HIGHLIGHTS OF OTHER VA RESEARCH PROGRAMS

PROSTHETICS

Edited by

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For progress during this report period, see "Summary of Activities of the Committees on Prosthetics Research and Development and Prosthetic-Orthotic Education for the Period July 1 to December 31, 1972," appearing elsewhere in this issue of the Bulletin.

Research and Development in the Field of Artificial Limbs
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From the repair and maintenance circulation pattern of the S-N-S systems, it became apparent in August 1972 that the 18 improvements which had been applied over the previous 15 months were having the desired beneficial effect. Because some of these improvements were introduced only recently, it is too early to conclude that the goal of an average 2-year maintenance-free life has been achieved. However, for some time now a longer guarantee period than the former 6 months has been gradually applied to the repair of systems, and it is planned to adopt a general 12-month guarantee as soon as possible.

Although all the clearly known shortcomings had been eliminated, there was one somewhat elusive malfunction left: namely, the accumulation of a small amount of air in the swing-control part of the hydraulic system was causing a "swishing" noise. This problem has been difficult to analyze because the malfunction occurs inconsistently. Some systems are in active use for 3 years without this occurrence, while others develop it after only a few months. It can be produced by prolonged operation of the system in an upside-down or downward-inclined position, such as in a kneeling-rock motion. In this activity, air can gradually work its way from above the reserve oil space, which in the normal position is above the accumulator piston, into the hydraulic system proper. On the other hand, from discussions of practical cases with prosthetists it seems that the air also accumulates in normal walking without any unusual activities. This suggests that the air may enter the system through the piston-rod seal.

For several months, means were studied to provide pathways inside the system for the accumulated air to bleed gradually into the air space above the accumulator piston. Such a "self-healing" function would circumvent the difficulty of analyzing how the air gets into the wrong spaces in the first place.

In September, the efforts were successful. The design change, which was applied to the present production run and all systems repaired in November, consists of a number of successive ports, the last one including a check valve, which connect the space at the top of the swing-control elements with a point outside the dash-pot at the upper seat of the large spring. During knee flexion, whenever the piston rod is pushed into the hydraulic system and lifts the accumulator piston off its seat against the force of the large spring, the increased oil pressure in the working spaces, which accompanies this event, will propel oil and any air that may be present through the aforementioned ports into the air space above the accumulator piston and reserve oil. This flow will be very slow as long as there is only oil involved, but will be much faster if *air* moves through the ports. The net effect of this arrangement is that any air that may accumulate inside the system will be removed by the walking motions during the first few steps after the air entered the system.

The slow oil circulation through the ports, which persists even if there is no air to be expelled, has the additional desirable effect that any abrasive particles that may be produced inside the swing-control portion of the system will not stay there, but instead will be carried with the oil and will eventually be deposited in the bottom of the cylinder where they can do no harm. This will prolong the life of the swing-control piston and the surrounding control bushing, and should reduce maintenance needs.

In addition to this very important improvement, three additional improvements have been included in the system during the reporting period.

The S-N-S movie underwent several revisions and is now completed. A discussion guide will be worked out in cooperation with the VA, New York, and will accompany prints of the movie films which are to be distributed to VA field stations.

The shakedown tests of the Hydraulic Ankle Control Unit, which had started on June 9th with the third test amputee in the New York area, continued uneventfully until the beginning of August. The amputee repeatedly expressed his satisfaction. His comments generally confirmed the findings of the previous two test amputees.

On August 7 the ankle unit, including the shank and foot of his prosthesis, arrived in Dayton because of oil leakage. This leakage was caused by the separation of the top of the rubber boot from the shoulder (at the base of the piston rod), to which it was attached by rubber cement. From the appearance of the separated parts, it seems that the kneading of the boot wall, from the pressure exerted by the weight of the amputee, gradually produced the deterioration of the cement bond. In the future design, a larger support area will be provided at that location to reduce the unit pressure on the boot wall and on the cement bond.

Test wearing in New York resumed in the middle of August; however, the leg was returned to Dayton shortly thereafter, because the front wall of the rubber boot of the hydraulic unit had been pierced by a sharp edge on the keyhole attachment plate inside the foot. To prevent this in the future more clearance was provided in the foot. The leg was returned to New York during the second half of September.

In the meantime the basic design of the modified ankle has been completed. It includes the following features:

a. Hydraulic system proper: The 5 deg. forward motion of the shank to initiate the dorsiflexion stop has been eliminated, and the dorsiflexion stop will now be produced solely by the application of the amputee's weight onto the ankle unit. However, no troublesome portholes on the top of the vane piston to be closed by the amputee's weight application will be used. Instead, the existing orifice for the steel ball inside the housing will also serve as a bypass. This is accomplished by interposing an obstacle between the ball and the orifice. When the amputee bears weight on the ankle unit the obstacle is removed, thus permitting the ball to close the orifice as soon as the shank reaches the vertical position. This leads to a much simpler design using proven elements.

The design change also permits the elimination of the steel lever, which was used in the past for achieving certain kinematic effects which are no longer needed. This results in a longer spring travel and in less

critical port dimensions for the toe-slap damping, which is controlled by the moving spring support.

The basic configuration of the modified design of the hydraulic unit is much simpler than the previous one, but still so similar in shape that the existing castings can be used (with some modifications) for the prototypes of this new design.

b. Foot attachment and eversion/inversion: The control principle for eversion/inversion has been changed. There no longer will be a motion in both the eversion and inversion directions, nor a friction effect to hold the foot in a laterally slanted position. Instead, the eversion will be blocked by polyurethane washers to provide stability in the lateral direction, and the inversion will be permitted against a moderate elastically yielding resistance. This eliminates the former keyhole-shaped front attachment of the hydraulic system to the foot. Instead, a vertical screw, similar to the one used so far in the rear of the hydraulic system, will now also be used in front of the system. Furthermore, the vertical position of the rear screw will no longer be adjustable to provide variation of the degree of toe pick-up. In the new design, the prosthetist can vary the toe pick-up by rearranging leather washers located on the two screws above and below the support pads which protrude from the front and rear of the hydraulic system.

c. Shank attachment and transverse-rotation control: After discussions with prosthetists, it was decided to eliminate the anterior/posterior adjustability of the top end of the vane piston rod inside the shank. This adjustment permitted a correction of the onset of the dorsiflexion stop, similar in effect to a change of the thickness of the front bumper in a standard single-bolt ankle. This thickness change is rarely done, and in a SACH foot such an adjustment is not possible in principle. The elimination of this adjustment not only simplifies the design considerably, but also permits the installation of the ankle system in standard small-diameter pylons (down to 1 in. i.d.). It also makes possible a design which enables the prosthetist to either block or to permit transverse rotation by rearranging or exchanging rubber elements located around the top of the vane piston rod. This optional reintroduction of the transverse-rotation feature may be preferred by the amputee.

The new design of the foot and shank attachments is much simpler, less expensive, less noise-prone, easier to install, and probably more durable and maintenance-free than the previous design, without loss of significant functional features.

Stump Stress Analysis
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For progress during this report period, see "Transferring Load to Flesh: Part V. Experimental Work," appearing elsewhere in this issue of the Bulletin.

Prosthetic Research
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Prototypes and drawings of several new prosthetic components have been completed.

Drawings of the orthogonal cylinder glenohumeral joint have been completed. It is ready now for wider evaluation and/or production. This heavy-duty joint exhibits essentially no "stick-slip" phenomena. The unit was initially thought to be valuable only in prostheses designed for interscapulothoracic amputations. It has now been determined that it may also be fitted in shoulder-disarticulation cases. This added indication greatly expands the usefulness of the design.

A mechanism has been developed for making the dual-control system for above-elbow prostheses functionally more nearly equivalent to triple-control. This mechanism is called a "lift lock" and it physically replaces the lift-tab assembly. It functions so that cable forces associated with lifting the forearm are not transmitted to the terminal device. Initial patient reaction to this mechanism has been favorable.

The principles of myo-pulse control and of synergetic prehension were disclosed in a paper given at the Fourth International Symposium on External Control of Human Extremities, in Dubrovnik, Yugoslovia, August 28–September 2, 1972. The myo-pulse control principle is used in the new VA/NU myo-electric system. Three powered hooks which make use of the principle of synergetic prehension have been constructed and are being tried on amputees. Myo-pulse control and synergetic prehension in combination form an interesting approach to powered grasp.

The control principle used in the "Fitch Arm" has been applied to the control of a VAPC electric elbow. Preliminary evidence indicated that this principle is not effective when "on-off" type of activation is

used. Proportional control applied to this position-servo-mechanism approach may yet prove the Fitch control principle to be valuable for electric elbows.

