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HIGHLIGHTS OF OTHER VA RESEARCH PROGRAMS

PROSTHETICS

Edited by

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Because the Committee on Prosthetics Research and Development/Committee on Prosthetic-Orthotic Education (CPRD/CPOE) is in a phaseout status no new projects were undertaken and no meetings of the Committee were held. The remaining staff of the Committee addressed itself to the task of completing a number of reports which had been pending.

Reports and Activities Completed:

Since the last Progress Report the following reports and activities have been completed:

Evaluation of the Ortho-Walk Type B Pneumatic Orthosis on 37 Paraplegic Patients.—This report has been designated as a Category C report (for general distribution) by the *Ad Hoc* Committee to review CPRD/CPOE reports. It has been distributed to sponsoring agencies, participants in the evaluation, and others interested in the subject. A number of copies remain available for further distribution.

Informal Papers of a Workshop on Control of Operating Room Airborne Bacteria.—This report was given a Category B rating (limited distribution) by the *Ad Hoc* Report Review Committee. It has been distributed only to sponsoring agencies and participants in the workshop.

Newsletter . . . Amputee Clinics.—The July 1976 issue, which is the last issue to be published by CPRD/CPOE, has been distributed. The American Academy of Orthotists and Prosthetists (AAOP) has requested that it be permitted to continue publication of the Newsletter under its sponsorship. Efforts are being made to effect the transfer of this activity to AAOP.

Reports in Progress:

Informal Papers from a Workshop on the Role of Engineering in Spinal-Cord Injury Programs.—Because the cost of printing this report in its original format greatly exceeded the amount budgeted, the report had to be redone. Some papers have been consolidated and some illustrations omitted to obtain a cost more in keeping with the amount allotted in the budget. It is ready to be sent for manuscript approval and will be printed and distributed shortly.

Final Report. — A Final Report of CPRD/CPOE activities is being prepared to be submitted to the sponsoring agencies.

Other Activities:

CPRD/CPOE staff continues to respond to requests for publications, reprints, or technical information. Each request is responded to either with a copy of the publication or reprint requested or, in the case of technical information, referral to another source.

Research and Development in the Field of Artificial Limbs

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Work on the Hydraulic Ankle Control System has been continued, with the highest priority involving test wearing by two amputees, one in Dayton, Ohio, and one in Arizona. Good progress has been made in several areas despite unexpected findings and the need for various design improvements. The findings and design improvements included the following.

1. The foot molds for the test amputees (sizes 9L and 10R) worked well.

2. The foam foot which evolved after various experiments with different foam compounds, mixing and pouring techniques, and reinforcement inserts in the shaft surrounding the lower shank, has stood up well so far in practical use.

3. The likelihood of the foot attachment screws inside the aluminum keel coming loose was greatly reduced by the use of self-locking HeliCoil inserts in the keel, by spot-facing the areas surrounding the screw holes, and by the elimination of nickel plating from the washers next to the screw threads.

4. The shank, including the extruded aluminum tubing and its attachment elements for the top of the hydraulic unit, worked well.

5. The amputees' reaction to the "feel" of the new foot was very favorable.

6. The hydraulic units proper worked surprisingly well without functional difficulties and without noises or noticeable wear and maintenance needs.

7. The most troublesome problem has been the need to eliminate various noises caused outside the hydraulic unit at the various contact points between it and the foot and shank attachment areas. Efforts which were only partially successful included experimenting with rubber compounds having different hardnesses and friction reducing additives, the use of Teflon coatings and Teflon film coverings, dry and conventional lubricants, and variations in the shape and configuration of the rubber elements used for noise absorption at the various interfaces. The efforts are continuing.

8. Good progress was made in the preparations for assembling the remaining nine hydraulic test units in a simplified and more economical manner by the use of improved measuring and machining methods and fixtures.

9. Good progress was also made in making foot molds in additional sizes for the upcoming VA tests with various amputees, by modifying existing old SACH foot molds. Molds of sizes 9, 10, and 11, L and R, are practically completed. Work on size 8 molds has started.

The preliminary studies on a simple Hydraulic Knee Control System for Geriatrics have been continued whenever time permitted.

No reportable progress was made with the Voluntarily Actuated Swing and Stance Control System. However, very good progress has been made with the Three-Part Knee Bolt. The experimental bolts incorporating the alternate approach provided in our contingency plans, (a special thread form) has been worn by an athletically very active (racquet ball playing) amputee since 25 February. Repeated inquiries—the last one on 6 July—confirmed that the screws had remained tight for over 4 months. This development is now practically completed except

for the replacement of the first generation bolts (standard thread form) in the field. Final drawings are being prepared.

Stump Stress Analysis

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Introduction

A flexible prosthetic socket, as compared to the conventional rigid socket, offers advantages in the distribution of static and dynamic loads. As developed previously (1, 2) a well-designed flexible socket will redistribute stresses within the stump arising from static and dynamic loading so as to reduce their contributions to soft tissue trauma. In particular, those shear stresses and stress-concentration zones inherent with rigid prosthetic sockets can be avoided through proper flexible socket design. Potential advantages of increased comfort and superior circulation characteristics are also foreseen for the flexible socket concept.

Modern efforts to produce flexible sockets have typically employed a two-part construction in which a relatively soft and flexible liner is placed in a rigid outer shell. To obtain the desired deflection under load, it is necessary that the inner liner be quite soft. In clinical use such systems suffer from large strain—one so large as to cause permanent plastic set or actual liner material migration after several months of use.

Another version of a two-part socket employs a somewhat stiffer liner in conjunction with carefully located holes or other selective local reliefs cut into the rigid outer shell. This concept entails bending deflections of the liner about the cutout perimeter to obtain the necessary large deflections. This system has been reported (3) in the case of below-knee sockets. However, application of a similar concept to above-knee sockets by this author (4) has not succeeded in clinical trials—numerous cracks of the liner developed within several months of use and total structural failures occurred on occasion.

The two-part socket presents additional difficulty beyond those given above—it is inherently more expensive to fabricate than the standard one-piece rigid socket. Given the technical and cost disadvantages associated with the flexible two-part socket, it appeared reasonable to investigate the feasibility of a one-piece flexible socket.

In the following, material choices for a hypothetical one-piece flexible

[a] Mr. Leon Bennett has joined the staff of the Research Center for Prosthetics as of September 13, 1976.

socket are considered. In particular, we are concerned with optimum resin-and-reinforcement combinations to be employed in conventional lamination procedures for fabrication of such a socket.

The essential material problem is one of absorbing large local strains repeatedly without failure, where failure is defined as material breakdown or distortion to a degree where the material, when freed of load, does not spring back to its initial unloaded position. The solution to the latter problem is one of avoiding the plastic flow region of the material; i.e., staying well below the yield point. The classic approach in so doing utilizes either inherently stiff materials, or thick sections of softer materials, to minimize stress. However, in this application the product requires a great deal of strain if it is to be functional; avoiding high stresses by preventing large strains undercuts the entire concept of a flexible socket. Within these conflicting requirements—a desired large strain to accompany a low stress—a difficult design problem exists. A further difficulty is that the product should last for roughly 3 years with continual use, a period equal to the typical life span of conventional prosthetic sockets. Within this time period many thousands of loading cycles must be sustained. In other words, fatigue considerations are highly significant.

Design Considerations

In a one-piece flexible prosthetic socket, fabricated using resin/reinforcement combinations and conventional lamination methods, the result is a laminated plastic composite, consisting of some type of filaments embedded in a matrix. This composite must withstand large deflections under cyclic loading. If we consider such a material under tension, the composite stiffness (Young's modulus) depends on the sum of the stiffness of the filaments times the area of filaments plus the stiffness of the matrix times the area of the matrix. Thus for a given matrix, we may control the composite stiffness by regulating the filament stiffness (chemical makeup) or filament area. Conversely, for a fixed filament contribution to strength, we may alter the matrix makeup or area.

The actual strength of the composite depends not only on the properties of the components, but on the matching of component properties. Specifically, should a relatively few strong filaments be placed within a large area of a soft matrix, the full potential of the matrix cannot be realized owing to failure of the filaments in strain well before the matrix. See Figure 1., in which typical stress-strain curves of filament and matrix materials are shown. Note that the filaments, as compared to the matrix, are able to accept a larger stress and smaller strain prior to failure. However, when acting as a composite, the strain of filament and matrix must be identical, or relative motion will occur. Thus the limiting strain

upon the composite (shown by the vertical dashed line) is that imposed by the filaments. It follows that, to achieve large composite deflections, it is best to choose filaments of modest or low stiffness. Recently developed materials such as carbon and boron filaments, which offer high stiffness values, are not useful in this context; older filaments such as cotton and nylon appear desirable.

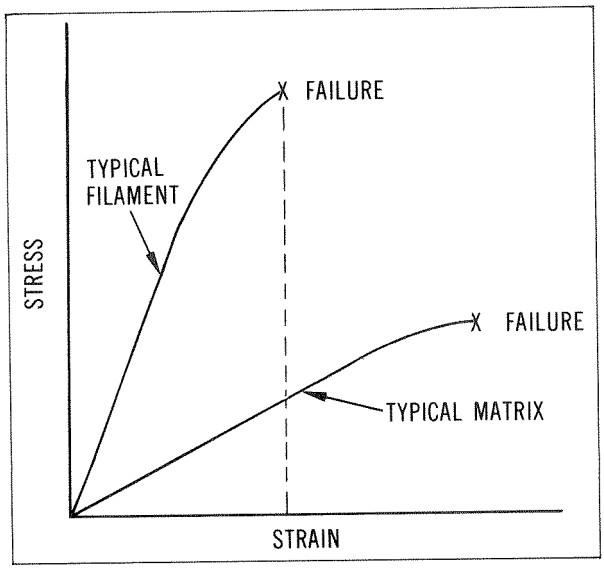

FIGURE 1. — Typical failure modes of filament and matrix elements.

In addition to the matching of filament and matrix materials in terms of mechanical properties, chemical matching is also required. The filaments must be properly "wetted" by the matrix so as to obtain sound bonds. Not only chemical affinity is involved; filament strand size and weave are significant factors. Chemical contamination (as from water or grease) is also a significant factor in determining the chemical affinity between the matrix and filaments. Also, as the product is ultimately to be fabricated in the field where quality control is uncertain, it is desirable that only slight laminating skill be required, and that there be tolerance for resin with outdated shelf life, and porous matrix compounds.

In other words, of all the elements involved in composite design, some are not under the control of the designer. Realistic compromise such as employing available materials and techniques are required to assure a practical end product. To proceed in this area, knowledge of the properties of sample composites fabricated under realistic field conditions is useful. In what follows, such results are considered.

Experimental Procedure

A series of composite laminates was fabricated using conventional prosthetic lamination methods and readily available materials. Test strips were cut from the laminates and subjected to large deflections for thousands of cycles. Observations of test strips for signs of failure followed. Details of this procedure follow.

Fabrication techniques followed conventional prosthetic practice utilizing PVA sleeves and vacuum pump resin injection. The mold (Fig. 2) is a simplified version of a prosthetic cast, fashioned with flat, tapered sides permitting the cutting of flat samples. Each test sample was cut 5 in. long, ⅝ in. wide, and cast about 0.1 in. thick.

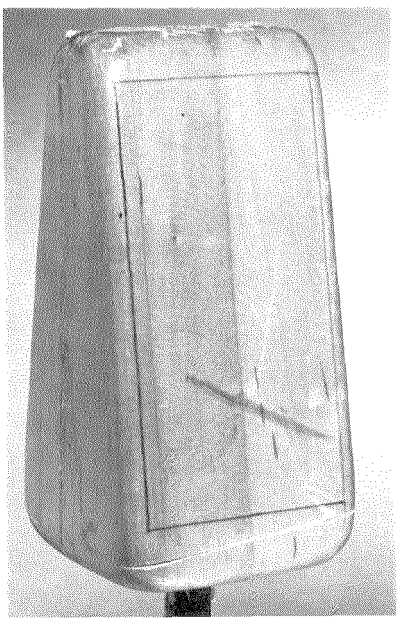

FIGURE 2. — The mold is a simplified version (in wood) of a prosthetic cast.

Once cut, the sample was inserted into a deflection apparatus (Fig. 3) consisting of a motor-driven cam capable of forcing the cantilevered specimen through a ¾-in. deflection at a rate of 10,000 cycles per hour. The low frequency was chosen to avoid problems of heat buildup within the specimen.

It is to be understood that only large-deflection characteristics are of interest in this work; a constant large-deflection loading system is more appropriate for our purposes than the usual constant loading system. However, should a specimen offer considerable stiffness, the stress level produced by a fixed deflection will be correspondingly higher than that

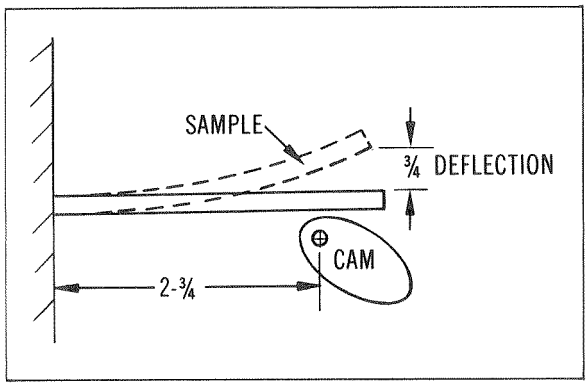

FIGURE 3.—Test apparatus. The motor-driven cam imposed a deflection of ¾ in. at a rate of 10,000 cycles per hour.

induced in a soft specimen. Indeed it can be shown that the stress level, for a fixed deflection of a cantilever beam, is directly proportional to the beam stiffness. Within this context, "strong" specimens may fail more readily than "weak" specimens.

Failure was defined to occur in two possible forms. The first involved cracking, splitting or shearing of the specimen. Extensive display of stress lines (whitening of filament strands) was regarded as a precursor to mechanical failure and considered as such. The second mode of failure was taken to consist of a large permanent set, creep or hysteresis, such that the specimen did not return to its initial position when loading was removed.

Results

All test results are given in Tables 1 and 2. Two basic types of plastic resins were employed in these tests: polyester resin, for which results are given in Table 1, and acrylic resin (in particular the Degaplast resin marketed by Otto Bock) for which results are given in Table 2.

The goal through testing has been to match the flexing characteristics of a conventional wooden tongue depressor, which on test produced no signs of failure or hysteresis during 50,000 cycles. This goal has not been met—no tested material matches the particular combination of fatigue resistance and elastic "springy" action under deflection offered by the tongue depressor.

A typical reinforced plastic under test is much less satisfactory. When it is compounded so as to flex readily, severe hysteresis usually results. When the matrix is stiffened the hysteresis is greatly reduced—however, stress cracks appear. For example, consider samples 1 and 2, Table 1. Both samples are alike in their reinforcing filaments, but slightly differ-

TABLE 1.

Sample Number	Resin	Reinforcement	Thick.	Load Cycles	Results
1	Poly 2/3 Flex	8 layers Poly cloth	.112	80,000	No cracks; hysteresis 60% deflection
2	Poly 1/2 Flex	8 layers Poly cloth	.103	145,000	Cracks both tension and compression sides
3	Poly 1/2 Flex	6 layers Acrylic cloth	.133	90,000	No cracks; hysteresis 60% deflection
4	Poly 1/4 Flex	5 layers Perlon Tricot	.100	50,000	Cracks tension side
5	Poly 3/4 Flex	8 layers Perlon Tricot	.129	—	Too soft; not tested further
6	Poly 1/2 Flex	5 layers Perlon Tricot		—	Too soft; not tested further
7	Poly All Flex	2 layers Dacron mat 3 layers Perlon Tricot	.192	400,000	Cracks on fabric side (compression)
8	Poly All Flex	2 layers Dacron mat 3 layers Perlon Tricot	.205	200,000	Cracks on fabric side (tension)
9	Poly 1/10 Flex	5 layers Perlon Tricot	.095	70,000	Cracks on tension side
10	Poly 1/2 Flex	6 layers Poly cloth	.120	150,00	Cracks on tension side
11	Poly 1/4 Flex	5 layers Perlon Tricot	.092	200,000	Cracks on tension side
12	Poly 1/2 Flex	8 layers Perlon Tricot	.152	180,000	Cracks on tension side
13	Poly 1/3 Flex	8 layers Perlon Tricot	.142	230,000	Cracks both tension and compression side; hysteresis 60% deflection
14	Poly 1/2 Flex	4 layers Nylon Stocknette	.088	100,000	Cracks on tension side
15	Poly 1/4 Flex	5 layers 10 oz. fiberglass cloth	.200	86,000	Cracks on tension side

TABLE 2.

Sample Number	Resin	Reinforcement	Thick.	Load Cycles	Results
16	Dega.[a] 1/2 Flex	6 layers acrylic cloth	.125	90,000	No Cracks; hysteresis 60% deflection
17	Dega. 2/5 Flex	6 layers Perlon Tricot	.130	320,000	Stress lines both tension and compression side; hysteresis 60% deflection
18	Dega. 2/5 Flex	7 layers Perlon Tricot	.110	200,000	Stress lines both tension and compression side; hysteresis 50% deflection
19	Dega. All Flex	Sandwich[b]	.162	—	Too soft; not tested further

[a] Degaplast Acrylic

[b] Sandwich (from outside towards inside) 1 layer Perlon Tricot, 2 layers fiberglass 10-oz, 2 layers fiberglass 24 oz, 1 layer Dacron mat, 2 layers Perlon Tricot.

cast in their matrix compounds. Sample 1 was cast of ⅔ flexible resin and ⅓ rigid resin, by weight, whereas sample 2 was cast of ½ flexible resin and ½ rigid resin. Neither survived the test period; the more flexible sample 1 succumbed to hysteresis and the more rigid sample 2 to stress cracks.

The stiffness of the composite can be varied by altering the filament form as well as matrix compound. Thus sample 3, employing acrylic cloth, lost stiffness, as compared to sample 2, despite the greater thickness of sample 3. The failure mode (hysteresis) is typical of a "too flexible" specimen. The introduction of another reinforcement material, Perlon Tricot, also lessened the stiffness of the composite as may be seen by comparing samples 2 and 6.

Despite the same matrix composition and similar total thickness values, the Perlon Tricot reinforced sample 6 is much softer than that prepared with polyester cloth (sample 2); indeed sample 6 is too soft to warrant testing. But when sample 6 was thickened through the addition of three additional layers, the resulting specimen (sample 12) was, it is believed, best-suited of all those tested. While sample 12 produced considerable hysteresis under test, the hysteresis values are the lowest consistent with absence of mechanical failure.

By greatly increasing thickness through use of a mat filler (samples 7 and 8), a 100 percent flex resin composite may be prepared offering useful stiffness. However, cracks do develop under testing. In both tested cases, the cracks appeared on the fabric side of the material, without respect to the nature of the stress on the fabric side; i.e., tension or compression. The means of failure apparently is one of relative motion between the relatively stiff fabric and soft matrix. This in turn implies that the bonding strength of the resin is unequal to the task, or that greater care to avoid chemical contamination (to water) must be exercised. The latter is felt to be unrealistic considering our precautions and the state of the art as currently practiced in the prosthetics industry.

