HIGHLIGHTS OF OTHER VA RESEARCH PROGRAMS

PROSTHETICS

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Subcommittee on Fundamental Studies

The Subcommittee on Fundamental Studies seeks to stimulate re-
search which will provide basic information prerequisite to the design of
improved prosthetic and orthotic devices, and to provide a better under-
standing of treatment processes.

Panel on Locomotion and Gait Studies

The Panel on Locomotion and Gait Studies is preparing a report
which describes its efforts to standardize data collection procedures in
this area of research. To facilitate the future work of the panel, CPRD is
developing a bibliography of the literature dealing with gait analysis.
CPRD is also preparing a list of laboratories in North America and the
United Kingdom which have the facilities and staff necessary to under-
take gait analysis studies. This registry will indicate the capabilities of the
various laboratories.

Internal Structural Prostheses

Because of the high level of interest and activity in this area of surgery
and rehabilitation, a workshop focusing solely on internal knee prosthe-
ses was planned in cooperation with the American Academy of Or-
thopaedic Surgeons (AAOS). A steering committee met in Miami,
Florida, on December 13, 1973, to organize this workshop. It was subsequently held in Charlottesville, Virginia, on September 23-25, 1974. A report of the workshop is being prepared.

Workshop on the Control of Operating Room Airborne Bacteria

Postoperative wound infection continues to be a matter of concern in some modern surgical procedures, particularly, but not solely, in orthopedics. A committee of AAOS is specifically charged with the responsibility of studying this problem. Since the subject has wider implications than for orthopedics alone, AAOS approached CPRD with a suggestion that a jointly sponsored workshop be held to review current knowledge in the field and to make recommendations on future courses of action.

In November 1973, the Division of Medical Sciences authorized CPRD to proceed. A small ad hoc committee met in Dallas, Texas, during the AAOS meeting in January 1974, to establish a steering committee.

The steering committee held its first meeting on February 15, 1974, in Chicago, and a second meeting on June 29, 1974, also in Chicago. A multidisciplinary workshop of 40 invited participants was held at the National Academy of Sciences in Washington, D.C., on Friday, Saturday, and Sunday, November 8-10, 1974. Discussion centered on the origin and control of airborne bacteria in the operating room. It is intended that the papers, discussions, conclusions, and recommendations of the workshop be published in the Spring of 1975.

Subcommittee on Sensory Aids

The Subcommittee on Sensory Aids seeks to encourage and coordinate activities directed to the blind and near-blind, the deaf, and hard of hearing. The evaluation of newly developed aids has become a major portion of the Subcommittee’s task.

Clinical Evaluation of Mobility Aids for the Blind

The final report of the Advisory Panel for the Evaluation of the Laser Cane has been published. As a followup to the conference on mobility held in November 1972, a Task Group on the Objective Measurement on Mobility Performance has collected data from various centers for the blind. This and other information will be discussed at a meeting to be scheduled in FY 1975.

Panel on Hearing Aid Performance (PHAP)

The second meeting of this panel, held September 20-21, 1973, consisted of two sessions. In one, test procedures, including new tests for
Other VA Research Programs

directional and Contralateral-Routing-of-Signals aids, were discussed; other matters considered were: 1. changes in the contract for VA-procured hearing aids, 2. electric microphone characteristics, 3. use of a mannequin to simulate the head and trunk during testing, 4. a study of information handling by impaired ears, and 5. a proposed method of testing hearing aids assumed to be nonlinear. In the second session, representatives of SRS and other divisions of the DHEW were briefed on PHAP activities and invited to suggest means by which the panel might meet their needs as well as those of the VA.

The third meeting of the panel was held June 17-18, 1974. In addition to the annual review of test data, discussion of tests and criteria, and selection of aids for VA purchase in FY 1975, experimental test results for directional and compression aids were presented. VA procurement and contract matters were also discussed, as were methods of obtaining information on repair statistics and hearing-aid user satisfaction.

Conference on Low-Vision Mobility

A planning group for a Conference on Low-Vision Mobility met on December 8-9, 1974, in Minneapolis. The conference will specifically deal with the distance vision in the partially sighted individual as it pertains to his mobility performance.

Miscellaneous

The Staff Engineer for Sensory Aids visited the VA Prosthetic Distribution Center in Denver, Colorado, and made recommendations concerning procedures relating to hearing-aid repairs and data gatherings. He served on the Research Advisory Committee of the National Center for Deaf-Blind Youths and Adults, and continued the national survey of all sensory aids research, development, and evaluation studies.

Subcommittee on Evaluation

During the seven or more years of its operation, the clinical evaluation program has functioned successfully to provide an effective transition of prosthetic-orthotic and sensory aids devices and techniques from design and development into educational curricula and patient usage. As the program of clinical evaluation has developed, a fairly consistent pattern of operations has emerged. Essentially at any given time, two, three, or four studies will be in progress and, within the year, one or more will be completed and one or two new studies added.

Rancho Los Amigos Hospital-Medtronic Implanted Peroneal Stimulator

An evaluation of this device, which has a function similar to that of the
Ljubljana peroneal brace but requires that the stimulator be implanted in the patient's leg, was continued throughout 1973. The centers participating in the evaluation are: George Washington University, Department of Orthopedics, Washington, D.C.; Highland View Hospital, Cleveland; Moss Rehabilitation Hospital, Philadelphia; Northwestern University Prosthetic-Orthotics Center, Chicago; Texas Institute for Rehabilitation and Research, Houston; University of Indiana, Department of Orthopedics, Indianapolis; University of Miami, Department of Orthopaedics and Rehabilitation, Miami; and Veterans Administration Hospital, Seattle.

A meeting of evaluation center personnel was held in December 1973 in Miami, Florida, and progress reports were presented. At that time, 29 patients had received implants, 25 of which were working satisfactorily. During the course of the study, changes had been made in the hardware to improve its reliability and some changes in the surgical technique had been made. Further evaluation was considered necessary to obtain longer-term data. A final meeting of evaluation center personnel was held in Miami, December 16, 1974, and the study was completed. A report of the results of the evaluation is being prepared.

_Casting and Cast Modification Techniques for Below-Knee Amputations_

This evaluation was initiated in August 1973. The study involves a comparison of three different methods of taking casts of the stumps of below-knee amputees and the modification of these casts in preparation for prosthetic fabrication. A total of 18 sockets are being fitted to six below-knee amputees, each subject being fitted with three sockets (based on each of the three casting methods). Transparent polycarbonate sockets are being used as aids in determining the accuracy of fit.

A final meeting of participants in this study was held August 12, 1974, and a report is being prepared for distribution.

_Ortho-Walk Pneumatic Orthosis_

This item was originally developed in France but is now being manufactured and distributed in the United States. The purpose of the device is to permit patients with paraplegia to stand erect and to engage in assisted ambulation when the orthosis is inflated. Sitting and wheelchair existence are possible with the device deflated.

The evaluation of the Ortho-Walk was initiated by an orientation session for selected participants. This session was held July 1-3, 1974, and involved physicians, therapists, and orthotists. An interim meeting was held in Miami on December 15, 1974.
Comparative Evaluation of Ankle-Foot Orthoses

A biomechanical analysis and comparative study of 12 ankle-foot orthoses (AFOs) which began in January 1971, was continued. The study is being conducted at Moss Rehabilitation Hospital in Philadelphia, with general coordination from CPRD's evaluation subcommittee, and involves the following devices:

- AMBRL Posterior-Bar AFO
- AMBRL Two-Rod AFO
- Conventional “Short-Leg Brace”
- IRM Spiral AFO
- NYU Insert AFO
- Rancho Polypropylene AFO
- Solid-Ankle Rigid-Laminate AFO
- Teufel Ortholen AFO
- TIRR Polypropylene AFO
- UC-BL Dual Axis AFO
- VAPC Single-Bar AFO
- VAPC Shoe-Clasp AFO

The objects of this study are to clarify the functional characteristics, prescription criteria, and relative merits of each orthosis. Kinematic analyses of the test orthoses have been completed and force data are now being analyzed.

Cybernetics Research Institute (CRI) Communications Systems for the Severely Disabled

The clinical evaluation of three Cybercom communications systems was initiated in September 1973 and completed in May 1974. A meeting of participants in the evaluation was held June 10, 1974, and results of the study were discussed. A report is being prepared.

Cybertype

Twenty-five children from five children’s rehabilitation centers or schools took part in the evaluation of this adapted typing system. Most of them had severe athetoid cerebral palsy. Many had speech problems.

Results of the study indicated that this equipment would be useful for that segment of the disabled population which was unable to operate conventional electric typewriters, yet had the intelligence and motivation for written communication skills and sufficient gross motor coordination to operate any one of a variety of interfaces. With minimum design modifications suggested for the production model, it was concluded that this system would be particularly advantageous in children’s
rehabilitation centers and special schools for the physically handicapped.

Whispertype

Of the 37 subjects who participated in the assessment of this system at five spinal-cord-injury centers, 50 percent were high-level traumatic quadriplegics; the remaining had a variety of disabling neurological or muscular conditions.

Generally, there was a positive feeling about the Whispertype, in that all subjects were physically capable of operating at least one of the interfaces. Low motivation and the lack of need for written communication in this group were seen as perhaps the most limiting factors in the use of the equipment. However, with minor modifications and an improved visual feedback system, it was judged to be a valuable tool for rehabilitation centers.

Cyberbrailer

Of the nine subjects evaluating this system (an IBM brailler and an IBM electric typewriter operated by a common keyboard), seven were blind and two were fully sighted students working with the blind. Six of the blind subjects were proficient braille users.

Although nearly all the participants agreed with the concept of providing simultaneous braille and inkprint copies, only one-third found this feature to be advantageous in the actual work setting.

Indications from the evaluators were that perhaps the "expert" brailist and his coworkers did not need this system. However, before discouraging further efforts by the developers it was recommended that specific job descriptions and more recently blinded subjects should be investigated to determine if and where the Cyberbrailer might be a practical method of communication between the sighted and the blind in a working environment.

A detailed report of this study is being prepared.

Future Plans

Evaluation of a New Orthosis for Scoliosis Treatment

An experimental orthosis developed at the Children's Hospital in Boston to control scoliosis is being considered for evaluation. The orthosis appears to control the pelvis and lumbar spine more efficiently than present designs, and in many cases precludes the need for orthotic extensions to the base of the head. A steering committee met July 26, 1974, in Boston to develop the evaluation protocol. An orientation session for participants in the evaluation was held December 5, 1974.
Casting and Cast Modification Techniques for Below-Knee Amputations

Eighteen prostheses prepared by three different procedures are being fitted to evaluate the contribution of different casting and modification techniques to the fit and function of the prosthesis. The final meeting for this evaluation was held August 12, 1974, at Rancho Los Amigos Hospital, Downey, California. Reports were presented on socket-volume studies, skin-temperature studies, clear-socket observations, and 2-week clinical trial experiences.

Evaluation of the Ortho-Walk Pneumatic Orthosis

A steering committee meeting held in New York on May 1, 1974, established the evaluation protocol and procedures for the application of this device. It is planned that four Veterans Administration Spinal-Cord-Injury Services and three civilian rehabilitation hospitals will use the Ortho-Walk orthosis on a total of 35 patients as part of their physical therapy treatment programs. An orientation session was held July 1-3, 1974, at Bird S. Coler Hospital, with clinical trials beginning immediately thereafter.

Development of a Thermoformed Prosthesis

Initial evaluation of a design for a completely thermoplastic prosthesis will be initiated. It is anticipated that the construction will lower the weight of a below-knee prosthesis to less than 1 lb. and utilize a novel approach to prosthetic foot components, with a resulting decrease in the expenditure of energy for ambulation.

Continued Clinical Evaluation of Implantable Peroneal Stimulators

Ten implantable peroneal stimulator units from Ljubljana, Yugoslavia, have been ordered and will be evaluated by the three university hospitals that were involved in the evaluation of the Rancho Los Amigos Hospital-Medtronic devices.

Subcommittee on Child Prosthetics Problems

The Subcommittee on Child Prosthetics Problems maintained an active research program in the prosthetics management of children with limb deficits. Thirty-three clinics specializing in the treatment of the child with missing limbs are now participating in the cooperative research program under the aegis of the subcommittee. The Assistant Executive Director and Staff Officer maintain close contact with clinics already in the program and with developing clinics which may be participants in the future.

A symposium for clinic personnel involved in the cooperating pro-
gram was held at the Rehabilitation Institute of Montreal, Quebec, May 9-11. The program was devoted primarily to special management problems for children with limb deficiencies. An executive meeting of the subcommittee was held during the afternoon of May 11, 1974.

A workshop on Mobility Aids for Patients with Myelodysplasia was held September 12-14, 1974, at the Ontario Crippled Children's Centre in Toronto. At this meeting it was proposed that a cooperating program similar to that now in operation in prosthetics be developed for myelodysplasia clinics. An ad hoc planning committee met on December 15, 1974, in Miami to plan the organization of a network of such clinics.

