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Multiple Durometer Socket Liners for P.T.B. Prostheses

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INTRODUCTION

Patella tendon bearing socket liners have traditionally been fabricated using leather and Kemblo rubber.[1] In recent years, a variety of new materials have been successful in replacing the original technique. Liners composed of Pelite, Plastazote, silicone gel, etc., each provide slightly different characteristics as related to durometer and wear resistance. Certain qualities of each material are desirable in various applications and have been incorporated in inserts to solve residual limb problems.

This paper will examine the experimental and clinical applications of P.T.B. socket liners fabricated using an integration of materials with different durometers blended into the liners. The desirable durometer characteristic of a specific material may be strategically located within the interface of the liner. The primary use of multiple durometer liners may be seen with the problem experienced by below knee amputees with very boney, badly scarred or intermittently painful areas on the residual limb. In addition, the very active P.T.B. wearer, requiring added protective padding about the residual limb surface, will derive benefits from the below described techniques.

Nitschke[2] reported in 1972 the use of a copolymer liquid called "Cordo" that could be used as a liner material when impregnated in gauze. Plastizote was placed over the boney prominences, in particular, the anterior distal end of the tibia. Cordo is not widely used primarily because of a lengthy fabrication process.

In 1980, Graves developed a selectively placed silicone gel liner system for the P.T.B. prosthesis.[3] In that report it was stated that for ambulation and most routine activities, a P.T.B. prosthesis with either a hard socket or conventional liner is adequate. However, for more demanding activities, more protection is needed. The Graves system is a Pelite and leather liner with silicone gel applied over the anterolateral surface and crest of the tibia. Figure 1 shows Graves testing the selectively placed silicone liner on a specially designed ski leg, which incorporates a Lenox Hill brace over a below-knee prosthesis.

During the period from 1974 to 1980 at the University of California at Los Angeles Prosthetics-Orthotics Laboratory, a search for materials to replace silicone gel as a liner material inadvertently led to the development and clinical application of two hybrid P.T.B. liners known as multiple durometer liners.

Figure 1. Below knee ski leg with "selectively placed gel liner and Lenox Hill Brace to assist in stability and suspension."

Figure 2. Raw Haflex 1962.

THE HOT MELT LINER

The inherent problems of fabrication and longevity of silicone gel socket liners led to the first alternative material, called a "Hot Melt Copolymer Gel." In its raw state, hot melt gel or Haflex 1962[4] appears worm-like, and is used in the manufacturing of fishing lures and squishy toys (Figure 2). The hot melt liners are fabricated by melting raw Haflex 1962 in an oven at 400° Fahrenheit until the gel is molten. A leather liner applied in the standard manner over a plaster positive model is immersed into the molten material, developing a build-up of about ¼" thickness (Figure 3). The cast is carefully rotated until the hot material has cooled. Attempts to lay up a nylon mesh or stocking over the external surface of the molten material have proven to be difficult. While the technique described is crude, and equipment rudimentary, the resulting liner looks and feels promising.

Proper handling of the hot melt gel involves heating the material in a double boiler with a lid. The double boiler should have a bath of castor oil or a high flashpoint petroleum oil, such as golden Shell No. 40. It should withstand temperatures to 400° Fahrenheit.

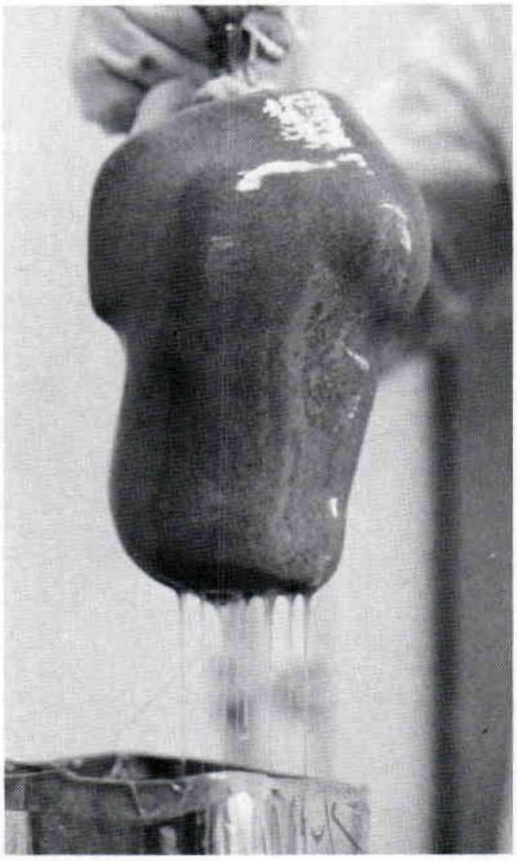

Figure 3. Hot-melt gel liner in dipping process.

