HIGHLIGHTS OF OTHER VA RESEARCH PROGRAMS

PROSTHETICS

Edited by

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Prosthetics, Orthotics, and Sensory Aids Research Services
Committee on Prosthetics Research and Development and Prosthetic and Orthotic Education and Information Program
Committee on Prosthetic-Orthotic Education
National Academy of Sciences
2101 Constitution Avenue, N.W.
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Colin A. McLaurin, Sc.D.

For progress during this report period, see "Committee on Prosthetics Research and Development, Committee on Prosthetic-Orthotic Education, Division of Medical Sciences—National Research Council, National Academy of Sciences—National Academy of Engineering, Annual Summary Report, Activities for Period Ended June 30, 1973," appearing elsewhere in this issue of the Bulletin.

Research and Development in the Field of Artificial Limbs
Mauch Laboratories, Inc.
3035 Dryden Road
Dayton, Ohio 45439
Hans A. Mauch

For progress during this report period, see "Abstract of Summary Report on Research and Development in the Field of Artificial Limbs (July 1973)," appearing elsewhere in this issue of the Bulletin.

Stump Stress Analysis
New York University
Center for Interdisciplinary Programs
West 177th Street and Harlem River
Bronx, New York 10453
Leon Bennett

For progress during this report period, see "Transferring Load to Flesh: Part VI. Socket Brim Radius Effects," appearing elsewhere in this issue of the Bulletin.

Prosthetic Research
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Robert G. Thompson, M.D., and Dudley S. Childress, Ph. D.

The Laboratory is deeply engaged in the development and evaluation of semi-flexible sockets for upper-limb amputation problems. These sockets are self-suspending and employ atmospheric pressure for soft tissue suspension or anatomical contouring for skeletal suspension. The use of a latex rubber has greatly facilitated the construction of these sockets. Preliminary results have been very encouraging.

Mr. Billock has developed a harnessing technique for the above-elbow amputation level which makes maximum use of the movement available in biscapular abduction and which relieves pressure in the axilla.

Mr. Billock is preparing teaching material based on experience developed through fitting upper-limb amputees with powered components. The Laboratory has had considerable experience in this area, and it seems well to systematize this information.

The so-called "lift-lock" mechanism has entered its final stage of prototype development and local evaluation. The device replaces the lift-tab in an above-elbow prosthesis and operates to make the terminal device and elbow independent when "dual" control is used.

Fundamental and Applied Research Related to the Design and Development of Upper-Extremity Externally Powered Prostheses
University of California, Los Angeles
School of Engineering and Applied Science
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Los Angeles, California 90024
John H. Lyman, Ph. D., Amos Freedy, Ph. D., and Ronald Prior, Ph. D.

Current research efforts in the Biotechnology Laboratory focus on the following objectives:

1. Test and evaluate the operation of an experimental arm prosthesis and the associated variable transformer control system,

2. Implement a prosthesis-oriented adaptive aiding system, and
3. Determine the feasibility of fabricating a self-contained microcomputer aided prosthesis.

An amputee subject was fitted with the arm, and a series of performance experiments were conducted in order to:

1. Collect data on the performance of the arm,
2. Evaluate the control concept of the skin motion transducers and their associated logic circuits,
3. Optimize the transducer variables, and
4. Evaluate the utility of shared computer control.

Four candidate locations for control sites were selected: abdomen contraction, right shoulder elevation, left shoulder elevation, relative motion between right and left shoulder.

The initial reactions to the prosthesis and control configuration were positive. Control for both directions of each degree of freedom was smooth, and limited simultaneous control was obtainable in two degrees of freedom as early as the second session. The amputee expressed his pleasure on the reduction of weight compared to the Boston Arm, along with the ease of manipulating the control characteristics of the variable transformer.

A special version of an adaptive control system (ACS) was developed and implemented on the UCLA Biotechnology minicomputer for control of a prosthesis with three degrees of freedom. The system is operational and is currently ready for experimental work. The concept behind the system involves shared patient/computer control, with the computer making control decisions about future directions of motion and the patient initiating the control actions.

Overriding computer decisions are achieved by the elbow control transducer. The elbow transducer is used as a four-position switch: rest, extend open, stand still, flex. In the rest position, the ACS is off line, and the elbow stands still. The operator has control over the wrist and claw. In the remaining three positions, the ACS is informed the operator wishes the elbow to extend, stand still, or flex. The ACS uses this information, along with the current and past positions of the prosthesis, to make a decision concerning the motion of the remaining two degrees of freedom. Finally, the output of the computer and the operator's remaining two transducers are summed, so that should the operator find any of the movement unacceptable, he can modify the output. Any modifications the operator makes will be learned by the ACS.

Finally, recent developments in microcomputer technology have brought about the feasibility of realizing a self-contained, self-supporting externally powered computer-aided prosthesis. Hence, the Laboratory has undertaken studies to review the state of microcomputer technology, recommend one or more microcomputer systems suitable for controlling a prosthesis, and establish a prelimi-

nary design of a microcomputer-aided prosthesis; all are viewed from the perspective of integrating and fitting this hardware according to control techniques developed by the laboratory and to human factors.

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, Howard D. Eberhart, Don M. Cunningham, and James M. Morris, M.D.

The development of essential computer programs for the minicomputer data acquisition system has been completed. Additional programing for implementation of the new graphical display terminal is underway. A four-bar polycentric knee above-knee prosthesis with pneumatic swing control and axial rotation unit has been fully instrumented including a new instrumented pylon and swing control force transducer. A complete study of the stance-and-swing phase dynamics over a range of walking speeds is now in progress.

The axial rotation unit (shank torque absorber) continues to be trouble-free in amputee testing.

A design for an internally expanding tube coupling which eliminates the need for external clamps between components of endoskeletal prostheses has been completed and additional test units are being manufactured.

A study is underway of possible designs for six-link knee prostheses for through-knee or supracondylar amputations. Three possible kinematic arrangements are being compared on the basis of cosmesis, mechanical design, control of knee stability in the stance phase, and swing-phase control.

Work continues on improvements in the adjustable height powered wheelchair. A short sound movie showing use of the wheelchair with a quadriplegic patient has been prepared.

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

The Prosthetics Research Study is a cooperating unit in the neuromuscular assist program, federally sponsored. Four electrodes

have been implanted, two in stroke patients and two in upper motor neuron head injury patients. No complications have been experienced. It is hoped that the surgery and rehabilitation of the designated 10 cases will be completed by the end of the current calendar year if appropriate subjects are available.

Also being studied, at the clinical level, is pain abatement using non-invasive electrical stimulation. Amputees with specific residual pain patterns are the clinical subjects under investigation.

Two patients with non-unions following fractures and subsequent bone grafting of the tibia are being investigated using electrical energy as a means of stimulating osteogenesis and new bone formation. This program will be extended to include the localized effects of electrical modalities in selected patients with osteoporosis.

The clinical and experimental effects of certain physical parameters (pressure, temperature, humidity, immobilization) on healing of the postoperative wound continue to be a source of major investigation. A full-time research fellow in orthopedic surgery is assigned to the wound-healing project. The fresh amputation stump is the primary clinical source of this investigation. Traumatic wounds in the extremities of rabbits provide the experimental animal data. The wound environment studies also relate to a continuing investigation into the laboratory means for level determination in amputations for peripheral vascular disease.

In the field of prosthetics, suspension mechanisms relative to muscle activity, both voluntary and involuntary, in the stump, particularly in the young lower-extremity amputee, are being studied. The "socket-grasping" capacity of stumps is being measured in terms of suspension capabilities. Twenty-five below-knee amputees are undergoing evaluation and training. It is anticipated that suspension prosthetic techniques may be appreciably simplified and altered under certain circumstances where the stump can be conditioned to utilize inherent muscle-stabilized, socket-grasping potential.

Also, a prosthetic study on interface mechanisms including special purpose limbs, particularly for recreational activities, continues.

The clinical caseload at the various hospitals affiliated with the Prosthetics Research Study continues at 10 to 12 amputations per month.

