Throughout the 18-month period covered by this report, activities of the Prosthetics Research Study (PRS) have centered on amputation surgical techniques, immediate postsurgical prosthetic fitting, related research, and evaluation. To accomplish a major part of these activities, an additional 126 patients have been treated using the techniques developed by the Prosthetics Research Study. There were 141 surgical procedures performed, and 699 rigid dressings with pylon prostheses were applied.

Throughout the period indicated, 47 definitive prostheses were fabricated, fitted, and delivered to patients by PRS. An additional 75 prostheses, both lower and upper extremity, were fabricated and fitted at local commercial prosthetic facilities.

Emphasis was placed on development, improvement, and evaluation of other than conventional prosthetic replacements whenever feasible. For immediate postsurgically fitted patients, the majority of prostheses, i.e., below knee and lower levels, were fabricated, fitted, and delivered in a finished or acceptable, safe, "rough" stage on the same day cast and measurements were taken, so as not to interrupt the patient’s rehabilitation progress and to avoid the additional cost of manufacturing intermediate or preparatory protheses.

Socket replacement for the average patient ranged between 9 months and 1 year. A small number of patients required socket replacements after 1 year or more.

* Based on work performed under VA Contract V663P-505.
1. CONTINUED SURGICAL RESEARCH OF AMPUTATION SURGERY INCLUDING TECHNICAL IMPROVEMENTS AND EVALUATION

Surgical experience in an additional 60 patients requiring major lower-extremity amputation for peripheral vascular disease has verified and extended earlier observations. At least 80 percent of these patients will heal a below-knee amputation using the PRS system of management; the amputation site will remain healed and the rehabilitation potential high. We have continued to modify and refine the surgical techniques. In the spring of 1970, the principal investigator (EMB) presented our amputation experience in peripheral vascular disease at the Combined Meeting of the English-Speaking Orthopedic Associations held in Sydney, Australia. In the course of this trip, clinics were held in a number of areas throughout the world. The below-knee surgery has been demonstrated at various medical centers and our experience duplicated by surgical-prosthetic teams worldwide. Variations in wound closure at the below-knee level have been used experimentally. The now well-established PRS below-knee amputation and immediate postsurgical prosthetic management is thus further reinforced statistically and is technically stabilized.

Clinical surgical research at the knee-disarticulation level is progressing. A transcondylar, fully endbearing knee-disarticulation technique at a level approximately 1½ in. above the distal end of the femoral condyles is being developed. The patella is removed with quadriceps integrity restored by suture. Moderate condylar shaving and contouring similar to the technique described by Mazet is then performed. This amputation is designed to conserve the advantages of endbearing, maintain a long femoral lever arm, and leave sufficient distal femoral condylar contours to aid stump-socket stability and socket suspension. The level permits the use of intrinsic prosthetic knee mechanisms with only slight lowering of the center of knee motion. Details of this modified knee disarticulation and the definitive prosthesis designed for it are being reported.

We are continuing to study surgery for more efficient muscle stabilization at the above-knee level. It is our firm conviction that adequate muscle stabilization in the above-knee amputation is of vital importance and essential to maximum function.

During the period covered by this report, PRS surgeons have acted in the capacity of consultants to the Office of the Surgeon General. Various Army general hospitals were visited to provide surgical services, to demonstrate techniques, and to review large numbers of amputee problems. The immediate postsurgical system of management modified and individualized for the Vietnam era amputee has gained acceptance in selected military hospitals.
2. CONTINUED IMMEDIATE POSTSURGICAL PROSTHETIC RESEARCH INCLUDING TECHNICAL IMPROVEMENTS AND EVALUATION

Pressure Relief Pads for Below-Knee Rigid Dressings: After overcoming initial difficulties in finalizing shapes, density, and general quality of compressed reticulated polyurethane pressure relief pads, the manufacturing dies were completed. Following our clinical evaluation, the manufacturer recently initiated production. The compressed reticulated polyurethane pressure relief pads simulate the density of the previously used felt pads and are provided with an adhesive peel-and-stick spot backing. They are gas-sterilized in the same manner as reticulated polyurethane distal pads and Orlon Lycra stump socks. The new relief pads should now be available through Knit-Rite, Inc.

