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Advanced Prosthetic Techniques for Below-Knee Amputations

Timothy B. Staats, MA, C.P.

INTRODUCTION

The below-knee amputation is the prevalent level of choice in the estimated 50,000 amputations done in the United States each year. The successful prosthetic rehabilitation of the below-knee amputee has been greatly advanced in the last five years not only by technical improvements in the materials and the manner in which they are used to fabricate prostheses, but also by clinical evaluation techniques and procedures that now assist the prosthetist in enhancing the comfort and biomechanical function of the prosthesis. In the early 1960s the term "patellar tendon bearing" (PTB) was introduced by Radcliffe and Foort[1] to describe what was to become the dominantly prescribed prosthesis for the next two decades. More recently, the term "total socket bearing" (TSB) has been more correctly used to describe the weight bearing characteristics of the below-knee prosthesis.[2] This change in terminology and philosophy, along with numerous developments in below-knee prosthetics, will be discussed in this monograph.

EVALUATION TECHNIQUES

The use of xeroradiography in prosthetic evaluations is rapidly becoming not only common but mandatory as an evaluation and fitting tool, particularly in below-knee amputations. The xeroradiograph offers both soft and bony detail not as easily seen in standard x-rays (Figure 1). The prosthetist can directly evaluate the shape of the cut ends of the tibia and fibula, and accurately envision the angle at which these bones have been resected. The amount of bone tailoring performed by the surgeon can be seen and planned for in the socket interface. The evaluation and occurrence of osteophytes, which have been found to be very common, can also be better accommodated for in the design of the socket.

Prosthetists generally requesting xeroradiographs will want true anteroposterior and mediolateral views taken in the negative mode, so that as much detail as possible is visible. Xeroradiographs may be taken after initial prosthetic fittings have been completed. Exposures are taken through the prosthesis with full weight bearing and with the prosthesis suspended off the ground to confirm that total contact and suspension has been achieved (Figure 2). The relative locations of bones with respect to socket shapes are carefully examined to confirm that the weight bearing design of the socket has been achieved. The socket design has also been greatly affected by the use of xerographs. The weight distribution characteristics throughout the socket are now designed to relate physiologically as well as biomechanically to the individual shapes of a particular amputation, rather than to classic patellar tendon bearing-like shapes, which were common until the last five years. In particular, the patellar ligament area is now generally flattened from just under the patella all the way down to the tibial tubercle. This shape takes advantage of this wide surface for weight distribution rather than with the narrow patellar tendon bars common in the