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

VA Hospital
4150 Clement Street
San Francisco, California 94121
Wesley L. Moore, M.D., Albert D. Hall, M.D., and Leigh A. Wilson

The prosthetics research project of the Veterans Administration Hospital, San Francisco, has continued in its evaluation of immediate postoperative prosthesis for patients with occlusive vascular disease. During this past quarter, data correlating skin blood flows with $Xenon^{133}$ clearance and success or failure of amputation healing were reported on and presented at the International Cardiovascular Society Meeting in Toronto.

Currently, work is being completed on a film describing the technique of Syme's amputation with immediate postoperative prosthesis. This film will also describe the use of the San Francisco exoskeletal prosthetic foot to be used in the immediate postoperative prosthetic fitting of Syme amputees.

Interdisciplinary Development and Evaluation of Externally Powered Upper-Limb Prosthesis

Applied Physics Laboratory
The Johns Hopkins University
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Woodrow Seamone and Gerhard Schmeisser, Jr., M.D.

During the first half of 1973, the work at Johns Hopkins was primarily aimed at clinical fittings of experimental powered prosthetic systems for high level upper-limb amputations as well as continued evaluation of a range of powered prosthetic systems which had previously been fitted. Refinements on powered upper-limb orthoses were also continued.

The powered system components under development at Johns Hopkins use as their basic power element the electrically driven cable puller which has been reported in previous issues of the Bulletin of Prosthetics Research. The original systems were controlled from single-site myoelectric sensors or by a skin motion displacement sensor and could control, sequentially, elbow and hook grasping functions.

In an effort to determine the capability of this system concept to provide additional upper-limb mobility such as shoulder motion, one such system was fabricated for a shoulder-disarticulation amputee. Another new case of interest involved fitting a powered system for a high level above-elbow amputee using body motion as an input. These cases and results to date are described below.

Shoulder-Disarticulation Prosthesis

A prosthesis which includes powered shoulder motion as well as elbow and hook grasping function is shown fitted on the volunteer patient in Figure 1. This man, a shoulder-disarticulation amputee, had previously been fitted with a JHU powered system to provide

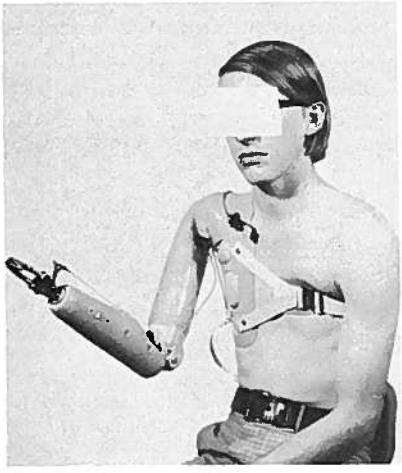

FIGURE 1.—Shoulder-disarticulation prosthesis (shoulder motion capability).

elbow and hook grasping functions. The original experimental system worked well for a period of 25 months, but lacked an important function, namely, shoulder extension motion.

A new prosthesis was designed which utilizes a slightly modified motor assembly in the elbow space and, by means of a pulley arrangement and shoulder locking mechanism, allows sequential control of shoulder, elbow, and hook (single motor). The system control electronics and rechargeable battery pack were contained in the forearm of the prosthesis. Two shoulder positions are provided, 0 deg. and 45 deg. from vertical, with the locking mechanism capable of positive locking against a high torque. Control of shoulder motion is achieved by a chin nudge switch located on the shell of the prosthesis. An integrated electromechanical unlocking scheme allows easy unlocking at either shoulder position followed by smooth shoulder motion and automatic locking with minimal amputee effort.

Elbow and hook grasping functions are controlled by a motion sensor connected to the skin over the pectoralis muscle. This technique had previously been reported in the Bulletin of Prosthetics Research, BPR 10–17. Unlocking the elbow allows the motor to control the arm flexing whereas, if the elbow is locked, the motor controls the hook grasping function. The elbow lock is a semi-automatic electromechanical device which is controlled by vertical shoulder motion causing the elbow locking mechanism to retract and is automatically relocked after approximately 2.5 seconds elapsed time after elbow first motion. As of this reporting period, the patient has used this new prosthesis for approximately 1 month. He finds it very useful for bimanual functions at his place of employment.

Short Above-Elbow Prosthesis

One of the more difficult amputee types to fit with conventional prostheses is the short above-elbow amputee. The stump in this case is generally too short for adequate contact surface in the prosthesis, and the typical high force levels required to operate the terminal device cause additional unwanted motion of the upper section of the prosthesis. Conventional systems fitted to amputees of this type are usually abandoned after little or no usage.

In order to determine the merit of a powered prosthesis for such cases, one such system has been fabricated and fitted to the patient shown in Figures 2a and b.

This 18-year-old girl sustained her amputation in a farm accident 8 years ago. Soon after the injury she was fitted with a conventional body-powered prosthesis. It was well fitted, designed for function, and included an internal locking elbow, VO terminal device, and an above-elbow figure-8 harness. However, the remaining portion of her humerus was too short to enable her to develop adequate cable force or excursion for useful function. After a fair trial, she abandoned it and adapted very successfully to single-handed function.

Subsequently, she decided to become a nurse and secured admission to a school of her choice; however, she was required by the school to obtain a functional prosthesis. When she contacted the Johns Hopkins Hospital Limb Prosthesis Clinic, it was decided that because of the very limited bone length in her stump and her earlier unsuccessful experience, a conventional prosthesis could not satisfy her needs.

Preliminary examination of the patient for possible control signals indicated this person had a weak myoelectric signal over the biceps muscle. The signal appeared barely adequate to operate the test system, but a decision was made to proceed to see if weak myoelectric signals could adequately control the prosthesis. The initial fittings proved the control site was unsatisfactory and, consequently, a new solution was needed.

The revised control technique selected for this case was to use gross body motion similar to body-powered systems, but reduce the stroke requirement to $^3/_4$-in. total and force requirements to 1–2 lb. These requirements were implemented such that body motion would be used to control a spring-loaded position transducer located within the prosthesis. External connections to this cable are identical to conventional practice for body-powered systems. Elbow unlocking was accomplished with an electromechanical arrangement which reduces the force level on the harness to an acceptable low value somewhat independent of load on the prosthesis. The elbow is