On November 11, 1974, a planning meeting for limb bank operations was held in cooperation with the Variety Club in Toronto. The purpose of the meeting was to effect liaison between CPRD's Subcommittee on Child Prosthetics Problems and the limb bank program of Variety Clubs International.

A joint study involving SCPP and the evaluation subcommittee is being planned concerning the Boston spinal orthosis. This item, which has various applications for spinal curvature in children, has several innovative features including a prefabricated pelvic girdle. A meeting with representatives of the Scoliosis Research Society was held September 11, 1974, to plan the study.

The Assistant Executive Director served as chairman and Leon M. Kruger, M.D., as rapporteur at a workshop conducted by ISPO on Classification and Nomenclature in Congenital Limb Deficiency. This workshop, held in Dundee, Scotland, June 17, 1973, established a new international terminology which was accepted by ISPO and is in the process of worldwide promulgation through ISPO and WHO.

The Assistant Executive Director continued to serve as editor of the publication *Inter-Clinic Information Bulletin*, which is published in cooperation with New York University. Approximately 3,500 copies are distributed monthly to physicians, prosthetists, therapists, and others interested in the care of the child amputee.

Committee on Prosthetic—Orthotic Education

Task Force on the Standardization of Prosthetic-Orthotic Terminology

During the past year and a half, two meetings of the CPRD/CPOE Task Force on the Standardization of Prosthetic-Orthotic Terminology were held.

At the first meeting held in Washington on November 16, 1973, Dr. Brian A. Roper from Great Britain attended as an invited guest. He and Dr. E.E. Harris, Staff Surgeon, reported on a meeting of the Subcommitteee on Terminology of the International Society for Prosthetics and
Orthotics (ISPO), of which they are members, which had been held in Dundee, Scotland, in June 1973.

They reported that the orthotic terminology, developed by the Task Force and which described an orthosis by the joints it encompassed and the controls it had over those joints, had proved acceptable to the international committee and would be submitted by it to ISPO for international use. It was considered, however, that a descriptive terminology of materials and systems of control used in the fabrication of orthoses was also needed.

Dr. Jacquelin Perry, Chairman of the Task Force, described work done by the Subcommittee on Prosthetics and Orthotics of the American Academy of Orthopaedic Surgeons (AAOS) and suggested that the report of this group would provide the required description of materials and systems.

Dr. Roper and Dr. Harris reported that the terminology proposed by CPOE's Task Force for prosthetics had not been acceptable to the international group.

At a second meeting held at Rancho Los Amigos Hospital in February 1974, it was agreed that the work of the Task Force in regard to orthotic terminology had been essentially completed. The new terms were being used in the orthotics schools and in the literature. Eleven states were using the nomenclature for fee scheduling, and it was being adopted by the Veterans Administration.

Mr. Hector Kay, Assistant Executive Director, described a terminology developed by the ISPO Subcommittee on Nomenclature for the Classification in Congenital Limb Deficiency, of which he is chairman. This terminology is undergoing international field trials. He suggested that there is a strong similarity between congenital transverse lesions and acquired amputations. The Task Force agreed and adopted the proposed congenital nomenclature for use also for acquired limb loss. The Task Force then made some headway in developing a system of functional descriptions for prosthetic components. A further meeting was held July 9, 1974.

Information Retrieval Systems

No formal meeting of the ad hoc Committee on Information Retrieval was held during the reporting period. However, direct contact was maintained between CPRD/CPOE staff, Mr. Warren Springer, Chairman of the ad hoc Committee, and Mr. Peter Nelson, operator of the Winnipeg Information Retrieval System. Frequent contacts were also made with the ISPO Subcommittee on Information Retrieval of which Mr. Springer is also chairman.

At a meeting in Dundee, Scotland, in June 1973, the Winnipeg Interna-
The International Prosthetic and Orthotic Research Reference Catalog was approved by the International Society as the system on which further development would be based. Since that time, steps have been taken to transfer the Winnipeg system to CPRD/CPOE jurisdiction. In the initial stages of this transfer, Mr. Nelson served as consultant to CPRD and joined the CPRD staff as full-time member on September 1, 1974.

On November 4, 1974, a meeting to coordinate activities in information retrieval systems was held in New York City. Representatives from various organizations and groups who are using information retrieval systems participated.

Newsletter . . . Amputee Clinics

Newsletter . . . Amputee Clinics, the bimonthly publication of CPOE, continues to grow, both in numbers and in reader participation. In the 4½ years since publication began, circulation has increased from 1,500 to approximately 4,500. In ever-increasing numbers, readers are responding to Newsletter surveys and participating in an exchange of viewpoints on amputation practice, prosthetics, and amputee care.

In the six regular and one supplemental issues published during the period January 1, 1974–December 31, 1974, readers considered such clinical problems as methods for checking total contact fittings, cardiologic problems of elderly amputees, cosmetic prostheses for unilateral and bilateral lower-limb amputees, and powered prosthetics systems for shoulder-disarticulation and short-above-elbow amputees. A series of articles on the roles of the various members of the amputee clinic team, begun with the October 1973 issue of Newsletter, was particularly well received. The initial article dealt with the role of the orthopedic surgeon, and subsequent articles and discussions considered the roles of the physiatrist, prosthetist, therapist, nurse, and patient.

Amputee Clinics in the United States and Canada

The 1974 edition of Amputee Clinics in the United States and Canada was distributed to over 500 listed clinics and, in response to requests, to approximately 600 other educational institutions, medical libraries, and allied health personnel involved in the care and management of amputee patients.

Originally developed as a mailing list for use in the distribution of educational materials relating to prosthetics, this roster has gradually been enlarged to include information useful for patient referral. The types of services offered and the meeting schedule for each clinic, as well as the clinic address and names of chiefs and cochiefs, are presented.
CPRD/CPOE/AOPA Amputee Survey

CPRD/CPOE, in cooperation with the American Orthotic and Prosthetic Association (AOPA), initiated a survey on July 1, 1973, to determine changes in the amputee population in the United States since 1964, when Dr. Harold W. Glattly, then Executive Secretary of the Committee on Prosthetic-Orthotic Education, National Research Council, reported the results of his 1961-1963 "Amputee Census." To provide a basis for comparison with the Glattly findings, the data sought is similar, i.e., age and sex of amputees; and date, cause, and levels of amputations. Two types of cases are being reported by volunteer prosthetics facilities during the year-long study: 1. amputees being fitted for the first time with a prosthesis and 2. patients who have been reamputated and are being fitted at the higher level for the first time.

A preliminary report, which compares 1,654 cases recorded during the period July 1-November 15, 1973, with 5,000 cases reported by Glattly during the first 11 months of his study, was published in Orthotics and Prosthetics, Vol. 28, No. 2, June 1974.

The present survey was terminated on June 30, 1974, and a further analysis of the data has been made and compared to the preliminary findings, and a report is in preparation.

Special Meetings and Activities

Educational Activities

The Assistant Executive Director continued to serve as honorary secretary of the University Council on Orthotics-Prosthetics Education (UCOPE) and the Conference on Orthotics-Prosthetics Education (COPE).

American Orthotic and Prosthetic Association (AOPA)

During the reporting period, continued close liaison was maintained with AOPA, the American Board for Certification (ABC), and the American Academy of Orthotists and Prosthetists (AAOP) by personal contact and by staff participation in various Association activities. CPRD staff members attended the AOPA National Assembly held in Atlanta, Georgia, October 23-26, 1974, and the staff prosthetist/orthotist participated in the scientific program of the Assembly.

American Academy of Orthopaedic Surgeons (AAOS)

Close liaison was maintained with the American Academy of Orthopaedic Surgeons throughout the year, including cosponsoring two workshops. The Assistant Executive Director and Staff Surgeon at-

**Powered Upper-Limb Prosthetics Course**

A meeting to develop a powered upper-limb prosthetics course was held at Northwestern University, October 4, 1974.

The purpose of the meeting was to determine the content of future courses on powered upper-limb prosthetics. Subjects such as myoelectric theory, components, maintenance, repair, and course prerequisites were discussed.

**Veterans Administration Conference of Prosthetics and Sensory Aids Research Project Leaders**

All of the CPRD professional staff participated in a Conference of Prosthetics and Sensory Aids Research Project Leaders held July 20-23, 1974, by the Veterans Administration at the Rehabilitation Institute of Chicago.

**University of Miami Seminar**

On December 16-18, 1974, the Executive Director, Assistant Executive Director, and other CPRD staff members participated in the Eleventh Annual Post-Graduate Course presented by the University of Miami Medical School and cosponsored by CPRD and the Veterans Administration. The subject of the course was “Fracture Bracing and New Orthotic Developments,” and the Executive Director and Staff Surgeon served as faculty members.

**International Activities**

The Executive Director attended a Workshop on Lower-Limb Modular Prostheses sponsored by the Department of Health and Social Security of Great Britain, and the United Kingdom National Society of ISPO. The meetings were held at Heathrow, London, England, March 25-29, 1974. He also attended the spring meeting of the British Orthopaedic Association at Stoke-on-Trent.

The Executive Director and the Assistant Executive Director attended the First International Conference of Rehabilitation Engineering Centers sponsored by the Rehabilitation Services Administration of the U.S. Department of Health, Education, and Welfare. The conference was held in Ljubljana, Yugoslavia, May 20-25, 1974.
The Executive Director presented a paper at the Prosthetic-Orthotic education and Training International Study Week held in Glasgow, Scotland, July 8-12, 1974. The study week was sponsored by the National Centre for Training and Education in Prosthetics of the University of Strathclyde.

CPRD chairman and staff members attended and presented papers at the First World Congress of the International Society for Prosthetics and Orthotics held in Montreux, Switzerland, October 8-12, 1974. A Pre-Congress Workshop in Prosthetics and Orthotics was held in Les Diablerets, Switzerland, October 2-4, 1974, and was chaired by the chairman of CPRD.

Proposals Reviewed on Behalf of Sponsors

A total of 32 proposals in the fields of prosthetics, orthotics, and sensory aids were reviewed and appraised by the Committee at the request of sponsors (seven new and 25 continuations).

Site Visits

At the request of sponsoring agencies, staff members of CPRD, together with Committee members and experts in the pertinent fields, made the following on-site visits:

- Children's Hospital, Boston
- Tufts University
- New York University Medical Center
- Temple University
- Sight Systems Institute
- Duke University
- Harvard-MIT Rehabilitation Engineering Center
- Emory University
- Texas Institute for Rehabilitation and Research

The Assistant Executive Director and the Staff Officer also made visits to several Child Amputee Centers, some already participating in the cooperative clinical research program coordinated by the Subcommittee on Child Prosthetics Problems and some prospective participants. These centers were: Baylor University Medical Center and University of Texas, Dallas, Texas; Shriners Hospitals at Springfield, Mass., and Lexington, Ky.; Sacramento Medical Center, Sacramento, Calif.; Massachusetts General Hospital, Boston, Mass.; Glenrose Hospital, Edmon-
Alberta, Canada; Milwaukee Children's Hospital, Milwaukee, Wis.; Bureau of Crippled Children, Orlando, Fla.; Newington Children's Hospital, Newington, Conn.; Home for Crippled Children and Children's Hospital, Pittsburgh, Pa.; University of Kentucky Medical Center, Lexington, Ky.; Operations Crossroads Rehabilitation Center, Chattanooga, Tenn.; Area Child Amputee Center, Grand Rapids, Mich.; Amputee Clinic, Children's Division, Institute of Rehabilitation Medicine, New York, N.Y.; Crippled Children's Hospital, New Orleans, La.; Georgia Juvenile Amputee Clinic, Atlanta, Ga.; Ohio State University, Columbus, Ohio; and University of Michigan, Ann Arbor, Mich.

Miscellaneous

The staff responded to more than 1,000 requests for publications and technical information.

Publications

July 1, 1974—December 31, 1974


Report of Meeting of Child Amputee Clinic Chiefs, Montreal, Quebec,
Canada, May 9-11, 1974, under the sponsorship of the Subcommittee on Child Prosthetics Problems. (In preparation.)
Report of Workshop on Control of Operating Room Airborne Bacteria, November 8-10, 1974. (In preparation.)
Inter-Clinic Information Bulletin. (Published monthly under the sponsorship of the Subcommittee on Child Prosthetics Problems; 12 issues.)

Research and Development in the Field of Artificial Limbs
Mauch Laboratories, Inc.
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Hans A. Mauch

The development of the Hydraulic Swing and Stance Control (S-N-S) System is nearly complete. Only minor improvements were found necessary during the reporting period. These were incorporated in the production and repair systems whenever possible.