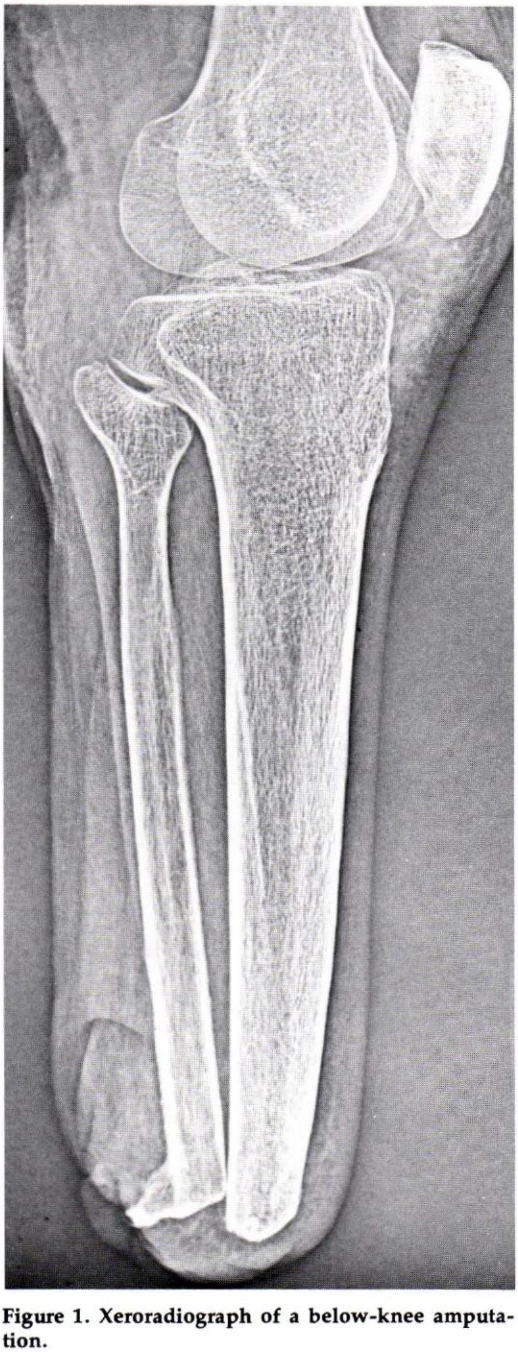

Figure 1. Xeroradiograph of a below-knee amputation.

Figure 2. Xeroradiograph of a below-knee weight bearing in a prosthesis.

patellar tendon bearing sockets. This change of shape is a direct result of the use of xeroradiography in the evaluation of the residual limb. Other areas of the socket interface have also undergone evolutionary shape changes as a result of xeroradiographic studies of the residual limb in the socket.

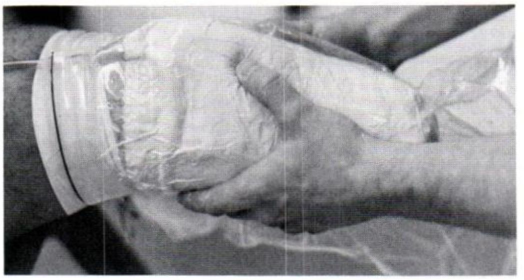

Figure 3. The Hittenberger vacuum casting procedure.

Figure 4. Elastic plaster bandage is used in the second stage of the wrap.

PRECISION PLASTER CASTING TECHNIQUES

The mold or cast impressions taken from the residual limb have changed drastically in the past five years. The recent use of stage casting and the application of controlled pressure[3] or vacuum over the plaster once it has been applied to the residual limb has resulted in improved accuracy.

The Diagonal Four Stage Casting technique[4] is an example of staged casting used not only for weight bearing and suspension, but also for the simultaneous establishment of knee flexion trimlines. The anterior and primarily bony structures of the residual limb are covered with about five layers of regular fast setting plaster bandage. Extreme care is taken in this application procedure to avoid any wrinkles and to assure that all bony structures are encased. Vacuum may be applied by placing a plastic sleeve over this initial stage in what is called the Hittenberger procedure[5] (Figure 3). The

Figure 5. The third stage creates the hamstring tendon reliefs.

Figure 6. The Otto Bock below-knee casting stand.

vacuum source draws the plaster against the tissues and will reflect accurately most of the bony structures. Some prosthetists apply small clay build ups over bony prominences to premodify sensitive areas. These clay buildups are removed from the mold when the residual limb is withdrawn from the cast.

A second stage (Figure 4) using elastic plaster bandage encapsulates the posterior compartment tissues and draws these tissues forward into the anterior shell. A third stage (Figure 5) creates the posterior proximal trimline in the mold, as well as the shapes needed for comfort in the hamstring tendon region of the socket. The cast must be taken in flexion during this stage, and care is taken to maintain total contact distally while also compressing the plaster wrap as high into the popliteal fossa as possible. The reason for this high trimline is to again attempt to distribute as much weight as possible over the greatest area.

The fourth and final stage of the wrap cast creates the supracondylar suspension through careful molding over the femoral condyles to conduct pressure to areas of the femur that can tolerate the downward force of the weight of a completed prosthesis. This final stage is removable so that the residual limb can be readily withdrawn from the cast. In the past, the plaster wrap cast was taken with one or more casting socks placed over the amputation prior to cast application. It is now more common to use no sock barrier or only a sheer nylon stocking so that as tight a cast as is possible can be obtained. Barrier creams are used on the skin when no stocking is used in casting.

