and ultimately necessitating reoperation. In order to avoid this, a great deal of research has been conducted upon improving the fixation of orthopaedic implants to their surrounding bones. The most favoured approach involves the use of a porous surface upon the implant to allow the bone to mechanically interlock with the implant. Even though this method has been demonstrated to produce good fixation, very little attention has been directed towards the effect that applying a porous coating to a solid substrate has upon the mechanical properties of that material. This question is obviously important if failure of a prosthesis by loosening is not to be replaced by mechanical failure. From an engineering standpoint, the application of a thin porous coating may affect the substrate in two ways—(i) the introduction of surface flaws enabling fatigue cracks to be more easily initiated, and (ii) the high temperature typically required to attach the porous coating to the substrate may severely impair the mechanical properties of that alloy.

This research project is designed to investigate the extent to which the application of a porous coating compromises the mechanical properties of a cobalt-base alloy. In this way, it is intended that the long-term aim of producing orthopaedic implants capable of extended service lives will be furthered.

Background

The use of metallic prostheses in the treatment of degenerative diseases, together with their use in the reconstruction of joints in trauma victims, has increased greatly in the last 10 to 15 years. A survey of Total Hip Replacement (THR) operations indicates that in the United States in 1976 approximately 80,000 total hip joints were implanted (1). At the same time, however, it is becoming recognized that the current designs offer only a limited service life, after which a reoperation may be necessitated. For this reason, many younger patients are being urged to forgo treatment until a later age.

In an attempt to improve upon this situation, a great deal of research has been concerned with developing a truly permanent prosthesis. That research has concentrated upon the areas of implant design and fixation. To be successful, a prosthesis must not only be able to withstand the stresses imposed upon it by the body but must also be able to impose upon the body stresses compatible with the maintenance of adequate bone stock. In this way, the surrounding bone continues to support the implant and thereby minimizes the danger of mechanical failure.

At present, orthopaedic implants are attached to the skeletal system by either a tight fit or use of a polymethyl methacrylate grouting agent. The latter technique has gained widespread acceptance, since it offers the possibility of immediate fixation for a large range of applications. It is generally considered a slowly-failing system, however, due to eventual failure of the cement resulting in implant loosening. The most promising new approach to implant fixation is the use of a porous coating upon the solid implant, a system which allows bone to grow into the surface and thereby provide a mechanical interlock.

The concept of using a porous surface to aid fixation of an implant is not new, having been introduced by Klawitter (2) in the late 1960's. Since then, the efficacy of this approach has been demonstrated by frequent clinical trials. These have shown that, provided a suitable pore structure is available, viable bone will grow into the implant (3). Indeed, at least two designs of THR are available commercially in which a porous surface is provided for implant fixation. Both of these, however, are of a comparatively simple shape and unlikely to find widespread acceptance.

The optimum pore structure for implants has been examined by a number of authors (4–6). Clemow et al (6) has indicated that, from a mechanical strength standpoint, the optimum pore size lies with the range 100—200 μm.

A large number of candidate materials have been examined for use as po-

rous implants, including ceramics (3), carbons (7), polymers (8, 9), and metals (6, 10, 11). Within this latter category, only two major groups of alloys, titanium and cobalt-based alloys, have been found to satisfy the major criteria of corrosion resistance, mechanical strength and biocompatibility. Stainless steel, although used extensively as a surgical implant material, is not suitable for porous coatings due to its insufficient corrosion resistance associated with the increased surface area of the metal (10).

Of all those materials which may be categorized as biomaterials, possibly the most successful (apart from the precious metals) is that alloy known variously at Vitallium, HS21, or Co-Cr-Mo Alloy. The alloy was developed in 1929 for use in dentistry where its excellent corrosion resistance and ease of casting could be utilized. Since that time, Co-Cr-Mo alloy has been used in jet engines and, more recently, in the field of orthopaedics. Surprisingly for an alloy with such a long life, a basic understanding of its physical metallurgy has only recently been achieved.

For the majority of purposes, Co-Cr-Mo alloy is fabricated by investment casting since this technique offers the advantage of excellent dimensional accuracy. The resultant product is generally referred to as being in the as-cast condition. As such its microstructure consists of a cored dendritic structure with an interdendritic dispersion of carbides. Until recently Co-Cr-Mo alloy was used in this as-cast condition. However, it was found that, by subjecting the alloy to a short high-temperature heat treatment, its ductility could be increased sufficiently to ensure passage through ASTM standard F-75. The reactions extensively studied by Clemow and Daniell (12), have been shown to consist of a series of carbide transformations preceding their dissolution into the matrix phase. As a result, a number of varied microstructures may be observed depending upon the time and temperature employed.

Due to its inherent importance with regard to the performance of total joint prosthesis, the mechanical properties of Co-Cr-Mo alloy have been examined by a number of investigators (13). The fatigue properties of the alloy have been examined by Miller, Rostaker and Galante (13) and Devine and Wulff (14). The former authors derived S-N curves to show that there existed, at the 95 percent confidence level, a chance that 0.1 percent of the specimens would fail when stressed for 5×10^7 cycles within the cyclic range of 6,900–46,500 p.s.i. This corresponds very closely with the results of Devine and Wulff (14) even though different techniques of testing and environments were used. Both reports, however, stress the importance that non-metallic inclusions and gas porosity have in determining the true fatigue strength of a specimen.

The influence of heat treatment upon the mechanical properties of Co-Cr-Mo alloy is confusing, with diverging results being reported.

Hollander and Wulff (15) have shown that by using a solution treatment program of 1280 degrees C for 2 hours, a substantial improvement in elongation, together with a slight improvement in yield and ultimate tensile strengths may result. Later work at the same institution, reported by Cohen, Rose and Wulff (16), indicates that by judicious use of heat treatment, a substantial improvement in all three properties may be obtained. Unfortunately, no fatigue properties are available for comparison.

Dobbs (17) found that the use of a solution treatment of 1250 degrees C for 2 hours caused a substantial decrease in mechanical properties. A probable explanation for this behavior is that the higher temperature used caused complete dissolution of the carbides and allowed extensive grain growth to occur once the grain boundaries were freed of any obstacles to motion. A similar anomaly was reported by Clauss, Garrett, and Weeton (18) in the early 1950's, when Co-Cr-Mo alloy was still being used in jet engines.

It is this danger of excessive grain growth, caused by a solution treatment at temperatures high enough to allow carbide dissolution, which constitutes the basis of this research project. Should this growth occur during the attachment of a porous coating, then the mechanical properties of the substrate would be severely compromised, and the possibility of fatigue failure in vivo increased.

As stated earlier, in order to obtain satisfactory growth of bone into a coating, it is necessary that a pore structure of at least 100 μm be provided. In order to achieve this, three methods of fabricating coatings have been used:

1. Gravity compaction in which spherical powder is allowed to settle around the substrate while being held in shape by a ceramic mold. The whole assembly is then heated to ensure proper sintering of the powder (19).

2. A binder technique in which an organic binder such as methyl cellulose is used to adhere the particles to the substrate. The binder is burnt off at high temperature when, as above, sintering of the particles occurs (11).

3. Thin wires of the desired material are mechanically kinked, pressed into the desired shape and sintered together (20).

An obvious similarity between all three methods is the use of a high temperature sintering period to achieve mechanical integrity. The temperature needed was found by Klawitter, Weinstein and Peterson (19) to depend upon the size of the particles being used—the larger the particles, the higher the temperature. For particles of 104–149μm diameter, a temperature of 1310 degrees C for 3 hours was required, while for particles of 420–595 μm diameter it was necessary to raise the temperature to 1330 degrees C. This is consistent with the results of Weloch, Pilliar, and McNab (11), who sintered Co-Cr-Mo alloy particles at 1200 degrees C, but in their case the diameter of the sphere was only around 4.4 μm. Such a size is unlikely to result in a pore structure large enough to allow adequate bone ingrowth.

It is apparent, therefore, that in order to produce a porous surface having a large enough pore size, it is necessary to use a sintering temperature in excess of 1300 degrees C. Since carbide dissolution in Co-Cr-Mo alloy occurs at 1210 degrees C and above, the sintering process introduces a substantial danger of complete carbide dissolution leading to massive grain growth and a substantial alteration in mechanical properties of the material.

The objective of this research project is to examine the extent to which the application of a porous surface influences the fatigue properties of implant grade Co-Cr-Mo alloy.

This work will consist of the following four stages—(i) Examination of the influence upon the microstructure of the addition of a porous Co-Cr-Mo alloy coating to a solid substrate, (ii) Determination of the fatigue properties of as-cast and heat treated Co-Cr-Mo alloy, (iii) Determination of the fatigue properties of porous coated Co-Cr-Mo alloy, and (iv) Examination of the relationship between microstructural changes and fa-

tigue properties for the coated specimens.

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Rehabilitative Engineering Research Program

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Amputee Survey

The objective is to define the population of amputees served by the San Francisco VAMC and identify the nature of any problems they are experiencing in obtaining prosthetics care.

To date questionnaires have been received from 176 (70 percent) of the original 251 amputees sampled. Of the nonrespondents, 12 were deceased, 22 could not be reached by mail or phone, and 41 did not respond for reasons unknown. Analysis of the available date yields the following statistics:

Type of Amputation	Number	Percent
Below Knee	98	55.7
Above-Knee	46	26.1
Syme	4	2.3
Knee Disartic.	1	0.6
Hip Disartic.	1	0.6
Bilateral	26	14.8
BK/BK	13	7.4
BK/AK	10	5.7
AK/KD	1	0.6
AK/AK	2	1.1
Cause of Amputation		
Trauma	129	73.3
Vascular	44	25.0
with Diabetes M.	17	9.7
without Diabetes	27	15.3
Tumor	3	1.7

Thirty-four of these respondents have been evaluated in the laboratory, with a goal of 50 evaluations to be completed by October 1981. The survey evaluation includes a physical examination, short medical history, prosthetic evaluation, subjective and objective gait analysis, videotaping, and discussion of the amputee's problems and needs regarding his prosthesis.

Evaluation of these 34 amputees indicates that a significant number of amputees experience deficiencies in prosthetic functioning and gait resulting from inadequate prosthetic fitting, fabrication, and alignment techniques.

The three most serious deficiencies encountered were: (i) poor socket fit, (ii) poor foot plantarflexion function and rollover, and (iii) faulty prosthetic alignment.

Employment post amputation	Dysvascular	Trauma	Tumor	Total,	%
Unable to work due to amputation	9	13	0	22	12
Unable to work for medical reasons	9	5	2	16	9
Changed occupation due to amputation	4	67	1	72	41
Retired	17	11	0	28	16
Unemployed	1	4	0	5	3
Part-time work or school	0	9	0	9	5
Same occupation	4	20	0	24	14
Daily Walking					
No Response	0	1	0	1	1
None	6	3	0	9	5
In House only	9	6	1	16	9
1 to 6 Blocks	24	58	2	84	47
Over 6 Blocks	4	29	0	33	19
Unlimited	1	32	0	33	19

46% of the 176 respondents feel they have socket fit problems, 35% feel their limbs are too noisy, and 73% identify additional activities or recreation they would like to perform but are unable.

The following results are based on 34 evaluations including 19 below-knee, 12 above-knee, and 3 bilateral amputees (22 BK limbs and 15 AK limbs).

The questionnaire responses from these same 34 amputees indicate that 55 percent of the BK amputees and 40 percent of the AK amputees felt that they had socket problems. The BK figure agrees well with the assessment of the clinic team, but the AK figure is markedly different. This suggests that the AK amputees often may not realize how poor the fit and function of their prostheses actually are! Since most of the socket problems were identifiable and correctible, there is hope for a significant improvement in the prosthetics care of this group of amputees.

	22 BK Limbs			15 AK Limbs		
Socket Problems		59%			80%	
Suspension Problems		59%			40%	
Knee Problems		—			60%	
Foot Problems		82%			60%	
	Good	Fair	Poor	Good	Fair	Poor
Alignment	45%	35%	20%	27%	60%	13%
Cosmesis	73%	27%	0%	67%	27%	6%

Problem-Case Referrals

The objective is to provide specialized prosthetics treatment for amputees referred to the program because of unusual problems.

The research staff has become involved in the care of problem amputees referred for evaluation both from within this facility and from outside of it. Six problem cases of veterans with lower limb disabilities have been referred to the RERP during this report period. Three of these were unilaterial BK amputees with longstanding fitting problems and skin breakdown, one was a bilateral BK amputee with multiple epidermoid cysts, one was a quadrilateral amputee with AK and BK leg amputations and one was a diabetic with structurally collapsed foot and ankle secondary to osteoarthritis. All the BK amputations were successfully fitted with lightweight PTS prostheses incorporating removable wedge suspension air-cushion sockets with soft insert liners. The AK amputation was fitted with a quadrilateral socket with hip joint and pelvic belt. The patient with foot problems was fitted with a PTB fracture brace.

Prosthetic Device Evaluation

The purpose of the evaluation projects is to evaluate the safety, durability, and functional value of new lower-limb prosthetic devices, and to gather all the information necessary to manufacture, prescribe, fit and fabricate (and teach the use of) the tested devices. More details are to be found in the previous progress report, in BPR 10-35. The initial object of testing is the UC-BL Four-Bar Linkage Polycentric Knee.

Since the initiation of this evaluation project on July 1, 1980, a total of 32 above-knee veteran amputees have been evaluated as potential candidates for clinical trial of the Four-Bar Linkage polycentric knee unit. Of the 24 subjects who have been included in the study, 18 have undergone followup evaluations after using the Four-Bar Knee Unit for periods ranging from 4 to 11 months. Thus the evaluation project is progressing steadily—but not at the projected rate of 25 six-month follow-ups by June of 81. (That goal is now projected for November 1981.)

Preliminary clinical experience with the Four-Bar Knee Unit indicates that, with few exceptions, it has been well received by the amputees. Factors such as the more "natural" behavior of the linkage during level walking, and the unusually large knee flexion angle allowed by the design, have received especially favorable comment. A few subjects have reported feeling that less total energy is required for daily ambulation with their research limbs compared to previous ones.

Subjects who previously had worn hydraulic knee units have frequently noted some initial difficulty in getting used to the characteristics of the pneumatic swing-phase control of the Four-Bar Knee Unit. At the three-month examinations and later follow-up examinations, however, reactions generally have been favorable.

Early problems were encountered with excessive noise due to loose bearings, erratic swing-phase-control action due to leaks in the damper piston seals, and deformation of the cosmetic cover resulting from improper shaping. These problems with the prototype devices have been solved by minor modifications, which have been duly noted in the instructions for manufacture.

Occasional problems in achieving adequate socket fit and optimal alignment have been experienced by local prosthetists, resulting in some amputee dissatisfaction. Solutions to these problems have been worked out on an individual basis with the assistance of the RERP research prosthetist, and descriptions of the improved fitting/alignment procedures have been included in the prosthetist's instruction manual.

Design and Development of Lower-Limb Prosthetic Devices

The objective is to develop new concepts, methods, and devices for improved prosthetics care. The Biomechanics Laboratory of the University of California at Berkeley conducts engineering development projects for the RERP under VA contract. Current projects include prosthetic foot design and experimental studies of knee stability control in above-knee amputees.

Metal Keel—SACH Foot—Six production prototypes, as shown in Figure 1, have completed a 1,000,000 cycle accelerated toe-flexion testing program at Kingsley Manufacturing Co. with no externally visible signs of damage. A slight delamination of the foam material from the metal keel was apparent after sectioning of the feet, but all test specimens were considered fully functional at the end of the test.

Microcomputer Control of an Above-Knee Prosthesis—Improvements to the servo-valve that controls the hydraulic swing-control damper were completed during this report period. Amputee tests of the latest prototype prosthesis have shown excellent control of swing phase and have demonstrated the advantages of individual programing of the table-look-up system for generating the resistance pattern desired by the amputee. The control program is being modified to allow true adaptive control that will

respond automatically to changes in walking speed. Tests of the stance phase control mode have shown the need for an improved servo-valve design which can be isolated from the compliance of the accumulator in the modified U.S. Manufacturing Co. Dyna-Plex unit. The present valve provides good control for flexion resistance but is ineffective in controlling the rate of knee extension. A new valve under construction will provide identical control of flexion and extension resistance, which is important in allowing for control of knee extension at heel contact, followed by control of knee flexion prior to push off.

Mobility Aids for the Severely Disabled

The objective is to develop mobility aids for people with severe locomotor disabilities.

Powered Spring Suspension Wheelchair—Components for five wheelchairs less seats and footrests were delivered in December 1980, and two units have been assembled, as shown in Figure 2. A new seat was designed with a contoured backrest and simple body-compatible recline kinematics suitable for use in either a powered or manual recliner. A simple linkage-type latch mechanism allows easy adjustment of armrest length to any of three positions, plus a fourth position folded back out of the way for transfers in and out of the chair. The armrests follow the recline motion in any of the three normal armrest positions. Footrests were further developed for increased strength and improved impact resistance. A new dead-man switch was designed, with a thin, lightly spring-loaded music-wire activator that is easily held in the "on" position while driving but readily released to shut down the controller and apply the chair's fail-safe brakes. One chair has been fitted with the new seat, footrests, and dead-man switch, and has performed well in extensive driving by project staff. Daily use testing of the chair is beginning.

FIGURE 2.
The UC-BL powered spring-suspension wheelchair.

Solid State Controller—Five Bowman UC-BL controllers were delivered in October 1980, and the units fitted to the first two powered spring-suspension wheelchairs have performed flawlessly.

Spring Suspension Caster Forks—Parts for twenty forks were delivered in December 1980, and the eight units assembled so far have performed very well on three different kinds of electric wheelchairs.

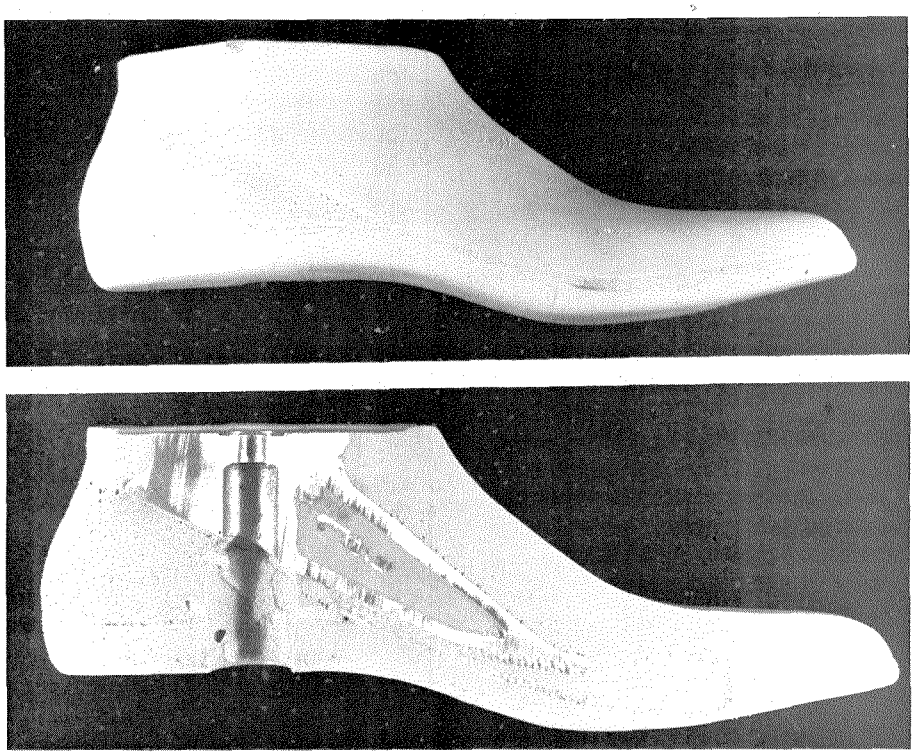

FIGURE 1.
The UC-BL/Kingsley metal keel SACH foot.

Total Hip Joint Loosening

The objective is to examine the causes of loosening in implanted total hip joint prostheses. Working under a VA contract, researchers* in the Department of Radiology at the University of California Medical Center in San Francisco (UC-SF) have adapted the algebraic reconstruction technique (ART) to the imaging problem in computed tomography (CT) created by the presence of metallic prostheses in the reconstruction field. The filtered back-projection methods currently employed by commercial scanners are unable to eliminate the artifacts that arise from x-ray opacity of

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the prosthesis, as shown in Figure 3. In the case of bilateral femoral head replacements, the severity of these artifacts is compounded. Since the image in the ART approach is reconstructed iteratively ray-by-ray, it can be reconstructed without using the rays that are severely attenuated by passing through the metal object.

In the present application of ART, the location of the prosthesis within the slice is determined using the software provided by the manufacturer of the CT scanner. After the rays which pass through the prosthesis are flagged, the image is reconstructed by an iterative process consisting of: (i) constructing a set of pseudo-projections based on an estimation of the image, (ii) comparing these pseudo-projections with the corresponding real projection data, and (iii) back-projecting onto the pixel matrix the appropriately weighted differences between the real and the pseudo-data. For the flagged rays in the region of "hollow" data created by the opacity of the prosthesis, the differences between the real data and the pseudo-data are set to interpolated values that insure a convergence to an artifact-free image.

Figure 4 shows an ART reconstruction of the same data used to generate Figure 3. The CT numbers are accurate in the part of the image that shows the cement-bone interface, the region of primary interest for this prosthesis loosening study. At present, the additional calculations required for such a reconstruction procedure require a significant additional expenditure of computer time, but the procedure is now suitable for limited application as a research tool in the study of hip-joint loosening.

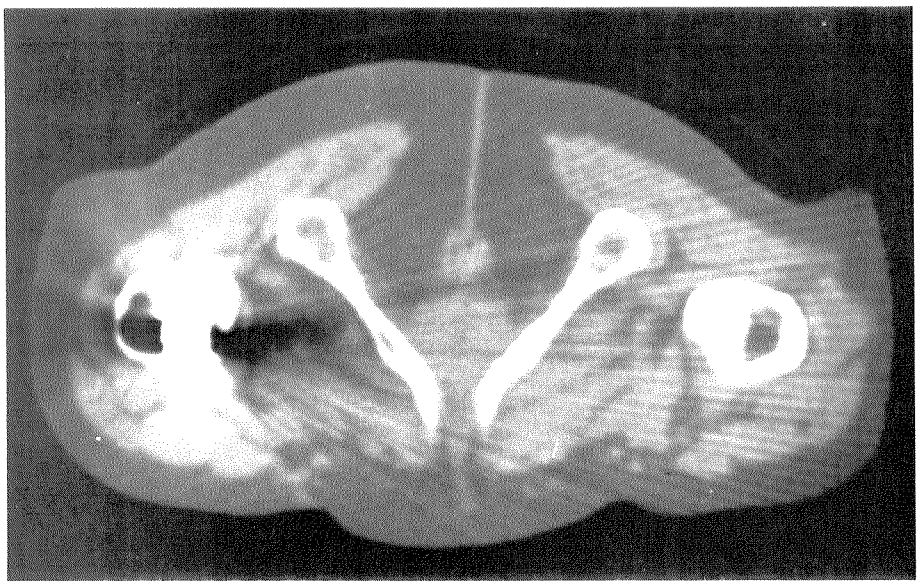

FIGURE 3.
A conventional Computed Tomography (CT) scan through the distal pelvis of a total hip patient. When standard CT reconstruction algorithms are used, the presence of metal in the plane of the scan results in a so-called "STAR" artifact that obliterates much of the information in the reconstructed image.

