HIGHLIGHTS OF OTHER VA RESEARCH PROGRAMS

PROSTHETICS

Edited by

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Prosthetics, Orthotics, and Sensory Aids Research Services
Committee on Prosthetics Research and Development and
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Committee on Prosthetic-Orthotic Education
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During the period July 1 to December 31, 1973, the ongoing and highly productive system of workshop panels sponsored by the various subcommittees of the Committee on Prosthetics Research and Development/Committee on Prosthetic-Orthotic Education was continued. At the same time, a wide variety of new projects was undertaken or old activities expanded. Events occurring during the reporting period were:

Subcommittee on Fundamental Studies

Because of the high level of interest and activity generated as a result of the Workshop on Fundamental Studies on Internal Structural Prostheses held in April 1972, a further workshop focusing solely on internal knee prostheses is being considered. A planning committee met in Miami, Florida, on December 13, 1973, to discuss details of the proposed event.

Control of the Environment in the Operating Room

CPRD has been invited by the American Academy of Orthopaedic Surgeons to organize and co-sponsor a symposium on Control of the

Operating Room Environment. Preliminary discussions concerning the appointment of a steering committee to plan this event have been held.

Subcommittee on Child Prosthetics Problems

Children's Orthopedics

CPRD has been invited by the International Society for Prosthetics and Orthotics (ISPO) to conduct three meetings related to children's orthopedic problems and their treatment:

Mobility aids for children with myelomeningocele

Upper- and lower-limb body-powered prostheses

Foot problems and footwear

Similar meetings are to be conducted in the United Kingdom and Europe and the results of all three reported at the first ISPO Assembly at Montreux, Switzerland, in October 1974.

A steering committee met in Miami, Florida, on December 18, 1973, to consider plans for the first of the above meetings.

Inter-Clinic Information Bulletin

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.

Subcommittee on Sensory Aids

Clinical Evaluation of Reading Aids for the Blind

Fifty Stereotoners purchased by VA are being evaluated by American Institutes for Research, the contractor recommended by CPRD's Panel on Evaluation of Inkprint Readers. An additional 15 units, purchased by another sponsor, have been delivered to CPRD. These units will also be evaluated by the American Institutes for Research and will serve to broaden the sample by including civilian as well as veteran subjects.

Panel on Hearing Aid Performance

The Veterans Administration requested that CPRD form a panel of consultants to develop criteria on hearing-aid performance which could be used in selection of aids for VA purchase. At its first meeting, June 25–26, 1973, the panel selected devices for VA purchase in FY 1974 on the basis of test data and clinical experience. At its second meeting,

held September 20 and 21, 1973, the panel explained the VA performance criteria to representatives of other government agencies and polled them as to their needs. Possible changes in testing procedures for hearing aids were considered.

Task Force on Rehabilitation Engineering for the Hearing Handicapped

This task force was formed to produce a "statement of national goals for research that can presently be identified as a prerequisite to the development of new or improved devices or service delivery" for the hearing-handicapped. The statement is to be included as part of the revision of REHABILITATION ENGINEERING . . . referred to elsewhere in this proposal. The task force met on December 17, 1973, after a preliminary exchange of information by mail.

Low-Vision Aids

A continuing series of contacts between subcommittee members and staff and other interested organizations culminated in a meeting with the American Foundation for the Blind (AFB) on October 2, 1973. At this meeting it was decided that AFB would take the leadership role in promoting better deployment of low-vision aids, and that CPRD would assist, when requested, in any way possible.

Aids to the Deaf-Blind

At the request of the Social and Rehabilitation Service, the Staff Engineer for Sensory Aids is cooperating with the National Center for Deaf-Blind Youths and Adults in expediting the development of aids for this population. A Workshop on Communication and Sensory Aids for the Deaf-Blind was held at the National Center on November 29–30, 1973. Representatives from "high-technology" industry and government laboratories were briefed on rehabilitation of the deaf-blind during the first day, and on the second day their help was sought in developing improved aids.

Miscellaneous

The Staff Engineer for Sensory Aids has visited three Veterans Administration Blind Rehabilitation Centers, and civilian schools for the deaf, blind, and deaf-blind, to assess needs for research and the development of devices. A national questionnaire survey of all sensory aids research, development, and evaluation studies being conducted in FY 1973 was completed.

Subcommittee on Design and Development

Upper-Limb Orthotics

The fourth in a series of workshops on the orthotics management of patients with hand and arm impairments was held in Denver, Colorado, July 19–20, 1973. This workshop undertook the task of analyzing and delineating the prospective advantages/disadvantages and indications/contraindications of three commercially available ULO systems. A report summarizing the findings of the workshop was distributed to the orthotics educational institutions and other interested parties.

The Patient With a Spinal-Cord Injury

At the request of the sponsors, CPRD/CPOE gave increased attention during the year to the problems of the patient who had suffered a spinal-cord injury, particularly one which had occurred at a high level resulting in quadriplegia. Initial activity included:

- Environmental Control

Ongoing work in devices and systems which provide the SCI patient with some degree of control over his immediate environment, as in turning on and off lights, radios, TV sets, etc., was reviewed at a meeting held in Washington, D.C., August 13–14, 1973. Recommendations concerning required research and coordination of efforts in this area were developed.

- Mobility Aids

On November 21, 1973, a steering committee met in Washington, D.C., to plan a three-day workshop (February 22–24, 1974) on Mobility of Spinal-Cord-Injured People. Under consideration are standard and powered wheelchairs, other off-the-street vehicles, hand-controlled cars, special vans, and various other possibilities for getting from one place to another efficiently and safely.

- Expedited Total Programs

Superimposed on these areas of activity was a request by the sponsors for recommendations as to programs and funding necessary to accelerate the provision of improved total rehabilitation care services to SCI patients. This request was discussed at a meeting held in Washington, D.C., on November 8, 1973.

Subcommittee on Evaluation

Clinical Evaluation of the Cybernetics Research Institute (CRI) "Cybertype" and "Cyberbrailler" Systems

These are man-machine systems which allow severely disabled persons to communicate in written form.

An orientation to the "Cybertype" (and "Whispertype") was held on September 5–7, 1973, for the participating centers.

Children's Centers

Alfred I. Dupont Institute, Wilmington, Delaware
Newington Children's Hospital, Newington, Connecticut
New York State Rehabilitation Hospital, West Haverstraw, New York
Ontario Crippled Children's Centre, Toronto, Canada
UCLA Cerebral Palsy Program, Los Angeles, California

Spinal Cord Injury Centers

Good Samaritan Hospital, Phoenix, Arizona
Northwestern University, Chicago, Illinois
Rancho Los Amigos Hospital, Downey, California
University of Virginia Children's Hospital, Charlottesville, Virginia
Veterans Administration Hospital, Castle Point, New York

An orientation to the Cyberbrailler was held on September 13, 1973, the participating centers being:

Blind Centers

Library of Congress, Division for Blind and Physically Handicapped, Washington, D. C.
University of Connecticut, Storrs, Connecticut
Selected Individuals for Vocational Use

All systems (one for each center) have been delivered and properly installed, and the centers have begun the selection of suitable subjects for the evaluation.

Evaluation of Three Below-Knee Prosthetics (BKP)
Casting and Cast-Modification Techniques

Two new techniques for casting below-knee stumps and for modifying plaster-of-paris stump models were presented at the Workshop on Below-Knee and Above-Knee Prosthetics in Seattle, Washington, on January 27–29, 1973. As a result of recommendations made at this workshop, a study of the two new techniques in comparison with the standard UCB technique was initiated on August 15–23, 1973, at Rancho Los Amigos Hospital. The three techniques being evaluated are:

Fillauer three-step
Zettl/Traub pre-modified
Standard UCB

Study of Upper-Limb Prosthetic (ULP) Components

As a result of recommendations at the Ninth Workshop on Upper-Limb Prosthetics held October 23–27, 1971, Mr. Bert Titus at Duke University is conducting an informal study of the following ULP components:

Rehabilitation Institute of Montreal Wrist-Flexion Unit
Ontario Crippled Children's Centre Open-Shoulder AE Socket
J. A. Pentland's AE Suction Socket
Northwestern University's AE Self-Suspending Socket

Committee on Prosthetic-Orthotic Education

The Task Force on Standardization of Prosthetic-Orthotic Terminology

The Fifth Workshop of the Task Force on Standardization of Prosthetic-Orthotic Terminology was held on November 16, 1973, in Washington, D.C. In orthotics, technical analysis forms for both lower and upper limbs had undergone clinical trials at selected centers. It was found that the form for lower limbs was excellent for recording routine clinical data, but that the upper-limb form was felt to be too detailed for such use; however, both forms were considered to be effective teaching aids. Appropriate prescription charts are now included in the technical analysis forms for both lower and upper limbs. In prosthetics, CPRD/CPOE has employed part-time help to compile and define lists of terms to supplement those developed at earlier workshops. These newly defined terms will be distributed in small batches to selected members of the Task Force to be checked for technical accuracy.

Newsletter . . . Amputeee Clinics

In the four years since the initial publication of *Newsletter . . . Amputee Clinics,* subscribers in ever-increasing numbers have responded to frequent survey questionnaires featured in this periodical. Discussions have been lively, and circulation has tripled. Today, this eight-page publication finds its way to medical centers and rehabilitation facilities around the world.

Normally, six issues of the *Newsletter* are published each year by CPOE. During the calendar year 1973, however, one additional issue was published to accommodate articles which the editors felt would be of special interest to readers.

Amputee Clinics in the United States and Canada — 1973

Amputee Clinics in the United States and Canada was originally developed by CPOE as a mailing list for use in the distribution of educational materials relating to prosthetics. Through the interest and cooperation of amputee clinic chiefs and others in the field of rehabilitation, the listing has gradually been enlarged to include information that might be useful for patient referral. This roster of amputee clinics is updated yearly and distributed to all listed clinics, as well as to the libraries of medical and paramedical schools, and is made available to all interested groups and individuals upon request. The 1973 edition lists 482 clinics and indicates types of services available at each.

SPECIAL MEETINGS AND ACTIVITIES

Rehabilitation Engineering Centers

The Executive Director and members of the Committee on Prosthetics Research and Development participated in meetings of the Rehabilitation Engineering Centers August 6–7, 1973, at Rancho Los Amigos Hospital, and November 19–20, 1973, at Moss Rehabilitation Hospital.