Samples 6, 9, and 11 again demonstrate the sensitivity of the composite to the precise blend of matrix components. These samples are of essentially equal thickness and contain the same number of reinforcement layers (5 layers of Perlon Tricot). Sample 6, consisting of ½ flex resin, is overly soft to the point where it can not be tested. Sample 9 consisting of 1/10 flex resin is suitably stiff, but cracks readily as does sample 11 containing ¼ flex resin.

Sample 12 is viewed as the optimum composite construction. As compared to the group just discussed (samples 6, 9, and 11), sample 12 reflects an increase of thickness (more layers of cloth) and a soft resin mixture identical to sample 6. The effect of the soft resin is to inhibit cracking; the effect of the increased thickness is to increase stiffness. The only defect of sample 12 is the large hysteresis remaining after

testing. It is not clear whether the hysteresis is acceptable in terms of field use; it can only be said that sample 12 is best of all those tested.

Acrylic resins were tested in a short series (Table 2). It was hoped that by using matching acrylic cloth and resin (sample 16) the hysteresis problem would be reduced. The results do not support this expectation. Employing acrylic resin with assorted other reinforcement materials pointed to the same difficulties of cracking and hysteresis experienced with the polyester resin. As the acrylic resin seemed to offer no advantage, tests were limited.

In addition to the factors entered in Tables 1 and 2, there is another variable that affects all results — porosity. Unfortunately, porosity is difficult both to control and to measure. Therefore it is necessary to speak of its presence or effects in somewhat uncertain terms. It can be said that mechanical failures frequently originate in areas with local porosity and that a number of samples, rejected on the basis of porosity, proved to offer little fatigue resistance.

Porosity, in connection with polyester resins, was believed to arise largely in the mixing process via air bubble inclusion. By using smaller amounts of catalyst and promoter, it proved possible to prepare resins that hardened slowly. Such mixtures, after preparation, were set aside for 5 min. to permit air bubbles to rise to the surface. Only then was the resin poured into the lamination lay-up form. Some additional bubbles were produced by the act of pouring. When the resin was truly slow to harden (about 40 min) entrapped bubbles dissipated, usually into the vacuum line.

The same procedure with the acrylic resin proved less successful. Apparently, gas bubbles are sometimes manufactured in the process of polymerization. Such bubbles are quite small (about 0.016 in. dia.) and therefore move very slowly through the resin. Purging such bubbles from the gelling resin is difficult and likely to be impossible. The only practical means of solving this problem is to prevent the initial bubble formation.

The little information available on bubble formation suggests that such generation is occasional and is keyed to the chemistry of polymerization. Not only are the precise ratios of chemicals important but the total mass as well.

Discussion

Composite reinforced plastics capable of accepting large strain values repeatedly without failure are readily generated by conventional prosthetic processes, equipment, and materials. However, no tested material matched the flexion characteristics of a simple wooden tongue depressor. The optimum material choice of all tested composites (sample 12) remains inferior to the tongue depressor in terms of hysteresis

characteristics. Let us consider this point.

Wood is a particularly fatigue-resistant material. For practical design purposes the working stress is not influenced by fatigue considerations. In other words, if a wooden structure is able to accept a given load or strain once without failure, it will continue to do so for millions of cycles. Conversely, plastics tend to creep under load, becoming weaker and softer as either the applied stress or time of testing increases. When the applied stress approaches the yield point, as is the case in all tests described in this work, and is repeated for many thousands of cycles, a major creep strain or hysteresis is experienced by most plastics. While there are creep-resistant plastics, these tend to be epoxy and/or fiberglass-reinforced, and these have been ruled out owing to problems of skin sensitivity. For these reasons the tested plastics did not match the wooden specimen in terms of hysteresis.

It is conceivable that our testing rate (10,000 strokes per hour) tends to exaggerate hysteresis. Obviously no socket will be subject to so high a loading rate. Unfortunately, testing at true cyclic conditions will take years and is therefore not suited for mass test purposes. It is to be hoped that at least the optimum material design will be so tested.

As concerns a comparison between polyester and acrylic resins, it would appear that a suitable composite, subject to hysteresis limitations, may be prepared with either resin. However, our efforts with the acrylic stopped short of this goal owing to the presence of a number of practical acrylic disadvantages. These include a price roughly two-and-one-half times that of the polyester, the unsolved problem of bubble generation with the acrylic, and an odor that prosthetists seem to find objectionable. The only known advantage of the acrylic resin over the polyester is its capability to chemically bond to previously polymerized (cured) specimens. While the latter is a significant advantage, the disadvantages of acrylic (especially bubble formation) seem to outweigh the merits.

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A modular myoelectric system for the below-elbow amputee, featuring hook-hand interchangeability, has been completed. Commercial prototypes are under development. This system is shown in Figures 4 and 5.

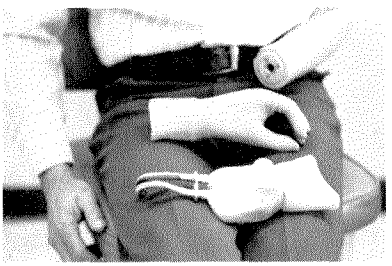

FIGURE 4. — Below-elbow myoelectric prosthesis with hook-hand interchangeability.

FIGURE 5.—Subject wearing a myoelectric hand and holding a hook replacement.

A laboratory model of a prosthesis with a myoelectrically controlled hand and a switch-controlled elbow for shoulder disarticulation amputees is under development. This prosthesis has three degrees of freedom of motion: elbow flexion-extension, pronation-supination, and prehension. The extended physiological proprioception (EPP) control principle introduced by Dr. David Simpson of Edinburgh, Scotland, is to be used with the prosthesis.

The Laboratory is cooperating with Rehabilitation Engineering Centers in the evaluation of lightweight prostheses for the below-knee amputee. This effort, which is the result of A. Bennett Wilson's work, appears to be an appropriate way to accelerate the movement of a new concept through the developmental stage and into clinical application. Five polypropylene prostheses have been fitted since active participation began.

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

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Research activities at the UCLA Biotechnology Laboratory during the reported period concerned the following areas: 1. Completion of design specifications for a microcomputer-based control system for an externally powered arm; and 2. Evaluation of design concepts for multichannel artificial sensory augmentation (ASAS) for an upper-limb prosthesis.

The tasks performed are part of a broad research program which is directed toward the integration of computer technology and advanced prosthesis control techniques into practical arm prostheses, to achieve an operational system for clinical application. A description of the work accomplished follows.

Microcomputer Control System

The microcomputer control system is directed to advance control capabilities in the three-degree-of-freedom UCLA/VA arm prosthesis. The arm, which was described in the progress report in BPR 10–25, will be controlled by an EMG pattern recognition system. The microcomputer will make a miniature control system practical in terms of size and weight. The EMG pattern recognition system has been developed, emulated and evaluated in a laboratory minicomputer (BPR 10–25), and has been found to be promising for practical prosthesis implementation. Design specifications for the microcomputer system have been completed, and program transition from the minicomputer to the micro system is in progress. Design of hardware-computer interfacing and packaging has been completed.

Several microprocessors have been evaluated for possible use in a microcomputer-controlled prosthesis. The major constraints on the choices were low power requirements and size restrictions. The RCA COSMAC 1802 microprocessor was chosen as best meeting these constraints. As a CMOS device, it has low power requirements and, due to its particular architecture, it requires less total additional circuitry, for the given application, than other microprocessors that were considered.

Development is to proceed in two concurrent and converging tracts. The software required to control the arm must be coded. It has been implemented on an INTERDATA Model 70, but must be written and coded for the 1802 microprocessor. This will be done using the COS-

MAC Development System (CDS), a COSMAC 1802 based microcomputer system specifically designed by RCA for use in program development. At the same time, the prototype prosthesis microcomputer system (for stand-alone patient use) will be built from discrete components (e.g., the microprocessor chips, A/D chip, RAM IC's etc.). Software for the prototype system initially will be debugged and tested on the CDS system, and later transferred to the prototype system for additional testing.

Prototype software will consist of: 1. an input routine to read EMG electrode signals; 2. a decision algorithm to generate arm control signals; and 3. an output routine to use the control signals in driving prosthesis motors.

Prototype hardware will consist of:

1. COSMAC microprocessor. The prototype will use RAM memory to allow program changes, if necessary, but most of the RAM memory can be replaced by ROM (to reduce system size).
2. Input circuitry (A/D convertor for EMG electrode inputs and related circuitry).
3. Output circuitry to provide signals to motors for clockwise, counterclockwise, or no rotation.

The next several months will be devoted to building and testing the prototype system. The system packaging concept has not yet been finalized. It is anticipated that the initial electronic package will be the size of a pocket calculator. Upon prototype functional evaluation, additional effort will be expended to reduce the physical size of the system.

Sensory Feedback Studies

Studies of the feasibility of electrotactile, frequency-modulated, two-point discrimination as a design concept for a multi-channel artificial sensory augmentation system (ASAS) for an upper-limb prosthesis are in progress. Work on the two-point discrimination threshold (TPDT) is necessary in order to develop a clinically feasible system directed toward sensory communication replacement. This work is directed toward the evaluation of the effect of stimulation parameters (such as frequency, distance between electrodes, and body location) on the information content and the reliability of perception (BPR 10–25). Current efforts focus on extensive experimental work which has thus far revealed the following:

a. TPDT varies as a function of frequency over a range of 0–100 pps (pulses per second).
b. There exists an absolute minimum TPDT (MTPDT) at a specific frequency.

c. The value of the minimum TPDT, or MTPDT, is a function of body location, but the frequency at which it occurs is the same for all body locations of the same individual.
d. The frequency at which TPDT is at a minimum (F_m) is different from subject to subject.
e. The MTPDT for a given body location is different for different individuals, i.e., MTPDT at the middle fingertip of one individual is not the same as the MTPDT at the same location of another individual.
f. The sensitive band width (SBW) is different for different individuals, but is fairly consistent for various body locations on the same individual.
g. In several subjects, the existence of a second critical TPDT (STPDT) with its corresponding frequency F_m has been observed.

In addition, three stimulation codes were tested to determine the most appropriate code in terms of optimization of discrimination, information transfer, and display size: *the spatial code* used synchronized pulses at both electrodes; *the temporal code* used 180-deg phaseshift between the pulses at the two electrodes; *The frequency-on-frequency (FOF) code* introduced a 5-pps train at one electrode while the second electrode delivered pulses over the range of 0–100 pps. Comparison in TPDT showed that the FOF code was superior to the temporal code while the spatial code followed in third place.

Further studies are planned to determine appropriate body locations for such a display, differences in contralateral body parts, and the relationships of ascending and descending thresholds.

Design of Prosthetic and Orthotic Devices and Biomechanical Studies of Locomotion

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Design of Lower-Limb Prosthetic and Orthotic Devices

1. *UC-BL Four-Bar Polycentric Pneumatic Knee*

Favorable VAPC test results were obtained on five subjects wearing the Four-Bar Pneumatic Knee. These units were praised for ease of walking over a range of speeds, for an unusually large flexion angle, and

for attractive appearance. Some minor structural problems, as well as difficulties with fitting cosmetic covers, were noted. Design revisions have been completed to correct the structural problems, to adapt the unit to 35mm (1⅜ in) pylon tubing, and to simplify manufacturing. Figure 6 illustrates the nature of these revisions.

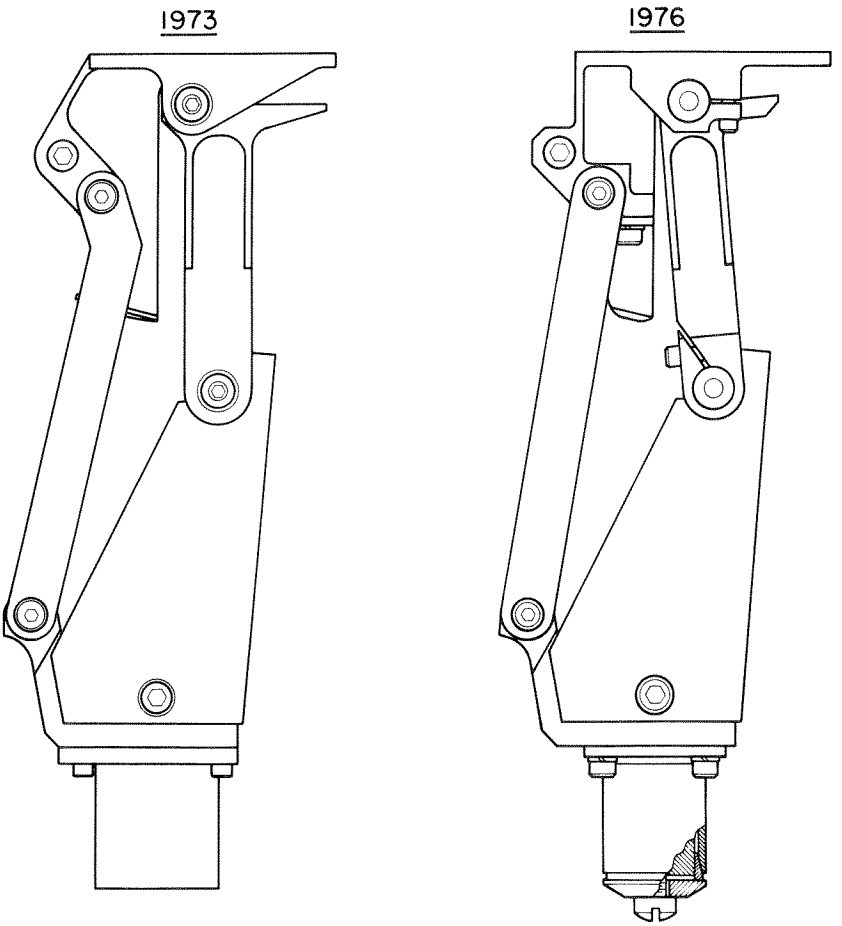


FIGURE 6.—The UC–BL Four-Bar Knee has been revised, in the 1976 version, to accept 35 mm pylon tubing and to simplify manufacturing.

2. *UC-BL Six-Bar Knee-Disarticulation Prosthesis with Mechanical Swing-Phase Control.*

As shown in Figure 7, the unit is smaller, lighter, stronger, and easier to make than the one equipped with pneumatic swing-phase control. Although it is somewhat less effective in swing-phase control than the pneumatic unit, it is superior in these characteristics to conventional

single-axis knees. Good cosmetic treatment has been achieved with one-piece and two-piece cosmetic covers. The two-piece cover with elastic stocking is shown in Figure 8.

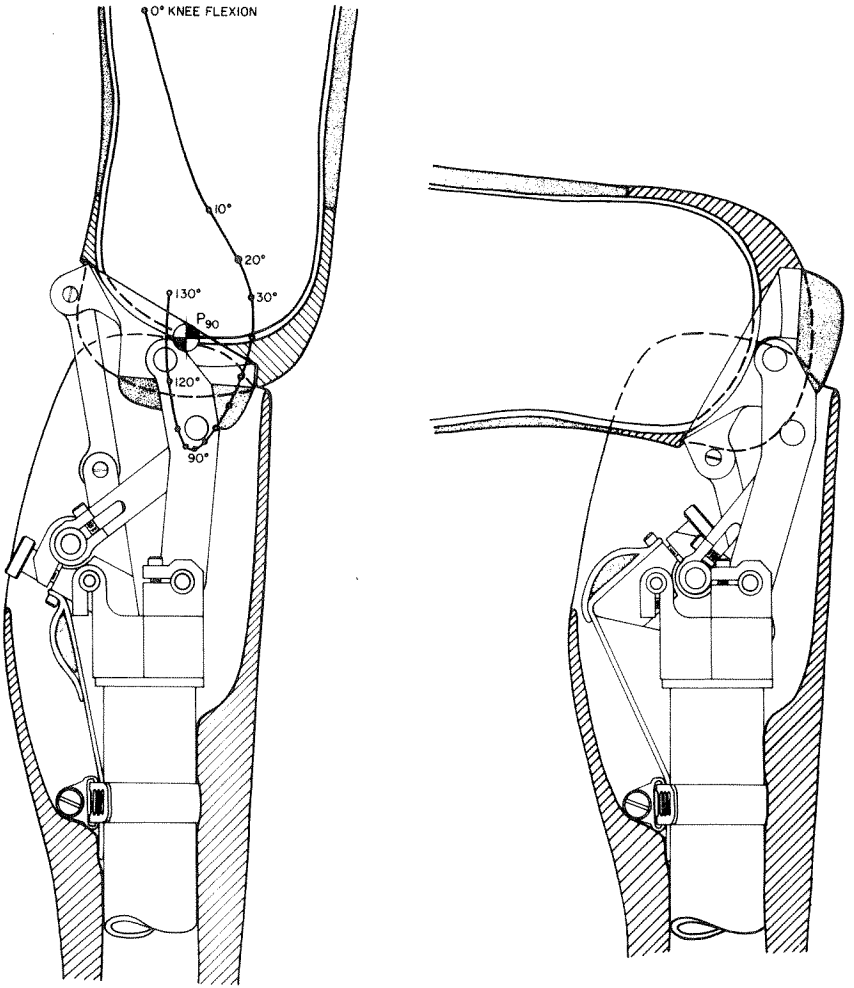


FIGURE 7.—Linkage layout of the UC–BL Six-Bar Polycentric Knee, with friction swing-phase control, for knee disarticulation amputees.

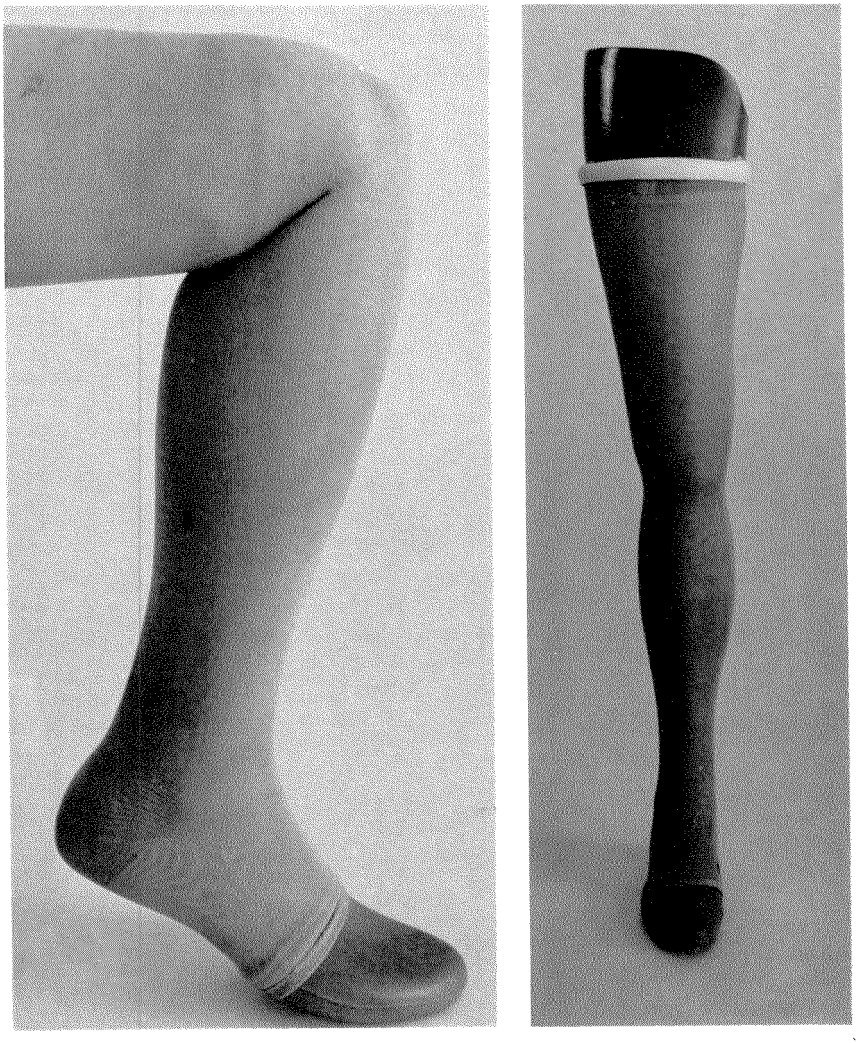


FIGURE 8.—Friction Six-Bar Knee with two-piece cosmetic cover plus elastic stocking.

