HIGHLIGHTS OF OTHER VA 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

Prosthetics, Orthotics, and Sensory Aids Research Services
Committee on Prosthetics Research and Development
Committee on Prosthetic-Orthotic Education
Division of Medical Sciences – Assembly of Life Sciences
National Research Council – National Academy of Sciences
2101 Constitution Avenue, N.W.
Washington, D.C. 20418
James Reswick, M.D.

During the January-June 1975 period, progress was made in the following activities by the Committee on Prosthetics Research and Development/Committee on Prosthetic-Orthotic Education:

Operation of Informal Clearinghouse for Information of Rehabilitation Engineering

During the past 6 months CPRD/CPOE staff has responded to approximately 550 requests for technical information and publications.

Review of Proposals for Research and Education

The Rehabilitation Engineering Review Panel met June 25-26, 1975, to review 19 proposals for the Veterans Administration. The Sensory Aids Review Panel met on June 26 to review seven proposals for the VA, and one for both the Social and Rehabilitation Service and the VA.

The reports of the review panels have been prepared by staff and approved by the chairmen of the panels, George T. Aitken, M.D., and Carl Sherrick, Ph. D., and transmitted to the Veterans Administration and Rehabilitation Services Administration. The next meeting of the Rehabilitation Engineering Review Panel is scheduled for October 1975.

Maintaining Liaison with Educational Programs

The purpose of this activity is to maintain a close working relationship with the university programs in prosthetics and orthotics in order to input recent research developments and to help resolve problems that may occur in the educational system. The late Hector W. Kay, Acting Executive Director, CPRD, was the Secretary of the University Council on Orthotics/Prosthetics Education (UCOPE). The last meeting of UCOPE was in October 1974. The next meeting will be in October 1975.

Participation in the American Society for Testing and Materials (ASTM) Committee F-19 on Orthotics and External Prosthetics

The Committee met in Philadelphia, Pennsylvania, April 1-2, 1975 to nominate members of working subcommittees. The next ASTM meeting is scheduled for the Fall of 1975. An executive committee meeting will be held sometime prior to the fall meeting. A working committee on Lower-Limb Orthotics is meeting in Chicago in August.

Workshop on Clinical Instruments for Gait Analysis

This workshop is being planned to bring together researchers in the gait analysis field to discuss instrumentation with the goal of standardizing data, defining important gait parameters, and making recommendations for future work and development of instruments suitable for use in a clinic setting. This project was approved for 1975, at the March 21st CPRD meeting. The workshop is planned for early 1976.

Revision of "Rehabilitation Engineering – A Plan for Continued Progress"

The purpose of this activity is to update the April 1971 publication, which is a state-of-the-art document that also provides recommendations for research and development. A coordinated effort between CPRD and the Committee on National Needs in Rehabilitation is currently being explored. A workshop is planned for early 1976.

Compilation of a Directory of Locomotion Laboratories

The purpose of this project is to encourage communication between researchers, prevent duplication of effort, and enable interested persons to be aware of the locations of laboratories with unique capabilities. The Directory is in draft form at present. When published, it will be sent to locomotion laboratories and funding agencies.

Operation of the Winnipeg Information Retrieval System

This project will make the existence of literature in the rehabilitation engineering field known and provide easy access to this literature through detailed references. A 560 item edition is now in the process of publication, through the National Academy of Sciences Printing and Publishing Office.

Newsletter . . . Amputee Clinics

This *Newsletter* disseminates information on prosthetics patient management, mainly concentrating on controversial areas and reporting on opinion surveys in these areas. The June 1975 issue has been distributed and the August issue is at the printer's.

Roster of Amputee Clinics

The Roster provides a directory of services to be used by physicians, surgeons, therapists, prothetists, and orthotists for purposes of patient referral. The 1975 Roster has been completed, sent to the printer, and will be distributed in August 1975.

Workshop on Functional Electrical Stimulation

This workshop will bring together researchers in the U.S. and abroad to address a number of important questions on the effectiveness, mechanisms, nerve and muscle responses, and applications of functional electrical stimulation. The workshop was approved at the March 21st CPRD meeting. The workshop plan has been developed in collaboration with the National Institutes of Health. Steering committee members have been selected and will meet in July 1975 to design the workshop and nominate participants. The Workshop is planned for the Fall of 1975.

Workshop on Lower-Limb Prosthetics

This is another in a series of workshops on this subject to define the state of the art and make recommendations for future work.

New components, such as transverse rotation units and modular systems, different alignment techniques, and vacuum forming have come into common use since the last workshop. Fifteen of the 22 recommendations made at the last workshop, in January 1973, have been acted upon, and it is hoped that a 1975 workshop will stimulate more work in this area. This workshop was approved at the March 21st CPRD meeting. A detailed proposal has been prepared, and steering committee members selected. The steering committee met at Rancho Los Amigos Hospital, July 18th, to design the workshop and nominate participants. The workshop is scheduled for October 1975.

Workshop on Environmental Controls for Quadriplegic Patients

A great variety of these devices have been developed in recent years. The purpose of the workshop will be to prepare a state-of-the art document on the subject, with recommendations for design criteria and for future work. The work shop was approved at the March 21st CPRD meeting and incorporated into the CPRD/CPOE Annual Program Plan. A detailed proposal will be developed and a steering committee selected. The workshop is planned for early in 1976.

Clinical Evaluation of the Ortho-Walk Pneumatic Lower-Limb Orthosis

The purpose of this project was to evaluate the fit, function, and practicality of the orthosis in four VA and three non-VA hospitals. The clinical trials have been completed. The final meeting was held March 17, 1975, in Denver, Colo. The report is in draft form, and will be reviewed by the participants and CPRD committee members.

Panel on Hearing-Aid Performance

This Panel evaluates hearing aids and recommends types to be purchased by the Veterans Administration. Two meetings are held each year. However, the Spring 1975 meeting was cancelled. It has been suggested that the Panel be expanded in both scope and membership to provide services to agencies other than the Veteran's Administration and to disseminate the Panel's information more widely.

Workshop on Low-Vision Mobility

The purpose of this Workshop is to collect and evaluate information on the use of distance vision in the partially sighted as it per-

tains to mobility performance, a presently neglected subject area. The workshop will produce a state-of-the-art summary for immediate clinical applications and develop an integrated plan of action for future research. A preliminary planning group was formed and met December 8-9, 1974, to detail subject areas for the proposed workshop. Tentative authors for five position papers were selected and a list of possible workshop participants was prepared. A detailed proposal, in the form of an agenda item, has been prepared. This proposal has been circulated to interested parties within the Assembly of Life Sciences and the National Research Council and within the sponsoring and collaborating agencies. The workshop will be scheduled for three days in November 1975.

Aids for The Deaf-Blind

This project assists in the development and deployment of aids for the deaf-blind; an area where devices are seriously needed, but the required numbers are very small. This work is being accomplished through coooperation with the National Center for Deaf-Blind Youths and Adults. A workshop held in November 1973 defined needs and obtained cooperation from industrial and other organizations. The report of this workshop includes a list of available aids for the deaf-blind and has been distributed to all participants, to those on CPRD's sensory aids mailing list, and to other interested personnel.

Low-Vision Aids

This project assists in the development and deployment of low-vision aids. A great variety of such devices are becoming available for the benefit of the large number of people with visual impairments. The American Foundation for the Blind has agreed to assume responsibility for this activity as soon as it can make necessary reorganizations and hire appropriate staff. CPRD will continue to cooperate with the American Foundation for the Blind.

Task Force on Rehabilitation Engineering for the Hearing Handicapped (TFHH)

The purpose of the Task Force is to formulate a set of recommendations on future research and research utilization to be included in the revision of "Rehabilitation Engineering – A Plan for Continued Progress." A meeting was held early in 1974, the results of which have yet to be reported. Development of an independent report (involving considerable additional work on the part of the TFHH chairman and CPRD staff) is now planned. Part or all of this

report will probably be incorporated at a later date into the report "Rehabilitation Engineering – A Plan for Continued Progress."

Panel on Evaluation of Inkprint Readers

The Panel's purpose is to formulate plans for the evaluation of the Optacon and the Stereotoner, particularly as aids to adventitiously blinded veterans. The first meeting of this Panel was held in December 1972, at which time a report was prepared advising the Veterans Administration of detailed services to request in future evaluation contracts with the American Institute for Research (AIR). This evaluation work is still being carried on by AIR.

Reports in Progress

Report of the Workshop on Control of Operating Room Airborne Bacteria

This workshop was cosponsored by the American Academy of Orthopaedic Surgeons (AAOS) and CPRD, and was held November 1974. The report will list the conclusions and recommendations of the workshop panels. A number of state-of-the-art papers will also be published in the report.

Clinical Evaluation of the Rancho Los Amigos Hospital/Medtronic, Inc., Implanted Neuromuscular Assist Device

The final meeting of the participants of the evaluation was held in 1974. The reports details the organization and the results of the clinical evaluation, with recommendations for future work in this area.

Workshop on Total Knee Arthoplasty

This workshop was cosponsored by AAOS and CPRD, and was held September 1974. The report will list the conclusions and recommendations of the workshop panels. A number of state-of-the-art papers by researchers and clinicians will also be included in the report.

Research and Development in the Field of Artificial Limbs

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

Only minor improvements of the Swing and Stance Control System were found to be necessary during the reporting period,

indicating that this project has reached the point where the research and development effort has come to an end. The only thing left to do is the completion of the so-called "bible" describing the design and manufacturing of the S-N-S system. About 30 percent of this work was postponed with VA approval in order to free personnel for another higher priority project. Except for that, reporting on this item will now be discontinued.

Work on the Hydraulic Ankle Control System which has been going on with the highest priority throughout the contract year has resulted in a great number of test findings and subsequent design improvements. It has culminated at the end of the reporting period in the construction of the first production prototype ankle system (Fig. 1).

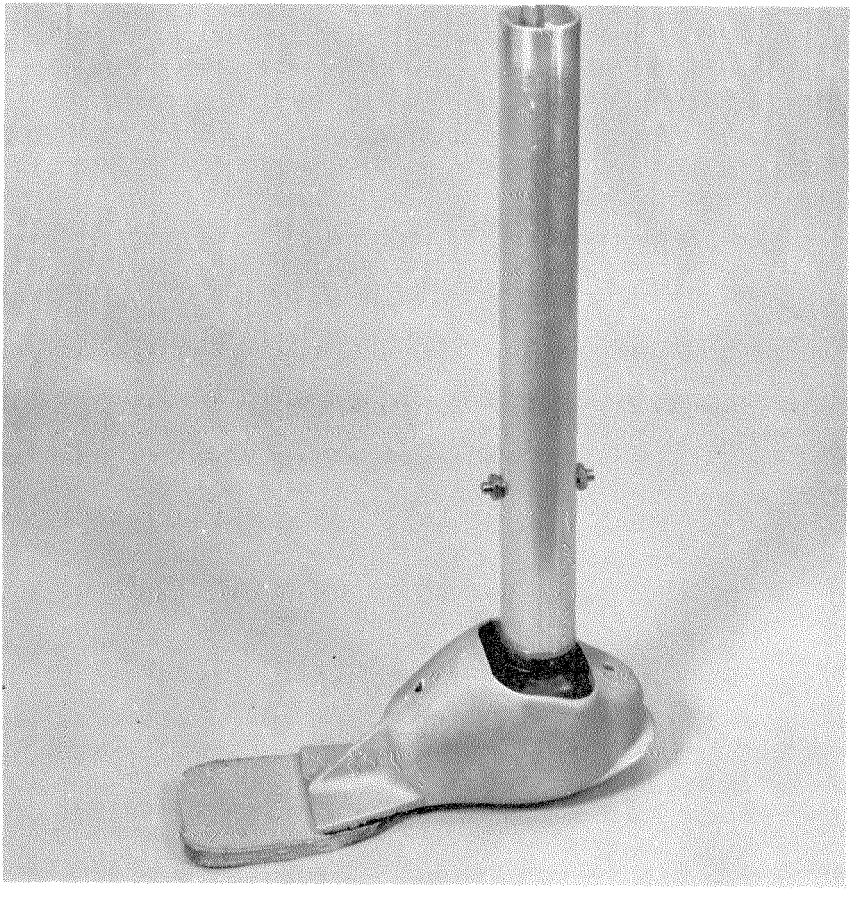

FIGURE 1. – Hydraulic Ankle Control System.