A large electric roaster has been used for this purpose and will hold up to 30 pounds of the hot melt. The hot melt is completely reclaimable, although scraps should be cut for ease in melting. Overheating or prolonged heating will weaken the hot melt material. Detailed manufacturers instructions are available and should be consulted.[4] Open heating in an oven is slow and produces smoke, and is, therefore, not recommended.

Three problem below-knee amputees consented to try the new hot melt liners. Figure 4 shows one typically difficult below-knee residual limb with painful boney areas and a deep scar over the medial tibial flare. The scar had a slightly draining sinus that was irritated by every attempt at fitting and ambulation despite a variety of sockets and liners, that included a silicone gel liner. The other two patients fitted with hot melt gel liners had residual limbs with different yet classical fitting problems.

In Figure 5 the hot melt liner is shown donned with a patient wearing a three-ply residual limb sock. No reports of skin irritation or allergic reactions have been encountered. The prostheses were fabricated and aligned in the standard manner. In Figure 6, a P.T.B.-S.C.-S.P. or P.T.S. with Fillauer removable medial wall proved excellent, functionally and cosmetically. The patients who have been fitted with hot melt liners were remarkably comfortable.

Within a period of three months, the hot melt liners developed cracks at the patellar notch area (Figure 7). Reinforcement of the hot melt liner in this area is necessary for better wear. The hot melt liner was repaired by locally heating the liner with a heat gun to reconstitute the gel (Figure 8). Months later, additional repairs involved sewing in place Kemblo patches over the patellar notch area. This multiple durometer approach stabilized the AP dimension of the socket and prevented further tearing.

The hot melt multiple durometer liner provides the same mechanism of comfort as the silicone gel liner. The gel-like consistency of the liner reduces shear forces on the residual limb by absorbing shock and rotation. Due to lack of facilities and time for research, the hot melt insert was dis-

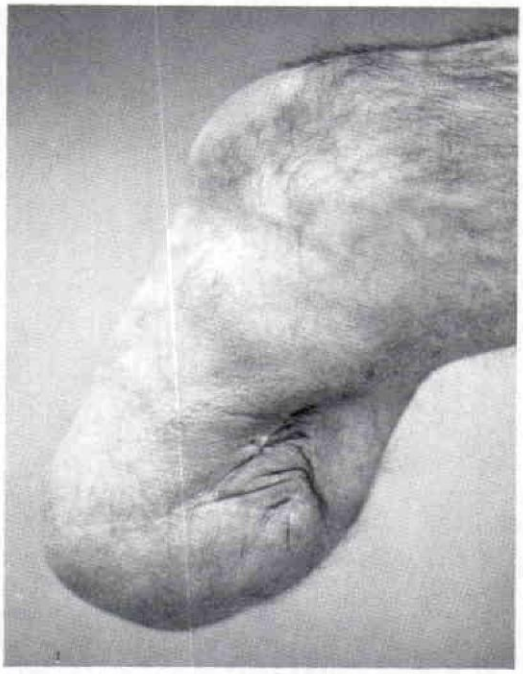

Figure 4. Badly scarred below knee residual limb, a typical candidate for the multiple durometer liner.

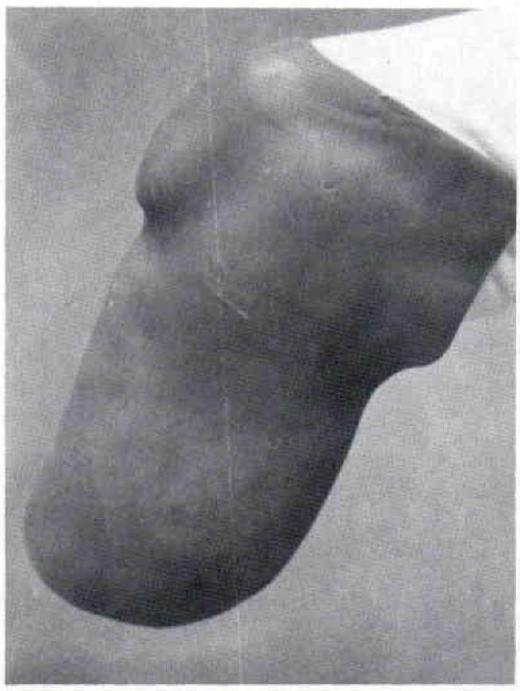

Figure 5. The hot-melt gel liner.

