

HIGHLIGHTS OF OTHER VA RESEARCH PROGRAMS

PROSTHETICS

Edited by

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Birmingham, Mich.

The intramedullary prostheses of Teflon have been in place for over a year in two dogs and almost 6 years in one dog. The animals have been observed and exercised frequently. They use the stumps freely with no pain and no skin breakdown on the stump end. This method of end bearing is quite satisfactory and might be applicable to human use in the future.

The two semi-buried materials that were worked within the last 6 months are Dacron mesh and Vitallium wire mesh. From earlier tissue examinations, the Dacron mesh has proved to be a readily acceptable foreign material in the semi-buried state and has the added advantage of being reasonably resistant to external fragmentation.

Efforts to do surgical tissue examination of the soft tissue in which Vitallium was embedded were hampered by the hardness of the metal. In order to be able to get an acceptable slice for tissue examination, the block of soft tissue and Vitallium was mounted in epoxy. Since epoxy and Vitallium could not be cut on a pathologist's microtome, the people at Ford Motor Co. gave assistance. Their metallurgy department has been working with the specimens, taking cuts with a glass knife and attempting to review the interface between the skin and Vitallium and the subcuticular tissue and Vitallium.

They are also working with the block specimen using electron microprobe X-ray analysis. With this technique, which employs the Roland Circle Principle, identifying each element present by its own X-ray characteristic, they found that the Vitallium, after being in the skin over 4 years, did not diffuse out into the surrounding tissue.

Work will commence with the block specimens containing Dacron.

Gilmatic, Northridge, Calif.

Gilbert M. Motis

The electric elbow has been modified to reduce noise, the limit device was included, the battery charging system is now a fixed part of the elbow, and general improvement of the gear system was accomplished. Three units have been made up as test models, and one unit is on a test amputee in the Los Angeles area.

Improvements in the muscle pressure switch have resulted in a much thinner and smaller switch which may be made to operate at various pressure ranges.

Mauch Laboratories, Inc., Dayton, Ohio

Hans A. Mauch

Additional improvements were incorporated in the Swing and Stance Control System: Bench and amputee tests were carried out with a swing control bushing having deeper fluid channels in order to reduce the swing-control resistances at minimum settings. After various modifications, a groove pattern was worked out which not only produces the lower minimum resistances sought, but also improves the resistance characteristics in both the extension and bending direction. This was achieved by reducing the depth of grooves stepwise toward both ends of the stroke. In the extension direction, this principle has been used in a less pronounced way all the time for what is called "terminal deceleration." However, in the bending direction this principle was not applied in the past. It helps significantly in limiting heel rise. This modification has become desirable as a result of the new geometry for the attachment of the hydraulic system inside the setup, described in previous reports. The use of terminal deceleration for the bending stroke is desirable not so much for walking, but for running, in which case the new geometry tended to permit excessive heel rise.

Additional theoretical studies and bench tests made it seem desirable to increase the terminal deceleration of knee bending beyond the increase achieved by changing the groove depths. This was done in a relatively simple way by changing the location of two of the four last control bushing ports, located at the end of the bending stroke of the damping piston, in such a way that they will not remain open in sitting down as was the case before, but will be passed over by the progressing damping piston at approximately 70 deg. of knee bending angle.

In order to distinguish the future Stance Control System from the one that has been used up to now and which has been referred to by the term "Type A," it was decided to name the new system "Type S-N-S" (short for SWING-N-STANCE). This S-N-S system differs from the

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Type A system used in the clinical tests not only by the improvements of the hydraulic unit mentioned above and in the last Bulletin, but also by the absence of side straps, by use of a more conventional setup, and by the new geometry which results in improved resistance characteristics and in a 1-in.-length reduction allowing better cosmesis of the shank and accommodating $\frac{1}{2}$ in. more stump length.

Work on the Hydraulic Ankle Control Unit has been continued. Rather than going ahead with all the eight production prototype units, it was decided to complete one of them first in order to test the changes in design and in drawing tolerances introduced during the past months. Fifty percent of the parts for this unit were completed in August 1968. Before the remainder can be completed, final details of the design of the lever arrangement for the restoring spring will have to be worked out. This work was 60 percent complete in September 1968.