Six powered hooks of the 10X size have been developed for Dr. Aitken at the Area Child Amputee Program, Division of Services to Crippled Children, Grand Rapids, Michigan. Four of the units have been fitted. Despite minor problems, they have had a cordial reception.

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

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Prosthetics research in the UCLA Biotechnology Laboratory is focused on the problem of providing a versatile control system for a multi-degree-of-freedom, electrically powered prosthesis. Current emphasis is placed upon the application of past and present experimental work to a clinical testing situation.

The goals of the control-system studies remain: 1. development of efficient electromechanical skin-motion transducers, 2. design of an optimal control mode for coupling the transducers to a prosthesis, 3. specification of an adaptive aiding system to relieve the patient of some portion of the control load, and 4. development of a practical miniature adaptive aiding system using microcomputer technology.

A parallel effort is directed toward preparation of an experimental electric arm prosthesis and a comprehensive testing program for evaluation of the transducers, the control mode, and the aiding system in terms of patient performance.

Progress to Date

The Experimental Prosthesis

Prior to this term, an experimental electrically powered three-degree-of-freedom prosthesis was assembled from standard components: an Otto Bock hand, an AMBRL electric elbow, and a Northwestern electric wrist rotator. This assembly has been undergoing final modifications specifically aimed at strengthening and lightening the mechanical parts. The weight of the powered portion (elbow, forearm, and hand) is now 3.6 lb.; with the socket attached, the complete device weighs 4.8 lb. Figure 1 shows the experimental prosthesis in its present state of modifications.

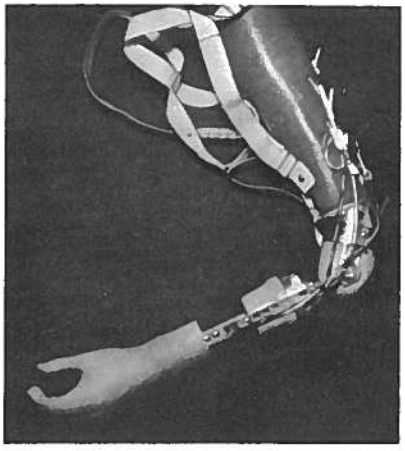

FIGURE 1.—The assembled UVP arm.

FIGURE 2.—Subject fitted with the UVP arm.

After a subject was chosen and fitted with a socket, it was necessary to prepare a special bracket to couple the above-elbow socket to the lower portion of the powered prosthesis assembly. Figure 3 shows that coupling. The final shape of the elbow is somewhat irregular because the extended motor of the AMBRL elbow was positioned to avoid the subject's long stump.

Figure 2 shows the subject wearing the complete experimental prosthesis.

Transducers

A method of controlling orthotic/prosthetic devices by means of variable-transformer skin-motion transducers (VTSMT) was developed. Three prototype transducers (BPR 10–18, pp. 256–258) have been constructed and will be used in conjunction with the adaptive aiding system. The VTSMT can be mounted at any convenient location on the body and need not be mechanically linked to the prosthesis. Figure 4 illustrates a subject wearing a VTSMT.

In operation, changes in the distance between the tranducer baseplate and skin-anchor button move the VTSMT plunger in and out, thereby varying the voltage induced in the secondary winding of the transformer. This secondary voltage is then electronically processed to produce different control modes and functions.

Control Modes

Several different control modes were considered which would allow bidirectional control of prosthesis motion from a single transducer. The control mode which seemed optimum, from both a human factors stand-

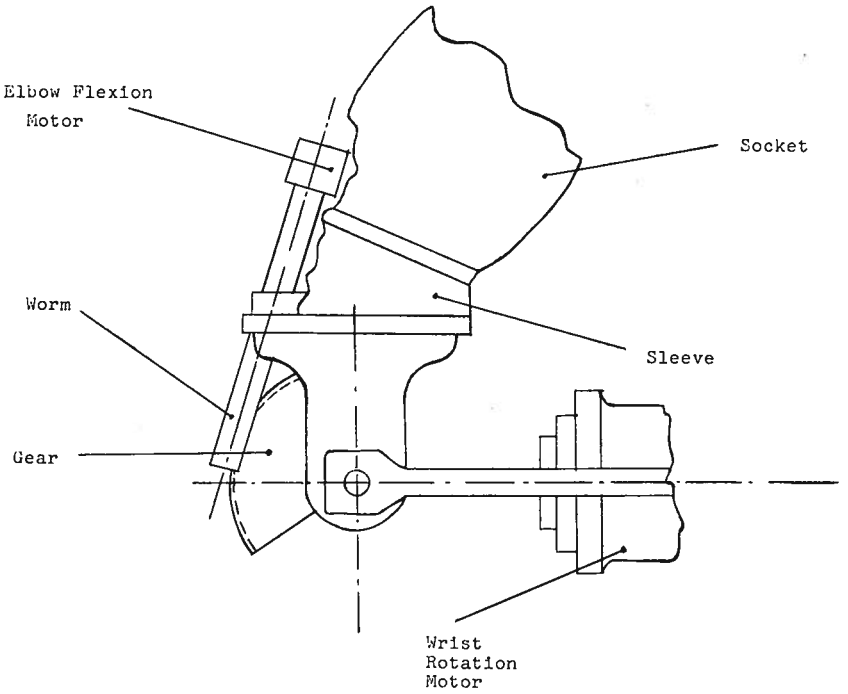

FIGURE 3

point as well as intuition, has been designed and constructed. Eventually others will be implemented and comparisons made.

The existing VTSMT control mode operates in the following manner: When the transducer is initially in the rest position (i.e., plunger fully inserted and in the standby region), the output voltage is zero (see Fig. 5). As the plunger is withdrawn, the output voltage remains at zero until the set point is reached (point 1). At the set point, a relay closes altering the transfer function to that labeled "control region." Bipolar output voltage is now produced with the zero point being *exactly* at the set point. Inserting the plunger beyond stroke 2 causes the servo motor to rotate in one direction, while withdrawing the plunger beyond stroke 3 causes the motor to rotate in the opposite direction. In order to return from the "control region" to the "standby region," the plunger must be in the "timed-stroke-reset zone" (between strokes 2 and 3) for a preset length of time (adjustable between 0.4 and 3.5 seconds). Complete insertion of the plunger also causes the transducer to reset to the rest position. Once reset (i.e., returned to the standby region), the control region is no longer accessible until the plunger is inserted to at least the enable point (point 4) and then returned to the set point. The experi-

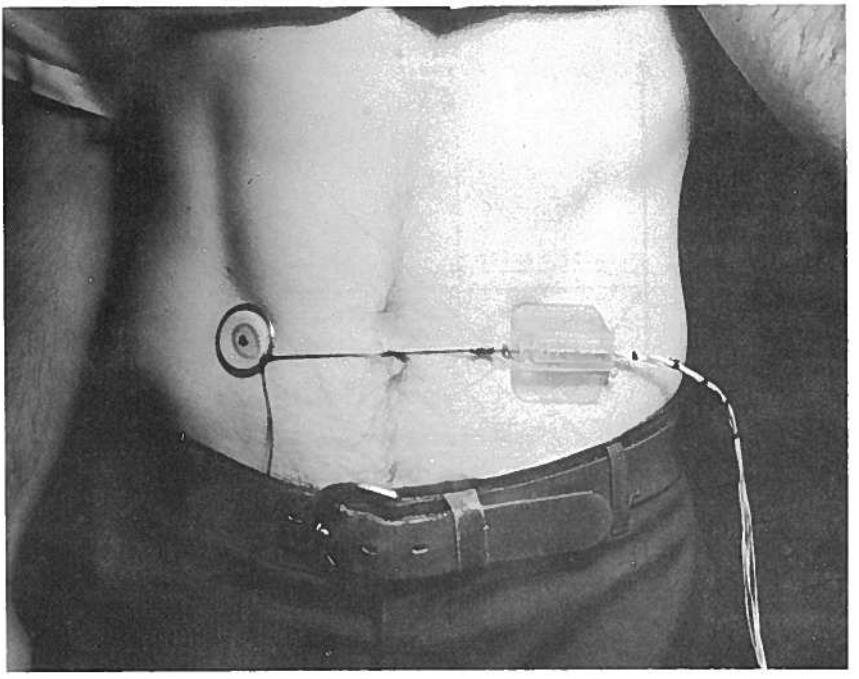

FIGURE 4.—A subject wearing the VTSMT transducer.

mental system contains light displays which are used to indicate whether the electronics are either in the standby or in the control region.

