# HIGHLIGHTS OF OTHER RESEARCH PROGRAMS

## PROSTHETICS

*Edited by*

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### Synergetic Hook: Preliminary Evaluation

A preliminary small-scale clinical evaluation of the synergetic hook, conducted by the Veterans Administration Prosthetics Center and the Research Center for Prosthetics, has been completed. Although this laboratory has not received a final report, personal contact with the evaluators, patients, and prosthetists indicates that the results are generally favorable. Based on the information thus received, several changes are being made and incorporated into one hook for preliminary evaluation by this laboratory, to be followed by a more extensive clinical evaluation.

The important changes being made are: (i) reversal of slow and fast fingers, which puts the fast finger on the medial side; (ii) canting the entire hook so that the amputee can approach and grip an object in the same attitude as with a conventional hook (such as the Dorrance 5X); (iii) change to lower voltage motors to reduce the battery size; (iv) use of a current cut-off to the fast motor, to eliminate battery drain under stall conditions.

These changes are being made in addition to the changes discussed in the last report.

### Powered Arm for Shoulder Disarticulation Amputees

The previous report discussed the feedback mechanism fitted to a VAPC elbow (BPR 10-28, 135). An electric wrist rotator with a similar servomechanism has been added. Sterno-clavicular position

in two planes determines the position of the elbow and wrist. Both functions are "unbeatable"; i.e., the position of the powered function cannot change without a corresponding change in sternoclavicular position. At present the prosthesis mock-up is mounted to a bench, giving the prosthesis and operator different bases of reference, inhibiting a true feeling of feedback. A socket-like device is being constructed to allow laboratory personnel to evaluate the system under conditions more equal to actual use by an amputee.

### Below-Elbow Myoelectric Fitting Technique

The Alginate Impression Technique for below-elbow amputation was presented at the 1977 AOPA National Assembly, San Francisco,

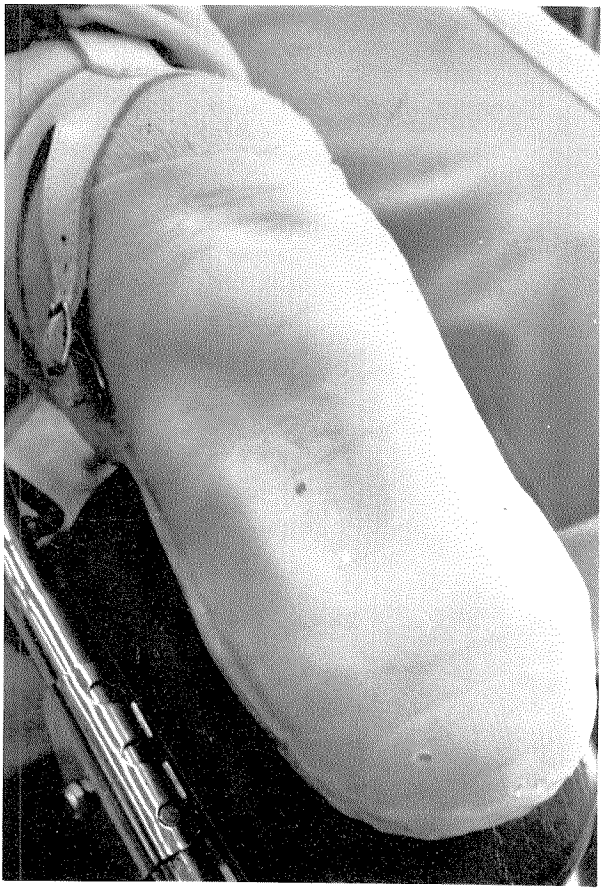

FIGURE 1.—Aquaplast inner socket

California. The technique has been modified to accommodate the proximal motion of the soft tissues when the prosthesis is donned. This is done by pulling two layers of tube gauze over the limb and applying a proximal force to the gauze before the impression is taken.

### Lightweight Below-Knee Prostheses

Work on the lightweight polypropylene prosthesis design has been completed. In November 1977, this laboratory in cooperation with the Midwest Chapter of the American Academy of Orthotists and Prosthetists, sponsored a workshop on the fabrication and fitting of the prosthesis. The workshop was attended by 12 prosthetists from the private sector. The attendees fabricated six lightweight prostheses, four of which were fitted to amputees.

### Temporary Thermoplastic B/K Prostheses

A temporary prosthesis for below-knee amputees is being investigated. It consists of a low-temperature thermoplastic inner socket of Aquaplast (Fig. 1) and an outer socket of polypropylene which is

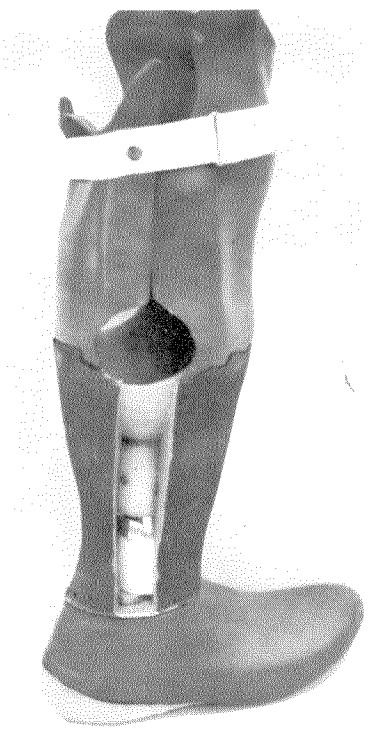

FIGURE 2.—Polypropylene outer socket and PVC (polyvinyl chloride) pylon attached to the foot.

attached to the foot by a PVC (polyvinyl chloride) pylon (Fig. 2). The Aquaplast socket can be formed directly over the limb or over a modified cast. (If applied directly to the limb some protection from the heat must be used such as cast socks.) Volume changes can be accommodated by localized heating and reshaping. The inner socket may also be worn instead of an elastic bandage or shrinker sock.

One patient has been fitted using this technique (Fig. 3). After 6 months of wearing the prosthesis, the limb has stabilized and has decreased in circumference distally by 6 cm. The inner socket was adjusted four times during that period. The results of this fitting are encouraging. The investigation will be expanded to include more amputees.

FIGURE 3.—Amputee donning outer portion of temporary prosthesis.

## 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 a general clinical applications methodology for electrotactile sensory aids for amputees using limb prostheses, and for the blind, the deaf, and spinal-cord-injured patients.

The project has been conducted in three parallel routes:

1. Collection of basic data on the response of cutaneous receptors to simultaneous multi-stimuli;
2. Development of optimal multichannel electrotactile displays based on the basic data; and
3. Development of application specifications for several sensory aids for amputees, and for blind and deaf patients.

The two-point-discrimination theory has been developed as a design concept for tactile sensory aid displays. The TPDT (two-point-discrimination threshold), as a function of body site, laterality, frequency, stimulation codes, stimulus pulse width and pulse time delay, has been experimentally defined. The effect of the TPDT variations in long and short time periods, TPDT hysteresis for ascending and descending thresholds, and electrode size, are being investigated.

Three classes of optimal displays have been developed: space-optimal, frequency optimal, and space-frequency optimal. Additional upgrading of the display types is being done concurrently with the additional data obtained regarding the TPDT response as a function of several variables.

Application of the TPDT data and theory is currently directed toward several sensory aids in the tactile, kinesthetic, visual, and auditory categories.

*Functional Neuromuscular Stimulation of Limbs*

A new project has been initiated in collaboration with Dr. Moshe Solomonow of the UCLA Biotechnology Laboratory, Dr. John

Foster of the VA Hospital, Brentwood, California, and Dr. E. Eldred of the UCLA Brain Research Institute. The program objectives are to develop an advanced functional neuromuscular stimulation (FNS) technique, with a goal toward allowing proportional control of paralyzed muscles.

A control scheme utilizing a proximal supramaximal driving stimulus at 60 pps (60 Hz) in conjunction with simultaneous distal partial block stimulus at 600 pps (600 Hz), both placed on a mixed peripheral nerve, is being tested for feasibility.

Data to date have demonstrated that three control variables have potential for proportional muscle contraction:

1. Block pulse-amplitude variations of the subthreshold to suprathreshold range;
2. Block pulse-width variations in the range of 10 μs-500 μs;
3. Block frequency variations in the range 100 pps-1000 pps (100 Hz-1000 Hz).

Efforts are currently directed toward quantification of the data and definition of optimal block parameters for maximal dynamic range of proportional muscular contraction.

*Upper-Limb Prosthesis Project Using Microprocessor Hardware*

All subsystems, including the prosthesis structure, the control circuitry, belt-mounted microprocessor, myoelectric amplifiers, and ADC were built, tested, and debugged. The pattern recognition software was also tested, on the portable system, and is ready to be evaluated. Current efforts are directed toward the selection of several amputee subjects, to cooperate in the clinical evaluation and system integration program planned for the remainder of this year.

### Evaluation of Medical Manipulators

The Biotechnology Laboratory at UCLA has continued to implement its three-stage evaluation protocol on remote medical manipulators. This report will summarize the progress throughout the evaluation of the manipulator systems which were received from the Veterans Administration.

*1. Rancho Los Amigos Remote Manipulator No. 12 (Golden Arm) Articulated Seven-Degrees-of-Freedom Remote Manipulator*

After a full bench-testing phase, the Golden Arm was introduced into our clinical evaluation stage at the VA Hospital, Long Beach, California. The parameters of interest were patient speed, accuracy, functional range, control modality, and subjective acceptance. Objective tests were designed to assess the patient/manipulator

system in these areas, which require learning and practice in activities of daily living.

In summary, the results indicate faster learning speed, in performance tests, with a proportional-control method. However, patients using the "bang bang" switch control establish a learning plateau, after time, at about the same performance level as patients using the proportional control (about 1.5 min/high accuracy movement). The implication is that this plateau reflects a system limitation rather than a patient performance limit.

Unobtrusive long-term monitoring with a Swedish HMS microcounter system has been instituted, and patient use will be monitored and recorded. This record will be maintained after the patient leaves the clinic, as an indicator of manipulator utility in a daily-living situation.

*2. Telescoping Manipulator Models*

Two telescoping models were evaluated through the bench test phase of our evaluation. One was voice controlled (the Santa Barbara Voice Control System); the other was proportional joystick controlled.

Before they would be suitable for clinical evaluation, both telescoping manipulators were found to need major modification in damping, telescope extension and retraction, and in the prehension subsystem. These modifications are currently being effected by General Teleoperators, Inc.

*The Santa Barbara Voice Control System* was tested for percent recognition rate and to determine if there was any effect on that recognition rate by the order and combination of the command words used (co-articulation effect). In summary, the results indicate that with use of the retraining feature, the 10 word vocabulary of the system could be processed at above a 90 percent recognition rate. There were no significant co-articulation effects in the two-word command sequences.

*3. The Johns Hopkins Manipulator-plus-Worktable System.* This system was being bench-tested when an electrical problem developed in the control circuitry. The problem was corrected by the Johns Hopkins Applied Physics Laboratory, and bench-testing of the system has resumed. Following completion of the engineering evaluation, the manipulator system will be evaluated in a clinical setting.

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

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Work on the multifunctional above-elbow prosthesis, during the report's 6-month period (July 1, 1977-Dec. 31, 1977), has been spent on preparing a number of demonstrations of the system to VA-arranged site visitors. We were asked to demonstrate that we are able to discriminate among several limb functions from a single muscle signal site. This has been successfully demonstrated and reports from the site visits testify clearly to this.

It appeared that there was difficulty in understanding the concept that cross-talk between two muscles could be used (rather than being filtered out) if surface electrodes were located between two muscles (such as between the biceps and triceps muscles) so as to maximize cross-talk. By processing the complete information in such a signal, through modern time series analysis techniques and using microprocessor hardware, we can accomplish the discrimination described, such that several limb functions can be reliably actuated from a single signal source.

The understanding of this concept is analogous to that of the problem of discrimination between "Yes" and "No" when it is well known that the level of speech in pronouncing the words cannot, alone, yield discrimination between the two words. It was as if we were looking at all parameters of the time series of the signals "Yes" and "No", rather than at the level (speech power) of these words, such that discrimination becomes possible.

We differ considerably (and not at all surprisingly) from investigators accustomed to considering signal level (power) alone.

Our demonstrations were all based on using a real time microprocessor (Intel 8080) system.

In addition to the "mere" ability to discriminate between limb functions from a single signal site, we have found and demonstrated that the time series parameters are almost independent of the level of actuation, to indicate the feasibility of employing signal level for proportional speed/torque control. Also, we have shown that parameter values were repeatable within a very few percent from visit to visit (over several months), even though the electrode location varied at ±0.5 cm. Furthermore, we have shown in these demonstrations that, on non-amputees, parameters for a given electrode location and for a given limb function varied only by a few percent

from person to person, again with locations wtihin 0.5 cm. at best. The latter result points to the possiblity of using our approach also for diagnosing muscular and neural disorders in amputees and in non-amputees, the diagnosis being dependent on establishing a library of parameter values per given disorder.

All of the capabilities demonstrated and the possibilities indicated here require clinical testing. We have established cooperation with John Boswick, M.D., of the University of Colorado Medical School, Colorado General Hospital, in Denver, Colorado, and the VA Hospital, Denver. We are, therefore, very hopeful that with the vast clinical experience of Dr. Boswick, meaningful clinical tests will be possible in the near future.

During the period of this report, a second patent application has been prepared on the above work, in addition to the recently awarded US Patent No. 4, 030,141 by D. Graupe. The latter patent has been filed in several foreign countries.

Finally, several papers on this work have appeared or have been accepted for publication, during this six-month period, to bring the total number of publications on this project to 13, excluding reports and guest lectures, and also excluding several discussions of this work in surveys and review papers published by workers who are not members of this group.

A report of a Peer Review has been submitted to the VA during the same period.

**Position Control of Above-Elbow Prostheses**

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The upper limb can be thought of as having two functional components: a grasping device (the hand) and a means to position the hand in space. Direct position control offers many advantages for controlling the latter task. Extended physiological proprioception (EPP), as developed in Scotland by David Simpson, has proved to be a very successful implementation of position control. Unfortunately, his system controls pneumatic prostheses as fitted in the United Kingdom, which are incompatible with the electric systems as fitted in this country.

The basic principle of EPP is to use relative body displacement to control prosthesis displacement directly. A mechanical feedback

link from the prosthetic joint to the input transducer links the input to the output, thus extending the body's proprioception into the prosthesis. Control of a prosthesis is therefore very much like conventional cable control but with greatly reduced force and excursion requirements.