Shoulder Suspension Belt for Cast Application: To create a satisfactory stump-cast socket environment during application of the rigid dressing, initial tissue immobilization and support has been achieved by firm manual tension on the proximal aspect of the Orlon Lycra stump sock by an assistant. If this tension is allowed to vary before the plaster bandage has hardened, the pressure relief pads may become displaced. Inadequate tension can also allow wrinkles in the stump sock and lack of tissue support over the operative site. We now use an adjustable right or left interchangeable shoulder suspension belt made of a 2-in. webbing shoulder strap and two 1-in. elastic webbing straps to which two metal hooks are attached for suspension of the stump sock. The assembly is adjustable for individual needs. Thus the desired tension on the stump can be achieved and maintained effectively through the entire casting procedure. The shoulder suspension belt can be quickly fabricated in any prosthetic facility.

“Lightcast” to Substitute Plaster Bandage in the Immediate Postsurgical Rigid Dressing: The recent introduction of “Lightcast” as a substitute for plaster-of-paris bandage encouraged a preliminary investigation into the use of this material for our current plaster wrap technique at the time of initial cast change or later. As introduced by the manufacturer, “Lightcast” consists of fiber glass fabric bandages in various widths that are impregnated with an unsaturated polyester plastic and whose polymerization has been interrupted prior to its completion at which time it was packaged in metal foil. Upon application of the fiber glass bandages, the polymerization process is completed by a special ultraviolet lamp in 6 min., or less with the newer improved type of lamp. While the manufacturer recommends application of polypropylene stockinet prior to the fiber glass bandages, nylon and cotton stockinet including Orlon Lycra, cotton, and wool stump socks have been used without particular difficulties. To gain sufficient experience with the “Lightcast” material, cast-sockets were applied to well-healed
and mature stumps. While the resulting sockets proved relatively acceptable as an intermediate preparatory or short-term prosthesis, the value of "Lightcast" to replace the current PRS rigid dressing casting system for immediate postsurgical prosthetic fitting is questionable. Among the difficulties encountered is the wrapping of the fiber glass bandage which does not allow the tissue manipulation of the customary anterior-posterior wrap possible as with the elastic plaster bandage. A major problem is the need for the ultraviolet lamp, not available in all hospitals, to complete polymerization of the fiber glass bandage. "Lightcast" below-knee sockets for intermediate prostheses, after primary healing has occurred, are under investigation and reported in the section "Experimental Prosthesis Research."

3. CONTINUED IMMEDIATE POSTSURGICAL PROSTHETIC COMPONENTS AND EQUIPMENT RESEARCH INCLUDING TECHNICAL IMPROVEMENTS AND EVALUATION

Articulating Knee Joint with Manual Lock for Immediate Postsurgical Hip-Disarticulation Prosthesis: Efforts to design an immediate postsurgical hip-disarticulation prosthetic unit with manual locking knee mechanism were considered and abandoned when it was found that such a system could be produced simply by converting already existing units for this purpose. Combining the U.S. Manufacturing Co. adjustable above-knee and below-knee postsurgical prostheses into one unit allowed a postsurgical prosthesis for the hip-disarticulation amputee to be made. This prosthesis provides the means for an improved gait pattern in the postsurgical period and circumvents hiking on the sound side including circumduction of the prosthesis during swing phase. For detailed description and illustrations, see "The Hip-Disarticulation and Short Above-Knee Immediate Postsurgical Adjustable Pylon Prosthesis," Bulletin of Prosthetics Research, BPR 10–13 Spring 1970, pp. 64-69.

