HIGHLIGHTS OF OTHER VA RESEARCH PROGRAMS

PROSTHETICS

Edited by
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Prosthetics Research
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Synergetic Hook Modifications

The results of the VA preliminary small-scale clinical evaluation of this device suggested several modifications, which have now been incorporated into a new prototype. The mechanical changes are being accompanied by changes in the electrical design. The system is being converted for operation at 6 V. The lower voltage will permit a smaller battery package to be used and should also improve battery reliability. (It also will make it possible to fit the myoelectric hook/hand prosthesis to amputees with wrist disarticulations.) The batteries will be removable from an external opening. Therefore, the system will be more modular.

To diminish drain on the batteries the "fast" finger drive motor must have its drive current cut off after the finger stalls. Considerable effort has been expended in order to accomplish this in a reliable and inexpensive way; at present, a motor rotation detector is being used.

Powered Arm for Shoulder-Disarticulation Amputees

This electric arm, based on the principles developed by Dr. David Simpson, is still in fundamental stages of development. A socket-like

jacket has been fabricated of polypropylene to allow laboratory personnel to use the system. The arm is mounted on an aluminum frame attached to the socket. The passive shoulder joint is the orthogonal cylinder glenohumeral joint developed at Northwestern and now available from Pope Brace Company.

A Ph. D. candidate is beginning studies related to control of this multifunctional arm.

Atmospheric Pressure Suspension Sockets

The difficulties which have been experienced over the last few years in fitting above-elbow sockets supported by atmospheric pressure have been overcome through the use of transparent cellulose acetate butyrate check sockets. Clear check sockets permit modifications which are based on visual inspection of the socket's fit. Therefore, the cast can be initially made by measurements and then refined by using the clear check socket.

The completed socket has a latex liner which collapses on the limb when the socket is pulled distally. The latex liner is needed so that movement of the socket does not cause loss of the pressure differential. A sports prosthesis with this type of suspension is shown in Figure 1. (The chest strap is for safety purposes only and is not the support mechanism.)

The racketball prosthesis is an excellent test of the socket's ability to remain secured to the arm because the prosthesis is used very actively and in the presence of much perspiration. The details of socket construction were presented in July 1978 at the AAOP National Continuing Education Seminar in Orthotics and Prosthetics (Chicago, Illinois).

Lightweight Below-Knee Prostheses

The laboratory is investigating the fabrication of lightweight below-knee prostheses with polyethylene. Foam is kept in the prosthesis for strength and this increases the weight, compared with polypropylene prostheses (approximately ½ lb. heavier). However, fabrication time is greatly reduced using polyethylene and this explains our interest in this material.

Two polyethylene prostheses (one with rigid and one with flexible forefoot) have been fabricated for testing under static loads.

Intermediate Below-Knee Prostheses

A second bilateral subject has been fitted with intermediate below-knee prostheses. These prostheses have a removable socket of Aquaplast® which can be reduced in size on its posterior and distal aspect

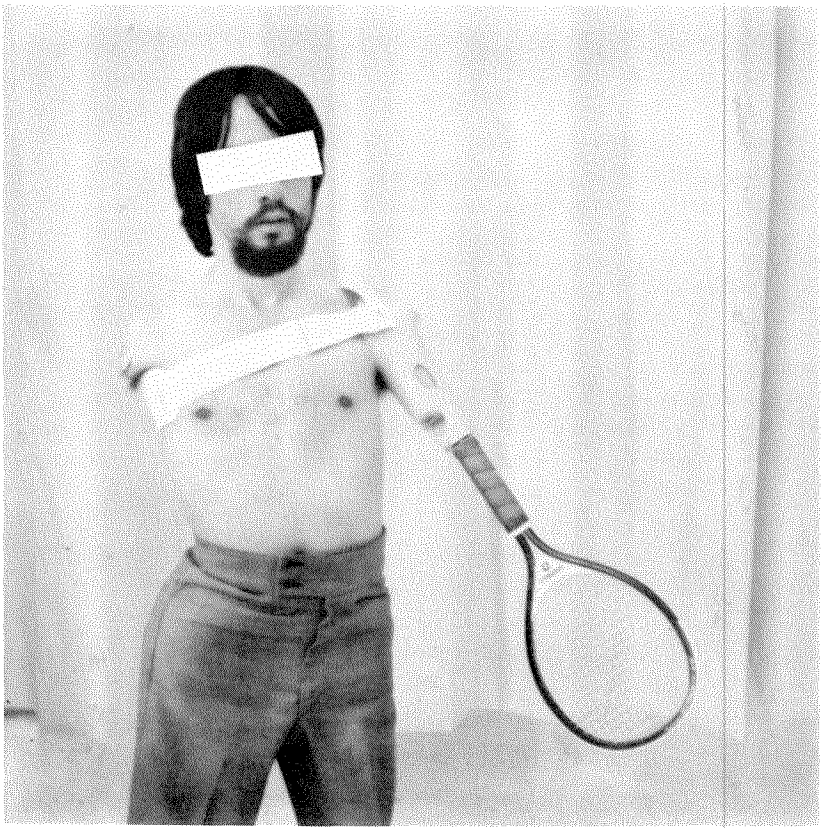

FIGURE 1.–Sports prosthesis which utilizes an atmospheric pressure suspension socket. The chest strap is for safety purposes only and is not the support mechanism.

as the limb matures. This socket may also be worn at night or at other times when the prosthesis is not worn. A paper on this subject is to be presented at the AOPA National Assembly, November 1978, San Diego, Calif.

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

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Neurophysiological Studies

Electrotactile Sensory Aids

The objective of this project is to develop electrotactile sensory aids for amputees, spinal-cord-injured persons, the blind, and the deaf.

The basic data phase concerning the response of tactile receptors to simultaneous multi-stimuli has quantified experimentally the Two Point Discrimination Threshold (TPDT) as a function of body site, laterality, frequency, stimulation codes, pulse width and pulse time delay. To determine habituation and practice changes, stimulation over 14 days was investigated. Preliminary data show that subjects learn to distinguish two simultaneous stimuli, with substantial improvement in the TPDT, the Sensitive Band Width (SBW), and the stimulation codes.

The implications of the effect of learning were incorporated in the development of several optimal electrotactile displays. These applications include implementation for tactile and kinesthetic feedback from lower-limb prostheses and an electrotactile lumbosacral brace. The clinical applications phase is coordinated with Dr. A. Bonebakker and Dr. A. Mehta, of the Rehabilitation Medicine Service of the VA Hospital in Sepulveda, California.

Upper-Limb Prostheses Using Microprocessor Hardware

The microprocessor-based arm prosthesis is in its clinical phase. All subsystems were reduced to a portable self-contained unit, and preliminary testing was performed.

Two above-elbow amputee patients were selected for the clinical evaluation phase. The patients underwent 3 weeks of training aimed at recovering muscle tone in the residual limb and shoulder muscles so that myoelectric recordings are possible. Sockets were fabricated in cooperation with the Prosthetic Clinic of the VA Hospital, Wadsworth, Calif.

Current efforts are concentrated on advanced harnessing techniques and the prostheses performance evaluations.

Evaluation of Medical Manipulators and Design Specifications for Improved Control

The Biotechnology Laboratory has continued work in the comparative evaluation of remote medical manipulators and associated control systems for the seriously disabled patient. Our work has progressed in three areas:

1. Clinical evaluation;
2. Pre-clinical testing; and
3. Bench testing.

This report will briefly summarize results to date under these research headings.

1. *Clinical Evaluation*

Rancho Los Amigos Golden Arm—Clinical evaluation of the Rancho Los Amigos Golden Arm (remote manipulator No. 12) has progressed to the long term stage of patient use. A male C-4 quadriplegic, who has been trained and previously tested in the use of the Rancho Golden Arm, has been discharged from the VA Hospital, Long Beach, Acute Care Section, and has taken up residence in a local nursing home. The manipulator equipment has been made available to him for use at his discretion. Monitoring indicates the patient uses the manipulator rarely.

This, we feel, reflects both manipulator utility (which is limited because of required individual sequential and motor control through seven degrees of freedom) and lack of defined rehabilitation goals on the part of the patient. The patient's physical needs are well cared for by nursing home staff, and the manipulator serves no goal-oriented purpose in the patient's daily life.

The interaction of machine control complexity and patient motivation indicates that: control aiding is needed in manipulator use, and selection of manipulators for patients on a prescriptive basis must incorporate the patient's rehabilitative goals.

2. *Pre-Clinical Testing*

Pre-clinical testing of the manipulator systems made available during the last 6 months has not been possible due to mechanical and electrical difficulties encountered in the bench testing phase of the evaluation. The manipulators, either for reliability or safety reasons, have not been ready for patient use.

Repairs have been made on the units and they are presently ready

to be used by supervised patients. Arrangements with local VA hospitals are being finalized to make the Johns Hopkins and the General Teleoperators Telescoping Manipulator System available for patient use.

3. *Bench Testing*

Bench testing has been completed, and engineering profiles have been compiled, for the Johns Hopkins manipulator/worktable system and for the General Teleoperators wheelchair and manipulator system.

The Johns Hopkins system is being prepared for patient use. This system exhibited some control difficulties during bench testing. These have been corrected by the Johns Hopkins Applied Physics Laboratory.

The General Teleoperators system has been evaluated. It is presently unsuited for patient use due to unsafe wheelchair acceleration rates and system unreliability. Modification of the system to allow patient use is being negotiated with General Teleoperators.

Progress is being made toward constructing interface specifications for the Denver Research Institute ocular-control unit with a remote manipulator, and the development of an evaluation protocol for voice control of manipulators and environmental control units.

Control of an Artificial Upper-Limb Prosthesis in Several Degrees of Freedom

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Work on the multifunctional myoelectric above-elbow prosthesis control system during this period was affected by preparation for the move to Illinois Institute of Technology (with an association with the VA Hospital at Hines, Illinois). As of June 1, 1978, work will again progress as anticipated.

However, during the last 6 weeks of this report period, work on the present project was performed without the laboratory equipment, which has not yet arrived from Colorado. For this reason, part of the work performed during this report period was theoretical only.

The work over the last 6 months was concerned with three main aspects:

1. Preliminary clinical evaluations;
2. Hardware and software modifications on the microcomputer system used for the present prosthesis control; and
3. Analytical and off-line studies toward improving speed and accuracy of the controller's performance.

Preliminary Clinical Study

The preliminary clinical study was performed at Dr. John Boswick's clinic at Colorado General Hospital, Denver, Colorado. Due to the author's projected move to Illinois, and to the schedule of Dr. Boswick at the time, only one session with an amputee eventually took place, following the temporary installation and testing of the equipment at Colorado General Hospital. This session was concerned mostly with studying aspects of training the amputee (who had no previous experience with any myoelectric device) to generate informationally meaningful myoelectric signals. During the first half hour, the amputee's raw myoelectric signals, taken with a single electrode pair at a single location, yielded parameters with no consistency at all. By the end of the day, however, consistency increased considerably and yielded adequate discrimination between two, and later three, limb-functions.

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[a] As of June 1, 1978, Dr. Graupe has transferred to the Department of Electrical Engineering, Illinois Institute of Technology, Chicago, Illinois 60616.

Continuation of this work will be performed at the VA Hospital, Hines, Illinois, where the equipment is to be permanently installed once it arrives from Colorado. (Previously, the equipment has had to be repeatedly re-set as it was moved back and forth between Denver and Fort Collins.)

Equipment Modification

Equipment modifications performed were mainly concerned with optimizing the discretization intervals used in the time series model. Here, parameters as identified by the system for on-line myoelectric data were compared for myoelectric time series models using different discretization intervals for maximal accuracy in the resultant limb-function discrimination. A program for a 16-bit microprocessor has been prepared and tested on a 16-bit microprocessor on loan from VAPC, New York. It is hoped that a similar 16-bit system will be made available for the project in the near future.

Analytical Work

The off-line analytical work was concerned with the study and the off-line testing of various modified least-squares identification algorithms, for the purpose of improving either their computational speed per iteration, or their convergence rate, or their robustness (sensitivity to finite-word-length processing). Here the major modified least-squares algorithms that were published over the years, and other major identification algorithms, were compared both theoretically and computationally, having the above aspects in mind. The algorithms considered were: various stochastic approximations algorithms, modified least-squares such as the equation-error algorithms and their modified forms, various sequential-learning algorithms, square-root algorithms, lattice algorithms, Durbin's partial-correlation algorithm, versions of Gabai and Merhav's algorithm, etc.

The result was that the sequential least-squares algorithm presently used out-performed all others in at least one of the above aspects. The only aspect in which sequential least-squares was occasionally behind was that of computational-speed-per-iteration. However, whenever this happened, the other algorithm was either very sensitive to finite word-length, or slow in convergence, or both, to an extent that it could not be used (this was the case especially with respect to "par-cor" and lattice algorithms). Regarding robustness, the only algorithm that has been found to equal the fundamental sequential least-squares was the square-root algorithm, but in this case the sequential least-squares was faster in its computational-time per iteration, whereas convergence rate was the same for both.

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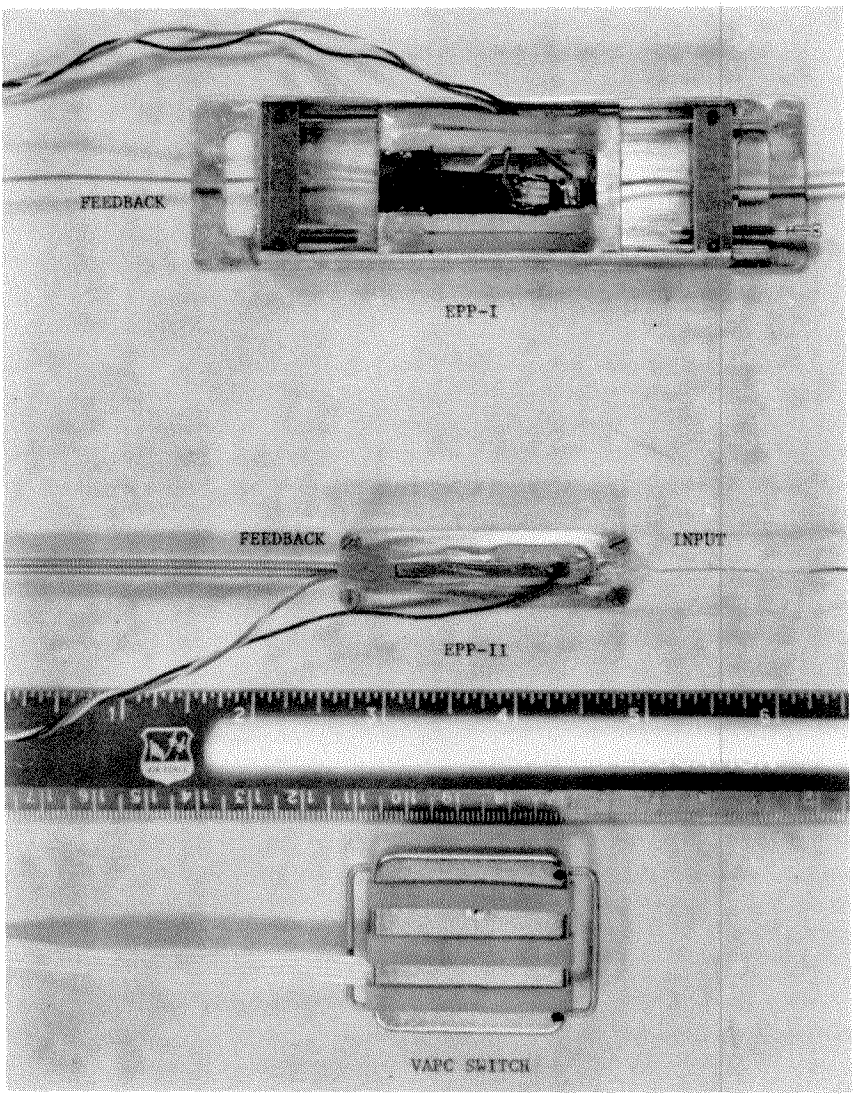

FIGURE 2.–First and second generation EPP transducers compared with a VAPC pull switch.

The goal of this research is to develop a means of implementing Extended Physiological Proprioception (EPP) to control the VA electric elbow in a position-control mode rather than velocity control. Evaluation of the first prototype transducer, EPP-I, on a normal subject was very encouraging.

Recent work has focused on miniaturizing the transducer and circuitry. As shown in Figure 2, a new transducer, EPP-II, has been designed and constructed. It is much smaller and lighter than EPP-I, allowing it to be located at a wide variety of control sites on the body. The mechanical feedback to the transducer is still provided by a flexible Bowden cable. The necessary circuitry to power the system has been incorporated onto a small printed-circuit board which will fit inside the turntable of the VA elbow.

The next phase will be to fit EPP-II to an amputee for evaluation. Initial tests will include pursuit tracking of a random command signal, and blind positioning tests in which the elbow must be flexed repeatedly to an arbitrary angle without visual feedback cues.

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

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During the reporting period, January-June 1978, the research program at Johns Hopkins was concentrated on completion of the design and fabrication of components of an integrated wheelchair, robotic arm, and worktable system for the high spinal-cord-injured person. Testing was continued on the previously developed model of the microprocessor controlled robotic arm/worktable, and limited testing was conducted on the new chin-controlled powered wheelchair.

The latest robotic arm/worktable model incorporates a microprocessor controller, with several programed sequences to simplify the user generated command signals required to control the robotic arm. An important new addition to the control of this system (added late in 1977) is the integration of wheelchair mobility with robotic arm control. This concept allows the full range of mobility permitted by an electric wheelchair, along with the capability to drive up to and operate a worktable equipped with a robotic arm. The quadriplegic so equipped may choose either control of the wheelchair or

of the robotic arm at his convenience, without assistance from an attendant.

A significant feature of this wheelchair controller (in addition to its dual-mode capability) is its small size and minimum obstruction in the vicinity of the user's face. Progress made during the reporting period includes engineering and clinical testing of many of the elements of this system.[a]

Chin Controlled Electric Wheelchair with Dual Mode Capability

The chin controller was redesigned during the reporting period to minimize the mechanism in the vicinity of the user's face. The new

FIGURE 3.—Dual mode chin-controlled powered wheelchair with mouthstick compatibility.

[a]A paper entitled "A Microprocessor-Controlled Robotic Arm/Worktable System with Wheelchair Chin-Controller Compatibility," by W. Seamone, G. Schmeisser, and W. Schneider, was presented September 4-6, 1978, at the International Conference on Telemanipulators for the Physically Handicapped, Rocquencourt, France. For further information: Institut De Recherche, D'Automatique, Projet Pilott Spartacus, Domaine de Voluceau—Rocquencourt, 78150 Le Chesnay, France.

design is shown in Figure 3. In this figure, the quadriplegic is shown depressing the chin controller slightly and a mouthstick is shown in its holder on the wheelchair. Basic control of wheelchair steering is achieved by lateral motion of the chin controller. Torque of the drive motors, hence wheelchair motion, is controlled by how far the chin lever is depressed. Reverse mode is selected by means of the microswitch button located on the chin control lever. Once reverse mode is selected, a logic circuit permits the user to drive in reverse only as long as the chin lever is depressed. Control reverts to forward direction upon relaxing of the chin lever to its off position. The user may easily push the chin controller aside when he has no need for mobility control and may recover it later when needed.