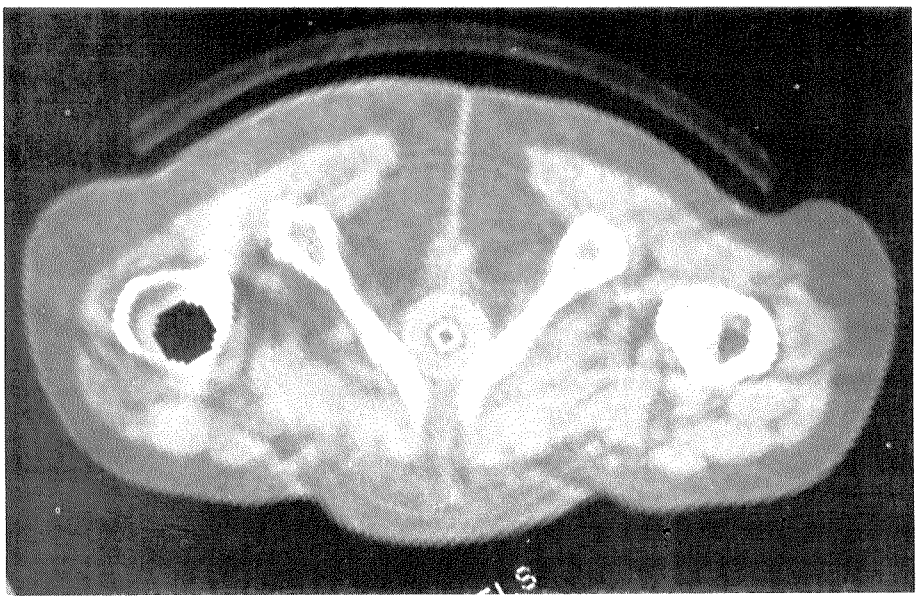

FIGURE 4.
The Algebraic Reconstruction Technique (ART) can be used to eliminate or greatly reduce the STAR artifact and thereby permit the use of CT scans in the study of total hip joint loosening.

Total Knee Implant—Biotelemetry

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During the previous report period, continual evaluation of clinical results involving various knee designs has remained a primary emphasis. Proposals for companion total hip and total knee implant biotelemetry studies have been generated and are currently under review. The total hip biotelemetry project represents a continuation of a joint venture between the UCLA Biomechanics research section and the Jet Propulsion Laboratory to fabricate and test in vitro several laboratory prototypes. The companion knee project requests resources for the initial design and debugging phase of the project. In conjunction with anticipated funding for the projects, a computer system has been installed and the elimination of installation related problems is underway. Several general programs for data acquisition and display are also under development.

Numerous commercial prosthetic designs are currently being evaluated as suitable recipients for the necessary electronic assemblies, but no such unit has been found to date. Total component redesign as well as modifications to only the tibial component are alternatives currently being contemplated. Clinical, developmental and manufac-

turing considerations have served as deterrents to a design consensus to date.

Finally, a few customized tibial components have been implanted for problem cases, and short and long term followups will be evaluated relative to their standard component counterparts.

Program for Evaluating and Monitoring the Disvascular Patient

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This program (initially reported in BPR 10-35, Spring 1981) concerns the development and use of a technique for polarographic monitoring of local hydrogen gas desaturation for measuring myocutaneous perfusion in rehabilitation of the amputee and in evaluating the effects of lumbar sympathectomy in the management of atherosclerotic occlusive disease. This report concerns completion of initial work in the application of the technique of polarographic monitoring of local hydrogen gas desaturation for measuring myocutaneous perfusion rates in the dog (Fig. 1).

To study the effect of lumbar sympathectomy on myocutaneous perfusion, four dogs underwent unilateral lumbary sympathectomy (right) with the contralateral limb (left) serving as a control. Local hydrogen gas desaturation was monitored at the gastrocnemius muscle. Anesthesia was established and maintained throughout the procedure using a 0.2% intravenous drip of sodium thiopental. After anesthesia was induced, the dog inhaled a mixture of 3 percent H_2 gas in room air until full tissue saturation was achieved. The hydrogen gas concentration was monitored using hydrogen-sensitive polarized needle electrodes inserted into the gastrocnemius muscle. Once full tissue saturation was achieved, the dog's inhalation of the H_2-room-air mixture was stopped and normal ventilation of room air was initiated. Simultaneous bilateral recordings of the hydrogen gas washout were made on a stripchart. The hydrogen gas concentration in the muscle tissue gradually falls to zero; the local desaturation of the hydrogen gas follows an exponential decay in accordance with Fick's Law of indication dilution. A total of 47 hydrogen gas washout curves were analyzed. Obtained myocutaneous perfusion rates ranged from 7.42 to 24.15 ml/min/100 g tissue with an average myocutaneous perfusion rate of 12.57 cc/min/100 g tissue obtained for the nonsympathectomized limb. At approximately one week intervals following right lumbar sympathectomy, follow-up bilateral myocutaneous perfusion measurement was done. A representative tracing (shown in Fig. 1) demonstrates an almost three-fold increase in myocutaneous perfusion of the sympathectomized gastrocnemius muscle as compared to the non-sympathectomized contralateral muscle.

These initial data demonstrate an increase in myocutaneous perfusion following lumbar sympathectomy. Additional studies will be made to evaluate repeatability of flows and to establish a trend in myocutaneous perfusion changes following lumbar sympathectomy.

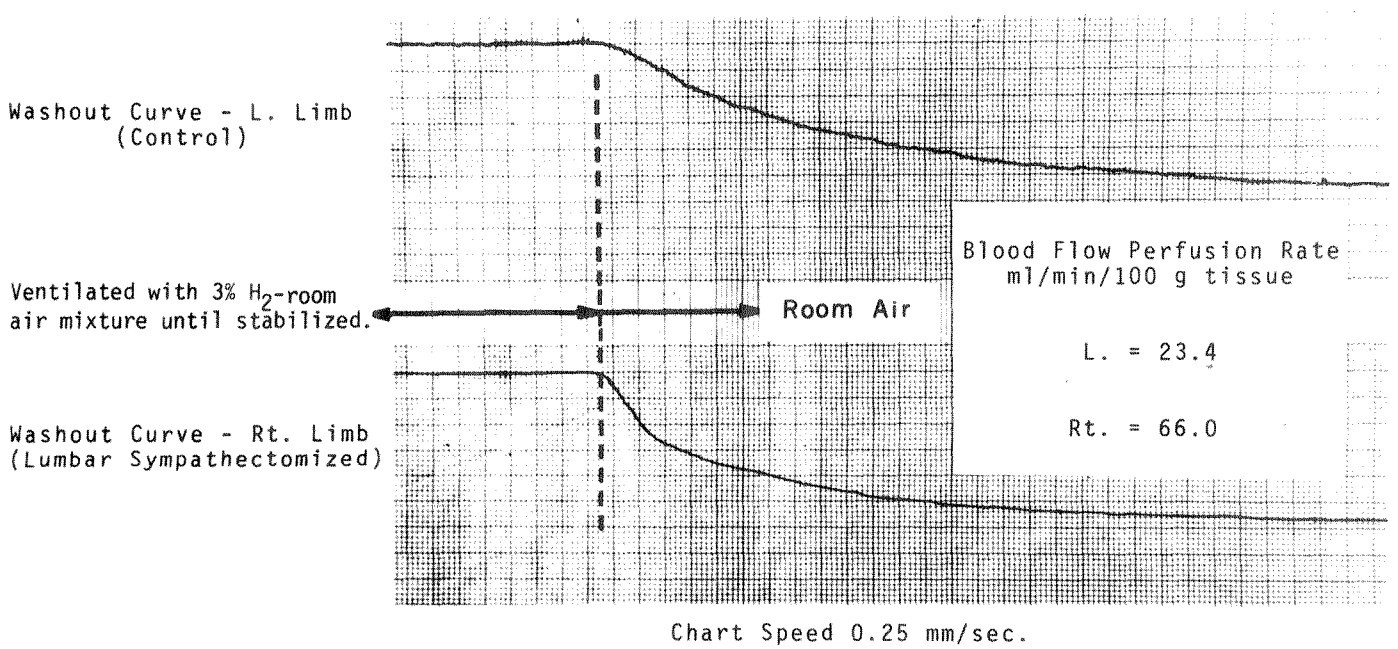

FIGURE 1.
Myocutaneous perfusion measured by hydrogen washout. Curves were obtained from electrodes inserted into gastrocnemius muscle (Canine). Dales: Rt. Lumbar Sympathectomy 2/10/81; Perfusion Study 2/19/81.

Seating Systems for Body Support and Prevention of Tissue Trauma

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To date, 57 prototypes of the Veteran's Administration Seating Interface Orthosis-Paraplegic (VASIO–P) have been evaluated by patients with spinal cord injuries between T1 and T12.

After a minimum of 3 months on the cushion, responses of the patients have reinforced originally favorable comments relating to comfort, balance, posture, practicality, and cleanliness. One noticeable and frequently cited advantage of VASIO–P is a continual increase in the patients' sitting tolerance.

Highly active patients, those involved in sports, gardening, or farming, have presented problems concerning accelerated deterioration of the cushion with constant use. This difficulty could be alleviated by distributing two cushions to the patients for alternate use.

Transfers remain difficult for many due to height of the cushion. Solutions to this problem are being investigated. Data obtained in clinical testing is being used in the formulation of prescription guidelines for clinicians.

Research and development on a seat cushion for quadriplegics, designated VASIO–Q (Q–quadriplegic), is now complete. In this model the surface features have been modified to accommodate the special biomechanical and pressure-reduction needs of patients with quadriplegia who cannot perform pressure reliefs independently. Clinical testing of VASIO–Q is scheduled for July 1981. A lap tray, and leg and trunk supports, will also be designed as accessories to this total body support system.

Design of a third cushion, specific for patients with a cauda equina injury, will permit the increased movement and postural changes exhibited by these patients. Research and development on this cushion will start after clinical testing of VASIO–Q.

Test data on VASIO–P indicate that it performs quite satisfactorily in reducing sitting pressures to acceptable levels. This research further shows that modular seating systems can meet the orthopedic and pressure reduction needs of a wide population of spinal-cord-injured or otherwise asensory persons. Steps are underway to make VASIO–P commercially available.

Clinical and Laboratory Study of Amputation

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Limb Viability—Elective amputations were performed on 52 patients at VA Medical Center, Seattle, during the 6-month period. An additional number of patients were included from other hospitals within the University system. This smaller group of patients was selected for their specific research value. Following up on earlier double-blind investigation using transcutaneous pO_2 determination at several limb sites, this test is now included as a routine preoperative amputation determination. The surgeon is informed of the perfusion levels prior to the amputation. This rapidly increasing statistical base will establish the value of noninvasive gas perfusion measurements for limb viability and preoperative determination of correct amputation level.

The **microwound research** is now actively underway. A small standardized and carefully controlled microwound is made on the threatened limb at a predetermined site distal to the level of amputation. The wound is harvested from the amputated limb, then subjected to a variety of histological and biochemical observations. This "in vivo" examination uses the clinical wound healing at the amputation site as a control and also forms a yardstick against which other non-invasive tests carried out at the same site can be measured.

Preoperative tissue viability is also being studied experimentally using a laser Doppler and multispectral reflectometry. These objective laboratory parameters are non-invasive, inexpensive, without hazard or discomfort to the patient, and potentially valuable. We have not, during the time covered in this progress report, used radioactive isotope measurements (Xenon 133). An excellent study of that test continues at VAMC Tucson (Malone et al). The Seattle facility is in regular communication with science persons at Tucson and at other limb viability laboratories in this country and abroad.

Significance of these studies extends well beyond the more accurate preoperative determination of amputation level in the ischemic limb. There is very little current information about the nature of wound healing in the presence of ischemia. This work is directed to more fully understand this process.

Prosthetics Research—A synthetic composite energy-storing foot has been developed in conjunction with the Boeing Technology Services. It is designed to improve functional performance for active lower-extremity amputees. Prototypes have been bench tested and stress analyzed. Design and materials are now standardized. The foot is undergoing testing on ten selected amputees. Performance evaluation will be reported within the next few months.

The Prosthetics Research Study has enlarged its Amputee Evaluation Group to include fifty subjects. These individuals have been carefully selected from a larger volunteer group and are available for field testing of new and modified lower-extremity prostheses and components. The majority of these individuals are from the veteran amputee population.

Surgical and Immediate Postsurgical Amputation Research—Clinical research continues concentrating on distal levels of amputation in the ischemic lower limb. Of particular investigative concern are amputations through the forefoot and midfoot. This area of lower limb amputation is least well understood. Healing failure following surgery is frequent requiring higher secondary amputation. A more precise knowledge of the healing capability, as measured by preoperative studies of the type PRS is investigating, and innovative surgical techniques, are urgently needed.

PRS continues to evaluate statistically all amputations carried out by its staff. These data form a base for inhouse critique and comparison with other services.

Education—A list of current publications is as follows:

1. Burgess EM: Postoperative Management. Atlas of Limb Prosthetics, Surgical and Prosthetic Principles. American Academy of Orthopaedic Surgeons. The C.V. Mosby Co., pp. 19–23, 1981.
2. Burgess EM: General Principles of Amputation Surgery, Atlas of Limb Prosthetics, Surgical and Prosthetic Principles. American Academy of Orthopaedic Surgeons. The C.V. Mosby Co., pp. 14–18, 1981.
3. Burgess EM: Principles of Amputation Surgery in the Upper Limb. Atlas of Limb Prosthetics, Surgical and Prosthetic Principles. American Academy of Orthopaedic Surgeons. The C.V. Mosby Co., pp. 92–94, 1981.
4. Kegel B: Prostheses and Assistive Devices for Special Activities. Atlas of Limb Prosthetics, Surgical and Prosthetic Principles. American Academy of Orthopaedic Surgeons. The C.V. Mosby Co., pp. 423–434, 1981.
5. Burgess EM: Principles of Amputation Surgery in the Lower Limb. Atlas of Limb Prosthetics, Surgical and Prosthetic Principles. American Academy of Orthopaedic Surgeons. The C.V. Mosby Co., pp. 272–276, 1981.

A list of publications submitted for publication is as follows:

Enoka R, Miller DI, Burgess EM: Below-knee amputee running gait. Accepted by Amer J Phys Med.

Burgess EM, Matsen FA: Current concepts for determining amputation levels in peripheral vascular disease. Accepted by J Bone & Joint Surg.

Johansen KH, Burgess EM: Improvement of amputation levels in limb revascularization. Accepted by Surg Gyn Obstet.

Kegel B, Burgess EM, Starr TW, Daly WK: Effects of isometric muscle training on residual limb volume, strength, and gait of below-knee amputees. Accepted by Phys Ther.

Burgess EM & Forsgren SM: The Prosthetist. Chapter in Orthopedic Rehabilitation edited by V.L. Nickel. New York, Churchill Livingstone. In Press.

Burgess EM: Amputations of the Lower Extremity. Chapter in Orthopedic Rehabilitation edited by V. L. Nickel. New York, Churchill Livingstone. In press.

Burgess EM: Amputation Surgery and Postoperative Care. Chapter Three in Rehabilitation Management of Amputees, edited by S. N. Banerjee and J.V. Basmajian. Baltimore, Williams and Wilkins. In press.

There were two **presentations** in this time period:

1. Dr. Ernest M. Burgess: Instructional Course, "Advances in Amputations," American Academy of Orthopedic Surgeons Annual Meeting, Las Vegas, Nevada, March 1, 1981.
2. Shirley M. Forsgren: "Prosthetic Foot for Active Sports—Preliminary Studies" American Orthotics and Prosthetics Association Region IX and California Orthotics and Prosthetics Association Combined Meeting, Monterey, California, June 5–7, 1981.

The Prosthetics Research Study staff supported by an excellent national faculty is conducting a Continuing Education workshop in Seattle, September 11–12, 1981. This course is entitled "Modern Amputation Surgery and Prosthetic Rehabilitation" and is sponsored by the American Academy of Orthopaedic Surgeons.

Transcutaneous Oxygen Tension as Predictor of Wound Healing

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Frederick A. Matsen III, M.D., Craig Wyss, Ph. D.

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Ernest M. Burgess, M.D.

This project is directed at exploring the use of transcutaneous oxygen measurements as a means of evaluating noninvasively the severity of peripheral vascular disease and the effect of therapeutic measures. Five separate studies are in progress: (i) prospective evaluation of transcutaneous PO_2 before amputation for peripheral vascular insufficiency; (ii) a longitudinal evaluation of transcutaneous PO_2 values over time in a patient population at risk for peripheral vascular disease; (iii) pre- and post-vascular-reconstruction measurements of segmental transcutaneous oxygen values; (iv) measurement of transcutaneous oxygen during and after exercise on a treadmill in patients with claudication; and (v) development of a multi-probe transcutaneous PO_2 monitor for mapping transcutaneous oxygen over the extremities.

A preliminary paper has been submitted covering a double-blind study of 58 amputations with respect to the prospective evaluation of amputation success or failure using transcutaneous oxygen measurement at the proposed site of amputation. Of 38 below-knee amputations, all patients having prospective transcutaneous PO_2 values greater than 40 mm Hg healed primarily; 15 of 19 patients having transcutaneous PO_2 values greater than zero but less than 40 mm Hg healed primarily, 2 after local revision but 2 failed after intercurrent thrombosis. All three patients having prospective transcutaneous PO_2 values of zero failed to heal and required revision to an above-knee amputation. There were only 3 primary above-knee amputations and the balance of this group were various types of foot amputations. Patients are being added to this data pool continually.

Patients appropriate for longitudinal study, pre- and post-vascular-reconstruction, and exercise testing are picked up as they appear on the vascular or amputation services at the Veterans Administration Hospital. For the longitudinal study, limbs contralateral to an amputation are studied at 6-month intervals when patients return for check-ups. Segmental transcutaneous oxygens are measured in patients scheduled for vascular reconstruction and then are measured again about 1 week after their surgery to evaluate the effectiveness of the treatment. Patients who come into the vascular lab for exercise testing are measured with transcutaneous oxygen electrodes just above the ankle cuffs (used for evaluating ankle blood pressure); these patients are followed during and after exercise, and results are compared to the ankle pressure measurements.

Development of the multi-probe transcutaneous oxygen sensor is in the prototype stage and will be completed in about nine months. This multi-probe sensor will be used to measure simultaneously a number of skin sites for mapping out prospective amputation flaps and for monitoring the changes in transcutaneous oxygen that attend exercise over the extremities of patients experiencing claudication.

References

1. Matsen FA, Wyss CR, Simmons CW: The effects of compression and elevation on the circulation to the skin of the hand as reflected by transcutaneous PO_2. Plast. Reconstr. Surg. In press.
2. Burgess EM, Matsen FA: Current concepts for determining amputation levels in peripheral vascular disease. (Editorial) Accepted by J Bone Jt Surg.

Maxillofacial Restorative Materials and Techniques

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Introduction

The research and development effort continues with five project efforts integrated into a comprehensive development plan (1) from basic science and technology to clinical servicing throughout the VA system and interested non-VA maxillofacial clinics. Inasmuch as small maxillofacial prosthetics attracts very little commercial interest or shows the prospect of profitable venture opportunity because of low market volume (2), the development plan has been extended in the direction of large prosthetic devices. Accordingly, special effort, as will be recounted in the succeeding five project sections, has been imposed on producing more flowable modification of PDM siloxane without changing the inherent chemistry, and devising or inventing a stone mold reinforced and stabilized with metal framing to protect the stone mold, despite its hardness, from fracturing and breaking into pieces during the pressuring operation. Salient progress and success have been achieved in this.

Although not extensively reported at this time, the project section on human-safe aspects continues to engage a major portion of the effort in support of a biocompatibility test protocol which has already been submitted for panel review in a committee of the American Society for Testing and Materials. The most pressing task is in separating and specifying the factors in cell growth medium that are in accord with current developments in cell growth. The major burden of this obligatory work is the detailing, fine-tuning so to speak, of the specified testing media and procedures to assure reproducibility of the test results by other tissue culture laboratories.

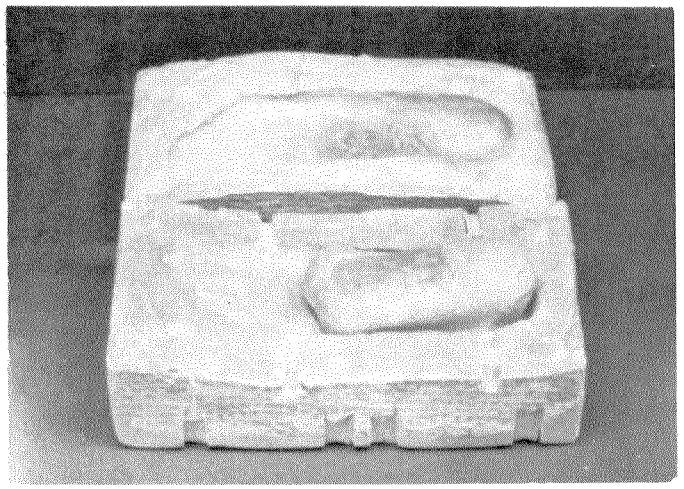

Figure 1(a)—Starting two-part split mold of dental stone. Dimensions are: Length: 11 inches; Width: 7 inches; and Height: 5 inches. Weight is 16.5 lb. (7.49 Kg.).

FIGURE 1.
Simplified, inexpensive Design B of large dental stone mold for fabricating large prosthetic devices, beyond current limits with conventional dental stone molds, using angle-iron encasing to stabilize the stone mold against fracture from imposed-pressure molding and from thermal stresses during polymerization at 100° C.

