VETERANS ADMINISTRATION REHABILITATIVE ENGINEERING RESEARCH AND DEVELOPMENT SERVICE PROGRAMS

Rehabilitative Engineering Research and Development Center
Hines VA Medical Center
Hines, Illinois 60141
Wilton H. Bunch, M.D., Ph. D.

Introduction

During the period from January 1, 1979 through June 30, 1979, significant progress was noted in several projects of interest to the Hines RER&D Center working in collaboration with the Stritch School of Medicine of Loyola University and the Illinois Institute of Technology.

This 6-month period has been marked by the increased clinical activity of the Hines RER&D Center, the expansion of research space, the upgrading of equipment, and securing the services of additional personnel.

Some details of this progress are reported here.

Simulation of Ligaments with Composites

L. J. Broutman, Ph. D., D. Shulak, M.D., and W. H. Bunch, M.D. Ph. D.

Thus far, these studies have included a detailed literature review to define the properties of the human anterior cruciate knee ligament, to determine the forces placed on this ligament during various motions of the knee joint, and to review other ligament prostheses which have been investigated.

While this study had nearly been completed, review of the literature will be continued throughout this year, for greater familiarity with the biomedical literature and to remain abreast of the most current references. Also, a review of the properties of fibers and polymers has been completed to help in the process of material selection for ligament prostheses. Experimental studies were initiated on a model composite system containing nylon fibers in a rubber matrix. as

an aid in determining acceptable composite geometries for ligament prosthesis.

The nylon-cord-reinforced rubber sheets were tensile tested at various angles to the fiber direction, to characterize the shape of the resulting tensile stress/strain curve. Specimens were cut from the sheet material at angles of 15 deg., 30 deg., 45 deg., 60 deg. and 75 deg. to the fiber direction. An Instron testing machine was utilized for the testing at an elongation rate of 2 in. per minute. The great influence of fiber orientation on the resulting stress/strain curve was demonstrated by these studies, and it was shown that the curve at 15 deg is similar in shape to that of the anterior cruciate ligament, although the strength is not as great.

Since the properties of fiber composites can be controlled easily by altering the fiber volume fraction, type of fiber or matrix, and fiber orientation, initial studies have also been conducted on potentially useful composites. For example, graphite and Kevlar fibers were ordered in fabric form and used to reinforce a silicone rubber matrix. These materials also have the potential of being used in medical devices. Composites have been fabricated and the stress/strain response at various angles to the fiber direction has been characterized.

Another approach adopted for a potential ligament prosthesis is the use of highly oriented solid polymers. For example, the failure of the Richards prosthesis fabricated from ultra-high molecular weight (UHMW) polyethylene appeared to be related to the viscoelastic properties of the polymer. That is, when subjected to long term cyclic loading, the creep of the material was excessive. This center has initiated a study utilizing a highly oriented form of UHMW polyethylene to determine whether its creep characteristics or compliance can be reduced. Flat plates (¼ in. in thickness) of UHMW polyethylene were purchased from Cadillac Plastics, and tensile specimens have been prepared. A strain-measuring extensometer is placed on the specimen (2 in. gage length) and the stress/strain response up to 50 percent strain is measured at various strain rates. The yield properties for this unoriented material compare closely to the Richards ligament materials as shown below:

	RER&D Study	Richards Ligament
Yield Strain (%)	12.25	12
Yield Stress (psi)	3204	3185

In order to determine the creep behavior, studies are in progress to measure the stress/strain curves at various strain rates and at various temperatures above room temperature. Stress relaxation and creep

curves as well as isochronous stress/strain curves will then be constructed.

Comparison is also being made with known viscoelastic behavior of the anterior cruciate ligament as reported in the literature.

Orientation of UHMW polyethelene is being accomplished by several methods: both biaxial and uniaxial orientation are being performed. Uniaxial orientation is accomplished by simply cold-drawing the tensile specimens in the Instron. Samples have been prepared by stretching the material approximately 400 percent. Test specimens are then cut from the central portion of the gage length for evaluation; oriented specimens have also been prepared by rolling and strip drawing in a fixture mounted in a tensile testing machine. Biaxial orientation has been produced by compressing a sheet between the platens of a hydraulic press which causes the sheet to expand in its plane as well as reduce its thickness. The viscoelastic properties of the highly oriented samples will be established during the remainder of this year, for use in selection of the best material for further study.

Improving the Crack Propagation Resistance and Durability of Acrylic Bone Cement

L. J. Broutman, Ph. D., and W. H. Bunch, M.D., Ph. D.

Acrylic bone cements are generally a mixture of a methylmethacrylate monomer and polymerized polymethylmethacrylate powder to increase viscosity and reduce exothermic temperatures. In addition, minor amounts of chemicals are added to achieve self-curing without the addition of heat. In radiopaque cements, barium sulphate at approximately 10 percent by weight is often added. Charnley cautions that failure of early attempts to use acrylic cements in orthopedic surgery was probably the result of surgeons having an incorrect mental picture of the way the cement functions. "Many surgeons thought it was an adhesive, and many subconsciously still do, as indicated by the fact that it is still frequently called a glue." Charnley refers to the cement as a fixation medium and not an adhesive.

Clinical studies have indicated that cement cracking is intimately involved in the loosening and subsequent failure of metal prostheses. As cracks initiate and propagate through the acrylic, the metal prosthesis loosens, thereby promoting further crack growth in the acrylic as well as high stresses in the metallic stem. It has been postulated that prostheses failures in vivo are due to these high stresses which cause crack initiation, which, in turn, leads to the eventual failure of the stem.

At the start of this program, as mentioned, a literature search on

acrylic bone cements was conducted and the current literature is continually being reviewed. The ASTM Standard Specification for acrylic bone cements (F451-76) was obtained and the following items of equipment were constructed: exothermic heat mold, intrusion mold, and specimen mold.

This equipment allows one to evaluate bone cements to determine if they meet the specifications such as doughing time, maximum temperature, setting time, intrusion and compression strength.

The Zimmer Co. was contacted and several samples of acrylic bone cement were obtained to serve as a reference point in the proposed studies. A few samples of cement were tested following the ASTM specification test methods to gain experience in performing these tests. This is necessary because any modifications proposed for the cement composition should not substantially alter those cement characteristics necessary to allow the surgeon to use it in the operating room. Sections of cement samples were also polished and examined microscopically to confirm the nature of the 2-phase structure of the cement. The original boundaries of the PMMA powder can be observed surrounded by the PMMA matrix polymerized in place from the monomer.

Materials which will be used in the investigation of new cement compositions have been ordered and received. These include various methacrylate and acrylate monomers and polymers as shown in Table 1. Also, the free radical initiators used in polymerizing the cements have been received. Finally, the test specimens which were proposed for use have been designed and all grips necessary to install them in the testing machine have been fabricated.

During the next few months, it is anticipated that the following studies will be completed:

1. Commercial bone cement specimens will be prepared in order to determine their fracture toughness. Of particular interest will be the effect of cement porosity on fracture toughness in order to judge the effect of cement quality (as influenced during insertion by the surgeon) on fracture toughness and strength.

2. Cyclic load experiments will also be conducted on the above samples in order to measure crack growth rates during fatigue.

3. One change in cement composition to be evaluated will use ethylmethacrylate-methylmethacrylate copolymer as the surrounding matrix. Fracture toughness and crack growth resistance will be determined as well as the performance of the standard ASTM tests to insure that the cement conforms to the current specifications.

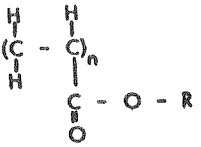
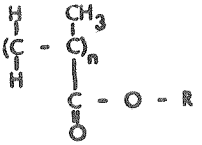
Acrylates 	Methacrylates 	
R –	Tg (°C) of Acrylate	Tg (°C) of Methacrylate
methyl ($-CH_3$)	+3	+105
ethyl ($-CH_2-CH_3$)	-22	+65
n-propyl ($-CH_2-CH_2-CH_3$)	-44	+35
n-butyl ($-CH_2-CH_2-CH_2-CH_3$)	-56	+21
iso-butyl ($-CH_2-CH(CH_3)-CH_3$)		+54
n-hexyl $-(CH_2)_5-CH_3$		-5
n-octyl $-(CH_2)_7-CH_3$		-20

TABLE 1.—*Glass Transition Temperatures of Acrylate and Methacrylate Polymers*

Improving Intelligibility of Information in Ultrasonic Sensing Systems for the Blind

G. Saletta, Ph. D., K. Haag, Ph. D., and W. H. Bunch, M.D., Ph. D.

The goal of this project is to develop an ultrasonic sensing system which provides information that is intermediate in complexity compared to available systems. This will be accomplished by decomposing distance, direction and size information into distinct bits of audio tones.

The initial phase of the project, which has been completed, involved development of the simplest electronic system which would provide the desired information to the user. The purpose of the system is to evaluate the information coding scheme in dynamic situations, and to determine the electronic and ultrasonic problems which must be resolved to obtain a reliable system.

The prototype unit detects obstacles in the vicinity of the user by means of ultrasonic energy. The device transmits a short ultrasonic burst of energy, which, after being reflected from a nearby obstacle, is

detected by receiver transducers. Electronic circuits then transform the reflected signal to an audio code which is presented to the user.

Radial distances from the user of the device are divided into ten zones approximately 1.5 ft wide. The presence of an obstacle in the nearest zone is coded as a low-frequency tone (300 Hz) while an obstacle in the farthest zone is coded as a high-frequency tone (3000 Hz). Distance information is enhanced by the coding scheme since the two different tones are separated in time by about a half-second for obstacles in the nearest and farthest zones. Obstacles in an intermediate zone are similarly coded as tones which are separated in time and frequency.

Information about the angular location of the obstacle is derived by the use of two receiver transducers. The two transducers are skewed with respect to the forward direction so the ultrasonic energy reflected from an obstacle is received by the "left" or "right" transducer in proportion to direction. The coding scheme processes the tones to the user's left and right ears to simulate a stereo effect. Thus an obstacle directly in front of the user would "sound" equally loud in both ears while an obstacle to the user's left would "sound" louder in the left ear.

Information about size of the obstacle is coded as amplitude (volume) of the tone presented to the user—large objects produce louder tones than do small objects.

Field tests using the first prototype unit have revealed three major deficiencies:

1. Directional resolution is inadequate for objects which are within a ± 10-deg azimuth angle in front of the user;
2. Non-stationary reflectors such as the human body do not provide consistent ultrasonic reflections. Due to absorption, multipath cancellation, and scattering, the ultrasonic signal is occasionally lost resulting in aperiodic fading of the audio signal presented to the user; and
3. Obstacle size information is not distinctive.

The problems associated with directional resolution and loss of ultrasonic signals from nonstationary reflectors (points 1 and 2 above) have been resolved by experimental determination of radiation patterns for various orientations of the ultrasonic transducers. Test data indicate that adequate directivity over a ± 30-deg azimuth angle is obtained when two individual pairs of transmitter-receiver transducers are used, with each pair operating at a different center frequency. In addition to directivity improvement, dual frequency operation reduces multipath cancellation from nonstationary reflectors.

To further reduce the effects of signal fading, an improved system

has been designed in which ten samples of the return signal from each contour are used as the basis for encoding the audio signal which is presented to the user. The first prototype used a single signal sample from each contour for this purpose.

The problem associated with distinguishing obstacle size (point 3 above) stems from the relatively small dynamic range available from the ear-plug speakers. To effectively extend this dynamic range, the new system will provide obstacle size information to the user by controlling both amplitude of and presentation time for the audio tone associated with each contour. The two degrees of stimulus control to the ear will provide a greater range of discrimination.

Spine Stiffness Measurement Fixture

C. Sciammarella, Ph. D., D. Smith, M. D., and W. H. Bunch, M.D., Ph. D.

A special loading fixture has been designed by Illinois Institute of Technology (IIT) for measuring the structural properties of two adjacent vertebrae. The fixture applies controlled forces and torques to encapsulated canine vertebra specimens, and measures the resultant displacements along three orthogonal axes. Loading components are applied separately along each axis by repositioning the hydraulic actuators and specimen. Translational and rotational displacements are measured with potentiometers with digital readouts.

Data produced by the fixture will provide information on healing time, revascularization of solid fusions, fracture strength, and modes of failure. The fixture will also be used to investigate the viscoelastic, inelastic, and anisotropic properties and to develop biomechanical models of spinal segments.

The fixture is scheduled for completion in August of 1979.

Harrington Rod Axial Force Transducer

R. Dix, Ph. D., C. Sciammarrella, Ph. D., D. Smith, M.D., and W. H. Bunch, M.D., Ph. D.

A removable transducer, for measuring the axial force in Harrington rods during surgical management of the spine, was designed, fabricated, and tested. It consists of a thin-wall split tube, with clamps at each end that provide non-slip attachment to the Harrington rod. Strain gages mounted on the outer surface of the split tube detect small changes in the length of the Harrington rod and thus measure the axial force applied to the spine. Although the transducer was successfully calibrated at the time of fabrication it was found unsuited

to clinical use. It needed to be designed in a more rugged configuration and with smaller, more effective clamps. An improved configuration is being developed.

Spinal Computer Modeling

R. Dix, Ph. D., C. Sciammarrella, Ph. D., D. Smith, M.D., and W. H. Bunch, M.D., Ph. D.

Two computer models of spine force-vs.-displacement behavior are being developed. The first represents the viscoelastic response of a scoliotic spine to forces applied through a Harrington rod during surgery. The second models the displacement of a normal or abnormal spine under an arbitrary set of applied loads.

The first model was used in correlating clinical data. A set of coefficients were selected which led to accurate correlations of both distraction and relaxation force-vs.-displacement behavior at the load application points. Literature review for developing a more detailed second model is underway.

Frequency Response Characteristics of the Somatosensory Evoked Response System

D. E. Dallman, P.E., J. Trimble, Ph. D., and D. Smith, M.D.

Somatosensory evoked responses to transient stimuli (SER's) have received widespread application in diagnosis of somatosensory disorders. Such disorders frequently alter SER latency, amplitude or waveform. However, this is not always the case, and it is often difficult to correlate SER changes with the underlying neurophysiology (Hume, A.L., and Cant, B.R., EEG. Clin. Neurophysiol., 45:361-875, 1978). One reason for this is the difficulty in describing the complex SER waveform.

Recently, Namerow et al. (EEG. Clin. Neurophysiol., 37:11-21, 1974) introduced a method utilizing high-frequency stimuli which produces a sinusoidal SER (steady-state SER or SSER) quantifiable by two parameters: amplitude, and latency or phase. They report a relation between stimulus frequency and response amplitude (frequency-response curve or FRC) which changes with diseases such as multiple sclerosis.

This center has used a variation of this method to study the FRC for the somatosensory system, as well as FRC changes with disease. Five neurologically normal adults were tested on three occasions. Pulsatile stimuli at frequencies from 5 Hz to 50 Hz were delivered transcutaneously to either median or peroneal nerves, at current levels

between 2 mA and 6 mA. The SSER was recorded bipolarly from electrodes at Fz and Pz using a reference at Cz (10/20 system). Potentials were amplified by 2×10^5 with a passband of 1 Hz to 1 kHz, and stored on FM tape for off-line analysis by digital computer (DEC PDP 11/10).

Recorded data were digitized at 200 pts/sec. Ensemble averages were computed for 50 responses with a sample epoch of 400 ms. The ensemble averages were then filtered with a high-Q, narrow-band digital filter centered at the stimulus frequency. The SSER magnitude was estimated from the root-mean-square value of the filtered ensemble average. The FRC's were then made by plotting SSER magnitude vs. stimulus frequency.

In the frequency range tested, for normals, the FRC's for median nerve stimulation show bandpass characteristics with a center frequency near 20 Hz. The FRC's for peroneal nerve stimulation show lowpass characteristics with a cutoff frequency between 5 and 10 Hz. Three patients with sciatica were then tested. Their neurological exam was unremarkable. The transient SER for one patient showed increased onset latency to L5 stimulation. For all three patients, the FRC's from the affected side were abnormal. With peroneal stimulation there was a marked decrease in the magnitude of the lower-frequency portion. In one case, this change correlated with surgical findings. For median nerve stimulation, the FRC peak shifted to lower frequencies. These results suggest the FRC may be an important measure of somatosensory function.

NOTE: For additional progress reporting, see Daniel Graupe, Ph. D., and John Fisk, M.D., elsewhere in this section. Dr.'s Graupe and Fisk work with this center through IIT and Loyola University.

Rehabilitative Engineering Research and Development Center
Palo Alto VA Medical Center
3801 Miranda Avenue
Palo Alto, California 94304
Larry J. Leifer, Ph. D.

No progress report was submitted for this 6 month period. A 1 year report will appear in the next issue.

Control of an Artificial Upper Limb in Several Degrees of Freedom

Department of Electrical Engineering
Illinois Institute of Technology
Chicago, Illinois 60616
Daniel Graupe, Ph. D.

Orthopedic Surgery Department
Loyola University
Chicago, Illinois
John Fisk, M.D.

Rehabilitative Engineering Research and Development Center
Hines VA Medical Center
Hines, Illinois 60141

EMG Signature Identification for Multifunction Prosthesis Control

During the 6 months period of January 1, 1979 to June 30, 1979, work on the microcomputer system for multifunctional control of an above-elbow artificial limb by means of EMG signal signature identification has been mainly concerned with enhancing recognition reliability, clinical tests, and improving amputee training procedures.

Clinical testing (using bench-size prototype) was done at the VA Medical Center, Hines, Illinois, on several amputees. Most tests were performed on an above-elbow amputee with residual limb of three inches (who could almost be classified as shoulder-disarticulation) who is also paralyzed in his remaining arm. Other tests were made on a congenital bilateral shoulder-disarticulation amputee, and on a unilateral shoulder-disarticulation amputee for a single short session with duration between 15 min. and 1 hour. Two unilateral above-elbow amputees were also subjects.

In all tests, (except for the first) consistent and repeatable correct actuation was accomplished even at the first training session. Success rate varied with the degree of training and the type of injury, but was consistently improving with the training. Almost errorless actuation of 2 to 4 limb functions, all via a single electrode pair, was achieved in some cases within the very first session—these cases included one of the unilateral above-elbow amputees and the congenital bilateral shoulder-disarticulation amputee.

The success rate was of course greatly related to the availability of healthy muscles for electrode placement. This location varied with the type of amputation and was, in the cases of shoulder-disarticulation or very short above-elbow amputation, at the top of the shoulder or at the back of the shoulder. In those cases (and, for certain limb functions, also with some other amputees) direct correlations between the

muscle activation (straining or relaxing), and the desired joint movement of the artifical limb, could not be kept. Those amputees were requested to generate repeatedly and consistently one pattern of muscle tension or relaxation and then a different one, and so on. By displaying to them the signal's time-series parameter values as computed by the microcomputer, they could check themselves as to how close they were to a desired pattern (to be translated to a desired limb-function to be activated). The subject of the best and most convenient relation between the type of willed muscle activation by the amputee and the desired limb function still remains open.

Major factors which caused difficulty in amputee training were:

1. Only a single bench-size unit is available—a subject cannot take it home to improve training and to "get used" to the actuation. They have, therefore, to train at intervals of 1 to several weeks and for only short periods; and

2. The system uses a slow microcomputer (INTEL 8080 of 1975 vintage) which is an 8-bit machine. Computation is very slow, especially since 16-bit precision is required. Thus computation is presently in lengthy double-precision operation. This causes a delay of about 1.5 to 2.0 sec between the muscle actuation by the amputee and the arm mechanism's response (this delay increases to 20–30 sec if printout of parameters is also performed). The lack of a more immediate response is confusing and time consuming, thus tiring the amputee.

The two main factors described are merely technical, and should be overcome if and when a pocket-size 16-bit modern microprocessor replaces the present equipment. In that case, the actuation delay will be down to 0.15 sec which is adequate for normal operation. It should be noted that signal data for signature identification is at present collected over 80 milliseconds. The rest of the delay is merely pure computation time, which is totally a function of the computer's speed. The 80 ms. sample covers an EMG spectrum range of 25-to-2500 Hz, which is the normally accepted range of information in the signal. Note that even if information were to lie beyond this spectral range, such information would be redundant, because adequate discrimination among the limb functions considered is possible with the 25-to-2500 Hz sample, and discrimination is the sole purpose here.

Further work is planned on and around a 16-bit fast system to be worn by the amputee, noting that no theoretical problems prevent this, and that such microcomputer hardware is presently available.

Interference-Insensitive System for Spinal Cord Monitoring During Surgery

The present approach aims at providing fast, repeatable, and

interference-insensitive monitoring results, otherwise similar to what one aims at with standard evoked-potential methods, which use ad-hoc relatively high-voltage interrogation signals of fixed shape, amplitude, and intervals. In contrast, the present system scans, and modifies the interrogation signals and the intervals between them to eventually improve and adapt interrogation to the system that is interrogated; namely, to the neural channel between the area where the signal is applied and the area where the response to it is measured. The channel parameters are then evaluated from an input/output relationship which is stochastic rather than (in standard methods) deterministic.

This stochastic approach is justified because of the stochastic nature of other electrical activity in the body which interferes with the response measurements, and due to the stochastic design of the interrogation signal. The interrogation signal has a random statistical distribution such that the probability of its being correlated with electrical activities in the body (other than those of responses to that signal) is negligible, to yield interference insensitivity. The adaptation feature to the channel properties is unbiasedly achieved through having the inter-signal intervals randomly span several possible time interval values, to cover any neural firing rate intervals.

In contrast to standard methods, the whole statistical pattern of the interrogation signal is then taken into account in response evaluation, rather than a fixed timing value, in such a manner that any information available on the input (which is the interrogation signal) is accounted for in the output. Noise and interference removal is obtained in a feedback fashion, with past performance being used to update filtering in a manner that minimizes the expected error variance by weighting the present error according to the previous error estimates. As a result, both input history and past error-filtering history can serve to reduce the interference in a non-optimal fashion. In this manner one can theoretically, as well as intuitively, show and understand that interference removal should be superior to results via averaging where no "history" or "input" information is considered. Obviously if you have "history" and "input" information, and if it affects the response (and it obviously does, by definition), then neglecting to use that information will lead to deterioration in performance; conversely, if the information is effectively used, one obviously could expect better and more consistent parameter estimation; i.e., diagnosis. That should lead to both lower interrogation voltage levels and to faster evaluation time.

The first animal results have suffered from equipment problems and from skin-conductivity effects, and are unfortunately most in-

conclusive. The next report period should, however, provide useful animal results. During that next period both manual and adaptive interval and amplitude variation of the interrogation signal will be studied as a function of the response parameters that are identified, and results will be compared with results via standard evoked-potential methods. They will also be analysed in terms of their compatability with neural physiological knowledge.

For a theoretical basis to some of the discussion, see the following references:

1. Wiener, N.: Time Series Analysis, MIT Press, Cambridge, MA, 1964.
2. Kalman, R.: A New Approach to Prediction and Filtering, ASME Trans. Basic Eng., Mar. 1960.
3. Graupe, D.: Identification of Systems, 2nd Ed., Krieger Publishing Co., Huntington, N.Y., 1976.

Prosthetics Research
Northwestern University, Prosthetics Research Laboratory
Room 1441, 345 East Superior Street
Chicago, Illinois 60611
Robert G. Thompson, M.D., and Dudley S. Childress, Ph. D.

Powered Arm for Shoulder Disarticulation Levels

Work continues on a total arm prosthesis for shoulder disarticulation amputees. A fundamental part of this development is the design and analysis of an "unbeatable" position servocontrol system in which shoulder motion will be used to control prosthesis wrist rotation and elbow flexion-extension. To facilitate the design of an efficient and effective prosthetic system, a systematic analysis is being undertaken to study certain dynamic characteristics of physiological control of the elbow and wrist. The results of this study will be used to determine a set of optimal functional characteristics to serve as the design goals during the development of the prosthesis mechanism and control system.

A minicomputer-based data acquisition system has been implemented which will be used in recording and analyzing experimental data pertaining to physiological control of the upper limb, the dynamic mechanical characteristics of available powered prosthesis components, and possible shoulder motion transduction techniques. As the initial stage of this analysis, goniometers have been built for analyzing physiological control of elbow flexion/extension and wrist

rotation. The essential elements of these goniometers are tachometers which yield a voltage signal linearly related to the angular velocity of each movement. These signals are recorded and processed on-line with a minicomputer system, and the corresponding position (integrated velocity) of each joint can be accurately displayed on an oscilloscope. Software has been written to allow analysis of the time, course, and accuracy of various independent and coupled elbow and wrist movements. Specifically, the velocity profiles of movements of various magnitudes are to be derived, as well as the ability of persons to control accurately the positioning of their physiological joints without visual feedback. Random tracking experiments are also to be performed. This analysis is currently being started.

Synergetic Hook

Three hooks, one left and two right, of the model II type have been fabricated for clinical evaluation. They await refinement of a current cut-off device before evaluation can begin. Development of the motor rotation detection system previously discussed has been discontinued in favor of limit switches. The former system would have required additional conductors between terminal device and wrist. This was deemed an unacceptable design feature.

A prototype of model III (removable fingers) has been fabricated

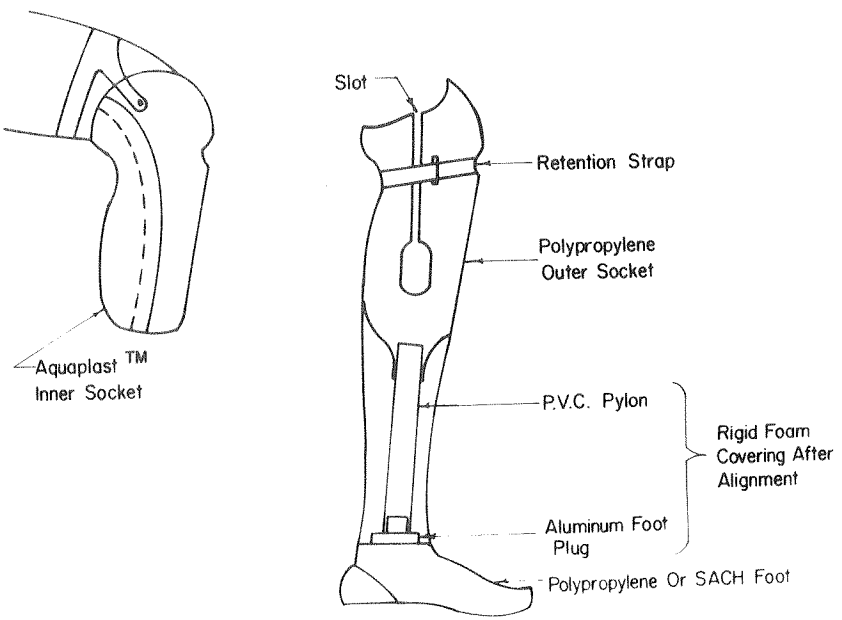


FIGURE 1. — Preparatory BK prosthesis.

using APRL fingers. Further development awaits the current cut-off device mentioned above.

Preparatory Lower-Limb Prostheses

Development of the preparatory B/K prosthesis (Fig. 1) has been completed with a total of nine fittings. The Aquaplast interface is now fabricated over a modified cast and not directly on the limb. Experiments in vacuum-forming the polypropylene outer socket directly over the interface have shown this method to be feasible, thus reducing total fabrication time.

An article on the preparatory B/K prosthesis has been accepted for publication in the July Newsletter . . . Prosthetics Orthotics Clinics.

Fundamental and Applied Research Related to the Design and Development of Upper-Limb Externally Powered Prostheses

University of California, Los Angeles
School of Engineering and Applied Science
Biotechnology Laboratory, 3116 Engineering 1
Los Angeles, California 90024
John H. Lyman, Ph. D., Moshe Solomonow, Ph. D., and Amos Freedy, Ph. D.

No report was received for this six-month period.

Position Control of Above-Elbow Prostheses

Department of Engineering Design and Economic Evaluation
Engineering Center OT 6-34
University of Colorado
Boulder, Colorado 80309
Lawrence E. Carlson, Ph. D.

Previous work has demonstrated the feasibility of Extended Physiological Proprioception (EPP) for position control of the VA electric elbow. Tracking and blind positioning tests conducted by an amputee in the laboratory showed that closed-loop position control yielded significantly better performance than on-off velocity control.

The only problem encountered in the amputee evaluation concerned the location of the transducer at the control site on the harness. Although fairly small (less than 2 cm thick), the transducer caused a bulge in clothing that the subject deemed undesirable. Also,

wires must connect the transducers to the elbow; this represents a potential for breakage and tangling. The sensor itself was a specially constructed linear potentiometer which had poor long-term reliability.

To overcome these problems, new transducers have been designed that will be located in the elbow housing (Figs. 2-4) which will eliminate any external wires. A commercially available rotary potentiometer is used for greatly improved reliability, and feedback to the transducer is provided by a small sprocket and chain drive.

In addition, a new solid state electronic control circuit has been designed and bench-tested. Employing pulse-width modulation for more efficient speed control, the circuit also has a rate-sensitive feature that will enable the amputee to shut the system off by applying a quick jerk to the input cable; it is turned on again with another quick motion. This will allow the amputee to maintain any elbow angle without having to maintain an input signal.

The new system will be totally self-contained within the prosthesis. The mechanical input signal will be routed by cable to the elbow with conventional methods, although using a much lighter, more flexible

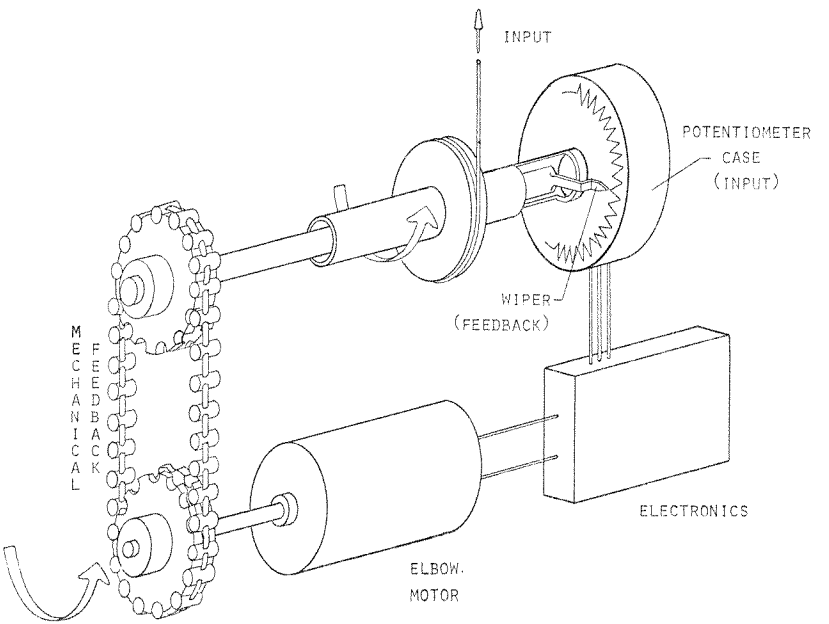


FIGURE 2.—Schematic of rotary transducer shows feedback sprocket and chain (at left) connecting elbow motor with the rotary transducer's shaft. At right is rotary potentiometer which replaced a linear version.