Through an intensive test program involving two highly qualified and very active amputees and simultaneous theoretical and experimental design studies, further improvements in several portions were achieved. They include the following:

1. Hydraulic Unit

New castings for the housing and vane piston, each formerly composed of several assembled parts, are now only one part each.

Stress relief was provided for the rubber boot where the bypass valve control motion is transmitted from the outside to the inside of the hydraulic unit through the boot wall, by giving all contacting parts smooth rounded contours and by limiting the down stroke during weight application.

The spherical bearing around the piston rod is now shaped so that its mounting is only possible in the correct orientation. It was also given increased stiffness against radial compression to avoid its closing in on the piston rod (causing friction noise) until the end of the down stroke, where zero play is essential to avoid a clicking noise when walking over the ball of the foot.

The overpressure, relief valve seat was pre-compressed to form a tight seal.

The periphery of the toe-slap damping orifice was chrome-plated for low wear. The plantar flexion spring assembly was reinforced.

2. Shank Attachment

The attachment tubing, formerly assembled of several parts, is now a single extruded aluminum tubing including keys inside to keep the top rubber bumpers from rotating. Reinforced front and back walls support threaded inserts to hold set screws and locknuts securely. This tubing serves as a pylon in modular prostheses. In wooden or plastic shanks a shorter length of it is mounted inside the shank.

The top bumpers are now produced by slicing them from a long molded strip. They fit snugly inside the extruded shank tube. The prosthetist can cut relief slits in suitable locations to produce any of various resistance patterns for transverse rotation.

The paddle-shaped tip of the piston rod, which fits between the top bumpers allowing forward-backward adjustment by means of the set screws, is now covered with Teflon film for low friction and made thinner and longer to reduce the maximum possible pressure on the rubber bumpers.

A lid was placed into the shank tubing on the top of the piston rod to keep dirt out and noises in.

3. Foot Attachment

A new concept was introduced consisting of a hollow SACH footlike aluminum keel, with enough space inside to accommodate the hydraulic unit, provide support for it, and permit elastic resistance to inversion and (if desired) to eversion by means of shaped rubber pads. This keel and a belt-like fore-foot extension will be imbedded in polyurethane foam in a mold. Sizes from 5½ on up can be provided.

4. Cosmetic Foot-Shank Transition

It is intended to mold onto the top of the foot a tubular, flexible, 5-in. high, foam rubber extension, shaped on its outside like a SACH foot-shank section of the appropriate size. The hollow inside of this extension will receive the lower tapered end of the shank which can rotate within it. The tubular flexible extension, tightly fitting against the tapered shank, will follow the shank during eversion/inversion and plantar flexion/dorsiflexion motions.

Eleven additional production prototype systems to be used in an expanded shakedown test are under construction while the test wearing of the experimental prototypes by the two amputees continues.

The development of a Voluntarily Actuated Swing and Stance Control System proceeded with lower priority due to the work concentration on the ankle project. Nevertheless, significant progress has been made regarding the problem of "fail safe" reactions of the system in the case of malfunctions such as battery failure, loose contacts, etc.

Other developments included the completion of the design phase and initiation of a limited field test (24 legs) of a simplified new bolt for above-knee legs, which permits better control of the knee block side play, simplifies installation and disassembly, and costs less than the present standard bolt.

Future plans are outlined at the end of the Mauch Laboratory Annual Report, which will be available for limited distribution from the Research Center for Prosthetics.

Stump Stress Analysis

New York University, Division of Applied Science
26-36 Stuyvesant Street
New York, New York 10003
Leon Bennett

Previous work dealing with the stresses on flesh leading to stasis has been conducted under static loading conditions, simulating the

sitting condition. In this report period, oscillating stresses were introduced to determine stasis sensitivity to alternating stress.

A loading cyclic rate of 30 cycles per minute, representing slow walking, was established with about 54 percent of each period devoted to stress and the remainder unloaded. The flesh model flow vessel was equipped with a relief valve, simulating a vein valve.

It was learned that the oscillating stress impeded flow to a smaller extent than did the steady stress. If in the unloaded state, flow is taken as 100 percent, a typical value of flow under medium static stress is 60 percent while the corresponding dynamic stress flow is 85 percent. Thus, it would appear correct that gait will improve circulation in the stump as compared to sitting. However, no flow augmentation of any kind was noted under dynamic stress as compared to the totally unloaded state.

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

Hook/hand interchangeability has been considered a desirable feature of powered prostheses for some years. Nevertheless, the attainment of this goal has been elusive, partly because an electric hook was not available. This project has developed an electric hook which has been tested on amputees for a period of over 2 years. The powered hook is now being adapted so that it will be interchangeable with the VA/NU electric hand by simply unscrewing one and attaching the other.

Adaptation of the electric hook to make it compatible with the electric hand is part of a larger project to develop a myoelectrically controlled, electrically powered system which is more streamlined that the present one and which is completely modular.

The Veterans Administration is planning to purchase a limited number of the electric hooks (synergetic electric hooks) developed in this laboratory for evaluation in their clinical evaluation program. This is a typical "second phase" in the evaluation cycle of a new device.

Work is continuing on evaluation and improvement of the following items: thoracic-suspension harness for above-elbow amputees, lift-lock mechanism for above-below amputees, and atmospheric suspension of sockets for above-elbow and below-elbow amputees.

Sensory feedback by cutaneous electrical stimulation continues to be investigated. The main problem is to decouple the stimulus

from the myoelectric amplifier when it is applied by myoelectrically controled prostheses.

A new project has been initiated to develop a powered locking/unlocking unit for the conventional body-powered elbow.

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

University of California, Los Angeles
School of Engineering and Applied Science
405 Hilgard Avenue
Los Angeles, California 90024
John H. Lyman, Ph. D., Amos Freedy, Ph. D., and Ronald Prior, Ph. D.

Design and development of a three degree of freedom myoelectrically controlled upper-limb prosthesis, and system integration of a pattern recognition adaptive aided prosthesis utilizing microprocessor technology, have been the main goals of the Biotechnology Laboratory activity (Fig. 2). The design of the myoelectrically controlled prosthesis is aimed toward immediate application of available technology to a three degree of freedom arm, self-contained, and clinically oriented. The three degrees of freedom include hand opening and closing, wrist pronation-supination, and elbow flexion-extension.

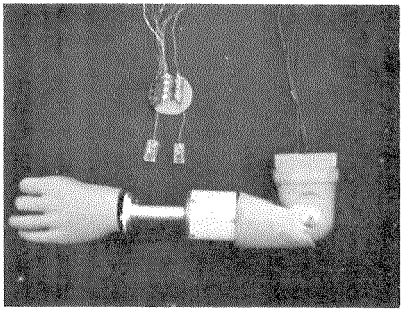

FIGURE 2.—UCLA Arm with Control Electronics and EMG Amplifiers.

The actuators used for the arm are the VAPC elbow unit and its modified version, which was developed at our laboratory as a wrist rotator. The hand is the VA/NU hand. Control is derived from myoelectric signals of residual stump muscles, as well as muscles of the shoulder girdle, to yield proportional control of the actuator.

Several control system alternatives for the arm are presently under design evaluation with respect to ease and reliability of con-

trol, power consumption, size, and weight. The following control schemes have been found to be potentially promising:

1. Push-pull control derived from two separate muscles; for example, the myoelectric signal from the biceps and triceps residuals can control elbow flexion and extension, respectively.

2. Electronic simulation of a cable action derived from a single muscle site. Strong contraction will result in full flexion of the elbow, while a mild contraction will produce fractional flexion. The control system includes an electronic lock mechanism, analogous to mechanisms in a cable-operated prosthesis.

Combinations of the two control methods are also under test as part of our effort to optimize the patient's voluntary control.

Two dimensional sensory feedback is to be incorporated in the prosthesis. The parameters to be fed to the operator are fingertip pressure and elbow position. The system will utilize cutaneous stimulation by electricity in conjunction with two point discrimination in such a way that the stimulation frequency will indicate proportionally the fingertip pressure, while the location of the stimulus indicates the elbow angle.

System integration of a pattern recognition adaptive aided prosthesis is underway. Recent experiments with realized software indicated a good potential for controlling three degrees of freedom, i.e., humeral rotation, elbow flexion-extension, and wrist rotation. The problem of terminal device prehension has not yet been addressed. Present work includes increasing the decision reliability of the software with respect to EMG patterns by optimizing EMG pattern differences and by more sophisticated filtering techniques in the software. An important stage in the integration process is the implementation of a microprocessor. A Teledyne TDY-52B microcomputer has been selected, and current work includes redesign of the system for such a version. Additional work is directed toward packaging techniques to include the microprocessor in the prosthesis to yield a self-contained artificial arm.

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, and James M. Morris, M.D.

Design of Lower-Limb Prosthetic and Orthotic Devices

Clinical trials of the Four-Bar-Linkage Polycentric Pneumatic Knee are underway at VAPC, with additional units being tested at the Biomechanical Research and Development Unit (BRADU), Queen Mary's Hospital, Roehampton, England, and Uppsala, Sweden.

Early clinical trials of the UC-BL Shank Axial-rotation unit at VAPC revealed that pylon tubes were coming loose from the rotation units being used. The tubes had been clamped in place by means of an expanding rubber plug, creep in the rubber was allowing the couplings to loosen. A new all-metal plug was designed, and 10 units were forwarded to VAPC for continued testing.

No problems have been reported with the internal-expanding foot-to-pylon coupling for use with 35 mm pylon tubing. Test units of this coupling are undergoing evaluation along with the Axial Rotation Unit. Prototypes of a refined design have been produced which utilize the same two-level internal-expanding fixation principle, but are simpler to make.

Two prototype six-bar-linkage knee units for knee disarticulation amputees have undergone limited clinical testing on an above-knee amputee. One of the units utilizes pneumatic swing-phase control, and the other utilizes dry friction, as reported previously. Initial reaction to both polycentric action and swing control has been favorable. Cosmetic covers and a suitably compact angular alignment coupling are currently under development.

Biomechanical Studies of Human Locomotion

An instrumentation system for measurement of three-dimensional angular motions in the foot/ankle complex has been completed, and selection of suitable research subjects for an examination of structure and function within the ankle is underway. This system consists of the three-dimensional Self-Aligning Electrogoniometer reported previously, as well as treadmill instruments for measuring toe-out, goniometers for locating anatomic joint axes in relation to an external reference coordinate system, and a computer program to transform measurements about reference axes into motions about anatomic joints. Application of this equipment to both normal and pathological ankles is expected to provide new insight into foot and ankle function, in terms of the influence of joint placement and anatomic structure.

Instrumentation for clinical measurement of average velocity, step length, and step frequency of completely unencumbered patients is nearing completion. This equipment will provide a practical

basis for telling the difference between changes in gait which are caused by changes in speed and changes in gait which are the result of therapeutic procedures. Initial application of this device will be conducted in cooperation with clinical facilities in the San Francisco Bay Area.

The previously reported one-dimensional Self-Aligning-Goniometer linkages for measurement of flexion-extension angles have been documented, and drawings are available. The structures for attachment of these linkages to torso, thighs, and shanks are being modified, primarily to insure retention of zero reference angles during adjustment, but also to provide more secure attachment to body members, and to allow easier adjustment to different-sized subjects. Completion of detail drawings of the attachment structures is expected during fall 1975.