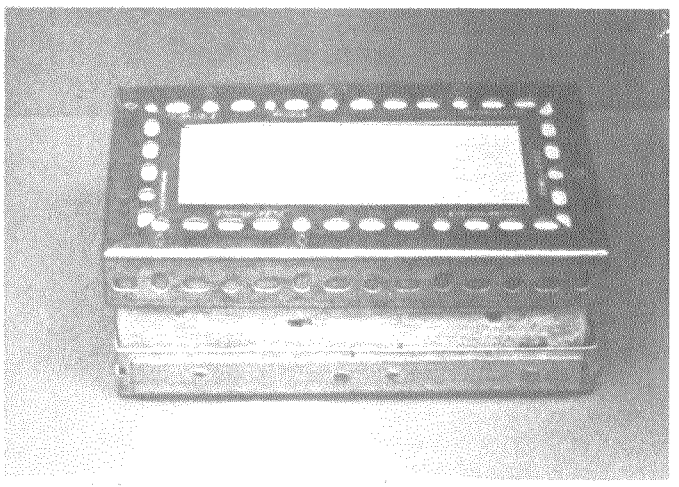

Figure 1(c)—Assembled, closed arrangement of stone mold with the reinforcing case ready for filling in with additional stone, set from water slurry, to lock the rectangular reinforcing case to the two-part stone mold.

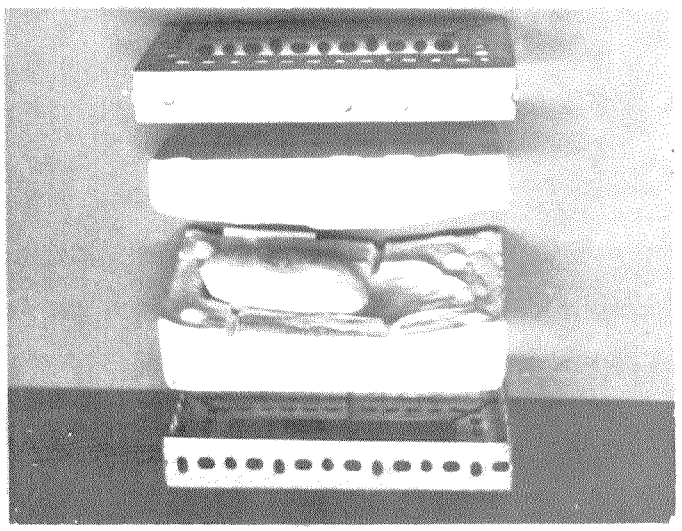

Figure 1(b)—Extended display introducing the rectangular angle iron reinforcing case to encase the two-part components of the stone mold.

Product Development

Of the tentative Performance Standards as required by FDA regulations (1) and listed in a recent BPR (3), that of the elastic modulus is being particularly scrutinized for the 18 production campaigns (to supply the VA-wide needs) for effects of milling schedules, shelf life, and applied tensile straining rates. These effects constitute the essential features for quality and uniformity which increasing clinical acceptance of oligomerized PDM siloxane depends upon.

It has been observed that the specified range of 60–80 lb/sq in (0.41–0.55 MPa) in tensile modulus has been increasing with consequent production campaigns to 100–140 lb/sq in (0.69–0.97 MPa). This is tentatively ascribed to more efficient blending of the prepolymer and oligomer, based on longer milling time in combination with elevated milling temperatures. These milling adjustments have been observed to produce a more tractable, more moldable stock.

The milling adjustments have been undertaken as one aspect of the Comprehensive Development Plan (1) to attain lower viscosity (plastisol) oligomerized stocks, with increased oligomer content, for large prostheses molding in dimensions beyond those limited by the 5-inch diameter dental stone molds (4). As recounted in the ensuing fabrication project section, this task effort proved highly successful. The new 70/30 (prepolymer/oligomer) composition is programmed for studies on effect of oligomer unit dimethylsiloxane lengths in combination with a range of catalyst levels on the extensile properties as was done with the 80/20 composition.

Fabrication

Maxillofacial restorations heretofore have been limited to cross-sectional areas of 16 square inches with a maximum circular width of 4 inches and a maximum depth of 2.5 inches, using the largest (Hanau Giant) dental stone mold. These dimensions preclude the fabrication of a significant number of facial and cranial reconstructions, of functional and cosmetic augmentation of congenital amputated limb defects, and of various cosmetic implants. These enlarged reconstructions are served by prosthetic forms made from a variety of undefined, often untraceable ingredient sources, compounded forms of unspecified, proprietary grades of latex rubber, acrylics, and polyvinylchloride plastisols, etc. Presently available proprietary compositions have one or more serious consumer (end-use) deficiency, among these being age-cracking (rubber), detergent and solvent gumming (acrylic terpolymers), tear rupture (RTV silicones), shrinkage and stiffening (polyvinyl chloride), and gradual elastic distortion or set. In general, the proprietary formulations, usually left to the particular skill or preference of the prostheses technologist, are deficient in mechanical endurance, especially tear resistance and sustained elasticity. All or most of these deficiencies can be eliminated or substantially reduced in the larger prostheses by use of PDM siloxane (5), with the availability and use of a new series of molds larger than the current dental stone mold sizes. Consequently, in this project section, several developments have been undertaken to (i) provide simple, inexpensive mold frames to reinforce the fracturable stone mold compounded from gypsum, (ii) develop a modified form of the current PDM siloxane (80/20 prepolymer/oligomer ratio) for increased viscous flow, and (iii) work out the technical details for thermal schedule for polymerization to performance standards. During this period of these three tasks, initiated as reported in the previous BPR, each has been advanced to the point at which the first successful right-foot prosthesis has been made (and accepted by the client for consumer end-use testing) using the new 70/30 prepolymer/oligomer PDM siloxane composition.

The initial trial of pressure-forming of a 11 in × 7 in (77 in² area) rectangular mold was carried out in the fabrication of an internally pigmented (SY–2) form of a prosthetic forward toe section of a right foot, measuring seven inches in length with an area of approximately 21 square inches extending to the back of the client's heel. Repeating the model foot molding described in a previous BPR (5), the new rectangular box mold, depicted in Figure 1, withstood successfuly without any fracturing the 2000 lb applied forming force with the new 70/30 prepolymer/oligomer PDM siloxane composition and the ensuing 3 hour thermal polymerization schedule. This first molded cosmetic foot prosthesis, endowed with substantial tear resistance (lacking with RTV silicones) has been accepted by the client with satisfaction. A series of replicate moldings are in progress for the purpose of (i) retrieval, client-wear evaluation (tear resistance, comfort, hygienic maintenance, and signs of dermal sensitivity) and (ii) ascertaining pressure limits of the new rectangular box mold design with the specified hardware. The client wear evaluation will include a series of 3, 6 and 12 months usage with selected tests for elastomer deterioration.

Pigmentation (Internal Shade Stocks)

The current standard six-shade internal pigmentation has been augmented with a melanin replicating color for which Monastral Gold (DuPont) has been selected from a series of dry pigments resistant to color fading and to hygienic (sodium hypochlorite) disinfecting.

Unlike most darkening or red-surpressing artist's chars or carbon, Monastral Gold has imposed less than a 5 percent diminution in the arterial red/carotene yellow ratio (Hunter DCD b/a as described in (6)). The first of a series of production runs (Shade SY–2A) of internally pigmented PDM siloxane has been sent to outside maxillofacial prosthetics clinics for esthetic replication of Afro cosmetic skin coloration to augment the current standard 6-shade range, from carotene (yellow) dominant to arterial (red) dominant shades of stock material.

Toxicity and Potential Tumorigenicity

Under the regulatory provisions of the Medical Devices Act (7), the protocol for testing and demonstrating non-toxicity of PDM siloxane has been formally submitted to the American Society for Testing Material (ASTM) Committee F04, Medical and Surgical Materials and Devices, at the Spring meeting, May 13–15, 1981, at Phoenix, Arizona, and assigned the ASTM Designation F04.20.06.52. Under the title, Standard Practice for Assessment of Orofacial Materials and Devices by Culturing with Human Excised Donor (HED) Tissues, the proposal now undergoes study by a committee of panelists representing producers, users and general interest reviewers from whom comments will be forthcoming, ranging from constructive modifications to challenges for various reasons of rationale, relevance, and so on. Thus a series of committee reviews are expected with prospects of modifications and experimental verifi-

cation of changes obligated to attain ultimate ASTM approval (8). It is expected this may take from 2 to 3 years at the ASTM level serving as the voluntary agency (7) for FDA approval.

The principal components of the HED tissue biocompatibility testing procedure for nontoxicity include (a) specifications for chemically defined medium, (b) augmentation with minimal and specific human serum protein factors for attachment, viability, and division, and (c) provision for preliminary (7 day) qualification of selected (a) and (b) components with an established HED cell line followed by extended (7 and 30 day) testing with specific HED primary tissue for rated (specification) biocompatibility. This protocol provides ample options and flexibility to the proposed recommended practice for favorable panel review.

Present emphasis is accorded to the separation of the Holmes alpha-l-protein growth factor (AGF) from human serum and blood fractions (9) and establishing an appropriate activity titer for the above qualification test. It is expected that as the proposing laboratory for the biocompatibility test, this project will provide samples of the qualified AGF to reviewing participants of the ASTM F04 Committee. At present there are three biocompatibility test proposals under review by the F04 Committee relating to other medical and surgical prosthetic biomaterials of which only the HED has the highest degree of human relevancy.

Field Participation

The total number of participants, based on requests for starter sets (kits) of PDM siloxane, has reached a total of 52 VA and non-VA maxillofacial clinics. This number represents only a fraction, by about one-fifth, of expected participants as the initial program was set up. Despite the drop-out of an estimated one-fourth of the participants starting in 1978, there is evidence that private clinics, especially those furnishing artificial eyes, are coming into the program.

The principal problem continues to reside first in the lack of professional or technical job classification and secondly, on the fulltime commitment of a prosthodontist or D.D.S. clinician. The latter in most of the participating clinics has to undertake the time-consuming burden of the non-dental tasks of (i) maxillofacial, sculptural replicating from hydrogels to stone molds, followed by (ii) thermal molding, and by (iii) external painting for cosmetic matching, tasks which more properly can and should be carried out by skilled technicians, particularly medical sculpturists. These tasks require special laboratory devices and supply items. Except for the devices, notably forming molds, press, and oven (or autoclaves), the supply items are furnished in the starter kit shown in Figure 2 with a complete array of pigments for external cosmetic matching and items special to molding along with a manual of procedure.

In the meantime, inquiries continue to come for non-pigmented PDM siloxane to be constructed into implants, an area that would give a new impetus to medical or surgical sculpturists. This area is being purposely restrained until the biocompatibility test procedure now under review by ASTM is formally adopted. Although normal laboratory, environmental and personal cleanliness in an isolated room is the practice in the production of PDM siloxane, it is necessary and planned to set up a clean room normally required for medical or surgical grade devices meeting Federal guidelines.

To continue the availability and competent utilization of PDM siloxane, this project program continues to report on the research and development and clinical utilization at conferences of several national professional organizations. Additionally, a workshop similar to that organized in the Spring of 1979 is planned for the Fall of 1981.

Production

A total of 18 production campaigns and over 600 one-pound units of PDM siloxane have been produced since inception of the program in 1979. Each campaign is specific to repeated lots of prepolymer (General Electric SE4524U), oligomer (Dow DC 200 silicone fluid), catalysts (CST and AST), and modifications of processing procedures. The modifications are related to the product development tasks, mentioned in the earlier section of this report, specifically to extend the milling time and temperature range of operation and to incorporate higher levels of oligomer. Each production campaign is monitored by quality control on expected product performance, especially tensile constants and tear resistance, and biocompatibility quality assurance.

References

1. Lontz, John F. and James W. Schweiger: (ibid in succeeding reference) Maxillofacial Restorative Materials and Techniques, Bulletin of Prosthetics Research

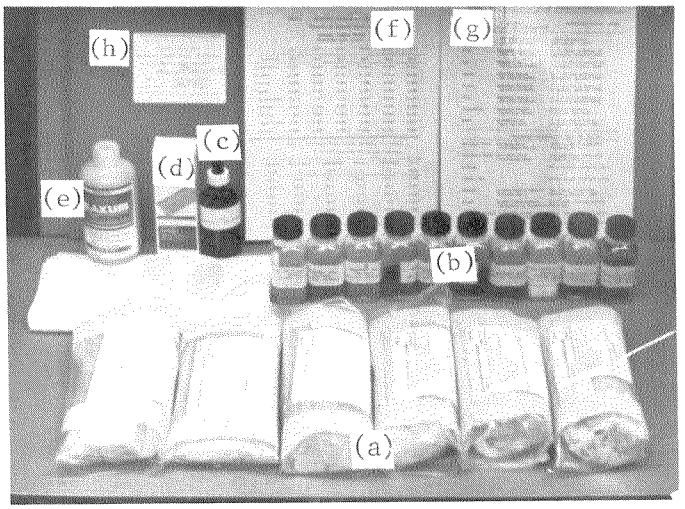

FIGURE 2.
Starter kit of internally pigmented PDM siloxane in six (6) internally pigmented shade with accessories for external, cosmetic painting to match patient skin coloration. The kit includes:
(a) 6 one-pound stocks of PDM siloxane,
(b) 10 pure pigments for external cosmetic painting,
(c) xylene thinner for vehicle (d),
(d) adhesive vehicle (Silastic Type A Adhesive),
(e) separator (foiling over stone mold) compound,
(f) product description list by chemical types,
(g) accessory list with sources of commercial supply, and
(h) manual (draft) of procedure for molding and painting.

BPR 10-32 Fall 1979; see Table 1, pages 378–379 detailing the six project efforts with defined tasks (specific objectives) integrated and consolidated toward the goal of providing a standard, continuing supply of safe and effective prosthesis stocks and their derived prosthetic devices.
2. Ibid BPR 10-32 Fall 1979; see pages 401–402, Clinical Services and Cost Advantage.
3. Ibid BPR 10-34 (Vol. 17, No. 2) Fall 1980; see Table 2, page 105.
4. Teledyne Hanau Company, 80 Sonevil Drive, Buffalo, N.Y. 14225, Hanau Recon Flask Cat. No. 155-1, Manganese Bronze, overall dimensions 11½′ length × 7¼″ width, and 7 7/16″ height, priced at $350, August 11, 1978.
5. Ibid BPR 10-35 (Vol. 17, No. 3) Spring 1981; see the project section II (Fabrication), molding a foot prosthesis.
6. Ibid BPR 10-27 Spring 1977; see pages 162-164, section on digital color difference indices on human skin. Also BPR 10-28 Fall 1977; p. 195–186.
7. Federal Register, July 25, 1978, Part V. FDA, Medical Devices, Procedures for Development of Standards.
8. Standards Survey, publication prepared by Bureau of Medical Devices, FDA, 1980. This survey lists the ASTM among the various voluntary standards agencies (see Reference (7)) providing biomaterials standards for materials and devices; the ASTM acceptance of standards is by series of panel reviews from a consensus of interested producers and users.
9. Holmes, Richard, Gretchen Mercer and M. Foght: Properties and Function of Human alpha-I-Protein Growth Factor. In Vitro 3:139, 1967; one of a series of papers reporting on the role of human serum-derived growth factors now adopted in the human excised donor (HED) tissue culturing system.

Rehabilitative Engineering Support for the Atlanta VA Medical Center

Georgia Institute of Technology

Office of Interdisciplinary Programs, 225 North Ave. N.W. Atlanta, Georgia 30332

Gary W. Kelly

A Manual Wheelchair Wheel with Integral Anti-Rollback (Gary Kelly, Principal Investigator, and Theresa Ackerman, Research Technologist.)

The first prototype of the wheelchair wheel was developed and tested. Among the problems appearing in the design were: the unit weighed too much, rolling friction was too high, spacing of the push rings was inadequate, a lock-out was needed to disable the anti-rollback feature, and surfaces needed to be smoother with fewer prominences to catch the user's hands.

The efforts this year have been in two directions: to determine further user suggestions as to improvements in design, and to begin designing a wheel that would meet as many of the known criteria as possible.

Work is continuing on gathering as much user input as possible, in order to obtain enough information to rank-order the preferences in design changes. At present, it appears that the highest preference is the reduction of friction, followed by need for a lock-out, reduced weight, cleaner surfaces, etc.

Design modification will continue, taking into consideration the preferences and the intent of providing future options such as forward dynamic braking, 2-to-1 or 1-to-2 gearing, and other options.

It is anticipated that within the next 6 months the design decisions will be made, and the second prototype with reduced weight and friction as well as many other human-factors improvements will be constructed. In addition, alternate construction methods are being considered to reduce the cost and enhance the manufacturing feasibility of the wheel.

An Alternate Vehicle for the Physically Handicapped. (Gary W. Kelly, Principal Investigator, and Theresa Ackerman, Research Technologist.)

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. Work will continue on analysis of the control design and this is expected to evolve into a major project in itself. The control system presently designed may offer some surprising advantages compared with present wheelchairs. The addition of a microprocessor and the innate capability of self-leveling provides the additional attraction of programmable weight-shifting and control of accessories that is far superior to that of any system presently offered or proposed, as far as is known.

Some new accessories have been perfected for use in power chairs (including the proposed vehicle) by the research staff at the Georgia Institute of Technology. Among these are the automatic leg-bag evacuator complete with a robotic arm which would allow the independent use of restroom facilities. This student project is nearing completion of a first prototype for use on conventional power chairs. Research is continuing on other accessories that would be useful in promoting independence of the vehicle user. It is intended that the final design be a system design rather than a model with add-ons; each component will be a modular unit integral to the whole, which is expected to reduce production costs.

Mr. Ken Morgan has been the graduate student who carried the majority of the work to its present state. This report draws upon his graduate thesis for the Master's Degree in Mechanical Engineering. The study will be carried on by a new team who will further develop a clear description and graphics presentation that will be used in additional discussions with wheelchair users, to gain more insight into their needs and also to involve them further in the design process.

In addition, the planning for the electronic control system will continue along with studies of vehicle dynamics, structure, and human-factors design. It is estimated that this study is approximately 2 years from completion of detailed engineering drawings—from which a prototype can be built.

Sonic Orientation and Navigational Aid (SONA) (Gary W. Kelly, Principal Investigator, Robert D. Atkins, Research Scientist, and Theresa Ackerman, Research Technologist.)

The present design of the sonic orientation and navigational aid (SONA) has reduced the size of the packaging required for the transmitter. Efforts at reduction beyond this point may not make sense, since the limits of available touch-tone keyboard sizes is being reached. Tests with present units demonstrate the packaging to be satisfactory, though much more actual evaluation is needed.

With the addition of the new General Instruments music board to the receivers, the tone quality problems have been solved. Virtually all the technical problems associated with this project seem to have been eliminated.

The receivers have been improved by the addition of new tone synthesizer chips. The best version is the programmable General Instruments board. This promises to provide an infinite variety of tones at low cost and with high quality. Similar boards are appearing on the market with highly attractive low costs. This problem appears solved with even greater simplicity than was initially anticipated.

This project now intends to address the utilization of more complex transmitters and receivers. These new devices are replacing the older ones rapidly and have considerably more coding possibilities. Future plans for SONA include the use of the device for elevator control, a decentralized environmental control system, and (coupled with speech output) an information system for blind travelers. The hardware will be updated to provide the capability for these uses later.

Special consideration will be given over the next 18 months to coding. Adoption of reasonable standard codes and location for SONA must be determined. Efforts will continue to involve other centers in testing and evaluating this unique orientation aid which allows the visually impaired traveler to identify and locate specific kinds of known elements within his environment, such as entrances and exits, elevator call buttons, etc.

Electronic Typewriter for the Visually Impaired (Gary W. Kelly, Principal Investigator, Lawrence Moriarty, Research Scientist, and Theresa Ackerman, Research Technologist.)

A typewriter for the visually impaired, designed to meet the needs of persons with usable residual vision who could utilize large print, is based on word-processor technology. It consists of a keyboard, a processor with memory, cassette storage of information, and a large character display.

The philosophy of the device's construction has changed in the last 6 months, and the attempt has been to modularize the entire device into electronic subsystems that are compatible with almost any TTL circuitry. At this time the video board, the RS232 serial interface, the display, the display software, and the cassette interface board are separate operational subsystems interrelated through the central 1802 processor.

The research team is developing a system that is not tied to one processor or mainframe word-processing/text-editing system. This may have some unique design advantages.

The decision to modularize the entire device into electronic subsystems was made to accommodate the newly emerging word-processors, which may ultimately be readily modified to meet the needs of this device—rather than requiring the specialty manufacture of a dedicated device for the visually impaired. At present, the research staff is studying several new word-processors that are portable and have the capability of being modified with one or more of the presently developed subsystems to allow their performance as cassettes to a large-print reading machine for the visually impaired. This effort is expected to be successful, and technical discussions have begun with one large electronics manufacturer to modify one of their machines for the purpose of demonstrating this capability.

The users would aid in evaluating this approach over that of continued construction of a dedicated system. We expect that the piggy-back approach of loading additional subsystems onto existing devices will provide, at lower cost, a device superior to the present prototype. We anticipate having the first successful system operating in 12 months.

A Musical Language Computer Terminal for the Visually Impaired (Gary W. Kelly, Principal Researcher, and David Ross, Graduate Research Assistant.)

The most recent accomplishments in the project have been the development of improved software which allows more versatility, including use as a preliminary training tool. The tone-generating software for the ALF Products music board has been improved to allow use of the nine-voice board. This board, while lacking some of the features of the earlier three-voice boards, is still suitable for this use at a significantly reduced cost.

In addition, improvements have been made in the teaching programs to allow for an increased vocabulary. These programs have been useful in the preliminary work done with a small sample of blind students.

It is expected that, over the next 6-to-9 months, additional software will be developed to allow this musical language to be used with a text editor package available for the Apple II Plus. It is anticipated that even better software for teaching the language will also be available. Efforts will continue to obtain the cooperation of other facilities to evaluate the language and its uses.

Communicator for the Speech Impaired (Gary W. Kelly, Principal Investigator, and Theresa Ackerman, Research Technologist.)

This portable battery-operated device consists of a Morse Code entry system, a microprocessor, memory, and a display. It is designed to permit the user to input any phrase or set of characters into the Morse entry system for translation into normal alphanumeric text appearing on the display.

The Communicator has undergone several design alterations since the construction of the first prototype, each adding versatility and cost effectiveness. The most recent design, initiated in May 1981 and rapidly approaching fruition in the form of a fully working prototype, is technically state-of-the-art and gives the power and versatility to make the communicator an extremely useful device to the widest possible user population.

There are now two models, one with the Morse Code input and one with a pushbutton keypad input. With the ex-

ception of the input, the two models are functionally and operationally identical. All of the software and 95 percent of the hardware is identical between them, thus giving added versatility without losing economies of scale.