3. *Design of a SACH foot with Metal Keel*

Strength tests of prosthetic legs have shown that the coupling between foot and shank is often the weakest part of the limb and is bulky as well, complicating cosmetic treatment and adding extra mass to the distal part of the limb where it is most objectionable. In order to increase strength and reduce both size and weight, an aluminum keel was designed to replace the conventional keel in a molded SACH foot (Fig. 9). An inverted channel serves as the main structural member of the keel and

transmits the loads to the foot from the pylon via an internally expanding coupling. At the distal tip of the keel, load is transferred through a shaped solid block of rubber for cushioning and allowing some inversion and eversion.

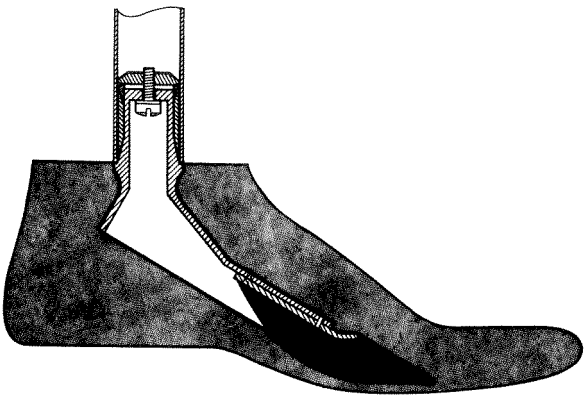


FIGURE 9.—Construction details of the metal-keel SACH foot with integral pylon coupling.

4. *Friction Stabilized Knee.*

A knee unit of this type has been designed and constructed (Fig. 10). This unit, like the Otto Bock Modular Knee and the Kolman Safety Knee, uses the direction of the ground reaction to control knee stability. The brake is actuated at heel contact when the load line is along P as shown in Figure 11 and is automatically released at toe-off when the load

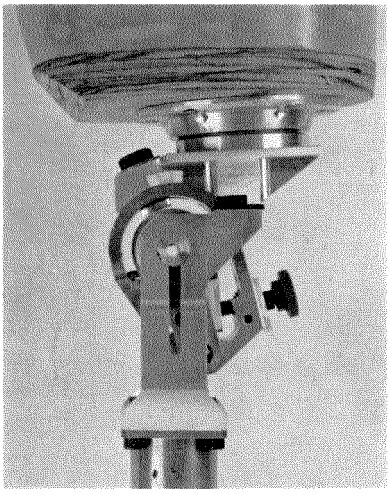


FIGURE 10. — Prototype friction-stabilized knee.

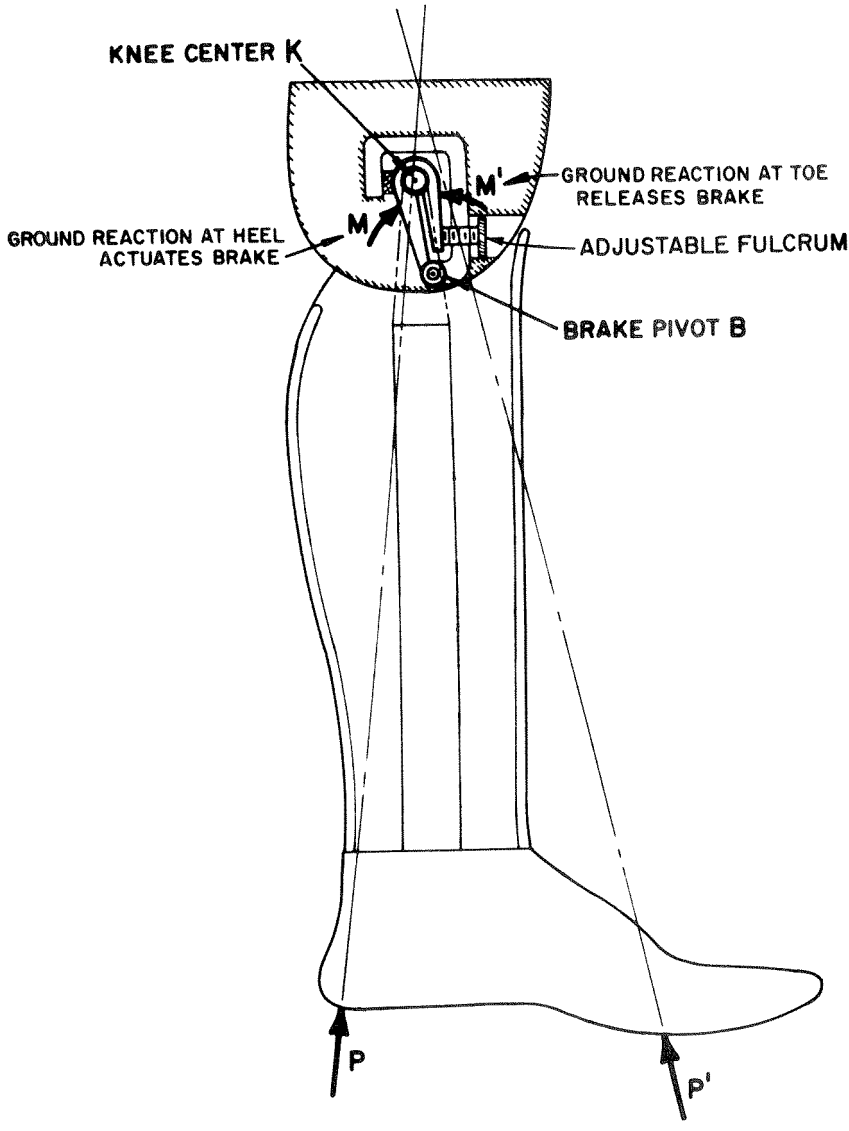


FIGURE 11.—Functional features of the friction-stabilized knee.

line is oriented along P. Although the unit did provide a useful amount of friction at heel contact, and the brake released properly at toe-off the brake reactivated when the knee was flexed under load. This relocking prevented the desired smooth entry into swing phase. A redesign of this knee unit is currently being undertaken to eliminate this problem.

This type of unit should be particularly useful to the geriatric amputee because it can be developed as a light-weight modular device.

5. *Fabrication and Preliminary Test of PRAHN Wheelchair.*

The first seven preproduction PRAHN (Powered, Reclining, Adjustable-Height and Narrowing) wheelchairs (Fig. 12) underwent their final inspection in April 1976. One of the chairs has been tested extensively at Berkeley, first by one of the project staff members, who commuted half a mile to work in the chair 3 days a week from November 1975 to February 1976, then by a disabled person from February to May 1976.

FIGURE 12.—Six of the seven preproduction PRAHN wheelchairs, showing the range of positions.

During the tests the chair was driven hard over fairly hilly terrain. It has proved to be fast, maneuverable, comfortable, rugged, and flexible during general daily activities and patient transferring. These tests on the chair at Berkeley uncovered minor design and fabrication problems which were corrected on all chairs. Many improvements were added to the chair, including limiting the speed of the chair as it moves to the high position, and the provision of lateral foot restraints, strong adjustable joystick box mounts and switch handles, a refined recline linkage, and manual parking brakes.

6. *Spring Suspension Bolt-on Powering Unit*

A chain driven, relatively high-powered bolt-on powering unit for an E & J (Everest and Jennings) manual wheelchair frame has been designed and built. Initial tests in Berkeley have shown excellent speed and

hill climbing ability, a range in excess of 20 miles, and a marked increase in comfort provided by the unit's spring suspension. The unit is being refined into a form suitable for production.

Biomechanical Studies of Human Locomotion

1. *Gait Dynamics.*

One of the main objectives of the Locomotion Laboratory is to make available reliable comprehensive kinematic data for studies of the mechanics of walking. Such studies are useful for improving diagnosis and repair of locomotor disabilities. Progress has been made in several areas related to human gait dynamics, and particularly regarding energy exchanges in the body.

a. *Energy Optimization in Gait.*—Relationships expressing metabolic cost as a function of speed alone are incomplete because they describe only the free walking pattern characterized by freely selected step rates at prescribed speeds. A general metabolic energy relationship incorporating both the step length and step rate has been derived on the basis of extensive testing of one subject. The condition of minimal energy, as predicted from the equation, requires that the step lengths be proportional to the step rates.

Tests on seven male subjects indicate that if the subjects are given the choice, they unconsciously adopt the step rate that results in minimal energy expenditure; forcing them to walk at any other step rate results in increased energy expenditure. It is expected that the optimization criteria that govern normal walking also govern pathological walking; however, the resources that can be used to satisfy the criteria are different.

b. *Computer Generation of Gait Kinematics.* — The system of measurements in the laboratory defines only the absolute position of the trunk in space. The position of each lower-limb segment is determined relative to the segment proximal to it. It is therefore necessary to convert the relative displacements into absolute form suitable for further dynamic analyses. A general program has been written to compute absolute motion data from internally stored harmonic coefficients. To simplify use, the program was designed so that the user need supply only six parameters identifying the desired gait variables.

c. *Energy Level and Power of Body Segments.* — Generated absolute kinematic data were used to compute the energy levels of body segments, as well as the body as a whole, for several walking speeds and at step rates chosen by the subject (Fig. 13, 14). The corresponding average positive mechanical power is computed by differentiation of the energy

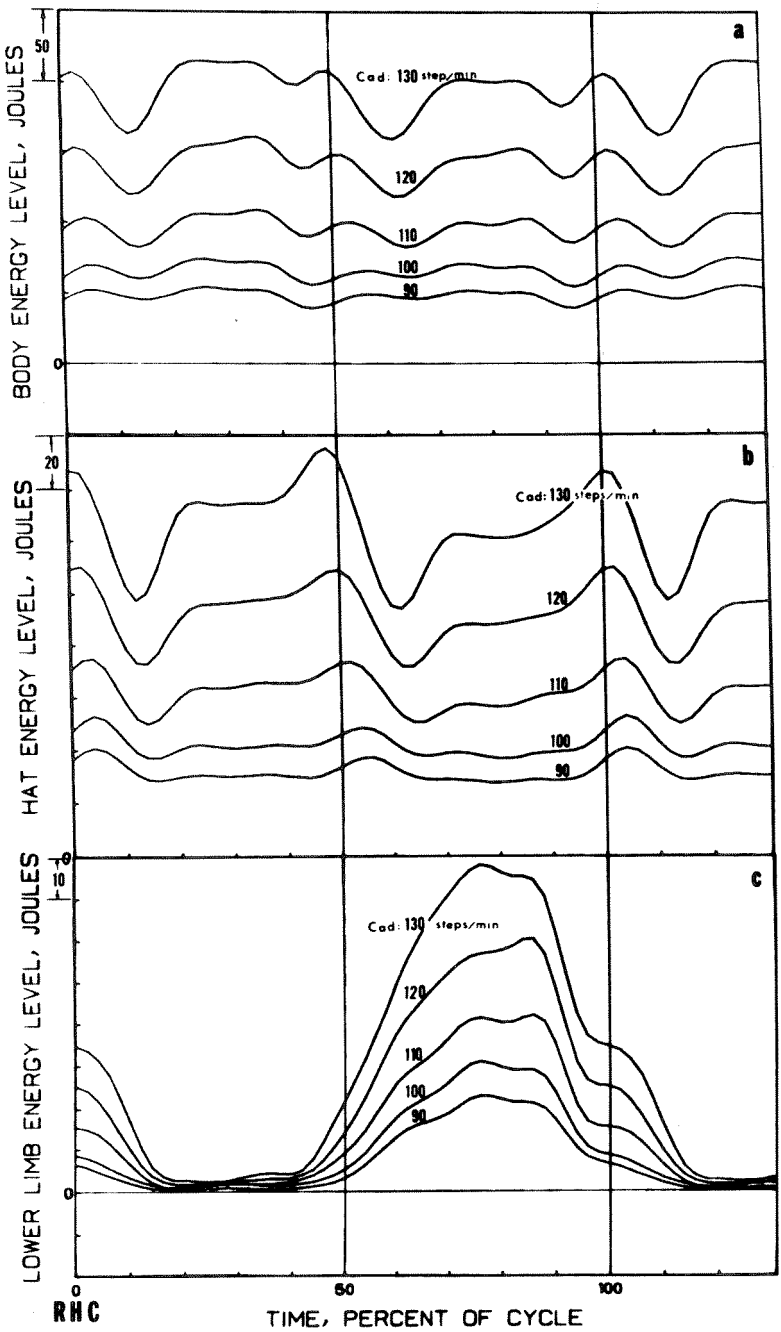
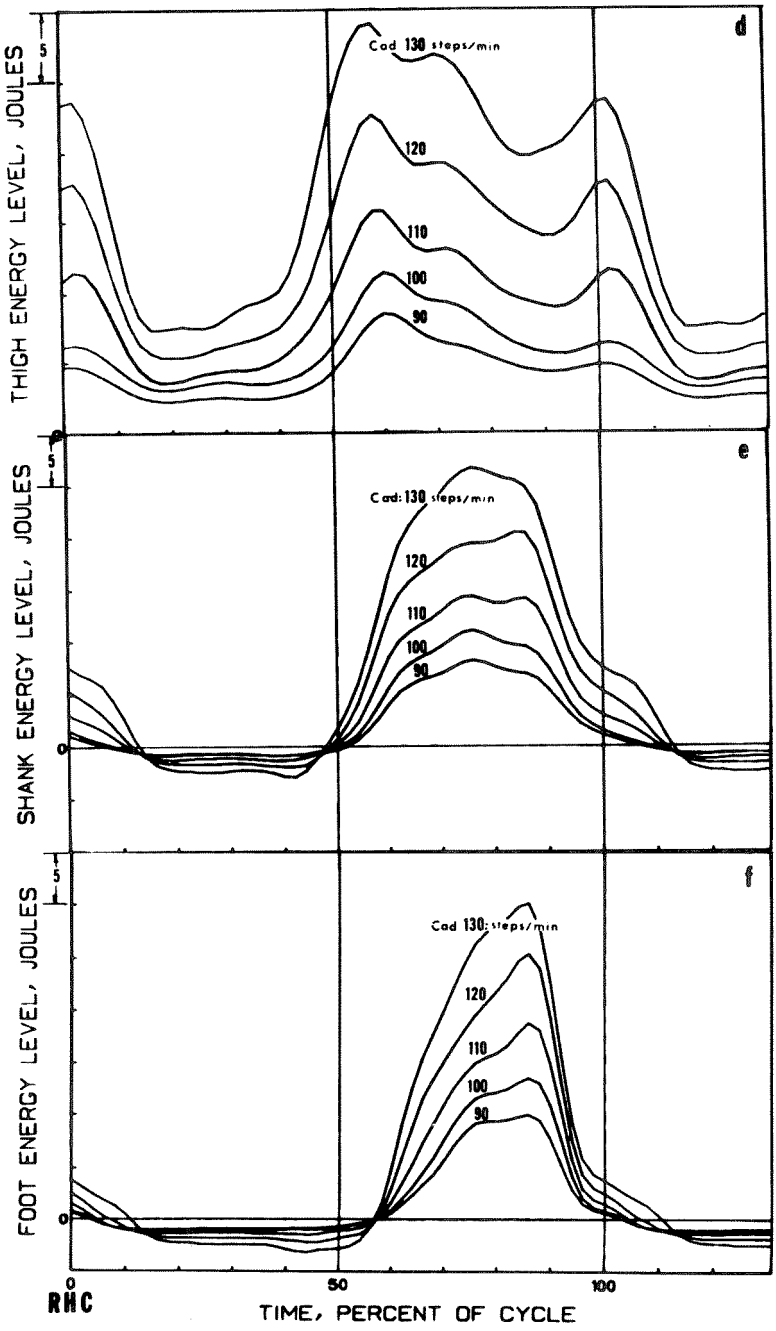


FIGURE 13. (above) and 14. (right)—Energy level of the body and its components during treadmill walking with freely chosen step rates (cadences) at prescribed speeds.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RHC
TIME, PERCENT OF CYCLE

FIGURE 14.

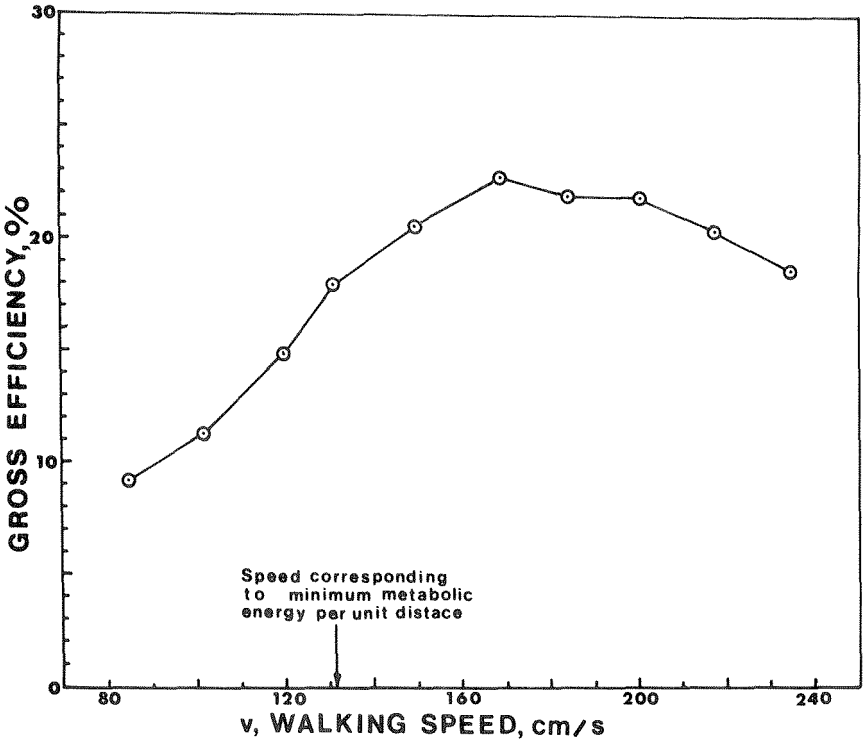

FIGURE 15.—Gross efficiency variation with speed in free walking.

level. The power requirements of the body as a whole are compared with metabolic energy expenditure to arrive at the gross mechanical efficiency of the body as a function of speed or step rate. It was found that the gross mechanical efficiency of free walking increases rapidly with speed in the low speed range up to 172 cm/s, where the efficiency reaches a maximum of 22 percent (Fig. 15). Thereafter, it decreases slowly with speed.