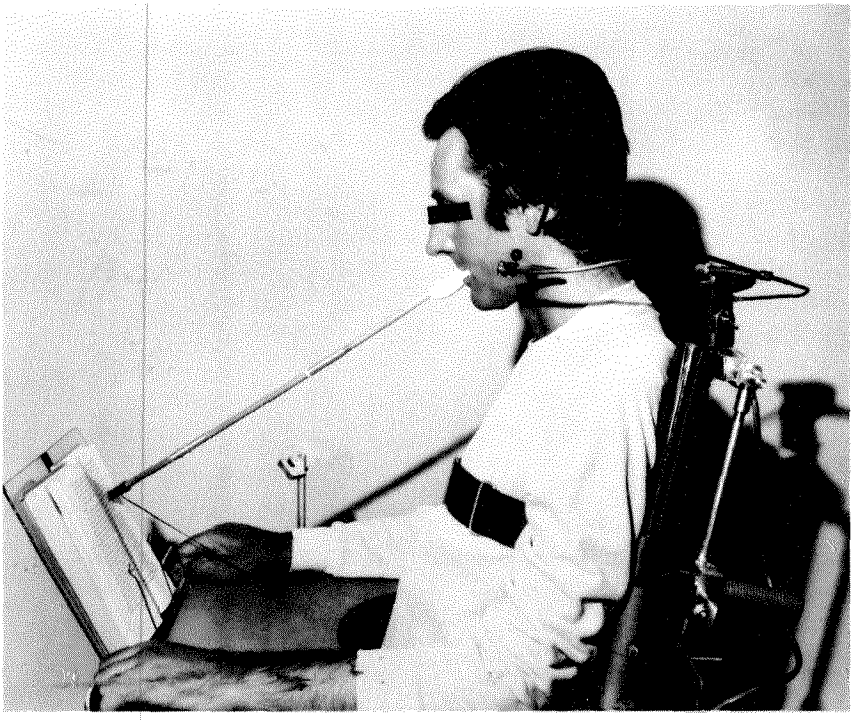

FIGURE 4.—Quadriplegic using a mouthstick in chin-controlled powered wheelchair.

The new chin controller permits a fully compatible arrangement for use of a mouthstick while the user is in the wheelchair. In this mode, the quadriplegic may remove the mouthstick from its holder on the wheelchair frame and use it to perform functions such as turning pages of a book (Fig. 4), operating ordinary low-force-level electrical switches, operating Touch-Tone telephones, typing on a

typewriter or other keyboard devices, and other tasks appropriate for a mouthstick. The user achieves a degree of environmental control capability by driving up to the location of the device to be controlled and using direct mechanical input via the mouthstick to effect control.

Clinical Testing

This wheelchair control concept has undergone limited clinical testing by two quadriplegics during the reporting period. One evaluator lives at home. He commutes (by a van driven by one of his employees) to the office where he manages the business affairs of his company. He has used this prototype electric wheelchair for about two weeks in daily activities. This chair was returned because of its poor back support and is being replaced by a high-back Everest & Jennings powered chair. This new chair has been interfaced with this controller (Fig. 5) and engineering testing and clinical evaluation will be initiated in July 1978.

The second evaluator is the same quadriplegic who has been conducting tests on the APL/JHMI experimental robotic arm/worktable system for almost 3 years. Thus far, he has used this wheelchair with the new chin controller for over 60 hours of test time, both indoors and outside, in basic mobility tests. He finds the wheelchair easy to control and particularly likes the arrangement that allows him to push the controller out of his way during periods of conversation with others.

The new chin controller was demonstrated to representatives of the E&J Wheelchair Co. on April 19, 1978, and they have subsequently furnished a wheelchair for modification to this design. Testing has begun on this model in the Laboratory.

Microprocessor-Controlled Robotic Arm/Worktable System

In September 1977, a microprocessor controlled robotic arm/worktable system was furnished to a quadriplegic for evaluation. This system was described in detail in BPR 10-29, the Spring 1978 issue. More than 9 months of test time have now been accumulated on this model. The user finds it easy to use, and superior in control to previous non-computer-aided models. These tests are continuing.

Latest System, with Optical Link, in Final Construction Phase

The latest microprocessor controlled robotic arm system, now in its final construction phase, is shown in block diagram form (Fig. 6). It uses the wheelchair dual-mode chin controller to control, via an optical link, the robotic arm when the chair is positioned in front of the worktable. The programed sequences for portions of any task

FIGURE 5.—Modified E&J wheelchair with dual-mode chin controller.

may now be put into the computer memory via a direct keyboard. A simple language is utilized, which allows the program to be entered by the quadriplegic himself or by an assistant with minimal training.

Another feature of this latest model is its ability to interface with outside signals in addition to commanding remote devices. This input/output capability may be used to control directly such external devices as lights, TV or other appliances, and to trigger program

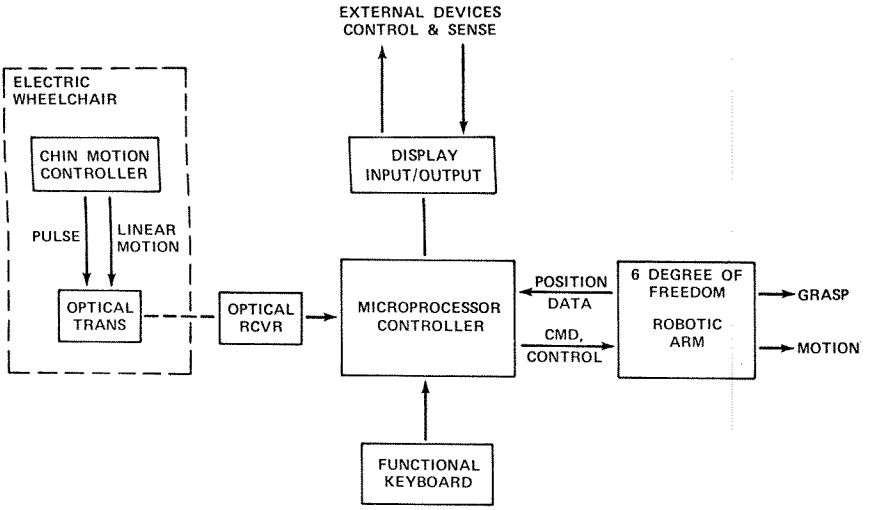

FIGURE 6.—Block diagram of microprocessor controlled robotic arm with wheelchair interface.

execution of robotic arm function from external events (if enabled). For example, a telephone bell-ring sensor may automatically call up the telephone answering program. Communication between the display input-output unit and microcomputer is via a bidirectional serial link.

A new display panel has been designed, using an alphanumeric display, to aid the user in the selection of an automated program. If this mode is selected, the first nine programs are called up on the display by depressing the chin lever. Callouts such as "PICK UP BOOK, TYPEWRITER, ANSWER TELEPHONE, EAT", etc., appear on the display. Subsequent "pages" of additional programs may be called up by selecting "NEXT PAGE" and a new list appears. Selection of a particular program is achieved by nudging the microswitch ball on the chin controller.

The result of these modifications is to offer the user the following options:

1. A direct environmental control system;
2. A directly controlled manipulator;
3. A programed robotic arm initiated by the user;
4. A programed robotic arm initiated by externally generated (non-user) commands.

This system offers user override and user self-programing capability in all of its modes. This new advanced system is nearing completion of the fabrication phase and is expected to be into clinical evaluation by late summer, 1978.

FIGURE 7.—Experimental model of powered assist wheelchair with hand rim control.

Powered Assist Wheelchair

In a related program (not funded by the Veterans Administration), a controller has been developed for powered wheelchairs for those persons who have limited capability to operate manual type wheelchairs. This design is aimed at those handicapped persons who have little or no hand grip, or who become easily fatigued and thus lack any real mobility capability. Elderly persons or persons with muscular deficiencies also fall into this category. In this model, full or partial power assist is achieved by using the hand rim for control. A transducer measures the velocity of the hand rim (which is decoupled from the drive wheel) and this signal is compared to the feedback tachometer in the power drive. The power-driven wheel follows the hand rim motions to minimize the servo error (and thus is similar in operation to automotive power steering).

A patent (No. 4,050,533) was granted on this concept in September 1977, assigned to the Veterans Administration. A modest funded program was provided by the Applied Physics Laboratory to build a demonstration model (Fig. 7). This powered wheelchair is controlled by pushing on the hand rims (simulated in this model by outboard bicycle wheels) the motion of which is sensed by a tachometer. This arrangement gives the ease and precision of control of a manual wheelchair but with the power assist from the power drive.

Subsequent models will use conventional hand rims to keep the wheelchair width to its normal dimensions.

Force levels as low as ¼ lb can be utilized to operate this wheelchair, or the system can be set up in a partial-power-assist mode allowing the user to provide 2 to 5 lb of force, with the power motors providing the balance of required force.

Limited testing, conducted on irregular sidewalks, grades, office and commercial store environments, verifies the ease of control of this experimental wheelchair in all of these situations. Control on steep grades is particularly effective with this control technique. Very limited testing with handicapped volunteers shows promise of an easy to learn power system.

A program plan is being prepared proposing further development and evaluation of this concept.

Research and Development in the Field of Artificial Limbs

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No progress report was submitted by this contractor for this report period.

Design of Prosthetic and Orthotic Devices and Biomechanical Studies of Locomotion

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Design of Lower-Limb Prosthetic and Orthotic Devices

1. *Four-Bar-Linkage Polycentric Pneumatic Knee*

Bids for production of 50 knee units under subcontract from the University of California have been requested from four companies. Two bids have been received and a contract will be awarded to the lowest bidder during the next report period. Testing of knee units on patients at VA Hospital, San Francisco, is expected to commence in November 1978.

2. *Six-Bar-Linkage Knee with Friction Swing-Control*

The final prototype model of this knee-disarticulation prosthesis has been fabricated. A very active amputee will be fitted with the first model.

3. *Friction-Stabilized Knee*

This previously reported knee is designed to engage a knee brake at heel contact, but to release the brake prior to toe-off in order to allow smooth entry into swing phase. The same brake also serves as an adjustable friction swing-phase control. A practical elastic extension spring has been added to the prototype, and more than 20 km of walking have been logged on the laboratory treadmill in preliminary tests of brake durability and wear. Function is very smooth and reliable, with no indications of rapid wear or erratic friction. Design of a more compact and cosmetic unit is underway.

4. *SACH Foot with Metal Keel*

Testing and development continues on this previously reported unit. Arrangements for procurement of prototype cast-aluminum keel units are nearly complete, and two firms have been contacted for possible fabrication of molded feet. Production of about 20 units is anticipated for testing in conjunction with the Four-Bar-Linkage Polycentric Knee units.

5. *Multi-Input Control of Knee Stability*

The experimental multi-input computer controlled knee prosthesis consists of the following elements:

1. Single-axis knee prosthesis;
2. Hydraulic damper with position-controlled servo valve;
3. NOVA minicomputer;
4. Knee-angle and knee-angular-velocity sensors; and
5. Transducer for sensing voluntary knee control inputs.

Initially, the servo-motor that drives the hydraulic damper valve was controlled by a computer program. It performed very well, with quick response, but it required constant attention from the digital computer, thereby severely limiting the scope of control that could be provided by the computer. A position-controlling servo network was installed in place of the digital motor controller. The new system is self-contained and requires only a reference position input from the digital computer. (The computer has only to specify or update the reference position whenever a change of position is desired.)

During normal walking the digital computer is programed to perform the following tasks:

1. Control swing phase by specifying the desired valve setting as a function of knee angle;
2. Locate the end of swing phase by waiting for and detecting terminal impact;
3. Lock the knee to ensure stability during stance phase;
4. Wait for the voluntary knee flexion command at the end of stance; and
5. Unlock the knee and go into swing phase again.

The experimental knee prosthesis computer is also programed so that the normal walking sequence can be overridden, in which case the control of the prosthesis becomes voluntary. In the voluntary mode, control is focused on stability; the knee angular velocity is specified and controlled by the voluntary control signal. This voluntary control signal is obtained from a transducer, set up to measure the amount of hip moment. The transducer is an electromechanical (strain gage) system, which is free of the inherent problems of a sensing system dependent on EMG signals.

Several trial runs have been conducted to test the operation of the experimental knee prosthesis. A bent-knee socket was fabricated, to eliminate the need for a real amputee in trial runs and to provide the designer with the experience of wearing a prosthesis. Knee control function was tested in both the normal walking mode and the voluntary-control mode. In descending stairs, voluntary control of knee flexion under load was readily accomplished. In walking, swing phase control was smooth and adaptable to different speeds. The experimental prosthesis has proved that stability control based on knee angular velocity is practical and safe.

Because of the experimental nature of the project, little consideration has been given to cosmetic treatment of the limb. The task remains to refine the design and compress the bulk, to produce a practical and portable unit.

Biomechanical Studies of Human Locomotion

1. *Clinical Gait-Assessment Project*

A cooperative project with the Department of Orthopaedics at Uppsala University, in Sweden, was started in 1976. The goal of the project was to measure (on total-joint-replacement patients both before and after surgery) the full range of practical walking speeds, average velocity, step rate, step length, and flexion angles of both hip joints and both knees. The time and distance measurements were obtained on a walkway with two light-beam detectors, the joint angle measurements by means of the UC-BL self-aligning goniometers. Joint angle data were recorded in the form of hip/knee angle diagrams.

The measurement phase of the project was completed in May 1978, with both preoperative and postoperative measurements on a total of seven knee patients and five hip patients. Results were encouraging for further use of simple objective measurements in gait assessment. Even the simplest measurement, the range of each patient's available walking speeds, supported the surgeon's assessment of patient progress after surgery. Practical experience gained in the project clearly pointed out the fundamental importance of simplicity and reliability in clinical measurement techniques. A final report is in preparation.

Mobility Aids for the Physically Disabled

PRAHN Wheelchairs

The first prototype of the PC2 (formerly PRAHN II) wheelchair has been completed, and modifications suggested by initial tests are

being made. The chair will be ready for testing in daily use in Berkeley in October 1978.

Ultralight Below-Knee Prosthesis

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At the request of the Veterans Administration, the Rehabilitation Engineering Center at Moss Rehabilitation Hospital has undertaken a clinical application study in which 30-40 below-knee amputees will be fitted with the ultralight prosthesis developed at Moss (1). This is an all-polypropylene system that results in a prosthesis weight about one-third that of a conventional PTB for the same patient.

The original objective of the development project was to provide the geriatric amputee with extremely light below-knee prosthesis, with the hope of reducing energy consumption and problems of suspension.

Trials with younger patients including children indicated the possibility that patients of all ages would appreciate a substantial weight reduction. Consequently, the clinical study will involve below-knee amputees in all age ranges. New amputees receiving a prosthesis for the first time will be included as well as patients requiring a replacement.

Six private certified prosthetics facilities in the Philadelphia area are participating in the study. In January, 1978, 12 prosthetists from these facilities attended a 12-hour course on the fabrication of the prosthesis. Frank Malone, Jr., who has had previous experience with the ultralight prosthesis, assisted in the instruction. Each participant was furnished with a copy of the manual.

The participants were:

Joseph Botkin	J. E. Hanger of Philadelphia
Frank N. Cocco	Cocco Brothers
Virgil Faulkner and Amin K. Hajj	INA O&P Research Lab./University of Pittsburgh Hosp.
Harry J. Lawall	Harry Lawall & Son
Harry J. Lawall, Jr.	Harry Lawall & Son
Frank J. Malone, Jr.	Frank Malone & Son, Inc.
Edward F. Moran	Cocco Brothers
Blondell Smith	Nu-Way Limb & Brace, Inc.
Thomas Sulima	Modern Limb & Brace Co.

John Swoyer — Modern Limb & Brace Co.
Charles Wright — J. E. Hanger of Philadelphia

Fittings were begun in February. Patients are referred to the study from the VA Regional Office Clinic, Philadelphia, Pa., The Moss Rehabilitation Hospital Clinic, and through the private practices of the participating prosthetists.

To date, 20 subjects have agreed to participate in the study. Nine have been fitted with the ultralight prosthesis. Patients' and prosthetists' reactions to the prosthesis are being assessed by questionnaire, which will provide information regarding patient preference, fabrication problems, and the applicability of the device as a first definitive prosthesis versus a PTB replacement.

The Rehabilitation Engineering Center has been asked to present the ultralight technique at the Clinical Session of the Interagency Conference on Rehabilitation Engineering in Washington, D.C., Sept. 4-8, 1978. The ultralight below-knee prosthesis will be included in an exhibit to be displayed at the same event.

Reference

1. Wilson, A. B. Jr., M. Stills: Ultra-light Prostheses for Below-Knee Amputees. Orth. and Prosth. 30:1, 43-47, Mar. 1976.

Immediate Postoperative Prostheses Research Study

Prosthetics Research Study
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A number of on-going programs have been completed at Prosthetics Research Study during the past 6 months. (See list of publications.) The clinical service at VA Hospital, Seattle, has been reorganized to provide additional research output in the management of the ischemic amputee, and a new protocol established with effective biostatistical input.

The service is a combined clinical-research endeavor with the goal of progressive upgrading of amputee care in the VA system. Primary aims are objective and more precise measurement of dynamic limb blood flow. The goal is a reduction in error of level-selection for amputation, implication for surgical technique (particularly as it relates to soft tissue and skin management), and further innovation in post-surgical wound environment for effective primary healing.

In addition to the now well established Xenon blood flow tests, our pre- and post-operative studies include the Laser-Doppler technique, segmental Doppler measurement, and non-invasive pO_2 determination in skin and subcutaneous tissues.

By far the greatest single challenge to amputee management in the Veterans Administration system involves the increasing load of older people with peripheral vascular disease. Prosthetics Research Study, with its research input and careful supervision and control over the amputee program at VA Hospital, Seattle, considers this service an instruction model for the VA Hospital system. We are prepared to use it in this intramural teaching role.

Ongoing investigations of physiological limb suspension with below-knee amputees include volumetric measurements of the residual limb, prosthetic suspension capability (determined by a traction device developed in the P.R.S. Laboratory), and performance EMG study of residual limb muscles. This information is transferred to experimental socket designs.

Publications

Kegel, B., and A. Moore: Load Cell. A Device to Monitor Weightbearing for Lower Extremity Amputees. Phys. Ther., 57(6):652-654, June 1977.

Kegel, B. and J. Byers: Amputee's Manual . . . Mauch S-N-S Knee. Medic Publishing Co., Bellevue, Washington, July 1977.

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Burgess, E.: Disarticulation of the Knee – A Modified Technique. Arch. Surg., (112):1250-1255, Oct. 1977.

Pedegana, L., E. Burgess, and M. Carpenter: Prevention of Thromboembolic Disease by External Pneumatic Compression in Patients Undergoing Total Hip Arthroplasty. Clin. Ortho. and Rel. Res., (128), 190-193, Oct. 1977.

Kegel, B., M. Carpenter, and E. Burgess: A Survey of Lower Limb Amputees: Prostheses, Phantom Sensations, and Psychosocial Aspects. Bull. Pros. Res., BPR 10-27, 43-60, Spring 1977.

Kegel, B., M. Carpenter, and E. Burgess: Functional Capabilities of Lower Extremity Amputees. Arch. Phys. Med. and Rehab. (59), 109-120, Mar. 1978.

Burgess, E.: Wound Healing after Amputation: Effect of Controlled Environment Treatment. J. Bone and Joint Surg., 60-A (2), 245-246, Mar. 1978.

Holloway, G. and E. Burgess: Cutaneous Blood Flow and Its Relation to Healing of Below Knee Amputation. Surg., Gyn. and Obst., (146), 750-756 May 1978.

Below-Knee Amputation with Immediate Postoperative Fitting of Prosthesis

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In the past 6 months the Vascular Research Program has been reestablished.

At the present time our randomized study, comparing the technique of immediate postoperative prosthesis with use of the controlled environment treatment unit, has been reestablished with the hiring of a Research Prosthetist who will manage the immediate postoperative prosthetic fittings.

We are in the process of establishing a Research Prosthetics Laboratory, and anticipate its opening early next fiscal year. At that time, we will continue to develop newer techniques of noninvasive diagnosis for amputation level management, using $Xenon^{133}$ clearance data as a standard for comparison.

Hemodynamic Evaluation of Postoperative and Preoperative Amputees

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Non-invasive Techniques as an Aid to Determination of Amputation Level

Work has been completed for a progress report on the use of noninvasive techniques as an aid to clinical judgment in the selection of amputation level. Noninvasive techniques used include segmental Doppler systolic pressures, arterial impedance plethysmography, photoplethysmography, noninvasive electromagnetic flowmetry, and skin thermistor thermometry.

Since our initial report in 1974 (BPR 10-22, Fall 1974), 30 consecutive patients who had major or minor amputation have been evaluated using the above noninvasive techniques in the determination of the lowest possible level of amputation that is consistent with wound healing. All amputations done in this series were for gangrene. Toe gangrene was present in 8 limbs, foot gangrene in 18 limbs, and leg gangrene in 8 limbs. There was diabetic involvement in 17 of the 34 limbs, and the average patient age was 64 ± 18 years (range of 35-91 years). Of the 34 amputations done, 6 were for toes, 2 were amputations of the foot, 14 were below-the-knee, and 12 above-the-knee.

