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BELOW-KNEE AND ABOVE-KNEE PROSTHESES

A REPORT OF A WORKSHOP SPONSORED BY THE
COMMITTEE ON PROSTHETICS RESEARCH AND DEVELOPMENT
DIVISION OF MEDICAL SCIENCES, NATIONAL RESEARCH COUNCIL

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B E L O W - K N E E A N D A B O V E - K N E E
P R O S T H E S E S

A Report of a Workshop Sponsored by the
COMMITTEE ON PROSTHETICS RESEARCH AND DEVELOPMENT

of the

DIVISION OF MEDICAL SCIENCES
NATIONAL RESEARCH COUNCIL

held at the

Veterans Administration Hospital
Seattle, Washington
January 27-29, 1973

NATIONAL ACADEMY OF SCIENCES

Washington, D.C.

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The project which is the subject of this report was approved by the Governing Board of the National Research Council, acting in behalf of the National Academy of Sciences. Such approval reflects the Board's judgment that the project is of national importance and appropriate with respect to both the purposes and resources of the National Research Council.

The members of the committee selected to undertake this project and prepare this report were chosen for recognized scholarly competence and with due consideration for the balance of disciplines appropriate to the project. Responsibility for the detailed aspects of this report rests with that committee.

Each report issuing from a study committee of the National Research Council is reviewed by an independent group of qualified individuals according to procedures established and monitored by the Report Review Committee of the National Academy of Sciences. Distribution of the report is approved, by the President of the Academy, upon satisfactory completion of the review process.

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JUL 25 1973

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Workshop on
BELOW-KNEE AND ABOVE-KNEE PROSTHESES

I. OPENING REMARKS

Mr. Joseph H. Zettl, Chairman of the Workshop, introduced Mr. William Stonebraker, Administrator of the Seattle Veterans Administration Hospital. Mr. Stonebraker welcomed the Workshop participants on behalf of the VA Hospital, which had made its facilities available for the meeting. He noted that although the hospital, opened in 1951, was not the largest in the country, it did have an excellent prosthetics workshop and that Dr. Ernest Burgess had contributed significantly to the development of this workshop. All participants were invited to tour the limb facility, if they so desired.

Dr. Burgess welcomed the gathering on behalf of the Prosthetics Research Study. He stated that significant changes in amputation surgery had occurred over the past ten years, resulting in improvement in the configuration of the stump, which called for changes in prosthetics design. The surgeon was now taking his rightful role as a partner to the prosthetist, doing better amputations and providing better stumps. Dr. Burgess emphasized that the modern stump is at the below-knee level and calls for a total-contact, end-bearing type of fitting.

Mr. Zettl reminded the participants that the focus of the present Workshop was on AK and BK prostheses and fittings. He recalled that the last BK workshop had been held in 1968, and the last AK workshop even further back than that. Hence, the plan of the present Workshop was to conduct a comprehensive review of both amputation levels in accordance with the agenda (Appendix A).

A list of participants is included in this report as Appendix B.

A. Report of Meeting at Ascot, England

Mr. Anthony Staros stated that the Ascot meeting had been sponsored by the Ministry of Health, United Kingdom, and was primarily concerned with modular lower-limb prostheses. The United Kingdom, apparently, has a serious problem in the delivery of services to patients. It was hoped that the findings and recommendations of the meeting would help solve these problems. A report of the conference at Ascot will be published this spring and will contain a number of the papers presented, together with recommendations of the various syndicates or work groups. At the Ascot conference it was agreed that patients were entitled to quick service and improved cosmesis, and that there was need for an aggressive research effort to accomplish the desired improvement in cosmesis. Improved test standards for modular prostheses were desirable, but requirements should not be made so rigid as to inhibit innovative design.

Mr. Staros introduced the conferees to the British word "bespoke," meaning "custom-made."

II. BELOW-KNEE PROSTHESES

A. Casting

1. Three-Step Plaster-Wrap Technique

Mr. Carlton Fillauer stated that he had developed the three-step casting procedure because of dissatisfaction with the conventional plaster-wrap technique. He contended that the conventional wrapping procedure tends to convert the cross section of a BK stump, which is typically triangular, to a circular configuration. The three-step procedure provides an accurate reproduction of critical areas of the stump. The first of the three steps in the procedure involves the formation of a rigid splint cast over the bony anterior half of the stump; the second, a circumferential wrap over the first splint to a level just below the patella; and the third, splint casting of the

anterior, medial, and lateral supracondylar areas. Details of the procedure are to be found in the article, "A Patellar-Tendon-Bearing Socket With a Detachable Medial Brim," printed in the December 1971 issue of Orthotics and Prosthetics.³

According to Mr. Fillauer, this method of casting produces a mold which requires very little modification.

2. Utrecht Dilatancy Technique

Mr. Wilson described briefly the stump-casting technique developed at the Institute of Medical Physics TNO, in Utrecht, The Netherlands. This technique had been viewed in its developmental stages by American visitors to the Institute, and a report has recently been written entitled "Equipment for Evacuated Grain Impressing,"⁶ by M. W. Koster. A rubber sheath is applied to the stump, which is then inserted into a container partially filled with fine casting sand. To facilitate entry of the stump, the sand is fluidized by blowing air into it. The air is then evacuated from the container, leaving the negative mold of the stump sharply defined in the sand. The amputee may exert a desired amount of weight-bearing on the stump prior to the evacuation of air from the container. The negative mold is filled with plaster of paris; fabrication then proceeds in the usual manner.

3. VAPC Technique

Mr. Thomas Pirrello reported that VAPC was seeking to develop a suction-socket BK prosthesis and had been experimenting with many methods of cast-taking. It was believed, he said, that present stump-casting methods do not provide sockets which meet all the requirements of comfort, control, and suspension because of the many physiological changes that occur in the stump. In an effort to compensate for these variables, the VAPC is currently seeking to combine "proven" socket fabrication methods with several innovations in fitting all levels of lower-limb prostheses.

Mr. Pirrello itemized the following concepts which are being applied to modular and endoskeletal prostheses wherever possible:

- A soft insert liner to provide a more comfortable stump receptacle.
- A suction-socket valve to reduce the relative motion between stump and socket.
- Total contact to improve support of body weight.
- Air cushioning to minimize stump displacement and improve socket comfort.
- An insert liner which will permit donning of, first, the liner, and then the shell of a suction socket in the sitting position.
- A removable liner to facilitate minor socket adjustments.

