HIGHLIGHTS OF OTHER RESEARCH PROGRAMS

PROSTHETICS

Edited by
Eugene F. Murphy, Ph. D., Director
Research Center for Prosthetics
Veterans Administration
252 Seventh Avenue
New York, N.Y. 10001

Research and Development in the Field of Artificial Limbs

Mauch Laboratories
3035 Dryden Road
Dayton, Ohio 45439
Hans A. Mauch

Hydraulic Ankle Control System

The shakedown tests of the Hydraulic Ankle by the Research Center for Prosthetics and the VA Prosthetics Center, New York, are under way. Two amputees (one AK, one BK) were fitted and began wearing the experimental ankle at the end of May and the end of June, 1977, respectively. In both cases the initial amputee reactions were very favorable. Four more amputees (one bilateral AK/BK with the experimental ankle to be fitted on the BK side first and then on the AK side, and one hip disarticulation, a bilateral AK, and another BK) were recruited and will be fitted in due time.

The first test results (which relate mostly to noise) are being received and acted upon. Although the shortcomings seem minor, some tedious yet difficult work lies ahead, especially in two areas (piston rod neck and tip) where the hydraulic unit is attached to the shank. (The foot attachment appears to be working satisfactorily.) In both areas mentioned, compound motions (longitudinal plus rotatory plus tilting) occur at every step under several hundred pounds of pressure. These areas must be accommodated by suitably designed bearing surfaces to last for at least 1 year (approximately

one million cycles) without maintenance and without the need for non-solid lubricants. The present solutions work for a few weeks (depending on the activity and stress level); then noise develops as a result of wear.

The hydraulic unit itself, the development of which was a much more formidable problem, continues to work well. At the beginning of January 1977, the Dayton test amputee reported that he had been shoveling snow early in the morning at -20 deg C (-5 deg F) without noticing any change in the unit's function. In April, he experienced difficulties in initiating flexion of his prosthesis when walking down a ramp with inclinations in excess of 10 deg. By design, the dorsiflexion stop, produced by the Hydraulic Ankle with the shank vertical and the foot pointing downward parallel with the incline, created too much alignment stability. Some degree of pole-vaulting was necessary on the part of the amputee to walk over the ball of the foot in this situation. As a remedy the forward travel of the ceramic control ball inside the hydraulic unit was limited to 10 degs by bending the front ends of the ball cage slightly inward. This had the effect of making the descent of ramps steeper than 10 degs much less precipitous because pole-vaulting was no longer necessary in both weightbearing and jack-knifing descent. This important improvement was adopted and incorporated in all test units.

At the end of April a program was started to improve the cosmesis of the transition between the lower end of the shank and the upper edge of the shaft of the foam foot (a thin, slender, reinforced upper edge). After a number of mold changes to this effect, a preliminary foot was made and put on the Dayton test amputee's prosthesis. It was found that the foam quality achieved was not satisfactory for this design: the foam at a density of 32 lb/f^3 was too stiff. A foam mixture resulting in a lighter density (25 lb/f^3) did not fill the mold properly when mixed by hand in paper cups. It also produced too thick a skin and the pores of the foam were too large. It became clear that a small commercial type metering and mixing machine was needed in order to produce high quality foam feet for the ankles used in the shakedown testing program. The purchase of such a machine was approved by the VA in June, 1977; the machine was ordered and will be delivered in the middle of July 1977. It is hoped that a softer textured foam foot will also help to overcome "swishing" noises produced on occasion by friction between the upper edge of the foam foot and the outside of the lower shank.

Hydraulic Knee Control System for Geriatric Amputees

In February and March, 1977, the swing-control part of the Hydraulic Knee Control System for Geriatrics was completely redesigned. (Further tests with the previous design had revealed a lack of adaptability in obtaining various resistance profiles.) The new design still uses shaped recesses on the piston rod surface. However, the surrounding elements now contain vertical rows of suitably-spaced fluid exit holes (similar to the present design of the S-N-S system, but simpler). An added advantage of this new design, which will not add to the cost, is the fact that in the adjustment of the swing resistances for the various needs of the amputee, resistance increases and decreases are in proportion with the positioning of the adjustment elements. This is an improvement over the present S-N-S system where the resistance change is steeper at the high end of the adjustment range. In addition, several improvements were made in the design with the purpose of increasing its life expectancy and decreasing the work necessary in repairing it. These improvements will facilitate disassembly and reassembly.

Voluntarily Actuated Swing and Stance Control System

No reportable progress was made in the development of the Voluntarily Actuated Swing and Stance Control System due to higher priority work.

Other Developments

The adoption of the three-part bolt by the prosthetic supply industry is progressing satisfactorily.

The Ohio Willow Wood Co. has ordered 5,000 bolt assemblies from the All Metal Screw Product Co. They will soon have their wooden setups, also used for the S-N-S system, equipped with the new bolt. The Hosmer Corp. is also planning to incorporate the new bolt into their foam setup.

Stump Stress Analysis

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

No progress report was submitted for this report period.

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

Design of a Powered Arm for Shoulder Disarticulation Amputees

One of the many challenging problems of limb prosthetics is the design of a multifunctional artificial arm which can be controlled easily with some degree of subconscious control. This laboratory has continued the development of a laboratory prototype arm which uses Dr. David Simpson's concept of extended physiological proprioception (E.P.P.). Mechanically, this particular prototype arm is constructed around "unbeatable" position servomechanisms which have inputs from sterno-clavicular position.

An early prototype of the arm is shown in Figure 1. In this case only the VAPC elbow has been fitted with the feedback mechanism. The output position is fed back to the input lever through a "hydraulic link". This link also makes the system "unbeatable" by physically linking output and input. The error-detection scheme used (at this stage) is of the "on-off" (Bang-Bang) variety in an effort to keep the system simple.

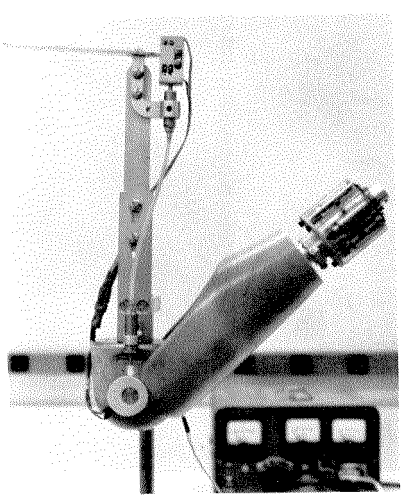


FIGURE 1. – Early prototype of a multifunctional artificial arm for the shoulder-disarticulation amputee.

Synergetic Hook Preliminary Evaluation

The synergetic hook, developed in this laboratory, is being clinically evaluated on a small scale by the VA Prosthetics Center and the VA Research Center for Prosthetics, New York. This laboratory is providing repair for the field units. The study is yielding valuable design information, and the redesign of this prehension device has already begun. The system is being redesigned to permit easy fitting of the wrist disarticulation amputee, to allow reduced voltage and power, and to permit the use of exchangeable battery packs.

Below-Elbow Myoelectric Fitting Techniques

A new casting fixture has been developed for the Northwestern below-elbow socket (Fig. 2). The fixture maintains the arm in 45 deg of flexion and is adjustable for various arm lengths.

Alginate is used to take an undistorted cast of the limb. After the alginate has set, the limb is removed, the alginate supported, and a positive cast poured. Small pads are placed on the arm to mark the electrode locations. This casting technique, used in conjunction with the transparent Cellulose Acetate Butyrate (CAB) check sockets, has proved to be useful in the fabrication of below-elbow sockets for myoelectric prostheses.

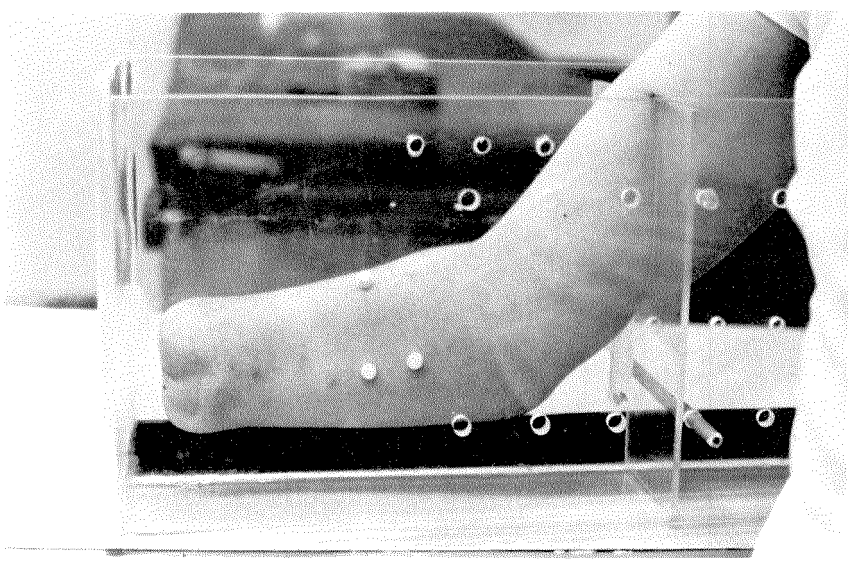


FIGURE 2. – A below-elbow myoelectric fitting technique.

Lightweight Below-Knee Prostheses

Three amputees (one bilateral) have been fitted with four of these prostheses. Work has been completed on improving cosmesis and on developing a fabrication technique for combining soft inserts with the polypropylene sockets. A bilateral amputee wearing the lightweight prostheses is shown in Figure 3. This illustrates that good cosmesis and lightweight construction can be combined. Figure 4 shows this subject removing her left prosthesis (note the soft Pelite insert).

The laboratory is planning to assist the Mid-West Chapter of AAOP with a workshop on lightweight prostheses during November 1977. It is hoped that this workshop will stimulate the use of this type of prosthesis in the private sector.

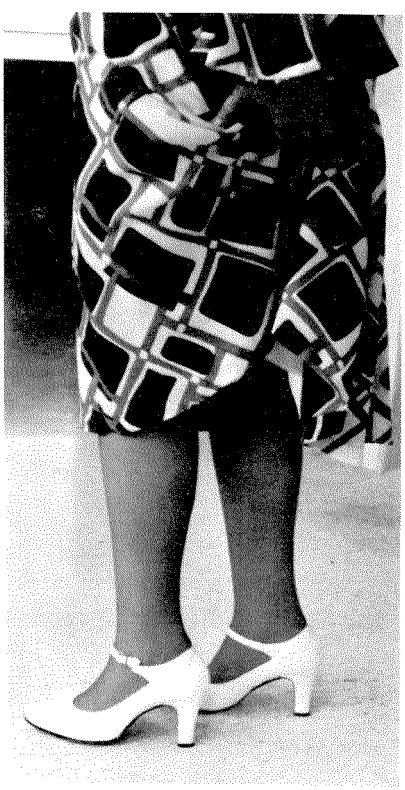


FIGURE 3. – Bilateral below-knee amputee wearing lightweight prostheses.

FIGURE 4. – Same subject with soft Pelite insert.

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

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

Upper-Limb Prosthetic Research — Control of an Artificial Limb with Several Degrees of Freedom of Motion

Efforts toward a self-contained, microprocessor controlled, above-elbow prosthesis were continued during the 6-month period of January through June, 1977. System integration and upgrading were included in the work, whose aim is a clinical prosthesis.

The VA-UCLA prosthesis with three degrees of freedom of motion was improved by the inclusion of the new VAPC motors (now commercially available from the manufacturer, Fidelity Electronics, Inc.) for the elbow, wrist rotator, and hand. The prosthesis was tested and was interfaced to the development system (RCA COSMAC) for testing. UCLA miniature myoelectric amplifiers were also tested and interfaced to the development system.

The self-contained microprocessing system was completed and debugged and is now ready for software injection.

Interface circuitry, to input myoelectric signals (MES) and convert them to digital values for use by the computer, was constructed and debugged. All parts of the circuit were exercised. Amplification values were determined for the MES inputs. The input multiplexer and the analog-to-digital converter (ADC) were driven, using DC and MES inputs, to test them. Interface circuitry to output motor drive signals was also built and debugged.

The circuitry described here was connected to the RCA COSMAC micro-computer development system to allow the convenient writing and debugging of the Nearest Neighbor Classifier (NNC) system used in prosthesis control. The NNC system has been written and is in the process of being debugged and tested. The system uses the Nearest Neighbor Pattern Classification technique (distance calculations are made using a City Block Distance Algorithm). At the time of this report the system occupies approximately 1k of 8-bit computer memory, with room for some expansion if necessary.

Current work on this project includes:

a. Subject testing experiments to debug final version of software and to calibrate the system before its injection into

the microprocessor.

b. Construction of circuitry to allow transfer of the software from the development system to the microprocessor.

c. Development of a belt-mounted power pack to energize the system.

Prosthesis Sensory Feedback

Work in the prosthesis sensory feedback project was continued in the completion of the investigation of the effects of pulse width and pulse time-delay effects on the electrotactile two-point discrimination of a sensory feedback display. It was found in subject testing that 100-μs pulse-width results in superior discrimination, and allows larger numbers of channels to be included in the display.

It was also found that a pulse time-delay of 180 deg resulted in superior discrimination.

Current work on this project includes the investigation of electrotactile two-point discrimination hysteresis for ascending and descending thresholds, as additional necessary data for the specifications of the optimal electrotactile display.

Effectiveness for Veteran Quadriplegics of Medical Manipulators, and Design Specifications for Improved Control

Over the past 6 months, work on the evaluation of the effectiveness of medical manipulators has proceeded in two areas.

The first area has been the development of an effective evaluation protocol. The protocol has been designed to be sensitive to the extreme disability of the patient for whom the manipulators have been designed, and to the intimacy of interface which the patient's disability necessitates. The protocol has been designed in these three parts:

1. Bench Testing – Rigorous assessment of the safety and engineering aspects of the manipulator's function.

2. Performance Testing – Evaluation of training and performance of patients (associated with VA Hospital, Long Beach, California) in experimentally controlled tasks.

3. Clinical Testing – Assessment of the actual usefulness of the manipulator to patients, through monitoring of long-term use.

The second area of progress has been the implementation of the above protocol in the evaluation of the manipulators supplied through the VA Prosthetics Center, (VAPC), New York. The Biotechnology Laboratory has received two manipulators: the Rancho Los Amigos Remote Manipulator #12, and the General Teleoperator Telescoping Arm. The Telescoping Arm developed mechanical difficulty in the bench-testing phase of the evaluation, and conse-

quently is presently unsuitable for patient use. The Rancho Los Amigos Manipulator has proceeded through the safety and engineering evaluations, and is currently being used by four patients, representing a wide range of disabilities, in the performance-testing phase of our protocol.

Design of Prosthetic and Orthotic Devices and Biomechanical Studies of Locomotion

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

Design of Lower-Limb Prosthetic and Orthotic Devices

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

A preshaped, flexible foam knee-cover has been designed, and a mold for its fabrication is being made with the assistance of the Navy Prosthetics Research Laboratory (NPRL), Oakland, Calif. Several elements of the knee unit have been revised in response to information obtained in clinical trials. These modified parts have been fabricated and assembled into a final revised prototype (Fig. 5). Complete engineering drawings of that prototype, along with the mold for the resilient knee fairing, will be delivered to the VA Prosthetics Center, New York, by the end of FY 1977. Extended clinical trials with commercially fabricated units are planned.

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

Clinical trials on three amputees at the Naval Hospital in Oakland have resulted in clinical acceptance on a functional basis, but the trials revealed inadequate strength and durability in the proximal bearings. One amputee fitted at VAPC, New York, has rejected the unit in favor of the OHC (Orthopaedic Hospital in Copenhagen) unit with hydraulic swing-control. (The VAPC trial also indicated the need for stronger bearings.) Partial revisions to two existing units have been made (Fig. 6) in order to increase bearing capacity and provide a positive extension stop. A thorough review of the design is underway, with the aim of obtaining even greater bearing capacity, along with improved appearance in the flexed position.

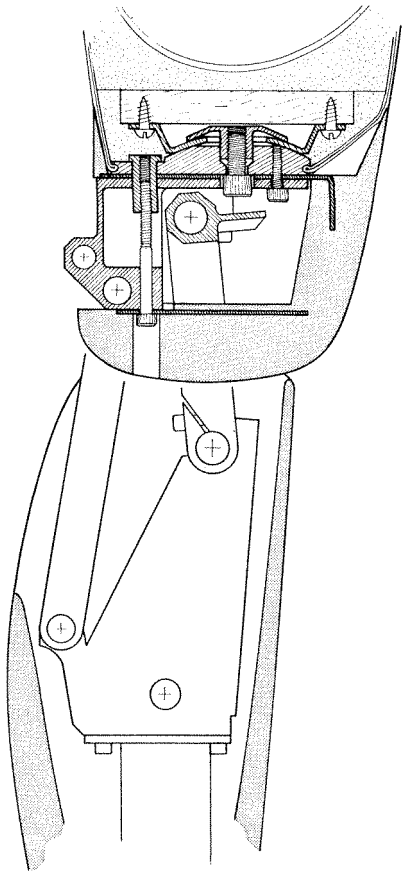


FIGURE 5. – The UC-BL four-bar-linkage polycentric knee unit, with spherical socket coupling and polyurethane foam knee-fairing system.

3. *Friction-Stabilized Knee*

There were three design goals for this knee unit: 1. friction knee-lock at heel contact, 2. release of knee friction prior to toe-off, and 3. adjustable friction swing-phase control from the same brake that provides knee lock. The second prototype (reported previously) satisfied the first two requirements, but not the third. That unit is shown schematically in Figure 7. Further experiments, with elastic

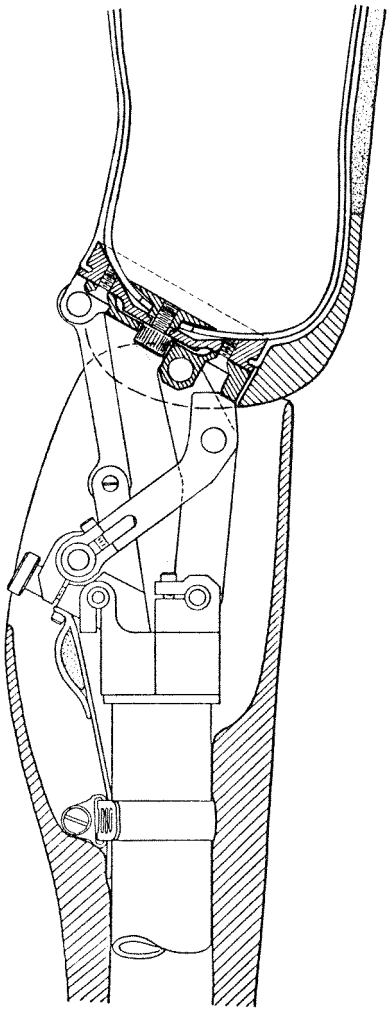


FIGURE 6. – The UC-BL six-bar-linkage knee disarticulation prosthesis with spherical socket coupling.

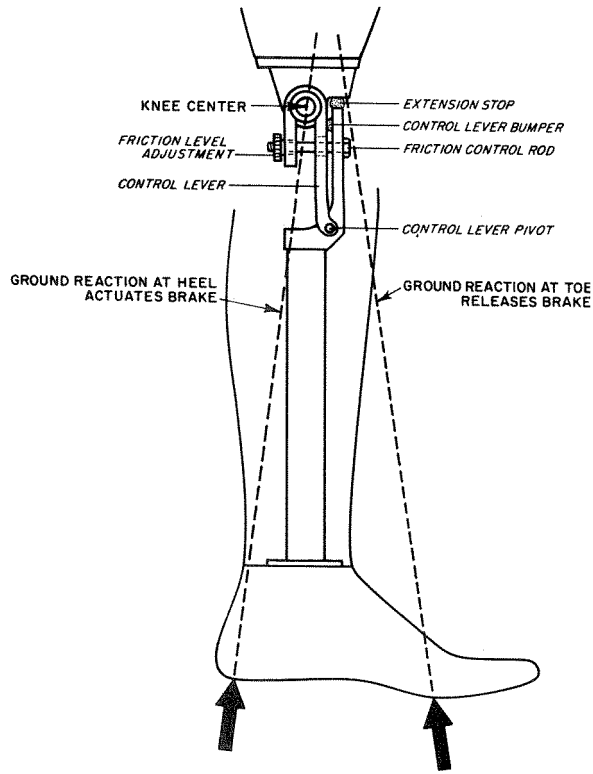


FIGURE 7. – Schematic representation of the UC-BL dual-action safety knee with heel lock and toe release.

knee extension straps and spring forces that push the control lever forward, resulted in satisfactory swing control without degradation of the desired stance-phase characteristics. A third prototype, incorporating the required changes, is being designed.

4. *Tube Coupling for Modular Prostheses*

The internal, expanding, tubular-pylon couplings have undergone continued amputee and machine testing. Included in the tests were two couplings built into the new metal-keel SACH foot, three couplings for use with commercial SACH feet, and three couplings integrated into the design of linkage knee units. No problems have been encountered with loosening during use. Tests of a variety of materials have shown that a canvas-and-phenolic collar on an aluminum post with a brass locking-ring provides the best combination of sim-

ple manufacture, easy assembly into the tubing, and easy disassembly after long use. Two examples of the coupling are shown, one in Figure 8 and another in Figure 9. More widespread testing of this

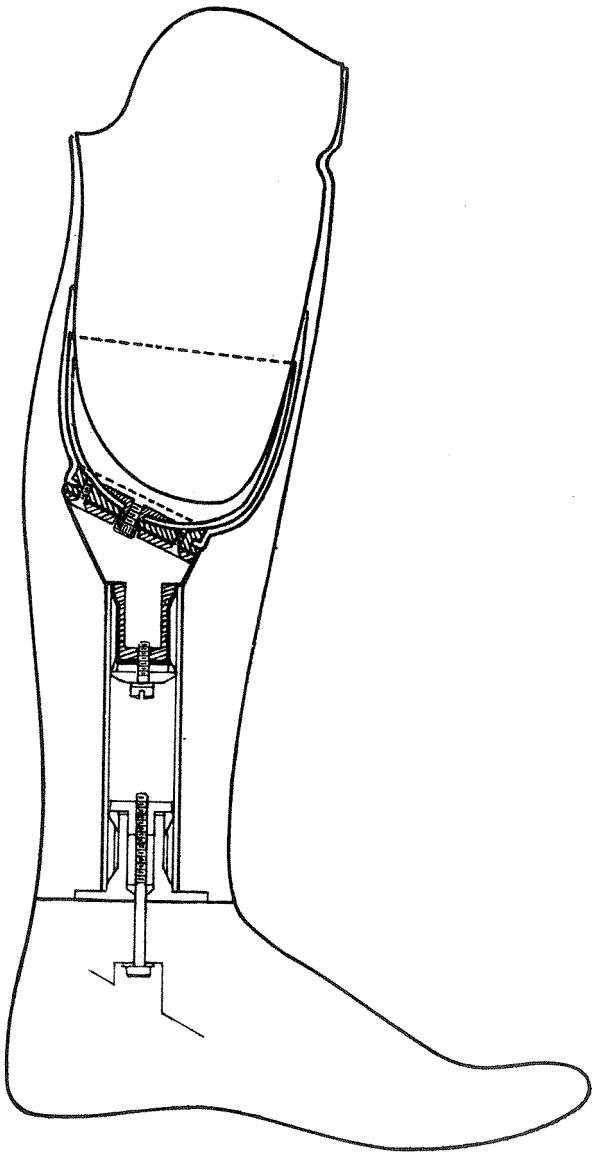


FIGURE 8. – The UC-BL modular pylon system for below-knee prosthesis, using the internal expanding tube coupling and spherical alignment coupling.