Above-Knee Amputations

Patients who underwent an initial above-knee amputation were found to have ankle and thigh Doppler systolic pressures below 50 mm Hg, no detectable photoplethysmographic waveforms at the toes, and a reduced skin temperature below the knee. Arterial impedance showed very poor waveforms for the below-knee segment, and noninvasive electromagnetic flowmeter measurements of peak pulsatile flow showed flow $\leqslant 20$ c^3/min for the calf and $\leqslant 100$ c^3/min for the thigh with poor pulsatile waveforms.

Below-Knee Amputations

Patients showing good healing of an initial below-knee amputation had Doppler systolic pressures $\geqslant 50$ mm Hg for the ankle with acceptable waveforms by arterial impedance for the below-knee segment. Noninvasive electromagnetic flowmetry showed acceptable pulsatile waveforms for the thigh with flows $\geqslant 150$ c^3/min. Skin thermistor thermometry measurements showed an excellent line of demarcation. Photoplethysmography showed no detectable waveforms at the toes.

The two patients who had initial amputations of the foot required revision to above-knee amputation. Noninvasive measurements were similar to those of patients undergoing initial above-knee amputation.

Those patients who had healing of toe amputations showed an ankle/arm Doppler systolic pressure ratio that approximated 1.00. Viable toes showed photoplethysmographic pressures $\geqslant 50$ mm Hg. Skin thermistor thermometry showed excellent demarcation between viable and non-viable toes and portions of the foot. Arterial impedance showed excellent waveforms to the ankle and noninvasive electromagnetic flowmetry showed calf flows $\geqslant 60$ c^3/min and thigh flows $\geqslant 175$ c^3/min with acceptable pulsatile waveforms for both leg segments.

These results show noninvasive measurements of pressure and flow in the lower limb to be reliable in predicting the lowest possible level of amputation that is consistent with wound healing, and of definite value as an aid to clinical judgment in selection of amputation level.

Engineering Applications in Orthotic and Prosthetic Treatment of Musculoskeletal Defects

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Our foot contact system is continuing to provide clinical information on patient gait to physicians and therapists. Modifications are continuing to make the evaluation more efficient and to increase the relevance of the data to the clinician. A study is being developed to investigate the effect of the quantitative gait data on patient treatment.

Modification of the Selspot System for kinematic gait analysis continues. Dr. Herman Woltring, of the University of Nijmegen, the Netherlands, will be with us as an Orthopaedic Engineering Research Fellow for one year, to help get the system operational on a clinical basis.

The study of electrical stimulation of the lower limb continues with further work on stimulation of individual muscles. We are looking forward to completion of the microprocessor-controlled 12-channel stimulator, which will allow some dynamic gait augmentation.

Patient Evaluation of a Functional Electrical Stimulation Hand Orthosis

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Introduction

The purpose of this project is to fabricate and evaluate an orthotic system employing electrical excitation of paralyzed muscle. The system is intended to provide C-5 quadriplegic patients with controlled grasp and release of the hand, through electrical stimulation of the forearm finger flexor and extensor muscles, respectively.

Stimulator Development

The stimulator under development has been described in detail in previous reports. Briefly, the device receives both proportional and on/off commands from the patient, and performs the necessary processing on these command signals to ouput the appropriate electrical stimuli to the muscles. The proportional commands are derived from position transducers mounted on either the shoulder or head, and on/off commands are derived from myoelectric activity. The on/off commands enable the subject to specify the reference position of his proportional controller (i.e., initialize the system) and allow him to hold a given stimulus output regardless of variations in the proportional command signal. (The rationale behind the choice of these operating modes has been described previously (BPR 10-28).)

In the past 6-month period, emphasis has been placed on completion of the miniature stimulators in the initial packaging configuration. Three devices have been completed, and one has undergone all final testing and has been placed with a subject. The device in the initial commercial package measures 6 x 3 x 2 inches. The design of the stimulator provides for simple donning by the patient; for example, a single wiring harness is provided which connects the EMG electrodes, stimulating electrodes, and proportional controller to the stimulator. No on/off switch or other external controls are provided on the stimulator package—the EMG amplifier and a part of the control logic are activated by plugging the wiring harness into the stimulator. All control and stimulus parameters are fixed within the stimulator at the time it is fitted to the individual patient.

Two mercury batteries provide power for the system: in the present package, no provision has been made for the subject to change batteries, but this will be included in the revised package design. Approximately 6 to 8 weeks of battery life is expected, depending upon the time the device is on the subject and the time during which stimulation is applied.

Patient Evaluation

Four patients are presently involved in this program: two are involved in studies supported by the Veterans Administration, and two are involved in similar studies supported by the Rehabilitation Services Administration, Department of Health, Education and Welfare.

The first miniature stimulator has been provided to a Cleveland Veterans Administration patient. He is a 27-year-old male who sustained quadriplegia secondary to fracture-dislocation of C-5, C-6 in April 1975. His voluntary strength is greater in his left arm than his

right, and for this reason the left arm was chosen for stimulation. His left shoulder flexion and abduction and elbow flexion strengths are good, but he has no motor function distal to his elbow. His right arm has a fair grade for the same functions. Chronically indwelling percutaneous coiled wire stimulating electrodes (type 316 stainless steel) are implanted into the flexor digitorum superficialis and profundus muscles for finger flexion and the extensor digitorum communis for finger extension. The implant site is covered with a small connector, for protection of the site and to provide easy electrical access to the electrodes. A percutaneous electrode is implanted in the contralateral (right) biceps for myoelectric signals acquisition. These electrodes have been intact for 200 days at the time of this writing.

Stimulation parameters to be set into the patient stimulator were determined from laboratory tests in which the stimulus-force (input-output) characteristics of each electrode were measured. Stimulus parameters were then chosen which compensated for differences in threshold and recruitment characteristics of the electrodes, and therefore provided smooth contractions when the stimulus was sequenced from one electrode to the next (see BPR 10-28). These stimulus parameters were then set into the laboratory based stimulator (which operates identically to the small patient units) and the function observed. Minor modification of stimulus parameters was made at this time to improve functional operation. Finally, the proportional control and EMG switch were added into the system, and appropriate control parameters determined. All parameters were then hardwired into the patient module.

The patient has had the stimulator for 2 weeks at this writing. To date, use has been limited while further modifications are being made on his orthosis. He anticipates increased use when this is completed and he reenters college in the next semester.

The other three subjects will be the next recipients of the patient modules. We intend to have these fitted in the next report period.

Functional Neuromuscular Stimulation of Limbs: A Feasibility Study

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Background

Because of spinal-cord trauma or cerebrovascular accident, many veterans no longer have full use of one or more limbs. Several func-

tional electrical orthotic systems have been under development in recent years to compensate in part for this loss of motor function. These systems utilize electrical stimulation of nerves at suprathreshold levels and at 10-60 pps frequencies. Unfortunately, that technique provides predominantly an ON-OFF control of muscular tension with little significant variation of muscle force possible between these two limits. Thus, complex and finely resolved movements have not been possible.

The basis of this feasibility study is the development of advanced functional neuromuscular stimulation techniques which will permit the necessary proportional control of muscle tension so that graded limb movements can be performed. This study is examining the combination of electrical nerve block technique with artificial electrical drive stimuli to modulate peripheral muscular contraction. The recruitment and rate coding processes present in the normal intact neuromuscular system are thought to be stimulated in a paralyzed limb by this simultaneous combination of drive and block techniques.

Methods

A gastrocnemius-soleus preparation in the cat is used to evaluate the concept of simultaneously combining drive and block techniques to elicit graded control of muscle force. With reference to Figure 8, the isometric force produced by the gastrocnemius-soleus muscle bodies is detected by a force transducer, amplified, and graphically displayed. Electrical stimuli are applied to two wrap-around electrodes placed on the sciatic nerve. Drive stimuli are applied to the proximal electrode and block stimuli are applied to the distal electrode. Typical drive parameters are at suprathreshold amplitude and 100 μs pulse-width at a rate of 60 pps. Electrical block parameters of amplitude and pulse width are systematically examined over ranges found to produce a reduction of muscular force. Pulse rate of the electrical block stimulus is fixed at 600 pps during this initial part of the feasibility study. Subsequent work will examine the effect of different block pulse rates on force reduction.

The sequence of stimulus application is: Drive On; Block On; Block Off; Drive Off. The sequence duration is about 10 sec. The interstimulus interval is experimentally selected to minimize fatigue carryover effects from prior stimuli and, typically, is about 60 sec. The force amplitude data are analyzed by dividing the difference between the maximum value during the early portion of the drive stimulus, and the residual value at the onset of block, by the maximum value. Expressed as a percentage, this ratio is designated as the blocking effectiveness.

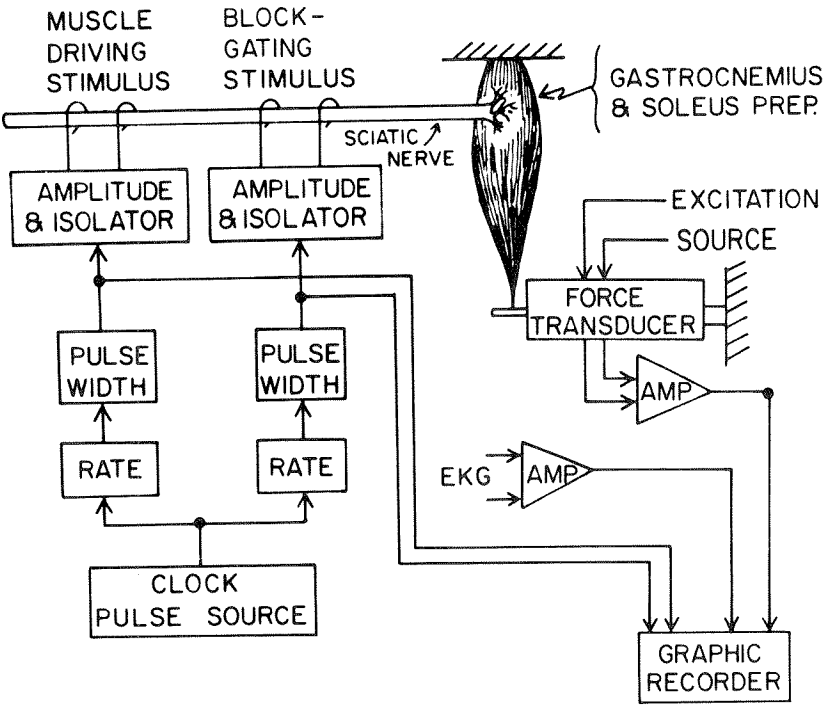

FIGURE 8.—Schematic of experiment: FNS Feasibility Study.

Results

The results of the work conducted during the first 6 months of the program indicate:

1. there are ranges of block pulse amplitude and block pulse width over which the blocking effectiveness varies linearly with each parameter;
2. the contractile force is regulated from 4 percent to 100 percent of the tetanic force by either of the two parameters;
3. the regulated force is always fused;
4. short-term repeatability of a prescribed level of force is very good; and
5. manually-introduced time-varying changes in either parameter indicate dynamic feasibility.

Research and Development Project on Advanced Orthotic Devices for Adult Paraplegics

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Martin T. Prast

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Testing of the PACO III units got underway in April of 1978. At this time the modified wheelchair armrests for assisting a paraplegic in elevating himself have proven to be functioning satisfactorily. Minor adjustments were needed to compensate for wheelchair design differences between manufacturers. The universal adjustability in the orthotic design has functioned well in fitting the unit to individual paraplegics.

The self-locking knee locks, at present, are not functioning as well as hoped. Further evaluation into what can be done to remedy this problem with the existing design is being investigated. Also, a new design concept is being looked into. Contact has been made with Moog, Inc., a leader in the field of hydraulic controls.

Evaluation of Electrical Techniques for Stimulation of Hard Tissue Growth

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Electrical Osteogenesis—Basic Studies

The Orthopedic Research Laboratory (Syracuse VAH) has completed the in vitro phase of its testing of electrode materials. This project was undertaken to evaluate the electrochemical behavior of various metals which could be used for electrical stimulation of bone growth (Pt,Ag,Au,Ti,Ta,Pt-Ir,Ss-316L and Vitallium).

1. Current-potential behavior under steady-state conditions was measured in biological culture medium with fetal calf serum, under potentiostatic and galvanostatic conditions. The metals tested fell

into three approximate groups as measured by surface conductivity over the useful potential range. Pt and Pt-Ir were the most efficient interfaces; Ag, Au and Ss-316L were an order of magnitude lower in conductivity, and Ti, Vitallium and Ta were an order of magnitude still lower (Ta being by far the most inefficient interface). Thus it would seem that Pt and Pt-Ir would require the lowest interfacial potential to pass a given amount of cathodic current in vivo (Fig. 9).

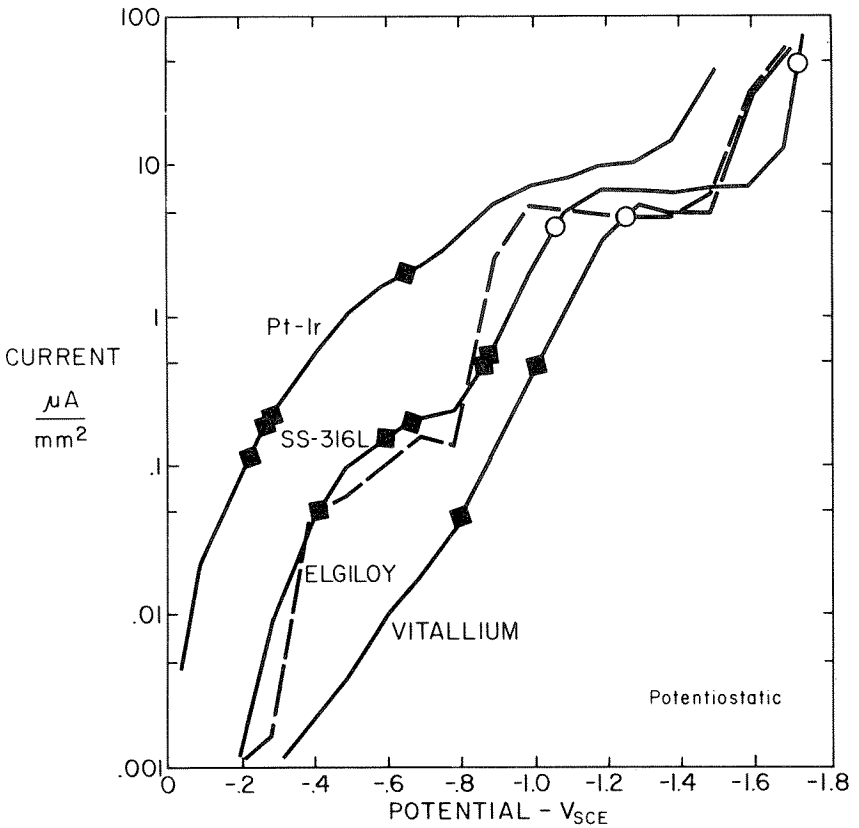

FIGURE 9.—Current-potential relationship for several metal alloy cathodes in cell culture medium (Dulbecco's, GIBCO, with 10 percent fetal calf serum added). The current density is determined at the geometric surface area of the metal and the potential is measured with respect to a calomel reference. Note the ten-fold differences between metals in the 0 to 0.8 V region in which the reduction of molecular oxygen occurs at the electrode. Above 0.8 V the electrode generates increasing amounts of hydrogen. The black squares indicate the conditions (and metals) at which electrical osteogenesis has been found to occur by several scientific groups. The open circles indicate conditions at which necrosis has been reported at such electrodes.

2. By changing the amount of oxygen available to the electrodes in these experiments, it was found, in the potential ranges below which deleterious hydrolysis would be expected, that the cathodic current is primarily transmitted by means of reactions involving chemical reduction of molecular oxygen; this is a factor which may be intimately related to the mechanism of action of electrical osteogenesis.

3. Simultaneously, in vivo experiments using rabbits are being completed in which the ability of these various metal cathodes to induce bone growth in the relatively uninjured femoral canal is being measured. Results thus far, at 500 nA constant current, seem to show that the cathode Pt is, in fact, an efficient promoter of bone growth. Further evaluation is in progress, and plans include the use of both higher and lower current levels. The implants used include a tiny transitorized constant-current DC circuit and battery. The encapsulation is in epoxy and silicone; this has been quite adequate for the 3-week duration of implantation used, although failure of the leads has been an occasional complication. Over 40 animals have been completed thus far.

Electrical Osteogenesis – Clinical Studies

Patients with resistant non-united fractures continue to be treated with the low-intensity direct-current system which has been successful in the past. These cases generally present in the orthopedic section of this hospital and are not solicited for. Thus far, 20 trials have been performed with a success rate of 75 percent. The median age of the non-unions was 2.5 yr and the mean follow-up time was 21 mo.

The use of anodic silver in the treatment of osteomyelitis in human patients continues on the same "as available" basis. Thus far, 14 patients have been treated, either using silver-impregnated nylon fabric or the solid silver wire as the bacteriostatic anode, depending on the nature of the lesion. The latter agent is used in conjunction with cathodic bone stimulation in fractures complicated by infection (a full description of the use of anodic silver in osteomyelitis is presently in press in the Journal of Bone and Joint Surgery).

Regeneration

Progress continues toward the international meeting on "Mechanisms of Stimulation and Control of Regenerative Growth and Its Clinical Application". This three day conference will be held in Syracuse in the Fall of 1979 and will be sponsored by the VA with assistance from the State University of New York (Upstate Medical Center). It will bring together recognized authorities in regeneration

and stimulation of bone growth to discuss the state of basic research and relate it to the future clinical application of regenerative phenomena.

Fracture Healing

Fundamental studies are in progress on the relationship of innervation to fracture healing. Using the rat fibula, the normal fracture healing sequence has been followed and documented. Preliminary work has indicated that denervation retards the rate of healing of long bone fractures and reduces the periosteal callus formation. The time between nerve resection and the fracture itself appears to be an important variable as well.

Acceleration of Bone Healing by Electrical Stimulation

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Work on this project continues. At present, we are utilizing a 16 mm defect in the ulna of beagles as a model non-union. Three stainless steel cathodes are placed, one in the defect center and one near the end of each bone fragment. An anode is placed subcutaneously. Each cathode is supplied separately with d.c. current in the range shown to produce new bone by Friedenburg, Brighton and other investigators. The object is to determine the importance of cathode location (in relation to pre-existing bone or bone elements) to the process of stimulating new bone formation in non-unions.

In Vivo Loading of Knee Joint Replacements

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Introduction

As stated in BPR 10-28 (Fall 1977), this project suffered an unfortunate setback in that the original dual condylar prostheses developed for telemetrized implantation were ruined during a commercial manufacturer's attempt to polish the devices to the necessary degree

of sphericity and surface finish for implant acceptability. Because of this unfortunate incident, we were faced with the necessity of remanufacturing our total prosthetic supply. Instead of simply remanufacturing what was becoming a somewhat obsolete design in the light of recent prosthetic advances, we utilized this period to totally reevaluate the project. The results of this reevaluation indicated that the most common and useful prosthetic device currently in use is that of the total condylar femoral design. It was decided that the investigation should proceed along the lines of determining the load data from the currently most-utilized implant devices. Therefore, it was decided to utilize a standard femoral prosthetic device of commercial manufacture, and shift the design effort to development of a tibial component that would incorporate a standard tibial plateau normally associated with the given prosthetic femoral component, yet be capable of containing all the necessary telemetry electronics to telemeter out the desired in vivo load data. Our effort is now directed toward this approach.