These improvements include switching over to another supplier for Buna-N rubber O-rings because it was found that the O-rings supplied by the previous manufacturer were recently made of a compound that took a more permanent set than before. This led to occasional leakages and inadvertent movement of parts which were supposed to be held in place by the friction of the O-ring. Another improvement concerned the hole into which the expandable rubber plug for the control of the Dynamic Self-Bleeding is installed. This hole was formerly produced by a normal drilling operation. As a result the inside wall of the hole was sometimes rough which occasionally produced sufficient abrasion on the plug surface to eventually create a small leak. The holes are now reamed after drilling to a smooth finish. The last improvement was applied to the thread which joins the cylinder bottom with the cylinder. The engagement length of this thread will be doubled in the next production run in order to provide more safety in cases where this thread connection is subjected to strong impact forces as a result of
continued use of the hydraulic system after it has lost more of its oil. Preparations for writing the “Bible” describing in detail the design and manufacture of the S-N-S system were initiated and are scheduled to be completed at the end of the present contract year (June 1975).

Considerable progress was achieved in the development of the Hydraulic Ankle as a result of shakedown testing by two amputees (one in the Dayton and one in the New York area) who wore prototypes for various time intervals throughout the reporting period. A great number of findings (approximately 15) were analyzed, leading to design improvements, most of which were immediately applied to the shakedown testing prototypes for further evaluation. Although none of these improvements altered in any way the established design principles but rather confirmed them, they were nevertheless quite essential to improve the reliability, longevity, and appearance of the system, to eliminate noises, and to simplify its maintenance, adjustment, and installation, and exchange by the prosthetist. Improvements in this respect may sometimes seem trivial, but they are often decisive regarding the acceptance or rejection of a new device by the final users.

The following examples of improvements are typical for this phase of the development effort.

The cosmetic cover of the foot/shank transition was improved by the use of two saddle-shaped polypropylene covers, one in front and one in the back of the ankle joint, which are flexibly attached to the foot and whose upper ends hug the outside of the lower end of the shank during plantar flexion/dorsiflexion and eversion/inversion motions. The contact during the third type of motion (transverse rotation) is facilitated by giving the lowermost portion of the shank a nearly cylindrical cross section where it contacts the upper ends of the polypropylene covers.

Another improvement consists in the installation of a lid inside the shank on the top of the aluminum tubing which houses the upper elements of the hydraulic ankle. This lid prevents foreign matter from entering that space where it may contaminate and possibly score the bearing and sliding surfaces of various components. The lid and its equivalent in pylon-type legs will also serve as a barrier against potential noises which may originate within that space.

Still another improvement concerns the attachment of the top end of the hydraulic system to the inside of the shank. This top end is held in place by two rubber bumpers of basically semicircular cross section which permit limited transverse rotation and also forward-backward adjustment of the piston-rod tip of the hydraulic system. The durability of these bumpers was enhanced by making them 50 percent longer and avoiding stress concentrations by rounding corners of the bumpers themselves and of the surrounding holding elements inside the shank.
In addition, the flat paddle-shaped portion of the piston rod which is held between the two bumpers was made much thinner in order to make the angles of attack on the bumpers less tangential, producing lower compression forces for a given torque.

A third prototype of the hydraulic system to serve as a spare unit during shakedown testing was also completed during the reporting period and its testing was started.

Parallel to the test wearing activities described above, the redesign of the production-type ankle unit was completed by including in it all the modifications which were found necessary as a result of the test wearing experiences. At the same time modifications of all casting patterns including the core box for the housing were completed. Bids were invited for sample quantities of production-type castings of the housing and the piston. The design of the new U-seal was also completed and bids on a mold for producing samples were invited.

The development of the Voluntarily Actuated Swing and Stance Control Knee Unit was continued with the emphasis on the study of design elements which may malfunction. Such malfunctions may have more severe consequences in a voluntarily controlled leg than in an arm because they may lead to accidents. The study was started with the focus on the consequences of power failure. The most severe consequence found was that the spring-loaded electromagnetic actuator of the hydraulic control valves would go to “fully open” in such an event letting the leg collapse if it happened to be under load at that time. The other alternative to let the valve go to “fully closed” in such a case would result in a locked leg which might also be dangerous in certain situations. The least risky “fail safe” reaction to power failure would consist in letting the valves maintain the position they happen to be in when the power failure occurs. Then the leg would just keep on doing what it happened to be doing while the power was still on, and the amputees would have time to discover the changed situation and adjust to it. As a consequence the use of so-called stepper motors for the actuation of the control valves was studied. The results looked promising and may even lead to lower power consumption as compared with the spring-loaded actuators. Other possible sources of malfunctions were also studied.

Of other developments being conducted, a more important item is the design of a simplified knee bolt assembly for above-knee prostheses which will reduce side play, simplify installation, and reduce costs. The design was completed, and a prototype was built and installed into a wooden setup. This prototype was demonstrated to VA personnel in New York during a visit in November. As a result of this demonstration the VA requested a bid on 24 setups and six separate bolt assemblies; this was submitted in December.
For progress during this period, see "Transferring Load to Flesh: Part III. Stasis and Stress," appearing elsewhere in this issue.

The laboratory has been active in the design of a new myoelectric circuit for the VA-NU myoelectric hand. Field experience is invaluable in the improvement of design of equipment and has prompted several changes. These are as follows:

1. Construction from packaged solid-state components. This method permits simpler quality control of the components and simpler repair.
2. Double-sided construction of the printed circuit board. Plated-through holes permit solder joints which are strong mechanically. These joints are more reliable than those of single-sided circuit boards. These joints should minimize joint failure due to vibration or mechanical shock.
3. Quick-disconnect sockets were added to the board so that it may be quickly connected and disconnected from the system. These sockets facilitate repair and testing. Substitution of a disabled unit is easily and quickly accomplished. These sockets also minimize risk of damage to the connection wires.
4. The number of parts was reduced by about 15 percent. This reduction should increase reliability. Reduction of components was possible through single-stage amplification, use of integrated circuits, and an output circuit which provides its own inherent motor damping.
5. The myoelectric amplifiers were improved to give them greater sensitivity and radiofrequency immunity from strong FM transmitting stations. The input leads of the previous circuit would sometimes act as a "slope detector" of FM signals. This fault was corrected. Also, the amplifiers were designed to permit "tipping" the electrodes. "Tipping" is the process of touching the electrodes of a myoelectric prosthesis to activate by 60 Hz "noise" or electrical signal picked up by the body. Since everyone who works with or plays with a myoelectric system is inclined to "tip" it, the system was improved to permit this with impunity. The "tipping" feature does not improve the performance for an amputee, but should be valuable in simplifying instructions concerning the don-
ning, use, and maintenance of the system.

The new design has two slight disadvantages. These are: a. increased quiescent current and b. slightly reduced output power. Neither of these disadvantages appears to be of consequence in the total performance.

An electric powered hook is under clinical evaluation and design improvement. The requirement now is to develop special hook fingers for this terminal device. It is hoped that a prosthetic manufacturer will be interested in assistance with this project as the fabrication is beyond the capabilities of the laboratory. Considerable interest in this development has been evidenced in the prosthetic community, and the preliminary evaluation by two patients who are using the unit daily has been very positive. The laboratory is in the process of developing hook-hand interchangeability in a myoelectric prosthesis.

Sensory feedback from artificial limbs has long been a goal in prosthetics. Norbert Wiener thought it was essential for the development of reflex activity. Cable-driven prostheses provide a measure of feedback through the cable to the body. Myoelectric prostheses have minimal feedback, although there is some sense of muscle effort. Of course, most prostheses have visual and auditory feedback, but it is preferable to minimize the need for these pathways. Mechanical vibration or electrical stimulation of the skin of the residual limb has been proposed and examined experimentally. Dr. David Simpson has given logical and compelling arguments against this form of feedback. Nevertheless, it may still be useful in very simple systems (e.g., prehension only). The laboratory is developing a simple electrical stimulation approach for evaluation. This development has long been possible, but it was set aside because its importance was considered secondary and because of the lack of an extremely simple and elegant design.

Three more lift-lock mechanisms have been constructed for testing with above-elbow amputees who wear conventional above-elbow prostheses of the cable-driven type. The first user rejected the device because it slightly modified the control pattern which he had developed over many years of usage. The plans are now to apply it to new fittings so that a better assessment may be made of its mechanical function.

The harness used by above-elbow amputees needs improvement in efficiency and comfort. An experimental thoracic suspension harness has been developed and is being evaluated on several amputees.

Self-suspension sockets remain of primary importance in this laboratory. Several wrist-disarticulation amputees have been fitted with atmospheric-suspension sockets and myoelectric control. This approach has also been effective, under laboratory conditions, for persons with below-elbow amputations where the residual limb is moderately long. Successful results with the fitting technique may permit complete free-
om at the elbow joint, conservation of some supination-pronation motion, and improved comfort.

**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

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John H. Lyman, Ph. D., Amos Freedy, Ph. D., and Ronald Prior, Ph. D.

Research in progress at the UCLA Biotechnology Laboratory includes the following:

1. Development of an adaptive aiding and control system externally powered arm prostheses with four degrees of freedom. The system consists of a pattern recognition network with decisions currently based on eight myoelectric signal inputs from the shoulder area.

   Amputee experiments have revealed that coordinated joint motion of the prosthesis is possible when the subject moves his phantom limb simultaneously.

   Present work centers on the adjustment of the system’s parameters for optimal control.

2. Heuristic rules have been formulated by which interjoint relationships for certain patterned trajectories can be automatically incorporated in the prosthesis control system. Such rules include keeping the wrist leveled when reaching to grasp, and orientation of the wrist in relation to direction of arm motion. Investigation continues on additional possible rules to be incorporated in the system in order to relieve amputees as much as possible from conscious control burden.

   Arrangements have been made to test these rules, using an arm with ten degrees of freedom in conjunction with an INTERDATA 70 digital computer. The six degrees of freedom adds two degrees of shoulder movement to the four degrees of freedom already available in the artificial arm.

3. Several sensory feedback techniques for artificial upper limbs have been developed. Electrocutaneous stimulation proportional to fingertip pressure, as well as finger position, was implemented using frequency and pulse width variations respectively.

   Presently, a new approach is being implemented where fingertip pressure and elbow position will be displayed simultaneously, using frequency modulated skin orientation techniques. An arc-shaped array of electrodes is switched on and off according to elbow angular position, creating various stimulation orientations referenced to a middle electrode. Fingertip pressure upon grasp modulates the stimulation frequency in proportion to the pressure.

4. Our continuous microcomputer studies are directed toward
evaluating new devices capable of providing the requirements for the adaptive aiding control system as an integrated part of a self-contained externally powered prosthesis.

5. Packaging techniques for prosthesis hardware are being examined and developed. Several problems must be solved to yield a completely self-contained externally powered prosthesis, viz., power cell capacity and size, microcomputer and electronics, hardware weight distribution, skin electrode attachment, and harnessing.

Future plans include the integration of the various aspects of these developments into a self-contained, clinically practical prosthesis.

Design of Prosthetic and Orthotic Devices and Biomechanical Studies of Locomotion; Powered Reclinable Adjustable-Height Narrowing Wheelchair

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Charles W. Radcliffe, Don M. Cunningham, and James M. Morris, M.D.

Design and Development of Lower-Limb Prosthetic Devices

UC-BL Four-Bar Polycentric Pneumatic Knee

Amputee testing of the prototype-production models manufactured by Hosmer Corporation is continuing. Two successful fittings have been reported by VAPC. Seven units have been fitted in the San Francisco Bay Area. One unit has been supplied to the Biomechanical Research and Development Unit (BRADU), Queen Mary's Hospital, Roehampton, England, for functional testing and evaluation.

Initial amputee acceptance and durability of the units have been excellent. No mechanical malfunctions have occurred in 2 years of amputee testing. The alignment and assembly procedures as given in the instruction manual have been applied by the prosthetists without difficulty. The shank cosmetic cover and the knee-junction appearance will require continuing improvement but are considered satisfactory for initial production.

UC-BL Shank Axial-Rotation Device

The five laboratory-produced test units fitted in the San Francisco Bay Area have been in daily use for periods of up to 2 years. Amputee acceptance continues to be excellent.

Fifty prototype-production models have been purchased from U.S. Manufacturing Company with VA funds and are now available for extended clinical testing.

An installation manual and evaluation protocol have been prepared.
with VAPC assistance. Amputee testing will begin in early 1975 and continue into FY 1976.

This device was described in a paper presented at the World Congress of ISPO, INTERBOR, and APO in Montreux, Switzerland, during October 1974.

**UC-BL Six-Bar Linkage Knee-Disarticulation Prostheses**

A general review and consideration of linkage systems for prosthetic knee mechanisms for the through-knee amputee was presented at the Montreux World Congress.

Two distinctly different six-bar disarticulation units have been developed to working prototype stage. One contains a pneumatic swing control unit. The other, a much lighter version, may be especially useful for geriatric amputees, for whom the knee disarticulation has frequently been suggested.

**Tube Couplings for Modular Prostheses**

The need for a compact and reliable foot-to-pylon coupling for use with the proposed standard 35-mm. pylon tubing led to the design of an internal expanding coupling which has been described previously. Amputee trials of four of these devices during the past year have shown no malfunctions of any kind. Fifty preproduction units have been obtained by VAPC for extended clinical trials with the UC-BL Shank Axial-Rotation Device.