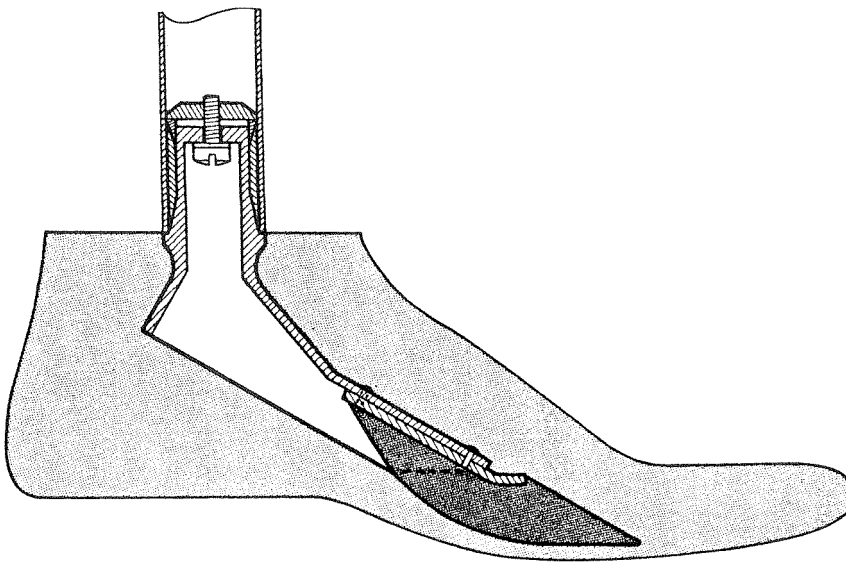


FIGURE 9. – The UC-BL metal-keel SACH foot.

coupling will occur during clinical evaluation of the four-bar-linkage polycentric knee, planned by VAPC for FY 1978.

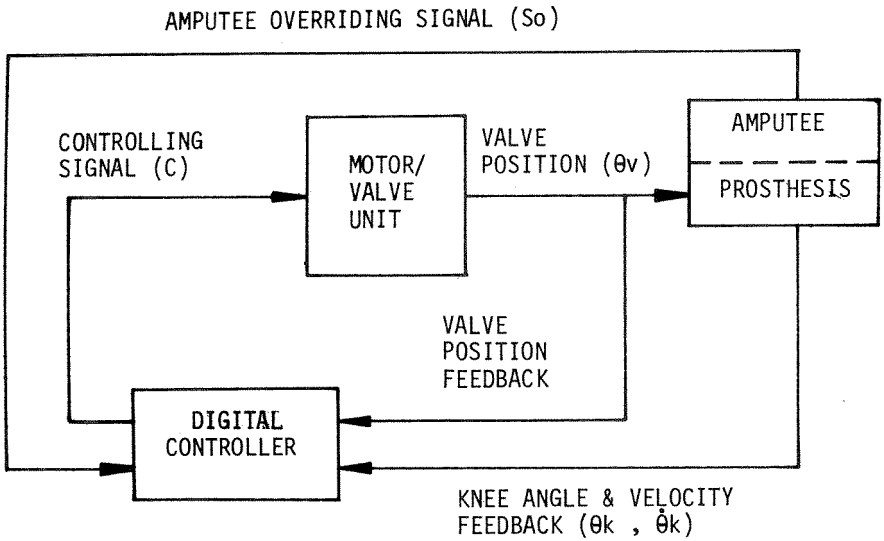
5. *Modular Pylon Structure for Below-Knee Prostheses*

A pylon structure for the below-knee amputee has been designed to make use of the internal, expanding, tubular-pylon coupling and the spherical-alignment coupling used with the six-bar linkage knee. (Figure 8 shows the construction.) Fabrication of a prototype is under way.

6. *SACH Foot with Metal Keel*

Two additional models of the metal-keel SACH foot with integral pylon coupling and solid rubber cushion forefoot (Fig. 9) have been molded with the aid of NPRL, Oakland. One of these units was subjected to 100,000 cycles of accelerated testing on the Hosmer-Dorrance testing machine.

The second was worn by an AK amputee for three months. At the end of each test, the feet had worn through the molded foam under the forefoot to expose the solid rubber cushion. The aluminum keels and expanding pylon couplings showed no structural weakness. Functional characteristics of the foot are considered good by the amputee test subject, a long-time wearer of SACH feet.



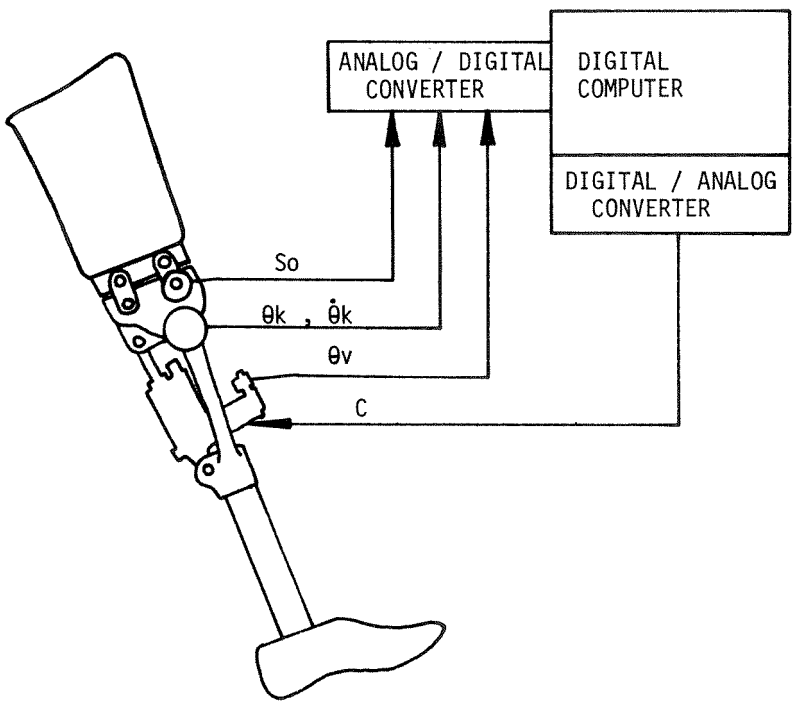


FIGURE 10. – Digital system for simulation of proposed analog/digital computer control of knee stability of above-knee prosthesis.

Design changes to improve the durability of the forefoot will be made and incorporated in future feet. The forefoot cushion will be broadened, and combined with belting in the sole, to provide an optimal combination of cushion forefoot, lateral motion, and forefoot durability.

7. *Multi-Input Control and Knee Stability*

Stability of the knee in an above-knee prosthesis can be defined in terms of knee angular velocity, as follows:

If the angular velocity is zero, the knee is stable; if less than a specified value, controllable; if greater than a specified value, unstable.

A project is under way to apply these concepts to the design of an active knee-stability controller. The initial prosthesis will incorporate a single-axis knee with remotely controllable hydraulic swing-phase control. Knee angle and angular velocity will be measured to provide the controller with information on the state of the knee. A measurement of hip flexion/extension moment will provide the basis for voluntary control of stability. Initial tests will be conducted using the laboratory minicomputer as an experimental controller. Figure 10 illustrates the system.

8. *Shank Axial Rotation Devices*

Continued amputee tests of the UC-BL shank axial-rotation unit confirm previous findings regarding durability and function. Problems, such as loosening of assembly screws and breakdown of the bond on the elastomer return spring, have occasionally been a nuisance, but the bearings have shown adequate strength and several trials of more than 2 years duration have been achieved. The major concern, from a design standpoint, has been with complaints of instability under certain circumstances due to lateral shear forces on the forefoot. A below-knee amputee walking over a slightly bent knee, or an above-knee amputee going up a ramp or walking on soft ground, may complain that the rotator suddenly rotates out of control until it hits the stop.

It was hypothesized that locating the axis of rotation concentric with the shank centerline provides an excessively large moment arm for shear forces on the forefoot, and that a relocation of the axis of rotation to equalize heel and toe moment arms should alleviate the problem. A prototype unit was built with rotation axis inclined to the shank centerline by 10 deg (Fig. 11). Amputee trials of that prosthesis indicate that the hypothesis was correct, and the problem has been corrected. This finding has direct implications for the design of more functional rotation units.

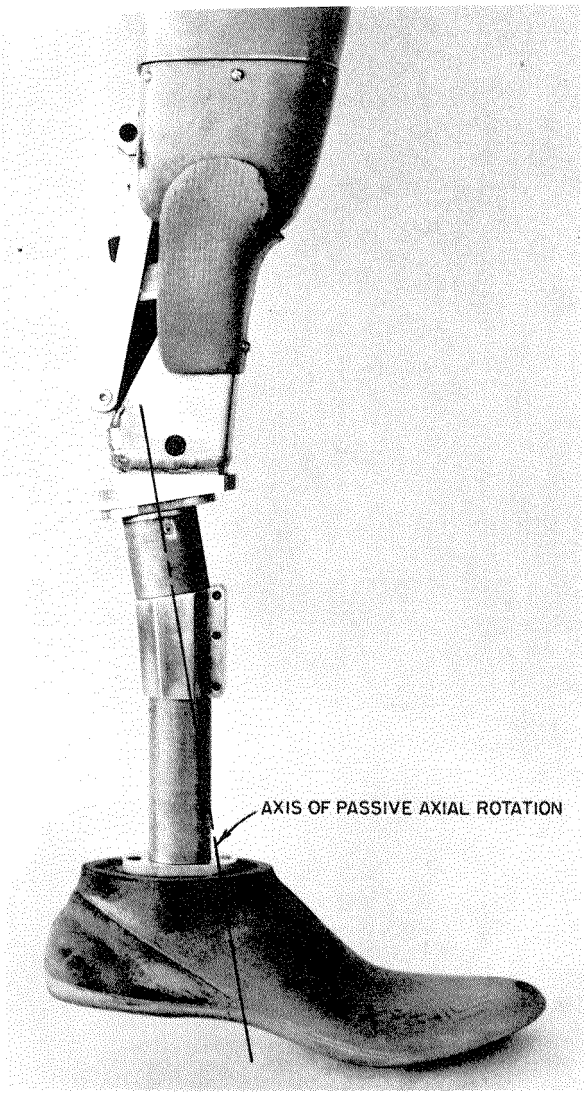


FIGURE 11. – Experimental installation of the UC-BL shank axial-rotation unit, with inclined axis of rotation designed to improve rotational stability when weight is borne on the forefoot.

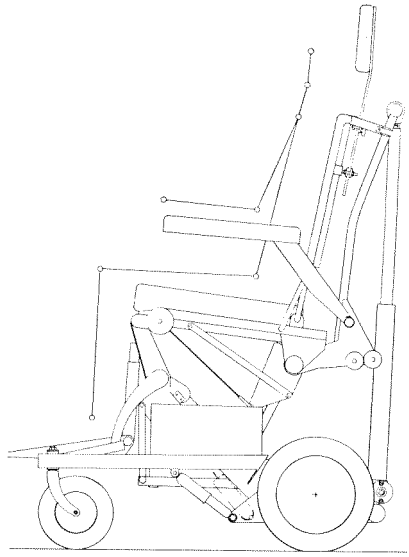


FIGURE 12a. – PRAHN II central-linkage wheelchair: high position.

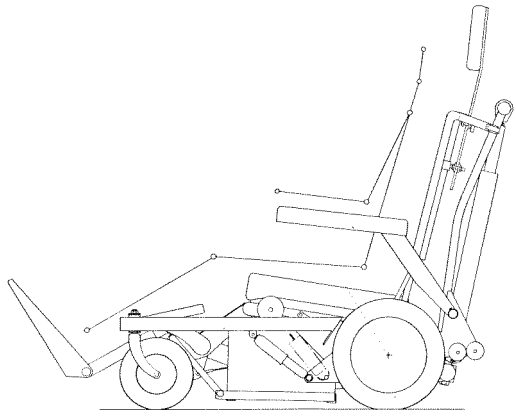


FIGURE 12b. – PRAHN II central-linkage wheelchair: low position.

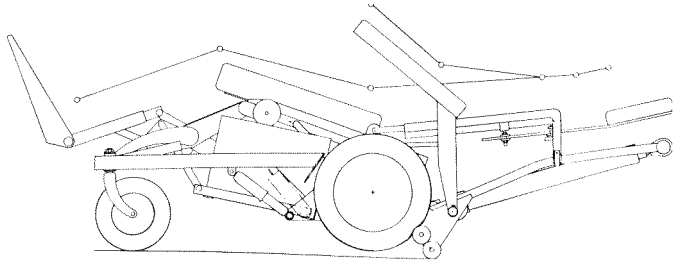


FIGURE 12c. – PRAHN II central-linkage wheelchair: reclined position.

The UC-BL shank axial-rotation unit has served its intended purpose as a medium for clinical assessment of the axial-rotation concept. It also has helped to stimulate increased industrial interest and activity in the development of production rotation units. In the future, the findings of this project will be applied to a comprehensive foot-design project rather than to the continued development of a separate rotation unit.

Mobility Aids for the Physically Disabled

1. *PRAHN Wheelchair*

The design of the PRAHN II wheelchair is virtually complete, and fabrication of the first of two prototypes is scheduled for completion by January 1978. Layout drawings of the chair in three positions are shown in Figure 12. This wheelchair has many improvements over PRAHN I, notably, larger battery capacity for range in excess of 20 miles over normal terrain, more powerful motors for improved hill climbing, a simplified linkage with lower-cost bearings, spring suspension, 2¾-in. ground clearance, electric failsafe emergency/parking brakes, and recline kinematics which simulate a hip pivot and keep the feet on the footrest. In addition, a curb climber for 8-in. curbs has been designed into the chair. As with PRAHN I, seat height is adjustable from 7 in. below to 6½ in. above normal seat height, with an articulated footrest which simulates a pivot at the knee as the feet "tuck in" during raising of the seat.

PRAHN II has a fixed 23-in. width, instead of the "narrowing" feature of PRAHN I.

One of the PRAHN II prototypes is scheduled for delivery to the VAPC for evaluation in October 1978.

2. *Spring Suspension Powering Unit*

The first prototype of this unit (Fig. 13) is still performing excellently after 15 months of daily use. A second prototype incorporating some changes will be delivered to the VAPC in March 1978.

3. *Urinal Bag Clamp*

A urinal bag clamp has been developed which allows a quadriplegic to empty his urinal bag by a 5-lb. pull on a leather thong. As can be seen in Figure 14, a spring-loaded roller squeezes closed

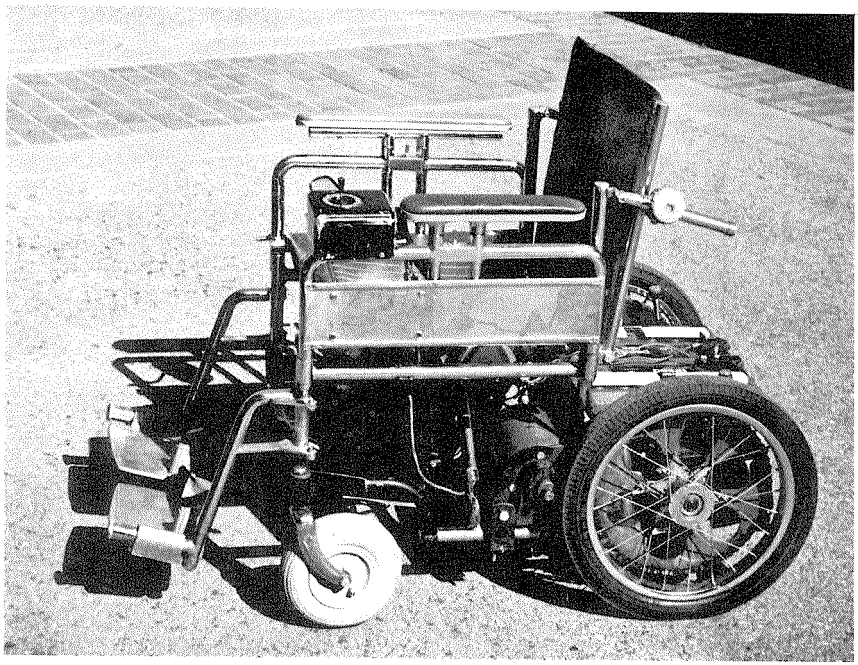


FIGURE 13a. – Spring-suspension powering unit: side view.

the rubber tube from the urinal bag, until the leather thong is pulled to empty the bag. All parts are external to the tube, so sterility is not a crucial problem. Local testing has been very successful, and five slightly simplified clamps are scheduled for delivery to the VAPC in September 1977 for evaluation.

Immediate Postoperative Prostheses Research Study

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

1. Controlled Environment Treatment

The 3-year research protocol, using Controlled Environment Treatment techniques for the immediate postoperative management of below-knee amputations, has been concluded.[a] The system has

[a] See article in this issue.

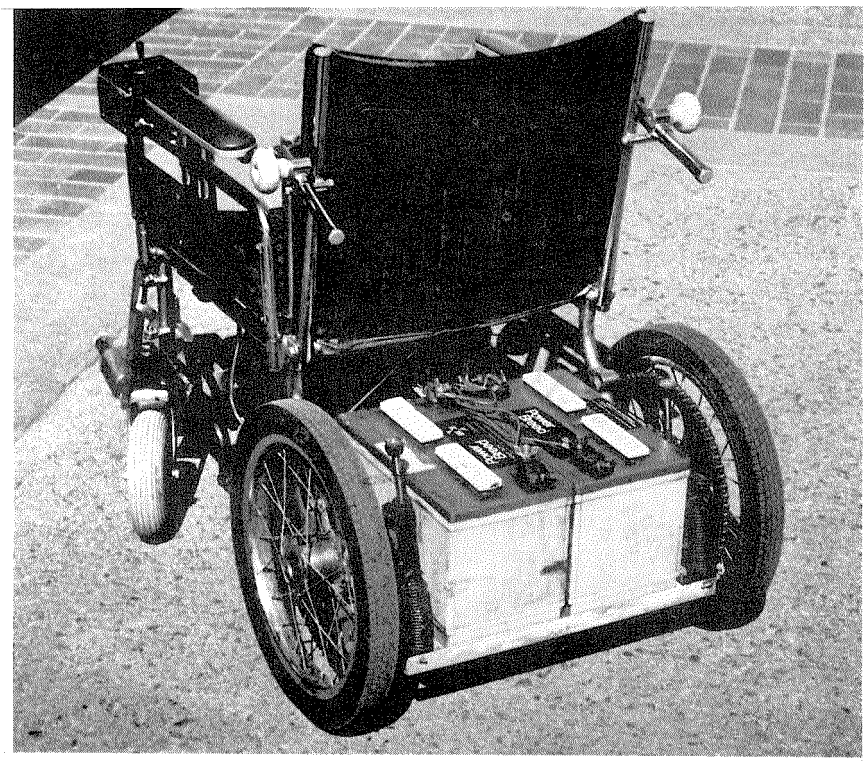


FIGURE 13b. – Spring-suspension powering unit: rear-quarter view.

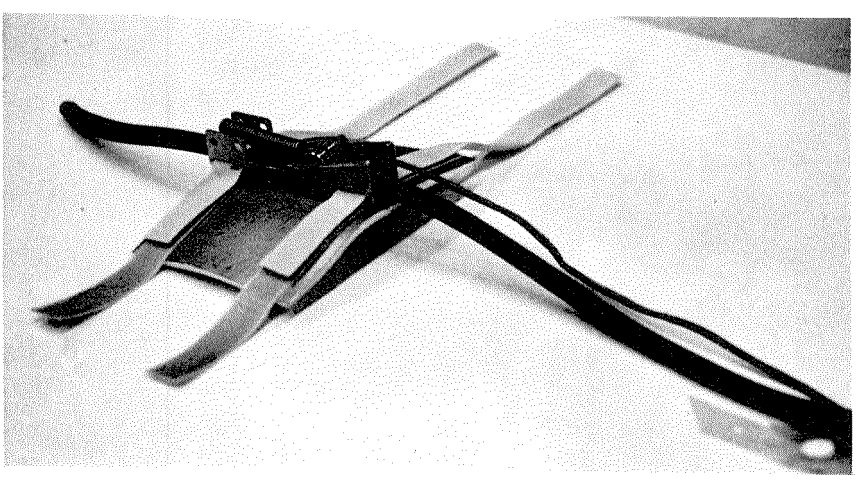


FIGURE 14. – Second prototype of urinal bag clamp.

now been incorporated into our regular postoperative treatment program where experience indicates its advantages. Prosthetics Research Study Group (PRS) has developed and produced a simplified mechanical unit incorporating basic CET principles (Fig. 15). Clinical applications of the CET include fresh trauma, acute and chronic limb edema states, pain abatement, alteration of peripheral circulation in ischemic diseases including stasis ulcers and gangrene-threatened digits, fresh limb surgery and trauma (exclusive of traumatic amputations), decubiti and related pressure-induced lesions. The smaller portable unit allows home use of CET.

Incorporation of thermal and electrical modalities in the CET system is being tried in the management of acute trauma, particularly severe ankle sprains, etc. We are also exploring the use of this

FIGURE 15. – PRS-designed MACE (Modulated Air Controlled Environment) unit for non-sterile pressure regimes.

means of external tissue environment control in Raynaud's disease, Buerger's disease, and similar vaso-spastic states.

A small model of the CET system has been made by James Moore of PRS and is being used by Dr. F. A. Matsen, III, and associates to study experimentally the effects of pressure on edema, skin and muscle circulation, and nerve conduction times. The rabbit is the experimental model.

2. Studies of Skin Blood Flow as Related to Amputation Level

Our initial experience using $Xenon^{133}$ to assay dynamic skin blood flow, pre- and post-amputation, in patients with ischemia has been accepted for publication by Surgery, Gynecology and Obstetrics. This work is continuing, in the hope that it can be made clinically useful generally. Further experimental inquiry into skin circulation is being initiated in cooperation with Dr. A. J. Holloway, using the non-invasive laser-doppler system which he has developed. This innocuous, non-invasive assay will also be used pre- and post-amputation in the study of ischemic limbs.

3. Physiological Suspension

Our ongoing work continues in the physiological suspension of the below-knee prosthesis using residual limb muscle activity.[b] We anticipate continuing observations in this area, with specific direction toward prosthetic design changes for incorporating interface contours to further improve physiological limb suspension. The functional benefit derived from this approach to physical interface relationships can have far-reaching effects on amputation surgery, physical rehabilitation of the residual limb, and prosthetics design.

4. Extra-ambulatory Function for the Lower-Limb Amputee

Working in cooperation with Drs. D. Miller and R. Hutton, Department of Physical Education, University of Washington, we have been objectively evaluating physical skills primarily related to sports and recreation, and how they can be improved in the lower-limb amputee, primarily the younger patient. Recently, separate funding from the Veterans Administration has been provided Drs. Miller and Hutton, who will continue and extend these studies under PRS supervision.

---

[b] See article in this issue.

5. Functional Capabilities of Lower-Limb Amputees

Bernice Kegel, R.P.T., and Margaret Carpenter, of our rehabilitation staff, have completed and reported an extensive functional capabilities survey on a statistically significant controlled amputee population during a 10 year follow-up. An extension of these studies is underway, monitoring social adjustment and lifestyle in depth.

6. Revision Amputation

There is a real need for definition of the principles of revision surgery, especially in the lower limb where the primary amputation was performed for ischemia. The past 10 years has seen a dramatic lowering of the level of primary amputation for peripheral vascular disease. Functional and economic benefits have been great. No modern guidelines exist to define the technique and levels for revision when this becomes necessary. Drs. E. M. Burgess and L. Pedegana are now reviewing 100 consecutive lower-limb amputations for the establishment of guidelines and anticipated results.

7. Amputee Service

The amputee service at the Seattle Veterans Administration Hospital continues active with a steady increase in the number of surgeries performed and rehabilitation problems referred.

Below-Knee Amputation with Immediate Postoperative Fitting of Prosthesis

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

Dr. Moore has recently moved this project from the VA Hospital, San Francisco, to the VA Hospital, Tucson, Arizona, in conjunction with his acceptance of a new position as Professor and Head, Section of Vascular Surgery, University of Arizona. He plans to continue the randomized controlled study, comparing immediate postoperative fitting of prosthesis with use of the controlled environment chamber, once appropriate arrangements are made in his new location.

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

Applied Physics Laboratory
The Johns Hopkins University
8621 Georgia Avenue
Silver Spring, Maryland 20910
Woodrow Seamone and Gerhard Schmeisser, Jr., M.D.

During the first half of 1977, research at Johns Hopkins continued to be focused on the completion of a computer-aided medical manipulator worktable system. In addition, clinical evaluation was continued on a manipulator/worktable with a quadriplegic volunteer who has now accumulated approximately 18 months of experience with this system.