CPRD has been requested by sponsors to update the report, REHABILITATION ENGINEERING, A PLAN FOR CONTINUED PROGRESS. A committee to plan the revision met in Washington, D.C., October 16, 1973. Revision of the sensory aids section of the report will be discussed at a meeting to be held January 14, 1974.

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). A combined meeting of these two groups was held in San Diego, California, October 11, 1973, while a meeting of UCOPE alone was held in Washington, D.C., on May 1, 1973. These meetings focused primarily on mutual financial problems and served to coordinate course offerings.

At the request of the Veterans Administration and supported by the Social and Rehabilitation Service, CPRD formed a task force to review past and current educational activities in prosthetics and orthotics, and to make recommendations for future programs in these areas. The task force has held three meetings, all in Washington, D.C., on August 29, September 26, and November 14, 1973. A draft of the

task force's report is now being prepared by staff for review by the group.

American Orthotic and Prosthetic Association (AOPA)

Continued close liaison was maintained with AOPA, the American Board for Certification (ABC), and the newly formed 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 in San Diego, California, October 10–14, 1973, and were participants in the Assembly program.

American Academy of Orthopaedic Surgeons

Close liaison was maintained with the American Academy of Orthopaedic Surgeons (AAOS). Staff members attended the Annual Meeting in Las Vegas, February 1–6, 1973. The Assistant Executive Director attended a meeting of the Committee on Prosthetics and Orthotics of AAOS held in Chicago, Illinois, December 6–7, 1973.

Postgraduate Course on Amputation Surgery, Prosthetics-Orthotics, and Fracture Bracing

On December 17–19, 1973, the Executive Director, Assistant Executive Director, Staff Surgeon, and Staff Prosthetist participated in a postgraduate course entitled, "Amputation Surgery, Prosthetics-Orthotics, and Fracture Bracing." The Executive Director and Staff Surgeon served as faculty members. The course was presented by the University of Miami Medical School and was cosponsored by CPRD, Veterans Administration, and the American Academy of Orthotists and Prosthetists. The staff members were also observers at the American Academy of Orthopaedic Surgeons' course on, "Current Status of Total Joint Replacement," immediately preceding the University of Miami course (December 14–16).

Stereophotogrammetry

The Assistant Executive Director attended two meetings which explored the state of the art in stereophotogrammetry, one in Vancouver, B.C., October 18, 1973, and the other in Washington, D.C., October 22, 1973. This technology appears to have application in prosthetics which could yield basic and highly useful information. Attempts will be made to stimulate research which employs stereophotogrammetric techniques.

International Activities

United States Chapter of the International Society for Prosthetics and Orthotics (ISPO)

The Executive Director is Chairman of the Publications Committee of ISPO, and the Assistant Executive Director is Vice-Chairman of the U.S. Chapter. Both attended a meeting of the U.S. Executive Committee at Duke University, September 22, 1973.

Proposals Reviewed on Behalf of Sponsors

Ten proposals in the fields of prosthetics, orthotics, and sensory aids were reviewed and appraised by the Committee at the request of sponsors.

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:

Mauch Laboratories
Haskins Laboratories
Vanderbilt University
University of Maryland
University of Arkansas
McDonnell Douglas Corporation

The Assistant Executive Director also made visits to several Child Amputee Centers, some already participating in the cooperative clinical research program coordinated by the SCPP and some prospective participants. These centers were: Shriners Hospital at Lexington, Kentucky; Child Amputee Clinic in Birmingham, Ala.; and Child Amputee Clinic in Orlando, Fla.

Miscellaneous

The staff responded to more than 800 requests for publications and technical information.

PUBLICATIONS

Annual Summary Report of Activities for Year Ending June 30, 1973. (Report to the Veterans Administration and the Social and Rehabilitation Service, from the Committee on Prosthetics Research and Development and the Committee on Prosthetic/Orthotic Education during the Fiscal Year 1972–1973.)

Special Considerations Relating to the Child with a Limb Deficiency, National Academy of Sciences. Proceedings of a symposium held March 23–24, 1972, under the sponsorship of the Subcommittee on Child Prosthetics Problems. (In preparation.)

Report of Workshop on Fundamental Studies for Internal Structural Prostheses, April 13–15, 1972.

Report of Tenth Workshop on Upper-Limb Prosthetics, September 21–22, 1972. (In preparation.)

Workshop on Injuries of Adolescents in Sports and Recreation, December 4–5, 1972. (In preparation.)

Report of a Workshop on Below-Knee and Above-Knee Prostheses, January 27–29, 1973.

Workshop on the Role of Engineering in Spinal Cord Injury Programs, May 3–5, 1973. (In preparation.)

Report of Small Working Meeting on Upper-Limb Orthotic Systems, July 19–20, 1973.

Amputee Clinics in the United States and Canada 1973.

Inter-Clinic Information Bulletin. (Published monthly under the sponsorship of the Subcommittee on Child Prosthetics Problems; six issues.)

Newsletter . . . Amputee Clinics. Three issues.

Research and Development in the Field of Artificial Limbs

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

Shortly before the beginning of the reporting period, letters were sent out to all prosthetists who use the S–N–S system, announcing the introduction of the Dynamic Air-Bleeding Feature. These letters also asked for suggestions regarding desirable improvements of the S–N–S system. A relatively high percentage of replies (15 percent) suggested lower swing-phase resistances at the minimum adjustment setting. Therefore, an intensive effort was made toward this goal.

After a number of tests, it was found that the main contribution to the minimum swing-phase resistances came from the polyurethane O–ring in the large piston. As mentioned before, it was known that this ring swelled after immersion in the hydraulic oil. At that time it was assumed that the wear of this ring in normal use would offset the influence of the swelling. However, upon reexamination of this point, it was found that the swelling far exceeded any possible wear and that, as a result, newly assembled S–N–S systems, which initially had acceptable swing phase resistances, acquired higher and higher resistances

over a period of several weeks. Thus, by the time a system reached the prosthetist and was given to an amputee these resistances had become too high for those amputees who had become used to low resistance swing characteristics in their past prostheses.

Discussions were held with manufacturers of O–rings made of polyurethane and Buna–N rubber compounds, with Air Force and Navy laboratories, and with several oil companies. Then standard swell tests (oil immersion for 168 hours at 158 deg. F.) were conducted with various oils and O–ring materials. As a result, a decision was made to stay with the present polyurethane O–rings and to pre-swell them by extended oil immersion after having shortened their circumference by grinding a slit through the O–ring body. This slit reduces the total circumference and provides a slanted overlap in such an orientation that the vulnerable feather edges of the slit will not contact either the cylinder wall or the side wall of the piston groove. Tests with pre-swelled polyurethane O–rings so modified were fully satisfactory and this type O–ring was adopted early in October for all production and repair systems with satisfactory results.

As a final solution the manufacturer of the present polyurethane O–rings will make a special mold which will produce O–rings having the correct circumference after pre-swelling. No slitting will then be necessary.

Several additional improvements were incorporated into the S–N–S setup. In a few cases hydraulic systems were damaged in the field because the prosthetist accidentally pushed one of the two Nyliners, which support the bottom of the hydraulic system, out of its aluminum bushing and into the shank. This produced a lopsided support, resulting in fatigue fractures. To avoid this in the future, the Nyliners in that location were provided with a bead around their outer edge to hold the Nyliner firmly in place with the aluminum bushing.

One setup came back from the field with the wood on the top of one aluminum bushing inside the shank broken out resulting in a loose aluminum bushing and a damaged hydraulic system. All setups still in Dayton which did not have enough wood in that location were reinforced with a dowel across the top of the aluminum bushing. In addition, the supplier for wooden shanks is now leaving inside the shank a minimum of 2 in. of wood extending upward from that location making a dowell unnecessary.

All these improvements were having their effect on the S–N–S systems. From the reduced frequency of loaner requests in spite of a steadily increasing number of systems in use, it was calculated that the average maintenance-free wear period for these improved systems has increased by approximately 40 percent to almost 2 years. This means that the total cost for the use of the S–N–S system over a given time

period has significantly decreased although the cost to buy and maintain it has somewhat increased due to higher wages.

The remaining design work and the shop work on the first prototype of the new hydraulic ankle design have progressed rapidly. The prototype is 85 percent complete. It will be ready for amputee testing at the end of January. In order to speed up the ankle development, a second engineering technician has been assigned to this project and a second prototype of the new ankle design was started. It is 15 percent complete. The first prototype will be used for the test amputee in Dayton and the second prototype will be installed into the leg of the VAPC test amputee in New York. Whatever will be learned from the test wearing of the first prototype by the Dayton test amputee will be applied to the second prototype during its construction. However, few changes are anticipated.

The attachment configuration of the ankle to the shank of the prosthesis was completely redesigned in order to accommodate pylon-type legs. It was possible to reintroduce a limited anterior-posterior adjustability into this new design without adding to the complexity or cost. The adjustment is possible by changing the position of two ¾-in.-long setscrews—one in front and one in the back of the shank—which are needed anyway to support and hold the upper end of the piston rod of the ankle inside the pylon. By loosening one or both of these setscrews the ankle system is disengaged from the pylon and can be extracted for inspection. When installed, the flat sides of the paddle-shaped upper end of the piston rod are held between two semi-circular polyurethane rubber bumpers. These rubber bumpers can either be made solid, which will permit only very little transverse rotation of the foot, or they can be provided with relief slits located in such positions that compression of the rubber will be possible for one rotational direction and prevented for the other direction. Left and right feet can be accommodated by reversing the two rubber bumpers. In the case of a wooden shank the entire design can be left basically unchanged by installing a 4-in.-long piece of the pylon tubing into the lower end of the wooden shank. The new design will accommodate without difficulties the latest standardization of the tube dimensions for pylon type legs of 35 mm. o.d. and approximately 2 mm. wall thickness.

It was also found advantageous to increase the radii of the hub part of the piston and of the surrounding housing, and to move the upper side parts of the U–seals to a location closer to the bolt. These changes have become possible because of the elimination of the control bushing. Larger radii will also permit smoother transitions of the U–seal shape resulting in better sealing and less wear. A new mold for this modified seal will become necessary. The opportunity of the changeover will also be used to modify the lip configuration of the U–seal in such a

way that it will no longer be necessary to cement the U–seals into the grooves on the piston. However, these changes cannot be applied to the presently built prototype which uses existing castings. A sufficient number of castings is still available for building six prototype units. It may, however, become advisable to introduce the new shape of the castings and the U-seals at an earlier stage.