In the diagonal four stage casting technique, the wrap cast is carefully mounted into a gimble mounted ring stand[6] (Figure 6). The inner surface of the wrap cast is coated with alginate, and the patient reenters the wrap cast to apply full weight into the liquid alginate. The pressure of the residual limb into the gelling alginate more accurately defines the shapes and volume of the residual limb. After the wrap cast is removed from the stump, it is immediately filled with plaster and will become the master model. The outer plaster mold and alginate is removed, leaving a very accurate model of the residual limb. The prosthetist must rectify this master model to measurements previously taken from the amputation to further enhance the weight distribution throughout what will become the entire socket surface. It has been found that the extra effort taken during casting not only defines more accurately the amputation tissues, but also results in more comfortable and repeatable socket shapes.

Figure 7. Molten transparent thermoplastic is vacuum-formed over the residual limb model.

TRANSPARENT CHECK SOCKETS

The general use of transparent sockets was introduced in clinical practice in the early 1970s.[7] A variety of plastics have been used for this purpose, including polycarbonate, polypropylene, acrylics, and Surlyn.™ The method of production generally involves heating the plastic material to a near molten state, at which time it is drawn over the plaster model (Figure 7). External air pressure resulting from inner vacuum forces hot plastic intimately against the model. The plastic is then allowed to cool prior to removal of the plaster model. The socket is trimmed to the shape of the prosthetic socket and mounted on an alignment pylon for the purpose of initial fit evaluation and, in some cases, dynamic walking trials.

The transparent check sockets are now fitted to the [residual limb] without fitting socks to permit careful visual examination of the skin. Generally, blanching of the skin indicates excess pressure, while redness denotes lack of contact or looseness. Holes may be drilled through the socket wall to permit probing for skin contact against the socket wall. A more recent technique of checking socket fit in transparent sockets involves injecting small amounts of glycerin into the regions of the socket that are perceived as being loose.[8] If improvement of fit is indicated by change of skin color, the glycerin is then removed from the socket and alginate introduced into the same region of the socket. Some prosthetists will, as a rule, apply alginate to the entire inner surface of the check socket and again pressure fit the check socket in a manner similar to that previously described during the wrap cast procedures.[9] The check socket is immediately filled with plaster to create a master model over which the definitive socket will be fabricated. It is becoming increasingly common for serial check socket fittings to be performed in problem cases or in cases where patients can afford the extra expense of this time consuming procedure, in order to achieve the superior results of the socket algination process.

PROSTHETIC SOCKETS AND SOCKET INTERFACES

A variety of new socket materials and socket types have recently been introduced into clinical prosthetics practices. In certain cases the materials are not actually new, but the more effective methods in fabrication have made their usage practical.

A socket interface material that increased in popularity in 1984 is the silicone laminate socket liner.[10,11] Fabricated from nylon impregnated with silicone elastomer (Figure 8), the silicone liner provides a soft interface

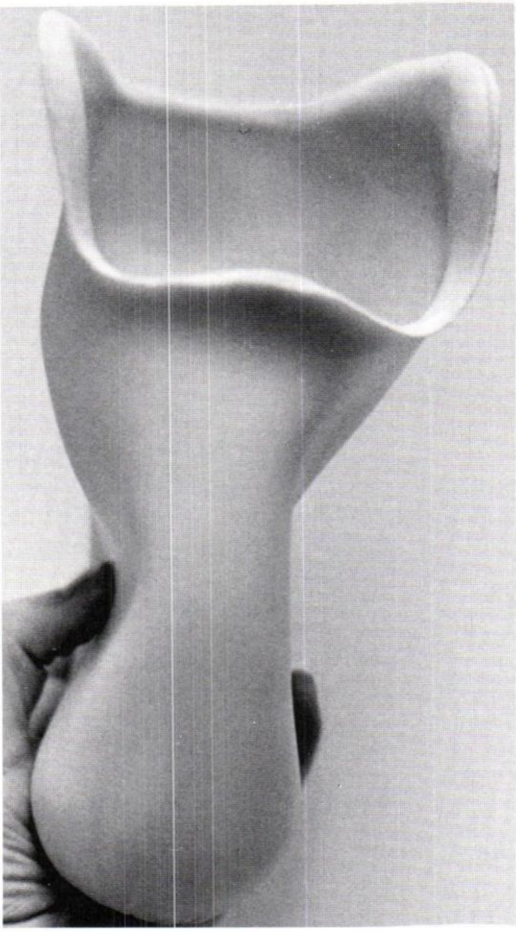

Figure 8. The laminated silicone elastomer socket liner.