In October 1968, the latest design changes were included in the core box and the casting patterns. The design work on the lever arrangement for the restoring spring has been continued. It is now 80 percent complete.

The theoretical studies of the problem of a Voluntarily Actuated Swing and Stance Control Unit have been continued. One problem area was found to exist with regard to power requirements of the muscle hardness sensor. It became clear that the energy drain for maintaining vibration of the probe as long as the leg was being worn would have been excessive. There was also some concern that constant vibration would produce numbness in the skin area under the sensor.

As a tentative solution for this problem, it is now intended to turn off the vibration of the probe when the leg is fully extended and when it is bent more than 70 deg. This means that there would be no vibration and no energy drain during the fully extended part of the stance phase and in sitting down. This would reduce the energy consumption substantially.

Since the vibrations would thus be restricted to flexed positions of the stance phase and to the swing phase, it is contemplated to use the frequency and/or the amplitude of the vibrations as a feedback for informing the wearer of the degree of flexion of the lower leg, for instance, by increasing either the frequency or the amplitude or both as the knee flexion angle increases. The benefit of such a feedback principle would be that the only contact point with the skin would be the vibratory probe itself, and no further mechanisms or skin areas would be involved for feedback purposes.

**Committee on Prosthetics Research and Development
National Academy of Sciences-National Research Council
Washington, D.C.
Herbert Elftman, Ph.D.**

For progress covering this report period see "Report on the Committee on Prosthetics Research and Development" appearing elsewhere in this issue.

**Committee on Prosthetic-Orthotic Education
National Academy of Sciences-National Research Council
Washington, D.C.
Herbert E. Pedersen, M.D.**

For progress covering this report period see "Report on the Committee on Prosthetic-Orthotic Education" appearing elsewhere in this issue.

**New York University, New York
Renato Contini**

Work on the socket modification program has increased during this report period with the addition of a second phase and three more subjects. The test socket of a second subject has been fitted with two distal inserts. Their size and shape were determined by the method outlined in BPR 10-9; however, the inserts are now made of Polysar^a synthetic rubber rather than the hard casting epoxy. Thus the pads can be reshaped by the application of heat.

The inserts will be tested separately and the test results will be compared with pressures obtained when no pads are used. The testing scheduled in January 1969 will include both gait analyses and any reactions of the subject and will be reported on in the next issue of the Bulletin.

In the second phase of the program transducer mounts have been added to the sockets of two subjects in order to investigate more fully known or suspected high pressure areas.

In one instance high pressures have been recorded at one sampling site on the laterodistal portion of a stump (2 in. proximal from the distal end). Four additional mounts have been inserted in the socket wall, each mount approximately $\frac{3}{4}$ in. from the original. If this high pressure is localized, the additional sites will give some indications of the pressure gradients involved. The socket will then be modified in an attempt to reduce or alter both the high pressure and the gradients. Suitable modifications will be made if the pressure acts over a more extensive area.

^a Registered trademark of the Polymer Corporation Limited.

In the second case, the subject has scar tissue on two small areas of the distal portion of his stump. The new mounts will position transducers on this tissue to determine whether pressure is the mechanism which produced skin breakdown.

The second-generation pressure transducers, which are usually taped to the inner wall or on the brim of a socket, protrude slightly into the flesh. The magnitude and pattern of the dynamic pressures being investigated could be affected by these irregularities on an otherwise smooth wall or brim. The extent to which pressure readings are affected by protrusion has been examined by means of a modified NYU transducer. The piston housing and piston rod have been lengthened $1\frac{1}{16}$ in., allowing the sensing head to protrude into the flesh. Four subjects are being tested. The results are presented in a more complete report appearing elsewhere in this issue.

Northwestern University, Chicago, Ill.
Robert G. Thompson, M.D.

Electric Power Assist

A forequarter amputee has now been using a unit for 29 months. During this 29-month period the only problems encountered were premature battery failure due to a defective cell and loosening of the charging jack. The battery was replaced and the charging jack soldered to prevent loosening. After 6 months the power screw was cleaned and lightly lubricated; however, for the past 23 months the unit has not been serviced and it is performing well.

The forequarter amputee who was to be fitted this latter quarter expired. A new forequarter amputee has been located and will be fitted in the near future.

