

PROSTHETICS RESEARCH STUDY ^a
PROGRESS REPORT
DECEMBER 1, 1967—JUNE 30, 1969

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INTRODUCTION

Throughout the period covered by this report, the activities of the Prosthetics Research Study in immediate postsurgical prosthetic fitting have been divided into:

1. Surgical research and technical improvements,
2. Prosthetic research and technical improvements,
3. Component and equipment research,
4. Basic investigation with specific emphasis on the effects of pressure on wound healing,
5. Intensive training for surgeon-prosthetist-therapist teams,
6. Preparation of educational material,
7. Statistical data collection and in-depth patient followup,
8. Experimental prosthesis evaluation,
9. General prosthetics activities.

To accomplish several of the above listed activities, an additional 117 patients have been treated using the techniques developed by the Prosthetics Research Study, including certain technical variations and improvements for evaluation purposes.

^a Based on work performed under VA Contract V5261P-438.

STATISTICS

December 1, 1967—June 30, 1969

1. TOTAL NUMBER OF PATIENTS—117 (92 males, 25 females):

2. AGE GROUP IN YEARS:

1-12 -----	4
13-24 -----	13
25-50 -----	27
51-75 -----	65
76 and over -----	8

3. ETIOLOGY:

Vascular with diabetes -----	36
Vascular without diabetes -----	27
Infection -----	14
Sarcoma -----	7
Trauma and post trauma complications -----	28
Congenital -----	3
Other -----	2
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Total -----	117

4. LEVEL OF AMPUTATION:

Hip disarticulation -----	3
Above knee -----	15
Knee disarticulation -----	3
Below knee -----	92
Syme -----	5
Transmetatarsal -----	1
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Total (see 5. below) -----	119

5. 119 primary amputations—117 total PRS patients. Two patients underwent a two-level procedure at the same surgery, i.e., PRS #22b, left below-knee amputation and right above-knee amputation. PRS #256, right below-knee amputation and left transmetatarsal.

Four two-stage procedures (open amputation with secondary closure) were performed.

6. DEFINITIVE PROSTHESES:

105 patients fitted with definitive prostheses

2 expired within 30 days of surgery from unrelated conditions

6 received no prosthesis^b
discontinued^c

3 still under treatment and not ready to be fitted.

91 percent of all 117 PRS patients were fitted with their definitive prostheses. Of the 9 percent not fitted, 5 percent had no wound healing problems.

7. COMPLICATIONS:

- 1 revision to higher level (knee disarticulation—above knee)
- 4 revisions to same level (below knee—below knee)
- 2 soft tissue revisions
- 3 debridements
- 4 delayed wound healing not requiring revision

All of the above listed patients were fitted with their definitive prostheses and are included in the 105 patients fitted with definitive prostheses.

^b No Prosthesis:

- 1—Healed 30th post-op day. No prosthesis due to psychosocial abnormal status.
- 2—Delayed healing (2 months post-op). No prosthesis due to psychosocial abnormal status.
- 3—Delayed healing (2½ months post-op). No prosthesis due to complications of opposite leg.
- 4—Healed 29th post-op day. No prosthesis because of lack of funds.
- 5—Healed 34th post-op day. No prosthesis due to psycho-social abnormal status.
- 6—Healed 38th post-op day. No prosthesis due to psycho-social abnormal status.

^c Discontinued cases:

- 1—Discontinued because of other medical complications.
- 2—Wound healed 32nd post-op day. Complication due to skin necrosis and non-PRS revision.
- 3—Discontinued due to infection. Above knee—above knee; non-PRS revision.

1. SURGICAL RESEARCH AND TECHNICAL IMPROVEMENTS

Early in our investigation of immediate postsurgical prosthetic fitting it was evident that variations in surgical technique played a primary role in the success or failure of this system of management. A major investigative effort has been directed toward appraising current surgical amputation techniques in the light of modern knowledge of collateral circulation, peripheral vascular reconstructive surgery, and tissue-healing potential under varying physical circumstances. Measures to obtain primary wound healing in lower-extremity amputations for peripheral vascular disease relative to the level of amputation have been statistically evaluated. A wide variety of technical modifications has been instituted in an attempt to lower the level of amputation in this major group of patients. We are now

in a position to state with certainty that 80 to 89 percent of all major lower-extremity amputations for peripheral vascular disease can be successfully performed at the below-knee level. Computerized recent and long-range followup of patients in this classification substantiates the thesis that amputations will heal at this level and remain healed when appropriate surgery and postsurgical management are carried out.