Nonlinear-function generators are being designed which will allow the control-region curve to be shaped to any desired function of stroke-versus-output voltage. The function being used at present is that which is generated directly by the VTSMT (see Fig. 6).

The advantages of this type of control mode are as follows:

1. Bidirectional, continuous-rate control is achieved with a single control site.

2. This method eliminates prosthesis movement in one direction before movement can occur in the opposite direction.

3. Small unintentional movements when in the standby region will not result in undesired prosthesis movement.

4. Voltages developed for control purposes can, in the future, be utilized in conjunction with tactual feedback displays placed in the transducer base plate.

Electric circuitry is nearly complete for the control mode and function depicted in Figures 5 and 6. One degree of freedom is complete

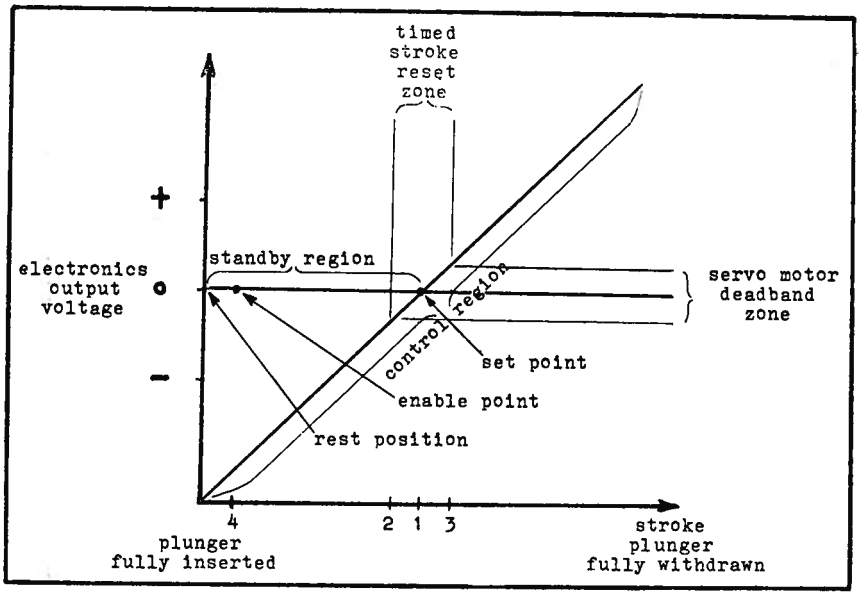

FIGURE 5.—Transducer and electronics control mode.

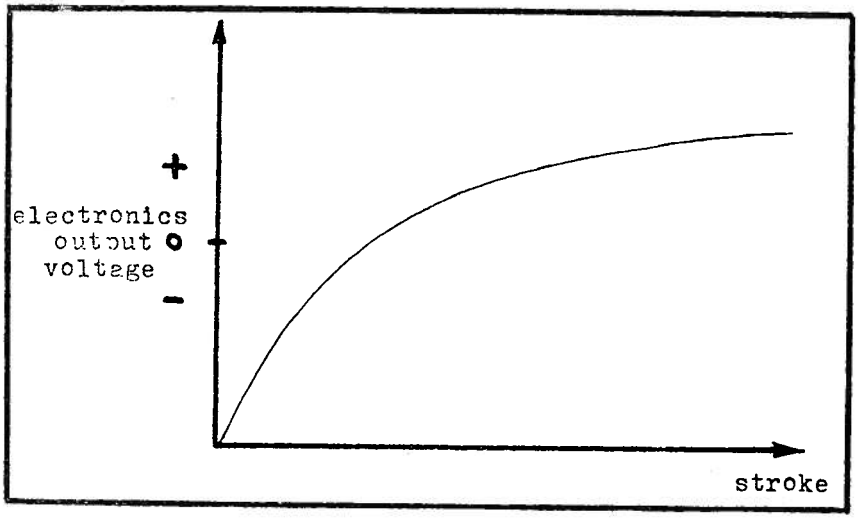

FIGURE 6.—VTSMT and electronic transfer function when in operation in the control region.

and functions as intended. Elbow flexion-extension, wrist rotation, and hand prehension are to be controlled by the skin-motion transducers, which will be mounted in experimentally selected locations on the body trunk. In operation with the adaptive aiding system, computer control of the prosthesis/orthosis will occur automatically when a predetermined confidence level concerning the next desired movement is achieved by the computer. Patient override will be effected by placing any one of the control transducers in the control rather than in the standby region, thereby returning control to the patient.

Adaptive Aiding

The concept of adaptive aiding for prosthesis control, which was previously examined and implemented with a human-operator-controlled manipulator, is now being molded for application to a three-degree-of-freedom electric arm. The basic principle of using maximum-likelihood-decision algorithms to predict future motions of the device, and thereby relieve the operator by assuming a part of the control burden, remains the same. However, the correspondence between physical space and decision space, the input information, the recognition of significant events, and the means of controlling device motion, will be different for the prosthesis application.

An aiding system for the UVP arm must use indirect position data, since absolute end-point position information is not directly available. Variations in the natural position of the patient's shoulder prevent the extraction of absolute position information. In addition to relative joint positions, horizontal-vertical orientation information will be used. For this, a pendulum-type sensor will be used to determine orientation with respect to gravity. Additional input information for the aiding system will be extracted with a simple force sensor in the hand.

A definite requirement of this aiding system is that it generate natural-looking movements. Algorithms for producing cosmetic motions are being designed.

The previous adaptive aiding system was cognizant only of the terminal device position at the end of a complete motion. These positions were recorded, and a prediction was made for the final position of the next motion. The path to that point was dependent only on servo-system dynamics. In the prosthesis application, the aiding system will continuously record data and predict motions; movement trajectories as well as final points will be controlled by the aiding system.

Continuous control can be achieved by repeated application of a decision algorithm similar to the old system. Such an aiding system would learn the exact trajectories followed while the patient controls the prosthesis. These paths, however, would rarely be natural-looking due to the difficulty of control using body transducers. So, the pre-

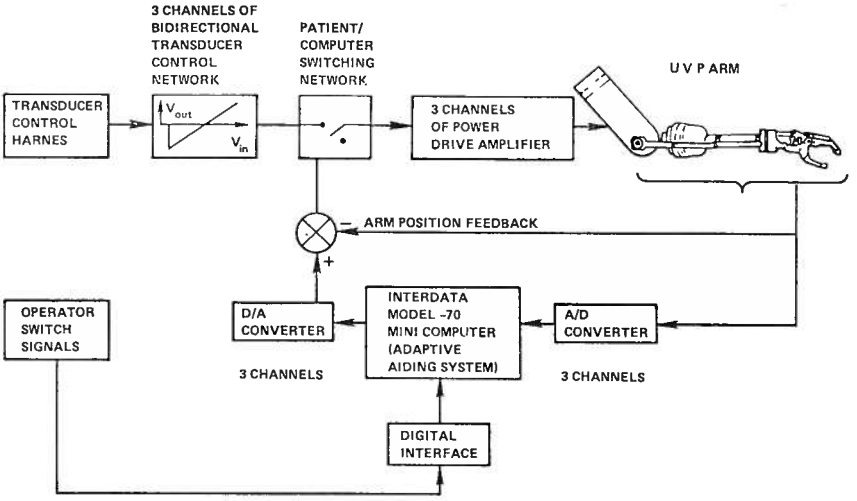

FIGURE 7.—The integrated operational system.

dicted path will be modified using rules for natural movement to produce cosmetically acceptable motions.

A preliminary system for learning trajectories as generated by an operator is presently being tested with the three-degree-of-freedom manipulator. This aiding system uses the position of the manipulator to predict continuously the direction of motion. When these learning programs are "debugged," they will be combined with algorithms of cosmetic motion for the prosthesis-aiding system.

Figure 7 is a block diagram showing how the adaptive aiding system is realized in the total control system.

Experimental Studies

Purpose

The purpose of the experimental work is to evaluate the operation of the UVP arm under the "case study" approach. An above-elbow amputee will be used as the subject to study both direct and computer-aided controls. The evaluation study will provide the following information:

1. Performance level and Functional regain achieved by the UVP arm.
2. The optimum transducer-attachment configuration for the control of the UVP arm.
3. A measure of the level of performance improvement attained with the aiding system.
4. What type of aiding function is best suited to this prosthesis-control system.

5. The values of the aiding system parameters which yield optimum performance.

Background

Techniques for upper-limb prosthetics evaluation were developed at the Biotechnology Laboratory beginning in the early 1950's by Groth and Lyman (1,2). Generally, the emphasis is on user performance rather than on simple engineering measures, such as structural characteristics, frequency response, etc.