The main activity regarding the development of a voluntarily actuated swing and stance control unit consisted in following publications describing related research work. Results obtained so far include:

a. No suitable myoelectric signal source based on skin contact has yet become available. The chances that this situation will change appear slim. This makes the development of the muscle hardness sensor the more important in order to avoid surgical procedures for implanting signal sources under the skin.

b. The decision made during the early stages of this project to use feedback in conjunction with any signal source was borne out as highly desirable by the work of other researchers.

c. Feeding back the *position* of the controlled limb part (shank) appears preferable to feeding back other types of information, especially if some *force* feedback can be sensed by the stump within the socket.

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

For progress during this report period, see "Transferring Load to Flesh: Part VII. Gel Liner Effects," appearing elsewhere in this issue of the Bulletin.

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

Two amputees have been fitted with electric hooks developed in the laboratory. The hooks employ the synergetic prehension concept and use myo-pulse modulation control techniques. Hands seem to be desired by most amputees who are candidates for below-elbow myoelectric sytems. However, powered hooks have application.

Several shoulder-disarticulation amputees have been fitted with myoelectrically controlled hand prostheses and endoskeletal arms. Myoelectric control seems to work optimally when related to prehension and when only one degree of freedom is controlled.

A new thoracic suspension and control harness for above-elbow amputees has been developed to relieve axillary pressure and to do so without loss of biomechanical efficiency. This approach is readily adaptable for use with switch control of powered prosthetic components.

A summary of myoelectric and switch control fitting techniques has been developed for use in the prescription of powered upper-limb prosthetic systems. The possible control motions or control sites for each amputation level are summarized.

A pneumatic cosmetic cover for below-knee endoskeletal prostheses is under development. The object is to develop a cosmetic and light cover which can be easily fabricated.

Development continues on the so-called lift-lock mechanism and the atmospheric pressure suspension socket.

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

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

Current research efforts at the Biotechnology Laboratory, UCLA, center around two major areas: 1. Studies and development of advanced control schemes and computational algorithms which enhance and improve control and 2. development of a basic externally powered arm and a set of control subsystems for practical testing of developed control schemes in a clinical environment.

During the last 6 months, the following work was performed:

1. *Design and assembly of an improved externally powered arm prosthesis and supporting servo systems.* The important feature of this arm was the conversion of VAPC elbow motors into wrist and humeral rotators, resulting in reduction of the number of different motors required, simplification of maintenance and repair, and reduction in the cost of the arm (if large production quantities become feasible). The conversions plus the powered terminal device, provide an arm which weighs under 4 lb. and which has four degrees of freedom.

2. *Design and construction of fingertip pressure sensory feedback subsystem.* Transducers suitable to monitor fingertip pressure were devel-

oped, as well as an information transformation system simulating a neural receptor. In its present form the system can be interfaced with the amputee via skin electrodes.

3. *Development and implementation of an Electromyographic Pattern Control (EPC) arm control logic.* This EMG control system is adaptive to the individual amputee. In a short learning period, the amputee finds the muscle contraction patterns which optimize control between the computer-assisted prosthesis trajectories and his intended movement.

4. *Preliminary design of heuristic and end-point control programs.* The approach involves the incorporation of a set of heuristic programs into end-point control to supplement the decision and control tasks of the operator. The development of mathematical algorithms is underway to provide end-point control with fewer input channels than the number of motion degrees of freedom of the prosthesis.

5. *Design of an implementable microcomputer system from commercially available components.* The microcomputer system provides a means for realizing advanced control schemes which involve on-line computation. Of particular interest is the use of this type of computer for auxiliary information processing to aid in the control tasks and reduce the control and information processing load on the patient.

6. *Evaluation by means of performance studies on the effectiveness of adaptive computer aiding.*

The ultimate goal continues to be the provision of practical and economical high performance, computer-controlled prosthesis adaptive to a wide range of amputee needs and requiring minimum conscious attention by the amputee.

Design of Prosthetic and Orthotic Devices and Biomechanical Studies of Locomotion

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

Design and Development of Lower-Limb Prosthetic Devices

The Polycentric Knee. A spherical alignment coupling has been developed for the four-bar linkage Polycentric Knee, and 10 complete units have been forwarded with a preliminary manual to VAPC for evaluation. Five units currently are being worn by amputees in the San Francisco Bay area. Figure 1 shows the bench alignment instructions from the manual.

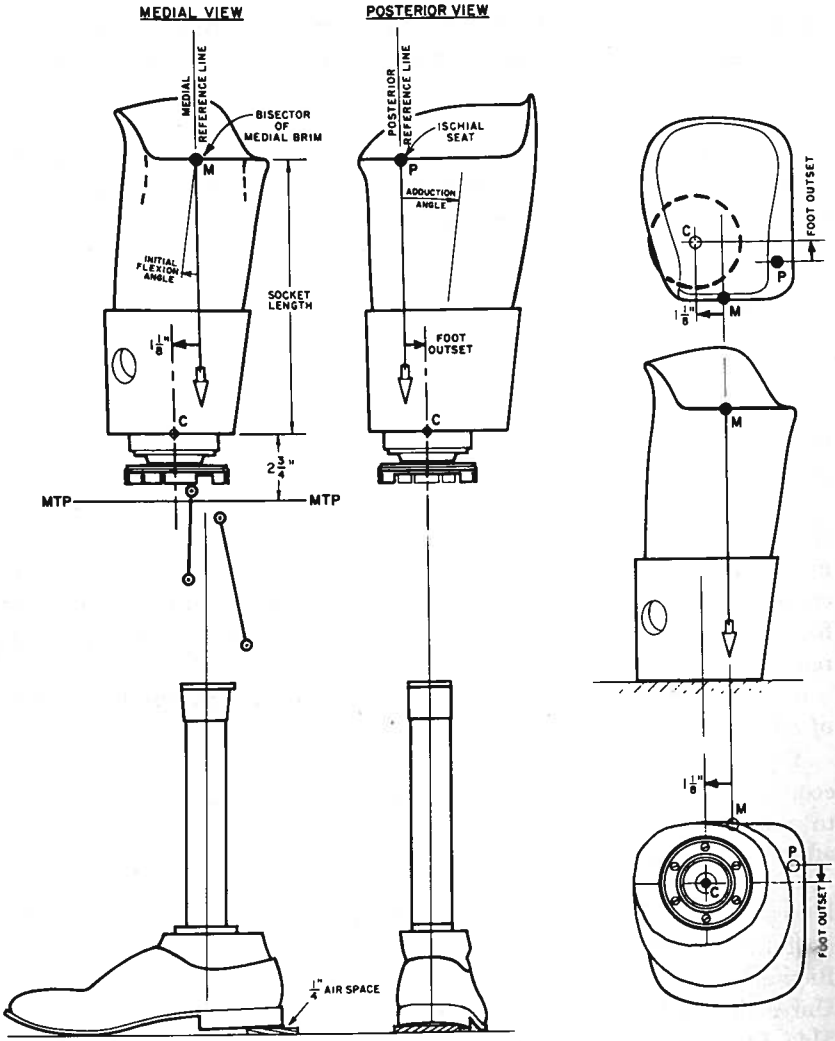

FIGURE 1.—Bench alignment of the UC-BL four-bar polycentric knee.

Shank Torque Absorber. Four prototypes of the torque absorber have been under daily uses by above-knee amputees for periods of up to 16 months. Both function and durability have been good. Complete drawings of the device have been forwarded to VAPC to allow production of a quantity of the devices for widespread evaluation.

Tube Couplings for Modular Prosthetic Limbs. An internal expanding tube coupling has been developed to use the new 35 mm. (1⅜ in.) pylon tubing. Although the new foot coupling is ½ in. smaller in diameter than the one previously used, tests have shown that it is

significantly stronger and stiffer. (See Fig. 2.) Drawings have been forwarded to VAPC.

Knee Disarticulation Prosthesis. The development of a six-bar linkage knee for the through-knee amputee now centers on two specific linkage arrangements. An earlier prototype, which has demonstrated

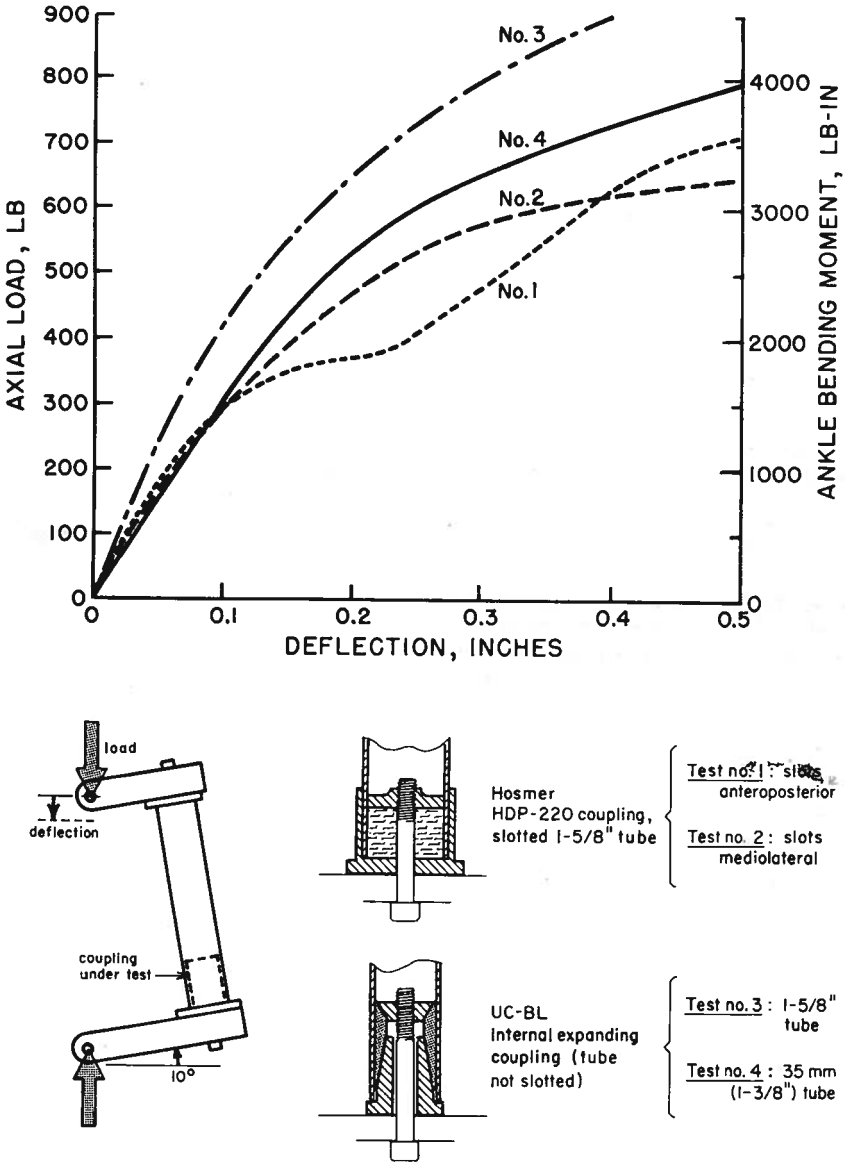

FIGURE 2.—Selected results of laboratory strength tests of modular foot couplings.

exceptionally good polycentric action and swing-phase control, is being revised for reduced size and increased strength. In addition, another linkage which offers a simpler structure and similar function is at the detail design stage.