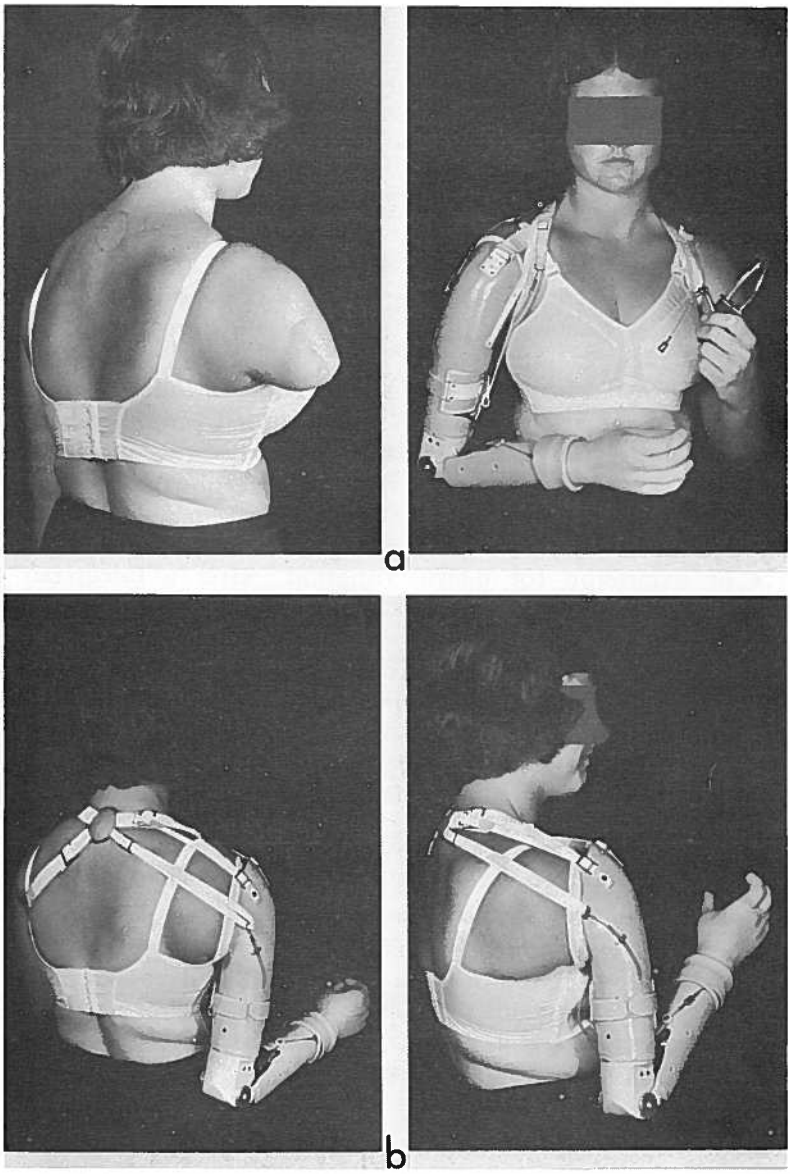

FIGURE 2.—a. Eighteen-year-old amputee with short flabby above-elbow stump fitted with electrically powered prosthesis controlled by minor body motions. Terminal device interchangeability is retained. An ancillary anterior stabilizing strap is seen between the lateral support strap and the elastic extension of the front support strap; b.¾. in. control cable excursion and 1-2 lb. control cable force would be inadequate for conventional control but operate a transducer controlling external power to provide full opening of terminal device with full elbow flexion. Low control force permits reduction in width of control cable attachment strap. An ancillary posterior stabilizing strap is seen between the lateral support strap and the control cable attachment strap.

automatically locked approximately 2.5 seconds after first motion of the arm.

Figure 2a shows the overall stump length in one view and the patient wearing her electrically powered prosthesis in the other. The soft tissues of the stump are quite flabby and the bone is considerably shorter than the stump. In this situation the two additional straps extending from the upper anterior and posterior edges of the socket to a common point on the front support strap back of the neck were required to stabilize the socket. The cable drive permits VO terminal device interchangeability as with traditional body-powered prostheses. In Figure 2b the small control cable excursion and low force level, which are required to open the terminal device even with the elbow fully flexed, are illustrated. These conditions permit reducing the width of the control attachment strap. In all other respects the harness is a conventional above-elbow figure-8 harness. The elastic extension of the front support strap serves both to return the elbow lock control cable and to assist in suspension of the prosthesis.

This patient is now wearing this prosthesis on a daily basis a large percentage of the time and is relearning how to perform bimanual functions. Evaluation of performance is to be conducted over the next several months.

Powered Orthosis

During the report period, development has been continued on the application of the external power pack/cable arrangement to power a flail elbow. The series of photographs, Figures 3a, b, and c, show the progression of the design from the initial complex harnessing arrangement with an external mechanical hinge (Fig. 3a), through an intermediate design using lightweight cloth strap arrangement on both the forearm and upper arm (Fig. 3b), to the latest arrangement (Fig. 3c) which supports the cable housing by means of an attachment to a suspenders-type body harness and continues to use the lightweight cloth strap forearm arrangement.

It is planned to fit this latest technique (Fig. 3c) to a patient with a fused shoulder joint, flail elbow, and a good hand.

Evaluation Progress

The Johns Hopkins external power technique has now been applied to 13 test patients with an assortment of occupations and ages and a full range of amputation levels. All amputees were fitted with functional, conventional, body-powered (BP) prostheses to facilitate comparison with the externally powered (EP) prostheses.

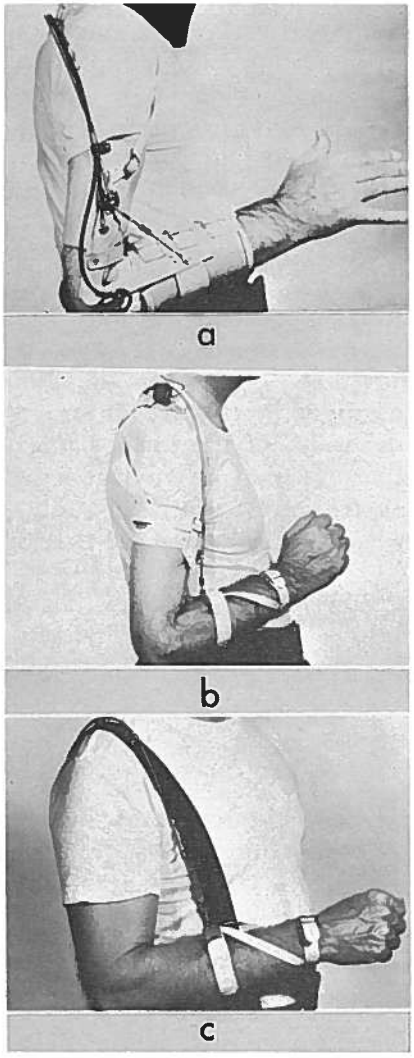

FIGURE 3.—a. Original design—powered elbow brace; b. intermediate design —powered orthosis (elbow); c. minimal harnessing—powered orthosis (elbow).

At the present time, 10 of these patients are still wearing these experimental units with a total cumulative test time of 25 man-years. A detailed technical and evaluation report is expected to be prepared and issued on this phase of the program during the next 6 months. Preliminary results to date indicate this technique may have merit over conventional body-powered systems in many selected situations.

The forthcoming limited clinical tests planned for the six units manufactured by the Pope Brace Company for the VA Prosthetics Center will allow an independent evaluation of this concept for possible future clinical use.

Future Plans

Engineering and development will be concentrated on application of power to upper-limb orthoses and development of additional control sites on the head. Evaluation will be continued on systems involving several modes of control to understand and perhaps simplify the control input requirements from the patient. The Applied Physics Laboratory will continue to evaluate system operation and performance on the 10 patients currently fitted with this system concept.

Development of Refined Fitting Procedures for Lower-Extremity Prosthesis

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Because of the problems encountered in cosmetically finishing a prosthesis with a socket constructed of Taslon, this project has been temporarily suspended until future developments make the system more practical. Research is being carried out in the area of socket fabrication utilizing thermoplastic material. To date, sockets have been constructed of polyethylene, polypropylene, and polycarbonate with emphasis on developing a practical system that can be used by the average practitioner. To date five patients have been fitted with polypropylene sockets reinforced with polyurethane foam. The advantages of utilizing polypropylene for socket construction are: ease of fabrication, light weight, and low expense. Adjustments may easily be made to the material by heating and remolding. However, the main advantage of utilizing this type of prosthesis is that the socket may be easily remolded or replaced without having to fabricate an entirely new prosthesis. As stump volume decreases to the point that a new socket is required, the old socket is removed from the container and a new socket inserted. Though a number of minor adjustments have been made successfully, none of the polypropylene prostheses fabricated in this manner has had socket replacements to date. This is because not enough time has elapsed to cause stump changes great enough to warrant fabrication of a new socket. Research is being carried out with other thermoplastic materials such as polycarbonate, PVC, and ABS in an effort to develop lower-extremity prosthetic sockets that may be directly attached to a pylon structure.

Future work in research will be based on a case study program initiated July 1, 1973. The case study program will include lower-extremity problems in both prosthetics and orthotics. The previously mentioned prosthetics research work will be continued and similar work utilizing various thermoplastic materials will be applied to lower-extremity orthotics. Emphasis will be on clinical applications of various new materials and designs with accurate documentation and followup. Clinical application of various new prosthetic and orthotic designs will enable us to accumulate a body of knowledge appropriate for teaching and further application to specific patient problems.

For example, the case study program may demonstrate that the use of polypropylene foot-ankle orthoses will lead to a standardization of various sizes. A series of standard polypropylene foot-ankle orthoses has been developed so there is no need for individual measuring or modification of plaster model for each patient. Patients with average drop-foot problems can be easily treated using this system. Additional patient requirements may be met by modification of the original orthoses or by the addition of standard modular components.