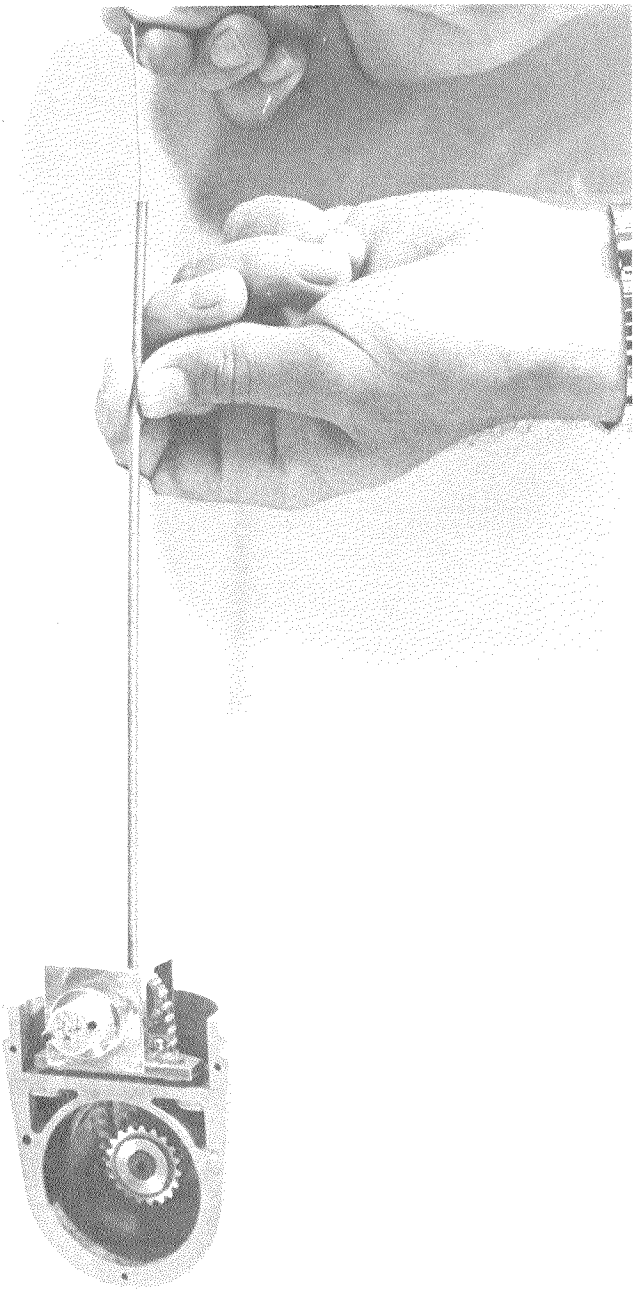


FIGURE 3. — Transducer mounted in elbow housing.

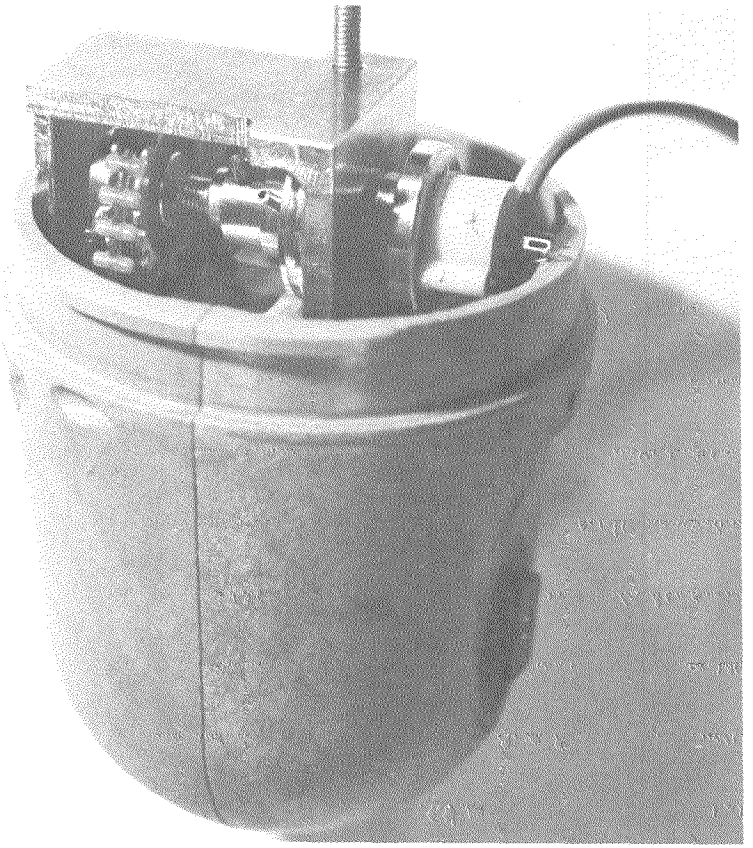


FIGURE 4. — Close-up of transducer.

cable and housing. Field testing will be undertaken to evaluate the prosthetic system by amputees in daily activities.

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

Applied Physics Laboratory
The Johns Hopkins University
Johns Hopkins Road
Laurel, Maryland 20810
Woodrow Seamone and Gerhard Schmeisser, Jr., M.D.

During the reporting period, January-June 1979, the research program at Johns Hopkins under Veterans Administration sponsorship

was focused on the continued development and evaluation of the chin controller for the powered wheelchair for the high spinal-cord-injured person, and its associated worktable. The details of this system and results of clinical evaluation by one quadriplegic volunteer are described elsewhere in this issue of the Bulletin of Prosthetics Research.

The chin controller circuitry has been modified to provide smoother control in steering, and the use of a new breath-actuated circuit for selection of reverse mode is now being evaluated. The advanced model of the microprocessor-controlled robotic arm has reached the stage of completed checkout of the software, and is ready for interfacing with the worktable elements.

Progress during this reporting period also includes initial clinical testing of the powered-assist wheelchair in a home environment.

Chin Controller for Wheelchair

Several important engineering changes have been made to the low-profile chin controller. One basic change, use of optical sensors instead of potentiometers to improve manufacturability, has been incorporated into the design and appears to meet all the functional needs of a two-axis controller. The electronic circuit design for this controller is complete and a printed circuit board has been designed and is now undergoing tests in a wheelchair model.

A second engineering change to this chin controller is the substitution of a new breath-actuated reverse selector, in lieu of the microswitch, to switch modes from forward to reverse. A temperature-sensitive thermistor is used in this device, to sense minute changes in airflow through a small pneumatic tube. This modification further minimizes the apparatus in front of the face of the user. Tests in the laboratory indicate this method of mode select may be superior to the microswitch method. The new selector is also less fragile. One wheelchair model has been updated with this controller and it is planned to have a quadriplegic volunteer compare the new selector with the original microswitch.

Other changes to the controller include additional electronic filtering to achieve smoother control in tight turns, and the addition of an on-off control.

Microprocessor Controlled Robotic Arm

During the reporting period, interface hardware/software problems were resolved on the advanced microprocessor-controlled robotic arm, and checkout is now complete on the arm assembly. The unit is now ready to be interfaced with the worktable components, such as

the reading rack, typewriter, telephone and other components. This advanced model features an easier-to-use display panel and includes a keyboard to allow the user or attendant to easily preprogram the desired motions. The servos incorporate closed-loop velocity control and are not sensitive to friction as in the previous models. This robotic arm will be controllable from the same type of chin-controlled wheelchair described elsewhere in this issue of the Bulletin. An electro-optical link is utilized to translate chin motion commands into robotic arm motions.

Powered-Assist Wheelchair

One aspect of the research program at Johns Hopkins during FY 79 is the modification and clinical testing of the powered-assist wheelchair. This concept employs the use of two handrims for wheelchair control which are instrumented with optical tachometers to sense handrim motion. It is operated similar to a manually operated wheelchair but requires very low input forces. The controller utilizes a closed velocity loop to allow forward the reverse velocity limits to be set independently. Thus a powered wheelchair can provide maximum torque as required, yet be velocity limited to protect the user from abrupt motions.

One E&J model 3P electric power wheelchair has been modified for the powered-assist mode and includes a high maneuver control mode as well as a cruise mode. These control modes can be switched at the user's choice and have adjustable loop gain and velocity limits for each mode. This experimental model is to be utilized to determine optimal settings for various tasks in a wheelchair.

Clinical testing has been initiated on this model by an individual who has Freidreich's ataxia. This individual normally uses a manually operated wheelchair but fatigues very easily. During the reporting period, this user used the experimental powered-assist wheelchair for 55 hours in the course of a one-week test period. The user participated in selecting optimum gain and velocity limits.

This individual was extremely enthusiastic about the ability to keep the high torque capability of the powered wheelchair yet control its velocity limit. A low velocity limit in reverse is particularly desirable. This user indicated this powered wheelchair has precise control in the home environment and is looking forward to additional tests with this chair.

Design of Prosthetic and Orthotic Devices and Biomechanical Studies of Locomotion

Biomechanics Laboratory
University of California, Berkeley
5144 Etcheverry Hall
Berkeley, California 94720
Charles W. Radcliffe, Donald M. Cunningham, James M. Morris, M.D., and Larry Lamoreux, Ph. D.

Design of Lower-Limb Prosthetic and Orthotic Devices

Four-Bar-Linkage Polycentric Pneumatic Knee

Development of the knee cap and shank cover has been completed, and evaluation fittings have begun.

Six-Bar-Linkage Knee with Friction Swing Control

Amputee tests of the prototype unit have led to design and modifications as shown in Figure 5. These are intended to improve the strength of the unit and the effectiveness of the friction swing control.

Friction-Stabilized Knee

The research model has been production engineered and complete drawings prepared for a production prototype (Fig. 6). This unit is interchangeable with the Four-Bar-Linkage knee, since it uses the same adjustable socket coupling and shank tube clamp.

SACH Foot with Metal Keel

The keel patterns have been redesigned for increased strength. A new pattern has been developed for a metal keel with a flat top surface, designed for installation in the same manner as current wooden-keel SACH feet. A machined casting from the new pattern is shown in Figure 7. Prototype molded SACH feet with the new metal keels will be available for testing in September 1979.

Multi-Input Control of Knee Stability

The second prototype of the multi-input microcomputer controlled knee has been designed with an improved rotary servo-valve and on-board servo amplifiers (Fig. 8). All hardware has been constructed. Further testing awaits delivery of the single board microprocessor which will allow back-pack amputee testing of the system. The new vertical arrangement of the rotary servo-valve is shown in Figure 9.

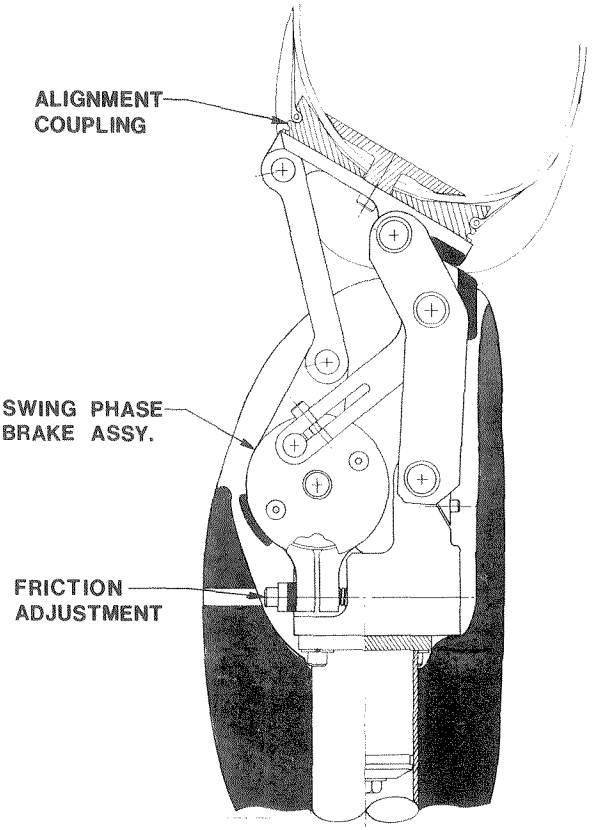


FIGURE 5. — Six-bar-linkage knee with improved friction swing-control.

Clinical Evaluation of Lower-Limb Prosthetic Devices

In October of 1978, an Orthopedic Rehabilitative Project was initiated at San Francisco VA Medical Center (Fort Miley) for the purpose of fostering the application of modern technology to improvements in the care of physically disabled veterans. The organizing concept of the project has been one of intimate cooperation between a specially recruited medical and paramedical team at Fort Miley and the staff of the Biomechanics Laboratory at the University of California in Berkeley (UC-BL). UC-BL staff members have been active in the planning of this project since its inception. In addition to providing assistance in space and program planning, they have accepted responsibility for the design, procurement, installation and initial operation of research instrumentation required to accomplish the goals of the Fort Miley Project.

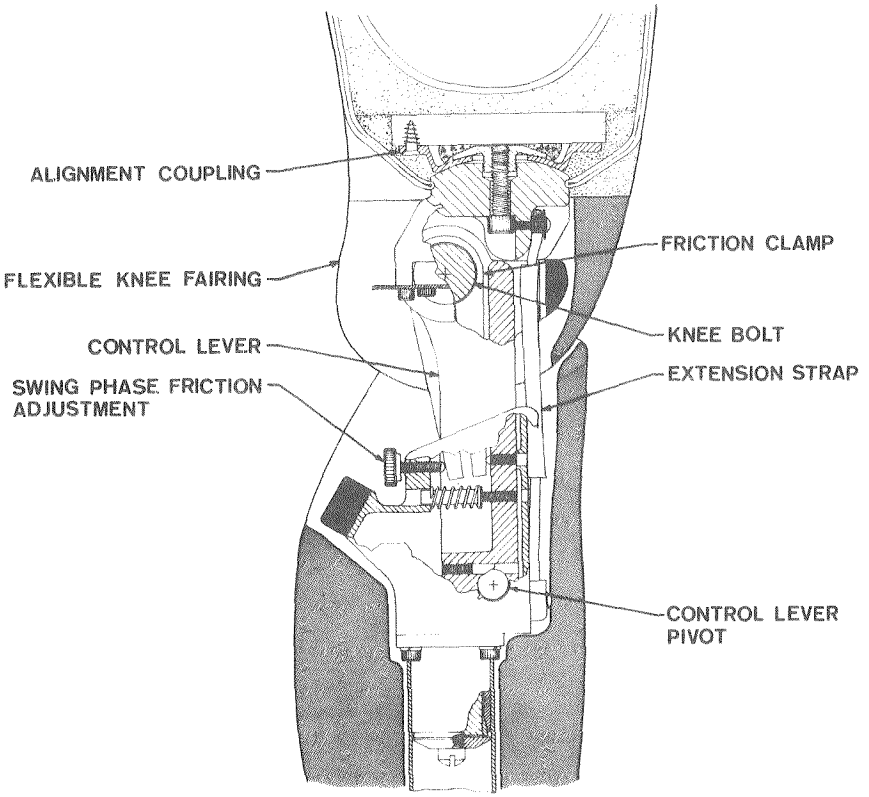


FIGURE 6—Production prototype friction stabilized knee with release during push-off.

As the project gets underway, attention will be directed initially to a limited number of areas. Foremost among these is a program to evaluate the prosthetic care of the above-knee amputee, with particular attention to the evaluation of stance-phase stability and locomotor function. This program will include functional evaluation of specific prosthetic devices and fitting techniques, and eventually will address the evaluation of devices for the below-knee amputee as well. Additional areas of cooperation that call for engineering support from UC-BL are an examination of the causes of loosening of femoral components in total hip arthroplasties, and the design of improved surgical instruments.

Approximately 2500 square feet (250 square meters) of space has been assigned to the project at Fort Miley, and funds for renovation of that space have been allocated. Plans for renovation have been submitted for bids. The staff of UC-BL will continue to work with the Engineering Service at Fort Miley, as needed, to expedite the completion

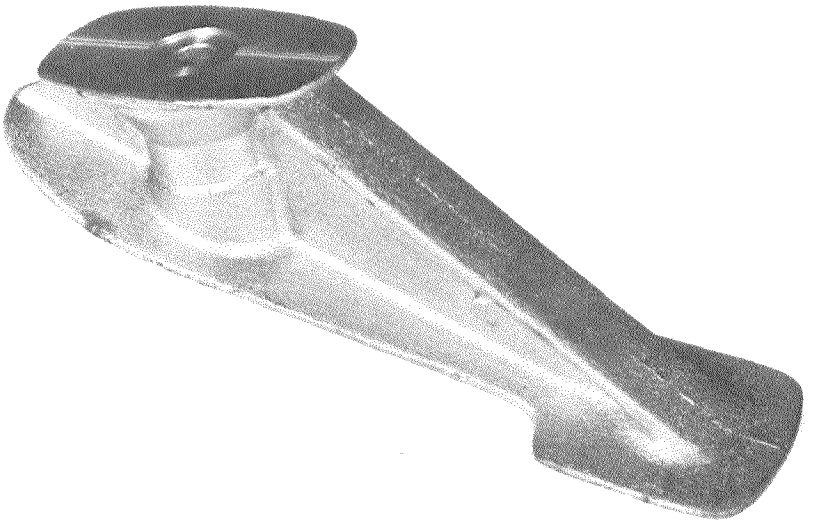


FIGURE 7.—Cast aluminum SACH foot keel with flat attachment surface.

of renovation and the installation of tools and measuring instruments. Completion of building renovation is projected for early 1980.

Mobility Aids for the Severely Disabled

PC2 Wheelchair

The PC 2 universal-height wheelchair has been extensively driven by project staff, has had a 2-week daily living test by a muscular dystrophy quadriplegic, and numerous short rides by ablebodied and disabled people (Fig. 10). Reactions have been generally enthusiastic, though with some reservations about the chair's length and complexity.

Testing has been hampered by the unsatisfactory performance of the fail-safe brakes designed for the chair. New dog-type brakes have been designed with a positive release feature, to prevent the dog from failing to disengage — as sometimes happened with the dog-type brakes on the SSPU wheelchairs. These brakes should be complete by August 1979.

Powered Spring Suspension Wheelchair

A prototype wheelchair is being fabricated which has the performance of the PC 2 and SSPU wheelchairs, with the PC 2 wheelchair's gearboxes, but without up/down and curb-climbing capability. The prototype should be complete by August 1979.

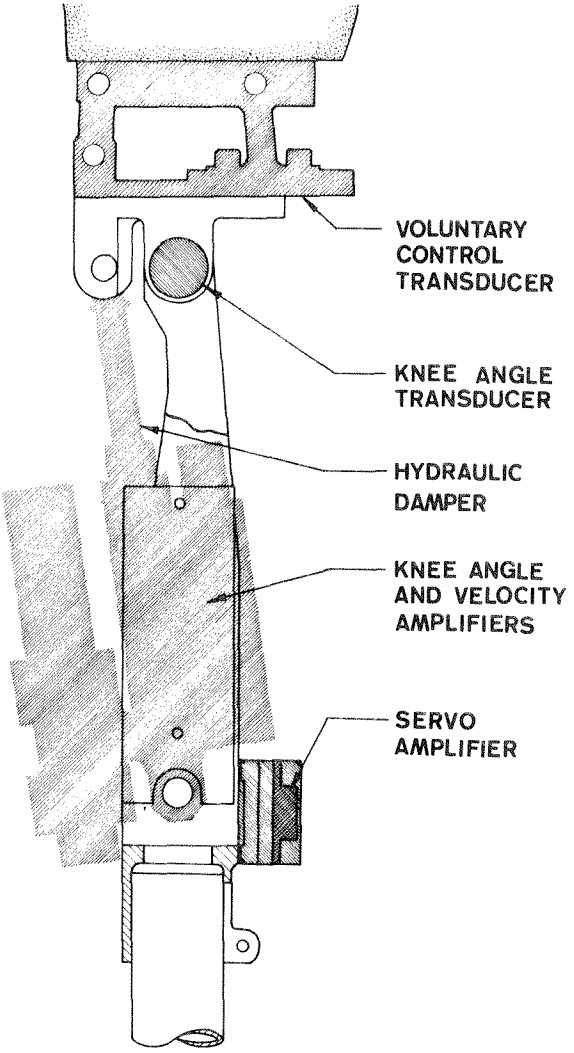


FIGURE 8.—Multi-input microprocessor-controlled knee unit with on-board servo-valve electronics.

Solid State Controller

During this report period, a switching scheme for a four-transistor bridge has been developed which allows smooth braking by a pulsed catch diode circuit (Fig. 11). Scott Bowman of Bowman Electronics is designing the controller on a subcontract basis, and has made a preliminary breadboard prototype which has exceptionally smooth steering and braking. The controller has current-limiting, to restrict

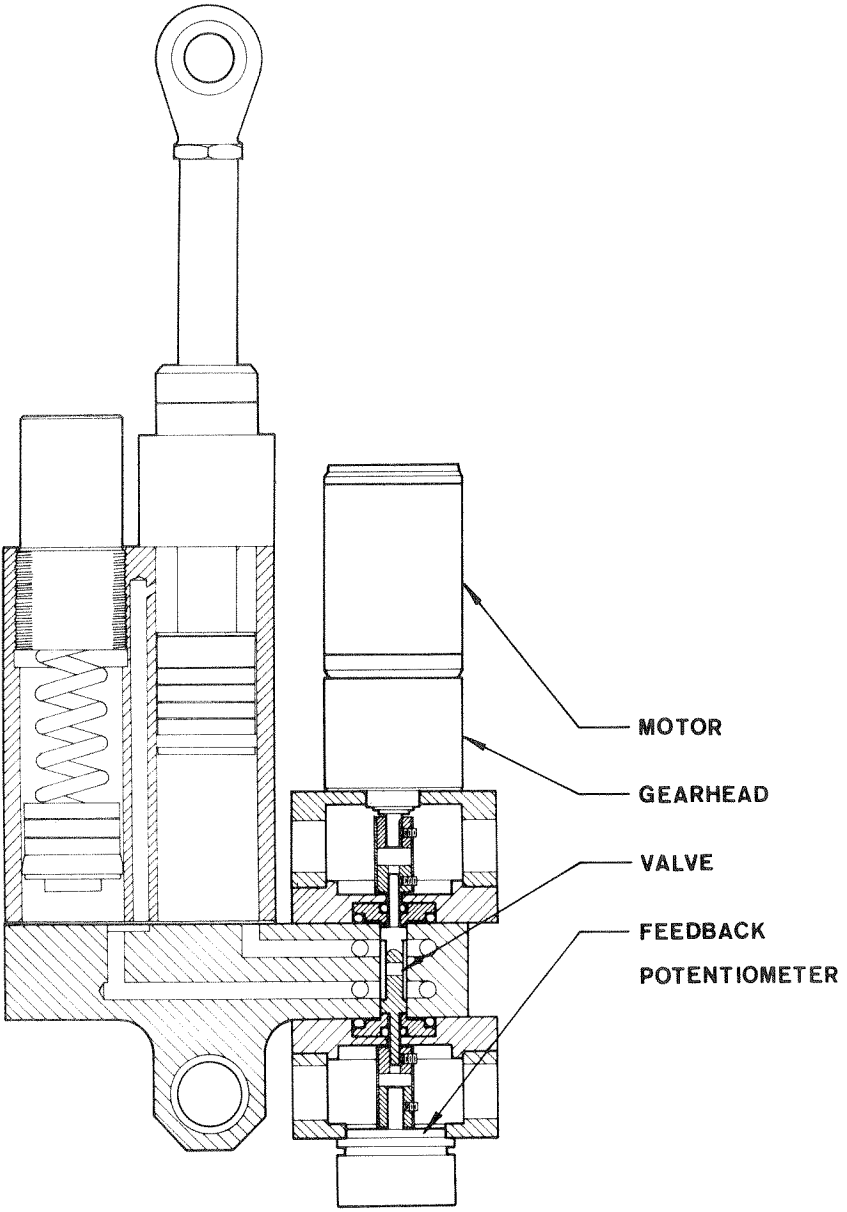


FIGURE 9.—Rotary servo-valve for microprocessor control knee unit.

maximum motor torque and to protect the output transistors against excessive current. Development work will continue, with a prototype suitable for use on a wheelchair expected by December of 1979.

FIGURE 10.—PC 2 Universal-Height Wheelchair, in normal daily activities position.

Spring Suspension Caster Fork

Figures 12 and 13 show two prototype caster forks designed during 1978-79 to improve wheelchair ride by providing spring suspension for the caster wheels. One configuration (Fig. 12) has a vertically telescoping action which allows a clean fork design which should have minimal problems with caster shimmy because of the low inertia of the fork, and the friction inherent in the caster pivot bushings. The plastic bushings which allow both vertical sliding and caster turning seem vulnerable to wear, however, and in addition they have added resistance to vertical motion when a horizontal force component is

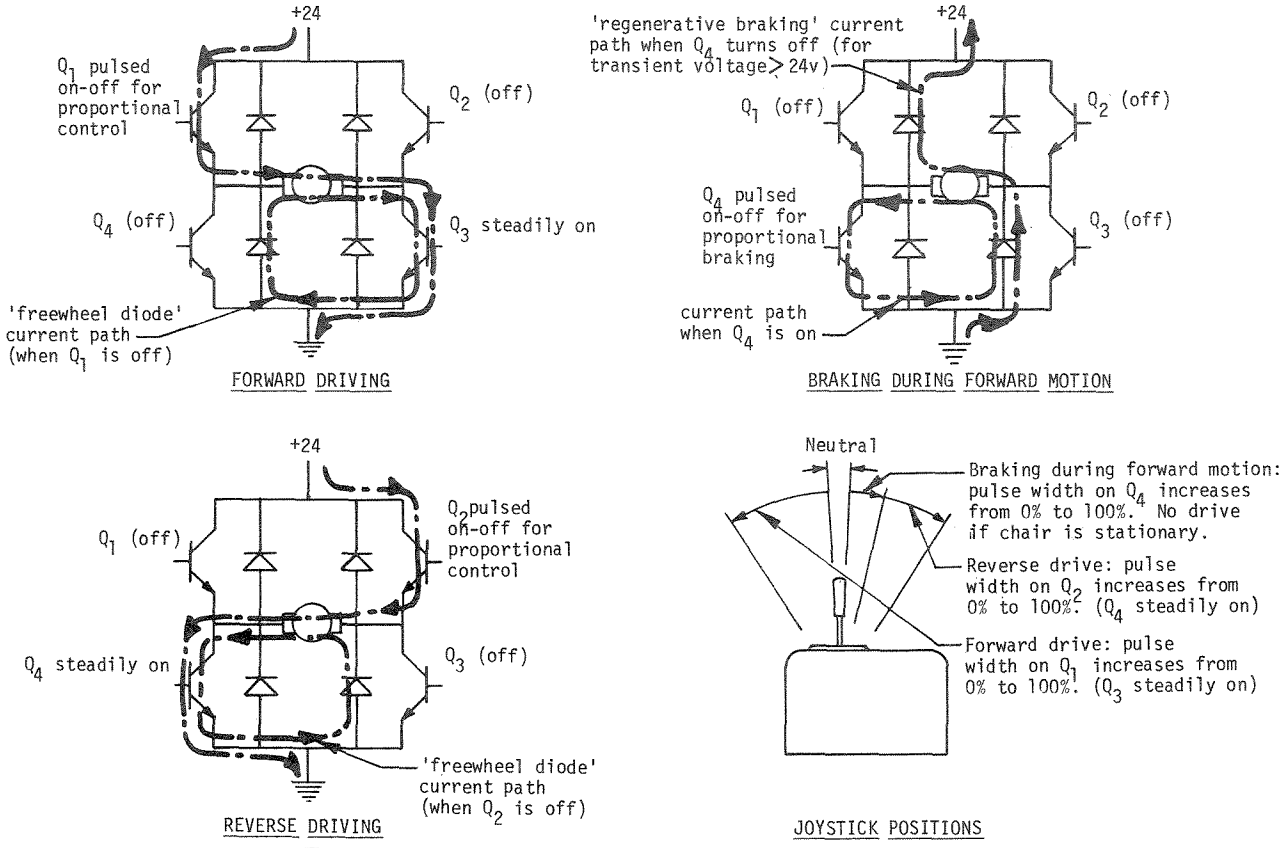


FIGURE 11 — Output bridge circuit of solid-state controller.

present. The second configuration (Fig. 13) has a swing arm horizontally pivoted above and ahead of the wheel axle, and is better suited to absorbing horizontal as well as vertical shocks.

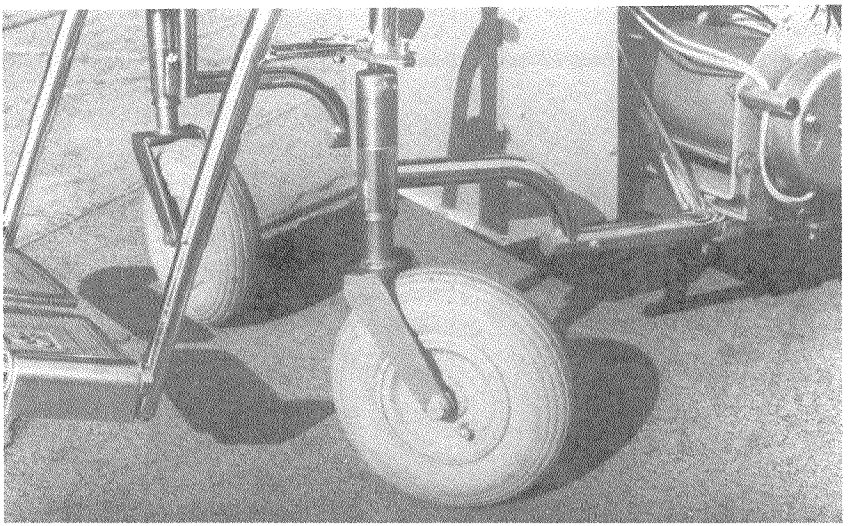


FIGURE 12. — Front caster fork spring suspension — telescoping type.