Powered Hand Splint

A quadriplegic has been using Model I (a modified Model I power assist unit) for 18 months with no problems. A second quadriplegic has been using Model III for 4 months with no problems. Two more units of Model III are being constructed for patient evaluation.

Powered Wrist Rotator

The first unit has been fitted to a bilateral above-elbow amputee for evaluation. The control is a miniature version of the Rancho Lever Switch attached to the medial aspect of the socket. Humeral adduction is the control motion; light adduction gives rotation in one direction, and heavy adduction reverses the rotation. A second unit is being prepared for fitting.

Model II is approximately half way through the construction stage.

Immediate Postsurgical Fitting

An above-elbow amputee was fitted postoperatively at Cook County Hospital. The plaster wrap followed the technique for a below-knee. The wrap was shaped at the proximal end to flatten the proximal medial aspect and contour the proximal lateral aspect around the humerus. The suspension was a shoulder saddle with chest strap. The wrap was secured by a lateral strap and by nylon cord running through polyethylene tubing on the medial aspect. The control cable was a braided Dacron fishline. A standard Hosmer forearm and a Dorrance 5XA hook were used. The elbow (Hosmer E-400) was modified to accept a Hosmer quick change wrist. (An FM disconnect would have been better, but it was not available at the time.)

Because of a minor infection, the cast was changed after 1 week and each week thereafter for 4 weeks until the infection cleared. On the fifth week a synthetic rubber socket was applied as a temporary prosthesis. At the time of this fitting the subject was able to use his prosthesis quite well.

Five below-knee and two above-knee immediate postsurgical fittings were carried out during this report period.

A sample of the modified above-knee suspension belt has been sent to the U.S. Naval Hospital in Oakland, Calif., for evaluation.

One of the above-knee early postsurgical fittings was accomplished during the past quarter. Six weeks after the initial fitting the amputee was fitted with a temporary plastic socket. The socket was fabricated using fiber glass tubing and polyester resin. This provided some transparency in the thigh section for the purpose of observing the marked stump sock for evaluating distal contact, fit, and pumping.

Myoelectric Amplifier

An improved amplifier has been developed which has made it possible to use button-type electrodes of stainless steel, without conducting paste, while at the same time keeping the unit free from extraneous noise signals. This was accomplished primarily by increasing the common-mode impedance and by adding a 60 Hz notch filter.

Below-Elbow Myoelectric Prosthesis and Three-State Controller

This unit has been modified and has been worn for 1 month. In December 1968 the three-state control system was changed from a four-level amplitude control to a rate-sensitive control. Opening of the hand is brought about by a rapid muscle contaction. Hand closing is produced by a moderate rate of contraction and the rate of closing is proportional to the strength of this new contraction. The patient, a 20-year-old man, preferred this new control method.

Synthetic Rubber B/K PTB Sockets

A total of five synthetic rubber below-knee sockets have been fabricated according to instructions issued by the Veterans Administration Prosthetics Center. A report of this evaluation has been prepared and submitted to the VAPC.

A/K Fluid-Lined Socket

A second "self-pressurizing" socket has been constructed and worn by an amputee for 1 month with no problems. This socket has a push button to release the positive air pressure during sitting. Due to the higher coefficient of friction of the silicone rubber panels more effort is required when donning the socket compared to the effort required with conventional suction sockets.

Thigh Kicker for Hip-Disarticulation and Hemipelvectomy Prosthesis

No progress to report this quarter.

Evaluation of Spenco (unicellular rubber material infused with nitrogen)

Evaluation of this material for application in prosthetics was carried out as follows: 1. Distal pad in Chopart and Symes prostheses; 2. Padding for the distal area of a bilateral hip-disarticulation socket; 3. Soft insert for below-knee PTB prosthesis; 4. Relief for olecranon for a below-elbow socket.

Results of these applications were very positive. These shoe insoles reduced pressure on the remaining bony prominences of the Chopart amputee, resulting in markedly improved comfort. The insole applied for the sore heel syndrome produced marked relief of symptoms. Initial fitting of the bilateral hip-disarticulation socket lined with Spenco in the distal portion was very comfortable; however, further evaluation is continuing to determine if other advantages (i.e., maintenance of healed scar tissue at distal stump) exist.