Prototype posterior knee joints are being developed in an effort to eliminate medial and lateral joints currently utilized in an above-knee orthotic system. This development hopefully will become a modular component which can be utilized in conjunction with the basic foot-ankle system.

Basic studies are presently underway in an attempt to gain a better understanding of the roles of the interosseous membrane and soft tissues which contribute to the success of the functional treatment of tibial fractures by early weight-bearing ambulation, first with a cast and soon an orthosis. These studies aim at providing the knowledge required to begin development of improved techniques for the treatment of many types of fractures of the long bones of the upper and lower extremities. Both the devices and the techniques will be clinically tested in the case-study program in cooperation with other ongoing activities at The University of Miami School of Medicine.

Immediate Postoperative Application of Upper-Extremity Orthoses

VA Hospital
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Richmond, Virginia 23219
Charles L. McDowell, M.D.

The combined efforts of orthotics and hand surgery services continue toward a goal of refinement in techniques of dynamic bracing for tetraplegic and arthritic patients.

A recent development is helping us achieve better positioning and dynamic correction in patients with rheumatoid arthritis than was possible with earlier models. The orthosis allows us to position the metacarpal-phalangeal joints and provides dynamic correction for metacarpal-phalangeal joint flexion contractures without a large dorsal outrigger. The large outrigger works well, but its bulk is a nuisance to the wearer and he is less inclined to wear it for activities. The new orthosis incorporates a flat hinge to allow wrist dorsiflexion and palmar flexion but prevents radial tilt which is often a problem in patients with the deformity in rheumatoid arthritis. A spring assist can be added where needed.

The orthosis was originally developed to assist in treating problems peculiar to the tetraplegic, but it was found to have application in rheumatoid arthritis as well. One of the great benefits of this orthosis to the patient with rheumatoid arthritis is the "lift" under the proximal phalanges which helps prevent dislocation of the metacarpal-phalangeal joint. It forces the patient to flex his interphalangeal joints and thereby maintain proper length of the intrinsic mechanism in his fingers. Also, intertrigo is prevented by controlled separation of the fingers (Fig. 4).

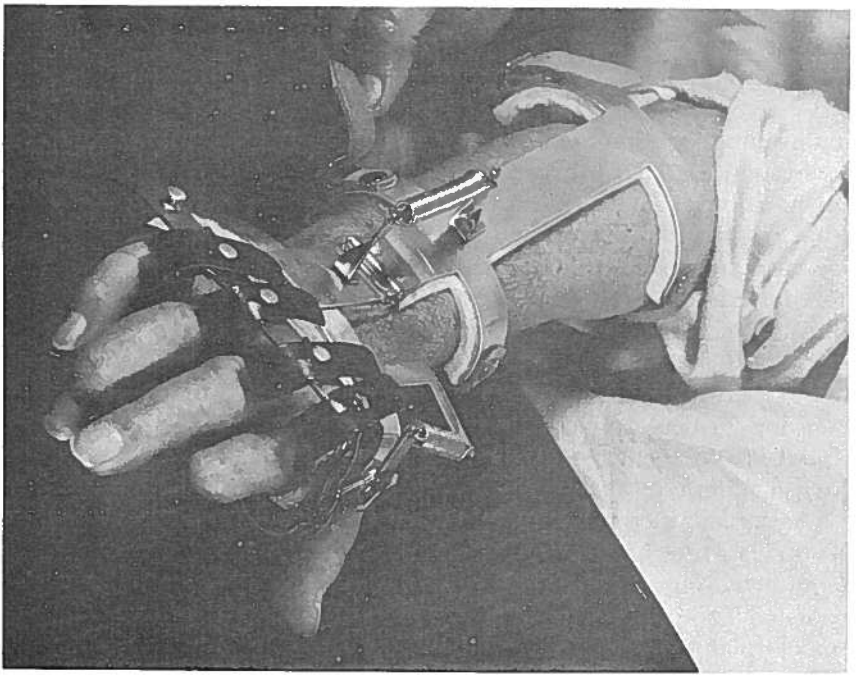

FIGURE 4

The Improvement of Assistance Systems Through Research, Design, Clinical Testing, and Team Evaluation

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Bioengineering Program
College Station, Texas 77843
Paul H. Newell, Jr., Ph. D., and Lewis A. Leavitt, M.D.

During the period from January 1 through June 30, 1973, the hip-disarticulation prosthesis developed as part of the research program underwent several significant modifications. The first change involved redesign of the leave-in alignment devices in order to obviate a wear problem. The second modification involved the knee joint. The cam arrangement in the joint was revised to make more effective use of the properties of the dilatant fluid while reducing the tendency for the fluid to separate irreversibly during severe stress.

Upon completing these modifications, the prosthesis was refitted on a patient for a 3-month test; to date the patient has reported no problems with the unit. The test terminated September 5, 1973, and the unit examined at that time.

An overview of the program on vehicle driving by the physically disabled was presented at the May meeting of the Society of Automotive Engineers in a session entitled Designing for the Handicapped.

A precision control test has been designed to support the continuing program on evaluating various driving methods (hand controls). In this test a voltage signal is generated which is proportional to a predetermined time varying velocity profile such as that resulting from a period of smooth acceleration, a second period of constant speed, and a third period of smooth deceleration. This predetermined voltage history is compared with a voltage proportional to the actual velocity of the vehicle and the difference displayed to the driver. The ability of the driver to minimize the error between the desired and actual velocity is then recorded for varying drivers and control devices. The unusual feature of visual feedback to the driver is intended to minimize differences due to driver judgment and to emphasize equipment capabilities.

As an adjunct to the evaluation of commercially available hand controls, and hand driving in general, a preliminary study was completed on a comparison between reaction times in braking of the normal foot controls, the common hand control, and a control mockup in which a trigger is pulled to achieve simulated braking. The mean reaction times for foot, hand, and trigger were found to be 0.50, 0.37, and 0.20 seconds. The significantly shorter time for

hand operations provides reassurance that, with appropriately designed equipment, hand driving does not present any fundamental limitations in performance but may, in fact, be a superior mode of operation.

A servo-control system for automobile steering is currently being bench tested in preparation for installing the system in a van. Also, an experiment related to this task is being conducted by personnel at Texas A&M University and at the Texas Institute for Rehabilitation and Research. The objective of this experiment is to determine whether an isometric or an isotonic controller (joystick) is best for use by the disabled in performing proportional control tasks (steering, braking, acceleration, etc.). The experiment protocol has been developed, apparatus has been designed and built, and data collection is currently in progress.

Control of an Artificial Upper Limb in Three Degrees of Freedom

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Daniel Graupe, Ph. D.

During the first half of 1973, the work on the present project of a three-degrees-of-freedom prosthesis controller has been concerned with the construction of the toe-actuation circuitry and of its interfacing with the logic control system that was completed earlier (see previous reports in BPR). For this purpose, semiconductor strain gages are being employed to actuate the main logic control system above by utilizing toe-movements as described in our earlier reports on this project. Sensitivity adjustments of the actuation circuit are being facilitated by the present circuitry that has now been completed and tested.

Investigations into extending the number of degrees of freedom beyond the present three via adding several EMG-actuated functions to the present three toe-actuated functions are underway. For this purpose, EMG signals at various locations and relating to different limb-functions have been recorded and processed. The joint probability densities of these signals have been examined and subsequently time-series analysis approaches have been applied to the recorded data. The initial investigations along these lines have demonstrated that the thus identified parameters of the autoregressive-moving-average models and of the corresponding Kalman-filter models of these signals facilitate almost globally optimal filtering and, above all (at least in part), recognition and separation of different limb functions. Furthermore, the identification-time (0.15–0.25 seconds),

the procedure complexity, and the memory requirements (1000 12-bit words) are such that practical real-time prosthesis application should be possible, using presently available microcomputer hardware, for reliable multi-functional EMG control, as required for the above extension in a number of degrees of freedom.