material capable of absorbing more shear forces than other interface materials. The objections to this material are its weight and limitations facing the prosthetist in making socket shape and size changes once the liner and socket have been fitted. These objections are generally overcome through more accurate fittings made possible by improved casting and check socket use. The weight problem has also been largely minimized through the use of ultra-light carbon graphite laminates for the rigid outer socket, which encases the silicone liner. An alternative silicone material in the form of a gel-like cloth introduced over ten years ago[12] is regaining popularity since previous problems with gel migration have been solved through the improved fabrication. It has also been discovered that both

Figure 9. The suction below-knee socket is donned using a stockinette pull sock.

Figure 10. The inner shell of the suction below-knee socket fits into a rigid outer socket.

types of silicone liners can, when properly fabricated, be fitted with only thin nylon sheaths or no covering over the stump at all. The traditional use of thick stump socks is now in question, as techniques using only precision socket fit gain acceptance.

One such technique is the suction below-knee socket. The suction socket is not new. Prosthetists in San Francisco have fitted soft liner suction sockets for at least 20 years.[13] Recently, however, in Uppsala, Sweden, Friestadt[14] and Grevsten[15] have fitted numerous below-knee patients using hard sockets with distal valves similar to those used in above-knee suction socket prostheses. This process is accomplished through the use of a thin inner socket of polyethylene or Surlyn® thermoplastic. A rigid outer shell of laminated acrylic or polyester plastic then reinforces and supports the thin inner shell. The inner socket is donned by pulling the socket on with a length of stockinette (Figure 9). Some patients prefer to slide into the inner shell using a small amount of lubricant, which easily permits the residual limb to enter the socket (referred to as UCLA "wet fit"). When the stump has settled into the socket, the suction valve is inserted into the valve seat, ensuring complete suction. The thin shell inner liner is then inserted into the more rigid outer structure (Figure 10). This interesting technique can be enhanced by a process in which air spaces are created opposite bony prominences outside of the thin inner shell. The thin and flexible inner shell only exerts tolerable pressure on the sensitive bony structures. The air space between the outer shell and the inner shell further protects any potentially sensitive areas.

In more conventional techniques for making socket liners the pressure transmission of forces can be controlled through the use of multiple durameter liners.[16, 17] Materials of different density and firmness are laminated together in such a way as to provide support on the one hand and pressure

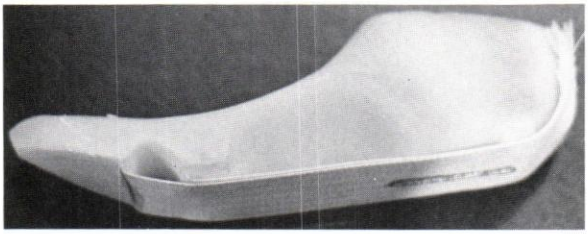

Figure 11. The SAFE™ foot keel is flexible and has a strong plantar band which stimulates the normal foot.

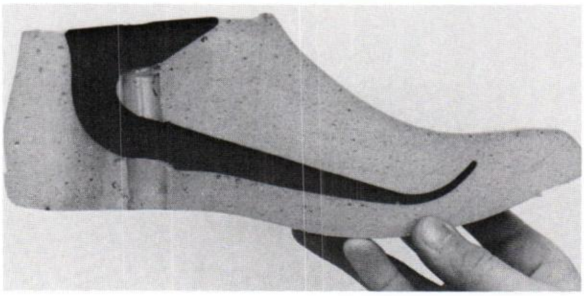

Figure 12. The Seattle™ foot keel design.