A soft insert for a below-knee PTB prosthesis produced greater comfort and elimination of abrasions of the stump having adherent scars, grafted areas, and sensitivity compared to the standard Kemblo insert. (Note: Spenco will compress if incorporated into a polyester laminate using the vacuum forming technique. A substitute piece of 1/8 in. Kemblo was used to form a receptacle in the laminate and a piece of Spenco was then cut, shaped, and glued.) On initial evaluation this technique is preferred.

Hip Disarticulation

A 46-year-old obese female with a true hip-disarticulation amputation

was presented to the Prosthetic Research Clinic for evaluation of her prosthetic problems. Lack of lateral support in the socket allowed migration of the stump out of the socket resulting in pressure on the ramus. On recommendation from the clinic team a weight-bearing prosthesis was fabricated for the amputee incorporating a hemipelvectomy socket. The socket provided adequate weight-bearing support eliminating tissue displacement and perineal pain. The amputee is ambulatory without discomfort and limited only by her reduced physical stamina.

**University of California at Los Angeles
Biotechnology Laboratory
John Lyman, Ph.D.**

VA-sponsored investigations have been directed toward the following objectives: Establishment of mathematical models to describe the dynamics of human arm motions, development of an EMG signal processing system, design of hybrid, electrically piloted/fluid-operated actuators, and the feasibility of computer aiding in the operation of powered appliances.

The study of voluntary human arm motions was conducted to determine the form of a model for multiple degree-of-freedom movements and to describe the movement of the arm about each axis of rotation during a target approach task. The goal of this study was to discover methods of simplifying man-machine interfaces and operator decision loading in the control of prostheses/orthoses. A model form involving switching from on-off to proportional control as motion progresses was developed. Parameter changes were required as a function of target size. It was also discovered that movement about all axes of rotation have the same form and that the onset of motion is sequential with respect to the rotation axes involved. Further effort is planned to determine values for model parameters and the form of coupling between the motions about the axes of rotation in a complex motion.

An EMG signal processing system has been developed which utilizes the shift in the average frequency of the myoelectrical signal to generate control information for powered prostheses/orthoses. The frequency shift is associated with changes in the level of muscular effort and can be detected through determining the average frequency of the EMG signal in the 150–1000 Hz band. This method yields an exploitable range of the frequency shift from zero to around 300–400 Hz associated with zero to maximum muscular effort. Experiments are being conducted to test the signal repeatability and its stability, the effect of fatigue of the subject and of his reaction time on the signal generation, and the subject's pursuit tracking performance.

A new approach to design of actuator assemblies for prosthetic/orthotic application seemed necessary since electrical motors appear well controllable, but too heavy, fluid actuators develop sufficient torque with respect to their weight but lack repeatability of operation if employed for both proportional driving and holding in the same application, and stepper units are normally heavier than d.c. motors generating equivalent torque. These considerations have led to the concept of stepper-piloted and fluid-operated actuators. The idea is to determine the position of the spool of a four-way valve via a differential linkage through a stepper motor and having the position of the actuator rod feed back into the spool control linkage. Design studies are in progress to dimension suitable actuator assemblies and test mechanisms. Simultaneously, specific stepper drive circuitry is under development.

To investigate further the feasibility for easing the decision load encountered by the user of powered appliances, a concept of real-time computer-aiding is being studied. This approach is called semi-autonomous control and it refers to a concept for systematically shifting the task of generating control decisions from the human operator to the equipment he wishes to control. The aiding system envisioned will have to respond to both the operator's skill and information about the environment where the appliance is operated. It is expected that through the establishment of favored paths of movements, or repeatedly utilized movement patterns, the sharing of the decision load between the patient and the powered appliance system he controls can be optimized.

University of California at San Francisco and Berkeley

Charles W. Radcliffe, Howard D. Eberhart, and James M. Morris, M.D.

The prototype UC-BL Polycentric-Pneumatic Prosthetic Knee unit is being tested in daily amputee use. Further development of adjustable socket-knee coupling systems is continuing.

A project for the design of an axial rotation device for the shank has been reactivated. New developments in bearing technology make the design of a much lighter and more durable unit now possible.

A digital computer program for the study of the dynamics of swing-control systems is being written which will allow the simulation and analysis of most of the currently available swing-control devices without resorting to amputee testing.