Evaluation and Further Development of New Design for Back Braces

Permission has finally been received for research studies with a needle pressure transducer which permits measurement of intradiscal pressures. Two studies which have been planned for some time may now proceed: the first is an examination of the effect of Chymopapain injections on intradiscal pressures and the second, measurement of changes in intradiscal pressures which result from the use of body-jacket-type spinal supports.

Mobility Aids for the Physically Disabled

Seven prototypes of the PRAHN (powered, reclining, adjustable-height, and narrowing) wheelchair are being built under VA contract, to be used in clinical testing. New features in these chairs include a quiet, compact, and fully enclosed worm-gear drive with the wheels mounted directly on the worm-gear shafts, as well as a four-bar-linkage which provides a smooth transition in backrest motion during reclining and eliminates an unwanted degree of freedom in the seat-to-backrest pivot. The worm-gear drives are of low enough ratio that they are not self-locking, and the unpowered chair is readily pushed.

Immediate Postoperative Prosthesis 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 continuing clinical research programs in the following areas: 1. engineering, 2. prosthetics,

3. amputation surgery and wound healing, and 4. miscellaneous support projects.

1. Engineering

Neuromuscular assist implants (Medtronic Inc.) continue to be used for assistive rehabilitation. Implants have been confined to the peroneal nerve in brain-damaged patients whose motor control review indicates them to be acceptable candidates. The engineering staff is cooperating with other investigators and manufacturers in improving and miniaturizing the units.

Pain abatement data with emphasis on external electrical stimulation is now well underway and includes approximately 20 patients to date. Data accumulation now covers a long enough period of time to justify meaningful evaluation and publication. The magnetic property permits simple temporary coupling of the electrical lead even without direct visual control, e.g., on the patients back. The present skin bridge system using vitrous-carbon buttons was developed at Rancho Los Amigos Hospital. The PRS protocol parallels their work. PRS now has available titanium intradermal magnetic electrodes for surgical implanting. The patient population is restricted to amputees with severe chronic pain who have been screened through a pain evaluation technique.

Electrical stimulation through surface electrodes is also being used in selected cases of cerebral palsy, surgical muscle transplantation, and cycled rehabilitation of muscles and other limb soft tissues following trauma or disease such as rheumatoid arthritis.

Further clinical investigation into electrically induced osteogenesis has been discontinued pending reports of additional animal studies. Models for clinical application in humans have not been sufficiently defined. Resumption of investigation is anticipated in the near future.

The Prosthetic Research Study has some peripheral involvement in the uses of electrical energy for the treatment of acute muscular ligamentous and articular athletic injuries.

Communication between certain PRS personnel and Dr. W. Bobechko at the University of Toronto propose PRS involvement in electrical energy application for the treatment of spinal deformities in humans, particularly scoliosis.

2. Prosthetics Research

Suspension capabilities by muscle activity in the below-knee stump continue to be observed. Selected subjects are being monitored for electrically recorded muscle activity, space displacement characteristics, and socket grasping. Suspension systems and socket

design are being modified based on accumulated information. The usefulness of photogrammetry for stump mapping is also being studied. Selected non-conventional limbs are fabricated in PRS facilities for certain patients whose clinical course can yield research data. In particular, this refers to badly scarred stumps, multiple limb loss, and adjacent joint disabilities all seen not infrequently in Vietnam casualties.

3. Amputation Surgery and Wound Healing

The Controlled Environment Chamber Program (CET) has been extended in its use to VAH, San Francisco; Rancho Los Amigos Hospital, Downey; Duke University School of Medicine, Durham; and VAH, Castle Point, New York. One unit is also assigned to the Department of Orthopedic Research, University of Washington School of Medicine, Seattle, where Dr. Frederick Matsen is conducting animal experiments in the CET chamber. The Prosthetics Research Study is the central facility for coordinating all CET data in this country. Below-knee amputees continue to be treated in the chamber at VAH, Seattle. In addition, a 5-mm strain gage with eye attachments is sewn near the closure of the wound to record changes in tissue tension during healing.

Modifications in knee-disarticulation techniques developed at PRS have proven to be advantageous. The technique can now be recommended.

Since low levels of amputation relate directly to amputee function, especially in the geriatric amputee, an active program of laboratory assay of dynamic skin circulation continues. Radioactive Xenon 133 has been demonstrated by Dr. W. Moore to give hitherto unavailable information regarding skin blood flow. These studies are being extended by PRS in conjunction with the Department of Bioengineering, University of Washington, using epicutaneous and transcutaneous techniques. Preoperative and postoperative emanation readout is measured and compared against clinical wound healing. Seven patients with severely ischemic limbs have been studied. Two or more patients each month are being included in this study.

The response of limb tissues to pressure is being further investigated using a mechanical device to provide alternating leg pressure (ALP 501). Laboratory data include preoperative and postoperative Doppler blood flow readings of the limbs supported by Technetium scan if Doppler data indicates abnormal postoperative changes. The study includes 100 consecutive randomized patients. Approximately one-quarter of the case load has been completed.

Finally, the PRS staff continues to perform a substantial number of amputations each month with immediate postoperative prosthetic

fitting. An active educational program in the area of clinical amputation surgery and amputee rehabilitation is an ongoing and significant part of PRS activity.

4. Miscellaneous Support Projects

Miscellaneous related activities include the continued medical direction of the amputee service and the Prosthetic Treatment Center at VAH, Seattle. The staff was host to the annual meetings of the Child Amputee Clinic Chief's meeting of CPRD held here in May. The staff is also sponsoring a course entitled "New Orthotics for Child and Adult Disabilities" on November 14-15, 1975, as part of the ongoing postgraduate education, American Academy of Orthopaedic Surgeons.

Below-Knee Amputation with Immediate Postoperative Fitting of Prosthesis

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

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

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 1975, research at Johns Hopkins was primarily focused on completing the initial experimental model of the powered medical manipulator and conducting initial clinical testing of this device. Followup on clinical testing of previously fitted powered upper-limb prostheses was also continued. An advanced engineering prototype model of a powered elbow/hook prosthesis was completed for studies related to product improvement for a possible clinical model.

Powered Medical Manipulator

The objective of the powered medical manipulator development is to study the practicality of a worktable-mounted manipulator

to meet some of the needs of the quadriplegic or severely disabled person.

The original worktable-manipulator arrangement is shown in Figure 3. This arrangement fixed the location of the manipulator at one corner of the table and allowed some capability for reading magazines, operating electrical switches or a touch-tone telephone, and limited self-feeding. The details of this design and the patient control interfaces are described in BPR 10-23 Spring 1975 issue. The unit provides the following motions:

1. shoulder flexion-extension
2. shoulder turntable
3. elbow flexion-extension
4. wrist pronation-supination
5. hook opening (can be locked in any open position)

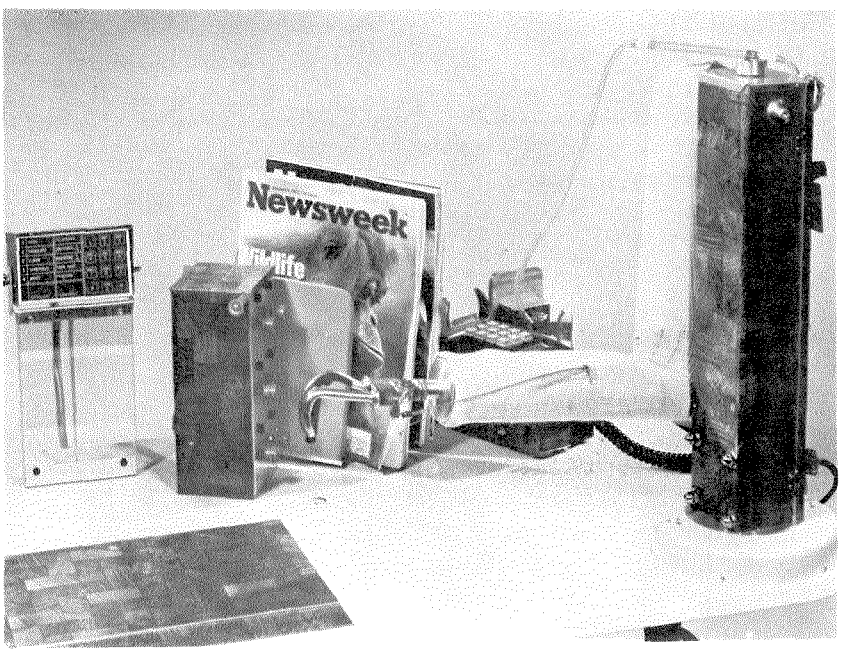

FIGURE 3. – Worktable-manipulator arrangement.

Any of the above motions may be controlled in a sequential manner by eyeglass control, thumb-wheel control, or by depressing a control paddle with a mouth stick or head stick.

A. Clinical Testing

The original remote powered manipulator, as developed during

the latter half of 1974, was subjected to clinical evaluation during the first half of 1975. Three severely disabled persons were selected to use the device. All three were functionally quadriplegics; however, each individual differed substantially from the other two both in the etiology of the condition and in the nature and magnitude of functional capability.

The first of these individuals is a 30-year-old electrical engineer employed full-time at the Johns Hopkins Applied Physics Laboratory. His facial muscle excursion and cervical spine control are normal, but as a consequence of poliomyelitis at 8 years of age, neuromuscular function below the cervical spine is limited entirely to weak scapulo-thoracic motion and certain weak finger and wrist motions. Active scapulo-humeral, elbow, and lower-limb motion are entirely absent. Trunk control is also absent. This individual is fully mobile in a powered wheelchair controlled with a joystick manipulated by small movements of his left hand. He is able to write and to operate keyboards with his fingers. With a swivel-mounted balanced forearm support he is able to reach above the the level of his lap and feed himself. With a small assortment of simple but highly reliable tools he is able to perform his work tasks as controls engineer and analyst in computer operations. These tools include a hook tied to his wheelchair which enables him to pull open doors and various sticks which enable him to push buttons, or manipulate light objects at some distance from his hands.

As the first clinical evaluator, this individual used the device for about 6 hours. This time was spent in development, analysis, and filming of operating skill. He was almost immediately able to master operation of the device to the extent of its design capabilities using any available combination of control signal inputs. He was also able to master operation of various secondary tools designed especially for use with the manipulator such as a magazine rack, a collapsible bookstand, a pageturner, and modified eating utensils as well as a common switchbox for household appliances, a typewriter, and an electronic keyboard equipment including calculator and touch-tone telephone.

This evaluator concluded that the manipulator was not useful to him because his remaining physical abilities enhanced by the tools to which he was already accustomed enabled him to perform these and other tasks without restriction to the vicinity of the manipulator and with equivalent or superior speed and dexterity.

Experience with this individual emphasized the significance of alignment of secondary tools for use with the manipulator as well as improvement of these tools and also suggested the need for additional freedoms of motion.

The second clinical evaluator used the device for about 8 hours at the Maryland Rehabilitation Center. He used the device intermittently with the third clinical evaluator. He was a 19-year-old male afflicted with rheumatoid arthritis to an extent which limited his musculoskeletal function to a few degrees of flexion/extension in his elbows and fingers. He operates an electrical wheelchair with manual joystick control. This individual is studying to be an accountant. He is able to write and to operate a calculator with his fingers and to push buttons and move light objects at a distance with a stick, but is unable to reach for ledgers or other bulky objects in order to bring them within his useful work space.

Using a manual control, he was quickly able to master operation of the manipulator and its secondary tools to the limit of the then existing design capability. However, the system did not permit him to fulfill his need to procure and move ledgers. His eyebrow motion was inadequate for control input. Although he was able to use the eyeglass-mounted vibration transducer satisfactorily for mode selection by clicking his teeth, it offered him no advantage over mode selection by fingertip pressure. Experience with this individual also showed a need for improved methods of storing, procuring, and handling bulky reference materials.