Background

In order to duplicate as nearly as possible the mechanisms in a total condylar joint replacement, a telemetrized tibial component was designed which utilizes the standard total condylar polyethylene

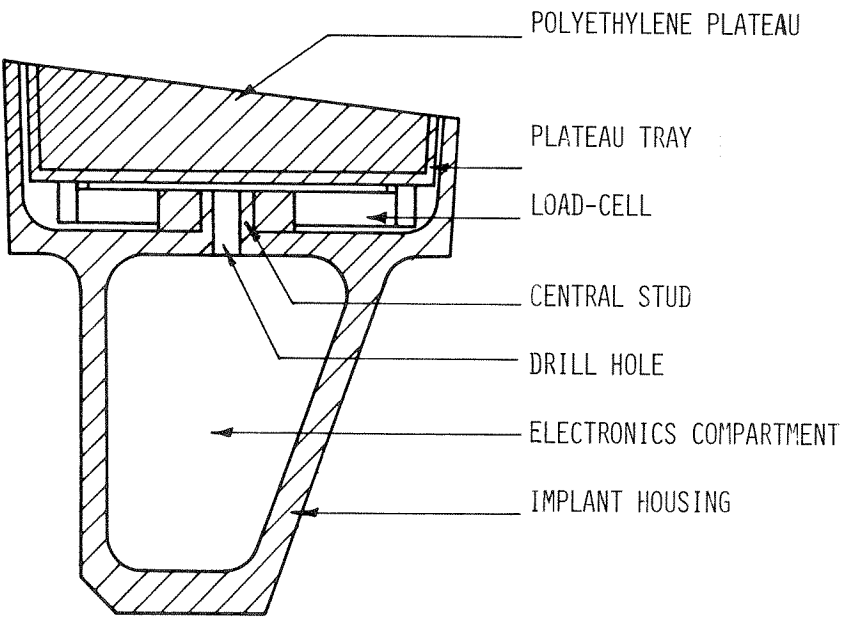

FIGURE 10.—Assembly drawing of telemetrized tibial component.

tibial plateau as its mating surface. The basic geometry of this design is shown in Figure 10. As can be seen from that illustration, the standard polyethylene plateau is supported in a metallic tray which in turn rests upon a load cell. The drill hole shown is for passing the wires from the load cell down into the electronics compartment which will house the necessary telemetry electronics for broadcasting the strain data. All metallic components in this design are being made of medical grade titanium.

In this design, the tibial plateau is totally supported by the load cell via the plateau tray. Much time and effort was devoted to optimizing the load cell design to provide the maximum amount of information possible. The result of the effort is shown in Figure 11.

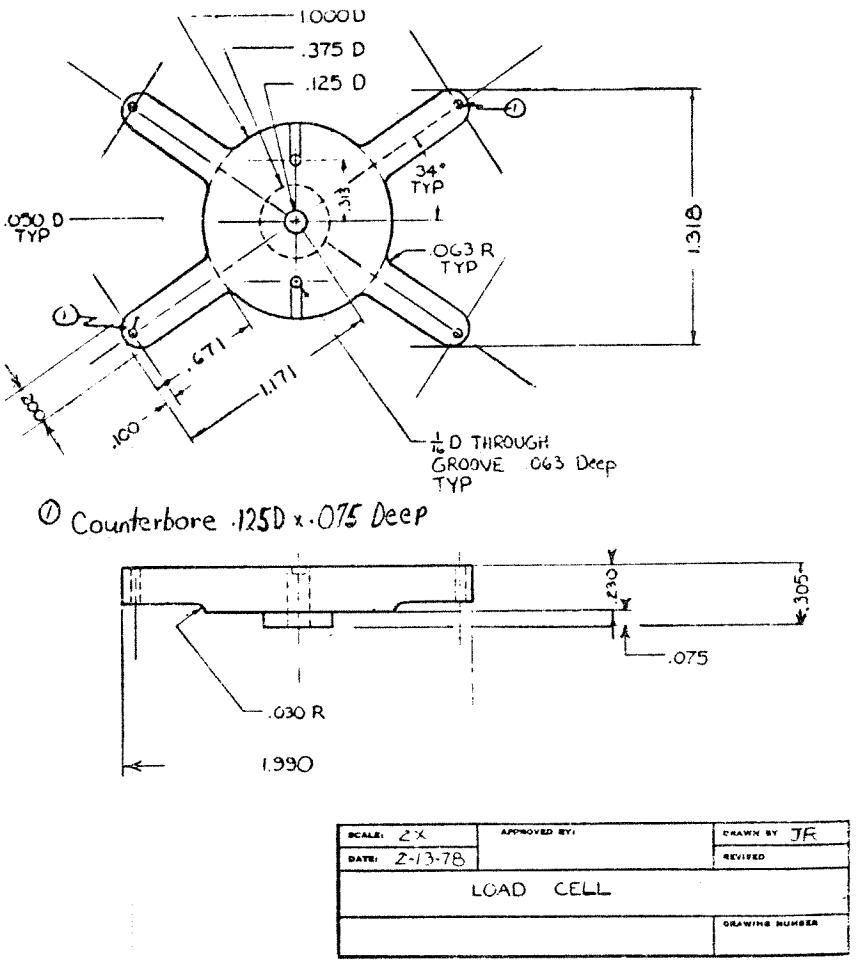

FIGURE 11.—Load cell design.

This design, together with the use of high-sensitivity semiconductor strain gages, has allowed the overall design to have the capability of resolving the three forces and three moments acting on the tibial plateau of this device.

To achieve this, it was necessary to provide eight separate channels of telemetry information in the circuit design. In order to simultaneously broadcast and ultimately resolve eight separate channels of information from one FM transmitter, it was necessary to refine not only the existing telemetry circuitry, but the external demodulation circuitry as well.

The present telemetry circuitry is shown in block diagram format in Figure 12. Oscillators 1 through 7 are used to energize seven separate bridge circuits on the load cell. Oscillator 8 is utilized as an internal calibration standard. Interchannel separation is achieved by having each measurement circuit's oscillator frequency at a discrete value no closer than 500 Hz to that of an adjacent channel.

The individual channel information is coded, in this system, by having the strain changes, as reflected by the solid-state gages, modulate (vary the amplitude of) the associated subcarrier oscillator's output. The eight information-carrying discrete frequencies are then linearly added together and simultaneously broadcast from the device, using an FM transmitter. Power for the implant circuitry is derived from microcells implanted with the electronics. To conserve power and maximize implant life, a magnetic latching-type switch is included in the design, which allows the power unit to be activated or deactivated through the use of an external electro-magnetic field.

To separate out this large number of closely-spaced individual channel frequencies, it was necessary to develop a highly selective demodulation system. The technique chosen to perform this task was that of a phase-lock loop superhetrodyned amplitude demodulator using coherent detection. The block diagram of the demodulation system is shown in Figure 13. Use of this demodulation system allows us to space the subcarrier channels as close as within 500 Hz of one another, yet still allow a 100-Hz bandwidth for the desired strain information. The output of the system is a d.c. time-varying signal that is directly proportional to the strain imparted to a given measurement bridge circuit within the implant.

Current Status

At the present time, a prototype load cell and plateau support tray assembly has been designed, built, and instrumented with strain gages. This prototype has been thoroughly tested with respect to measurement sensitivity, measurement cross-sensitivity, and mechanical strength: no problems were encountered in any of these

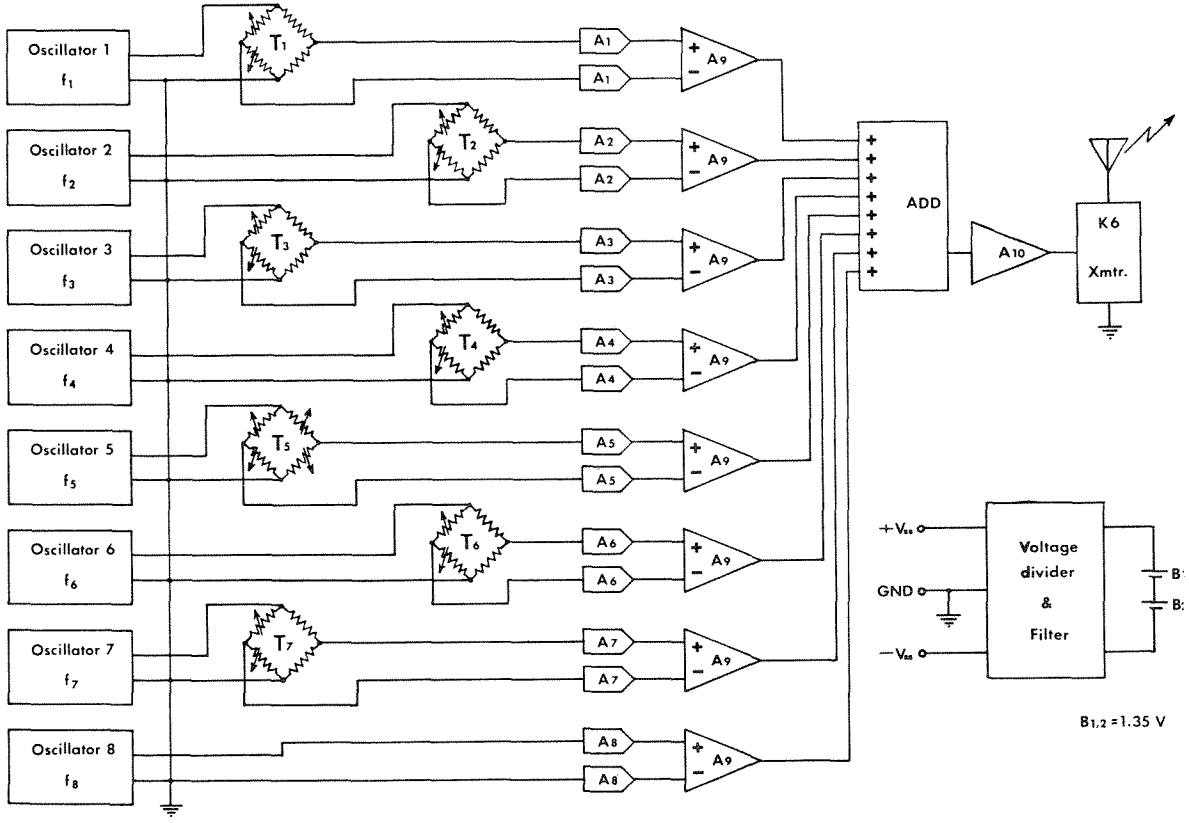

FIGURE 12.—Functional block diagram of knee transmitter package.

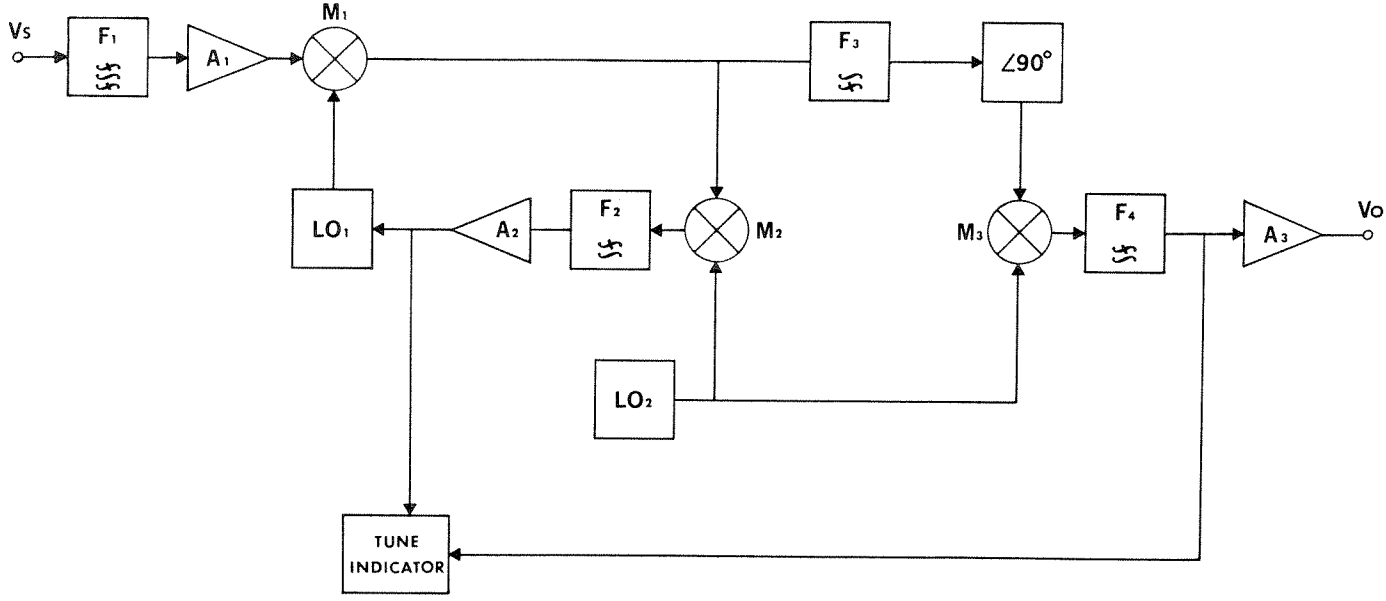

FIGURE 13.—Block diagram of phase-locked loop superhetrodyned amplitude demodulator using coherent detection.

areas. A complete prototype is currently being manufactured and instrumented in anticipation of full bench-testing of the device. Barring any unforseen problems in this bench testing, it is anticipated that a device will be ready for implant in early 1979.

Orthopedic Implant Device Retrieval and Analysis

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All orthopedic implant procedures are followed on a prospective basis, and all implants removed during the normal routine medical care of patients are collected.

There are currently more than 150 patients in the study; 17 percent retrospective and 83 percent prospective. The devices involved cover the standard armamentarium of the orthopedic surgeon, and are shown in Table 1.

In addition to the devices listed in Table 1, implants have been collected from the VA Hospitals in Columbia, South Carolina; Jackson, Miss.; and San Francisco, Calif. (These have not been catalogued as yet and do not appear in the totals.)

To date the implant analysis has focused on the screw-plate type and intramedullary rod fracture fixation devices, since they have been retrieved with the greatest frequency. Crevice corrosion has been observed in all of the 316L stainless steel screw plate type devices. This crevice corrosion may be a contributing factor to failure of devices left in situ for longer periods of time than 2 years. Structure-property relationships are being developed for the material from which the screw plate type devices are being fabricated. Both of these studies are continuing as more devices are retrieved.

TABLE 1.—*Devices Involved*

Device	Percent of total
Nail-Plate Internal Fixation Devices	43
Joint Prostheses	29
Intramedullary Rods	6
Screws and Pins	20
Miscellaneous	2
	100

With regard to the intramedullary implants, 4 of 7 rods examined exhibited cracking. These rods, which were fabricated from welded 316 stainless steel, had varying microstructures. The position of the

weld was found to be an important factor in the cracking of the rods. As a result of this study, a method of non-destructive testing is being sought which will allow detection of the weld zone in the rod prior to insertion, so that those rods with the weld zone near the slot may be identified and rejected.

Studies of Normal and Abnormal Motion

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Major emphasis continues to be in the area of quantitatively evaluating multiple components of functional performance of patients with severely disabling arthritis before and after various types of total joint replacements.

The results of studies in two other areas have recently been accepted for publication and these results are as follows:

1. Walking Patterns of Men with Parkinsonism

This study quantifies the deviations characteristic of the gait of patients with parkinsonism. Forty-four patients with parkinsonism were categorized according to the degree of disability on the bases of the findings of their neurologic examinations and their independence in self-care activities. Measurements of the patient groups were recorded using interrupted-light photography, and were compared with standards of walking performance which we had previously established for an appropriate control group of normal men. There were several components which did relate to the severity of the patient's disability, such as step lengths, vertical excursions of the head, extension of the hip and knee of the backward-directed limb at the onset of contralateral weight-bearing, toe-floor clearance distance at the onset of weight-bearing and en bloc movement of the pelvis and thorax. Some gait components, such as cadence and abnormality in arm swing, did not relate systematically to the severity of the patients' disability. The identification of these specific gait components should be useful in evaluation of the efficacy of treatment procedures aimed at improving walking performance in patients with parkinsonism.

2. Function of the Triceps Surae During Gait

We had the rare opportunity to measure the walking performance of a 30-year old woman who was referred to us by an orthopedic

surgeon because of a unilateral surgical excision of the entire triceps surae. While it is well known that the triceps surae muscle plays an important role in ambulation there are varying hypotheses concerning its function during walking. Hitherto the opportunity had not presented itself to study the gait of a patient who had been deprived of the triceps surae muscle but who had no neurological deficit or pain. The woman walked remarkably well despite the fact that we were able to establish that the muscle torque of the remaining 5 plantar flexors on the operated side generated only 38 percent of the plantar flexor torque on the sound side. We measured a prolonged and excessive excursion into dorsiflexion of the ankle during the stance phase. She compensated for this functionally shortened lower limb by excessive descent (lateral tilt) of the pelvis on the operated side during the late stance phase on the operated side, and she also used excessive and prolonged activity of the quadriceps muscle during the stance phase. Our measurements corroborated several of the different hypotheses concerning function of the triceps surae in locomotion (1).

References

1. Function of Triceps Surae During Gait—Compensatory Mechanisms for Unilateral Loss: M. P. Murray, G. N. Guten, S. B. Sepic, G. M. Gardner, and J. M. Baldwin. J. Bone & Joint Surg., 60-A(4):473-476, June 1978.

Electrophysiological Techniques in Evaluation and Correction of Neuromuscular Defects

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Biofeedback (Myofeedback) in Rehabilitation for Hemiplegia

The main purpose of this research is to test the usefulness of myofeedback for neuromuscular reeducation of patients who have suffered a cerebrovascular accident. There are several aspects of this program which include study of hemiplegic gait patterns and study of the usefulness of myofeedback for retraining control of single muscles and muscle synergies.

One segment of the program has been completed and its results are reported here. It is a detailed investigation of the feasibility of using myofeedback for the training of six lower-limb muscles which are essentially non-functional during the early recovery period.

Methodology

The main goals of the study were to determine –

1. If myofeedback enhances the control of muscle activity in hemiplegic patients;
2. If just the fact that the instrument is connected to and used with the patient has an effect equal to that of myofeedback; and
3. If myofeedback has any effect upon muscle strength.

Every patient suffering a CVA of thrombotic origin and entering the Veterans Administration Hospital was considered eligible. A patient formally entered the study only when he was able to sit erect in a wheelchair and communicate at a very basic level and understand simple instructions. To date 22 patients have been studied. They were divided into three groups: a control group of 8 patients, an instrumented group of 7 patients, and a myofeedback group of 7 patients. A patient was selected for a particular group in a random fashion (based on his Social Security number).

Control Group

All patients in the control (C) group underwent the normal physical therapy regimen. All had the strength of the muscles of their lower limb evaluated with a manual muscle test. Weekly muscle tests were performed on the tibialis anterior, gastrocnemius, soleus, medial hamstring, rectus femoris, and gluteus medius muscles. The numerical grading system for evaluation was utilized (muscle strengths were assigned grades 0 through 5 depending upon whether the muscle exerted a strength of zero, trace, poor, fair, good, and normal). These tests were performed weekly, from the time the patient entered the study until he was discharged from the hospital.

Instrumented and Myofeedback Groups

All the patients in the instrumented and myofeedback groups underwent the same regimen as those in the control group, but in addition to the muscle-strength tests, their muscle control was assessed using a portable electromyographic monitor (Motion Control, Salt Lake City, Utah). The monitor has a meter which displays the integrated EMG value, and a click generator for aural feedback. The click frequency is proportional to EMG intensity, and its sound can be turned off and on. The monitor was used to measure whether or not a particular muscle was activated in response to a *verbal command* to contract it. (Special care was maintained to preclude total limb synergies.) Success or failure of activation was recorded. The control of all six muscles was assessed five times a week.

Instrumented (I) group patients were requested to contract each muscle eleven times *without any external cues* (without feedback). Myofeedback group patients underwent a similar regimen; however, their control without feedback of a particular muscle was monitored for only six trials. Immediately thereafter, they were requested to activate a muscle while receiving *aural feedback* from the electromyographic monitor. The successes of both muscle-control trials—the myofeedback/retention trials (MF/R), and the feedback trials (MF)—were recorded.

All of the therapy and measurements were performed by the same physical therapist.

Data Analysis

The measured data were analyzed primarily by comparing the average rates-of-increase in muscle control and muscle strength among groups. The chart for a certain muscle may look like the curve marked I in Figure 14. On the first day of treatment, day 17, there was only 5 percent successful activations; on the first day of peak performance, day 31, there was 50 percent successful muscle activations. Between these two days the chart was not smooth but had several minor oscillations. The average rate of increase was calculated by dividing the difference between these percentages by the length of time (in weeks) between these two days.