Computer-Aided Powered Medical Manipulator

During FY 77, an advanced powered medical manipulator was designed with microprocessor control. The basic design approach for the system was described in BPR 10-27. Briefly, this system uses the microprocessor to effect smooth manual control, and more importantly, it allows the use of stored programs to assist in tasks which primarily involve deterministic trajectories.

One important change in this model compared with previous models is the incorporation of an integral microswitch on the chin transducer, for mode command. Slight forward motion of the chin against this microswitch selects the mode to be operated. Downward motion of the chin controls proportional motion. Thus, total control of the manipulator is achieved by chin motion, with excellent decoupling between the two control modes. Previous models used a separate microswitch located elsewhere (near a suitable muscle) or an eyeglass-mounted sensor responding to teeth-click inputs, for mode selection.

With the addition of the microprocessor, 12 programs have been placed in the system memory. Capability for a number of additional programs remains: Each prestored program is assigned a number from 1 to 20. When the operator desires to select (call up) a specific program, he or she presses the microswitch to stop the selection scanner at the moment PROGRAM is illuminated on the sequence display panel. After PROGRAM has been selected, the sequence display counts by tens and then by ones to enable the operator to designate the two-digit number which has been assigned to the desired program. The basic computer software was configured to simplify inputs required to generate these prestored

programs. For each step of the program, only the selected mode and end-point need be entered.

The software routine instructions provide for appropriate voltages for acceleration ramp up (linear increase), velocity limit, and ramp down, to insure smooth motion. Manual-mode control and/or PAUSE may be written into the program at any place in the sequence of motions. During the program generation phase, these programs are entered into the read/write memory, checked for accuracy of positioning, and then transferred to a programmable read-only memory (PROM) chip.

To illustrate the versatility of this concept, a description of some of the programs which have been implemented follows:

1. *Telephone Programs*

The general layout of the latest manipulator/worktable arrangement is shown in Figure 16. A Trimline Touch-tone wall phone is placed on a mounting bracket on the right side of the worktable. A small bracket is clamped to the hand set. The first of the telephone prestored programs directs the manipulator to go from its designated standby position to the phone location, pick up the phone and move it to the correct position adjacent to the user's head. The phone remains in this position until a single pulse is activated via the chin microswitch to return the phone to its holder. A second program is selected in the event the user would like to place a call. In this instance the manipulator brings the phone into a position suitable for "dialing" with the mouthstick. After the dialing of the number, the manipulator brings the phone to the ear and, after the call has been completed, returns the handset to the stand as before. In the event the user would like to stop motions during program mode, he need only activate one pulse with the microswitch to stop the motion and cause the manipulator to revert to manual control.

2. *Self-Feeding Programs*

Two self-feeding programs have been investigated. One allows manual control near the plate for food management with the spoon. It automatically transcends into an automatic motion, once the spoon is lifted past a certain point, to bring food to the user's mouth. The system pauses then, until the user takes a bite and activates the chin microswitch to automatically return the spoon to the vicinity of the plate. This cycle is repeated at the control of the user.

A second program provides for eating soup from a bowl. In this instance, the spoon will automatically go from the plate to the

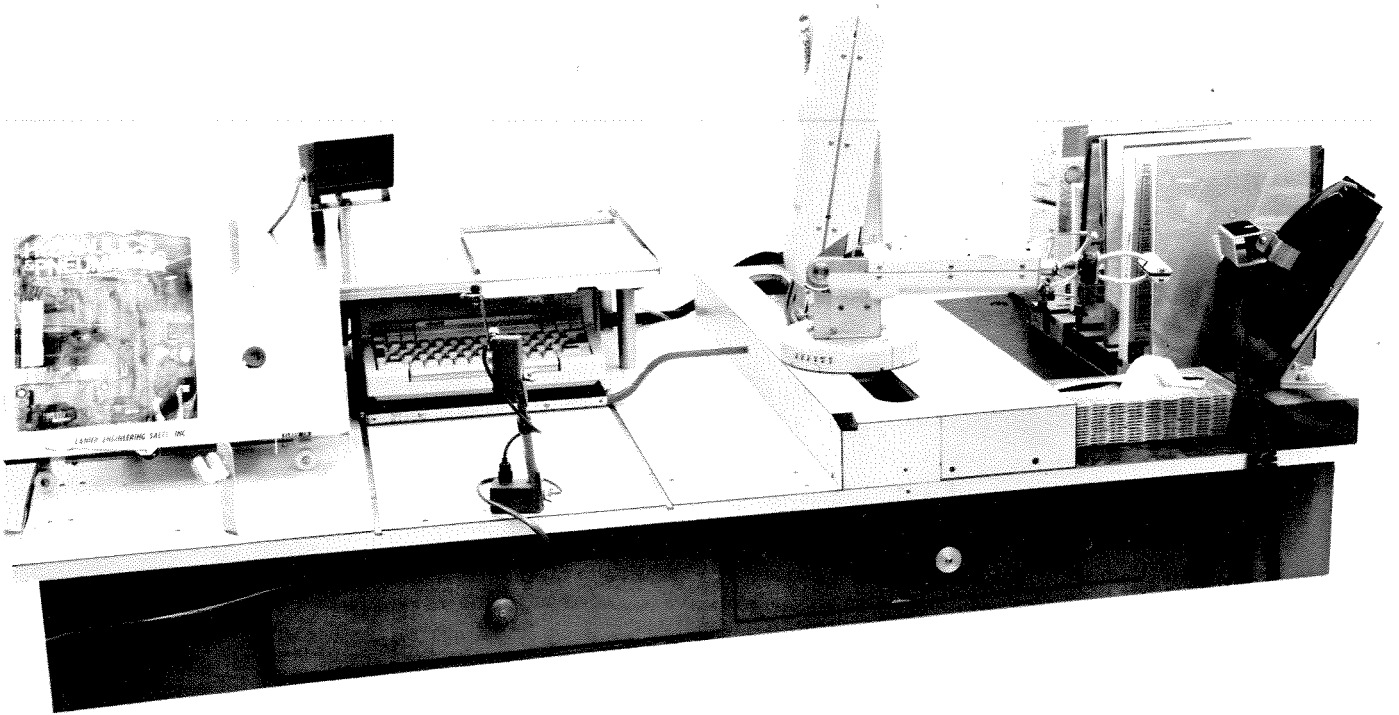


FIGURE 16. – Computer-aided powered medical manipulator worktable system: the latest table layout.

soup bowl, dip into the soup bowl, wipe the bottom of the spoon against the rim of the bowl to minimize dripping, and finally bring the soup to the user's mouth. A bowl of hot soup can be consumed in approximately 5 minutes.

Either self-feeding program requires minimal effort on the part of the user, and eating a complete meal may be accomplished in 15 to 25 minutes. During self-feeding, a cupholder with drinking straw is provided within reaching distance, to allow liquids to be taken during the meal.

3. *Book/Magazine Programs*

The book/magazine storage rack and the reading stand must each accommodate a variety of sizes of reading materials. This system as designed will handle small hardcover or paperback books, slick magazines measuring 21.6 cm by 27.9 cm (8½ by 11 inches), and stapled memoranda. Reading materials weighing up to .567 kg (1¼ pounds) may be managed.

The prestored program is written to move the arm automatically to the vicinity of the storage rack and adjust the hook to the open position facing the unbound edges of the book. Manual mode is then used to locate and grasp a particular book and lift it vertically. The program continues at this point in an automatic mode to place the book in its final reading position on the reading stand. Pages are turned with a mouthstick (and prevented from turning back by a wire finger mounted on the reading stand). The book may be returned to its original position in the storage rack by a similar prestored program which contains both automatic and manual modes to accommodate the shapes and sizes of books which must be handled.

4. *Typewriter program*

This program brings the typewriter out of its storage position and inserts a sheet of paper ready for typing. The program is fully automatic and is used in conjunction with use of the mouthstick to activate the typewriter carriage-paper roller to advance the paper. (A pause is provided in the prestored program to allow this to happen smoothly.) Upon completion of typing on a given sheet of paper, the vacuum fingers on the terminal device may be used to remove the sheet and place it elsewhere for storage.

5. *Kleenex program*

One possible task for the manipulator is to grasp a tissue such as a Kleenex and hold it near the patient's face. A prestored program has been written to accomplish this task: it automatically brings

the tissue to the user's face. He may then manually maneuver it into a desired position. The program ends by automatically depositing the tissue into a waste basket.

These programs were written to allow evaluation of the concept of an appropriate mix of manual and automatic control. Forthcoming clinical evaluation will provide a realistic assessment of the practicality of this approach. As of the end of this reporting period (July 1, 1977) the computer-aided manipulator was in its final stages of the fabrication of the worktable components, and preparation of prestored programs. The system is expected to be ready for clinical tests by mid-September 1977.

Continuation of Clinical Evaluation of the Manipulator

As of July 1, 1977, the manipulator/worktable module has undergone approximately 18 months of evaluation by a quadriplegic, with lesser evaluation of a previous model by an earlier user.

The present user typically uses the equipment approximately 3-5 hours per day, to carry out vocationally related tasks such as handling reading materials, the telephone, and the typewriter. Because that model did not incorporate the microprocessor controller, functions such as self-feeding were not deemed practical for long-term evaluation. However, demonstrations were made of the self-feeding mode, to verify that the geometry and basic mechanics of motion allow this function to be successfully carried out.

Various methods of inputting the system were investigated. The original system utilized a microswitch placed near the user's arm to provide the pulse input for sequence command. Upon selection of a desired function, proportional control was achieved by depressing the chin lever. As an alternative to the microswitch, a special pair of eyeglasses was fitted with a small accelerometer for sensing "teethclicks." The user preferred the ease of using the eyeglass system over the microswitch, but did not like the idea of wearing eyeglasses for long periods of time. That led to the concept of incorporating the microswitch as an integral part of the chin transducer, which has been accomplished in the new computer-aided model. It will be clinically evaluated by the same user during the Fall of 1977.

An alternative to the microswitch is a pneumatic sensor integral with the chin transducer: for this, a series of holes was drilled in the chin transducer support tube to allow breath puffs to be detected by a thermistor bridge air-velocity transducer. (This concept provides a good pulse signal but is highly directional and control is more difficult to carry out in a consistent manner: the concept

was demonstrated in the laboratory but did not seem practical for clinical use.)

The experimental manipulator/worktable system was scheduled for removal from the current user during August, to be updated with the computer-aided manipulator. Clinical tests are expected to be resumed in mid-September 1977.

Development of Refined Fitting Procedures for Lower-Limb Prostheses – Case Studies of Applied Research in Orthotics and Prosthetics, A Final Report

Department of Orthopaedics and Rehabilitation
University of Miami School of Medicine
P.O. Box 875, Biscayne Annex
Miami, Florida 33152
Augusto Sarmiento, M.D., Newton C. McCollough III, M.D., Loren L. Latta, P.E., and Fred R. Hampton, C.P.

Introduction

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 investigators realized that there exists a significant patient population who, due either to the severity or the multiplicity of their handicaps, cannot be adequately managed by "standard" prosthetic and orthotic approaches. It is also realized that although this total number is significant, the number of such patients with identical functional loss or identical complicating factors is small. It is difficult, therefore, to group these patients into categories of disability which would provide common bases for prosthetic or orthotic design.

In the past it has been the usual research practice to design a particular device to solve a problem which is common to a large number of patients. Even that problem, with variations, may not be well managed by the device, and patients who have relatively rare problems are generally not adequately managed by any standard available appliance. These patients are best managed by *individual* solutions to their problems: devices should be designed specifically to meet the needs of the individual patient. This is the opposite of attempting to fit the patient into pre-existing standard hardware.

To be effective, the individual approach requires careful and systematic clinical analysis by a team of professionals, including physicians, engineers, prosthetists, orthotists, and therapists.

Evaluation is followed by design and re-design of appropriate devices until the optimum solution to the biomechanical deficits has been achieved. Confirmation that this has been achieved requires careful study and followup including analysis of gait, an estimate of comfort, cosmesis, and function by both the patient and the clinic team, and determination of device durability.

The primary research aim of this project has been to demonstrate the feasibility of a careful, analytical approach to patients with difficult problems of the lower limb by a multi-disciplinary team, and the translation of information so gained to a satisfactory prosthetic or orthotic solution.

At this time the project is expanding, and the techniques developed will be incorporated into the more "routine" patient care of the clinical program which will continue the handling of the difficult cases. The new program will include upper-limb and spinal cases as well as lower-limb cases, but otherwise the technique of patient care and evaluation will be similar to that described.

Method

A clinic team met monthly at Jackson Memorial Hospital for special problems of the lower limb. In attendance at the clinic were two orthopedic surgeons, an engineer, a physical therapist, a prosthetist, an orthotist, and a secretary-photographer. Patients were referred to the clinic from a number of sources: these included the Veterans Administration Hospital, Jackson Memorial Hospital Amputee Clinic, the Rehabilitation Center at Jackson Memorial, outside physicians, prosthetists, orthotists, and professionals from other Veterans Administration Hospitals. A careful physical examination and functional evaluation by the entire team preceded the decision on whether to include a patient in the case study program. If a patient was included in the program, the team again collaborated to record a thorough, detailed physical examination, history, technical analysis, device analysis, and photographic record. The patient also evaluated his existing device and its function. A file was made on each patient, including the following records and materials:

1. General information sheet;
2. Medical dictation;
3. Technical analysis form for orthotics;
4. Analysis forms for prosthetics;
5. Device evaluation form;
6. Gait analysis form; and
7. Photographic envelope.

Following the initial evaluation of each selected patient, the clinic team collaborated to determine and define the best possible prosthetic or orthotic solution to the patient's problem. Patients were subsequently seen, measured and casted, and then fitted with the device prior to the next clinic. At the next clinic visit, if the device appeared to solve the problem adequately, (in the view of the patient as well as the clinic team) arrangements were made for further device evaluation by gait analysis studies, and subsequently by subjective and objective evaluation by both the patient and the team. If (at this point) the device was deemed unsatisfactory, a new solution was proposed and the process repeated.

Followup on each patient was for a minimum of 1 year after fitting of the final device and completion of training. Device evaluation by the patient and clinic team, and gait analysis, were performed at least every 6 months for original devices, subsequent devices, and without any device at all when feasible. A running photographic record was maintained.

Patients with two types of needs were included in the program:

1. Patients for whom no conventional orthotic or prosthetic device has been adequate for solution of the problem.
2. Patients for whom available conventional treatment proved sub-optimal in function, comfort and cosmesis. This group included patients with relatively severe disability, although not uncommon problems, who could be managed in a way superior to the conventional solution.

Examples of the first group included the multiple amputee, the patient with severe paralysis, the patient with a combination of paralysis and amputation, and the patient with a complicating condition such as contractures, spasticity, and skin breakdown.

Examples of the second group are those cases of paralysis and/or amputation for whom conventional solutions are sub-optimal because of excessive energy expenditure, functional handicap, or lack of comfort or cosmesis. Included were cases of polio, hemiplegia, unilateral below-knee amputees, or above-knee amputees with complicating problems.

Patient Population

Thirty-three patients have been included in this study. At the close of the study (as a research project) 25 out of 33 patients were being followed and these will continue into the clinical program. The 33 cases included 23 orthotic patients and 13 prosthetic patients. Three patients had both orthotic and prosthetic problems.

Of the orthotic patients, 11 had poliomyelitis, 3 hemophilia, 1 Charcot-Marie Tooth disease, 1 spina bifida, 1 tubercular meningitis, 3 trauma with secondary problems, 2 cerebral vascular accidents (CVA), 1 diabetes, and 1 Guillain-Barré syndrome. Paralysis was the major problem in 18 patients with secondary problems of spasticity in 1 case, severe skeletal deformity in 1 case, and balance dysfunction in 1. Joint deformity was the major problem in 6 cases, with secondary problems of pain in all 6, plus skin breakdown in 2, infection in 1, and limited range of motion in 3.

Of the prosthetic cases, 17 had multiple-limb involvement. Two had bilateral below-knee amputations, 3 had bilateral above-knee amputations, 2 had upper-limb involvement, 2 had bilateral hip disarticulations, 2 had unilateral Symes amputations, 2 had unilateral below-knee amputations, 1 had unilateral above-knee amputation, and 4 had skin problems. Secondary complications in the prosthetic cases included: 1 above-knee amputation with removal of the ischial tuberosity, 4 with skin breakdown problems, 1 with phantom pain, 2 with associated lower-limb paralysis, 1 with paraplegia, 2 with contractures, and 2 with extremely short residual limbs.

FIGURE 17. – Example of a pre-tibial shell design in thermoplastics, for control of the knee joint without the need of elaborate knee mechanism.

Orthotic Approach

In general the approach to orthotic paralytic problems in the lower limb included the use of custom-molded thermoplastic shells to which metallic joints were attached for the knee where necessary. All ankle mechanisms used were flexible polypropylene posterior joints, molded into the foot and calf sections as one piece.

Knee-control mechanisms included designs such as pretibial shells molded of polypropylene, inverted Klenzak extension joints for variable extension control, and locked hinge joints with short uprights laminated in the polypropylene shells (Fig. 17, 18, 19).

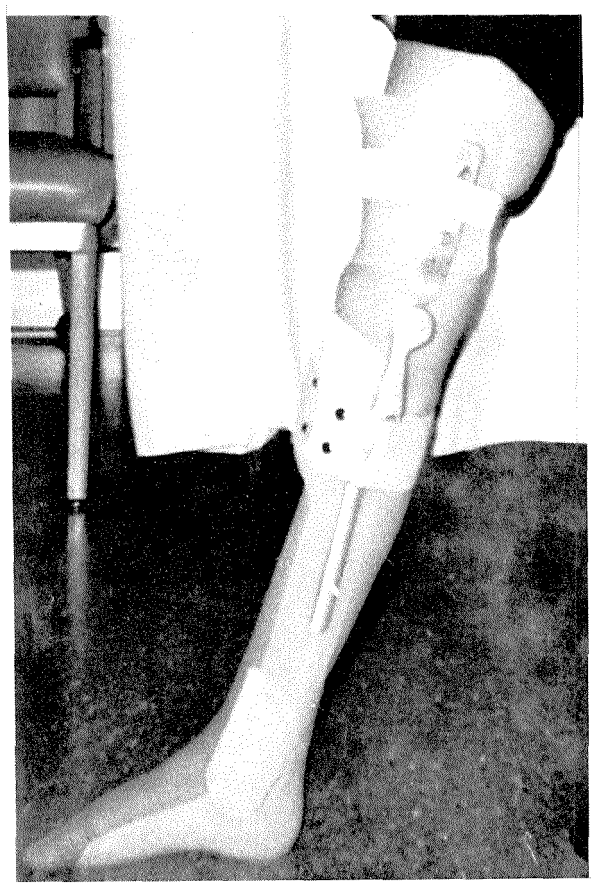


FIGURE 18. – An example of the typical use of thermoplastics with adjustable stop knee mechanisms and free knee flexion.

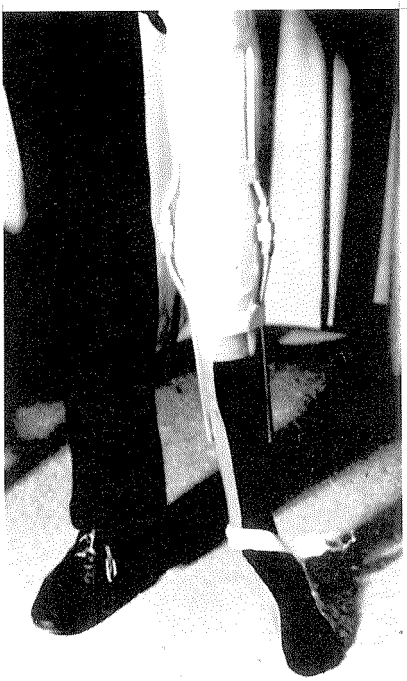


FIGURE 19. – An example of the use of thermoplastics with locked knee mechanisms.

Two new hardware component designs were attempted. The first requires further development. The idea was to provide good medial-lateral stability and a strong extension stop without using double uprights. A wide hinged posterior upright served this purpose but the collapsing links which provided the required length reduction of the upright in flexion did not operate consistently on patients when they flexed to sit. A linkage system needs to be developed to force the proper coordination of links during flexion (Fig. 20).

The second new knee component was designed to damp rapid knee motions and protect trauma. A knee cage with polypropylene shells had attached flexible metal cables across the joint to give resistance to knee motion. Although this device did not give a velocity-dependant resistance (for true damping) it did accomplish the required task and was much simpler to fabricate. Preliminary results appear promising (Fig. 21).

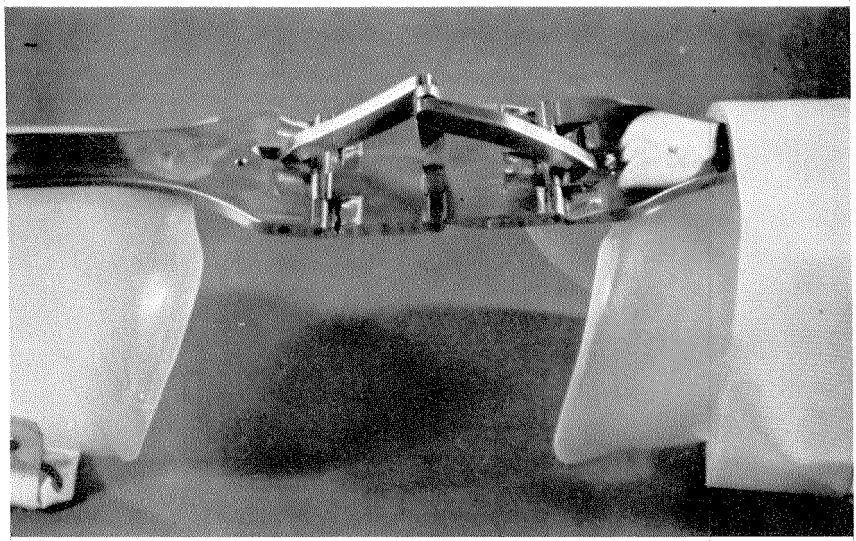


FIGURE 20. – The multiple-linkage posterior upright knee mechanism under development.

A representative example of orthotic cases treated by the team is reported as follows:

> *Diagnosis:* Poliomyelitis with severe bilateral lower-limb paralysis.
> *History:* This 30 year old female patient had poliomyelitis at the age of seven resulting in severe bilateral lower-limb paralysis. She had worn bilateral conventional KAFO's since that time. Her current orthoses were 17 years old but in good repair. They consisted of double uprights with drop ring knee locks, anterior knee pads, and limited-motion ankle joints. She desired lighter, more functional, and more cosmetic devices.
> *Physical Examination:* Upper limbs normal. Lower limbs: poor-to-zero muscle strength below the hips bilaterally, good hip extensors bilaterally, fair hip abductors, and fair-to-good hip extensors bilaterally. She exhibited moderately severe genu recurvatum standing and walking without orthoses. She walked without orthoses, but had aching fatigue in the knees secondary to genu recurvatum and drop foot. In orthoses, she walked with a swing-through or labored four-point gait.

FIGURE 21.—(a) Patient in his thermoplastic knee cage with flexible knee joint to damp knee motion, and (b) flexible cable knee mechanism for damping of knee motions, lateral view.

Problem: High energy expenditure and inefficient gait in 17-year-old orthoses, due to locked knees and weight of devices. It was decided to try to control knee hyperextension and foot drop with a lightweight and cosmetic device which would permit knee flexion during the swing phase of gait to decrease energy expenditure.

Solution: Bilateral KAFO's were fabricated from polypropylene, utilizing a posterior AFO design connected to an anterior supracondylar shell by means of reversed Klenzak ankle joints with pins and modified split stirrups (Fig. 22). The stops in the reversed ankle joints allow adjustability to permit just enough hyperextension for knee stability while still protecting against severe recurvatum. Free knee flexion is permitted.