The microprocessor is Intel's 8748, which has become the industry standard for one-chip microcomputers. We have designed the device using a slow clock (3.6 MHz) which cuts the cost of the microcomputer to as low as $19.00 in volume. This can be less, if the projected volumes justify mass programming. The use of Intel's revolutionary 2816 EEPROM, just introduced, gives the user the capability to program his own messages. Message capability has been increased to 112 programmable lines which are linkable to any length. The use of a liquid crystal display insures that the display will be visible even in direct sunlight and, when coupled with an increased use of CMOS components, promises 6 or more hours of continuous operation per charge.

We believe that the present configuration represents the final iteration in the design process, as all major shortcomings of the previous designs have been addressed and eliminated. It is still possible, however, for some minor "fine tuning" to be required as we continue to get feedback from potential users of this device.

The new model will feature 112 user-programmable messages. A good redesign providing an improved housing of the model, of optimal shape and size, is expected to be completed within the next 6 months.

SENSORY AIDS IN THE VA RER&D SERVICE PROGRAMS

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Development of the Autocuer Speech-Analyzing Lipreading Aid

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Introduction

Numerous approaches have been made to facilitate communication with hearing-impaired and profoundly deaf persons. A number of methods and variants are widely used. An extensive summary has been prepared by Garmon (1). Various forms of sign language, finger spelling, lip reading, oral gestures, cued speech, and amplification constitute elements of total communication. Instead of competition between elements, some now believe that combinations may be effective.

Cued speech is a very effective technique for facilitating speech communication with people who are deaf. Developed by Orin Cornett, cued speech makes use of eight hand shapes held at four different positions near the face by the speaker. These manual syllable cues, in combination with lipreading, can enable realtime speech perception by a deaf person with accuracy comparable to that of an individual with normal hearing (2). Not a form of sign language, cued speech is described as a code designed to take the guesswork out of lipreading. For it to enable clear communication, of course, the speaker must know and use cued speech.

Recognition of the limitations inherent in any communication method for deaf people that requires each speaker to learn a special code led to the establishment, in 1971, of a collaborative research effort between Gallaudet College and Research Triangle Institute (RTI). The objective of this project was and is the development of a wearable device, now called the automatic cuer or Autocuer, which through electronic speech analysis can present to the deaf wearer visual cues equivalent to those of manual cued speech.

Research demonstrating the feasibility of an autocuer—that such a hypothetical device could remove ambiguities from lipreading—was performed during the period 1973–76 with support primarily from the National Institute of Neurological and Communicative Disorders and Stroke. Gallaudet College trained deaf subjects, then tested them on their ability to perceive speech presented via computer-cued videotapes. RTI developed the hardware and software for this effort, including a minicomputer-based speech analyzer for automatic generation of cues. The results of this work are reported in (3).

Figure 1 illustrates how the Autocuer display will appear to the user. The display shows, on a syllable-by-syllable basis, the results of the speech analysis. Consonant ambiguity is removed by visual symbol shape; each shape represents one of nine groups of visually contrastive consonants. Vowel ambiguity is removed by visual symbol location; each of four locations represents one of four groups of visually contrastive vowels. As seen in the figure, the symbols and locations are produced using two seven-segment displays. The wearable Autocuer will incorporate two seven-segment light-emitting diode (LED) displays built into one lens of eyeglasses, to produce the symbols superimposed on the user's visual field; the user will move his head to position the cue symbols beside the speaker's mouth.

Initiation of VA and NASA Involvement

By 1978 sufficient progress in speech science and integrated circuit technology had been made to justify undertaking the development of the wearable Autocuer. RTI and Gallaudet began discussions with the Veterans Administra-

FIGURE 1.
"He can go" and "Get a coat" appear similar to the lipreader. The Autocuer analyzes the speech signal and displays visual symbols to clear up such ambiguities. Wearer can position eyeglass-mounted display so that symbols appear near speaker's mouth.

tion and with NASA concerning such an undertaking. Key technology required for the wearable Autocuer was identified in the results of NASA R&D programs, and a 3-month study funded by NASA was begun in March 1979 to examine all aspects of Autocuer feasibility. The study results did verify technical and commercial feasibility of the wearable Autocuer. A group of older deaf adults (primarily veterans) were trained and tested at Gallaudet to verify that older adults typical of the VA deaf population can accurately receive speech syllables through Autocuer cues plus lipreading.

The joint VA-NASA project to develop and field test a modest number of wearable Autocuers began in August 1979. Because of the active technical role to be played by NASA in transferring its technology to the project, the decision was made that NASA would be the contracting agency.

Project Status

Project key accomplishments through June 1981 include the following:

1. Autocuer and Autocuer Display patent applications were filed with the U.S. Patent Office in October 1980.

2. An exclusive license agreement (based on the above inventions) and a no-cost contract for the commercialization of the Autocuer were signed by RTI and Gallaudet with Telesensory Systems Inc. (TSI) of Palo Alto, CA in December 1980. Under the terms of the contract, TSI will build 24 wearable Autocuers for use in the field test.

3. Using output from the Autocuer speech analyzer, deaf subjects at Gallaudet College scored 77 percent correct word recognition accuracy as compared with 57 percent accuracy on equivalent uncued speech and 86 percent accuracy on error-free computer-cued speech. These tests were completed in April 1981.

4. As of June, 1981, the design of the wearable Autocuer was nearing completion, and construction of prototypes was under way at RTI. The first demonstration of wearable units to NASA and the VA was planned for November, 1981.

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Effect of Auditory Cues in Computer-Assisted Instruction in Lipreading

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Sensorineural hearing loss in adults is frequently accompanied by a problem in speech discrimination, that is, difficulty in phonemic differentiation at suprathreshold sound levels. Since the mere use of amplification does not alleviate the problem of reduced speech discrimination ability, instruction in lipreading becomes an important component of the aural rehabilitation program. Although the literature abounds in methods, materials, and approaches in lipreading instruction, very little reference is made to quantification of improvement resulting from lipreading instruction.

Communicative efficiency of a hearing-impaired person results from hearing and seeing others talk. However, the use of bisensory input in lipreading instruction has not been examined as a part of aural rehabilitation procedures. The application of computer-assisted instruction in lipreading with an auditory-visual interactive device, such as the David Instructional System (Vontech, Inc.), lends itself appropriately to a more scientific examination of the effects of auditory-visual stimulation than has been available in the past.

The goal of this project is to provide new information on the effectiveness of computer-assisted instruction as a supplementary procedure for drill and practice in a program of lipreading instruction for post-lingually hearing-impaired adults. The first-year objectives include the development, construction, and video-tape production of 12 lists of 25 sentences each which are sequentially and progressively more difficult as lipreading stimuli. These sentences will be used as drill and practice material in a program of lipreading instruction at Olin E. Teague Veterans' Center (OETVC).

Beginning the second year, 12 lipreading lessons will be developed. Twenty-four patients at OETVC will be given audiological evaluations, the Utley Lipreading Test, and the Hearing Performance Inventory which measures the degree of hearing handicap. These subjects will be given 12 1-hour group lipreading lessons. During the interval between group lipreading lessons, these subjects will receive supplementary drill and practice with computer-assisted instruction in lipreading provided by the David Instructional System. For one group of subjects, **linguistic** redundancy will be systematically increased to the degree necessary for correct identification of drill and practice sentences. For another group of subjects, **auditory** redundancy will be systematically increased to the degree necessary for correct identification of drill and practice sentences. Data will be analyzed to determine (i) whether the magnitude of the change in Utley lipreading scores in the Linguistic Redundancy group and the Auditory Redundancy group is significantly different, (ii) whether changes in the Hearing Performance Inventory profiles are related to Utley lipreading scores, and (iii) whether there are significant changes in the degree of hearing handicap as measured by the Hearing Performance Inventory following lipreading instruction.

The probable impact or long-term significance of this research will lie in a number of interdependent outcomes: (i) increased understanding of the effect of systematic use of auditory-visual stimulation on the development of lipreading skill, (ii) quantification of improvement in lipreading skill as a function of instruction and type of practice, (iii) the development of a more scientific basis for construction of lipreading stimulus materials that vary from easy to difficult, (iv) identification of the utility of computer-assisted instruction in lipreading for post-lingually hearing-impaired adults, and (v) a better understanding of the effects of lipreading instruction in terms of how improved lipreading skill relates to a person's degree of hearing handicap.

The Clinical and Acoustic Parameters of Hearing Aid Effectiveness

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Clinical evidence and experience indicate that there is a wide range of communicative (auditory) performance in persons whose thresholds range from normal to the limits of the audiometer. Even persons having similar audiograms with respect to severity and configuration can demonstrate varying abilities to extract meaning from speech and environmental stimuli. To measure this performance clinically, we must seek those tests whose scores reflect such a range of disability. It is most likely that no single score can adequately represent a hearing handicap.

In the continued search for a satisfactory discrimination test, it is necessary to compare existing tests and their properties to the test in question. Since the CID W-22 Auditory Test (Hirsh et al., 1952) is still commonly used in clinical settings and its performance is well-known, it is customary and proper to use it for comparison purposes. The basic underlying construction of the CID W-22 Test is phonetically balanced lists of monosyllabic words. In contrast, a phonemic balancing scheme was followed by Lehiste and Peterson (1959) and Peterson and Lehiste (1962) in the formation of the CNC (consonant-nucleus-consonant) Test. One of the outgrowths of the CNC Test has been the Northwestern University Auditory Test No. 6 (Tillman and Carhart, 1966), more commonly referred to as the NU 6. The present study utilizes these three auditory discrimination tests in a quest for information regarding the equivalency, reliability, and future utility of the NU 6 Auditory Test as it is presently recorded.

The commercially available recordings of the CID W-22 Test were used in this study. The CNC lists were recorded by a young male graduate student in broadcast communications. In an effort to incorporate the effects of coarticulation, a carrier phrase in which the test word was embedded was used. The phrase is "say the _____ again." A female speaker with considerable experi-

ence in radio and stage productions was employed to record the NU 6 lists. The carrier phrase "say the word _____" was utilized. Both talkers had general American speech with absence of regional dialect.

It was the purpose of the following experiments to (i) determine the performance-intensity (P-I) function of the NU 6 Auditory Test with normally-hearing subjects, (ii) determine the P-I function of the NU 6 with hearing-impaired subjects, (iii) determine the equivalency of the four lists of the NU 6, (iv) determine the reliability of the NU 6, and (v) compare performance scores on this test with those obtained on the CID W-22 and CNC Tests.

Experiment 1

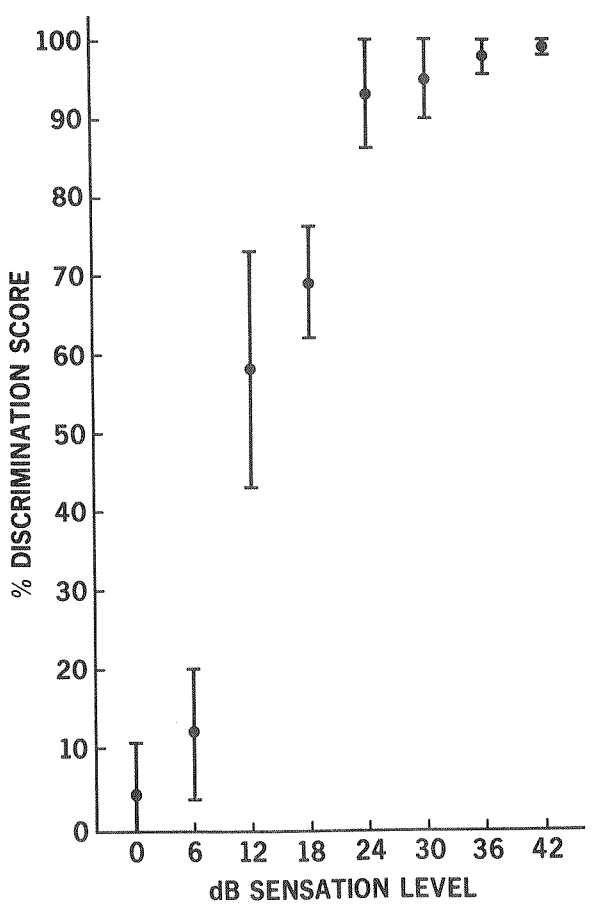
Procedure. Forty college students with normal hearing (thresholds < 20 dB HL from .25 to 8 kHz) and negative otological histories were used as subjects. The subjects ranged in age from 19 to 29 years with a mean age of 24 years. All subjects were tested in an IAC Series 1200 sound suite, using a Sony TC 353D tape recorder and the speech circuit of a Grason-Stadler 1701 audiometer. Test materials were administered via monaural earphone. Each subject was instructed to write his response and guess if not sure of the exact word.

A speech reception threshold (SRT) was established for each subject and used as the basis for administering the four lists at different sensation levels. The first 10 subjects received lists 1 through 4 at decreasing sensation levels of 42, 30, 18, and 6 dB. The second group of 10 subjects received lists one through four at increasing sensation levels starting with 6 dB and progressing to 18, 30, and 42 dB. The methods of presentation for the third and fourth groups replicated those for groups 1 and 2 except with different sensation levels: 36, 24, 12, and 0 dB. An equal number of right and left ears were used to minimize possible ear effects.

Results and discussion. The data were examined at eight different points along the P-I function with 20 subjects at each level. A mean and standard deviation were computed for each of the eight levels of presentation. These data points are plotted in Figure 1. The knee of the function occurs at a sensation level (SL) of 24 dB. The slope of the linear portion of the function was found to rise approximately 4.7 percent per decibel increase in intensity. This was determined using the mean scores at sensation levels of 6, 12, and 18 dB. This rise compares favorably with 5.6 percent per decibel increase reported by Tillman and Carhart (1966) for a different recording of the same test. The mean threshold of intelligibility for these subjects occurred at approximately 12 dB SL. This is somewhat higher than the 50 percent point on the function established by Tillman and Carhart. For their sample, the mean threshold of intelligibility was approximately 8 dB SL.

Experiment 2

Procedure. The subjects consisted of 40 male veterans ranging in age from 34 to 74 years, with a mean of 53 years. Each veteran received a complete hearing evaluation at the Audiology Service of the Veterans Administration Medical Center in Washington, D.C., immediately prior to participation in this inves-



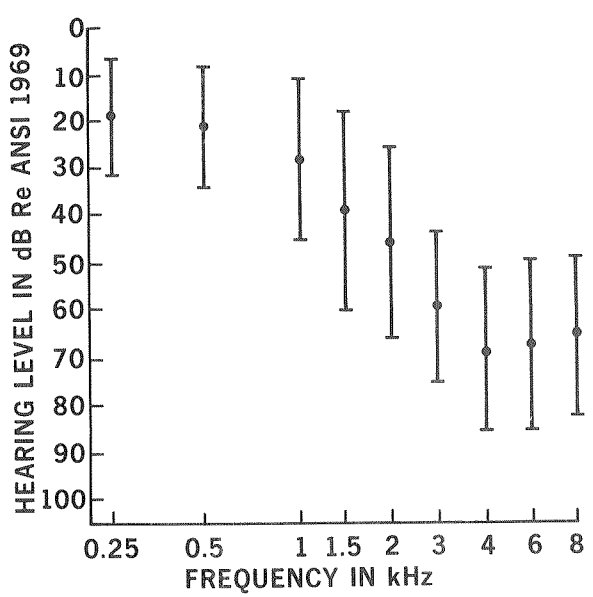


FIGURE 2.
Mean audiogram with standard deviations for the 160 sensorineurally-impaired subjects used in Experiments 2, 3, and part of 4.

FIGURE 1.
Performance-intensity function of 40 normally-hearing adults on the NU 6 Auditory Test and limits of one standard deviation.

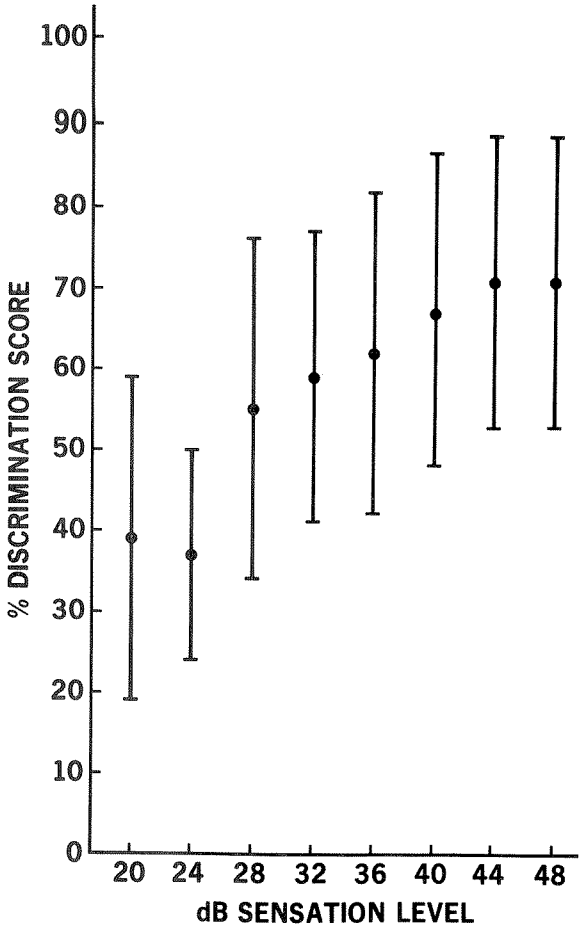


FIGURE 3.
Performance-intensity function of 40 sensorineurally-impaired adults on the NU 6 Auditory Test and limits of one standard deviation. Twenty scores were used to obtain each mean.

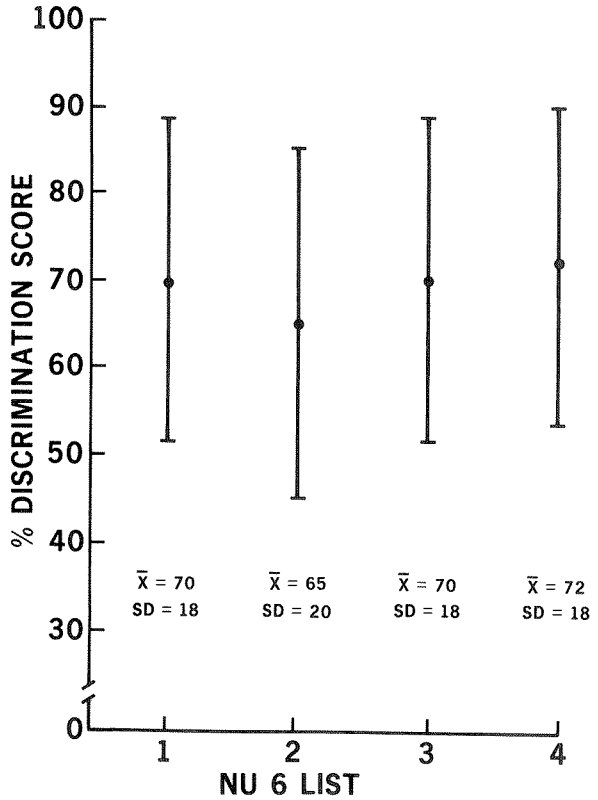


FIGURE 4.
Means and standard deviations of scores of 40 sensorineurally-impaired adults on each of the four lists of the NU 6 Auditory Test.

tigation. Only patients exhibiting hearing losses greater than 20 dB from 1 to 8 kHz were used as subjects. None had air-bone gaps greater than 10 dB, abnormal acoustic reflex thresholds, PI-PB rollover, or positive results on acoustic reflex decay measurements. The mean audiogram for these subjects is displayed in Figure 2.

All subjects were tested in an IAC Series 1200 sound suite, using a Grason-Stadler 1702 clinical audiometer with a Presto A908 tape recorder. Subjects were provided with answer sheets and instructed to write their responses and encouraged to guess if unsure of the exact word. Test materials were presented via monaural earphone and, to prevent lateralization at the higher sensation levels, appropriate masking was used in the nontest ear. The NU 6 Test, Lists 1 through 4, were presented in a counterbalanced manner. Eight presentation levels were employed to obtain eight data points along the function with 20 subjects receiving test stimuli at 20, 28, 36, and 44 dB SL (re SRT) and the other 20 at 24, 32, 40, and 48 dB SL.

Results and Discussion. Figure 3 displays the mean discrimination scores at the eight chosen sensation levels. Discrimination scores were better at an SL of 20 dB than at an SL of 24 dB without explanation. On the linear portion of the slope, there is approximately a 1 percent per decibel increase in performance in the range of 28 through 44 dB. The knee of the function occurs at a sensation level of 44 dB. This is somewhat higher than the 40 dB sensation level generally considered appropriate for achieving PB Max.

Experiment 3

Procedure. Forty male veterans ranging in age from 30 to 81 years with a mean of 54 years served as subjects. Each veteran met the previously-established criteria for sensorineural hearing loss. The test environment remained the same as in the previous experiment.

Each subject was administered all four lists of the NU 6 Test via monaural earphone at a sensation level of 48 dB (re SRT). The order of presentation of the lists was counterbalanced to avoid possible order effects.

Results and discussion. The results of the equivalency study are displayed in Figure 4. A repeated measures analysis indicated that a significant difference ($p < .001$) exists among the four lists. Pairwise comparisons were made among the means using the Tukey procedure (Winer, 1971). Results of these comparisons showed no significant difference ($p < .05$) between Lists 1, 3, and 4. However, List 2 does differ from each of the other lists (Table 1) by being more difficult. List 2 might be better utilized as a practice list while Lists 1, 3, and 4 can be considered equivalent.

Experiment 4

Procedure. Ten of the subjects who participated in the equivalency study returned for a second administration of the test in order to evaluate test-retest reliability. An average of 5 weeks elapsed between the first and second tests. Correlation coefficients comparing test and retest scores for each of the four lists were calculated.

Results and discussion. Results indicated that a significant correlation ($p < .001$) between test and retest scores does exist, thus demonstrating good test-retest reliability and stability of this

discrimination measure over time (Table 2).

Experiment 5

Procedure. Another group of 83 male veterans who met the previously-established criteria for sensorineural hearing loss served as subjects. As part of the routine audiological examination, PB Max was obtained using the CID W-22 Auditory Test. In all cases, the sensation levels necessary to achieve the optimum scores were greater than 44 dB.

Each subject was administered one of the two CNC Lists (1–4, and 1–10) and one of the three NU 6 Lists (1, 3, and 4), which are known to be equivalent, at the level of PB Max for the W-22 Test. The same clinical equipment was used for all measures. Results appear in Figure 5.