The instrumentation for the kinematic study of the simultaneous motions occurring at the joints of the lower extremity has been completed and is now being tested. This study is expected to give important information on basic parameters for the description of normal and abnormal gait patterns.

A workshop on spinal orthotics, with Dr. James Morris as Chairman, was held on March 28–29, 1969, at the University of California Medical Center, San Francisco. Topics covered included Biomechanics of the Spine, Bracing for Pathologic Conditions of the Spine, Bracing for Traumatic Injuries of the Spine, Bracing for Low Back Pain, and Future Areas of Research in Spinal Bracing.

Dr. Morris consulted with engineers at Goodyear Aerospace, Akron, Ohio; they have agreed to fabricate a prototype model of the inflatable back support. The support was scheduled for delivery in the middle of March 1969.

Design and engineering of a rotating mechanism for long spinal supports is proceeding satisfactorily. A graduate engineering student has been assigned to the project.

VA Hospital, Seattle, Wash.

Ernest M. Burgess, M.D., and Joseph H. Zetfl

The basic research program involves instrumenting above-knee and below-knee immediate postsurgical prostheses to record objectively pressures at stump-interface immediately following closed amputation and during the first 10-14 postoperative days. The technique requires the introduction of sterile transducers at fixed areas on the stump with the recording leads brought proximally above the cast. Recordings are made with the extremity in a number of different positions including controlled weight bearing and are plotted against time. The objective is to record pressures under existing, standardized techniques and determine, where possible, desirable or optimum pressures.

Temperature and surface EMG leads also are used under conditions noted above. The objective here is to record and correlate stump temperatures and stump muscle electrical activity with clinical course.

Clinical research is primarily involved in refinement of immediate postoperative prosthetics techniques including interface material (polyurethane foam), above-knee suspension, upper-extremity fitting and training, and improved and positive myoplasty-myodesis surgical muscle stabilization at both below-knee and above-knee levels. Guidelines are being established for the determination of level of amputation in the ischemic lower-extremity patient.

A much more detailed manual on the latest techniques in immediate postsurgical prosthetics is being prepared for printing. It will be available for purchase from the Superintendent of Documents. In addition, lectures, instructional courses, demonstrations, conferences in the United States and abroad, and the writing of three articles and a section of a new surgical text were accomplished.

VA Hospital, San Francisco, California

Wesley L. Moore, M.D., and Albert D. Hall, M.D.

In this report period the Veterans Administration Hospital, San Francisco, has continued to carry out a clinical evaluation of the immediate postoperative fitting of prosthesis in patients undergoing below-knee amputation for vascular insufficiency. The total number of patients now entered in the study is 32. There have been no postoperative deaths in this group of geriatric vascular amputees and the primary healing rate continues to be 90 percent. This is in agreement with the original report in the December 1968 issue of the Archives of Surgery. The rehabilitation rate of all patients who were ambulatory prior to their amputation remains 100 percent.

Assembly and construction of equipment to carry out measurements of skin blood flow utilizing the isotope Xenon¹³³ have now been completed. At the present time all new patients who will be entered into the amputation study will be studied with regard to skin blood flow utilizing isotope techniques, in addition to an evaluation of the applicability of the Doppler flow meter, as well as a clinical evaluation of capacitance plethysmography. The data obtained with these studies will be correlated with success or failure of the amputation level to heal. In this manner it is hoped to be able to establish the minimum blood flow requirements of skin in order to predict accurately the level of successful amputation.

Harvard Medical School

Boston, Mass.

Richard Warren, M.D.

As of January 1, 1969, there were 486 patients on whom Form 2 (the form that is completed at discharge or at 3 months, whichever comes sooner) had been received. Form 3 (the form that is completed at 1 year followup from the time of amputation) had been received on 335 patients. Since the latter excludes patients who have died, and who had later amputations, it represents a very high percent of expected submissions.

A meeting of the investigators was held in Atlantic City on October 14, 1968, and mutual problems were ironed out. Since two member hospitals had dropped out, namely, Long Beach and Philadelphia, 21 participating hospitals were left.

There had been five changes in principal investigators in the hospitals. The study will be closed at the end of the calendar year 1969. Analysis of results will be performed during the calendar year 1970. The employment of a half-time executive secretary, Mrs. Robert R. Marshall, to be the coordinating individual in the Central Office is recorded.