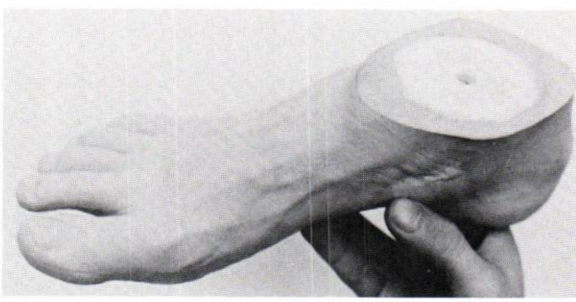

Figure 13. Life-like appearance of the Seattle™ foot.

relief where it is necessary. In particular, materials such as Pelite,™ a resilient thermoplastic foam, is used in conjunction with a super-soft polyethylene foam called Aliplast.™ The softer material is used over bony prominences, while the firmer material is used over tissue that is more pressure tolerant. When the multiple durameter socket liner was first used, it was thought that the softer foam would pack out and be virtually useless. It was found, however, that the soft foam only packed out the amount needed to relieve pressure and provide comfort. It appears that the use of suction fit and better suspension methods has also contributed to reducing friction between the stump and the socket interface.

PROSTHETIC FEET AND OTHER COMPONENTS

The recent introduction of several new prosthetic feet has sparked interest in the possibilities of increased activities for the below-knee amputee. There are also many benefits that less active patients can derive from these new foot variations.

The SAFE™ foot developed by Campbell and Childs[18] represents a major advance in

Figure 14. The Jaipur foot is demonstrated in a tree climbing exercise.

Figure 15. Below-knee pylon systems.

design of artificial feet. The SAFE™ foot has gained wide acceptance in a relatively short period of time due to its physiologic design. It is manufactured with a flexible inner skeleton keel with a strong plantar surface band, which acts in much the same manner as a normal foot (Figure 11). As the amputee rolls over the toe of the SAFE™ foot, the forefoot portion becomes more rigid. The flexible keel permits the patient to easily adapt to uneven surfaces and rugged terrain. The flexibility of the foot has had one interesting side effect in that the general alignment rules used by most prosthetists cannot be used with the SAFE™ foot.

The Seattle™ foot,[19] developed at the Prosthetic Research Study in Seattle, Washington, under the direction of Dr. Ernest Burgess, is now in the final developmental stages and is planned to be in production for commercial distribution in the near future. At present, the Seattle™ foot is still being tested. The principal feature of the Seattle™ foot is a unique keel design (Figure 12) that stores energy through compression. This stored energy is transmitted back to the amputee at toe off. Original designs consisted of a multiply laminated plastic leaf spring. Later designs tested carbon graphite leaf designs, and presently the keel is being tested with a special high strength nylon called Delrin. The outer covering of the Seattle™ foot is pleasingly realistic as it is manufactured using molds taken from human feet (Figure 13).

The Jaipur foot[20] (Figure 14) from India is another example of lifelike design and functional response. In this case a very flexible foot was designed for use by patients in conditions typical of rural India, and generally for barefoot usage. Interest in the Jaipur foot in the United States is related to use as a recreational prosthesis. Laboratory testing of the Jaipur foot has not proven it to be safe for usage in the United States, where patients are generally much heavier than the average Indian.

ALIGNMENT SYSTEMS

Numerous pylon alignment systems are now available for use during dynamic alignment of the below-knee prosthesis (Figure 15). Some of these alignment pylons are removed from the prosthesis during finishing, and others such as the popular Otto Bock Endoskeletal pylon system[21] (Figure 16) become integral to the finished prosthesis when covered with a soft foam cover. The alignment systems are divided into vertical and nonvertical systems, but all are used to perform essentially the same functions of establishing the optimum angular and linear relationship of the foot and socket.

Figure 16. The Otto Bock below-knee pylon.

One unusual development in the area of pylon systems and feet is called the "Flex-Foot™"[22] prosthesis (Figure 17). This prosthesis consists of a series of carbon graphite struts that can be aligned very much like other pylon systems. The one major difference in the Flex-Foot™ is that the entire structure can flex when weight is applied during walking and running. The carbon graphite strut's size and strength is calculated in relation to the patient's body weight and expected use requirements. While the full implication of this system is not known in relation to normal and sedentary use, its use in high performance athletic activities has shown