Pylon Thigh Extension System for the Short Above-Knee Immediate Postsurgical Pylon Prosthesis: Fitting the short above-knee stump with an immediate postsurgical pylon prosthesis originally required the incorporation of a short balsa or styrofoam extension block between the distal cast-socket and the socket attachment plate in order to place the effective prosthetic knee center in a functional position level with the sound side. The length requirement usually could not be predetermined prior to surgery, thus several extension blocks of various lengths were required. Also, proper alignment and incorporation of the extension block were time consuming and resulted in extensive plaster work. The new hip-disarticulation pylon system has eliminated the balsa or styrofoam thigh block extension and resulted in a quicker, less complicated application of the rigid dressing.
The PRS Adjustable Prosthetic Syme Unit: In the previous progress report that listed the commercial source for the PRS Adjustable Prosthetic Syme unit it was found that the company has since terminated its operation. A new manufacturer and supplier for this unit is in the process of being located.

4. CONTINUATION OF BASIC STUDIES ON THE EFFECTS OF PRESSURE ON WOUND HEALING INCLUDING EMG ACTIVITY OF STUMP MUSCULATURE

The basic research program conducted at PRS is carried out with the cooperation of the Bioengineering Service of the VA Prosthetics Center, New York City. These studies involve instrumentation of amputation stumps to record resulting pressures of stump-socket interface in immediate postsurgical and definitive prosthesis. Studies relevant to the EMG activity of stump musculature are also carried out. These studies were suspended temporarily to allow for replacement with improved and more compact electronic equipment by VAPC and have now been resumed.

5. AN INTENSIFIED AND STRICTLY MONITORED POSTSURGICAL MANAGEMENT AND TRAINING PROGRAM FOR ALL PATIENTS

Greater emphasis has been and will continue to be placed on muscle reeducation and controlled gait training to more effectively utilize muscle stabilization techniques. Increased muscle activity in normal gait sequence appears to provide increased position sense in the foot and thereby improves stability and control of the prosthesis. Continued research and clinical evaluation to further substantiate these observations should lead to more detailed and improved gait training techniques for the immediate postsurgical amputee patient.

6. CONTINUATION OF INTENSIVE TRAINING OF SURGEON-PROSTHETIST-THERAPIST TEAMS

Much time, energy, and effort by PRS personnel are directed toward education. Many individuals and surgeon-prosthetist-therapist teams visited the PRS laboratory in Seattle and were introduced, instructed, and trained in current techniques.

Staff members also presented lectures and demonstrations on immediate postsurgical prosthetic fitting and related subjects at various professional meetings and assemblies.

7. PREPARATION OF EDUCATION AND TECHNICAL REPORTS

The continued advances and improvements in immediate postsurgical prosthetic fitting and related research to be meaningful and effective
must be promptly disseminated to those interested and actively engaged in this work. PRS reports and articles are being published in professional journals to assist in accomplishing this goal.

Motion picture series for all levels of amputation surgery including immediate postsurgical prosthetic fitting and patient management are being prepared. These single-concept films will cover all major levels of amputation: postsurgical management and basic rehabilitation including prosthetics. A first of these films, i.e., the Below-Knee Amputation for Peripheral Vascular Disease, is in the process of completion.

8. CONTINUATION OF STATISTICAL DATA FOR COLLECTION AND IN-DEPTH PATIENT FOLLOWUP

Long term patient followup and review is continuing on all patients available and treated under the system of immediate postsurgical prosthetic fitting. An extensive statistical analysis and coding of unselected consecutive groups of patients amputated as the result of ischemia have been completed and the findings of this study have been submitted for publication in the Journal of Bone and Joint Surgery. A similar study for amputations as the result of trauma is presently being completed.