When several step rates are forced at a constant prescribed speed (forced walking), the average power requirements of the body remain essentially constant at the level associated with the free step rate, for the prescribed speed. Maximal efficiency is nevertheless obtained when the step rate is selected freely (Fig. 16).

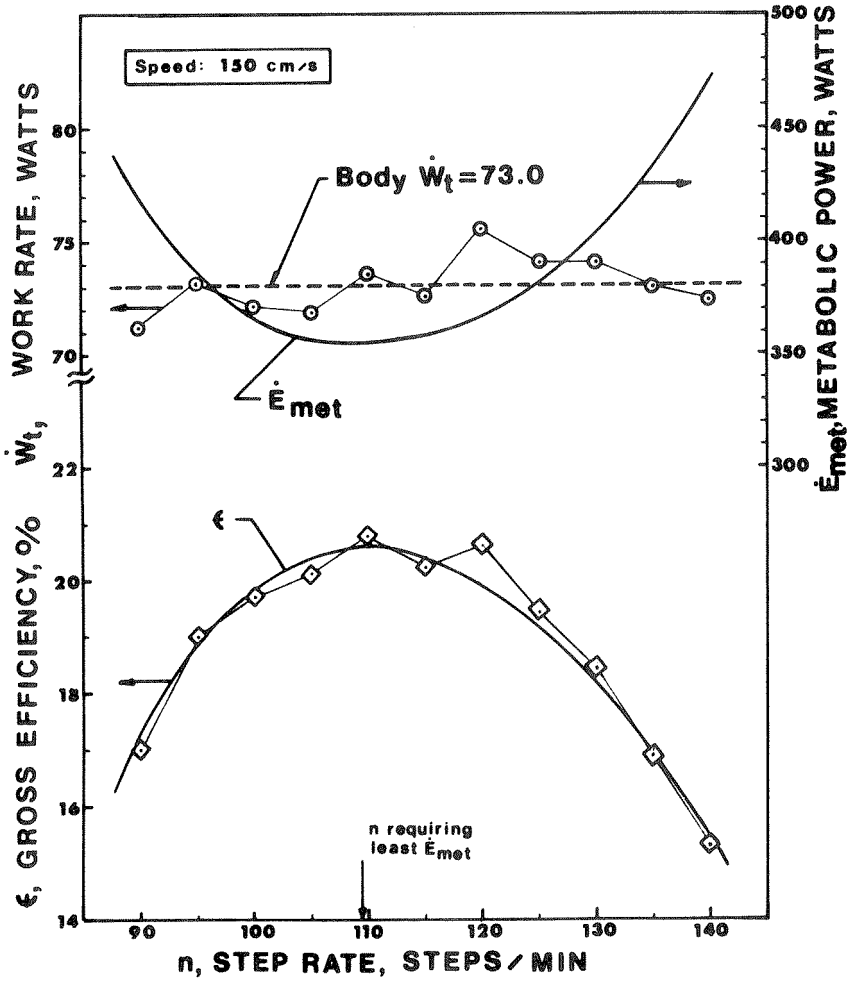

FIGURE 16.—The relationship between average positive work rate (W_t), metabolic power ($\dot{E}_{met}$), and efficiency (ϵ) and forced step rate (n) at a constant speed.

d. *Kinematic Prediction of Joint Loads and Power.* The forces between the feet and the ground are computed from absolute kinematic data. The moments and the forces in the joints of the right lower limb are determined from the computed ground forces and compared with published results. These loads compared well with the published results determined on the basis of force-plate data. The power requirements of the joints are calculated from the angular velocities of segments and the computed joint moments (Fig. 17). The power in both lower limbs is added to obtain the power supplied by the joints to the body as a whole. These are in turn compared with the power required by the body as

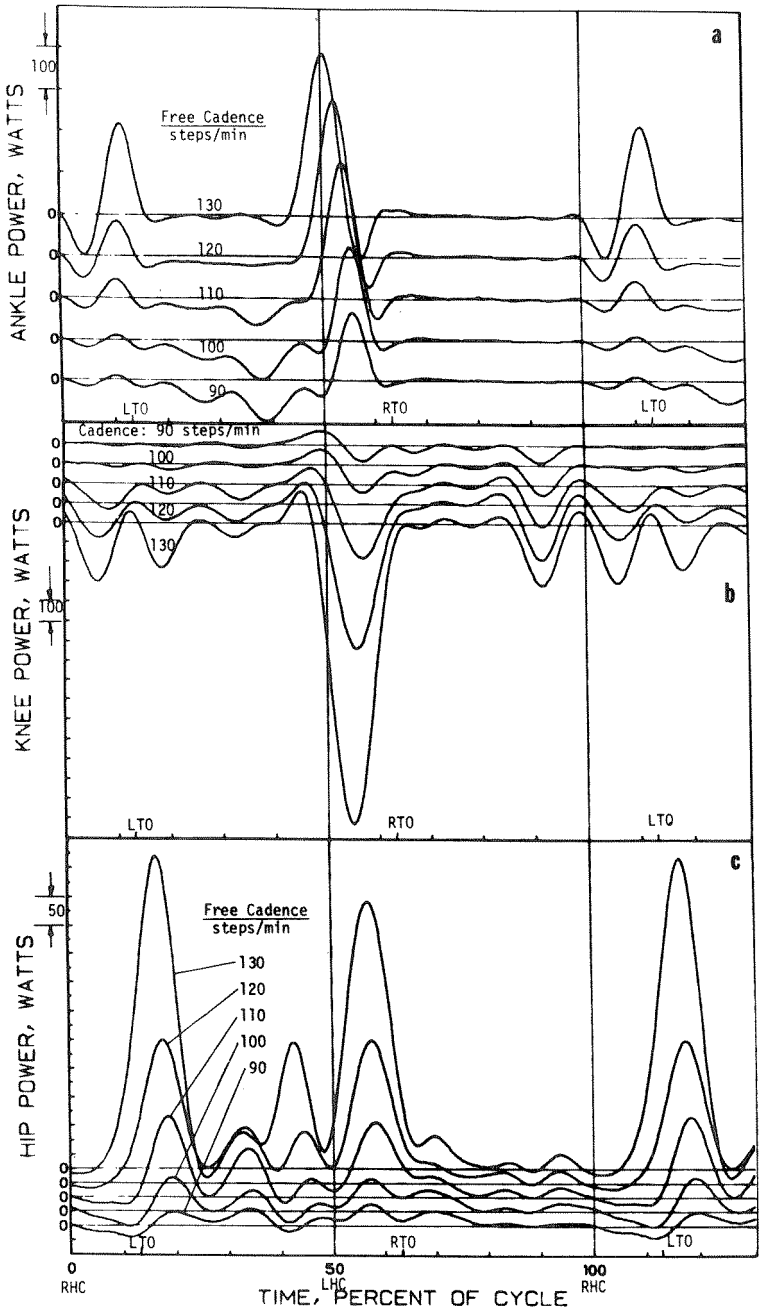

FIGURE 17.—Power in the joints of the right limb in walking at several free step rates.

computed from energy levels. Excellent agreement was obtained between power supply and demand.

Immediate Postoperative Prosthesis Research Study
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Controlled Environment Treatment

The Prosthetics Research Study continues to evaluate the Controlled Environment Treatment Device as an alternative to the Immediate Postoperative Prosthetic Technique of managing below-knee amputations. CET allows visual inspection (Fig. 18) of the surgical site and regulates the pressure, temperature, sterility, and humidity within the wound environment, thus providing a more accurate control of the healing process.

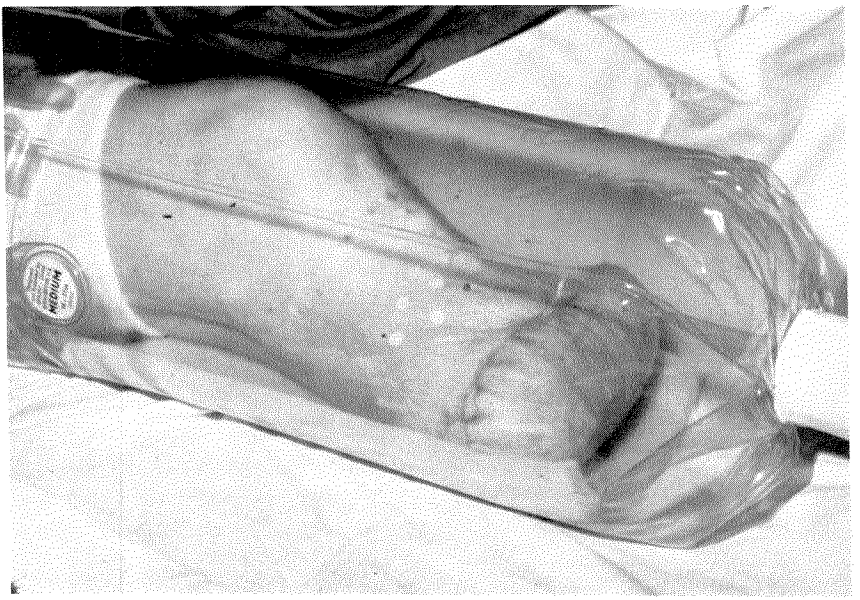

FIGURE 18. — Immediate postsurgical below-knee amputation in CET chamber (Controlled Environment Treatment Device).

[illegible] which began in 1971 under the auspices of the Biomechanical Research and Development Unit, Roehampton, England, now includes 29 cases.

On May 15, 1976, a meeting was held at Prosthetics Research Study to evaluate the effectiveness of Controlled Environment Treatment. Attending were representatives from VA Prosthetics Center, New York, and investigators from all CET Trial Centers: Rancho Los Amigos Hospital, Downey, California; San Francisco VA Hospital; Castle Point VA Hospital, New York; Duke University Medical Center, Durham, North Carolina; and the Biomechanical Research and Development Unit, Roehampton, England. A forthcoming report of this meeting will cover results and recommendations from this last year's CET trials.

During the next quarter, Prosthetics Research Study will write a CET operator manual, which will include suggestions from all of the Trial Centers.

We are now involved in the Phase II protocol of the CET study; the results of the Phase I study are now being published. Phase II protocol requires that study patients undergo Xenon 133 Skin Blood Flow testing prior to surgery. Comparison of flow values in IPOP and CET groups will eventually indicate whether or not CET is helpful as an aid to circulation in the amputated limb.

Overall results of the Controlled Environment Treatment technique have been encouraging at all Trial Centers; postsurgical pain and edema, as well as wound healing, have generally responded well to this mode of treatment. Further proposed studies of CET efficacy in edema control are being coordinated by Prosthetics Research Study with the University of Washington Department of Orthopaedics. At that facility, Dr. F.A. Matsen, III, M.D., plans to derive an animal model system in which the CET can be evaluated.

During the last 2 quarters, Prosthetics Research has continued to function as a center for coordinating and retrieving CET trial data. Much time has also been spent by the staff to obtain supplies for the CET Trial Centers and to sort out equipment problems by mail and by telephone.

Preamputation Level Determination and Skin Blood Flow Research

Skin blood flow studies, as they relate to level determination and ultimate wound healing in the field of below-knee amputation surgery, continue at the Prosthetics Research Study through a research program coordinated with the University of Washington, Department of Bioengineering.

Since February 1975, 11 patients have undergone testing which involves preoperative and postoperative injections of Xenon 133 at selected sites in the ischemic limb. The gamma radiation of the Xenon

133 is externally detected with a scintillation counter; the rate of skin blood flow is then computed from the initial rate of the Xenon 133 disappearance.

Since January 1975, skin blood flow studies have been carried out in conjunction with the Phase II Evaluation of the Controlled Environment Treatment Device. Both trial (CET) and control (IPOP) groups have undergone Xenon 133 testing to provide a basis for comparison of flow values as they relate to level of amputation, mode of postoperative treatment, healing time, presence or absence of complications, and the need for surgical revision. We plan to collect 20 to 30 cases under the Xenon 133 program as a minimum statistical figure for comparison with similar studies throughout the world.

During the last quarter, in conjunction with G. Allen Holloway, Jr., M.D., Principal Investigator of the Xenon Skin Blood Flow Studies at the University of Washington, we have undertaken the Laser-Doppler measurement of cutaneous blood flow, as reported and developed by Dr. Holloway. The Laser-Doppler Device evaluates the Doppler frequency shift of laser light reflected from red blood cells moving through cutaneous vessels; this frequency shift is proportional to the red blood cell velocity. Initial feasibility studies have shown correlation with the Xenon 133 clearance technique, and it is estimated that within 3 to 4 months the Laser-Doppler Device will be available for regular use in conjunction with Xenon 133 testing.

Investigators throughout the world are interested in similar laboratory indices of blood flow in ischemic limbs, relative to amputation levels. Studies of leg blood pressure by Doppler ultrasound are examples of currently reported techniques. Correlation of these techniques with our investigative studies, including pO_2 skin uptake, will significantly increase our understanding and knowledge of skin blood flow in the ischemic limb and its relationship to clinical amputation level healing.

Functional Electrical Stimulation

The Electrospinal Instrumentation for spinal curvature has been used on one patient to date, with a second patient scheduled for surgery on August 16, 1976. We continue to work closely with Medtronic, Incorporated, in furthering design of this experimental device.

The Pain Abatement Study, using transcutaneous stimulation in amputees, is now entering its third year, and publication of our accumulated results to date is pending. The critically developed pain protocol, which we use in this study, has been forwarded to a number of pain treatment centers at their request.

Osteogenesis. — The use of external electrical energy for osteogenesis

has been discontinued at Prosthetics Research Study, pending further animal investigations.

Functional Electrical Stimulation in Rehabilitation.—Prosthetics Research Study has been conducting a feasibility study of the use of Functional Electrical Stimulation for rehabilitation of patients with nerve and muscle damage. To date we have treated eight cases with varying degrees of muscle control problems. With this experience behind us, we are now setting up specific protocols for use of Functional Electrical Stimulation for active rehabilitation. The patients' functional capabilities will be evaluated by both the physical therapist and the engineer. Specific modalities for electrostimulation will be decided; the treatment will be on an outpatient basis. At predetermined intervals, the patients will be seen at Prosthetics Research Study for followup evaluations.

Functional Capabilities Study

A retrospective study of 300 amputees is being done in an attempt to determine functional levels achieved. Questionnaires are completed either by mail, telephone or personal interview. Our goal for assembling these data is October 1976.

PRS-Moore Load Cell

As previously reported, the PRS-Moore Load Cell is still being used on all patients. A few units have been loaned to selected centers for evaluation. Reports to date have been very favorable.

Multi-Leg Attachment Device

Many of our younger, active, below-knee amputees wish to maintain an active sports life after amputation. Because of the added expense of a sports-oriented prosthesis, many amputees are not able to participate to the full extent of their capabilities. We are working on an attachment device which would allow one socket to be used with a number of foot units. In this way an amputee could have a regular walking leg which could be switched with a special sports leg by changing only the lower unit. This device is now in the design stage; one prototype has been fabricated.

Physiological Suspension Study

As of this time, all photogrammetry drawings have been received on the patients being carried on this study. The target date for completion

of Phase I of this study is October 15, 1976. Included in the study is the ability to obtain a cross-sectional view of a below-knee residual limb in the prosthetic socket via a delta scanner (Figs. 19 and 20).

Seattle VA Hospital Amputee Service

The Prosthetics Research Sudy staff continues to direct the inpatient and outpatient amputee service at VA Hospital, Seattle, where 31 major amputations were performed during the first 6 months of 1976 and included in our research work. The hospital provides the base of clinical material for investigations.

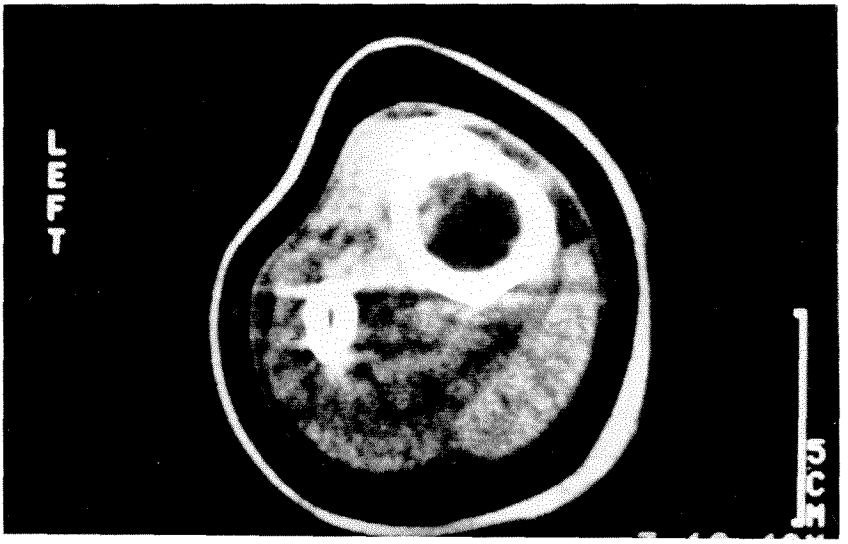

FIGURE 19.—Cross section of below-knee residual limb in prosthetic socket viewed with delta scanner.

FIGURE 20.—Placement of reference points on below-knee residual limb prior to photogrammetry technique in physiological suspension study.

Below-Knee Amputation with Immediate Postoperative Fitting of Prosthesis

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San Francisco, California 94121
Wesley S. Moore, M.D., Albert D. Hall, M.D., and Leigh A. Wilson

The Prosthetics Research Program at the VA Hospital, San Francisco, California, is continuing to gain experience in a randomized study comparing conventional immediate postoperative prosthetic management (IPPM) with the Controlled Environment Treatment Unit (CET) in the management of lower-limb amputation.

Validation of the use of Xenon 133 clearance, as a means of appropriately selecting an amputation level that has an adequate blood supply to provide for primary healing, continues. In addition to studying patients at the B-K level, Xenon clearance is being used to look at levels more distal. The Xenon is now being used in a prospective rather than a retrospective fashion.

We have recently reviewed this program's total amputation experience, particularly in regard to appropriateness of level selection and longterm followup. This information has been compiled and is being prepared for publication.