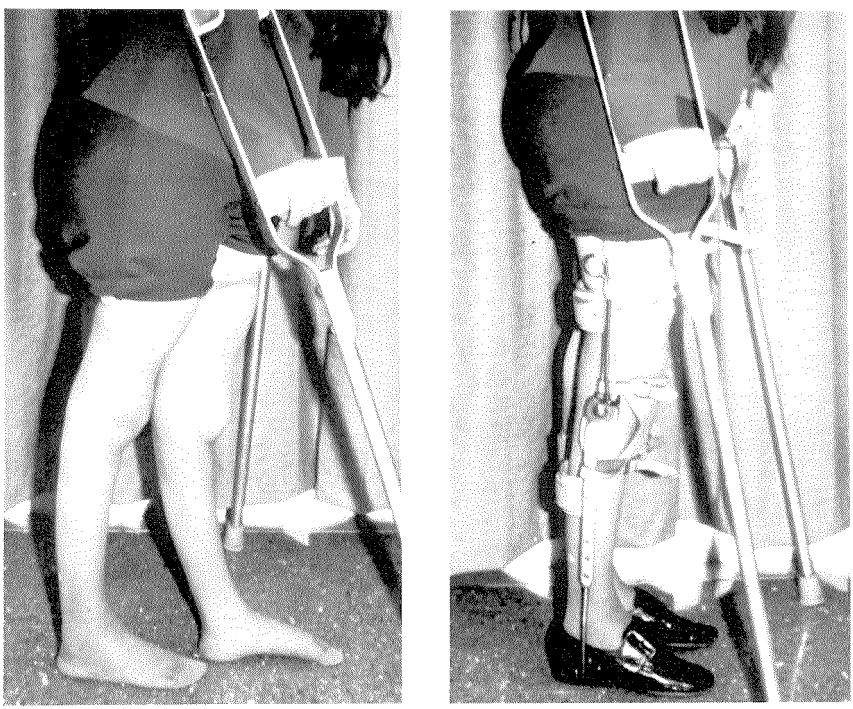


FIGURE 22. – (a) Above, left, the patient standing without orthoses. Note the degree of recurvatum that the patient exhibits without control of her knee joint. (b) The patient in her conventional metal upright orthosis. (See also Fig. 22 (c), (d), (e), and (f).)

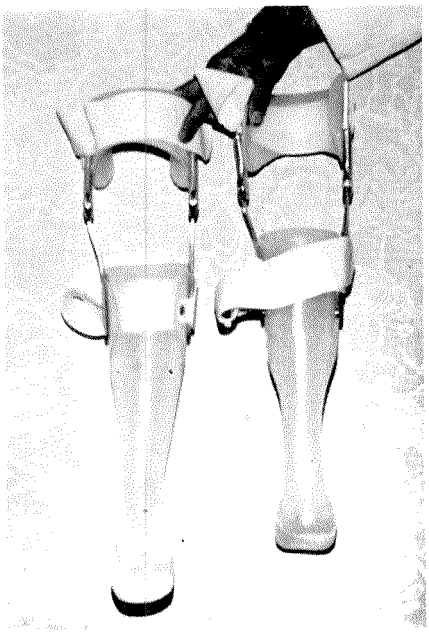
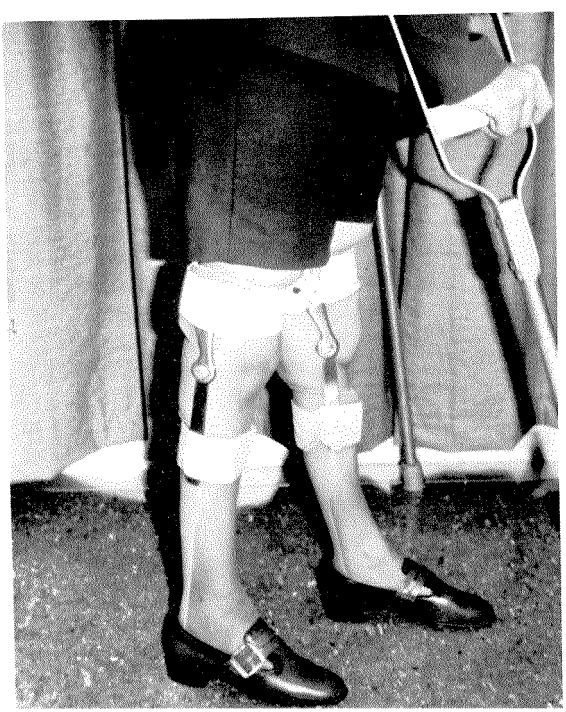


FIGURE 22. – (Continued) At left (c) the thermoplastic orthoses, and below (d) the patient ambulating in her thermoplastic orthoses. (See also Fig. 22 (e) and (f).)



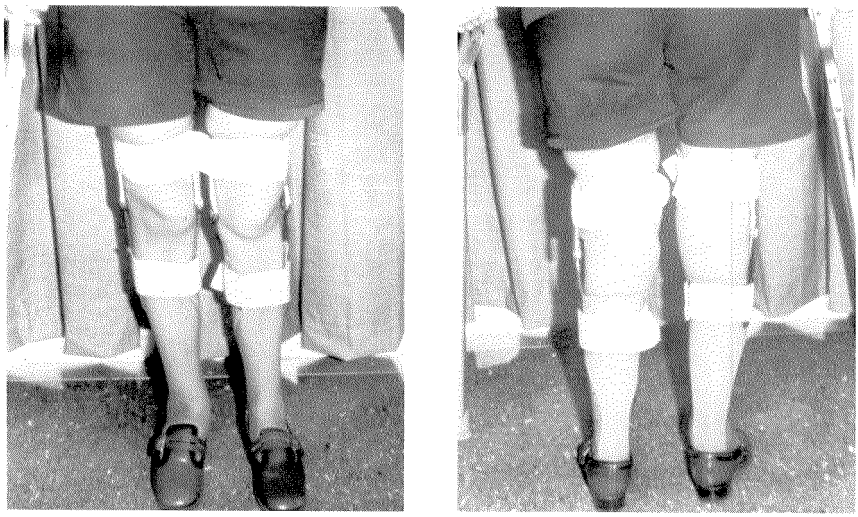


FIGURE 22. – (Continued) Frontal view of the patient standing in her thermoplastic orthoses (e), and (f) the posterior view of the orthoses.

Evaluation: The patient ambulated at a rate of .39 m/s (meters per sec.) in her old orthosis. Her stride length was .60 m/c, (meters per cycle) and stride rate was .66 Hz. With the old orthosis, the barograph indicated that only a slight amount of weight was borne on the ball of the foot, but because of the contour of the bottom of the shoe (caused by the steel shank) it was impossible to obtain a reading from the pressure switches on the ball of the feet. When the patient ambulated without an orthosis, her ambulation rate dropped to .36 m/s, due primarily to the drop in her stride rate to .59 Hz. Her stride length remained the same at .6 m/c. Again, because of the contour of the bottom of her shoe, the pressure switches indicated only load being borne on the heel of her shoe.

With her new orthosis, the patient increased her ambulation rate to .49 m/s, stride length icreased to .71 m/c, and stride rate increased to .69 Hz. Apparently due to the nature of the high heel on the shoe which the patient wore with her new orthosis, along with the dorsiflexion built into the new orthosis, there were no readings from the pressure switches on the ball of her feet, thus her foot switch sequence again showed only heel activity during ambulation in her new orthosis.

Device Evaluation: The patient felt that her new orthoses were excellent for working activities, very good for her home activities, and excellent for social activities: in each case, much better than her previous orthoses had been.

The patient felt that the durability of her old orthoses was about the same as that of her new orthoses.

She felt that she spent about the same amount of time on her feet with either device; however, it took less energy for her to spend a long time on her feet with the new orthoses because of their light weight. The patient felt that the new orthoses were highly superior in the ease of donning and doffing compared to her old orthoses. She also felt that her new orthoses were highly superior in comfort to the old orthoses and very much better cosmetically.

The team felt that the patient's new orthoses were very good in durability (no failures had occurred after 12 months of use) and the initial cost to the patient was considered satisfactory, probably similar to that of the old orthosis. In terms of function it was considered very good, and better than the old orthosis. Cosmesis was felt to be very good, and highly superior to the old orthosis. The new orthosis was judged to be easier to fabricate and fit than the old orthosis.

Discussion and Summary: This patient benefited greatly from her new orthotic design. She had, for some 23 years, been confined to relatively heavy metal double-upright lock-knee-type orthoses. Although these had been adequate to most of her needs, they did not present the ideal solution to her problem. The new devices are much lighter, much more cosmetic, and much more functional as demonstrated by her gait analysis (rate of ambulation increased by about 20 percent as did stride length and stride rate). From the cosmetic and comfort standpoints, her personal evaluation was that the new orthoses were highly satisfactory.

Our success with this type of orthosis once again illustrates the principle that the best orthosis is one which controls only the gait deviations, while allowing all normal functions to occur. In this case we were able to permit normal knee flexion and swing phase, and provide just sufficient hyperextension during stance phase for knee stability. At the same time we could protect the knee against the excessive genu recurvatum which would eventually have led to increasing deformity.

Control of the patient's bilateral drop foot was achieved by means of a posterior AFO shell. The reverse Klenzak ankle joint,

used as a knee hinge, provides a means of adjusting the degree of allowable knee extension. This adjustment is critical in a patient such as this.

Based on our experience with this patient, as well as others in the case studies, our opinion is that this type of orthosis may very well be the current orthosis of choice for this particular problem; i.e., the lower limb which is flaccid or flail with the exception of good hip extension, and which depends on hyperextension of the knee for knee stability.

Another device which has been reported to accomplish this objective is the Lehneis I.R.M. (Institute of Rehabilitation Medicine) SKA (Supracondylar Knee-Ankle) orthosis, made of plastic laminate. That orthosis, however, is heavier, does not distribute pressure on the anterior aspect of the thigh over as wide an area, and it protrudes well above the knee to the thigh level when sitting, since there is no knee hinge. Furthermore, it is not adjustable.

There still remains a question regarding the ultimate durability of the devices described as used for this patient. The present orthoses are now 12 months old, and there have been no breakage or repair problems.

Prosthetic Approach

The approach to prosthetic cases in general can be divided into two categories: the approach to residual limb problems, and the approach to ambulation problems.

For residual limb problems, the requirement was generally to redistribute weightbearing pressures away from areas of involvement, and as evenly as possible over viable areas of the residual limb. Techniques included modified air cushions, socket designs, windowed sockets, and modified suspension systems.

Ambulation problems included the high energy consumption of ambulation in bilateral AK amputations. The approach to these problems was to build lightweight short prostheses with rotators placed as far proximal as possible. Success is mixed, and seems to be related to patient age, motivation, length of residual limbs, etc.

A representative example of prosthetic cases treated by the team is reported as follows:

> *Diagnosis:* Above-Knee Amputee, Absent Ischial Tuberosity.
> *History:* This 38 year old white female sustained multiple injuries to both lower limbs with a resultant right above-knee amputation 1 year ago. Physical examination reveals exten-

sive skin grafting over the proximal portion of the posterior thigh and buttock with absent ischial tuberosity. Previous prosthetic fittings resulted in ulceration and breakdown along the gluteal fold.

Solution: A modified quadrilateral suction socket with minimal posterior seat, narrowing of the medial lateral diameter and slight increase in the anterior posterior diameter was attempted (Fig. 23). Relief was created in the area of skin breakdown. A torque rotator unit was inserted in the shank portion.

The ulceration has almost completely healed. The patient wears the prosthesis all day and reports much greater sitting comfort.

Evaluation: The patient is ambulating well, now that her ischial ulcerations are healed. Gait is consistent in pattern and rate for short runs. Average rate of ambulation is .4 m/s with stride length .63 m/c and a stride rate of .64 Hz (average). The patient walks with normal foot-switch sequence on the normal limb, but spends very little time on the heel and medial side of the ball of her foot. On the prosthetic side, she never reaches the outside of her foot. She spends about the normal amount of time on the heel, but then spends all of the midstance in the beginning of double support time on the medial side of the ball of the foot and her heel. About half way through double support, she goes into heel rise on the prosthetic side and pushes off on the medial side of the ball of her foot, only slightly using her toe. The barograph showed a similar pattern of weight distribution with good step-through gait.

Device Evaluation: In the initial evaluation of the new prosthesis, patient felt that her work, home, and social activities were improved, along with comfort. Durability of the new prosthesis and the ease of donning and doffing were judged to be the same as the old prosthesis. Cosmesis of the old prosthesis was better than that of the new, but she was able to spend much more time on her feet with the new prosthesis.

After three months of wearing the new prosthesis, she evaluated all of the above in the same manner.

The team rated the durability of the new prosthesis the same as the old, after three months. The initial fabrication cost of each device was also the same. The function of the new prosthesis was rated better than the old, both initially

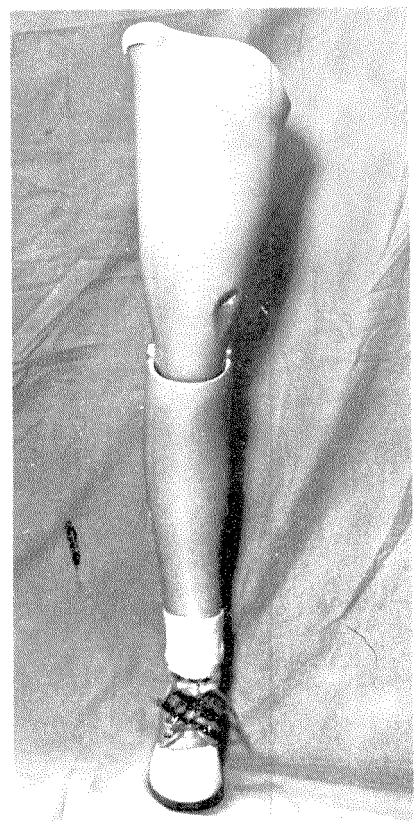


FIGURE 23. – (a) Above, patient showing ulcerated areas in the gluteal fold where the patient lacks an ischium for weightbearing purposes, and (b) the prosthesis the patient is wearing now, with a suction socket modified quadrilateral brim and rotator unit.

and three months later. Cosmesis of the new prosthesis was slightly worse and the initial cost to the patient slightly more than the old prosthesis.

The long-term cost of maintaining the two prostheses is believed to be the same, but because of the patient's increase in activity in the new prosthesis, there is an increase in the effort needed to maintain a good fit. This is due to continued stump shrinkage, attributed to the increased activity.

Discussion and Summary: The fitting of an AK amputation with absence of the ischial tuberosity requires weightbearing on the soft tissues of the residual limb. The residual limb presented posed the additional problems of scars and skin grafts in the area of the gluteal fold which were not conducive to withstanding the pressures of weightbearing. To overcome the problem of weightbearing on the fragile skin, and to prevent the problem of an adductor roll, the posterior proximal aspect of the quadrilateral socket had a generous radius and a narrow seat area to facilitate sitting. This is important because the patient is a typist and spends a major part of the day sitting.

The posterior wall was also relieved in the area of the ulceration. The torque rotator reduced the rotary motion between the residual limb and the socket during ambulation. The patient expressed a positive attitude toward the prosthesis in terms of comfort and function. Cosmetically, however, the rotator unit was not at first acceptable.

At 2 years, the patient is wearing the prosthesis routinely, and now presents a positive attitude toward the function of the torque rotator. The area of previous breakdown is well healed and poses no problem at this time. Liners have been added to the lateral wall of the socket to accommodate residual limb shrinkage, but the patient is losing weight and the residual limb is still shrinking. A new prosthesis is to be fabricated: at that time the rotator will be mounted just distal to the socket to improve cosmesis and weight distribution.

Results

Of the 33 patients included in the study, 11 have completed satisfactory fitting and initial treatment and have had at least 1-year followup evaluations. Of the remaining 22 patients, 4 have been lost to followup, 3 moved out of the state and have only remote contact, 4 have been recently fitted and are being followed

for the first year, 11 have been completed to the point where no followup is required. Fourteen patients currently require continuous followup. Four of these are listed as "complete" and 10 are not yet complete.

Summary

A total of 33 patients with difficult and unusual lower-limb problems are reported as to their orthotic and/or prosthetic management and the results obtained, with a minimum followup period of 1 year. Twenty-three orthotic and 13 prosthetic cases were included in this study.

This project demonstrates the effectiveness of a concerted team approach to the "problem patient" with limb disability, through individual solutions for each patient, and evaluation of the effectiveness of the prosthetic or orthotic solution. The team (physician, engineer, prosthetist, orthotist, and therapist) works closely together in all phases of problem identification, problem solving and solution evaluation, through the accumulation and analysis of both subjective and objective data.

When sufficient numbers of like clinical problems have been accumulated and the solutions to these problems have been analyzed, it is believed that it should be possible to make firm recommendations as to the optimum methods of management for these categories of limb disability.

In most cases of the kind selected for this investigation, optimum solutions cannot be obtained by conventional devices, but must be the result of design innovation. In the final analysis, proof of effectiveness of such non-standard devices must rest with the correlation of subjective and objective data gathered by a multidisciplinary evaluation team.

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

Department of Electrical Engineering
Colorado State University
Fort Collins, Colorado 80523
Daniel Graupe, Ph. D.

During the first half of 1977, work on this project has centered on enhancing the reliability and the speed of a myoelectric recognition system for multifunctional-actuating above-elbow prostheses, via microprocessor hardware. This system uses a single electrode

site for actuating several limb functions, on the basis of differences between identified time series parameters of the myoelectric signal for different limb functions.

During this period, U.S. patent No. 4,030,141 was awarded to the VA in the name of the present author as inventor ("Multi-Functional Control System for an Artifical Upper Extremity Prosthesis for Above-Elbow Amputees," award date: June 21, 1977).

Work on reliability enhancement included changing the microprocessor identification to a four-parameter autoregressive (AR) model form instead of the previous three-AR-parameter form, with the result that identification bias is reduced and thus discrimination accuracy is increased. Also, a longer word-length and faster hardware multiplier were incorporated into the Intel 8080 microprocessor system.

Lectures on the present system were given at Notre Dame University, Notre Dame, Indiana; Purdue University, West Lafayette, Indiana; and University of Michigan, Ann Arbor, Michigan. Also, several lectures and a colloquium were given at the University of California, at Berkeley. An invited paper describing the system was read at the Joint Automatic Control Conference (JACC) of the IEEE, ASME, SIAM, etc., in their San Francisco annual conference. All the above were accompanied by a movie presentation illustrating the performance of the discrimination system when used on-line with our Intel 8080 system. The test subject was an above-elbow amputee having 90 percent nerve and muscle damage of the residual limb.

Complete Fortran programs for the system, allowing it to be tested (off-line or on-line) on large-scale computers, are presently available at the Research Center for Prosthetics of the VA in New York. The programs are also available from the author. These Fortran programs can be tested using raw EMG recordings either on-line or off-line, via digitized tape, on any large-scale computer.

Acceleration of Bone Healing by Electrical Stimulation

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

The Surgical Research Service at Castle Point VA Hospital and the Biomechanics Research Unit at Helen Hayes Hospital have undertaken a cooperative project designed to test various parameters of electrical stimulation on a model of non-union created in

canine ulna. Work is now proceeding on a series of dogs, utilizing new stimulator and electrode systems developed at Helen Hayes Hospital. Work on the first four animals has now been completed and specimens are undergoing decalcification prior to evaluation. Additional experiments in the series now are scheduled on a regular basis.

Specifically, the project is designed to determine the effects of electrode location within a bone defect, and the effects of current density on healing of this standard model for non-union.

Hemodynamic Evaluation of Postoperative and Preoperative Amputees

VA Hospital
Castle Point, New York 12511
Bok Y. Lee, M.D., Frieda S. Trainor, Ph. D., and David Kavner, D. Eng.

Work has been completed for this program's first report of quantitative data for arterial blood flow in the lower limbs. Measurement of peak pulsatile blood flow for the thigh and calf has been done with the noninvasive electromagnetic blood flowmeter. Data are presented showing correlation of results using electromagnetic flowmetry, segmental Doppler systolic pressures, and arteriography. In this report 100 limbs have been categorized based on the patient's complaints: (i) asymptomatic, (ii) intermittent claudication, and (iii) rest pain, gangrene, and ulceration. Mean values and coefficients of variation for arm and ankle systolic pressures, the ischemic index, and thigh and calf peak pulsatile blood flow have been calculated. Significance has been tested between all three groupings using the t-test.

Table 1 summarizes some of the pertinent data obtained for the report.

A high degree of significant differences for thigh and calf blood flows was obtained for the three groups. From these data for calf blood flow, patients are divided into three discrete clinical categories corresponding to the chief complaints. In numerous instances, the noninvasive electromagnetic flowmeter provides information which cannot be obtained using segmental Doppler systolic pressure measurements. For example, in patients with grossly exaggerated ankle pressures due to severe hardening of arteries, the peak pulsatile flow provides the most accurate information: Doppler systolic pressures in these instances cannot be interpreted: however, the noninvasive flowmeter is not influenced by the hardened vessels

TABLE 1

	Group I Asymptomatic	Group II Intermittent claudication	Group III Rest pain Gangrene Ulceration
	(26 limbs)	(38 limbs)	(36 limbs)
Arm	124 mm Hg	136 mm Hg	136 mm Hg
Ankle	145 mm Hg	92 mm Hg	58 mm Hg
Ischemic Index	1.2	0.68	0.45
EMF Peak Pulsatile Flow in:			
Thigh	383 ml/min	166 ml/min	112 ml/min
Calf	130 ml/min	44 ml/min	44 ml/min

and flow in the vessels can be obtained. (As can be expected in these instances, the flow is somewhat diminished.)

The noninvasive electromagnetic flowmeter is particularly useful for patients with multiple occlusion (i.e., femoro-popliteal plus aorto-iliac) and the site of obstruction can be predicted. If peak pulsatile flow for the thigh region shows acceptable arterial inflow from the aorto-iliac area, then the femoro-popliteal bypass procedure is indicated. If the peak pulsatile flow is reduced at the thigh and the patient's symptoms include a combination of complaints (claudication, rest pain, gangrene or ulceration secondary to aorto-iliac occlusive disease)—then an aorto-femoral bypass is indicated. Once arterial inflow is brought to the level of the profunda-femoris artery, there is considerable improvement in the patient's complaints.

The implications from these data are that noninvasive quantitative measurements of blood flow in the limbs can provide the information for accurate decision-making leading to better care of the patient with vascular disease, and a consequent salvage of many limbs.

Maxillofacial Restorative Biomaterials and Techniques

Temple University School of Dentistry
Broad and Montgomery Ave., Philadelphia, Pa. 19122
John F. Lontz, Ph. D., and James W. Schweiger, D.D.S., M.S.

The activities of this research on maxillofacial (more properly termed orofacial) biomaterials, and on techniques for producing "safe and effective" prostheses, are summarized by topic in a Comprehensive Development Plan presented here as Table 2.

TABLE 2. – *Comprehensive Development Plan*[a]

I.	Product Development
	Principal materials (polymers, elastomers) selection
	Defined ingredient composition and critical processing (polymerization, curing)
	Selective testing and replication of living system
	Durability (end-use) testing: environment, exposure and maintenance
II.	Fabrication Techniques
	Determining critical temperature-time factors
	Designing forming (molding) components or equipment
	Standardization of applied processing (curing) variables
	Modifications in fabrication for complex structures
III.	Pigmentation and Cosmetic Matching
	Development of appropriate, simple measurements
	Developing dispersion into prosthetic materials
	Spectral assignment (registering) of selected pigments
	Color-stability testing against light exposure and maintenance
IV.	Toxicity Testing
	Develop direct approach to orofacial tissues (maxillofacial)
	Accumulate a cohort of excised oral (gingival) tissues for preliminary tests in tissue culture techniques – explore variables
	Develop biochemical and biophysical complements to culture techniques
	Extend to correlations with critical processing conditions (Phase I and II)
V.	Field (End-Use) Evaluation of Fabricated Prostheses (Clinical, Rehabilitative)
	Select representative and competitive participants
	Develop criteria for preference or acceptance (wearer)
	Assess merits and deficiencies for referral to Phases I, II, and III.

[a] This is merely a topical listing of programs, by phase and with descriptions of R&D efforts: as they are initiated, programs are assigned a time-table for the monitoring of such features as starting, reviewing, etc., and time-costs.

There is priority for the toxicity-testing and field (end-use) evaluation necessitated by the impact of the recent Toxic Substances Control Act (TSCA) (1). Simultaneously with the continued development of a quality-dependable silicone elastomer formulation cured under strictly defined polymerization conditions, there is the effort on biological proof of safety in terms of observed growth of specific human cultured tissues.