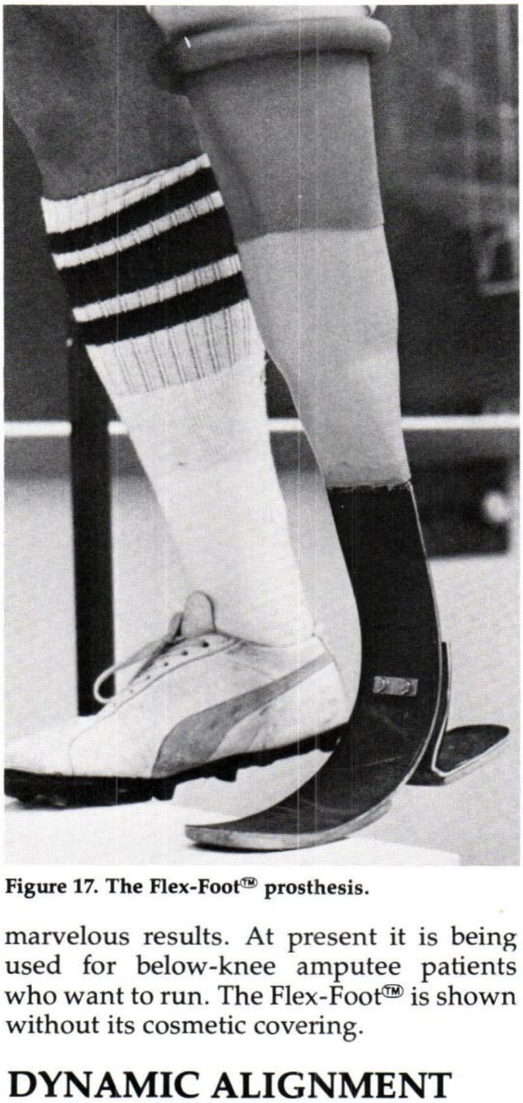

Figure 17. The Flex-Foot™ prosthesis.

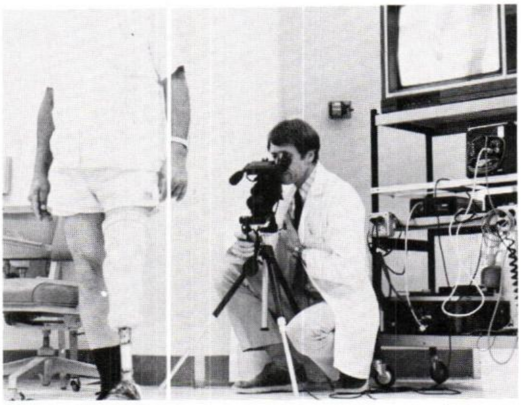

Figure 18. Videotaping walking trials of a below-knee amputee.

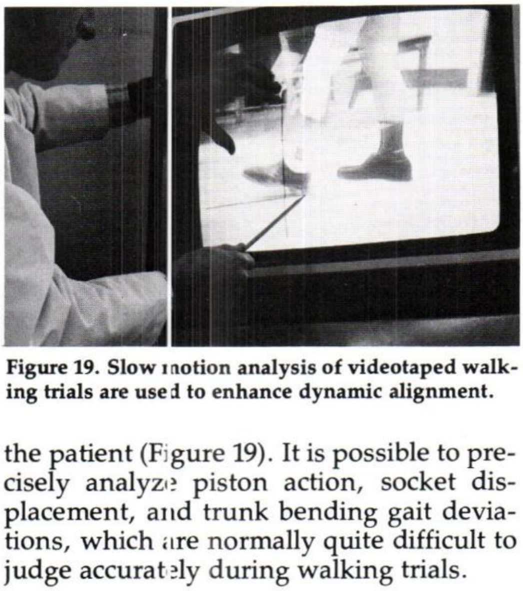

Figure 19. Slow motion analysis of videotaped walking trials are used to enhance dynamic alignment.

marvelous results. At present it is being used for below-knee amputee patients who want to run. The Flex-Foot™ is shown without its cosmetic covering.

DYNAMIC ALIGNMENT AND GAIT ANALYSIS

Beyond socket fit, gait analysis and dynamic alignment have always been regarded as the most difficult area of below-knee prosthetics. The use of video recording and slow motion analysis of the patient walking with the prosthesis (Figure 18) has been a great help to both the patient and the prosthetist doing the alignment. Careful observation of walking trials using closeup views of the foot, pylon system, and stump-socket system, as well as wide angle views of the patient during locomotion, are possible without exhausting repetitions by the patient (Figure 19). It is possible to precisely analyze piston action, socket displacement, and trunk bending gait deviations, which are normally quite difficult to judge accurately during walking trials.