The goal of this research project is to develop an EPP system for controlling a VA electric elbow with a minimum of modification. The project will include design and evaluation of the various components of the system, prototype testing on normal subjects, and evaluation of a refined system by amputees. In addition, studies will be performed to evaluate the suitability of various control sites for EPP.

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

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The primary activity during the latter half of 1977 was the continued development and evaluation of the powered medical manipulator system for the high-level spinal cord injured person. This project has focused on techniques which offer increased self-capability, along with mobility, for the quadriplegic. Three months of clinical evaluation of the computer-aided powered manipulator were conducted during this period.

### Dual-Purpose Wheelchair Controller

A new dual-purpose controller has been designed for an electric wheelchair. This device allows the quadriplegic to retain the mobility of an electric wheelchair in conjunction with the ability to operate the JHU powered medical manipulator/worktable system. The selection and control of either mode is accomplished without assistance from an attendant. Figure 4 illustrates a conventional chin-operated wheelchair controller. Although this controller provides good controllability, its size and location in front of the face are undesirable attributes of this system; a patient in such a wheelchair has mobility but cannot perform functions without help from an attendant after reaching a particular location.

FIGURE 4.—Conventional chin-operated electric wheelchair.

This same electric wheelchair (Invacare Model with Kollmorgen Drive) is illustrated in Figure 5 with new design features as follows:

1. A low-profile two-axis chin controller replaces the original joystick controller. Power to the wheelchair motors is applied by depressing the chin lever downward. Steering is accomplished by swinging the controller left or right. Thus, proportional control attained is similar to that attained with the original joystick. A main power relay was added. It remains in the off position until activated by the initial downward motion of the controller. A microswitch, integral on the chin piece, allows selection of reverse mode when the controller is in the upward or relaxed position. This arrangement results in an easy-to-control system. Figure 5 shows the chin controller in its normal wheelchair driving position. An important change in this system, compared with the original controller, is the

FIGURE 5.—Dual-purpose wheelchair controller provides control of wheelchair and powered medical manipulator/table.

lack of spring-force-centering in the lateral axis. This feature allows the user to push the chin controller off to the side, it then remains out of the way of his face during periods of non-use: this mode is illustrated in Figure 6. (A slight mechanical detent is provided to allow the operator to feel the straight-ahead position of the controller, when steering.)

2. Since the low-profile controller moves the control equipment away from the area directly in front of the mouth, a two-piece mouthstick in a holder (previously located on the JHU manipulator worktable) may now be located on the wheelchair lap board. This two-length mouthstick is available for use by the quadriplegic with-

FIGURE 6.—Wheelchair controller swung away from operating position by user.

out attendant assistance, to carry out tasks such as:

a. turning pages of a magazine or book;
b. operating easy-touch electrical switches on any wall within range of the wheelchair;
c. operating standard keyboard devices such as electric typewriters and computer terminals;
d. direct operation of channel select, volume controls and on-off switch for some TV sets such as the Sony push-button model; and
e. pushbotton operation of conventional telephones with the handset suitably mounted on a wall bracket.

3. This wheelchair lap board also incorporates a fold-down Lucite magazine/book reading stand with wire page-retaining fingers

FIGURE 7.—Wheelchair reading rack with page-holding wire fingers. Mouthstick is used for turning pages.

to allow the user to do his reading in a location of his choosing. Reading using the wheelchair's reading stand is illustrated in Figure 7. The mouthstick is used for page turning and adjusting the wire fingers to retain the pages of paperbacks. As an alternative, he would have the option of sitting in front of a table with books arranged on a plywood reading stand.

4. An optical coupling (not shown in the illustrations) is provided to allow use of the same wheelchair chin controller to operate the powered manipulator when the wheelchair is suitably located in front of the manipulator table. (The details of this interface are described later in this progress report.)

The wheelchair control configuration shown in Figures 5, 6, and 7 provides good controllability of wheelchair mobility in addition to allowing an expanded degree of usage for the mouthstick. This is accomplished with minimum addition of components over the existing electric wheelchair system. One Invacare electric wheelchair has been modified with the above features and successful testing has been accomplished in the Laboratory. Arrangements are now being planned to conduct clinical testing with a quadriplegic volunteer, to get additional data relative to this wheelchair control concept in an actual user environment.

**Powered Manipulator Design Improvements**

*1. Optical Coupler*

The chin controller (now located on the wheelchair) must of course also be capable of operating the powered medical manipulator on its worktable. This control function is accomplished by providing an optical signal-coupler between the wheelchair and the worktable. The dc or proportional signal of the chin-control potentiometer is changed to FM, transmitted via an optical link to the table and converted back to dc. This is accomplished by using a low-cost integrated circuit. The Teledyne 9400 voltage-to-frequency converter ($14.00) is used in this application. The pulse input from the microswitch on the chin controller is transmitted by blanking the FM signal and detected by a zero-voltage detector circuit. This optical coupling is designed to function when the wheelchair is driven to a location within ±2 cm of a designed alignment position on the manipulator table. Lifting up momentarily on the chin controller transfers control from the wheelchair motor signal path to the optical path, thereby allowing the user to select either wheelchair mobility or manipulator control. This is accomplished without assistance from an attendant. Laboratory demonstrations with the modified electric wheelchair have verified that this optical coupling alignment is non-critical, and the signal to the manipulator is noise-free.

*2. Mode Select/Program Select*

The Applied Physics Laboratory/JHU manipulator is controlled via a microprocessor, as indicated in Figure 8. This earlier system used a time scan sequence for function mode select and a two-digit numeric display for the automated programs.

Two changes are being explored to simplify the interface command. These changes are:

a. The display software has been modified to allow the initial

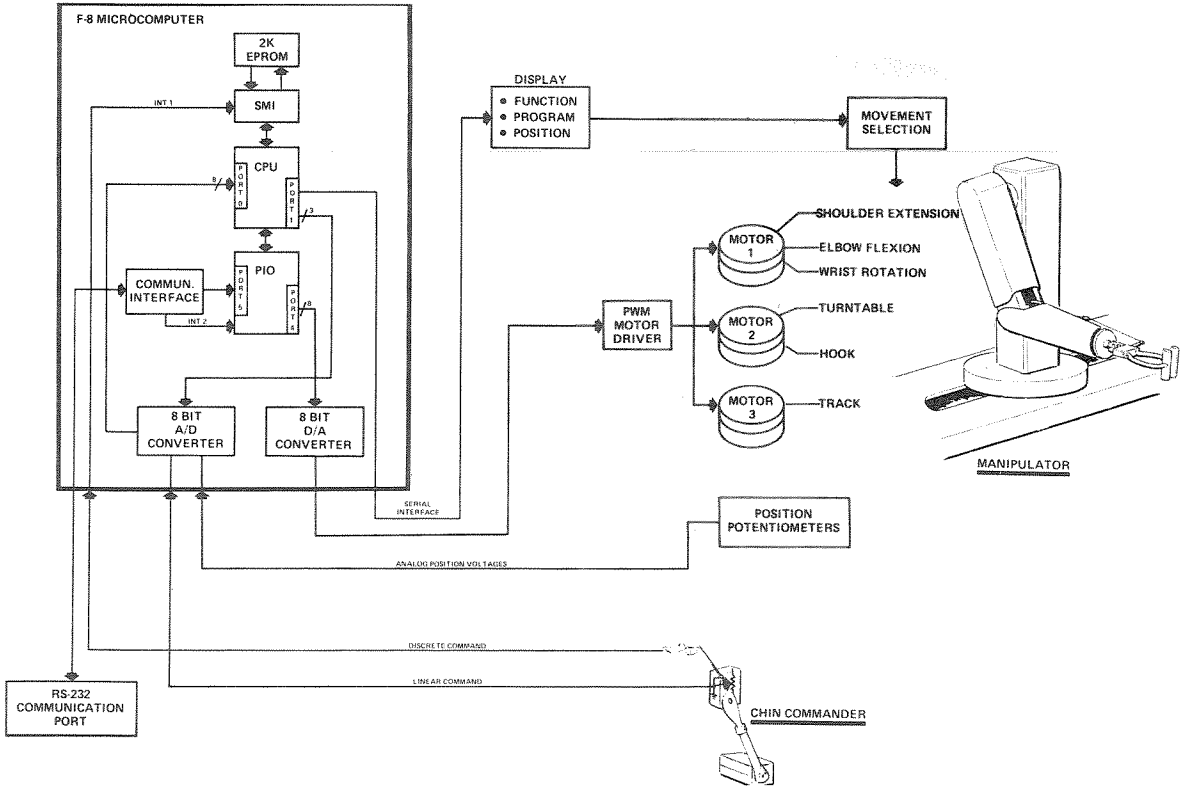


FIGURE 8.—Microcomputer-controlled manipulator.

depressing of the chin controller to call up basic operating functional modes as a function of how far the chin lever is depressed. Once the mode has been selected, the chin lever is used in its normal proportional mode to control the axis of motion. Laboratory tests of the modified system indicate that this method of mode select is easier than the time scan mode. The software of the clinical model of the manipulator has been modified with this change, and field tests have been started to verify the usefulness of the change.

b. A direct alphanumeric readout is being examined as the display for the automated programs, in lieu of the numeric readout presently utilized. This system has been breadboarded using Litronix alphanumeric display models to display 12 letters. This display module requires no support circuitry to interface with the microprocessor. Thus, when the user selects program mode, this display will directly read out the following listing, one line at a time, as a function of how far the chin lever is depressed—

| | |
|---|---|
| ANSWER PHONE | PICK UP BOOK |
| DIAL PHONE | RETURN BOOK |
| EAT | RETURN PHONE |
| KLEENEX | RETURN TYPE |
| LOAD PAPER | SOUP |
| PARK | TYPEWRITTER |
| | WATERCOLOR |

Tests indicate that this method of displaying stored program information may be easier to use than the numeric representation of each program. Tests are continuing to further refine and evaluate this technique.

### Clinical Evaluation Testing of the Computer Controlled Powered Medical Manipulator

The computer controlled version of this manipulator has been undergoing clinical testing by a quadriplegic, for a 3-month period as of this reporting date. Results from these tests have been very encouraging. They show a significant system operational improvement over previous non-computer models. Input effort is materially reduced for all tasks, yet manual control intervention is always possible. Self-feeding and eating soup from a bowl now require only minimal effort. This user has further requested that the plate capacity be increased in order to make self-feeding a practical reality. A new ceramic plate has been fabricated and additional self-feeding exercises are planned to further evaluate this function.

### Continuing Plans

Software and hardware design work is underway to implement the capability to program the manipulator more easily, with a functional keyboard to execute desired automated motion sequences. The software structure and electronic modifications necessary for combined multi-axis motion during program mode are being defined.

Clinical tests will be continued with the experimental system to evaluate design improvements as they evolve. One earlier model of the JHU manipulator work table system is being returned from the VA Hospital, West Roxbury, Mass., for refurbishment with the microprocessor controller and wheelchair modifications as described earlier.

## Research and Development in the Field of Artificial Limbs

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### Hydraulic Ankle Control System

On July 20, 1977, the foam mixing and pouring machine was received. Putting the machine into operation turned out to be more complicated than expected, due to the need for compressed air of higher than shop pressure, for nitrogen under pressure, for three-phase 220-V current, various chemicals, and the correction of several minor malfunctions. It was also found that the molds had to be pre-heated to 140 deg F in order to avoid too-heavy skin formation on the foot surface, and that the resin component of the foam had to be stirred with a motor driven stirrer, before pouring, to counteract the separation of the resin ingredients of different specific gravity. Finally, it became necessary to install under the machine a small space-heater to prevent the temperature of the isocyanate foam component from dropping below its freezing point of 50 deg F during the night and over weekends, due to energy conservation measures. (Thawing can only be accomplished by putting the entire machine into some kind of environmental chamber at 180 deg F for several hours.)

All of these problems were eventually solved and the pouring of foam feet of good quality (which had never been done here before) has now become a routine matter.

The shakedown tests of the Hydraulic Ankle, by the VA in New York and by the two test amputees in Dayton and Arizona, have been continued. They had important results leading to five minor and five major design modifications. The five minor ones included: higher basic setting of the hydraulic over-pressure valve inside the hydraulic unit; switch from Viton rubber to polyurethane rubber for the U-seals to facilitate de-molding without tearing; more clearance for the ceramic control ball inside the hydraulic unit, to prevent contact with the rear vane piston surface which had caused occasional clicking noises; slitting the ankle bolt longitudinally throughout its length to provide better holding power upon expansion, thus preventing sideward migration and piercing of the rubber boot; and keeping the dorsiflexion spring assembly from getting out of adjustment by adding a counterlocking set screw.

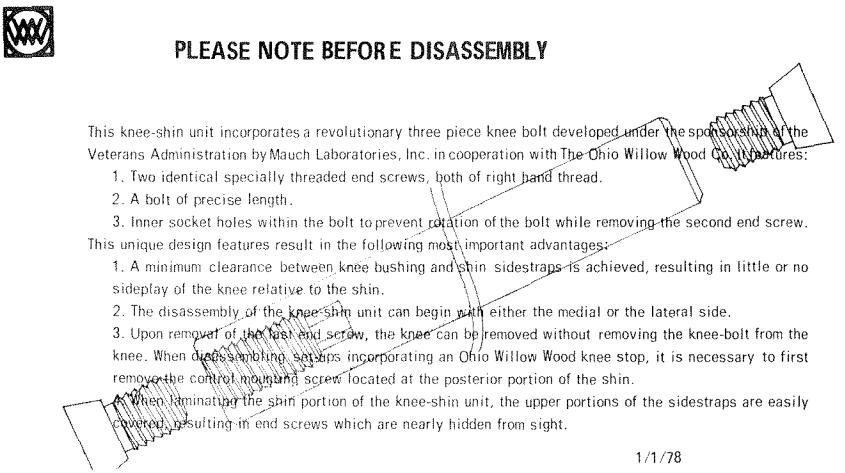
The five major design modifications included:

1. Redesigning of the bypass valve to prevent leaks and to avoid mechanical obstruction (by means of a larger orifice, wider overlap, and more freedom of motion);
2. Redesigning of the shaft of the foam foot, to eliminate noise caused by friction between its inside and the outside of the lower shank end (by molding onto the inside surface of the shaft two kinds of fabric, one stretchable and one non-stretchable, to provide non-rubbery surface and an adjustable elastic edge);
3. Redesigning of the bearing elements at the piston rod tip, which serve to attach it to the inside of the shank, in order to prevent clicking noises upon load reversal (because all clearances provided for adjustment purposes but not needed during actual walking are now reduced to zero by the pressure of the attachment screws);
4. Redesigning of the bearing elements at the piston rod neck to eliminate groaning noises upon weight application (through the use of special, multi-layered, Teflon based, steel jacketed bearing bushings, which will not compress under load, and thus allowing close tolerances); and
5. Reinforcing of the piston rod, one of which broke during the New York shakedown tests, to prevent fractures (by additional heat treatment for existing rods plus larger cross-sectional area in future ones).