At the same time, the broadened field evaluation for clinical appraisal of the intrinsically pigmented silicone elastomer has been in progress, to resolve competing claims of superiority for diverse polymer types.

Underlying all of these activities is the unequivocal chemical and physical description (and description of procedures of fabrication) for all ingredient materials, as frequently reported in numerous presentations (2, 3, 4, 5).

The coverage of the present research is unusual in that it extends from materials sciences and prosthetics technology to clinical affirmation of "safe and effective." (It should be noted that the basic polymer selected for this program is one that has been approved by FDA for commercial applications such as gaskets, etc., in food-handling and processing equipment where it is in sustained and intimate contact with food.)

Developments

Specification testing extends from the simple biomechanical tensile constants, and specified colorants, to measures for assuring biological compatibility through tests on cultured gingival tissue, with the ultimate goal being clinical proof of prosthetic effectiveness.

1. *Tissue Culture Test Development*

A test procedure has been developed using excised human gingival tissue grown under conditions optimized for discriminating between biomaterials for which there are previous reports (6) of levels of toxicity. The development involves adapting well-specified, documented procedures for (i) visual observation of fibroblast growth (Fig. 24), (ii) specifying growth and maintenance media, (iii) morphological characterization of the fibroblast through scanning electron microscopy (SEM), and ultimately (iv) genetic cell changes.

These developments bring to the problem of demonstrating that a material is "safe and effective for humans" criteria based directly on actual human tissue, including samples selected from the specific

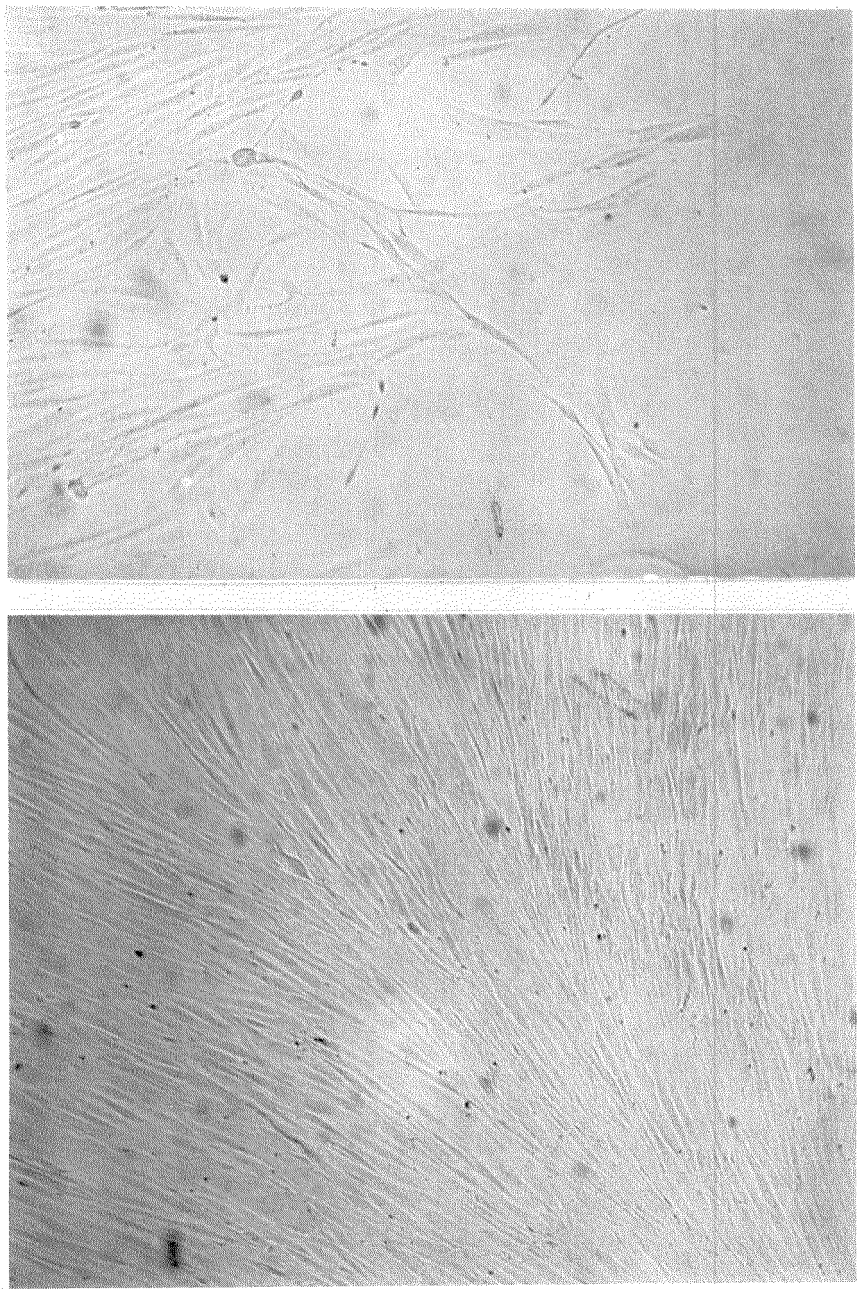


FIGURE 24. – Typical human gingival fibroblast cells: (a) peripheral growth initially (first passage), and (b) continued mature growth. Magnification is 105x. The subject is a 60-year-old white male with Parkinson's disease.

patient to be fitted with the prosthesis. They thereby eliminate the problem of the relevancy of pre-clinical animal testing.

2. *Field Evaluation*

An indispensible phase of the development of an effective prosthesis is the evaluation from patient/wearer experience, conducted at several locations to offset subjective attitudes that may be prevalent in specific clinics and centers. Therefore, an extra-mural evaluation program has been initiated whereby this project provides a range of HTV polysiloxane fabricated prostheses for nose, ear, orbital, and internal oral reconstructions down to the esophagus, for actual patient wearing. The range of prostheses is supplied in a range of yellow-to-red color indices. Thus far, one Veterans Administration Maxillofacial Clinic (New York) and two non-VA maxillofacial clinics have been provided with more than 30 diverse intrinsically-pigmented prostheses, involving at present 9 cases.

This effort has been made possible by the previously reported accomplishment (5) in adapting the HTV polysiloxane to curing in ordinary dental stone molds, thereby eliminating the expense, time, and special skill that were required when metal molds had to be used.

This extra-mural portion of the Comprehensive Development Plan can support up to eight outside maxillofacial clinics, for 1 or 2 years, based on the capability of making up to 16 prostheses per day. That is enough to take care of all estimated orofacial cancer cases for the Veterans Administration. Significant savings are possible, compared with current cost levels for work done in small-shop, often one-man, facilities.

Accomplishments

Reviewed in the order of Table 1, the accomplishments involve the following:

1. *Product development* of a material composition from a reliable, low-cost, available, high-quality polysiloxane elastomer (GE 4524U);

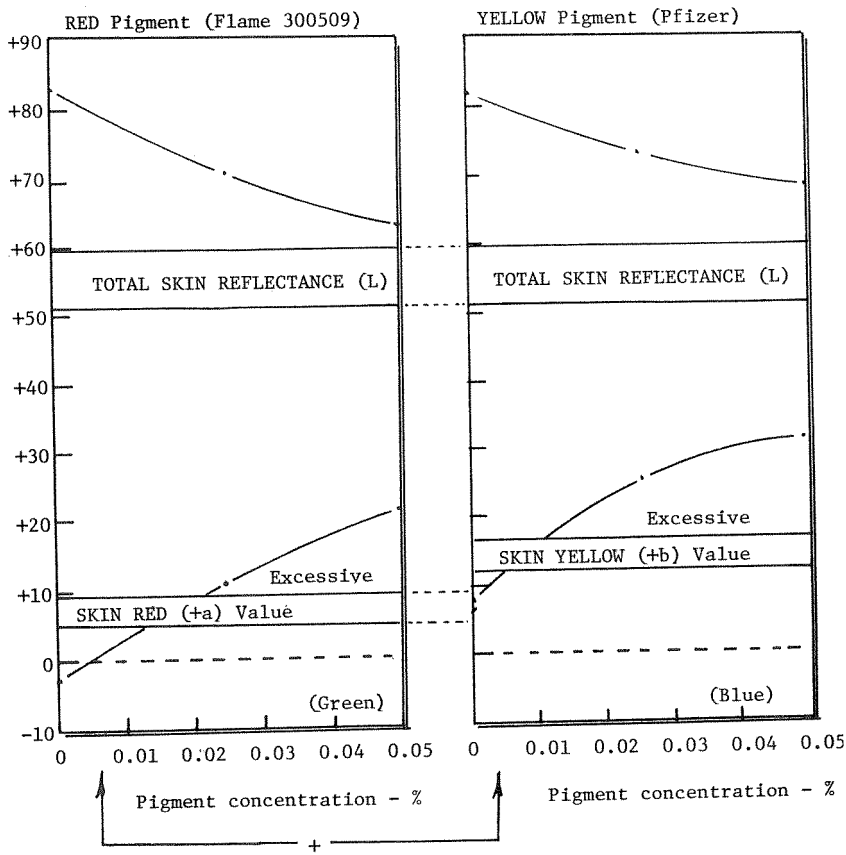
2. *Development of a simple fabrication technique* that can be carried out in a dental laboratory. (These efforts will require still further investigation.)

3. *Pigmentation and Cosmetic Matching.*

Instead of depending on proprietory pigment sources, which would mean composition and concentration would be undisclosed,

the effort has been to use pure, commercially specified and defined pigments, to which the measurement of reflectance and the proportion of red vs. yellow can be applied and reproduced universally. In addition to U.S. sources of pigments, a series used in European prosthesis cosmetic-matching has been included in this program.

Figure 25 illustrates the concentration-dependent color reflectance from which, by arithmetic proportioning, the matching with human skin can be predicted and thus competently matched by the prosthetist.



(C) Arithmetic proportion for INTRINSIC coloration.

FIGURE 25. – Concentration-dependence plots of two standard commercial pigments matching the two essential skin pigments, namely hemoglobin red (with FLAME 300509) and carotenoid yellow (OXIDE YELLOW – Pfizer). The arrows at "C" indicate in a general way the arithmetic proportions of the pigments to attain intrinsic coloration of a prosthesis, to be finished by final extrinsic cosmetic matching. Heat-cured (HTV) polysiloxane elastomer-oligomer formulation was used as base.

4. *Tissue Culture Testing*

During this period 28 human gingiva tissue samples have been collected and used to develop a fibroblast growth procedure, adapted from the numerous techniques (mostly for animal tissue) described in the literature. A significant accomplishment in this program has been the adjustment of sustaining nutrient media by which it is possible to grow human gingiva fibroblast cells reproducibly, with the cells having been taken from a single human (patient) source. These cells and a cohort of other patient cells are now being accumulated to establish the method's applicability to a broad range of patients of all ages, races, states of health, and degrees of exposure to cancer-controlling radiation. The 28 gingival tissue samples already collected represent a patient age range from 19 to 72 years, white and black racial groups, and various states of health.

In studies using (i) known non-toxic Teflon, and (ii) known toxic PVC, and comparing their effect on mouse fibroblast with their effect on human gingival fibroblast, preliminary results have revealed a significant difference in the rated toxicity to the extent that the mouse fibroblast tests do not conform to the results with human gingival fibroblast. This implies that the mouse fibroblast may not be required and, in fact, should be eliminated owing to its non-conformance with the results observed with human gingival tissues. For this reason, as stated earlier, a collection or cohort of various species-individual tests must be performed. This effort, still in progress, is to be reported on in succeeding reports.

5. *Field Evaluation*

As mentioned earlier, intrinsically pigmented, fabricated orofacial prostheses are being sent to VA and non-VA maxillofacial reconstruction participants. The procedure involves this laboratory first receiving either a wax model, a formed prosthesis, or even a photograph. Prostheses, reconstructing noses, ears, orbits, and internal sections, involving 12 patient reconstructions, have been sent out since March 1977. The results in terms of wearer acceptance (or dislike for any reason) and inspection of returned prostheses for quality defects, constitute an important feature of this phase of the project. In due course this feedback will be the subject of a report.

References

1. Editorial, Science Vol. 192, p. 1216, *Medical Devices Act of 1976,* an amended and toughened regulatory law on medical devices that requires proof of safety with data to be reviewed for each individual case by special panels. This now imposes stricter

requirements on proving "safe" in terms of toxicity or some form of harm, and "effectiveness" which implies useful service and durability, including any handling, such as cleaning with scouring agents and deodorizing agents that require chemical stability of the biomaterial to assure in turn "safe" quality.

2. Lontz, John F., James W. Schweiger, and A. William Burger: Development and Standardization of Polysiloxane Maxillofacial Prostheses. Presentation at the Twenty-Second Annual Meeting, American Academy of Maxillofacial Prosthetics, November 1975, Williamsburg, Virginia.
3. Lontz, John F., James W. Schweiger, and A. William Burger: Reconstruction Materials. Biomechanical Needs for Acceptance and Durability. Presentation at the First International Symposium for Facial Prosthetics, April 1976, Arnhem, The Netherlands.
4. Lontz, John F., James W. Schweiger, and A. William Burger: Comparative Merits of Polymer and Elastomer Materials Fabricated for Maxillofacial Reconstructions. Presentation at the Twenty-Third Annual Meeting, American Academy of Maxillofacial Prosthetics, November 1976, Lake Geneva, Wisconsin.
5. Lontz, John F., James W. Schweiger, and A. William Burger: New, Inexpensive HTV Silicone Prostheses Material Formable in Dental Molds. Presentation at the Twenty-Fourth Annual Meeting, American Academy of Maxillofacial Prosthetics, November 1976, San Diego, California.
6. Rosenbluth, S. A., and Co-workers. Tissue Culture Method for Screening Toxicity of Plastics Materials to be Used in Medical Practice. J. Pharm. Sciences, 54: 156-159, see also 54: 1545-1547, 1965.

Permanently Attached Artificial Limbs
Southwest Research Institute
8500 Culebra Road
San Antonio, Texas 78284
C. William Hall, M.D. and William Mallow

An Involuted Intramedullary Skeletal Extension

Introduction

A previous report in the Bulletin (BPR 10-27, Spring 1977) described the "involuted" approach for bringing a skeletal extension through the skin. This approach had been adopted to alleviate the problem of skin retraction about a direct skeletal extension penetrating the integument. Skin acts like an elastic membrane in that biaxial forces will cause a pre-existing hole to enlarge. The involuted approach places the three skin-penetrating lugs of the skeletal extension in position to exit at points of uniaxial skin stress.

Methods and Results

Several models of the involuted bucket-type prosthesis were designed, although the last design (Fig. 26) was the only one used in quantity. Twelve of these later designs were implanted, with bone cement used to anchor the prosthesis to the tibial stump.

As was predicted, all had problems caused by necrosis of the distal 1-1½ cm of the tibial stump. This was of relatively little concern, since the experiment was designed to test the new skin-penetrating technique and not to address itself to the bone-interfacing problem.

None of these 12 implants showed any tendency of the skin to retract from the penetrating lugs. There was some tendency for the distal 1-2 cm of the skin to mummify, which demonstrates the necessity of having a short skin flap. These results were the same regardless of the skin-interfacing material, which consisted of either nylon velour, Orthoplate® carbon, or Proplast®.

Once the skin retraction problem appeared to have been solved, it was considered timely to move into other facets of this complicated program. Due to the demand for keeping a short skin flap, it was necessary to shorten the cup. The optimum way of shortening the cup was to return to the intramedullary approach. Because of the problems associated with disruption of the nutrient artery

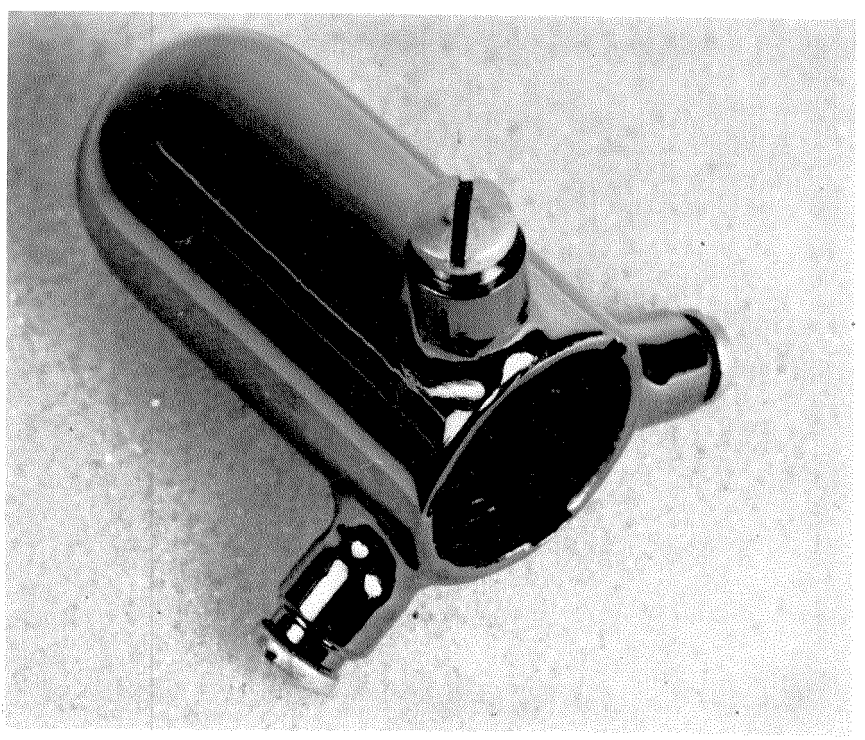


FIGURE 26. – This tri-lugged involuted bucket has been coated with Orthoplate® carbon by General Atomic Company. Buckets similar in construction were also coated with nylon velour, and others with Proplast.®

and its tributaries, we naturally experienced some ambivalence about returning to the intramedullary approach.

Rhinelander, (3) however, has demonstrated that the intramedullary circulation can be either maintained or reestablished by the use of a Schneider nail coated with Proplast.® Therefore, it appears feasible to use a device similar to the Schneider nail, with a short cup attached to the distal end which would hold the three percutaneous lugs. Such a device has been fabricated, and two have been implanted into the tibia of goats. The first such implant had an uncoated Schneider nail, with the attached bucket and lugs coated with nylon velour. The second implant had the Schneider nail coated with Proplast® (Fig. 27).

The uncoated prototype was used mainly to test the design concept and to determine if any modifications in the surgical technique would be necessary. This animal was sacrificed after 6 weeks and was found to have a loosened prosthesis. Since the intramedullary Schneider nail had not been coated with an interfacing material, loosening of the rod was predictable. The skin showed no retraction about the lugs and no tendency to mummify.

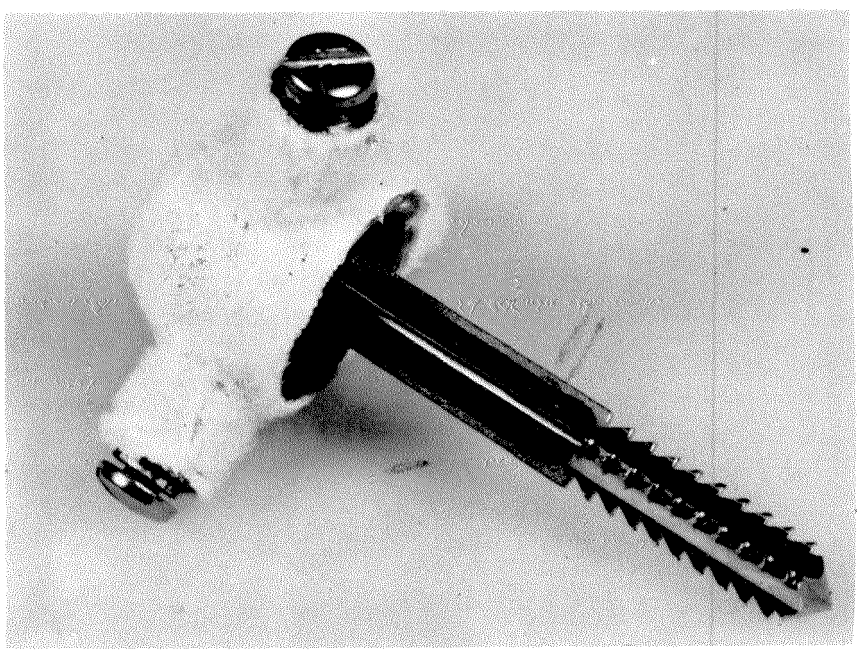


FIGURE 27. – This tri-lugged involuted intramedullary prosthesis has the Schneider nail coated with Proplast® in its channels, and has the bucket and lugs coated with nylon velour.

A slight modification is being made in future models, in that the intramedullary nail will be trifluted, rather than quadrafluted. This will give the nutrient vessels more space within the intramedullary canal.

Summary

The hypothesis set forth to explain the problem of skin retracting from a direct percutaneous skeletal extension appears to have validity. When the involuted tri-lugged approach has been used, no skin retraction has been observed. Because mummification of the skin can occur if the skin flap is exceptionally long, it became necessary to redesign the involuted prosthesis and to shorten the cup. That resulted in a return to the intramedullary approach, utilizing a modified Schneider nail. This, it is hoped, will allow reestablishment of the intramedullary circulation. The new design is being coated with a variety of materials, including Proplast,® Orthoplate® carbon, bioglass, and velour. Within the next 6 months, it should be determined whether or not a successful marriage has been performed to accomplish both proper skin-interfacing and proper bone-interfacing simultaneously.

References

1. Hall, C. William: Involution: A New Method for Percutaneous Skeletal Attachment. Bull. Pros. Res., BPR 10-27: 166-168 Spring 1977.
2. Hall, C. William, William Mallow, and Fred Hoese: Progress Toward a Permanent Skeletal Extension. Trans. Amer. Soc. for Artific. Organs, 1977.
3. Rhinelander, Frederic W.: Vascular and Histologic Effects of Implantation of Biomaterials in Bone. Keynote address, 2nd Annual Meeting of the Soc. for Biomaterials, Phil., Penna., April 13, 1976.

Mobility Engineering for the Severely Handicapped
Mobility Engineering and Development (MED), Inc.
6905 Shoup Avenue
Canoga Park, California 91306
Charles M. Scott and Ronald E. Prior, Ph. D.

Van Compatible Wheelchair

Road-testing of the first preproduction model chassis has been completed, to a point where sufficient test information is available to finalize the chassis design for the next three clinical test units. Many changes in the chassis were made to improve performance and ability to handle rough terrain. An estimated 400 miles were covered during the rough terrain testing, including an open field and a prepared obstacle course. The obstacle course included mul-

tiple obstructions, triangular in shape, 2½ in. high, alternating right and left, as well as wheel ramps with 3-in. drops.

The only structural problems occurred in the raise-and-lower actuator system: there, the design now includes an improved traveling-ball linear actuator with greatly strengthened attachment points.

No structural failures of the suspension occurred during the testing, nor were any problems detected at tear-down. Unsatisfactory wear occurred only at the bronze-bushed joints in the forward control arm bushings. This area has been redesigned to use tapered roller bearings, so that adjustment for wear can be accomplished.

The performance of the rubber torsion springs was of interest. Their performance on the rough terrain tests was excellent: the natural damping of the rubber made the ride surprisingly soft without the excessive bounce which had been expected. They also absorbed lateral shocks, which greatly reduced the stress on structural members without creating any control or stabilization problems.

All engineering drawings are now complete. The second-generation chassis is now 80 percent complete.

The electronic control package performed well during testing, but all services were not functioning during the tests. The areas still under development are: (i) reduced speed at high seat elevations, (ii) variable steering versus forward speed, and (iii) limited reverse speeds. All of the advanced circuitry is bench-tested and is now being installed on the test unit for road testing.

Electronically Controlled Van

The long procurement delay on the computer components is now over. The unit is assembled and debugging is under way.

The components for the hydraulic and electronic servomechanisms have been selected and ordered. The preliminary hydraulic layout is complete. Complete bench testing will precede installation in the vehicles.

MED expects to move into new facilities approximately September 1, 1977. This will bring the electronic lab and vehicle assembly room adjacent to each other, permitting direct electrical connection between the vehicle and the electronic development equipment. This will greatly improve the efficiency of the operation.