**Biomechanical Studies of Human Locomotion**

**Laboratory Instrumentation**

The Locomotion Laboratory has been developed to obtain previously unavailable experimental data on normal and pathological walking. Such data are needed for establishment of specific design criteria for prosthetic and orthotic devices, for analysis of gait dynamics, and for clinical evaluation of specific devices and disabilities. During this report period progress has been made in computer programs for more versatile graphic display of experimental data, in computer programs for input of telemetry data to the computer, and in instrumentation and computer programs for measurements of angular motions in the ankle complex. This last project represents substantial progress and will be described in more detail.

**Structure and Function in the Ankle**

A long-term goal of the Laboratory has been to obtain experimental
data which could advance our understanding of the interactive functioning of the several joints which make up the foot/ankle complex. Self-Aligning Goniometers have previously been developed in the Laboratory for two-dimensional measurements of knee and ankle angles, and for one-dimensional measurements of hip and knee flexion angles. These devices have been very useful for obtaining precise measurements of joint motions during walking. Based on experiences with these
existing devices, a new three-dimensional Self-Aligning Goniometer has been developed for detailed examination of ankle function.

**Foot-Ankle Goniometer**

The instrument is complete, as shown in Figure 1, and despite its unwieldy appearance has been found to be very practical for laboratory measurements. In addition, string-type goniometers have been built to record toe-out angles during the ankle measurements. Also complete is a computer program which transforms the measured angular motions into equivalent motions about anatomic joints. Under construction is a special manual goniometer which will permit rapid readout of the angular positions of estimated anatomic axes in terms of the original measurements in the instrument coordinate system.

Application of this instrumentation to a range of subjects representing a wide variety of foot structures from pes cavus to pes planus will begin in Spring 1975.

**Clinical Instrumentation**

A primary objective of the instrumentation development project is the transfer of useful laboratory measurement techniques into a realistic clinical environment whenever possible. This objective is being accomplished by specific projects in three areas. First, simplified versions of selected instruments are being developed for clinical use. Second, radio telemetry equipment especially suited to locomotion data gathering is being developed in collaboration with other research groups. Third, consultation in the development of practical instrumentation of clinical evaluation tasks is being provided to local research projects which have requested such assistance.

**Time and Distance Measurements**

Measurements of step length and step frequency are fundamental to any comprehensive study of walking. This subject was discussed in a paper presented at the Montreux World Congress. Simplified portable walkway instrumentation, which will permit measurement of these parameters on completely unencumbered subjects in many different environments, has been designed and is under construction. Local rehabilitation centers have expressed interest in assisting in clinical tests of this device.

**Angle Diagrams**

Cross plots of hip angle versus knee angle have shown great promise as effective displays for purposes of clinical evaluation. New portable
Other VA Research Programs

Instruments are under construction for immediate display of such diagrams for both legs simultaneously in a clinical environment. This portable display unit will be used with the latest version of the hip/knee Self-Aligning Goniometer. The new Self-Aligning Goniometer was described in detail in a paper presented at the Montreux World Congress.

Effect of the UC-BL Shank Axial-Rotation Unit on Selected Gait Variables

One of the principal uses of the Locomotion Laboratory is to provide gait measurements which can be used to evaluate the function of experimental prosthetic devices. During this report period, measurements were obtained for two above-knee amputees walking over a range of speeds both with and without the Shank Axial-Rotation Unit operating. These included measurements of linear and angular pelvis motions, axial rotation of both thighs, shank torque, and shank axial rotation. The measurements provided some unexpected results, which shed new light on the character of the stump/socket interface. These findings were presented in a paper at the Montreux World Congress in October 1974.

Evaluation and Further Development of New Designs for Back Braces

Semiflexible Body Jackets

The semiflexible body jacket made of laminated polyester resin (4110) with Fiberglas reinforcement was reviewed and evaluated by a subcommittee of CPRD at a meeting arranged by the National Research Council in Washington, D.C., on March 5-6, 1974. The results obtained were considered generally good, but the objection was raised that these jackets were expensive and required too much time to fabricate.

Other materials were then investigated. It was found that polypropylene jackets could be fabricated in less time, and the material was also considerably less expensive. Forty patients at the University of California, San Francisco, have now worn the new model. With proper selection of patients, results have been good.

A clinic on problems of low back pain is being held on Monday mornings at the University of California Orthopaedic Clinic. Physical therapists are giving a 3-day course of instruction to patients with this problem.

Mobility Aids for the Physically Disabled

All of the drawings of the U.C. PRAHN (powered, reclining, adjustable-height, and narrowing) wheelchair were completed. A complete set of Xeroxed master tracings was sent to Mr. Joseph Landi at the VA Hospital, New York, which provides supply services for the VA
rothetics Center. Included were complete details and dimensions, arts list, list of vendors, and an assembly procedure. Basically, this is the same wheelchair with identical functions as the 1973-74 version. However, many detailed changes were incorporated in the drawings to improve performance and simplify construction.

Immediate Postoperative Prosthesis Research Study;
Wound Healing
Prosthetics Research Study
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Amputation Surgery and Amputee Rehabilitation

The major and continuing contribution of the Prosthetics Research Study is in the area of amputation surgery and early rehabilitation. Clinical studies and objective laboratory tests are investigated to determine the need for amputation, the level of amputation, the surgical technique of the amputation, and the appropriate postsurgical environment to promote prompt, uneventful wound healing and early rehabilitation. A sizable and varied source of amputation surgery is required. This primary and major patient load is obtained at the Veterans Administration Hospital, Seattle, where the PRS staff directs the amputee service, together with the supervisor of the Veterans Administration Amputee Treatment and Prosthetic Center. During the current calendar year (1975) it is estimated that the PRS staff will perform 100 to 20 major amputations at the VAH, supervise and direct their in-hospital after-care, attend and direct approximately 50 amputation and prosthetic clinics involving many hundreds of veteran amputees, supervise and direct prosthetic and orthotic activities at the hospital based prosthetic-orthotic facility, and consult with other medical and surgical departments within the Seattle VA Hospital system. These services are provided under the PRS contract and involve no expense or outlay of funds by the hospital.

In addition to the amputation program at VAH, Seattle, selected additional patients from other services throughout the area (Amputee and Prosthetics Services, Childrens Orthopedic Hospital; Amputation Services, university affiliated hospitals, including the University Hospital, Swedish Hospital, Providence Hospital, and Harborview Medical Center) are included in the PRS research study protocol. These non-veteran cases are included only when they present some highly unique and specific research impact. All patients included in the PRS studies are recorded and coded on a clinical research protocol and are serially photographed. The VAH computer center is used for statistical data

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collection in our work. This documentation over the past few years has resulted in what is believed to be one of the largest completely studied groups of amputees in the world.

Current and ongoing research in amputation surgery and postoperative management is as follows:

1. The study of skin circulation and dynamic skin and limb blood flow relevant to wound healing and preoperative decision for level of amputation. This work applies particularly to the ischemic limb. In conjunction with the Department of Biomedical Engineering at the University of Washington, Schools of Medicine and Engineering, we are assaying skin circulation and skin blood flow using radio-active Xenon 133 gas administered percutaneously. Computer radioactivity readout is recorded at selected limb skin sites and under varying controlled degrees of externally applied pressure. Similar studies are conducted on the healed amputation stump at identical sites. This technique holds the promise of enhancing our knowledge of skin circulation and applying it effectively to preoperative determinations of correct amputation level. We also continue to use the more conventional and accepted laboratory and clinical means of assaying skin and limb blood flow. The combined protocol of Dr. Bok Lee, VAH, Castle Point, New York, is still available to us and used in selected cases.

2. Specific surgical technique, as it involves the appropriate location of the skin flaps, muscle management, bone level, etc., is modified on the basis of the information obtained preoperatively in the ischemic limb. The long posterior flap below-knee amputation is now accepted worldwide as a major factor in lowering the level of amputation to below the knee in the ischemic limb. Further surgical research of this type is being investigated and reported.

3. Postsurgical wound management study includes continuing appropriate modifications in the immediate postsurgical rigid-dressing prosthetic techniques developed in this laboratory, and more recently the controlled environment treatment (CET) chamber, jointly under study by ourselves and the British Research and Development Unit, Roehampton, England.

In March 1974 a BRADU-controlled environment chamber was installed at the VAH under PRS supervision. Thirteen below-knee amputations on veteran patients have been treated using this CET method. These data have been collated and jointly published with the Roehampton study group. As a result of a workshop held at PRS, February 1974, and attended by members of the Roehampton team and selected surgeons and engineers throughout the United States, five additional machines are now being installed in North America. One machine will be placed at the University of Washington, Department of Orthopedic Surgery, Seattle, under the direct supervision of PRS staff to be used f
asic research. The four additional units are located as follows: VAH, San Francisco, Calif. (Dr. Wesley S. Moore), Rancho Los Amigos Medical Center, Downey, Calif. (Dr. William Wagner), Duke University Medical Center, Durham, N.C. (Dr. Frank Clippinger), and VAH, Castle Point, N.Y. (Dr. Bok Y. Lee).

A 1-year study on the controlled environment treatment of selected limb wounds and surgery, including amputations, is now underway. RS will collect, refine, and evaluate data from all centers in this country. This information will then be jointly reviewed by the BRADU Roehampton group and ourselves, then published. This major research effort holds forth the prospect of radically improving postsurgical and posttraumatic wound care in many types of limb pathology.

4. A pressure transducer tensometer has been developed to measure certain physical aspects of wound healing across suture lines in amputations. This device is designed to measure edema and the developing tensile tissue strength in the healing wound. It will be used with conventional immediate postoperative prosthetic amputee management and in the CET chamber.

5. We continue to explore, modify, and perfect amputation surgical techniques, particularly related to muscle stabilization, improvements in the knee-disarticulation level, tibial-fibular synostosis, and initial electrode implant for myoelectric controls.

**Prosthetics Research**

Prosthetics Research Study is becoming increasingly active in the area of design and prototype fabrication of new prosthetic-orthotic aids, materials, and special devices, as well as special prostheses for individual cases. Several have been initiated by the Prosthetics Research Department and then designed and fabricated by the Bioengineering Department. The following projects are being conducted:

1. **Symes Alignment Device**

The Symes alignment device will be used to achieve the ultimate dynamic alignment for Symes amputees as it is designed to be an integral part of the prosthetic socket allowing angular changes in the sagittal and coronal planes. In the past, major problems occurred either with the foot or with breakage of the foot attachment bolt. The Kingsley Manufacturing Symes foot with aluminum keel has been redesigned to be used with the alignment device. The wood portion of the Symes foot was completely eliminated and replaced with a polyurethane flexible foam, thereby eliminating the possibility of degradation of the wood due to moisture, compression, etc.

The alignment device is lightweight, inexpensive, and has sufficient
strength to withstand the forces generated at the Symes level. It also allows for simple height adjustments from 1 to 3 in.

When maximum dynamic alignment has been achieved, the prostheses and foot are permanently attached with polyurethane rigid foam (density 10 lb./cu. ft.); thus the total prosthesis is completely waterproof, requiring no further finishing, i.e., lamination and attachment of the foot.

There are presently two prototypes in use and preliminary clinical evaluation is in progress. Evaluation will continue with additional Symes amputees participating in this study.

Termination of the project will be completed in 6 to 12 months with a minimum of six amputees being evaluated.

2. *AK Casting Brim Technique*

The use of the “old” immediate fit casting technique for above-knee amputees has remained a difficult and complicated procedure. However, the polyethylene (PE) brim used in fracture bracing has been substituted for the PRS, AK casting fixture (Fig. 2). With the PE brim it is possible for one person to apply an above-knee cast immediately following surgery and in subsequent cast changes with little or no difficulty.

![Figure 2.—New AK casting technique, showing brim and suspension system.](image-url)

The cumbersome belt and Bowden cable system required to suspend the cast has been eliminated. A suspension strap across the contralateral
shoulder of the amputee is now being used. An axilla pad, used in upper-limb prosthetics, allows the suspension strap to slide freely through the axilla pad, providing a pivot point that duplicates the previous Bowden cable system.

The new casting technique provides a lightweight rigid cast with improved suspension and minimal restrictions to the patient. The entire procedure is more economical, i.e., less plaster is used in the cast and the suspension strap is less expensive to fabricate.

Initially, 13 patients, one a bilateral, have been casted using the new system, with no resultant problems.

3. Phenolic Foot Attachment Insert

Reevaluation and redesign of the phenolic foot attachment insert was initiated to decrease the weight and increase the surface area of the insert. The redesign of the insert is to be used for all definitive prostheses of polyurethane rigid foam construction, resulting in a lightweight, waterproof prosthesis, thus eliminating the need for a second prosthesis for use strictly as a beach or swimming prosthesis.

At present there are 12 prototypes in use; some patients have had them for over 1 year with excellent results. This project will be continued on all PRS patients for clinical evaluation.