The Prosthetics Research Study has further amplified and is in the process of technically developing the "dynamic stump" approach to all amputations in which blood supply permits maximum utilization of remaining functional elements in the stump, particularly transected muscle groups. A surgical method of muscle stabilization at the various levels of upper- and lower-extremity amputation has been exploited experimentally and clinically. This study continues. Of particular importance is the surgical means of attaining appropriate muscle stabilization in the above-knee amputee and in amputations throughout the upper extremity. Anticipating a greatly increased demand for implant surgery, we are seeking appropriate ways of obtaining voluntary muscle activity in stump musculature heretofore largely ignored. We believe that future prosthetic advances will, to the large degree, relate directly to the type of amputation stump which can now be provided and which future surgical improvements will create. The immediate postsurgical concept has crystallized as never before the realization that amputee rehabilitation cannot be compartmentalized. We are proceeding on the belief that major advances in amputation surgery will continue at an accelerated pace during the immediate months and years ahead. Both the clinical and research prosthetist must more fully understand the nature, the problems, and the possibilities inherent in amputation surgery. Likewise, the clinical and experimental amputee surgeon must become increasingly knowledgeable in prosthetic restoration. Immediate postsurgical prosthetic systems of management continue to firmly weld the two disciplines.

Muscle and bone exteriorization techniques (as with cineplasty) present another aspect of amputation surgery under consideration by this Study. Nerve exteriorization for afferentation, considered by us over the past 2 or 3 years, has not been applied clinically but is still on our agenda. Bone bonding agents (acrylics) may well have a role in amputation surgical techniques. These substances are under consideration.

2. PROSTHETIC RESEARCH AND TECHNICAL IMPROVEMENTS

Silastic Foam Pads

While it was evident that these custom-made perforated foam pads of a mixture of Silastic 388 Denture Release and Silastic 386 Foam Elastomer showed improved tissue support and compression over the amputation site, their use was discontinued. It was suspected that the perforations or vent holes were not sufficient in number and were closing up under compression

either through application of the elastic plaster bandage or during weight-bearing activities. The chance of skin maceration through nonabsorbent material, heat creation, the weight factor, and the economics involved in producing these pads made this approach questionable.

Reticulated Polyurethane Distal Pads

With the assistance of the manufacturer of this material, the problems of achieving satisfactorily shaped end pads were solved. Initially, three densities were evaluated, with the 20 pores per inch proving to be most suitable. These open-celled preformed pads permit free passing of fluids while retaining their elasticity for an unlimited time. The material is non-irritating, inexpensive, and can be gas or steam sterilized. Results of clinical applications in approximately one hundred cases have shown the desired effectiveness of this interface agent. Reticulated polyurethane distal pads in 3, 4, 5, and 6 in. sizes are now commercially available through Knit-Rite, Inc.

Reticulated Polyurethane in Sheet Form

This material, identical to the above-mentioned distal pads, is available in 1/2-in.-thick sheets. It is used as a compression interface for Syme amputation and hip-disarticulation immediate postsurgical prosthetic fitting. Evaluation will continue in using this material for wound dressings in other surgical procedures.

Relief Pads for Below-Knee Cast Sockets

Presently, efforts are being made to replace the felt relief pads of the below-knee rigid dressing with adhesive-backed compressed reticulated polyurethane in the same density as orthopedic felt. The dies are being prepared at this time.

Above-Knee Suspension Waistbelts

The initial PRS above-knee webbing suspension belt was redesigned as the result of definite shortcomings in the original design. The new type incorporates a tailored garment which is more comfortable to the patient, provides improved rotational stability, and includes increased suspension for the rigid dressing. Adjustability is greatly increased with the use of anterior adjustment straps and lacing pull tabs located laterally for posterior adjustment. The above-knee suspension waistbelt is interchangeable for left and right amputations and is made in appropriate sizes, i.e., extra small, small, medium, large, and extra large. They are commercially available through the S. H. Camp Co., and through Knit-Rite, Inc.

Below-Knee and Syme Suspension Waistbelts

A redesigned and improved version of the below-knee and Syme suspension waistbelt was made available by the VA Prosthetics Center, New York. It has been evaluated and found more acceptable and comfortable by the

patients who wore them. This suspension belt is being made in our prosthetics laboratory and is used routinely for our below-knee and Syme patients.