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

The Veterans Administration orthopedic departments service two types of patients with arthritic knee difficulties. In the first category are those with disabling rheumatoid arthritis. The second category contains those with degenerative arthritis usually on the basis of prior trauma. This second group contains men still at working age who possess work capabilities. Their knees are exposed to heavy loading situations.

Currently designed prostheses have been developed for the older age group and for other patients with disabilities such as rheumatoid arthritis. The load data developed in this present study will aid in understanding the types of loads that may be permitted in the younger working patients. Engineering design data will be produced that should allow for better prostheses from the standpoint of load, life, and fatigueability.

This project will also aid in the rehabilitation of patients following knee arthroplasty and other disorders about the knee joint, by revealing the loads the knee joint is exposed to with such activities as ambulation, assisted ambulation, exercise, and the activities of daily living. The data will be further useful in ascertaining some of the underlying pathomechanics of knee disorders.

During this report period, major technical difficulties were encountered during manufacture of unicondylar knee prostheses to be used for telemeterized knee implantation. The difficulties involved welding of two of the mechanical subcomponents. The welded junction, which is located outside of the region of major stresses, required the development of some new technology in conjunction with N.A.S.A. Lewis Research Laboratories. Development of this new technology required approximately 6 months, and therefore required the modification of our work schedule. The technical development necessary to produce necessary acceptable weldments was accomplished.

Unfortunately, during the next stage of the development of the unicondylar prosthesis, significant additional problems were encountered. Specifically, the devices were sent out to a commercial polishing firm, recommended and routinely used by commercial

manufacturers, to polish the devices to the necessary degree of sphericity and surface finish for acceptable implants. The firm chosen encountered significant difficulties in accomplishing this task, and in fact, actually ruined two of the units beyond any hope of salvage. The remaining units are of suspect quality at this time. It is felt by the present investigators that for technical reasons these should be considered unacceptable for long-term implant in human subjects. (These units were, however, salvaged and installed in cadavers without loading them, to gain experience in surgical technique.)

Several reasons for the problems in polishing were given. Due to the custom-made nature of these designs and the lack of normal polishing and holding jigs that would be used in such sphericity grinding and polishing, unusual difficulties were encountered. We shall have to consider this carefully in trying to achieve an acceptable implant for human use as we redo this portion of the work. We are held to a standard for human implantation equal to or better than that of the present commercially acceptable, available units, and this imposes very stringent requirements and unusual difficulties on the manufacturing of a telemeterized implant, for use in a human subject, that can pass both our own Human Experimentation Committees and our own personal standards. Therefore, as a result of this unfortunate experience, the remanufacturing process for the proposed new series of 15 units will be conducted keeping in mind the end necessity of having these devices passivated and polished. We will, therefore, include the necessary manufacturing and jigging for these new devices, and those jigs and devices necessary to utilize commercial polishing procedures on the remanufactured implants, and will insure that all necessary mechanical holding and polishing criteria are met before attempting further work on the units. If necessary, one of the investigators in this project will personally supervise this operation either at Case, or at the commercial polishers on site.

Research and Development Project on Advanced Orthotic Devices for Adult Paraplegics

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

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

Prast Research has completed production of four new PACO III units for testing by paraplegics in the VA system.

The new units will be distributed to four locations in the country: one to Boulder, Colorado (to be followed up by Lawrence Carlson), one to Lubbock, Texas, one to Buffalo, New York (to be followed up by Mr. Prast) and the fourth to VAH, Castle Point, New York.

Engineering Applications in Orthotic and Prosthetic Treatment of Musculoskeletal Defects

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

Three-Dimensional Automated Motion and Joint Force Analysis

1. *Three-Dimensional Stroboscopic Gait Analysis System*

This system was developed to serve as a prototype for studying the techniques, used by such other investigators as Paul (1), Morrison (2), and Bresler and Frankel (3), for the estimation of forces in the hip and knee joints.

Progress. Since the configuration of the system components for this technique is identical to that of proposed totally automated system, its value as a prototype has been significant. The computer analysis has been thoroughly worked out and several of the errors that existed at the beginning of this reporting period have been eliminated.

Several analyses have been performed on normal subjects and computer presentations of results in both graphic and tabulated form have been worked out. Some of the kinds of computer-generated graphics possible are shown in Figure 28.

The stroboscopic gait analysis system was moved to the Veterans Administration Hospital from the Biomechanics Laboratory, Case Western Reserve University, at the start of this reporting period. Since then, it has been reassembled. A new wider and lower walkway has been constructed, and three normal knee joint studies have been performed. The results obtained, in general, corroborate Morrison's results but some discrepancies do exist. One of the most questionable aspects of this analysis, in both Morrison's and our system, concerns the electromyographic data. The difficulty is in determining the start and end of muscle activity for a specific muscle group during a gait cycle. Variability from one cycle to the next is significant. This problem has been studied and several improvements have been made, as follows:

1. Electrode placement has been studied and optimum spacing and positioning determined;

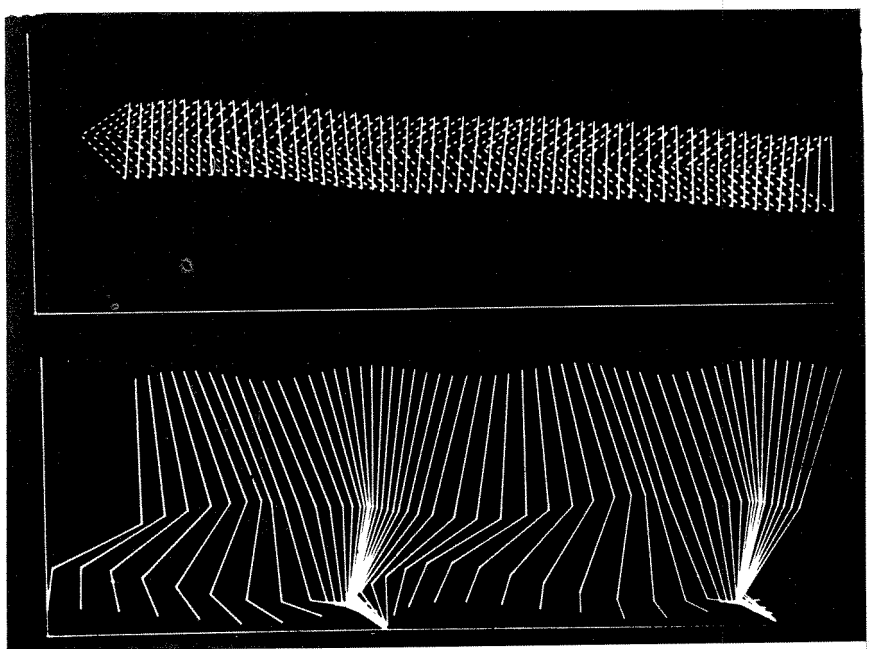


FIGURE 28a. – Top: Progression of triangles representing the three pelvic markers, during normal level walking, as seen from above. Bottom: Progression of stick figure representing the right pelvis, knee, ankle, and toe markers, during normal level walking, as seen normal to the walkway.

2. Significant filtering is applied to eliminate unwanted signals;
3. The raw EMG is rectified and integrated to provide a more interpretable signal; and
4. Use of intramuscular electrodes has been studied and far superior results are indicated.

The entire knee analysis computer program has been rewritten to run on our PDP 11/45 computer system, and the programs to generate computer graphics of results have been written and tested. The graphics programs have been found to be valuable in locating errors generated during data reduction and analysis procedures. They have also proved invaluable in understanding the significance of results. A graphic data digitizer has been interfaced to the computer to allow direct entry of X-Y coordinates of kinematic data from multiple exposure pictures produced during the stroboscopic analysis. This results in a four-fold reduction in time required to complete this process.

Conclusions. Although this is a fully functional system, its value as a clinical tool is limited because of the tremendous effort necessary to arrive at the final results. This effort is necessary primarily

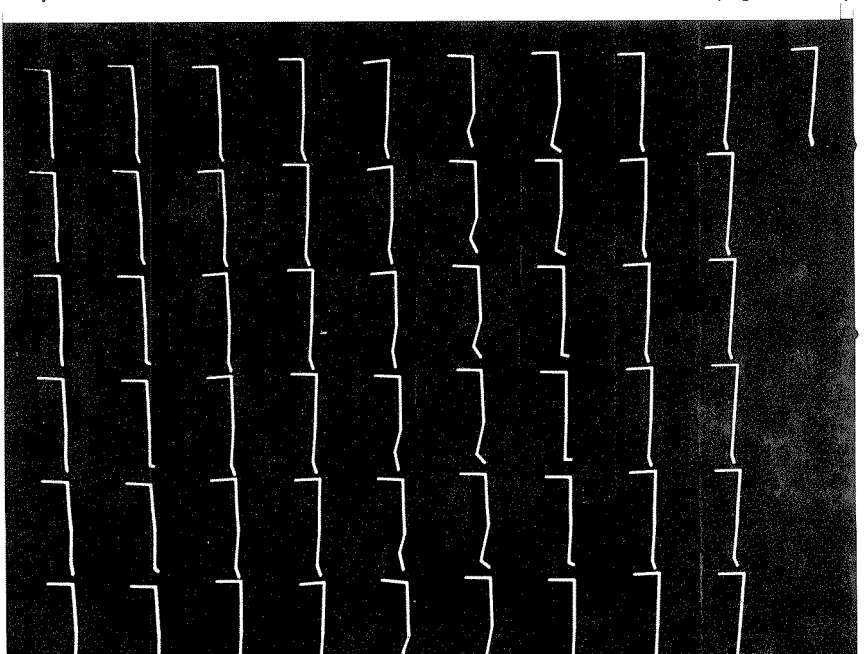


FIGURE 28b. – Frame-by-frame stick figure representing the rear pelvis, right pelvis, knee, ankle, and toe markers during normal level walking as seen from the left end of the walkway.

because, with this system, kinematic data reduction cannot be automated. Each evaluation involves thousands of measurements and therefore results are sometimes not available until several weeks after the gait analysis was performed in the laboratory. However, as a prototype, this system has served its purpose excellently.

Use of the strobe system will be limited to occasional studies for systems comparisons and possibly to study the effects of having a subject encumbered by cables or gear carried by him.

2. *Automated Three-Dimensional Motion and Joint Force Analysis Using the Selspot*[a] *System*

A gait analysis, such as is involved in estimating forces in joints and related muscle groups and ligaments, necessarily results in a great volume of data. Unless the collection, reduction, and analysis of this data can be automated, the clinical application of such a measurement technique is not realizable. Incorporation of elec-

[a] Motion monitoring system manufactured by Selcom, A.P.B., Sweden.

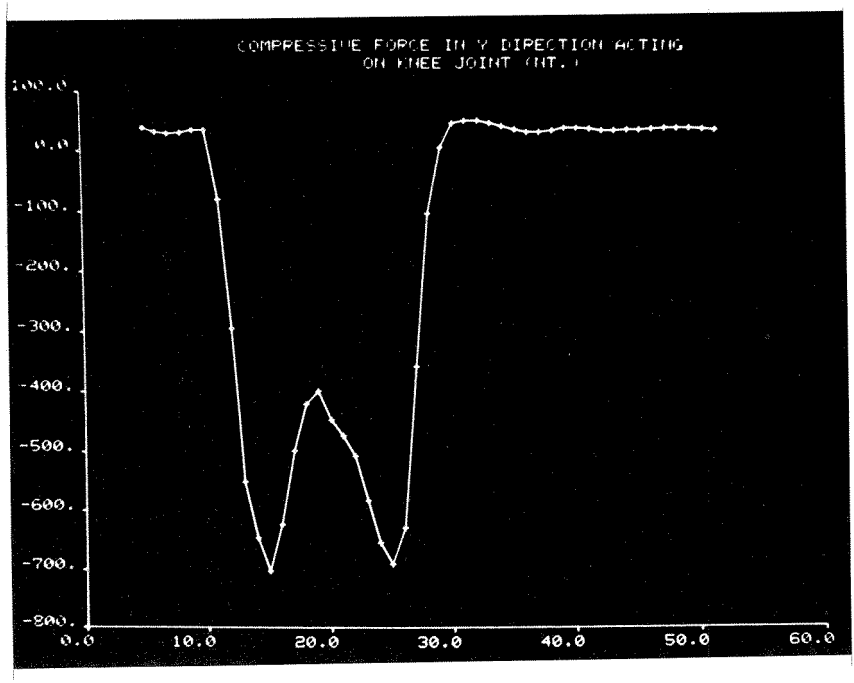


FIGURE 28c. – Compressive force in the knee joint during normal level walking as a function of the strobe flash number. (Heel-strike occurs at flash 10 and toe-off at flash 30.)

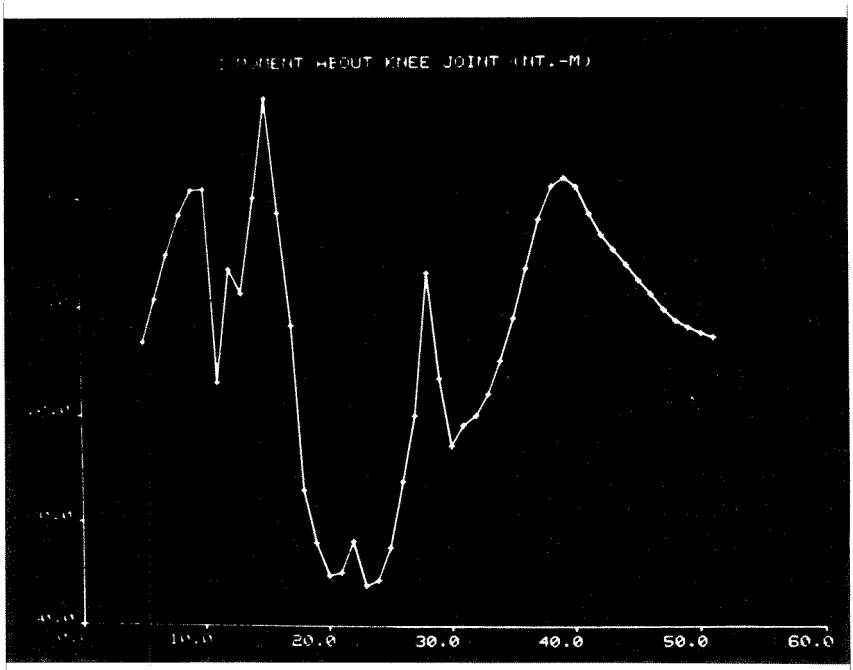


FIGURE 28d. – The moment normal to the plane of progression acting at the knee joint during normal level walking as a function of the strobe flash number.

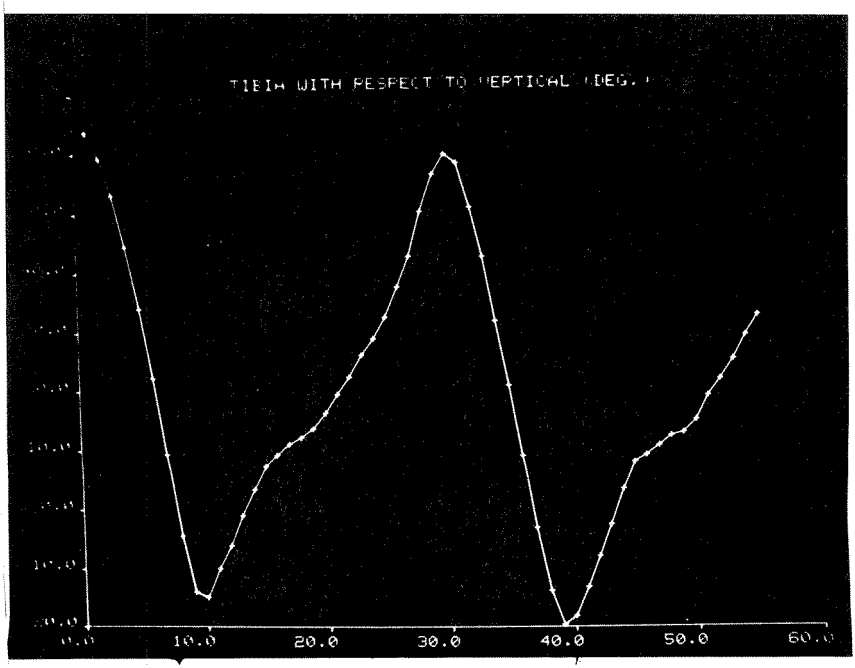


FIGURE 28e. – Position of the tibia in the plane of progression, with respect to the vertical, as a function of the strobe flash number.

tronic cameras, such as are used in the Selspot System, and an on-line computer system, allows such total automation.

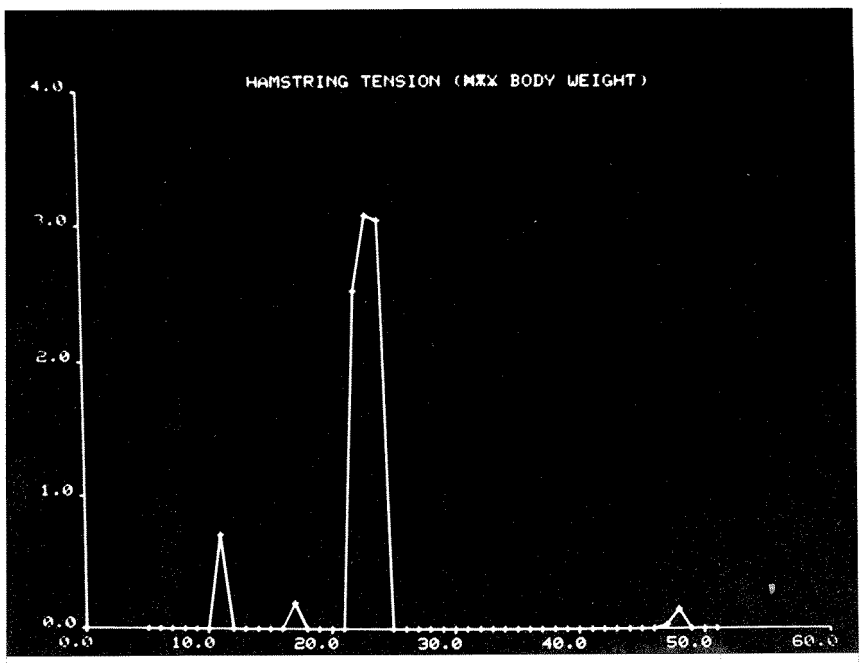


FIGURE 28f. – Hamstring tension during normal level walking as a function of the strobe flash number.

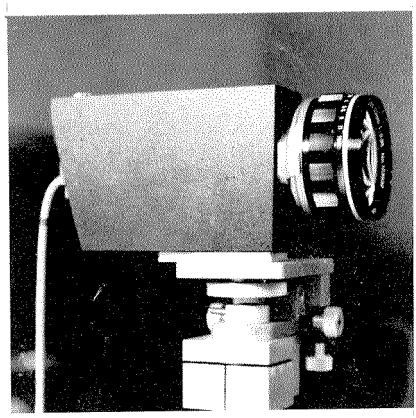


FIGURE 29. – Selspot camera mounted on the adjustable camera head.

Progress. Camera pedestals have been installed and camera heads fabricated which allow accurate alignment of cameras (Fig. 29). The Selspot cameras have been tested in their intended orientation (Fig. 30) to determine the capabilities of the system.

Three-dimensional gait analysis, it appears, is one of the more complex applications of this system and taxes it to its limits. In fact, the system as purchased is not adequate for a gait analysis of this kind. The results of our studies, thus far, have yielded the following information:

1. The primary weakness of the system is due to insufficient intensity of the infrared-light-emitting diodes provided. These are the light sources which are mounted at the various anatomical targets to be monitored during a gait analysis. Even if the LED's provided with the system are aimed directly at a camera, they cannot be accurately monitored at the most distant points of the analysis.

2. The power requirements to drive the light-emitting diodes are significant. Without design changes, battery powered operation of LED's is not reasonable.

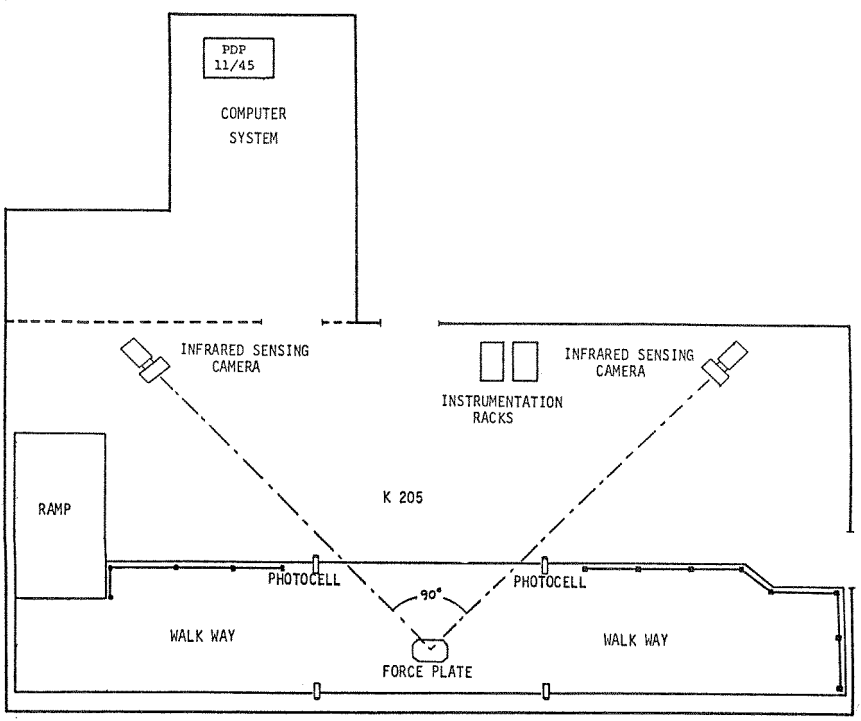


FIGURE 30. – Three-dimensional computer-based motion-study system laboratory layout.

3. Two LED's at each landmark target will be necessary to allow each of the individual anatomical landmarks to be monitored simultaneously by both cameras. The two LED's of each pair must be mounted as closely together as possible, and in such a manner that each is aimed as directly as possible at its corresponding camera.

4. The angular distribution of infrared radiation of the provided LED's is much too limited. This is largely due to the manufacturer's design. The LED is provided with a reflector designed to produce a more intense signal; consequently, the angle of radiation is small. Although intensity is important, a broader angular distribution is also necessary because the orientation of this light source with respect to the cameras continuously changes during a gait cycle.

5. Although optical synchronization is functional, it is not reliable when LED intensity is not sufficient.

Most of the above problems were significantly reduced when new LED's were acquired: these have an output with extremely broad angular distribution, and provide a considerable increase in the incident light intensity.

It may be possible to use only one of these new LED's per anatomical target. However, to prevent any possibility of losing sight of the signal, a two-LED-per-target scheme has been worked out. This scheme provides a strong signal for each camera.

To mount each pair of LED's, a 3-inch by 1-inch piece of 1/16-inch-thick polypropylene is used. Hinges are formed at appropriate intervals by repeated flexing of the polypropylene. The LED's are mounted on the two central sections of the hinged polypropylene (Fig. 31). In this fashion a variable-angle mount is produced. The assembly is attached to the subject's skin by means of double-stick adhesive tape on the outside tabs. Initially, power will be provided to the LED's through a cable from a line powered source. Design changes may allow battery powered operation, but since the weight of a battery pack will probably be on the order of 2 lb, the logic of having a patient carry it is questionable, especially since he is already required to carry the LED control unit and EMG transmitters. Cable synchronization will be used as long as line powered operation of the LED's is necessary. This insures that synchronization is never lost. However, ways to insure adequate optical synchronization will be investigated.

It is anticipated that by judicious use of software filtering techniques, much weaker LED signals will be acceptable, thus opening the possibility of using a single LED per target. This would significantly reduce the bulk and weight of the LED mounting fixture and simplify mounting procedures.