All these improvements are having their expected beneficial effects, resulting in trouble-free operation of the three systems under test at this writing. However, only future shakedown testing with additional amputees will tell whether the necessary long range performance (at least one year of maintenance-free operation) is within reach.

## Voluntarily Actuated Swing and Stance Control System

Very limited time could be devoted to the Voluntarily Actuated Swing and Stance Control System project, because of the high priority given to the Hydraulic Ankle as just described. However, some studies were undertaken with the purpose of assessing the possibili-



**PLEASE NOTE BEFORE DISASSEMBLY**

This knee-shin unit incorporates a revolutionary three piece knee bolt developed under the sponsorship of the Veterans Administration by Mauch Laboratories, Inc. in cooperation with The Ohio Willow Wood Co. It features:

1. Two identical specially threaded end screws, both of right hand thread.
2. A bolt of precise length.
3. Inner socket holes within the bolt to prevent rotation of the bolt while removing the second end screw.

This unique design features result in the following most important advantages:

1. A minimum clearance between knee bushing and shin sidestraps is achieved, resulting in little or no sideplay of the knee relative to the shin.
2. The disassembly of the knee-shin unit can begin with either the medial or the lateral side.
3. Upon removal of the last end screw, the knee can be removed without removing the knee-bolt from the knee. When disassembling set-ups incorporating an Ohio Willow Wood knee stop, it is necessary to first remove the control mounting screw located at the posterior portion of the shin.
4. When laminating the shin portion of the knee-shin unit, the upper portions of the sidestraps are easily covered, resulting in end screws which are nearly hidden from sight.

1/1/78

FIGURE 9.—Label on wooden setups explaining the three-part bolt. The text of the label reads as follows:

> This knee-shin unit incorporates a revolutionary three piece knee bolt developed under the sponsorship of the Veterans Administration by Mauch Laboratories, Inc., in cooperation with The Ohio Willow Wood Co. It features:
>
> 1. Two identical specially threaded end screws, both of right hand thread.
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ties made available by the advent of the microprocessor in the electronics field. It seems possible to widen the scope of the control functions for swing as well as stance situations in a voluntarily controlled hydraulic knee system, by utilizing this breakthrough in electronic technology.

#### Three-Part Knee Bolt

The first shipment of wooden setups with the new Three-Part Knee Bolt was received from The Ohio Willow Wood Co. on December 22, 1977. This marks the beginning of the commercial availability of this new bolt. A copy of the label which will accompany the setups is shown (Fig. 9). As can be seen, the three-part knee bolt has many advantages over, and will most likely in time replace, the standard A-K knee bolt which has been in use since the last century. For this reason, the word "revolutionary" used in the label may be forgiven.

The bolt is made by the Allmetal subsidiary C & A Manufacturing Corp., 24-30 Brooklyn-Queens Expressway, West Woodside, Queens, New York 11377. (There are no commercial rights or patents involved in this matter.)

### 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*

Requests for bids from the prosthetics industry on the construction of 50 complete units, including knee mechanism, spherical alignment coupling, pneumatic damper, and pylon structure with coupling for a SACH foot, were sent out by VA Prosthetics Center during this report period. Bids were received from three companies, but all three bids were rejected by the VA procurement officer in New York because of variances from the engineering drawings submitted. (One bid suggested replacement of a welded subassembly by a fully machined part, and another proposed the use of a modified commercial swing-control unit rather than a whole new unit.)

During the next report period, possibilities will be investigated for production of the units under a subcontract directly from the University of California project, in an effort to better utilize the production engineering capabilities of the prosthetics industry to achieve faster progress from prototype to production item.

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

This knee-disarticulation prosthesis has been revised for increased bearing strength, and a single prototype will be fabricated to the new drawings during the next report period. Cosmetic covers patterned after the new molded foam covers for the Four-Bar Knee will also be developed.

3. *Dual-Action Safety Knee (Friction-Stabilized Knee)*

A friction stabilized knee is often prescribed for amputees who need assistance in achieving reliable knee stability at heel contact. The dual-action safety knee was designed to provide knee friction at heel contact, but to release the friction at toe off, allowing easier initiation of swing phase. The same friction brake also provides an adjustable swing-phase control. A third prototype unit has been constructed and tested in the laboratory. This unit appears to satisfy all design goals. Preparation of cosmetic covers is underway to permit extended amputee trials.

4. *SACH Foot with Metal Keel*

The metal-keel SACH foot is performing well in amputee trials. Metal keels produced to date have been machined from solid aluminum. A pattern is being prepared for production of 25 or more cast aluminum keels to allow more extensive amputee trials.

5. *Multi-Input Control of Knee Stability*

A single-axis knee has been assembled that incorporates a hydraulic damper, and transducers that measure knee angle, knee angular velocity, and hip flexion/extension moment. The hydraulic damper provides swing-phase control and stance-phase control. The amount of resistance is controlled by a motor-driven rotary valve. For development of optimal control logic based on the measured variables, the laboratory minicomputer is being used as a controller. When the safest and most functional control logic has been established, a compact hybrid controller can be constructed.

Control algorithms have been developed for active swing-phase control, terminal impact detection, knee lock when going into

stance phase, and detection of voluntary knee-yielding at the end of stance phase and emergence into swing phase.

At present, it is assumed that total knee lock during mid-stance is desirable. The immediate goal is to further refine and control the knee buckling process to fully utilize the knee angular velocity control feature of the prosthesis. In addition to the normal mode of operation, a hip-moment override allows the amputee to voluntarily flex the knee when he encounters unusual situations such as descending ramps or stairs.

A special bent-knee socket has been fabricated to permit testing by normal subjects. Amputee trials will proceed when control is judged to be suitably safe and functional.

**Mobility Aids for the Physically Disabled**

1. *PRAHN Wheelchair*

Detail drawings for the first PRAHN II prototype are nearing completion and the fabrication of parts is under way. The first prototype is scheduled for completion by April 1978, when it will begin testing and evaluation in Berkeley.

2. *Wheelchair Spring Suspension Powering Unit (SSPU)*

Parts for the second SSPU prototype have been fabricated, and assembly is expected to be complete by March 1978. The unit will be tested in Berkeley and perhaps also at the VA Prosthetics Center.

3. *Urinal Bag Clamp*

Five urinal bag clamps are being used in Berkeley. They have performed well following some initial leakage problems caused by faulty forming of the end hooks on the springs. Five clamps were sent to the VA Prosthetics Center in September 1977 for evaluation.

**Ultralight Below-Knee Prosthesis**
**Rehabilitation Engineering Center**
**Moss Rehabilitation Hospital**
**12th Street and Tabor Road**
**Philadelphia, Pennsylvania 19141**
**A. Bennett Wilson, Jr.**

The original 6-month contract was completed April 30, 1977. A manual on the fabrication procedure for an ultralight below-knee

prosthesis and a final report were prepared for the VA.

It was recommended that the VA undertake a nationwide clinical evaluation program through their formal amputee clinic teams.

The VA requested that the Rehabilitation Engineering Center, Moss Rehabilitation Hospital, submit a proposal for a local clinical study, and a proposal was submitted in May 1977 for the conduct of such a study. This proposal was approved and contact was reestablished with the local prosthetics representative and the clinic teams serving the VA in this area. All other local prosthetics facilities certified by the American Board for Certification in Prosthetics and Orthotics were also offered an opportunity to participate. All but one facility responded positively.

A draft protocol for the clinical study was prepared and presented to prosthetists representing facilities in the area. (Two facilities were unable to attend a workshop but they agreed to participate in the study.)

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

A number of clinical evaluation and research studies which have been underway for some time at PRS have, in the last few months, been finalized. The Bernice Kegel, et al., report, "A Survey of Lower-Limb Amputees: Prostheses, Phantom Sensations, and Psychosocial Aspects," appeared in BPR 10-27. A comprehensive additional survey by the same authors, relating to amputee function, has been accepted for publication and will appear in the Archives of Physical Medicine and Rehabilitation.

Accepted for publication and/or recently published are the following:

1. Prevention of Thromoboembolic Disease by External Pneumatic Compression in Patients Undergoing Total Hip Arthroplasty, by L. Pedegana, M.D., E. M. Burgess, M.D., and M. Carpenter. Clin. Orthop. Rel. Res., 128:190-193, Oct. 1977.
2. Cutaneous Blood Flow and Its Relation to Healing of Below-Knee Amputation, by G. Allen Holloway, Jr., M.D., and E. M. Burgess, M.D., Surg. Gyn. Obstet., accepted.
3. Wound Healing after Amputation: Effect of Controlled Environment Treatment: A Preliminary Study, by E. M. Burgess,

M.D., J. Bone & Joint Surg., 60-A(2): 245-246, March 1978.

In addition to our ongoing clinical research in surgery and post-surgical amputation management conducted at the VA Hospital, Seattle, PRS is investigating, in depth, laboratory means for the determination of dynamic limb, skin and subcutaneous tissue bloodflow using Xenon 133, laser-doppler, and skin and subcutaneous $pO_2$ (partial pressure of oxygen) measurements. Correlation of our laboratory findings with the work of Wesley Moore, M.D., VA Hospital, Tucson, Arizona, F. William Wagner, M.D. of Rancho Los Amigos, and others, should culminate in a much more objective means of determining amputation levels preoperatively in the ischemic limb. This is a major challenge for amputation rehabilitation at this time.

The physiological suspension studies are continuing in cooperation with Dr. Fred Lippert and associates at the VA Hospital, Seattle.

The VA Hospital, Seattle, has developed a protocol for investigating muscle volume and muscle strength in the residual limb. Volumetric measurement equipment has been developed to accurately measure changes in residual limb volume. Muscle strength and electrical response of the muscles in the residual limb are also a part of this study.

A statistical review of sports and other extra-ambulatory activities of lower-limb amputees has been completed. This in-depth review of the physical activities of a sizeable number of amputees is being conducted by Jeffrey Webster of PRS, himself an athletic individual who has sustained a knee disarticulation amputation. These studies parallel the basic investigation conducted under our supervision by Professors Robert S. Hutton, Ph. D., and Doris Miller, Ph. D., at the Department of Physical Education, University of Washington, and in conjunction with the VA Hospital, Seattle.

## Below-Knee Amputation with Immediate Postoperative Fitting of Prosthesis

**VA Hospital**
**Tucson, Arizona 85723**
**Wesley S. Moore, M.D.**

Work on amputation level determination as a function of skin capillary bloodflow continues.

The intervening 6 months have been utilized in reestablishing the program from the San Francisco VA Hospital to the VA Hospital, Tucson: developing space, securing new equipment, and reorganiz-

ing the program in a new setting.

A full-time prosthetist is being recruited, so that the randomized study comparing immediate postoperative prosthesis with postoperative management in the controlled environment treatment (C.E.T.) unit may be reinstituted.

## Hemodynamic Evaluation of Postoperative and Preoperative Amputees

VA Hospital
Castle Point, New York 12511
Bok Y. Lee, M.D., F.A.C.S., Frieda S. Trainor, Ph. D., David Kavner, D. Eng., John L. Madden, M.D., F.A.C.S., and Emilio Ejercito, M.D.

### The Efficacy of Lumbar Sympathectomy in the Treatment of Gangrene of the Lower Limb

Work has been completed for our initial report on the efficacy of lumbar sympathectomy in the treatment of gangrene of the lower limb. A review of our records of the past 15 years (1962-1977) yielded 100 cases (111 limbs) with gangrene of the lower limb initially treated with lumbar sympathectomy. The 111 limbs were categorized into three groups: (i) toe gangrene, (ii) foot gangrene, and (iii) leg gangrene. Each limb was studied as to its outcome after sympathectomy: significantly improved without further operative treatment; required bypass surgery; required minor amputation (below the ankle); and required major amputation (above the ankle). Table 1 summarizes the pertinent data obtained.

TABLE 1.

| | Area of gangrene | | | Totals |
|---|---|---|---|---|
| | Toes | Foot | Leg | |
| Patients | 52 | 37 | 11 | 100 |
| Limbs | 57 | 40 | 14 | 111 |
| Age (averages) | 64 | 63 | 65 | 64 |
| Diabetics | 24 | 19 | 4 | 47 |
| Limb outcome | | | | |
| Significantly improved after sympathectomy | 27 | 10 | 1 | 38 |
| Required bypass procedure | 7 | 3 | 1 | 11 |
| Required minor amputation | 9 | 2 | 0 | 11 |
| Limb salvage | 43 (75%) | 15 (38%) | 2 (14%) | 60 (54%) |
| Major amputation | 14 (25%) | 25 (62%) | 12 (86%) | 51 (46%) |

*Patients with Toe Gangrene*

Patients with toe gangrene (1 to 5 toes) showed a high percentage of limb salvage after initiated sympathectomy (75 percent) with almost half of the limbs (47 percent) being significantly improved by sympathectomy alone. Bypass procedures which were done after sympathectomy yielded significant improvement in an additional 12 percent of the limbs. Any form of amputation was thus avoided in 59 percent of the limbs with toe gangrene.

Minor amputations (7 for toe or toes, 1 foot, 1 transmetatarsal amputation) required in 16 percent of the limbs, averaging 2½ months post-sympathectomy. Thus, 75 percent of the limbs with toe gangrene were salvaged. Loss of the limb through major amputation occurred in 25 percent of the cases (9 A/K and 5 B/K) averaging almost 9 months post-sympathectomy.

Of the limbs with gangrenous toes, 24 were diabetic, 19 of whom had their limb salvaged (13 significantly improved after sympathectomy alone, 1 after bypass, and 5 after minor amputations) and 5 required a major amputation. Of the limbs salvaged, one patient shows completely healed feet almost 11 years after sympathectomy alone and one is completely healed almost 12 years after sympathectomy and bypass.

*Patients with Gangrene of the Foot*

In patients with gangrene of the foot, 25 percent of the limbs involved showed significant improvement after sympathectomy alone. One patient at the time of his death (myocardial infarction) almost 8½ years after sympathectomy, showed a healed foot and another patient with bilateral gangrene, possessed both feet at the time of his death (M.I.) 3½ years post-sympathectomy. Two patients who underwent bypass procedures still possess their feet at 4 and 12 years post-sympathectomy. Two patients underwent minor amputation, one transmetatarsal amputation 7 years post-sympathectomy and one a toe amputation 41 days post-sympathectomy. Limb salvage occurred in 38 percent of the limbs with gangrenous feet. Limb loss through major amputation occurred in 63 percent of the cases (15 B/K and 10 A/K). In two instances, major amputation was done simultaneously with sympathectomy, and in two cases, major amputation was done simultaneously with sympathectomy, and in two cases, major amputation was done simultaneously with sympathectomy, and in two cases, major amputation was postponed for several years, one 5 years and one 6 years. Of the limbs with foot gangrene, 19 were diabetic with 6 having limb salvage (2 significantly improved by sympathectomy alone, 2 bypass, and

2 minor amputations) and 13 requiring major amputations.