4. Child Prosthetics

Prostheses are fabricated for children with difficult levels of amputations or congenital anomalies. Each child who receives a prosthesis from PRS is interesting enough prosthetically to warrant publication of an article, possibly in I.C.I.B. One example is PRS# 592, a 13-year-old male with osteogenic imperfecta who underwent bilateral knee disarticulations. This boy had not been able to walk before his amputations; later he was fitted with "stubbies," and when he becomes proficient with these types of prostheses, he will graduate to articulated prostheses.

5. Extra-Ambulatory Prostheses

It is the practice and policy of PRS to make special prostheses for particular sports, hobbies, etc. Examples are ski prostheses, both water and snow, and swimming prostheses. These are to be made on an individual basis as each case arises.

6. Socket Suspension

a. Muscle grasping: A study of muscle grasping as an auxiliary or initial means of socket suspension is presently in progress. At this time,
after the initial report on muscle grasping and socket suspension, we have one patient using a PTS prosthesis with muscle grasping as the only means of socket suspension. This project will be continued to include several patients at the below-knee level.

b. BK suction socket: The PTB suction socket means of suspension is presently at a standstill with no patients using this particular type of socket suspension. One patient was fitted for an initial evaluation and results of that prosthesis are being evaluated for further use of this system. Patients for this particular type of prosthesis initially will be selected for stump characteristics, such as cylindrical stump with anterior suture line and muscle stabilization.

7. PRS-Moore Prosthetic Load Cell

Another aspect of wound management that has been under investigation for some time is the problem of preventing excessive stump weight-bearing. Previous audible warning devices have proved unsatisfactory due to overall size and weight. The PRS-Moore prosthetics load cell was designed to be a more practical and economical device. The load cell is now in regular use for all of our below-knee amputees, as well as beginning use on above-knee amputees (Fig. 3). The low cost (under $100), minimal weight (6 oz.), and small size, combined with the simplicity of operation, have made it successful for everyone involved.

Figure 3.—PRS-Moore Prosthetic Load Cell.
Patients know when they are exceeding the determined level of weight-bearing and can adjust their gait pattern accordingly; physical therapists in the hospital can work with other patients, yet still “hear” when someone is overdoing their weight-bearing.

It is hoped that in a short time we can make a few of these load cells available to other centers for further evaluation.

8. PRS-Moore Cast Load Cell

This device is a further refinement on the audible warning device or load cell. Size and weight are reduced so that the cell can be inserted inside a standard rubber heel of a fracture leg cast.

One prototype has been fabricated which demonstrated with minimal laboratory testing that the idea is workable. Further design work is needed, however, before clinical trials can be initiated.

9. Torque Absorber

This device is being designed to absorb the torque which occurs during the stance phase of the gait cycle. The primary difference between this unit and others is that varying amounts of torque can be absorbed, depending on the direction of rotation.

No prototypes have been fabricated as the device is still in the design stage.

10. Flexion Contracture Knee Joint

Two devices to eliminate knee flexion contractures are being designed. One will be passive, the other will be active.

At this time, one passive unit has been fabricated and used on a patient. Indications demonstrate that the passive joint will function as designed. As yet, the active unit is still in the design stage.

11. Prosthetic Education

A program at the University of Washington, entitled “Prosthetics Orientation for Orthopedic Residents,” is presently being organized in conjunction with the Chief of Orthopedics at the Veterans Administration Hospital, Seattle. The program will be designed to give the orthopedic resident a concentrated orientation into prosthetics with emphasis on biomechanics, kinesiology, management of the immediate fit prosthesis, and material necessary to familiarize the orthopedic residents with the types of prostheses currently in use. Initially, an orthopedic resident will spend a 2-week period at PRS, seeing patients daily, consulting on medical/prosthetic problems, managing patients, and attending amputation surgeries. This program will give orthopedic
residents a knowledge of the special problems of the ever-increasing population of amputees.

**The Use of External Electrical Energy in Neuromuscular Rehabilitation**

Prosthetics Research Study is actively engaged in electrical energy application to improve certain functional deficits and to relieve pain. These are as follows:

1. **Neuromuscular Assist**

   Prosthetics Research Study is one of several centers cooperating in a program to study neuromuscular assist through implanted electrical stimulation. Stroke or upper motor neuron injury patients who have sustained minimal damage to their peroneal nerve are included in the study. Our cases have remained low due to a limited patient population who fulfill this qualification.

   To date, we have implanted four units, two in stroke patients and two in upper motor neuron injury patients. No complications have been experienced with either implant procedures or patient tolerance; however, problems have been encountered with acceptance of the external hardware, which is cumbersome and uncosmetic. Updated NMA devices will soon become available, at which time we plan on doing an additional six more cases.

2. **Pain Abatement by Electrical Stimulation**

   Another area of functional electrical stimulation under investigation is pain abatement using transcutaneous nerve stimulation. No invasive techniques are used in this program. As the study is restricted to lower-limb amputees, only 12 patients with specific pain syndromes have been treated since October 1973. The pain control study is being conducted by utilizing a careful prestimulation workup, including psychological testing in an attempt to classify etiology, location, duration, and severity of chronic pain. We are attempting to determine an optimum stimulation regimen for each pain syndrome.

   Because of PRS's large patient population, cases will be continuously referred to this facility for alleviation of pain. After careful documentation by both the patients and PRS staff, all the data will be collected and a paper will be submitted for publication, reviewing the various pain syndromes encountered and treated.

3. **Osteogenesis**

   Pulsed electrical energy has been applied to two patients with comminuted fracture defects of the tibia to effect repair of the existing non-
union rather than to perform extensive bone grafting or below-knee amputation. Through careful clinical observation and frequent X-rays, significant osteogenic activity was demonstrated and was felt to be of primary importance in the healing process; however, the amount of response attributable to the electrical stimulation was undetermined. A combination of other factors, including time, cast immobilization, and minimal weight-bearing of 25 lb., may have had a significant influence on the healing rate.

No further studies have been conducted as we are awaiting design and fabrication of newer equipment; also, the patient population with this specific type of diagnosis is infrequently encountered. A preliminary report on this project has been submitted and accepted for publication in *Clinical Orthopedics and Related Research*.

4. **Surface Stimulation**

Cyclic electrical stimulation for muscle and joint rehabilitation has also been introduced as a research project at PRS. The purpose of this program is to assist in the rehabilitation process by activating muscles through stimulation of their motor nerves. Its possible areas of application include postsurgery, posttrauma, rheumatoid arthritis, muscle-tendon transfers, shoulder subluxation, cerebral palsy, and any other areas where electrical stimulation would assist in recovery or in rehabilitation of the patient.

To date, two patients have been treated by means of cyclic electrical surface stimulation. Both patients have evidenced marked signs of improvement over their previous physical condition, and have been very satisfied with the results. This system of rehabilitation together with physical therapy could begin a whole new era of rehabilitative medicine.

5. **Miniature Implantable Electrodes**

A study on electrode implantation for investigative purposes is being conducted as a cooperative project between PRS and the INSERM Biomechanics Unit, Montpellier, France. Electrodes have been implanted into major peripheral nerves on one below-knee amputee; several studies have been done using animals. This study is being supported by Research Center for Prosthetics, Department of Medicine and Surgery, United States Veterans Administration. For further information, see Professor Pierre Rabischong's studies in BPR 10-22, pp. 261-290.

6. **The Treatment of Scoliosis and Other Dynamic Spinal Deformities by Electrode Implantation and External Electrical Stimulation**

It is proposed that beginning during the current calendar year in
conjunction with Dr. W. Bobechko at the University of Toronto, School of Medicine, we will initiate a study on electrical stimulation of spinal muscles for paralytic and idiopathic spinal deformities. This will be under the specific direction of the Toronto workers and in cooperation with them based on their present protocol and accumulated knowledge.

**Affiliated Research**

PRS is involved in certain affiliated research studies (noncontract financed). These projects are centered at PRS but are independently conducted. They include:

1. **Chemonucleolysis**
   
   Approximately 1,000 patients treated for low back pain and leg pain with a drug known as chymopapain have been documented. Privately financed, this work was done in conjunction with other centers under the sanction of the FDA.

2. **ALP 501**
   
   We are now conducting a clinical evaluation of the Alternating Leg Pressure Unit, ALP 501, of which six units have been donated for research purposes. This device was designed to reduce or prevent all types of limb thrombosis by creating an alternating peripheral vascular pump with external application of a “boot,” contracted by air pressure, over both lower limbs before, during, and after surgery. This study is being confined to total hip replacement surgeries, with the units being used on an alternating patient basis. Results will be clinically evaluated on two groups, i.e., those using the ALP 501 and those not using it.

3. **Atlas on Orthopedic Appliances**
   
   The staff of PRS is editing a section of the Atlas on Orthopedic Appliances being published under the supervision of the American Academy of Orthopedic Surgery. A chapter has been written by the PRS staff and an entire section edited.

**Miscellaneous Projects**

Plans include the completion of the motion picture “Above-Knee Amputation: Surgical Technique and Post-Surgical Management,” and the revision of the monograph, “The Management of Lower Extremity Amputations.”
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

The Prosthetics Research Program at San Francisco Veterans Administration Hospital continues to expand its experience with xenon flow as an indicator for amputation level determination in patients with peripheral vascular disease. The minimum flow rate of 2.4 ml./100 gm. tissue/minute previously reported continues to be valid at the below-knee level. A limited experience with xenon clearance studies at the transmetatarsal and Syme’s amputation levels suggests that this value will also be applicable in preoperative determination of the suitability of these levels in patients with occlusive disease. As soon as more cases are gathered so that statistically significant data can be provided, further publication will be forthcoming.

This past year the program produced a motion picture film describing the technique of Syme’s amputation with immediate postoperative fitting of prosthesis. This film was shown at the 1974 Clinical Congress of the American College of Surgeons and has been subsequently selected for inclusion in the American College of Surgeons library.

The prosthetics research program at San Francisco Veterans Administration Hospital has just joined with Dr. Ernest Burgess for purposes of carrying out a joint evaluation of the Controlled Environment Treatment (CET) chamber developed at the Rehabilitation Unit at Roehampton, England. We intend to do a random study comparing the value of the CET unit with immediate postoperative fitting in the management of lower-limb amputees with peripheral vascular disease. Preliminary data from Seattle and Roehampton suggest that this unit may represent an advance in the immediate postoperative management of the geriatric amputee.

Interdisciplinary Development and Evaluation of Externally Powered Upper-Limb Prostheses and Orthoses
Applied Physics Laboratory
The Johns Hopkins University
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Woodrow Seamone and Gerhard Schmeisser, Jr., M.D.

During the latter half of 1974, research at Johns Hopkins was continued on the application of the external power pack to upper-limb orthoses as well as clinical followup on previously fitted powered prostheses. An experimental model of the powered manipulator, a machine with which to study the control interface problem for assistive devices
Other VA Research Programs

for the quadriplegic, was completed and initial laboratory tests have begun.

Since the VA program at JHU is now 5 years old and many of the early developmental models of externally powered prostheses and orthoses are still undergoing clinical evaluation, a 5-year review of clinical experience with these devices appears elsewhere in this issue of the Bulletin. Also discussed in the article is a summary of clinical determinants utilized in this program in the prescription of appropriate sensor and power unit for each case.

A summary of the status of the powered manipulator follows:

Experimental Manipulator System Requirements

In a continuing effort to determine the applicability of powered devices for the handicapped, the research work during calendar year 1974 at Johns Hopkins has included a look into the requirements and possible design concepts for powered devices which could assist a highly disabled person such as a spinal-cord-injury patient. One possible approach, fitting a powered orthosis to the upper limb of the spinal-cord-injury patient, was rejected because of the complex interaction with the patient's limb. The alternative, a remote powered manipulator, appeared to offer the most promise for a flexible machine with which to study control techniques and patient/manipulator interfaces.

The design rationale for this manipulator was aimed at providing specific functional capabilities to the highly disabled person who has little or no use of his arms and hands. These goals include:

1. Providing a capability for handling and reading magazines and newspapers.
2. Providing a capability for self-feeding with a spoon or fork (it is assumed that an attendant would bring the tray containing food dishes to the patient and would prepare the food in bite-size portions).
3. Providing the patient the capability to operate push-button devices, such as the touch-tone telephone, electric typewriter, desk calculator, and tape recorder, without equipment modification.
4. Providing an electrical multiple receptacle outlet box and, by the use of conventional push-type electrical switches, allowing the patient the capability of turning appliances and environmental controls on and off.

For the initial stage of development, it was decided to use common techniques and components from the Johns Hopkins power pack systems developed for the prosthetics and orthotics program previously reported in the Bulletin of Prosthetics Research (BPR 10-16 Fall 1971 thru BPR 10-21 Spring 1974). Such an approach would also allow successful features of the manipulator to be applied to powered orthotic and prosthetic systems as appropriate. In order to meet the system's functional requirements, the manipulator and work table were designed
s an integrated system to allow the patient to accomplish the desired task in a self-sufficient manner. Self-sufficiency requires that he must be able to carry each task through completion without additional assistance from other individuals. In the reading task, for example, the manipulator must be able to open up the collapsible book stand, reach for the magazine in the book rack, place it in position, turn the pages, and return the magazine to its original location when finished.