The recent development of a thin-walled, closed socket for the Syme's prosthesis has been found to be superior in strength to the type with open walls, i.e., posterior or medial windows and panels (Fig. 1). The removable Cordo-Plastazote liner reduces the overall size and weight of the prosthesis and provides a method of obtaining the effects of suction-socket suspension without the use of a valve.

Mr. Pirrello further reported that the below-knee socket liner was also being fabricated in Cordo-Plastazote with controlled flexibility. The liner is held to the stump by means of an air-expulsion (suction) valve located in the distal socket (Fig. 2). The patient gains access to the liner in the same manner as for an above-knee suction socket. Since the liner is flexible and has a reasonable degree of elasticity, it remains in contact with the stump for longer periods of time and compensates for minor volumetric stump changes. The outer surface of the liner is contoured to "key" into the rigid socket shell and lock the liner in place (Fig. 3). The rigid socket is deeper than the liner, thus providing an air chamber



Fig. 1 (upper left.) Closed-wall Syme's prosthesis with Cordo-Plastazote liner.

Fig. 2 (lower left). Cordo-Plastazote liner with suction valve for BK prosthesis.

Fig. 3 (lower right). Liner inserted into rigid BK socket.



in the socket beneath the liner. The liner end is free to expand and contract with stump volume changes. A second valve is placed in the outer socket wall, opening into the chamber beneath the liner. The resistance settings of the two valves are adjusted to maintain a lower positive pressure in the air chamber beneath the liner, producing an air cushion. The external valve is easily depressed through the foam to release the liner from the socket.

The above-knee socket liner is fabricated in the same method as the below-knee, except that the liner walls are heavier. The liner may be supported distally by the rigid socket. Where the liner is in contact with the rigid socket, an opening is made in the socket wall for access to the valve. If air cushioning is desired, a second valve is installed in a space below the liner in the same manner as for the below-knee use. In both methods the outer surface of the liner is "keyed" into the socket walls for retention.

4. Prosthetics Research Study (PRS) Pre-Modification Technique

Mr. Zettl described the pre-modified casting technique developed at the Prosthetics Research Study for the patellar tendon-bearing prosthesis. This technique has been written up in considerable detail elsewhere. He cited such references as "The Management of Lower-Extremity Amputations" by Burgess, Romano, and Zettl¹ and "Pre-Modified Casting for the PTB Prosthesis," by Zettl and Traub.¹⁷ According to Mr. Zettl, the pre-modified casting procedure can be used with relatively minor modifications for the supracondylar or the supracondylar-suprapatellar (PTS) prosthesis with wedge suspension.

The pre-modification technique involves the application of a heavyweight sock, together with suitably sized and shaped pressure-relief pads. A second (lightweight) cast sock is then applied, very wet, and provision is made for hamstring-tendon relief by the use of special pads. Compression pads are then glued to the stump sock over pressure-tolerant areas. Beginning at the distal-lateral aspect of the stump, an elastic plaster-of-paris wrap is applied in a pre-

scribed sequence. When the wrapping is completed, the below-knee PRS-Model casting fixture is used to define the patella.

B. Sockets

1. Clear Sockets

Mr. Snelson described the work being done at Rancho Los Amigos with transparent BK sockets made of the polycarbonate material, "Lexan." He proposed that the prime application of these sockets should be as "check" or "study" sockets. Breakage had been experienced when attempts had been made to use these sockets on a long-term basis. He mentioned the difficulties experienced in handling the polycarbonate sheets and the need to dry them out thoroughly. Drying time and temperatures apparently varied in different climates. The Rancho Los Amigos procedures on the fabrication and fitting of transparent polycarbonate sockets are described in the March 1972 issue of Orthotics and Prosthetics.⁷

2. Soft Sockets

Mr. Nitschke expressed the opinion that a BK socket with a soft insert was easier to fit -- and easier to adjust in order to maintain good fit -- than was a hard socket. For more than two years he had been using inserts made of "Cordo," a polyvinyl chloride compound. A detailed description of the procedures followed, using Cordo, is contained in Mr. Nitschke's article entitled "Cordo: A New Material in Prosthetics and Orthotics," in the September 1972 issue of Orthotics and Prosthetics.⁹

3. Silicone Gel Sockets

Dr. Koepke described the BK prosthesis developed at the University of Michigan, especially designed for the fitting of difficult stumps. Essentially, the item involves a standard patellar-tendon-bearing prosthesis with a SACH foot, modified by substituting

silicone gel in an envelope of lightweight horsehide for the conventional Kemblo socket liner. Cotton, wool, or nylon stump socks are applied to the stump before the prosthesis is donned. The prosthesis is suspended by a rubber thigh sleeve. The silicone gel below-knee prosthesis is more fully described in the September 1971 issue of the Inter-Clinic Information Bulletin.⁵

4. The Wellington Socket

Mr. Titus reported on experiences at Duke University in evaluating the Wellington foam-fitting technique on three patients who had experienced excessive shrinkage in standard PTB hard-socket prostheses, so that they were wearing at least two 5-ply stump socks over the entire stump, with up to five 5-ply socks over the distal end. All the stump socks were removed, then one thin 3-ply cotton stump sock was put on and a rubber balloon pulled over the stump and sock. The so-called "Wellington foam" was then mixed and poured into the bottom of the socket. (The Wellington foam is apparently a polyurethane made by Cooke Paint Co. of New Orleans.) The stump was inserted into the socket, and an attempt was made to stabilize it while the material was foamed around between the stump and the wall of the socket. Two-pound foam was used in two sockets and 10-lb. in one.

However, after the sockets were formed, the patients could not tolerate them because of discomfort to their stumps caused by the rough texture of the foam material. Mr. Titus indicated he would make a further effort with the technique, using the 10-lb. foam which seemed the more promising of the two.

5. University of Miami Sockets

Mr. Sinclair described the University of Miami experiences with sockets made of Tazlon. This intermeshed material conforms to the shape of the stump. It is applied as a sleeve and tied off at the end. Considerable experimentation over a period of more than a year had failed to produce a satisfactory application in that patients complained of too much distal pressure on the stump.