A repeated measures analysis indicated that a significant difference exists among the three discrimination texts ($p < .001$). Pairwise comparisons (Tukey procedure) among the test differences showed no significant difference between the NU 6 and CNC Tests (Table 3). However, the W-22 Test was shown to differ quite significantly from the other two measures. Examination of the data shows that the W-22 scores are much higher and have less variability.

Figure 6 was generated from data obtained from selected subjects included in the previous comparisons and from additional subjects with hearing loss isolated to higher frequency regions. These data demonstrate the conspicuous difference between the W-22 and CNC and NU 6 Tests as a function of hearing loss configuration. With one exception, the CNC and NU 6 Tests perform remarkably alike. That one exception is with subjects who have normal hearing only at 0.25 kHz. In that category, the difference in mean scores between the two tests is approximately 23 percent with the CNC Test scoring better.

An analysis of a selected portion of each of those two tests was conducted to determine if there were any obvious differences in spectrum. There appears to be much more energy in the region 0.3 to 0.6 kHz in the CNC Test than in the NU 6 Test, attributable to the difference between the talkers. This may have produced the performance distinction between the two tests in subjects with normal hearing at 0.25 kHz and impaired hearing at all other frequencies.

TABLE 1.
Differences between mean scores for the four lists of the NU 6 Auditory Test for 40 male veterans with sensorineural hearing loss.

List	1A	2A	3A	4A
1A	—	4.60*	.15	2.10
2A	—	—	4.45*	6.70*
3A	—	—	—	2.25

*$p < .05$

TABLE 2.
Mean discrimination scores for the lists of the NU 6 Auditory Test obtained on test and retest, differences between means, and correlation coefficients for 10 male veterans with sensorineural hearing loss.

List	Test	Retest	Difference	r
1A	74.20	78.00	3.80	.96*
2A	71.00	74.00	3.00	.92*
3A	76.00	77.20	1.20	.93*
4A	77.80	79.60	1.80	.95*

*$p < .001$

TABLE 3.
Differences between mean scores for W-22, CNC, and NU 6 speech discrimination tests for 80 ears with sensorineural hearing loss.

Test	W-22	CNC	NU 6 (female speaker)
W-22	—	13.63*	14.40*
CNC	—	—	0.77

*$p < .05$

Summary

As Kruel, Bell, and Nixon (1969) and Hood and Poole (1980) point out, speech discrimination tests should be thought of not as lists of words but as recordings of those words. The particular circumstances of a recording, i.e., talker, equipment, environment, etc., impart a set of characteristics to the recordings that are unique. Therefore, it should be understood that the results described herein pertain to a particular recording of the NU 6 by a female voice.

With regard to the ability to understand monosyllables in quiet surroundings, it is felt that the data on the NU 6 (female voice) demonstrates a decided advantage over the CID W-22 Auditory Test. The data on test-retest reliability and equivalency, the degree of relationship to the CNC Test, and the distinctions the NU 6 makes between individuals with varying degrees of high frequency loss, strongly support its use clinically. Further investigations of this recording of the test are warranted.

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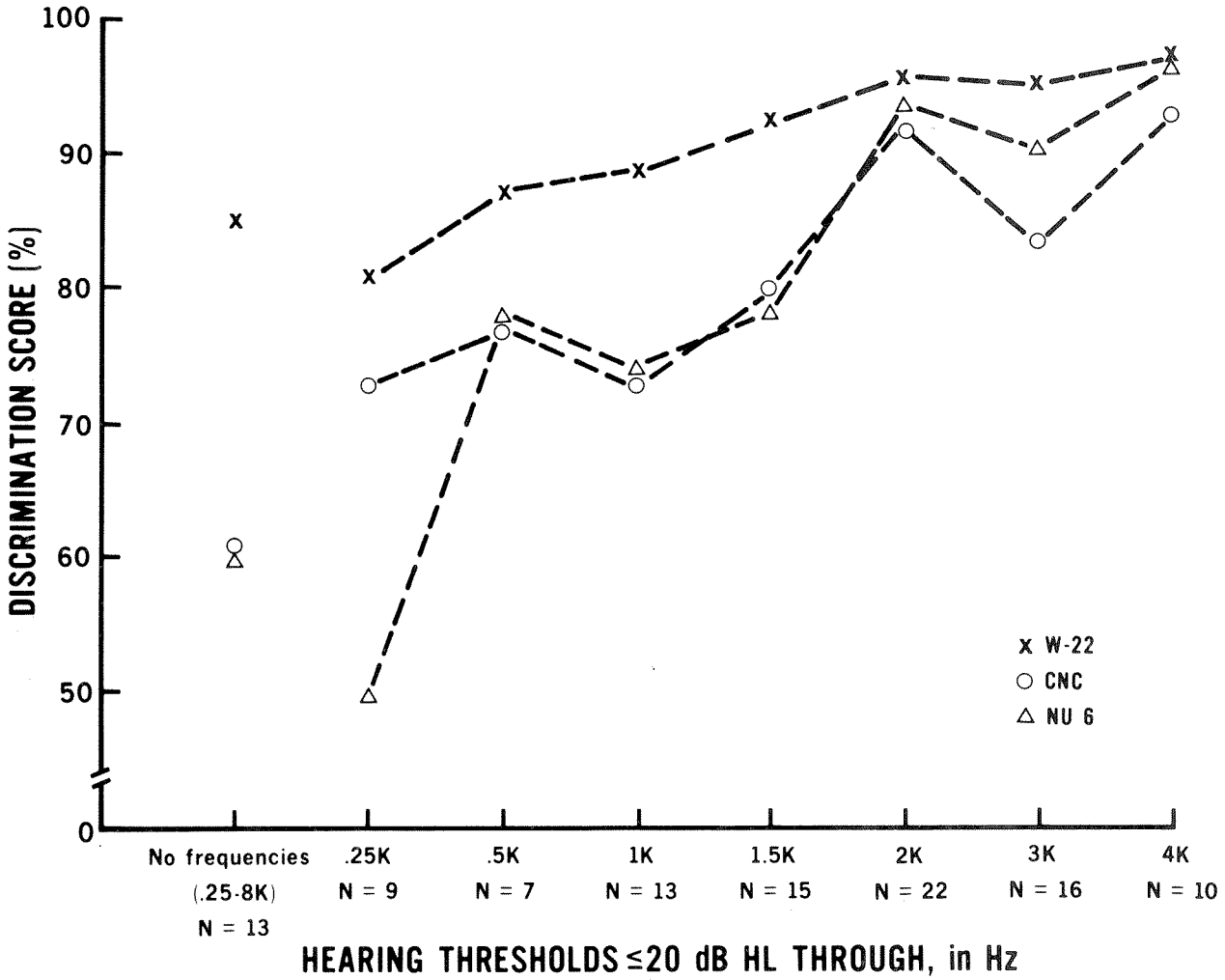

FIGURE 6.
Comparison of performance on W-22, CNC, and NU 6 Tests for groups that differ in region of normal hearing sensitivity.

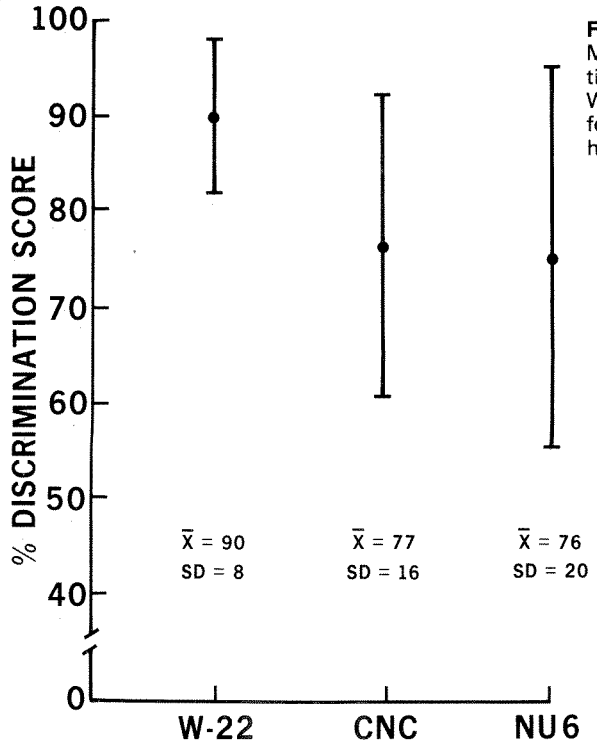

FIGURE 5.
Means and standard deviations of scores obtained on W-22, CNC, and NU 6 Tests for 80 ears with sensorineural hearing loss.

A Tactile Aid for the Treatment of Sensorineural Hearing Loss and Aphasia

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This 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 converts the frequency, intensity, and temporal information of an auditory signal into electrical pulses and presents these as

electrotactile patterns on the skin. A 16-week controlled treatment trial is being conducted with patients with severe sensorineural hearing loss and patients with severe aphasia to compare performance when wearing Teletactor with their performance when not wearing Teletactor.

During the period from January 1, 1981 through June 30, 1981, the computer system to generate and present acoustic stimuli and record subject responses was designed and ordered. In addition, screening for patients to identify those who meet selection criteria was initiated. Individual treatment programs have been written for four pilot subjects, three with aphasia and one with sensorineural hearing loss. These pilot subjects have been entered into a treatment trial that utilizes "live voice" stimuli while we await the arrival and assembly of our computer system.

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 a hand-held camera for use in a reading machine for the blind. With this reading machine a user should be able to scan printed material using a hand-held camera and hear spoken English output. The new camera will provide good quality images for input to a character recognition module which identifies the images as individual characters and words. This stream of characters will 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 pt. and 20 pt. type, which roughly corresponds to type with a capital letter height between .05 inches and .2 inches and includes most common reading material.

The camera will be compatible with the Optacon, a tactile reading device which is a product of Telesensory Systems Inc (TSI), and with the Voice Output Reading System, HS-2, which will be developed by TSI. The currently used Optacon camera limits the potential performance of the Voice Output Reading System. The details of the problems which arise when this camera is used were discussed in the previous issue of the Bulletin of Prosthetics Research. It is expected that the improved quality of the images from the new camera, 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.

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 provide high resolution input images for an image preprocessing stage. This stage will simultaneously determine both the size and the orientation of the printed text. The resulting information will be used to automatically track a line of text, even if skewed, and to extract individual character images which will be transformed to a uniform size. This automatic control of line tracking will make camera positioning and movement much less critical. In addition, the automatic magnification control will replace one critical adjustment now required of the user. The result of both these features will be that much less skill, effort, and training will be needed in order to operate the reading system.

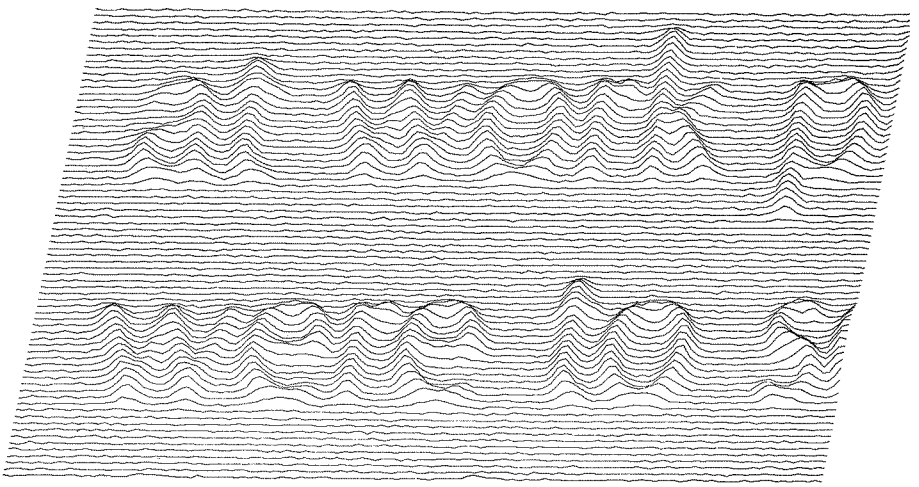

FIGURE 1a.
This image was digitized to 6 bits of grey level from a half inch strip of text printed in 14 point (rather large) type.

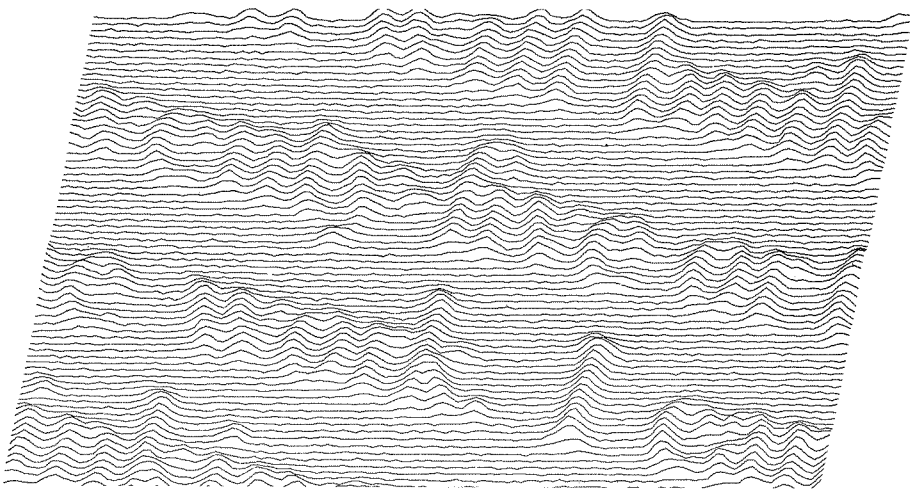

FIGURE 1b.
This image was digitized from text printed in 10 point type (a commonly used size) with about 12 degrees of line skew. This skew is slightly exaggerated by the display angle.

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 may also contain a 6x24 Optacon retina for motion detection and tactile feedback. This would allow camera motion to be detected by image cross correlation so that no external encoders which might hamper camera movement would be needed.

Summary of Previous Work

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. Motion detection software, which uses cross-correlation of sequential 6x24 Optacon images, is currently operating in the HS-1 prototype systems which are now under evaluation under a separate merit review contract.

Current Status

During the past six months an investigation of threshold, orientation, and magnification detection algorithms was begun at the Palo Alto RER&D Center. Images of pages printed in a variety of fonts were digitized to 8 bits of grey level. The image size was 512x512 and the spot size was about .006 inches. The type size varied from 6 point to 14 point, and a line skew of up to 12 degrees was tested.

A small section of 14 point type, set in the Optima font which is a sans-serif style, is shown in Figure 1a. Sampled horizontal scans through the image, which would subsequently be thresholded, are shown for a strip of the original text which is a little less than .5 inches deep. Although the image was digitized to 8 bits, the limited dynamic range made effective use of only 6 bits. With this resolution a digitized small letter ("x-height") would be 15 picture elements tall. This can be observed by counting the number of horizontal traces through a character. Even though this resolution is 25 percent greater than the minimum recommended by earlier studies using the Optacon input for character recognition, the problem of choosing a thresholding algorithm that resolves the crossbars of the two "t" 's shown is readily apparent.

A sample of 10-point Caledonia type with a 12-degree line skew is shown in Figure 1b. In this case the x-height is 11 which is within the recommended range for Optacon use with the reading machine. An image of 6-point type with this resolution was appropriate for magnification and orientation detection, but it was not as easily interpreted by visual observation as the two figures shown.

Preliminary work shows that orientation-dependent line integrals through segments of the digitized image yield a reliable magnification and orientation estimate. This method will be further investigated to establish performance limits. Filtering algorithms suitable for automatic thresholding to reduce the image to one bit of grey level per picture element will be tested using these images.

Three prototype cameras will be designed and built under contract by TSI. Blind subjects will test and evaluate the Voice Output Reading System, HS-2, using the new camera. This work will begin upon completion of contract negotiations.

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

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

Telesensory Systems, Inc. is developing a family of devices intended to meet the print reading needs of blind people. One of these devices, the Optacon, was introduced in 1971. There are now over 7,000 in use throughout the world. Two additional devices are under development. One is an accessory for the Optacon that recognizes printed characters and speaks words intelligibly in a synthetic voice as the reader scans print by hand. The other is a speech-output reading system that automatically scans print under the control of a blind user. The research and development leading to the new devices is partially supported by an inter-agency contract from the Veterans Administration, the Bureau of Education for the Handicapped, and the Rehabilitation Services Administration. Over a 30-month period, it is intended 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 27-month effort (starting September, 1978) were previously reported. By the end of 1980 five hand-scan prototype units had been built and successfully demonstrated to representatives of the sponsoring agencies. During the first months of 1981 these units were used daily by blind TSI employees. In June 1981, TSI received a contract from the Veterans Administration to conduct a design evaluation of the hand-scan prototypes. Three additional units were built and will be subjected to a formal field evaluation at private sites.

During the final months of the project much effort went into refining the breadboard unit of the automatically scanned reading system. New optical elements were introduced to reduce reflection and to increase reliability. New circuitry for signal detection and thresholding was added. Distortion correction hardware and software were implemented. Software to deal with format and read pages was moved from the mainframe computer to the breadboard hardware.

The result of these efforts is a stand alone system which, under operator control, can scan a single sheet of material. The breadboard scanner can perform a low-resolution "format" pass over the page to locate and identify page features such as columns, titles, and page numbers. The results of this pass can be displayed in real time on a graphics terminal attached to the breadboard. It can also perform a high-resolution "read" pass to collect image data which is then enhanced and formatted for input to an OCR (Optical Character Recognition) program. The enhanced data can either be displayed locally or written on a floppy disk for transmission to the OCR program which runs in a mainframe computer.

A number of tasks have to be accomplished before this breadboard system can become a manufacturable product. Packaging will have to be designed to allow the system to read bound books. The optical and mechanical systems must be further designed for improved

reliability and ease of production in volume. The electronics will have to be expanded to include interfaces to an OCR and TTS (Text to Speech) computer. The page-formatting software should be developed further to handle complex formats. A set of user controls must be integrated and subjected to human factors evaluations. The current breadboard system proves that most of the technical problems have been solved; many practical problems remain.

Design Evaluation of the Hand-Scan Voice Output Reading System

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There is a need for a thorough design evaluation of the Telesensory Systems, Inc. (TSI) Voice Output Reading System based on the Optacon. This initial Hand-Scan Voice Output Reading System has been developed at TSI, in part utilizing funds from the VA, The Bureau of Education for the Handicapped, and the Rehabilitation Services Administration. Extensive consumer feedback is needed in order to review the design and performance of this system, which could substantially overcome the print handicap of blindness for many individuals.

The TSI Hand-Scan Voice Output Reading System prototype (HS-1) will be evaluated through a period of extensive field trials. These trials will involve the placement of four units in diverse evaluation sites for use and review by blind people with a variety of reading needs. The units will be placed in the VA Blind Rehabilitation Centers in Palo Alto, California and Hines, Illinois, in a public school system in DeKalb County, Georgia, and a series of individual employment settings in the San Francisco Bay Area near TSI. In addition, three units apart from these VA systems have been placed at The Cleveland Society for the Blind Sight Center, The Braille Institute of America in Los Angeles, and the American Council of the Blind national office in Washington, D.C.

Each evaluation site will be managed by a site coordinator, trained by project staff concerning HS-1 operation, training techniques and research protocol. Site coordinators will assess individuals for the requisite skills needed to successfully operate the system, train screened individuals, test for reading speed and comprehension, and interview participants concerning response to the system following training. They will also provide following-along support for participants as needed, schedule the system for independent use training, and report performance problems to project staff.

The project Principal Investigator will interview all participants in depth concerning their use of the system and response to it, and compile data concerning the following areas: system features (user controls, optical character recognition, text reformatting), the system's tracking aid, general system performance, and the device's applications and limitations.

All data will be compiled and reported to the VA and to TSI for the purpose of recommending design changes for a future production unit.

Status.—A training program for site coordinators was held during the week of July 20, 1981. Site coordinators were brought to TSI for the 3-day program concerning all aspects of the evaluation project. Following the training, units were shipped to the various sites.

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 proved to be 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 not often 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, specifically cochlear pathology, in individual patients 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. Indeed, 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.

During the period from January 1 to June 30, 1981, six subjects with varying degrees of SNHL have begun the series of monaural and dichotic tests necessary to characterize each of their hearing losses. Four normal-hearing controls have also begun the same series. The results obtained thus far are restricted to frequencies at 1000 Hz and below and must be considered preliminary at this time, but it is clear now that the techniques (used previously only in subjects with normal hearing) can be applied successfully to SNHL subjects. Of par-

ticular interest is the stage of the theoretical model (the intensity-response or I-R function) which corresponds to the ear's ability to determine the intensity of a sound and generate the appropriate neural response for that intensity (3). Of course, it is well known that the ear with SNHL is not operating normally with respect to its intensity-response transduction mechanism—threshold elevation alone established that—but no techniques have been available previously to measure the shape of the I-R function throughout the intensity range in either SNHL or normal-hearing subjects. Previous work in this laboratory has led to an innovative method of measuring the I-R function in normal-hearing subjects. One major aspect of the current study is to perform similar measurements with SNHL subjects.

The I-R functions of normal-hearing subjects tend to have a constant slope in the range of 50-to-90 dB SPL, and when the slope does change, it changes in a gradual, regular way. In contrast, the I-R functions measured so far for hearing-loss subjects at 1000 Hz have shown somewhat more rapid and irregular changes in slope than those of control subjects. Although it is much too early to draw conclusions concerning the significance or utility of these measurements, such abnormalities in the intensity-response transduction mechanism could account for some deterioration or loss of information in the processing of complex acoustic signals (e.g. speech). Further testing will continue on these and other subjects, and tests will be added as computer hardware acquisition and software development progress. The first test of a computer simulated hearing-aid for one of the current hearing-loss subjects will probably occur in about 1 year. It is such hearing-aid simulation tests which will determine the significance and utility of the measurement of the I-R function in subjects with sensorineural hearing loss.

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Communication Aids Research for the Blind

Central Rehabilitation Section for Visually Impaired and Blinded Veterans
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Harvey Lauer and Leonard Mowinski

(The studies and evaluations covered in this report are not funded as research by the Rehabilitative Engineering Research and Development Service.)

Communication aids research at the Central Blind Rehabilitation Section is conducted by Harvey Lauer and Leonard Mowinski. It includes some basic research, testing, evaluation, and dissemination of information.

The urgent need for some blind people to use computers if they are to compete with their sighted peers has given rise to several instruments. An example is the VersaBraille made by Telesensory Systems, Inc. As a stand-alone device it can serve for braille reading, composing, editing, and personal filing. The model we have acquired for an evaluation project being done by VAREC, New York, serves also as a computer terminal. A formal protocol has been written in New York: however, all aspects of VersaBraille (except for extensive reading) have already been experienced by subjects eager for familiarization.