The swing arm version is being redesigned for production as a fork for the PC 2 and Spring Suspension wheelchairs, and as a retrofit fork for conventional chairs. In this report period (January-June 1979), the swing arm pivot has been changed to a large diameter bushing to provide anti-bounce damping, and the caster pin and box structure has been redesigned as a casting. Three pairs of these revised forks have been completed. Anti-shimmy damping will be provided by a plastic thrust bushing on the caster axis. This provides dry friction type damping, which produces unnecessarily high resistance to turning at low speeds.

There are at least two schemes for shimmy damping which do not interfere with low speed maneuverability:

1. A pneumatic damper connected to an offset arm on the center pivot, which damps shimmy oscillation; and
2. A "tuned" vibration absorber. A multiple pole permanent magnet "mass" vibration absorber with torsional spring and aluminum, copper (or other paramagnetic) eddy current plate (as used on an watt hour meter).

The second method is preferred for its efficiency and simplicity if enough vibrational energy can be absorbed to avoid caster shimmy. Both schemes are beyond the preliminary sketch stage. Both will be implemented, design parameters iterated, and devices tested.

Manually Operated Spring-Suspension Wheelchair

A conventional manual wheelchair was modified by mounting the

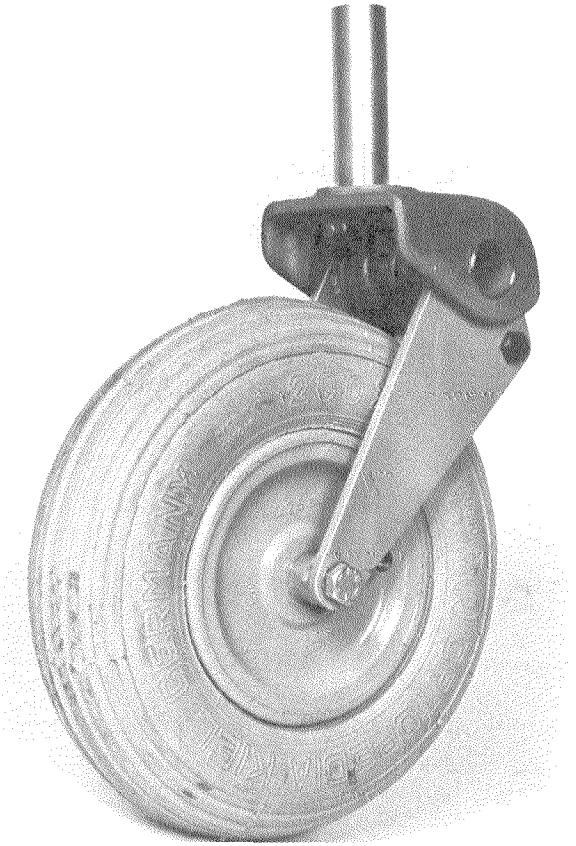


FIGURE 13. — Front caster fork spring suspension, swing arm type.

rear wheels on swing arms which pivoted from the upper horizontal side frame member. The location and inclination of the swing arms was chosen to minimize the vertical "bouncing" which would otherwise accompany propulsion if, say, the swing arms were nearly horizontal (Fig. 14). The location axis of the floating axles was kept at approximately the same location as before the modification. The wheelchair's ride smoothness is much improved, and the chair is as easy to propel as it was without the spring suspension. Limited testing will be undertaken to determine to what extent people like the chair's ride.

Lever-Drive System for Manual Wheelchair

Parts for a prototype lever-drive system were fabricated, but have not yet been assembled.

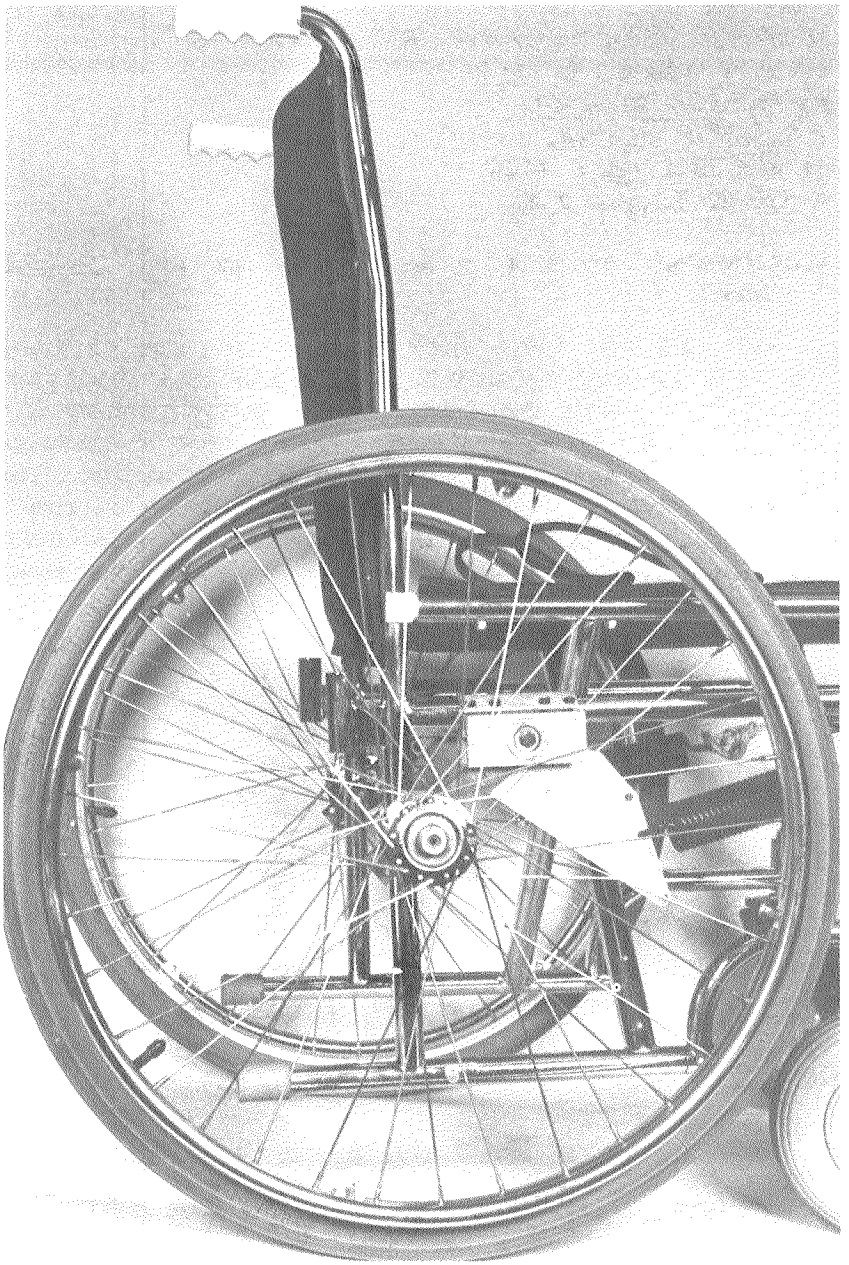


FIGURE 14. — Add-on swing arm rear wheel spring suspension on a conventional wheelchair.

Immediate Postoperative Prostheses Research Study
Prosthetics Research Study
Eklind Hall, Room 409
1102 Columbia Street
Seattle, Washington 98104
Ernest M. Burgess, M.D.

Biomechanical Analysis of Lower-Limb Amputee Extra-Ambulatory Activities

This project has been completed and the final report has been submitted in monograph form to the VA RER&DS, in Washington, D.C. This study was conducted as a joint project with the School of Physical and Health Education at the University of Washington, and Prosthetics Research Study. Portions of accumulated data have been presented at relevant national meetings, conferences and workshops. Publications are forthcoming. The information obtained is unique, original and can be translated for the clinical benefit of many veteran and non-veteran amputees.

These studies will now extend into the development and improvement of running skill in unilateral lower-limb amputees. The ability to run at least short distances holds the key to a more active life for many of these individuals. The potential benefits linked both directly and indirectly to the performance of this skill are far reaching. At the most basic level, running can be classified as a "self preservation skill" employed in certain emergency situations. As one of the fundamental motor patterns required in many games and sports it can enhance self-esteem and quality of life, by allowing the individuals satisfying participation and achievement in physical activities of a recreational or competitive nature; consequently there is a trend in amputee rehabilitation to give recreational training precedence over vocational skills, the rationale being that success in the former will have positive carryover to the latter. From the standpoint of cardiovascular fitness and weight control, jogging is unquestionably an excellent form of aerobic exercise. Lack of such aerobic activity has been identified as one of the coronary risk factors—thus the recent report by Hrubec and Ryder (1978) (see pp 29 in this issue) revealing an excessive mortality due to cardiovascular disease in individuals with amputations at or above the knee leads to speculation that the relatively sedentary existance may predispose amputees to cardiac failure. This finding suggests the need to encourage amputees to incorporate regular exercise into their lifestyle.

The initial project left no doubt about the ability of many below-knee amputees to run; several individuals who had not previously

attempted this skill while wearing an artificial limb made encouraging progress after only a very brief period of instruction. A lack of confidence is demonstrated by the amputee keeping the intact limb almost straight during its recovery. They also tend to lock the prosthetic knee during stance phase to increase stability and/or reduce the pressure of the infra-patellar tendon against the PTB prosthesis in the BK amputee.

It is hypothesized that gait can be improved and discomfort reduced by individual programs of prosthetic modification, skill instruction, and practice. Such programs, when administered to new amputees or those without running experience following amputation, should result in the development of comfortable functional running patterns. Combined with improved skill there should be accompanying increases in body images and self-esteem, as well as improved cardiorespiratory endurance. The purpose of continuing research is to design, implement and assess procedures for developing and improving running gait. Such an evaluation will provide further insight into the execution of the skill, and necessary adaptations and modifications in the prosthesis, related to successful performance.

Evaluation of Residual Limb Physical Characteristics Using Volumetric and Other Measurement Devices

Initial studies in this area are being completed.With confidence in the protocol as a result of the preliminary investigation, PRS is proceeding with a larger group of patients to confirm and extend initial observations and to apply them clinically. This study proposes to evaluate the volume, external configuration, muscle electrical activity, gait characteristics and socket suspension stability of below-knee amputees, with or without supervised residual limb muscle training, and under specified prosthetic circumstances.

These goals are being achieved by a multidisciplinary group using original equipment. Residual limb and prosthetic evaluation is accomplished using a microcomputer-operated volume measurement device, external photogrammetry, X-rays, and equipment which utilizes an artificial paradigm to quantify measured differences in muscle-induced suspension stability. Prosthetic evaluation is further enhanced by studies of gait characteristics as monitored by the Rancho Los Amigos Gait Analyzer and by a second device which utilizes the same foot switches to delineate EMG activity within the socket during gait. A CARS-UBC electrogoniometer has not yet been introduced into the study but its use will further refine the final results.

A training program utilizing biofeedback and EMG information has been created to enhance limb suspension capability. The results of

this program will be studied with the help of the described equipment. Prosthetic refinements which are found to be indicated will then be accomplished and studied with emphasis on functional improvement.

Dynamic Evaluation of Blood Flow and the Vascular Characteristics of Ischemic Limbs

This large segment of PRS research is a coordinated effort of the Departments of Orthopedic Surgery, Vascular Surgery, Biomedical Engineering, and Rehabilitation at the VA Medical Center and the University of Washington. Patients whose ischemic lower limbe are at risk of amputation have been studied preoperatively and postoperatively. The routine general medical and vascular workup is supplemented experimentally by segmental Doppler readings, laser Doppler data, $Xenon^{133}$ radioactive uptake and surface pO_2 determinations at selected sites. These data are coordinated with the findings at surgery and the postsurgical clinical course, specifically as they relate to wound healing and rehabilitation. These findings are being published as this ongoing research continues. The vascular studies are coordinated with other VA research centers engaged in similar studies, and with colleagues throughout the world. The implications of this research work at the clinical level indicate its high priority for many persons in the VA population. Working as a cooperative team are Doctors Pedegana, Matsen, Holloway, and Thiele, together with supportive technical staff.

An excellent animal model has been developed to conduct basic research using the rabbit limb. Selected degrees of ischemia are produced surgically in the limb—then studied with the modalities under consideration.

Clinical Amputee Service, VA Medical Center, Seattle

Under the supervision of Dr. Burgess and Dr. Pedegana, the large and active amputee service, both inpatient and outpatient, at the VA Medical Center, Seattle, is the base for clinical improvement of amputee care of veterans. The amputee center and prosthetic and orthotic facilities provide backup support. Patient load at this time averages 10 to 15 amputations per month. PRS maintains a research file and protocol on the majority of these patients. They are included in evaluation and wound-healing studies; in surgical and postoperative management techniques and in rehabilitation. This facility serves as a basic teaching source locally and nationally. It is also frequently visited by science persons and clinicians from other countries observing our management system.

Amputee Workshop

A national workshop, on care of the amputee within the Veterans Administration, was held in Seattle on March 29–30, 1979. The 49 people attending represented resource expertise from both within and without the Veterans Administration. VA RER&DS persons and amputee veterans themselves were also present and participated. The preliminary findings of this workshop have been sent to the VA-RER&DS, Washington, D.C. The report is underway with recommendations.

Foot Biomechanics: Force and Pressure Distribution in Health and Disease

VA Medical Center
Iowa City, Iowa 52240
Reginald R. Cooper, M.D.

The magnitude of foot problems, the pain and suffering produced, and the disability and economic loss demand greater attention to these conditions than they have received in the past.

Data Development

Data will be developed (semiquantitative and quantitative) upon which to base better foot care (medical, surgical, rehabilitative) for patients with neurovascular disease (diabetes, rheumatoid arthritis, neuromuscular disorders) and "common foot disorders". Thousands of dollars are spent each year on "special shoes", foot devices, and orthoses, prescribed with little if any data to support their use. By determining normal foot dynamics in stance and during gait, and by delineating alterations in disease, the data collected will be of help in the design of footwear, orthoses, and surgical procedures to return force and pressure distribution toward normal.

A major thrust of this research will be to develop methods to monitor pressure distribution between the foot and the sole of the shoe. Much past research has measured the force between the foot or shoe and the floor; however, when studying abnormalities of the foot, measurements of local pressure under various parts of the foot within the shoe assume much greater significance. Measurement of foot contact pressure within the shoe presents numerous interesting technological problems.

Specific aims of this research are:

1. To develop, modify, and apply methods of recording absolute and relative pressure distribution during stance and gait (static

and dynamic recording), with and without shoes. (Short term: 1-to-2 yrs).

a. Semiquantitative methods: photometric, Harris mat footprint, slipper socks.

b. Quantitative methods: modification of existing transducers and development of a transducer that is easy to apply, will not alter gait, that is capable of use inside shoes, is linear in response, and comfortable.

2. To develop, modify, and apply quantitative recording of temporal dimensions of pressure application, by determining the activity levels of patients before and after treatment. (Short term: 1-to-2 yrs). Podometers fitted into shoes, to count the number of times a person steps on the foot with a load above a given percentage of body weight, will be used.
3. To quantitatively record force transmission through the foot by a piezoelectric force plate capable of measuring the three orthog-

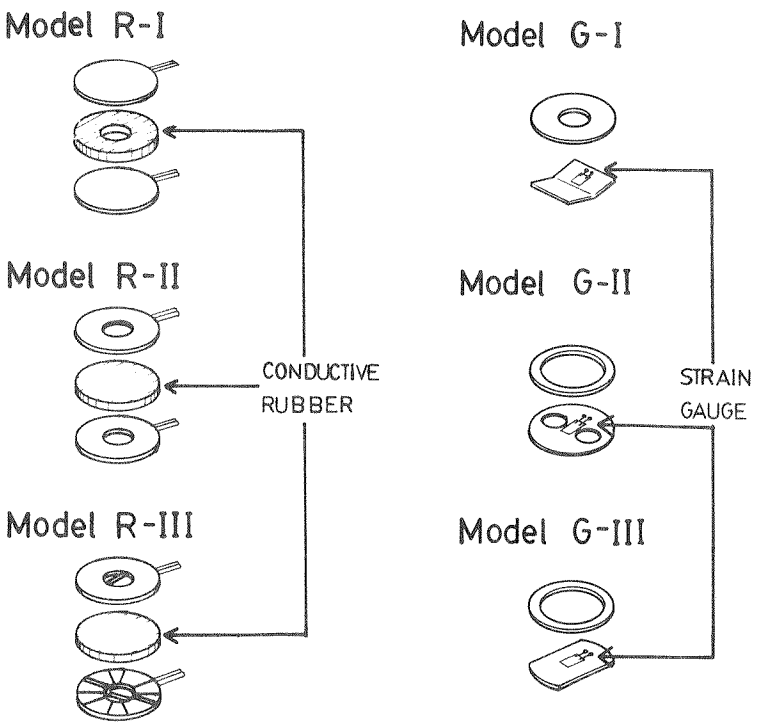


FIGURE 15. — Diagram of Pressure Transducer Assembly.

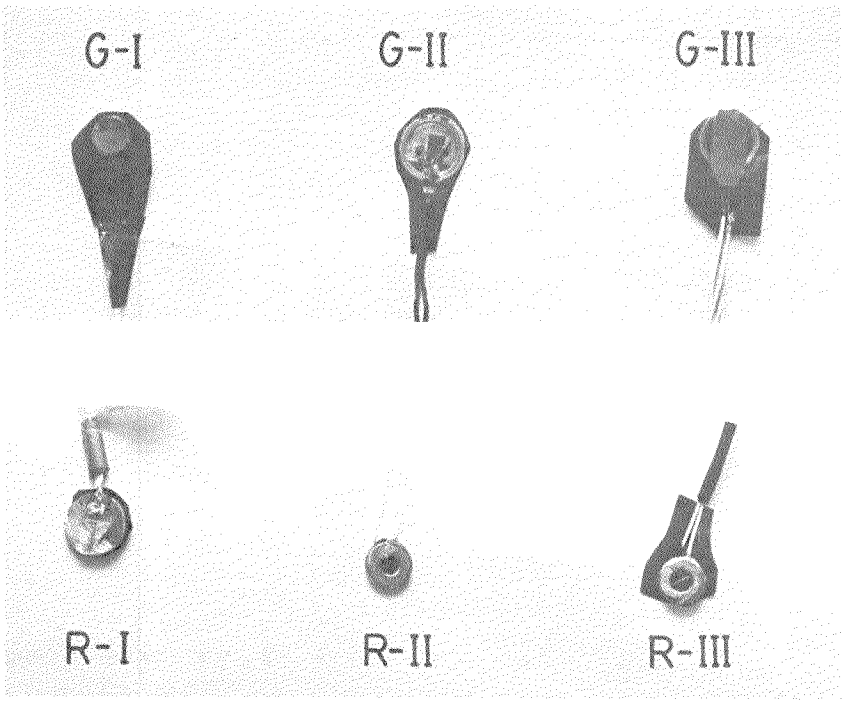


FIGURE 16.—Thin (2 mm) transducers which can be attached to the sole of the foot.

onal components of the floor reaction force and the moment generated in the horizontal plane. (Long term: 3-to-5 yrs).

4. To quantitatively record thermal output from the skin over the foot by thermography. (Long term: 3-to-5 yrs).
5. To develop photographic and X-ray techniques for recording foot configuration. (Short term: 1-to-2 yrs).
6. To apply these measurements to normal feet. (Short term: 1-to-2 yrs).
7. To apply these measurements to normal feet in various types of shoes and with a variety of insoles and heel and shoe sole modifications. (Intermediate: 2-to-3 yrs).
8. To apply these measurements in a variety of static and dynamic foot disorders in diabetics, rheumatoid arthritics, those with neuromuscular disease, and in patients with cavus feet, prominent metatarsal heads, heel spurs, etc. (Long term: 2-to-5 yrs).
9. To identify and apply the measurements (from those listed above) which are useful in determining which shoe alterations, orthoses, or surgery return foot mechanics toward normal in the disorders listed in "8" above. (Long term: 2-to-5 yrs).

10. To design new types of insoles, shoe alterations, orthoses, and operations for the unfortunate victims of these rather common disorders. (Long term: 2-to-5 yrs).
11. To establish baseline determinations for more sophisticated biomechanical studies in future years.

Progress Report: October 1, 1978-June 1979

The major initial effort, along with Dr. Roy Crowninshield, engineer, and Sachio Nokamura, has been the beginning of development and testing of thin (2 mm) transducers which can be attached to the sole of the foot (Fig. 16 and 17). The first models were based on the electrical-mechanical behavior of carbon-impregnated silicone rubber. A typical output of a current model: Figure 17.

Development continues on transducers. Mathematical models of the foot and parts of the shoe, using a finite-element technique, will be started, and experimental validation of the models will be sought.

Permanently Attached Artificial Limbs

Southwest Research Institute
8500 Culebra Road
San Antonio, Texas 78284
C. William Hall, M.D. and William H. Mallow

During the development of the permanently attached artificial limb, considerable knowledge has been attained in the use of skin interfacing techniques. There are many applications that can be made using these techniques to solve the problems encountered where long-term percutaneous penetration is required. Among these requirements are skeletal traction using Steinmann's pin and external fixation devices using percutaneous bone screws.

The most common complication of skeletal traction and external fixation devices used to immobilize fractures is infection occuring at the pin-skin interface. While there are several causes for these infections, including motion of the pin and improper insertion techniques, the most common cause is the persistent sinus itself which allows constant communication between the deep tissues and the external environment. Two materials have been successfully applied as a skin interface between the metallic lug of the permanently attached artificial limb and the surrounding tissue — Proplast and velour fabric woven from Dacron. These materials provide a scaffold for fibrous tissue ingrowth and effectively seal a skin defect.

These two materials have been fabricated into a sleeve that can be

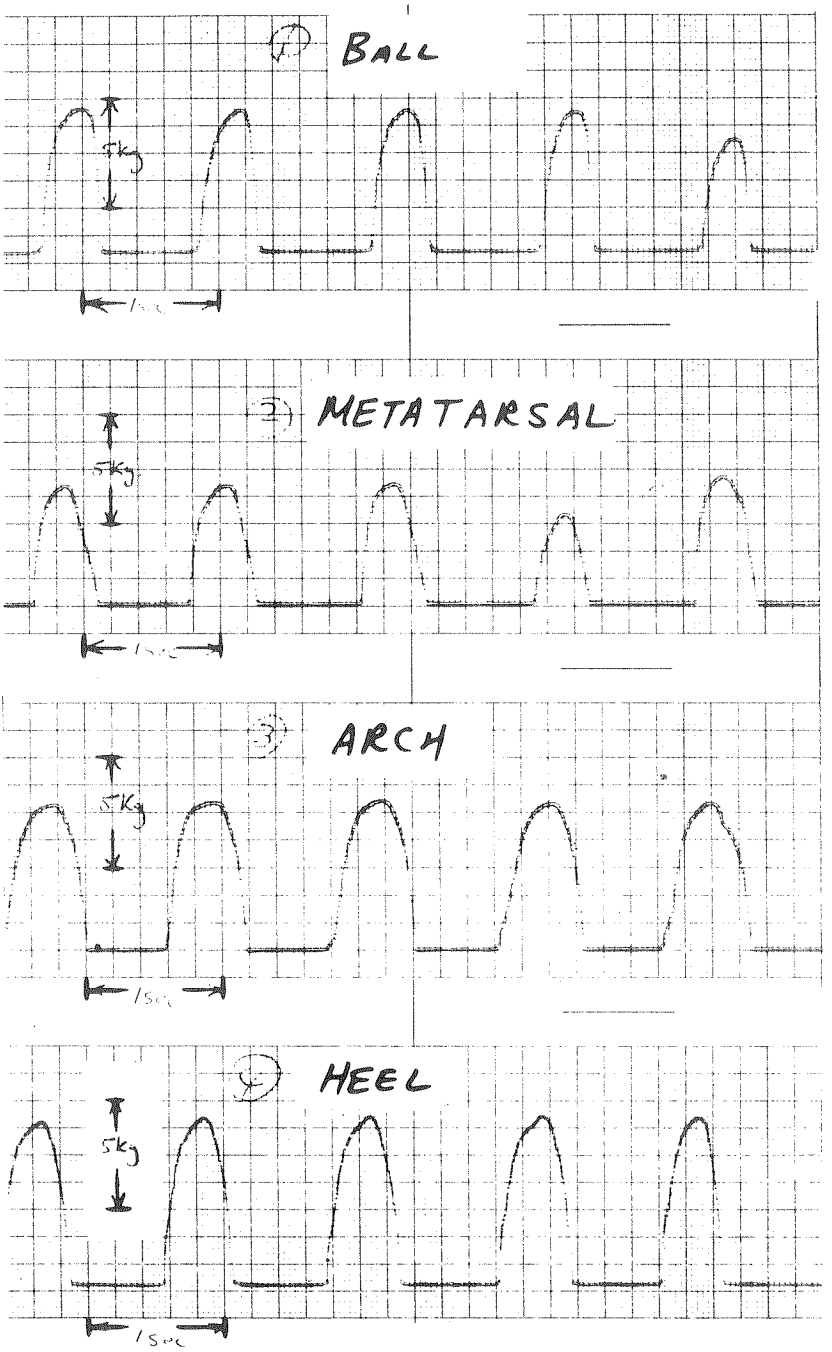


FIGURE 17 — Force/time displacements of foot sensors

positioned over the pin at the skin exit site. The sleeve is made from Silastic tubing of an appropriate caliber that has the interfacing material (either Proplast or velour) bonded to its outer surface (Fig. 18). Once in place, fibrous tissue ingrowth into the sleeve forms a basement upon which epithelial tissue grows, thus providing a bacteriologic seal to prevent microbial invasion. Both materials have been previously implanted in humans and have shown good tissue ingrowth. No deleterious side effects from these materials have been reported.

Since sufficient animal studies have been obtained to document the effectiveness of these materials and human implant data also exists, it appears timely to evaluate these sleeves in humans. The following protocol was submitted to the Institutional Review Board of the University of Texas Health Science Center at San Antonio and was approved as submitted.

"The Effect of Dacron and Proplast Cuffs Upon the Rate of Skeletal Pin Tract Infection"

James D. Heckman, M.D.
Assistant Professor, Department of Surgery
The University of Texas Health Science Center
at San Antonio

C. William Hall, M.D.
Institute Medical Scientist
Southwest Research Institute
San Antonio, Texas

One hundred fifty consecutive fracture patients, for whom the standard method of treatment would include skeletal traction, and/or external pin fixation, will be used in the study. All patients, after giving informed consent, will have standard traction or external fixation devices placed in a sterile fashion as would be appropriate for the care of their particular fracture.

The patients will then be randomly divided into three groups. Group "A" will have Proplast cuffs applied to the pins at the skin interfaces. Group "B" will have Dacron Velour cuffs applied at the skin interfaces. Group "C", the controls, will have no cuffs applied.

A sterile dressing will be applied to all pins for 48 hours. Following this, a standard method of pin care will be established and used in all patients. The pin tract sites will be cleaned daily with hydrogen peroxide and a sterile dressing will be reapplied.

At 48 hours, and daily thereafter until pin removal or hospital

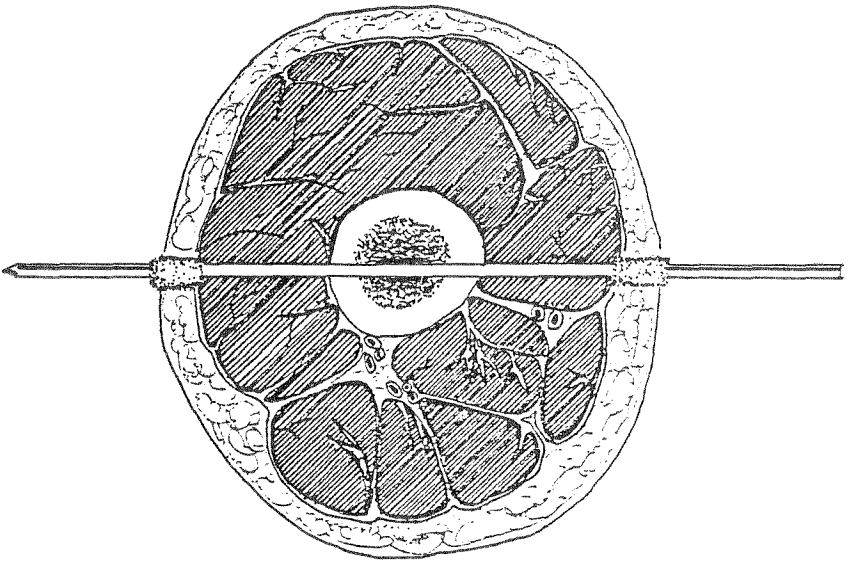


FIGURE 18. — Invention disclosure description.

lischarge, the pin sites will be examined for: a. Redness, b. Swelling, ınd c. Serous or purulent drainage. All drainage will be cultured. Any hanges will be documented photographically.

After pin removal, all pin sites will be rechecked at three and six ınonths from the time of insertion. Any symptomatic pin site will be examined by X-ray for evidence of bony changes (i.e., failure to heal or infection).

The rates of cellulitis, purulent drainage, loosening of the pin, skin necrosis, pin breakage, premature pin removal, deep bone infection, pin tract pain, swelling, and positive bacteria cultures will be determined and compared between the three groups. These comparisons will be used to assess the efficacy of decreasing pin tract complication by the use of the Proplast or Dacron Velour cuffs.

The Proplast sleeves were fabricated by Dr. Charles Homsy of Vitek Corporation, Houston, Texas, and the Dacron velour Sleeves were fabricated by Ms. Cindy Lew of Southwest Research Institute, San Antonio, Texas. The drawings shown in Fig. 18 are from the origional patent disclosure submitted to the Veterans Administration by Dr. C. William Hall. This marks the first clinical application of material and techniques involving the research efforts of this program.

Clinical and Laboratory Investigation of the Application of Transcutaneous PO_2 Monitoring in the Assessment of Local Circulation

University of Washington Department of Orthopaedics Limb Viability Laboratory
Frederick A. Matsen III, M.D., and Craig R. Wyss, Ph. D.

Prosthetics Research Study
Eklind Hall, Room 409
1102 Columbia Street, Seattle Washington 98104
Ernest M. Burgess, M.D., Larry R. Pedegana, M.D., and Charles W. Simmons

Veterans Administration Medical Center
Seattle, Washington
Brian L. Thiele, M.D.