Mr. Sinclair also spoke of working with other thermo-plastic materials, particularly polypropylene, which he thought easier to work with than polyurethane.

6. The VAPC Socket

Mr. Pirrello reiterated the VA interest in developing a BK suction socket, as discussed on page 3 of this report.

7. The NPRL Socket

Mr. Asbelle described the Navy Prosthetic Research Laboratory's experiences with the use of "Lightcast" as a socket material. More recently, Merck, Sharp and Dohme have arranged with Solar Laboratories (who developed Lightcast) to develop and promote "Lightcast II." A special company, MSD Orthopaedics Company, Inc., of West Point, Pennsylvania, was formed for this purpose. Sockets of Lightcast II are formed directly on the stump. Two BK stump sockets were displayed, one made with the original Solar Laboratories system, the other with Lightcast II. The finer, closer structure of the older material provides a smooth inner socket surface. The newer material has a more open fiber glass construction, but both offer a satisfactory structure promoting ventilation for stump tissues (Fig. 4). The most significant change is in the ultra-violet light and the increased speed of polymerization -- the combination of the newer type of light plus the more open structure of the fabric completes polymerization in three minutes. The new lamp is more easily adjusted to positions required, and after three minutes the Lightcast II socket is sufficiently hardened for immediate use. (Fig. 5).

Disadvantages of Lightcast II include surface roughness and irregularity of the inner socket surface because of the more open structure of the material; the problem of dust and exposure of the fiber glass to contact with the skin when cut edges are filed;

and difficulty in cleaning the stump sockets. These areas require further work on the part of the Navy Research Laboratory.



Fig. 4. Demonstration of the porosity of Lightcast socket.



Fig. 5. Lightcast socket on adjustable prosthesis.

Mr. Zettl, also, spoke of his experience with direct molding of Lightcast. Mr. Dillee spoke of the superior qualities of Pe Lite as a material for socket liners and reported that use of Pe Lite had been included in the BK course at NYU. Pe Lite is described in ISPO Bulletin No. 1, January 1972.¹⁰

C. Suspension

1. The Detachable Medial Brim

Mr. Fillauer indicated that in his practice the insert or removable wedge-suspension mechanism for the supracondylar BK prosthesis had been almost entirely supplanted by the use of the removable medial-brim technique. This technique had been described in Orthotics and

Prosthetics, December 1971³ (previously cited), and had been summarized in Newsletter . . . Amputee Clinics, August 1972.⁸ Essentially,

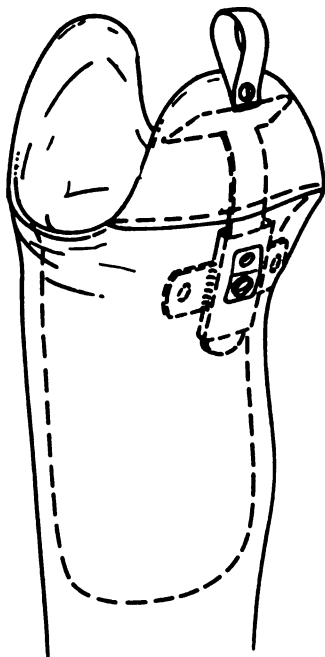


Fig. 6. Fillauer removable brim suspension system for BK prostheses.

the mechanism involved the fabrication of the prosthesis so that the proximal medial portion could be detached (and replaced) at about the level of the medial-tibial plateau. The separation mechanism (Fig. 6) involves a stainless steel bar laminated into the detachable brim, then inserted into a channel laminated into the lower portion of the socket. The channel has a spring-ball assembly for retention of the upper bar. With this method of suspension, no additional straps or accessories were required.

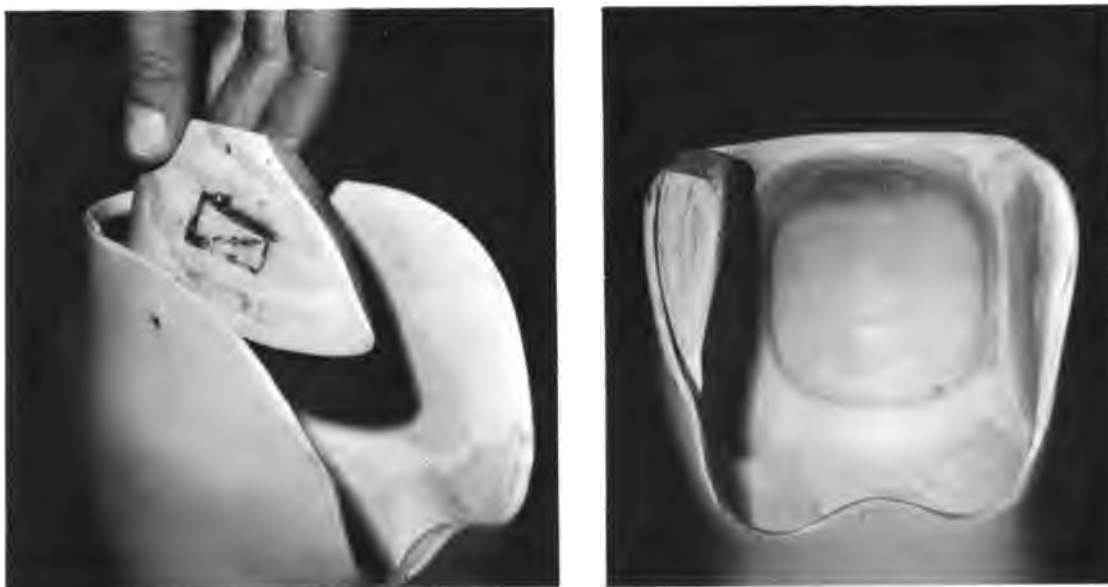
2. Cordo-Plastazote Wedges

Mr. Nitschke remarked that he couldn't completely agree with Mr. Fillauer in the use of the detachable medial brim, which was essentially a hard laminated segment over the medial condyle. He felt that some softness and flexibility in the wedge area was necessary for comfort, particularly for older amputees. In his own practice, therefore, Mr. Nitschke said he had been using a Plastazote wedge over the area of the medial femoral condyle. This wedge was covered with the required layers of gauze, saturated with Cordo and allowed to dry overnight. The insert was then taken off the cast and allowed to dry for two additional days. When dry, the insert was again placed on the cast for the completion of fabrication.