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

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Silver Spring, Maryland 20910
Woodrow Seamone and Gerhard Schmeisser, Jr., M.D.

During the first half of 1976, research at Johns Hopkins was primarily focused on investigation, modification, and evaluation of patient control interface with the externally powered medical manipulator. In addition, by prior agreement, a second entirely new externally powered medical manipulator with work table was completed and delivered to the Castle Point Veterans Administration Hospital for evaluation by VAPC. Construction of a third unit was also undertaken, for future evaluation at the Veterans Administration Hospital, West Roxbury, Mass.

Observation of the clinical performance of externally powered upper-limb prostheses, previously fitted as an activity of this research effort in previous years, was continued.

The improved powered orthosis for a flaccid elbow described in BPR

10–25 was delivered by request of VAPC to that facility in New York in December 1975. As with the two manipulators mentioned above, evaluation of this unit was thereby also placed outside the jurisdiction of the Johns Hopkins Research Group.

Powered Medical Manipulator

The objective of the powered medical manipulator development is to study the practicality of, and determine the possible role(s) of, a worktable-mounted manipulator in the rehabilitation of a high-level quadriplegic or severely disabled person. The basic concept and early clinical experience have been described in the BPR 10–23, 10–24, and 10–25 issues.

After about 150 hours of manipulator use at the Maryland Rehabilitation Center by a middle-aged male quadriplegic person with a total neurological deficit below C-4 (who was mobile in an electric wheelchair and skillful with a headstick) it was recognized that the manipulator reached its maximum ease of operation, efficiency and usefulness when integrated into a worktable arrangement with appropriate vocational tools. It was also recognized that these tools must be spatially oriented and secured to the table with great care to minimize necessary motions in the operation of this equipment. The patient's performance with the system was optimal when the equipment was arranged to exploit skill which the operator already possessed, rather than attempting to replace this skill with the manipulator.

An important feature of the manipulator is its ability to bring work materials and tools within comfortable range of the head (or mouth) stick, and to position and secure these materials or tools optimally for manipulation by the stick. From these preliminary tests it was noted that to satisfy the needs of an individual performing different work tasks, or to allow individuals with different skills and disabilities to perform the same tasks, additional control features and equipment modifications to the manipulator/worktable systems were desirable.

In November 1975, the Mod 0 manipulator was returned to the APL for modifications and installations to satisfy the needs recognized from clinical experience. Consequent and subsequent to these alterations, this unit with its worktable was designated as a Mod I manipulator. Its new features, as described in detail in BPR 10–25, and shown here (Fig. 21 through 24) include—

1. *New Control Mode Options*

a) Direct keyboard operation for mode selection with the mouthstick, and b) Automatic sequence with stop on pulse command. (Note: The patient can select desired control option to suit his task at hand.)

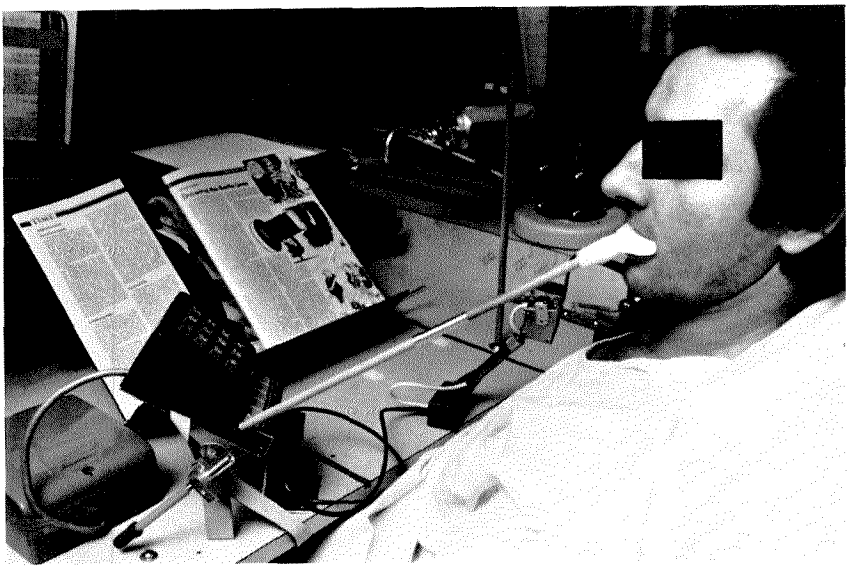

FIGURE 21.—Two-piece mouthstick for use with Powered Medical Manipulator.

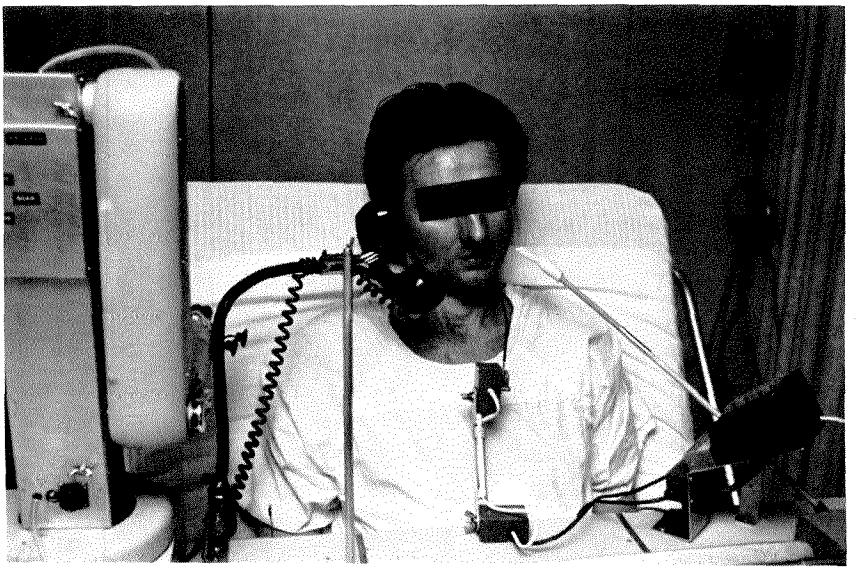

FIGURE 22.—Powered manipulator holding phone in position for use: system is controlled with chin nudge control transducer.

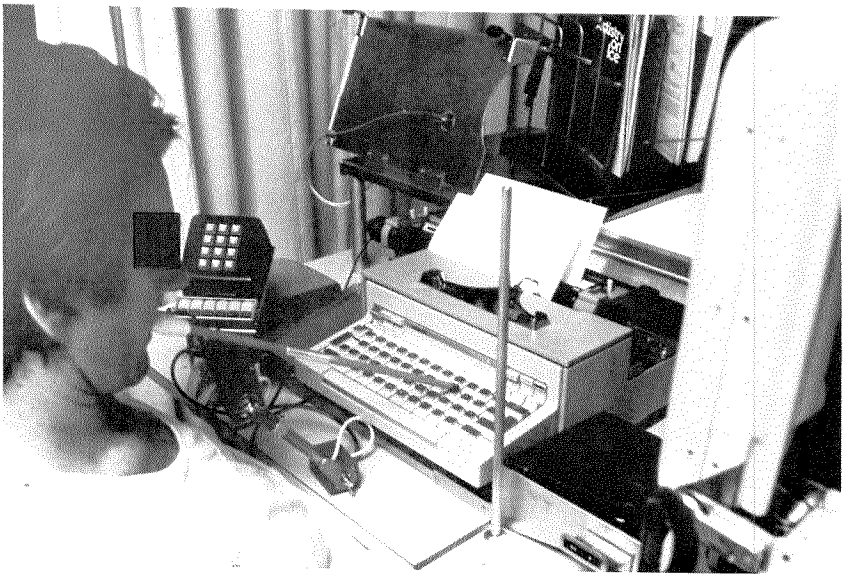

FIGURE 23.—Equipment layout for written communications with powered manipulator and mouthstick combination. Manipulator moves typewriter into position, loads and removes paper. Typing is accomplished with mouthstick.

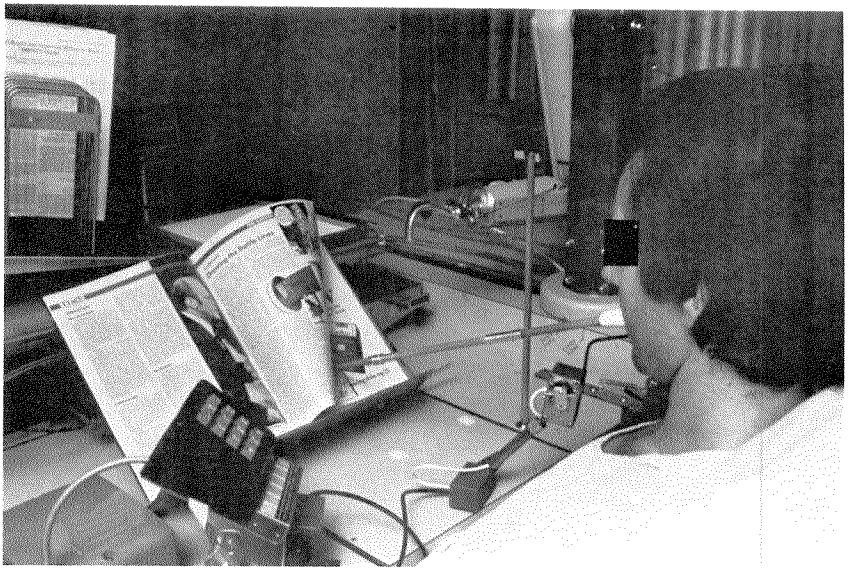

FIGURE 24.—Magazine is placed into reading position with manipulator; mouthstick is used to turn pages.

2. *Chin Nudge Control*

A chin nudge transducer was added to effect proportional control of the desired motion of the manipulator. The transducer is attached to the worktable and may be swiveled in or out of contact with the chin by the patient's head motion. Good proportional control is achieved with this transducer.

3. *Telephone Option*

(For those patients who desire or need to use the telephone.) All telephone components are unmodified and the system employs a standard hand-held receiver. A touch-tone module is suitably located on the worktable to allow the patient to touch-tone dial with his mouthstick. The handset is swung to the patient's head with the manipulator when making or receiving a call. This motion also turns the phone on or off. The handset final position is predetermined and requires no precision for placement.

4. *Two-Length Mouth Stick*

A suitable holder is provided on the worktable for the mouthstick; the patient may retrieve or store the mouthstick in this holder as desired. The mouthstick is made in two pieces with a magnetic coupling inside an aluminum sleeve. Depending upon how the stick is removed from the holder, the patient may pick it up in its longer length (approximately 20 in.), or in a shorter length (approximately 15 in.). The longer length, with the rubber tip, is generally used for reading. The shorter length is used to touch-tone dial the phone, type on the typewriter, and for direct keyboard control of the manipulator.

5. *Optional Reading Tray*

The original worktable had a semi-automatic page turning device on the reading tray. Since the patient undergoing current clinical testing of the manipulator has good use of a mouthstick, this feature has been temporarily removed and replaced by a tray for holding books and magazines. The manipulator is utilized to bring the reading material to the tray and the mouthstick is utilized for turning pages.

New Clinical Observations on the Manipulator in Use

This manipulator and integrated worktable, with these advanced features, was fitted to another totally paralyzed high level quadriplegic in a nearby nursing home on January 22, 1976. This individual spends most of the day in bed. Results from the first 5 weeks of testing with this second patient were reported in BPR 10-25.

This individual has continued to use the Mod I unit on a daily basis for 2-4 hours per day for the past 7 months. He has evolved from using it

primarily to evaluate its various features for research purposes to depending on it to support himself financially by reviewing and preparing technical reports in his profession as a salaried consulting physicist for a government agency. The system permits him to select items of literature of diverse sizes and physical characteristics from a file, to position them for examination, and to turn the pages forward or backward. Using a standard electric typewriter, he can type out appropriate letters and technical reports on the material read. By using the manipulator to position the standard telephone handset, he receives and places telephone calls directly and without human assistance. As a consequence of these capabilities, he has become an enthusiastic advocate, readily performing demonstrations on the equipment, and receiving and answering numerous inquiries from interested persons.

A standard, inexpensive, unmodified tape recorder has been integrated into the system after design and fabrication of an appropriate mounting bracket and identification of an appropriate location on the worktable. Although the patient can easily operate all features of this tape recorder with the manipulator, he prefers to type his reports himself rather than to record them for transcription by a secretary.

To facilitate self-feeding with the manipulator, a unique eating utensil has been designed, fabricated, and subjected to clinical trial. This accessory consists of a "spork" (combination spoon/fork) gimbled to swing (roll) sideways. This utensil is attached by the attendant to the terminal device when food is brought to the patient. This arrangement is shown in Figure 25. The utensil is unique in having a second swivel, the rotational axis of which is perpendicular to the first swivel, but also oriented in a horizontal plane thereby permitting the spork to pitch down. A small cylinder attached to the spork serves as a brake drum for rotational control. This cylinder is situated so that it can be squeezed in the mode of a brake shoe by the other finger of the terminal device when desired by the operator. This design permits the operator, by opening the terminal device, to drop the tip of the utensil in order to scoop up small or soft morsels of food in the mode of a spoon. As the operator scoops up the food, he leaves the terminal device closed, thereby maintaining pressure on the cylinder and maintaining the spork in a level attitude as he brings the food to his mouth. By rotating the wrist the operator can rotate the utensil to a vertical position to pierce larger, firm morsels of food in the mode of a fork. Figure 26 shows the patient utilizing the spoon to eat a bowl of cereal. Chin control provides precise control of the spoon as he moves it to his mouth.

The quadriplegic who has been using the manipulator during this report period has found that the spork functions satisfactorily in association with a food guard attached to one side of the plate, where it serves as a backstop. He can readily select food from any portion of the plate, but

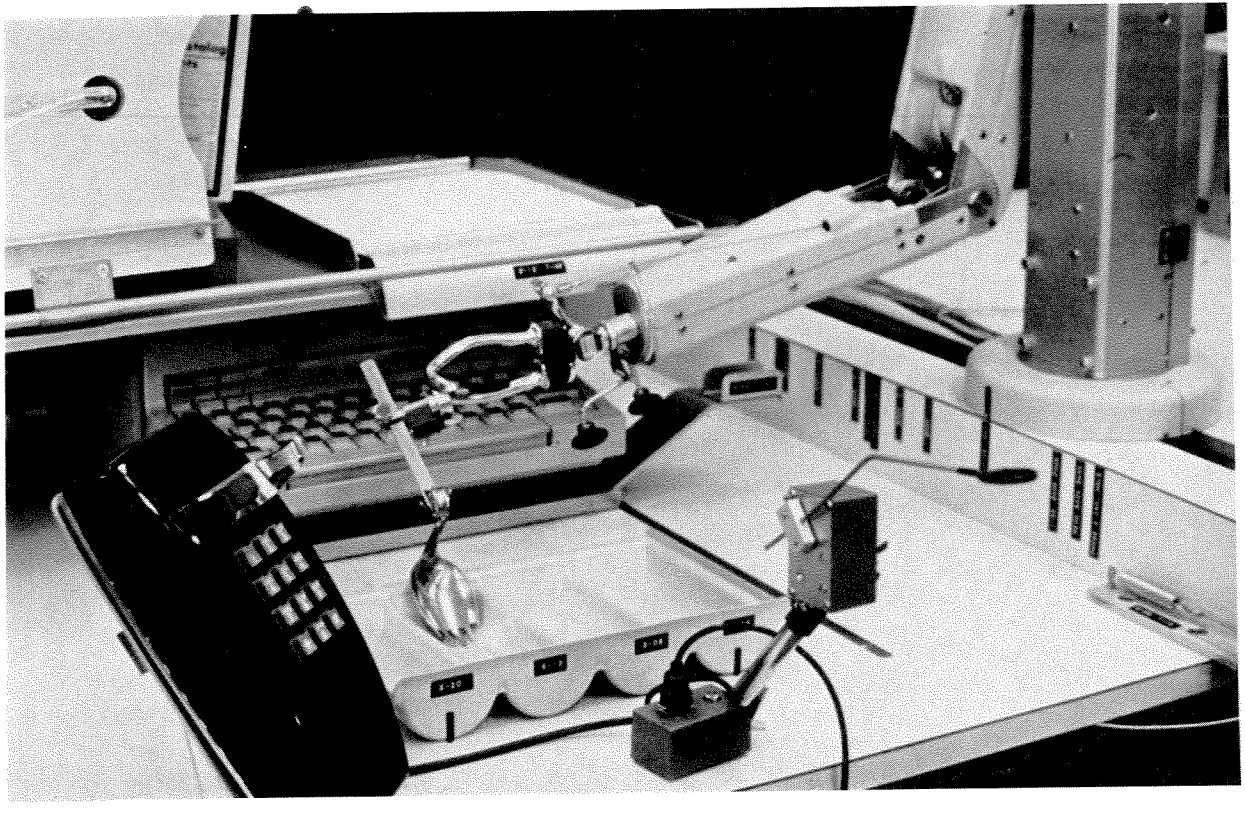

FIGURE 25.—Combination spoon/fork ("spork") utensil for powered manipulator.

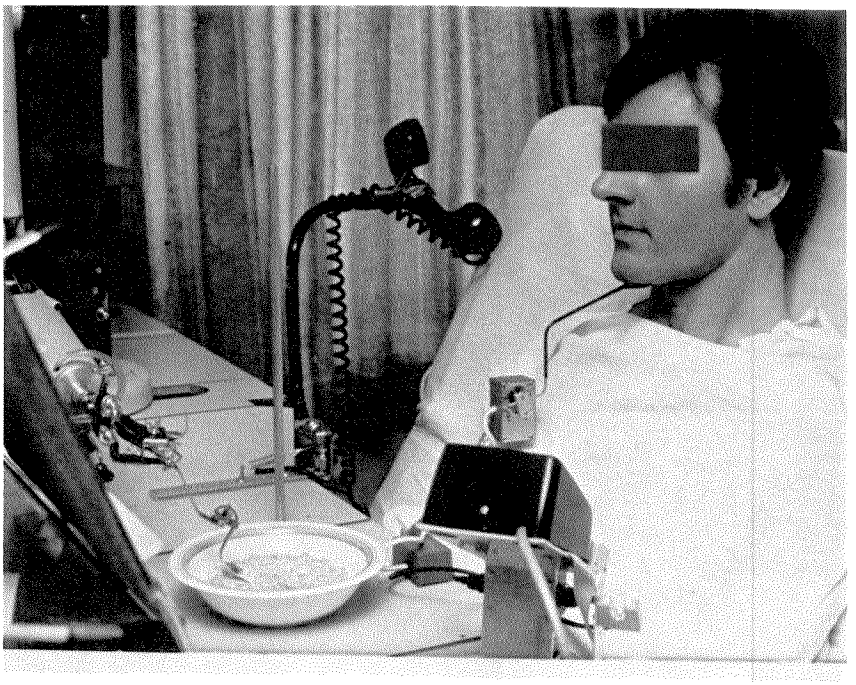

FIGURE 26. — Patient uses manipulator, controlled through chin nudge transducer, to bring food to his mouth. (Combination spoon/fork is shown in position to scoop food from bowl.)

mixing tends to occur as food is scooped up. A segmented plate shown in Figure 24 has been constructed to minimize mixing, but clinical experience has not yet been obtained with this device.