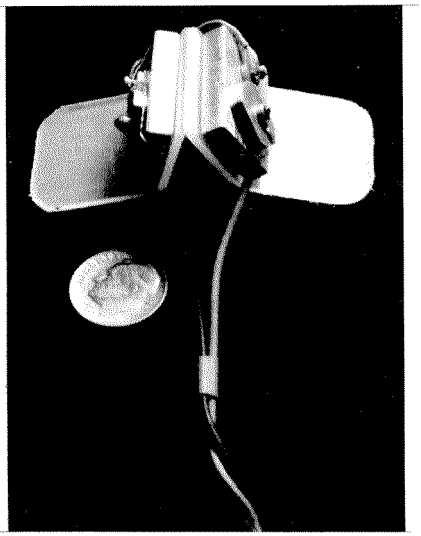


FIGURE 31. – Hinged polypropylene mounts for two light-emitting diodes. The LED's are visible as small spherical projections.

With regard to computer programing, the analysis already developed for the strobe system will be exactly applicable to the automated system. The difference between the two techniques is manifested entirely in the data-entry methods. In the strobe system this is a manual process, and in the automated system all data enter the computer directly without operator intervention. Thus the additional programing effort involves routines that control data acquisition, interpretation, and storage. To a large degree this has been accomplished, with only refinements necessary to insure faultless operation for simultaneous synchronous acquisition of Selspot, forceplate, EMG, and footswitch information. Once the data are filed in memory, the analysis and the generation and display of results are identical for strobe or Selspot systems, and are operational software at this time.

Kinematic data can be viewed within minutes after a run. A computer-generated stick-figure representing two LED's mounted on a subject's body is shown in Figure 32. Such output is a check on the validity of an experiment. If problems are indicated, the experiment can be repeated while the subject is still in the laboratory.

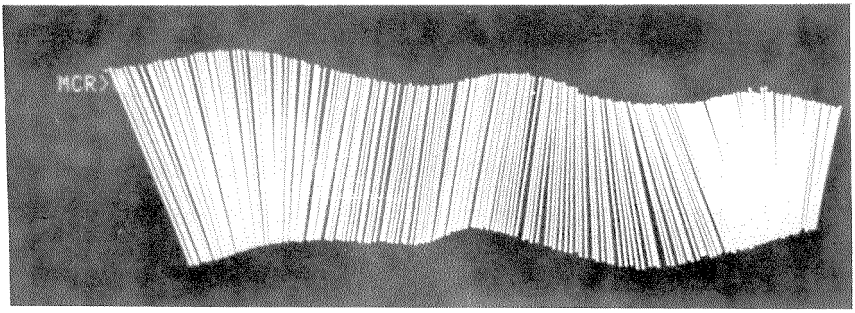


FIGURE 32. – Computer-generated stick figure progression representing two LED's, one on the left pelvis, and the other at the knee of a normal subject during fast level walking. The sample rate is approximately 150 Hz.

Conclusions. There is no doubt, at this point, that the automated system will be functional. In certain respects, such as encumbrance of the subject, this system is not as good as the strobe system, but the ability to provide results in minutes, as compared to weeks, far out-weighs the shortcomings.

Applications of Motion Analysis in Orthotics and Prosthetics

1. *Comparison of Implanted Electrical Stimulation (Neuromuscular Assist) to Five Other Methods of Treating the Equinovarus Foot in the Hemiplegic Adult*

Seven patients have been implanted with the NMA (Fig. 33). The original protocol suggested using a general anaesthetic for implantation. In view of past experience with surgery on patients of this type, the procedure was attempted with local anaesthesia and found to be reasonable. Several advantages were noted, as follows:

1. No recovery period from anaesthesia was needed;
2. Good feedback existed from the patient to warn of any undue pressure on the peroneal nerve; and
3. Cooperation of the patient in evaluating the interaction of his voluntary control with the functioning of the stimulator was possible.

Five of the seven patients still have their devices implanted. Two have been removed. One patient required a below-knee amputation of the opposite leg 3½ yr post implantation because of atherosclerosis. An above-knee amputation was required about 7 months later on the implanted leg. The implant continued to function well until surgical removal. Another patient was implanted with the

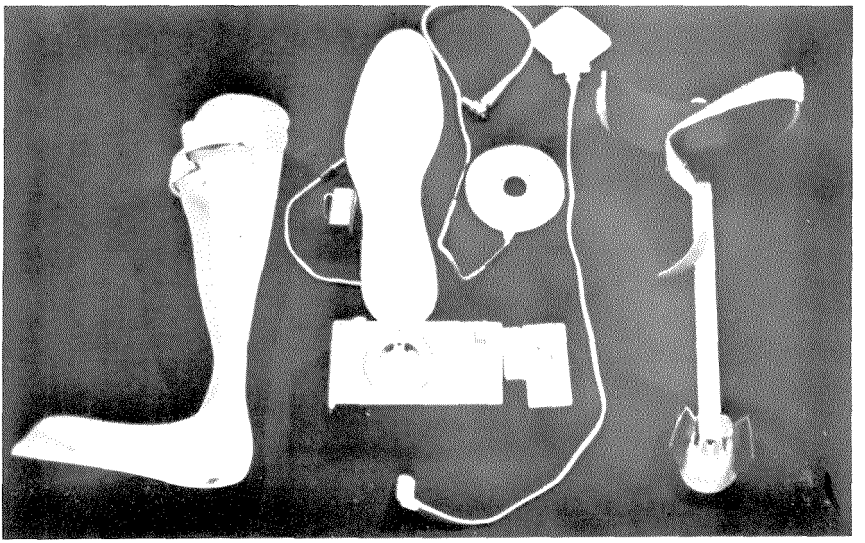


FIGURE 33a. – The NMA is in the center. The Engen AFO is on the left and the VAPC Clip is on the right.

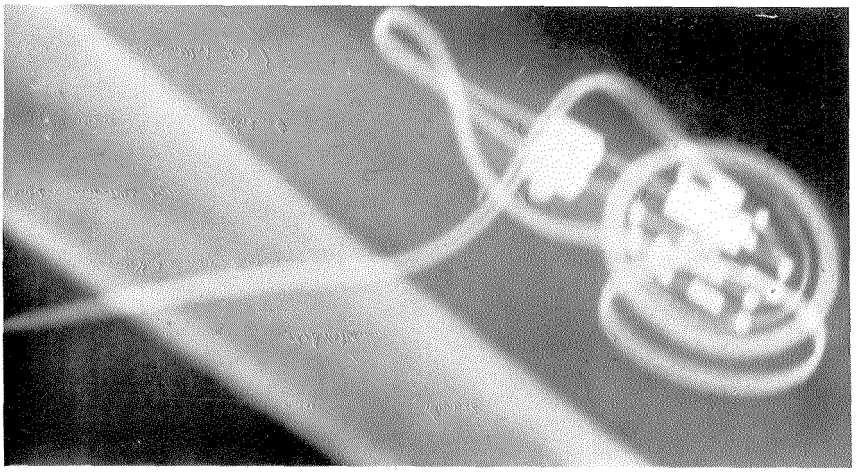


FIGURE 33b. – X-ray of implanted NMA.

NMA 1.4 yr post cerebral aneurysm repair. She had been stable prior to the implant. Following implantation, she continued to improve until she had regained complete voluntary control over the stroke-affected foot. She then asked to have the device removed because she feared possible future damage to the peroneal nerve. She was asked to go without the brace for 3 months and then was re-evaluated. The improvement in function remained and the im-

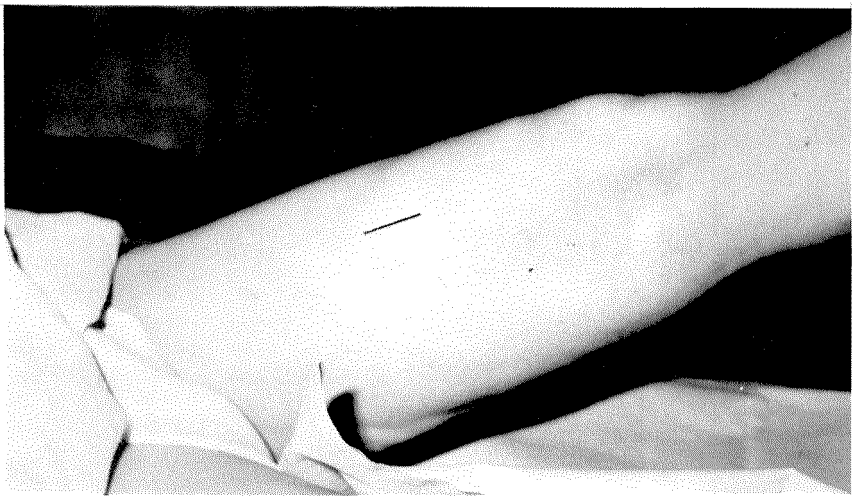


FIGURE 34a. – Line showing area of thigh incision on medial thigh. Actual incision was too cosmetic to show in photograph.

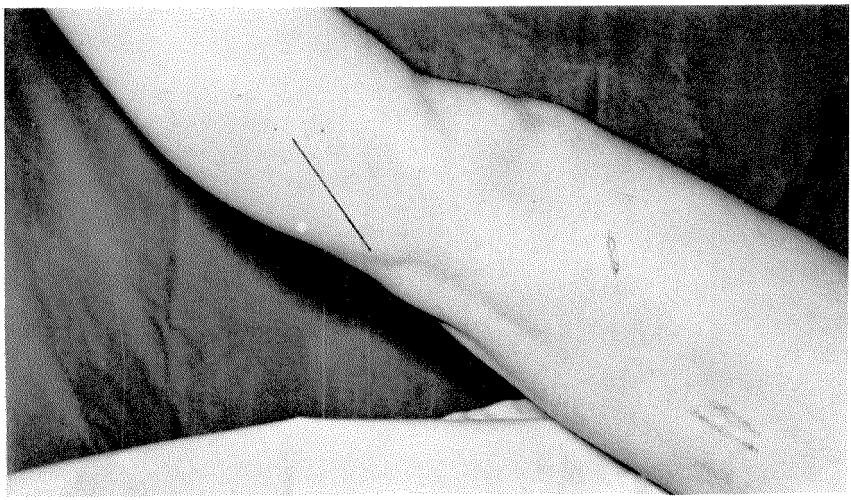


FIGURE 34b. – Line showing area of incision in lateral leg over peroneal nerve.

plant was then removed under local anaesthesia (Fig. 34). Tissue had grown into the Dacron mesh providing a very secure fixation. From this experience, it is our recommendation that any implant with the likelihood of requiring repeated re-insertion should not

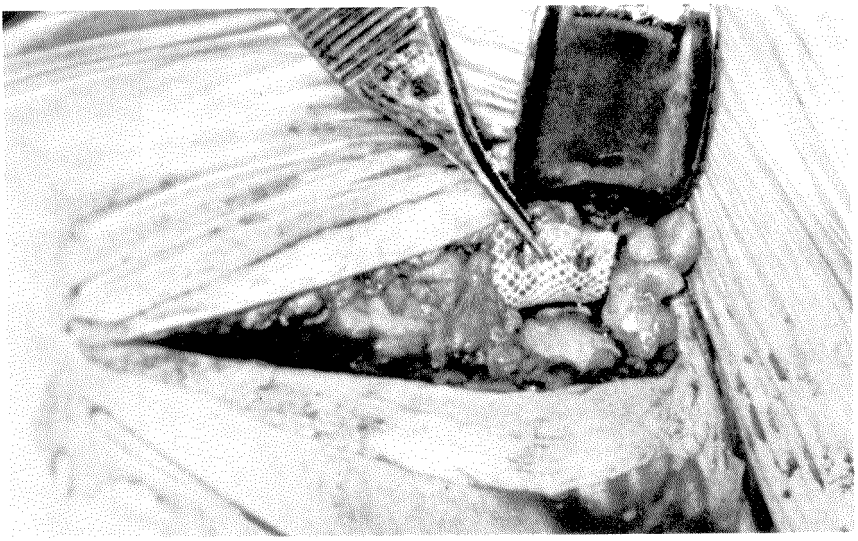


FIGURE 34c. – The electrode is partially removed showing the smooth gray membrane around the apparently normal nerve.

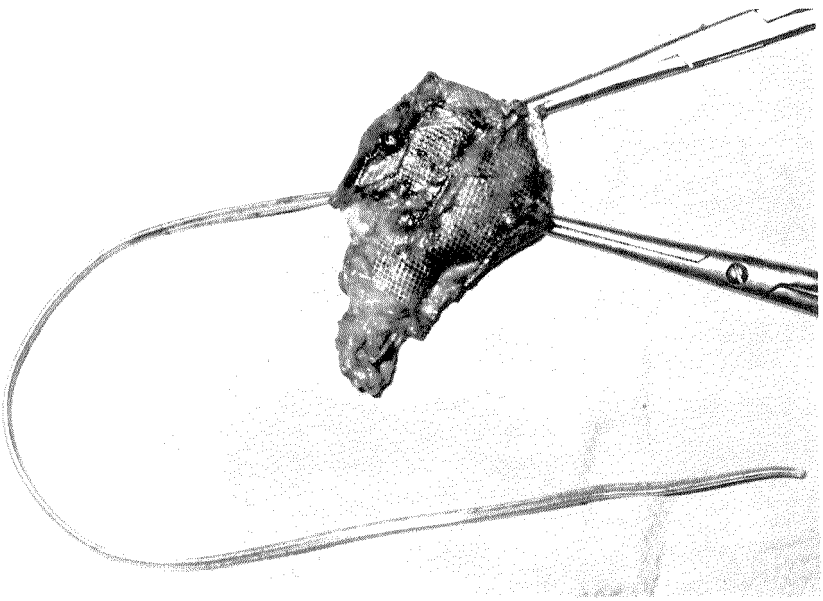


FIGURE 34d. – Hip portion immediately post removal. Note the ingrowth of tissue.

have a total Dacron covering. A few Dacron tabs should be sufficient for initial anchoring prior to the establishment of the connective tissue capsule.

There have been no infections and no failures of the implanted portion of the equipment. One implant failed to function at the time of initial insertion and a spare was substituted. The defective unit was returned to Medtronic, Inc. We have had numerous failures of the external equipment; foot switches, foot transmitters, belt transmitters, and antennae have all broken at various times. At the current state of the hardware, inspection of components is needed at least at 2 month intervals to maintain good function in an active patient.

The Foot Contact Laboratory was constructed to quantitate function of the various braces, since the Strobe System required too much time to allow the large number of determinations desired. Detailed analysis of the data is not yet completed, but 6 patients have expressed strong preference for the NMA over the other devices. One patient demonstrated excessive eversion post implantation and had difficulty walking safely due to this. She had demonstrated some valgus instability of her ankle prior to surgery. A reimplantation leaving out some peroneal fibers was suggested to her but she has not as yet decided to have this done. Some other patients initially demonstrated more than optimal ankle valgus but with exercise and subsequent anterior tibialis hypertrophy, this disappeared. The routine operating procedure is to always balance the foot in slight valgus on the operating table in order to avoid any varus since even a slight varus is very disabling. This balancing was initially done by separating the branches of the peroneal nerve and including only those that gave desirable motion inside the electrode. Balance was achieved in later patients by rotating the electrode on the entire nerve until satisfactory motion was achieved. Another problem is the effect of the postural reflexes on stimulator performance. Implantation and testing must be done in the supine position at the present time, but function must occur in the upright position. These difficulties indicate the strong desirability of being able to alter the varus-valgus balance of the system without reoperation.

Much difficulty was encountered in fitting patients with the FEPB (external electronic brace) and in teaching them and their families to put it on properly. In view of this, we doubt that the external electronic brace will ever be useful for large numbers of patients but feel it is valuable as a training device for the hospitalized patient where trained personnel can closely supervise its

use. The VAPC Clip, the Engen AFO, and the double upright orthoses presented no major problems.

We are currently evaluating the automated gait laboratory data on our seven patients even though we have not reached the goal of ten. The cooperative study (of which the implant portion of this project was once a part) is completed (4). The Medtronic Company, Inc., is no longer interested in pursuing the device at this time, but has agreed to provide us with materials necessary to complete our ten implants and to repair existing braces as needed. Our plan is to complete the analysis of our present patients and to continue implants during the analysis period as suitable subjects become available.

2. *Stimulation of the Paralyzed Hip to Return Functional Use*

Electrodes have been implanted in the iliopsoas on one hemiplegic patient obtaining sufficient force to flex the hip. The patient was placed on an electrical exercise program. His spasticity markedly decreased, and his gait improved. After removal of the electrodes, the spasticity slowly returned. The rectus femoris of another patient was implanted. This patient was an above-elbow amputee with a below-knee amputation on the same side. He was wheelchair bound due to a 60 deg flexion contracture. The rectus femoris was implanted with 3 percutaneous electrodes and he was placed on an

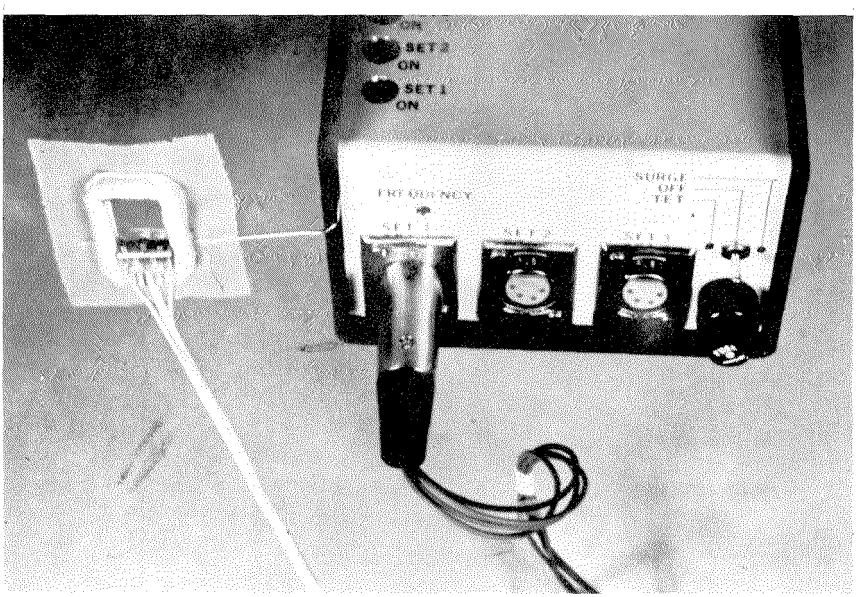


FIGURE 35a. – Stimulator and connector.

exercise program. There was some improvement in the reduction of the contracture to about 45 deg but there was marked improvement in quadriceps strength and the patient was able to walk without assistance.

An exercise stimulator to allow simultaneous activation of 3 electrodes was constructed. A new soft electrode connector to provide protection to the percutaneous electrodes in the groin area was devised. The stimulator, connector, and a set of implanted electrodes are shown in Figure 35.

A Brown-Séquard patient, who is currently about 1 yr post injury and is unable to walk, has expressed interest in our project. We plan to continue the project with him and other patients as they become available. A protocol for evaluating the effect of the electrical exercise has been established utilizing Cybex. We will continue the investigation of the muscles around the hip including the gluteus medius and gluteus maximus.

3. *Development of Femoral Shaft Fracture Cast Brace and Manual*

Initiation of this portion of the project has been postponed since a major portion was under Dr. Albert Burstein. He has transferred from Cleveland to the Hospital for Special Surgery, New York City, New York.

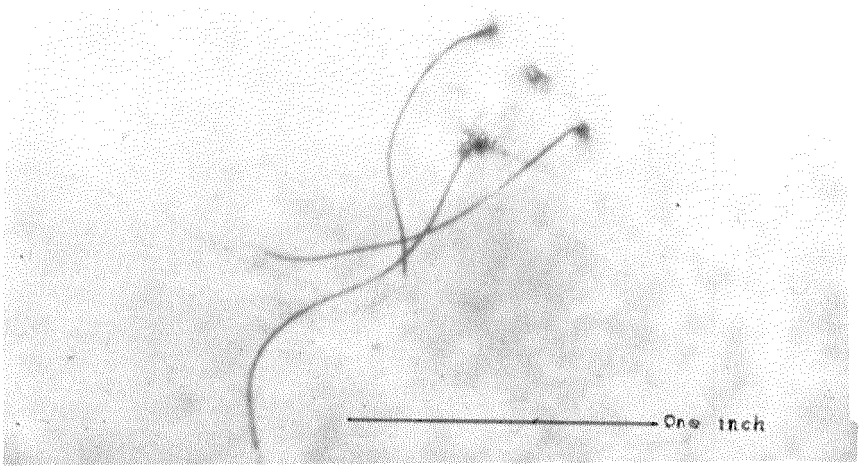


FIGURE 35b. – Percutaneous microelectrodes in place in skin. They are shown at about twice actual size.

Collaborative Research

1. *In Vivo Loading on Hip Joint Replacements*

The telemetry receiving equipment has been constructed and installed in the Motion Study Laboratory to allow receiving of data from the implanted instrumented hips. No device has yet been implanted but we anticipate the eventual successful completion of this project. (See pages 193-194 in this issue.)

2. *In Vivo Loading on Knee Joint Replacements*

This project uses the same telemetry equipment as the hip. An extension of the project has been submitted and eventual successful completion is anticipated. (See pages 193-194 in this issue.)

3. *Investigation of the Response of the Righting Mechanism to Small Perturbations in Scoliotic Versus Normal Individuals*

This project is not being pursued at the present time. Scoliosis studies are being done pre and post fusion, to evaluate the effect of fusion on gait.

Effects of Neuromuscular Diseases, Joint Disease, Surgery, Drugs, and Exercise on Body Motion

The Foot Contact Laboratory is used on a regular basis to provide direct clinical information to the physician concerning his patient's gait. The evaluation is requested by the physician in the same way as electromyography or nerve conduction studies are requested. A large body of data documenting the effects of many variables on gait is being built. At present, these studies are being done in conjunction with evaluation with the Rancho Los Amigos Gait Analyzer in order to obtain a comparative evaluation.

Other Related Work Accomplished

The orthosis comparison study required an objective measure of orthosis performance. The strobe system was considered too cumbersome, and the automated 3-D system was not anticipated to be functional for some time. It was decided that a foot-to-floor contact analysis would be adequate.

In a search of the literature, it was soon realized that no suitable normal data base information existed for foot contact measurements. Therefore a significant effort was expended in establishing such a data base.

A completely automated foot contact analysis system was designed and constructed at the beginning of this reporting period.

This system is capable of providing temporal component measurements immediately following a run. A block diagram is shown in Figure 36.

Two normal studies were performed. One involved 51 male and female subjects walking at normal speeds only, and the other involved 14 male and female subjects each walking at a broad range of speeds from about 0.2 m/sec to as fast as each could reasonably walk. The data resulting from the larger study were normalized with respect to cycle duration and subjected to a linear multiple regression analysis in order to determine the equations that best predict the stance, swing, double support, heel, foot flat, and forefoot phase percentages. The independent variables included in this analysis were age, height, weight, speed, and cycle duration. The resulting equations were:

$$\text{Stance (\%)} = 75.63+(.043\times W)-(8.04\times S)-(3.79\times C) \quad [1]$$

$$\text{Swing (\%)} = 24.41-(.043\times W)+(8.06\times S)+(3.73\times C) \quad [2]$$

$$\text{Double support (\%)} = 25.83+(.043\times W)-(8.16\times S)-(3.80\times C) \quad [3]$$

$$\text{Foot flat (\%)} = 50.26+(.066\times W)-(14.78\times S) \quad [4]$$

$$\text{Forefoot (\%)} = 25.56+(4.98\times S)-(10.64\times C) \quad [5]$$

$$\text{Heel (\%)} = 1.14+(6.51\times C) \quad [6]$$

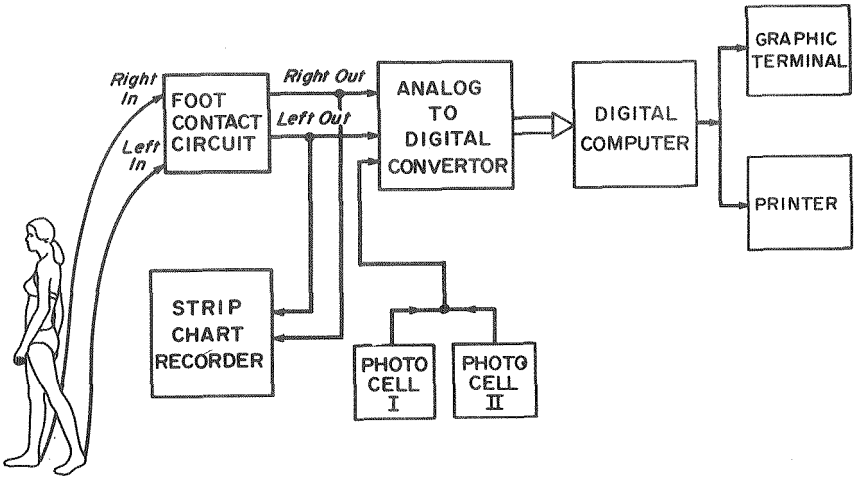


FIGURE 36. – Block diagram of foot-to-floor contact analysis system.

where W, S, and C correspond to weight in Kg, speed in m/sec, and cycle duration in sec, respectively. Note that none of the phase measurements are related to either height or age. Equations [5] and [6] for forefoot and heel are not considered to be reliable outside of the range of normal speeds, as they account for only 12 percent of the variability in these parameters.