The third clinical evaluator is a middle aged male who has used the manipulator for about 60 hours at the Maryland Rehabilitation Center. As a consequence of spinal cord injury about 8 years ago he has a total neurological deficit below C-4 with absolutely no residual hand, wrist, elbow, or scapulo-humeral motion. He retains only about 50 percent of normal cervical spine range of motion and some weak scapulo-thoracic elevation/depression. His scapulo-thoracic motion is complicated by intermittent muscle spasms. He operates an electrical wheelchair with a joystick control which he grasps with his teeth and operates by moving his head. He can turn pages, move small lightweight objects, and operate electronic keyboard equipment within a small work area with a head stick. He is striving to achieve the ability to process bills and accounts for a small family-operated business.

This individual was able to operate the manipulator and associated tools using eyebrow motion for proportional control and teeth clicks for mode selection. However, placement of the eyebrow button conflicted with the brow band of the head stick. In order to circumvent this problem a pedal-type proportional position command transducer was devised to govern manipulator movements by pressing on the pedals with his head stick. For mode selection a microswitch was mounted near the elbow and tripped by scapulo-thoracic elevation/depression.

Control was improved, but further use emphasized the individual's need to move a substantial number of work objects of assorted weights, shapes, and sizes into and out of his small workspace and to move other objects into accurate alignment with the first set, in order to carry out precise activities. One such activity was placing paper in a typewriter so he could use his head stick to type.

An alternate to the original worktable arrangement was to detach the manipulator from its fixed position on the worktable, mount it on a mobile stand, and evaluate its usefulness. From this study, which included varying the alignment of the operator, the manipulator, and a variety of work objects, it becomes apparent that a wide assortment of accurate alignments are required to permit a quadriplegic with this magnitude of disability to derive useful function from the system.

B. The Modified Powered Medical Manipulator

As a result of these initial clinical tests, the following modifications of the worktable arrangement were made in order to increase its work-function capabilities:

1. Increase the basic work table area to 34 in. × 60 in.
2. Provide a linear motion of the manipulator base along one dimension of the worktable.
3. Provide a movable tray for holding an electric typewriter, electronic calculator, and telephone touch-tone key pad.
4. Addition of fixed vacuum fingers to the hook to allow single sheets of paper to be picked up, transported, and then released.
5. Provide a simple means for loading paper into the typewriter and for removal of finished copies.
6. Provide versatile handling capability for packets of working papers as well as individual sheets.

The modified manipulator-worktable arrangement incorporating the above features is shown in Figures 4 through 9. Figure 4 shows the manipulator and peripheral equipment mounted on a 34 in. × 60 in. worktable. This arrangement has one additional degree of motion for the manipulator, translation across the table, which allows a significant increase in movement capabilities. The typewriter-calculator-telephone touch-tone pad are mounted in a thin flat cart in order to allow the manipulator to move these objects in or out of the range of the head or mouth stick. Figure 5 shows the typewriter in position for mouth stick operation. In this position the typewriter may be loaded by use of the special vacuum fingers permanently attached to the terminal device. For patients with good head-stick or mouth-stick control, a mechanical paddle con-

trol input may be preferable to other facial control techniques. Moving the typewriter tray a small distance rearward with the manipulator allows the mouth stick to reach the touch-tone phone keys. In this instance, the manipulator would be utilized to pick up the telephone handset and hold it near the patient's head for normal phone conversation.

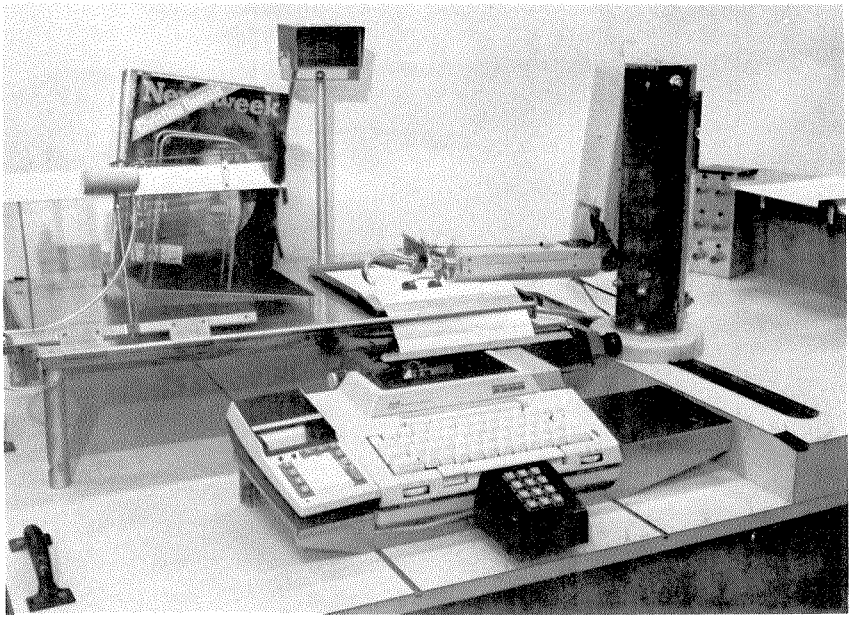

FIGURE 4. – Modified worktable-manipulator arrangement.

In an office environment, it is important to be able to manipulate paperwork. The modified system provides significant capability for such tasks. Figure 6 shows the vacuum fingers carrying a single sheet of paper from one location to another to bring the appropriate information sheet to the top of the paper stack. Opening the hook slightly will allow the vacuum fingers to release the paper, since the open end of the vacuum hose is normally clamped shut by the hook in its closed position. Since such a work environment may also require access to different kinds of data or information sheets, three movable trays for multiple sheets of paper are provided. The trays may be moved from their storage area to an appropriate location for use as shown in Figure 7.

The magazine holding rack and reading table have been redesigned from the original model to simplify handling and improve its capability in carrying out this task. Figure 8 shows the magazine in

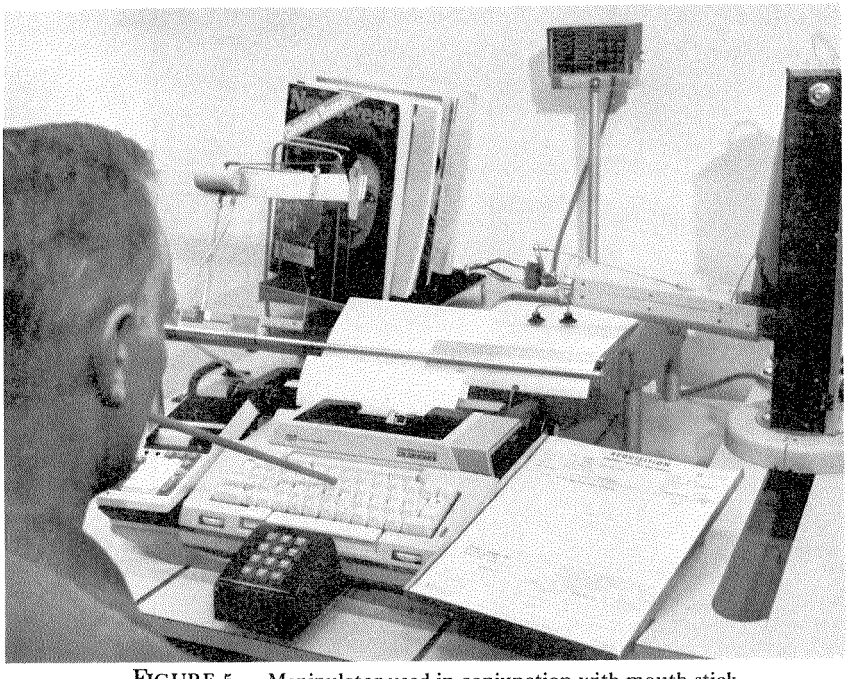

FIGURE 5. – Manipulator used in conjunction with mouth stick.

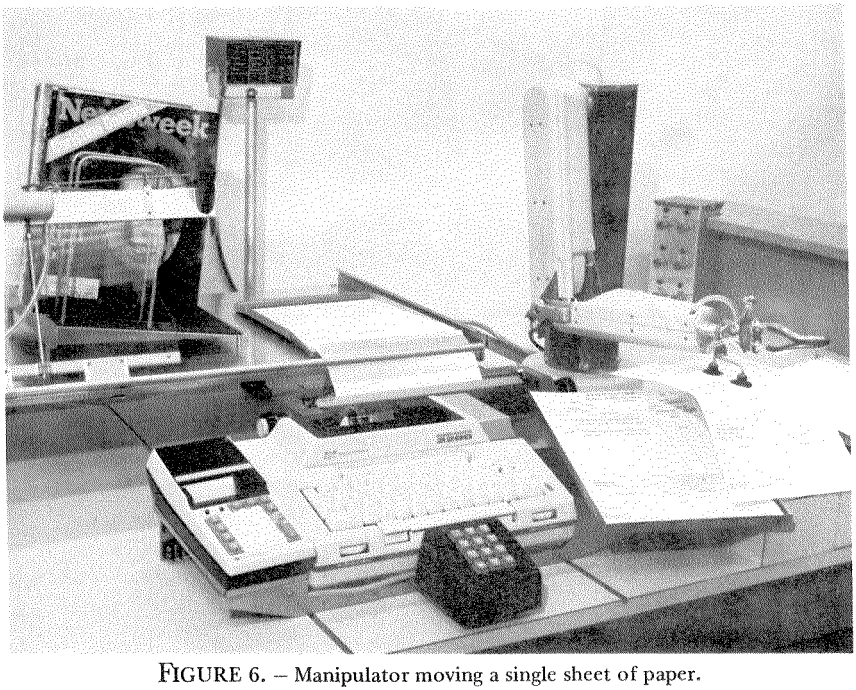

FIGURE 6. – Manipulator moving a single sheet of paper.

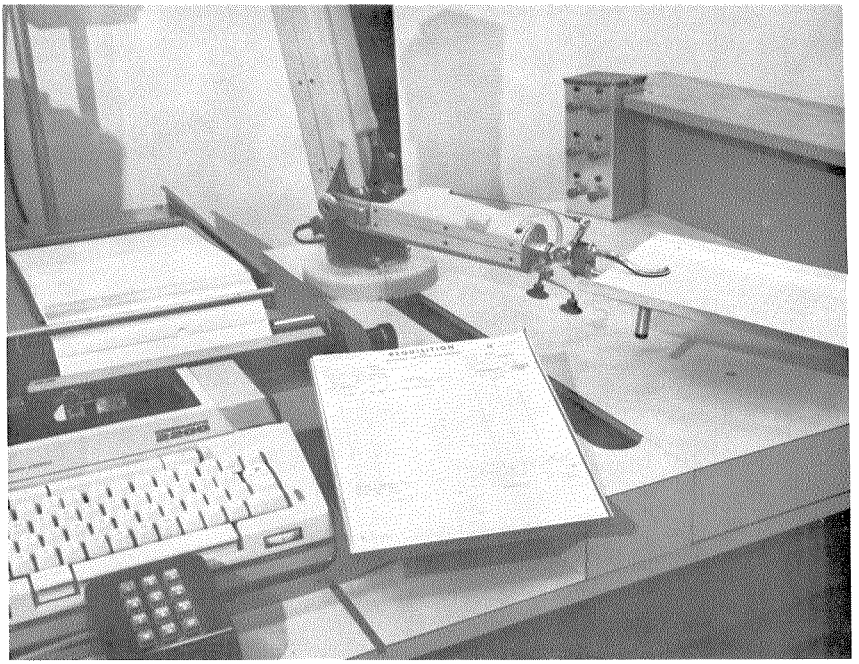

FIGURE 7. – Manipulator moving paper handling trays.

FIGURE 8. – Magazine in position for reading.