The work table-manipulator arrangement which appeared to meet these functional requirements is shown in Figure 4. Included on this work table is a touch-tone telephone, a magazine rack, and a collapsible book stand. A display panel provides cues to assist the patient in using the manipulator. Some of the more important design constraints for the manipulator include:

![Work table-manipulator arrangement.](image)

1. The control effort required to control the device must be within acceptable limits.
2. Output motions and force levels must be limited considering the safety interface between the patient and the machine.
3. The electromechanical design must be reliable and acceptably quiet.
Design Approach

A schematic diagram of the mechanical implementation for the powered manipulator is shown in Figure 5. The degrees of freedom for this system include:

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).

The physical motions and force capabilities of the system are shown in Table 1. These force levels, which result from use of the previously developed cable drive power packs, appear to be adequate for all of the tasks planned for the experimental model. A parallelogram linkage in the upper arm provides horizontal motion of the terminal device over a 10-in. stroke by use of shoulder flexion-extension.
The mechanical system is configured as a sequentially operating system. Only one degree of freedom may be operated at a time. Since proportional control is utilized, the desired motion may be accomplished in a smooth manner with precision. A schematic diagram of the system showing the motor-mechanical locking arrangement is given in Figure 6.

Control of the manipulator is achieved by first generating a pulse train of from one to four pulses to mode enable the desired axis of motion. This is then followed by proportional control of an input signal transducer which unlocks the desired axis of motion and then positions the...
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**APL/JHMI POWERED MANIPULATOR**

- **INPUT PULSES** → ENABLE LOGIC
- **CONTROL MOTION INPUT** → ELECTRONIC GAIN SHAPING
- **SWITCHING & POWER CIRCUITS** → POSITION INDICATOR
- **SOLENOID CONTROLLED LOCKS**
  - WRIST
  - ELBOW
  - SHOULDER
  - TURNTABLE
  - HOOK
- **MOVEMENTS**
  - SHOULDER EXTENSION
  - ELBOW FLEXION
  - WRIST ROTATION
  - TURNTABLE
  - HOOK

**MANIPULATOR SEQUENCE**

- **MUSCLE MOVEMENT CONTROL**
- **ARM MOTION**
- **CONTROL MOTION**
- **INPUT PULSES**

A single pulse stops the motion and locks the mechanism. Figure 7 illustrates typical control signal-motion interrelationships for a typical shoulder command. Input commands for the pulse train (mode enable command) in the experimental model are achieved by clicking the teeth. This motion is sensed by a small vibration transducer located in the eyeglass frame which converts the movement of the manipulator to its desired final position.
input to electrical pulses. Input commands for the proportional control signal are obtained from eyebrow motion utilizing a skin motion sensor or from any residual muscle capable of operating a proportional position command transducer. Various alternative transducer arrangements, including “puff and sip,” are under consideration for the pulse enable command and for proportional control. It is expected that individual patients may require options of different transducers in order to give the system maximum flexibility in the machine-patient interface.

Incremental position transducers have been incorporated in the mechanism to read out the position of shoulder extension-flexion motion and shoulder turntable motion. Numeric readouts of these functions on the display panel assist the patient in placing the manipulator in the desired position on the work table. Use of low-cost electronic comparator circuits allows conversion of numerics to other forms of display to further reduce the patient’s effort. Other electronic circuitry allow certain functions which are repetitious in nature, i.e., eating with a fork, to be sequenced programed. In this mode, the patient has complete freedom in his use of a fork near the plate, but converts to an automatic sequence of commands in the motions between the plate and the patient’s mouth. The patient maintains proportional control of the device, but does not have to generate command pulses. This mode of control simplifies the task of controlling the manipulator during the eating function. The automatic sequence also insure that the eating motions do not result in unwanted motions of the fork near the patient’s face.

Preliminary Testing of the Manipulator

The powered manipulator under development at Johns Hopkins has not yet been evaluated in clinical testing. Some preliminary testing has been conducted by test subjects, however, to verify basic functional capabilities of the system.

The powered manipulator is mounted on a 22 in. × 34 in. worktable as shown in Figure 4. The locations of the magazine rack, telephone, and other devices relative to the manipulator have been chosen to simplify manipulator motions and allow maximum flexibility to accomplish the desired tasks. Two or three magazines may be stored in the bookrack and may be transferred to the collapsible bookstand by the manipulator. A simple vacuum operated tool is used to turn the pages as can be seen in Figure 8. A touch-tone telephone and conventional electrical on-off switches are appropriately located on the worktable to be compatible with the manipulator motion capabilities. The numeric display assists the patient in placing the manipulator to the desired position with ease and precision. Experimental tests on this work table have demonstrated
that the manipulator can touch-tone dial a phone number as well as perform other functions, such as operating the electrical switches to remotely turn appliances on and off. The manipulator is capable of opening up the collapsible book stand, reaching for a magazine in the bookrack, placing it in position for reading, turning pages, and returning the magazine to its original location.

A quadriplegic, an engineer employed at APL, is shown with his wheelchair rolled up to the worktable in Figure 9. Control of the manipulator in this instance is achieved by use of the special eyeglasses worn by the subject. This man operated the equipment through its various modes, utilizing the teeth click as the pulse command and using either the eyebrow skin motion input or finger motion control of a position transducer for proportional control. He was capable of operating the equipment with either mode of control. A series of training sessions is, of course, required in order for the patient to gain ease of control and to develop skill in the use of the manipulator.

Bite size food may be eaten by the patient by means of the snap attachment of the appropriate utensil, such as a spoon or fork as shown in Figure 9. Use of wrist rotation and the parallelogram linkage motion results in smooth motion in the self-feeding function. The patient may move the fork or spoon in or out of the eating position by pushing the
utensil against a post on the worktable. Preliminary tests indicate the eating mode of the manipulator holds promise for self-feeding for patients who can provide the necessary control inputs. The eating task appears to be compatible with necessary control input requirements, such as the teeth clicking and proportional control inputs. The automatic sequence program under investigation for the eating function appears to materially reduce the patient workload, yet allow him adequate control of the device.

Figure 10 shows the manipulator worktable placed in position relative to a volunteer operator in a circoclectric bed. Tasks, such as reading a magazine, self-feeding, reading a newspaper, and typing, may also be accomplished in this bedside arrangement. Figure 11 shows the manipulator carrying out one of these tasks.

Future Plans

Additional work is required to bring a device such as the powered manipulator to a stage of development ready for extensive clinical trials. Preliminary testing in the laboratory has indicated the experimental model described in this report may accomplish the desired functional goals to give the patient some independence in certain tasks. The unit is quiet, reliable, and the patient is capable of positioning the terminal
Other VA Research Programs

**Figure 10.**—Powered manipulator and work table for circolectric bed.

**Figure 11.**—Using the powered manipulator for typing.
device to within less than 1 cm. of any desired position. Some preliminary work using position feedback displays indicates such displays appear to ease the patient’s task of placing the manipulator in a desired location quickly. Much additional work is required to determine optimal feedback or cues required to minimize the patient’s input effort.

Clinical tests are planned to determine the practicality of system principles. These tests are planned to be initiated during the early part of 1975.

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

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On September 30, 1974, the first Clinic for Special Problems of the Lower Limb was held specifically for patients to be evaluated for inclusion in the case study program for this research project. Since that time there have been four clinics of this type, with 23 patients included in this case study program.

The staff attending the Special Clinic includes two orthopaedic surgeons, two orthotists, one prosthetist, one C.P.O., one engineer, one nurse, and two photographer-secretaries. Patients were referred to this clinic through the VA Hospital in Miami, the VAPC in New York, various clinics at the Rehabilitation Center and Jackson Memorial Hospital, and private patients of local orthopedic surgeons.

Careful physical examination and functional evaluation by the entire team precede the decision to include or exclude each patient in the case study program. If a patient is included in the program, the team again collaborates to record a thorough detailed physical examination and technical analysis, device and functional analysis, and taking of photographs. Next the patient evaluates his existing device and function, and a file is made on each patient. Each patient file includes records on the following forms:

1. General Information Sheet
2. Medical History
3. Technical Analysis Form for Orthotics
4. Physical Examination Form for Prosthetics
5. Device Evaluation Form
6. Gait Analysis Form and Data
7. Envelope containing photographs of devices and patients

Followup on each patient is anticipated for a minimum of 1 year after fitting of the final device and completion of training. Device evaluation
Other VA Research Programs

by patient and clinic team, and gait analysis are performed at least every 6 months for original devices, subsequent devices, and no device. Photographs and dictation will be expanded on each patient for every clinic visit.

The 23 patients included to date in the program will continue to be followed in the Special Clinic. Present cases include:

1. 11 patients with lower-limb paralysis
2. 5 multiple amputees
3. 4 patients with lower-limb musculoskeletal deformities
4. 3 amputees with unusual stump problems
5. 23 patients

Three of these patients have since been eliminated from the program because they have either moved away, or could not be contacted for followup. Of the remaining 20 patients, 12 have been fitted with at least one device and are being followed, and the rest have devices in the process of being constructed.

Patients with two types of needs are included in the program: patients for whom no conventional orthotic or prosthetic treatment is available for even partial rehabilitation; and patients for whom available conventional treatment is suboptimal. New designs, new materials, and/or new applications of devices, as well as other aspects of total patient care, are instituted by the combined efforts of the team members to meet the special needs of the patients.

With only 23 patients, it is impractical to begin to categorize patients and devices with such limited data. However, new devices presently being designed and supplied show two major trends: in orthoses, the majority of the devices provide knee stability in stance phase while allowing flexion freely in swing phase. All designs utilize some type of thermoplastics, some in conjunction with metal components, others without. In prostheses, the major trend is to apply the air cushion socket to many new applications at all levels. Other concepts being developed are of importance but simply not of significant quantity yet. Examples include: new designs of self-suspending below-knee prostheses, new designs for the bilateral hip disarticulation prosthesis, floor reaction devices and free ankle-subtalar control devices utilized in conjunction with thermoplastic orthoses, and new designs in single-upright orthoses.

Immediate Postoperative Application of Upper-Limb Orthoses
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No report was submitted by this contractor for this report period.
The Improvement of Assistive Systems Through Research, Design, Clinical Testing and Team Evaluation
Texas A&M University College of Engineering
Bioengineering Program
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Paul H. Newell, Jr., Ph. D., and Lewis A. Leavitt, M.D.

During the reporting period (July 1 – December 31, 1974) project accomplishments have included:
1. testing of automobile/driver braking performance using hand controls,
2. completion of experiments comparing isotonic and isometric joysticks for use by the disabled, and
3. continued development and testing of van systems for wheelchair-bound quadriplegics.

The tests of braking performance using hand controls demonstrated that the important parameter is the arm strength of the driver. As previously reported, braking reaction times for hand control users are less than those for foot operation. As would be expected, braking performance tests indicated that if comparable force can be applied to the brake pedal, performance will be equal or better for hand control users. The required force at the hand control is 40-50 lb., varying with the mechanical advantage incorporated in the design of the particular hand control.

A series of experiments was conducted which indicated that an isotonic controller (joystick with constant force but variable displacement) is better than an isometric controller for use by the target disabled population in performing a proportional control task. Results of this experiment were presented at the Fall 1974 Annual Conference on Engineering in Biology and Medicine. This result influenced the choice of an isotonic controller for the steering, braking, and acceleration functions in the van being developed by the project. Two versions of a joystick-operated servo control system for steering a van have been built and tested. One system is a position controller with vehicle front wheel turn angle proportional to joystick deflection; the other system is a rate controller with vehicle front wheel turning rate proportional to joystick deflection. Driving tests showed the rate control system to be superior, since the high gain required by the position control system made small steering corrections very difficult. Current and future development is being concentrated on the rate control system.

Control of an Artificial Upper Limb in Several Degrees of Freedom
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During the second half of 1974, work on the present project of controlling an upper-limb prosthesis for above-elbow amputees in several degrees of freedom has been concerned with two major aspects. The first was related to the toe-actuated above-elbow prosthesis, and the second was related to the EMG-actuated system.

The basic above-elbow, toe-actuated prosthesis providing control of independent power actuation of three degrees of freedom, namely elbow, grasp, and wrist functions, each in two directions and with simultaneous grasp/wrist and grasp/elbow functions (plus certain proportional speed control), has been completed. It has subsequently been fitted to an amputee at the Prosthetics Treatment Center of the VA Wadsworth Hospital in Los Angeles, California (Fig. 12 and 13). The prosthesis is presently undergoing evaluation in Los Angeles.

Modifications to enhance reliability, to simplify training, and to reduce size and weight were performed since. These have resulted in all electronics and batteries being fitted in the upper arm (Fig. 14 and 15) rather than in the belt pocket as shown in Figure 13.
FIGURE 14.—Modified version of AE prosthesis—electronics and batteries in upper arm.
First reports of these tests appear to be very encouraging, especially noting that a bilateral amputee has been fitted who cannot substitute prosthesis functions by a healthy limb, and whose amputation took place over 30 years ago. Extensions of the design tested as above-elbow to shoulder-disarticulation cases and to amputees also having a foot disability are under way. Extensions to a two-artificial limb system for bilateral amputees will also be performed (note that the present bilateral amputee was fitted with our system on only one arm). These extensions are based on either a pure toe-actuated design or on a combined toe actuation and EMG actuation.