An Effort to Make Self-Feeding Practical

Although the patient can demonstrate the capability of eating an ordinary meal with this manipulator/spork combination, the requirements of consciously commanding and controlling each motion of each joint of the manipulator during each plate-to-mouth (and return) portion of the feeding cycle are too tedious to be practical. In an effort to overcome this difficulty, an automatic sequence program whereby the appropriate sequence of joint motions is preprogramed, but the velocity and range of motion are still controlled by the chin nudge transducer, has been developed and some clinical testing has been accomplished. Experience to date indicates that additional work in preprograming may be required in order to make self-feeding practical.

Other common operations, such as fetching the typewriter from its stored position and loading it with paper, or fetching reading materials from the file to the reading stand, could also be expedited by appropriate preprograming. Additional work is planned in this area.

Model IA for VAPC Testing

During FY 76, one powered manipulator/worktable was designed and fabricated similar to the JHU experimental model, for delivery to the VA Hospital in Castle Point, N.Y. This unit (Mod IA) will undergo limited clinical evaluation to get basic data on its value to the high-cervically injured patient.

A photograph of this system is shown in Figure 27. Layout of components and basic design is similar to the model undergoing evaluation (Mod I) described herein. The electronics for this model is on a plug-in card located inside the vertical post. In the event of a system electronic malfunction, the plug-in board may easily be replaced. Experience to date on the Mod I system indicates the electronic controls for the manipulator have been highly reliable and very few failures have been experienced. The Model IA was delivered on June 2, 1976 and evaluation tests will be conducted by VAPC.

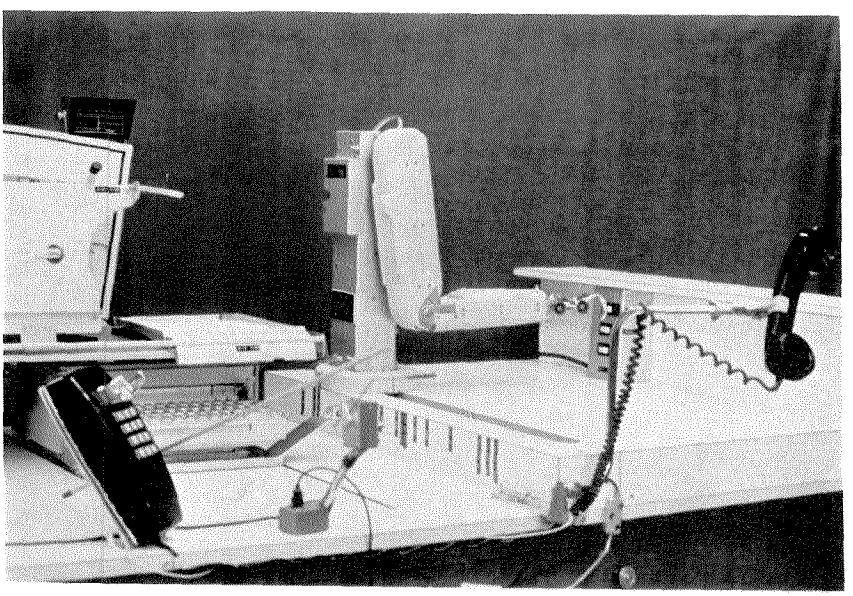

FIGURE 27.—Mod IA JHU type manipulator/worktable which is being evaluated by VAPC at VA Hospital, Castle Point, N.Y.

Clinical followup of the use of the externally powered upper-limb prosthetic systems previously developed under this program is continuing. Between January 1970 and January 1974, 15 experimental prostheses encompassing various design applications of the external power for a full range of amputation levels were fitted to 13 amputees. These included:

1 wrist-disarticulation amputee, 1 unit
3 below-elbow amputees, 3 units
2 elbow-disarticulation amputees, 2 units
4 above-elbow amputees, 5 units
2 shoulder-disarticulation amputees, 3 units
1 bilateral shoulder-disarticulation amputee, 1 double unit

All prostheses were taken home by the amputees. They were encouraged to use them on a full time basis and for all physical activities appropriate to an non-externally-powered prosthesis. All but two of these prostheses were used regularly for more than 1 year. As of this report date, over 42 man-years of in-use field trial test time has been accumulated with these systems. Two of these prostheses are still in daily functional use and considered by the users as essential in their work-related activities—one 5½ years after original fitting, the other 4 years after original fitting. Now 4 of the remainder are retained by the users for occasional use either for cosmesis or to assist in some uncommon or necessary bimanual activity: the remaining 7 are no longer in use. One was returned due to thermal damage, sustained when the user's clothing was ignited by sparks from his welding torch. The others have been retired due to change in the user's work status or life style, aging, wear and breakage of conventional prosthesis components, deterioration of socket stump fit, and the patient's growth—as well as factors characteristic of electrically powered prostheses such as impaired proprioceptive feedback, greater weight, and slower response. Wire and other electrical component malfunctions or failures occasionally occurred but were not significant factors in the retirement of any of these prostheses.

None of the amputees considered acoustical noise of any significance with these prostheses.

Evaluation of the prostheses still in use is continuing, along with a more detailed study of the factors involved in rejection or retirement.

Development of Refined Fitting Procedures for Lower-Limb Prostheses

Case Studies of Applied Research in Orthotics and Prosthetics

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This project was designed as a research approach in the management of patients with limb loss and/or dysfunction of the lower limb who present difficult problems in prosthetic substitution or in orthotic control. The specific aim of this project is to individualize solutions to difficult and unusual problems which do not lend themselves to the standard orthotic and prosthetic solutions which have been generalized to meet the needs of a large class of patients. The goal of the project is generation of a data bank on treatment of rare and unusual prosthetic and orthotic problems, through team evaluation, analysis and implementation of new treatment techniques, with thorough recordkeeping on each case.

With sufficient case material this bank of data could provide sufficient information so that unusual problems of a particular type may be categorized as to the general special needs of the patient and a general specialized approach for treatment which has proven successful.

The special clinic presently has accepted 33 patients for inclusion in the case study program. The team is presently following 17 of 20 orthotic patients, 10 of 15 prosthetic patients, and 3 out of 3 prosthetic-orthotic patients. The patients not presently being followed have moved or for some other reason are lost to followup.

The present program will terminate October 1, 1976. Thus a final report of the case studies will be available in detail with illustrations shortly. Nineteen patients will be specifically reported upon in great detail as representative examples of the group. These are patients for which a final or relatively final result is available with full followup details and patient analysis.

This program will be extended to the development of a regional center for the treatment and evaluation of difficult cases in orthotics and prosthetics.

Development and Evaluation of Advanced Automotive Adaptive Equipment.

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During this reporting period, work has continued in three areas:

Servocontrol System Evaluation, Wheelchair Lift Evaluation, and Wheelchair Restraint Evaluation.

Servocontrol System Evaluation

Servocontrolled vans have been received from Mobility Engineering (Scott) and Sevier Manufacturing; the 2,000 mile tests of these vans are currently in progress. These two vans, the Southwest Research Institute (SWRI) van, and the Hardin-CCI control system in a Ford sedan, were taken to Washington, D.C., in June 1976 and demonstrated at the Workshop on Personal Licensed Vehicles for the Severely Disabled.

The 2,000 mile test is nearing completion on the Scott van and tests will be conducted in Houston, Texas, on August 16-20, 1976, using five quadriplegic subjects as test drivers. Comparisons will then be made among performance of normal drivers in a standard van, performance of normal drivers in the servocontrolled Scott van, and performance of disabled drivers in the Scott van. There have been no problems with the primary servocontrols in this vehicle to date; however, there have been problems with the secondary control systems, in particular the shifter and the layout of the secondary control switches.

The Sevier van was delivered with a complete primary control system for acceleration, steering, and braking. Secondary controls for shifting, driver wheelchair restraint, and turn signals were added at Texas A&M University. Due to malfunctions in the steering control system this vehicle has not completed the 2,000 mile test and will not be included in the disabled driver tests to be conducted in August. Testing of this vehicle cannot be continued until the steering control servo malfunction has been corrected.

Future plans are to conduct the prescribed testing on the Sevier van, as well as on the SWRI and Hardin-CCI vehicles when they are received.

Wheelchair Lift Evaluation

1. The initial phase of evaluation was completed on the remaining three lifts from the original group of nine: Braun, Casady Safety Van Lift, and Collins. This phase consisted of an assessment of the installation and mechanical operation of the lifts, an engineering evaluation of the design and the fabrication techniques, a human factors analysis, and a systems safety evaluation. The results of these evaluations were transmitted to the VA.

2. An accelerated-life test fixture was fabricated and five lifts were installed on it for repetitive cycling. The Helper, Maxon, Paralift, Ricon, and Speedy Wagon lifts were each operated through some 4,700 cycles. During approximately half of the cycles the lifts had no load, and for the other half a load of 260 lbs was placed on the platform. The load/no-load sequence was changed each 100 cycles. The value of 4,700 cycles approx-

imates 2 year's use of the lifts by an average user, as determined by a telephone survey of 24 lift users.

The Braun, Casady Safety Van Lift, and Collins lifts are currently undergoing the accelerated life cycle tests.

3. In-van evaluations were performed on the Compass, Helper, and Speedy Wagon lifts. This included using the lifts for wheelchair entry/exit with the van on a horizontal surface with unrestricted wheelchair access (e.g., a shopping center parking lot), on a horizontal surface adjacent to a raised sidewalk, on a sloping surface adjacent to a raised sidewalk (e.g., a crowned street), and on an uphill/downhill surface.

4. The development of a standard for wheelchair lifts continued during the reporting period. A preliminary draft was reviewed with VA personnel in early June, and since that time considerable effort has been expended revising the draft and preparing a statement of the rationale behind each requirement. The standard will incorporate existing industry standards (ANSI, SAE, ASTM, and others) as much as possible, and will reflect the experience gained in the evaluations of the nine lifts.

The accelerated life tests on the Braun, Casady Safety Van Lift, and Collins lifts will be continued until approximately 4,700 cycles have been reached. Additional in-van tests will be conducted on other lifts, as well as some destructive tests of lift components such as wire rope and hydraulic hose.

A final draft of the standard, and accompanying rationale statements, will be submitted to the VA during the next reporting period.

Wheelchair Restraint Evaluation

All known commercially available wheelchair restraint systems were ordered and received. A test plan was written to define human factors and structural testing to be conducted. A test stand and other testing devices were designed and fabricated for static load testing. The restraints tested were manufactured by Collins, Speedy Wagon, Motorette, Atlantic Research, Double D, and a Texas A&M (prototype).

All the restraints, except those manufactured by Atlantic Research and the Texas A&M prototype, showed serious defects in fabrication and/or design. After the testing of these restraint systems was completed, the problem was approached analytically to verify the stresses present in the wheelchair during testing.

Some of the manufacturers of the restraints received to date have failed to provide the necessary literature (installation instructions, operating instructions, parts list, model designation, etc.). Consequently, testing of these restraints must be postponed until such literature is available to insure that the restraints are installed and used according to the manufacturers' specifications.

Further testing of the wheelchair restraint systems is planned to find

the weak and strong points of each type of restraint. Some dynamic testing of the more reliable restraint systems is planned so that a correlation between static and dynamic testing can be made. A report is currently being drafted on the results of the testing to date. The goal is to provide information for draft of a standard for wheelchair restraint systems.

Control of an Artificial Upper Limb in Several Degrees of Freedom

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During the first half of 1976 the main emphasis of this work was on myoelectric control of a multi-degree-of-freedom prosthesis. Here the main effort was directed toward enhancing the reliability and the speed of identification of the myoelectric signals for different limb functions obtained from a single electrode location. Solutions to this problem were sought in two directions. First, in modifications of the microcomputer hardware, and secondly, in modifications of the algorithms used, (i.e., software modification). It was recognized that, basically, reliability enhancement requires more computation, which in turn increases the discrimination time and thus slows down control. Hence, faster microcomputer hardware is seen as a solution to both the reliability and the speed problems.

At present the design goals of 99.5 percent reliability and an actuation time of 0.2 s have yet to be attained. It is noted in this respect that the microcomputer hardware presently used (an 8-bit Intellec 8-80) is no longer the fastest or the best, as technology has made such rapid progress in the 2 years since the hardware was purchased. With this older hardware considerable speed is lost due to the need for operation in double precision for reasons of accuracy and thus of reliability. Major hardware changes are not planned at this time, however, as it is felt that in this laboratory research they would be impractical due to the expense involved—and noting that the progress in microcomputer hardware is so rapid that equipment purchased today will again be overtaken in a few months. Therefore, apart from the addition of hardware multipliers which were recently incorporated into the system, the main portion of this research has been directed into software modification. It is noted that once the present system is speeded up by a factor of 4 via software improvements, the use of new equivalent hardware which is n-times faster will further speed up the computation time for signal processing by another factor of n—the software mentioned above being

translatable to any hardware that is to be used in the final product.

The software modifications pursued during the last 6 months were related to two alternative discrimination schemes (described in earlier reports) both of which are based on first performing parameter reduction of the myoelectric signal via AR (autoregressive) model identification such that a linear-optimal "squeezing of the information content of the myoelectric signal into a polyhedron of the smallest possible dimension" is accomplished. The two approaches are thus the following—I. direct discrimination in the parameter vector space, and II. discrimination via parallel AR filtering (see BPR 10-25, Spring 1976).

Further details of approach I are in references 1–3, whereas those related to approach II are in references 4–5.

It was indicated in the previous report that approach II leads to a considerable speeding-up of the required recognition time since it eliminates the need for on-line identification during normal prosthesis use. However, by its nature, approach II is very sensitive to identification bias (5), the reason being that a scalar RMS error value, rather than a distance vector, is used for discrimination between signals for different limb functions. Reduction of this bias is possible through increasing the order of the AR models used, the true order being theoretically infinite, though only a small number of parameters are taken to be non-zero in practice. Here, an increase in the order of the AR model requires more identification time. Hence, efforts to reduce the time required for identification should not only speed up approach I but also serve to reduce the bias in approach II. It is further noted that once such an increase in speed is possible, higher-order models can be used in both approaches to enhance their reliability.

Because of its fast convergence (minimal number of iterations) and because of its statistical efficiency, the least squares identification algorithm has been used in the past. However, this algorithm requires a large number of computations per iteration. During this reporting period effort was directed toward investigation of less efficient algorithms which take more iterations to converge but which require fewer computations per iteration. The algorithms tested were those of stochastic approximation and sequential learning (6, 7). These algorithms are known to converge and are computationally far simpler than the least squares identification algorithm. Experiments performed thus far have, however, indicated that although the computation time per iteration is faster by a factor of about 10 for both of these cases, convergence to a degree that facilitates recognition within an allowable error takes considerably more than 10 times the number of iterations required using the least squares algorithm. Hence, both of these approaches were abandoned. Stochastic approximation algorithms with improved convergence rate (based on material contained in Ref. 8) were

also found to afford no improvement. Consequently, effort was directed toward development of accelerated least squares algorithms. Accelerated least squares algorithms based on material contained in Ref. 9 were tried first. These failed, as the short word-length prevented convergence (essentially, these algorithms are sensitive to division by small values). Presently a gradient version (10) of the least squares identification algorithm has been tested and found to yield good results. It has been translated into the Intellec assembler language and run on that microcomputer using simulated EMG data. Testing of these algorithms with amputee subjects is scheduled for the summer of 1976.

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Acceleration of Bone Healing by Electrical Stimulation

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No progress report was submitted for this period.

Hemodynamic Evaluation of Preoperative and Postoperative Amputees

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During the past 6 months all efforts have been directed toward retrospective review of vascular cases; to date, 200 patient folders have

been reviewed. This review is contributing to the implementation of the computerized vascular registry. Records of all patients who have had lumbar sympathectomy are being reviewed with respect to short and long term benefits of this procedure, and all patients are being retested and their current vascular status reviewed. The major objective of the data retrieval is to classify, categorize, and correlate the degree of involvement of each patient with the objective quantitative data obtained during the evaluation. When all data are retrieved and filed in the computer data bank, more accurate and rapid decisions can be reached with respect to the appropriate treatment of a patient.

Two other important aims of the program are to study in depth the problems of the patient with diabetes, and to determine the significance of early sympathectomy (especially for the diabetic patient). Analyses have begun to determine the precise implications of this procedure. Significant for this goal is the fact that on an average, 50 percent of the patients who have one or more vascular-surgical procedures have the associated diagnosis of diabetes. And 50 percent of these diabetic-vascular patients present with signs of impending gangrene. Lumbar sympathectomy appears to alleviate this problem and the signs of impending gangrene disappear. It is anticipated that as the data are analyzed definitive answers will be obtained regarding the pros and cons of lumbar sympathectomy.

Maxillofacial Restorative Biomaterials and Techniques
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Comparative evaluation has been completed on the four principal types of elastomer polymers, namely: polyvinyl chloride (PVC); polyacrylic terpolymer (PAT); polyurethane (PU); room temperature vulcanized (RTV) polysiloxane; and high temperature vulcanized (HTV) polysiloxane — with respect to (a) replication of the biomechanical characteristics of living tissue, (b) stability when exposed to actinic (light), (c) changes in tactile (stiffness-softness) quality due to cold and hot temperature changes and, finally, a characteristic recently discovered to be of extreme importance to patients' desire to wear the prosthesis (d) durability of the prosthesis following repeated sanitary/hygienic maintenance (which is most severe on all but the polysiloxane maxillofacial prostheses) (1).

Most prominent in the effort during this semi-annual period has been the successful adaptation of HTV polysiloxane to fabrication of prostheses in simple, regular dental molds. This adaptation removes the need for special techniques and expensive molds, and also permits a compe-

tent dental laboratory to carry out the overall procedure easily. The HTV polysiloxane is available from two commercial suppliers, with preference given to a virgin gum stock readily available from a primary manufacturer.

The research work has been directed toward product (formulation) and process (curing) standardization. These are currently being checked by on-going toxicological testing for compliance with the recent statutory Federal regulations prompted by the New Devices Act. Efforts are aimed at specifying the chemical ingredients involved along with the descriptions of processing or curing methods that will impose no deleterious toxic, tissue (dermal) inflammatory, or allergenic effects.