9. CONTINUATION OF EXPERIMENTAL PROSTHESIS RESEARCH, IMPROVED FITTING AND FABRICATION PROCEDURES INCLUDING EVALUATION

Patellar-Tendon-Supracondylar Below-Knee Prosthesis: Basically two types of suspension systems are being evaluated here. One approach, the supracondylar system, encloses the femoral condyles into the prosthetic socket. The other system, the supracondylar-suprapatellar, encloses the condyles and the patella into the prosthetic socket. Both systems incorporate a custom-made laminated wedge of Solka floc fitted over the medial femoral condyle to provide socket suspension. The wedge suspension system has been further modified by eliminating one of the two pins that locate and lock the wedge securely in place against the medial proximal prosthetic socket brim. This allows the wedge to swivel slightly on the remaining pin as the patient is seated and during swing of the prosthesis providing a more comfortable stump flexion positioning. These modified PTS prostheses have been fabricated with satisfactory results.

PRS Closed Syme Prosthesis: The approach of incorporating an insert type of sleeve fabricated from a combination of Silastic foam and Kemblo rubber into a closed Syme prosthesis has resulted in highly favorable reactions by the patients fitted. None of the Syme prostheses fitted so far has shown any evidence of structural failure, with two having been
in service now over 3 years. More fittings are planned as patients become available.

PRS Closed Knee-Disarticulation Prosthesis: Six additional prostheses have been fitted for knee-disarticulation amputees that incorporate the same principles described for the closed Syme prosthesis. While patient comfort is high, the disadvantage is in the additional bulk as the insert causes poor cosmesis in the classical knee-disarticulation amputee. Modifications to the surgical procedure appear to be a more effective solution to the problem.

Synthetic Rubber Polysar Direct Molding of Temporary and/or Definitive Below-Knee Prosthesis: Through the assistance and cooperation of the VA Prosthetics Center, New York, who furnished the necessary materials and instructions, the PRS engaged in a study of direct forming of a series of below-knee prosthetic sockets using Polysar synthetic balata.

For evaluation purposes initially, patients with mature, well-stabilized stumps (2 years postsurgery or more) were fitted who were wearing an equivalent type of PTB or PTS hard socket prosthesis successfully since amputation. After initial adjustments, the resulting socket comfort was compatible to the patients who were wearing conventionally laminated plastic PTB or PTS prostheses. Nevertheless, patients seemed to show a preference toward their conventional prosthesis since this was the one they chose to wear permanently.

A second group of patients fitted with direct molded synthetic sockets were those fitted with their first socket other than plaster of paris approximately 4 to 6 weeks postsurgically. The initial time saved in fabrication of the prosthesis was lost when periodic socket adjustments were required due to atrophic stump changes. Stump atrophy taking place in the area of the gastrocnemius soleus and the pretibials necessitated complete socket removal including remolding to alleviate the problem. By filling a mixture of polyester resin and micro balloon spheres into appropriate areas of a conventional laminated hard PTB or PTS socket, similar results are achieved in less time. In our initial experience with modular or pylon systems, aside from some noticeable bulk, a weight increase over conventional prostheses was evident. Also, occasional mechanical problems related to the adjustable pylon prosthesis including the foot attachment have been experienced. Since these problems are absent in the conventional laminated PTB or PTS (total absence of mechanical segments), the pylon system should be equally durable and safe. The adjustable segment of a pylon or modular system is only valuable during static and dynamic alignment of the limb and instead of adding unnecessary weight to the prosthesis should be removed by

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b Registered trademark of the Polymer Corporation, Ltd., Sarnia, Ontario, Canada.
transfer upon completion of prosthetic alignment and replaced with a pylon tube alone. More fittings are planned in an effort to widen experience and to seek possible improvements.