A number of simple, essential tasks, representative of the activities an amputee might perform in daily life, are the emphasis of the prosthesis-testing programs. Lucaccini et al. (3) list 15 tasks and evaluation procedures for testing these programs. Numerous additional tasks are detailed by McWilliam (4). Of these, 12 tasks were chosen for usefulness, completeness of motion, and comparability with previous experimental work.

The amputee will perform the 12 tasks under the supervision of laboratory personnel. Time and joint-motion scores will be recorded and processed by an Interdata Model 70 computer, and error scores will be recorded by the experimenter for each trial. Subjective estimates of performance by the subject and by the observer will also be made.

Preliminary Experiments

The preliminary phase of testing will include arm, transducer, and task testing without computer aiding. In this phase, a standard series of trials will be made.

First, the amputee will be instructed in the method of task performance. He will then practice the task until, in the judgment of the observer and of the amputee, he has reached a stable level of performance. The amputee will begin a series of 50 trials on the task, with 5-minute rest periods after every five or 10 trials. All performance measures will be recorded.

Timing will begin when the subject is told to begin the task, and timing will be stopped when he has returned the prosthesis to the initial position after completing the task. All trials will begin and end with the amputee at a standard starting position—either standing or sitting.

After a session on a task, the amputee will be asked to indicate his rating of the task performance on a 10-point scale, ranging from "excellent" to "unacceptable—physical damage."

The tasks to be performed are listed below:

1. Sharpening pencil
2. Pencil to pocket
3. Eat soup with spoon

4. Water glass drinking
5. Hanger transport
6. Answer telephone
7. Open and close door
8. Zip and unzip trousers
9. Table setting—plate, bowl, cup, saucer, silverware
10. Remove and replace jar lid
11. Movement of cylindrical object between shelves
12. Insert key into door lock

Detailed descriptions of these tasks are given in Gottlieb et al. (2) and Luccaccini et al. (3).

The equipment to be used in the standard sequence of tasks includes that given in the task description, and a table and chair of 31- and 17-in. heights, respectively. These items have been collected and organized into a satisfactory workspace.

Testing itself will be conducted in a closed, well-lighted laboratory room.

Main Experiment

The main experiment will involve a balanced design determining the differences between computer-aided and non-computer-aided operation, low and high computer learning rates, feedback types, and possibly transducer control methods.

In addition to the performance measures and rating estimates employed in the preliminary testing, separate measures of time, motion, and errors, will be taken for manual and computer control. Also subjective estimates of net computer aiding will be made by the subject after each trial on a 0—100 percent rating scale.

When training with the 12 tasks has progressed to a stable level, the subject will begin a series of trials of the tasks given in random order. Each session will be conducted under a different set of conditions according to a balanced design. This design is not yet completed, as there may be modifications to the number of conditions after completion of the transducer and ACS systems.

Future Work

Specific tasks planned are:

1. Design and build alternate control-mode circuitry.
2. Add gravity and force sensors to the experimental prosthesis.
3. Prepare equipment and accessories for evaluation experiments.
4. Finish design and programing of adaptive aiding system.
5. Begin training and preliminary experiments with amputee—

especially aimed at evaluation of transducers and comparison of control modes.

6. Conduct feasibility study of a self-contained adaptive-aided prosthesis using microcomputer technology.

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Design of Prosthetic and Orthotic Devices and Biomechanical Studies of Locomotion

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The Biomechanics Laboratory continues a dual effort, combining design and development of prosthetic devices and mobility aids with fundamental studies of human walking.

Prosthetic Devices

A revised version of a previously reported axial torque absorber, which permits axial rotation of the socket relative to the prosthetic foot, has been worn by an active above-knee amputee for a period of 6 months without incident. He is pleased with the function of the device and reports improved skin condition on his stump. Upon development of practical procedures for adapting the torque absorber to wood and plastic prostheses, the design will be forwarded to VAPC for evaluation.

Aluminum alloy tubing of 1⅝-in. outside diameter has been widely used as a structural element for pylon-type modular prostheses. This size tubing very rarely fails in service, but is so large that it often interferes with cosmetic treatment at the ankle. Two new internally expanding foot couplings have been designed for use with smaller tubing of 35-mm. (1⅜ in.) outside diameter, which was recommended as a new standard tubing size by the International Working Group on Specifications for Lower Extremity Modular Prostheses, held near London in

October 1972. Both vibration tests and ultimate strength tests will be used to evaluate the durability of these new couplings in comparison to existing designs.

Mobility System for the Severely Disabled

This project is aimed at providing independent mobility for quadriplegics or those with extremely limited muscular functions. The system involves a multi-purpose "wheelchair" and an automobile-loading mechanism which will enable the quadriplegic to drive a car while seated in the wheelchair. A prototype of the wheelchair has been built as described in a doctoral dissertation by David M. Anderson. The current prototype is an electrically powered wheelchair, whose seat adjusts in height from 7 in. to 27 in. above the ground. In the high position, the wheelchair is designed to pull the quadriplegic's feet under his knees, so that he can frontally approach kitchen counters or bookcases. The width of the wheelchair also decreases in the high position from the normal 25 in. to 21 in. for negotiating narrow doorways as in bathrooms. The wheelchair can be adjusted easily for increased stability by increasing all width dimensions by 2 in. In the low position, the wheelchair reclines to near horizontal. The wheelchair linkage is also designed to climp curbs up to 12 in. high. All seat-adjustment and stair-climbing functions are driven by a single recirculating ball-screw with electric actuator. All dimensions that must be varied to fit different individuals are adjustable with simple hand tools.

Fundamental Studies

Final preparations of the computer data-acquisition system for large-scale gathering of locomotion data were delayed during the previous reporting period by heavy time demands for development of devices. During the present reporting period, preparations have continued at an increased rate in two principal areas: The writing of data-manipulation computer programs, and the design and fabrication of specialized data-input devices.

An operating system has been written, which makes better use of the existing computer peripherals, to speed up the preparation of programs for data collection and data processing. A basic data-acquisition program has been written, which gathers data from 20 different input channels 200 times per second, formats these measurements in the computer memory, and stores them on magnetic tape. Programs are now being written for data processing, which will take place after data collection as a separate operation. Data will be read back from the magnetic tape, either into the small laboratory computer or a large computer at the campus computer center.

New data-input devices for studies of normal and of amputee gaits include a simplified control panel to allow inexperienced users to collect and process data with the computer system, an instrumented pylon to measure forces and torques in prosthetic limbs, a flexion angle transducer for the polycentric knee, a torsion-angle transducer for the axial torque absorber, and practical, highly reliable heel-contact switches made from commercial switch elements.

Immediate Postoperative Prostheses Research Study
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The Prosthetics Research Study continues its investigation into surgical amputation techniques and immediate postsurgical amputee management. At this time the case load averages 15 new amputations per month. Specific attention is being directed to the knee-disarticulation level, above-knee and above-elbow muscle stabilization techniques, and surgical nerve management. A new biomedical engineering laboratory is now being completed under the direction of Mr. Charles P. Rubenstein, biomedical engineer.

At the request of Dr. Robert E. Stewart, the PRS Study team is currently working as one of the research facilities throughout the United States cooperating in the Rancho Los Amigos-Medtronic Neuromuscular Assist Study. In the last 8 weeks, two peroneal nerve stimulators have been implanted in patients with upper-motor-neuron lesions. A total of 10 implants is planned over the next few months as part of this program.

Electrode implantation for investigative purpose has also been performed in one below-knee amputee, using 25-micron platinum-coated electrodes placed into major peripheral nerves. This study is being carried out as a cooperative project between Prosthetics Research Study and the INSERM (Institut National de la Santé et de la Recherche Médicale) Biomechanics Unit, Montpellier, France. Support for this investigation is provided by the Prosthetic and Sensory Aids Service of the United States Veterans Administration.

The need for objective simple laboratory data to assist amputation-level determination in ischemia has high priority in our unit. We are reviewing, analyzing, and coordinating several established parameters to provide practical preoperative guidelines supporting clinical information for determining levels of amputation.

The Prosthetic Treatment Center established at the Veterans Administration Hospital, Seattle, in 1972, receives the support and close cooperation of the Prosthetics Research Study. The number of amputee and related problems has increased progressively during the past several months.

The influence of electrical current on bone growth and bone healing is under investigation as a cooperative project with the Department of Orthopaedic Surgery, Columbia University, New York City, under a Veterans Administration-sponsored investigation.

In the area of prosthetics research, continuing design variations in lower-limb prostheses for extra-ambulatory function are being developed to allow amputee participation in sports and other vocational and recreational activities.