Biomechanical Replication of Living Tissue (Tensile Characteristics) (2)

In order to gain the unique replication of the tactile, tensile quality of living tissue, extensive testing for measured tensile constants has been carried out for comparative evaluation. In this effort, a characteristic dimensionless strength (S) to modulus (M) quotient has been used effectively to guide the ingredient formulation and processing, which involves numerous polymerization factors, in replicating the tensile characteristics of living tissue. At the same time this S/M quotient serves to quantify the comparative merits of all competitive polymers, all of those mentioned here, for determining which most nearly approximates the tactile quality of living tissue. Table 3 summarizes the values ob-

TABLE 3. —*Comparative Merit Ranking by Strength/Modulus Quotient*

Material	S/M quotient	Merit rank
Living tissue (excised artery)	17.5+	(Ideal—goal)
HTV Silastic SF[a] (80/20)	5.9	1
RTV Silastic SF[a] (80/20)	3.4	2
Polyvinyl chloride—plastisol[b]	3.3	2
HTV Silastic unmodified	2.3	3
RTV Silastic unmodified	2.1	3
Acrylic terpolymer	2.1	3
Polyvinyl chloride—medical grade[c]	1.8	4
Polyurethane	1.9	4
Polymethyl methacrylate	0.02	–

[a] Silicone fluid composition.
[b] PVC Plastisol (Cordobond)—high plasticizer content, about 60%.
[c] PVC Blood bag (Cutter Laboratories)—low plasticizer content, about 33%.

tained for the principal candidate materials, and at the same time indicates the obvious preference for HTV polysiloxane modified with silicone oligomer with appropriate cross-linking (2).

Stability to Actinic Exposure

Outdoor exposure causes marked discoloration of prosthetic materials measurable by yellowing of the base material. A simple light-exposure test has been used to assess the principal polymer types utilizing spectral (yellowing) changes. Table 4 summarizes the changes with each of the polymer types, the results of which single out the polysiloxanes as most resistant to actinic activity. Discoloration with marked yellowing is a problem of concern in the needed, lasting esthetic appearance for which the polysiloxanes offer the best solution.

TABLE 4.—*Discoloration on Long-Term Exposure to Fluorescent and Day Light*
(Non-standard, exploratory test procedure)

Material	Colorimeter Values [a]	Days of Exposure Initial	60	180	Assessment
RTV Silastic 382	(L) Reflectance	76.9	76.4	76.9	No Change
	(a) Red/Green	−2.6	−2.7	−2.7	No Change
	(b) Yellow/Blue	+8.8	+8.8	+9.2	No Change
HTV Silastic MDX (Dow)	(L) Reflectance	74.8	76.8	76.0	No Change
	(a) Red/Green	−2.4	−2.7	−2.9	No Change
	(b) Yellow/Blue	+8.6	+8.8	+9.1	No Change
Polyvinyl chloride [b]	(L) Reflectance	74.5	74.2	74.6	No Change
	(a) Red/Green	−2.2	−3.0	−3.0	Sl. Change
	(b) Yellow/Blue	+8.9	+10.9	+12.6	Yellowing
Polyurethane [c]	(L) Reflectance	72.8	72.6	72.8	No Change
	(a) Red/Green	−2.9	−3.2	−3.3	No Change
	(b) Yellow/Blue	+8.6	+10.4	±11.9	Yellowing

[a] Hunter Lab Colorimeter
[b] Plastisol (Cordobond) high plasticizer content (about 60%)
[c] Polyesther urethane elastomer

Changes in Tactile Quality with Temperature

Summer and winter temperature fluctuations have imparted marked noticeable changes in the prosthesis, softening in the summer and stiffening in the winter, the latter affecting the adhesability of retention. This variability and hence an annoyance to the wearer is particularly

evident with plasticized polyvinyl chloride and with polyurethane as indicative of the changes in modulus shown in Table 5. In this comparison HTV as well as RTV polysiloxane are least affected by the changes in temperature.

TABLE 5.—*Changes in Tactile Modulus from Ambient to Cold and to Warm Temperatures*

Material Polymer	Cold 0–5 deg C Modulus kg/cm²	Cold Change %	Ambient 20–25 deg C Modulus kg/cm²	Warm 40–45 deg C Modulus kg/cm²	Warm Change %
RTV Polysiloxane SF [a] (80/20)	20.0	+14	17.6	15.4	−12
HTV Polysiloxane SF [a] (80/20)	19.3	+16	18.3	17.9	−14
Acrylic terpolymer	54.0	+42	38.0	15.1	−40
Polyvinyl chloride (plasticized) [b]	56.4	+74	32.3	14.4	−57
Polyvinyl chloride (medical grade) [c]	305.7	+85	165.2	76.8	−54
Polyurethane	54.6	+76	30.9	14.6	−53

[a] Silicone fluid modified composition.
[b] PVC Plastisol (Cordobond) high plasticizer content–about 60%.
[c] PVC Blood bag (Cutter Laboratories)—low plasticizer content–about 33%.

TABLE 6.—*Summary of Changes in Tensile Modulus with Simulated, Intense Cleansing Procedures*

Material	Hours	Soap washing % Change	Soap washing Rating	Isopropanol washing % Change	Isopropanol washing Rating
RTV Silastic SF [a] (80/20)	1	(0)	Negligible	+15.4	No effect
	3	+8.0	Slight	+15.4	Slight
	10	+15.2	Slight	−12.2	Slight
HTV Silastic SF [b] (80/20) (b)	1	(0)	No effect	(0)	No effect
	3	—	(In progress)	—	—
	10	—	(In progress)	—	—
Polyvinyl chloride plastisol [c]	1	+28.2	Stiffer	+25.8	Stiffer
	3	+52.2	Stiffer	+82.3	Stiffer
	10	+87.8	Stiffer	+81.8	Stiffer
Polyurethane	1	+54.2	Stiffer	−34.4	Softer
	3	−33.0	Softer	−58.8	Softer
	10	−76.8	Softer	−78.3	Softer

[a] See Reference (3) 80/20 Silastic 382/silicone fluid.
[b] See Reference (4) 80/20 Silastic MDX 44515/silicone fluids.
[c] Vinyl plastisol (Cordobond, Ferro Corp.) Reference (1).

Changes in Tactile Quality with Hygienic Cleaning

Prostheses, like any apparel adjacent to the skin, accumulate body perspiration with attendant odorous bacterial and fungal decay, the situation being especially malodorous with nasal and orbital prostheses in contact with mucous drainage and exhalation. Patients tend to apply intense and severe cleansing, often using oxidative bleach preparations in the extreme cases. The recommended hygienic procedure is to use ordinary soap and, as needed, regular isopropyl alcohol. An unofficial test method and standard has been employed to compare the durability of each of the principal types of polymers using Ivory soap solution and isopropyl alcohol, results of which are summarized in Table 6.

In this hygienic maintenance it is again evident that the relative chemical inertness of the polysiloxane configuration serves to single out the polysiloxane as the biomaterial-of-choice over the polyvinyl chloride and the polyurethane. Of all of the factors in establishing the relative merits (or more specifically the selection of the material-of-choice for orofacial prostheses) this test emphasizes the choice of polysiloxane for anatomical restoration. This choice of a single polymer configuration is especially cogent because the ensuing evaluation for safety to patient use is a costly effort of biological testing for ethical (3) and statutory approval (4).

Color Standardization

The esthetic or cosmetic merit of a facial reconstruction prosthesis is no less important to the patient wearer than the already recounted requirements of living-tissue replication, and of durability especially for hygienic maintenance. The often-complained-of discoloration is attributable not only to actinic yellowing of the base material, but also to use of dyes rendering the prosthesis completely faded, whereas, more properly, pigments capable also of withstanding the discoloring action of acid fumes and intense hygienic cleansing might have been used. The matter of dye versus pigments has been settled in so far as the current effort is concerned—made strikingly clear by the data shown in Figure 28 comparing the color loss of carmine red dye to that of a red pigment when tested under fluorescent light for 3 months.

During this report period, emphasis has been placed on selecting the proper pigments, especially those replicating the natural yellow carotene coloration in living skin and the red arterial-venial capillaries contained therein. Presently, this effort includes testing candidate red and yellow pigments applying a standard color difference system. A complete report on the aspect of colorant standardization has been proposed in a formal presentation at the First International Symposium on Facial Prosthetics (5). Currently, caucasian and negroid coloration indices (for reflectance (L), red/green (a) ratio and yellow/blue (b) ratio)

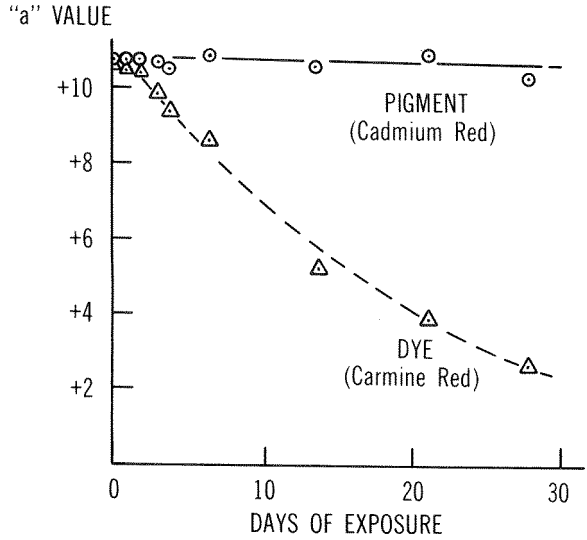

FIGURE 28. — Comparison of color loss of a red pigment (Cadmium Red) with that of a dye (Carmine Red), formulated in HTV polysiloxane. Exposure in days under Sylvania fluorescent "Daylight" (total of 120 watts, d = 15 cm).

are being devised for intrinsic coloration over which the extrinsic matching color can be applied by the prosthetist as the final matching cosmetic. With the Hunter Color Difference System for the L, a, b indices, a standard series of intrinsic coloration formulations are being developed for a master batch of concentrate for a production run of poundage level (10 to 20 lbs.) for a stock material from which prostheses can be made from packaged or dispensible containers or tubes, much like those used for caulking compounds. It is in this area that a major emphasis is being applied since cosmetic matching is rated as being of equal importance to the biomechanical acceptance.

Adhesive Formulation

Currently the medical grade adhesive, in the form of a tubing extrudate of paste and as an aerosol, is being used but with complaints about early loss of adhesion (in a matter of hours) and difficulty in cleaning off for freshened application, and in some cases, with indications of skin inflammation. This is particularly true with patients who have undergone some facial radiation in the course of arresting or removing internal carcinoma. For these cases special consideration needs to be accorded for a benign, emollient adhesive. Since all known proprietary adhesives including the medical grade do not disclose the specific ingredient formulary, a program is in progress to develop an adhesive system

to provide adequate retention, with no dermal reaction, coupled with ease of removal and replacement with freshened application. Recent statutory banning of numerous aerosols (6) applied as adhesives makes this facet of product development with toxicological assessment a mandatory addition to the overall prosthetic materials development program.

Toxicological Testing for Product and Process Certification

With the new and amended regulatory requirements on product and process safety (that is, proper compounding and polymerization) for medical devices (4), an uncompromising need exists for applying appropriate biological screening and testing (3). The biological testing programs, however, are yet to be specified, especially with the general recognition that the usual animal tissue tests such as the mouse fibroblast may be inadequate. Consequently, an on-going program on human tissue, firstly with buccal mucosa, has been initiated with the view to utilizing this for the screening of RTV polysiloxane with myriads of formulating and polymerization variables, prior to animal implant tests. It is expected that, during this period, a standard procedure will be devised for correlating existing tissue culture screening procedures to chemical identity of extractables that may cause dermal reaction.

Economic and Practical Considerations

The principal accomplishment during this period has been the polymerization of polysiloxane gum virgin stock at temperatures just above the activating peroxide temperature (80 deg C) but below the hemihydrate decomposition temperature (117 deg C) of gypsum, the base material for dental reconstructions. Thus, with HTV polysiloxanes, the regular, ordinary dental stone can be used at polymerization/curing temperatures with an active peroxide catalyst, at temperatures below that of hemihydrate decomposition. Presently, the standard curing procedure is specified at 100 deg C, a readily available curing temperature even in household ovens. This eliminates the need for any special casting molds, such as the many-step epoxide-aluminum casting polymer, or the Linotype metal molds or even special ovens. With such a simplification, the cost reduction in obviating the latter and allowing the use of ordinary dental stone flask molds available in any dental laboratory or clinic, can amount to several hundreds of dollars of savings in technical labor time alone, plus expensive molding materials and curing ovens.

In addition, a mail-order fabrication of intrinsically colored prostheses is offered to all Veterans Administration Restorations Technicians to produce limited molded, intrinsically colored prostheses. In this program wax models or molds of any facial reconstruction are welcome for making prostheses which would be finished off cosmetically by the

requesting clinic anywhere in the Veterans Administration system. This program is believed to be a significant cost saving to the rehabilitation program throughout the VA system.

Presentations

The above work is regularly reported to the American Academy of Maxillofacial Prosthetics and has been reported at the First International Symposium on Facial Prosthetics, held recently in Arnhem, the Netherlands, with reprints of the presentations now available on request. Several of these reports have been presented for publication in the Journal of Prosthetic Dentistry and the Bulletin of Prosthetic Research since 1973.

Work During Next Quarterly Period

The current effort is divided into three areas of research and development: (a) promote the widened usage of the HTV polysiloxane composition modified with siloxane oligomer (silicone fluid, medical grade) for extra-mural adoption of the composition and extended to production quantities; (b) develop and standardize the intrinsic coloration with a master color batch suitable for poundage production; (c) investigate the reaction of adhesive components applied to skin areas based on group function changes that could be correlated to inflammation; and (d) conduct tissue toxicity tests with primary emphasis on human tissues especially buccal mucosa.

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2. Lontz, J., J. Schweiger, and A. Burger: Development and Standardization of Polysiloxane Maxillofacial Prostheses. Presentation at the Twenty-Second Annual Meeting, American Academy of Maxillofacial Prosthetics, Williamsburg, Virginia, 1974.
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4. Amendment to the Medical Devices Act, 1976.
5. Lontz, J., J. Schweiger, and A. Burger: Standards of Color Matching. General Concepts for Pigment Selection. Presentation at the First International Symposium of Facial Prosthetics. Arnhem, the Netherlands, April 1976.
6. Federal Register, August 22 and 28, 1973. This publication lists several proprietary spray adhesives as being an "imminent hazard."

Permanently Attached Artificial Limbs
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C. William Hall, M.D.

The period of January 1 through June 1976 is covered in the article "Skeletal Extension Development: Criteria for Future Designs" appearing in BPR 10–25.

Mobility Aids for the Severely Handicapped
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Charles M. Scott and Ronald E. Prior, Ph. D.

For progress during this report period, see the article, "Mobility Aids for the Severely Handicapped," appearing elsewhere in this issue of the Bulletin.

VA-Rancho Gait Analyzer
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Jacquelin Perry, M.D.

The fabrication of two complete "second prototype" systems was completed. These hand wired systems (Figs. 29 and 30) were tested extensively to determine their accuracy. Foot switch data were recorded from patients simultaneously on the Gait Analyzer and a strip chart

FIGURE 29.—VA-Rancho Gait Analyzer Recorder.

FIGURE 30. — VA-Rancho Gait Analyzer Calculator.

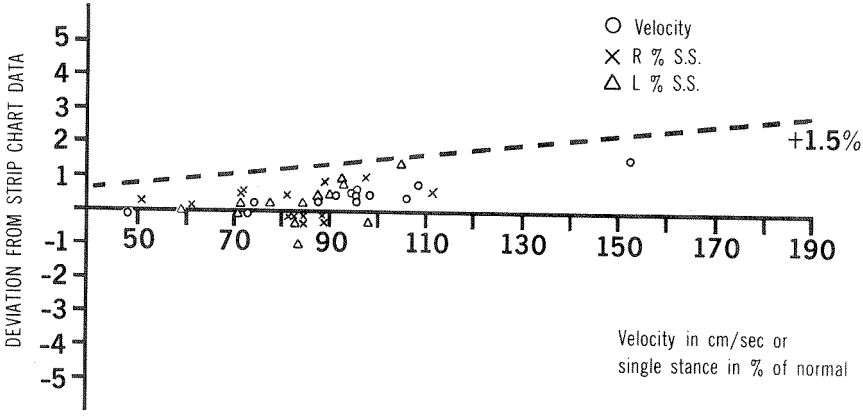

FIGURE 31.—Deviation of Gait Analyzer data from strip chart (measured data for patients).

recorder. A comparison of the results (Fig. 31) shows that the accuracy of the Gait Analyzer falls within the expected range (error range of + or − 1.5 percent).

A "start/stop controller" with special triggering lights (Fig. 32) was designed to automatically start and stop each test. This system performs well in normal ambient light and will trigger the circuitry at distances up to 4 ft from the triggering lights.

Printed circuit boards were designed and a set of prototype boards has been assembled and tested. Following these tests, minor modifications were made in the circuit design. New sets of circuit boards incorporating these modifications were manufactured for the production of six Gait Analyzers. Fabrication of these systems is proceeding. Upon completion the six systems will be evaluated at selected clinical centers throughout this country.

An operation manual has been prepared for the latest system. This incorporates the changes in operating procedure required by the design modifications that resulted from the tests of the "second prototype" systems.

FIGURE 32.—Subject walking with Recorder. Start/Stop Controller (taped to upper arm) is being actuated by triggering light.

Mobile Bed/Chair for High Level Quadriplegics (A Final Report)

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Purpose

The objective of this project was to develop a bed with the dimensions and features of a standard hospital bed, but with the additional capability of folding into a configuration resembling a wheelchair, under control of the patient. Such a device could provide mobility (and considerable maneuverability) for a paralyzed patient within the confines of the hospital and its immediate level ground surroundings, without the necessity of transfer from bed to a conventional powered wheelchair. The most significant gain in rehabilitation which can be expected from the bed/wheelchair combination is the independent mobility available to such a patient without waiting for attendants to assist in the transfer in or out of bed. Thus, availability of the chair could result in substantial savings of hospital staff time. In principle, such a bed/wheelchair combination could also be useful in a patient's home where movement from bedroom to porch or living room would be possible.

Background

Paraplegics who have normal arm strength and range of motion can transfer their bodies from the bed to a wheelchair and vice versa. Thus they have full access to the mobility provided by a wheelchair, whether manual or electric. By contrast, a spinal cord injury patient with lesion levels at C5 or higher lacks the arm strength and range of motion to move from his or her bed to a wheelchair without external assistance. While a modern wheelchair provides considerable assistance to the quadriplegic by using such devices as chin controls, tongue switches or pneumatic controls, the patient requires help in getting to the chair. This dependence on external assistance is not only costly but humiliating to the patient, making him dependent on others even in a home environment.

In the past, the traditional attempts to bridge the gap between bed and wheelchair have been based on the use of hoists or lifts, such as the Hoyer patient lift. While some of these lifts can be controlled by the patient, they still require that a sling be placed under his body in advance, and removed at the appropriate time.

The program described in this report was concerned with an alternative approach, based on the notion of converting a portion of the patient's bed into a wheelchair-like self-propelled unit which would

provide him with mobility and its attendant independence, either in a home or hospital environment.

Organization of the Project

The development of the bed/wheelchair, from an engineering concept to a production prototype for clinical evaluation, was divided into three phases.

Phase 1: In this phase a standard hospital bed was modified and provided with electric controls in order to test the feasibility of the basic idea.

Phase 2: In this phase an improved model was built, in order to overcome some of the limitations of the Phase 1 development.