It was found that braille users can easily read the "soft copy" braille output and that professionals who would have need for such an instrument can readily learn to use it as a stand-alone device. Though the manual is very good, those who have not had experience with computing machinery would be best advised to receive personal instruction. Use as a computer terminal was successful in many instances. The Model P2 VersaBraille was interfaced with computers, modems, a printer, and the Kurzweil Reading Machine for interacting, editing, and the production of hard-copy print. Initial instruction and installation can be complex and may require special skills and even a site visit.

Electronic technology for the sighted is undergoing yet another revolution, and many of the results are especially useful to the visually impaired. Even more surprising is the fact that fewer adaptations are needed. The staff, therefore, attended a computer convention and an exhibition on consumer electronics, and contacted dealers and distributors for information and demonstrations. Following is a list of items and categories about which Lauer and Mowinski can supply information and some written reports: talking clocks and watches, speech compressors, talking calculators, musical calculators, new features of tape machines such as indexing or tabulation, digitally-tuned radios, new radios with TV audio bands, personal stereo radios and tape machines with miniature headsets, computer games blind people can play, and making music with synthesizers and computers. Talking tools including microwave ovens, thermometer, currency identifier, multimeters, computer terminals, etc., and dictating machines with microprocessors.

Two of those items deserve special mention. The revolutionary design of new miniature headsets is very welcomed by blind people because it combines comfort, high fidelity, and minimal reduction of sounds from the environment. The Type N' Talk, made by Votrax, is a text-to-speech converter which can be plugged into many computer systems. Its small size, low cost and clear speech may revolutionize talking terminals and computers.

The Voxcom is a module which attaches to a modified cassette recorder. It is a card reader permitting recordings of fifty seconds or more to be stored on a single card. Because it may serve as a filing medium for those who cannot use braille, it is being tested in the Blind Center. (The Voxcom is being tested at the CBRC in a project supervised by the research staff and conducted by an intern in Rehabilitation Teaching, Shif Toda.) The popular APH player/recorder has been modified to work well with the Voxcom.

The staff is working with researchers at the Hines RER&D Center who are conducting a project to evaluate performance of blind people with reading aids and with braille. Basic research into the value of the tonal output for the Optacon described in the previous report is also underway.

The evaluation of the Hand Scan-1 (HS-1), an optical character recognition speech-output system for the Optacon reading machine has begun. The Central Blind Rehabilitation Center is one of six sites where this prototype unit from

Telesensory Systems, Inc., will be evaluated. Development of this unit was supported by an interagency contract from the Veterans Administration, the Bureau of Education for the Handicapped, and the Rehabilitation Services Administration.

Mr. Mowinski attended a 3-day training seminar at Telesensory Systems to learn the function and operation of the HS–1. The unit was delivered on July 29. Protocol for the evaluation was supplied by TSI. The Blind Center will provide the manufacturer with documentation on system reliability, optical character recognition, user controls, tracking accuracy, training and training materials, and application of the system. The veteran population tested will consist of experienced Optacon users as well as veterans with no reading machine experience.

In June, Mr. Lauer served on an advisory panel for the American Foundation for the Blind. It concerned the development and evaluation of a full-page "soft copy" braille display for which the AFB has a National Science Foundation Grant.

Mr. Lauer was selected as one of several consumer respondents at the 1981 conference of the Rehabilitation Engineering Society of North America in Washington, D.C. Two of his papers to be published in the proceedings deal with the role of consumers in rehabilitation engineering, and the rationale for employing several communication media or channels for the blind.

Clinical Application Study of Reading and Mobility Aids for the Visually Impaired

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(The studies and evaluations covered in this report are not funded as research by the RER&D Service of the VA. The period covered here is from January 1, 1981, through June 30, 1981.)

HS-1 Evaluation—The HS-1 (Hand Scan 1 or "Talking Optacon"), a reading machine for the blind, is currently being developed by Telesensory Systems, Inc. (TSI). Under a contract from the VA, prototypes are presently being evaluated at the Braille Institute of America in Los Angeles, The Cleveland Sight Center, and our own site, the Western Blind Rehabilitation Center (WBRC) in Palo Alto. Other sites soon to be added to this evaluation are the DeKalb County schools in Atlanta, The American Council for the Blind in Washington, D.C., and the Central Blind Rehabilitation Center at the Hines VA facility.

The unit has three components. The CPU (central processing unit) is about 17 inches wide, 20 inches deep, and 13 inches high, and weighs about 55 pounds. The operator's console (into which a standard Optacon is inserted) measures approximately 8 inches wide, 8 inches deep, and 4 inches high. The tracking aid, about the size of a clipboard, provides the surface onto which the reading material is clipped and the Optacon camera is attached for easier tracking. The entire unit weighs about 66 pounds.

The controls are simple, conveniently located, and few in number. On the CPU are the on/off switch, jacks for a tape recorder and earphones, the volume control, and the rate control with settings for 60, 100, 180 and 300 words per minute. The operator's console has the intensity and threshold controls—which are on the inserted Optacon—plus three other switches for controlling the system. There are two 3-way switches. The first has settings for record, ready (normal voice output code), and Optacon mode (tactile reading only). The second switch has settings for spell speech only, normal spoken word output, and spell last word. There is also a paddle switch to control the memory (which holds 1000 characters). On the camera there is the magnification control.

The synthetic speech is of high quality, clear, and easy for all students to understand after a listening time of 1 to 3 hours.

The system is programmed to recognize 12 major type fonts, and does well with many of the variations on these fonts. It recognizes many of the common symbols, but there is a need for additional ones, such as the percent (%) symbol. Some consideration is being given to making it possible for the user to choose the types of symbols to be recognized—mathematical, scientific, and other specialized symbols. The programming is on tape, so it is easy to change, but it takes 6 minutes to download.

Evaluation of the optical character recognition error rate is an area where more research is needed. At present, it is difficult to separate this error rate from the human error rate when tracking with the hand-scanned camera. Tracking is one of the more difficult skills needed to operate the system, and hours of training are required before it is mastered. The present tracking aid allows for too much vertical movement of the camera, and a very tight tracking tolerance is required before individual characters are recognized accurately. The general error rate varies greatly, depending upon the tracking skill of the individual user. However, if the tracking can be mastered, it allows the user to read material with a more complicated format than an automatic scanner could deal with.

Thus far, maintenance has not been a major problem. There have been only two problems requiring the attention of a TSI engineer. On one occasion, with the use of a telephone MODEM, the problem was diagnosed from TSI and the appropriate action was taken.

There are many questions yet to be resolved about reading machines in general and this one in particular. It is hoped that we can begin to find answers to some of these during the next year's evaluation.

Night Vision Aid and Wide Angle Mobility Light (Evaluations)—The WBRC has completed its study evaluating the effectiveness of the Night Vision Aid (NVA) and Wide Angle Mobility Light (WAML) in reducing the mobility problems of people with night blindness. An explanation of the operation of the aids and the research methodology have been included in a previous issue of the Bulletin of Prosthetics Research (BPR 10-33, Spring 1980).

Thirty-five subjects participated in the study over a 15-month period, and 24 of them completed all phases of the project. The remaining 11 subjects did not complete the study because of scheduling conflicts, visual acuity and/or visual fields which did not warrant the need of a night mobility aid, discharge from the rehabilitation program prior to completion of the research project, or further loss of vision during the project.

Twenty-one of the subjects were vet-

erans who were either enrolled in the WBRC program at the time of their participation in the study, or were formerly in the WBRC program. The remaining three subjects were nonveterans from local communities who were referred to the project by VA optometrists and ophthalmologists. The participants were between 25–82 years old, with an average age of 52. Of the 24 subjects, there were 21 men and 3 women.

The results of the study have been summarized and analyzed, and a complete description of the study is being prepared for publication. The data showed that, on the average, the subjects' night mobility with the WAML more closely approximated their daytime mobility than did their night mobility with the NVA. This was true for both of the objective measures used: (i) measurement of time to complete the evaluation routes and (ii) number of errors counted during the routes. The results showed that the subjects averaged approximately the same number of errors when using the NVA as when traveling at night without the aid. The average time to complete the route was slightly greater when employing the NVA than when negotiating the environment at night without any aid. In all, 20 subjects had better times and scores with the WAML and 3 performed best with the NVA. One individual had a better time with the NVA but a better score with the WAML.

In addition to the objective results, participants' subjective comments regarding both devices were recorded. Seventeen subjects stated that they preferred using the WAML and seven preferred the NVA. Subjects who preferred the NVA gave such reasons as its size and portability, inconspicuousness and acceptable cosmetic appearance. A few subjects preferred the NVA because the maximum focal range extended to infinity, and they could therefore see for greater distances with the NVA than with the WAML. Although the majority of the subjects preferred the WAML, they cited drawbacks such as weight, size and conspicuousness.

The Central Blind Rehabilitation Center (CBRC) in Hines, Illionis, and the Eastern Blind Rehabilitation Center (EBRC) in West Haven, Connecticut, are conducting evaluation projects following the same protocol.

Mowat Sensor Study—A follow-up study was begun on the Mowat Sensor, an electronic mobility aid designed for the visually handicapped. The operation of the device and the evaluation protocol for this study were described in the previous issue of the Bulletin of Prosthetics Research (BPR 10-35, Spring 1981). A preliminary followup study had previously been conducted by the authors and was reported in the Journal of Visual Impairment and Blindness (Morrissette, Goodrich and Hennessey, 1981).

The start-up date for the project had been delayed due to a delay in completion of a monitoring device which is to be added to the Mowat to gather additional project data. (The monitoring device is being developed by the Palo Alto VAMC RER&D Program.) Since the monitor will not be completed for approximately 6 more months, the project has been modified to accommodate for the delay.

Wide Angle Mobility Light Followup Study—A followup study of the Wide Angle Mobility Light (WAML) has been completed. The purpose of the study was to ascertain the effectiveness of the WAML as a night mobility aid for people with night blindness, as well as determining its maintenance reliability, usage rates, limitations, and user-suggested modifications.

A telephone survey was conducted of all known professionals and visually handicapped individuals who had either purchased the device or had it purchased for them. The names of the purchasers were supplied by the manufacturer, Farallon-Oceanic Industries in San Leandro, California, and the distributor, Innovative Rehabilitation Technology, Inc., in Los Altos, California.

Thirty-two visually handicapped individuals and 23 professionals in the field of low vision were contacted. All individuals who were contacted agreed to answer the survey questions, and each interview required 15–45 minutes. The data are presently being summarized and analyzed, and when this is completed the results will be submitted for publication.

Head-High Obstacle Detector—The WBRC is working cooperatively with the VAMC Palo Alto RER&D Center to develop an object detector to aid in the safe mobility of the visually handicapped. Visually limited and totally blind people who negotiate the environment with the long cane receive advance information and protection from the cane. The cane protects the user from waist height and below. Even with perfect cane skills, however, the cane does not offer any protection to the user above the waist. As a result, the visually handicapped traveler is not protected from contacting overhanging tree branches, bent poles, head-high signs attached to poles and similar hazards. A head-high obstacle detector has been proposed which would act as a warning system for such hazards.

The goal of the project is to develop a small, lightweight, cosmetically acceptable aid which would provide the user with consistent, reliable information regarding the presence of obstacles located at head level. Other goals specify a device which is simple to operate, inexpensive, and usable by visually impaired individuals with additional handicaps.

A first-generation prototype has been developed by the project engineer, Dan Pliskin. The device employs two 40 kh crystal transducers which emit ultrasonic bursts. Reflected signals are then converted into a tactile output. The aid is worn like a medallion around the neck, and tactile feedback to the user is provided by a vibrator located in the neckstrap. The body of the prototype measures approximately 3¼ inches wide, 3¼ inches high and 1 inch deep. With the neck strap, the device measures 10½ inches long. One of the project goals is to design an aid which is smaller and less conspicuous.

The design criteria call for a beam which extends horizontally from 1 to 2 inches beyond the shoulder width of the user and, vertically, covers from the upper chest area to a point 1 to 2 inches above the head. The precise range has yet to be determined, but the objective is to enable the user to detect obstacles in the immediate area and still allow the individual sufficient time to react to the signal.

A second-generation prototype, presently being devised, will be tested with subjects prior to further development and evaluation on a larger scale.

Investigations of Acoustic Reflex in Elderly Persons

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The human acoustic reflex is a brainstem-mediated system that produces contraction of the middle-ear muscles upon presentation of an appropriate acoustic stimulus to an ear. Certain aspects of the acoustic reflex have clinical application, and investigations in recent years have provided useful data for prediction of hearing loss from reflex thresholds (Popelka, 1981) and for assessment of certain auditory pathology (Borg, 1976).

The primary goal of this research program is provision of quantitative information on the effect of aging on the human acoustic reflex. Subject samples for most studies are composed of normally-hearing persons in the 20–79 year age range. Data are gathered with an aural acoustic-immittance[a] instrument, which is the basic instrument in a noninvasive procedure for analysis of the acoustic reflex.

The initial phase of the project is centered around interfacing and calibration of computer hardware and analog instrumentation, development of software for acquisition and analysis of aural acoustic-immittance measures, and location of suitable subjects in the 50-to-80-year age range. The major activity during the reporting period has been the development of an efficient algorithm for computer-controlled measures of perstimulatory adaptation of the acoustic reflex. Written on a Nicolet MED–80 computer, these programs control stimulus generation, direct memory acquisition of data in 4 kbyte segments, and routines for direct-memory-access of data for absolute measurement of quantitative characteristics. This program set is the first of a family of programs for automated measurement of aural acoustic-immittance measures, including tympanogram, acoustic-reflex threshold, and the input-output function of the acoustic reflex.

Other activities have included work on a report on transcranial conduction of signals used for contralateral activation of acoustic reflex, and the development of graphics software for representation of acoustic-reflex measures.

[a]Refers to measures of acoustic impedance or acoustic admittance acquired in the (human) ear canal (ANSI Standards for Aural Acoustic-Immittance Instruments, Draft 1980A).

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1981 is the International Year of Disabled Persons, by resolution of the General Assembly of the United Nations. The expressed purpose of the International Year of Disabled Persons is to "undertake to further full participation of disabled persons in the life of their society." The efforts of this center have focused upon heightening public awareness of the large disabled community, and reducing the number of barriers faced by many of these individuals because of physical limitations.

This year, the RERanD Center has undertaken a program directly attuned to public education regarding rehabilitation research. The Center hosted a public Open House on Saturday, April 11, 1981, presenting current research of the RER&D staff as well as rehabilitation-oriented projects by Stanford University engineering graduate and undergraduate students. A high degree of interest and enthusiasm was evident throughout the 4-hour event. The Center continues to receive requests for tours and presentations from individuals as well as professional and service-oriented groups interested in rehabilitation. An average of 4 such groups per month are accommodated.

In addition to such public education endeavors, a weekly seminar series has been initiated for the purpose of educating both investigators and support staff at the Center. Experts from various rehabilitation-related fields of research and clinical service conduct seminars in their area of expertise at the Palo Alto RER&D Center, facilitating an exchange of information and ideas.

Toward the goal of reducing the number of barriers encountered by disabled persons, Center personnel continue research on the design and development of rehabilitative devices using high technology. It is expected that these efforts, both short and long term, will facilitate the increased integration of physically limited persons into the mainstream of society.

The following summaries represent work that has been accomplished on the various projects under way at our Center during the period January–June, 1981. An additional seven proposals are being prepared for submission to the Fall 1981 VA RER&D Merit Review, and another has been submitted for consideration to the Paralyzed Veterans of America Technology and Research Foundation.

Toward Better Methods of Nerve Repair and Evaluation

Personnel: **Vincent R. Hentz, M.D.** (VA); **Larry J. Leifer, Ph. D.** (VA); and **Gordon S. Abraham, M.S.** (VA).

This is a new VA Merit Review project.

Need—Further investigation of better methods of nerve repair and regeneration must address two fundamental and interrelated problems: (i) the inability to surgically restore normal anatomical configuration at the repair site; and (ii) the present lack of objective techniques to evaluate the results of repair and subsequent regeneration.

Background—Previous investigations of nerve repair techniques have utilized either suture methods at the epineurial or perineurial level, or sutureless methods applied at the epineurial level. Inconsistent results have been obtained,

both because objective methods to measure return of function in clinical and laboratory studies have not existed and because the repair methods mentioned above failed to restore normal anatomical configuration at the severance site.

Goals—This project is designed to test the following two hypotheses: (i) sutureless repair techniques utilizing newly developed biodegradable membranes at the perineurial level can better restore anatomical configuration at the repair site than conventional suture methods, and can increase the number of axons proximal to the repair site making functional distal connections; (ii) recently developed computer derived methods that permit mapping of mixed and motor nerves by axon conduction velocity distributions (NCVD) can provide a quantitative evaluation of functionally connected axons.

Method

Following preoperative nerve conduction velocity distribution studies, controlled injuries will be created in the median and ulnar nerves of a previously developed primate model, the macaca fascicularis or cynomolgus monkeys. Tensionless nerve anastomoses will then be performed, using either standard repair techniques such as epineurial or perineurial suture methods, or perineurial tubulization techniques utilizing several newly developed biodegradable materials (including hypoantigenic collagen and polyglycolic acid membranes). Early events will be studied by standard histologic methods. Serial nerve conduction velocity distribution studies will be used to observe changes in the nerve proximal to the repair site. At varying postoperative intervals, regeneration across the repair site will be assessed using conventional electrophysiologic techniques and newly developed computer-derived nerve conduction velocity distribution methods and methods to integrate the area under the compound action potential. This information will be correlated with standard histologically derived axon histometrics. These studies of repairs performed in a tensionless manner will be modified in a nerve gap model to study the effects of tension on nerve repair and regeneration in the primate.

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Measurement of Muscle Mechanical Properties in vivo Using a Buckle Transducer

Personnel: **Parvati Dev, Ph. D.** (VA); **Michael R. Zomlefer, Ph. D.** (VA), and **Vincent R. Hentz, M.D.** (VA, Stanford)

This new project is supported through the RER&D Center core budget.

Need—Tendon transfer surgery for reconstruction of the upper limb is based on knowledge of the force and maximum excursion of the muscle whose tendon is transferred. The changes in muscle tension with changes in muscle length during contraction are not well-known, but will significantly affect the performance of the transferred muscle at different joint angles. There is a need to know the length-tension relation for all muscles used in reconstruction of the upper limb.

Approach

A small (2 cm × 1 cm) E-shaped chromium-steel buckle has been developed, based on a design available in the literature, which can be slipped onto the tendon. As the tendon is tensed, the buckle is stressed and the corresponding strain is measured by strain gauges glued to the buckle. During surgery, when the tendon to be transferred is exposed, the buckle can be slipped onto the tendon before it is cut to determine the muscle's resting tension (which is often the tension at which it is reattached at its new insertion). Once the tendon is cut, the muscle's length-tension relation can be measured for both passive muscle and muscle that is electrically stimulated. During reattachment, tendon tension is monitored so that the desired tension can be precisely established.

Status—A working prototype of the buckle transducer has been tested on the cat's Achilles tendon. A larger version, suitable for use on human wrist and finger tendons, is being developed. Permission for the experiment is being sought from the Human Subjects Committee.

Pending—Once the required permission for experimentation is obtained, the buckle will be used in the operating room during elective surgery for hand reconstruction. The informed consent of the patients will be sought.

Talking Computerized Bulletin Board

Personnel: **Gregory L. Goodrich, Ph. D.** (VA); **David L. Jaffe, M.S.**; **Sue Melrose** (VA); **Douglas H. Williams** (Psycho-Linguistics Research); **Carol A. Simpson** (Psycho-Linguistics Research), and **Susan H. Phillips** (Sensory Aids Foundation).

Support for this new project is provided from RER&D core budget.

Need—Therapists, physicians, researchers, consumers, manufacturers, and engineers are all a part of the rehabilitation community. Many local, state, national, public, and private organizations participate in providing aid for the disabled. Despite conferences, newsletters, and local meetings, the diverse nature of rehabilitation makes it difficult for segments of the community to keep abreast of research activities, new products, new services, events, and current information.

Approach:

A similar lack of efficient information transfer prompted computer hobbyists to implement "Computerized Bulletin Board Systems." Using terminals, modems, and the telephone, they were able to access a centralized computerized communication node to send and receive messages regarding club meetings, new programs or hardware, equipment for sale, or just gossip. These

systems have multiplied to over 200 and now exist in all parts of the country. Systems have also been developed to meet the specialized needs of amateur radio operators and some non-technically-oriented common-interest groups.

A computerized bulletin board system would provide an ideal information node for the rehabilitation community. Its advantages are:

1. It removes the temporal and spacial coincidence requirement from the information transfer. The sender transmits information to the computer at his convenience. The computer stores that message digitally until the recipient is ready to access the system and read it.
2. Both private and broadcast modes are implemented. Message senders can specify a specific person as the destination or they can designate the message open to "all interested parties."
3. "To," "From," "Date," and "Subject" fields are an integral part of the message. Users can perform a computerized keyword search on these fields to read only messages in which they have interest.

The main disadvantage of the above system, for rehabilitation use, is that a user must access the system using a terminal and a modem. Many members of the rehabilitation community do not have this type of equipment at their disposal. Others, such as vision-impaired individuals, would find such a system difficult to use unless they employ an Optacon.

To overcome this problem, a "talking bulletin board" is proposed. In this system, a computer-operated speech synthesizer is used to convert the digitally stored messages to audio speech for transmission over the telephone lines. (Digital communication would still be supported.) The system would prompt the user for the various modes of operation. These would include: (i) Enter a message, (ii) Request help, (iii) Read a message, (iv) Scan messages for keywords, (v) Enter 'expert' mode, and (vi) Hang up.

For the purpose of entering text and performing mode changes, the user would use the Touch-Tone pad to communicate with the system. A $40 commercial adapter that fits over the telephone would make non-Touch-Tone phones compatible with the bulletin board system.

Among the uses contemplated for the completed system are:

1. Generalized information mode: information relevant to the rehabilitation community can be exchanged without the need for personal phone conversations, newsletter publications, or periodic meetings.
2. On-Line Evaluation: prescribed rehabilitation devices can be evaluated systematically by requiring users to fill out a computerized form message on a regular basis. Problems with those devices can be communicated via this system as well.
3. Employment: a 'Position Wanted' and 'Jobs Available' section can be incorporated into the message scheme. The system can then act as an automated clearing house for employment opportunities for the handicapped.
4. Consumer feedback: comments in regard to the usefulness or modification of specific rehabilitation devices can be made.