*Patients with Leg Gangrene*

Patients with leg gangrene showed a high incidence of major amputation (86 percent) averaging about 3 months post sympathectomy. In two patients, major amputation was postponed for a considerable period of time, and 7 months and one 10 months. Only in one patient was amputation avoided by sympathectomy alone. One patient who underwent a bypass procedure died 1 day post bypass and 35 days post-sympathectomy. Of the 14 limbs with gangrene, 3 were diabetic, two of which required major amputation and one dying from pulmonary embolism after a bypass procedure.

### Conclusions

The data presented in this initial report appears to support the use of lumbar sympathectomy in the treatment program of the patient with gangrene of the lower limb. These results show lumbar sympathectomy, particularly in the patient with toe gangrene, to be extremely effective in limb salvage.

In many instances, a lumbar sympathectomy alone is sufficient to initiate the healing process and avoid any amputation and when amputation is necessary, a major amputation can frequently be prevented, with a transmetatarsal or toe amputation after sympathectomy being sufficient to promote healing. Once the sympathectomy has been accomplished, evidence of the healing process can be documented by noninvasive means using photoplethysmography and skin thermistor thermometry. These noninvasive techniques, as well as noninvasive electromagnetic flowmetry, can also be used to accurately determine amputation level when required, and they therefore aid in salvaging as much of the limb as possible.

The use of lumbar sympathectomy and noninvasive quantitative measurements of blood flow in the limbs can lead to better care of the patient with peripheral vascular disease, with consequent salvage of many limbs.

**Engineering Applications in Orthotic and Prosthetic Treatment of Musculoskeletal Defects**

**Motion Study Laboratory**
**Rehabilitation Medicine Service**
**Veterans Administration Hospital**
**10701 East Boulevard**
**Wade Park, Cleveland, Ohio 44106**
**E. Byron Marsolais, M.D., Ph. D., and Eduard Schulz, E.E.**

## Applications of Motion Analysis in Orthotics and Prosthetics

### 1. *Comparison of Implanted Electrical Stimulation (Neuromuscular Assist) to Other Methods of Treating the Equinovarus Foot*

This study, which began in 1971, compared the Neuromuscular Assist (implanted) Electronic Brace with four other ankle-foot orthoses. It has now been completed. Orthoses compared were: (i) the Texas Institute of Rehabilitation and Research (TIRR) polypropylene device which has also been referred to as the "Engen brace" in these reports; (ii) the external FEPB (Functional Electronic Peroneal Brace); (iii) the conventional metal double-upright orthosis; (iv) the VAPC Shoe Clip; and (v) no device at all. The orthoses were compared on a pre-selected and screened group of hemiplegics rather than at random.

A total of 7 patients were implanted with electrodes. The results showed the NMA gave the greatest velocity, stride length and cadence, with a more normal heel and toe contact time. There tended to be some overcorrection of the varus deformity. All orthoses had acceptable correction of the hemiplegic varus deformity.

It was concluded that the NMA represents a clinically usable method for dropfoot correction. Further use must be by the preference of the individual patient and surgeon. The FEPB proved too complicated for our patients to use outside the hospital (see BPR 10-27, Spring 1977, p. 173).

### 2. *Foot Contact System*

Our foot contact system for gait analysis is providing information to physicians on a limited clinical basis. About 70 patients have been analyzed.

In reference to a reader's question regarding double support (BPR 10-28, Fall 1977, page 212): *Two* periods of double support occur within a gait cycle. This Laboratory defines Left Double Support as that period beginning with left heel strike and ending with right toe-off, leading to single support on the left leg during swing phase of the right. The second or Right Double Support period is initiated by right heel strike and terminated by left toe-off. In normal gait, these periods are equal, so *total* double support time during a cycle is *double* the value given for *one* leg by Equation [3]. In pathological gaits, these periods often differ markedly. Monitoring of changes is important in assessing progress of a patient.

### 3. *Stimulation of the Paralyzed Hip to Return Functional Use*

Functional electrical stimulation of the paralyzed hip has to date involved two patients. One below-knee amputee has a fixed knee contracture and was unable to walk with an artificial limb. After

stimulation of the rectus femoris muscle on a chronic basis, the patient was able to walk without support.

Another patient lacked hip flexion and the iliopsoas was stimulated. Good hip flexion was obtained; however, the patient did not wish to leave the electrodes in on a prolonged basis. The electrode breakage problem we had previously been experiencing has been much improved. A microprocessor-based stimulation system is nearing final stages of construction, and will be used in the study for programed hip and knee control in the hemiplegic patient.

#### Three-Dimensional Automated Motion and Joint Force Analysis

Using a three-dimensional computer based technique for automated motion/force analysis of human walking, surface electromyographic electrode placement has been studied and optimal spacing and positioning of these electrodes determined. Intramuscular electrodes, however, appear to be superior.

Further testing of the Selspot system for determining the position of the body in 3-dimensional space has indicated that the system is not usable in its present state for gait analysis. It is our opinion that modifying the present electronics can convert it into a valuable tool for gait analysis.

#### Other Activities

The Cleveland Veterans Administration Hospital Motion Study Laboratory is one of six facilities involved in the clinical evaluation of the VA/Rancho Los Amigos Gait Analyzer. The unit calculates the parameters of velocity and right and left single-stance duration. Normal subjects and patients with a variety of gait problems were evaluated with the analyzer while they walked over our 6-m walkway. Concomitant data were gathered using the Cleveland Foot Contact System. It is our opinion that the analyzer is an excellent initial effort to meet a serious need. We feel that, with some modification, the system will become a very important adjunct to patient evaluation.

A program has been established for the rotation of medical students from Case Western Reserve University to the Motion Study Laboratory. Students are exposed to the mechanics of normal and pathological gait, as well as to the various systems available for gait analysis. The rotation is 6 weeks in length.

# Patient Evaluation of a Functional Electrical Stimulation Hand Orthosis

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## Introduction

The purpose of this project is to develop and evaluate a system employing electrical stimulation to provide controlled prehension and release in the high level spinal cord injury patient. The function and operation of the unit was described in detail in the previous progress report. In this period, development of the miniature stimulator and work with patients using prototype systems has continued.

## Stimulator Development

The stimulator is being constructed in two versions; as a laboratory-based instrument and as a device for use by patients. The philosophy for constructing these two versions was discussed in the previous report. Briefly: the laboratory based unit is used initially to evaluate the patient's performance and determine proper stimulation parameters; these parameters are then set into the miniature unit. The patient units are designed to operate in the same manner as the laboratory-based unit, but are small and portable.

The laboratory unit has been completed and is in use for patient studies.

The miniature units have been completely designed and the first unit is nearing completion. The miniature stimulator's electronic circuits are implemented on three printed circuit boards. These boards are approximately 3 X 4½ inches and are stacked vertically over each other. One of these three boards has been assembled and completely tested while the other two are currently being etched commercially.

The initial patient device will be packaged in an off-the-shelf plastic enclosure 6 in long, 3 in wide, and 2 in high. This unit will be used to obtain preliminary patient feedback on possible improvements in system packaging, cabling, attachment, etc. Later a custom enclosure will be made which will be smaller and will make patient attachment easier; e.g., holster or belt attachment.

## Operation of the System

The operation of the system was described in detail in the previous report. Emphasis in this period has been placed on two spe-

cific aspects of the control logic; that associated with the patient's input to the system, and that associated with feedback of the control state to the patient. Control logic enables the patient to transform movement of either his head or shoulder into the proper stimulus for activation of the muscle, and also to activate functions which simplify the patient's control task. These functions enable the subject to turn the system on and off, to specify his zero reference position, and to hold a desired control output independent of his shoulder position.

The circuitry has been generated to provide two alternative control schemes. The difference in these schemes relates to the means by which the patient regains volitional control over the stimulator from the HOLD mode, and the audio feedback cues used to signal the state of the control logic. In both control modes, a low-level myoelectric signal (MES) triggers activation of the HOLD function and movement of the proportional control is ineffectual.

Two alternative control schemes are provided for regaining control. In the first scheme, the patient signals the desire to regain control with a low-level MES, but must "search" with the proportional controller to "find" the position at which he originally "held". The second control scheme enables the patient to regain control at any position of his shoulder (or head) by producing a low-level MES, which in effect provides a floating reference position. In either case, the subject can choose to rereference the zero position by producing a high-level MES twice in succession. The first signal turns the system off; the second turns the system back on, resetting the reference position of the proportional controller to the position which was sensed when the second high-level MES was generated.

Experience with the present system has demonstrated the need to provide the subject with information regarding the state of the control logic. Audio tones have been chosen to signal changes in the operating mode; e.g., rezero, enter hold, regain control. Control logic to perform these control and audio feedback functions has been completed in this period.

In the next period, we will begin to establish the advantages and limitations of each control scheme. The present intention is to investigate both schemes in every patient, since both alternatives are available by a simple programing change in both the laboratory and patient stimulators.

### Laboratory Development

Initial work has begun in the process of linking the instruments in the ward laboratory with the hospital's central research com-

puter. The computer, a PDP-11/45 with 15 Mbytes of disk storage, is a multi-user system and simultaneously performs tasks for several investigators. The primary objectives for connecting to the computer are to assist in: (i) organizing and performing routine patient tests (e.g., evaluation of a subject's muscle/electrode characteristics), (ii) organization and storage of test results, (iii) implementing new stimulation and/or control schemes with a minimum of additional hardware, and (iv) display and analysis of stored data.

### Patient Evaluation

Two C-5 quadriplegic patients continue to be involved in these studies, using the prototype system described in the previous report. These patients have been active participants in the design of the new stimulator systems, both as users expressing the features of construction and operation that they feel are important, and as subjects for experimental verification of proper operation of the device. These patients will be the first recipients of the new systems which will be completed in the next period.

## Research and Development Project on Advanced Orthotic Devices for Adult Paraplegics

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1094 Stony Point Road
Grand Island, New York 14072
Martin T. Prast

School of Engineering
University of Colorado
Boulder, Colorado 80302
Lawrence E. Carlson, Ph. D.

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

## Evaluation of Electrical Techniques for Stimulation of Hard Tissue Growth

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Robert O. Becker, M.D., J. A. Spadaro, Ph. D., and
A. A. Marino, Ph. D.

Over the past 12 months work has continued on the following projects:

### Electrically Injected Silver Ions as a Local Bactericidal Agent

1. The use of electrically injected silver ions as a local bactericidal agent has been under continuing investigation, both at the basic and the clinical level. At the basic level, we have re-evaluated the electrical parameters necessary for the bactericidal effect, using a more sophisticated electrode measuring system. We have found that the voltage on the silver electrode must be a minimum of 250 mV positive for the effect to occur. We have also found that the effect, in vitro, can be produced with the application of as short a time as 2 minutes. Presumably, the amount of silver ions ejected in this time is sufficient to inhibit completely the bacteria in the target zone. While this may not be possible in vivo, the information may prove useful in our future studies on the mechanisms of the silver bactericidal effect.

We continue to attempt to develop techniques enabling us to expand the diameter of the zone of inhibition, but have not been successful thus far.

The clinical evaluation of the electrically injected silver ion as a bactericidal agent has passed from the experimental to the application phase. We are now using this treatment against all of our osteomyelitis cases that require treatment. In the past 6 months, we have treated four additional patients (two with co-existing non-unions) and all have been successful. Two more patients are presently under study, and we are receiving referrals from other VA Hospitals specifically for the infected non-unions of long bones.

A complete report on our clinical usage of this technique has been accepted for publication in the Journal of Bone and Joint Surgery.

We are attempting to expand the clinical situations in which the technique is used, to include such cases as bladder infection in paraplegics, burns, and the recalcitrant skin ulcerations such as severe decubiti, etc.

**Silver Compounds as Additives to Bone Cement**

2. In a related study, we are determining the local bactericidal efficiency of various silver compounds as additives to methylmethacrylate bone cement. Total joint replacement necessitates the use of such a cementing agent which, in its setting phase, is exothermic to the extent of producing a narrow zone of bone necrosis surrounding the cement. This, coupled with the large mass of foreign material (cement plus prosthetic device), makes any local post-operative infection a clinical disaster. Various techniques have been employed to reduce the incidence of such infections ("clean room" operating techniques, intravenous antibiotics, addition of antibiotics to the cement, etc.). All have been less than totally effective since various studies list the present incidence of post-operative infections in total joint replacement to between 1 and 5 percent.

We theorized that the addition of silver compounds to the cement may be locally bactericidal by a diffusion process alone. Such a technique would be superior to the addition of antibiotics to the cement, since the exothermic reaction temperature that occurs with setting inactivates these complex organic molecules, but would have no effect upon inorganic silver salts. We have evaluated both the ability of silver ions to diffuse out of the cement (in sufficient numbers to be locally bactericidal) and the mechanical properties of the silver compound and methylmethacrylate mix. Silver salts that have been evaluated (in concentrations ranging from 0.05 to 1 percent) are: chloride, oxide, sulfate, and phosphate. We found that silver sulfate exhibited the maximum bactericidal effect for the longest period of time following implantation, and that this compound had no effect upon the mechanical properties of the methylmethacrylate. Antibacterial effects of $Ag_2SO_4$ methacrylate produced a visible, measurable, zone of inhibition in culture plates against both gram positive and gram negative organisms (Fig. 10). Some antibacterial activity was still obtainable after 49 days of soaking the silver methacrylate in warm normal saline, indicating a prolonged activity period.

At this point the concept of adding silver salts to methylmethacrylate bone cement as a local antibacterial agent appears to be both effective and without effect upon the mechanical properties of the cement. Biocompatibility studies will be started in the near future: should these indicate that there are no severe local toxic effects resulting from the added silver (as compared to the methylmethacrylate alone) we hope to arrange actual testing using total joint replacements in dogs (in cooperation with Cornell Veterinary College).