Our work on an EMG-actuated multi-degree of freedom above-elbow prosthesis has progressed from the stage of testing the function separability via our identification parametric pattern recognition approach, to the design of the controller. Also, initial design of the microcomputer-microprocessor hardware to perform the separation of the functions involved is now complete. Furthermore, we have now received the microprocessor hardware programing system such that the setting of microprocessor hardware according to our programs is possible. We have also written and tested our identification and recognition programs in the actual microprocessor language. As stated above, this approach should serve either as a pure EMG-actuated system or as a part of a combined EMG/toe-actuated system with five to six degrees of freedom.

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

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

Acceleration of Bone Healing by Electrical Stimulation

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Work has continued on our project to develop practical clinical methods for acceleration of bone healing by artificial electrical stimulation. Utilizing a defect in the dog ulna, created surgically, as a model for nonunion, we are attempting to alter the course of healing by means of appropriate electrical stimuli as delivered by implanted electrodes and electrical circuits.

Two important liaisons have added strength to our program this year.
irst, in working with Dr. Richard Pierson of the Department of Nuclear Medicine at St. Luke's Hospital Center, we are attempting to quantitate one formation in our test lesion by means of Technetium-99m. Second, working with Mr. Richard Derman, bioengineer at Helen Hayes Hospital, West Haverstraw, New York, we are measuring certain passive electrical properties of bone defect in order to better design circuits for stimulation. This work has technical support from the Center for Biomedical Engineering at Rensselaer Polytechnic Institute.

Implants were placed in 12 dogs during the second year of this project. During this year, a new series of stimulators and electrodes was designed by Avery Laboratories in an attempt to improve the reliability of technical failure, and a high rate of wound infection continued to mit significant results. Further development of equipment and techniques has taken place and steps are being taken (described below) to reduce these problems in the remaining animals to be tested during the remaining contract period.

Analysis of results has continued to be primarily by specimen X-ray and histology. Utilizing funds from Health Research, Inc., at New York state, a fully equipped histology laboratory has been installed at Helen Hayes Hospital and as of April 1975, preparation of histological specimens is now being accomplished there rather than with borrowed equipment at St. Luke's Hospital.

As yet, gross healing of test defects as a result of applied electrical stimulation has not been demonstrated. Nevertheless, evidence from specimen X-rays and histology (as yet incomplete on all animals) continues to demonstrate a beneficial effect of the electrical stimulation in selected cases. In addition, continuing reports from other investigators support the concept of developing electrical stimulation as a valuable clinical tool. Further laboratory development is still needed before clinical application of these techniques.

Important progress has been made in two basic areas:

1. **Determination of Electrical Characteristics of Bone Defect-Electrode System.** In nearly all of the test animals in this series, impedance measurements were made between the electrodes in control and active legs, both at surgery and at sacrifice. From these measurements phase-angle relationships between capacitance and resistance at various frequencies have been calculated. Further tests, now being completed, will distinguish between electrode effects from tissue effects.

2. **Development of a Technique for Monitoring Bone Healing by Means of Technetium-Diphosphonate Radioisotope.** This project has been carried out with the cooperation of Dr. Richard Pierson and the Department of Nuclear Medicine, St. Luke's Hospital. Eight dogs in this series have been scanned with the gamma camera over the nonunion site following injection of this isotope. Although results are as yet incomplete, a com-
puter technique has been developed whereby selected sections of the
dog's forelimb can be evaluated quantitatively for isotope retention.
This may provide an important index of local blood supply and/or bone
formation relevant to evaluation of nonunions and fractures, whether
treated by electrical stimulation or conventional techniques.

These results will be of use in two major areas. First, the basic data on
electrical characteristics will be of great value in designing better, more
effective stimulators. Second, results may provide a measure of the
long-term effects of electrical stimulation. Certain animals have shown
gross changes in electrical characteristics of the stimulated limb at 6
weeks. Correlation with histological findings, when complete, may show
that these measurements not only provide clues to the physiological
effects of electrical stimulation, but also serve as an important method of
monitoring bone formation.

Future Plan

Six additional animals will be studied in the remaining contract
period. Up to the present, electrical stimulation has been applied im-
mediately during the operation to the lesion created and then continued
for 6 weeks postoperatively. Although satisfactory results have been
obtained in some cases, there have been many failures due to technical
malfunctions and/or infection. This problem was compounded by the
necessity for multiple anesthesias necessitated by serial scan studies
utilized to develop the technetium-diphosphonate radioisotope uptake
evaluation techniques. In general, results to date indicate that it is
doubtful that the electrical stimulation has a significant effect during the
first 2 weeks of healing.

In two animals, an attempt was made to apply stimulation 6 weeks
after creation of the bone defect utilizing electrodes implanted at the
original operation; these experiments failed for technical reasons re-
lated to electrode leads.

The next six dogs will be treated in a different manner in order to
better simulate application of electrical currents to potential nonunions
and to reduce the incidence of failures due to implant failure and/or
infection.

The test lesions will be created in dogs bilaterally in the usual manner,
but no electrodes or stimulators will be implanted. These units will be
implanted at 2 weeks, and the dogs sacrificed after 6 additional weeks.
This procedure will reduce the incidence of infection since the electrode
units will not be implanted in a large wound "dead space."

Furthermore, Avery Laboratories has been informed of the defects
remaining in stimulator design and is correcting these before supplying
the units to be utilized in this series of experiments. Batteries will be
installed just prior to use to avoid wear during storage. Then each unit, prior to gas sterilization will be tested for output after functioning across a suitable load for 72 hours in saline at 38 deg. C. Utilizing ECG skin electrodes, monitoring stimulator function at weekly intervals will be attempted.

By these techniques, it is hoped that significant results can be obtained on these animals which will permit more effective design of new experiments.

**Publications**


**Hemodynamic Evaluation of Postoperative and Preoperative Amputee**

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During the past 6 months, attention has been focused on the three primary objects of this study: 1. Hemodynamic profile of pre- and post-operative amputees, 2. long-term and short-term effects of lumbar sympathectomy, and 3. effectiveness of the program for selection of amputation level.

All amputees listed in the vascular registry are now completing a hemodynamic evaluation which will be followed by a review of all test data acquired for these patients during the past 2 years. From the analysis, it is anticipated that answers to several questions will be obtained: What precise information does a hemodynamic evaluation provide with respect to a patient's vascular status? What is the contribution of this quantitative data to the establishment of the predictors of peripheral vascular disease? How will continued use of the evaluation contribute to improved diagnosis, prognosis, and treatment of the patient with vascular disease?

In preparation is a summary of observations made on patients who have received a lumbar sympathectomy. Over a period of 10 years, 340 sympathectomies on 250 patients have been completed in the surgical service. The implications of this procedure for the peripheral vascular patient are being reviewed. Of particular interest are the long-term effects of the procedure.
Currently available in the Vascular Clinic are test data folders for 236 patients with peripheral vascular disease who have returned to the clinic for repeated testing during the past year. These data are expected to form the core data for the computerized vascular registry. From this material it is anticipated a classification of the patient population will be obtained.

Efforts for determining the optimal level for amputation are continuing. The use of appropriate test procedures which include segmental surface temperatures, pressure gradients, and impedance waveforms, do aid in successful decision making with respect to amputation level.

Maxillofacial Restorative Biomaterials and Techniques
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In support of the Clinical Center that has provided 114 maxillofacial reconstructions in the past 18 months, the primary objective has been development and standardization of medical grades of polysiloxanes replicating or conforming to the initial tactile quality of physiological tissue as determined by conventional stress-strain profile and the principal tensile constants namely (a) initial modulus for feel, (b) tensile strength for durability, and (c) tensile elongation with low stress for facial function such as eating, talking, etc. The stress-strain profiles of selected and identified polysiloxanes, some of which are already used in surgical applications, are illustrated in Figure 16, compared with one example of highly compliant and extensile tissue (muscle fiber).

The graphic illustration serves to point out that the steep slope synthetic prosthesis, which patients regard as too stiff, has to be modified to a low stress profile that would respond more nearly like a living tissue. Silastic 382, a room-temperature vulcanized (RTV) grade of polysiloxane elastomer, is too stiff with an initial tensile modulus of 280 lb./sq. in., but by formulation with low molecular weight components, such as used for sealants, a more compliant prosthesis can be produced with 1/3 (90 lb/sq. in.) the initial modulus. This modification, now in general use with current patients, involves some trade-off with lowered strength and elongation. This example illustrates the possibilities of attempting to replicate a specific human tissue, at least over an important range.

Moreover, an additional attribute terminal strengthening also tends to accomplish the replication to living tissue, especially to increase the tear or pulling strength of the prosthesis. The living tissue as a model stress-strain profile is an excellent example of resisting tearing with a sharp rise in stress toward the end of the strain. A ratio of strength (S) at failure to initial modulus (M) is a simple numerical way, expressed as
S/M quotient, of ascertaining this tear-resistant attribute.

In general, the RTV Silastic 382 formulations give an S/M range of 2 to 3. By using a heat cured (HTV) series identified as MDX 44514, -5, and -6, it has been possible to attain S/M quotients as high as 6–8, thereby making available a second generation of candidates as base elastomers for prosthetic reconstructions. The MDX series now provides a softness or compliance to a modulus level of 60 lb/sq. in., at the same time being stronger and more stretchable than the RTV formulations. The results of these efforts have been proposed to the American Academy of Maxillofacial Prosthetics for more general acceptance as a standard material for tactile specifications.

Colorants

An important facet of assuring a durable prosthesis, in progress with
the above, is the standardization of colorants and their spectral indices. This effort is now ranked high in our research since it has been observed that marked changes, including fading and loss of or change in original color, become evident generally after about 6 months of wearing, or even less when cleaned by as yet nonstandard cleaning procedures. A standard color difference meter is now being used to develop data on the loss and changes in color in relation to chemically defined pigments used for base coloration and for extrinsic matching; this would especially note their susceptibility to light, atmospheric contaminants (nicotine from smoke, acid fumes, etc.), and cleaning solvents and detergents.

Adhesives

A third facet of the research is selection or development of reliable, nonirritating adhesives which are easy to remove and reapply. For adherence a tensile pull test is being used to develop force levels on the elastomer-adhesive-skin systems (simulated, and later actual tissue) correlated with identity of skin exudates, using gas chromatography and infrared analytical techniques as interferents that impose loss in adherence.

As with the colorants, there is yet to be developed some standard test and identity methodology to serve the ever-growing patient input to the maxillofacial reconstruction program of this Center. This implies providing chemical and physical identity and specifications in line with FDA regulations for safety and efficacy.

Permanently Attached Artificial Limbs
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Introduction

In order to obtain a functional permanently attached artificial limb, three tissue interfacing requirements must be met, and the materials selected must likewise have the strength and durability to perform the tasks of a weight-bearing limb. The most important of the tissue interfacing requirements is with the skin, because it is here that bacteria gain entrance to the implant site. Once infection occurs, the entire implant must be removed as there is no other way of controlling the infection.

The second most important tissue interface is between the bone and whatever foreign material that lies adjacent to it. Many authorities feel that in order to attain long-term stability in any orthopedic implant, it will probably be necessary for bone to grow into or become otherwise attached to the surface of the material. Porous material made of ceramic,
lastic, or metal seems to offer the greatest promise at present. The last tissue interface to concern us is the musculotendinous portion of skeletal muscles. In order to couple the skeletal muscles to a permanently attached artificial limb, it seems desirable to attach an artificial tendon to the muscle and to bring the artificial tendon out through the skin. Here again, it is of primary importance to have proper skin interfacing. Also, simple suturing of an artificial tendon to the muscle would be of only short-term value and destined to tear out. A new technique for attaching an artificial tendon to the muscle will be escribed in the body of this report.