In his experience, Mr. Nitschke said, adjustments to the Cordo insert can be made more easily than with any other type.

3. Modified Supracondylar Suspension System

Mr. Zettl reported that, since 1967, the Prosthetics Research Study in Seattle has incorporated a custom-fitted supracondylar wedge suspension for both supracondylar and supracondylar-suprapatellar below-knee prostheses (Figs. 7A and 7B). While the hard socket, hard-end type of prosthesis is advocated and used routinely at this center, this system can be used successfully in conjunction with any type of soft insert.



Figs. 7A and 7B. Seattle supracondylar wedge suspension system.

The wedge is fabricated on the positive stump model, using a laminate lay-up of nylon stockinette and dacron felt saturated with No. 4110 polyester resin and Solka Floc mixture. Thickness of the wedge is predetermined by measuring the difference between the medio-lateral dimensions at the epicondyles and the supracondylar thigh. Bulk is held to an absolute minimum, the proximal socket shell being made just large enough to allow donning and doffing of the prosthesis.

Two protruding stainless steel pins (1/8 in. stainless steel rivets) are incorporated into the laminate wedge lay-up, and corresponding holes are drilled into the medial proximal socket brim, locking the wedge securely in place.

Active knee flexion during gait, including muscle activity, not only results in a minimal amount of atrophy in the tissue under the wedge, but also occasionally causes chafing of the skin. By eliminating one of the two suspension pins, the wedge is allowed to rotate during swing or extreme stump flexion when the patient is seated, thus providing a more comfortable stump positioning which avoids chafing and discomfort.

Since a proximal brim retention lip is not required in this system, the bulk of the resulting proximal medial socket is minimal. This suspension wedge can be readily adjusted to accommodate atrophic stump changes. Soft sponge or rubber can be added to suit individual patient requirements or preferences.

4. Inflatable Wedges

Mr. Staats described a method of supracondylar suspension developed at the UCLA Prosthetics-Orthotics Program by Lincoln Baird, an inventor and amputee. The "inflatable wedge suspension system" (Figs. 8, 9, 10, and 11) consists of two fluid-filled bladders connected by a piece of tubing with a needle valve between the two bladders. One bladder is wedge-shaped and serves as the suspension bulb, while the other is the inflation bulb, or reservoir. The casting procedure and fabrication of the inflatable wedge system are similar to those of the Fillauer hard-wedge variant. The major difference is that the inflatable wedge is not as critical as the hard wedge in terms of placement about the knee, partly because of the tendency of the inflating wedge to conform to the shape of the condyle. Prototype models of the inflatable wedge fitted to amputees showed that the wedge provided secure, comfortable, reliable suspension with a built-in adjustment not available in other suspension methods.



Fig. 8. Inflatable wedge prototypes.



Fig. 9. Medial condyle placement, similar to Fillauer wedge.



Fig. 10 (above). Inflating wedge using knee pressure.



Fig. 11 (right). Inflated bulb is buried in depression made in gastrocnemius bulge area.

Development is continuing. Additional material on this technique may be found in the March 1973 issue of Orthotics and Prosthetics.¹⁴

5. University of Miami Soft Wedges

Mr. William Sinclair reported that he had tried the Fillauer supracondylar wedge system for the suspension of BK prostheses. However, in Miami a move had been made to the use of soft wedges. Generally, these wedges were made of polyurethane and, in fact, were carved from the material used in the construction of heels for SACH feet. A piece approximately the size of a Fillauer wedge and $3/8$ to $1/8$ in. in thickness is shaped and attached to the supracondylar "ear" of the prosthesis. In approximately 80 percent of the cases, a medial wedge only is found to be necessary, but, in some cases, both medial and lateral wedges are used. In supracondylar-suprapatellar-type fittings, wedge material is also added anteriorly above the patella.

D. Construction

1. Report from Ascot Meeting

Mr. Muilenburg presented a number of points from the Ascot meeting which he thought were of particular significance:

- Modular and endoskeletal systems enable prosthetists to supply continuous treatment.
- All parts of prostheses should be interchangeable within a period of 24 hours.
- The socket is one part that cannot be prefabricated; it must be custom-made or "bespoke."
- There was probably a place for both heavy-duty and light-duty modular or endoskeletal systems.

A considerable discussion ensued concerning the strength and durability of current endoskeletal prostheses. Failure of systems to hold up had been a problem with some prosthetists, although

Mr. Muilenburg stressed that breakdown was minimal when the devices were correctly applied. However, he indicated that he used them primarily for female patients.

Mr. Foort urged that modular systems be taught in the schools. He felt that, with increased use, present problems would be eliminated.

2. The Indian Method

Mr. A. Bennett Wilson, Jr., described some of the features of the below-knee prostheses being made at the Christian Medical Hospital in Vellore, Southeast India. (The components of these limbs are made by craftsmen who understand very little about the principles of prosthetic alignment.)

- The heel height in the SACH foot used is lower than standard in order to accommodate the local footwear, so this configuration allows the patient to walk short distances without shoes.
- For the patellar-tendon-bearing prosthesis fitted, a hollow laminated polyester shell is used with a wooden ankle block laminated into it.
- In place of the standard PTB cuff a 1/2 meter length of 25 mm (1 in.) wide tape is used. This tape is passed in a figure 8 around the knee through slots in the prosthesis, and then tied with a knot at about the level of the patella tendon bar.

The Indian techniques are more fully described by Girling and Comings in Prosthetics International, Vol. 4, No. 2, 1972.⁴

3. Barredo/USN Method of Fabricating Ultra-Lightweight Below-Knee Leg.

Dr. Joseph Barredo, a physicist and below-knee amputee (traumatic), believes that weight in the below-knee prosthesis is very important, and with the cooperation of the U. S. Naval Hospital, Philadelphia, has fabricated a completely crustacean PTB-type below-knee prosthesis that weighs in the neighborhood of 19 oz. Certainly a reduction in weight makes suspension less of a problem. The method used is similar to that described by Wollstein in Prosthetics International, Vol. 4, No. 2, 1972,¹⁶ but Barredo relies on the shape of the "foot," rather than elastic material, to provide function. Force plate data on various foot configurations will be obtained at Moss Rehabilitation Hospital, and attempts will be made to fabricate the crustacean prosthesis of polypropylene or some other sheet plastic, using the vacuum-forming equipment. It is felt that this type of prosthesis might very well be appropriate for the geriatric patient, if not for others.