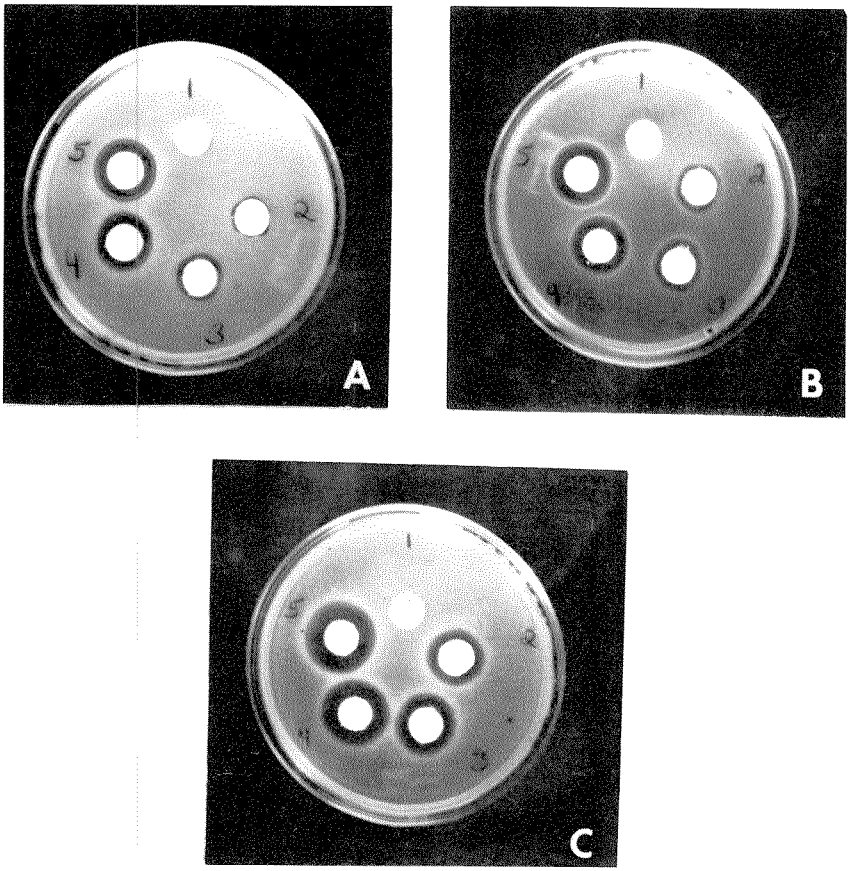


FIGURE 10.—Bacterial culture plates showing inhibition of: (A) Staphylococcus aureus; (B) E. Coli, and (C) Pseudomonas aeruginosa, by silver antibacterial bone cement (SABC). In these tablets, $Ag_2SO_4$ was added to Simplex-P Radiopaque Bone Cement in concentrations of 0, 0.05, 0.1, 0.5, and 1 percent, reading clockwise from the top tablet in each dish.

The entire concept of silver ions as effective broad-spectrum local antibacterial agents leads to a number of possible clinical applications of interest beyond those presently under study. These would include the use of silver coatings on prosthetic attachment devices designed to provide bony anchors for attachment by penetrating the skin barrier. The silver would appear to obviate the problem of local bacterial infections at this site, and its ability to be attached to a variety of fabric materials may provide for dermal ingrowth directly into the attachment.

### Electrical Stimulation of Bone Growth

3. The electrical stimulation of bone growth in the human by low-intensity direct current continues to be evaluated. A full report was published (Clinical Experience with Low Intensity Direct Current Stimulation of Bone Growth. Clin. Orthop. & Rel. Res. 124: 75-83, 1977. Becker, R. O., J. A. Spadaro, and A. A. Marino) last year and a number of additional cases have been carried to completion since then.

An international meeting with the theme of "The Mechanisms Involved in the Stimulation and Control of Regenerative Growth and Their Clinical Application" is being planned for the Fall of 1979. This will bring together a number of lines of inquiry in basic research, such as stimulation by electrical factors, chemical growth stimulation, and inductive substrate stimulation, and will relate them to ongoing clinical research such as the electrical stimulation of bone growth. It is expected that such a meeting will hasten the clinical application of additional techniques and increase the scope of such applications to include tissues other than bone.

### Acceleration of Bone and Soft Tissue Healing by Electrical Stimulation

VA Hospital
Castle Point, N.Y. 12511

Helen Hayes Hospital
Biomechanics Research Unit
Route 9-W, West Haverstraw, N.Y. 10993

George Van B. Cochran, M. D.

This project is designed to study the effects of electrical stimulation on the healing of experimental non-union in canine bone. The object is to increase understanding of clinical applications of this new technique in treatment of non-union, especially in those major injuries involving large defects in bone.

During the report period, work on further adaptation of the investigator's model has continued. The prior technique, originated for large mongrel dogs, now has been modified and tested successfully for use in laboratory bred beagles. This advance will improve reproducibility and uniformity of the model so that various effects of stimulation parameters, including electrode design and placement, can be compared more effectively.

In Vivo Loading of Knee Joint Replacement
Biomechanics Laboratory
Bingham Engineering Building
Case Western Reserve University
2040 Adelbert Road
Cleveland, Ohio 44106
Richard H. Brown, Ph. D., Kingsbury Heiple, M.D., and
Victor M. Goldberg, M.D.

Since our last report there has been a change in the methods of procedure. Formerly, we stated specifically that we would determine the loads borne by a total knee joint replacement in the human knee by instrumenting a dual condylar prosthesis system of our own design. However, the prostheses already designed and fabricated were destroyed in the process of micropolishing by an outside concern. 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 re-evaluate the project. The results of this re-evaluation indicated that the most common and useful prosthetic device currently being utilized was that of the total condylar femoral design. Because of this, it was decided that the investigation should proceed along the lines of determining the load data from the most currently utilized implant devices. Based on this decision, it was further decided that the study could best be fulfilled by utilizing a standard femoral prosthetic device of commercial manufacture, and shifting the design effort to the construction of a tibial component that would incorporate a normal 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 current efforts are now directed towards this approach.

Although this represents a significant engineering change in the project, we feel it also represents a significant improvement in the ultimate ability of the project to give current meaningful clinical data, which is the stated purpose of the study.

Orthopedic Implant Device Retrieval and Analysis
VA Hospital
New Orleans, Louisiana 70146
Allan M. Weinstein, Ph. D.

We are continuing to retrieve and analyze orthopedic implants removed from patients at the Veterans Administration Hospital, New Orleans, La., and the Veterans Administration Hospital, Columbia, South Carolina. Parts of the implants retrieved from this program, the screw plate type devices, were incorporated into a study to determine the clinical significance, if any, of crevice and/or fretting corrosion. All devices were either routinely removed or considered "clinical failures." No mechanical failures of any of the devices were observed. Correlations of the time in situ, reason for removal, and degree of corrosion was performed. Correlations of chemistry microstructure, micro- and Rockwell hardness, and tensile properties, were also performed.

*Screws and their respective holes* were graded for severity of corrosion, from none to very severe, using a numbering system. The devices were next subjected to basic metallographic examination in which inclusion content and grain size were determined. Chemical compositions were also determined on some of the devices. Macro- and microhardness measurements were made on all components. Tensile properties were determined on some of the Jewett-type nails, using a microtensile bar sample machined from the proximal plate area. Scanning electron microscopy was performed on several areas of corrosion to distinguish the differences between crevice and fretting corrosion.

The following conclusions were drawn from this study:

1. Crevice corrosion was observed in all of the 316L stainless steel devices studied. It was apparently not clinically significant for those in situ up to 16-18 months; that is, it did not contribute to the clinical failure. However, it may be a contributing factor to failure of devices left in situ for longer periods of time;
2. No correlation between degree of corrosion, time in situ and reason for removal was observed in these cases;
3. The potential effect of copper on the mechanical properties of 316L stainless steel is such that it should be brought under ASTM specifications for chemical composition for special quality material;
4. A good correlation, in general, was shown between tensile properties, microstructure, and both Rockwell and microhardness;
5. Crevice and fretting corrosion are two separate and distin-

guishable mechanisms, but may act simultaneously and may become indistinguishable from each other at low magnifications (<50X).

*Intramedullary rods*—In addition to the screw-plate type devices, a study was made of 25 cases of open reduction and internal fixation of several fractures using the AO intramedullary rod. Seven rods have been retrieved during the normal clinical care of patients. Five of these rods have exhibited cracks emanating from the proximal end of the longitudinal slot. It was noted that the crack had progressed a varying amount circumferentially for each case, and that one case had resulted in the proximal portion becoming detached from the remainder of the rod during removal. This necessitated leaving the remaining distal portion implanted in the patient. A complete failure analysis including detailed review of all radiographs, medical records, surgical procedures, and metallurgical analyses of the implants was performed on each case. All implants were fabricated from stainless steel and no gross chemical or microstructural deviations from accepted standards were identified. It was interesting to note that the rods were fabricated from welded tubing. Non-destructive dye penetrant inspection revealed no secondary surface cracking. At the present time the results of this investigation are still under analysis, and no definitive conclusions have been reached.

**Studies of Normal and Abnormal Motion**
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**VA Center**
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**Mary Patricia Murray, Ph. D.**

This research began July 1, 1964, under the sponsorship of Veterans Administration Medical Research and Development. In FY 1978 the program's funding was transferred to the newly established VA Rehabilitative Engineering Research and Development Service, Washington, D.C.

The major emphasis this past year has been 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 multifaceted tests of functional performance are done preoperatively and at specified periods up to 4 years postoperatively whenever possible. The multifaceted patient testing includes measurements of: the strength of the

muscles spanning the operative joint; joint mobility; weight-supporting activity during upright posture; the amount of force applied to canes or crutches; and multiple simultaneous displacement patterns and temporal components of gait. All of these measurements are compared with standards of normal variability which we have previously established.

We believe the tests which we have devised provide extremely sensitive indicators of the level of improvement or decline in overall function, and such quantitative information is essential for a critical analysis of a given procedure or in comparisons of the results obtained with different procedures.

### Total Hip Joint Replacement Study

This year, we published a study comparing multiple aspects of functional performance of 143 patients with McKee-Farrar, Charnley, and Müller total hip replacement, before and 6 months after surgery (1). A comparison of the three groups revealed some early postoperative differences.

The patients with Charnley implants had the smallest average total postoperative ranges of hip motion in all three planes, while the patients with McKee-Farrar had the largest average excursions in the sagittal and transverse planes, and those with Müller had the largest excursions in the frontal plane.

The group with McKee-Farrar replacement had the most, and the group with Charnley the least, improvement in hip adductor muscle torque, but the three groups were similar in their improvement in hip abductor muscle torque.

The group with Charnley replacement had the most patients who improved in weight-supporting ability on their operated limbs, but the average amount of improvement in weight-bearing ability was similar for the three groups.

There were no consistent differences among the various components of walking, or in the amount of force applied to canes or crutches, to indicate that one group's overall walking performance was better than the others. On the basis of average values, each group improved in every component of function, and it is gratifying that, except for a few patients who developed postoperative infection, each patient could be considered to have had successful reconstruction 6 months after surgery.

While the functional performance during the early postoperative period after total hip replacement is important, particularly for the elderly and those with limited life expectancy, evaluations of the long-term effects are of equal importance. Accordingly, we have made substantial progress in a study of functional performance

of 104 patients with Charnley and Müller total hip replacement, before and 6 and 24 months after surgery. We have collected all of the records and are in the process of analyzing the data. Preliminary results indicate a significant amount of improvement in all aspects of functional performance 6 months after surgery and also further improvement between the 6th and 24th postoperative months.

### Roentgenographic Measurements after Müller Total Hip Replacements

A study correlating roentgenographic measurements of prosthetic component positioning with hip muscle torque and mobility, in 52 patients with Müller total hip replacement, was completed and published in March 1977 (2). Compared with the normal side, the average position of the center of the prosthetic head was more medial and superior in the pelvis, and the greater trochanter was more distal and lateral. Increasing the neck length (distance from the prosthetic head center to the lesser trochanter) and a more distal position of the greater trochanter, were among the measurements which related favorably to patient function. More superior placement of the center of the prosthetic head in the pelvis was associated with a more superior position of the lesser trochanter, which related adversely to function. Although the final position of the prosthetic components depends partly on the anatomy of each patient, it also depends on the prosthetic components used and the manner in which the procedure is performed, both of which are dependent on the judgment, skill, and philosophy of the surgeon. The results presented in this paper should provide useful guidelines to orthopedic surgeons.

During fiscal year 1977, we will have completed more than 215 extensive multifaceted tests of functional performance of patients before and during the early and late postoperative periods following various kinds of total hip and total knee replacements.

### Kinesiological Measurements of Functional Performance Before and After Geometric Total Knee Replacement (3)

In this followup of 20 cases, tests of functional performance were conducted before surgery and 3, 6, and 12 months afterwards. Measurements included joint motion, extensor lag, isometric strength of the knee flexor and extensor muscles, cane or crutch force during walking, selected measurements of free-speed and fast walking, and weight distribution between the feet during 1 min of comfortable standing. These measurements, except for range of motion, were compared with standards of variability for normal men in appropriate age groups.

The group of patients with rheumatoid arthritis improved more than those with osteoarthritis, but they did not generally reach the functional level of the group with osteoarthritis, and neither group reached the lower limits of normal variability 1 yr postoperatively.

The findings also suggest the importance of emphasizing maintenance of full knee extension in the postoperative regimen as well as continuing knee muscle strengthening exercises for a prolonged postoperative period.

On the average, both groups gained knee extension, lost knee flexion, and gained isometric knee flexor muscle strength postoperatively. Every patient with osteoarthritis lost extensor muscle strength one year after surgery, while most with rheumatoid arthritis gained. During quiet standing, most patients had straighter knees postoperatively and bore a greater percentage of body weight on the operated limb. Patients with rheumatoid arthritis improved more than patients with osteoarthritis in the type and amount of force applied to canes and crutches. Most patients walked faster postoperatively, took longer and more rapid steps, improved the pattern of knee motion used, and had smoother forward, lateral, and vertical head motion.

### Maximum Isometric Knee Flexor and Extensor Muscle Contractions

We have completed a study documenting the ranges of normal variability in isometric torque of the knee flexor and extensor muscles during maximum isometric contraction. This study was published in June 1977 (4).

While many studies concerning the strength of the knee flexor and extensor muscles have been previously reported, most of those have dealt with the strength of young adults. The 48 subjects in our study were healthy men in age groups from 20-35 and 45-65 yr of age.

Isometric torque of the knee flexor and extensor muscles was recorded for 5 sec at knee joint positioning of 30, 45 and 60 deg. For each contraction, we measured the amplitude and duration of peak torque, and the time from the onset of the contraction to the time of peak torque. The paper describes the differences in individual patterns of torque output with respect to time, since little information has been reported quantifying the nature of the dynamics of the forces generated during isometric contraction of individual subjects. Careful scrutiny of all of the patterns of torque output over time indicated that no single pattern could be considered representative, and this was usually true even within all of the tests of a given subject. Peak torque was usually maintained for less than 0.1 sec and never longer than 0.9 sec. At each knee

joint position, the mean extensor muscle torque was higher than the mean flexor muscle torque for both age groups. And, at each knee joint position, the strength of the men in the older age group averaged 75–80 percent of that of the men in the younger age group.