FINISHING TECHNIQUES

Cosmetic restoration is as important to some below-knee amputees as functional replacement. Two advances are noteworthy in the area of finishing techniques: the mirror image finishing technique[22] and cosmetic skin coverings.[24]

The mirror image finishing technique involves taking a careful impression of the sound leg of the patient, creating a master model from this mold, and laminating a shell over this model. Before the laminate becomes rigid it is removed from the model and quickly reversed, creating a mirror

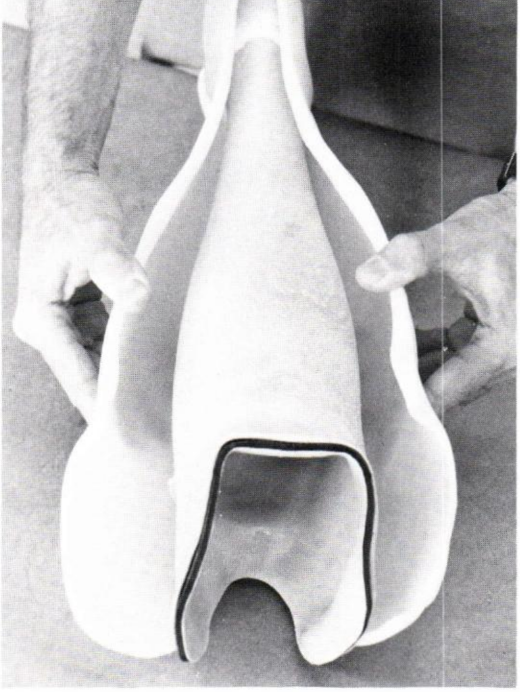

Figure 20. The mirror image finishing technique.

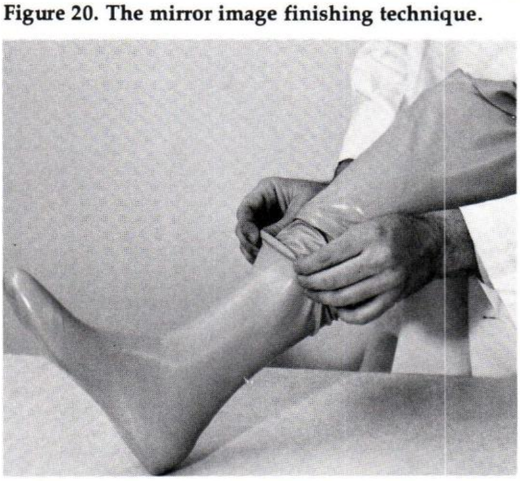

Figure 21. Prosthetic skin is carefully donned over the prosthesis to create cosmesis.

image of the opposite side. This mirror image shell is then placed over the aligned prosthetic pylon stem. A flexible urethane foam is injected into the cavity. When the foam has cured, the outer shell is removed (Figure 20), leaving a dimensionally accurate replica of the sound side.

The finish of the prosthesis can be further enhanced through the use of prosthetic

Figure 22. The prosthetic skin covers may be colored using an airbrush system/coloring.

skin covers, which are pulled over the shaped prosthesis (Figure 21). Prosthetic skin covers are available in copolymer vinyls, silicones, and acrylic latex materials. It is possible to air brush colors (Figure 22) on the skin covers with the use of special coloring systems.[25] Patients must expect to pay as much for these advanced finishing and cosmetic techniques as for the cost of the prosthesis itself. True cosmetic restoration is time consuming and artistic (Figure 23). It is not available from all prosthetists, and any patient who has great expectations for the cosmetics of the prosthesis should be warned to seek consultation in advance of beginning work on a prosthesis. It often is not possible to cosmetically convert a prosthesis that is made in a conventional manner.

COMPUTER AIDED SOCKET DESIGN AND MANUFACTURING

Research and clinical applications in the area of computer aided socket design[26] and computer aided manufacturing[27] of be-

Figure 23. The "Massey" prosthetic skin.