Future work will be concerned first with the linkage design and construction for the toe-actuated controller, and secondly, with optimizing the identification procedure above, such that a most compact and fast microcomputer design for the EMG-actuation part of the system be possible, noting that the controller used for the toe-actuated system also can handle the EMG-actuated system.

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

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Durham, North Carolina 27710
Frank W. Clippinger, Jr., M.D.

No progress report was received from this contractor for this report period.

Acceleration of Bone Healing by Electrical Stimulation

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George Van B. Cochran, M.D., Med. Sc.D.

Laboratory evidence from a number of investigators has indicated that electric currents can accelerate healing of fractures and other bone defects. Both continuous and pulsed d.c. currents apparently are effective in experimental animals; certain case reports also have been published concerning the use of electrical stimuli to treat non-unions in humans.

At present the most effective type of electrical stimulus is unknown. Furthermore, the stimulation of bone formation tends to occur only within a limited area around the cathode.

This study was designed to aid in developing this new technique into a useful clinical tool, capable of producing *clinically significant* amounts of new bone, particularly in non-unions. The effects of different types of currents and electrode arrays are being studied, utilizing defects in canine ulna as a model for non-union. Initially, implanted battery packs are being utilized as a power source, but radio-frequency transmission of power through the skin to the stimulus generator is planned.

During the first 6 months of this project, begun Dec. 1972, electrode arrays and stimulus generators have been designed and tested in association with Avery Laboratories, and pilot implantations in four dogs have been completed. As yet, it is too early to report results.

Success of this study would provide great benefits to VA patients in terms of reduced morbidity and improved rehabilitation from non-unions and other bone defects. Clinical tests are planned in cooperation with the Seattle Prosthetics Research Study.

Hemodynamic Evaluation of Postoperative and Preoperative Amputee

VA Hospital
Castle Point, New York 12511
Bok Y. Lee, M.D., F.S. Trainor, Ph. D., John L. Madden, M.D., and E. Ejercito, M.D.

In a program to establish the nature of the many underlying problems of peripheral vascular disease (PVD), continuing efforts have been directed toward establishment of a hemodynamic profile for postoperative unilateral amputees and preoperative amputee candidates. The vascular changes in PVD are progressive and often times rapid. This can be especially true for a unilateral amputee and his remaining limb.

The circulatory status of the remaining limb of the amputee and the limbs of all PVD patients is assessed, specific procedures determined, therapeutic regimens instituted, and followup evaluations scheduled. Analyses of data obtained by varied test procedures provide clues and predictors related to the progressive nature of vascular changes.

During the past 6 months, a review of 250 peripheral vascular disease cases has been completed. Twenty-eight of these have received very detailed study in preparation for the establishment of data files and the computerization of patient data.

Establishment of the hemodynamic profile for the patient begins at the time the initial visit is made and the history, physical examination, and initial evaluation of peripheral pulses completed. Generally, the patient is scheduled for admission to the hospital for further testing and observation. The sequence of observations and test procedures is dependent upon the nature of the patient's complaint. Initial tests will include arteriography, noninvasive electromagnetic flowmetry and impedance plethysmography, ultrasonic flowmetry, peripheral pressures, and skin thermometry.

A typical example is that of patient (P.A.), a 77-year-old man whose first admission to this hospital occurred 3 weeks after the development of gangrene in the toes of the right foot. As the patient indicated at the time of his admission, his present problem had developed gradually first with pain in the right foot and toes which became progressively worse and then gangrene developed. The patient had a long history of cigarette smoking, emphysema, cirrhosis, and bi-inguinal hernia. Blood pressure was 160/90 mm. Hg. The five toes of the right foot showed evidence of gangrene. A bilateral femoral arteriogram showed extensive arteriosclerotic changes especially in the deep femoral vessels; however, no obstruction was noted. The impedance waveforms obtained at this time confirmed the presence of relatively good flow in the three limb segments (thigh to ankle, at knee, below knee to ankle). Temperatures for the ankle and toes were diminished (26 deg. C.) and a 5 deg. C. temperature gradient (thigh to ankle) was present; however, relatively good systolic pressure readings (110 mm. Hg) were obtained bilaterally.

As a result of these observations no major amputation was contemplated and a right lumbar sympathectomy was completed. This was followed by debridement of the necrotic tissue of the right foot with the MP joints maintained. The patient responded well to his program and he received physical therapy and ambulation training. He remains completely independent, ambulates well and is capable of all self-care activities.

As indicated in the initial report (Spring 1973 issue of this Bulletin), the computer program for analysis of impedance waveforms has been completed and is being used routinely to obtain the quantitative data for the descriptors of pulsatile waveforms. Analyses of the impedance waveforms (bilateral or unilateral) allow for a determination of the degree of involvement. The presence or absence of distorted waveforms, depression of peak amplitudes, prolonged deceleration, deceleration duration, and time for recovery of resting waveforms, all present clues as to the degree of the disease, the amount of collateral circulation, and the amount of functional reserve. The presence of "normal" limb volume waveforms at rest does not preclude the presence of arteriosclerotic occlusive disease; thus a dynamic evaluation determining the effect of and response to exercise is always included as part of the evaluation program.

The Cardio-Thoracic vascular clinic has become the center of activity for initiation of the vascular test procedures. A total of 850 patient visits has been recorded during the past 6 months and at least 200 of these patients have received complete hemodynamic

evaluations. Currently, a major objective is that of categorization, classification, and correlation of the degree of involvement of each patient with the objective quantitative data obtained during his evaluation.

Maxillofacial Restorative Biomaterials and Techniques
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The research during this period has emphasized modifications of moldable polysiloxanes (silicone elastomers) with: a. dilating (or swelling) additives including solvents and b. cross-linking agents in order to develop a broad range of compliance and resilience properties to approximate those of living tissue and anatomical structures.

The modifications, employing several grades of silicone elastomers and sealants, are given standardized polymerization, beyond that prescribed in proprietary directions. These include: a. bulk curing at elevated temperatures in order to develop and regulate the initial modulus represented as Phase I, and b. solvent curing in boiling xylene serving to extract un-polymerized entities but also to impart extensibility and, with added cross-linking agents, increased terminal strength.

The admixture of low molecular weight silicones serves to depress the modulus and at the same time convert the stress-strain profile, as shown in Figure 5, into an elongating, stretchable characteristic compared to the original stock elastomer.

In these stress-strain profiles, the modifications are now evident in three phases, that are defined as: a. Phase I for the lowering of the

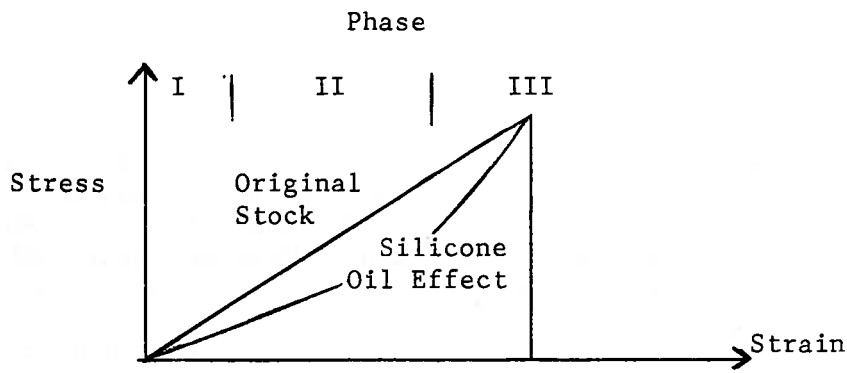

FIGURE 5

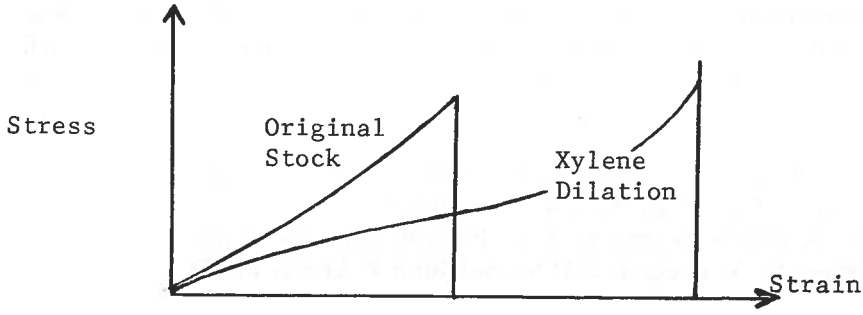

FIGURE 6

initial modulus corresponding to the initial tactile feel, such as one would feel with the ear lobe, b. Phase II as the easily stretched or compliant quality so necessary for a smile or grimace, and c. the ultimate tensile strength (Phase III) as a measure of resistance to rupture.