4. The PVC Tube and the Weber-Watkins Rotator

Mr. Staros reported on two items that the VA was following with interest.

The first of these was the PVC tube introduced by Mr. Lehneis of the Institute of Rehabilitation Medicine for use in place of metal on some light-duty temporary prostheses (Fig. 12). Mr. Lehneis had made a number of applications of these tubes and reported that assembly was quick and easy. Postfitting changes in alignment could be made simply by heating and bending the tube. Mr. Staros commented that, for heavy-duty use, aluminum would probably have to be substituted for the PVC, or a laminate layer used over the plastic tube to provide the needed strength.

The second item was the Weber and Watkins rotator which consists of two thrust bearings connected to each other by a piece of rubber hose and several hose clamps (Fig. 13). In rather limited

18.



Fig. 12. The PVC tube.

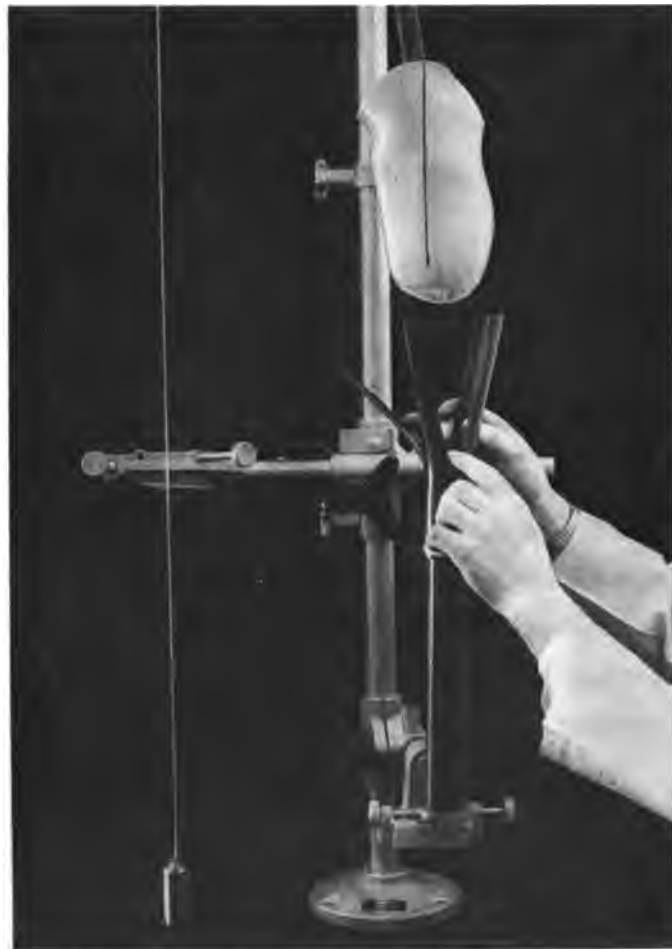


Fig. 13. The Weber and Watkins rotator.

applications to date, this system has proved to be quite durable. Mr. Nitschke has fitted two patients, and VAPC is following up on three units which have been in service for periods of up to eight months. These three units are being worn by two unilateral above-knee amputees and one below-knee amputee who is a golfing enthusiast. Mr. Staros mentioned that the rotator weighed 700 grams, which was excessive. However, a change in materials might help to reduce the weight significantly. It was also necessary to check whether the rotation capability in each director would produce instability during normal walking, the possible benefits of a reduction in shear between stump and socket, as well as any benefits the rotator might have for the amputee's golf game.

5. Vacuum Forming

Mr. Snelson remarked that additional experience needed to be gained with some of the newer materials, such as polyethylene and polypropylene for use in prosthetic sockets. However, vacuum-forming techniques lend themselves extremely well to the central fabrication concept. There is evident need for a continuing exchange of information between the people who are experimenting and working in the field of vacuum forming. With an increasing number of centers possessing vacuum-forming apparatus, the time is ripe for an exchange of "know-how" between the various centers.

E. Foot and Ankle

1. Mauch Modified Ankle

Mr. Mauch reported that the basic design of the modified ankle had been completed, and it included the following features:

- The hydraulic system proper. The 5 deg. forward motion of the shank to initiate the dorsiflexion stop had been eliminated. The dorsiflexion stop will now be produced solely by the application of the amputee's weight to the ankle unit. Technical details concerning the hydraulic

mechanism are contained in the Quarterly Progress Report of Mauch Laboratories, Inc., for the period ending December 31, 1972.¹²

The basic configuration of the modified design is much simpler than the previous one, but it is still so similar in shape that the existing castings can be used, with some modifications, for the prototypes of the new design.

- Foot attachment and eversion/inversion. The control principle for eversion/inversion has been changed. Eversion will be blocked to provide stability in the mediolateral direction, and inversion will be permitted against a moderate elastically yielding resistance. Toe pick-up can be varied by the prosthetist by the rearrangement of leather washers.
- Shank attachment and transverse rotation control. Elimination of the anterior/posterior adjustability has simplified the design considerably and permits the installation of the ankle system in standard small-diameter pylons (down to 1 in. I.D.). The design change also allows the prosthetist to either block or permit transverse rotation to accommodate preferences of amputees.

All in all, the new design of the foot and shank attachments is much simpler, less expensive, less noise-prone, easier to install, and probably more durable and maintenance-free than the previous design, without loss of significant functional features. Test wearing of the prototype unit will resume shortly.

F. Cosmesis

1. Otto Bock Modular Systems

In discussing the Otto Bock modular prostheses, Mr. John Hendrickson mentioned that design objectives of the company, in

order of importance, were (1) cosmesis, (2) comfort, (3) operational safety, and (4) function. The Otto Bock endoskeletal system had been introduced to the United States in the fall of 1970, and from January 1971 until March 1972, six instructional seminars were conducted with close to 100 prosthetists attending. They were instructed in the correct alignment and fabrication procedures for this new type of prosthesis.