Investigations into the level of amputation versus level of function, and the utilization of stumps with stabilized muscle to improve socket suspension and gait proficiency, are presently under way.

Below-Knee Amputation for Vascular Insufficiency with Immediate Postoperative Fitting of Prosthesis

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Lower-limb amputation at the Syme's level is amenable to immediate postoperative prosthetic fitting and ambulation; however, the prosthetic components available for this level of amputation present some difficulties. The purpose of this report is to describe a new approach in which an exoskeletal-type prosthesis was developed for incorporation with the immediate postoperative prosthetic cast.

Description and Fabrication of Prosthesis

This prosthesis (Fig. 8) consists of a one-piece, semi-flexible, thin plastic laminate extending from the tibial tuberosity proximally, and fitting over the distal, bulbous end of the plaster cast distally. The end of the plastic laminate incorporates a SACH foot. The laminated shell of the prosthesis is fabricated in advance using nylon stockinet, Fiberglas cloth, a thin wooden keel reinforced with Fiberglas, and a laminated SACH foot. The medial and lateral walls of the laminate are cut out, leaving two support bars anteriorly and posteriorly, 1¼ in. wide. A 3-in. cuff proximally, and a cup or receptacle approximately 1½ in. deep, and 4 in. diameter distally, are laminated in continuity with the support bars. The cuff and receptacle are perforated with ⅛-in. holes to provide bonding to the plaster-of-paris cast by wet plaster. The proximal cuff is cut

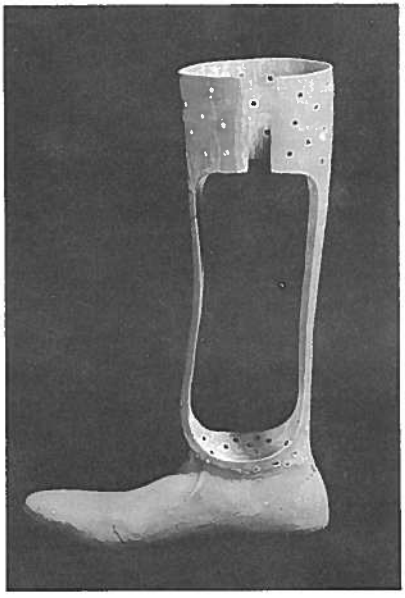

FIGURE 8.—One-piece, semi-flexible Syme prosthesis for immediate post-surgical prosthetic application.

vertically through its medial wall to enable the cuff to be spread open in order to provide for application of the prosthesis over the plaster-of-paris cast.

Application of the Prosthesis

Following completion of the paster-of-paris cast in the operating room, medium consistency plaster of paris is applied over the end of the cast and around the area corresponding to the final location of the proximal cuff. Additional plaster of paris is applied in the socket end of the prosthesis as well as the inner aspect of the proximal cuff. The proximal end of the prosthesis is then spread open so that the prosthesis can be slid over the plaster-of-paris cast, allowing the distal end of the cast to engage the distal socket. The prosthesis is then fixed to the cast by taking several turns of plaster wrap around the proximal cuff as well as around the distal socket.

Alignment Procedure

Since the prosthesis is a solid unit there are limited alignment adjustments required. An average "bench" alignment is established during the fabrication of the prosthesis. Additional adjustments can be made as follows: 1. Socket flexion can be modified by reducing or increasing the heel wedge. 2. Rotation of the foot about a vertical axis (toe-out) can be controlled by removing the prosthesis and repositioning. 3. The prosthesis may be lengthened by removing it from the cast and applying

and additional wedge between the end of the cast and the socket. 4. The foot may be modified by sanding or adding material.

Clinical Experience

The prosthesis has now been used on three patients undergoing Syme's amputation for peripheral vascular disease. All three patients went on to primary healing of their amputation and have achieved an excellent functional result. All three patients were started on weight-bearing the morning following the operation. In observing the gait of these patients following surgery, the following advantages of the exoskeletal prosthesis are evident: 1. the prosthesis is applied easily and quickly; 2. use of this prosthesis permits equivalent simulated dorsi-plantar flexion of the foot during ambulation by cantilever bending of the SACH toe and compression of the SACH heel wedge, as would be the case in the definitive prosthesis; 3. this immediate postoperative prosthesis can also be used as a temporary prosthesis once the patient is through the healing phase, while his permanent prosthesis is being fabricated; and 4. this prosthesis is quite light, yet it has remarkable strength so that a lighter cast may be used for the initial wrap.

Summary

A new, lightweight, durable, laminated plastic prosthesis for immediate postoperative fitting following Syme's amputation is described. This prosthesis enables immediate ambulation and rapid rehabilitation to be carried out in the patient having undergone Syme's amputation, which will be similar in nature to the characteristics of walking with a permanent prosthesis. Healing and rehabilitation results obtained in three patients undergoing amputation for peripheral vascular disease are described.

Interdisciplinary Development and Evaluation of Externally Powered Upper-Limb Prosthesis

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During the latter half of 1972, the work at Johns Hopkins was primarily aimed at continued clinical evaluation and design refinement of the electrically driven cable design concept for powering upper-limb prosthetic and orthotic systems.

The basic concept is design of a non-joint-specific power and control unit capable of powering various joints for upper-limb amputations by using the device in the mode of an artificial muscle. The system provides

proportional control, and it requires only an input from an EMG sensor or a skin-displacement sensor at a single site to control its output. A single quiet motor is utilized to control motion of one or more joints by appropriate routing of the power cable, together with the use of integrated electromechanical locking devices. Many of the detailed engineering features of the design, as well as the basic operating characteristics, were described in earlier issues of the BPR. Though past efforts demonstrated values in prosthetics, the current efforts not only extended clinical trails in that area, but also extended applications to bilateral cases and to orthotics.

Work during the reporting period was concentrated in four areas:

1. Improvements to a powered orthosis for a flail elbow.
2. Modifications to powered bilateral prostheses.
3. Engineering design improvements on the electronic and mechanical components for the power-pack system.
4. Continued evaluation of powered systems previously fitted.

1. *Powered Orthosis*

One of the promising alternate applications for the remote power-pack concept being developed at Johns Hopkins is for powered upper-limb orthoses. The remote location of the motor/battery pack and the use of a cable drive enhance the possibility of achieving a functional, lightweight orthosis for elbow motion or hand grasp.

An experimental model of a powered orthosis utilizing this concept has been fitted to a individual with bilaterally severe flaccid shoulder-muscle weakness and only a trace of elbow-flexor muscle function. The original orthosis design, using somewhat traditional concepts, is shown in Figure 9a. This design utilized a cuff about the humeral section, only a single outside hinge near the elbow joint, and a leather/plastic enclosure around the forearm. Power to control the elbow motion was achieved through a sheathed (Bowden) cable routed across the patient's back to the motor power pack worn on the waist. This system provided the desired function, but this individual was not happy with the bulk and weight of the equipment worn on the arm.

In order to mitigate these problems, a new lightweight design was undertaken as shown in Figure 10. In this model, the peripheral end of the cable was attached to a lightweight forearm portion designed for transferring the load from the forearm to the cable with minimal strapping on the forearm, but with no need for laminates or cuffs. The geometry of this strap arrangement distributes the load in such a manner as to make all forearm positions functional and comfortable. The mechanical hinge joint at the elbow was removed entirely, thus relying upon the patient's own elbow joint.

The peripheral end of the cable housing is anchored to a bicipital cuff

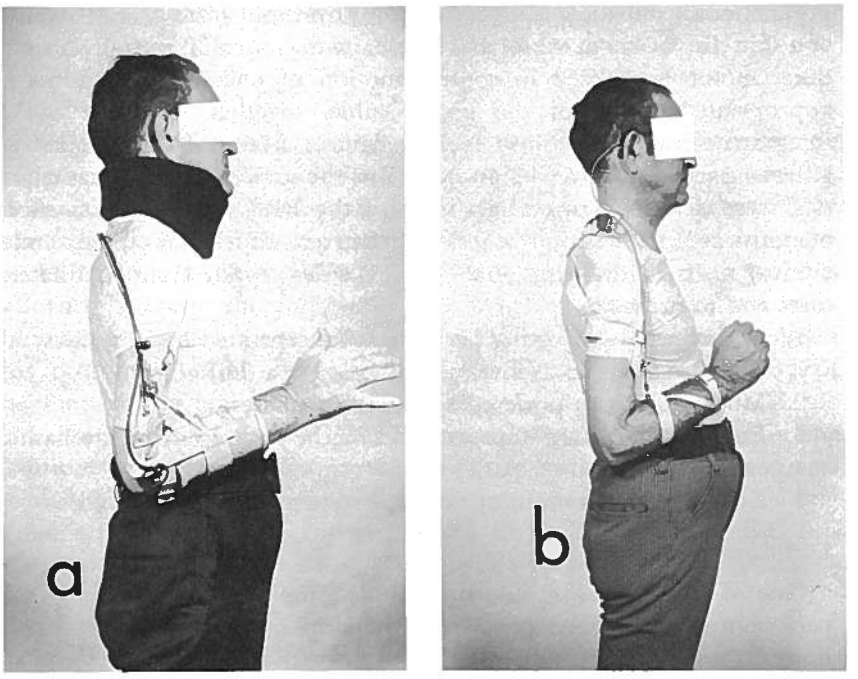

FIGURE 9.—a. Powered elbow orthosis with myoelectric control from biceps, b. lightweight synthetic muscle—myoelectric control from facial muscles.

attached to a lightweight shoulder-arm harness. For comparison, the new arrangement fitted to the volunteer patient is shown in Figure 9b.