POLYSAR^d Synthetic Rubber for Immediate Postsurgical Below-Knee Prostheses

Attempts to substitute this material for our current plaster wrap technique at the time of initial cast change were considered but were found not to be safe, in our judgment, using the application methods known to us at this time. The danger of wound separation, including discomfort to the patient in the early stage of wound healing, call for responsible caution in handling of the amputation stump. However, direct forming of synthetic rubber sockets, for use in intermediate and/or definitive prostheses after primary healing has occurred, is under investigation and is reported on in the section "Experimental Prosthesis Evaluation."

3. COMPONENT AND EQUIPMENT RESEARCH

The PRS Adjustable Prosthetic Syme Unit

The original design of this unit has been further improved providing, in addition to dorsiflexion and plantar flexion, a true horizontal slide adjustment in the mediolateral plane. In addition, the new design permits flexion and horizontal adjustments independent from each other. The unit is commercially available through KWD, Inc., 5409 Russell N.W., Seattle, Wash. 98107.

Immediate Postsurgical Prosthetic Weight-Bearing Control Device

To measure amounts of static weight bearing on an immediate postsurgical prosthesis by means of bathroom scales is both advisable and practical. However, dynamic control of weight bearing requires a monitor which can be incorporated directly into the prosthetic pylon and/or foot to measure vertical displacement. Prosthetics Research Study attempts to create a warning system have been discontinued to avoid duplication of effort when it was found that this device was under development elsewhere.

Articulating Knee Joint With Manual Lock for Immediate Postsurgical Hip-Disarticulation Prosthesis

Efforts are being made to produce or convert an existing prosthetic unit for this purpose since we feel that such a device would considerably simplify and improve ambulation activities of the patients. This hopefully would provide the means for an improved gait pattern and avoid hiking and circumduction during swing phase present in the system that lacks articulation.

The PRS Above-Knee Casting Fixture

Clinical evaluation of the added convenience of a left or right interchangeable and adjustable lateral wall to the above-knee casting fixture

^d Registered trademark of the Polymer Corp., Ltd.

substantiates our earlier findings as to the usefulness and necessity of this feature. It not only frees one hand of the operator during the application of the rigid dressing but results at the same time in a better fitting cast socket, avoiding the common proximal lateral gapping and providing more effective lateral support of the femur. The PRS casting fixture is used on all our above-knee immediate postsurgical and definitive prosthesis casting.

4. BASIC INVESTIGATION WITH SPECIFIC EMPHASIS ON THE EFFECTS OF PRESSURE ON WOUND HEALING

With the assistance of Dr. Edward Peizer, Chief, and Mr. Carl Mason, staff engineer, both of the Bioengineering Research Service, VA Prosthetics Center, New York, the Prosthetics Research Study conducted an investigation of the stump-socket interface relationship, stump musculature activity as monitored by EMG leads, and finally, skin temperature measurements including differences between anterior and posterior skin flaps of the stump. The results of this investigation are available in an article in the Bulletin of Prosthetics Research, BPR 10-10 Fall 1968, entitled "A Preliminary Report of Basic Studies from Prosthetics Research Study."

5. INTENSIVE TRAINING PROGRAMS OF SURGEON-PROSTHETIST-THERAPIST TEAMS

Members of the Prosthetics Research Study staff participated as principal instructors on the subject of immediate postsurgical prosthetic fitting in a series of three intra-VA training courses, arranged by the Prosthetic and Sensory Aids Service of the Veterans Administration, in Miami, Fla.; Houston, Tex.; and Portland, Ore.

Staff members of PRS also conducted lectures and demonstrations at UCLA Postgraduate Medical School Prosthetic-Orthotic Education courses on immediate postsurgical prosthetic fitting.

Many individuals and surgeon-prosthetist-therapist teams visited the PRS in Seattle and were introduced to and instructed in current techniques. Notable among the larger groups was the Study Tour of the Swiss Association for Prosthetics and Orthotics which included 31 participants.

6. PREPARATION OF EDUCATIONAL MATERIAL

Recent advances and improvements of the techniques, combined with continuously growing interest, required a complete rewriting of the manual on immediate postsurgical prosthetic fitting. This technical manual is quite extensive and outlines specifically, each concept of surgery, prosthetics, and postoperative management. The manual is in press and will be available soon from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, under the title, "The Management of

Lower-Extremity Amputations, Surgery—Immediate Postsurgical Fitting—Patient care,” by Burgess, Romano, and Zettl.^e

7. STATISTICAL DATA COLLECTION AND IN-DEPTH PATIENT FOLLOWUP

Long term patient followup and review is continuing on all patients available treated under this system of management. Statistical studies and coding of unselected consecutive groups of patients amputated as the result of ischemia have been completed, and the result of this study has been submitted for publication in “The Journal of Bone and Joint Surgery.” In the process of this study, the PRS amputee code sheets were further revised and improved. A similar study for amputations as a result of trauma is planned.