Mr. Hendrickson reported that improvements were constantly being made to the Otto Bock system as the result of experiences in the field. One of these improvements was an improved extension assist and the provision of the modular system hip joints in two models, one with lock and one without, the devices being interchangeable. Moreover, when the Bock system was first offered, it included only a single-axis, constant-friction knee that could be used with or without an extension assist and a SACH foot. Currently, two knee units are offered: (1) a single-axis, constant-friction knee and (2) a single-axis, constant-friction knee with a manual lock and improved mechanical swing-phase control, and a choice of three foot-ankle mechanisms -- SACH, single-axis, and five-way. A prototype yielding-friction knee similar in function to the Bock safety knee has been designed, fabricated, and is scheduled for production in the near future. Plans are also being made for a polycentric knee unit and a swing-phase control unit that will provide the same functions as present pneumatic or hydraulic units, or better.

2. Hosmer BK Modular Prostheses and Soft Covers

In the absence of Mr. Cecil Benton who was called away from the meeting, Mr. Leigh Wilson reported on the Hosmer/Dorrance below-knee modular prostheses and the Prosmetic soft covers. More than 300 stock sizes and shapes of the soft BK covers are now considered to provide the ultimate in prosthetic cosmesis. These covers are said to be lightweight, tough, and exceptionally durable, and their composition of urethane and integrated skin provides a natural appearance and softness.

The soft covers are for use with plastic sockets laminated to the PSL-100 adjustable pylon or with the so-called "modular two-stage system" where the plastic socket is dynamically aligned on an adjustable leg and then transferred into a duplicating jig. The special attachment plate of the PPK 200 fixed pylon is then laminated into the aligned socket with the pylon in the correct M-L and A-P positions. These applications are more fully described in the Hosmer/Dorrance Prosthetic Hotline, Vol. 48, Series 1-71.¹¹

3. Kingsley Items

Mr. Kenneth Kingsley presented two items of fairly recent development at the Kingsley Mfg. Co. He called one of them the "sculpted-toe ladies' foot" (Figs. 14A and 14B). This item had been developed for a secretary at the insistence of Roy Snelson, Project Director of the Amputee and Problem Fracture Service, Rancho Los Amigos Hospital, Downey, California. The second item was the so-called "flat foot" (Fig. 15). Originally designed for barefoot ambulation with an immediate-postoperative prosthesis at the instigation of Dr. Vert Mooney and Roy Snelson at Rancho Los Amigos Hospital, its applications have since expanded into use with prostheses for



Figs. 14A and 14B. Sculpted-toe ladies' foot.

swimming and water-skiing, and the wearing of flat-heeled shoes. Flexible leather applied to the sole enhances the foot's wearing qualities. If sufficient demand developed, this leather could be attached during production.



Fig. 15. The flat foot.

III. DISCUSSION

It was emphasized that the stump socket interface was still a matter of prime concern, particularly at the BK level since BKs constitute the majority of amputations at the present time. A concept was introduced of sockets that would grasp the stump and stumps that would grasp the socket.

The desirability of spelling out prescription criteria for the various casting, fitting, and suspension techniques was discussed. It was agreed that the delineation of prescription criteria was very difficult, and that, ultimately, the technique used for a given patient was the one that the prosthetist did best and with which he was most comfortable.

The desirability of a comparative evaluation of various casting procedures with a check of the outcome by means of transparent sockets was stressed by various speakers.

The inclusion of administrators in workshops and meetings dealing with the delivery of services was stressed. Items made available to patients are frequently determined by lists and

and fee schedules, and it was felt that development of administrative procedures was necessary to make possible the delivery of the best available prostheses.

IV. ABOVE-KNEE PROSTHESES

A. Casting

1. The BRADU Above-Knee Socket

Dr. Harris described briefly the socket which is being developed for selected AK amputations in BRADU at Roehampton. Dr. Verne Inman of Berkeley had suggested that if pressures could be evenly distributed over the whole surface, the AK stump would support the body weight without producing high loads on the ischial tuberosity. This concept had greatly interested Dr. McKenzie of Roehampton who had made many attempts to cast the AK stump with weight-bearing in the stance phase. The problem was that in casting the stump with weight-bearing, the soft tissues were displaced proximally, thus shortening the soft-tissue elements of the stump and increasing its circumference. Consequently, when the stump was pulled into the socket that had been fabricated from this cast, the soft tissues elongated and patients complained that the socket was too short. In the swing phase, the weight of the prosthesis distracted the soft tissues of the stump, elongated them, and reduced the circumference of the stump. The socket could then no longer maintain its pressure differential.

Redhead and Alcock of Roehampton then postulated that if the stump could be cast in stance with the soft tissue distracted as much as possible, there could be no further distraction in the swing phase, and the pressure differential would be maintained. They developed a method of casting the stump on this principle. The stump is pulled into long-underwear-type trunks made of specially woven elastic and distracted, thus producing an evenly distributed circumferential pressure over the surface of the stump. A cast is then made with the patient supine. Pressure applied evenly and circumferentially over

soft tissue must result in a round cross section; hence, BRADU-type sockets are round, rather than quadrilateral, and are not ischial-bearing. Sockets made by their method on selected patients who were previously suction-socket wearers have proved successful in approximately 70 percent of the cases. Difficulties had arisen because of inability to cast the end of the stump under pressure, and there had been other problems. Dr. Redhead had made a number of modifications to the technique and was still revising it. Dr. Harris said that those who had a satisfactory fit were very satisfied, but the whole method of weight transference was totally different from that of other prostheses. If the procedure were abandoned at any time, not only the suspension but also the whole method of loading would be changed. He suggested that the concept showed promise, but was still under development and, pending further development, it should not as yet be considered for U. S. evaluation.

B. New Techniques

1. Suction Socket for the Geriatric AK Amputee

Mr. Sinclair described the above-knee socket which had been developed at the University of Miami for aged patients. This socket incorporates an RTV liner made with three layers of stockinette and a suction valve. The outer laminated shell of the socket had been fabricated with variously located cutouts in efforts to determine the configuration which provided adequate strength and retention with minimum weight (Fig. 16). The amputee dons the liner, inserts the stump with liner into the socket, and connects the two with Velcro.