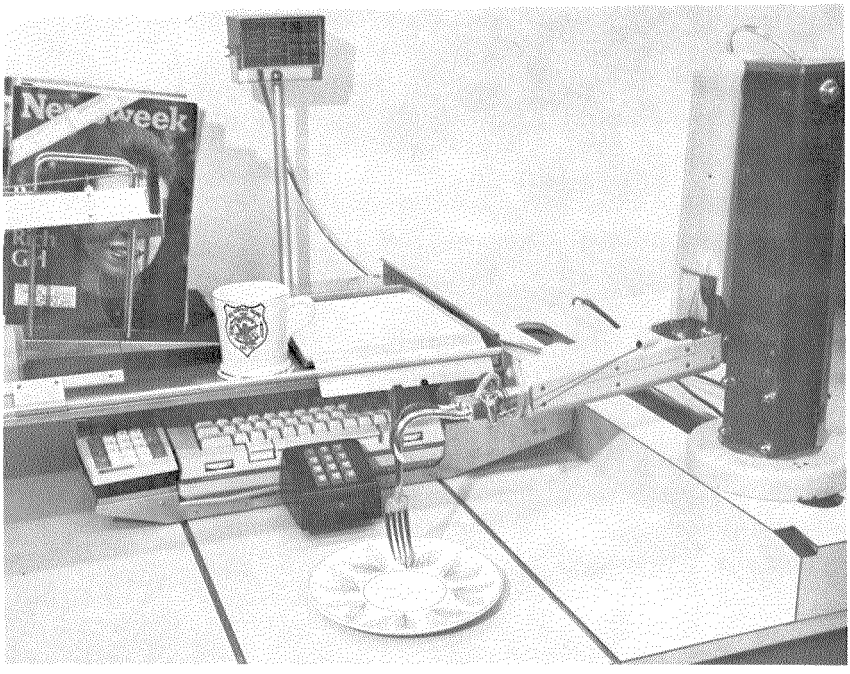

FIGURE 9. – Manipulator in position for self-feeding.

reading position after it has been moved by the manipulator from its storage rack at the rear of the work table. As in the previous design, the magazine vacuum finger lifts the page followed by shoulder extension motion to turn the page. This provides smooth turning of the pages with minimal input motions.

In addition to the work environment capabilities described above, this system can provide some self-feeding capability to the highly disabled patient. The typewriter is moved back to its storage position by the manipulator to clear the area directly in front of the patient for the feeding task. Figure 9 shows the worktable setup for self-feeding of the patient for certain bite-size food. It is assumed an attendant would bring the food and attach the pivoting fork to the hook. This eating mode has been tested in the laboratory with some success, but has not been evaluated on a patient.

Future Plans

Additional clinical testing is planned for the modified powered medical manipulator on selected patients at the Maryland Rehabilitation Center in Baltimore, Maryland. These tests should help sort out the adequacy of various patient-machine interfaces and input

controls, and should determine the practicality of this device to accomplish work functions or communication tasks. After sufficient clinical data is gained from these trials, a second manipulator model (with appropriate changes) will be fabricated for additional clinical evaluation. This evaluation will be documented in subsequent Bulletins of Prosthetics Research.

Development of Refined Fitting Procedures for Lower-Limb Prosthesis/Case Studies of Applied Research in Orthotics and Prosthetics

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

This project was designed as a research approach or case study in the management of patients with limb loss and/or dysfunction of the lower limb who present difficult problems in prosthetic substitution or in orthotic control. The specific aim of this project is to individualize solutions to difficult and unusual problems which do not lend themselves to the standard orthotic and prosthetic solutions which have been generalized to meet the needs of a large class of patients. The ultimate goal of the project is to generate, through team evaluation, analysis, and implementation of new treatment techniques along with thorough recordkeeping on each case, a bank of data on rare and unusual problems, possible solutions, and evaluation of results. With sufficient case material this bank of data could provide sufficient information so that unusual problems of a particular type may be categorized as to the special needs of the patient and a specialized approach for treatment which has proven successful in comparable cases.

In order to implement this program, a special clinic has been organized for special problems of the lower limb. The clinic is held monthly at Jackson Memorial Hospital. In attendance at the clinic are two orthopedic surgeons, an engineer, a prosthetist, an orthotist, a therapist, and a secretary who also serves as clinic photographer. Patients are referred to the clinic from a number of sources including the Veterans Administration Hospital, Jackson Memorial Hospital clinics and the Rehabilitation Center at Jackson Memorial Hospital, outside physicians, prosthetists, orthotists, and other Veterans Administration Hospitals. The special clinic presently has accepted for inclusion in the case study program and is following 15

patients with special orthotic problems and 10 patients with specialized prosthetic problems. Of these 25 patients, 6 orthotic patients and 6 prosthetic patients have been reported in detail to the VA. Of the 15 orthotic patients, 14 have some form of paralysis or paresis in the lower limbs. Nine of these are secondary to some form of polio, one to Charcot-Marie-Tooth disease, one to Guillain-Barre syndrome, one to myelomeningocele, one to arteriovenous malformation, and one to tubercular meningitis. The one other orthotic patient has bilateral ankle arthritis secondary to hemophilia. Of the ten prosthetic patients (some with multiple problems), two have a combination of amputation and paresis, two have contractures in addition to amputation, and six are multiple amputees, three have unusual types of stumps, and one has poor sensory feedback.

Through our present means of operation, the team expects that we can handle approximately 25 new cases per year with minimum followup on each individual case of 1 year after successful fitting.

The Improvement of Prosthetic and Orthotic Devices Through Materials Research, Analysis, Design, Clinical Testing, and Team Evaluation

Texas A&M University College of Engineering
Bioengineering Program
College Station, Texas 77843
Make McDermott, Ph. D., and Lewis A. Leavitt, M.D.

During the reporting period from January 1 through June 30, 1975, the project activity consisted of testing and evaluation of commercially available powered wheelchair lift systems for use in vans, and development and checkout of data acquisition and processing systems for testing and evaluation of servo-control systems for disabled drivers.

The data acquisition and processing systems are of a supportive nature to the overall testing and evaluation program, and thus will not be reported on in detail. Transducers, signal conditioning, and recording equipment have been installed on a van to record driver inputs (steering, brake, and accelerator) and vehicle response (acceleration, speed, distance, and steer angle) for both normal and servo-controlled driving. These data will then be processed and will be used for evaluation of overall system performance for servo-control driving equipment.

The commercially available lifts provide a means of entry and exit for a wheelchair-bound driver or passenger of a van. All of these lifts use as a power source the standard vehicle battery or an

auxiliary battery which drives an electric motor. Power from the motor operates the lift through either a hydraulic system, a mechanical system (cables, chairs, gears, etc.), or a combination of the two.

Six lifts are currently being tested on the basis of the following:

a. An assessment of the extent to which the lift can be installed and operated according to the manufacturer's claims. Some factors considered are physical dimensions, written instructions and procedures, ease of installation and adjustment, load lifting capacity, redundancies, battery drain during operation, and cycle time.

b. An engineering evaluation of the electromechanical design and fabrication of the lift. Considered here are cables and chains, fasteners, welds, materials and purchased components, tolerances, electrical subsystems, interferences, adjustability, and neatness.

c. An analysis of the lift operation from the user standpoint. For example, would a particular handicap preclude usage? Location of actuating switches, switch operating characteristics, reach distances, wheelchair orientation, need for an attendant, and need for seeing a particular area or point are other considerations.

d. Identification of potential user errors and possible results. Some areas to be noted are wrong orientation of a wheelchair, actuation of a wrong switch, failure to secure a wheelchair on a lift platform, wheelchair movement during a lift cycle, and grasping moving or dangerous parts.

e. An evaluation of the system safety aspects of the design. Attention is given to pinch points, rough or sharp objects, results of failures of various components, undue stress on an occupant (accelerations, head movements, etc.), possibility of wheelchair wheels rolling off or falling through the platform or opening, safety or limit switches, and human factors considerations as to hand holds, shapes, noise, etc.

The lifts currently being evaluated are Casady Safety Van Lift, Helper Industries, Maxon, Para-Lift, Speedy-Wagon, and Ricon. Others will be evaluated as received. Results of evaluations are being transmitted to the VA for their use in further evaluation and procurement decisions.

Control of an Artificial Upper Limb in Three Degrees of Freedom

Department of Electrical Engineering
Colorado State University
Fort Collins, Colorado 80521
Daniel Graupe, Ph. D.

During the first half of 1975 work continued on both the toe-controlled prosthesis and the EMG-controlled system.

The toe-controlled system has been reduced in size via modifications in the control logic and in the microelectronic actuation circuitry, as well as in the motor control system, such that the complete electronic system with its related power supplies, batteries, etc., was fitted inside the artificial arm (Fig. 10 and 11). This has been delivered to the VA Wadsworth Hospital in Los Angeles, California, and fitted on a bilateral above-elbow amputee. A movie, illustrating the performance of this system when used by the above amputee, has also been prepared and is available at the VA Research Center for Prosthetics in New York. The design of modified versions of the toe-controlled prosthesis for cases of shoulder disarticulation and of a disability of one foot has also been completed as has a design of a bilateral version to control two arms.

Work on the multi-functional EMG-controlled arm has been concerned with the setting of the microprocessor hardware such that it conforms with the programs for: 1. identification of a small set of parameters from the continuous signal, 2. recognition from the above parameters of the limb function, desired by the patient, and 3. final control of the prosthesis based on the above. The software

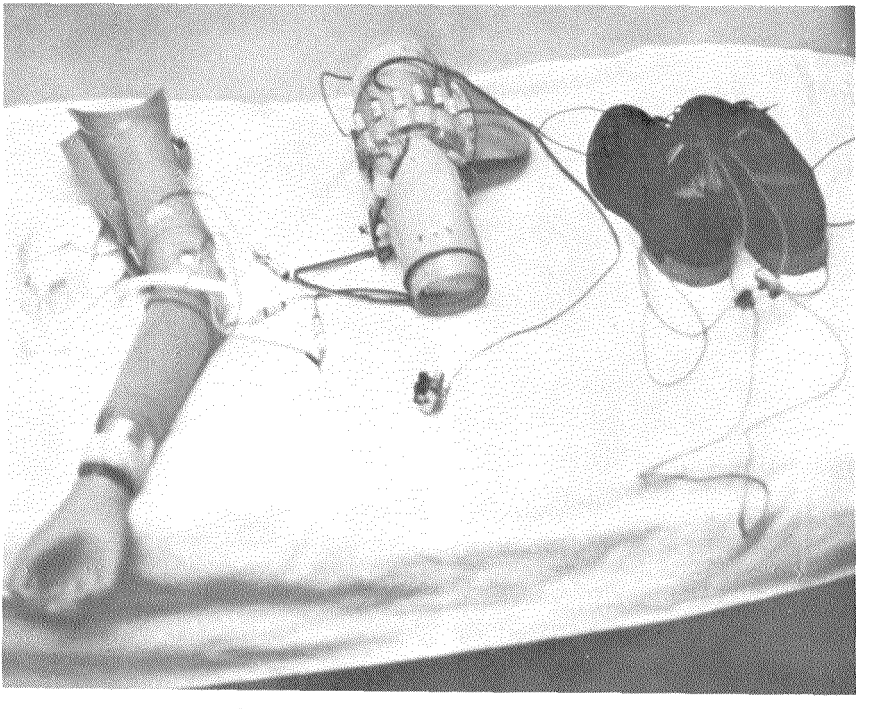

FIGURE 10. – Toe-controlled system.