Two possible sites have been investigated for locating the myoelectric sensor which controls the device in a proportional manner. Locations over the biceps muscle and behind the ear have been investigated in a tradeoff study to determine an optimal location for the control site. Final determination has not been made of the best location on this man. This individual, who is an office executive working at a desk, finds the system helpful in moving objects from his lower file drawers to the desk top without having to stand up. The live-lift capability of the powered orthosis is 0.9 kg. Evaluation tests will be continued with this device to further evaluate the potential of this concept.

A fitting of a powered orthosis to another volunteer subject is planned for early 1973. This volunteer patient has totally flail upper limbs except for limited grasp in one hand. He is in the process of being fitted with a powered finger flexion-extension orthosis, using a belt-mounted motor/battery pack. A synthetic biceps muscle, similar to that described previously in this progress report, will be utilized to power elbow motion.

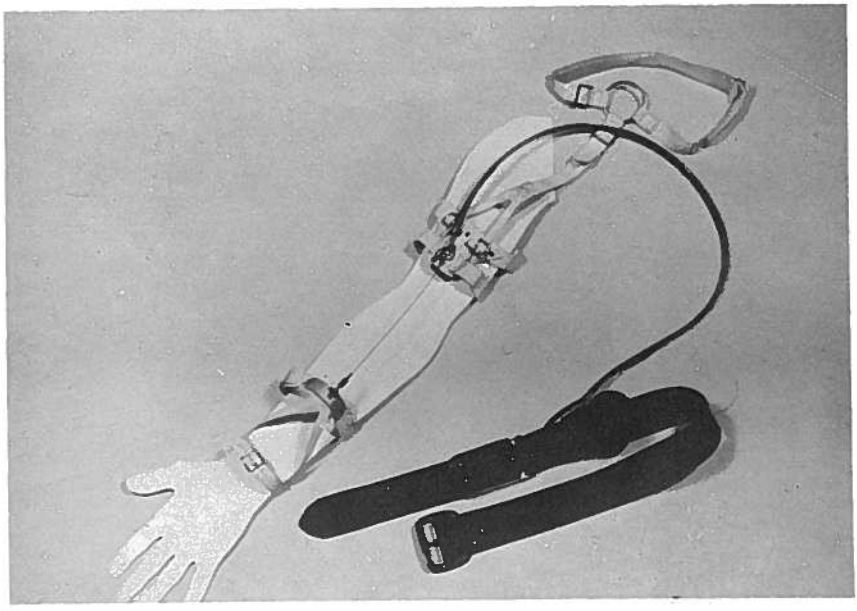

FIGURE 10.—Powered synthetic muscle for a flail elbow.

2. *Modifications of Powered Bilateral Prostheses*

During the previous reporting period, an externally powered bilateral shoulder-disarticulation prosthesis had been fitted to a congenital bilateral shoulder-disarticulation amputee (Fig. 11). For most of her life, she has used foot and toe motions skillfully, but has had a bilateral shoulder-disarticulation prosthesis powered by motion of her left thigh pulling on a separate plastic laminate thigh cuff attached to a Bowden

FIGURE 11.—Congenital bilateral shoulder-disarticulation amputee.

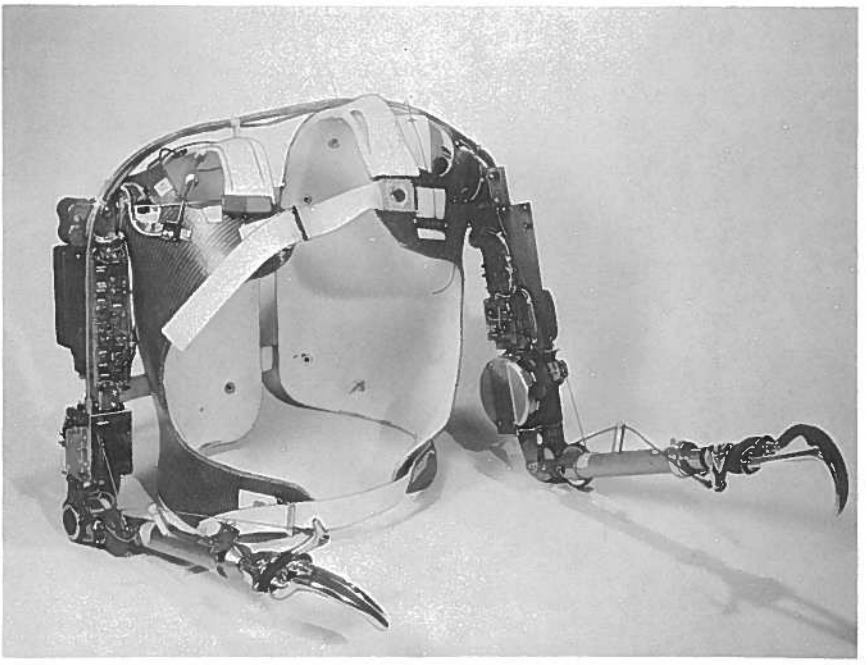

FIGURE 12.—Multicontrol of bilateral prostheses by a single motor and electromechanical logic.

cable. The elbows were locked by chin-nudge controls. This device provided negligible function and was worn rarely and for appearance only. Her electrically powered bilateral shoulder-disarticulation prosthesis is of modular endoskeletal design. It uses a single motor located just above the left elbow (Fig. 12). The cable from this single motor is routed to power both elbows, both terminal devices, and wrist rotation on one side, i.e., five functions from one motor, selected by various locking methods and electromechanical logic.

This amputee's powered equipment was originally arranged to use two primary proportional control inputs (one for each limb) derived on each side from a particular motion of the tip of the ipsilateral acromion process. A skin-motion sensor was used on each limb. After the appliance was fitted, it was determined that the patient was only able to concentrate on one prosthesis joint at a time. The system was therefore altered to use a single primary proportional control of motor motion from one (the right) acromion process, the best available site, and switching logic to select the desired joint to be operated by an independent motion of the right shoulder, by one of two independent motions of the left shoulder or by combinations. After allowing the volunteer subject to

wear this unit for a few months, it became apparent that a remote means of rotating the left wrist would be a desirable feature for this individual. This was accomplished by the addition of a chin-nudge electromechanical switch, which mechanically unlocks the wrist and provides a signal to the motor to cause tension on the spiralling cable to rotate the unit 90 deg., then lock it in this new position. The patient finds this additional mode easy to use, and it may make the device more useful.

This amputee has now completed about 3 months of evaluation on this system. Aided by her toes, she can change and recharge the batteries, make minor adjustments, and apply, fasten, and activate the prostheses herself without assistance of any kind. She now uses these prostheses daily, when in public, for carrying objects, and for certain other functions. The entire appliance weighs 3.6 kg. The only problems which have occurred with this appliance were a structural failure of a shoulder joint (standard prosthetic component) caused when carrying a heavy briefcase with books, and some slight damage caused when the patient fell with the prosthesis. These problems have been corrected and evaluation tests are being continued.

3. *Engineering Design Improvements*

The results to date of the evaluation of 11 powered prostheses clearly indicate the potential merit of the Johns Hopkins approach for a power and control mechanization for upper-limb prostheses and possible applicability to orthoses. In order to broaden its potential value, the system design was reviewed to determine if the weight could be reduced and lower cost electronic components utilized. The results of this design study are showing in the newly developed alternate components shown in Figure 13.