This information will contribute to an increased understanding of the dynamics of the motor response during attempted maximum isometric contraction. In addition, this study provides standards of normal variability to serve as baselines for assessing the strength of patients with knee joint disabilities.

### Gait Patterns of the Parkinsonian Patient

We have finished collecting data for a study characterizing the gait of patients with parkinsonism during free-speed and fast walking, and are in the final stages of data analysis.

In order to identify the specific gait components which relate systematically to the severity of the disability, the 44 patients were categorized into groups with mild, moderate, and severe disability on the basis of their independence in self-care activities.

The measurements of walking performance of the groups will be compared to those of an appropriate control group of normal men.

This study will provide guidelines for critical evaluation of the efficacy of various treatment procedures directed at improving functional performance of patients with parkinsonism.

### Publications

1. Murray, M. P., D. R. Gore, B. J. Brewer, R. C. Zuege, and G. M. Gardner: Comparison of Functional Performance After McKee-Farrar, Charnley and Müller Total Hip Replacement: A Six-Month Follow-Up of One Hundred Sixty-Five Cases. Clin. Orthop. and Rel. Res., 121:33–43, 1976.
2. Gore, D. R., M. P. Murray, G. M. Gardner, and S. B. Sepic: Roentgenographic Measurements After Müller Total Hip Replacements: Correlations Among Roentgenographic Measurements and Hip Strength and Mobility. J. Bone and Joint Surg., 59-A/7: 948–953, Oct. 1977.
3. Collopy, M. C., M. P. Murray, G. M. Gardner, R. A. DiUlio, and D. R. Gore: Kinesiologic Measurements of Functional Performance Before and After Geometric Total Knee Replacement: One-Year Follow-Up of Twenty Cases. Clin. Orthop. and Rel. Res., 126:196-202, July-August 1977.
4. Murray, M. P., J. M. Baldwin, G. M. Gardner, S. B. Sepic, and W. J. Downs: Maximum Isometric Knee Flexor and Extensor Muscle Contractions: Normal Patterns of Torque Versus Time. Phys. Ther. 57:637–643, June 1977.

## Electrophysiological Techniques in Evaluation and Correction of Neuromuscular Defects

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Within this project there are several investigations in various stages of progress. These are devoted to investigating gait patterns during ascending and descending stairs, gait patterns during level walking at various walking speeds, biomechanics of normal human locomotion, and the function of the patello-femoral mechanism after arthroplasty.

### Ascending and Descending Stairs: A Pilot Study

A pilot study concerning the ascending and descending of stairs has just been completed. Electromyographic patterns of selected lower-limb muscles were investigated in male athletes and non-athletes during ascending and descending of stairs and level walking. Significant variability is found between the individual patterns for ascending and descending, although primary patterns can be identified. Some of the primary patterns found are different from those previously reported in the literature. The atypicalities did not appear related to athletic training nor to the incidence of knee injury/surgery among the athletes. All gaits appeared kinematically similar.

### Biomechanics of Normal Human Locomotion

Twenty normal subjects have been studied while they were walking on a level surface at fast, normal, slow, and very slow speeds. Preliminary results indicate that a small percentage of the population has muscle synergy patterns appreciably different from the accepted "norm." Changes in speed of progression from slow to fast do not in general cause a major alternation in muscle synergies. However, gait patterns at slow speeds mimic some pathologic gaits.

A detailed method for assessing the actual muscle forces and joint torques during ambulation is now being developed. It will estimate these quantities from measured kinematic and electromyographic data.

### Patello-Femoral Mechanism

The investigation of the patello-femoral mechanism after arthroplasty has just been initiated. Its main goals are:

1. To determine the most effective surgical approach to the

patello-femoral compartment with total knee replacement arthroplasty. Effectiveness is defined as the degree of pain relief during transfer and stair climbing activities.

2. To define clinical, radiographic, dynamic resistance, and quantitative EMG criteria for determining pre-operatively the preferred surgical approach to the patello-femoral compartment in individual patients.

## Maxillofacial Restorative Materials and Techniques

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

During the period of this report (June 30, 1977, to Dec. 31, 1977) research has been pursued on a broad front. It has included fundamental molecular polymerization mechanisms for optimum biomechanical replication of living tissue, controlled fabrication technology, and toxic and carcinogenic assessment of the materials. The former are indispensable to providing sound scientific data that will assure the reproduceability of high quality prostheses compatible with anatomical tissues. The latter is a high priority effort in response to the more stringent statutory requirements for medical devices imposed by the recently enacted Medical Devices Act (1976).

Within this broad front, the project has been developing and defining the technical/spectral aspects of intrinsic pigmentation for cosmetic matching that would suit the prosthetist specialist, and ascertaining the merits and shortcomings of the prostheses when they are worn for reasonable lengths of time. For the latter effort, the project has also served as a production facility capable of producing orofacial prostheses for 10 new patients per week (500 yearly). With modest expansion, the present fabricating equipment could accommodate all of the requirements for the entire Veterans Administration, with quality control and performance standards and records that are believed to be acceptable to the Food and Drug Administration, with the data now being accumulated.

### Safety and Performance of Maxillofacial Prostheses—Conformity with Medical Devices Act (1976)

Polydimethylsiloxane prosthetic materials developed in this project have been shown to be non-toxic to excised human orofacial tissues taken from patients (ages 21 to 59) using a novel test

system involving direct-patient assessment by tissue culture technique. The test system, aimed at accumulating data for conformity with the regulatory requirements of the Toxic Substances Act of 1976 (1) for medical devices and cosmetic applications, discriminates between non-toxic polydimethylsiloxane elastomers and incidental sampling of highly toxic polyvinyl chloride formulation (2) and polyurethane composition used for maxillofacial prosthetics. In particular, the new test system, devised in this project, circumvents the use of, and dependence upon, conventional animal testing. Conventional animal testing involves various animal species of controversal acceptance as being correlatable and valid to human physiology and toxicology; such animal tests take up to several years to attain biometric validity, and involve costs prohibitive for use in marketing medical devices and especially those for maxillofacial reconstructions.

Before the new law was enacted, the Food and Drug Administration initiated anticipated standards development activities for 15 groups of medical devices, including orthopedic and surgical implants, dental materials and devices, and others (1). This portion of the project has been designed (3) to provide proof and data for

TABLE 1.—*Accumulation of Selected Human Excised Tissue for On-going Toxicity Testing in Progress*[a] *with PDMS (Polydimethylsiloxane Elastomer) Prostheses*

| Patient Code | Age | Sex | Race | Tissue | Comment |
|---|---|---|---|---|---|
| A. Control Group (no carcinoma) | | | | | |
| DG | 46 | M | W | Gingiva | Routine dental |
| CN | 62 | M | W | Gingiva | Routine dental |
| HJ | 62 | M | W | Gingiva | Routine dental |
| RX[b] | 21 | M | W | Gingiva | Routine dental |
| PX | 19 | F | W | Gingiva | Routine dental |
| BJ | 48 | M | W | Gingiva | Routine dental |
| OE | 20 | F | W | Gingiva | Routine dental |
| HD | 51 | M | W | Gingiva | Routine dental |
| TJ | 20 | M | W | Rhino-mucosa | Surgery |
| B. Carcinoma cases (or surgery) | | | | | |
| JC[c] | 54 | M | W | Rhino-mucosa | Surgery |
| FW | – | M | W | Rhino-mucosa | Surgery |

Goal: Biometric Data Base shown in Figure 12, with at least 32 patients in each matrix block.

[a]The table shown here is only a select listing to illustrate the accumulating cohort.

[b]Used as reference standard because of youth and no adverse physiological profile.

[c]First case of direct patient testing: see Figure 13.

safety, involving toxicity and carcinogenicity testing on the excised orofacial tissues, and for performance, in conformance with the regulations. This entails well-defined materials and product specifications, and controlled fabrication processes with detailed record keeping. The statutory requirement also applies to proof of safety and performance even after repeated hygienic maintenance which can result (for certain materials) in chemical attack to the prosthesis with attendant toxicogenic reactivity to human tissues. Illustrative of the unique chemical resistance of the dimethylsilicone configuration (4) used exclusively in this project, limited comparisons have been made with the competitive maxillofacial materials, namely, polyvinyl chloride plasticized with low molecular weight additives (5) and polyurethane polymerized to low modulus products (6).

*Testing Details and Results*

Table 1 summarizes the accumulation of selected human excised tissue from over 40 candidate samplings to develop the pool (or cohort[a] as this is currently termed in studies on human exposure to toxic chemicals or environments) from which a biometric data base can be periodically evaluated for risk/benefit estimates, for tracing special susceptibility such as allergenicity, and for tracing any harmful effects that may have been due to sub-standard materials or improper fabrication.

The accumulating data base in depicted in Figure 11 (which lists three principal groups of human tissues that are relevant to use of biomaterials including skeletal extensions) and in Figure 12. Group I concerns safety and performance to mucosal tissues, which may not themselves reveal toxic or growth inhibitive effects, but through which migratable toxicants could reach target tissues in Group II, giving rise not only to organ toxicity but also chemical oncogenicity. Considering that a significant segment of the patients contributing to the accumulating pool or cohort have on-going carcinoma that could metastasize, it becomes important to include the Group II target cells. This becomes especially true for the bladder organ which has come into much prominence from industrial and environ-

[a]The term cohort, according to current usage by the National Institute of Occupational Health, relates to a methodology of assembling biometric information on a target group of individuals from which causative factors leading to pathological conditions are extracted for establishing risk/benefit value judgment. This same methodology is used in this project to obtain the analogous risk/benefit, using actual excised human tissues. Thus, if it can be shown that 32 patient tissues times 32 prostheses showed negative toxicity (using, of course, positive controls) then such data could constitute a basis for FDA approval of the specified PDMS formulation and the certified polymerization conditions.

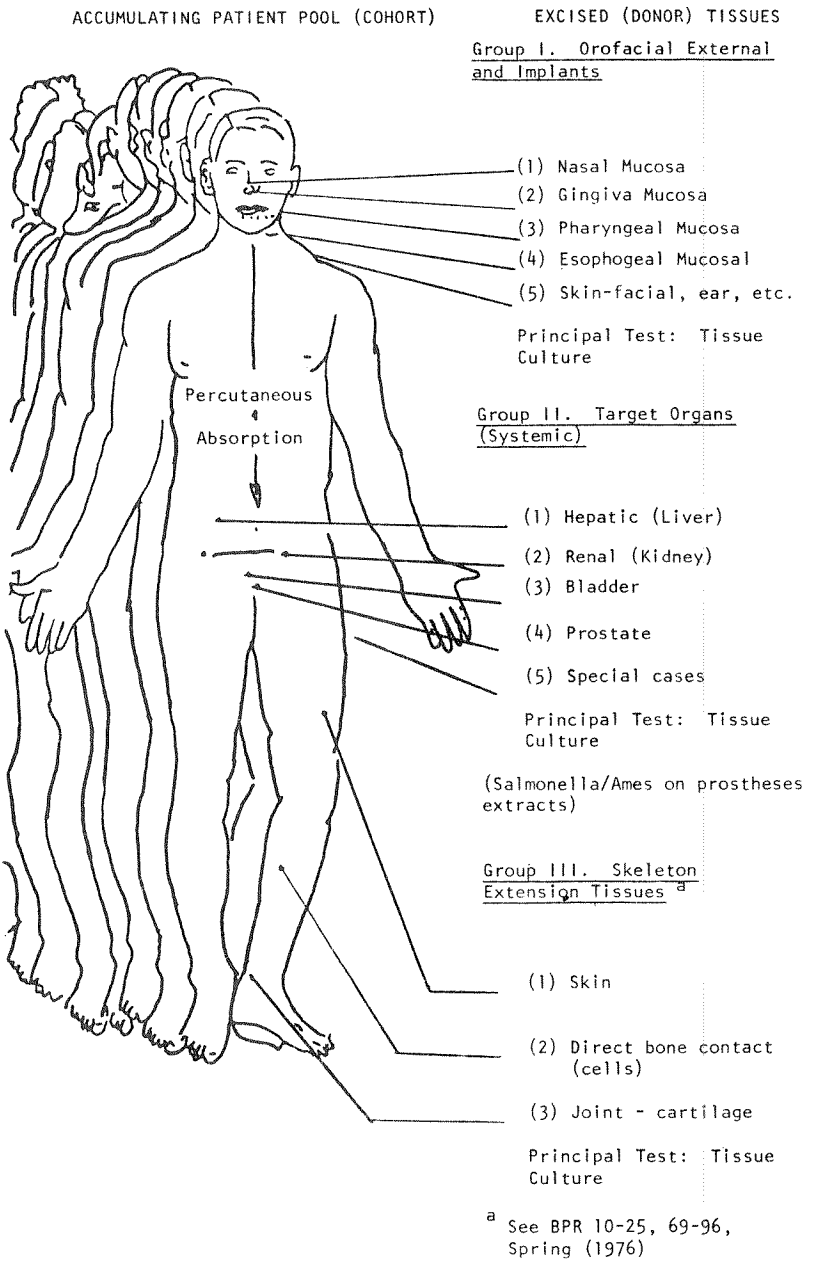


FIGURE 11.–Human excised (donor) tissue from orofacial patients subjected to related tissue culture toxicity test, involving mucosal and target organs for the biometric data base shown schematically in Figure 12. The method is applicable to skeletal extension prostheses.

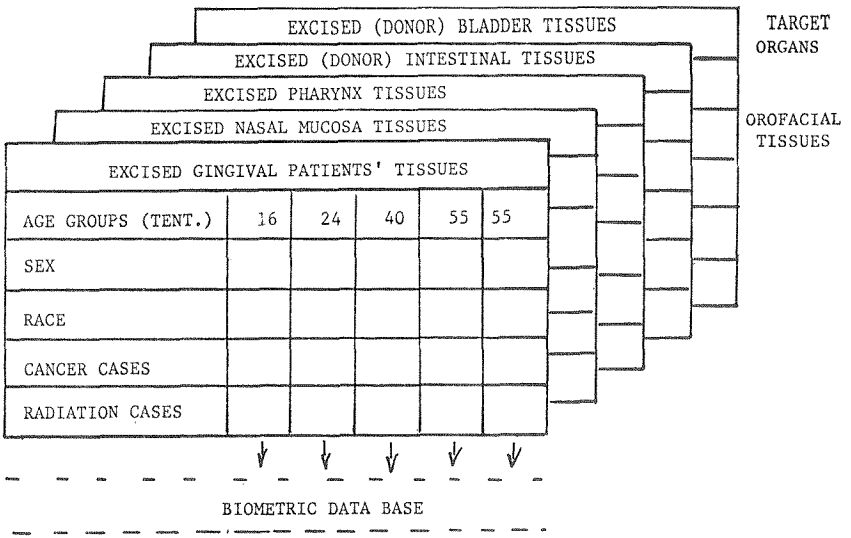


FIGURE 12.—Biometric Data Base: direct patient-donor tissue and target organ cell toxicity-testing for developing an accumulated cohort of non-toxicity for FDA review and approval (11).