Proper evaluation and management of patients with peripheral vascular disease requires a practical method for quantitating the severity of peripheral vascular insufficiency. The Limb Viability Research Group is investigating the application of transcutaneous PO_2 ($TcPO_2$) monitoring to this clinical situation. Preliminary results with this simple, non-invasive technique are encouraging: $TcPO_2$ values appear to correlate with the severity of peripheral vascular disease and to respond appropriately to placing the limb in the elevated and dependent positions. The result of initial clinical studies are summarized in two papers (3,4).

The Limb Viability Research Group is also investigating $TcPO_2$ monitoring in animal model systems. In a model of peripheral vascular disease in the rabbit, $TcPO_2$ measurements correlated well with the patency of the femoral artery and with the presence or absence of collateral circulation(1). In other animal investigations, a decrease in $TcPO_2$ values appeared to be an early sign of hemorrhagic shock(2).

Encouraged by these early results, the research group wishes to further investigate $TcPO_2$ monitoring as a clinical tool for the assessment of oxygen delivery to the skin, with particular application in the evaluation of the patients with peripheral vascular disease, patients at risk of shock, patients requiring amputation, and patients having replantation of amputated parts.

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Below-Knee Amputation with Immediate Postoperative Fitting of Prosthesis

Tucson VA Medical Center
Tucson, Arizona 85723
Wesley S. Moore, M.D.

The Prosthetics Study Research Program at the Veterans Administration Hospital, Tucson, is pleased to report that the remodeling of the Prosthetics Research Laboratory is now complete, the equipment has been ordered, and it will be installed shortly. The clinical evaluation of $Xenon^{133}$ clearance, used in a prospective fashion for amputation level selection, is proceeding better than expected. To date, more than 68 amputations have been performed with level selection based upon capillary skin blood flow. The original observation that flow rates in excess of 2.6 ml/100g tissue/min are adequate to permit primary skin healing continues to be substantiated. All amputation levels—ranging from partial foot through BK, knee disarticulation, and AK — have healed primarily when this flow criterion has been met.

Plans are proceeding well for the trial of a pilot program to study the feasibility of a regional referral amputation center within the Veterans Administration.[a] As soon as the laboratory is complete and functional, contact will be made with the other VA Hospitals in the region to solicit their cooperation in referring their amputation cases to the Tucson VA Hospital for primary care.

[a]An article by Dr. Moore and his associates in this issue of BPR discusses the concept of regional referral amputation centers within the VA.

Hemodynamic Evaluation of Postoperative and Preoperative Amputees

Castle Point VA Medical Center
Castle Point, New York 12511
Bok Y. Lee, M.D., Frieda S. Trainor, Ph. D., David Kavner, D.Eng., and John L. Madden, M.D.

Data Analysis of Effectiveness of Lumbar Sympathectomy

Initial analysis of data has been accomplished, and preliminary predictive criteria of the effectiveness of lumbar sympathectomy in the treatment of severe ischemia of the lower limb have been established. The noninvasive techniques used to establish these criteria were thermistor thermometry, Doppler ultrasound flowmetry, and noninvasive electromagnetic flowmetry.

Ninety-three consecutive lumbar sympathectomies done for severe tissue ischemia, rest pain, or pregangrenous changes, in patients not amenable to direct arterial surgery, formed the basis of this study. Patients were divided into two groups on the basis of whether the patient underwent subsequent amputation (A group) or amputation was not required (non-A group). The presence of atherosclerotic occlusive disease was documented by arteriography. Thermistor thermometry was used to measure room, forehead, ankle, and toe temperatures; Doppler ultrasonic flowmetry was used to determine ankle systolic pressure; and noninvasive electromagnetic flowmetry was used to determine peak pulsatile calf blood flow.

Room, forehead, and ankle temperatures were relatively constant for both groups, with no statistically significant differences observed.

Toe/forehead and toe/room temperature ratios were of low significance ($P>0.02$).

Toe temperature differences (non-A: 29.25±2.36°C, A: 27.25 ±2.25°C), toe/ankle ratio differences (non-A: 0.96 ±0.05, A: 0.89±0.07), and ankle/room ratio differences (non-A: 1.21±0.09, A: 1.17±0.05) were all found to be highly significant ($P<0.001$).

The ischemic index was also statistically significant (non-A: 0.60±0.26, A: 0.32±0.37, $P<0.01$).

A large difference in peak pulsatile calf flow (non-A: 30.78±32ml/min, A: 16.27±12.38ml/min) was found to be of low significance ($P>0.05$) because of large intragroup variation.

It has been concluded that patients with an ischemic index >0.40, peak pulsatile calf blood flow >30ml/min, with an absence of an ankle-toe temperature gradient, and an ankle/room temperature ratio >1.17 should be expected to benefit from lumbar sympathectomy.

Identification of Muscle Fatigue by EMG Power Spectrum Analysis

Orthopedic Surgery Section
VA Medical Center
4500 S. Lancaster
Dallas, Texas 75216
Richard E. Jones, M.D., Vert Mooney, M.D., and Timothy Carmichael, Engr.

Introduction

The purpose of this project is to develop clinically useful methods and equipment for identifying localized muscle fatigue by the use of electromyogram power spectrum analysis. This research was initiated January 1, 1979.

Background

Muscle fatigue is an important limitation to rehabilitation of postinjury or postsurgical problems related to the musculoskeletal system. At present there are two clinical methods of evaluating fatigue:

1. Measurement of muscle mechanical strength, which requires considerable patient motivation and cooperation; and
2. Biochemical analysis involving invasive biopsy procedures, a method which is suitable only in limited situations.

Recent studies of the electromyogram frequency power spectrum have confirmed the presence of spectral power shifts associated with muscular fatigue. Spectrum analysis can provide an effective technique for evaluating fatigue. The objective of this project is to develop a functional myoelectric analysis method.

Methodology

The scheduled research will involve four phases:

1. Develop a reliable technique of obtaining and recording EMG data, using surface and needle electrodes.
2. Accurately characterize the EMG power spectrum signatures for both normal and fatigued muscles.
3. Determine an analytical method of identifying fatigue-related EMG spectral shifts.
4. Design, manufacture, and test a microcomputer-based clinical instrument which performs fatigue analysis.

Project Status

All equipment required to amplify, filter, record, and display analog EMG data has been ordered, and assembly has been initiated. Data collection should begin in July, 1979.

Engineering Applications in Orthotic and Prosthetic Treatment of Musculoskeletal Defects

Motion Study Laboratory
Rehabilitation Medicine Service
Cleveland VA Medical Center
10701 East Boulevard
Wade Park, Cleveland, Ohio 44106
E. Byron Marsolais, M.D., Ph. D.

No progress report for this period was received in time for publication in this issue of BPR.

Patient Evaluation of a Functional Electrical Stimulation Hand Orthosis

Cleveland VA Medical Center
10701 East Boulevard
Wade Park, Cleveland, Ohio 44106
P. Hunter Peckham, Ph. D.

Introduction

The purpose of this project is to develop and evaluate upper-limb orthotic systems activated by functional electrical stimulation of paralyzed muscle. Two systems are under development. The first is designed to provide prehension and release in the C-5 quadriplegic patient; the second to provide control of lateral pinch, or key grip and release, in the C-6 quadriplegic.

Prehension and Release in the C-5 Quadriplegic

Electrical excitation applied to the finger flexor and extensor muscles is commanded, proportionally, by a control signal derived from the position of the shoulder or head. Zero reference position (on/off) and hold commands are activated by a two-level myoelectric signal. Hand movement is restricted to the metacarpal-phalangeal joint, with other joints stabilized by a wrist-hand orthosis. Details are provided in previous BPR reports.

Two patients, described in BPR 10-31, are involved in the evaluation of this system. For both M.V.R. and J.H.L., usage has not been regular, but rather has been limited to situations primarily in the home, when independence was important. Formerly, both have used the systems regularly in their employment or while attending college. However, at present neither is actively pursuing activity away from the home where they formerly used their systems. In addition, for subject J.H.L., some inadvertent activation of the myoelectric switch

has been encountered, either through interaction between movement with shoulder controller and the biceps, or by biceps spasms. Other sites which are acceptable, such as the sternocleidomastoid muscle, are being investigated.

Lateral Pinch and Release in the C-6 Quadriplegic

Lateral pinch is the primary grasping pattern for the C-6 quadriplegic, and is achieved by passive tenodesis which accompanies voluntary wrist extension. The grasp achieved generally is sufficient to manipulate lightweight objects, but is insufficient to hold them securely. Functional electrical stimulation of paralyzed hand/forearm musculature is being investigated for augmentation of tenodesis grip, to enable these patients to grasp securely, primarily during tonic activities.

The system that has been developed is described in block diagram form in Figure 19. Briefly, myoelectric activity from a muscle with voluntary activity is sensed and processed, and used to control the stimulus applied to the musculature. The muscles activated are the adductor pollicus (AdP) or opponens pollicus (OP) for thumb motion, the flexor digitorum superficialis and/or profundus (FDS/P) for finger flexion, and extensor pollicus longus (EPL) for thumb extension. No external orthosis is used in conjunction with this system. To enable a single command site to govern activation of all muscles used in grasp, a timing sequence was adopted which always activated the finger flexor muscles before the thumb. This insured that the thumb closed on the lateral aspect of the index finger.

Myoelectric control was chosen for this system because of its potential simplicity of operation and ease of donning. To obtain pro-

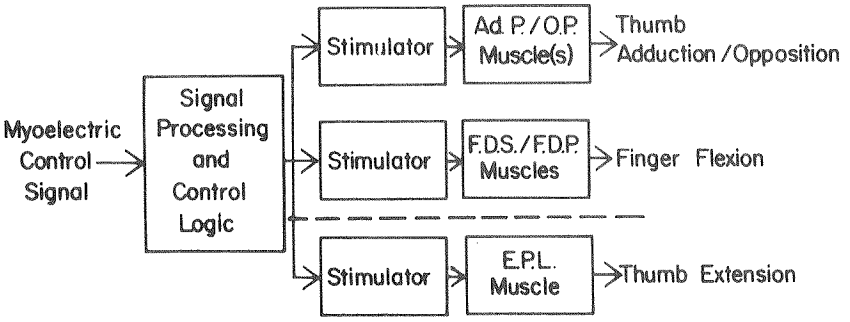

FIGURE 19.—Block diagram of system used for control of lateral pinch and release by functional electrical stimulation. Myoelectric activity is sensed from a single site retaining voluntary activity and used to control the stimulus applied to each of the muscle groups.

portional control of the command signal, as required for precise manipulation of the hand, a control scheme was devised which was proportional in time. Figure 20 illustrates the techniques employed in that system.

The acknowledged limitation of such a control scheme is the sacrifice in speed. To compensate in part for this limitation, the ramping speed can be tailored to the individual subject, with the release ramping rate generally being several times faster than grasping rate. When used in conjunction with a system employing functional electrical stimulation, the use of this control technique eliminates one of the significant assets (speed of response) which is inherent in electrically excited muscle. However, in this particular application that tradeoff appears to be justified, based on the mode of use (tonic activities requiring infrequent and slow control) and the other advantages previously alluded to. Further studies are required to investigate functional advantages with other proportional control sources, such as those employed in the C-5 system.

The sternocleidomastoid (SCM) muscle is presently being used as the control site. This muscle has been easy for subjects to learn to activate, only infrequently generates erroneous commands, and is relatively insensitive to electrode positioning (with surface recording electrodes), but has the disadvantage of electrodes being partially visible above the collar. Presently, pediatric surface electrodes are utilized for signal acquisition, but more cost-effective techniques are warranted and will receive future consideration.

Several sites for implantation of the percutaneous stimulating electrodes have been utilized. All are on the forearm just proximal to the wrist and require electrodes to be implanted both proximally and distally from the surface connector block. The initial technique utilized both volar and dorsal connectors (the former for the OP and FDS/P; the latter for EPL). The use of a single volar connector was achieved by passing the EPL electrode either through the interosseus membrane or subcutaneously around the radius with a curved needle. Recently, a single dorsal implant site has been utilized, which provides for direct implantation to the AdP. The dorsal site was selected to reduce mechanical abrasion to the connector during routine daily activity, such as pushing a wheelchair. To date, only one dislodgement of connectors on the distal forearm has occurred.

In the past period, the MES control circuitry has been completed in breadboard form and implemented in conjunction with one patient stimulator (see BPR 10-31). This circuitry is presently being implemented in a printed circuit version to speed fabrication of additional units and insure reliability.

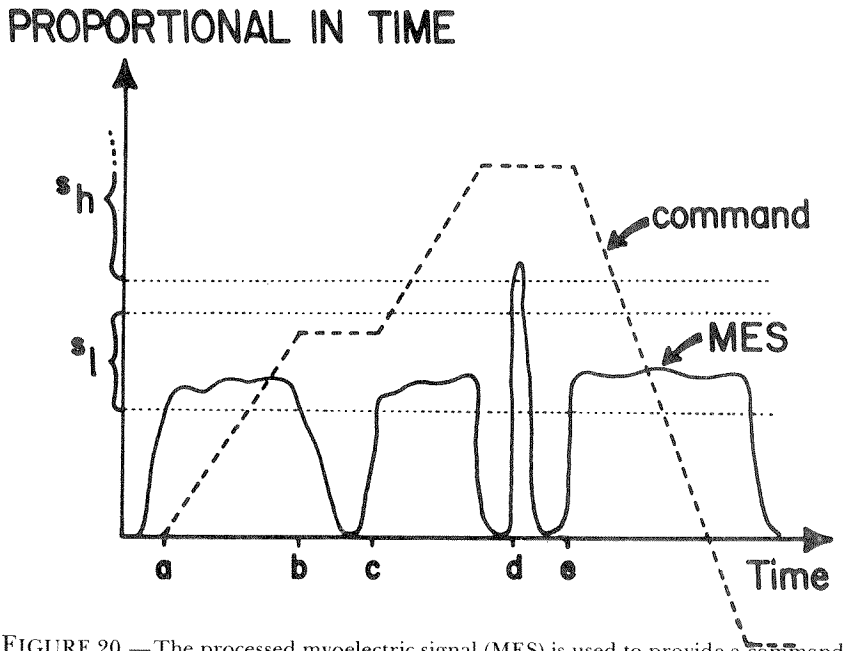

FIGURE 20.—The processed myoelectric signal (MES) is used to provide a command which is proportional in time. A low-level MES increased or decreased the command in proportion to the amount of time the level was held; a short high-level MES reversed the direction of command change; a long high-level MES turned the system off; a subthreshold MES did not alter the command.

In the example, when a patient wishing to grasp exceeds the low level (a), the output increases to provide grasp. When the force reaches the desired level, the patient allows his MES level to fall to subthreshold (b), and the output remains fixed until another low level (c) causes the output to increase further. In release, a short high MES (d) and then a low MES (e) are given to decrease the grasp force and then increase the thumb extension command. To turn the system off a high MES is held for longer than 500 ms.

At present, five subjects are involved in this aspect of the program. Four are C-6 quadriplegic subjects, one of whom has been fitted with the initial patient system. He is currently attending college and uses the system in daily activities. The others are in various phases of the program and will be fitted with stimulators as fabrication is completed. The fifth subject is a C-5 quadriplegic who is implanted with electrodes for both the prehension-release and the lateral pinch-release systems. With this subject, the various combinations of control shemes and active muscles which are alternatives to the present systems will be investigated. In particular, the use of position control with the lateral pinch-release system will be explored, using a conventional dorsal wrist support for wrist stabilization. This has the poten-

tial advantage of eliminating the orthosis used in the present prehension release system.

Studies of Normal and Abnormal Motion
Kinesiology Research Laboratory
Wood VA Medical Center
Wood, Wisconsin 33193
Mary Patricia Murray, Ph. D.

A study was completed to determine whether there are differences in the functional performance of patients with Müller and Charnley total hip replacements (1). The determination was based on comprehensive kinesiologic measurements of the functional performance of 75 patients who had 89 hip replacements. The measurements, which were made before surgery and 6 and 24 months after surgery, included the strength of the hip abductor and adductor muscles, range of hip joint motion, the amount of weight borne on the involved limb during standing posture, multiple components of free-speed and fast walking, and forces applied to canes and crutches.

The patients with both types of hip replacement improved significantly in most components of function after surgery. The greatest amount of improvement usually occurred during the first 6 postoperative months, but there was often substantial additional improvement between 6 months and 2 years postoperatively.

A 4-year followup study of these patients, to determine how long significant improvement is sustained after total hip replacement, is well underway. Assessment of the functional performance of patients with different types of total hip and total knee replacements, and with different types of surgical approaches to total hip replacement, is continuing as are measurements of the walking performance of patients with different types of prostheses for above-knee amputations.

Data collected at the Kinesiology Research Laboratory were used by Leon Bennett, M.A.E., et al., to calculate the accelerative and braking cane impulses during locomotion for nine subjects with hip pain (2). The data supplied included the amplitude and duration of the force applied parallel to the shaft of the cane and simultaneous kinematic data of the average velocity and the changes in cane angle with respect to the floor. The average accelerative impulse was about two times greater than the average braking impulse. Accelerating impulses ranged from 0.6 to 3.8 lbf-sec and braking impulses ranged from 0.1 to 2.3 lbf-sec. The angles of the canes never exceeded more than 20 deg from the vertical during the walking cycle, indicating that

the largest part of the applied load was being used to decrease the vertical load on the hip joint.

Force plate, kinematic and electromyographic data of disabled patients measured at the Kinesiology Research Laboratory are being used to help validate a mathematical model of the human musculoskeletal system developed by Dr. Ali Seireg, Professor of Mechanical Engineering, University of Wisconsin—Madison, and consultant to the Kinesiology Research Laboratory. The model can be used to predict muscle activity and the changes in joint forces which will accompany various surgical procedures which alter the relative alignment of the body parts, such as in patients with tibial osteotomy.

Figure 21 shows the amount of increase in hip flexion-extension used during walking, and the decrease in lateral lurching of the head after surgery, for the men and women in both patient groups at both speeds of walking. In these components of function and most of the others, the patient groups did not reach the lower limits of the range of normal variability. Both groups did, however, reach or nearly reach the lower limits of normal variability in cadence during walking, in some components which relate to the smoothness of walking performance, and in tests which measured the amount of weight borne on the operated limb during quiet standing. The groups with Müller and with Charnley replacements differed from each other in only a few components of function: the amount of improvement in hip abductor muscle torque, movement into hip abduction, and movement into outward rotation. The differences between the groups were statistically significant for these components, but nevertheless appeared to be too small to conceivably affect the overall function of the patients.

Since our last progress report, a paper has been published which quantifies the deviations characteristic of the gait of patients with Parkinsonism (3). The 44 patients were categorized into groups with mild, moderate and severe disability, and the gait components which related to the degree of disability were identified.

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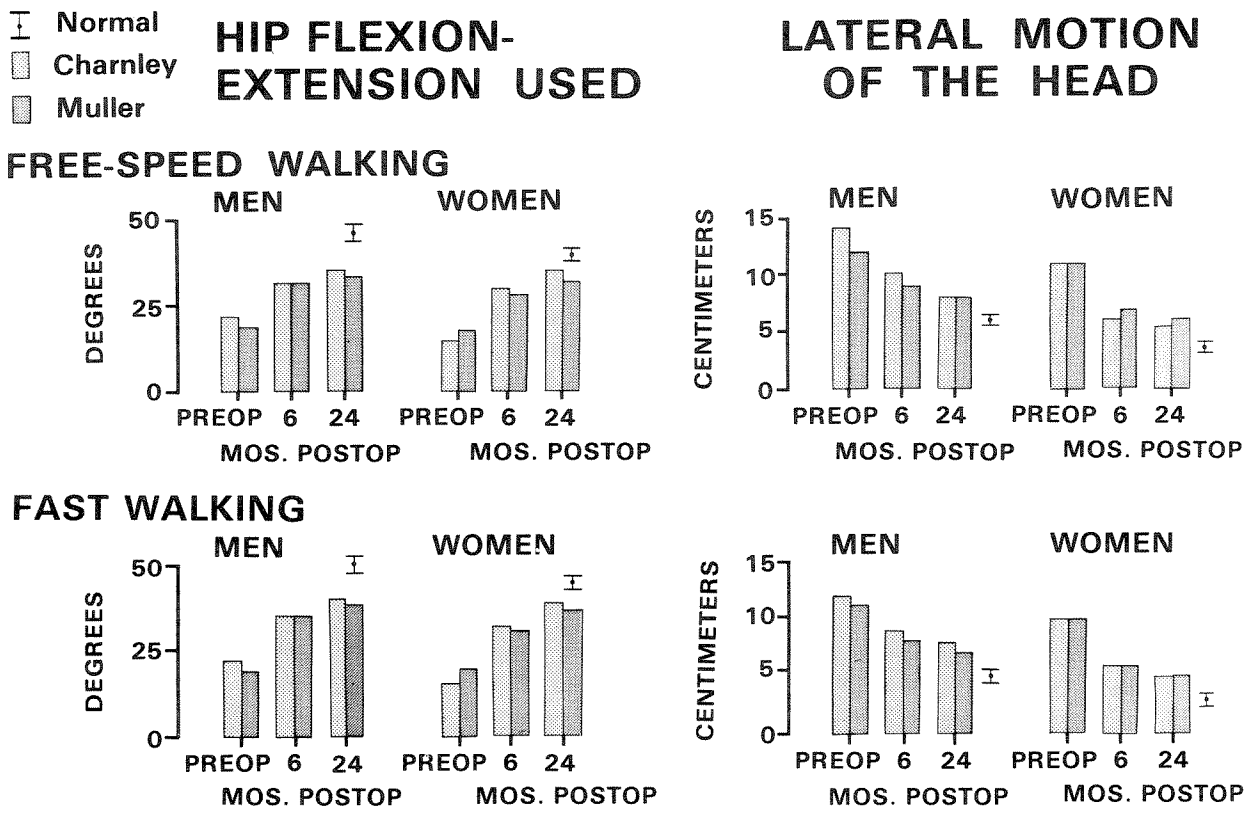

FIGURE 21.—Differences in the functional performance of patients with Müller and Charnley total hip replacements (1). Shown is the amount of increase in hip flexion-extension used during walking, and the decrease in lateral lurching of the head after surgery, at two speeds of walking.

Evaluation of Electrical Techniques for Stimulation of Hard Tissue Growth

Syracuse VA Medical Center
Irving Avenue and University Place
Syracuse, New York 13210
Robert O. Becker, M.D., J. A. Spadaro, Ph. D., and A. A. Marino, Ph. D.

This laboratory continues to study electrode induced bone growth in the rabbit medullary model. In this model, electrodes are inserted into the relatively undisturbed medullary canal of the rabbit femur and the resulting growth of bone around the electrode is measured (Fig. 22 and 23). Preliminary findings show that bone growth is enhanced by a cathodic DC current flow, but that bone also appears in lesser amounts around control electrodes which have not been stimulated. These effects seem at this time to be dependent on the type of metal chosen to be used as the electrode. Different current levels are being tested with these electrodes to see the dependence on this parameter.

Reports of this progress were made at the Orthopaedic Research Society meeting in February, 1979, and also at the special workshop held by the American Academy of Orthopaedic Surgeons in Atlanta, Georgia in April.

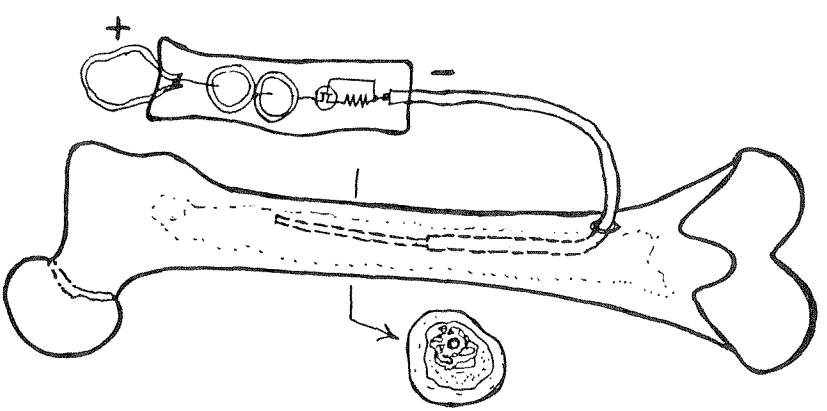

FIGURE 22.—Cathodic medullary implant in the rabbit femur. In this model, the response of the marrow and endosteal tissue is determined, while mechanical or surgical intervention at the site is minimized. The electrodes are of pure or surgical grade Pt, Au, Ag, Ti, 316L stainless steel and Vitallium F-90. The DC current levels used thus far are 0.02 and 0.2 $\mu A/mm^2$. The implant is epoxy and Silastic coated and the return electrode (anode) is silver in all cases. Non-active control electrodes were implanted on the contralateral femur throughout.

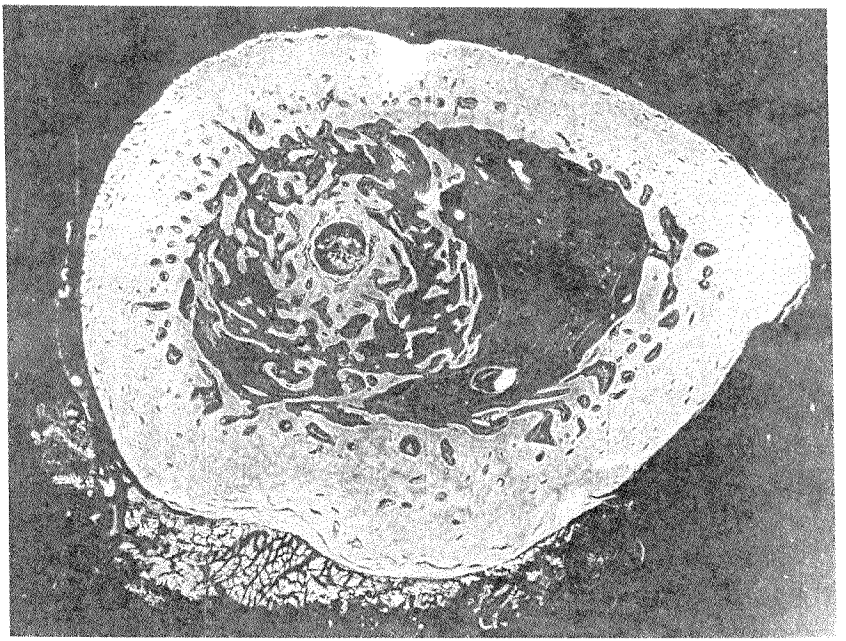

FIGURE 23.—A cross-section of rabbit femur having a platinum cathode (active) for three weeks. Note the trabecular bone pattern around the electrode hole and how it integrates with the endosteal bone. Quantitative measurements of bone mass are being made using about 90 animals (180 femurs), using a few representative cross-sections per specimen.

At the same time we are exploring the possibilities of electrical stimulation for healing of non-united fractures in cancellous bones, such as the scaphoid. Exploratory testing of the influence of weak electrically active materials such as bimetallic couplings and electrets are being made, first in tissue culture preparations of mammalian fibroblasts. Animal implants of the materials are also beginning in the laboratory.

A collaborative preliminary study of the utility of silver antibacterial bone cement to prevent acute infections in a rabbit model have been completed. This study was conducted at the Laboratory for Experimental Surgery at Davos, Switzerland. Collaborating were Dr. R. Dueland and the Davos research group under Dr. S.M. Perren. The findings showed that the silver cement could prevent significant mortality following the introduction of large amounts of bacteria into the long bones of the animals. It was almost as effective as adding gentamycin to the cement. Further studies of this material seem warranted.

Nicolas Andry Award

Dr. Robert O. Becker, Chief of Orthopedics, VA Medical Center, Syracuse, New York, was recently awarded the Nicolas Andry Award of the Association of Bone and Joint Surgeons for outstanding achievement in the field of orthopedic surgery. At the recent meeting of the Association in Toronto, Canada, Dr. Becker presented an overview of the present techniques for electrical stimulation of bone growth.

The Syracuse group is continuing to evaluate the newest techniques of electrically injected silver ions as local bactericidal agents. The clinical results to date have been sufficiently positive to warrant the institution of a large scale test program involving a number of other medical centers. This is planned to begin in August of 1979.

Acceleration of Bone Healing by Electrical Stimulation

Helen Hayes Hospital Biomechanics Research Unit
Route 9-W, West Haverstraw, New York 10933
George Van B. Cochran, M.D., Sc. D.

Development of the experimental model for non-union in the beagle ulna was completed at the end of last year. Efforts then turned to the study of stimulation of osteogenesis in the 1.5-cm bone defects by means of suitable microampere electric currents applied through stainless steel electrodes.

The object was to determine the effects of electrical current in different zones of the healing defect, using independently powered electrodes. The lead wires were passed subcutaneously to the dorsum where external power circuits were carried in a special jacket. Unfortunately, continued technical problems with this approach, including a high incidence of infection and electrode breakage, have made this method impractical. At present, the experiment is being continued utilizing commercial, planted stimulating units (Osteostim™ — implantable bone-growth stimulators).

Implantations of units with controls have been recently completed in four animals with no problems of infection. Evaluation of the results is in progress. This shift in technique has the advantage that, in addition to the original goals of the experiment, it will be possible to provide information on performance of a commercial bone stimulation unit intended for human implantations.

Acoustic Emission in Bone[a]

Section of Orthopedics
VA Medical Center
Augusta, Georgia 30904
Ed Berg, M.D.

Section of Orthopedics, Department of Surgery
Medical College of Georgia
Augusta, Georgia 30912
Paul J. Nicholls, M.D.

Airesearch Manufacturing Co. of California
2525 West 190th Street
Torrance, California 90509
Donald Nicholls, Instrumentation Engineer

Introduction

Sound has been used in physical diagnosis for many years. Peltier (1) credits René Laennec (2) with first using auscultation in diagnosis and his colleague LisFranc (3) in fracture diagnosis. Since that time, the use of sound has become much more sophisticated, to the point that ultrasound is at least an investigative technique for monitoring fracture progression to osseous union. Acoustic emission, on the other hand, evaluates the autogenous sound from a structure under stress.

Joseph Kaisar (4) first described acoustic emmission in 1950. He found that each metal tested produced sound when put under stress. He was also apparently the first person to electronically record and evaluate these properties. Since that time, the techniques of acoustic emission monitoring have improved to their current useful state. Hanagud et al. (5) (6) (7) (8) first used acoustic emission to study a biological material. They stressed bovine bone and attempted to define a different acoustic emission "signature" in a pathological condition, acetic-acid-induced osteoporosis (a calcium leach). The origin of these sounds, however, may have many causes: microcrack propagation, twining, or boundary shift are some of the recognized sources of these sounds. The technique has become a valuable method for assessing the structural integrity of pressure vessels, pipelines, aircraft components and glass-fiber-reinforced cherrypicker booms. The application of this technique to orthopedics remains to be described.