Biomechanical Studies of Human Locomotion

The computer data acquisition system has been used for preliminary examination of the kinematics and kinetics of above-knee amputee gait. A floor walkway 9 meters (29 ft.) in length and a Tektronix graphics display terminal are being incorporated into the computer system.

Evaluation and Further Development of New Design for Back Braces

The UC semiflexible body jackets are being evaluated at four locations under CPRD auspices. At the San Francisco Medical Center 35 patients have worn the device with generally favorable results.

Instrumentation has been completed for direct measurement and recording of intradiscal pressures. This equipment is to be used for direct evaluation of the effectiveness of various spinal braces and for examining the effects of the drug Chymopapain on spinal mechanics.

Mobility Aids for the Severely Disabled

Activity has centered on development of the Variable-Height Wheelchair. A prototype was completed and tested by a quadriplegic, and a documentary motion picture film was prepared. Production engineering continues with particular attention to gear drives for the wheels, improved arm rests and seat assembly, and more compact electrical control system.

Immediate Postoperative Prostheses Research Study

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

The Prosthetics Research Study is engaged in four areas of clinical research utilizing the application of external electrical energy:

1. Neuromuscular Assist: Four Rancho-Medtronic-type peroneal nerve neuromuscular assist devices have been implanted surgically. Six additional units are programed for patient implantation to complete the initial participatory phase in this program.

2. Two patients with established non-union fractures of the tibia have been treated by electrode implantation at the non-union site and the application of electrical energy to stimulate osteogenesis. As suitable patients become available further needle electrode implants will be carried out. The electrodes and the protocol for electrical input to the non-union site were developed at the PRS Bioengineering Laboratory.

3. A selected series of amputees are being treated for specific pain syndromes using transcutaneous electrical stimulation. This pain abatement study is being confined to using the non-invasive technique. Five patients are now under active treatment with this technique.

4. Electrical cyclo-stimulation is being investigated as a rehabilitation aid in postsurgical and post-trauma conditions involving the knee and shoulder. We are also using the technique for certain arthritic joints. This patient-controlled, muscle activating, non-invasive unit is being supplied to us by the Medtronic Company.

The Roehampton-BRADU Controlled Environment Chamber has been made available to PRS staff at the Seattle Veterans Administration Hospital. Pressure, humidity, temperature, and gas composition are controlled in a transparent device which allows wound inspection. The initial series of cases are closed amputations. The limb is placed in the chamber immediately following surgery where studies on wound-healing are being conducted. Control patients are treated with the classical PRS rigid-dressing management.

Continuing studies on objective methods of level determination to obtain low amputations in peripheral vascular disease are underway. This ongoing major project continues to be translated into effective clinical application for the management of the peripheral vascular disease amputee in this country and throughout the world.

Eleven selected below-knee amputees with muscle stabilized stumps have been reviewed to determine the prosthetic suspension capability of this type of amputation. Modifications in below-knee socket design and suspension have been carried out consistent with the data collected.

Mr. James L. Byers, Chief of Prosthetics, is experimenting with a wide range of interface materials particularly in the below-knee prosthesis. Among the products studied are foamed elastomers, a self-vulcanizing Hypalon elastomer, and continued investigation with Cordo.

On-site, regional, and national educational activities including publications continue as an integral part of the PRS commitment.

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

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

During the past 6 months, the program has continued to accumulate favorable data with regard to the application of immediate postoperative prosthesis in patients requiring lower-limb amputation for vascular occlusive disease.

Experiences at VAH San Francisco with amputation level determination using Xenon 133 clearance as an estimation of blood flow was recently published (Determination of Amputation Level Measurement of Skin Blood Flow with Xenon 133, Wesley S. Moore, M.D., Arch. Surg., 107:798–802, Nov. 1973). Following successful correlation of blood flow clearance data with success or failure of healing at the below-knee level, studies have now begun to include more distal levels of proposed amputation. Currently patients are being surveyed for potential Syme or transmetatarsal amputation by using Xenon 133 clearance as a substitute for conventional parameters of operability at these levels. Along with this program, new immediate fitting prostheses have been developed for the Syme and transmetatarsal levels that have continued to be most satisfactory.

Since the current technique of Xenon clearance determination involves the measurement of only one point on the circumference of a potential incision, collaboration is now taking place with the Department of Nuclear Medicine to employ the Gamma Camera and its advanced technology to sample several points along the course of potential amputation incision.

Interdisciplinary Development and Evaluation of Externally Powered Upper-Limb Prosthesis

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Woodrow Seamone and Gerhard Schmeisser, Jr., M.D.

During the latter half of 1973, clinical fittings were continued on selected patients at Johns Hopkins in order to evaluate further the relative merits of different input sensors for experimental powered prosthetics systems for high level upper-limb amputations. Continued refinement of a powered upper-limb orthosis for a flail elbow and fitting of a powered hand clasping device were also conducted during this period.

The powered system components under development at Johns Hopkins use as their basic power element the electrically driven cable puller which has been reported on in previous issues of the Bulletin of Prosthetics Research. A family of devices has been developed which may be controlled from any one of three sensors, namely, a single-site electromyographic input, a displacement sensor of skin motion or a displacement sensor of body motion. Experimental prostheses have been fabricated and a small number evaluated clinically to demonstrate the systems' capability to provide powered control of hook grasping, elbow motion, and shoulder flexion. The clinical evaluation results of recent fittings of powered prostheses and orthoses utilizing these components are described below.

Shoulder-Disarticulation Prosthesis

Fitting of an adult unilateral shoulder-disarticulation amputee with a prosthesis featuring active shoulder flexion as well as active terminal device and elbow motion (see Fig. 3) was performed 9 months ago. Details of this prosthesis were presented in the last BPR progress

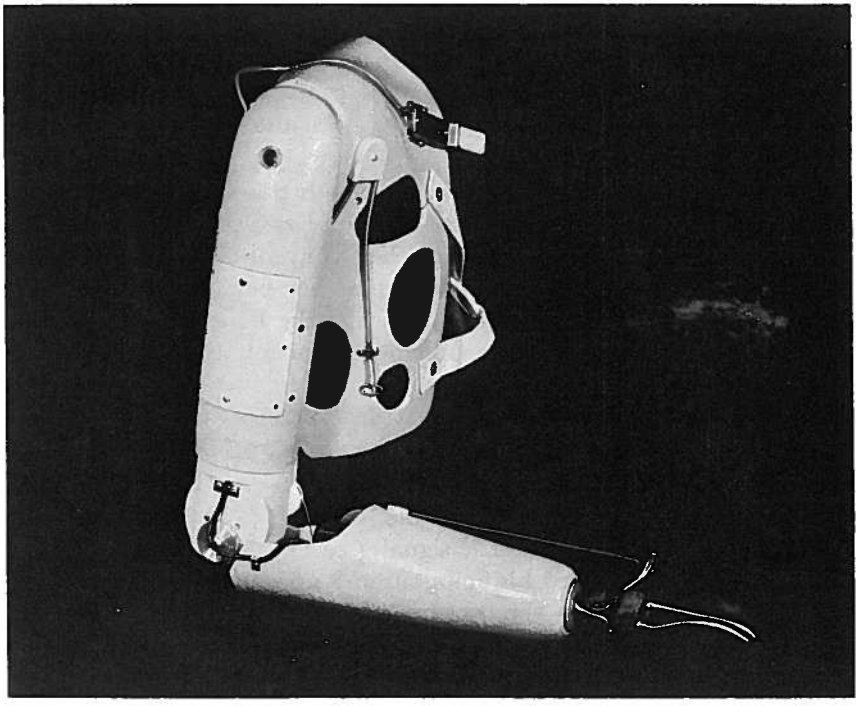

FIGURE 3.—Experimental prosthesis with powered control of shoulder flexion, elbow, and hook.

report. During the current report period, this amputee has been using this prosthesis heavily for bimanual work activities at the company in which he is employed. He reports that the addition of active shoulder flexion has significantly improved the usefulness of the prosthesis by increasing his work envelope. He relies on his prosthesis so heavily that he is reluctant to part with it for more than short periods of time. Mechanical problems have been minor. Changes consisted of adjusting the chin nudge shoulder lock control and securing mechanical parts which tended to loosen. Evaluation of this prosthesis is continuing.

Short Above-Elbow Prosthesis

Traditional upper-limb body-powered prostheses have usually been unsatisfactory for patients with unilateral short above-elbow (AE) stumps. The socket cannot be stabilized on the stump and the patient cannot generate adequate force and cable excursion. Useful function of the prosthesis is especially unlikely if the soft tissues of the stump are flabby. In this situation the prosthesis is usually abandoned. The authors have previously reported using a powered system in an AE prosthesis to reduce the input stroke and force requirements to acceptable levels. Due to inadequate myoelectric signals in the stump, a spring-loaded position transducer was placed in the prosthesis and connected to the shoulder harness to permit control with low-effort body motions. Elbow locking and unlocking was also simplified with an electro-mechanical arrangement.

An 18-year-old student nurse was fitted with this system prior to the current report period. She has now had this prosthesis for 11 months. Seven years earlier she abandoned her conventional body-powered prosthesis as functionless. She reports that her new prosthesis is easy to operate and is a great improvement, and she hopes to keep it. But she actually uses it only when bimanual function is unavoidable or when required by her nursing supervisors. It is believed that she would use the new prosthesis a great deal more if she had not previously become well adapted to single-handed function.