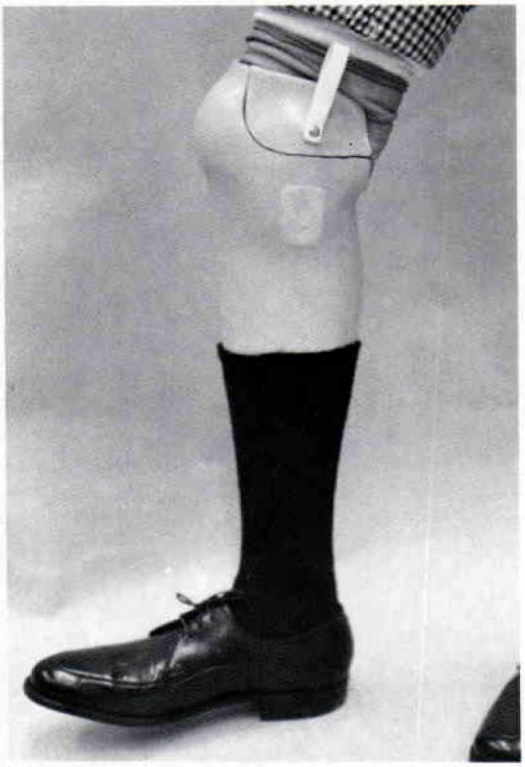

Figure 6. A P.T.B.-SC-SP prosthesis with the Fillauer removable brim and hot-melt gel liner.

Figure 7. Common area of deterioration in hot-melt liners.

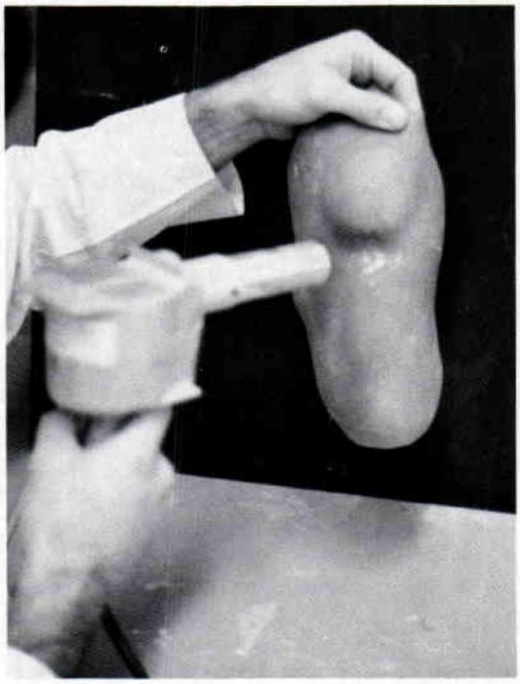

Figure 8. Repair of the hot-melt liner is accomplished by reheating the deteriorated area with a heat gun.

continued, and more traditional materials and methods were again used on a regular basis.

After three years, the hot melt liner patients returned to the U.C.L.A. lab. It was at this point that the durability of the hot melt liner was fully recognized. After long term wear, the hot melt liners were intact, although somewhat compacted and worn. The compression of the hot melt gel appeared uniform and without the migration that is common in silicone gel liners. No further research is planned or anticipated on hot melt liners. However, information and technical experience is available on this material for anyone wishing to pursue its applications.

THE ALIPLAST-KEMBLO LINER

By 1979 a variation of Kemblo-leather P.T.B. liner was fabricated as a replacement

Figure 9. A below-knee amputee who is a candidate for the Kemblo Aliplast multidurometer liner.

for hot-melt liner wearers. An Aliplast-Kemblo multiple durometer liner was designed for the problem below-knee amputee shown in Figure 9. The oddly shaped residual limb was extremely boney in areas where normally there is more padding. Furthermore, a rather fragile scarred area over the anterior tibia made a hard socket or conventional liners extremely difficult, if not impossible, to fit.