The smaller study of 14 subjects suggests that the stance, swing, double support, and foot flat equations are valid for all speeds of 0.6 m/sec or greater. Below that speed equations [1] through [4] do not hold. This smaller study also showed that the heel and forefoot phase percentages are essentially constants of 8.5 percent and 20 percent of the gait cycle, respectively, over the entire measurable range of speeds. It also provided equations for predicting stance, swing, double support, and foot flat percentages for speeds between 0.2 and 0.6 m/sec:

$$\text{Stance (\%)} = 78.73-(19.08 \times S) \quad [7]$$

$$\text{Swing (\%)} = 21.38+(19.08 \times S) \quad [8]$$

$$\text{Double support (\%)} = 28.84-(19.48 \times S) \quad [9]$$

$$\text{Foot flat (\%)} = 47.85-(12.41 \times S) \quad [10]$$

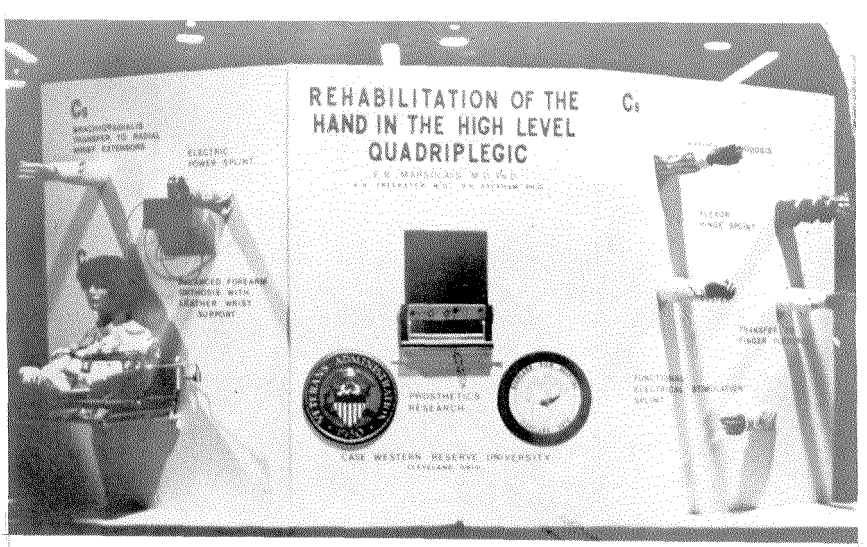


FIGURE 37. – Laboratory exhibit.

where S is the speed in m/sec. The methodology of this study was such that only the relationships between phase percentages and speed are meaningful.

Another special project of the laboratory was an exhibit entitled "Rehabilitation of the Hand in the High Level Quadriplegic" which was presented to the American Academy of Orthopaedic Surgery at the 1977 meeting in Las Vegas, Nevada (Fig. 37). The project was done in conjunction with Dr. A. A. Freehafer and Dr. P. H. Peckham. It consisted of moving prosthetic electric hands depicting various surgical and non-surgical approaches used to improve function in the quadriplegic hand. The exhibit was well received.

References

1. Paul, J. P.: Forces at the Human Hip Joint. Thesis submitted for the degree of Doctor of Philosophy in Engineering of the University of Glasgow, October, 1967.
2. Morrison, J. B.: The Forces Transmitted by the Human Knee Joint During Activity. Thesis presented for the degree of Doctor of Philosophy in Engineering of the University of Strathclyde, September 1967.
3. Bresler, B. and J. P. Frankel: The Forces and Moments in the Leg During Level Walking. Trans. Am. Soc. Mech. Engrs.: 72:27-36, 1950.
4. Subcommittee on Evaluation, Committee on Prosthetics Research and Development, Division of Medical Sciences – Assembly of Life Sciences, National Research Council – National Academy of Sciences: Clinical Evaluation of Rancho Los Amigos Hospital/ Medtronic, Inc., Implanted Neuromuscular Assist Device. National Academy of Sciences, Report E-8.

Patient Evaluation of a Functional Electrical Stimulation Hand Orthosis

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

Introduction

The purpose of this project is to develop and evaluate an orthotic system employing electrical stimulation of paralyzed muscle. This system is intended to provide C-5 quadriplegic patients with controlled grasp and release of the hand, through electrical stimulation of the forearm finger flexor and extensor muscles, respectively. The operation of the system under development is based on a prototype system developed in the Applied Neural Control Laboratory at Case Western Reserve University, Cleveland, Ohio, under H.E.W. sponsorship. The system under development is a miniaturized version of the prototype version and is designed to be easily donned and carried.

Operation of the System

Control of hand function is achieved in the following manner. Movement of the head or shoulder in one plane is transduced and used as the proportional control input for governing the strength of contraction. Movement in one direction from a neutral position activates the finger flexor muscles; movement in the opposite direction activates finger extension.

External stability provided by an orthosis is necessary to insure proper motion in the hand. A polypropylene orthosis, developed earlier, provides stability to the wrist or thumb, and finger rings are used to stabilize the interphalangeal joints.

Proportional control of contractile strength is achieved through both recruitment (activation of previously inactive fibers) and summation (addition of active responses). These are achieved by pulse width modulation and interpulse interval modulation, respectively, in the stimulation scheme.

Chronically in-dwelling percutaneous coiled wires are utilized for the active electrodes. For the finger flexor muscles, three electrodes are implanted into physically separate areas of the flexor digitorum superficialis or profundus. These electrodes are activated sequentially, 120 deg out of phase. For the finger extensor, a single electrode is implanted into the extensor digitorum communis.

Movement of the proportional controller, performed by the patient, controls the strength of contraction through a preset algorithm. This algorithm relates the control voltage to the output stimulus pulse width and stimulus frequency applied to each electrode set. Briefly, a demand for increased contraction strength is answered by increasing the pulse width(s) with the stimulus frequency held constant until a predetermined control level is reached. Further demands for increased strength are met by increasing the stimulus frequency while holding the pulse width fixed at its maximum values.

The system being developed incorporates control logic which simplifies the patient's control task. The two functions provided by the control logic are to enable him (i) to turn the system on and off which specifies his zero reference position at any point in time, and (ii) to "hold" a desired control level (stimulus output) independent of his shoulder position. Previous studies have demonstrated that these control functions are necessary if the high level quadriplegics are to operate this type of system. This is principally because postural changes, which occur in performing various tasks, would otherwise require the patient to exert extensive, continuous, conscious control. In the system under development, these functions are activated by a two-level processed myoelectric signal,

obtained from a site with some remaining voluntary activity. Exceeding a lower level with the myoelectric activity activates the "hold" function; exceeding the upper level activates the "on/off" function. Signal acquisition for the myoelectric switch is through a chronically indwelling bifilar coil wire recording-type electrode.

Device Design and Fabrication

The hardware implementation of the system functions was developed with the constraints of (i) small size and light weight, to allow the unit to be carried by the patient, (ii) low power consumption, to permit infrequent battery recharging or replacement, (iii) ease of attachment to patient transducers and electrodes, and (iv) a maximum degree of patient safety in the event of a circuit failure.

The various circuit functions are built on three miniature printed circuit boards. These appear as boards #1, #2, and #3 in the block diagram of the basic system (Figure 38). The use of printed circuits enables a high component density to be achieved while still maintaining a reliable and easily reproduced device. The circuit density is further enhanced by the elimination of internal switches and potentiometers: the exact parameters of stimulation, which vary from patient to patient, will be set by smaller fixed-value resistors and jumpers. The three boards (each approximately 3 X 5 inches) are stacked vertically over one another; interconnection of the boards

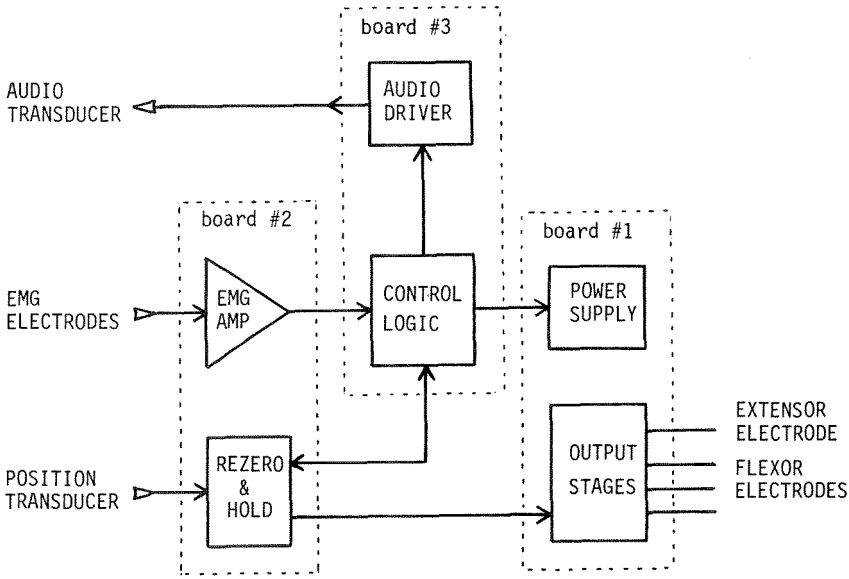


FIGURE 38. – Block diagram of electrical stimulation hand orthosis.

is through simple strip connectors at the ends. The complexity of this interconnection was minimized to avoid future contact problems as the units are used and serviced.

The objective of minimal power consumption is realized through two basic approaches: 1. each of the individual circuit functions is implemented with low-current components and designs, and 2. during the OFF state, power is supplied only to the EMG amplifier and part of the control logic. Thus, when the system is in the OFF state (which is true much of the time) only about 20 percent of system circuitry is supplied with power. The power supply receives its power up or down commands from that portion of the control logic which is always powered. The power to the unit as a whole is turned on by the act of attaching the single connector going to the patient electrodes and transducers. This eliminates the need for a separate on-off switch.

Two non-rechargable mercury batteries are expected to operate the system for about two months of service. This was determined to be more desirable than using rechargable batteries of comparable size.

Emphasis was placed on safety considerations in the design of the stimulator. Electrical isolation between the EMG amplifier and the stimulator section insures that no current can flow to or from the indwelling EMG electrodes, even during a system failure. In the stimulator section, four identical output stages are used. Each stage generates a controlled current pulse which is capacitively coupled to the patient's stimulating electrode (cathode) to produce a net biphasic current flow. The stimulator outputs are monitored by a protection circuit whose function is to shut down the system should the stimulating pulse width or rate become excessive: this redundant circuit operates in the event of a device failure, to prevent damage to the electrode, and/or muscle tissue injury.

A laboratory version of the stimulator has been built and tested. This larger device has been used to verify the design and function of the various circuits which, in turn, were designed into the miniature system. The laboratory stimulator has panel-mounted potentiometers and switches which allow the various stimulation parameters to be varied. Predetermined parameters for a patient's stimulator will be set into the laboratory unit, his usage of the system observed, and any necessary parameter modifications made. These parameters will then be fixed into the miniature unit for that patient. Later changes, if necessary, can be made by repeating the process. Completed, in addition to the laboratory device, is board #1 which is currently being etched commercially. This board is the most complex of the three, and contains largely analog circuit

functions. Boards #2 and #3 are now being laid out; when completed they will also be etched and assembled.

Patient Evaluation

Two C-5 quadriplegic patients have been involved in these studies in the period reported upon here. These patients, who have used the C.W.R.U. prototype system in previous work, have been involved in two aspects of development of the present system. First, they have worked with the laboratory stimulator to insure its proper operation. Specifically, studies with these patients have allowed the measurement of interaction between the electromyographic signal and the output stimulus, and determination of the necessity for feedback of the control state to the patient. Secondly, these changes have been incorporated, whenever possible, into the prototype system to determine, preliminarily, the efficacy of the modification. The patients involved in this stage of evaluation are presently fitted with the modified prototype systems, and they will be the first to receive new systems, which are expected to be completed in the next period.

Ultralight Below-Knee Prosthesis

Rehabilitation Engineering Center
Moss Rehabilitation Hospital
12th Street and Tabor Road
Philadelphia, Pennsylvania 19141
A. Bennett Wilson, Jr.

The goal of a 6-month contract with the Veterans Administration (contract ended April 30, 1977) was to demonstrate the feasibility of an ultralight below-knee prosthesis. Practical techniques for fabrication of below-knee prostheses that weigh 60 percent less, size-for-size, than the comparable conventional PTB type were developed and presented in an instruction manual.

Fabrication is by molding sheet polypropylene. Although the fabrication time is about the same as that required by the more conventional techniques, labor can be reduced after one or more manufacturers make available either permanent molds, or temporary foot sections, for use in molding the foot-ankle part of the prosthesis.

Although designed with problems of the geriatric patient in mind, the ultralight below-knee prosthesis has been received extremely well by BK patients of all ages and all categories. An addi-

tional advantage of weight reduction is a reduction in the suspension problem. The current technique of fitting does not require any suspension other than the supracondylar tabs that are an integral part of the socket.

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

All orthopedic implant procedures are followed on a prospective basis, and all implants that are removed during the normal and routine medical care of patients are collected. Patients receiving orthopedic implants are followed from the time of insertion until removal (if removed). A photographic record of each implant is made in vitro just prior to implantation, and in vivo immediately post-implantation. Also, a culture of the tissue area at the implantation site is performed at implantation and removal.

The essential components of our retrieval and analysis program are outlined as follows.

1. Implantation
   a. Case history
   b. Roentgenogram review
   c. Culture implantation area
   d. Record of implant

2. Recovery of Implant
   a. Case history review
   b. Roentgenogram review
   c. Tissue sample adjacent to implant
   d. Culture adjacent to implant
   e. Photographic record of implant

3. Examination of Implant
   a. Macroscopic
   b. Microscopic
   c. Properties
   d. Chemistry

4. Examination of Tissue
   a. Histology
   b. Identification of culturable organisms, if any
   c. Quantitative determination of foreign bodies if present

5. Correlation
   a. Reason for removal
   b. Implant performance
      (i) Clinical
      (ii) Engineering
   c. Operative procedure
      (i) Implant choice
      (ii) Technique
   d. Diagnosis
   e. Histology
   f. Radiographic changes
   g. Materials characteristics

We are currently using data forms essentially identical to those being developed within ASTM F-4 and described in an ASTM draft document entitled "Recommended Practice for the Retrieval and Analysis of Metallic Orthopaedic Implants."

There are currently 23 patients in the study; 13 of them prospective and 10 retrospective. (One of the prospective implants has been retrieved.) The devices involved cover the standard armamentarium of the orthopedist, and are shown in Table 3.

A typical summary of the clinical and metallurgical analyses performed for each case is illustrated, from an actual case, in Table 4 and Table 5.

TABLE 3. – *Devices Involved*

	Prospective	Retrospective
Jewett nail plate	6	1
Screws or pins	–	4
Intramedullary rods	–	1
Joint endoprostheses	4	2
Hip nail	1	–
Bone plate	2	2

TABLE 4. – *Summary of Case History Review*

Length of time implanted	1 month
Implant type	Jewett nail
Patient sex and age	Male – 76
Diagnosis at insertion	Fracture; right hip
Reasons for removal	Pain, infection, instability

TABLE 5. – *Summary of Metallurgical Examination*

	Number of components: 5				
	Nail-plate	Screw #1	Screw #2	Screw #3	Screw #4
Galling	–	–	–	–	–
Burnishing	mild	–	–	–	–
Change of shape	–	–	–	–	–
Mechanical damage	severe	–	–	moderate	–
Microporosity	–	–	–	–	–
Corrosion	fretting	crevice pitting	crevice	crevice pitting	crevice
Chemical composition	316L[a]	–	–	–	–
Knoop hardness test (microhardness)	nail 220 plate 170	380	340	390	390
Hardness (R_B"B") (Rockwell method)	80	–	–	–	–
Grain size	nail 6.5 plate 7.5	–	–	7	–
Inclusion content	nail 2-heavy plate 1-medium				

[a] Stainless steel, A.I.S.I. Type 316L, salt-water-resistant.

The microstructure of this particular implant is shown in Figure 39.

In order to evaluate the mechanical properties of these implants, a microtensile specimen is fabricated from each implant when possible. A typical sample is shown in Figure 40. This sample will facilitate a determination of yield strength, tensile strength, percent elongation and percent reduction in area. These data can then be correlated with the hardness and microstructural data and compared to the properties determined from testing larger samples of the same materials in the same metallurgical conditions. To date,

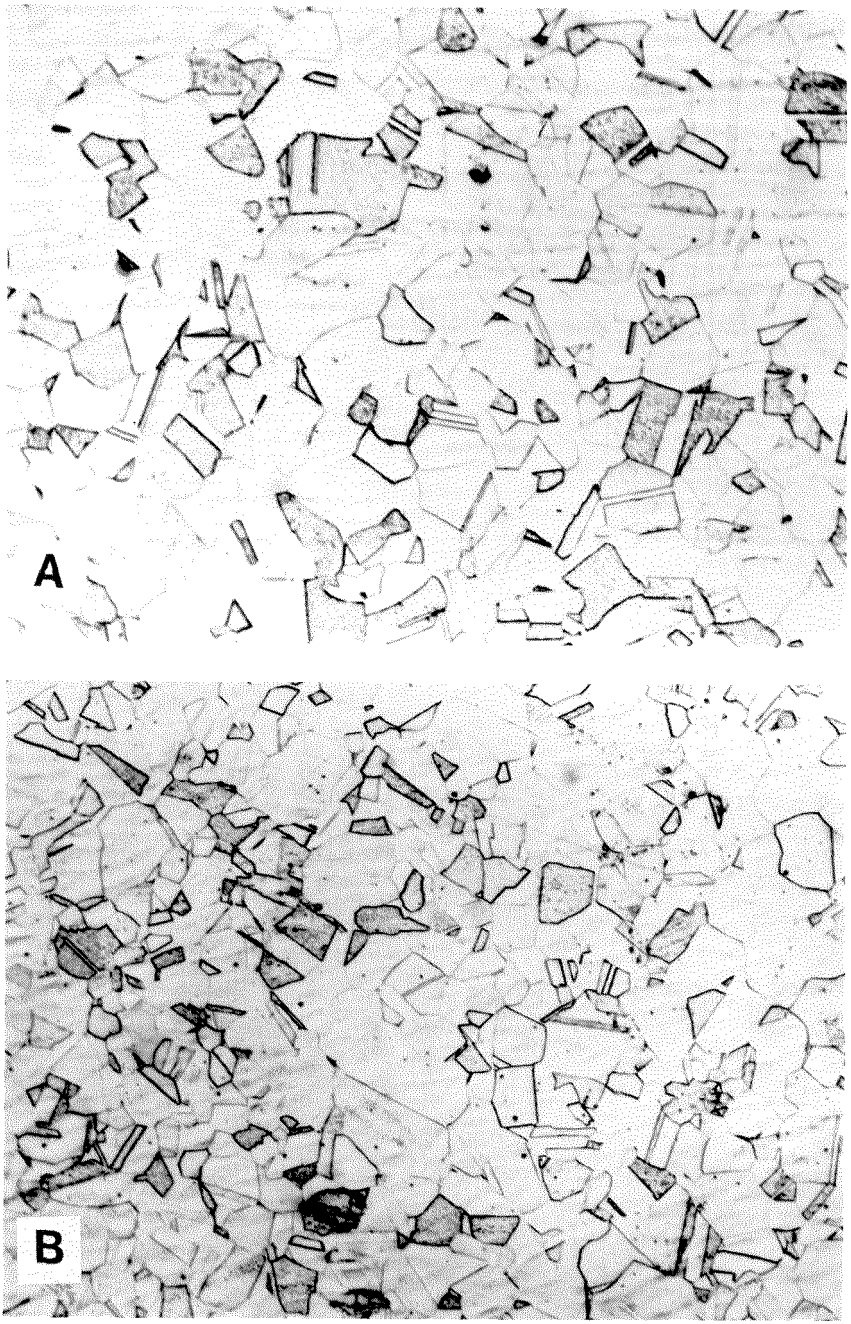


FIGURE 39. – Representative microstructure of the plate portion of the device: (a) longitudinal and (b) transverse sections. Magnification 250x.

no correlations of data have as yet been attempted, as a sufficient number of implants has not been retrieved.

Toward a Nationwide Retrieval Program

As part of the project, the feasibility of extending this study to a nationwide retrieval program for the entire VA system is being investigated. Collaborative arrangements are being made with other VA hospitals and engineering centers to expand the retrieval program. The VA Hospital, Columbia, South Carolina, is retrieving implants and forwarding them to the Tulane University Biomaterials Laboratory for analysis. The VA hospital in Irvine, California, has agreed to participate. In addition, the Utah Biomedical Test Laboratory and the University of Pennsylvania have each expressed interest in establishing regional implant analysis locations. Their respective VA hospitals (Salt Lake City and Philadelphia) are also interested in this study.

The engineering centers would obtain implants from a certain geographic area adjacent to each center. All data would ultimately be correlated by one group: in fact, it is envisioned that if one center has a unique expertise, then that center would be responsible for all implant evaluations involving that expertise. It should be pointed out that it appears that establishing an engineering

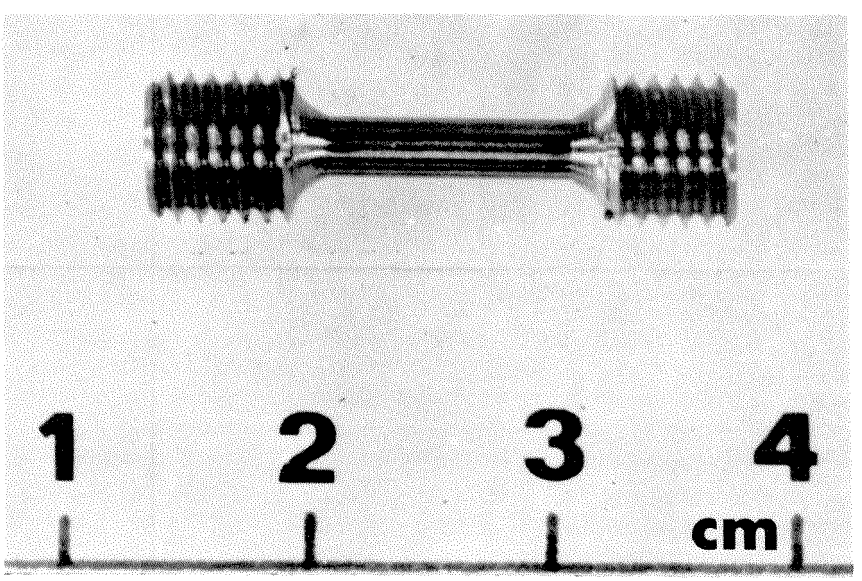


FIGURE 40. – Typical microtensile specimen machined from the plate portion to determine mechanical properties.

center at each VA hospital is not necessary, as the implant output is insufficient. It will be quite feasible for one engineering laboratory to handle the output of multiple hospitals.

Goals for the coming year are —

1. To continue the retrieval and analysis program at the VA hospitals in New Orleans, Louisiana, and Columbia, South Carolina;
2. To expand the southern regional collections to other local hospitals such as Atlanta, Gulfport, Augusta, etc.; and
3. To establish two other engineering centers, one at the Utah Biomedical Test Laboratory, and the other at the University of Pennsylvania.

Evaluation of Electrical Techniques for Stimulation of Hard Tissue Growth

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

No progress report was submitted by this contractor for this report period. A full report will be in the next issue.