The new battery pack, reduced in weight to 5 oz., can provide power from 4 hours up to one full day and may be easily interchanged during the day. The motor package shown in the center of the photograph uses a small motor with less total cable-force capability (21 lb. vs. 30 lb.—old motor), but it appears to have adequate force levels for the elbow and hook for a typical above-elbow prosthesis. Its total weight is 10.0 oz. which is a reduction of 6.5 oz. below the standard motor assembly.

Lower cost electronic components and use of multi-pack operational amplifiers have allowed the electronics to be reduced in size and cost. The new physical arrangement of circuits continues to locate the preamplifier board on the back of the EMG sensor, with the remainder of the servo electronics packaged on one board which can be located near the battery pack. The new electronic modules are shown in the right of the photograph (Fig. 13). Two powered prosthetic systems using the

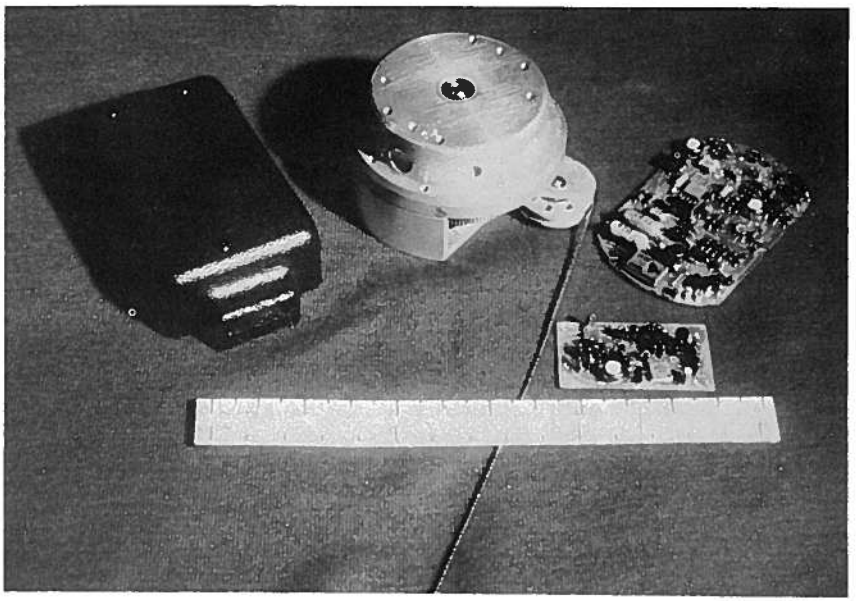

FIGURE 13.—Lightweight system components.

above components are being fabricated in calendar year 1973 for evaluation on amputees to compare performance of these components with the original system.

In addition to the engineering of these new components, some experimental breadboard tests have been conducted on an alternative approach for mechanization of the cable drive system to provide a more functional control mode, particularly for hand orthoses. For this new mode of operation, the motor torque is used to drive the hook closed rather than open (against a spring or rubberbands). The use of a small solenoid-actuated capstan lock, located between the motor and the terminal device or hand orthosis, provides a locking function to maintain the desired grasp force. The hand orthosis may be left at rest in any flexion-extension position.

The use of the motor to close the orthosis results in a more efficient utilization of the motor and battery power as compared to the present system. Further work is planned on this technique during the coming year.

4. *Amputee Evaluation*

Twelve adults, consisting of one paralytic and 11 amputees, have been fitted with the Johns Hopkins experimental powered system over the past 3 years. The distribution of amputation levels includes one wrist-

disarticulation, three below-elbow, two elbow-disarticulation, two above-elbow, and three shoulder-disarticulation amputees, of whom one was a bilateral. With the exception of one case, each amputee had been fitted with a traditional harness- or body-powered-type prosthesis. Scarred skin about the left shoulder due to high voltage burns contraindicated a shoulder harness for the body-powered prosthesis for this one exception. The body-powered system was used for functional comparison with the electrically powered prosthesis for a wide range of tasks.

After a total of 17 cumulative man-years of evaluation results with this equipment, seven amputees preferred to use their electrically powered unit exclusively. Two preferred to have both types of prostheses, using each for different functions. One man rejected his electrical prosthesis due to its excessive weight, and one man abandoned wearing his electrical prothesis because he did not have the time to participate in followup evaluation. The paralyzed individual wears his equipment on a part-time basis, because of the limited capability of his arm to carry any excess weight.

During the past year, the incidence of failures and malfunctions of the powered equipment was minimal; they consisted of cable failures typically after 1 year's wear, a small number of wire breakages at the cable interface to the battery, and replacement of two dead battery cells and one operational amplifier. The failure rate of the non-electrical conventional prosthesis components was greater, but was within acceptable bounds.

In order for the Veterans Administration to determine the producibility of this design by private manufacturing concerns, the Applied Physics Laboratory supplied drawings and specifications for the EXPAC system for an above-elbow prosthesis. This was submitted to industry by the VA Prosthetics Center in New York for bids on a limited quantity. A contract for six above-elbow units was awarded by the VA to Pope Brace Co., Inc., Kankakee, Illinois. These systems are to be complete such that prosthetists can readily use them in fabrication of complete prostheses. The system components include a myoelectric signal sensor, drive motor, control electronics, battery pack, and forearm pulley assembly. These components in the present APL design are shown in Figure 14. The units will provide elbow flexion and voluntary-opening terminal device operation. Fabrication of these units by the contractor is well under way and should be available for incorporation into the finished prostheses in late spring 1973.

Future Plans

Evaluation testing will be continued on units fitted to existing patients in order to get long-term data. One new system currently being fitted to a shoulder-disarticulation amputee will provide limited shoulder

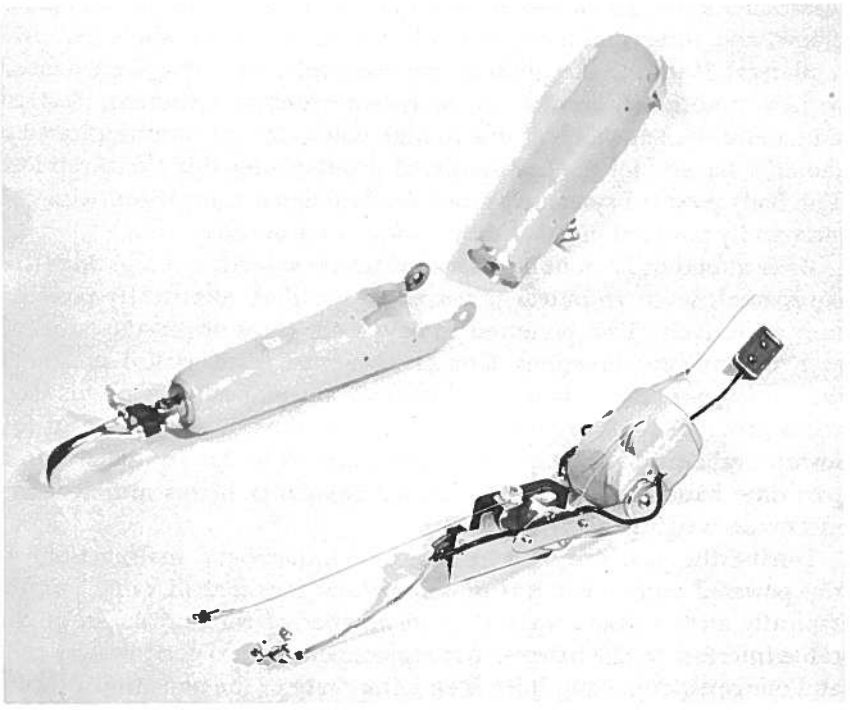

FIGURE 14.—Power and control unit assembly for above-elbow prosthesis.

flexion in addition to elbow and terminal device motion. Another powered prosthetic system currently in the initial fitting stage incorporates the new lightweight motor in an above-elbow unit with an integral electromechanical elbow lock. A powered orthosis is also in the initial fitting stage to provide finger flexion-extension in combination with a synthetic biceps muscle. All systems use the same basic approach with some variations of the motor-module size and type of input sensors.

Development of Refined Fitting Procedures for Lower-Extremity Prosthesis

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Studies were continued with the development of Taslon-lined prostheses for below- and above-knee amputees. Different weave patterns

were tested in an attempt to eliminate fraying and fatigue of the material. RTV-rubber impregnation failed to resolve those problems, since it deprived the material of its inherent mechanical properties.

Due to the rapid deterioration of the Taslon-lined prostheses, studies were conducted in the development of polypropylene sockets in an effort to facilitate construction of prostheses that would accommodate changes of stump volume.

These experimental prostheses of lighter weight have been tested in above- and below-knee amputees, as well as with upper-limb amputation stumps. It appears that the technique of fabrication of the new type of prosthesis will soon be standardized.