For further evaluation, similar systems were fitted to two additional AE amputees. One was an 11-year-old boy also with a short flabby stump and negligible myoelectric signal (see Fig. 4). In contrast to the first case, he had sustained his amputation 8 months prior to prosthesis delivery. He has now had the prosthesis for 2 months. He has acquired good functional capability with no training other than verbal instructions at delivery and at one followup visit. He wears this appliance most of the time. It has been found that the elbow sometimes fails to lock when the turntable is in full internal rotation. This is due to binding of the elbow locking cable housing resulting in friction of the

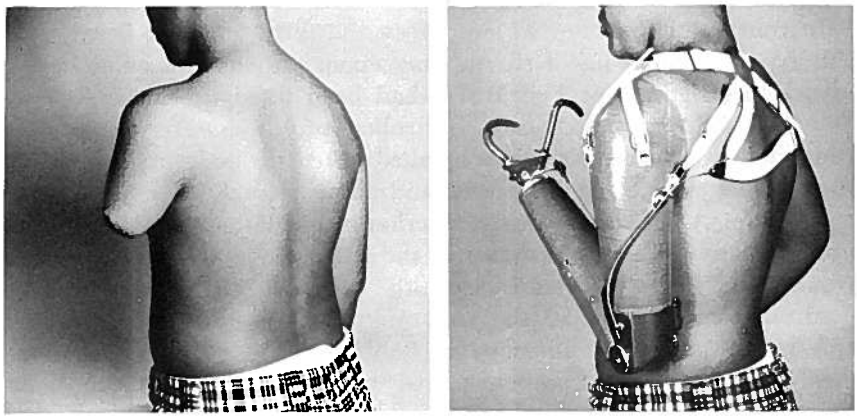

FIGURE 4.—Short above-elbow amputee with externally powered prosthesis controlled by low effort shoulder motions. Note full opening of terminal device and full elbow flexion with light force on control cable.

elbow locking cable. It has also been found that since such low force levels are now required to actuate the power system, care must be given to adjusting the main control cable harness to avoid inadvertent function when the patient slouches or droops his shoulders. Use of the conventional AE figure 8 harness permits easy adjustment. Additional investigations are planned on the interface between the harness and the powered prosthesis.

FIGURE 5.—Long above-elbow amputee with substantial portion of biceps muscle belly remaining and associated with a biceps myoelectric signal suitable for good proportional control of externally powered prostheses.

In contrast with these two amputees, the third amputee fitted with this type of system has a stump long enough to have a good biceps myoelectric signal (see Fig. 5). He had been fitted previously with a Johns Hopkins myoelectrically controlled prosthesis. His system was converted from a myoelectric controlled system to body motion sensor input to determine relative merits and amputee preference of the two approaches. A 6-month evaluation period of this latter system following approximately 3 years of wearing the myoelectric controlled system resulted in a strong preference of the amputee for the myoelectric controlled system, due to the larger bimanual work envelope which this sensor permits. The amputee can open and close his terminal device fully with one or both arms at full reach. Tests with body motion control have been terminated for this patient, who will continue to wear the myoelectric controlled system to obtain additional system reliability data.

Powered Orthosis

Further evaluation of powered orthoses for paralytics has been carried out during this report period on three patients.

Two of these were fitted with devices designed to provide active elbow flexion. The third was fitted with a device for grasp. Clinical experience on these cases has resulted in significant improvement in the design evolution of these devices. The first patient, who had bilateral unstable flail shoulders and elbows, assisted in the early tests of basis system concepts but later withdrew from our evaluation program because he could achieve no useful function from the elbow flexion appliance. Part of the problem stemmed from the scapulo-humeral joint hyperextending as the elbow flexed. Since the patient could not reach out in front of him he could find no significant merit to the system.

The second paralytic patient, now in his fourth month of evaluating the elbow flexion device, had originally sustained a brachial plexus injury resulting in a flail scapulo-humeral joint and total paralysis of elbow flexors. He had an adequate triceps, good scapulo-thoracic control and good hand and wrist control. Surgical fusion of his scapulo-humeral joint gave him good shoulder control; therefore, his residual disability was limited to lack of active elbow flexion. As anticipated, the improved powered elbow flexion device has operated well in this situation. The conceptual model underging engineering tests is shown in Figure 6.

The myoelectric signal from one of the wrist extensors is being used to control the elbow motion but the patient objects to resulting cross control problems. Inadvertent function of the appliance occurs too commonly with hand/wrist motions. An acceptable control mode which makes this device truly functional is yet to be identified. Potential

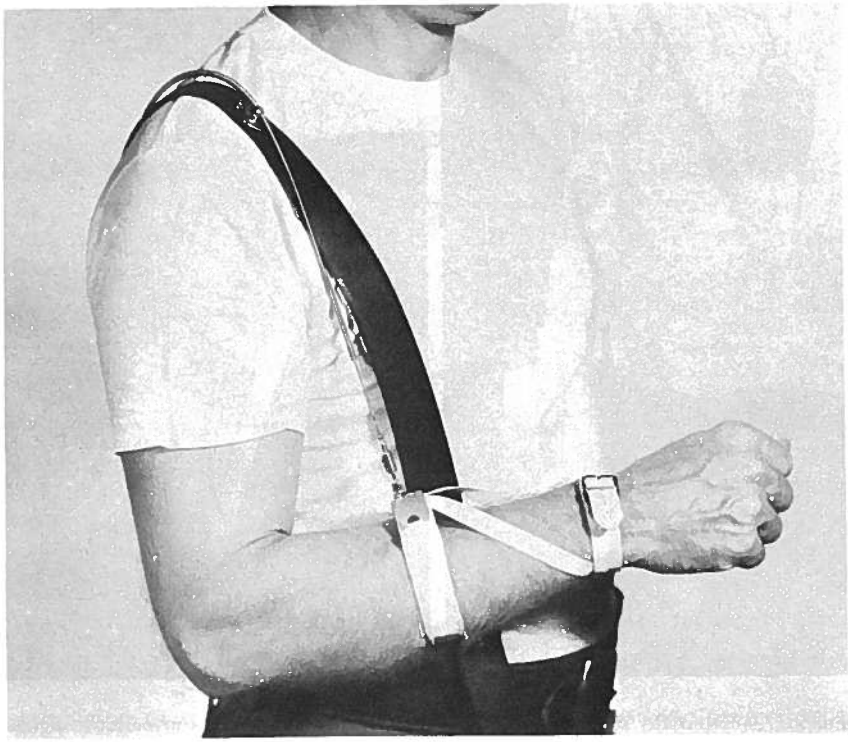

FIGURE 6.—Harnessing arrangement—powered elbow orthosis.

control input signals such as facial motion inputs to new sensors are being evaluated.

The third paralytic has flail shoulders and elbows bilaterally. He has no active muscle power in the left hand and wrist. Although his left biceps muscle lacks useful power, it generates a myoelectric signal. This patient's paralysis was a result of infantile poliomyelitis; hence he has no sensory impairment. Furthermore, because of the underdevelopment of the digits and thumb web space of his left hand, attempts to fit him with an orthosis designed to oppose the thumb and first two digits were unsuccessful. Careful analysis of his existing functional capabilities and needs revealed that he used the fingers of his right hand very capably for manipulating objects; but he needed some means of carrying objects in his left hand which did not depend on its digits. The clasping device illustrated in Figure 7 was developed for this purpose. This patient uses his biceps myoelectric signal to control the power unit mounted on the forearm shell. The motor opens the appliance. When he relaxes, spring tension closes the palmar shell against his palm. He has now been using this device for about two

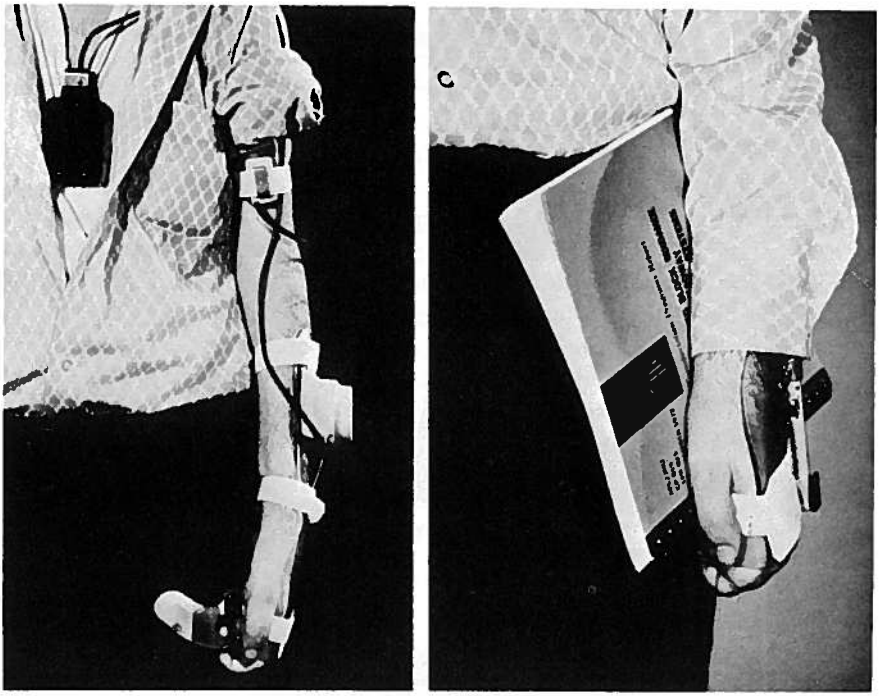

FIGURE 7.—Externally powered clasping device controlled by biceps myoelectric signal. Device enables paralytic to carry objects in his left hand. Battery hangs on undershirt. Motor is mounted on forearm shell. With shirtsleeve rolled down device is inconspicuous.

months. It is easy for him to apply and is inconspicuous when covered by his shirt sleeve. It is performing as intended and is proving useful in his work activities. Evaluation of this device will be continued.

Control Input Sensor Development

One of the key elements in a powered orthosis or prosthesis is the interface sensor between the patient and his machine. Three sensor techniques have been exploited in the Hopkins research program and include an electromyographic sensor, a skin motion sensor, and a body motion sensor. These techniques have been included in various experimental powered orthotic and prosthetic systems currently under evaluation at Johns Hopkins.