TABLE 2.—*Summary of Selected Tissue Culture Tests on PDMS Fabricated Prostheses*

| Composition | No. | Prostheses for patient | Form | Patient (donor) | (age) | Tissue | Result (toxicity) |
|---|---|---|---|---|---|---|---|
| L-124-21-S-3 | P-621 | S.N. | Nose | R.L. | (59) | Gingiva | Neg. |
| L-124-21-S-1 | P-624 | M.A. | Orbit | R.L. | (59) | Gingiva | Neg. |
| L-124-21-S-4 | P-640 | R.E. | Orbit | R.L. | (59) | Gingiva | Neg. |
| L-124-21-S-4 | P-641 | K.R. | Ear | R.L. | (59) | Gingiva | Neg. |
| L-124-21-S-4 | P-643 | B.N. | Ear | R.L. | (59) | Gingiva | Neg. |
| L-124-21-S-3 | P-621 | S.N. | Nose | H.E. | (51) | Gingiva | Neg. |
| L-124-21-S-4 | P-640 | R.E. | Orbit | J.C. | (54) | N-Mucosa | Neg. |
| L-124-21-S-4 | P-641 | R.E. | Orbit | J.C. | (54) | N-Mucosa | Neg. |
| L-124-21-S-4 | P-653 | B.N. | Ear | J.C. | (54) | N-Mucosa | Neg. |
| Direct Prosthesis-to-Patient[a] (Figure 13) | | | | | | | |
| L-124-21-S-1 | P-689 | J.C. | Nose | J.C. | (54) | N-Mucosa | |

[a]A first in this project, i.e., testing the formed prostheses on the patient's excised, in this case orofacial tissue, cultured and stored for testing.

mental long term exposure.

Table 2 summarizes the test data obtained thus far with gingival and rhino-mucosal tissues taken from the pool, with tests carried out in what is becoming a routine clearance of a fabricated prosthesis designated for a specific patient. It is of particular significance that the system is being adapted to a direct-patient test of the fitted prosthesis, using segments taken as excess flash-out from the molding process. Thus, as indicated in Table 2, Patient JC has his own N-nasal (Nose) mucosal tissue tested against his prosthesis designated as P-689. This provides a system of prosthesis check-out specific to the patient, according to the scheme depicted in Figure 13. Thus, during the operation (in this case the removal of a nose carcinoma) a section of non-carcinoma area is subjected to tissue culture growth and tests in the presence of the prosthesis flash-out material. Following a period of convalescence to allow the remaining orofacial anatomy to be stabilized, the prosthesis can then be fitted with the assurance that it is not harmful to the nasal mucosa.

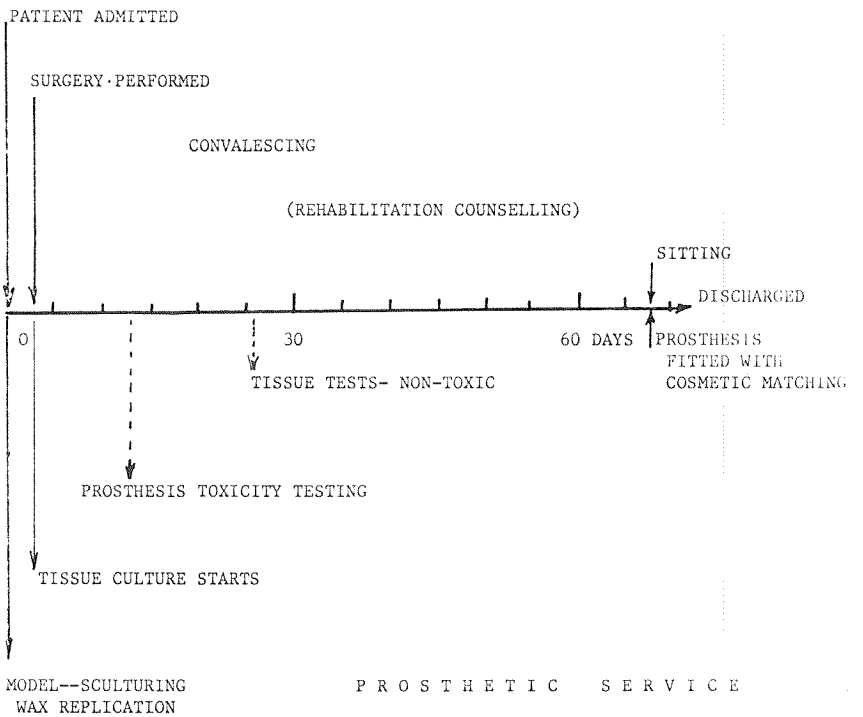


FIGURE 13.—Direct patient tissue-prosthesis testing, using excised orofacial tissue (gingiva, rhino-mucosa, etc.) taken during surgery. Protocol formally initiated with Patient JC (10/13/77) (Table 1).

TABLE 3.—*Summary of Tissue Culture Tests on Competitive Polymers for Orofacial Prostheses.*

| Chemical Designation | Code | Source | Form | Patient source | (Age) | Tissue form | |
|---|---|---|---|---|---|---|---|
| Polyvinyl chloride (PVC) plasticized | PVC-121 | Esschem Co.[a] | Molded Sheet | R.L. | (59) | Gingiva | Highly Toxic |
| | PVC-121 | Esschem Co.[a] | Molded Sheet | J.C. | (54) | N-Mucosa | Highly Toxic |
| Polyurethane (Dermathane) | L-124-91-A (untreated) | Gonzalez[b] | Nose | S.T. | (60) | Gingiva | Highly Toxic |
| | | | | S.T. | (60) | Gingiva | Highly Toxic |
| | L-124-91-B | Gonzalez[b] | Nose | J.C. | (54) | N-Mucosa | Highly Toxic |
| | (NaOCl)[c] | | | J.C. | (54) | N-Mucosa | Highly Toxic |

[a]Prototype III made according to Sweeney, A.B., et al. (Reference 2) Evaluation of Improved Maxillofacial Prosthetic Material. J. Prosthetic Dentistry, 27, 297-305, March, 1972.
[b]Obtained from Dr. Juan B. Gonzalez (Letter, Lontz, John F., April 10, 1977).
[c]Hygienic maintenance in sodium hypochlorite (USP).

Table 3 summarizes an on-going surveillance of competitive maxillofacial materials, namely polyvinyl chloride with plasticizer (5, 7) and polyurethane which depends upon dibutyl tin dilaurate, a toxic substance (8), to effect the polymerization (6). This surveillance is deemed appropriate for providing technical guidance in adjusting these materials with their catalysts and other components that would eliminate the contributing toxic factor or factors.

*Clinical Rehabilitative Evaluation*

Concurrent with the toxicity testing, using excised human tissue in tissue-culture techniques, there is an active field evaluation program. Solicitations have been extended to a number of maxillofacial centers (Table 4). This portion of the project is intended to obtain the consensus among cosmetic prosthetic specialists or technicians in regard to the intrinsic coloring that is applied to the polydimethylsiloxane formulation described in Table 5. For the simplest possible formulation of the pigmentation, the nearest match to the red hemoglobin is achieved by means of an organic pigment and the match to the yellow carotene is achieved by means of pure yellow iron oxide. (To accommodate specialists accustomed to employing red and blue flock, these have also been prepared and sent out for field evaluation.)

TABLE 4.—*Summary of Extramural Participants in PMDS Prosthesis Evaluation Period: Jan. 1 to Dec. 31, 1977*

| Prosthetic Center (Hospital) | Number of patients | Number of compositions | Number of prostheses |
|---|---|---|---|
| Veterans Administration, New York | 9 | 5 | 26 |
| Memorial Hospital, New York | 6 | 4 | 18 |
| Temple University School of Dentistry, Philadelphia, Pa. | 3 | 3 | 12 |
| Duke University, Durham, N.C. | 1 | 4 | 4 |
| (Private practice) Kantor | 1 | 4 | 4 |
| Cracow Medical Academy | 4 | 3 | 14 |
| Pending – solicited to participate: | | | |
| M.D. Anderson Tumor Institute, Houston, Texas | 4 allotted | 4 | 16 |
| Mayo Clinic, Rochester, Minn. | 4 allotted | 4 | 16 |
| Zoller Clinic, Chicago, Ill. | 4 allotted | 4 | 16 |

TABLE 5.—*Base PDMS Prepolymer-Oligomer (80/20) Composition with Intrinsic Pigmentation*

| | | Weight Grams | Weight Parts (%) |
|---|---|---|---|
| (a) | Prepolymer (gum stock) | 16.0 | (80.0) |
| | General Electric SE-4524U or Dow Corning MDX 44514 | | |
| (b) | Oligomer | 4.0 | (20.0) |
| | Dow Corning Silicone Fluid 200 or General Electric Equivalent | | |
| (c) | Pigments (from 100X Concentrate) | 0.2 | 0.1 0.05[a] |
| | Pure Yellow Oxide (Pfizer) 0.375 | | |
| | Pure Titanium Dioxide (DuPont) 2.00 | | |
| | Red Flock (Claremont) 2.50 | | |
| | Blue Flock (Claremont) (Varied preferences) | | |
| (d) | Total | 20.2 | (100) |

[a]Progressive intensities

During the past year 699 prostheses have been made in the simple and inexpensive dental stone molds (9) which can be used more than 40 times within the prescribed thermal range (100 deg to 120 deg C) of the polymerization (curing) conditions for the polysiloxane elastomer fabrication.

The field evaluation program commenced in April 1977, and to date there have been no reported deficiencies. This experience is in line with the experience in our own Maxillofacial Prosthetic Center as far back as 3 years, using the polydimethylsiloxane prepared according to the formulation indicated in Table 5. The participants are expected to return unserviceable prostheses for chemical, physical, and microbial inspection and evaluation.

### Product Development

Fundamental to the priority efforts of toxicity testing for safety, and field evaluation for performance, has been the indispensible product development portion of the project with its dependent programs of fabrication technique and pigmentation of the fabricated prosthesis. The principal feature of the polydimethylsiloxane prosthesis formulation is the use of a prepolymer (usually referred to as the gum stock) to which is added an oligomer to lower the modulus to more nearly approximate that of living tissue in the sense of the stress-strain profile or the stress-elongation response (10). From the standpoint of polymer mechanisms and kinetics, this aspect of polymer science has not been accorded any basic investigation of what happens when process variables, with different free-radical catalysts, are imposed to convert the prepolymer into a well-characterized elastomer.

Table 6 illustrates a typical case in which these variables have a pronounced effect on the tensile characteristics of the formulation indicated in Table 5, with an interpretation of the mechanisms that are believed to be involved. Applying a novel correlation of the net elongation after polymerization, with the two free-radical catalysts benzoyl peroxide and 2,4-dichlorobenzoyl peroxide (designated BZPO and 2,4-DCBP, respectively) it becomes apparent that raw materials from a single manufacturer of silicone materials can acquire entirely different sets of tensile properties. It is on this kind of basic information that the eventual specifications for effectiveness of the prosthesis as a medical device will have to be based.

At present, the fabricating conditions are restricted to the temperature and time conditions indicated in Table 6. The program will require a reasonable exploration of the limits of these conditions. On the one hand this may supply the data to identify excessive application of the polymerization conditions, excessive use of catalysts, and so on, that can crop up unsuspectedly and thereby fail to provide the quality of performance and possibly compromise the safety that could be evident in the tissue toxicity tests. On the other hand, insufficient application of the polymerization condi-

TABLE 6.—*Comparison of BZPO and 2,4-DCBP using SE 4524 Prepolymer*

Formulation: Prepolymer – 16 grams (80 parts)
Oligomer – 4 grams (20 parts)
Polymerization 100° C for 2 hours (curing)

| Code notebook reference | Catalyst | Amount (grams) | Tensile constants | | | |
|---|---|---|---|---|---|---|
| | | | Modulus (lb/sq in) (M) | Strength (lb/sq in) (S) | Elongation (%) | S/M quotient |
| L-124-27-A | BZPO | 0.05 | 80.10 | 210.5 | 649.7 | 2.63 |
| L-124-17-A | 2,4-DCBP | 0.05 | 32.66 | 128.5 | 1270 | 3.93 |
| L-124-27-B | BZPO | 0.10 | 129.5 | 251.3 | 426.9 | 1.94 |
| L-124-17-B | 2,4-DCBP | 0.10 | 54.77 | 313.9 | 1141 | 5.73 |
| L-124-27-C | BZPO | 0.20 | 203.0 | 261.5 | 259.1 | 1.29 |
| L-124-17-C | 2,4-DCBP | 0.20 | 115.1 | 568.8 | 836.2 | 4.94 |

To convert to metric system: _____ lb/sq in × 0.07037 = _____ kg/cm²

Possible mechanistic interpretation:
Chain lengthening related to increase in elongation
Chain branching related to decrease in elongation and decrease in modulus
Chain cross-linking related to increase in modulus and increase in stress at failure

tions may give prostheses that would fail to meet the expected performance, and especially durability.

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## Permanently Attached Artifical Limbs

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### Introduction

Attempts to bring a skeletal extension out through the skin, in order to develop a permanently attached artificial limb, have gone through a variety of methods for bone attachment. The tibia of spanish goats has served as the animal model. We have previously reported our early attempts to use intramedullary rods, supracortical and supraperiosteal devices. All of these had a common denominator that caused them to fail: this common denominator was restricted bone circulation leading to distal diaphyseal necrosis.

### Intramedullary Approaches

The early intramedullary rods necessitated counterboring the intramedullary canal, thereby destroying the nutrient artery. Our attention had subsequently been drawn to Dr. Frederick W. Rhinelander's work, in which he describes the bone's circulation as being from the central nutrient arteries of long bones out to the periphery of the cortex. This accounts for perhaps 3/4 of the bone's total circulation with the remainder being supplied via the periosteum.