The Aliplast-Kemblo liner is fabricated by first constructing a leather insert in the standard manner. Very soft Aliplast patches are glued to the insert and carefully beveled to blend imperceptibly into the leather (Figure 10). The positioning of the patches relates directly to the locations in the liner where extra softness is desired. Normally the patches are placed over the crest of the tibia, beginning approximately

Figure 10. Appearance of liner with Aliplast patches in position.

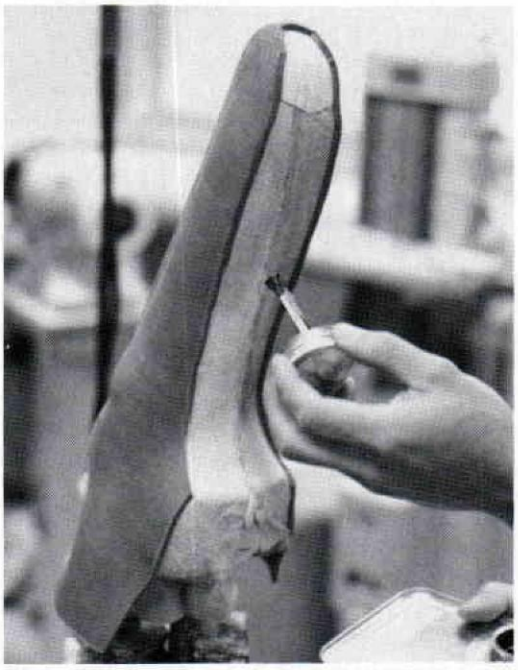

Figure 11. The Kemblo backing is applied in the standard manner over the Aliplast patches.

½" distal to the patellar tendon, and covering the entire anterior and distal area of the tibia and over any boney areas around the knee. Additional Aliplast patches are applied over the head of the fibula (Note: The positive model has been modified in the standard manner and standard plaster of Paris buildups have been applied). The multiple durometer liner is completed by adding a layer of Kemblo in the conventional manner (Figure 11). Pelite or Spenco could also be used in this final fabrication step.

Clinically, the results with the multiple durometer liner (Aliplast-Kemblo) have been excellent. The first six below-knee patients selected for liners were either previous silicone gel, hot melt gel insert wearers, or classified as difficult to fit patients. An additional type of residual limb was found to benefit from the multiple durometer technique. In cases where the cut tibia is not carefully beveled, and skin covering is drawn tautly over the cut edges of the bone, an intermittently painful residual limb often results. Multiple durometer liners can also be used when this type of problem is anticipated.

When worn for the first time, the multiple durometer liner feels somewhat tight yet comparable to other liners. Patients have consistently reported that, within one week, the liner adjusts to the residual limb by partially packing out the Aliplast material. Initially it was thought that the Aliplast would continue to pack out completely, thereby ruining the fit of the liner. However, this speculation proved unfounded as the liners seemed to pack only to the degree required for relief of the boney prominences. The added support of the Kemblo not only maintains the fit, but enhances the wear resistance of the liner.

At least six multiple durometer liners have been worn for over one year with no problems other than those normally associated with maintaining the A-P fit in a Kemblo-leather liner. The Aliplast buildups still continue to provide cushioning. It has been speculated that with careful casting and bone identification, buildups on the positive model of the residual limb may not be as necessary when the properly fabricated multiple durometer liner is used. The above technique is now used frequently, and multiple durometer liners can be included routinely in prostheses by asymptomatic amputees.

CONCLUSION

In conclusion, the clinical success of the multiple durometer liner does not signal any major philosophical shift in the fitting of P.T.B. prostheses. This simple variation has proven to be exceptionally beneficial and functional in a wide variety of below-knee amputees using liners in their prostheses. The method of fabrication makes it easy to adapt to techniques already in common practice.

The hot melt get liner with a Kemblo A-P insert has worthwhile aspects that warrant further research. The hot melt liner is less difficult to fabricate than is the silicone gel liner, and it appears to be stronger and less prone to cold flow or migration, which is common in silicone gel liners. When the technical development of the hot melt gel liner is continued, it could lead to a good alternative to the silicone gel liner.

In high activity sports prostheses, multiple durometer liners are indicated. The support and suspension of the Lenox Hill brace may also be considered as a viable addition to the multiple durometer liners for high activity P.T.B. prosthesis wearing patients, where high stress forces are placed on the patient and the prosthesis.

AUTHOR

Mr. Staats is currently the Director of the Prosthetic/Orthotic Education Program at the University of California at Los Angeles.

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