Status—A prototype version of the above system is being implemented. The initial hardware includes a Votrax Type-N-Talk speech synthesizer, a Z80 microprocessor, a telephone interface, and a Touch-Tone decoder. Software is written in BASIC for ease of testing and development. A stand-alone system will subsequently include large off-line disk storage and be supervised by a human system operator.

Pending—Funding for this project will be sought from the Veterans Administration.

Publications

Goodrich, Gregory; "Consideration of Standards for Computer Sensory Aids for the Handicapped," Conference at Western Blind Rehabilitation Center; Feburary, 1980. Bull Prosth Res BPR 10-34, Fall 1980 17(2):201–205, 1980.

Ultrasonic Head Control Unit for Smart Wheelchair

Personnel: **David L. Jaffe, M.S.** (VA).

Support for this continuing project is provided by RER&D core budget and by the Paralyzed Veterans of America.

Need—The lack of mobility is a disability that an estimated 50,000 quadriplegic individuals encounter. It is their top priority to be able to personally command any mechanical mobility they do acquire, and thereby achieve a higher level of independent living.

Approach

Although the use of an electric wheelchair provides the most obvious means of providing mobility to quadriplegics, attempts to produce a compatible vehicle have involved a mechanical user/device interface such as a chin or head controlled joystick. These interface devices are far from ideal, since intimate contact with them must be maintained and critical positioning is required to accommodate the user. Limited chin extension and marginal control of those movements aggravate the control problem and prove frustrating in use, for many. Additionally, chair motion tends to be quite jerky due to the acceleration feedback effect of the chair motion on the user's chin position. Other chair control designs, such as pneumatic switch control, suffer from similar disadvantages as well as increased difficulty in mastering control and sanitation problems (aesthetic factors frequently have been overlooked in the design of wheelchair systems for quadriplegics).

By utilizing ultrasonic distance-ranging technology to track the user's head position and proportionally control the chair's movement in joystick fashion with this head position, many problems that plague current designs for quadriplegic individuals can be overcome. Minimal motion of the user's head to the front directs the chair to move forward, while positioning the head to the left, right, or to the rear produce corresponding motions. Combinations of those orthogonal positions allow smooth turns, while the magnitude of motion defines the speed of travel. Since very minimal motion is required to use this system, and the control is easy to learn; this non-contacting, remote-sensing ultrasonic method of wheelchair control offers the possibility of an improved method of quadriplegic control of electric wheelchair.

Status—Currently, work is focused on producing a flexible independent ultrasonic head control unit which will be a stand-alone transducer of head position. Information acquired by this unit would then be used for electric wheelchair navigation and also for robotic arm control and communication board input.

Pending—Hardware and software are currently being developed to implement the ultrasonic head control unit. Once operational, the unit will be integrated

with an electric wheelchair and the robotic arm.

On the wheelchair, DC bridge controllers will be used for increased efficiency as well as the elimination of the bulky and noisy motor relays used in the existing configuration. These controllers will feature motor current sensing circuits and a regenerative system that recharges the batteries during braking. In addition to its superior performance, the DC bridge circuit has the advantage that it can be directly driven by a computer-generated pulse-width-modulation output signal.

To increase the overall gain of the wheelchair system, an inertial frame will be employed. This will serve to minimize the effects of acceleration on performance. Additionally, this feature will indicate the approach of vehicle instability as well as inform the user of an attempt to climb a grade that is too steep. Low-battery alarm, computer watch-dog circuits, and a user-accessible panic switch will be required for a reliable system.

The microcomputer systems for the wheelchair and the ultrasonic head control unit will be designed to dynamically adjust to the user. In such a design, the microcomputer will 'learn' the user's range of motion as well as his rest position. The final design will attempt to capture the above features on a single circuit board that can be fitted onto an existing commercial electric wheelchair at a cost of less than $500.

Publications:

Jaffe, David L., "Smart Wheelchair," Sixth West Coast Computer Faire, San Francisco, Calif.; April, 1981.

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La, Bill; Koogle, Tim; and Jaffe, David L., "Toward Total Mobility: An Omnidirectional Wheelchair," Fourth Annual Conference on Rehabilitation Engineering, Washington, DC; August 1981.

Development/Evaluation of Recreational Bicycles for the Disabled

Personnel: **Douglas F. Schwandt, MSME** (VA), **Peter W. Axelson, BSME** (VA), and **Larry J. Leifer, Ph. D.** (VA, Stanford).

Support for this continuing project is provided by RER&D core budget and the Northern California Charpets of the Telephone Pioneers of America.

Need—As a recreational activity engendering both physical and emotional vitality, bicycling is particularly appropriate for an individual endeavoring to overcome difficulties involving mobility and participation. Existent cycling equipment does not meet this need.

Approach

Our continuing approach focuses on: (i) improving the Para-Bike, a hand-pedaled prototype bicycle initially developed under VA support in the Stanford University Design Division Master's Program; (ii) developing a tandem version of the Para-Bike (for able-bodied and disabled to ride together); and (iii) identifying appropriate manufacturers and ways to move the Para-Bike concepts into the marketplace for the direct benefit of disabled riders.

Status

Two working prototypes of the Para-Bike have been developed: One is the Para-Bike with adjustable steering geometry, the result of a VA funded student pilot project in the Stanford University Design Division Master's Program (completed June 1980). The other is the competition version of the Para-Bike, which demonstrated the versatility and potential of the concept by allowing a paralyzed veteran (within one year of spinal injury), and a recently paralyzed 54-year-old individual, to participate in the Annual International Human Powered Vehicle Championships (Pomona, California, May 2–3, 1981) and ride the Para-Bike to the arm-powered world record speed of 24 mph. This latest prototype has advanced and simplified the Para-Bike design (with improvements in efficiency, compactness, ridability and manufacturability) as a recreational bicycle for the disabled.

The first prototype with adjustable steering geometry has proved to be a valuable ongoing resource in the optimization of steering and drive performance in subsequent design and prototyping. The seating has also been found to be a very important aspect of the vehicle design, as it is the rider/vehicle interface combined with the steering configuration which present the greatest influence on the performance of the Para-Bike for a particular rider.

Pending—Further refinements in the design of the Para-Bike are underway to prepare for the transition into production. A tandem version of the Para-Bike (for able-bodied and disabled individuals to ride together) is on the drawing board. A cooperative effort with the University of British Columbia will involve tandem prototyping and placement of the first production prototypes of the Para-Bike into a comprehensive disabled physical educational curriculum in the spirit of this International Year of the Disabled Person.

Publication

Schwandt, Doug, "Para-Bike," Sports 'n Spokes, Phoenix, Arizona, November/December 1980, pp. 18–19, 21.

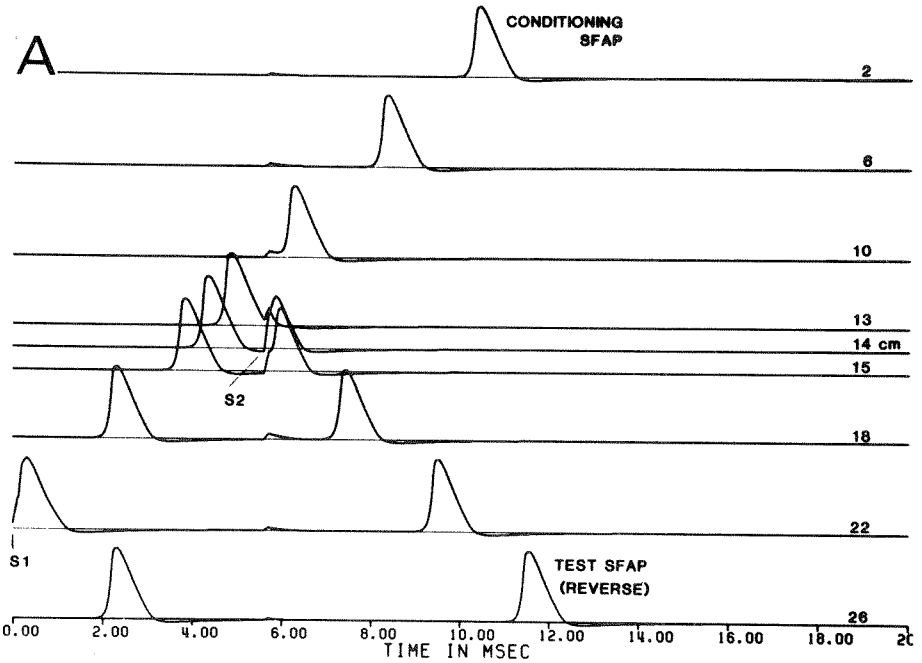
Patterns of Conduction Of Impulse Trains in Myelinated Fibers

Personnel: **Sally L. Wood, Ph. D.** (VA); **Kenneth L. Cummins, Ph. D.** (VA); **Stephen G. Waxman, M.D.** (VA, Stanford), and **Jeffrey D. Kocsis, Ph. D.** (Stanford).

Support for this continuing project comes from the RER&D core budget.

Simulations of collision neurography techniques have been run [1] in which two stimulus pulses are applied at different points along a nerve. The minimum time required for the initiation of a propagating response from the second (test) stimulus in each direction is used as a measure of the stimulus-parameter-dependent forward and reverse refractory characteristics. This time was adjusted for the conduction delay from the first (conditioning) stimulus site. The refractory period was examined as a function of the conduction velocity (CV), depth of the axon, and amplitude of the test stimulus pulse.

These results showed the expected variation of refractory period with CV at small depths and low stimulus intensities. As stimulus intensity and depth increased, the forward and reverse refractory periods began to differ due



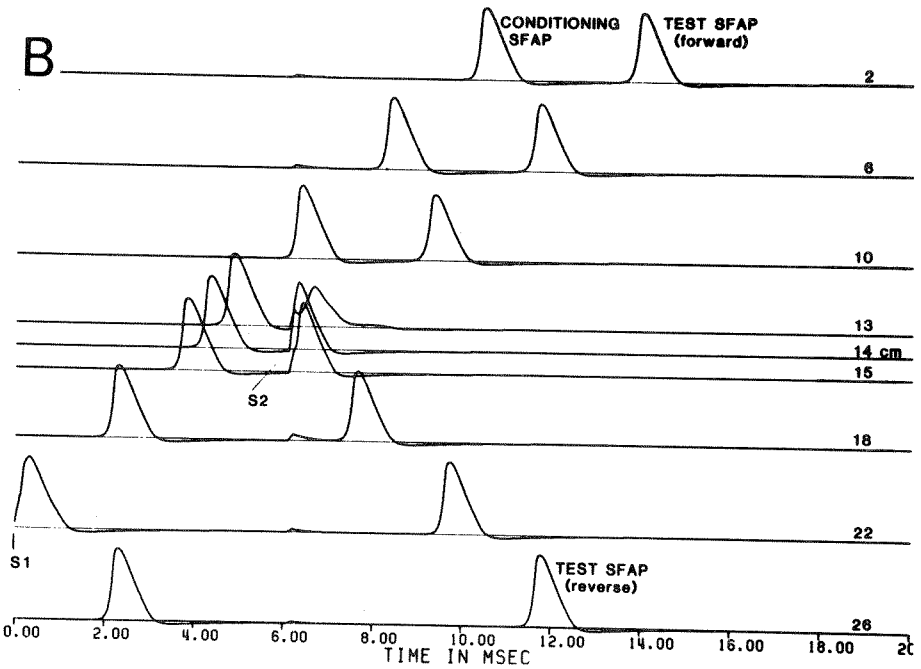


FIGURE 1.
This figure shows an example of the differences in forward and reverse refractory periods. Each horizontal trace is a time waveform "recorded" at a specific position along a 28 cm length of axon. The vertical axis represents distance along the axon. At time t=0 a conditioning stimulus (S1) is applied at the 22 cm point. At some time later a test stimulus (S2) is applied at the 14 cm point.

In Figure 1a the test stimulus was sufficient to excite a propagating response in the reverse direction only. In Figure 1b the increase in IBI (interval-between-impulses) allows the test stimulus to generate a propagating response in both directions. The propagating response in the forward direction travels at a much slower velocity than the reverse direction as can be seen by the arrival time of the second impulse at a distance of 12 cm on either side of S2.

to virtual cathode effect of the spatial spread of the stimulus (Fig. 1). These effects reduced the effective interval-between-impulses (IBI) in the forward direction while increasing the effective IBI in the reverse direction. Similar patterns of forward and reverse refractory period behavior were observed at all CV's tested, although the specific depths and intensities at which a particular type of behavior was observed were CV dependent. These results provide one explanation for previously reported discrepancies in experimental findings regarding the CV dependence of refractory period.

Pending—The simulation program is being modified to include recently available empirical data on ionic channels in mammalian CNS and a more general temperature dependence. It will be restructured to allow easier and more direct interaction with the user, so that extensive previous computer experience is not required. The program will be used to study propagation in single axons under normal, and a variety of pathological, conditions. Results of the simulations can be combined to give estimates of compound responses recorded remotely. For example, 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, in conjunction with modified sodium and leakage conductances, will also be simulated.

Publications

Wood SL, Cummins KL: Bidirectional nerve refractory characteristics: simulations of conduction resulting from direct and remote stimulation. Proc. 3rd Annual Conf. of the IEEE Engineering in Medicine and Biology Society, Houston, Texas, Sept. 19–20, 1981.

Spinal Injury Patient Transport System

Personnel: **Eric E. Sabelman, Ph. D.** (VA); **Timothy A. Koogle, Eng. D.** (VA); **Robert L. Piziali, Ph. D.** (VA, Stanford), and **Connel Wilmot, M.D.** (Santa Clara Valley Medical Center).

This continuing project is supported by RER&D core budget.

Status—Two of these transport systems have been completed in a prototype configuration and are currently being used at the Santa Clara Valley Medical Center for transporting patients. Feedback to date has been very positive. We will be using inputs from the SCVMC to produce production prototypes in which we will be using more advanced materials and more convenient fixation systems.

(Note: the device, previously described and illustrated, is a stretcher-like transporter incorporating a traction device and lateral head, axial shoulder, and torso-strap restraints. Editor)

Analytical Modeling of the Human Lumbar Spine

Personnel: **Lyle W. Swenson, Jr., Ph. D.** (VA); **Robert L. Piziali, Ph. D.** (VA, Stanford), and **Timothy A. Koogle, Ph. D.** (VA).

Support for this continuing project is provided by RER&D core budget.

Status—This project has continued to develop general capabilities in numerical methods appropriate for spinal modeling and general modeling of the human musculo-skeletal system. The project is currently awaiting appropriate data to test the performance of the model. It is anticipated that this will be completed in the next six months.

(Note: among the features of the analytical model developed by this project is the use of non-linear spring force-deflection data in accounting for ligamentous and intervertebral disc interactions. Editor)

The Mechanics of Human Cancellous Bone

Personnel: **Lyle W. Swenson, Jr., Ph. D.** (VA); **Robert L. Piziali, Ph. D.** (VA, Stanford), and **Kil-Soo Kim, M.S.** (Stanford).

Support for this continuing program is provided by RER&D core funding.

Status—Work in this project area has been continuing. The static two- and three-dimensional problems have been completed and work is underway on the dynamic problem.

Improved Predictive Filtering Techniques for Non-Invasive Analysis of Neuromuscular System

Personnel: **C. C. Boylls, Ph. D.** (VA), and **F. E. Zajac, Ph. D.** (VA).

Support for this continuing project is provided by RER&D Center core budget.

Need—The evaluation of therapies for human neuromuscular disease processes benefits from the replacement of invasive assessment techniques by noninvasive methods of comparable sensitivity. We thus have examined the feasibility of extracting the contractile properties of motor-units in muscle using indirect predictive filtering methods as a replacement for muscle biopsy.

Approach

Following the discharge of a motor unit, the fibers of the unit contribute a small increment to the tension in a muscle. If one records (with a needle electrode) both the time-series of motor-unit discharges and the corresponding whole-muscle tension, then a filter can be mathematically constructed which tries to predict the time-course of tension change following each motor-unit volley. If accurate, then this time-course allows the unit to be identified according to its twitch-contraction properties.

The construction of an accurate predictive filter, however, is made difficult by such factors as: (i) nonlinearities and time-dependence in the unit's twitch-contraction behavior; (ii) statistical nonstationarity in the motor-unit discharge train and nonuniformity of the frequency representation within that train; and (iii) the presence of correlated activity (e.g., synchrony) in other motor-units within the muscle. We have been evaluating the sensitivity to these sources of error of predictive filters constructed by various methods.

Status—The behavior of the "simplest" predictive-filter technique, Wiener's least-squares linear predictor, has been studied with reference to motor-unit models derived from Hill's equation. For a linearized Hill's-equation model, the filter predicts tension exactly, provided that the unit's time-series of discharges contains all frequencies (not necessarily uniformly) within the bandpass of the model. However, for the nonlinear model, the extracted twitch-contraction profiles nearly always underestimate both the time-to-peak and the duration of the twitch. The underestimates, in many instances, fall below 70 percent of the actual values. We believe, therefore, that a considerably more sophisticated predictive-filter technique will be required before the goal of accurate twitch-contraction estimation can be achieved.

Pending—This project has been **suspended** until a suitable filtering technique can be found. We expect to consider both Volterra-series estimators and methods based upon model-referenced system identification in making that choice.

Development and Evaluation of an Omnidirectional Wheelchair

Personnel: **William H. T. La, Ph. D.** (VA); **Timothy A. Koogle, Eng. D.** (VA); **David L. Jaffe, M.S.**, and **Larry J. Leifer, Ph. D.**, (VA, Stanford).

Support for this continuing project is provided by RER&D Center core budget.

Need—Conventional wheelchairs have limited mobility, requiring a large area in which to maneuver. Homes, buildings and public transportation systems have to be modified at great costs in order to accommodate these chairs. There is a need for a wheelchair that has no maneuvering constraints beyond the mobility limitations of its physical size.

Approach

Total mobility of a vehicle on the ground plane requires three degrees of freedom of motion: forward-backward translation, left-right translation and rotation on the vertical axis. This total mobility can be achieved in the simplest way with three independently driven wheels that provide positive traction along three lines of action forming a well-defined triangle. The wheels have to be capable of moving sideways without binding or slipping, and must therefore be fitted with idle peripheral rollers.

Status—An experimental prototype of the three-wheel-drive, omnidirectional wheelchair has been built, using mostly

FIGURE 2
Experimental Prototype of the Omnidirectional Wheelchair

available components (modified E&J frame, automobile bucket seat, Solo motors and controller, and Bowman controller (Bowman Electronics, San Anselmo, CA.)). An analog translator converts the inputs from a three-axis joystick and feeds them into the Solo and Bowman units. The three omnidirectional wheels were built by graduate students at Stanford University under the sponsorship of Unimation. The 24-volt electrical system is powered by two Gel Cell batteries.

The prototype exhibits some imprecision in direction control. Pure low-speed translation in odd directions is difficult to achieve, due to the dead zones in controller and motor response. The wheelchair also has a tendency to veer when accelerating or braking. The three-axis joystick requires some adaptation on the part of people who are used to the operation of a conventional electric wheelchair. The present wheels give a rather rough ride due to their limited size and the lack of resilience of the rollers (Fig. 2).

Pending—Different designs of the frame and wheels are being studied. Shaft encoders will be mounted on the motors to implement feedback control. A microprocessor-based digital controller is being assembled; it will enable us to test various control schemes and will help us investigate the dynamics of this wheelchair.

Publication

La, H.T., "Omnidirectional Vehicle," U.S. patent no. 4,237,990. 1980.

Experimental and Theoretical Study of Mammalian Movement

Personnel: **F. E. Zajac, Ph. D.** (VA), and **W.S. Levine, Ph.D.** (University of Maryland).

Support for this continuing project is provided by the RER&D Center core budget and by National Institutes of Health (NS 11971).

Status—Since our last report we have solved the optimal control problem for a human subject jumping to his maximum height using only his calf muscles for propulsion. When these computer and analytical results are compared with experimental data, we find good agreement even for simple muscle models. Critical to this agreement, however, is accurate specification of the properties inherent to these models. Future work will concentrate on more complicated jumps so that we can understand the interaction of externally-imposed and internal body constraints on the biomechanics and neural control of movement.

Development and Evaluation of a Downhill Ski-Sledding System for Persons with Disabilities

Personnel: **Peter W. Axelson, B.S.** (VA); **Larry J. Leifer, Ph. D.** (VA, Stanford), and **John J. Csongradi, M.D.** (VA, Stanford).

Support for this project is provided by RER&D Center core budget.

Status—User and Instructor questionnaire information was used to develop the Arroya V ski-sled which incorporates user feedback and suggested modifications from the 1979-80 ski season. (During that ski season, 15 Arroya IV ski-sleds were field-tested at nine ski areas, including Winter Park Ski Area in Colorado and Snoqualmie Ski Summit near Seattle, Washington). Users indicated that, while turns were easy to complete, they were difficult to initiate. This suggestion led to the use of four edges on the Arroya V, two forward edges which allow skiers to initiate turns and two rear edges which allow completion of a turn.

RERanD Center core budget funded the construction of ten Arroya V prototypes which were ready in March of the 1980–81 ski season. These sleds were used in slalom and giant slalom com-

petitions, at the 1981 National Handicapped Ski Championships at Winter Park Ski Area in Colorado, by 35 skiers with varying disabilities. (The freestyle event was eliminated this year. However, an official downhill event was added.) The competition was close and exciting for all of the racers involved. The all-around top male and female Arroya competitor will represent the United States at the World Handicapped Ski Championships in Switzerland in March 1982.

Representatives from all of the RER&D evaluation centers and other ski-sledding programs met to discuss the various issues associated with downhill ski-sledding programs. The issues covered were (i) tethering vs. nontethering, (ii) ski area insurance problems, (iii) and ski area personnel involvement with chairlift loading and unloading procedures.

Pending—This RER&D Center will seek to locate a manufacturer capable of producing the Arroya in its current state of development. The Center also plans to continue to monitor the evaluation of Arroya V ski-sleds, to publish a user/instructor manual for downhill ski-sledding, to monitor the certification of Level I, II, and III ski-sledding instructors and the certification of advanced users.

Study of Upper-Limb Biomechanics Using Ultrasound Transmission Imaging

Personnel: **Vincent R. Hentz, M.D.** (VA, Stanford); **Parvati Dev, Ph. D.** (VA), and **Kenneth W. Marich, M.B.A.** (S.R.I. International).

Support for this continuing project is provided by the RER&D Center core budget.

Need—Modern functional, and especially biomechanical, analysis of living hands has been restricted because, until now, no safe non-invasive method for studying bone and soft tissue relationships has existed. Ultrasonic transmission imaging combines the advantages of X-ray laminography and fluoroscopy, and permits risk-free visualization of soft tissues and bone in real time.