**Skin Interfacing. Techniques**

Many materials have been implanted and evaluated for skin interfacing. Materials to be tested were first bonded to solid Silastic rods and after sterilizing they were implanted into the dorsum of canines, goats, and swine. These were observed and photographically documented periodically prior to subjecting them to excisional biopsy. Thin sections were then cut and stained for microscopic evaluation. The following table shows the materials that have undergone such valuations and the results:

<table>
<thead>
<tr>
<th>Material</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pylon and Dacron velour</td>
<td>Excellent, only problem is eventual extrusion of rod—“Growth Phenomena.”</td>
</tr>
<tr>
<td>Polypeptide with rough cast</td>
<td>Good for short-term usage but is biodegradable.</td>
</tr>
<tr>
<td>surface or nonwoven fabric</td>
<td></td>
</tr>
<tr>
<td>Polyurethane foam</td>
<td>Good for short-term usage but not as predictable as nylon velour.</td>
</tr>
<tr>
<td>Nylon foam</td>
<td>Poor. Probably due to closed cell construction of foamed material.</td>
</tr>
<tr>
<td>Vitreous carbon buttons</td>
<td>No wound infections seen, but excisional biopsies demonstrated complete marsupialization of implant.</td>
</tr>
<tr>
<td>Solid uncoated Silastic rod</td>
<td>Sinus tract invariably formed. Could always be easily withdrawn if retaining suture was removed.</td>
</tr>
</tbody>
</table>

This study was supported by research contract NIH-70-2109, National Institute of Arthritis and Metabolic Diseases.
In general, foams were felt to be less predictable than the velour fabrics, probably due to the numerous dead spaces which are prone to become a nidus for infection. Although carbon buttons cause no tissue reaction, they exhibit no actual adhesive bond to epithelial tissue, and in our experience are always marsupialized. Because of this, they probably have no place as a skin interfacing material, with the possible exception of implanted skin electrodes. Currently, this leaves the velour and felt fabrics as the most appropriate materials to solve these problems.

It should be noted that porous ceramics have been advocated as a skin interfacing material by Hulbert, Klawitter, and others. Although we have had no experience with porous ceramic other than as a bone interfacing material, we would anticipate problems due to an impedance mismatch and dead spaces similar to foamed plastics.

As noted in the above summation, velour fabrics have specialized problems of their own. Epithelium coming in contact with nylon or Dacron velour appears to satisfy its desire to join other epithelial tissue. A tenacious, mechanical-chemical bond made between the basal epithelial layer and the velour is kept as a permanent “marriage” during the maturation and migration of the individual epithelial cells. This results in a “growth phenomenon” causing the velour to migrate with the maturing epithelial cells. This growth phenomenon is more noticeable on the dorsum of the test animals than on the ventral surface or on the limbs. This is probably due to a difference in the maturation rate of one anatomical site as compared to another.

II. Bone Interfacing Technique

Early work at this project discounted the importance of this area of research. Progress in the development of a permanently attached artificial limb has been impeded by this problem area more than any other. Early implants were made of 316 stainless steel or Vitallium having a sandblasted surface. These implants consisted of a metal rod having a bonded plastic pedestal affixed near the distal end. Nylon velour was bonded to the surface of the pedestal which now served both as a surface to which the skin could adhere and as a weight-bearing surface for the forces transmitted through the amputated distal end of a goat’s tibia. Each rod was of about 5 in. length and ¼ in. diameter.

Models having only the bare metal interfacing with bone have sometimes been cemented in place during implantation using methylmethacrylate bone cement (Surgical Simplex-P, North Hill Plastics Ltd., London, England). For short periods of time, this method was quite satisfactory. However, for permanency it is felt that actual bone ingrowth into a porous surface will prove to be optimum.

Metallic rods holding porous ceramic (aluminum oxide) sections were used during the preceding 12-month period. Although bone ingrowth
could be demonstrated, the ceramic sections proved too weak to support the stresses applied by the animal. All of our experiments have utilized goats as the animal model. These are very active animals capable of withstanding not only the strength of the implant but also the patience of the investigator.

More recently employed was a surface of porous polymethyl methacrylate bonded to intramedullary rods of stainless steel, Fiberglas composite (Wonderrod-Shakespear), or carbon fiber composite (HMG-Fenwick). 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. The polymer salt mixture was cast onto the rod (steel, Fiberglas, or carbon composite) which provided the mechanical and structural base for the implant. Urea microcapsules (a commercial fertilizer) are being used currently in place of the ascorbic acid crystals as the extractable material. Spherical pores having a diameter of 300-600 μ are thereby created.

After casting the polymer-urea mixture onto the rod surface, the rod is placed in a lathe and turned to proper dimension. The implant is then soaked in water to remove the urea, leaving spherical voids permanently cast in the polymer's surface. The completed implant is gas sterilized and allowed to outgas for at least 72 hours prior to implantation.

While the animal is still under anesthesia, the amputated stump is sprayed with Furacin and dressed with a sterile dry dressing. A short pylon is then bolted to the exteriorized skeletal extension. We had previously used a machined aluminum pylon having a rubber stopper on its tip which served as a shock absorber and hoof. Problems arose relating to shock forces being transmitted to the intramedullary rod. Because of these problems we had advocated designing a hydraulic external unit. This problem was solved by using a shorter pylon having a stiff, high-pressure reinforced rubber hose clamped to its distal end. This appears to have answered that particular problem in a very economical way. Figure 17 illustrates a permanently attached artificial limb in place.

III. Tendon Interfacing Technique

The third interfacing problem has to do with connecting the existing skeletal muscles to an exteriorized joint. This involves the use of an artificial tendon coupled to the musculotendinous portion of the muscle, exiting through the skin, and connected to the external joint. The foregoing sentence glibly glides over three rather sticky problems. Coupling an artificial tendon to a powerful skeletal muscle requires some heretofore undeveloped surgical techniques since simple sutures would pull through and tear the tissue to which it was anchored. Bringing an artificial tendon through the skin so as not to be conquered ultimately by
Infection is likewise not a simple maneuver. Finally, there is the problem of linear motion of the tendon necessary for its very function.

We have constructed an artificial tendon starting with the commercially available device manufactured by Dow Corning. This consists of a narrow strip of Dacron tape covered with Silastic. These are cut into 6-in. segments, one end of which is bonded to a 1½-in. × 1¼-in. rectangle of nylon velour. This will eventually be used to create a large surface area for tissue ingrowth from the muscle. Forces transferred from the skeletal muscle to the artificial tendon are thereby distributed over a wide surface area and are less likely to tear through the tissues.
Near the point where the artificial tendon exits through the skin, a ball of 5/16 in. diameter is formed using Dow Corning’s Medical Adhesive, Type A. Nylon velour covers the surface of the ball and for a short distance on the artificial tendon toward its distal end.

During the actual operation, the artificial tendon (complete with its velour coatings) is first sutured to each head of the bipenniform Achilles tendon, thus forming a velour sheath circumscribing the Achilles. A stab wound in the skin allows the narrow artificial tendon to penetrate the integument but the 5/16 in. velour coated ball is impeded from exiting the small stab wound. As previously described, the skin grows into the interstices of the velour creating a bacterial barrier around the artificial tendon.

With the initial incision, the skin is divided between the tibia and the Achilles tendon. When these wounds are closed a pantaloon-type construction is created. The skin tunnel, which forms one leg of the pantaloon, acts somewhat like a bellows which takes up the slack as the muscle shortens. This creates a skin flap which allows the artificial tendon to have a method of shortening and elongating its length without actually sliding through a skin opening. This could be termed a modified cineplasty.

The musculotendinous attachment to the artificial tendon has been tested as a complete implant (i.e., without exiting through the skin) in one animal which is now over 1 year postoperative. This animal possesses no discernible limp and is as agile as she was before her surgery.

**Progress to Date**

Twenty-six goats have had the tibia amputated and have had one form of the aforementioned skeletal extension models implanted. The longest surviving model of 14 months used a Vitallium rod cemented into the intramedullary canal with Surgical Simplex-P. All of the ceramic implants crumbled under the complex forces transmitted to the implant by an active animal. One of the Fiberglas rods, one carbon fiber composite (not the HMG-Fenwick), and one Vitallium rod broke at or near the pedestal junction. These could all be attributed to iatrogenic defects created during fabrication.

Seven additional animals have had the tibial prosthetic implant plus the tendon implant. These are late experiments and only one animal has had the articulated extension bolted to the stump and the artificial tendon coupled in place. It took 3-4 days before any significant weight could be borne by the animal. Just as the animal was beginning to trust the appliance, the tendon pulled loose from the muscular attachment. This particular model had the velour sutured to the artificial tendon, and these sutures gave way leaving the velour behind still attached to the muscle. We have since bonded the velour to the artificial tendon using
Dow Corning Medical Adhesive, Type A. Two of these animals were described earlier as having broken the intramedullary rod. Four animals remain to be tested. These four animals have a simple pylon bolted to the extension allowing them to remain quadruped. After a healing period of 6 weeks, we will couple the tendon to an articulated limb.

**Mobility Aids for the Severely Handicapped**

**Mobility Engineering and Development, Inc.**

7830 Paseo Del Rey

Playa Del Rey, California 90291

Charles M. Scott

Mobility Engineering and Development, Inc., is concentrating on two major projects during this period—the high performance adjustable-height driver’s seat base unit and a compatible safety seat for the quadriplegic driver.

**Base Unit**

A working prototype model of the base unit has been completed and has undergone preliminary powered tests. The four point Elastomeric Torsion suspension system gives an exceptionally smooth ride over even fairly rough terrain. Very little shock is transmitted to the seat. Friction-type shock absorbers are being modified for application to control pitch and bounce. Roll is well controlled by the fore and aft torsion bars.

The power control system is smooth and responsive with excellent constant speed control and good dynamic braking characteristics. The integrated power steering system is not yet functional. Breadboard tests look very good and full system tests will be done shortly.

Production drawings are nearing completion. Fabrication has been started on a lightweight production prototype which should be completed in about 60 days. This unit should be fully operational and allow initial patient testing and vehicle entry.

**Seat Design**

Two molded seat modules have been prepared providing more erect posture and greater seat width with variations in the seat length. They are being tested by various quadriplegic drivers for long-term comfort.

The custom molded cushion system does not appear to lend itself to easy modification to the high back seat without extensive tooling.

A new source has been found for a filled foam cushion material with some very interesting properties. Viscous flow with delayed recovery makes it by far the most promising material so far examined. Tests with two patients using earlier sample material indicated greater comfort on a 1 1/4-in.-thick cushion than previously obtained with 5 in. of regular foam.
Sufficient material has now been ordered to fabricate a one-piece cover for the contoured seats and for additional tests as regular seat cushions.

Spinal-Cord-Injury Studies: Paralysis, Spasticity, and Pain
Veterans Administration Hospital
1201 N.W. 16th Street
Miami, Florida 33125
John W. Gesink, Ph. D. Michael Rosen, Ph. D.,
Eric Falkenberg, and Jorge D. Jacobi, M.D.

During this report period, effort has been devoted to a number of projects with reportable progress occurring in the following areas:

Electronic Gait Assist Device

Development of a prototype gait assist device for patients with paraparesis is continuing. Delivery of a noxious electrical stimulus using surface EEG electrodes placed on the peroneal nerve near the head of the fibula triggers the nociceptive reflex, producing ipsilateral knee flexion and contralateral knee extension. Both of these, if triggered at the proper moment, act to enhance gait. The current prototype, which uses heel switch closure as a trigger, is prone to false triggering in some situations. An alternative triggering scheme which uses a finger-controlled trigger switch mounted in crutch handles is being investigated.

Wrist Orthosis for Management of Tremor

Initial phases of the development and evaluation of a viscously damped wrist orthosis for management of tremor are nearing completion. Results are encouraging. In some tasks, the orthosis is effective in reducing intention tremor by 75 percent. Investigation of improved methods of evaluating the effectiveness of the orthosis, including power spectral density analysis, is proceeding. Also, development of an orthosis which incorporates a commercial rotary damper into the hinge of the orthosis is being carried out.

Investigation of the Mechanism of Spasticity

A study is underway to determine the mechanism of spasticity in experimental animals. Specifically, we intend to produce long-term, nondestructive, reversible spinal cord conduction blocks in order to make it possible to distinguish between the effects of descending fiber death and interruption of descending activity. To this end, technique is being developed to provide sustained extradural anesthetic release from a silicone collar implanted around the spinal cord. We have demonstrated in several experimental cats that the surgical manipulation of the
Other VA Research Programs

cord necessary for such an implant and for the introduction of chronic sacral root electrodes produces little clinically apparent deficit. In addition, one cat has endured 5 weeks with an inert silicone implant without functional loss. Silicone samples have been prepared with various proportions of elastomer, thinning fluid, and catalyst in order to optimize curing time, mechanical characteristics, and drug-incorporation properties.

The H-Reflex as a Titration Indicator During Phenol Injections

The H-reflex is being used as an indicator in the titration of 5 percent phenol injections for the relief of spasticity. The phenol is injected into a nerve (e.g., the ulna or radial nerve for spasticity or contractures of the hand) with the intent of selectively destroying the relatively thin gamma fibers. A certain amount of phenol may adequately inactivate the gamma fibers; more than that amount may also have the undesirable effect of destroying the larger alpha motor and Ia afferent fibers. By monitoring the H-reflex produced by stimulation at a site distal to the point of injection, any effect of the phenol on the Ia or alpha fibers may be observed as a change in the H-reflex.

Initial work has demonstrated that the H-reflex in the lower leg is blocked by injection of phenol into the sciatic nerve at a midthigh location. These results were obtained in primates since, at present, there are no patients in the Spinal Cord Injury Unit requiring phenol for the management of spasticity. Two trials on humans were run using 1½ percent xylocaine (which has the same effect as phenol but lasts only hours as opposed to months). The results showed that the approach is feasible and that undesirable blockage of nerve conduction can be monitored.

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

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

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.