The rates were calculated for the instrumented group and (in both myofeedback trials and retention trials) for the myofeedback group.

For these same times the average improvement in muscle strength was calculated. The rate of increase in muscle strengths was also calculated for the control group patients; however, since they did not have a day at which we could define their peak performance for control of muscle activity, their day of "maximum" was considered to be a comparable day at which their increase in muscle strengths seemed to stabilize. This happened to be on the order of one month.

The rates of improvement in muscle control and in muscle strength were compared, using non-parametric statistical methods called ranking procedures. The ranking procedure was used simply because a wide disparity in increments of muscle strength and muscle control of patients within each group sometimes occurred. Using the absolute values of these rates would then bias the values of the rates of any specific group, especially when one person learned to control his muscles rather rapidly.

The comparison of the improvements in muscle *control* between the instrumental group and the myofeedback group was made using a rank sum procedure.

The rates of increase in muscle *strength* were compared between any two groups and among all three groups. (The paired groups, that is, comparing the improvements in strength between control and myofeedback group, were tested using a rank sum test. The comparison of all three groups was made using a third order ranking procedure.)

Results and Discussion

Muscle Control

The rates of increase in muscle control were calculated, and are shown in Table 2. Each figure represents a percent increase in activations of the given muscle in response to command. When one compares the instrumented group with the myofeedback group, one can clearly see that the rates of increase for the myofeedback group are greater on the average. (The greatest difference occurs in the gastrocnemius, soleus, hamstrings, and rectus femoris muscles, while the smallest difference of increase is with the tibialis anterior and the gluteus medius muscles.) For each muscle the rates of increase between groups were compared using a rank sum procedure. The rates of increase for the first four mentioned muscles were greatly different at the 90 percent significance level. This shows that there is a significant difference in the rate of increase between the two groups, and that the myofeedback group is far superior in its performance. The significance level for tibialis anterior muscle is 74 percent and for the gluteus medius is 66 percent—these figures do not correspond to significant differences.

TABLE 2.—*Average Percent Increase of Muscle Control Per Week*

Muscle	Percent increase		
	Inst.[a]	MF[b]	MF/R[c]
TA	15	18	7
GAS	16	33	37
SOL	18	38	20
HAM	43	74	21
RF	41	49	32
GM	19	22	24

[a] Instrumented

[b] Myofeedback

[c] Myofeedback/Retention

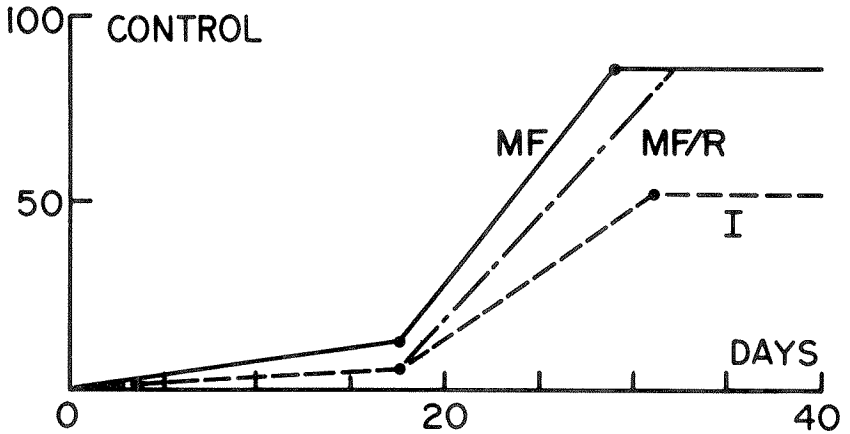

FIGURE 14.—Average muscle control of each group as a function of time post-CVA.

The superior performance of the myofeedback group is shown in Figure 14. In it is plotted the total average performance levels of all muscles, in percent of maximum as a function of time post CVA. Examination of the curves for the myofeedback (MF) and instrumented (I) group shows that, although both groups start out at approximately the same level at 17 days post CVA, the patients in the myofeedback group not only increase their performance at a much faster rate, but also reach their maximum performance several days earlier.

Another aspect of using myofeedback can be expressed as "how long does it take for a patient to remember permanently the control learned using a myofeedback instrument?" An answer was sought by using pre-myofeedback trials as a measure of the memory of muscle control. As described earlier, before each patient received the day's myofeedback treatment he was requested to activate a particular muscle without receiving any feedback. Performance here was measured and results are labeled as myofeedback/retention (MF/R) on the curve shown in Figure 14. The figure shows that in tests made without myofeedback, the patient reaches his maximum level several days later than he does in tests made with the myofeedback. However, once that maximum performance is attained, it is retained. The significance is that the patient does retain, without myofeedback, the control achieved with myofeedback. Several days of treatment of maximum performance are needed for the patient to gain full retention.

Muscle Strength

For each of the six muscles, the results of the statistical tests show that there was no significant difference between rates of increase in muscle strength for any given group. Because there is no difference, the average strength for all patients for all muscles were calculated (Fig. 15). It is assumed that muscle strength is zero at day of CVA; at the day of beginning of treatment muscle strength was an average strength of 0.45. It increased to an average strength of approximately 2.1 at the average day of maximum performance. Naturally, the different muscles had faster or slower recovery, and these are shown by the dashes. For instance, the gluteus medius had the fastest increase in muscle strength and also had the largest amount of strength at the beginning of treatment. Its boundary is shown by the upper dashes. The tibialis anterior had the lowest initial strength at the day of maximum performance, and this is shown by the lower pairs of dashes. These results demonstrate that there is no significant correlation between increase in muscle performance and increase in muscle strength, within the first 30 to 40 days of treatment. This length of time is perhaps too short for the therapy to have a significant effect on increasing muscle strength.

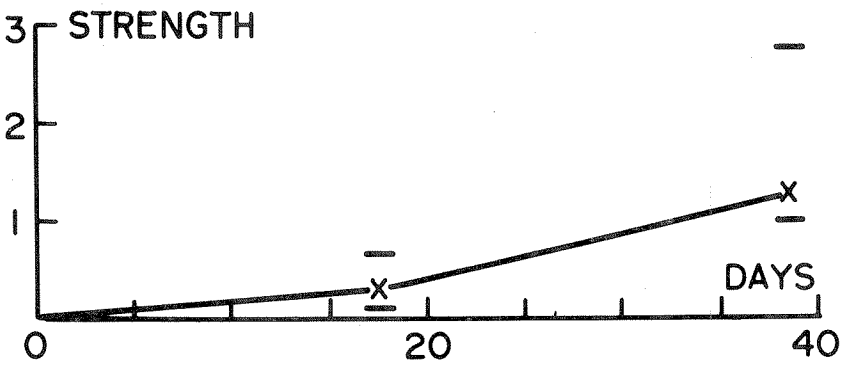

FIGURE 15.—Average muscle strength of patient population as a function of time post-CVA.

Conclusions

The results of the data analysis show that myofeedback therapy increases appreciably a CVA patient's control of activity of lower-limb muscles during the early recovery period. For four of the six muscles tested, this improvement is significant. For the tibialis anterior muscle, this increase is not as great, and it seems to have no effect upon learning control of the gluteus medius muscle.

The period of time a patient needs to convert his peak feedback-assisted performance to peak independent performance is 2 days, on the average for all muscles, but varies between 1 to 4 days.

Since there is no significant difference in the increase in muscle strength among all the patients, it can be concluded that myofeedback does not contribute to muscle strength during this short period of time.

It is recommended that myofeedback therapy be used in the therapy regimen for patients suffering from a cerebral vascular accident. Myofeedback would be applied from the first day of treatment until muscle activity approaches 100 percent on a consistent basis. After the patient's performance with a particular muscle has stabilized for 4 or more days, then the myofeedback therapy may be discontinued for that muscle.

Maxillofacial Restorative Materials and Techniques

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Introduction

The five program phases listed in a previous report (BPR 10-28, Fall 1977) have been augmented by Phase VI, production. Campaigns for producing polydimethylsiloxane in pound quantities are advancing the Comprehensive Development Program of the project from research and development efforts to the stage of full-scale production. Two production campaigns have been carried out successfully, scaling-up the nominal one-ounce laboratory mill blending of prepolymer ("gum stock") with the corresponding low molecular weight oligomers, plus a series of pigments for intrinsic cosmetic coloring.

The start of the production phase was made possible by the continued favorable results in the Field (Patient) Evaluation program (Phase V) and in the on-going Toxicity Testing (Phase IV) program using the human excised donor (HED) tissues, taken from patients of a broad range of ages in which the polydimethylsiloxane prostheses

have shown no toxic manifestations in the tissue culture tests (1).

A commercial three-roll high-speed mill, commonly used for blending viscous mixtures and capable of serving either as a production unit or as a pilot or laboratory unit, has been contracted for on a rental basis. It has a daily output of 16 to 20 lb in production runs. The production program has been undertaken to comply with existing regulations of the Food and Drug Administration requiring data and documentation of good manufacturing practices (GMP) as now prescribed by the recently enacted Medical Devices Amendment of 1976 (2).

Phase VI – Production

Quality Evaluation and Performance

The ingredient materials, reported in previous BPR reports, are exclusively the single chemical elastomeric product comprising (i) polydimethylsiloxane prepolymer ("gum stock") with molecular chain units numbering in the several thousands and (ii) the corresponding oligomer with similar chain units numbering from 10 to 200 units. These are polymerized by thermal free-radical mechanisms, so-called HTV (high-temperature vulcanized) elastomer technology, using bis (2,4-dichlorobenzoyl) peroxide (3). The prepolymer provides the principal elastomer (or rubber-like) characteristics, while the chemically equivalent oligomer serves to modify the tactile feel or quality by causing the elastomer to acquire skin-like (low modulus) elasticity. In effect, as described in previous BPR reports, the oligomer modification developed in this project lowers the initial tensile modulus from an original range of 400-to-800 lb/in^2 (28-to-56 kg/cm^2) to 40-to-80 lb/in^2 (2.8-to-5.6 kg/cm^2) to more nearly replicate that of living tissue.

The ingredient compositions used in the first exploratory production effort involving one-pound scaled runs (Campaign I) are listed in Table 3. That is the maximum amount of ingredients that can be accommodated in a commercial 4 x 8 in. high-speed three-roll mill (Kent mill) manufactured and sold by the Charles Rose and Son Co., Hauppauge, Long Island, New York.

TABLE 3.—*Production Campaign I—To Develop Scaled-Up Operating Conditions*

Ingredients	Composition Percent by weight S-2 (Shades)	S-3
(a) Pre-polymer silicone gum stock General Electric SE 4524U Lot FF1 6	80	80
(b) Oligomer – dimethylsiloxane Dow 200 Fluid – 350 cs or Dow 200 Fluid – 100 cs	20	20
(c) Catalyst Bis(2,4-dichlorobenzoyl) peroxide	0.5	0.5
(d) Pigment Concentrate L-124-21-series (See Table 5)	0.1	0.05
Optimum operating conditions		
Roll speeds – 30 x 90 x 270 rpm		
Water chilling		
Time schedule (minutes) elapsed:		
(e) Denerving 0- 4		
(f) Banding 5- 6		
(g) Oligomerization 6-16		
(h) Cross-blending (pigments) 16-18		
(i) Cross-blending (catalyst) 18-20		

TABLE 4.—*Production Campaign II—to Ascertain Effect of Range of Oligomer Molecular Weight on Product Quality*

Ingredients	Compositions (Number of runs) SR-1	SR-2	SR-3
(a) Pre-polymer silicone gum stock General Electric SE 4524U Lot GE226	80	80	80
(b) Oligomer – dimethylsiloxane	20	20	20
Dow 200 Fluid – 10 cs[a]	(3)	(2)	(4)
Dow 200 Fluid – 100 cs	–	(4)	(4)
Dow 200 Fluid – 200 cs	–	–	–
Dow 200 Fluid – 350 cs	(1)	–	–
(c) Catalyst Bis(2,4-dichlorobenzoyl) peroxide	0.5	0.5	0.5
(d) Pigment Concentrate L-124-94-series (See Table 5)	0.2	0.1	0.05
Operating conditions—same as the optimum indicated in Table 3.			

[a] centistokes (kinematic viscosity)

Table 4 lists the ingredients used in the second, repeat production (Campaign II) which was undertaken to ascertain the processing effects of varying the molecular weight specifications of the polydimethylsiloxane oligomers in terms of viscosity ranging from 10 to 350 cs (centistokes). The two production "campaigns" were undertaken in order to establish the optimum milling schedules of the blending operations. Schedules must be specified to satisfy FDA regulations on good manufacturing process (GMP). The production program is expected to extend the range of intrinsic pigmented compositions to take care of all possible variations in the skintones and color of all races and ages. This is also currently an aspect of the on-going Field (Patient) Evaluation program of the project (Phase V).

The production campaigns should result in a significant reduction in materials cost, besides making the PDMS orofacial prosthesis material more generally available in quantities. (The limited, one-ounce laboratory research preparations have been supporting not only the R & D efforts of the Comprehensive Development Program, but also the clinical maxillofacial reconstructions for over 300 patients treated in the Maxillofacial Prosthetic Center at the Wilmington, Delaware, Veterans Administration Center.) The production campaigns now provide a means for maxillofacial use of the HTV silicone elastomers that have been utilized, as the preferred material as subcutaneous and bony implants for patients, by the Veterans Administration since 1970 (4). The HTV elastomers are initially too stiff for flexible orofacial reconstructions, and require intense blending to obtain the required oligomer modification and the intrinsic pigmentation. Few if any maxillofacial clinics are equipped to conduct these blending operations, which require a special laboratory mill and the skill to develop the required technology. These technical difficulties, therefore, obligate Phase VI production.

Whereas the laboratory research procedure (with the special Erweka three-roll slow speed mill) produces nominally one ounce (20 to 28 g) of milled pigmented shades of the prepolymer-oligomer mixture (for curing in dental stone molds) in a period of 40 to 50 min, the Kent 4x8-in. high-speed, three-roll mill produces one pound (454 g) in 15 to 20 min. of operating time. Each one-pound batch can make from 25 to 30 orofacial prostheses. Thus the highspeed mill can serve the entire needs of VA maxillofacial or orofacial reconstructions, with considerable saving of working time on the part of the prosthetists making the prostheses. The potential capability of this type of blending mill far exceeds any expected clinical requirement. For the entire VA requirement, the estimated number of full days of mill operation is on the order of 8 to 12 days/year,

leaving much time for other needed research tasks such as development of adhesives for orofacial attachment, for composites to produce integrated laminates of high and low moduli, and incidental biomechanical engineering parts. The main capital investment for the mill is approximately $6,500.00 and the mill can be located in the present research facilities of the VA at Wilmington, Delaware.

The production runs of Campaign I and II, in conformity with good commercial manufacturing practices, have been and continue to be checked for quality control features and performance standards, for comparison with the quality standards demonstrated with the research laboratory preparations.

Intrinsic Pigmentation — Reproducibility of Quality and Product Specifications

Each of the one-pound runs of the two campaigns have been checked for a series of tri-color indices using the Hunter Digital Color Difference (DCD) Colorimeter for tentative shade standards. Table 5 summarized the "L" (Reflectance), "a" (Redness), and "b" (Yellowness) values or indices for balanced yellow-red shades, designated S-series, produced in Campaign I, and for a more transparent SR-series, produced in Campaign II. Both series use the simplest combination of artificial pigments. The sub-dermal yellow carotenoids are imitated by pure yellow iron oxide pigment (Pfizer Company) and the subdermal arteriole-veniole capillaries are imitated

TABLE 5.—*Pigment Levels for Production Campaigns*[a]

Pigment Ingredients		Color Specifications (DCD Indices)	Shade series	Pigment Levels (Parts per 100) - 1	- 2	- 3
White Titania (DuPont RUTILE)	"L"	Transparency versus Opaqueness	S	0.100	0.050	0.025
			SR	0.050	0.025	0.0125
Red Rayon Flock (Claremont)	"a"	Redness	S	0.125	0.0625	0.0313
			SR	0.125	0.0625	0.0313
Yellow Iron Oxide (Pfizer)	"b"	Yellowness	S	0.018	0.0090	0.0045
			SR	0.018	0.0090	0.0045

The levels are from pre-prepared concentrates starting from the S-1 or SR-1 shade of saturation and then halved for successive shades, a conventional practice in industry and in retail color selection of paints. Table 6 summarizes the Hunter digital color differences (DCD) colorimeter measurements of the production campaigns.

[a]See table 3 and table 4.

by red rayon flock (Claremont Company). Both series utilize titania white (Du Pont titanium oxide), to replicate the colorless subdermal nodes of lipoidal or fatty tissue, at an ingredient level that provides a range of transparency such as is evident in certain regions of the human ear.

TABLE 6.—*Intrinsic Pigmentation Measurements for Quality and Product Reproducibility*

	Reflectance (L)	Digital Color Difference (Hunter) Redness (a)	Yellowness (b)	Ratio (b)/(a)
S-1 Series (Highest pigmentation)				
Research Preparation	69.0	+ 12.3	+ 19.3	1.56
Campaign I		(to be made in Campaign III)		
S-2 Series (Mid-range pigmentation)				
Research preparation	72.1	+ 7.7	+ 19.6	2.55
Campaign I	71.7	+ 7.8	+ 20.0	2.56
S-3 Series (Lowest pigmentation)				
Research preparation	73.8	+ 3.3	+ 16.3	4.94
Campaign I	74.1	+ 3.8	+ 18.4	4.84
SR-1 Series (Highest pigmentation)				
Campaign II	71.3	+ 11.7	+ 12.7	1.09
SR-2 Series (Mid-range pigmentation)				
Campaign II	73.0	+ 5.2	+ 11.8	2.27
SR-3 Series (Lowest pigmentation)				
Campaign II	79.2	+ 0.0	+ 8.1	8.1

N. B. The principal difference between the S-series and the SR-series is the reduced level of the white titania serving as an opaque dispersant imitating that of the sub-dermal lipoid clusters and at the same time modifying the transparency such as required of the ears.

Table 5 lists the commercial sources and designations of the pigment ingredients involved. The S-series of intrinsic pigmentation shades utilize 1.0 percent titania while the SR-series shades utilize one half that of the S-series. Titania levels are halved progressively for the S-2 and S-3 and for the SR-2 and SR-3 pigment levels. The SR-series (as indicated by the "L" reflectance values) are more transparent as indicated in Table 6. For more discernible differences in the intrinsic color values the data are indicated graphically in Figure 16 providing qualitative features for each member of the two series, as follows:

1. The transparency (versus opaqueness) as indicated by the "L" reflectance values are markedly affected by the white pigment, color-dispersing titania, which serves to decrease the transparency (nominally the difference between complete reflectance of 100 per-

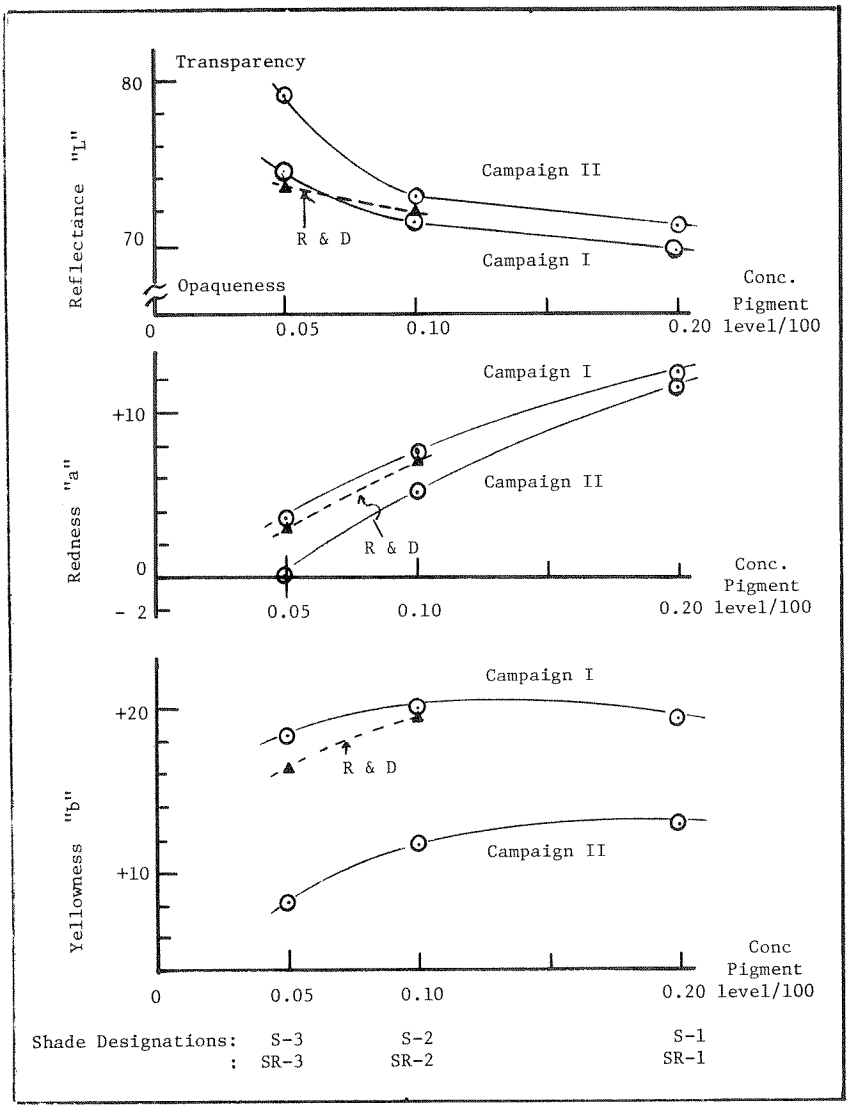


FIGURE 16.—Graphic comparisons of color values of pigmented Campaign I and Campaign II productions, and laboratory (R&D) preparations, using Hunter Digital Color Difference notation.

cent and the measured "L" values). In the two instances indicated, the S-shades of the products from Campaign I coincide, within experimental instrumental error, with that made in laboratory research preparations. Thus, the pigment blending or dispersion produced by the milling action of the two different three-roll mills are comparable.