During FY'73, work was initiated on integrating a small magnetic diode within the frame of eyeglasses and placing a small high energy magnet on the skin near the eyebrow area. Tests in the laboratory on an experimental model have demonstrated that proportional control can be achieved with little training. The technique looks sufficiently

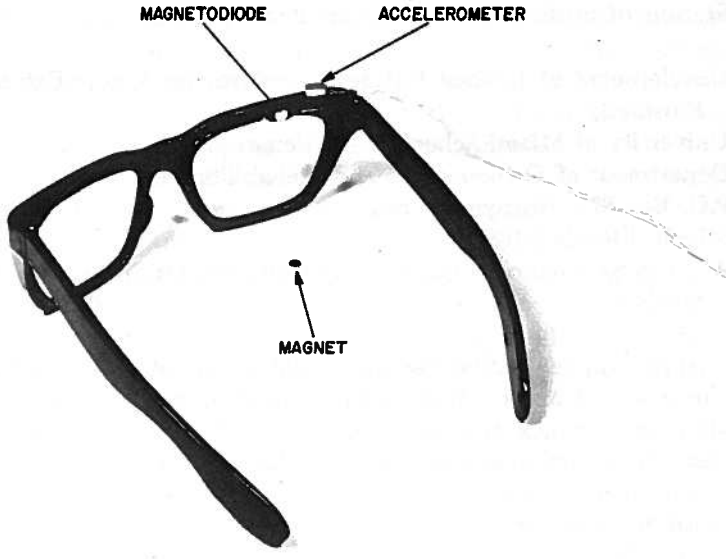

FIGURE 8.—Experimental eyeglass frames with proportional and on-off sensors.

promising to warrant further investigation for possible application to quadriplegics for control of power devices. A second sensor device (a small accelerometer) is also being investigated for use with the eyeglass frames. Preliminary tests indicate there may be signals related to audio sounds, such as teeth clicking or special temporo-mandibular joint motions, to provide on-off function control. A photograph of eyeglass frames fitted with these two new sensors is shown in Figure 8. Preliminary results from tests with these devices indicate that proportional control is achievable by locating the very small magnet over the eyebrow and using eyebrow motion for control. The second sensor, a small accelerometer located on the eyeglass frames, picks up the sharp vibration pulse caused by teeth clicking with the mouth closed. An electronic detector-filter circuit provides good rejection of unwanted signals. Continued development and evaluation are planned on these sensors to provide additional sensory inputs for a highly disabled person to interface with a powered appliance. A powered orthosis controlled by one or more of these sensors will be fabricated late in FY'74.

Future Plans

Engineering and development will be continued on the basic sensor interfaces in addition to total system integration of powered orthoses and prostheses. Clinical evaluation of experimental models will pro-

vide qualitative data on system performance and will aid in the identification of areas requiring further development.

Development of Refined Fitting Procedures for Lower-Extremity Prosthesis

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Approximately 9 months ago 1,500 sq. ft. of space located in the University of Miami, Basic Science Building at the Jackson Memorial Hospital complex was designated as a Prosthetic-Orthotic Research area. Since that time equipment has been purchased and made operational in this new area. Now, a fully equipped prosthetic-orthotic research laboratory includes: lathe, mill, bandsaw, grinders, thermovacuum forming equipment, and high temperature ovens.

To date, at the Rehabilitation Institute, over 300 patients have been evaluated and fitted with ankle-foot orthoses constructed of polypropylene. These orthoses have been fabricated from standard molds made up in lefts and rights in four different sizes.

Evaluation of patients is now underway to select certain disabilities to be included in the case study program. Three patients are currently being fitted with posterior knee joint orthoses designed to control hyperextension of the knee. This type of orthosis constructed of molded polypropylene with a posterior knee joint hopefully can be adapted to control undesirable knee motions in other planes and may be applicable for patients requiring conventional long-leg braces.

Other recent developments which will be clinically evaluated include:

a. A series of standard, "off-the-shelf," polypropylene ankle-foot orthoses (AFO's) with standard modular components for modifying the basic system to expand its applicability.
b. A series of posterior upright knee-ankle-foot orthoses (KAFO's) of molded polypropylene in combination with metallic and non-metallic modular knee joint components.

Related projects which will soon lead to new developments for clinical use:

c. A model is being developed for testing the soft tissue-socket interface for various socket designs and end-pad designs. It should be in use shortly.
d. Preliminary studies of the role of soft tissues in providing mechanical stability for tibial fractures are near completion.

The followup studies of clinical material to qualify our laboratory models is presently underway. We anticipate that the knowledge gained from these studies will give the required insight for development of improved methods of fracture treatment of femoral fractures as well as fractures of all the long bones in both the upper and lower extremities.

e. An animal model for study of fracture healing is being developed, to study the relative effects of immobilization vs. functional, ambulatory treatment of fractures and integrity of early fracture callus and its relative importance in providing mechanical stability to fractures during treatment. Development of diagnostic tools for clinical measuring of early stability of fractures for use in closed functional treatment in being included with this work.

f. A generalized cycle testing machine is under development for use in testing of total joint replacements and orthotic and prosthetic devices.

Immediate Postoperative Application of Upper-Extremity Orthoses
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Richmond, Virginia 23219
Charles L. McDowell, M.D.

Work during the past year has been considerably curtailed because of the retirement of the orthotist, Mr. Homer Hughes. His innovative talent and skill in application were critical to the project. Presently, the project is attempting to have him return on a consultation basis, which will allow continuation of early application of orthotics for the purposes of speeding the process of rehabilitation and improving postoperative results.

In the first year the project concentrated on applying upper-limb orthoses immediately following reconstructive surgery to quadriplegic patients. Since that time, the applications have expanded to the areas of rheumatoid arthritis, Dupuytren's contracture, and other specific disease diagnoses.

At the time of Mr. Hughes' retirement, project members were in the process of modifying the tenodesis orthoses used for quadriplegic patients who have active wrist extensors in order to give them prehension. The modification consists of attempts to provide thumb abduction and adduction as well as metacarpal-phalangeal joint extension and flexion. The goal is to give the patient options of precision grasp in the usual manner with the thumb as a post or of side pinch with the thumb pressing on the side of the index finger as one would grasp

a key to turn it. Hopefully, these two possibilities will be built into each base so that the patient can use either method of pinch that he wishes by moving a selector on the orthosis.

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

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

During this report period, the cosmetic cover (see BPR 10–16 Fall 1971 for further details) for endoskeletal prosthetic systems has been perfected and used to fabricate a below-knee unit which is being clinically evaluated. A preliminary document on the fabrication process has been prepared and is being reviewed by the project's prosthetist consultant. The cosmetic cover has also been used for above knee prostheses, and the bending characteristics of the system are currently being refined to improve the cover's behavior during knee flexure greater than 45 deg.

As part of the evaluation of existing driving aids, a group of ten commercially available hand controls were installed on a rotating basis in three 1973 standard size vehicles. These installations were evaluated with respect to design, materials, method of attachment to the vehicle and anthropometric considerations. They were also road tested on the driving facilities at the Texas A&M Research Annex in coordination with the Texas Transportation Institute. The results of this study are contained in a report entitled "An Evaluation of Several Commercially Available Automotive Hand Controls." This report contains suggestions for improvement of each of the specific controls tested as well as generalized recommendations.

In order to improve the data based on existing regulations with respect to adaptive controls, a survey was undertaken of the inspection procedures with respect to such equipment in the motor vehicle inspection programs of the various states. The results of this survey indicate that the state inspection programs do not include specific regulations or procedures for adaptive equipment. However, many of the respondents indicated that inspection procedures were carried out. The District of Columbia does have an inspection program for such equipment and its approval must be obtained prior to the issuance of a driver permit.

Research has been initiated to develop necessary control systems to allow a severely disabled individual to drive an automobile. The target population is the individual who has no lower-limb control and only

one functioning upper limb, with limited range of motion of that limb, and with no appreciable hand motion. With these restrictions, it becomes necessary to automate as many driver functions as possible, and to provide maximum mechanization of the remainder. The primary control functions in driving (steering, acceleration, and braking) are being implemented using a joy-stick controller similar to that found on wheelchairs. A prototype steering system is currently being tested. Prototypes of the following secondary control units are now being tested:

1. an automatic windshield wiper actuation circuit,
2. an electronic ignition lock (pushbutton actuated)
3. logic control of headlights (on, off, bright-dim),
4. logic control of turn signals.

The choice of logic-level control was made to maximize the capability for interfacing with a variety of control devices attached to, or interfacing with, the driver. Thus, the automotive control system can be a relatively standard system, with the prescription of the driver interface completely flexible to meet specific needs.

Control of an Artificial Upper Limb in Three Degrees of Freedom
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Daniel Graupe, Ph. D.

During the second half of 1973, work on the present project of controlling an upper-limb prosthesis in several degrees of freedom has been concerned with both the toe-actuated controller (Fig. 9) and with the EMG-actuated controller.

The work on the toe-actuated system was mainly devoted to interconnecting the logic controller with the toe-actuation subsystem and with the drive mechanisms. This has implied the construction of the linkages required for interconnection, and the performing of the necessary adjustments of the three degrees of freedom (elbow bending, wrist rotation, and grasp) whose control is now complete. Consequently, the toe-actuated system is now ready for testing in these three degrees of freedom, using a special stand and actuation sandals that have been constructed for that purpose. Furthermore, an alternative design of certain parts of the controller to facilitate the employment of permanent-magnet continuous d.c. motors rather than stepper motors has also been performed.