[a]Supported by the Rehabilitative Engineering Research and Development Service of the Veterans Administration; Section of Orthopedics, Medical College of Georgia; and Department of Energy, Savannah River Plant.

Method

Fourteen rabbit tibiae had 45 deg surgical midshaft osteotomies performed and then with internal fixation were allowed to heal for various periods of time. Two miniature piezoelectric, flat-response, transducers were used to record sounds on Dunegan/Endevco equipment (Dunegan/Endevco, Rancho Viejo Road, San Juan Capistrano, California 92675) as the specimen was loaded axially to failure. This equipment monitored the number of sound events generated in the bone as the fracture was stressed in shear (Fig. 24).

Results

Shown are graphs of the results of these experiments which plot the number of acoustic events on the ordinate against the load in pounds on the abscissa (Fig. 25). It can be seen that, with the exception of one fracture, all of the specimens remained essentially quiet until shortly prior to and during failure. On these charts, failure is the point where load can no longer be sustained by the oblique osteotomy.

Discussion

In rabbit tibiae, little sound is generated as the fracture callus is stressed until just prior to failure, at which point many acoustic events are generated, thus telling the observer that the bone is undergoing failure. The acoustic emission to Instron correlation at detecting failure is 93 percent in this study. This technique has a potential clinical application in that it is a nondestructive and noninvasive reliable means of assessing bony structural integrity. These possibilities are currently being studied.

This technique has been used to date in 55 patients with healing fractures. We have found 100 percent correlation in prediction of healing. The only nonunion was in a patient who had excessive noise

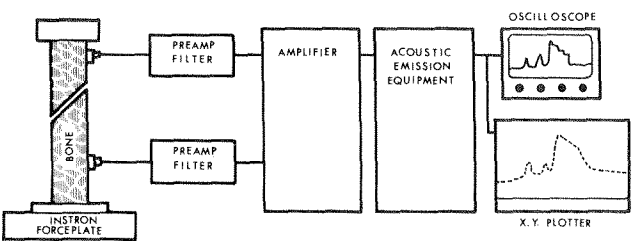

FIGURE 24.—This scheme depicts the test set-up, with acoustic emission monitoring devices attached to bone.

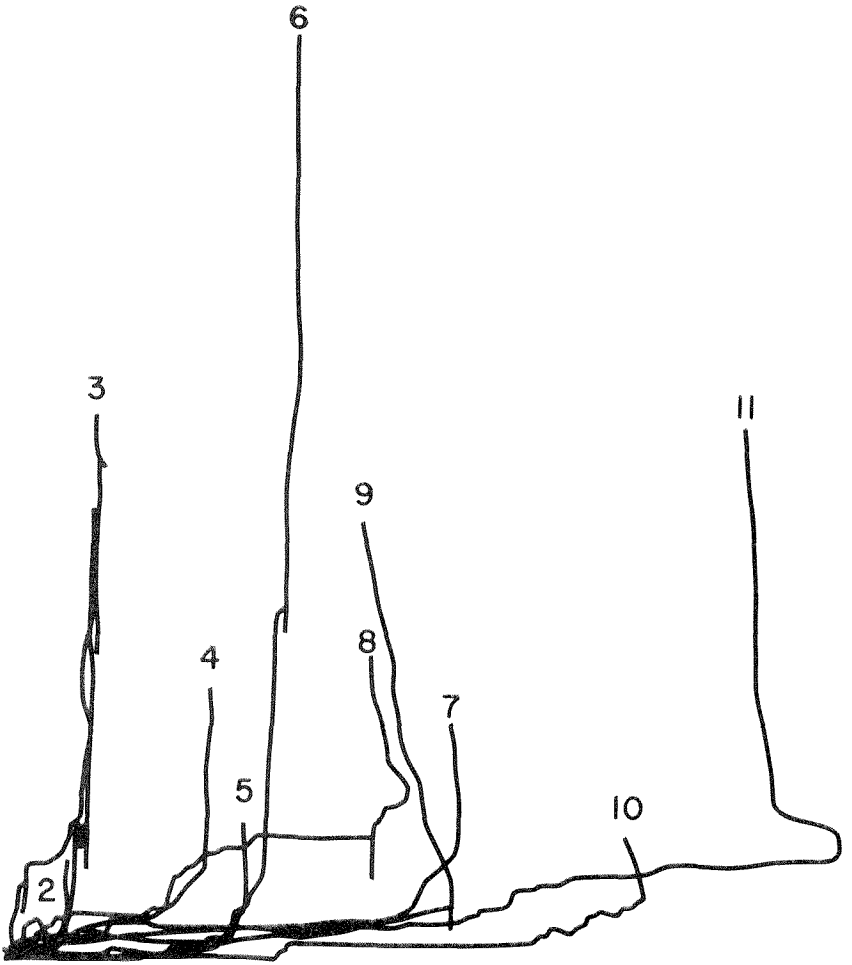

FIGURE 25.—Loads on horizontal axis and events on vertical axis. This figure depicts how 11 fractured tibiae responded to load when monitored with acoustic emission. Failure is the furthest progression of the lines to the right.

from the day of the initial fracture and did not match the other test results.

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Orthopedic Implant Device Retrieval and Analysis

New Orleans VA Medical Center
New Orleans, Louisiana 70146
Allan M. Weinstein, Ph. D.

In the period of January through June, 1979, mechanical testing on bone plates was completed. The plates were tested in the four-point loading configuration shown in Figure 26. The ASTM bend strength is defined as the bending moment required to produce a permanent deflection of 0.005 in. when tested in that configuration.

The bend strengths of the devices were related to the Rockwell hardness values for each implant. For the purposes of comparison, it was found convenient to group the implants according to type, size, and design. The Type 1 implants had an average width of .47 in. and an average thickness of .11 in. The heavier Type 2 implants had an average width of .63 in. and an average thickness of .17 in..

Figures 27 and 28 indicate a strong dependence of bend strength on hardness. In each case, a small increase in hardness results in a large increase in bend strength. Following mechanical testing, transverse and longitudinal sections of the bone plates and screws were mounted and metallographically prepared for microstructural examination. After polishing to a 0.3 μ finish, the inclusion contents were determined; the samples were then electrolytically etched in 10 percent ammonium persulfate. The grain sizes were determined by the ASTM comparison method. The vast majority of the samples had inclusion contents to 1 to 1½ and grain sizes of 6 to 7½ and were, therefore, within the relevant ASTM standards.

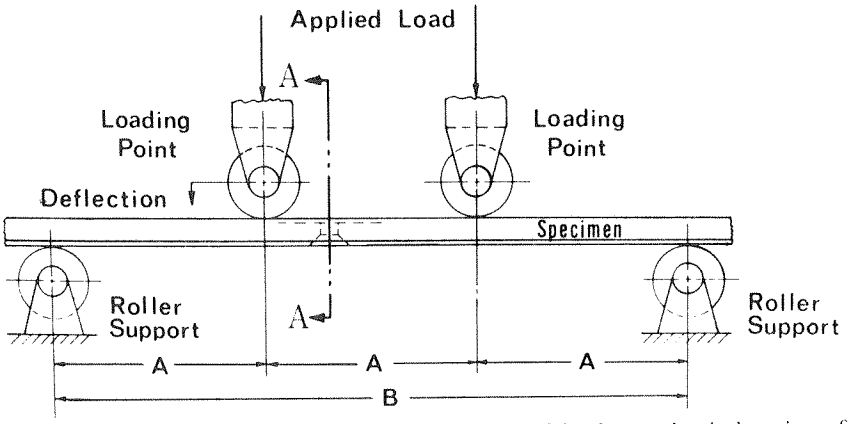

FIGURE 26. — Four-point loading configuration used in the mechanical testing of retrieved bone plates.

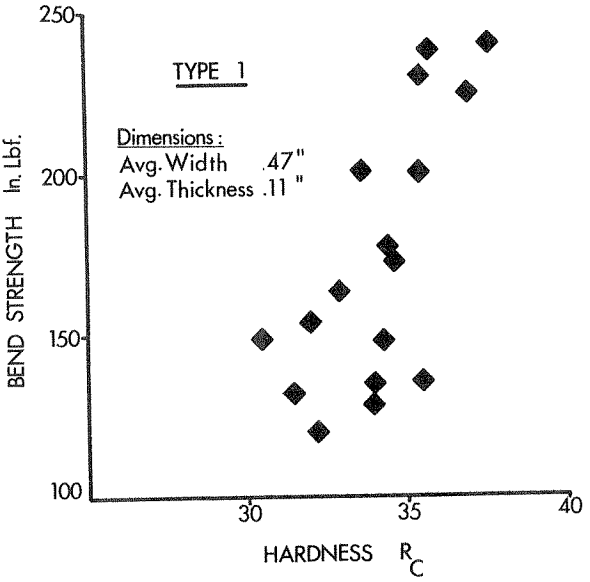

FIGURE 27. — Bend strength vs. Rockwell hardness for Type 1 bone plates.

Knoop microhardness measurements were made for each sample. The hardness values ranged from 161 to 404.

The severity of the corrosion in the bone plates was compared with that found in the screws. The corrosion grading scheme used is the same as that described in a previous report. Figures 29 and 30 com-

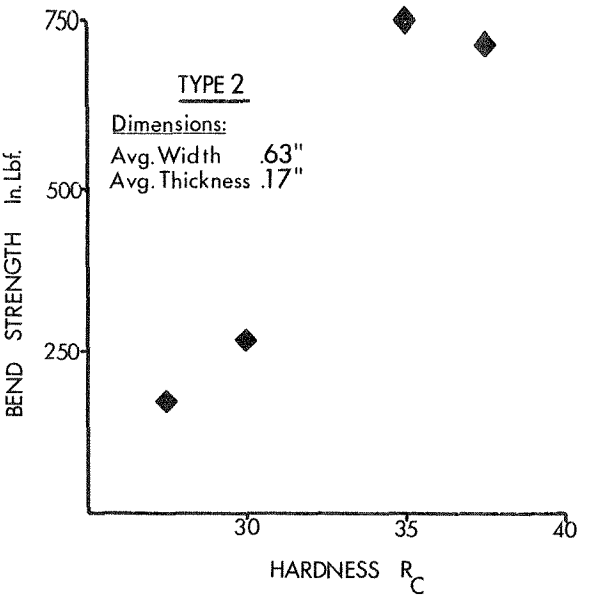

FIGURE 28. — Bend strength vs. Rockwell hardness for Type 2 bone plates.

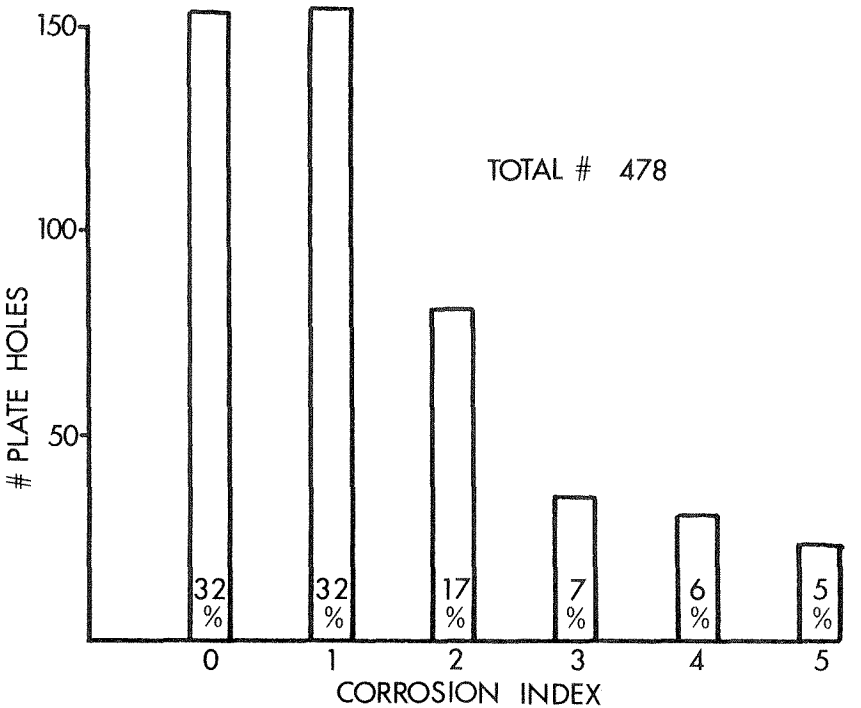

FIGURE 29. — Number of plate holes vs. corrosion index.

pare the number of plate holes vs. corrosion index with the number of screws vs. corrosion index; both screws and plates had corroded to a similar degree. Roughly one third of both screws and plate holes had undergone no corrosion while 81 percent and 79 percent of the plate holes and screws respectively had corrosion indices of 2 or less.

The percentage of the total number of plates having a given corrosion index can be seen in Figure 31. The mean corrosion index of 1.3 is also indicated on the histogram. It is apparent from this Figure and the preceding two that most of the plates had undergone mild-to-moderate corrosion. The average corrosion index is plotted against Rockwell hardness (Fig. 32) and against implantation time (Fig. 33). In both instances, there is no apparent correlation. Similarly, the extent of corrosion was found to be independent of grain size.

This information (coupled with the fact that the severity of corrosion in the bone plates varies from one screwhole to the next) suggests that crevice corrosion in bone plates depends on local factors such as tightness and perpendicularity of the individual screws, proximity to the fracture site, and motion of the patient.

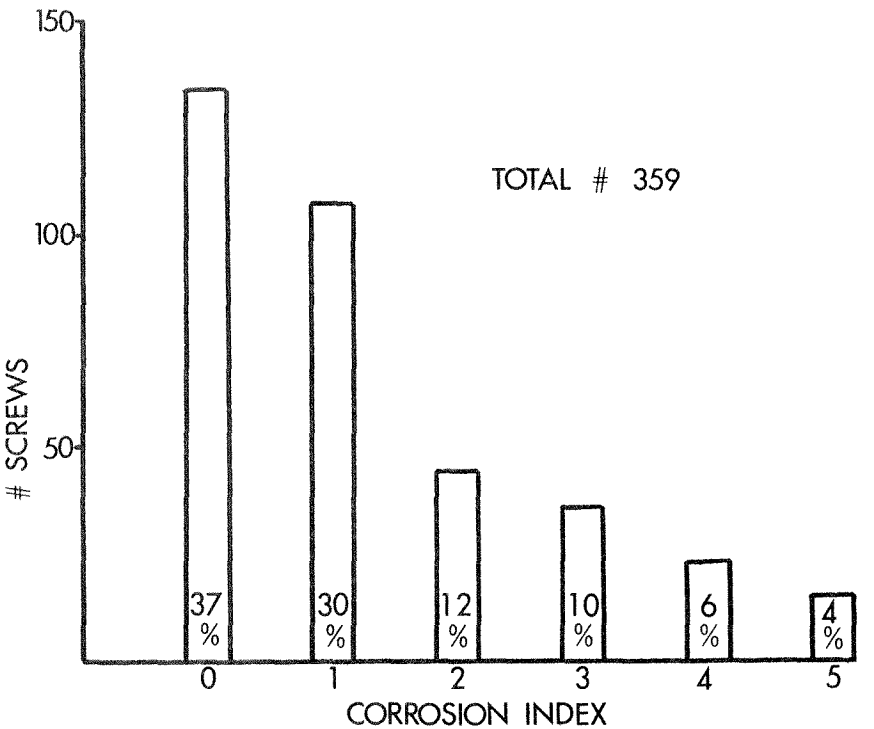

FIGURE 30. — Number of screws vs. corrosion index.

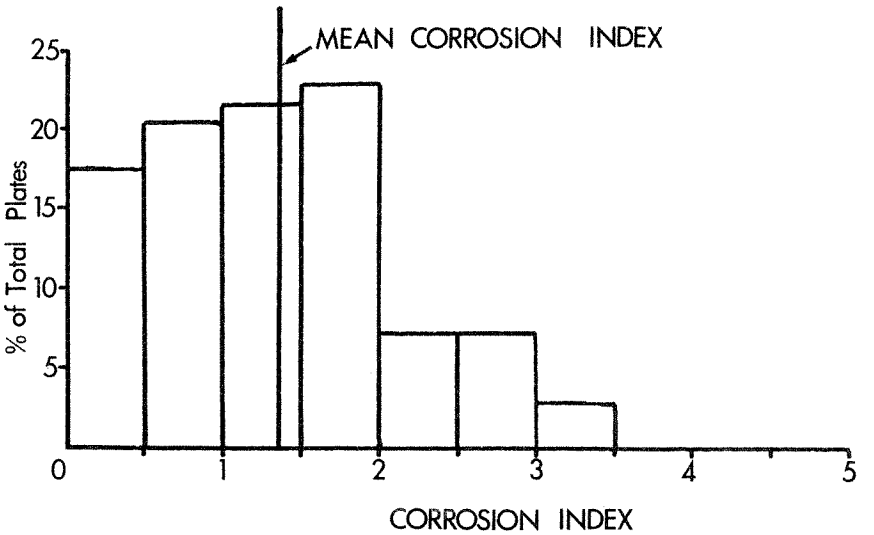

FIGURE 31. — Percentage of bone plates vs. corrosion index.

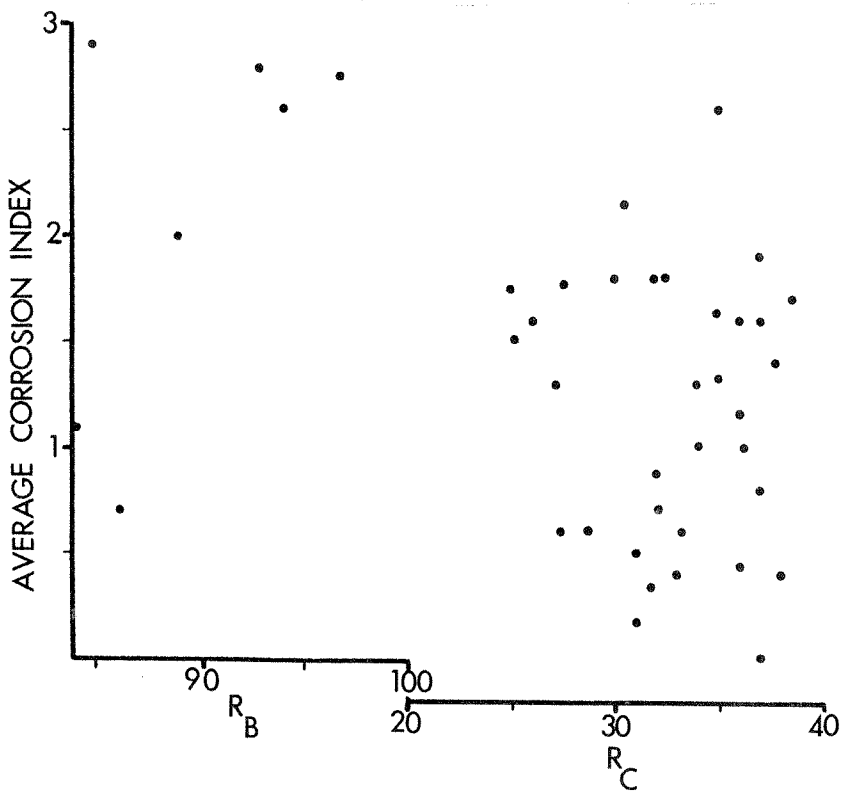

FIGURE 32. — Average corrosion index vs. Rockwell hardness.

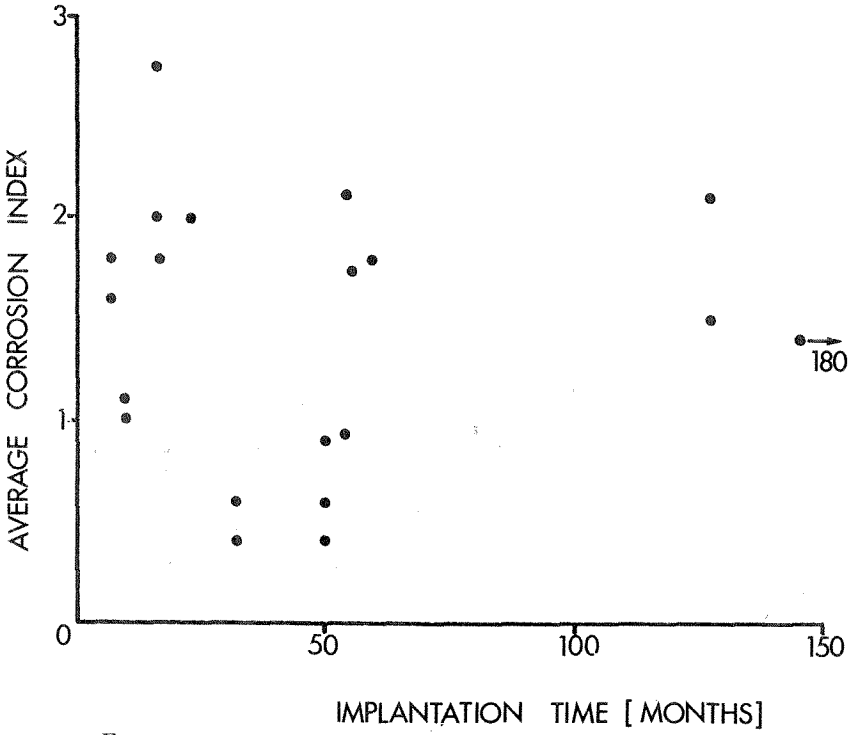

FIGURE 33. — Average corrosion index vs. implantation time.

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

Cleveland VA Medical Center
10701 East Boulevard
Wade Park, Cleveland, Ohio 44106

Case Western Reserve University
Department of Orthopaedic Surgery
2040 Adelbert Road
Cleveland, Ohio, 44106

David L. Green, M.D., Ernest B. Marsolais, M.D., Ph. D., and Eugene Bahniuk, Ph. D.

The goal is to determine if partial weightbearing (30 to 50 lb) 4 months postoperatively in total joint replacement (hip and knee) affects late complication of aseptic loosening. Loosening without infec-

tion, months to years postoperatively, is becoming an increasingly frequent complication without a history of severe trauma.

This ongoing prospective study consists of a randomized selection of patients receiving a total joint replacement (hip or knee). The parameters for evaluation include the following: history and physical including standardized hip evaluation form, routine X-rays, and biplane X-rays with computerized reduction of data for micromotion. Standardized X-rays are utilized to evaluate generalized as well as localized osteoporosis. The Case Western Reserve-VA gait laboratory with three-dimensional photoanalysis (Selspot) of the gait pattern is also utilized. Specific intervals of evaluation include preoperatively, post-operatively (prior to discharge), then 4, 6, 12, 24 and 36 months postoperatively.

Present work has included insertion of metallic markers in over 20 patients with maximum followup of over 2 years. Biplane X-rays taken on a test model reveal accuracy of displacement of .2 mm or a rotation of .8 deg using two standard deviations. One postoperative patient became symptomatic and biplane X-rays revealed displacement magnitude of approximately .9 mm of the tibial component. This loosening was confirmed at surgery and the tibial component was replaced. The previously mentioned postoperative studies are continuing with the analysis of the data.

Microsurgical Techniques Applied to Orthopaedics and Hand Surgery — John W. Schaffer, M.D.

A microsurgery laboratory has been established to study the factors that affect patency of vein grafts when microsurgical techniques are used to anastomose small vessels (less than 1 mm diameter). The rat groin experimental model is being used to permit an understanding of immediate and long-term patency of vein grafts. The concept of microsurgical use of vein grafts is becoming widely accepted by clinical microsurgeons where small-vein grafts are used to bridge vessel defects quite often encountered in injured limbs or in bridging defects with microsurgery reconstruction.

To date, 50 vein grafts have been studied. A 1 cm segment of superficial epigastric vein has been interposed into the femoral artery of a rat using microsurgical technique and the patency of the vessel has been assessed before and after the anastomosis using the flicker test, patency test, and Doppler. The animals have been divided into four groups with equal numbers per group with reexploration accomplished at 1 week, 2 weeks, 1 month, or 3 months. On reexplora-

tion, vein grafts have been evaluated for patency using techniques as indicated above. Animals have been sacrificed and postmortem histologic evaluation has included examination of the vessels with both light and scanning electron microscopy.

Nearly 100 percent acute patency of the vein grafts has been demonstrated and on reexploration, patency has persisted in better than 75 percent of the vein grafts in all groups. Some of the vein grafts on reexploration have had aneurysms, but this does not appear to have affected patency rate. It has also been demonstrated with the light microscope that the proximal artery usually appears normal while the vein graft itself shows a thickening, irregular lumen, and is of a larger caliber than the recipient artery. The artery distal to the vein graft has shown irregularity of the lumen with subintimal hyperplasia. Usually in those vein grafts that were not patent we could demonstrate obliteration of the lumen upon microscopy with total disarray of the sutures suggesting nonanatomic apposition of the cut vessel edges at the time of the original procedure. Using the scanning electron microscope reveals moderate platelet aggregation on the vein side of each anastomosis and suture placement variations and tightness, bite size, and platelet aggregation. At reexploration the platelets have been very randomly distributed and have been quite sparse. The healing of the vessel endothelial carpet on both the artery and vein side has been uniform and the anastomosis line has healed in all groups.

The vessel patency has persisted on reexploration up to 3 months after anastomosis, and the results emphasize that vein grafts when performed with precision provide reliable and durable conduits for orthopedic microsurgeons to bridge vessel gaps.

The project will continue in upcoming months with further study into the patency of vein grafts where caliber and length are varied. In addition, investigation on the effects of ambient temperature variation will be begun; and plans to determine whether vein grafts can be harvested and inserted 24 hours after the initial exploratory procedure will commence. The second part of the protocol calls for the staff to study hind limb replantation of a rat and to assess bone healing in this model. This will permit a better understanding of the factors that affect soft tissue healing following replantation in experimental animals; and, hopefully, these principles can apply to mammals in general. This may ultimately lead to more widespread application of microsurgical technique to veterans with amputated parts and the need for free bone vascularized transplant.

In Vivo Loading of Knee Joint Replacements

Orthpaedic Engineering Laboratory
Glennon Engineering Building
Case Western Reserve University
2040 Adelbert Road
Cleveland, Ohio 44106
Richard H. Brown, Ph. D., Kingsbury G. Heiple, M.D., and Victor M. Goldberg, M.D.

During the past year, the design of the telemetrized knee prosthesis was finalized (Fig. 34). A standard total condylar polyethylene plateau is recessed into a plateau tray which, in turn, is secured to the load-cell. This assembly is then mounted in a load-cell housing with all connections from the load-cell passed down into an electronics housing which also serves as the stem of the device.

Contained within this electronic housing will be all the necessary instrumentation to telemeter out 7 channels of strain data from the device. These 7 channels will contain all necessary information to totally determine the equivalent 3 forces (compression and AP and lateral shear) and 3 moments (torque and AP and lateral tilt) acting upon the tibial plateau. Following final assembly, the electronics compartment is sealed with both medical grade epoxy and Silastic and a cover plate with tight-fitting dove-tail mating surfaces.

All metallic components used in the design are implant-grade ELI Ti-6AL-4V. Component assembly is effected using electron-beam welding at NASA's Lewis Research Center in Cleveland, Ohio. The services of NASA Lewis Research Center were also utilized to coat all internal components in the device with medical-grade Parylene to further insure biocompatibility of the implant. A cross-sectional view of the final assembly is illustrated in Figure 35.

Extensive bench testing and calibration of the prototype load-cell resulted in several design changes (Fig. 36). First, the depth of each load-cell beam was increased to 6.60 mm, while the maximum deflection was reduced to .31 mm by incorporating a stop in the load-cell housing underneath each beam. These changes allowed each load-cell beam to support a larger load at a reduced stress. The end result was that the load-cell supported a 400 percent overload (17,800 N based on a design load of 4450 N) with a maximum beam stress of 430 MPa. The second change involved incorporating two grooves in the load-cell to protect the strain gage wires as they passed between the top surface of the load-cell and the plateau tray.

Utilizing this design, a final prototype prosthesis has been built and tested in our mechanical testing laboratory. Results of this testing

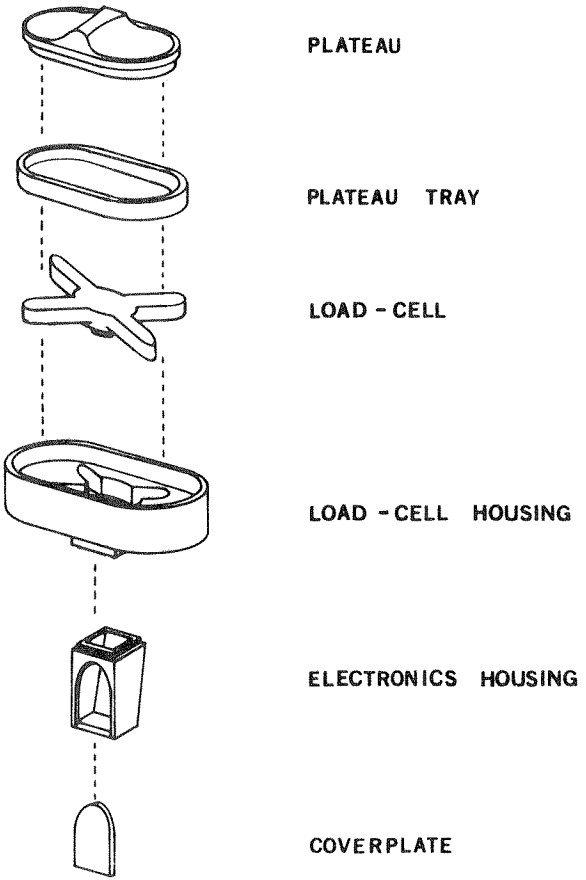

FIGURE 34. — Telemetrized knee prosthesis, exploded assembly.