Having gained this much insight, attempts were then directed toward making a bony attachment without disturbing the intramedullary canal. However, these methods (supracortical and supraperiosteal) were evidently causing local artery damage and venous occlusion. Although the resulting necrosis did not approach that noted using intramedullary reamers, there was still necrosis of the

distal 1-1½cm of the tibial shaft.

After discussing this problem with Dr. Rhinelander, we fabricated a prosthesis utilizing a self-broaching intramedullary Schneider nail. Theoretically, the area between the flutes allows room for retaining the intramedullary vascular channels. In order to increase the area between the flutes, we redesigned the nail to one which is trifluted, rather than quadrafluted. The pedestal remains very much the same as the supraperiosteal cup, which has three lugs penetrating the skin in areas of a uniaxial force field.

It was found rather early that flutes having a diameter large enough to stabilize the intramedullary nail were too large to be seated with a single pass with a broach. Attempts to use the self-broaching teeth invariably shattered the somewhat brittle shaft of the goat tibia. Step broaches of increasing diameter were fabricated and used in the last two attempts with excellent results.

Although the pilot model (based on the original quadrafluted Schneider nail) was successfully placed in a goat, no attempt had been made to alter the highly polished stainless steel surface to provide for bony ingrowth (Fig. 14). The pedestal and lugs were

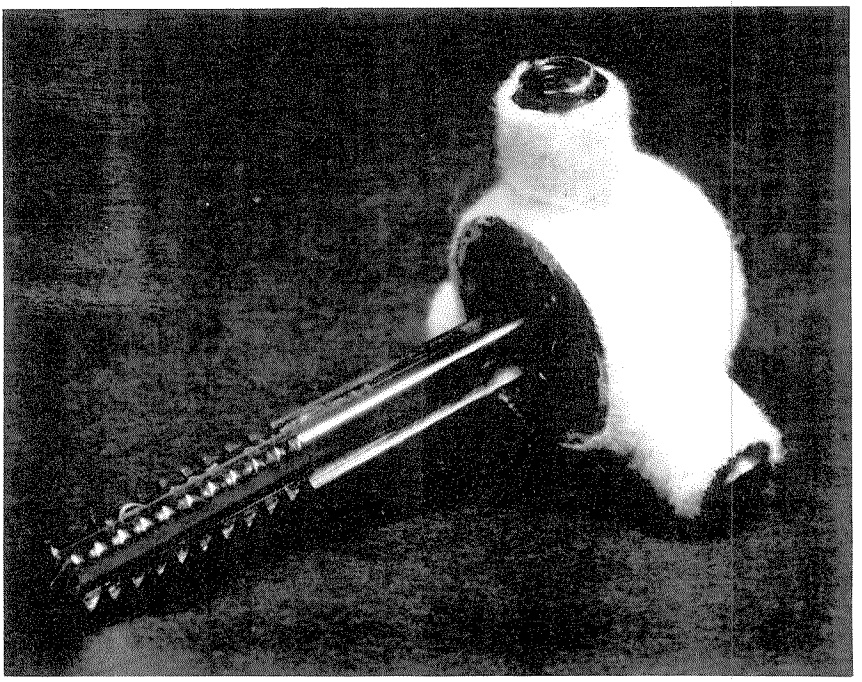

FIGURE 14.—One end of a Schneider nail has been affixed to a trilugged stainless steel pedestal. The pedestal and lugs have been coated with nylon velour for the skin-interfacing requirements. The surface of the nail remains unaltered in this prototype.

FIGURE 15.—Modified intramedullary nail having three, rather than four, flutes. Except for the broaching teeth, the entire device has been covered with Proplast®.

coated with nylon velour to provide for skin interfacing only. Ultimately, the intramedullary pin loosened and the animal had to be sacrificed. There was no evidence of bone necrosis either radiographically or grossly after 4 months' implantation.

Subsequent models (Fig. 15) have been sent to Dr. Charles Homsy of Houston, Texas, for coating with Proplast®. This material has gained wide acceptance as a tissue interfacing material and is being used clinically for maxillofacial reconstruction. Its skin interfacing properties are unknown at this time, but it appears to be on par with velour.

The above described approach seems a step closer to the ultimate for the following reasons:

1. It leaves the intramedullary and periosteal circulation pretty much intact;
2. The device is coated with a tissue interfacing material, which (it is hoped) will suffice for both bone and skin; and
3. Penetration of the skin utilizes the involuted approach, which should keep the skin from retracting away from the penetrating members.

Currently, we are applying a Thomas leg splint to the limb at the time of surgery. This is left in place for 6-8 weeks, after which the splint is replaced with the permanently attached exterior pylon.

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

**Development of a Wheelchair Using a Myoelectric Control System**
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**Alain B. Rossier, M.D., Mehdi Sarkarati, M.D., and G.E. Crawford, Jr.**

The object of this research is to develop a myoelectric control system that will operate, with barely perceptible twitches of surface muscles, in environments having levels of electrical interference that are typically encountered by one traveling in a wheelchair. The system is to be microprocessor controlled, and have electrical stimulation for feedback, both to avoid excessive muscular activity by the operator and to assist in the control function.

During the period from June 30 to December 31, 1977, development of the myoelectric portion of the equipment was completed, a preliminary breadboard of an electrical stimulation module was constructed, and writing of the microprocessor program started. The achievement of high myoelectric sensitivity simultaneously with a high degree of interference immunity was accomplished by use of a combination of the following techniques:

1. Totally shielding the amplifiers providing the first 70 db of gain in a small (5.8 X 2.6 X 0.9 cm) enclosure;
2. Placing this enclosure (with silver disc electrodes built into its surface) on the skin directly over the muscle to be monitored;
3. Using a shielded cable from this enclosure to the shielded postamplification and signal processing equipment;
4. Providing both a high common mode rejection ratio, and blocking the flow of common mode interference current, (by using an optical coupler in the signal path and a 29 MHz radio frequency

coupling system for the primary power source);

5. Using low-noise transistors (equivalent input noise voltage of 5 $nV/\sqrt{Hz}$) in a configuration that provides a low-system-noise figure;

6. Limiting the system bandwidth to include only frequencies of significant myoelectric energy; and

7. Extracting the information from the myoelectric signal in a manner that depends only upon the detection of minute bursts (rather than resolving differences in amplitude or extracting features of the wave form, both of which require myoelectric activity of greater amplitude and duration).

Preliminary tests of the myoelectric equipment have resulted in interference-free performance in typical laboratory and hospital environments.

The microprocessor program, partially written during the 6-month period covered by this report, will convert the coded outputs of the two myoelectric channels into motor control signals similar to those developed by a joystick assembly. It will also initiate the electrical stimulation mentioned above. In order to develop and evaluate the system without risk to the patients who volunteer to be experimental subjects, the motor control outputs will be further decoded to present the commands (forward, right, left, reverse, and stop) on a visual display, rather than actually activating the motors of a wheelchair.

The previously open consideration as whether to use random logic or a microprocessor was resolved in favor of the microprocessor. This facilitates the incorporation of such safety features as the insertion of a time delay if the operator generates a reverse command when the chair is traveling forward or a forward command when the chair is traveling in reverse, and the use of a decoding system that treats muscle spasms as stop commands. The decision to use a microprocessor also facilitates the flexibility to implement suggestions (for applications in addition to that of wheelchair operation) that resulted from the exposure of the myoelectric equipment to a group of people during its preliminary testing. These suggestions include using the system as an interface means for microprocessor-based TV games, and as a general purpose environmental control unit. Such suggestions could be implemented in future programs by changing the integrated circuit which holds the program for a specific application in memory and then connecting the peripheral equipment to be controlled.

## Clinical and Physiological Evaluation of Seat Cushions for the Paralyzed

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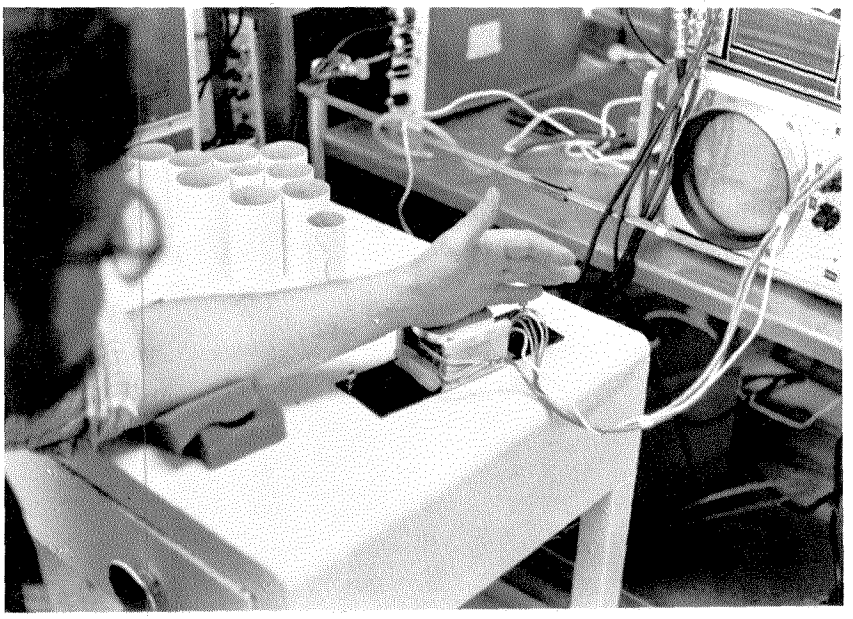
To design superior cushions for the paralyzed, it is first necessary to determine the significance of all loads in the seated condition. The importance of normal load (or pressure) in this connection is clear and a number of workers have detailed the seated pressure magnitude and resulting physiological consequences. Tangential load (or shear) has been relatively neglected. While most workers believe that shear effects are highly significant to the traumatic process, such beliefs appear intuitively based; no measures of seated shear magnitudes or effects are known to these investigators.

To assess shear load significance, a device has been constructed (Fig. 16) which simultaneously measures local blood flow and externally applied pressure and shear. With sufficient data, it should be possible to separate the independent effects of pressure and shear in reducing local blood flow.

Implicit in the experimental design is the belief that a dearth of local blood flow is a precursor to trauma—that factors tending to reduce local blood flow are "bad." While a dearth of local blood flow is certainly associated with trauma, such a dearth may constitute only a necessary condition and not a sufficient condition. For example, actual tissue failure owing to internal stresses may also be required to produce trauma. It is to be appreciated that in dealing with human volunteer subjects we are not in a position to create such failures. Thus we employ only the presence or absence of blood flow as an indicator of potential trauma.

The blood-flow monitoring device is a conventional optical plethysmograph, roughly 2 cm wide, capable of generating and monitoring red light reflected from the skin. Surrounding this device are three load pickups, of which two measure pressure and one, shear. All these devices are mounted flush with a heavy aluminum plate roughly the size of the palm of the hand.

Pressure and shear devices employ conventional SR-4 strain gages in a standard beam and column approach. The sensor design features small displacements (on the order of 0.001 in); large displacements, despite their attractive large signals, produce compli-



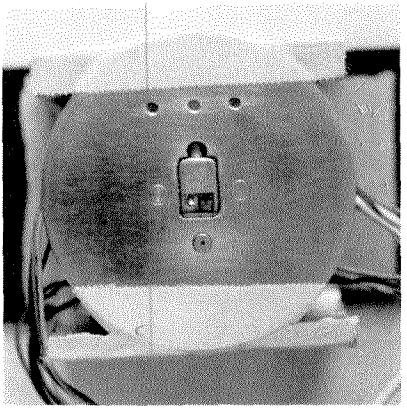


FIGURE 16.—Device for simultaneously measuring local blood flow and externally applied pressure and shear. A. Contact surface of the device shows optical plethysmograph at center; circular objects to right and left are load pickups for measuring pressure, and object below is load pickup for measuring shear. (Row of circular indentations are fastenings.) B. Measuring device in use.

ance difficulties in which the sensors act as displacement transducers rather than load cells.

The gathering of data has just started; we have no comment on the results, except to note that scatter is appreciable and that a statistical type of treatment will likely be necessary.

## Seating Systems for Body Support and Prevention of Tissue Trauma

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### Purpose

This project is an attempt to reduce the incidence of decubitus ulcers in the spinal cord injured population.

The problem is a significant one, evidenced by estimates that one-half of admissions to VA Spinal Cord Injury Services are due to decubitus ulcers, and the cost per ulcer is $5,000-$10,000.

In addition to prevention of tissue trauma, seating systems can offer body support for the trunk, head, legs, and feet, which is especially necessary for people with high spinal cord lesions.

### Concept

Custom-molded special seating systems are usually made either by shaping blocks of foam in a seat shell to fit the patient, or by taking a negative cast of the patient and then making a molded seat shell over a positive model. Both of these methods are lengthy in time and therefore expensive in cost.

In search of methods whereby more efficient provision of seating systems can be achieved, the concept of using pre-fabricated sections seemed a promising one and was selected to pursue in this project. With judicious selection of shapes and sizes, the seat, trunk, head and leg/foot sections can be put together clinically, on the spot, by using these off-the-shelf components.

If a significant percentage of patients could be fitted successfully in this manner, it would provide a valuable resource, allowing clinicians to fit patients faster, easier, and less expensively. Presumably, this would also allow more patients to have seating systems suited for their needs. There will always be certain patients who will need special attention and custom molding for proper fitting: the goal of this project is to reach the majority first.

### Plan

The most essential part of a seating system is the seat itself, which distributes body weight of the individual over weight-bearing areas. Therefore, the project has started with the seat section.

The plan is, first, to design, fabricate and clinically evaluate the seat section. Then, presuming success (with redesign if necessary),

to work on other sections, adding one-by-one until a complete seating system is available and tested for use.

### Comments

The project is progressing well thus far. Technical work in the design and fabrication of the seating system is being done at the Rehabilitation Engineering Center at Children's Hospital at Stanford, under the direction of Wallace Motloch, C.O. Trial use of the seating system and evaluation of results is being done at the VA Hospital, Palo Alto, under the supervision of Dr. Perkash and staff therapist Daryl Wright, O.T.R. The project will be continued in 1978.

## Stump Stress Analysis

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This project has been terminated. For the concluding report on this research, see BPR 10-26, Fall 1976, 257-285.

A follow-on effort has been initiated with Mr. A. Bennett Wilson, Jr.'s group at Moss Rehabilitation Hospital, Philadelphia. The new program will focus on the feasibility of forming an AK socket of thermoplastic materials. The greatest single problem, in prior development efforts using lamination concepts, has been in fatiguing of that material in proximity to the flexible brim. It is hoped that the use of fatigue-resistant materials, such as polypropylene, may resolve the difficult problem.

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[a] As of April 1978, Mr. Bennett has joined the staff of the VAPC.