Investigations into a multi-functional myoelectric or EMG-actuated subsystem have been continued. Here efforts have been concentrated on the recognition and discrimination of three limb-functions from

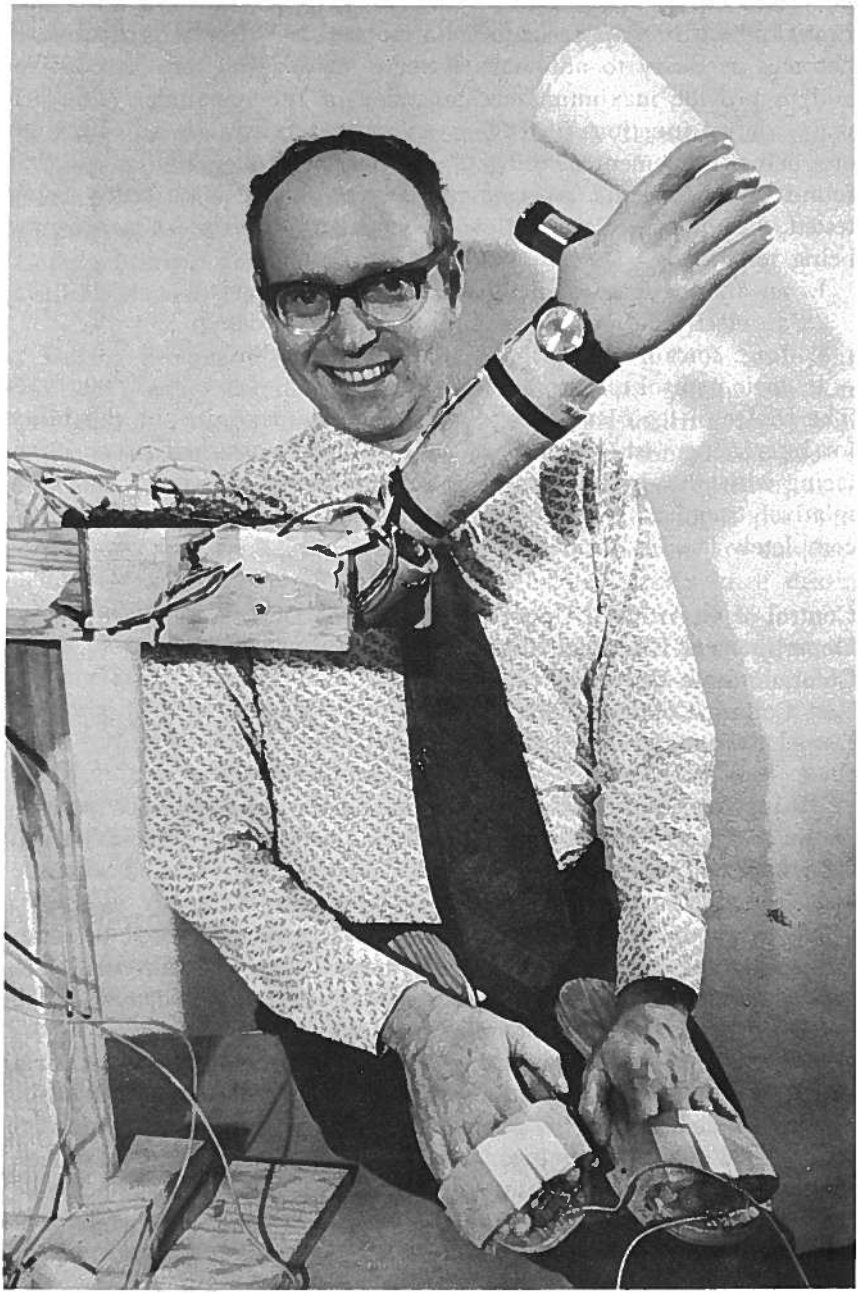

FIGURE 9

recorded EMG patterns using only two to three electrodes, via first reducing the pattern data to a small number of parameters to be identified. Following the computer analysis of this approach which has yielded satisfactory recognition and discrimination, an initial hardware design for this recognition subsystem has been made on the basis of using microcomputer microprocessor hardware. This initial design has already demonstrated that the present approach can satisfy the constraints on weight and cost that are involved in any practical prosthesis application via using recent microcomputer hardware that is presently available. It is noted that the EMG recognition subsystem can feed directly to the controller of the toe-actuated system above whose present microelectronic hardware will be further reduced in volume when using the more compact microprocessor hardware.

Future work will be concerned with the testing of the present toe-actuated system and comparing its performances using either stepper motors or continuous motors (the latter alternative hardware will thus also be constructed). The detailed design and programing of the microprocessors for the EMG recognition system will be performed to facilitate its incorporation in the controller.

A System to Provide Physiologic Sensation from an Upper-limb Amputation Prosthesis
Duke University Medical Center
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Frank W. Clippinger, Jr., M.D.

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

Acceleration of Bone Healing by Electrical Stimulation
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George Van B. Cochran, M.D., Med. Sc.D.

Significant progress related to this project was accomplished in 1973 and reported in a paper presented by Dr. Cochran at the 1974 Orthopaedic Research Society meeting in Dallas, Texas.

As a corollary to experiments on stimulation of bone healing at non-union sites, measurements were made on the electrical signals generated by bone during gait in living animals.

Special silver chloride electrodes were implanted in a dog's radius at surgery. In addition, specially encapsulated electrical resistance strain gages were bonded to the bone between the electrodes by a

technique reported previously by Dr. Cochran. Following wound healing, the dog was allowed to walk normally while measurements of stress-generated electric potentials and mechanical strain were recorded simultaneously from bone. This represents the *first time* that these mechanical and electrical data have been recorded from the skeleton during normal physiologic activity, such as gait.

Data from this new technique are expected to be an important adjunct in the study of mechanisms of bone remodeling under Wolff's Law, and to the advancement of techniques for artificial electrical stimulation of bone healing.

Results of this work are being applied to design of stimulating devices employed in this project. During this first year, development of an experimental animal model for non-unions was completed, together with preliminary tests of electrode systems and implantable stimulating devices. The project is intended to develop clinically effective techniques for accelerating the healing of non-unions and other defects in bone.

Hemodynamic Evaluation of Postoperative and Preoperative Amputee

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Work is continuing in an effort to delineate the many underlying problems of peripheral vascular disease, and acquisition of a hemodynamic profile for each patient assumes considerable importance. New instrumentation and new methods of measurement are utilized in order to develop the appropriate techniques for standardizing test procedures in peripheral vascular disease.

During the past 6 months of this project, use of a new non-invasive electromagnetic flowmeter in the clinic has occupied much time. The fundamental principle governing its operation is the same as that for the invasive electromagnetic flowmeter in that, a moving conductor (blood) in a magnetic field generates a voltage potential perpendicular both to the magnetic field and to the direction of flow. The potential uses for this device are many, especially for: 1. detection and evaluation of arteriosclerotic occlusive disease, 2. objective analysis of blood flow changes following surgical procedures, 3. repeated followup studies of surgical patients, 4. screening for peripheral vascular disease, and 5. monitoring changes in peripheral blood flow due to exercise, smoking, eating, temperature, use of vasodilators, anesthetics, etc.

The device offers comfort and safety for the patient. Measurements can be repeated many times, and as development proceeds, its opera-

tion can be done by nurses and technicians. The test procedure and analysis of results is rapid, and it can be used in test areas other than the O.R. It is expected that the device will assume an important role in quantitative vascular testing procedures. Results of initial observations with this device were presented at the American College of Angiology, which met in Phoenix, Arizona (Jan. 22–27, 1974), in a paper entitled: "A Clinical Evaluation of a Non-Invasive Electromagnetic Flowmeter."

Since this device utilized a computer mechanism, some adaptations have made it possible to use it also for "on-line" analysis of electrical impedance waveforms. A tetrapolar electrical impedance plethysmograph is now in use in the Vascular Clinic, and a computerized mode of analysis has been developed to eliminate manual computation of multiple waveforms which is tedious and severly limited with respect to the number of studies which can be done. This computerized analysis increases objectivity by decreasing the potential human bias in the analysis process. Many waveforms for each session are computed and provision is made for determining curve parameters and the statistical analysis of waveforms from clinical data. Thus computerization of waveform analysis allows "one-line" utilization of peripheral blood flow data during patient monitoring and in the O.R.

Since a major objective of the project is correlation of the degree of involvement of each patient with the objective quanitative data obtained during an evaluation, considerable progress has been made in the establishment of a Vascular Registry, a Vascular Data Bank, and a Number Code System in an effort to define the predictors of peripheral vascular disease.

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

Investigation of Elastomers and Polymers for Compatibility with Maxillofacial Reconstructions, Part I.

In order to provide tactile duplication of maxillofacial anatomical tissue, a systematic modification of stress-strain profiles of polysiloxane elastomers, using Silastic 382 as the model, has been undertaken involving a. lowering the initial modulus of elasticity (from 22 to 8 kg./cm.^{2}) and b. developing a restraining, elastic rather than viscous reactance so as to conform to the tissue response.

The lowering of the modulus, helping make the part feel more natural, is accomplished by formulating with compatible viscous siloxane fluid and intermediate molecular weight analogs. Data have

been developed on physical properties of a range of samples which will be tested for on-going patient preference. For the second case (b), essential for durability and tear resistance, cross-linking agents and modifiers are being investigated in terms of the stress-strain profiles. Tetraethyl orthosilicate (TEOS) has been found to provide this effect by restoring the rupture strength and elongation lowered by the siloxane while retaining the beneficial low modulus achieved in the first case (a).

These investigations make it possible to adjust artificial elastomers used for prostheses, usually less compliant than anatomical tissues, in tactile quality to replicate that of the recontructed maxillofacial region. Several candidate modifications are now available in a program for evaluation by patients.

Investigation of Elastomers and Polymers for Compatibility with Maxillofacial Reconstructions, Part II.

In order to approximate living tissue and thus acquire a "natural feel" with maxillofacial reconstructions, a study is in progress comparing the stress-strain profile of: 1. two-component plasticized polymers, using polyvinyl chloride as a model, compared to 2. living tissue with its multivariant composition of: a. fibrillar material, b. the sarcolemma, an encasing membrane, and c. the protoplasmic fluid. The computer models of these two systems, namely, the non-biogenic versus the biogenic models, in which the respective stress-strain profiles are reconstructed with systematically varied proportions of viscous and elastic components, suggest several significant adjustments in the non-biogenic models if they are to approximate the living tissue, not only as extra-oral prostheses but also as implants. The first of these include assessment of polymer chain flexibility involving segments of the polymer or elastomer backbone that would impose much lower elastic resistance than those relatively stiff values so common with synthetic polymers.