Further studies are being conducted in the development of an improved suspension mechanism for the below-knee PTS prosthesis. The technique of fabrication of a soft medial wedge suspension was standardized.

An expandable inner wall knee-disarticulation prostheses was developed, based on principles similar to those utilized in the fabrication of the Syme's windowless prosthesis developed at the University of Miami in 1963 (Sarmiento, A., Gilmer, R.E., Jr., and Finnieston, C.P.: A New Surgical-Prosthetic Approach to Syme's Amputation. A Preliminary Report. Artificial Limbs, April 1966).

Considerable experimental work was conducted in the area of orthotics and polypropylene orthoses utilizing prosthetic principles. These orthoses were used in the treatment of multiple neuromuscular skeletal conditions such as hemiplegia, spasticity, cerebral palsy, and hemophilia. Special developments took place in the area of bracing in the treatment of fractures of the tibia, femur, and forearm.

Immediate Postoperative Application of Upper-Extremity Orthoses
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No progress report was received from this contractor for this report period.

The Improvement of Assistance Systems Through Research, Design, Clinical Testing, and Team Evaluation
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During the period July 1 through December 31, 1972, the Veterans Administration-sponsored research program at Texas A&M University has substantially expanded its scope. The program now includes projects that relate to the development of driving aids for the physically impaired, as well as the development of improved lower-limb prostheses.

The project's effort on mobility aids for vehicle driving has focused on two parallel activities. The first of these activities involves the evaluation of existing driving aids and the proposal of standards and specifications for such equipment. In carrying out this activity, close cooperation has been maintained with VAPC in order to improve the safety of those disabled currently driving, as well as to provide a means for other disabled individuals to drive who cannot use existing equipment. This activity involves the parallel development of: 1. servo controls for vehicle systems (steering, brakes, accelerator, shifting, etc.), and 2. man-machine interface controls appropriate for various handicaps. Several design concepts for the man-machine interface are currently being pursued.

Preparations for road-testing of both existing and new devices are being made at the Texas A&M University Driving Range, which provides facilities for simulating all driving tasks. The unique capabilities of the A&M Texas Transportation Institute in measuring and recording driving parameters are being utilized.

The hip-disarticulation prosthesis, described in the Fall 1972 issue of the Bulletin, has undergone a 3-month clinical test during this report period. During this time, the patient commented favorably about the lightness of the device, the improved comfort afforded by the girdle with variable stiffness, and the ease with which ambulation was possible. However, the need for a swing damper in the hip joint was noted, and the "leave-in" alignment devices showed excessive wear. These defects have necessitated several minor design modifications in the system, and the modified prosthesis is scheduled for further clinical evaluation starting in February 1973.

Control of an Artificial Upper Limb in Three Degrees of Freedom

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During the second half of 1972, the work on the present project of toe-actuated control of upper-limb prostheses in three degrees of freedom has mainly been concerned with the construction of the interface between the micro-electronic logic controller and the stepper-motor drives. This interface, which involves circuitry for conversion of analog-to-pulse-rate and pulse-distribution circuitry for the specific stepper

motors selected (73 oz./in., 5.3 oz. high stall torque motors), has now been completed. The interface and the previously constructed controller have subsequently been tested for the joint controller-motor performance as compared with the design requirements in the three degrees of freedom, namely, elbow bending, wrist rotation, and grasp. Different alternatives to the actuating switch (sock-type) design have been studied, to provide the toe-actuated input signals to be processed and manipulated by the controller. Investigations into incorporating additional myoelectric (EMG) signals into the present controller are being performed, so that an increase in degrees of freedom may be possible. This extension, which necessitates reliable filtering of noise and of interacting EMG and other signals, involves statistical modeling of the EMG signals. It is hoped that results from this approach, when complete, will facilitate reliable employment of EMG signals to provide two more noninteracting degrees of freedom.

Future work will concentrate first on the completion (including calibration and testing) of the prototype of the three-degrees-of-freedom toe-actuated controller with its actuators and linkages, and secondly, on the incorporation of EMG signals and their filtering to add two additional degrees of freedom to the prosthesis.

A System to Provide Physiologic Sensation from an Upper-limb Amputation Prosthesis

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This is the first year of a 3-year project for clinical research and development of a sensory feedback mechanism to provide an estimate of gripping force, consisting of an implanted RF receiver and median nerve stimulator. The apparatus is powered by induction to avoid percutaneous leads and is driven by an amplifier and transmitter mounted in the forearm of the prosthesis. The transducer is a strain gage either on the stationary finger of the terminal device or in series with the motivating Bowden cable from the shoulder harness.

A previous pilot study had suggested that this is a feasible approach, so the intent of this project is to apply the system to 10 below-elbow and five above-elbow amputees to determine consistency of response and applicability in daily use, and to perfect the apparatus.

Possible ancillary projects, which will be ongoing at the same time, are a trial of the system in lower-limb amputees and application of the apparatus in cases of irrevocable median-ulnar nerve palsy, and possibly in the quadriplegic.

Acceleration of Bone Healing by Electrical Stimulation

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The object of this new research program, begun in December 1972, is to develop practical clinical techniques for electrical stimulation of the healing of bone.

In the laboratory several investigators have demonstrated stimulation of the formation of bone and acceleration of fracture healing under the influence of specific types of electrical currents. Further investigation is necessary to confirm these findings and to bring a laboratory phenomenon to the level of an effective clinical tool. The problem is to develop an electronic implant system that will utilize minimal electric power to stimulate osteogenesis over a sufficiently large area to be of clinical value.

Initial experiments on a series of dogs will determine the effect of pulsed d.c. currents on the healing of large surgically created defects in the ulna, under carefully controlled conditions. The bone model selected is known to produce non-union consistently in mature dogs. Specially constructed implanted electronic circuits and electrode arrays will be employed in attempts to stimulate bone formation in these defects. These and later tests are intended to form a basis for eventual clinical trials on patients with established non-union and other bone defects that have been refractory to surgical treatment.

Additional studies on other modes of electrical stimulation are planned for the future.

Hemodynamic Evaluation of Postoperative and Preoperative Amputee

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Bok Y. Lee, M.D.

Since there appear to be no existing indepth studies of the progression of vascular changes in the remaining limb of the amputee, nor any detailed studies of the acute and chronic effects of a prosthesis and of drug therapy on this limb, a program has been established to develop hemodynamic profiles for postoperative amputees and preoperative amputee candidates. A hemodynamic profile consists of multiple limb-segment measurements of several blood-flow parameters, that is, pulsatile blood-flow waveforms, pulse pressure, and skin-surface temperatures, both baseline and in response to exercise.

The remaining limb of an amputee can be expected to manifest vascular problems. Thus, it is essential that the extremity be evaluated and,

if at all possible, a second amputation avoided. All patients who are to be fitted with some type of prosthetic or orthotic device are being evaluated from serial studies to determine those devices which are physiologically most appropriate for the individual patient. At the same time, information is being gathered which hopefully will aid in predicting the interactions between the patient and his prosthesis, the period of time a limb can be expected to remain viable, and the sites of expected changes as the disease progresses.

From a large population of patients with peripheral vascular disease who have had previous vascular procedures, those patients who have had a lumbar sympathectomy are being selected for further observation. Since lumbar sympathectomy produced denervated structures, which manifest supersensitivity to circulating neurohumors, the implications from this phenomenon for the amputee and his remaining limb are important. Observations are being made to determine the short- and long-term effects of this procedure on the remaining extremity.

All patients with vascular problems are screened in the Vascular Clinic, where a battery of vascular tests are done. Of particular importance is the use of a dynamic evaluation which includes blood-flow determinations before and after exercise, using electrical impedance plethysmography, Doppler ultrasonic flowmetry, and skin-surface thermometry and thermography.

Can an amputation be prevented? If methods for detecting early signs of vascular problems are used, the vascular status of the extremities can be evaluated early so appropriate limb salvaging measures can be instituted. Similar measures can be taken at later stages of the disease, and, again, the appropriate evaluation can lead to a decision for salvage of the limb. These integrated studies are new and much data are yet to be obtained. Continued observations may provide the empirical data to determine the critical points at which decisions must be made.

Several phases of the study have begun, and developments to date include the following:

1. Establishment of a program for evaluation of a new non-invasive electromagnetic flowmeter;
2. An initial trial of a computer program for analysis of electrical impedance waveforms;
3. A dynamic evaluation procedure as part of the testing of all vascular patients;
4. A critical review of all postoperative vascular cases to establish their current status;
5. A program to correlate clinical symptoms with the hemodynamic profiles; and
6. A vascular clinic for total work-up of all preoperative and postoperative patients.