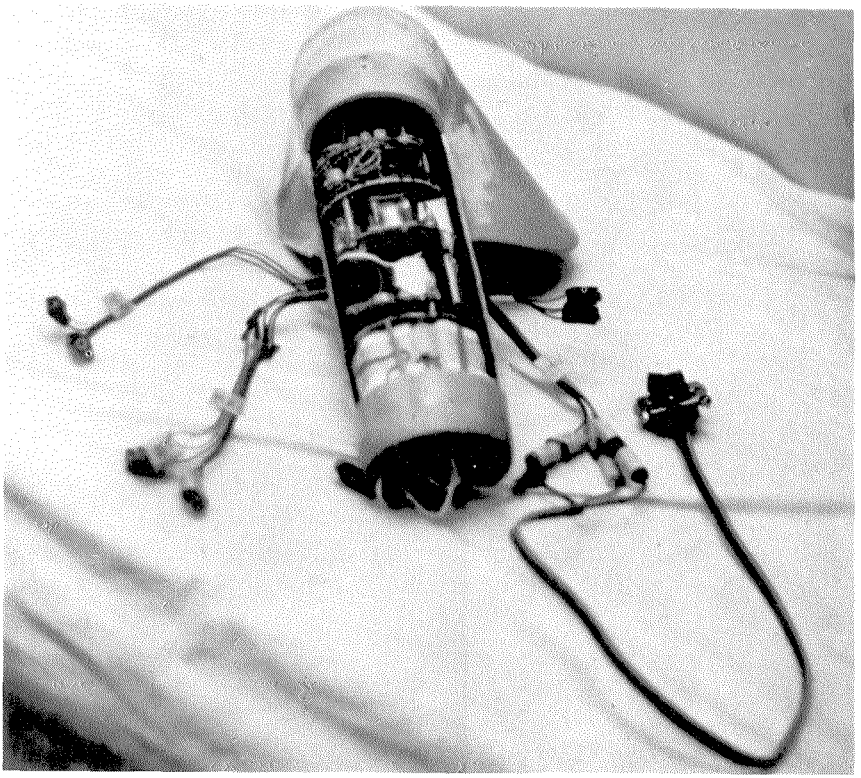

FIGURE 11.—The complete electronic system with its related power supplies, batteries, etc. fitted inside the artificial arm.

for these programs was tested previously (see previous reports in the BPR).

Work on the interface design (between electrodes and microprocessor and between the drive mechanisms and the microprocessor) has also been completed and its hardware realization is underway.

Finally, the design of a hybrid toe-controlled/EMG-controlled system has been completed.

Acceleration of Bone Healing by Electrical Stimulation
St. Luke's Hospital Center
Amsterdam Ave. at 114th Street
New York, New York 10025
George Van B. Cochran, M.D., Med. Sc.D.

The ultimate goal of this project has been to develp clinically effective means of accelerating bone formation by electrical stimula-

tion. To this end, an experimental model of non-union in a canine ulna has been developed, tested, and found to be ideal for tests of electrical stimulation modalities.

In the course of developing the model and assessing several modalities of stimulation, tests on 25 animals have been completed to date, although evaluation of all results is not yet finished. Technical problems with implanted stimulators, designed commercially for this work, have hindered progress, but we have demonstrated that bone formation in the model defects can be augmented by the electrical stimulation in some instances. Further work still is required to improve the bone forming response to a level of clinical applicability for VA patients.

The present research contract at St. Luke's Hospital expires November 30, 1975. Application has been made for a new contract for continuation of this work at Helen Hayes Hospital in association with Rensselaer Polytechnic Institute and the VA Hospital at Castle Point, N. Y., After adequate responses are obtained in the laboratory, clinical trials in association with the Seattle Prosthetics Research Study are planned.

Hemodynamic Evaluation of Postoperative and Preoperative Amputee

VA Hospital
Castle Point, New York 12511
Bok Y. Lee, M.D.

In reviewing the hemodynamic profiles of potential candidates for amputation and postoperative amputees, a careful categorization of the patient population is a critical issue, i.e., arteriosclerotic occlusive disease with and without diabetes. This classification is especially important with respect to the response to lumbar sympathectomy. Do all patients benefit? How is this determined? What factors distinguish arteriosclerotic occlusive disease from arteriosclerotic occlusive disease with diabetes? What tests are indicated for each group? How do the results differ? How is this information utilized in making decisions relating to the appropriate course of action for the patient?

During FY-1975, 53 patients received one or more vascular surgical procedures. Twenty-two of these patients had a diagnosis of diabetes. This group of 22 patients was divided into three categories:

1. Diabetes with the first signs of impending gangrene. For this group of 10 patients, lumbar sympathectomy has corrected the problem and the signs of impending gangrene have disappeared.

These patients are now being followed in the clinic with testing every 3 months or sooner if indicated.

2. Six patients with a diagnosis of diabetes and established gangrene have presented a more complex set of problems. One of the six had had a sympathectomy 3 years prior to the onset of gangrene of the big toe. He has done well with debridement and skin graft. Two of the six patients who had not had prior lumbar sympathectomies now had a lumbar sympathectomy which was subsequently followed by a distal below-knee amputation for one and a foot amputation for the other. The amputation was followed by a contralateral lumbar sympathectomy. Both patients have been fitted with a prosthesis and are now ambulating.

3. The three remaining patients represent the geriatric amputee. One patient, already a unilateral above-knee amputee for many years, sustained disarticulation of the big toe after a recent lumbar sympathectomy. Following a lumbar sympathectomy, a second patient sustained several revisions and progressed from toe amputation, through below-knee, to above-knee amputation. The above-knee amputation was necessary because of a severe knee contracture. The third patient, 5 years after bilateral sympathectomy, now has sustained a disarticulation of the big toe.

In evaluating the patient with diabetes with and without arteriosclerotic occlusive disease, determination of ankle and toe pressure and visualization of hemorheographic waveforms for all toes provide the clues for decision regarding site of involvement status of the vasculature.

Twenty-two patients were presented with severe arteriosclerotic occlusive disease. Eight of these patients had bypass procedures. For this group 10 lumbar sympathectomies were done. Of particular importance is the incidence of two above-knee amputations in this group of 22 patients. In one instance amputation was necessary due to severe involvement for which the patient had a bypass procedure but refused to follow instructions regarding positioning of the leg which resulted in subsequent thrombosis of the graft. In the second patient, neglect by the patient regarding his followup visits as well as his generally poor dietary and health habits resulted in a long delay between the occurrence of thrombosis of the bypass graft and the patient's return to the hospital. The remaining 20 patients are continuing to return to the clinic for periodic monitoring of their hemodynamic status.

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

The projects' research efforts have significantly approached the following objectives with modification of commercially available polysiloxanes: development of a material for prosthetic reconstruction which replicates the stress-strain profile, strength, elasticity, extensibility, compliance, resilience, cosmetic coloration, and tactile quality of living tissue and with enhanced durability

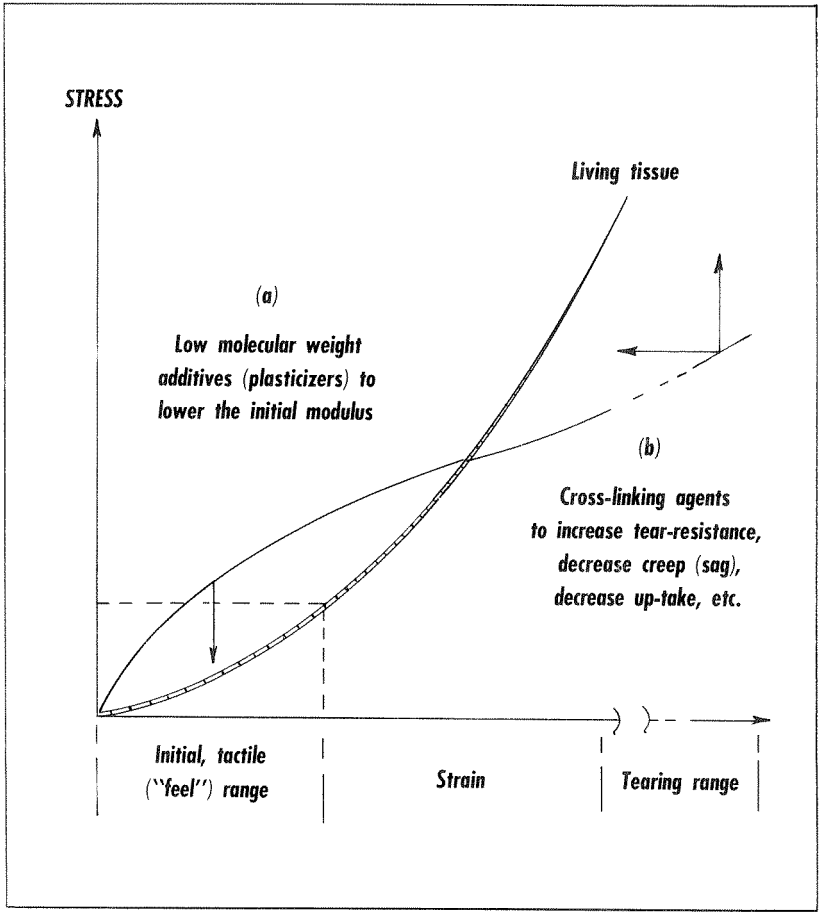

FIGURE 12. – An experimental approach to lower the modulus of elasticity of commercially available polysiloxane (Silastic 382) by adding low molecular weight silicone fluid.

especially with respect to repeated cleaning, exposure to sunlight, and absorption of skin exudates.

The experimental approach has been to lower the modulus of elasticity of commercially available polysiloxane (Silastic 382) by adding low molecular weight silicone fluid (Fig. 12). The low molecular weight silicone also acts as a cross-linking agent, grafting the polysiloxane polymers together. Table 1 is representative of the stress-strain profiles obtained from tests of the modified RTV (room temperature vulcanizing) Silastic 382. Initial tissue toxicity tests on various of these Silastic 382 modifications indicate they are nontoxic. Thus, the formulation used may be that which each individual patient feels most closely resembles his living tissue in biomechanical response, appearance, and tactual quality.

Standards for a wide range of ingredient content and catalyst levels of silicone modified RTV polysiloxanes have been proposed to the American Academy of Maxillofacial Prosthetics for broad adoption in clinical restoration prosthetics.

TABLE 1

Formulation		Tensile constants			
Silastic 382 (parts)	Silicone fluid (parts)	Modulus (M) lb/sq in.[a]	Strength (S) lb/sq in.[a]	Elongation %	S/M quotient
100	0 (RTV stock)	240 - 300	240 - 400	180 - 310	1.0 - 1.3
80	20	220	310	250	1.4
60	40	47	82	200	1.7
Arterial tissue		8 - 12	140 - 240	40 - 120	17.5 - 20.0
Goal of project		30 - 40	300 - 400	600 - 800	10.0
Prosthetic import		Tactile feel	Tear-resistance		

[a]To convert to kg/sq mm, $(N/m^2) \times 7.03 \times 10^{-3}$ (6,900).

The toughness and tear strength of RTV polysiloxanes still require improvement, especially on thin, feathered edges of cosmetic prostheses. The product development effort was consequently shifted to commercially available, linear macromolecular polysiloxanes which require activated, peroxide curing at higher temperatures. These HTV elastomers have considerably higher strength, elasticity, and extensibility than the RTV polysiloxanes.

As in the case of the RTV polysiloxanes, a similar program of modification and standardization has been carried out with the HTV polysiloxanes. Low molecular weight silicone fluid has been

used to graft on to the backbone of the elastomer chain and produce cross-linking of the polymers. This eliminates the tendency of the plasticizer (silicone fluid) to migrate in time, producing a marked loss in compliance and increase in stiffness, as occurs with the polyvinyl chloride plastisols and their phthalate ester plasticizers.

Table 2 is representative of the stress-strain profiles obtained from tests of the modified HTV polysiloxanes. It demonstrates that the modified HTV polysiloxanes more closely approach the desired goal. Furthermore, the ratio of the strength (S) to the modulus of elasticity (M), the S/M Quotient, ranges from 2.2-5.6 for the modified HTV polysiloxanes, which is considerably higher than the 1.0-1.7 for their RTV counterparts. This quotient is an indication of the tear-resistance, giving a measure of the strength, coupled with the amount of elongation before failure under tensile stress.