“Lightcast” for Direct Molding of a Temporary and/or Definitive Below-Knee Prosthesis: Six “Lightcast” sockets were fitted by direct molding. The principles of direct molding of below-knee sockets using “Polysar,” a synthetic balata, were expanded and modified for this purpose. The advantages of the resulting fiber glass sockets lie in the material’s inherent characteristics of porosity and extreme lightness. Furthermore, the material itself remains unaffected when submerged in water thus yielding a socket that is theoretically suitable for hot, humid climates. Application techniques varied considerably until a suitable approach was developed. Most satisfactory results were obtained by applying initially a thin cast sock over the stump and by applying felt relief pads over pressure sensitive areas of the stump and for relief of the hamstring tendons. A second heavier stump sock was applied over the initial cast sock prior to application of the “Lightcast” bandages. Finally the socket was molded over the pressure tolerant areas of the stump, i.e., the areas of the patellar tendon and the pretibial muscle group and over the shaft of the fibula, as the polymerization process was being completed under the ultraviolet lamp.

Difficulties were experienced in the application of “Lightcast” bandage since it lacks the characteristics of elastic plaster bandage which allow controlled pressures and tissue manipulation. The stickiness of the bandages as a result of the required partial polymerization proved troublesome. Distal socket contours could be covered effectively only with “Lightcast” bandages cut into splints. While pressure areas of the socket can be relieved when heated, the material will not shrink. Thus, an attempted adjustment, for example, decreasing the medio-lateral socket dimension, will result in an increase of the anterior-posterior dimension. Socket comfort was not comparable with a definitive, conventionally laminated below-knee socket.

In view of this limited experience, these findings are considered preliminary and more fittings are planned in an effort to obtain more experience. “Lightcast” is also applicable for a variety of splints.

Premodified Casting for Definitive PTB Below-Knee Prosthesis: After several years of improvements and redesign, a system to modify PTB casts at the time of casting and measuring for the definitive prosthesis has been finalized by PRS. In essence, the completed cast represents all fixed characteristics of a finished PTB socket without the customary modifications to the positive mold. This eliminates guesswork on the part of the prosthetist and results in a more accurate stump replica being

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obtained even by a less experienced individual.

This casting system has been applied effectively on several hundred patients with good results achieved even by student prosthetists under relatively primitive teaching conditions and with minimal supervision. A detailed step-by-step description is published in the Spring 1971 issue of ARTIFICIAL LIMBS under the title, “Premodified Casting for the Patellar-Tendon-Bearing Below-Knee Prosthesis.”

Fabrication of Special Prostheses: Several patients from various geographical areas in the United States were among those multiple amputees with severely burned, scarred, and/or skin grafted stumps who presented themselves at PRS to be evaluated, fitted, and trained with specially modified, experimental and/or standard types of prostheses. All of the patients were eventually fitted with limbs. Those already wearing a prosthesis but having various difficulties were refitted and trained with new prostheses.

10. EVALUATION OF PROSTHETIC COMPONENTS AND RELATED HARDWARE

Approximately a year ago, VA Prosthetics Center, New York, launched a nationwide evaluation program for prosthetic components and related hardware at various Veterans Administration-sponsored research centers. PRS in Seattle is participating in these studies at the clinical level to evaluate and gain experience with these items. The initial evaluation program on the BSK (Blatchford Stabilized Knee) is presently being completed. The second study on power units for wheelchairs has been initiated and is in progress.

SUMMARY

This progress report documents, in a general manner, the activities of the Prosthetics Research Study team in Seattle, supported by the U.S. Veterans Administration. PRS has a unique continuing investigative opportunity in that the amputation surgery volume is relatively high and reflects a total cross section of amputees as encountered in civilian life. The farsighted policy of the Prosthetic and Sensory Aids Service of the United States Veterans Administration in allowing this research unit to utilize clinical material from sources other than the veterans population, i.e., children’s amputee services, industrial amputee services, and amputees from university affiliated hospitals system, permits accumulation of diverse material for investigative purposes. This material continues to increase in volume and interest. A regional amputation center is now being established at the Veterans Administration Hospital, Seattle. PRS staff will direct and coordinate its activities on both a research and clinical basis.