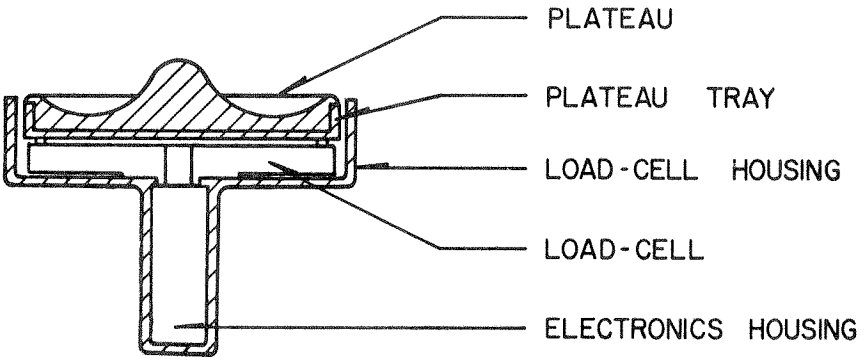

FIGURE 35. — Cross-section of assembled prothesis.

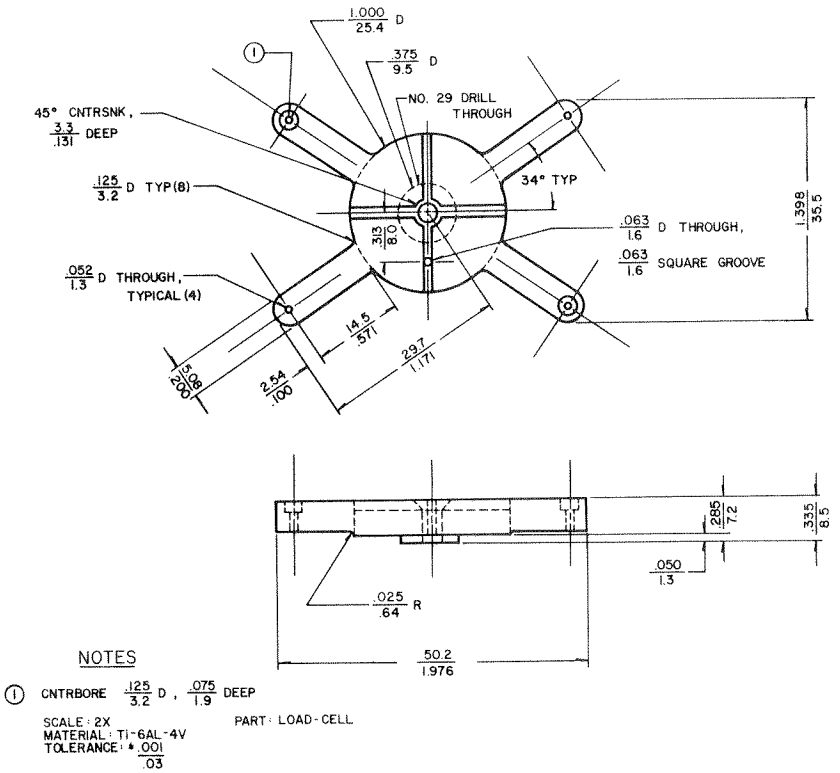

FIGURE 36. — Drawing includes changes incorporated in prototype load cell.

demonstrate that the design is capable of resolving the desired three forces and three moments with acceptable resolution. Non-linearity of the seven data channels was less than one percent while the hysteresis was typically less than three percent.

Current Status

At present, construction of a complete set of components for the first implantable telemetrized prosthesis has been accomplished. The laboratory is currently awaiting the completion of strain gage application to the load-cell, at which time all components will be assembled by electron-beam welding. Final construction and calibration of 8 demodulator channels is being carried out. Then a transmitter package will be sealed within the electronics housing. A final calibration procedure will be performed, and the load-cell compartment will be coated with Parylene. Following the insertion of a fresh battery pack and sterilization, the device will be ready for implantation. The first implantation of a telemetrized prosthesis is anticipated for the early

In Vitro and In Vivo Quantitative Analysis of Acetabular Failure in Total Hip Arthroplasty

Gainesville VA Medical Center
Gainesville, Florida 32602
William Petty, M.D.

No progress report was submitted for this period.

Mobility Engineering for the Severely Handicapped

Mobility Engineering and Development (MED), Inc.
7131 Havenhurst Avenue
Van Nuys, California 91405
Charles M. Scott and Ronald E. Prior, Ph. D.

No progress report was submitted for this period.

Maxillofacial Restorative Materials and Techniques

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

Wilmington VA Medical Center
1601 Kirkwood Highway
Wilmington, Delaware 19805

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

Introduction

Polydimethylsiloxane (PDM siloxane for short) has been shown in extensive comparison tests (1) with several competitive prosthesis materials, to be more effective, more durable, non-toxic, and safe to human excised donor (HED) tissues.

The on-going research and development program continues along a broad, integrated, comprehensive development plan. This research is designed to assure intensive scientific product development for simplified fabrication, for internal pigmentation producing lifelike cosmetic matching, and for extensive toxicological and tumorgenic testing for safety as medical devices with quality standards. This scientific effort, based on polymer science and technology, is currently involved in an in-house production program for supplying all of the

maxillofacial reconstruction needs of the Veterans Administration, plus those of interested non-VA clinics (some of which treat veteran cases). A field evaluation program for clinical application will include technical assistance for fabrication, cosmetic fitting and lifelike coloring, hygienic maintenance, and collateral testing for toxicity and turmorgenicity.

The first of a series of VA regional conferences, organized and sponsored by the Northeast Regional Medical Education Center (NRMEC) and co-sponsored by the Rehabilitative Engineering Research and Development Service, has been held. This was a step toward prompt adoption of PDM siloxane as a standard prosthetic material.

The integrated Comprehensive Development Plan (Table 1) comprises six major programs or projects, interrelated from product development to clinical application and evaluation, and supported by production of stock material to ensure the availability of high quality standard material that will comply fully with the regulatory FDA standards for safe and effective medical devices (2). Each of these programs is discussed in the following pages.

I. Product Development Project

The product development effort is based on adopting the PDM siloxane chemical configuration utilizing two molecular-weight components: one is a prepolymer available as a high purity standard elastomer gum stock, and the other is an oligomer of the same chemical configuration, available in a broad range of dimethylsiloxane units (Table 2). As indicated in the previous BPR reports (3), the prepolymer-oligomer mixture is converted to low-modulus elastomer by free radical polymerization using peroxide catalyst now at a standardized temperature of 100 deg C for 2 hours. The polymerization serves to provide the usual crosslinking between the prepolymer chains, and simultaneously to impose chain branches from the oligomer to the prepolymer chain by the same free radical formation in each species. It is this unique feature of direct covalent, interchain dimethylene siloxane

$$-O-Si-CH_2-CH_2-Si-O-$$

(shown in brackets in Figure 37) that distinguishes the thermally induced (HTV) free-radical siloxane (a superior tear-resistant and durable elastomer) from the room-temperature, metal-coordinated interchange using alkyl tin or ionic platinum catalyst (both highly toxic).

TABLE 1. — *Comprehensive Development Plan: Phases and Descriptive R&D Tasks*

I. Product Development

Principal polymer, elastomer selection
Defined, specified composition in relation to critical processing
Selected testing and replicating anatomic mechanical properties
Durability, end-use testing — environment, exposure and maintenance

New Tasks

PDM siloxane 80/20 composition extended to organisols (fluid systems)
Composite mesh laminates
Bonding systems — PDM siloxane to dentures and obturators
Improved adhesives for external retention of orofacial prostheses
New polymeric chemical structures

II. Fabrication

Determining and standardizing critical temperature-time factors
Designing forming (molding) components or equipment
Standardization of applied processing (curing) variables
Modifications in fabrication for complex structures of prostheses

New Task

Adapting innovative products of Phase I for practical fabrication

III. Pigmentation and Cosmetic Matching

Development of appropriate, simple spectral measurements
Developing dispersion method into prosthetic materials
Spectral assignment (digital registering) of non-toxic pigments
Color stability testing against light exposure and effects of hygienic maintenance

IV. Toxicity, Test Development, and Testing

Develop direct approach to orofacial (maxillofacial) tissue exposure
Accumulate a cohort of human excised donor (HED) tissues for preliminary tests in tissue culture techniques
Develop biochemical and biophysical complements to culture techniques
Maintain surveillance on effects of products (I), fabrication (II), and production (VI)

New Tasks

Assess HED stored and cloned cells for cell differentiation by chromosome scoring for changes
Ascertain potential carcinogenicity in HED testing of tissues based on chromosome characterization
Explore suitability of using Ames salmonella-microsome testing for carcinogenicity
Explore possibility of using sister chromatid exchange (SCE) testing method for carcinogenicity supplementing the HED tissue testing
Prepare documentation for FDA panel review for clearance of PDM siloxane as safe and effective form of external and internal prostheses

V. Field (End-Use) Evaluation of Fabricated Prostheses (Clinical, Rehabilitative)

Selection of representative, reputable VA and non-VA clinics
Develop criteria for preference and wearer acceptance
Ascertain merits and deficiencies for referral to Phases I, II, and V

New Tasks

Obtain consensus on the 6-membered internal pigmentation
Conduct conferences and training sessions on fabrication techniques

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VI. Production

Produce pound quantities of internally pigmented stocks for Phase V
Affirm product quality of PDM siloxane for technical specifications
Affirm FDA regulatory safety in terms of non-toxicity in HED system
Make available PDM siloxane stocks and technical assistance to other VA clinics involved in orofacial prosthesis and medical devices
Prepare technical process and product manual

TABLE 2.—*Dimethylsiloxane unit lengths from various grades of silicone oligomers (Dow DC 200 Fluids)*

Viscosity grade (Centistokes)	Approximate number of dimethylsiloxane units	
	From number average molecular weight	From weight average molecular weight
1	3	3
2	5	5
10[a]	16	17
50	46	60
100[a]	70	100
350[a]	130	200
1000	200	350

Source: Dow Corning Technical Bulletin — Silicone Fluids
[a] New tasks

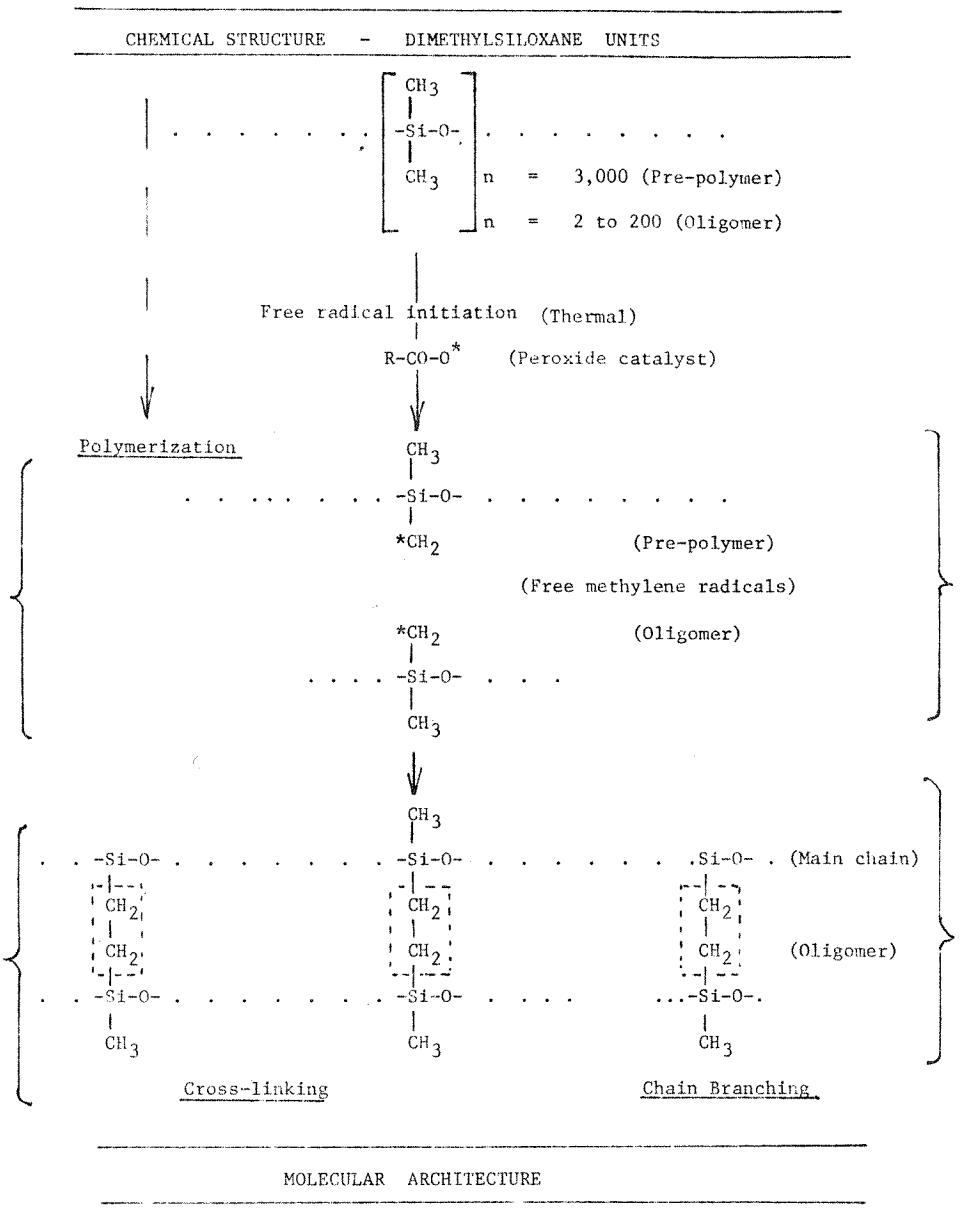


FIGURE 37. — Initial chemical structures of polydimethylsiloxane prepolymer and oligomer components polymerized to crosslinked and chain-branched elastomer.

The specific objective during this period has been to maintain an on-going basic scientific effort for two cogent needs:

1. Continually improving and innovating the polydimethylsiloxane; and

2. Investigating alternates in essential ingredients and polymerization, especially to anticipate any deficiencies that may become evident in the pursuit of the other phases of the comprehensive development plan, especially in Toxicity Testing (Phase IV) and in Clinical Field Evaluation (Phase V). These needs were pursued in two experimental plans using, respectively, alternate, simpler polymerization by autoclaving in available clinical sterilizers, and an alternate polymerization catalyst (non-chloro-bearing benzoyl peroxide) as a substitute for the 2,4-dichlorobenzoyl peroxide which has been used for the current standard (VA) PDM siloxane 80/20 prepolymer/oligomer composition. This substitution is merely to divest the standard composition of any suspicion (such as is currently prevalent with chloro-organic compounds) of carcinogenicity in cases where inept polymerization is applied during fabrication practices, especially by novices without appreciation of precise temperature-time techniques. The two catalysts are listed as general specification in Table 3 (which notes the numbers of their registration in the Code of Federal Regulations as safe food additives).

TABLE 3. — *Peroxide Catalysts for PDM Siloxane Polymerization for Orofacial Prostheses*

Peroxide catalysts				
Chemical (generic) name	Trade name	Specification	Code of FDA	
2,4-Dichlorobenzoyl peroxide	LUPERCO CST[a]	50% paste in silicone oil[b]	0121.2562	
Benzoyl peroxide	LUPERCO AST[a]	50% paste in silicone oil[b]	121.2520 121.2562	121.2526 121.2176
Lauryl peroxide	ALPEROX F[a]	98% flakes	121.2520 121.2576	121.2526

[a]Trademark of Lucidol Division, Pennwalt Corp., Reference (4).
[b]Efficiently dispersed in silicone oil for Production (Phase VI). Solids or flakes are not efficiently dispersed for the PDM siloxane prepolymer/oligomer formulations.

It is obvious that myriads of combinations and permutations of crosslinking and chain branching could result from variations in the unit dimethylsiloxane lengths of the available oligomers shown in Table 2. These warrant investigation in this project, for the purpose of ascertaining optimum unit lengths for all-around properties of effectiveness and durability, and for possible inclusion in ultimate specifications required for FDA registry for safe and effective medical devices. It is on this course that three of the unit lengths (marked by asterisks in Table 2) have been accorded study for tensile charac-

teristics based on the standardized 80/20 prepolymer/oligomer weight composition (3). The resulting data (summarized in Table 4 and shown graphically in Figures 38 to 41) are based on a progressively increasing level of catalyst concentration. The principal features of the effects of three dimethylsiloxane units of the oligomer in terms of the essential tensile constants are described in the following sections.

TABLE 4.—*Effect of Catalyst Level (Benzoyl Peroxide Replacing 2,4-Dichlorobenzoyl peroxide) on Principal Tensile Constants*

Oligomer		Catalyst Level — parts/100 parts of 80/20 Composition				
Grade (cs)	[a]DMS units	0.25	0.50	1.0	2.0	3.0
		Initial Modulus — lb/in²				
10	17	24.1	54.4	81.0	107	118
100	100	42.1	60.2	93.5	118	126
350	200	(24.5)	(59.1)	(84.9)	131	143
		Ultimate Strength — lb/in²				
10	17	77.3	236	323	310	321
100	100	200	327	423	398	368
350	200	(115)	(291)	(386)	484	326
		Elongation — percent				
10	17	793	989	927	631	525
100	100	1122	1106	926	608	465
350	200	(919)	(941)	(831)	673	387
		S/M Quotient				
10	17	3.21	4.34	4.02	2.89	2.72
100	100	4.75	5.43	4.53	3.36	2.92
350	200	4.71	4.93	4.55	3.70	2.29

Test results based on duplicate sets of 8 measurements on 2 moldings, except parenthetical values which are based on only 1 set of moldings.

Conversions:

_____ lb/in² × 0.07307 = _____ kg/cm²

_____ lb/in² × 0.6994 = _____ kilopascals (kPa)

[a]DMS units means dimethylsiloxane units.

Effect of Catalyst Level

As was to be expected, the level of the catalyst (in this instance the alternative benzoyl peroxide) imposes a pronounced progressive effect on each of three principal tensile characteristics; the initial modulus (M), the ultimate tensile strength (S) and the elongation-to-break at the ultimate tensile strength. Increasing catalyst level serves primarily to impose increasing incidences of crosslinks on the prepolymer configuration (Fig. 1). The role of the oligomer unit length can be via any one of the following three mechanisms:

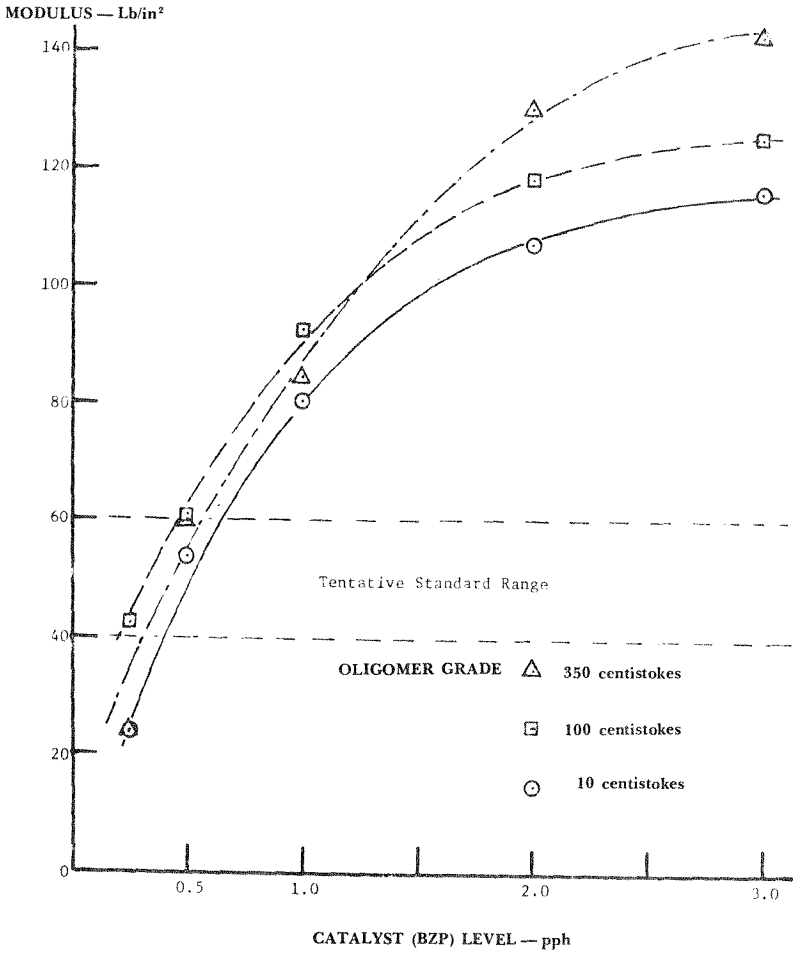


FIGURE 38. — Effect of catalyst (BZP) level on tensile modulus of PDM siloxane (80/20) prothesis composition.

a. Intramolecular oligomer chain growth, independent of that of the prepolymer chain growth,

b. Intramolecular oligomer cross-linking, and

c. Oligomer-prepolymer chain branching.

The last-named structural modification is preferred over that of the preceding two mechanisms because it is desired to distend or disrupt the interchain contiguity so as to develop low tactile modulus. The ideal molecular architecture (depicted in Figure 37) replicates the structural array of (i) high-molecular-weight (MW~10^6 range) pre-

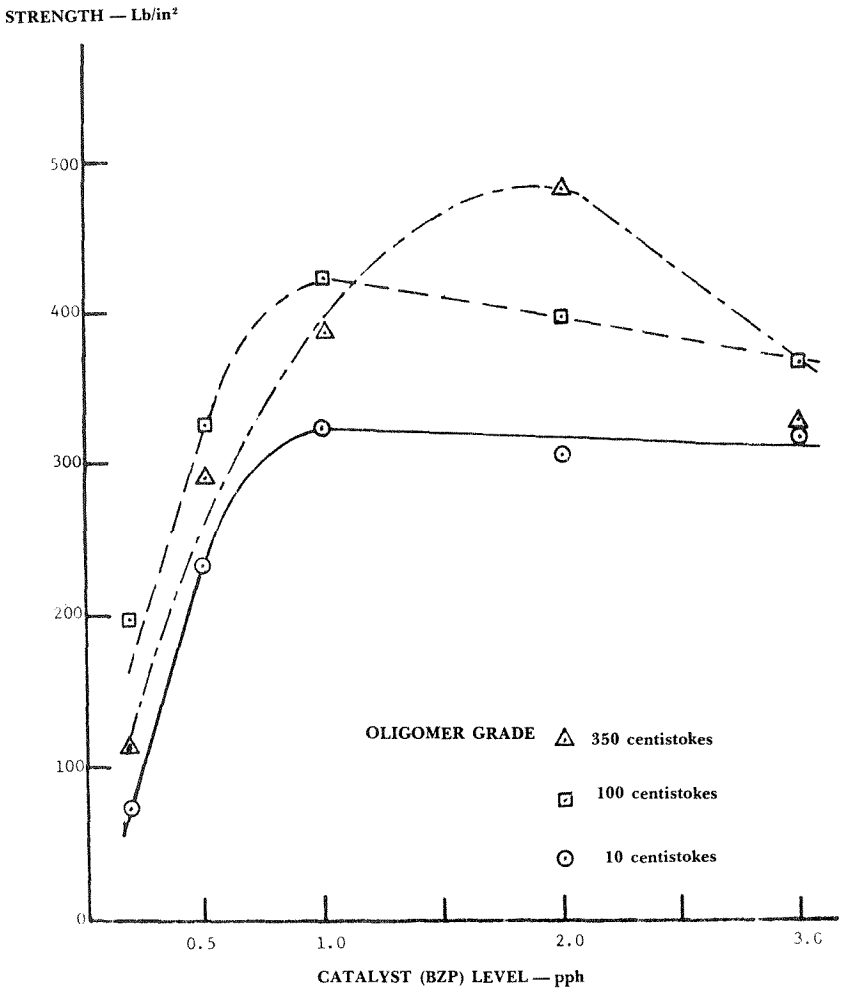


FIGURE 39. — Effect of catalyst (BZP) level on tensile strength of PDM siloxane (80/20) prosthesis composition.

tein chains, especially that of tissue collagen, with interchain coils, and of (ii) associated lipid molecules (MW~10^3) serving to provide the viscous plasticizing effect. In effect, the role of PDM siloxane prepolymer is to replicate the protein chain while that of the PDM siloxane oligomer is to replicate the viscous plasticizing effect, using the free radical mechanism to accomplish the permanent covalent, durable intermolecular and intramolecular linkages through the dimethylene -0-Si-CH_2CH_2-Si-0- formations (Fig. 37).

Table 4 summarizes the tensile constants obtained from a uniform

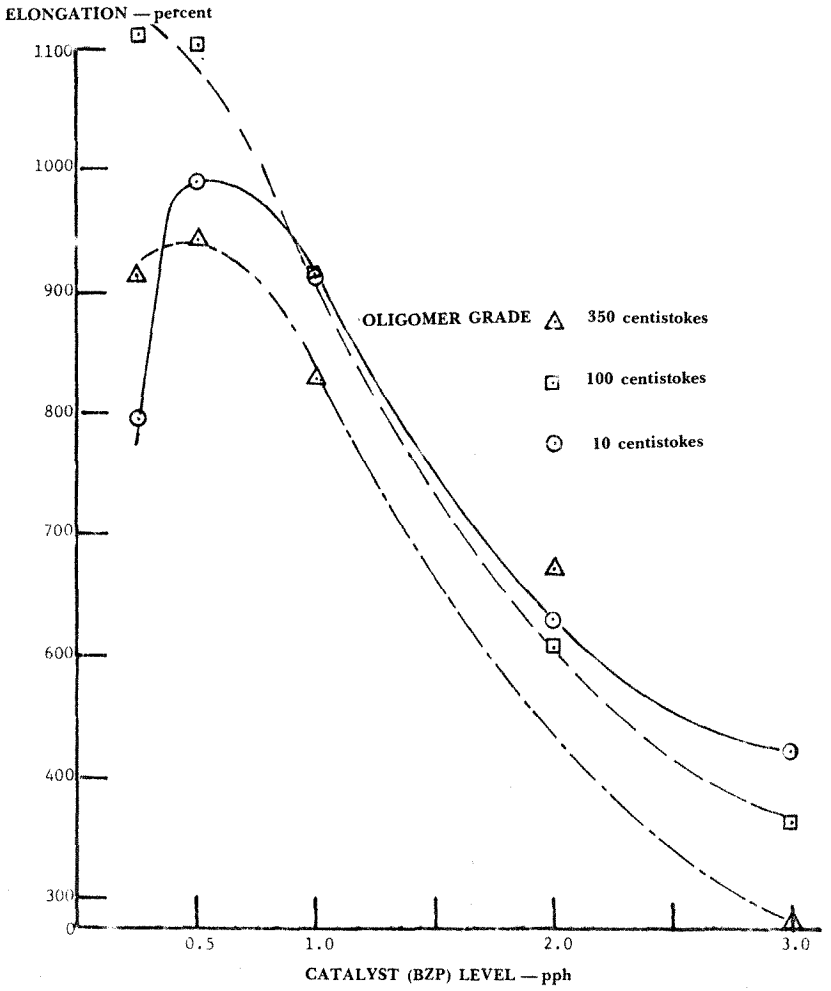


FIGURE 40. — Effect of catalyst (BZP) level on elongation of PDM siloxane (80/20) prosthesis composition.

series of catalyst levels of benzoyl peroxide (BZP), which is used in these tests as an alternative to and ready substitute for 2,4-dichlorobenzoyl peroxide. This initiates a polymatrical series of experimental designs involving the standard PDM siloxane — which is now undergoing clinical field evaluation. That standard for PDM siloxane is based on the 80/20 prepolymer/oligomer composition and a thermal polymerization standard of 100 deg C for 2 hours. Modifications in composition and thermal

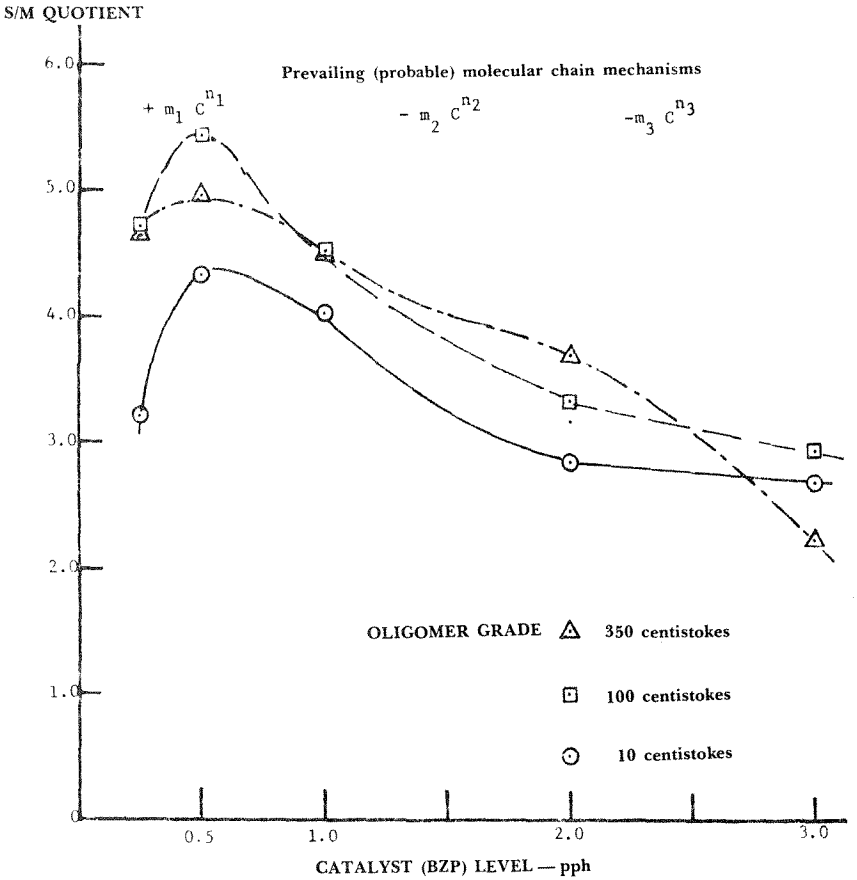


FIGURE 41.—Effect of catalyst (BZP) level on S/M quotient of PDM siloxane (80/20) prosthesis composition.

compass polymatrical series from which the ultimate or ideal combination of composition and thermal polymerization can be ascertained.

The specific tensile constants are discussed in the ensuing sections, based on the more readily discernible figurative depictions in Figures 38 to 41 inclusive for the modulus (M), strength (S) (ultimate), elongation, and strength/modulus (S/M ratio). The last-named is an indicator of how well the PDM siloxane approaches living tissue in the tactile quality of replicating the life-like feel of physiological skin.