Numerous stress-strain profiles have been generated by the inclusion of 10, 20, or 40 percent of low molecular weight silicones to medical grade polysiloxane and dilating solvents, notably xylene. In the latter case, an unusual increase in stretching elongation, as depicted by Figure 6, has been achieved by admixing dilating solvent, xylene, in a proprietary silicone sealant in which the stretching feature has been about doubled, a necessary attribute for tactile conformity.

The formulations with their resultant stress-strain properties are assessed by standard ASTM Method. The approach of developing the stress-strain profile is to accommodate to patient's comfort and acceptability and at the same time to standardize the dilatant formulation with the tensile constants that can be reproduced universally.

Concurrently with this program, the cosmetic matching is being standardized by a tricolor, quantitative index for each patient as a registry for replacement prosthesis. A digital color unit is one component of this effort with preliminary indications of considerable merit in eliminating subjective and often indeterminate cosmetic matching.

While not yet in active progress, these efforts are being supplemented with tissue tests to clear the improved compositions against risks of dermal irritation or deleterious effects.

Permanently Attached Artificial Limbs
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I. *Introduction*

Since implementing the current program, only two of the three outlined objectives have been investigated. These include: a. investigation of materials and techniques to satisfy bone interfacing requirements, and b. investigation of materials and techniques to satisfy the skin-interfacing requirements. The investigation of materials and techniques to interface with skeletal muscle and/or tendon has as yet received none of our attention. The program has suffered somewhat in that we were unable to duplicate procedures published in the literature concerning fabrication of ceramic parts having a particular pore size. It was apparent after a few futile attempts that much of the published literature failed to emphasize the problem of quality control. Because of this SwRI ceramic engineers had to solve the problem almost from scratch. The SwRI procedure follows.

II. *Ceramic Implant Materials*

At the time this study was undertaken, reported findings[1] of others studying ceramic materials in bone implant applications indicated that calcium aluminate implants exhibited less ingrowth than corresponding aluminum oxide implants. Also, when calcium aluminate was used, an osteoid seam had been found separating mineralized bone from the ceramic. This was thought to be caused by surface hydration of the calcium aluminate interfacing with the bone mineralization. Little or no osteoid seam was found separating aluminum oxide implants and mineralized bone. In addition, aluminum oxide has generally been considered to be non-toxic, chemically stable, and not conducive to inflammatory responses when used for implants. Because of these factors, plus the ready availability of high purity powders, aluminum oxide was chosen as the ceramic implant material in this study.

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[a] S.F. Hulbert, J.J. Klawitter, B.W. Sauer, and J.R. Mathews, "Characterization of Tissue ingrowth Into Porous Bioceramics," Technical Report No. 2, ONR Contract No. N00014–71–A–0339–100001 (Project No. NR 032–52D), Division of Interdisciplinary Studies, College of Engineering, Clemson University.

A. *Porous Aluminum Oxide Implant Components*

A number of methods and techniques can be employed for producing ceramic articles having porous structures. Since it had been learned that the method involving introduction of a gas-forming agent into a thick slurry made with a powdered ceramic plus liquid vehicle and binder had been used with acceptable results in work at Clemson University, initial attempts to produce porous aluminum oxide specimens employed that technique. The main considerations were that: 1. the size and distribution of the pores could be reasonably well controlled, 2. there should be interconnecting passages between pores, 3. the specimens cast from the slurry could be dried without cracking or loss of pore structure, 4. the dried specimens should be sufficiently strong to permit handling and machining, and 5. any materials added as binders or conditioners could be completely removed without leaving residues. The materials used in efforts to produce porous specimens by the slurry method were as follows:

Material	*Identification/source*
Aluminum oxide	calcined low soda aluminum oxide, dry-milled to 1-3-micron size Grade RC 152 DBM Reynolds Metals Company, Richmond, Va.
water	freshly deionized water
polyvinyl alcohol	ELVANOL 51–05 DuPont Company, Wilmington, Delaware
hydrogen peroxide	Reagent Grade J. T. Baker Chemical Company Phillipsburg, New Jersey

In slurries containing these materials, the aluminum oxide is the primary ingredient and in the final product is virtually the only remaining substance. The water is the vehicle in which the aluminum oxide is suspended while the polyvinyl alcohol serves as an aid to aluminum oxide suspension in the slurry and as a binder after the water is removed. The hydrogen peroxide serves as a pore-forming agent by virtue of its release of oxygen gas upon dissociation.

Numerous combinations and mixtures of the above materials were used in attempts to produce porous aluminum oxide specimens having pores in the size range of about 200–300 microns with interconnecting openings 100–150 microns in diameter. Proportions of all ingredients were varied in efforts to adjust slurry viscosity, obtain desired pore structures, and achieve good drying behavior.

Prepared slurries were poured into open-top aluminum molds measuring about $^5/_8 \times 2 \times {}^5/_8$ in. Difficulties were encountered due to instability of porous structure, poor controls of pore size and distribution, and excessive shrinkage and cracking during drying. In view of the problems, a less complex and more easily controllable method of producing porous specimens was sought.

A method was selected which held the promise of eliminating the use of slurries with high water content and solving the problems of high shrinkage and cracking associated with drying. This method involved the use of mixtures containing aluminum oxide powder and pre-sized crystal-line biphenyl as primary constituents, plus a small amount of binder such as polyvinyl alcohol or polyvinyl acetate or methylcellulose, and a small amount of water-soluble wax (Carbowax 20–M, Union Carbide Corporation, New York) as a lubricant. Controlling the volume and size of the biphenyl particles would afford a means of varying the pore structure of the final aluminum oxide specimens. Neither the aluminum oxide nor the biphenyl is water soluble, but the binder materials noted and the Carbowax can be dissolved to a greater or lesser extent in water. This is convenient for combining the binder and the lubricant in one solution which is then added in an amount sufficient to moisten the mixture and to place therein the desired quantities of those materials. (Polyvinyl acetate is but slightly soluble in water and its addition to the mixtures by this means is limited to about 0.2 to 0.25 gm. per 10 ml. of water.)

Mixtures made as noted above were pressed in a 1-in. diameter steel mold to provide specimens for furnace studies to examine procedures for burnout of biphenyl, binder(s) and lubricant, observe firing behavior, and determine firing shrinkage. All of the organic materials were removed by heating specimens slowly to 800 deg. F. From this temperature, the firing schedule consisted of rapid heating to 2600 deg. F. and holding at that level for 1-$^1/_2$ hours followed by overnight cooling in the furnace. This constituted the first stage firing which had the purpose of carrying firing shrinkage to about the halfway point and developing sufficient strength to permit machining of specimens. Final firing was for 1-$^1/_2$ hours at 2800 deg. F. This yielded specimens that were quite white and which exhibited a desirable porous structure.