8. EXPERIMENTAL PROSTHESIS EVALUATION

Patellar-Tendon-Supracondylar Prosthesis

An additional 15 PTS prostheses were fitted and evaluated since our previous progress report. The PRS interpretation of this prosthesis results in a hard plastic socket without the customary Kembro insert or soft distal socket ends. The PRS approach to the wedge suspension system requires a custom-made wedge of Solka-Floc. Incorporated into the wedge are two protruding pins which locate and lock the wedge securely in place against the medial proximal prosthetic socket brim in a predetermined position. This system enjoys favorable reaction from both patients and prosthetists alike and is in routine use at this center. Our results indicate this to be an effective and improved suspension system suitable for most patients, but especially those with short stumps or who are indigent, irresponsible, or for physical reasons not capable of handling conventional suspension systems. Also, it is beneficial for patients who suffered amputations as the result of peripheral vascular disease, with or without diabetes, and the severely scarred stump as a result of trauma. This means of suspension decreases piston action of the stump in the prosthetic socket. Increased mediolateral knee stability is also notable, reducing the need for side joints and thigh lacers. The fine results obtained definitely warrant continuation of fittings with the PTS.

PRS Closed Syme Prosthesis

Two additional prostheses of this type were fitted. Our approach to a Syme prosthesis without the usual medial or posterior opening to allow

^e This Publication, designated as TR 10-6, dated August 1969, is now available for purchase from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, at \$1.50.

insertion and removal of the stump, differs from the expansible, flexible inner socket developed elsewhere.

The PRS procedure utilizes a removable sleeve constructed of Silastic foam and Kemblo rubber, which is modified to accommodate the stump prior to its insertion into the prosthetic socket. This results in a socket which allows relief and adjustment to accommodate atrophic stump changes. Patients fitted with this type of prosthesis continue to react favorably. Four patients have worn their initial prosthesis over a 2-year period without evidence of skin irritation or stump breakdown. More fittings are planned as patients are available.

PRS Closed Knee-Disarticulation Prosthesis

A similar method as described for the closed Syme prosthesis has been applied for the through-knee prosthesis with very gratifying results in several fittings. More attempts are planned as the patients present themselves.

POLYSAR^a Synthetic Rubber for Temporary and/or Definitive Below-Knee Prosthesis

Through the assistance of Mr. Staros, Dr. Peizer, Mr. Gardner, and Mr. Pirrello the VA Prosthetics Center, New York, who furnished the necessary materials and instructions, the PRS is participating in a study of direct forming of below-knee prosthetic sockets using POLYSAR^a synthetic rubber. Revised instructional material from the VA Prosthetics Center and our own increasing experience have been encouraging and promise far-reaching possibilities with this technique. More fittings are planned in an effort to widen our experience.

9. GENERAL PROSTHETICS ACTIVITIES

In the period indicated, 23 definitive prostheses were fabricated and fitted by PRS. Emphasis was placed on evaluation, improvement, and development of other than conventional prosthetic replacement. The majority of the 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 that 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 prostheses.

Prosthetic followup, including adjustments to the prosthesis, was performed to avoid socket replacements before a 6-month period. Prosthetic socket replacement for the average patient was between 9 months and 1 year. A smaller number of patients required socket replacements after 1 year or more.

^a Registered trademark of the Polymer Corp., Ltd.

Burgess et al.: PRS Progress Report

PRS Level Distribution of Definitive Prostheses:

Chopart	1
Syme, PRS type.....	2
PTB, hard socket.....	3
PTS, hard socket.....	15
Above knee.....	2
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Total	23

An additional 82 prostheses were fabricated and fitted at local commercial prosthetic facilities. Level distribution is as follows:

Syme	3
PTB, hard socket.....	27
PTB, soft insert.....	11
PTS, hard socket.....	23
Above knee.....	14
Hip disarticulation.....	2
Bent knee, hard socket.....	1
Split socket, soft insert.....	1
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Total	82

SUMMARY

Activities of this research facility over an 18-month period have been documented. Our initial responsibility, investigation into the feasibility of the immediate postsurgical fitting concept, has extended into the study and development of a total system of amputee management. Continued basic and clinical research should accelerate the progress now being made.