Initial (Tactile) Modulus

As indicated in Figure 38, each of the three oligomers (of 10, 100, and 350 centistoke) give rise to parallel increase in modulus with increasing BZP catalyst concentration. In Figure 38 is indicated the

current, tentative standard range of 40-to-60 lb/in^2 for the tactile quality attainable at between 0.4 to 0.5 catalyst level—beyond which the modulus increases about 3-fold. The most pronounced in this regard is with increasing oligomer unit lengths, suggesting increasing level of cross-linking giving rise to modulus values beyond the currently accepted standard range.

Tensile Strength

Figure 39 depicts an unusual array of increases in this property with increasing BZP concentration, with each of the oligomers imposing different dependencies in this regard. The 10-centistoke oligomer attains a constant maximum at the 1.0-pph BZP level. The 100-centistoke oligomer also attains maximum strength at 1.0 BZP level and then diminishes significantly. The 350-centistoke oligomer provides a different, higher, maximum shifted to 2.0 catalyst level, followed by marked decrease.

The results for the tensile strength attained and the corresponding modulus data point out the importance of specifying the optimum catalyst level to assure uniform quality of prostheses. In addition, the first matrix series with 80/20 prepolymer/oligomer composition provides a frame of reference for continued, systematic adjustments to other prepolymer/oligomer ratios, and also to other variables, such as temperature-time. The experimental results now set up a valuable data source for estimating average crosslink density and chain segments (Mc) with parametric time-dependent stress decay at various extensions (oc values).

Elongation (Ultimate)

Figure 40 depicts the effect of an increasing BZP catalyst level on elongation-to-failure. This constitutes a measure of the overall molecular entities, networks of covalent and innate cyclic chain entanglements which decrease with increasing cross-linking action — with evident stiffening as indicated by the increasing module (Fig. 39) and increasing strength (Fig. 40). The data in this regard provide an interesting single case of collective phenomena (5,6) especially in the sense of mathematical physics. This concept is treated in more detail in the ensuing section.

It might be mentioned that PDM siloxane, as developed in this program's Comprehensive Development Plan has more-than-adequate elongation or extension-to-failure (in the range of 400 to 1100 percent) for other as yet un-programmed product development ventures, considering that many living tissues sustain elongations in the range of 40 to 120 percent.

S/M Quotient

This dimensionless characteristic derived from the ultimate strength/modulus ratio (heretofore used as the criterion of success in replicating the biomechanical extensile criteria, as summarized in Table 3) reveals consistent maximum values at 0.5-pph catalyst level for each of the three oligomer configurations. A more dramatic evidence of these consistent maxima is shown in Figure 41, with three indicated speculative phases which can be accommodated by conventional array of a third order (cubic) polynomial inferred as mathematical physics of collective phenomena. The three speculative phases, imposed by the progressively increasing catalyst level, can be ascribed by appropriate phenomenological interpretations with conventional coefficients (m_1, m_2, m_3 .... etc.) as summarized in Table 5. The merit of this seemingly esoteric treatment of the tensile characteristics is that it promises to provide an invaluable data source for new approaches to the devising of molecular forms of polydimethylsiloxane

Table 5. Polymerization Mechanisms Induced by Catalyst Levels on tensile constants reflected in Figures 2 to 5 for probable n-order (cubic) polynomial: $f(x) = \pm m_1C^{n_1} \pm m_2C^{n_2} \pm m_3C^{n_3}$

Phase Designation	Molecular (m) Mechanisms (Competing Effects)	Probable Changes in -		
		Modulus	Strength	Elongation
I	m_1C^n(cross-linking)	+	+	±
II	m_2C^n(chain-branching)	-	-	-
III	m_3C^n(oligomerization)	±	-	- -

f (x) represesents measured tensile constant

m_1, m_2, m_3 represents probable molecular chain units

C, C, C represents catalyst (Concentration) level, and

n_1, n_2, n_3 represents empirical orthognal exponents, to account for three possible cross-linking mechanisms, namely, (1) within pre-polymer, (2) between pre-polymer and oligomer, and (3) within the oligomer, as Collective Phenomena (5).

looking toward the ultimate replication of the biomechanical characteristics of living tissue.

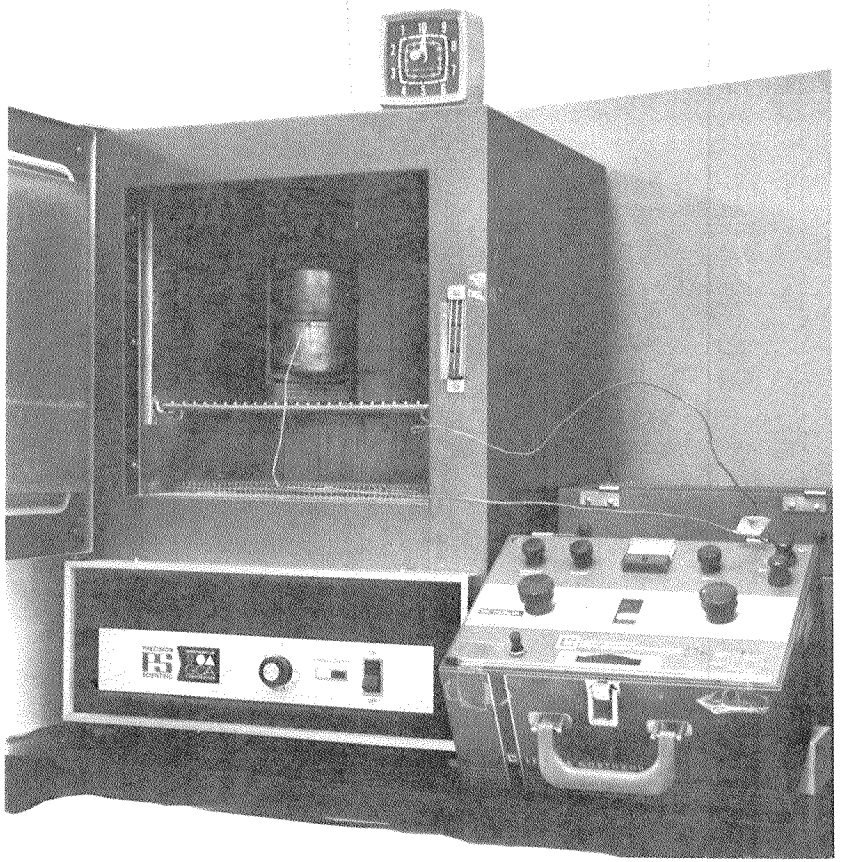
In consequence thereof, the continued product development is planned to include use of other oligomers and peroxide catalysts, in the expectation that the sequences of crosslinking and long chain branching can be further modified in a cascade of variables—notably, varied prepolymer/oligomer ratios, and varied temperature conditions. In effect, this phase of the Comprehensive Development Plan replaces the hitherto empirical methodology in elastomer polymer physics and biomechanics with a definitive fundamental base.

II. Fabrication Techniques

The fabrication conditions, standardized at 100±5 deg C for 2 hours in air dry ovens, can now be attained reliably by polymerization of the PDM siloxane compositions confined in regular dental stone molds in ordinary clinical, or dental, steam autoclaves or sterilizers. This now provides a third major simplification and significant cost avoidance, the first being the use of regular dental stone molds displacing expensive and cumbersome metal molds, and the second being the use of inexpensive light-weight angle iron bolt clamps instead of expensive, heavy brass clamps.

This third important technical simplification (for which procedural details are being included in a standard Manual of Operations and Specifications (MOPS), places the fabrication of medical devices within the fabrication skill of competent dental technicians who are experienced in working with acrylics and alloy prosthodontics. In the past, the fabrication of orofacial prosthetic devices has been, and still is in some clinics, to a large extent ventured by only a few prosthodontists, medical artists, and others. Often these workers have been forced to employ makeshift, ill-advised, costly and time-consuming unscientific procedures, with no defined standards for polymerization.

The specific objective during this period has been to investigate the use of clinical sterilizers available as steam autoclaves (or even as domestic pressure cookers) that can be readily controlled by the simple feature of adjusting the steam temperature in the particular autoclave employed. The standard polymerization at 100 ± 5 deg for 2 hours duplicates the temperature-time profile used heretofore in air-heating laboratory ovens of various sizes, such as those shown in Figures 42 and 43 which are typical of the moderate size and small hot plate size ovens, respectively, used in making a prosthesis. The air oven temperature-time schedule, as currently developed for simplicity and uniformity, involves two-stage thermal input and control, with an initial high heat input and a steady-state equilibrium heat input.



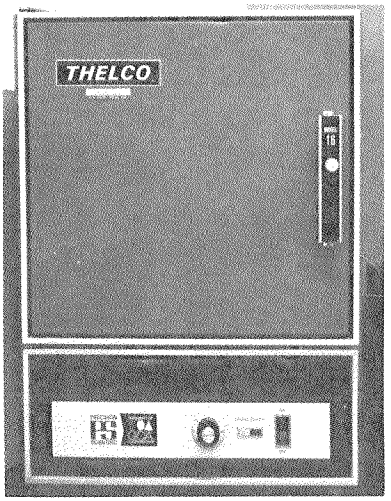
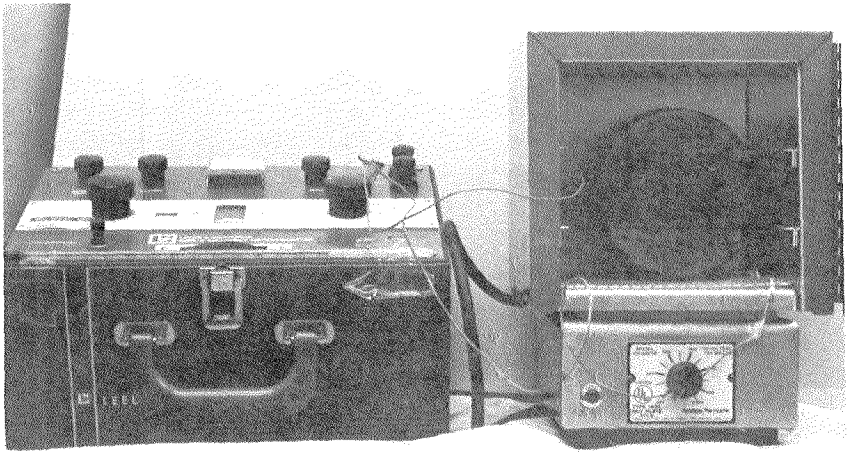


FIGURE 42. — Air convection (gravity) oven for multiple dental stone mold polymerization (curing) of PDM siloxane prostheses. Thelco Model 16 oven (left) has inside chamber 13x14x13 inches (1.37 ft^3). Temp. is 225 deg C maximum. Electrical requirements: 120 V, 820 W. Above, air oven polymerization (curing) is shown, monitored with potentiometer (Leeds and Northrup) for internal mold temperatures.

These two heat loads (Fig. 44 and 45) have been established from a series of detailed recordings of the temperatures, monitored potentiometrically with thermocouples inside the stone mold, for various types of air ovens of differing wattage, cubic space, and insulation efficiency.

With the now established thermal profile as a standard reference or model with air-ovens (which are not generally available in dental clinics, and which require frequent temperature calibration and standardization with a potentiometer-thermocouple system) the alternate course of using clinical sterilizers or autoclaves was undertaken in the search for a simplified, single thermal input. This involves developing a single thermostatic setting specified for each type of dental stone flask molding. The thermal control for the two systems is quite differ-



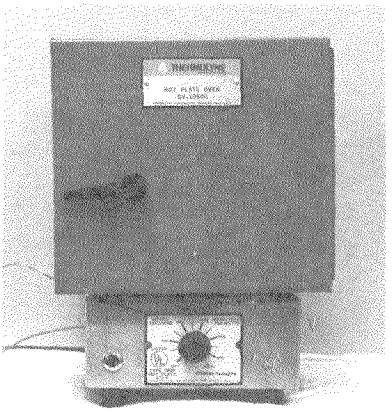


FIGURE 43. — Compact hotplate air-convection (gravity) oven for single dental stone mold polymerization (curing) of PDM siloxane prostheses. Shown atop hotplate (left) is Thermolyne laboratory model, with interior chamber 6½x6½x6⅛ inches (0.15 ft^3). Temperature (max.) 300 deg C. Electrical requirements 120 V, 750 W. Above, air-oven polymerization (curing) of a single large dental stone molding monitored with potentiometer (Leeds and Northrup) for control of internal temperatures.

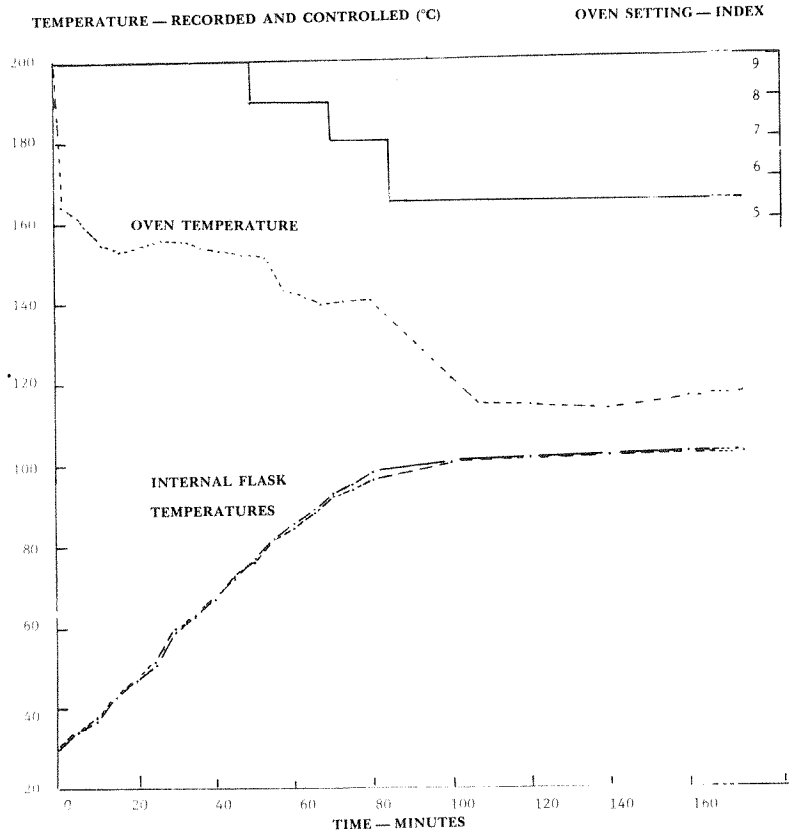


FIGURE 44.—Polymerization temperature-time profile for multiple (five) moldings in air-convection (gravity) oven shown in Figure 42. Dental stone molds: Hanau Regular (Varsity) (four) and Hanau Giant, (one).

ent in that the air-oven has primarily a radiation form of heat input which is rapidly responsive to adjustments within the 100±5° limits, whereas the steam sterilizer or autoclave functions primarily by vapor convection and therefore has a longer time lag in maintaining this thermal limit.

Data are now available on the thermal dwell for a clinical sterilizer (AMSCO table model shown in Figure 46) with an added innovation to reduce the polymerization time from 2 hours to 1 hour. Figure 47 depicts the thermal dwell profile for 1-hour and 2-hour polymerization, with the corresponding tensile constants from the respective moldings (Table 6). Since there is no statistical difference in the ten-

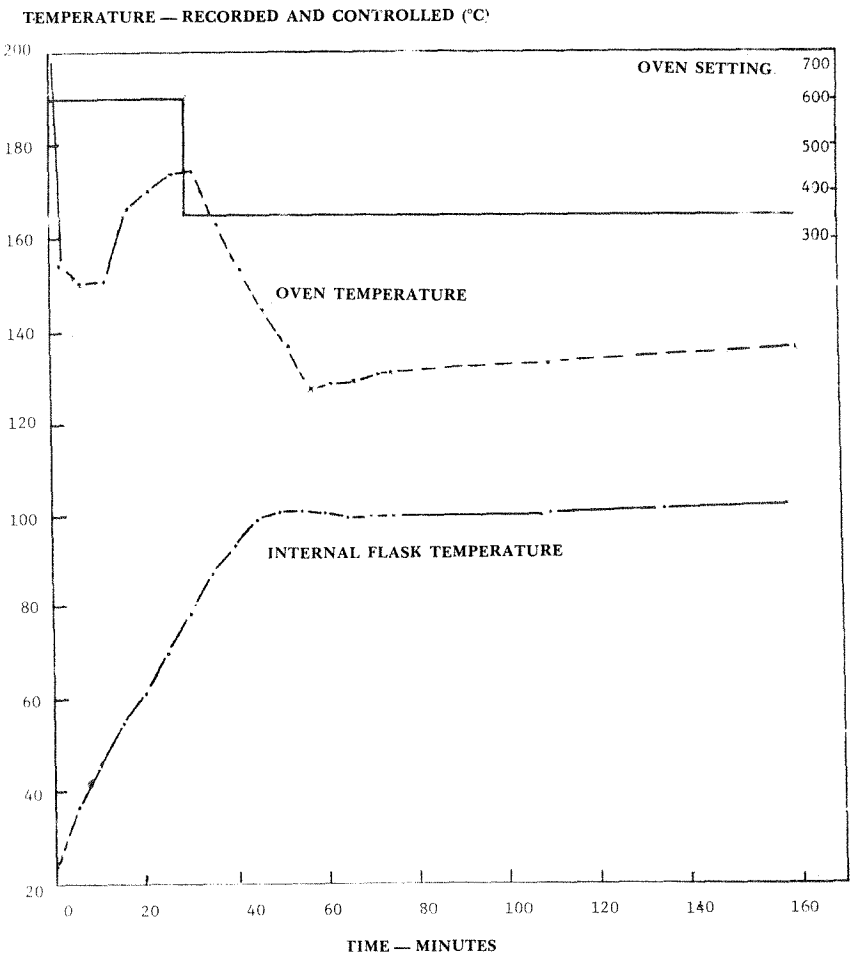
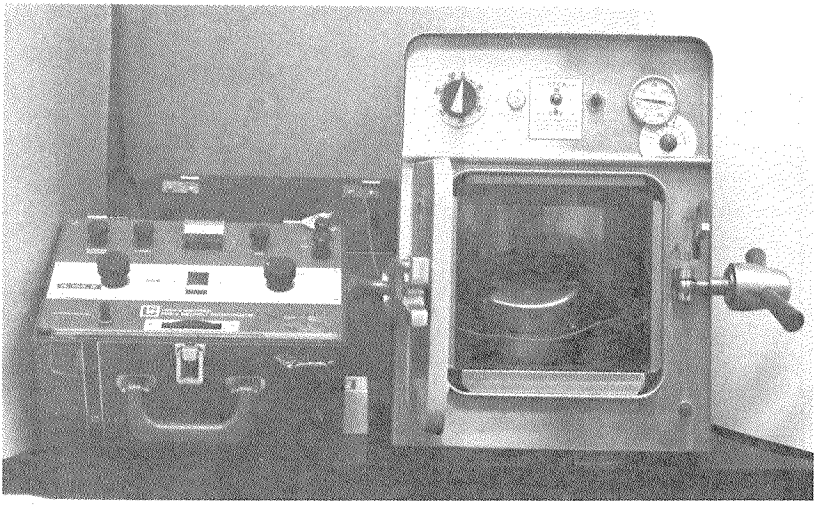


FIGURE 45. — Polymerization temperature-time profile for single molding in the compact air-convection (gravity) hotplate oven shown in Figure 43. The dental stone mold is a Hanau Giant.

sile constants between 1-hour and 2-hour sterilizer polymerization, the shortened time provides an important simplification and saving of time in the fabrication of prostheses, as compared with either polyvinyl chloride or polyurethane prostheses.

III. Pigmentation

The six-member yellow-red (Shade Yellow — SY dominant, and Shade Red — SR dominant) panel, listed in Table 7 with the digital (numerical) color difference (DCD) values, have been standardized for the production campaigns referred to in Phase V. The principal



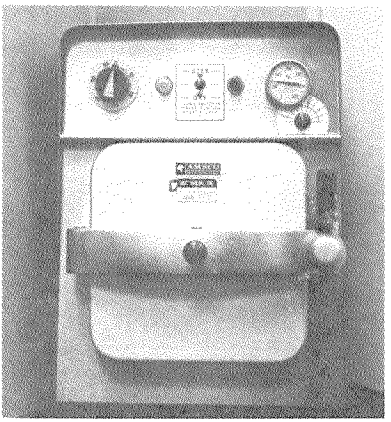


FIGURE 46. — Clinical sterilizer (autoclave) suitable for polymerization (curing) of PDM siloxane in dental stone molds. At left: AMSCO Sterilizer, Table Model 1600A, with chamber 8x7½x16 inches (0.76 ft^3). Operates in 150-deg C temperature range, with pressure relief. Electrical requirements: 120 V, 1600 W. Above: autoclave pressured steam polymerization (curing) monitored with potentiometer (Leeds and Northrup) for control of internal mold temperature.

TABLE 6. — *Effect of Shortened (1 hour) Polymerization in Sterilizer for Fabricating PDM Siloxane Prostheses (Production Lot L-125-66)*

Tensile property ASTM D638	Unit dimensions	Polymerization 1 Hour (Figure 11)	Polymerization 2 Hours (Figure 11)	Statistical (t-Test) significance
Modulus	lb/in^2	86.8 ± 9.7	93.5 ± 6.3	n/s
Strength	lb/in^2	434.2 ± 43.1	412.7 ± 75.8	n/s
Elongation	percent	1718 ± 76	1638 ± 177	n/s
S/M Quotient	(dimensionless)	5.00	4.41± 75.8	—
Molding No.		P-1328	P-1327	

Conversions (Modulus and Strength):
0.07307 × lb/in^2 = _____ kg/cm^2
0.6994 × lb/in^2 = _____ kilopascals (kPa)

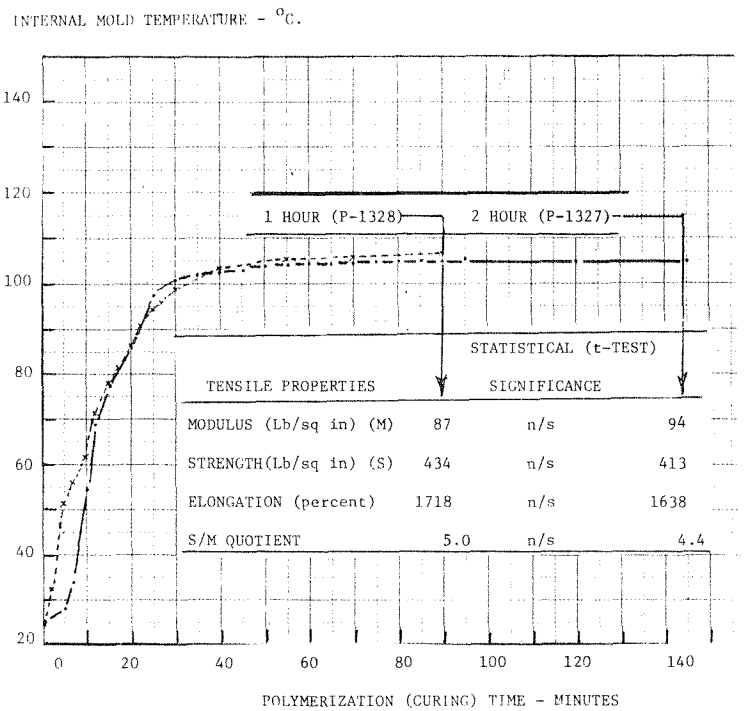


FIGURE 47. — Polymerization temperature-time profile in AMSCO sterilizer. Sterilizer setting: one-half range of thermal control. Dental stone mold and flask weights: dental stone, gypsum base, 760 grams; brass Hanau Giant flask, 3825 grams; iron clamp, 650 grams; and PDM siloxane for prosthesis, 14.5 grams. Temperature recording system: iron-constantan thermocouple inside of dental stone, with L & N Potentiometer Model 8690-2.

internal colorants are based on three simple functional components:

1. yellow iron oxide for the physiological carotene color;
2. red rayon flock for the arteriole/veniole coloration; and
3. white opacifying titanium dioxide for the subdermal cellular structure.

The internally pigmented PDM siloxane six-shade stocks therefore provide a uniform range of replicated physiological pigments and obviate the trial-and-error, time-consuming and often unsuccessful cosmetic color matching with proprietary (chemically non-disclosed) colorants. The internally pigmented six-shade range enables the prosthetist to choose one or two near matches to the patient and finish off

TABLE 7.—*Standard Six-Member Internally Pigmented PDM Siloxane Color Specifications (Hunter DCD[a] System)*

Pigment Shade	Reflectance L	Transmission 100-1	Redness a	Yellowness b	b/a Ratio
SY-1	67.9	32.1	+9.0	+18.7	2.08
SY-2	69.5	30.5	+7.5	+19.7	2.63
SY-3	74.7	25.3	+3.8	+18.1	4.76
SR-3	79.2	20.8	+0.7	+7.9	11.29
SR-2	75.2	24.8	+3.8	+10.6	2.79
SR-1	70.8	29.7	+11.2	+12.8	1.14

[a]DCD represents Digital Color Difference

with the external pigments provided in the coloration kit, as discussed in the Field Evaluation (Phase V) and Production (Phase VI) sections. These two technical features of this (Phase III) program save considerable time, by as much as a whole days' work, in making not only one but duplicate, or even three or four, prostheses for the patient.

Additional work on this program phase is planned for adjustment or extensions to one or more internal pigmentations with the planned survey of needs and preference in the field evaluation program. Still another facet is the correlation of the Hunter DCD indexing system to the Munsell color registration and to the Lovibond system used generally in Europe.

IV. Toxicity and Tumorgenicity Testing (HED Tissue Culture System)

A mainstay of the Comprehensive Development Plan, this program is continuing along the course described in detail in BPR 10-31, Spring 1979. The three-way assessment (depicted here in Figure 48) includes biochemical surveillance for tumorgenicity, a feature essential to this program phase because implanted polymers have frequently been reported to induce tumor growth (7). The biochemical surveillance is intended to provide a corollary affirmation of the non-tumorgenic quality of PDM siloxane in consonance with the biophysical surveillance based on parallel chromosomal surveillance.

The biochemical surveillance must be provided for in this project in order to anticipate the question of how valid is non-toxicity determined only by abundant cell growth during morphological assessment, inasmuch as abundant cell growth is also characteristic of tumorgenicity. Therefore, initially, the biochemical surveillance of HED cells and their ensuing changes during extensive culturing is directed toward study of time-dependent enzyme kinetics and selected catabolic metabolites (especially polyamines) in order to distinguish normal versus abnormal oncogenic cell metabolism when cultured in presence of various compositions and fabrications of PDM

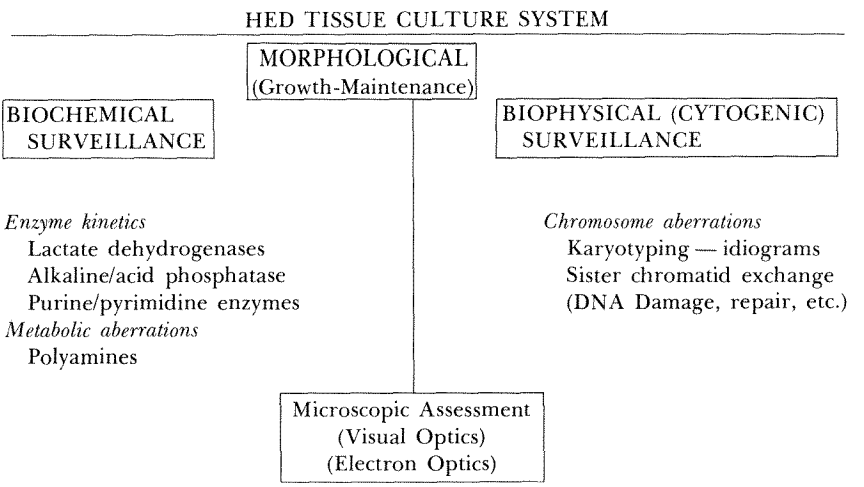


FIGURE 48.—Toxicogenic-tumorgenic assessment of polydimethylsiloxane based on the human excised donor (HED) tissue culture testing for demonstrating safe and effective usage in prostheses, implants, and medical devices.

siloxane. Initially, lactate dehydrogenase (LDH), commonly used in cell metabolism research (8) and clinically for diagnostic affirmations, is being analyzed in a time-dependent culturing series as a possible indicator of tumorgenic potential.

Meanwhile, the biophysical assessment, involving prolonged exposure of HED cells by the direct karyotyping assessment of chromosomal changes, is in progress based on photomicrographs of HED cells cultured in the presence of PDM siloxane. Figure 49 depicts normal karyotype of chromosome unaffected by PDM siloxane, with no evident tumorgenic propensity in a typical tissue culture test with human larynx tissue. The procedure is now being applied routinely with the HED overall test system for the statutory requirement of being safe in even permanent implants. The program involves standardization for reliability of the numerous test procedures, reagents, and photomicrographic techniques taken from published literature, in order to prepare the required Good Laboratory Practice protocol required by FDA.

V. Field (Clinical) Evaluation

This phase of the Comprehensive Development Plan provides a means for disseminating the results of the development of PDM siloxane as a safe and effective orofacial prosthetic material, made in accordance with the FDA provision of Good Manufacturing Practices (GMP) with Good Laboratory Practices (GLP) with clinical control for

FIGURE 49.—Typical human excised donor (HED) metaphase chromosome surveillance for tumorgenicity (Fig. 48, Biophysical Section) from cultured larynx cells indicating no tumorgenic aberrations. (Magnification: 2500x) Patient Tissue Source Code: CxW 29/M/C/NC/NR. PDM Siloxane Prosthesis Material Code: L-125-66-A-1.

quality assurance. Under the strict regulatory provisions for which PDM siloxane is currently providing the technical and clinical performance standards, PDM siloxane remains the only material— inasmuch as these provisions are not met by any of the previously used competing forms of proprietary RTV silicones, polyvinyl chloride plastisols, polyurethanes, and several recent sponsored contenders (9). Affirmed with regard to safety by the HED tissue toxicity/tumorgenicity assessment, and to effectiveness by mechanical properties, the PDM siloxane has been and is being made available to replace those competing materials whose deficiencies in endurance and qualification testing are described (10).