With favorable results being obtained in the experimental phase of the work, a steel mold was designed and fabricated for use in forming pressed aluminum oxide specimens of the approximate configuration needed for implanting. The specimens were cylindrical in shape, with semi-ball-and-socket mating ends, as shown in Figure

7. Length was variable, depending on depth of material fill in the mold and applied pressure.

B. *Metal Implant Component*

For support of the porous aluminum oxide components within the bone cavity and to provide an exterior fixture, a Vitallium implant

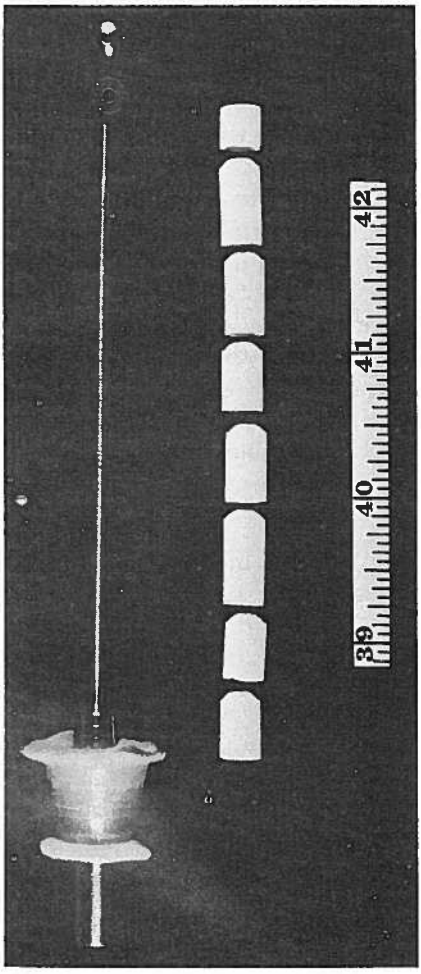

FIGURE 7.—Components of the composite bone implant unit, consisting of the Vitallium structural member with top nut and pressure washer (left), and porous aluminum sections (right).

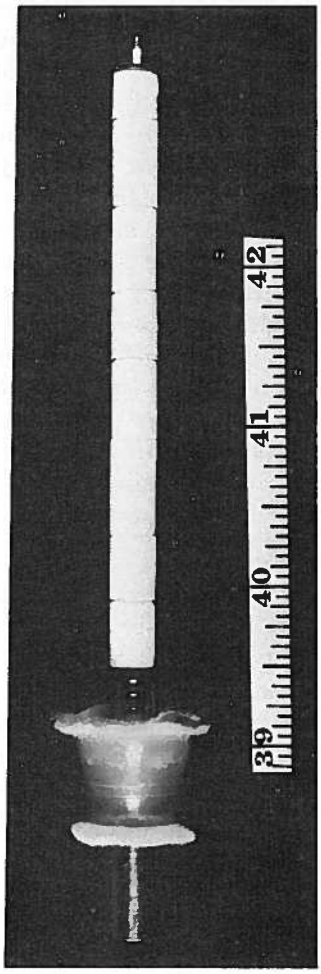

FIGURE 8.—Assembled composite bone implant unit.

device was modified to provide a fixture as shown in Figure 7. The top end was threaded to accept a round nut (top of photo) which applied pressure to the column of aluminum oxide pieces through the methyl methacrylate washer shown below the round nut. The slender center rod (beneath threaded end) was roughened to provide a mechanical "hold" for an adhesive to be applied during assembly of the total implant fixture. A circumferentially grooved section was provided at the base of the slender center rod to position the device in the end of the bone cavity. The base of this section had a diameter conforming to the inside diameter of the bone cavity. As shown in Figure 7, a polyethylene pedestal had been previously molded into the Vitallium rod to support the end of the bone.

In assembling the implant unit, the aluminum oxide pieces were slipped over the center rod which was coated with a thin layer of plastic adhesive (Surgical Simplex, North Hill Plastics, Ltd., London, England). The adhesive was prepared by combining polymeric powder and monomeric liquid in proportions to yield a syrupy liquid that would harden within a short time. After the aluminum oxide pieces had been bonded to the Vitallium center rod, the plastic washer and round nut were positioned. The assembly was then placed in a lathe and the column of aluminum oxide pieces machined to a diameter to fit that of the bone cavity. The finished implant is shown in Figure 8.

C. *Character of Aluminum Oxide Components*

The fired aluminum oxide was found to have a porous structure resulting from volatilization of the biphenyl, polyvinyl alcohol and Carbowax. As shown in Figures 9 and 10, the interconnected pores were of irregular size and shape. A high degree of permeability and pore interconnection was evidenced by very rapid absorption of water dripped onto the top surface of a cylindrical specimen about $^1/_2$-in. thick. Further, the water began to drip from the bottom surface within several minutes.

The average porosity of the aluminum oxide components was calculated to be approximately 66 percent. Bulk density, calculated from results of close measurements of specimens, was 1.53 gm/cc. Scanning electron microscope studies showed individual pores to range from about 70 microns to over 300 microns in size. There was little to distinguish between pores and interconnecting passages due to the overall irregularity of the structure. It was evident that a major percentage of the pores was in the size range of 200 to 300 microns.

An average load of slightly more than 3200 p.s.i. was required to crush test specimens. This value does not apply to compressive

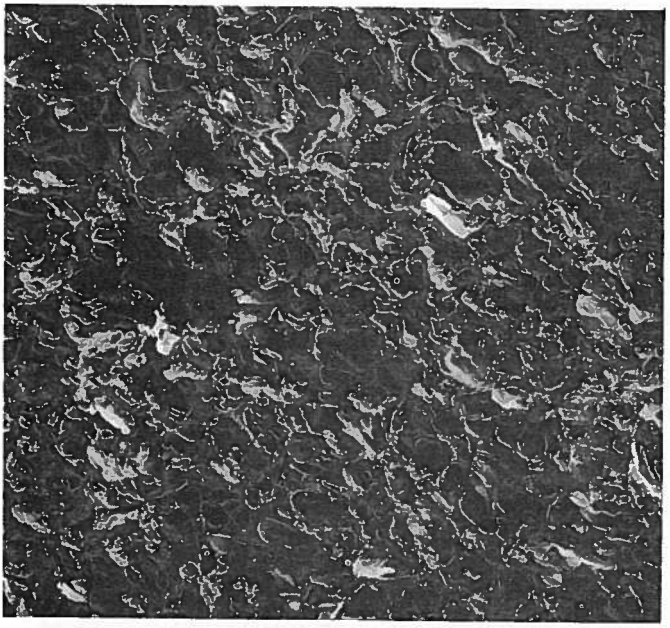

FIGURE 9.—Scanning electron microscope photomicrograph of structure of the porous aluminum oxide. Dark areas of the irregular, freshly fractured surface are voids. Magnification: 20X.

FIGURE 10.—Scanning electron microscope photomicrograph of structure of porous aluminum oxide. Darker holes are pores; granular textered areas are aluminum oxide. Magnification: 100X (1 inch =254 microns).

strength since the .5-in.-thick specimens showed only a crushed layer about 0.1-in. thick on the top side after testing. The portions of specimens below the crushed layers were sound and appeared not to have suffered significantly.

III. *Animal Implantation*

Only three implants in goats have been made to date. The first was accomplished using an old model Vitallium rod having a polypropylene-velour cone near the distal end. This was held in place using methyl methacrylate bone cement (Surgical Simplex-P, North Hill Plastics Ltd., London, England). For a period of two months this animal managed exceedingly well. A freak accident broke the Vitallium rod when the animal jumped a drainage ditch. He was, at the time, being pursued by the principal investigator who was attempting to rope the goat in order to inspect the leg. During this rodeo performance, the animal was leading the herd by several lengths, which proves the function of the artificial limb. Motion pictures had been previously made to document how well this animal managed with its artificial limb.

The second implant consisted of SwRI's first design model using porous ceramic as the bone interfacing material. No means to anchor the device was made other than making the tolerance between the internal diameter of the intramedullary canal and the outside diameter of the ceramic shaft as close as possible. A failure in anchoring of the second implant to the bone was due to the high shear forces placed at the interface when the external extension later was bolted in place. The skin seal was torn, and the animal ultimately developed osteomyelitis making euthanasia necessary.

The third and last implant was made using SwRI's second generation artificial limb. This differs from the first generation by having the polypropelene cone stair-stepped where it meets the bone. Matching the step with the distal end of the tibia creates a mortice which is less likely to be affected by torque applied to the shaft. It is too early to evaluate whether or not this has entirely solved the problem of rotation between the bone and the implant.