2. The redness "a" values increase proportionately in both series from the two campaigns, being higher in the materials from production Campaign I due to the higher titania content which serves to enhance the dispersed reflection (4).

3. The yellowness "b" values also increase proportionately in both series from the two campaigns, being higher in the production Campaign I due to the higher titania content.

In general, these shade series represent a range of internal or intrinsic colorations of the material over which the extrinsic pigmentation is to be applied by the skilled prosthesis technician or artist, by visual approximation of the patient in sittings under conditions of daylight or reasonably replicated daylight, applying surface pigmentations, tones, blotches, etc., as required to blend with the adjacent tissues.

The transition from laboratory research preparations of ounce or less milling charges to the production scale-up of 1 lb (454 g), has been accomplished with acceptable reproducibility in the incremental variations of reflectance (or transparency) and in the subdermal redness and yellowness. This represents an encouraging accomplishment: to provide details for good manufacturing procedures by scale-up usually requires a number of repeated campaigns or trials. Additional campaigns are contemplated to affirm the reproducibility of materials quality and process operations, and at the same time to provide pound lots to several other clinics participating in Field (Patient) Evaluation programs.

Moreover, the production campaigns, with their detailed recording of operating procedures and material specifications (hitherto not available in any stock material for orofacial prostheses or devices) are intended to attract reliable manufacturing firms to take on the marketing of the stock material. The detailed operating procedures, specifications, and performance in satisfying end-use standards, will be collated for appropriate registration with the Bureau of Medical Devices of the Food and Drug Administration for certified safe and effective materials and devices under provisions of Section 520 (f) (5).

Toxicity Testing – Reproducibility or Non-Toxic Quality

As a feature of demonstrated safety to humans, Table 7 summarizes the results of the on-going tissue culture toxicity tests on

prostheses made from each of the 1 lb production lots from Campaigns I and II, using an extended series of human excised donor tissues. Included also are typical results with two competitive chemical forms of prostheses elastomers, now being used as toxic references, and an inert fluorocarbon for non-toxic reference or control. The orofacial tissues used for this quality evaluation of the stock material and of the fabricated prostheses (which fabrication imposes thermal changes on the stock material) include that of the gingiva (gum), rhinomucosa (nasal interior tissue), pharyngeal and soft palate (mouth and throat), and epidermal (exterior skin) tissue.

The Tissue culture toxicity procedures follow the usual growth of fibroblasts, separated from the excised sections of tissues from the orofacial regions, in conventional growth and maintenance media (6). Additionally, a number of simplifications and tighter control on the culturing variations are being developed, with the intent to propose a specification method relevant to orofacial tissue exposure. One unique feature of the method, to cite an example, is to initiate the toxicity test at low cell density in the range of 100 cells per milliliter or less. This is in contrast to the 200,000 to 300,000 cells-per-ml density used by others in tissue culture studies. It is believed that the more sensitive young cells in contrast to the more mature growing cells, would provide a more differentiating manifestation of inhibitory or toxic effects. In general, the initial low-cell-density protocol affords a more stringent test method, involving the prostheses through the entire cell initiations and growths, on the reasonable presumption that mature cells can be more resistant to toxic environments.

Excised tissues, obtained incidental to surgery on patients undergoing some form of orofacial surgery, are processed immediately in tissue culturing that includes normal propagation for stored cell lines, from which clonal cells are further cultured for continued propagation without any included test items, some with toxic controls, some with non-toxic controls and some with prosthesis samples being made at the same time. In this system, the freshly obtained orofacial tissues are tested directly with on-going prostheses fabrication material. When the freshly excised tissues are not available, then the banked, ultra-low-temperature stored tissue or cells are used to check out the prostheses—in this case the materials from Campaigns I and II. As the Accumulated Pool or cohort of the human excised donor tissue accumulates, an approximate tissue match appropriate to the newly made prosthesis can be made from the banked, ultra-low-temperature stored tissues by age group, sex, race, and eventually other features related to tumorgenicity and radiation therapy. The tissues stored for the Accumulated Pool under low temperature storage (−80 deg) are to be used for (i) periodic re-checks of viability

TABLE 7.—*Human Excised Donor (HED) Tissue Toxicity Tests for FDA Approval*
Designations: - *Non-toxic* + *Toxic* n/t *Not tested*

Test material			Tissue culture toxicity response					
Shade	Prosthesis		Gingival		Nasal mucosa		Epiderm (skin)	
	Code	Form	Patient	Result	Patient	Result	Patient	Result
Production Campaign I								
S-2	822	Nose-lip	MxF	–	JJT	–	AxM	–
S-2	823	Nose	MxF	–	AxS	–	AxM	–
S-2	824	Nose	MxF	–	AxS	–	AxM	–
S-3	815	Nose	MxF	–	AxS	–	AxM	–
Production Campaign II								
S-1	903	Nose	NxC	–	RxK	–	AxM	–
S-1	905	Ear	NxC	–	RxK	–	AxM	–
S-1	907	Orbit	NxC	–	RxK	–	AxM	–
S-2	896	Ear	NxC	–	RxK	–	AxM	–
S-2	897	Orbit	NxC	–	RxK	–	AxM	–
S-2	898	Nose	NxC	–	RxK	–	AxM	–
S-2	900	Ear	NxC	–	RxK	–	AxM	–
S-2	901	Ear	NxC	–	RxK	–	AxM	–
S-3	902	Orbit	NxC	–	RxK	–	AxM	–
S-3	906	Ear	NxC	–	RxK	–	AxM	–
S-3	908	Nose	NxC	–	RxK	–	AxM	–
Competitive prosthetic materials								
Polyurethane (7)		Nose	PxV(a)	+	AxS (a)	+	AxM(2a)	++
Polyurethane (9)		Sheet	MxF	+	AxS(2)	++	n/t	
Polyvinyl chloride plastisol (Type III) (8)			MxF(4)	++++	AxS(2)	++	AxM(4)	++++
Impartial inert reference								
NAFION (DuPont) fluorocarbon			MxF	–	AxS	–	n/t	
			SxS	–	JJT	–	n/t	

Note: All tissues, except where indicated by (a), were taken from the ultra-low-temperature storage of the Accumulated Pool of HED tissues

Note: The HED patient designation as a source of the tissue is by using three initials representing the first name, second name, and the third name in capitol letters or, when not known or not given, the lower case letter "x".

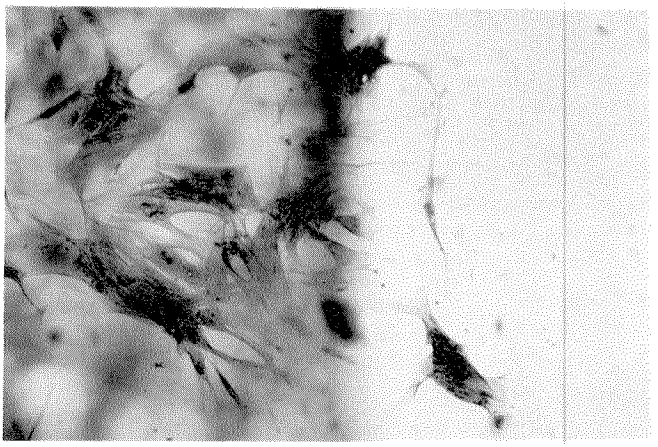
usually at 3-month intervals or more, and (ii) testing of future lots of production campaigns. This will be especially important as the pound runs of material are released to other clinics participating in the Field (Patient) Evaluation programs.

As the compilation of the test results (Table 7) indicates, the pound-quantities of material from the two production campaigns, which have been converted into a variety of anatomical prostheses (notably ears, noses, orbitals, and complex nose-lip sections) indicate consistently no toxic effects in the listed HED tissues. These tissues are cell growths from 4 to 14 days, more or less, depending upon the characteristic time for maturation to confluent monolayers, which in turn depends upon the type of tissue involved. (The procedures for each of these tissues will be made the subject of a separate report, as the maintenance details would over-burden this report: moreover, simplifications are in progress.

The consistent non-toxic response observed in connection with the prostheses from production Campaigns I and II, contrasts sharply with the inhibitory toxic response shown consistently with the competitive prosthesis materials; namely, polyurethane from two sources (7,8) and plasticized polyvinyl chloride, Type III (9). An impartial chemically inert-non-toxic fluorocarbon polymer is included as reference control with non-toxic effect. The tabulation of the HED test (in due course as the pool of tissues accumulates for the broad range of ages and several human features of distinctions or classifications) is intended to provide a data base for the production campaigns, present and future, that will provide the required assurance of safety to humans to the Food and Drug Administration.

Selected photomicrographs of the test results listed in Table 7 are shown in Figure 17 for the Campaign I prostheses, Figure 18 for the Campaign II prostheses, and Figure 19 for selected competitive prosthesis materials. The photomicrographs include two simultaneous sections of the tissue cells grown to maturity directly under (and in some cases over) the prosthesis sections, indicated on the left section of the photomicrograph, for comparison with the growth immediately away from the prosthesis test section. The mid-line shadow is due to the out-of-focus edge of the prosthesis material (especially likely to be out of focus if it is either much thicker than a fraction of a millimeter or taken at high magnification). Photomicrographs of this type are being accumulated, to be submitted in documentation to the Food and Drug Administration to obtain clearance of the polydimethylsiloxane compositions and fabricated medical devices for use with humans for both external and internal orofacial or maxillofacial reconstructions that come in contact with

(A)



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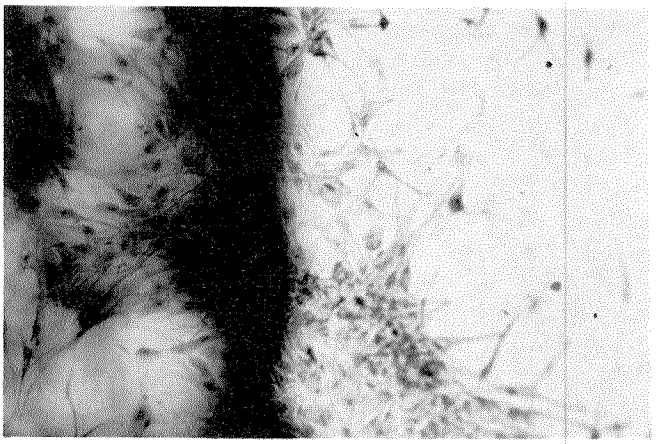

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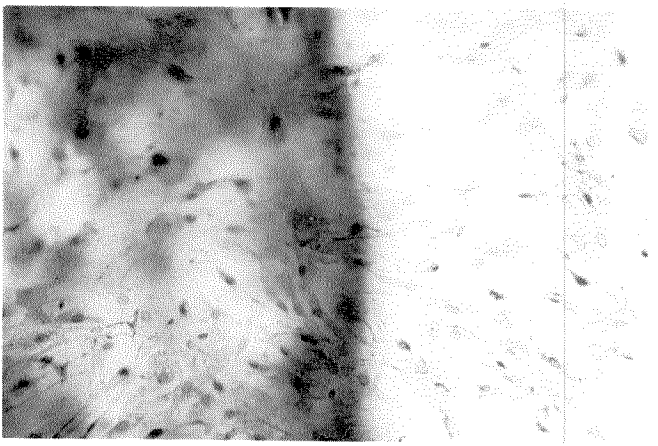


Prosthesis section Glass section

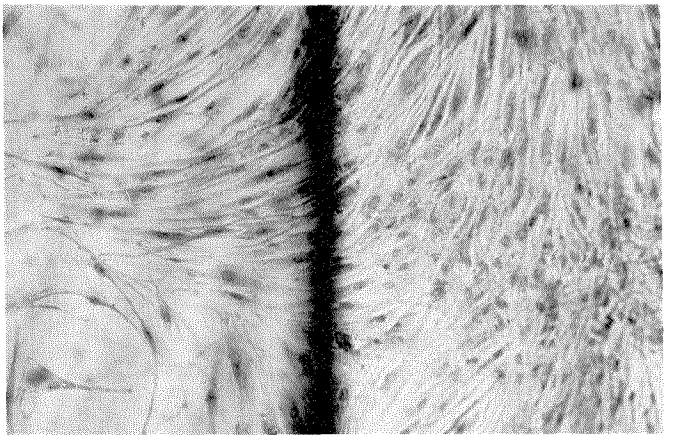
FIGURE 17.—Campaign I fabricated prostheses test sections (left half) in tissue culturing for toxicity evaluation.

(A) Polydimethylsiloxane Prosthesis
P-822
HED Gingiva Patient JxR
7 Days in culture
Normal, non-toxic growth to confluent monolayer over test area of prosthesis. (100x)

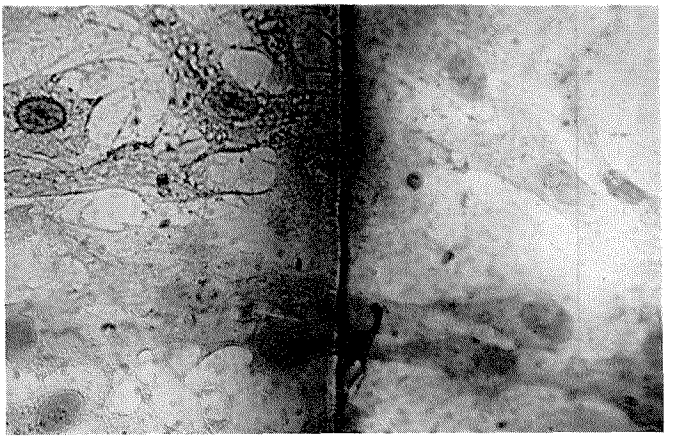
(B) Polydimethylsiloxane Prosthesis
P-822
HED Nasal mucosa AxS
11 Days in culture
Normal, non-toxic growth to confluent monolayer over test area of prosthesis. (100x)

(C) Polydimethylsiloxane Prosthesis
P-823
HED Epidermis AxM
11 Days in culture
Normal, non-toxic growth to confluent monolayer over test area of prosthesis. (100x)

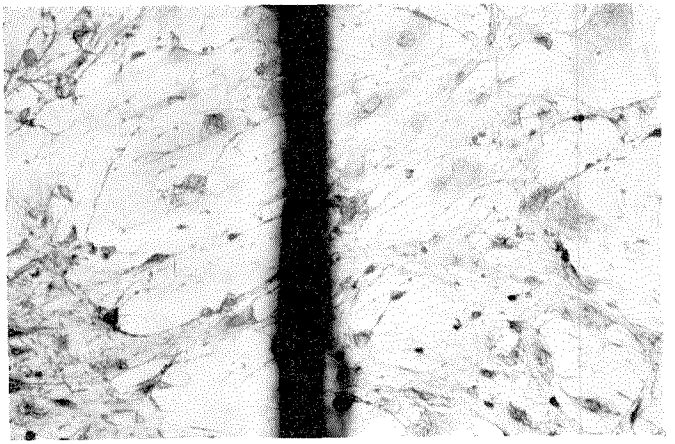
(A)



(B)



(C)



Prosthesis section Glass section

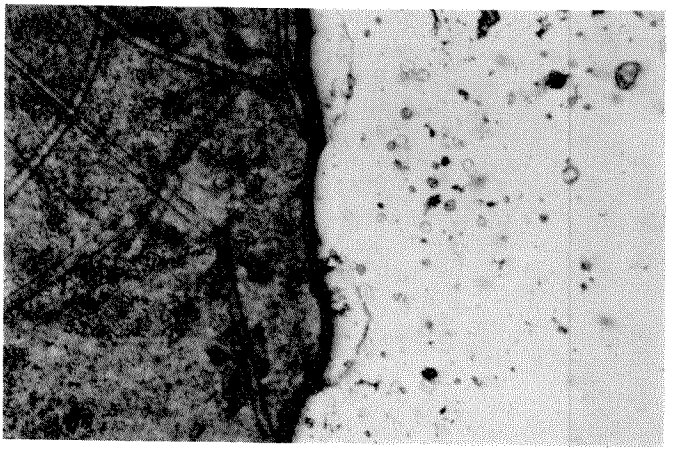
FIGURE 18.—Campaign II fabricated prosthesis test sections (left half in each photograph) in tissue culturing for toxicity evaluation.

(A) Polydimethylsiloxane Prosthesis
P-902
HED Gingiva NxC
7 Days in culture
Normal, non-toxic growth to confluent monolayer over test area of prosthesis section. (100x)

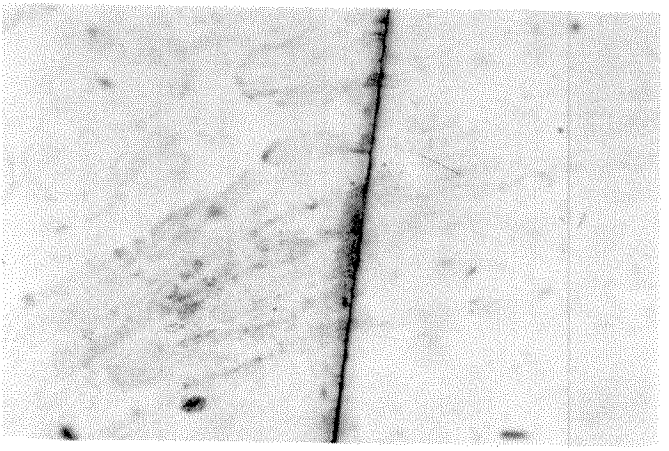
(B) Polydimethylsiloxane Prosthesis
P-896
HED Nasal mucosa RxK
11 Days in culture
Normal, non-toxic growth to confluent monolayer over test area of prosthesis section. (200x)

(C) Polydimethylsiloxane Prosthesis
P-902
HED Epidermis AxM
11 Days in culture
Normal, non-toxic growth to confluent monolayer over test area of prosthesis section. (100x)

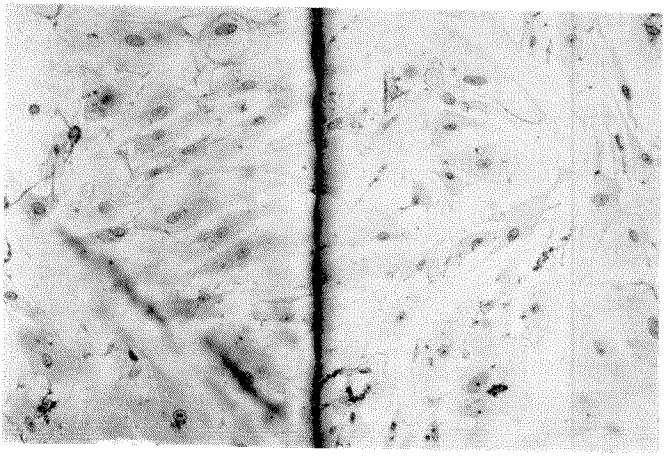
(A)



(B)



(C)



Test material Glass section

FIGURE 19.—Competitive prosthesis materials, and an inert reference, in HED tissue culturing for toxicity evaluation.