It has been found that polyvinyl chloride, even though plasticized with either low molecular weight (DOP) or moderately high molecular weight modifiers, is endowed with and maintains its exceptionally high segmental elasticity overcoming the low viscosity attributes. This is evident, especially from modulus measurements at a range of temperature from which the Arrhenius activation energy values, compared to polysiloxanes, denotes stiff chains in contrast to the almost freely rotating silicone-oxygen backbone of the polysiloxanes. Even the static tensile modulus of plasticized polyvinyl chloride from cold (4 deg. C.) to hot (45 deg. C.) environment increases or changes nearly 12X. Thus both: a. the computer models being used to guide the conversion with myriads of prospective viscous and non-viscous modifiers of the

tensile constants of non-biogenic prosthetic restorations to that typical of representative living tissue, and b. the stress-strain profiles obtained by experiment indicate that the tactile feel or approximation will emphasize small segment flexibility rather than plain plasticization. Both the model with its array of viscous and elastic components and the stress-strain profile, focused on additive modifications regardless of the polymer or elastomer substrate, are mutually supporting in the development of "natural feel" for the prosthesis.

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

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

Passenger Safety in Vehicles for the Handicapped
Mobility Engineering and Development, Inc.
78300 Paseo Del Rey
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Charles M. Scott

Vehicle Driver's Seat Module

The final modifications and completion of the VA training vehicles utilizing a modified version of the "Scat" adjustable height chair has led to minimum and maximum heights through which the seat must be capable of adjustment. A minimum of 14 in. above the ground must be available for best vehicular use. However, a seat height of 22 in. for use outside the vehicle is desirable. Therefore, the design of the elevating mechanism was modified to meet these requirements.

The use of commercially available molded Fiberglas seating is only partially successful. A limited sample of tests with quadriplegic patients indicates two unsatisfactory areas—insufficient widths and excessive backward tilt of the seat backs.

All patients commented favorably on the comfort and feeling of security obtained with the contoured seat. However, it does appear that more work is necessary to accommodate the special postural requirements of the quadriplegic driver.

The electrical control system requires special design in order to meet the criteria required for the power steering servo system and to integrate the power control to the driving wheels. The services of an

electronic consultant have been acquired and an elite system designed to integrate the steering and drive functions. Since some circuit functions are common to both, much simplification has already occurred. The system has been bread-boarded and partially tested. Upon completion of tests, it will be finally assembled and packaged.

Driver's Seat Holding Device

The seat holding and locking mechanism has been fabricated and installed in the VA training cars. It appears to meet the basic criteria for a safe seat and holding device. Preliminary static tests indicate that it meets the minimum strength requirements, however, further testing is required.

Passenger-Chair Holding Device

The passenger chair holding device is still a major problem. Several systems have been mocked-up and tried on patients in conventional wheelchairs. Objections are many and the extreme variety of conventional chair widths and seat heights with accompanying cushion thicknesses do not simplify the problem.

The "Stall" type of device still appears to be the safest approach; however, the compromises required to make it universal are many and difficult. Work is continuing on this portion of the project.

Spinal Cord Injury Studies: Paralysis, Spasticity, and Pain
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1201 Northwest 16th Street
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Ross M. Davis, M.D.

Evaluation of Transcutaneous Stimulation for the Treatment of Pain in Spinal-Cord-Injured Patients. It has been established that Transcutaneous Nerve Stimulation (TNS) is a worthwhile treatment for pain of many etiologies. About 5 to 10 percent of spinal-cord-injured patients experience chronic pain. This pain may be at site of injury, central phantom, or pain due to nerve root damage. In the past 1½ years, 31 spinal-cord-injured patients were treated and evaluated. About one-third of these treatments were "successful," that is, the patient received enough relief to allow a reduction in the dosage of analgesics taken and showed a strong desire to wear and use the nerve stimulator whenever pain was experienced. This preliminary study indicates that site-of-injury pain is more successfully treated than root pain, and that central pain is, in most cases, refractory to treatment. The data concerning TNS for the spinal-cord-injured patient are scant, so further

study would not only be useful clinically, but could produce useful information about the various theories concerning pain.

The Neurophysiological Basis of Spinal Cord Paralysis in Spasticity. Following the acute injury, spinal shock occurs, then weeks later reflex activity recovers below the level of injury. The bladder, through reflex activity, commences to fill and empty of urine; the bowels and blood pressure reflexes recover next. Other reflexes show activity by involuntary muscle spasms. If these reflexes become too sensitive, then spasms occur; interference with active daily living can occur. A neurophysiology laboratory has been established, and a team composed of a neurophysiologist, biomedical engineers, and a biologist has been assembled to study the synaptic reorganization that occurs with the appearance of exaggerated spasms. A detailed study of H-reflex in the lower extremities showing their ratio between the direct muscle responses and the reflex responses has been graphed. Monkeys have been made paraplegic, and the alterations to this ratio with paraplegics are now documented. A further study of synaptic inhibition of the motor neurons is now underway.

The Development of Implantable Multi-Lead Stimulators for the Control of Reflex Muscle Functions. Eighteen months ago a young paraplegic had bilateral peroneal nerve stimulators implanted for the study of long-term effects on the calf muscles. The startling effects were the complete reduction of marked spasticity to an almost normal tone in both lower extremities. He found this reaction of benefit when brace walking, as there were no longer the marked stiffness and spasms present prior to the implant and stimulation. The circumference of the calf muscles increased month by month reaching a plateau at 6 to 8 months with a 30 percent increase. A similar increase was also noted, to our surprise, in the thigh muscles but in a lesser magnitude (18 percent). Our studies are expanding and the use of multi-nerve-stimulators are being developed for implantation. This young man is being admitted in the near future to have further implants inserted in his lower extremities.

Clinical Application of Electrode Implantation in the Human Body

Brain Information Service
The Center for Health Sciences
University of California at Los Angeles
Los Angeles, California 90024
Michael H. Chase, Ph. D., and Margaret Babb, Ph. D.

The Brain Information Service at UCLA is conducting a project on the clinical applications of electrode implantation in the human body under Contract V101 (134) P–204. This project is under the direction

of Michael H. Chase, Ph. D., Director, Brain Information Service and Associate Professor of Anatomy and Physiology. Margaret Babb, Ph. D., will perform the actual work under Dr. Chase's direction. The purpose of the project is to provide a critical review of the literature in this field in order to improve communication among researchers and to prevent duplication of effort. The goals of this literature review will be: 1. to provide a survey of factors involved in electrode applications so as to allow a determination of the best methods presently available to accomplish specific clinical objectives; 2. to define the research areas in which electrodes are now used; and 3. to identify those areas which are currently the most active. This review should help to project future developments in the field of electrode implantation.

The critical review of the literature will discuss the properties of electrode-tissue interface which influence electrode behavior, and the ways in which various electrical waveforms passing through the interface affect it. The review will then deal successively with electrodes used for monitoring bioelectrical potentials and with electrodes used to pass current. The section on electrodes which pass current will be subdivided into the general areas of lesioning and stimulation. Within each area, the subject matter will be further subdivided on the basis of the various physiological systems under examination. For example, the area of stimulation will be broken down into stimulation of nervous system, muscles, and other tissues. Since at present the major area of emphasis concerns stimulation, the review will go into the greatest detail on this subject. Each section of the review will deal specifically with the questions of what is being attempted, what techniques are in use, and what successes and failures are being encountered. The final section will deal with new materials and techniques which may play a significant role in future electrode technology.

To date the following progress has been made: In order to survey the clinical applications of electrodes, a computer search of the literature from 1968 to the present was obtained using the following sources: Bioresearch Index, Biological Abstracts, NASA Literature Search, Compendex, Chemical Abstracts, U.S. Government Research and Development Report (USGRDR), Searchable Physics Information Notices (SPIN), Medlars/Medline and the Brain Information Service data base. Nearly 10,000 references were obtained which were then coded and sorted into a number of categories according to their primary content. At present, each category is being examined for the most promising references, with initial emphasis on review articles. This effort should produce a set of about 200 references which will form the core of this critical review. The report itself is intended to be not merely a set of references but a useful guide for those wishing to employ electrodes in the clinical setting.

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

Purpose

The purpose of this project will be to develop a compact, easily operated, reliable, and functionally significant system that will permit objective measurement of the patient's gait in a standard clinical environment. Specifically, a small electronic calculator will be developed which will accept floor-foot contact data from foot switches worn by the patient and will calculate the desired gait parameters (velocity, single support time, stride length, etc.) to assist the physician in making objective and clinically significant determinations about the patient's gait.

Method of Procedure

This project will be divided into the following four major categories or phases:

1. Determination of significance of gait parameters. A large group (approximately 30) of normal persons will be tested while wearing foot switches. They will be required to walk at a number of different velocities from very slow to fast while floor-foot contact data are recorded. These data will be analyzed statistically and a determination of the significance of the various gait parameters (velocity, single support time, stride length, double support time, etc.) will be made. Special attention will be given to single support time, as it has shown (in clinical tests in this laboratory) to be a good indication of gait abnormalities. The data from the normal subjects will make it possible to generate a normal single support time-velocity curve which can be used as a norm for patient data.

2. Prototype Design—Based upon the data obtained from the tests on normal subjects, a prototype of the Clinical Gait Analyzer will be designed and built. This will be a small portable electronic calculator which can be worn by the patient.

3. Clinical Testing of Prototype—Extensive clinical tests will be conducted with the prototype unit to determine what improvements will be required. Special attention will be given to reliability and ease of use.

4. Redesign of Prototype—The Clinical Gait Analyzer will be redesigned with those improvements being incorporated which were

recommended based on the results of the clinical tests. A few of the redesigned devices will be fabricated for distribution to clinics for final tests and evaluation.

Significance of this Project

Analysis of gait now follows one of two courses. In the clinic it is a visual estimate with the interpretations varying markedly according to the experience and observational skills of the examiner. The other extreme is detailed study at one of the few research centers in the country. Here sophisticated instrumentation offers precise data, but processing is so time consuming that the information is too delayed for individual patient application. Despite these limitations, definition of a patient's gait is the deciding factor in many clinical programs. Prosthetic fitting is a paramount example.

It is anticipated that the Clinical Gait Analyzer will overcome these limitations, providing a tool for clinical gait analysis much as the electrocardiograph has become an indispensable tool for cardiology.

Bed-Chair
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

Purpose

The purpose of this project is to investigate the feasibility of providing mobility for a high level spinal injury patient by means of a: 1. detachable self-propelled portion of a hospital bed, 2. a folding type self-propelled, or 3. any other self-propelled system that will decrease in width and place a patient in a position which will enable him to drive the mobile unit similar to that of an electric wheelchair.

The objective of the program will be to determine within 1 year the feasibility of the approach described above. At least one operating model will be in limited service for evaluation.

SENSORY AIDS

Edited by

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