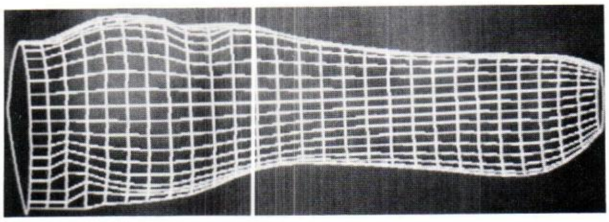

Figure 24. Computer aided socket design, as demonstrated at the Medical Engineering Research Unit in British Columbia, Canada.

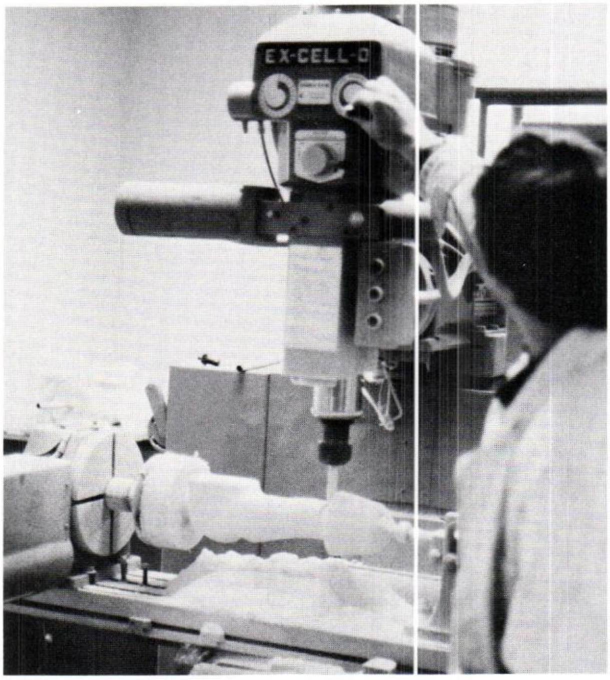

Figure 25. Computerized stump measurements are sent to a computer-driven milling machine to create the master stump model.

low-knee prostheses is underway in Canada and in the United Kingdom. With the aid of computers, the below-knee socket is designed on the monitor screen of the computer (Figure 24) using measurements taken from the patient. These measurements and the socket, which is shown on the screen, may be modified in much the same manner as a cast. When the model modification is completed, the digital information is transmitted to a computer driven milling machine, which in turn shapes a solid blank into a stump model (Figure 25). The model is then used to fabricate the below-knee socket in a more or less conventional manner.

Research is also being done in the area of shape sensing of amputation stumps, so that measurement information can be entered into the computer directly. It would appear that these approaches to prosthetics hold great promise and could unravel many of the mysteries regarding socket fit and alignment. It is unfortunate that these computer systems are becoming available during a period of limitation of medical services through cost containment. The systems are presently very expensive initially, but appear to offer cost benefit if they can be proven to be reliable. The actual acceptance of computer aided socket design and manufacturing systems by prosthetists will depend greatly on the design flexibility and freedom built into the software of the system. Initial reaction of prosthetists using the computer screen to shape sockets has been favorable. If the screen and computer can accurately reflect socket shapes, and these shapes can be easily moved and changed, it is no problem to make a prosthetic socket. Development of the computer programming needed to achieve this end is no small task, and those in research are commended for their efforts to this point in time.

Significant advances in below knee prosthetics philosophy and clinical practice have been achieved over the past 15 years. This monograph has pointed out many of the newer developments that will shape the prostheses to be used in the next decades. Many of the techniques have only recently been introduced into clinical practice and will take a number of years to spread to all prosthetists. Not all prosthetists will share in the author's enthusiasm for these new developments, and they will continue to practice using techniques that they have found successful. Prosthetics students are being taught these new techniques and can be expected to include them selectively in their practices.

AUTHOR

Timothy B. Staats, M.A., C.P. is adjunct professor of orthopedic surgery and director of Orthotics and Prosthetics Education of the University of California at Los Angeles School of Medicine, 1000 Veteran Avenue, Rehabilitation Center, Room 22-56, Los Angeles, California 90024.

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