(A) Polyurethane Prosthesis (7)
L-124-91-A (sterilized)
HED Gingiva ELO
3 Days in culture (terminated)
Severe lysis of initiating cells with total death extending from test section into culture medium. (100x)

(B) Polyvinyl chloride plastisol
(Type III) test molding (9)
HED Nasal mucosa RxK
T-121-23 (sterilized)
3 Days in culture (terminated)
Complete lysis of initiating cells with total death extending from test section into culture medium. (100x)

(C) Fluorocarbon sulfonate (inert reference – Du Pont NAFION)
T-121-25-A
HED Epidermis AxM
11 Days in culture
Normal, non-toxic growth to confluent monolayer over test area. (100x)

highly sensitive internal mucosa and post-operative healing tissues. Additionally, the clearance will be provided to the suppliers of the principal materials which will eventually be demanded by them for the sale of the desired materials, as otherwise the supply could be terminated.

Performance Standards

Performance standards, as required under Section 514 of the new Medical Devices Act of 1977, must be sufficiently comprehensive to take into consideration many contingencies not covered by conventional test data or standards on durability, and which even the mis-use by the patient during the Field (Patient) Evaluation program fails to reveal. The present and past history of the development and application of medical devices is replete with instances of improper choice of materials, where the effects of or exposure to the simplest end-use conditions and hygienic maintenance have been ignored. Prominent in the latter case is the action of sterilization by autoclaving, which many clinics will insist upon for the prosthesis after fabrication, as a routine safeguard. There is also hygienic maintenance at home, an inevitable requirement inasmuch as any prosthetic device can be expected to absorb or take in perspiration, clotting debris or scabs, tissues or mucosal exudates, thus often becoming malodorous or even irritating to the tissues in contact with the prosthesis. Therefore it is not sufficient to depend upon the numerical test data or standards based on just-fabricated (and not yet worn and hygienically maintained) conditions. Rather, it is necessary to include practical, corollary test exposure conditions in which the battery of physical, mechanical re-checks are made for durability, chemical analyses are made for signs of deterioration, and HED tissue toxicity tests are made for induced toxicity.

Stated generally in other terms, the performance standards must take into account the possible deteriorating effect of all kinds of chemical, mechanical, and actinic impositions that could diminish the expected durability or effectiveness, and/or could cause even the initially non-toxic medical device to become toxic from usage and maintenance. In this regard, a performance test series has been initiated with the Campaign I and II pound-quantity production lots, both as stock materials and as fabricated prostheses. Table 8 summarizes a select number of end-use tests which attempt to simulate or replicate the anticipated use (and mis-use, mostly inadvertent, by some patients) that would provide cogent proof and demonstration of effectiveness in orofacial use, as well as safety in terms of non-toxicity in the tissue culture testing. Pertinent to the listing in Table 8 are the following comments.

TABLE 8.—*End-Use Testing (Tentative, Exploratory) for Performance Standards*

Polydimethylsiloxane (Campaign I)	Polyvinyl chloride plastiosol (Type III)	Polyurethanes	
		Proprietary source (7)	N. I. D. R.[a] Contract source (8)
(1) Sterilization – 25 lb steam, 30 min.			
Unaffected in tensile constants	Turns opaque and discolors	Considerable degradation, becomes a tacky gum	Considerable shrinkage with discoloration and blistering
Unaffected, in HED tests	Toxic in HED tissue tests	Highly toxic in HED tests	Toxic to HED tissues
(2) Disinfecting – Sodium hypochlorite (U.S.P. 5%), 16 hours RT			
Unaffected in tensile constants	Some chlorination evident from IR analysis scans	Some chlorination evident from IR analysis scans	Some chlorination evident from IR analysis scans
Unaffected, non-toxic tests	Toxic in HED tissue tests	Toxic in HED tissue tests	Toxic in HED tissue tests
(3) Moisture Absorption – Distilled water, 37° C., 24 hours			
Unaffected in tensile constants	Unaffected	Unaffected	Unaffected
Unaffected, non-toxic in HED tests	Slight toxic in HED tests	Toxic in HED tests (with pre-emptive sterilization)	Toxic in HED tests (with pre-emptive sterilization)
(4) Lipid, Glyceride Absorption – MAZOLA oil, RT for 72 hours			
Unaffected in tensile constants Slight weight gain (less than 1%)	Softens and gains appreciable weight – more than 8%	Softens and gains appreciable weight – more than 12 %	Softens slightly and gains weight about 4%
(5) Mechanical, dimensional stability following (4)			
Unaffected in tensile constants	Decrease in modulus	Decrease in modulus	
Unaffected in strain recovery (hysteresis)	Noticeable hysteresis (under study)	Noticeable hysteresis increase	Noticeable hysteresis increase

[a]National Institute of Dental Research

Sterilizing The usual practice of precautionary sterilization with up to 25 lb of steam (often inadvertently applied in some hospital practice for as much as an hour) has imposed no mechanical changes in the polydimethylsiloxane. Thus this hydrolytic action singles out the polydimethylsiloxane, from the competitive polyurethanes and the polyvinyl chloride plastisol (Type III), as the material of choice. (The polyurethanes undergo severe hydrolysis, in one case becoming a tacky gum with complete loss of mechanical integrity and in another by severe blistering and shrinkage with distortion. The polyvinyl chloride plastisol (Type III) turned opaque due to high moisture absorption with considerable discoloration and some blistering.)

Disinfecting In order to inactivate micro-organisms such as bacteria, spores, viruses, fungi, and so on, along with any supporting organic contaminant that would support these microorganisms, it is often the domestic or at-home practice to use active agents (notably sodium hypochlorite) which acts as both an oxidizing agent and a chlorinating agent. While the desired hygienic maintenance may thus be accomplished, there is also the possibility of (i) mechanical and chemical deterioration and (ii) potential development of toxic and carcinogenic entities. The inherent chemical resistance of the dimethylsiloxane unit configuration is generally recognized as being superior to the polyurethane configurations, and to that of any ingredient component in plasticized polyvinyl chloride. On-going exposure tests using 5 percent sodium hypochlorite, U.S.P. grade, indicated no chemical changes (based on infra-red scan analyses) for the polydimethylsiloxane prosthesis test sections, whereas the polyurethanes and polyvinyl chloride plastisol (Type III) revealed significant introduction of new group frequency absorptions indicative of discernible carbonyl, ethylenic, chloro-carbon, and other configurations, suggesting that further research on stabilization of these two competitive prostheses materials is needed if they are to match the chemical resistance of the polydimethylsiloxane developed in this project.

Moisture absorption As expected by virtue of its hydrophobic nature, the polydimethylsiloxane indicates a low level of water absorption after 24 hr immersion in 37 deg C distilled water, in contrast to the inordinate moisture absorption by the competitive elastomers. It is conjectured that some level of moisture absorption may be tolerated but that beyond that level aqueous tissue exudates may diffuse into the prosthesis and assist in supporting the bacterial (or worse, fungal) growth which are often a source of discoloration.

Lipid, glyceride absorption Tissue exudates and human perspiration contain lipid or glyceride entities which are hydrophobic

materials, much like oils and greases that can swell or solvent-crack many commercial and industrial elastomer materials. Lipids and glycerides as organic materials can also support the growth of bacteria and fungi, to the detriment of the quality of the prosthesis. Practically all synthetic elastomers, except possibly neoprene, absorb certain levels of glycerides to varying degrees, depending upon the curing or polymerization mechanisms. Silicone elastomers are no exception, but it is necessary to make a marked distinction between elastomers cured by tin catalysts at ambient or room temperature (and thus high in hydrophobic absorption) and those elastomers cured by thermal free radical mechanisms which provide a high degree of cross-linking between chain units, and which provide orders-of-magnitude-lower glyceride absorption. On-going tests (which will be reported in due course) are providing data that indicate the current materials from Campaigns I and II, pressure-polymerized in dental stone molds, have on the order of 1/5 to 1/10 the lipid, glyceride absorption of the competitive prosthesis materials.

Mechanical, dimensional stability A common shortcoming of elastomeric materials (especially if inadequately cross-linked or if derived from long non-cross-linked chain segments in block polymers) is the slow retraction from straining which is characteristic of the phenomenon of hysteresis. The thermally and free-radical polymerized polydimethylsiloxane, even after exposure to the lipid triglyceride corn oil (Mazola) being developed for this performance standard and undergoing the above-mentioned lipid or triglyceride absorption, indicates considerably less hysteresis loss than the polyurethanes, which rank in the highest hysteresis loss, or of the polyvinyl chloride plastisol (Type III).

Some hysteresis loss can be acceptable as the wearer stretches for withdrawal from internal insertion. Some tolerable standards must be prescribed, especially if the absorptions by moisture and lipids may tend to increase the hysteresis to an unacceptable extent.

In general, the end-use implication of performance standards is a requisite for regulatory approval. This involves an array of imagined exposure and maintenance tests, even to include misuse or abuse. The performance standards described herein for the polydimethylsiloxane are not intended to prejudice any competitive materials: it is expected that developmental efforts in all cases can lead to acceptable performance in end-use.

Similarly, considering the specific regulatory feature of safety in terms of non-toxicity, the tissue culture testing (with initial prostheses and those subjected to repeated, at-home hygienic maintenance) accords the polydimethylsiloxanes produced according to the operating technology of Campaigns I and II a clear preference over any competitive elastomeric material presently in use or under

development. The results on toxicity with HED orofacial tissues are not intended to prejudice any material for use in orofacial reconstruction – given a modicum of effort applied to selection of proven non-toxic ingredients (10) coupled with well-controlled polymerization (or solvation as in the case of plastisols) and provision of minimal chemical resistance toward hydrolysis and action of oxidizing or chlorinating disinfectants, a case can be made that various types or classes of chemical structures can be made available as safe and effective medical devices, using the HED tissue toxicity testing system.

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Permanently Attached Artificial Limbs

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Previous reports have described an involuted approach for penetrating the skin, perpendicular to the long axis of the limb, with a percutaneous load-bearing skeletal extension (PLSE). The PLSE has a self-broaching, trifluted, intramedullary rod used for skeletal fixation, and a rounded pedestal containing the skin-penetrating lugs (Fig. 20). This report includes results from three of these devices that had been coated with Proplast® and implanted into limbs of Spanish goats.

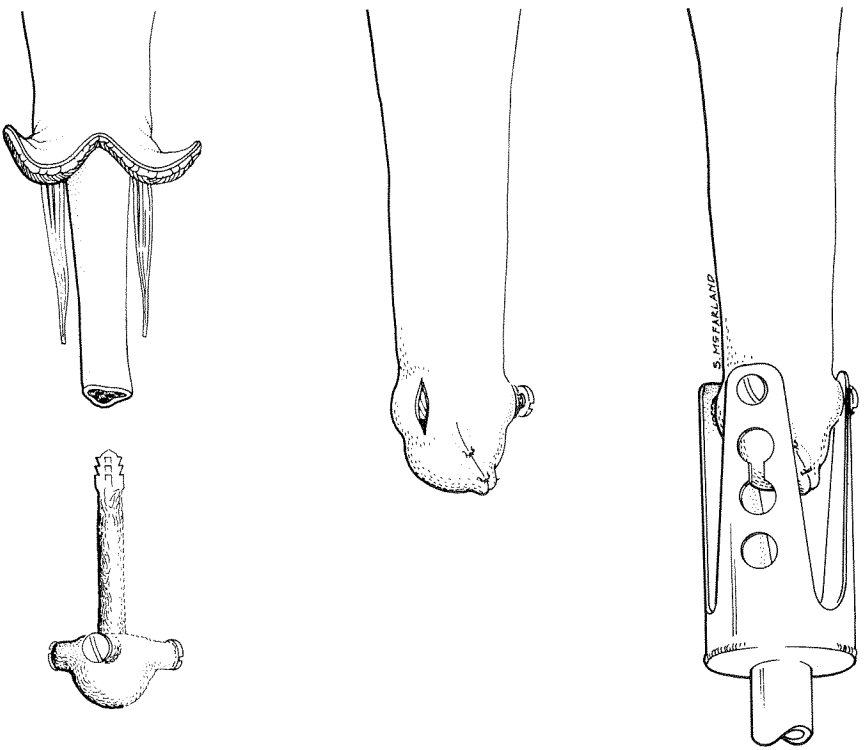

FIGURE 20.—Proplast® covered trifluted PLSE insertion into the medullary canal of the tibia. Note self-broaching teeth that form channels for the flutes to follow. After driving the PLSE as far as the shoulders permit, the extensor and flexor tendons are sutured together below the pedestal. Affixing the external extension follows exteriorizing the lugs.

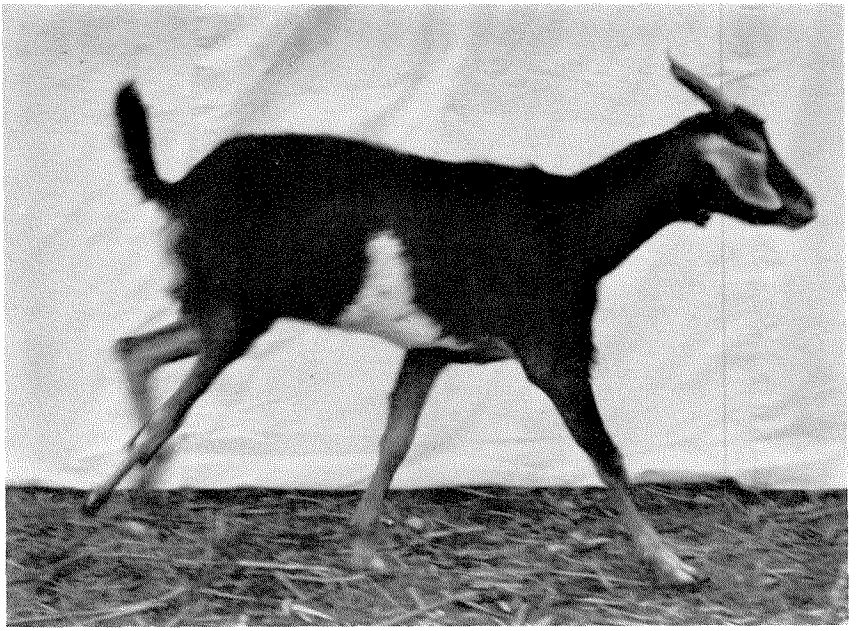

FIGURE 21.—An active Spanish goat shown running 7 months after implantation. Proprioception is excellent, often demonstrated by use of the artificial device to shoo away pesky flies.

One of these three animals (Fig. 21 and 22) has had an uneventful 7-month postoperative course. The other two animals each developed a limp and had to be sacrificed, at the end of 3½ months and 4 months respectively. At necropsy, both of these animals were found to have a caseous accumulation of epithelial debris between the distal skin flap and the pedestal. This was undoubtedly due to a sinus tract formation.

A difference in the surgical technique used in the two groups may have been significant in determining the results. The viable animal had the extensor and flexor tendons joined by suture below the pedestal, whereas the necropsied group did not. The downward growth of epithelium may have been impeded as it came into contact with muscle tissue, but in the case where muscle tissue was not encountered, epithelium was allowed to develop into an epidermial inclusion cyst. This is but a working theory.

It is significant that none of these animals developed skin retraction about the pedestal. We now feel more comfortable with the original supposition that skin forces at the end of the amputated stump will not permit long-term skin-penetration at the apex. Penetration of the skin perpendicular to the long axis of the limb (in

FIGURE 22.—Close up of PLSE on same goat shown in Figure 21. Note hair regrowth and absence of weeping. A high-pressure rubber hose secured to this end of the pylon serves as a nonskid shock-absorber.

regions of uniaxial skin stress) apparently has solved the problem of skin retraction.

Since our experience with the use of Proplast® as a skin interfacing material is limited, we can make no prediction as to its outcome. The bone interfacing of Proplast® results in a fibrous interface developing between the Proplast® surface and the cortex. Fibrous tissue grows into the Proplast® voids, developing a tenacious bond between implant and bone. Calcification of this layer has not yet been observed and does not appear necessary to stabilize the PLSE.

This newly designed PLSE has successfully answered two of the more complicating problems that have obstructed PLSE development. Specifically, it has solved the skin retraction problem, and has obtained a long-term tenaceous skeletal attachment.

Because of our experience in skin interfacing, we have also become interested in coating bone screws and Steinmann pins with skin interfacing material. Both have been coated with Proplast® and nylon velour, and implanted into the long bones of goats and pigs.

Edema about the wound site has caused us to give up on the pig. Goats, on the other hand, have loosened their implants by catching them on the sides of the stall or extracting them while running too close to a fence. Future attempts will try the posterior iliac crest in the goat. The object is to develop pins and screws that can be left in a percutaneous position for long periods of time without developing sinus tracts or infection.

Mobility Engineering for the Severely Handicapped
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Research Program Summary

A 5-yr five-task program for developing chair/van transportation systems is in progress. The specific objectives of the program are:

1. Design and develop van-compatible wheelchairs (powered driver's seats);
2. Clinically and experimentally evaluate these van-compatible wheelchairs, using different classes of patients, in collaboration with the VA Hospital, Wadsworth, Calif.
3. Investigate various aspects of sophisticated high-reliability chair-van control systems, using a mockup;
4. Incorporate the results of that investigation into the design and development of high-reliability chair/van systems for high-level

quadriplegic subjects; and

5. Clinically and experimentally evaluate the chair/van systems developed.

Report of Progress

1. *Van-compatible wheelchair design and development*

On July 1, 1973, MED, Inc., began the design and development of van-compatible wheelchairs which will meet nearly all of the needs of the independent quadriplegic subject. Two basic types are being developed; one uses discrete logic to control the wheelchair, and the other uses a microprocessor-based control system. Each system will include a combination of features heretofore unavailable in a single product. Many of the features are not presently available from any source. Features include the following:

a. *Powered Height Adjustment.* This provides a raised position for reaching overhead objects (Fig. 23(a)), and a lowered position required by the head clearance inside the van, which is about 50 inches floor-to-ceiling (Fig. 23(b)).

(a)

(b)

FIGURE 23.—Van-Compatible Wheelchair: (a) at left with wheelchair in the raised position, and (b) at right with wheelchair in the lowered position.

b. *Variable Wheelbase.* The long configuration provides increased stability in outdoor high-speed operation (Fig. 23(b)); short wheelbase is needed for good indoor maneuverability (Fig. 23(a)).

c. *Secure Hold-down Structure.* The rigid, high-strength structure transmits loads from the seat and subject directly to the van floor; a

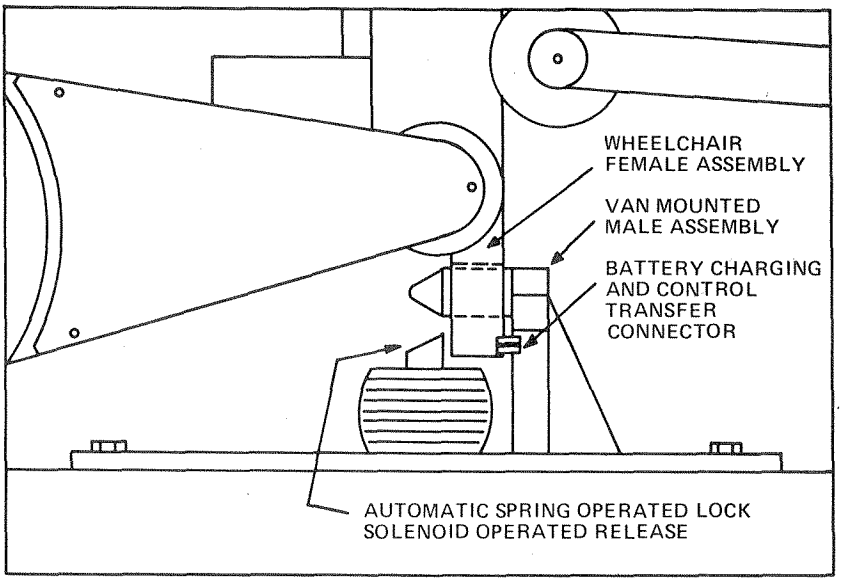

FIGURE 23.–(c) Van-Compatible Wheelchair hold-down assembly.