Approach

One major objective of this study is to extend the capabilities provided by ultrasonic transmission imaging to the study of upper-limb function. 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.

Status—Those areas of the project that deal with ultrasound transmission imaging, and require collaboration with SRI International, are **suspended** while awaiting the evaluation of a research proposal resubmitted to VA RERanD merit review.

In-house development of a mathematical model, and computer simulation of a single joint, the wrist, is **ongoing**. The wrist is modeled as a universal joint with two degrees of freedom. Tendons around the joint are acted on by simulated muscles with specified length-tension properties. The simulation is an interactive one, allowing the user to insert or delete muscles and to alter tendon moment arms and insertion points. The data for the model are derived from the literature and from anatomical measurements (Brand, Paul W.: Orthopedic Clinics of North America, Symposium on Tendon Transfer in the Upper Extremity, Vol. 5, No. 2, April 1974).

Instrumentation for the measurement of muscle mechanical properties is under development (see project by Dev, Zomlefer and Hentz).

Pending—The kinematics of the model will be compared with the kinematics of a cadaver wrist and the model will be refined as necessary. The model will then be made accessible to hand surgeons to determine its acceptability and level of usefulness.

Nerve Conduction Velocity Distributions: Clinical Research Applications

Personnel: **Kenneth L. Cummins, Ph. D.** (VA); **Leslie J. Dorfman, M.D.** (VA, Stanford); **Larry J. Leifer, Ph. D.** (VA, Stanford); **Gordon W. Abraham, M.S.** (VA).

Support for this continuing project is shared by the Muscular Dystrophy Association, the RER&D Center core budget, and the VA Merit Review research program.

Need—There is a need for sensitive non-invasive electrophysiologic techniques for the study of the dynamics of peripheral nerve growth, development, damage, disease, healing and response to treatment.

Status

Initial studies of DCVs (2-CAP method, Cummins et al.) in mixed motor/sensory median nerves suggest that DCV analysis, when controlled for stimulus intensity and temperature, provides a reliable measure of nerve-bundle conduction characteristics that can detect subtle peripheral nerve abnormality, even when conventional electrophysiologic techniques yield normal findings (see BPR 10-35, Spring 1981, VA RER&DS Progress Reports, pp. 131–132.)

We are continuing our study of diabetic patients in an effort to follow the course of diabetic neuropathy in response to dietary control and drug treatment. That study is principally an evaluation of the ability of our DCV methods to detect and follow the course of subtle peripheral neuropathy.

Also, patients with MS, hemiplegia, and spinal cord injury are being studied, in order to investigate the possible correlation of peripheral neuropathy with lesions of the central nervous system.

Our method for studying motor nerve DCVs (collision method, Leifer et al.) has shown an undesirable sensitivity to stimulus intensity. This sensitivity has been isolated to the intensity dependence of refractory period and its relationship to conduction velocity (CV) (Cummins and Abraham, 1981). The nature of the relationship between refractory period and CV has been studied via computer simulation (Wood and Cummins, 1981).

The refractory characteristic which is important in collision neurography is the minimum time interval between the arrival of an action potential at a specific point along a nerve and the time when a second (propagating) action potential can be elicited at that point (IBImin—minimum interval-between-impulses). This interval is, in general, dependent on CV, remoteness of the stimulus site from the nerve, and stimulus intensity. In fact, for high stimulus intensities this interval depends on the direction of propagation being considered ("forward" or "reverse," see Figure 3). This result may well account for the inability of many investigators to demonstrate a

clear inverse relationship between refractory period and CV for "forward" refractory period studies in humans (Hopf and Lowitzsch, 1975 and Betts et al., 1976).

For the collision paradigm, both empirical evidence and computer simulations indicate an inverse relationship between "reverse" IBImin and CV. Therefore any attempt to characterize the range or distribution of motor CVs in humans should take this relationship into account. Ignoring this fact results in errors on the order of 20–40 percent for the estimated range of CVs.

Pending—Development of a stand-alone system for estimating DCVs will begin in the near future. This computer-based instrument will be centered around a commercially available system for electrophysiological analysis of averaged evoked potentials and compound action potentials (Pathfinder II, Nicolet Instrument Corp.).

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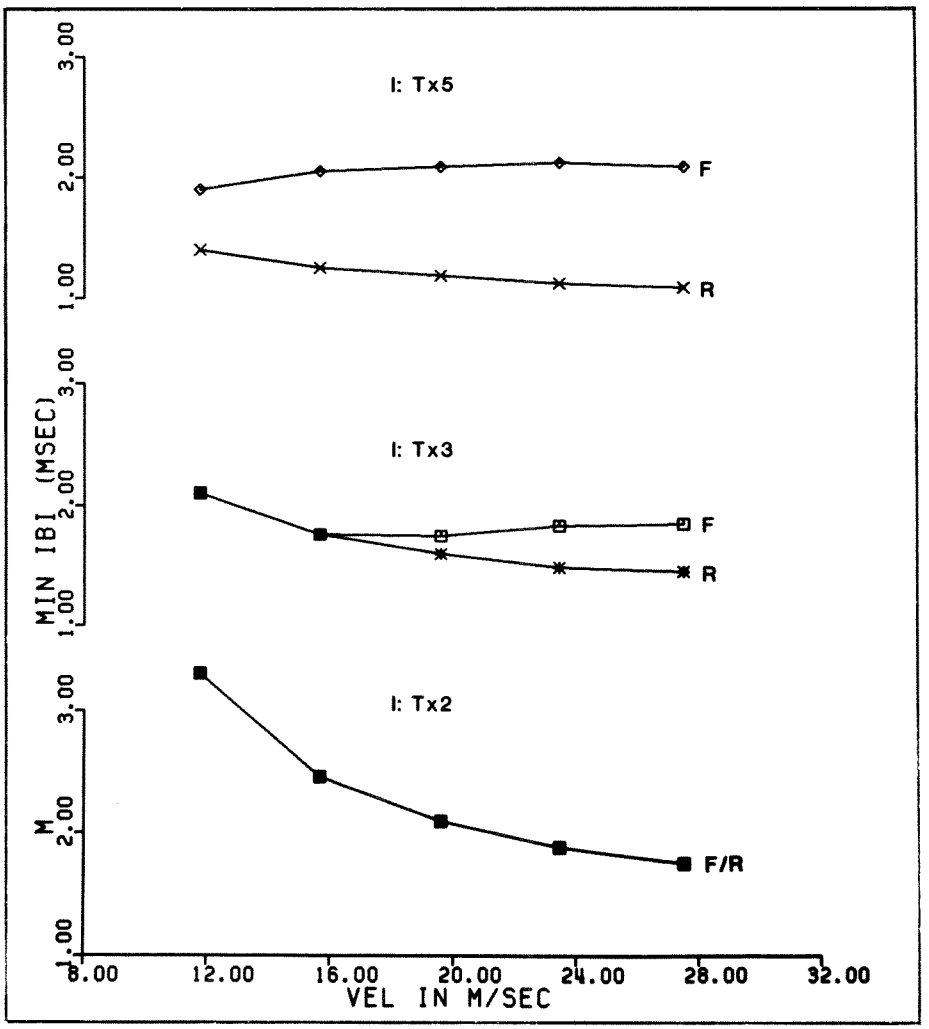

FIGURE 3.
Minimum interval between impulses (IBImin) as a function of conduction velocity (CV) for three different stimulus intensities. Results obtained from computer simulation of a myelinated nerve fiber. Forward (F) IBImin's, which represent conduction of the test action potential in the SAME direction as the conditioning action potential, are indicated by boxes or diamonds. Reverse (R) IBImin's, which represent conduction of test action potentials in the OPPOSITE direction of the conditioning action potential, are indicated by stars or X's. Nerve Depth is 0.5 cm.

For a Stimulus intensity of twice threshold (I: T×2) the forward and reverse IBImin's are identical; IBImin varies inversely with CV. When stimulus intensity is increased to five times threshold (I: T×5) the forward IBImin becomes greater than the reverse IBImin, and no longer varies inversely with CV. The transition in the relationship between forward IBImin and CV occurs at an intensity of three times threshold and a CV of 16 m/sec.

Internal and External Stabilization of the Disrupted Dorsal Lumbar Spine

Personnel: **Inder Perkash, M.D.** (VA); **Donald A. Nagel, M.D.** (Stanford); **Timothy A. Koogle, Eng. D.** (VA); **Robert L. Piziali, Ph. D.** (VA, Stanford), and **John J. Csongradi, M.D.** (VA, Stanford).

Support for this continuing project is provided by the Veterans Administration.

Status—This project has tested two cadavers using Harrington distraction rods, Harrington distraction rods with segmental wiring, Harrington compression rods, and the Luque segmental stabilizing system. These tests have been successful and will be part of the data base to compare the four different approaches. In addition, two cadavers have been tested with simulated cervical fracture dislocations. The normal Luque segmental wiring technique was investigated, followed by a study of a variation of the Luque rod developed by our research group. This latter system has performed better than the normal Luque approach and we are in the process of establishing an experimental protocol to fully evaluate the two approaches.

A completely instrumented Harrington rod has been received and is now being mated with a telemetry package appropriate for implantation. The current system has three channels and we are checking the performance of the system in the laboratory. Plans are underway for a complete telemetry package for the rod. In addition, initial contacts have been made with the NASA/Ames Research Center to con-

duct a cooperative effort using monkeys as test specimens. This will allow us to collect data on the performance of Harrington type instrumentation during the incorporation of bone grafts following fracture dislocation in an upright animal.

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.

Rehabilitative Engineering Research and Development Center Hines VA Medical Center Hines, Illinois 60141

Wilton H. Bunch, M.D., Ph. D., Director
John Trimble, Ph. D., Engineering Director

This report of the VA Rehabilitative Engineering Research and Development Center points out existing and new affiliations, functions, and facilities of core laboratories in applied biomechanics, applied neurophysiology, communicative and sensory aids, and systems evaluation and research design. It then gives samples of continuing and proposed work in the several laboratories, and a bibliography.

New affiliations include Northwestern University, University of Illinois, Rush-Presbyterian St. Luke's Medical Center, Rehabilitation Institute of Chicago, Field Electronic Publishing, and four additional Services within VA Hines Hospital.

Current work is reported as follows:

APPLIED BIOMECHANICS AND KINESIOLOGY CORE LABORATORY

Biomechanical Study of Spinal Fusion and its Effect on the Free Segments

Avinash Patwardhan, Ph. D., Ray Vanderby, Ph. D., and Wilton Bunch, M.D., Ph. D.

The **objectives** of the research are:

1. To perform a parametric study to generate quantitative data describing the range of motion of the spine and the magnitude and location of peak forces and moments acting on the fused segments, as well as on the free-motion segments above and below the level of fusion. The effects of the following parameters will be investigated: (i) the number of fused segments; (ii) the location of fusion along the length of the spine; (iii) the amount of residual motion at the fusion segment; (iv) the load-deformation properties of the motion segments; (v) the geometric configuration of the spine; and (vi) the applied loads.

2. To investigate the stress distribution within the fused as well as adjacent free-motion segments subjected to the segmental loads obtained as described above, as functions of the various parameters.

In order to meet these objectives, the following **activities** will be undertaken:

1. Experimental study to obtain the load-deformation properties of the motion segments of human spine;
2. Experimental study to obtain data describing the geometric configuration of the spine;
3. Formulation and validation of the motion simulation model of the spine;
4. Experimental study of residual motion in fused segments of canine spines and instrumented human spine segments;
5. A parametric study, using the validated motion simulation model of the spine, to generate data describing the range of motion of the spine, and the peak values of segmental loads acting on the fused as well as adjacent free-motion segments;
6. Experimental study of human articular facets to obtain force/deflection data;
7. Development and validation of a three-dimensional model of human articular facets;
8. Experimental study of effects to ligaments on spinal stiffness using transection approach to obtain individual ligament stiffness;
9. Formulation and validation of a three-dimensional finite element model of a human spinal motion segment incorporating the effects of ligaments and facets;
10. Comparative study of stress distributions in normal spinal motion segments versus fused segments, and also versus normal segments adjacent to fused segments when abnormal loading or motion is indicated.

APPLIED NEUROPHYSIOLOGY LABORATORY

An Animal Model for Spinal Cord Injury

John Trimble, Ph. D., Sami Dughman, M.D., Talat Khan, Ph. D., and Wilton Bunch, M.D., Ph. D.

At present, there is considerable conflict over the pathophysiological changes following experimental spinal cord injury. There is also conflict regarding the relationship between these changes and measures of spinal cord function. It is possible these conflicts result from the lack of reproducible and quantifiable injury models, as well as inaccuracies in the physiological and pathological measurements following experimental trauma. There is also the problem that the most commonly used experimental injury models are not directly relevant to clinical injuries.

The proposed project will attempt to resolve these conflicts and to create an experimental injury model which is closely relevant to clinical injuries. This will be done by developing reproducible and quantifiable injury models for both open and closed experimental injuries. In addition, accurate simultaneous measurement of physiological, histological, and functional variables will allow correlation between pathophysiological measurements and measures of spinal cord function.

An open contusion injury and a closed flexion injury will be used for experimental studies. In addition to vital signs and arterial blood gases, we will also measure tissue blood flow, tissue oxygen tension, somatosensory evoked response, monosynaptic reflex, and edema. Correlation of these measure-

ments following both types of experimental injury will be done to obtain a complete temporal description of pathophysiological and functional changes.

Psychophysical and Electrophysiological Measures of Somesthetic Function

John Trimble, Ph. D., Don Dallman, P.E., Don Stewart, R.EEG.T., and Wilton Bunch, M.D., Ph. D.

Most current electrophysiological measures of somesthetic function in humans involve the use of evoked potentials to electrical stimuli. Although these measures have proved clinically useful, their functional significance remains obscure. The primary reason for this problem is the lack of neuroanatomical specificity of electrical stimuli. The goal of this study is to produce electrophysiological or psychophysical measures of somesthetic function which provide an indication of the functional integrity of specific neuroanatomical pathways in humans.

This goal will be accomplished by comparing psychophysical and electrophysiological responses to both electrical and mechanical stimuli. Since the mechanical stimuli are mediated by well-defined receptor types as well as neuroanatomical pathways, comparison of electrophysiological responses to the different stimuli may provide information regarding pathways mediating the responses to electrical stimuli. In addition, comparisons of the psychophysical responses to both stimuli may provide an indication of the functional significance of the response to electrical stimuli.

Effects of Nerve Growth Factor on Functional Recovery After Spinal Cord Injury

Talat Khan, Ph. D.

Previous studies have shown that nerve growth factor (NGF) enhances regenerative growth of dorsal column axons following acute spinal-cord injury in cats. Functional recovery coincident with this regeneration was confirmed with evoked potential measures. The objective of this study is to further define the role of NGF in regeneration, as well as to expand knowledge of the morphological and functional changes induced by NGF.

Experimental contusion injuries will be produced in cats. The forces involved in the injury will be quantified using instrumentation constructed in this laboratory. Following injury, an implantable osmotic pump will be placed in the intramedullary grey matter for infusion of NGF. Infusion will be continued for six to twelve weeks following injury.

Following the recovery period, the functional recovery of the spinal cord will be assessed with kinesiological and electrophysiological measures. In addition, a quantitative histological study of the cord will be made to accurately describe the nature and extent of regeneration.

Preliminary results suggest NGF causes regenerative changes in both the dorsal funiculus (as reported previously) and also in the ventral funiculus. Future studies will be directed to determining the functional significance of the observed changes, and to quantification of the histological changes.

COMMUNICATIVE AND SENSORY AIDS LABORATORY

Factors Affecting the Use of Reading Aids by the Blind

B.L. Zuber, Ph. D., John Trimble, Ph. D., Harvey Lauer, Len Mowinski and Dave Hislop

This study embodies a quantitative and rational approach to the development of performance measures for three methods of reading by the blind: audible-output and tactile-output electronic aids, and braille.

A non-contact monitoring method allows recording of manual tracking patterns during reading by blind subjects, and provides both hand position and hand velocity information. The information available from these tracking patterns should allow identification of the major constraints on information processing during reading by the blind, and should indicate whether these constraints are physiologically or mechanically based.

Crucial to this study is the use of a controlled input. Subjects will be read texts which have been quantitatively graded and rank ordered along a scale of difficulty level. Such a controlled input allows separation of test-related effects from those reflecting the performance of the reader. This technique, and others to be utilized in this study, have proved effective in elucidating the nature of information processing by sighted readers.

Within the framework of the approach and methods outlined above, the major objectives of the proposed study are:

1. Development of baseline values for rational performance measures of reading by the blind;
2. Identification and localization of the major constraints in the man-machine system represented by the blind reader and the reading aid;
3. Elucidation of some fundamental characteristics of information processing mechanisms utilized by blind readers; and,
4. Extrapolation of experimental results to provide improved approaches to the training of blind readers, and to the development of future reading aids.

Measuring the Performance of Blind Travelers

John Trimble, Ph. D. and Rebecca Hollyfield, Ph. D.

Because limitations on independent travel impose serious handicaps on blind travelers, improvements in travel skills have been a major part of the rehabilitation effort. These efforts have taken two general forms: mobility training programs and electronic travel aids. Neither of these approaches, however, has been as effective as had been anticipated. Improvements in both of these areas depend upon increased knowledge about the tasks performed by the blind traveler, the information required to do them, and the cognitive and perceptual abilities that are the bases for successful mobility. Such a research program would require a quantifiable measuring system that is sensitive to the safety, efficiency, and stress of the blind pedestrian. While there have been problems associated with measuring the stress placed upon the blind traveler by the mobility task, safety and efficiency have proved useful in performance measurement. The measures used up to this time for these two variables have been averaged scores which do not permit an assessment of the responsiveness of those measures to particular environmental variables and thus do not permit a detailed task analysis of the mobility task. A continuously measured variable would permit such a correlation

between environment and mobility behavior. The project in progress concerns the development of such a measuring system. A position determining device, combined with time measures, will permit the estimation of such variables as speed and acceleration of walking, the proximity of the traveler to environmental objects, and the continuity and veering of the traveler's walking.

Such a measuring system will be created by placing a matrix of conductive tape on the floor and a piece of conductive material on the shoe of the subject who will be walking over the surface. By means of a special-purpose electronic circuit, the position of the pedestrian will be determined on each footfall based upon the coordinates of the two axes that are connected by the conductive material on the subject's shoe. This position, combined with previous position measures and time measures, will provide estimates of the distance and direction traveled, the speed and acceleration of travel, and proximity to predetermined environmental objects. While the resolution and linearity of the measures will be tested prior to subject involvement, the sensitivity of the system will be ascertained by comparing these measures for two groups of travelers, one of which will be trained cane users and the other naïve cane users.

SYSTEMS EVALUATION AND RESEARCH DESIGN CORE LABORATORY

A Study of the Effectiveness of a Blind Rehabilitation Program

Ross W. Lambert, Jr., M.D., Selwyn Becker, Ph. D., Ben Wright, Ph. D., Shelia Courington, M.S., and John Malamazian

The objective of this study is to discover ways of improving the effectiveness of blind rehabilitation training so that blind persons can develop a greater degree of personal and financial independence. We propose to do this by assessing the degree of effectiveness of the Central Blind Rehabilitation Center in bringing about positive changes in the lives of blind patients, and by developing means of predicting individual success in the rehabilitation training.

This broad goal of improving rehabilitation treatment can be subdivided into several key questions, each of which must be addressed by a specific research objective:

1. To what degree does the CBRC effect changes in a patient's life-state?

   The dimensions of life-state have been defined during the course of pilot studies preparatory to this study. We will use the scales derived from these pilot studies to assess patients' life-states prior to rehabilitation treatment, and again after treatment. This will permit us to measure the amount of change in patient's lives which is due to rehabilitation treatment. This process will demonstrate both strengths and weaknesses in the existing program, and thus lead to ways of improving that program.

2. How can we measure the outcomes of rehabilitation treatment and how can we measure the patient variables which predict positive and negative outcomes?

   The objective here is to create measuring instruments or scales which can be used to evaluate any blind rehabilitation program, and thus improve the quality of treatment and the efficiency of service allocation in all such programs. We will use a method of test design which permits an unusual degree of validity, reliability, and generalizability—and which allows a great precision in specifying the amount of a given skill or characteristic possessed by the individual patient.

3. Which personal, psychological and social factors seem to be associated with positive changes in life state subsequent to rehabilitation?

   We need to be able to predict which patients are more likely to succeed in being rehabilitated, and which are less likely to succeed. To accomplish this, we must examine the patterns of demographic, psychological, and social characteristics of individual patients to determine which patterns are related to positive outcomes. Once this is done, we can then use those patterns to predict the success of future patients, and therefore improve the degree of success, and increase the probability of successful outcomes.

The Effectiveness of Differing Outpatient Treatments of Low Back Pain

John Fisk, M.D., Ross Lambert, M.D., Selwyn Becker, Ph. D., Phyllis Dimonte, R.P.T., and Shelia Courington, M.S.

The basic purpose of this research is to assess rigorously the relative effectiveness of Back School as a treatment for low back pain (LBP), as compared to more traditional treatments. In order to do this we will execute a controlled experiment in which selected participants will be randomly assigned to the various treatments. Participants will be selected on the basis of criteria that ensure that they are LBP sufferers, and that the outcome variables are appropriate to the sample.

Although we are primarily interested in the treatment of veterans with LBP, there are no established outcome criteria for the purpose of assessing treatment effectiveness with this population. Therefore, the experiment will be carried out on a more general population of essentially healthy, employed persons. By doing this, we can determine the usefulness of a variety of other outcome variables in assessing treatment efficacy with the veteran population.

Patients who meet our selection criteria will be randomly assigned to one of the following treatments: (i) management with medication and therapy, (ii) Back School with personal instruction, (iii) Back School with audio-visual instruction only, (iv) diathermy placebo treatment, and (v) no treatment (control group).

These five treatments will be compared on two basic outcome variables: time from onset to remission of symptoms, and amount of time lost from work at 6 and 12 months after treatment. But we will also assess the usefulness of other outcome variables that are more appropriate to the veteran population. These are: (i) functional ability on specific tasks, before and after treatment, (ii) frequency of post-treatment medical attention for LBP, (iii) the patient's perception of discomfort and limitations of activities, (iv) psychological state and social adjustment, and (v) levels of medication for LBP.

Thus, the five possible treatments will be compared in terms of their effects on seven outcome variables. Data analysis

will serve two purposes: to assess the relative effectiveness of the treatments on all seven outcomes, and to correlate the two established outcome criteria with the five suggested criteria. This will permit us to define appropriate outcome criteria for persons who are not expected to return to work after treatment or remission of symptoms.

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