Phase 3: Several models of a prototype bed have been fabricated by a private company for the VA Prosthetics Center to undergo clinical evaluation.

Each phase of the project will be reviewed in turn.

Phase 1

The objective of Phase 1 was to build a prototype of the bed/chair which could be used to test the feasibility of the idea and its acceptance by patients. Design of the bed/chair was based on shortening the undercarriage (frame) of a standard, manually operated, foldable hospital bed by approximately 4 ft (Fig. 33 and 34). Under the shortened head was placed a 12V d.c. power drive system similar to the drive mechanism of

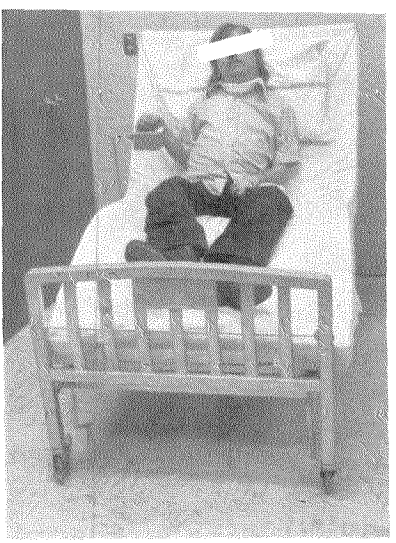

FIGURE 33. — Feasibility prototype of Mobile Bed/chair.

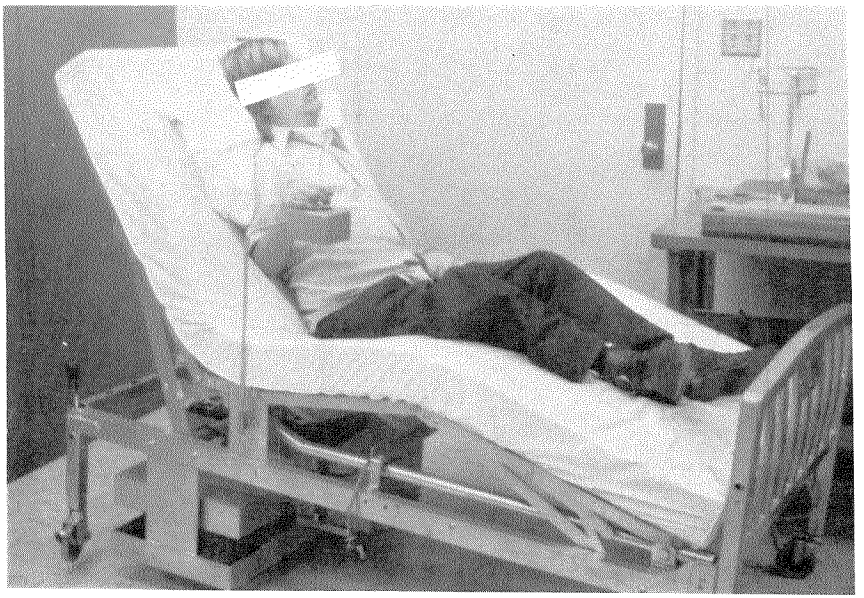

FIGURE 34.—Feasibility prototype of Mobile Bed/Chair. A conventional hospital bed was shortened and equipped with electric propulsion system.

the SCAT electric wheelchair [b]. The wheelchair control used consists of a joystick proportional control system which requires only relatively weak motions of one hand for its operation.

Operation of the Phase 1 prototype demonstrated that the folded bed, in spite of its longer width and size compared to conventional wheelchairs, was surprisingly maneuverable. Tests were performed with a quadriplegic volunteer. No major training problems were encountered. A motion picture demonstrating mobility of the bed/chair under control of the quadriplegic test subject was prepared.

Phase 2

On the basis of the encouraging results of Phase 1, an improved model was designed. This utilized a conventional electrically powered hospital bed, which was also shortened and mounted on a modified SCAT wheelchair (Fig. 35). The major features of this model were the following:

a) In the bed mode, the device was to have all the physical dimensions and characteristics of a standard electrically powered hospital bed.

[b] Manufactured by Wheelchairs, Inc., Downey, California.

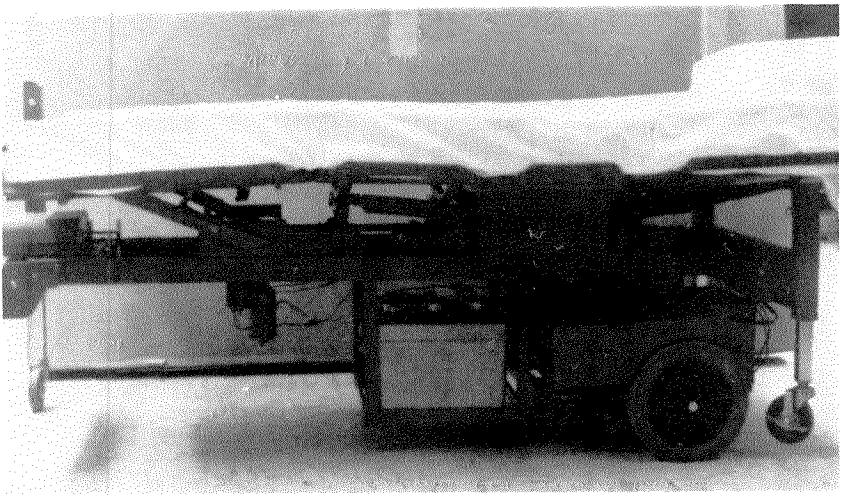

FIGURE 35. — Prototype. Electric folding hospital bed, shortened and equipped with electric propulsion system. Sides fold to decrease width of bed.

b) In the wheelchair mode, the device was to have a structural configuration similar to a normal electric wheelchair (though somewhat larger in physical size).

c) Conversion from one mode to another was to require only one input control command from the patient.

d) In the wheelchair mode, the control system was to be proportional, and adaptable to a large variety of input transducers including manual joystick, chin control, tongue control, pneumatic, etc.

All of these design objectives were attained. The bed folding mechanism used electric motors and a system of steel cable and pulleys to actuate the structural folding linkages. A foamrubber mattress was used rather than the conventional innerspring tufted mattress. Legs with small casters were provided under the head of the bed for additional stability.

When the folding linkages of the steel frame are fully extended, the full width of the bed is available (Fig. 36). In the wheelchair mode, the steel frame folds somewhat in width as well as in length, thus narrowing the bed. This narrowing has several advantages.

a) It makes it easier for the "wheelchair" to maneuver through doorways and hallways;

b) It buckles the foam mattress into a trough-like configuration which both supports and protects the patient (Fig. 37).

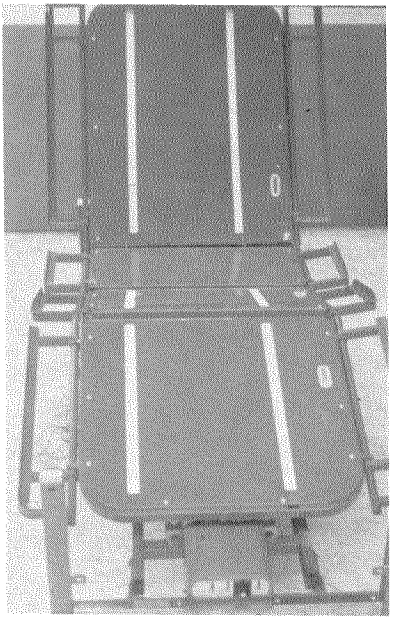

FIGURE 36.—Folding frame of Phase 2 prototype.

The side rails of the extended bed fold upward and inward to shape the foam mattress. Universal joints in the side rails supporting the outer

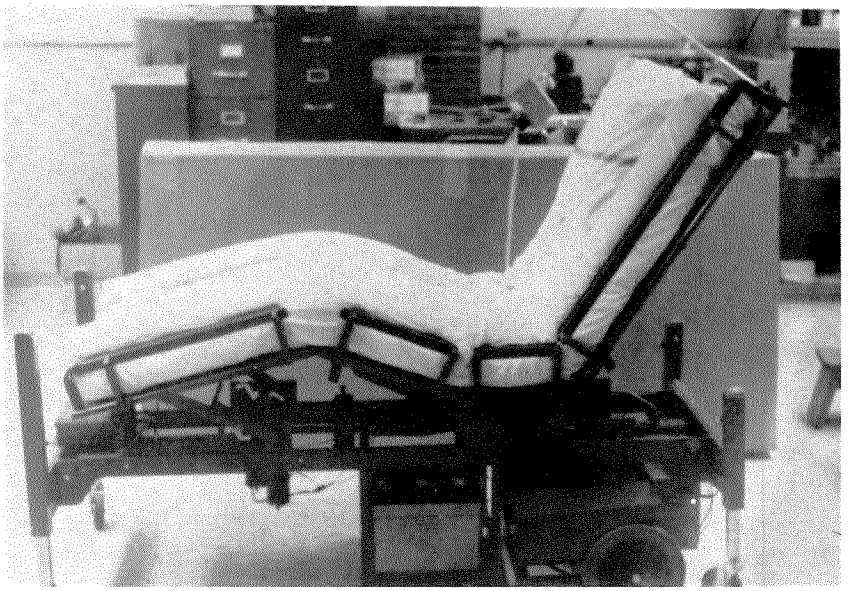

FIGURE 37.—Phase 2 prototype bed shown in folded position. Side rails fold inward to reduce width and provide lateral support for patient.

edges of the mattress are used to transmit torques generated as the bed is raised by means of cables anchored to the base of the bed.

Phase 3

Following the completion of the Phase 2 development and testing, a contract was awarded by the VA to a private company to manufacture several beds for clinical evaluation at several VA hospitals. Following the results of the clinical evaluation, any necessary modification of the bed/chair design will be made and the unit will go to commercial production.

One of the Phase 3 prototype units has been delivered to Rancho Los Amigos Hospital to undergo modification of the movable control arm and for further modifications of the control system.

In Vivo Loading of Knee Joint Replacement

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During this past year the telemeterized knee implants received their final finishing and polishing. One design change was instituted; the substitution of a plastic endplate for the original metal component. The reason for the substitution was the need to increase the RF power output of the transmitter through the implant. Since the endplate is non-loadbearing, substitution of high-density polyethylene for the metal would have no mechanical consequences. Some additional circuitry changes were incorporated in the telemetry package for the purpose of decreasing power consumption and thus increasing useful life.

Insertion instrumentation was designed in cooperation with Dr. Victor Goldberg. The insertion technique for this implant will closely parallel that of existing commercial designs. This instrumentation is now being constructed.

One of the key technical people involved in this project (Dennis Adamson) left Case Western Reserve University in April 1976. Because of his key role in this project, work was stopped until a replacement could be found and trained. This was accomplished by July and work resumed at that time. Another change that occurred was the re-location of the principal investigator, Dr. Albert H. Burstein, to the Hospital for Special Surgery in New York. Dr. Burstein will remain as a part-time faculty member at Case Western Reserve University until June 1977 and therefore he will still continue to direct this project. Because he will not

be full-time at CWRU, Mr. Richard Brown has been added to the research staff of this project. Mr. Brown has been closely associated with this project since its inception 9 years ago and is highly qualified to direct all of the electronic phases.

At a recent meeting of principal investigators and associate investigators, criteria for patient selection were established. A schedule was formulated which called for the first implantation insertion to take place in October. Final assembly and calibration of the first set of implants is now underway.

Research and Development Project on Advanced Orthotic Devices for Adult Paraplegics

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Since January 1, 1976, Prast Research Associates has started design modification of their Pivot Ambulating Crutchless Orthosis, better known as PACO III. This design modification was necessary to enable the system to have universal adjustable capabilities, rather than being a custom-fit item.

In January, Dr. L. Carlson, of the University of Colorado at Boulder, joined PRA as co-principal investigator. At that time he began work on redesigning the knee lock mechanisms to make these automatic. Also at this time, the total orthotic design was modified to insure adjustability.

Real progress on the project began in March when a new armrest design, which enables use of the armrests as a set of parallel bars, was completed and tested. With a minor adjustment these proved to be satisfactory.

In April the knee-lock design and preliminary fabrication was completed in Colorado. At that time Mr. Prast traveled to Colorado to confer with Dr. Carlson. Mr. Prast also contacted the Denver VA Hospital and Mr. Bruce MacKay about finding other paraplegics to test the new design. Also at this time a complete new base design was fabricated but proved to be unsatisfactory. PRA reverted to the original design of the base with slight modification for the new knee locks.

Study was begun to select local vacuum-forming facilities to produce

the plastic parts of the orthosis. Several firms were approached but cost proved to be prohibitive. Further work in this area is progressing at present.

In June Mr. Prast traveled to VA Hospital, Castle Point, New York, to discuss with Mr. M. Di Pompo the possibility of finding a paraplegic user in this area of the country.

Square tubing for the center portion of the orthosis was ordered but has still not arrived to date. The hip locks were slightly modified to accommodate the use of square tubing. The use of square tubing would be advantageous in that the hip and knee locks could be operated by the same throw lever. The knee lock could be connected to this lever by a cable hidden within the tubing.

As of the end of June PRA is looking forward to testing the new base assembly with the automatic knee locks. Dr. Carlson is scheduled to confer with Mr. Prast, and production of the upper portion of the orthosis should be completed.

Engineering Applications in Orthotic and Prosthetic Treatment of Musculoskeletal Defects

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This research began on a very small scale in 1972. The aim is to combine engineering and medical expertise to achieve improved clinical treatments for musculoskeletal problems. This is a two-part program. The first deals with improving and/or developing new, accurate, repeatable, and clinically practical biomechanical measuring techniques to provide essential design and evaluation data. The second involves the clinical application of these techniques to develop design criteria for orthotic and prosthetic devices and/or surgical procedures which will best improve the clinical condition of a patient and provide the greatest possible aid in his rehabilitation.

Computer Control for Stroboscopic System

At the beginning of the period covered by the present report a semi-automated three-dimensional stroboscopic motion-study system had been developed. This system provides the capability of measuring position, velocity, and acceleration of a moving body, as well as providing estimates of forces and moments acting at a particular joint and estimates of tension in the related muscle groups. Although this system,

in its current state, will provide all of the desired measurements, the time required to process the data for a single subject is approximately 40 man-hours. Thus, in its present state, the system is not a clinically practical tool.

This has been a problem common to all existing systems making comprehensive biomechanical measurements. If it is to be clinically practical, automation of the entire system is necessary, with real-time data processing on an on-line computer facility.

While the stroboscopic system was being developed, parallel efforts were in progress to acquire a computer system affording the necessary real-time capabilities for the Cleveland VA Hospital Research Wing, and the re-design of the motion study system for computer control.

A PDP-11 computer system was installed at the beginning of the period of this report. Since then, the stroboscopic system, which was previously located at the Medical School of Case Western Reserve University, has been moved to the new Research Wing of the Cleveland VA Hospital and the programs for data analysis have been revised to achieve compatibility with the new computer system.

Initial phases in establishing the computer-controlled system have been completed. Infrared-sensitive cameras which produce electric currents proportional to the x and y coordinates of small infrared light sources will replace the still cameras in the stroboscopic system — otherwise the systems are almost identical. With these cameras, position information is fed directly into the computer. All other data (force plate, EMG, and in-vivo forces) are also input directly to the computer. When completed this system will allow complete analysis of all data while the patient is still in the laboratory.

At this time, interfacing of the infrared camera system (Selspot System) is almost complete. Initial tests have been performed on the Selspot System. Optical synchronization has been found to be adequate over the desired range of distances. The field of view for the cameras as situated in the laboratory is ±4 ft. from the center of the walkway. This is sufficient for the present analysis as it covers the complete gait cycle during which contact with the force plate exists.

One disadvantage of this system is the requirement that light sources be positioned on the subject. It was determined that two light sources will be required on each of the individual anatomical landmarks that is to be monitored simultaneously by both cameras. These two light sources must be mounted as close together as possible, and in such a manner that each is aimed as directly as possible at its corresponding camera. An appropriate mounting scheme, or an equivalent solution, will be worked out in the next reporting period.

An additional problem is the high power requirements of these light sources. Direct connection to a line-powered source seems to be inevitable at this time.

Clinical Applications

One of the studies in the clinical applications portion of this program has been a biomechanical analysis of the knee joint. Initial results of a normal subject correlate fairly well with the results of Morrison (1). Evaluation of an instrumented total knee prosthetic implant patient, pre- and post-surgery, is planned for later this year.

Another clinical applications study being performed is a comparison of implanted electrical stimulators (neuromuscular assist) with four other methods of treatment for the equinovarus foot in the hemiplegic adult. The four other methods being studied are: the conventional double-bar metal upright AFO, the VAPC shoe clip AFO, the TIRR polypropylene AFO, and the Functional Electrical Stimulator (FES) Peroneal Brace.

Seven NMA devices have been implanted, with ten planned. A foot switch system for control of the stimulator, similar to ones used by other investigators, is being used.

A foot switch system has been interfaced with the PDP-11 computer for quantitative measurement of the parameters of gait. A study of 40 normal male and female subjects has been completed, from the accurate measurements of which a norm of each of the component phases of gait has been established. These results will be used as a baseline in evaluating abnormal gait. A method has been developed, based on foot contact results, whereby a numerical indicator of the quality of a patient's gait can be established—this work is being prepared for publication. Other clinical studies using the foot contact system are in progress or in the planning stages.

Functional Electrical Stimulation of the Muscles of the Hip

Initial success at Case Western Reserve University in the use of electrical stimulation to return functional use of the paralyzed hand, and in studies done at this laboratory in correcting foot drop, has prompted an attempt at control of the paralyzed hip through electrical stimulation.

An "intelligent" 12-channel programable stimulator is being designed to serve as the controller unit in a closed-loop system. This will respond to switch closures and position information to provide appropriate stimulation to each of the involved muscles during the appropriate phase of each gait cycle. Several prototype sections of this unit have been constructed and tested. Studies on stimulation of hip muscles, using the same techniques employed by Peckham (2) for the hand, are in progress. Initial results indicate that the stimulation is fairly well tolerated and can produce sufficient force. Techniques used for protecting the electrode site in the groin area have been found to be adequate.

In the near future, work in this study will include stimulation of muscles not yet tested to determine the possibility of producing functionally useful contractions, as well as a study of the fatigue characteris-

tics of hip muscles and whether these characteristics can be beneficially altered by an electrical stimulation exercise program.

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Patient Evaluation of a Functional Electrical Stimulation Hand Orthosis

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A new project has begun at the Cleveland VA Hospital to evaluate a hand orthosis, using functional electrical stimulation, which has been designed for high-level spinal cord injury patients. The preliminary feasibility of this orthosis has been demonstrated in studies performed over the past 4 years at Case Western Reserve University.

The orthosis utilizes electrical stimulation of the forearm finger flexor and extensor muscles to provide proportional control of prehension and release, respectively. The patient controls the contraction strength by movement of a shoulder or head position transducer. The stimulator and control will be portable and attached to the patient.

SENSORY AIDS

Edited by

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Research on Audible Outputs of Reading Machines for the Blind

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