TABLE 2

Formulation		Tensile constants			
MDX-44515[a] (parts)	Silicone fluid (parts)	Modulus (M) lb/sq in.	Strength (S) lb/sq in.	Elongation %	S/M quotient
100	0 (unmodified)	260-400	560-880	900-1100	2.2 - 2.3
80	20	72- 88	220-340	840- 960	3.1 - 3.8
60	40	32- 44	140-240	800- 900	4.4 - 5.5
Goal of project		30- 40	300-400	600- 800	10.0

[a]Dow Corning special grade of elastomer; an equivalent General Electric series, SE-4524U and SE-4525U are under experimentation.

Further work remains to be done, particularly with respect to achieving enhanced durability against repeated cleanings, sterilizations, deterioration from sunlight and absorption of skin exudates.

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

Introduction

In the future, individuals having the misfortune of undergoing amputation may be able to wear an articulated limb powered by

existing skeletal muscles and to bear their weight on the skeletal system. Above-knee amputees may look forward to a positive swing-through gait pattern independent of body attitude. Soft tissue breakdown due to improper weight distribution may become a problem of the past. Below-elbow amputees may have a grasping organ with an opposable thumb. Although not yet clinically applicable, these statements are fact. They are based on experimental evidence.

Using the goat as an experimental model, it is possible to produce a walking animal using a permanently implanted skeletal extension exiting through the skin. In most of the animals, a simple pylon bolted to the skeletal extension served as the prosthesis. A small series included an artificial tendon exiting through the integument which coupled the existing achilles tendon to an external articulating mechanical ankle (Fig. 13).

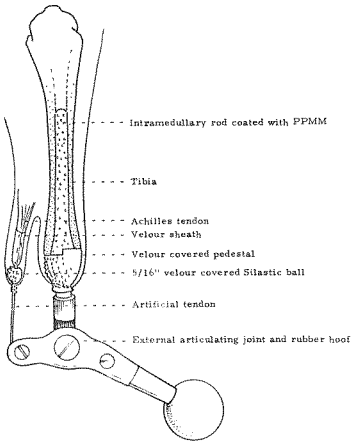

FIGURE 13.—Diagram of permanently attached artificial limb in place.

Materials and Methods

Earlier work in this area utilized canines as an animal model. Due however to their incessant licking of the wound edges and gnawing at the prosthesis, they have been abandoned in favor of the goat as the animal model of choice. One horse was used simply because it was offered at an opportune time in the program (1). All of the earlier implants were made of nonporous metallic rods fitted with a plastic pedestal covered with nylon velour. At that time, concern was only with the problem of skin interfacing with little or no attention given to bone interfacing requirements.

More recently, porous aluminum oxide (2,3), and porous polymethyl methacrylate (PPMM) (4) have been tried as bone inter-

facing surfaces. The porous aluminum oxide spools were strung onto a metallic rod and affixed in position with a locking nut.

Several problems arose with the ceramic model. The most spectacular was the instability of the long axis of the implant with relation to this intramedullary canal. The metal rod had a tendency to bend like a nail being pulled with a claw hammer. This caused fracturing of the ceramic spools and total failure of the implant. Another serious problem, which actually had been identified earlier, was the torque generated by the animal's change in direction as it walked. These forces, which were transmitted throughout the long axis of the rod, tended to shear any interfacial tissue growth.

The pedestal was redesigned so that a mortise joint between the pedestal and the amputated end of the long bone prevented torque from being applied to the intramedullary shaft. Only a break in the mortise joint could allow shearing of the interfacial surface.

Weakness in the strength of the porous ceramic led to an investigation of possible applications of PPMM. To date employment has been made of a surface of PPMM bonded to intramedullary rods of stainless steel, Fiberglas composite (Shakespear Wonderrod), and carbon fiber composite. The application of methyl methacrylate copolymers containing extractable salts has provided a convenient and controllable method for producing a porous surface on the intramedullary rod.

As stated above, the candidate materials being screened as mechanical and support components of the implant devices were metal alloys, Fiberglas-reinforced polyester composites, and graphite-reinforced epoxy composites. The selection of an optimum mechanical substrate continues to be dependent upon environmental, biological and mechanical stress demands, strength-to-weight considerations, and certain thermal and electrical conductivity properties. Stainless steel provides excellent mechanical properties assuring an adequate resistance to severe dynamic loading by the animal host, but it presents some problems with respect to its thermal conductivity and coefficient of thermal expansion. Continuous strand, Fiberglas-reinforced resins exhibit mechanical and physical properties such as tensile strength, modulus of flexure, thermal conductivity, and specific gravity which are closely akin to bone. Graphite-filled and reinforced resins add a measure of electrical and dielectric properties which may allow the introduction of electric currents to influence bone growth.

The ingredients for a successful implant include close tolerance of implant device and intramedullary canal, a good match of the mechanical impedances, biological acceptance of material, proper sterilization, meticulous surgical technique, and a proper convalescing environment for the host animal and the implant area.

To provide the preferred physical and biological interface between host and implant, the implants have been coated with porous acrylic polymers in whose surface a high degree of selected porosity (pore size, geometry, and density of pores) has been attained. The pores were induced by the aqueous extraction and leaching of water-soluble powders used as a filler in the molded plastic coating. Water-soluble crystals (granules or spheres of urea, ascorbic acid, sugar, and other biologically tolerated solids) were blended with an acrylic-styrene copolymer resin powder slurried with a monomer as follows:

Materials

Resin:	Styrene-methyl methacrylate copolymer (83.3 percent w/w) Poly (methyl methacrylate) powder (16.7 percent w/w)
Monomer:	Methyl methacrylate (97.4 percent v/v) N, N-dimethyl-para-toluidine (2.6 percent v/v) Hydroquinone (75 PPM)
Extractable Solids:	Urea[a] – microspheres of 100-600 μ diameter, or Ascorbic acid crystals – 40-400 μ diameter, or Sugar granules – 40-400 μ diameter

Typical Coating Recipe

Sugar, Ascorbic Acid, or Urea . . . . . 8 gm

Resin . . . . . 5 gm

Monomer . . . . . 5-6 ml

---

[a]Feed grade urea microspheres, Phillips Petroleum Co. These microspheres contain 95 percent urea and 5 percent coating and have an average size 300-500 μ.

Resin and urea were dry-blended then slurried in monomer to obtain a viscous paste which was immediately molded about the mechanical implant insert pin. The mold was an aluminum foil-lined cavity about 12 mm in diameter into which the 5 mm diameter pin was suspended. The cavity was then filled with the resin slurry. After one hour, the coated insert was removed, chucked in a lathe, and machined to a uniform geometry leaving a 1 mm thickness of

PPMM on the shaft. The machined part was then immersed in running water for about 10 minutes which leached out the exposed granules of urea leaving an acrylic coating of uniform porosity and por geometry. Urea microspheres produced a more predictable surface than the other uncoated salts or sugars.

To accommodate standardized inserts, the intramedullary canal was reamed and drilled to approximate closely the diameter of the insert and to a depth of 8 cm from the mortised surface. The intramedullary canal has a natural flare conforming to the distal end of the tibia and thus the insert must be cast to conform closely to this geometry. A conical reaming tool was used to impart an 8-deg slope. The insert was then gently tapped into place with a mallet. Excess skin was trimmed and tailored to fit the conical pedestal using 0000 silk to approximate the wound edges. The proximal skin edges were sutured to the nylon velour skirt embodied in the pedestal.

After bandaging the wound with a sterile dry dressing, a simple pylon prosthesis is bolted to the skeletal extension. Some animals have been seen to walk using the artificial leg upon awakening from anesthesia. Other animals present weeks of reluctance before bearing weight to the prosthesis.

A group of eight animals have thus far had an artificial tendon incorporated to the above-described procedure. Instead of a simple circumscribing initial skin incision, a linear incision between the tibia and Achilles tendon was made so as to divide these structures. Tibial amputation was performed as previously described, closing the skin about the implant before turning our attention to the tendon. This maneuver lessens the chance of contaminating the bone implant which has been the largest single cause for failure.

Artificial tendons made of Silastic coated Dacron tape procured from Dow-Corning were prepared for implantation by first dividing them into 15 cm segments. To one end of each segment, a 3 × 4 cm rectangle of nylon velour is bonded. This will eventually be used to create a large surface area for tissue ingrowth from the muscle. Forces transferred from this muscle group to the artificial tendon are distributed over a wide surface area, so the tendon is less likely to tear through tissues than would be the case with simple sutures.

Near the point where the artificial tendon will exit through the skin, a 1 cm ball was formed using Dow Corning's Medical Grade Adhesive "A." Nylon velour covers the surface of the ball and a short distance on the surface of the tendon creating a seal with the integument.

During implantation, the artificial tendon is first sutured to each head of the bipenniform tendon, thus forming a sheath of nylon

velour encasing the Achilles tendon. A stab wound in the skin allows the narrow artificial tendon to penetrate the integument but the incorporated velour-covered ball impedes further evulsion of the artificial tendon. Epithelium grows into the interstices of the velour creating a bacterial barrier around the artificial tendon.

Since the initial incision divided the tibia from the Achilles tendon, suturing the opposing skin edges together creates a pantaloon appearance to the complete structure. The purpose for creating pantaloons at the distal end of the stump is to allow separation of function. One leg of the pantaloon acts to contain the tibia and pedestal while the other leg containing the tendon acts somewhat like a bellows taking up the slack as the muscle shortens. This allows the tendon to lengthen or shorten without actually sliding through a skin opening. In reality, this is a modified cineplasty.

A 6-week healing period is allowed prior to coupling the artificial tendon to the prosthesis. During this 6-week interval, a straight pylon permits the animal the use of all four legs. Problems with the tendon have centered about its tensile strength. As tested on an Instron Universal TTC, the load at break registered 80.5 lb. It is small wonder that goats ranging from 60-80 lb have little trouble breaking the artificial tendon especially when one considers the leverage involved. For this application, a material which has a tensile strength three times as great as the material currently in use is needed.

Rather puzzling results have been obtained from one goat who has retained an implanted artificial tendon in place for well over 1-year without its breaking. The animal is quite agile and has no perceptible limp. Scar tissue may be contributing to the strength of the tendon. Another explanation is that perhaps degradation of the exteriorized portion of the other tendons due to ultraviolet radiation of the Dacron has occurred.

Prior to breaking the tendon, six animals experienced no difficulty in learning to control the articulated limb using existing orthotopic muscle groups. Needless to say, it is a heartbreaking experience to have the tendon snap just as the animal begins to trust it and applies its full weight to the system.

Summary

Thirty-two Spanish-Angora goats have had the left hind leg amputated just above the ankle. All of those having ceramic implants crumbled under the complex forces transmitted to the prosthesis by these active animals. One Fiberglas composite, one carbon fiber composite, and one Vitallium rod broke at or near

the pedestal junction. These failures have all been traced to defects created during fabrication. The longest survivor has been 14 months with a Vitallium rod cemented into place using Surgical Simplex-P (North Hill Plastics, Ltd., London, England). There is still displeasure with all of the bone interfacing techniques investigated to date.

Subsequently, nine animals have had the artificial tendon implanted in addition to the skeletal extension. The first in this group pulled the artificial tendon loose from the velour leaving the velour still affixed to the Achilles junction. Better bonding methods and the addition of the velour coated ball to the artificial tendon has alleviated this problem. Breaking of the exteriorized portion of the tendon remains a problem.

Skin interfacing using nylon velour to cover the pedestal of the skeletal extension and to cover the exiting portion of the artificial tendon has been no problem. Velour has also been used as the interfacing material to join the artificial tendon to the musculotendinous portion of the Achilles.

The pilot group of animals, having an articulating prosthesis powered by existing orthotopic muscle groups, succeeded in generating more enthusiasm than all the rest of the project. It is felt that the materials problem is minor.

References

1. Hall, C.W., R.H. Eppright, T. Engen, and D. Liotta: A Permanently Attached Artificial Limb. Trans. Am. Soc. Artif. Intern. Org. 13:329, 1967.
2. Hall, C.W.: Permanently Attached Artificial Limbs. Bull. Prosthetics Res., BPR 10-20: 337-345, Fall 1973.
3. Hall, C.W.: Developing a Permanently Attached Artificial Limb. Bull. Prosthetics Res., BPR 10-22: 144-157, Fall 1974.
4. Hall, C.W.: Development of a Skin Penetrating Skeletal Extension. Bull. Prosthetics Res., BPR 10-23: 321-327, Spring 1975.