Table 8 lists the centers (clinics, services) participating in this program. A significant impetus to this program was given by the recent conference on Maxillofacial Rehabilitation, organized by the VA Northeast Regional Medical Education Center (REMEC) for the purpose of formalizing a standard, uniform VA-wide program for maxillofacial reconstruction and rehabilitation. Following formal request

for participation by the interested VA and non-VA maxillofacial prosthetic services (center, clinic, or private practice), a complete 6-shade set of internally pigmented PDM siloxane is forwarded promptly with full regulatory descriptions as to ingredients, their labelled ingredient content (Table 9), and color specifications (Table 7). In addition, a complete kit of external pigments (listed in Table 10) is forwarded with appropriate painting media for cosmetic matching. Thus, VA standards for both (a) the principal prosthetic molding material and technique, and (b) the external color ingredients, are

TABLE 8. — *Field (Clinical) Evaluation Program Participants Furnished PDM Siloxane Stock Materials*

(A) Veterans Administration Medical Centers (clinics, dental services, etc.)
VAMC Wilmington, Delaware
VAMC New York, N.Y.
[a]VAPC New York, N.Y.
VAMC Los Angeles (Wadsworth), California
[a]VAMC Boston, Massachusetts
[a]VAOPC Boston, Massachusetts
[a]VAMC Bronx, N.Y.
[a]VAMC Washington, D.C.
[a]VAMC Pittsburgh, Pennsylvania
(B) Non-VA Centers (clinics, dental specialists, dental schools, etc.) U.S.A.
Temple University School of Dentistry, Philadelphia, Pennsylvania
Sloan-Memorial Hospital, New York, N.Y.
[a]Tufts University School of Dental Medicine, Boston, Massachusetts
Duke University Medical, Center, Durham, North Carolina
National Naval Medical Center, Bethesda, Maryland
Medical College of Georgia School of Dentistry, Augusta, Georgia
Harvard University School of Dentistry, Boston, Massachusetts
Hammond Clinic, Munster, Indiana
Franklin Medical Center, Denver, Colorado
Irving Street Medical Center, Portland, Oregon
Private Clinics and Dental Services (four)
(C) Non-VA Institutions — Foreign countries
Cancer Control Agency of British Columbia, Canada
Centre Dentaire Portland, Sherbrooke, Quebec, Canada
University of Groningen Medical Center, Groningen, The Netherlands
Oslo University Dental Faculty, Oslo, Norway
Cracow Medical Academy, Stomatological Clinic, Cracow, Poland
Rambam Hospital, Haifa, Israel
(Several additional institutions in England, Ireland, West Germany, Switzerland, and Spain are anticipated to request participation.)

[a]Attendees at the VA Northeast Regional Medical Education (REMEC) organized conference on maxillofacial rehabilitation. Other VA centers are anticipated to partici-

TABLE 9.—Ingredient Contents of Six-Member Shade Panel of Polydimethylsiloxane Prostheses Stocks (Production Lots — *Weight Percent*)

	Production, FDA labelled stocks					
	SY-1	SY-2	SY-3	SR-3	SR-2	SR-1
Prepolymer	78.4	78.8	79.0	79.0	78.8	78.4
Oligomer	19.6	19.7	19.8	19.8	19.7	19.6
Catalyst	0.98	0.99	0.98	0.99	0.99	0.98
Pigments:						
Polysiloxane	0.47	0.24	0.12	0.12	0.25	0.49
Oligomer	0.32	0.16	0.08	0.08	0.16	0.32
Red flock	0.099	0.050	0.025	0.026	0.052	0.102
Yellow iron oxide	0.015	0.007	0.004	0.004	0.008	0.015
Titanium dioxide	0.079	0.039	0.020	0.010	0.021	0.041

The above ingredients and their component percentages are indicated on all labelled packages of the production lots sent out for Field (Clinical) Evaluation.

TABLE 10. — *Colorants and Accessories for External Cosmetic Matching of Internally Pigmented PDM Siloxane*

Colorant	Trade name (Specification designation)	Manufacturer source
Yellow	Pure Yellow Iron Oxide (YO-2087) (Lot 131)	Pfizer Corp. New York, N.Y.
Gold Yellow	Monastral Gold (YT-823-D TS-84773)	E. I. du Pont de Nemours Co. Wilmington, Del. 19898
Red	Monastral Red (RT-759-D PS-97486)	E. I. du Pont de Nemours Co. Wilmington, Del. 19898'
Maroon	Monastral Maroon (RT-792-D SL-68504)	E. I. du Pont de Nemours Co. Wilmington, Del. 19898
Violet	Monastral Violet (RT-201-D TS-80907)	E. I. du Pont de Nemours Co. Wilmington, Del. 19898
Blue	Monastral Blue (BT-284-D PS-80920)	E. I. de Pont de Nemours Co. Wilmington, Del. 19898
Black/Brown	Manganese Dioxide (Analytical grade)	Harshaw Chemical Co. Cleveland, Ohio 44106
White	TI-PURE Rutile (R101)	E. I. du Pont de Nemours Co. Wilmington, Del. 19898
Red Rayon Flock	5019 Bright Red B5 (Flock)	Clarement Corp. Claremont, N.H. 03743
Blue Rayon Flock	3016 Medium Blue (Flock)	Claremont Corp. Claremont, N.H. 03743
Vehicle Base	Silastic Medical Adhesive (Silicone Type A)	Dow Corning Corp. Midland, Michigan 48640
Xylene Thinner	Xylene, Analytical Grade	(Local Chemical Supply Source)
Catalyst	Luperco CST or AST (Benzoyl Peroxide)	Pennwalt Corp. Lucidol Div., Buffalo, N.Y.

Note: additional items such as brushes, fibers (eyebrows), cleansing solutions, tissues, pigment mixing palette, hair dryer, etc. procured by prosthetist.

furnished at no cost to the participants, for prompt clinical trial. In addition, as a practical productive followup of the VA-NREMEC conference, appropriate training videotapes for (a) and (b) are now available for self-instruction and as means for standardization of PDM siloxane in the fabrication, fitting and coloring of the finished prosthetic devices.

Clinical Service and Cost Advantages

The Field (Clinical) Evaluation Program now provides a prosthetic service to various centers, clinics or even private practices. The purpose is to make available a prompt, dependable service without the difficulties that clinicians have complained about in utilizing proprietary kits offering little or no guidance or specifications for quality. Those shortcomings are being eliminated by the standardized PDM siloxane techniques, especially with a centralized source of supply with on-going technical service for the entire VA system. The technical service is particularly needed: a survey taken at the VA REMEC conference showed that of 23 attending centers, none had technicians with any academic background for the technical and coloring basics. This was also reported by the attending prosthodontists. Not surprisingly, there was considerable reluctance to undertake or maintain continuing maxillofacial reconstructions. The proprietary RTV silicones, polyvinyl chloride plastisols, and polyurethane provide no scientific techniques nor technical service support such as are now available for the PDM siloxane material and technique.

Cost estimates for the PDM siloxane indicate considerable savings, not only in technical and professional (prosthodontic) service time, but also in materials costs. The cost of PDM siloxane as a packaged item, depending upon volume demand, runs as low as $20 per pound (from a pound, an average of 25 prostheses can be made at a relatively inconsequential materials cost of $0.80 each). The highest cost has been no more than $60 per pound ($4.20 for each prosthesis) exclusive of the fabricating and coloring services which impose the major cost but are held down by the simplified PDM siloxane technology. This $.80–$4.20 range for a single prosthesis unfortunately has little commercial attraction or incentive. The total VA need is estimated at no more than 400 pounds per year for a market total of $8000 to $24,000 per year. The latter, if multiplied 3 to 4 times to take care of non-VA needs, amounts to an estimated maximum of $96,000 per year — still unattractive for a commercial venture. Therefore, the present VA commitment to provide the best safe and effective prosthetic material must be sustained for at least an additional 2 years. This time period is necessary in order to assure steady

maximum prosthetic servicing for the next 2–3 years, by which time the required GLP and GMP documentation (in conjunction with HED tissue/tumorgenicity and corollary clinical evaluation of this program) will have attained unequivocal stance for regulatory acceptance as medical prostheses. Only in that situation will it be likely to attract outside commercial takeover. Otherwise, lacking competent exemplary technical service with the kind of solid scientific background provided by the integrated Comprehensive Development Plan, the rehabilitative prospects of the facially disfigured would continue to depend on makeshift materials, noncontrolled fabrication, and guesswork on pigmented cosmetic fitting.

VI. Production

Since the inception of this Phase V in April 1978, ten production campaigns have been carried out as one-day runs producing a total of 221 one-pound lots of the 6-member shades panels listed in Table 11. The manufacturing operations require surprisingly little working area: an enclosed room of 144 square feet (12 x 12) which is being converted into a so-called "medical clean room" to assure zero contamination will accommodate complete processing to final packaging under provisions of FDA regulations on Good Manufacturing Practices as required under Section 520f of the Medical Device Amendments of 1976 (2).

To date, this program provides not only for the technical details and materials specifications monitored by toxicity (and now

TABLE 11.—*Production Campaigns of PDM Siloxane Pigmented Compositions for Field (Clinical) Evaluation Program* (One-pound Lots)

Campaign (NB)	Lot Number (L-125)	Internal pigmentation (Yellow/Red ratios) SY-1	SY-2	SY-3	SR-3	SR-2	SR-1	Total
I	1	—	3	1	—	—	—	4
II	12	—	—	—	6	6	4	16
III	24	6	8	6	—	2	2	24
IV	46	2	2	2	2	3	2	13
V	47	4	4	4	3	3	3	21
VI	49	4	6	4	4	4	4	26
VII	55	4	6	4	6	4	4	28
VIII	58	5	5	5	5	5	5	30
IX	70	4	6	4	6	4	5	29
X	78	5	6	4	5	5	5	30
Totals	—	34	46	34	37	36	34	221

Note: Each campaign has specific product and process variations, notably grades of oligomer (see Table 2) and alternate catalyst, to anticipate probable preferences from the field evaluation.

tumorgenicity) assessment testing (Phase III) but also for direct support of the Field Evaluation Program (Phase IV) with over a score of participating centers listed in Table 8. Although non-VA centers (clinics, etc.) involved in head and neck cancer provided the initial stimulus, largely because of direct, personal solicitation and presentations at annual meetings of the Academy of Maxillofacial Prosthetics, the recent conference in May 1979 on maxillofacial rehabilitation organized by the VA REMEC and sponsored by the VA Rehabilitative Engineering R & D Services, Washington, D.C., has given the program a noteworthy impetus.

As mentioned in previous BPR reports, the current production capacity can readily support an estimated 8,000 new VA-serviced cases of an extensive range of orofacial reconstructions, which includes not only the maxillofacial but also tracheal, esophogeal, subcranial and all components resulting from head-and-neck cancer ventures. An average orofacial prosthesis averages 18 grams (in a range from 8 to 32 grams) which implies that each one-pound lot provides for 25 prostheses. Assuming duplicate prostheses, the 8,000 yearly input will require 200 kilograms (or 440 pounds) as yearly production. This requirement can be more than adequately accomodated by the presently established production facility, operated on a biweekly schedule of one day's operation, 26 days x 24 pound/day, for a total of 664 pounds (or 301 kilograms) with surplus to take care of non-VA clinics, many of which actually service VA patients.

Acknowledgment

The participation of Miss Nanci E. Donacki, Research Biologist for Toxicology, is a most timely acquisition to the project with the supplemental responsibility as designated Quality Assurance Monitor under the provisions of Section 58.35, Good Laboratory Practice for Nonclinical Laboratory Studies (11).

The continued participation of Dr. Irene Mildan in the maintenance of the on-going HED tissue toxicity and tumorgenicity testing system, and the guidance and assistance from Dr. Mary D. Nadilcka, Cellular Biologist, are gratefully acknowledged, as is the interest and cooperation of Dr. W. Hayman Behringer and Dr. James S. Reilly, E.N.T. Section, VA Medical Center, Wilmington, Delaware, who are providing the orofacial tissues for the HED system. The assistance of the VA REMEC, under the supervision of Dr. Richard Adelson, in organizing the highly successful program on maxillofacial prosthetics at the VA Wilmington Medical Center, May 15–17, 1979, is gratefully appreciated as an effective impetus toward the extensive, VA-wide adoption of PDM siloxane for safe and effective prostheses as a

vitally important facet of rehabilitation of thousands of functionally and cosmetically disfigured patients.

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10. Lontz, John F., and James W. Schweiger: Maxillofacial Restorative Materials and Techniques, Bulletin of Prosthetics Research, BPR 10-30 Fall 1978, (Table 8 page 241).
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Development of a Wheelchair Using a Myoelectric Control System

West Roxbury VA Medical Center
1400 Veterans of Foreign Wars Parkway
West Roxbury, Massachusetts 02132
Alain B. Rossier, M.D., Mehdi Sarkarati, M.D., and George E. Crawford, Ph. D.

Major activity on the myoelectric wheelchair control system has been temporarily suspended during the reporting period from January 1, 1979 through June 30, 1979 while awaiting the review of a continuation proposal.

Plans have been made to:

1. Develop a mobile version of the simulated wheelchair control system described in the last 6-month progress report (BPR 10-31);
2. Investigate a technique for deriving a higher information rate from coded myoelectric signals than is obtainable from simple voluntary muscle contractions; and
3. Develop a second mobile system that will incorporate the results of the myoelectric coding investigation to require only one myoelectric pickup site.

Activity during the interim period has been limited to the development of some of the special-purpose instrumentation required for the myoelectric coding investigation.

Seat Cushions for the Paralyzed

Castle Point VA Medical Center
Castle Point, New York 12551
Bok Y. Lee, M.D.

Veterans Administration Prosthetics Center
252 Seventh Avenue
New York, New York 10001
Leon Bennett, M.A.E.

It is widely accepted that an excess of pressure, implicit in the act of sitting, acts to deprive local tissues of necessary nutrients. If sustained in time without relief (hours) such a process is believed to result in necrosis.

To prevent pressure sores it would be helpful to pinpoint those subjects who are particularly prone to a condition of low or no bloodflow when placed in a loadbearing condition. Once identified,

particular nursing care (frequent shifting and soft cushions) can be given those at risk.

A clinical device to identify high-risk patients has been developed under this program. (Fig. 50). The apparatus consists of a wheelchair equipped with a hard plastic seat containing instrumentation capable of monitoring pressure, shear, and skin arteriolar bloodflow in proximity to the ischium of a seated subject. Patients displaying a wide range of pathologies are to be tested on this device.

Data gathering has started with an examination of normals and geriatrics. Approximately four subjects in each category have been studied to date. It is clearly premature to describe the results; a much

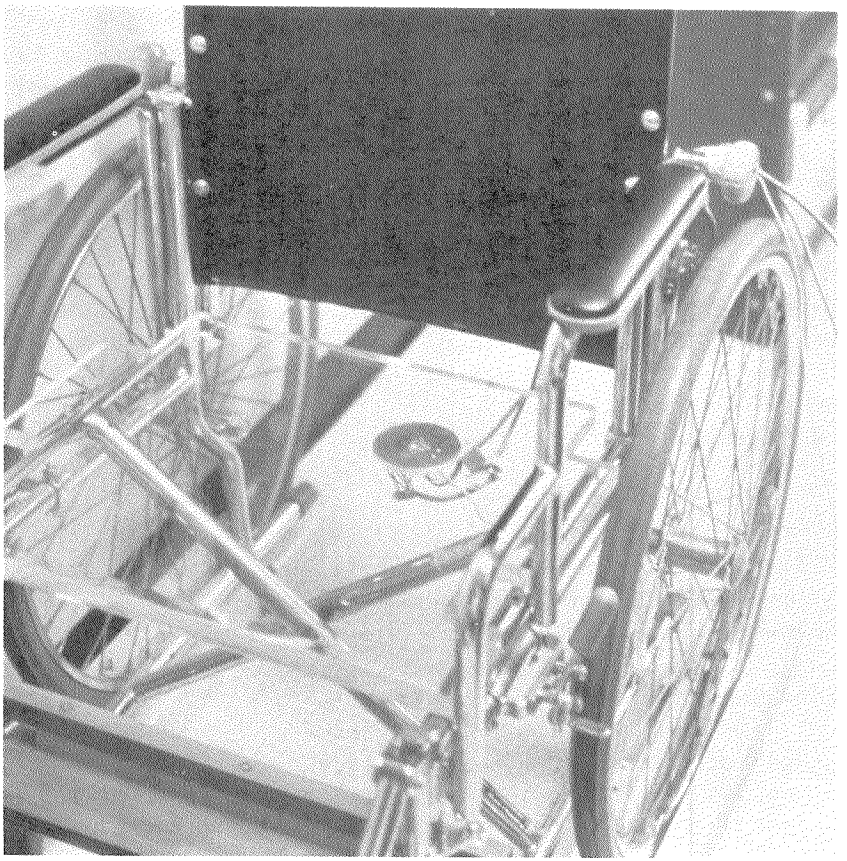

FIGURE 50.—Rigid transparent plastic seat in this wheelchair is fitted with instrumentation to monitor pressure, shear, and skin arteriolar bloodflow. Disk near left rear corner of seat contains sensors; wires can be seen through the transparent material of the seat.

larger sample will be necessary. It can only be said that this effort appears promising and is continuing.

Seating Systems for Body Support and Prevention of Tissue Trauma

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

Stanford University
Children's Hospital
Rehabilitation Engineering Center
520 Willow Road
Palo Alto, California 94304
Maurice Le Blanc, C.P., and Wallace Motloch, C.O.

Progress Report II, May 1979, outlines efforts from the beginning of 1978 through the fifth-generation cushion. A mushroom-shaped rigid foam fulcrum embedded in flexible polyurethane foam supports the posterior thighs but lowers pressures at the ischii and other areas to levels near those recommended by Rogers. Ablebodied people with sensation seem comfortable with weight primarily on the ischii, while SCI people require pressure relief there.

Copies of Progress Report II (37 pages, illustrated) are available on request.

Design Refinement of the StairCat Stair-Climbing Wheelchair

StairCat Incorporated
1 Pine Street
Nashua, New Hampshire 03060
Norman Van Dine

Introduction

The development of the StairCat stair-climbing wheelchair was initiated in the winter of 1970 by Malcolm C. Winsor, Mont Vernon, New Hampshire. Research and testing of numerous potentially attractive means for mechanically and/or electrically incorporating a stairclimbing capability in a chair that would retain full on-the-level utility, continued under his exclusive direction into early 1975, when the first demonstration StairCat wheelchair was demonstrated.

The VAPC reviewed the StairCat wheelchair's performance and took the lead in ordering an evaluation model, knowing that the development was in prototype stage. The StairCat wheelchair delivered to the VAPC showed promise of fulfilling a need for a manually operated stair-climbing wheelchair for use by a segment of the handicapped community (Fig. 51).

The VA Rehabilitative Engineering R & D Service has contracted

FIGURE 51.—StairCat.

with StairCat Incorporated to have the Mk III StairCat wheelchair refined to meet performance criteria established at a VAPC meeting of June 1977. Prior to that date, no goals existed for stairclimbing wheelchairs. The company has undertaken the modification of their previous design to allow for a lowering of the center of gravity by 5 cm, and an increase in the over-all mechanical efficiency above the then-existing 76 percent. Removable armrests were to be provided and the wheelchair was to be made more clinically acceptable.

The goal of this 9-month contract has been to deliver, to the Spinal-Cord-Injured Unit, West Roxbury VA Medical Center (attention Dr. Alain Rossier), two refined StairCat Mk IV stairclimbing wheelchairs that are both clinically and mechanically acceptable to the VA and the HEW Rehabilitation Services Administration.

In keeping with the design team concept, the company has continued to use the talents of Kendrick W. Lentz, Jr., program manager, Malcolm C. Winsor, the original inventor of the StairCat wheelchair, Bryce R. Milligan, lead designer, and company president Norman Van Dine.

Two wheelchairs have been delivered, and intensive testing is anticipated.

Functional Neuromuscular Stimulation of Limbs: A Feasibility Study

Brentwood VA Medical Center
Wilshire and Sawtelle Blvds.
Los Angeles, California 90073
John A. Foster, Ph. D.

Note: Because of delayed arrival, we were unable to place Dr. Foster's report in the same section of the Bulletin as other VA RER&DS progress reports dealing with functional electrical stimulation and closely related subjects.

The Field Control Electrode

Definition of a Field Control Electrode

A Field Control Electrode consists of four or more plate-like elements arranged in a cylindrical array and interposed between circumferential driver elements, the combination of which is designed for implantation around a peripheral nerve (Fig. 52). As conceived, the driver elements are in direct electrical contact with the nerve but the field control elements are electrically isolated from the nerve and the surrounding environment.

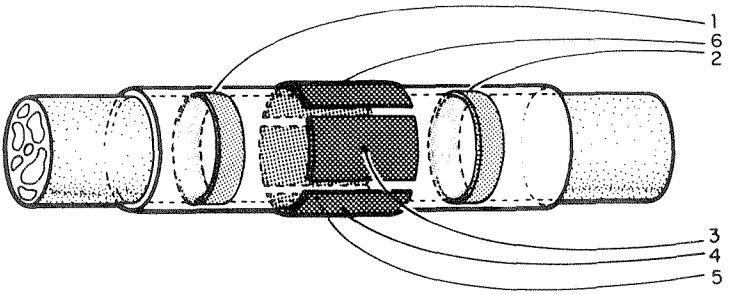

FIGURE 52.—Field control electrode around a nerve.

Purpose of the Field Control Electrode

Some persons experience a non-recoverable paralysis of internal organs or limb movement caused by spinal cord injury, stroke or by disease processes. In many of these cases, the neuromuscular system is functionally intact but no longer under volitional control. The Field Control Electrode was conceived as a way to artificially stimulate peripheral nerves to assist those persons in regaining some control of their bodily functions and/or their environment.

The application of short pulses of electrical current to the driver elements produces an ion-drift current in and along the nerve segment between those elements. Simultaneous application of electrical potentials to the field elements concentrates, or focuses, the ion-drift current into a small sub-region of the nerve (Fig. 53). Restated in a different way, the spatial ion density in the nerve segment enclosed by the Field Control Electrode is modified on a pulse-to-pulse basis by the electrical signals applied to the driver and field control elements. Controlled modification of the ion density spatial distribution results in selective excitation of a small subset of nerve axons. This capability, in combination with anatomic specificity of neuromuscular motor units, produces activation of targeted muscle groups (Fig. 54). Thus, an appropriate pattern of electrical signals to a Field Control Electrode is expected to generate excitation-patterning of neuromuscular motor units essential to coordinated movement of limbs or digits by an individual who no longer has volitional control.

Project Status

Three areas of research are believed necessary to investigate the concept. One is the development of experimental designs which can be used on animals to demonstrate the hypothesis of field control. Another

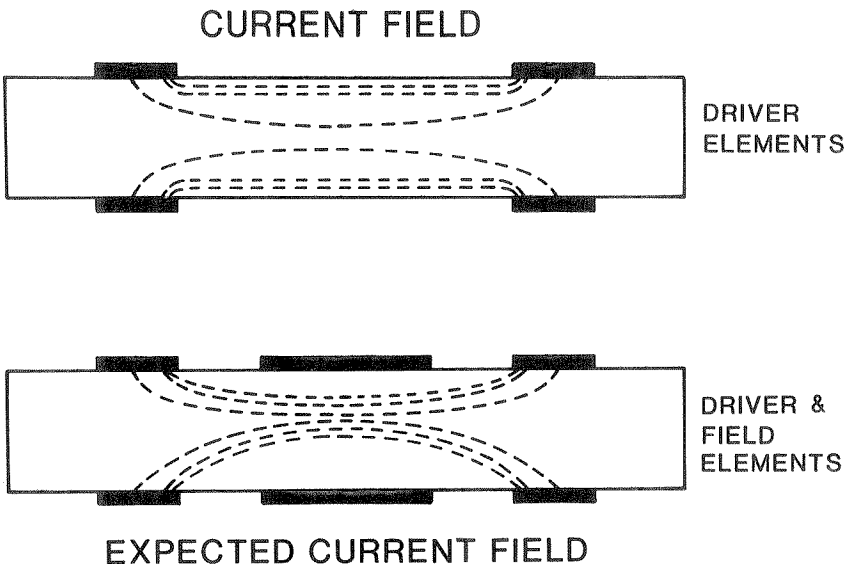

FIGURE 53.—Theoretical effect of field potentials.

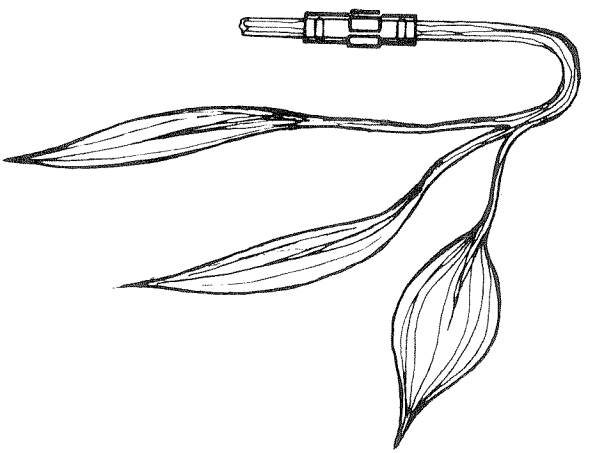

FIGURE 54.—Selective muscular contraction via field control electrode.

is the application of 10-times-size scale models, to measure the spatial electrical fields. The third area is computer simulation and modelling to evaluate the hypothesis and to develop design guidelines on the physical configuration and the applied electrical signals. At the Brentwood VA Medical Center progress has been made on the first two areas. The third has not yet been initiated, although JPL/NASA may start some work in the Fall of 1979.

The development of experimental designs for animal testing is based

on best "guesstimates" of patterns that are expected to demonstrate the concept. For clinical reasons (low mass, small size, reduced drag from movement of adjacent tissue, and self-adherence to avoid suturing) thin-film technology is used. Design examples use 0.5-mil or 1.0-mil Type H Kapton, furnished by Dupont, which has 2000 Å of metal vapor-deposited on both faces. (Silver has been used in these experimental designs because of lower cost, although platinum or its alloys appear to be the best material available at this date for clinical versions). Figure 55 illustrates the Type C design for the sciatic nerve of cat. Patterns were etched by commercial vendors on both faces of the plated Kapton, using a photo-sensitive resist. Parylene and Teflon appear to be strong candidates for an insulating layer over the field control elements. Edge connectors provide electrical connections to the driver and field elements on the experimental models.

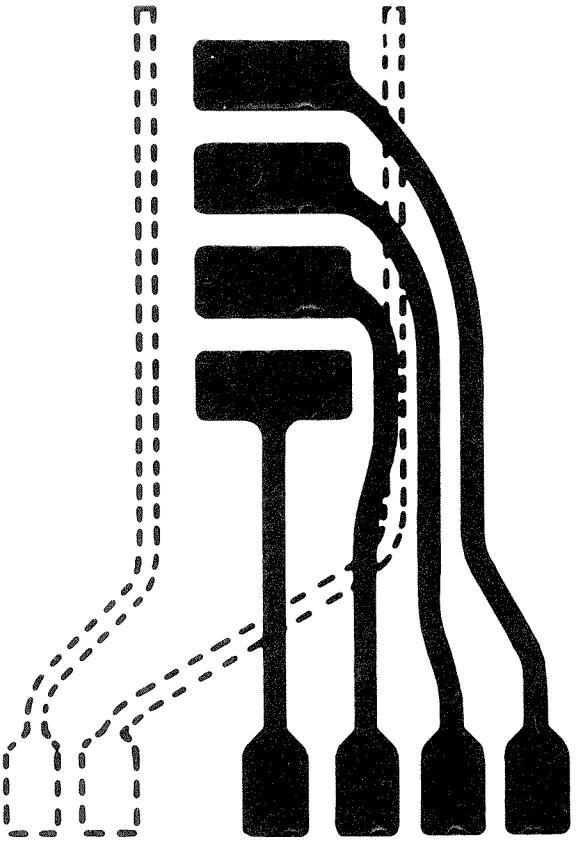

FIGURE 55.—Type C pattern of field control electrode for acute animal experiments.

Measurements of the electric field in a solution simulating the conductivity of nerve (250 ohm-cm) have been initiated with 10X scale models. Early work on driver elements alone (no field elements) was performed with 90-Hz sine wave signals. The measured fields generally meet the expectations from classical field theory. Electronics providing simultaneous pulse signals to driver and field control elements are currently under test/evaluation in the laboratory. Successful performance of the electronics in the scale models will justify acute animal experiments with the Type C Field Control Electrode design.

Directions for Future Work

An extensive computer modelling and simulation study is the most economical way to obtain answers to such questions as: What is the optimum width and spacing between the driver elements? How many field elements are required and what should be their shape and size in relation to the driver elements? What is the radial arrangement of field elements to produce the greatest effect? What are the optimum waveshapes and phase relationships between the driver and field potentials? This work should result in design specifications of the configuration parameters essential to electrode fabrication. Also, the design requirements on electronics to supply the Field Control Electrode with appropriate signals can be derived.

Work is needed to combine thinfilm techniques and materials technology in the fabrication of electrodes which are biocompatible for long-term implantation. Collaborative work with various NASA agencies on thinfilm technology and electrode fabrication is underway. Moisture absorption, material transfer due to current flow, material fatigue from flexing and bioreactivity are some of the problems requiring careful selection of materials and special fabrication methods.

Animal experiments must be carefully designed and conducted. The first goal is to demonstrate experimentally the Field Control Electrode concept. Follow-on activities would experimentally evaluate different electrode designs for performance comparison. These, and other related tests, would validate the model for computer simulation. Gaps in the literature for data on the electrical properties of nerve require experimental derivation to support the computer modelling study. Both acute and chronic animal experiments are necessary to evaluate the programming of a CPU for patterning of signals to a Field Control Electrode. Chronic experiments to investigate the mechanical, electrical and tissue interactions at the electrode-nerve interface must be conducted. Development and evaluation of a master-controller for the Field Control Electrode will require both acute and chronic animal experiments.

Systems engineering studies must examine the overall systems problems of the "Cybernoid" (the entity resulting from the integration of machine with man). What human factors must be considered in the integration of man with machine? How many Field Control Electrodes are to be implanted? Where is the air-skin interface occurring in the system and what information must be transmitted through that interface? What and where is the source of power? What are the feedback channels for movement control? What controls are available to the cybernoid?

Acknowledgments

The technical assistance of Sandra J. Neuschafer is noted with appreciation.

Engineering Applications in Orthotic and Prosthetic Treatment of Musculoskeletal Defects

Motion Study Laboratory
Rehabilitation Medicine Service
Cleveland VA Medical Center
10701 East Boulevard
Wade Park, Cleveland, Ohio 44106
E. Byron Marsolais, M.D., Ph. D.

The progress report for this period was not received in time for presentation in this issue of BPR.