Both nylon and Dacron velour have been used on the skin interfacing material. Because of past observations that either of these will support soft tissue ingrowth for long periods of time, an evaluation as to which is the best would be premature.

A modification of the simple pylon currently used as the external extension is needed. Such modification must have as its goal a method of absorbing some of the shock which is currently transmitted up the shaft and into the intramedullary canal. These stresses could be capable of shearing the interfacial tissue ingrowth. Already

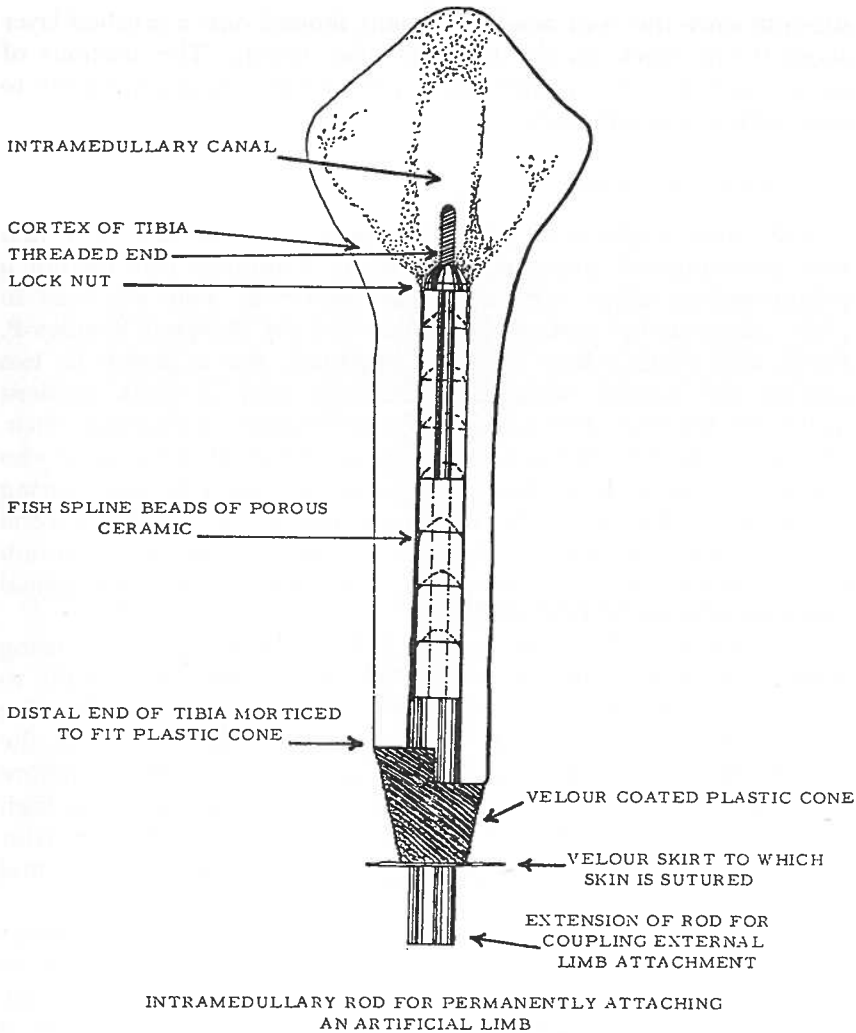

FIGURE 11.—Artist's drawing of component parts assembled and placed in the intramedullary canal. Note morticed cone and distal end of tibia to resist shaft torque. SwRI's second model.

we have witnessed the breaking of an implanted Vitallium rod. On the drawing board, but not yet reduced to a model, is a pylon using a bungee cord-type shock absorber. A more complex type using a hydraulic piston was considered but thought not to be justified for this type of program.

Permission to use Mr. Louis Feldman, a machinist from Baylor College of Medicine, was obtained from Dr. M. E. DeBakey. Mr.

Feldman's service to the program was to construct a mold to fabricate the stair-stepped polypropylene cone to the steel rod and cover the cone with velour. This entire operation can now be done simultaneously. Mr. Feldman understood the problem and was involved in constructing the original mold in 1967. Two devices were delivered on October 10, 1973. Ten more are forthcoming. All will be placed in animals during the next few weeks. Figure 11 shows a diagram of the completed second model.

Passenger Safety in Vehicles for the Handicapped
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Charles M. Scott

Mobility Engineering's primary interest is in development and fabrication of systems which enable the handicapped to achieve a greater degree of independence. Eight years of development has resulted in a series of control systems for automotive applications, principally van-type vehicles, which permit a quadriplegic to enter the vehicle, drive it to his destination, and leave the vehicle unaided.

The control systems are now in limited production with excellent results. However, two problem areas remain which require further attention.

The first is safety for the driver. The concept is that the driver is to remain in his wheelchair at all times. The problem is that the conventional powered wheelchair does not provide an adequately safe seating arrangement once it is in the driving position of a motor vehicle capable of high speeds. The structure of the chair was not designed to meet the structural requirements to which it can be subjected under emergency conditions. In addition, the patient's trunk is not stabilized and no head rest is provided.

The second problem is head room within the vehicle. While the van offers much more floor-to-ceiling heights than an automobile, wheelchair designs requiring thick cushions for patient welfare present overall heights which are unacceptable to a driver.

This organization is now addressing itself to these problems. It is now completing the design and will shortly begin fabrication of a motorized chair which will be adjustable in height and provide a seating arrangement which can be safely secured in the vehicle and provide comfortable and secure seating for the driver.

Spinal Cord Injury Studies: Paralysis, Spasticity, and Pain

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Three investigations are being carried out at the Spinal Cord Injury Service, Veterans Administration Hospital, Miami, Florida. The funds for these projects are mainly from the VA Prosthetic and Sensory Aids Service, Washington, D.C., and partly from the local station.

Evaluation of Transcutaneous Stimulation for the Treatment of Pain in Paraplegic Patients: Only 4 to 10 percent of patients experience chronic pain. This pain may be from the nerve roots or from the damaged spinal cord in the area of injury. In 20 patients that have been followed for up to 1 year using the transcutaneous stimulator who apply the pulses to the area of skin above the site of injury, there were seven patients who gained excellent to worthwhile relief of pain. The remaining majority of patients had a pain described as burning, which is one of the most resistive types of discomfort that can be encountered. It is being established that the transcutaneous stimulator is a worthwhile technique for the treatment of patients with thoracic and lumbar cord lesions, where sharp and aching pains respond to this therapy, but that it is less likely to help the burning dysesthesias. Modified inexpensive skin electrodes have also been developed for use with the transcutaneous stimulator. A description has been submitted to the Journal of Neurosurgery.

The Neurophysiological Basis of Spinal Cord Paralysis in Spasticity: Following the acute injury, spinal shock occurs; then weeks later reflex activity recovers below the level of injury. The bladder, through reflex activity, commences to fill and empty of urine, the bowels and blood pressure reflexes recover next. Other reflexes show activity by involuntary muscle spasms. If these reflexes become too sensitive, then spasms occur; interference with active daily living can occur. A neurophysiology laboratory has been established, and a team of neurophysiologist, biomedical engineers, and biologist has been assembled to study the synaptic reorganization that occurs with the appearance of exaggerated spasms. It is most important that this mechanism be understood so appropriate treatment can be applied for a better quality of life.

The Development of Implantable, Multi-Lead Stimulators for the Control of Reflex Muscle Functions: Twelve months ago a young paraplegic

had bilateral peroneal nerve stimulators implanted for the study of long-term effects on the calf muscles. The startling effect was the complete reduction of marked spasticity to an almost normal tone in both lower extremities. He found this of benefit when brace walking, as there were not the marked stiffness and spasms present prior to the implant and stimulation. The circumference of the calf muscle group increased month by month reaching a plateau at 6 to 8 months with a 30 percent increase. A similar increase was also noted, surprisingly, in the thigh muscles but in a lesser magnitude (18 percent). Studies are expanding and multi-nerve stimulators are being developed for implantation.