Mobility Aids for the Severely Handicapped

Mobility Engineering and Development, Inc.
7830 Paseo Del Rey
Playa Del Rey, California 90291
Charles M. Scott

Van Compatible Wheelchair

Work with the working mock-up is continuing to perfect the basic framework, the power steering, and control system.

Since the mock-up contains all of the elements of the suspension system, the steering and power trains, it has been possible to utilize

it to optimize the detail design of the first production model. As a result, working production drawings are nearing completion. Two lightweight pre-production models will be built and are scheduled for completion is early January.

These models will be complete working units with seat height adjustment and revised seating, and full 4-G hold down systems seating.

The molds are complete and a series of reinforced Fiberglas laminate seats are being layed up. Experimental upholstering using various densities of "T" Foam material have been tested on the mock-up. It is felt that the most reliable data will be obtained during tests of the pre-production models when patients can make the evaluations.

Electronic Van Control System

The logic for this ultimate control system is now well advanced. Work on fabrication of modules of this system has started. Although in its early stages of development, no state-of-the-art problems appear to exist. All basic components are commercially available.

Although much work remains to be done, this system is presently usable by the severely handicapped.

Spinal-Cord-Injury Studies: Paralysis, Spasticity, and Pain

Veterans Administration Hospital
1201 N.W. 16th Street
Miami, Florida 33125
Jorge D. Jacobi, M.D., and Eric Falkenberg

During this reporting period, the VAH Miami, Spinal Cord Injury Service, has been involved in several projects while reorganizing following several key personnel changes. Evaluation of electronic gait assist devices and wrist orthoses for management of tremor as reported in BPR 10-23 has continued. In addition, this project has participated in the clinical evaluation of four environmental control units for quadriplegic patients and several types of powered wheelchairs for the spinal cord impaired. Also, work was begun on the design of a circular standing walker for therapy and training of the spinal cord impaired.

Clinical Gait Analyzer
The Professional Staff Association of the Rancho Los Amigos Hospital, Inc.
7413 Golondrinas Street
Downey, California 90242
Jacquelin Perry, M.D.

The activities performed during this period can be divided into four areas. They are as follows:

1. Normal Rate

The normal data curve of single stance time vs. velocity had to be stored electronically in the calculator/display unit. In order to accomplish this task, a computer program was written which selected the values (251) to be stored in the form of a look up table. The 251 values were selected by the computer to insure that the error in the stored data would never exceed 1.5 percent. The 251 data points were the minimum number which would maintain the desired accuracy over the selected range (from a velocity of 15 cm/sec to 200 cm/sec). The computer also scaled the data to make it compatible with the hardware design.

2. Hardware Design

The design of the calculator-display unit was completed. Four basic operations were required in this design: 1. the automatic transfer of the test data from the memory unit (worn by the patient) into the calculator-display unit, 2. calculation of the velocity and the selection of the proper normal data value from the look up table, 3. calculation of the right and left single stance as a percentage of the normal, and 4. the display of the results.

3. Prototype Fabrication

A complete prototype system was fabricated (Fig. 14). This included the memory unit, the calculator-display unit, an interconnecting cable, a start-stop switch with cable, and three sets of foot switches.

4. System Test

Both bench tests and clinical tests of the system were performed. The bench tests were used to verify that the system performed logically in the way the design specified. This involved simulating data and verifying that the resultant calculations performed by the system were accurate. To check the system in a clinical environment, actual gait tests were performed with the subject wearing

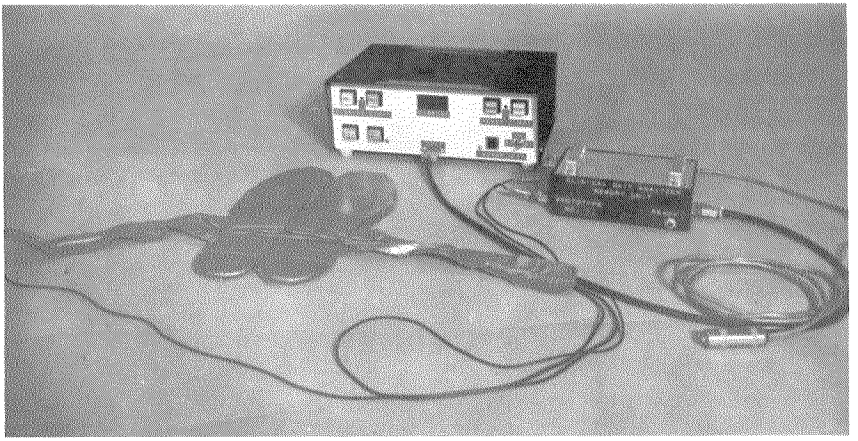

FIGURE 14. – Photograph of Clinical Gait Analyzer System.

FIGURE 15. – Memory Unit Attached to Person During Test.

the memory unit while normal foot switch data were recorded (Fig. 15). The velocity and percent single stance obtained from the clinical gait analyzer were compared with those values obtained from the normal foot switch data, thereby verifying the results.

A description of the system with operating instructions, was drafted and revised after trial by the Rancho Los Amigos staff. A prototype system will be sent to the Kinesiology Research De-

partment at the Veterans Administration Center, Wood, Wisconsin, for independent trial.

Mobile Bed/Chair for High Level Quadriplegics
The Professional Staff Association of the Rancho Los Amigos Hospital, Inc.
7413 Golondrinas Street
Downey, California 90242
Jacquelin Perry, M.D., and James R. Allen

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

In Vivo Loading of Knee Joint Replacement
Biomechanics Laboratory
Bingham Engineering Building
Case Western Reserve University
Cleveland, Ohio 44106
Albert H. Burstein, Ph. D., and Victor H. Frankel, M.D.

A modified polycentric total knee prosthesis has been designed that will accommodate a battery-powered, force-measuring telemetry appliance. The prosthesis is designed in such a way that the knee joint force will pass only up through a hollowed beam section within which three sets of strain gages have been mounted. The telemetry circuit contains three channels AM multiplexed on an FM carrier and can therefore detect three different components of the loads. As a result of the size of the telemetry appliance and the ensuing stress considerations, the designs for the prosthesis were considered either using MP-35N, a Co-Cr-Ni-Mo alloy with a maximum yield stress of 310 ksi, or from Titanium 6AL-4V (yield stress 170 ksi). The femoral articulating surface is spherically contoured with a radius of 1.25 in. while the overall height is 2.30 in. (0.30 in. higher than the current polycentric designs).

A prototype knee made from 2024-T3 aluminum alloy was used to evaluate the function of the device. The prosthesis will be calibrated using a series of compressive loads oriented at various angles to the long axis (90 deg and 0 deg and from 10 deg to 85 deg at intervals of 5 deg). The aluminum prototype was tested so that the sensitivity of the force transducer could be analyzed and the load and region at which yielding occurs could be determined.

Once the aluminum prototype of the telemetered total knee prosthesis was instrumented and tested, 12 implantable prostheses were constructed of Titanium 6AL-4V with extra low intrastitial

gas (ELI). The Titanium alloy was chosen in preference to the cobalt because the lower modulus of the Titanium material allowed the slight deflections needed for adequate sensitivity while maintaining adequate stiffness and safety of the total structure.

The one-piece shroud design of the aluminum prototype was modified to a two-piece design in which each component would be electron beam welded along the upper edge of the prosthesis. A mock-up of the weld pieces along with an apparatus to align and hold them was made in order to determine the feasibility of the welding procedure. The test was successful and the construction of 12 sets of one-piece shrouds was begun. To date, two knee prostheses have been welded and prepared for instrumentation. These prostheses will be used initially to determine the relation between calibration curves obtained from loading in a specially designed calibration jig and in fresh bone. Later they will be reused in vivo.

Progress in the construction of the telemetered knee prosthesis was slowed down by difficulty in locating a suitable electron beam welder and by delays in the machining of the shroud pieces. These problems now appear to be solved.

All associated electronic receiving and demodulation equipment has been constructed. It is anticipated that an implant and associated equipment will be available for insertion by January 1976.

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 Prast

The following presents two reports: the first covers the period July 1-December 31, 1974, which was omitted from the BPR Fall 10-23 issue, and the second report covers the period January 1-June 30, 1975. . . . . .Editor

July 1–December 31, 1974

During this report period, the PRA project has been able to provide the positive answers to the question of self-elevation from sitting to standing upright from a suitably modified wheelchair and from there to ambulation.

Since the last report, testing has been completed to determine the proper height modifications for hand positioning in self-elevation. Also, wheelchair modification has been completed. These

wheelchair modifications convert the armrests into rudimentary parallel bars which aid in standing. A previously mentioned modification in which the armrests could be flipped upward and forward has been abandoned at this time because they did not give the required height for erection. This idea would be useful for individuals who did not require the height of the present testing individual.

Sitting and standing away from a modified wheelchair is still a problem at present. PRA has not come up with any solutions for this but has some ideas regarding the future.

Continued evaluation of the lightweight brace has determined that weight reduction does not weaken the equipment for heavy day-to-day use. Having determined that the structural rigidity and integrity are intact, it is the belief of PRA personnel that the use of lightweight plastics and aluminum is an integral part of the brace's construction.

It has been demonstrated that doorways narrower than the standard 26 in. wide wheelchair can be passed through with apparent ease. Ambulation over door sills up to 3/4 in. in height has posed no problem to date. This is accomplished by the assistance of one hand on the frame of the door for balancing purposes. Ambulation over varied surfaces has also posed no problems to date. These surfaces include carpeting, tile floor, etc. Only one problem was encountered, and this was with a heavy shag carpet and a heavy undermatting.

It is thought that this new type of bracing system will eventually help more adult paraplegics to graduate from a wheelchair; or perhaps, more importantly, it will entice many to stay on their legs for at least part of each day.

January 1–June 30, 1975

Since the last report period, PRA has completed all testing of a suitably modified wheelchair, and PACO 11 (Pivot Ambulating Crutchless Orthosis) has been completed.

PRA is now in the process of developing a third prototype adult parapodium-swivel walker orthosis (PACO 111) for further testing and use by other paraplegics in the Veterans Administration system. PRA has designed and hopes to fabricate an orthotic configuration which has adjustable capabilities so that the orthosis can be adjusted to the patient's needs rather than building a custom-fit orthosis for each patient. Designing the orthosis in this fashion makes it relatively uniform and therefore more economical to construct.

Various makes of wheelchairs are being investigated in order to produce a uniform armrest to be used to aid the patient in self-elevation. The armrest modifications are designed to be completely self-contained and telescoping. The armrest elevates in height so that a patient can use it as a rudimentary parallel bar to assist in rising from the wheelchair to standing in the PACO.

SENSORY AIDS

Edited by

Howard Freiberger, A.M.
Electronics Engineer

Research Center for Prosthetics
Veterans Administration
252 Seventh Avenue
New York, N.Y. 10001

Laser Cane Blind Mobility Aid
Bionic Instruments, Inc.
221 Rock Hill Road
Bala Cynwyd, Pennsylvania 19004
J. Malvern Benjamin, Jr., Nazir A. Ali, and J. Ridgeley Bolgiano

A concluding report on this contract will appear in the next issue of the Bulletin.

Research on Audible Outputs of Reading Machines for the Blind
Haskins Laboratories, Inc.
270 Crown Street
New Haven, Connecticut 06510
Franklin S. Cooper, Ph. D., A.M. Liberman, Ph. D., Jane H. Gaitenby, Ignatius G. Mattingly, Ph. D., Patrick W. Nye, Ph. D., and George N. Sholes, Ph. D.

Introduction

The central objective of Haskins Laboratories' research on audible outputs is the production of clear intelligible English Speech by an