Unfortunately, Mr. Sinclair reported, this system did not work as well as had been hoped. Patients still found it difficult to don their prostheses in the sitting position. Development is continuing.

This suction socket for geriatric amputees is described in the spring 1969 issue of Artificial Limbs.



Fig. 16. Two-component type of total-contact AK suction socket designed for geriatric AK amputees. Left, flexible inner socket; center, rigid outer shell with anterior window; right, complete assembly of socket and shell held together by Velcro strap on lateral side.

2. Cordo Insert Sockets

Mr. Nitschke stated that, in the Rochester experience, Cordo inserts had proven to be very useful for many above- as well as below-knee amputees. Flexible liners had been fabricated for patients with very bony stumps, and padding had been added where very little natural padding was present, e.g., in such areas as the lateral distal femur and the ischial tuberosity. The liner not only greatly increased patient comfort, but adjustment between the liner and the socket could be made very easily.

In cases where suction sockets are required, Cordo inserts can still be used. The valve is inserted into a hole $\frac{1}{2}$ in. in diameter after the area around the hole has been heated. The flared portion of the insert can then be tied off in the groove in the valve with a nylon cord to make a permanent seal. The area around the valve may then be built up with Plastazote and blended into the contours of the stump. When desirable, the last layer of Cordo may be deferred until

the Plastazote has been added. It can then be used to finish off the liner.

Cordo inserts are apparently working very well in suction sockets for endoskeletal prostheses. The stump is first pulled into the insert and sealed with the valve; the amputee then inserts the stump with the liner into the plastic socket. A disk about 1 in. in diameter and $\frac{1}{4}$ in. thick is incorporated onto the Cordo insert, just lateral to the Scarpa's triangle area. This disk fits into a cutout in the same area of the plastic socket. This arrangement keeps the insert in proper position and prevents it from slipping out of the plastic socket. It is not necessary to pull the cosmetic cover down or install cutouts for the valve.

A schematic view showing installation of a suction socket valve into a Cordo liner is reproduced below (Fig. 17) from the Orthotics and Prosthetics article⁹ mentioned on page 7 of this report under the heading "Soft Sockets."

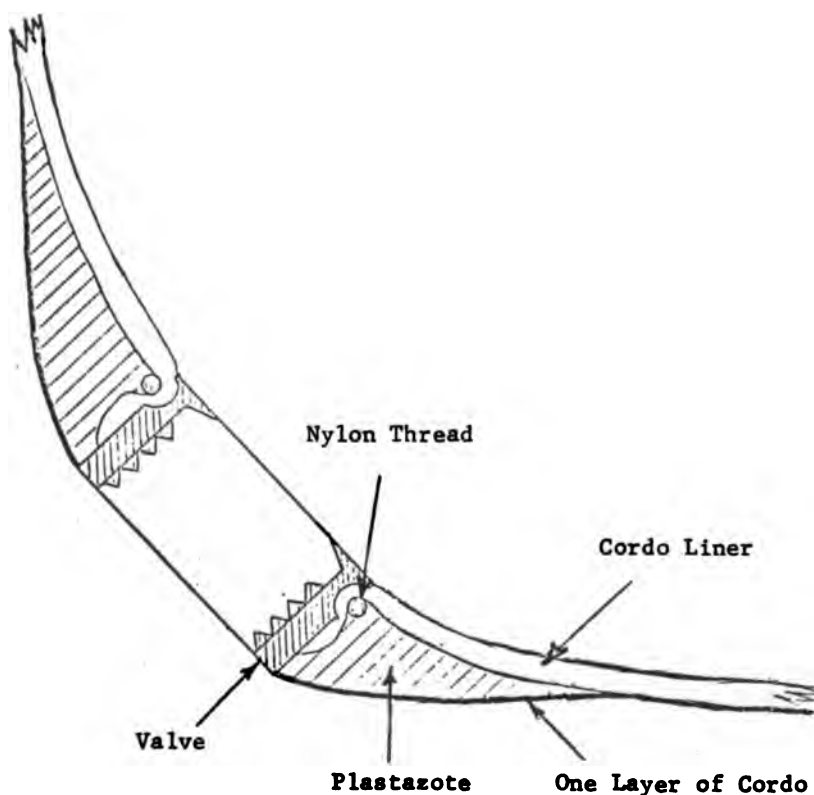


Fig. 17. Suction-socket AK prosthesis with Cordo liner. Digitized by Google

3. Air-Cushion Technique

Mr. J. E. Dillard of Nashville, Tennessee, described the fitting of air-cushion AK sockets to patients with problem stumps, particularly those with marked discoloration at the distal end. Excellent relief had been obtained (Figs. 18A and 18B).



Fig. 18A. Distal end of stump before fitting with air-cushion socket.



Fig. 18B. Showing major change following fitting with air-cushion socket.

The procedures for fabricating the AK air-cushion socket were based on those developed at the University of California San Francisco Medical Center by Wilson, Lyquist, and Radcliffe for BK prostheses. Essentially, the distal two-thirds of the socket was made of three layers of stockinette impregnated with No. 384 Silastic Elastomer. A suction valve is located distally, and an air space is provided between the Silastic inner socket and the outer shell. A more complete description may be found in the article, "A.K. Air-Cushion Sockets," in the June 1970 issue of Orthotics and Prosthetics.²

V. OTHER ITEMS

A. The Vermillion Leg Mechanisms

Mr. Charles W. Vermillion of Roseburg, Oregon, presented a film showing above-knee and hip-disarticulation prostheses he had developed. These prostheses could be manually adjusted to control the forward movement of the hip and the backward movement of the knee, and permitted selective locking or unlocking. The mechanism of the prosthesis is described in greater detail in U. S. Patent No. 3,663,967, entitled "Joint Movement Limiting Arrangement for Prosthetic Legs."¹⁵

B. Seattle Prostheses for Sports and Recreation

Mr. Jack Graves described at some length his skiing experiences as a below-knee amputee, using prostheses that he had developed. It was recommended that Mr. Graves prepare this material for publication in one of the prosthetic-orthotic journals.