FIGURE 23.–(d) Van-Compatible Wheelchair in a partially reclined position.

hole in the wheelchair box center section mates with a pin in the van floor structure (Fig. 23(c)). Structure exceeds minimum DOT restraint requirements of 20g seat, 4g seat and driver. There is automatic-locking, pushbutton release, and easy operation by the user from the chair.

d. *Positive Power Steering* (optional equipment). This provides better rough and hilly terrain stability than traditional castered front wheels.

e. *Independent Four-Wheel Torsion-Spring Antisway Suspension.* Rubber torsion springs on each wheel, and front and rear antisway torsion bars, provides a soft ride and excellent accommodation to uneven terrain.

f. *Full Power-Recline of Seat Back* (optional equipment). This permits redistribution of buttocks pressure, reduces the likelihood of pressure sores (Fig. 23(d)).

g. *Three Speed/Steering Ranges* (low, medium, high). This is required equipment if power steering is ordered, but is unavailable otherwise. It allows sharp turns at low speeds and prevents unsafe turns at high speeds.

h. *Speed, Acceleration, Deceleration, and Attitude Limiters* (required equipment if power steering is ordered, optional otherwise). These ensure safe speeds when backing or traveling forward at low or medium speed and eliminate "jack-rabbit" starts and too-abrupt stops. They are internally adjustable to the needs of the patient. The attitude limiters lock out medium and high speed operation when the seat is too low or too high, or the seatback is excessively reclined.

i. *Electrically Actuated Emergency and Parking Brakes* (optional equipment). These bring the wheelchair to a safe stop, in the minimum stopping distance, from any speed; they automatically inhibit both drivewheel servoamplifiers when set. These brakes consume power only momentarily, when being set or released; they securely hold the wheelchair in place during transfers or on hills. They are electrically operated by the user from a switch on the control head.

j. *Powerful 12-V Drive Train.* The power-steering versions use a ½-HP PM (pulse-modulated) motor with a two-stage belt-and-chain reduction drive train on each drive wheel. Closed-loop (tachometer) velocity feedback is available as optional equipment; this ensures that the speed the subject desires is maintained even on hills and rough terrain. Castered versions use ¼-HP PM motors with two-stage reduction drive, without the tachometer feedback. Either drive train is capable of moving the wheelchair forward on level smooth terrain.

k. *Fully Protected Electronics Package.* High-speed current limiters protect drive wheel electronics from damage in the event of sustained stall conditions, protect even against direct shorts in the motor leads. Moving the joystick from full forward to full reverse should never damage the drive trains or electronics package. Steering servoamplifier is protected by fuse.

l. *High Top Speed.* This is approximately 8 mph in power-steered versions, 4 mph in castered versions.

m. *Excellent Hilly and Rough Terrain Performance.* Power-steered versions will negotiate 20 percent grades and drive easily across wet lawns.

n. *Human-Factors-Engineered Seating.* Good hip and lateral support, including use of bilateral shoulder and lap safety belts, maintain the driver comfortably in the proper driving position. Integral headrest prevents whiplash injuries. There are good subject posture and weight-distribution characteristics; an articulated footrest swings the feet up and forward in the lowered position, down and under the knees in the raised position (Fig. 23(a) and (b)). Armrest/control-head assemblies rotate up and out of the way to provide obstruction-free transfer from either side of the seat. Most dimensions are adjustable to accommodate 90 percent of the adult population.

o. *Informative, Subject-Compatible, Control Head* (Fig. 23(e)). Activation forces of less than 8 oz operate all controls; LED lamp display indicates power on, wheelchair properly mated, speed range selected, medium and high speed lock-out, brake application, pause mode in progress, and current limited drive wheels. Optional equipindicator, ammeter, steering indicator, speedometer, and battery voltage indicator.

p. *Automatic Battery-Saving Pause Mode* (optional equipment which is available on power-steered versions only). This ensures minimal current drain whenever the wheelchair is not moving.

q. *External Lighting Package* (optional equipment). Low-current-drain parking lights ensure that the subject can be seen at night; high-intensity headlamps can be switched on so the subject can see the road in dimly lit areas.

r. *Horn and Rear-View Mirrors* (optional equipment). These increase subject safety when traffic must be negotiated.

s. *Attendant's Control Panel* (optional equipment). This allows attendant to control wheelchair movement while walking behind the wheelchair.

t. *CB Radio* (optional equipment). May be used for summoning aid in an emergency.

u. *Auxiliary Control Switch and Connector* (optional equipment). Used for controlling user-supplied accessories: radios, tape recorders, respirators, etc.

v. *24-V Respirator Power Supply* (optional equipment). A second 12V battery is not required when this power supply is installed.

w. *Excellent Cruise Radius.* Radius is > 10 mi with standard 95-Ahr 12 V battery; > 20 mi with optional 215-Ahr 12 V battery.

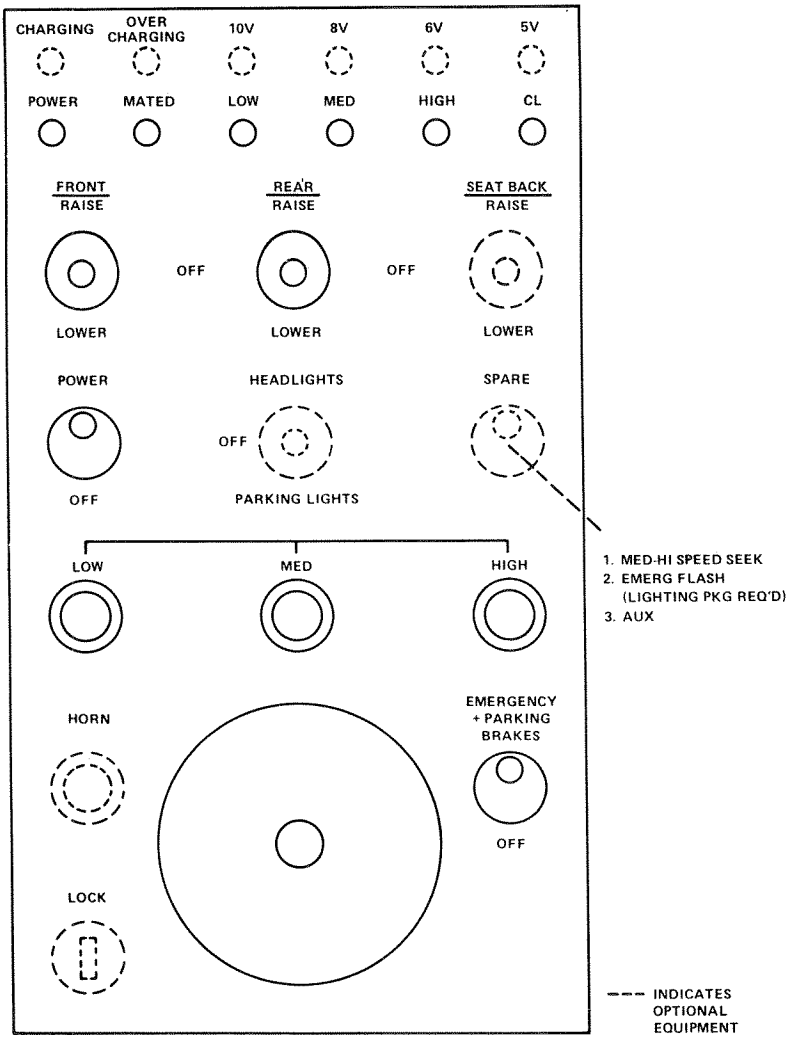

FIGURE 23.—(e) Van-Compatible Wheelchair standard control head.

The discrete-logic versions of the wheelchair are being designed to allow the van-compatible wheelchair to be offered as a commercial product early in 1979. Completion of the microprocessor versions is expected sometime in 1980.

2. *Van-compatible wheelchair evaluation*

A thorough clinical and experimental evaluation of the discrete-logic version of the van-compatible wheelchair is planned. Collaborative arrangements with the VA Hospital, Wadsworth, Calif., have

been made. The results of objective tests, subject impressions, and the suggestions of VA hospital staff members will be used by MED, Inc., as a basis for refining the wheelchair.

Details of the evaluation are being formulated at this time. The VA Hospital, Wadsworth, staff will be responsible for subject selection and training, and (with MED, Inc., staff) for the experiment design and protocol. MED, Inc., staff will become involved as needed. Methods such as interviews and questionnaires will be utilized to gather subject impressions. Performance may also be assessed using an on-the-road evaluation course and other objective techniques. Physical characteristics of the van-compatible wheelchair have already been compared with popular commercially available powered wheelchairs; such comparative techniques will be continued throughout the refinement phase of the development. Various classes of subjects will be represented in the evaluation, probably including at least one from each of the following disability categories:

1. post-polio with residuals in at least one arm;
2. muscular dystrophy;
3. spinal-cord injury with an incomplete lesion at the C-5 level;
4. spinal-cord injury with an incomplete lesion at the C-6 level; and
5. multiple sclerosis.

3. *High-Reliability Chair-Van Control System Investigation*

In order to efficiently investigate and optimize the relevant parameters for the next generation chair-van systems, MED, Inc., is assembling a mockup system consisting of a general purpose microcomputer (LSI-11) interfaced to controls and actuators installed in a van which is mounted on blocks adjacent to the computer room. The mockup is primarily electro-hydraulic in nature, though some pneumatic and electro-mechanical systems are also present. Usually the mockup will be powered from 110-V a.c. lines and a hydraulic test station, though provisions for operating self-contained (from the van engine and electrical system) while the van is in motion have also been included.

Nearly all apparatus for the mockup has been procured, the servo-amplifiers designed and breadboarded, and the software partially written. The mockup should be fully functional late in 1978.

4. *High-Reliability Chair-Van Design and Development*

In April 1976, MED, Inc., began the development of high-reliability chair-van systems for high-level quadriplegic subjects. The systems will allow a subject to drive the van-compatible wheelchair into the van, using an elevator lift installed in the rear or side

of the van, and position the chair approximately where the driver's seat is located in a conventional van. A special guide-rail system built into the van will facilitate mating the wheelchair to the van. During mating, the wheelchair will be secured to the van to meet DOT standards. A control panel mounted on the wheelchair or in the van will become active to control such functions as starting and turning off the van ignition, operating lights and turn signals, gear-shifting, radio operation, etc. When the van ignition is turned on in this manner, the wheelchair joystick is automatically switched from controlling the wheelchair to controlling the van. Another control panel, permanently mounted in the van, will be used for controlling less-frequently-adjusted accessories such as heaters, airconditioners, windshield wipers, etc.

The control system for the van must be a high-reliability one with safety backups that operate in the event of failure. The purpose of the previously described (mockup) research is to optimize system tradeoffs among reliability, cost, safety, patient compatibility, and features offered. Results will be incorporated into the systems to be offered for sale during the 1980's.

5. *Evaluation of the High-Reliability Chair-Van System*

A thorough clinical and experimental evaluation of the high-reliability chair-van systems is planned. Collaborative arrangements with the VA Hospital, Wadsworth, have been made. Results will be used by MED, Inc., to refine the vehicles. Details of the experimental evaluation have not been formulated at this time.

Development of a Wheelchair Using a Myoelectric Control System

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Development of a Wheelchair Using a Myoelectric Control System

During the period of December 31, 1977, to July 1, 1978, a simulated wheelchair control system was made operational. Preliminary tests were performed on one patient. Following an introductory explanation of how to operate the system, the patient was able to generate wheelchair control commands after a few minutes of practice.

The system uses two myoelectric channels (Ch. 1 and Ch. 2), each of which detects minute bursts of myoelectric activity. The upper

portion of the right trapezius muscle was chosen for Ch. 1 and the left trapezius muscle was correspondingly chosen for Ch. 2.

A STOP command is given by the simultaneous generation of myoelectric activity in both channels. Upon detection of this command by the microprocessor, the STOP is immediately executed and remains in effect, without further activity on the part of the patient, until another command is issued. A code that uses simultaneous activity on both channels for STOP was chosen for two reasons: (i) the time required to execute a STOP command is limited only by the patient's reaction time to activate both muscles, and (ii) a muscle spasm will not result in loss of control. (If a spasm occurs in only one of the two muscles, the other can be voluntarily activated to result in STOP.)

The simulated wheelchair control system uses a display board to indicate the status of motion of a wheelchair. STOP is indicated by the illumination of a red light in the center of the display board.

The code for FORWARD uses two sequential bursts of myoelectric activity, the first on Ch. 1 and the second on Ch. 2. Electrical stimulation is used to assist the patient in timing the two sequential bursts. Stimulation is provided at the end of the time period allowed for the first burst; this provides the patient with the information required to generate the FORWARD command as fast as is possible without the two bursts being treated as simultaneous by the microprocessor, a condition which would result in a STOP. Stimulation is also provided after the time allowed for the second burst, in order to notify the patient as soon as it is possible for him to generate another command. (The allowable burst duration is adjustable so that it can be shortened as a patient gains proficiency.) As was the case for the STOP command, the FORWARD command remains in effect, without additional activity on the part of the patient, until another command is given. The FORWARD command is indicated on the display board by the illumination of a green light over an arrow pointing upward on the top of the display board.

All of the comments above that pertain to the FORWARD command also pertain to the REVERSE command, with the following two exceptions: (i) the code for REVERSE is a burst on Ch. 2 followed by a burst on Ch. 1, and (ii) the REVERSE command is indicated on the display board by the illumination of a yellow light (over an arrow pointing downward) at the bottom of the display board.

The code for RIGHT uses two sequential bursts of myoelectric activity, both on Ch. 1. This choice in the coding is not arbitrary, but was made to facilitate the learning of the code by the patient. (Ch. 1 monitors myoelectric activity in the right trapezius muscle.)

The RIGHT command corresponds to switching on the motor that drives the left wheel of a wheelchair in the direction of rotation that would make the wheelchair go forward. The resulting motion would be forward and to the right, as would result from pushing a joystick in the forward-right position. The RIGHT command is indicated on the display board by the illumination of a blue light, above an arrow pointing upward and to the right. As with the other commands, the RIGHT command remains in effect, without additional activity on the part of the patient, until another command is given.

All of the comments above that pertain to the coding and display of the RIGHT command, also pertain to the LEFT command with the following two exceptions: (i) the code of LEFT is two sequential bursts on Ch. 2 (the left channel), and (ii) the LEFT command is indicated on the display board by the illumination of a blue light over an arrow pointing upward and to the left.

Initial tests were performed with a 17-year-old male C-4 quadriplegic patient. After a few minutes of practice, he was able to generate the commands discussed above.

Feedback provisions are currently being made, to train patients to operate the system more proficiently. One could reduce the adjustable time that is allowed for myoelectric bursts, to the point of taxing the proficiency level of the patient, but the feedback which would be of assistance in gaining proficiency would consist of errors in command generation. The technique currently being implemented will provide such feedback via a second electrical stimulation channel without requiring simultaneous command errors. Two adjustable burst-duration timers will be used, one for the coding function discussed above, and a second (set for shorter time) that will activate the feedback channel whenever the burst duration of the second timer is exceeded by the patient's myoelectrical activity. With the appropriate settings of the two timers, a patient at any stage in the process of gaining proficiency can operate the system with relatively error-free performance, but at the same time, receive feedback that he can use to learn to generate smaller myoelectric bursts that will, in turn allow him to operate the system faster and with less effort.

Seat Cushions for the Paralyzed

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An instrument was developed to measure the external pressure, shear and pulsatile arteriolar blood flow existent at a given portion of the anatomy.

Applying this device to the thenar eminence of four healthy subjects, it was learned that externally applied pressure was roughly twice as effective as shear in reducing pulsatile arteriolar blood flow. The combination of pressure plus shear was found particularly effective in causing blood flow occlusion. At a sufficiently high level of shear (roughly 100 g/cm^2) the pressure necessary to produce occlusion was half that required when little shear was present.

Seating Systems for Body Support and Prevention of Tissue Trauma

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The primary area of investigation is the design of pre-fabricated sections for seating systems for the high-level spinal-cord-injury patient. The area presently being investigated is the shape of the contour of the seat cushion, and the nature of its waterproof covering.

1. Based on preliminary clinical trials and pressure measurements, the original shape and thickness of the contoured cushion has been refined as follows:
   a. An extra 2 in. of thickness has been added, to avoid the problem of having to adjust the wheelchair footrest.
   b. The mold has been reshaped to make room for the bladder

neck, and the lower the abduction block and deepen the seat.

2. The cushion covering is a major part of our work, and presently we are not getting sufficient skin on the self-skinning urethane foams to render the cushion waterproof.

Most of our efforts are now going into porous Teflon coverings, which can be made to let the air through but not the moisture. An alternative solution to this skin problem could be urethane in sheet form. We have ordered this material from England.

The work on the "bed of nails" surface is temporarily suspended, because of inability to calculate the most desirable tip shape for elimination of shear, and because we now feel that a hexagonal-shaped tip would give the largest proportion of support area to ventilation grooves.

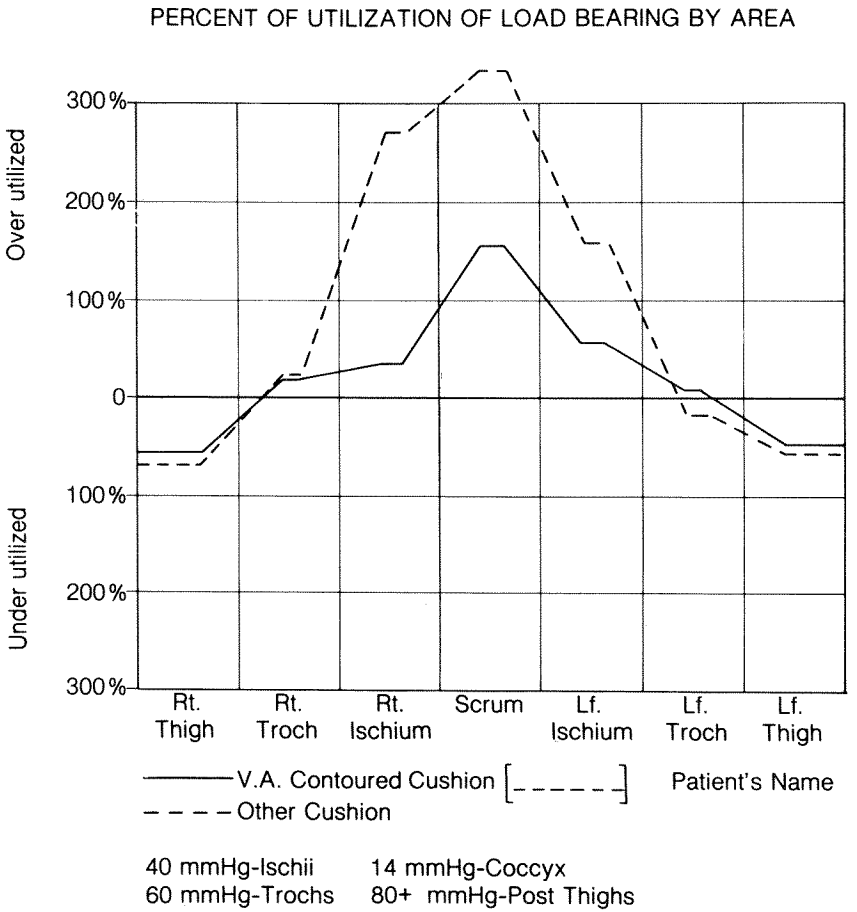

FIGURE 24.—"Percent of load-bearing by area," shown graphically.

3. Based on the work published by Rancho Los Amigos Hospital (Annual Report 1975) we have developed a method of showing, graphically, the "percent of load-bearing by area." The graph (Fig. 24), is typical for patients we tested.