VI. RECOMMENDATIONS

In an effort to bring together the various agreements that had been reached during the workshop, Messrs. Foort and Hampton presented a list of proposed recommendations for consideration by the group. These items were:

- Carlton Fillauer's three-stage casting technique and Joe Zettl's pre-modified plaster impression technique should be evaluated as quickly as possible (within six months, including preparation of teaching material). All necessary information needed for the evaluations should be supplied by the developers. Transparent sockets with modular components should be used to evaluate the products of these casting techniques.

Casting techniques which would permit the making of impressions under dynamic conditions should be investigated.

- Other institutions besides Rancho Los Amigos Hospital, and including the prosthetics schools, should investigate the values of transparent sockets as check sockets.
- A manual on the fabrication of gel-socket prostheses should be made available to the schools.
- Investigations to develop the VAPC below-knee suction socket and the NPRL method of socket fabrication should be continued.
- Efforts to develop prescription criteria for use of the numerous variants of the BK prosthesis should be intensified.
- Participants in the workshop should make available to the schools all pertinent information concerning their variations in the PTS wedge suspension techniques. The schools

should include these techniques in their teaching programs, as appropriate.

- The prosthetics schools should obtain vacuum-forming equipment so that they can keep abreast of developers in applications of the technique, and they should disseminate information on uses, as appropriate.
- Functional characteristics and design criteria for the SACH foot should be periodically reviewed in the light of field experience.
- Flexible, custom-made, cosmetic-cover techniques should be written up and made available to the schools so that prosthetists may become familiar with them.
- The schools should include laboratory demonstrations of the new materials, such as those used to make custom cosmetic covers, vacuum forms, etc., and the sources of the materials should be indicated.
- With regard to modular systems, it is recommended that the schools use the systems available (1) in the investigation and evaluation of the new techniques referred to (casting techniques, transparent sockets), and (2) as alignment devices for use in teaching. This approach will allow quick assembly of trial devices and familiarize students with modular devices without necessarily recommending them for general use at this time.
- Manufacturers should supply models of their equipment to the schools so that students can become familiar with them. Manufacturers should be encouraged to contribute to the schools, and this would be a good way to do so.
- All of the new developments in AK socket design, which have been shown at the workshop, are of sufficient value

to warrant the preparation of manuals. Evaluation should be undertaken so that indications and contraindications for use can be established.

- Various methods for sheathing the stump, including stump-sock design, should be vigorously investigated, and manufacturers should be made aware of their importance.
- Study of the effects of shear and other forces on living tissue should be intensified.
- It is strongly recommended that a functional terminology related to prosthetics and orthotics be developed and that investigators use this terminology to identify their inventions.
- Surgeons should be encouraged to experiment with stump design in an effort to improve weight-bearing characteristics and the socket-grasping capabilities of muscle-stabilized stumps.
- A strong effort should be made to improve prosthetics for children and women. Women should be encouraged to involve themselves in the solution of this problem.
- CPRD should look into the possibility of relating to the various information retrieval systems of such professions as the various groups of engineers with a view to solving problems which relate to these specialties, e.g., materials.
- A "by-mail" brainstorming operation sponsored by CPRD on the problem of cosmetic restoration of modular prostheses is recommended. Contributors would be asked to attend a workshop designed to further the brainstorming. The expectation would be that some research group would involve itself vigorously in the problem of cosmetic restoration of modular devices, on a high-priority basis.

- The ski prosthesis presented by Jack Graves should be written up and published as an article.
- Studies on James Foort's electric alignment unit should be reactivated.

AGENDA

WORKSHOP ON BELOW-KNEE AND ABOVE-KNEE PROSTHESES
Committee on Prosthetics Research and Development

January 27-29, 1973
Veterans Administration Hospital
Seattle, Washington

Joseph H. Zettl, Chairman

Saturday, January 27

9:00 a.m.

Welcoming Remarks	William Stonebraker Ernest Burgess
Introduction to Workshop	Joseph Zettl
General Report of Meeting in Ascot, England	Anthony Staros
BELOW-KNEE PROSTHESES	
Casting:	Three-Step Plaster-Wrap Technique Utrecht Dilatancy Technique VAPC Technique PRS Pre-Modification Technique BRADU Techniques
	Carlton Fillauer A. Bennett Wilson, Jr. Henry Gardner Joseph Zettl A. Bennett Wilson, Jr.
Sockets:	Clear Sockets Soft Sockets Gel Sockets Wellington Socket University of Miami Socket VAPC Socket NPRL Socket
	Roy Snelson { Bert Titus Robert Nitschke George Koepke Bert Titus William Sinclair Henry Gardner Charles Asbelle
Suspension:	{ Carlton Fillauer Robert Nitschke Joseph Zettl

Sunday, January 28

9:00 a.m.

BELOW-KNEE PROSTHESES (Cont'd.)

Construction:	Report from Ascot Meeting on BK Indian Method Barredo/USN Method Vacuum Forming
	Alvin Muilenburg A. Bennett Wilson, Jr. A. Bennett Wilson, Jr. { Roy Snelson Colin McLaurin Anthony Staros
Foot and Ankle:	{ Hans Mauch Charles Radcliffe Carl Sumida

Cosmesis:	Australian Method VAPC Method Otto Bock Method Hosmer Method Realastic Industries Kingsley Mfg. Co.	Hector W. Kay Henry Gardner John Hendrickson, Sr. Cecil Benton Len Townsend Kenneth Kingsley
Discussion and Recommendations		All Participants

ABOVE-KNEE PROSTHESES

Casting:	BRADU Technique	A. Bennett Wilson, Jr.
Sockets:	New Techniques	{ Alvin Muilenbrug Robert Nitschke William Sinclair Henry Gardner
	BRADU Technique	A. Bennett Wilson, Jr.
	Air Cushion Technique	J. E. Dillard

Monday, January 299:00 a.m.**ABOVE-KNEE PROSTHESES (Cont'd.)**

Construction:	Report from Ascot Meeting on AK	Alvin Muilenburg
	Foot and Ankle/Rotator	Charles Radcliffe
Cosmesis:	VAPC Method Bock Method Hosmer Method	Henry Gardner John Hendrickson, Sr. Cecil Benton
Discussion and Recommendations		All Participants

OTHER ITEMS

Review of Seattle Prosthesis for Sports and Recreation	{ Ernest Burgess Jack Graves
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