

Technical Note:

ORTHOSIL Silicone Gel for Pads and Soft Insert Liners

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INTRODUCTION

Before becoming concerned with the functional components of prostheses and their alignment, we must first address the connection between body and prosthesis. "Considerable forces are involved in standing and walking"¹ which must be absorbed by the prosthesis, and most importantly, by the interface between the soft tissues of the residual limb and the prosthetic socket. "These soft tissues will be deformed and displaced by the external forces,"¹ affecting the prosthesis. During casting, and through socket design, these soft tissues are purposely manipulated and shaped. These external forces and the forces resulting from movement of the human body are taken into consideration in the design of the prosthetic socket.

In the majority of cases, amputees can tolerate these forces if they have a well fitted socket, with or without a soft insert liner. However, there are always exceptions. Even with conventional inserts of leather, kemblo, or polyurethane foam materials, patients with extensive scar tissue, skin grafts, or minimal tissue covering of the skeleton may require something special to prevent tissue breakdown.

SILICONE GEL

When silicone gel was introduced, its unique properties seemed to be ideal to meet the special needs of these amputees.

Silicone gel is a semi-fluid material that will maintain a constant volume. Pure silicone gel padding provides an excellent weight-bearing support.² When used to fabricate soft insert liners, it can help absorb external forces by allowing movement within the gel, rather than between the skin and the socket or liner.

Although silicone gel has many excellent characteristics, there have been some disadvantages with using it. Previously, it required a complicated fabrication technique which took a great deal of time. Silicone gel was often bonded or injected between layers of leather. There were problems of durability. Delamination would occur between the leather and the silicone. Sometimes, if the leather were not sealed properly, the silicone gel leaked through the liner. After repeated weight-bearing, there also was a tendency for the silicone gel to migrate, thus no longer providing protection for those areas where it may be needed most.

A NEW APPROACH

This article will describe a new product and a simplified fabrication technique for silicone gel padding and soft insert liners. The product is ORTHOSIL Silicone Gel, available from OTTO BOCK Orthopedic Industry.

PROPERTIES OF ORTHOSIL

ORTHOSIL Silicone Gel consists of two liquid components which are combined to fabricate a socket insert liner or padding. ORTHOSIL was developed so that its physical and chemical properties would meet the special requirements of the prosthetics field. Advantages include:

1. It does not irritate the skin and is physiologically non toxic.
2. Due to its special molecular structure, its mechanical properties are similar to the physical characteristics of subcutaneous tissue.
3. There should not be any problems with migration of the ORTHOSIL Silicone Gel Liner. The Liner can be washed with mild soap and water and temperatures up to 356°F will not harm it.
4. ORTHOSIL Silicone Gel is available in two different types. One produces a flexible product and is used for the fabrication of soft insert liners. The other produces a more firm product, which may be used for end pads and distal end-bearing cushions for Symes and knee-bearing sockets. The flexible silicone and the more firm silicone can be mixed together in varying amounts before adding the catalyst, to achieve varying degrees of density and elasticity.

FABRICATION TECHNIQUES

To fabricate an ORTHOSIL silicone gel below knee socket liner, prepare the plaster positive model the same way as you would for lamination. Use PVA sheeting as a parting agent for dry plaster models. To seal wet plaster models, use a parting lacquer and then PVA Sheeting. Do not get talcum powder on the outside of the PVA. If talcum powder is absorbed into the silicone, it will reduce the sheer strength of the silicone gel.

To make a distal end-bearing cushion in a socket liner, a plastic mold in the shape of a cup is available. Spray the mold with silicone spray and then pull it over the dis-

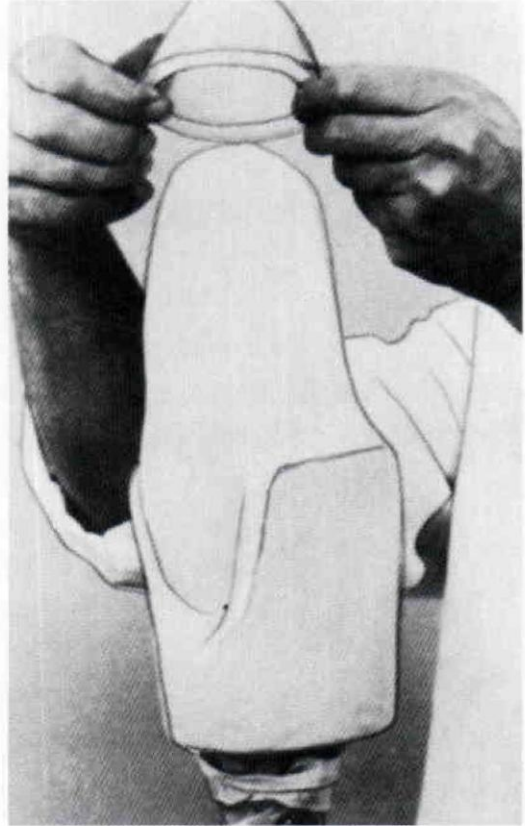


Figure 1: A plastic mold in the shape of a cup is pulled over the distal end of the positive model.

tal end of the plaster positive model (Figure 1). 617H44 Silicone Gel and 617H45 ORTHOSIL Catalyst are carefully measured by weight. The mixing proportion is nine parts of silicone gel to one part of ORTHOSIL catalyst. The liquid components must be thoroughly mixed with care, yet not whipped.

The mixture is then poured into the opening in the top of the distal end pad mold (Figure 2). To make a pull sock hole in the socket liner, sand a 4 mm thick, $\frac{3}{4}$ inch wide piece of polyethylene to the contour of the distal end of the plaster model. Insert this polyethylene piece vertically into the opening in the distal end pad mold (Figure 3). A bigger slot can be made for patients who may have trouble removing the pull sock. After about 45 minutes, the silicone mixture will vulcanize so that the mold can be removed.

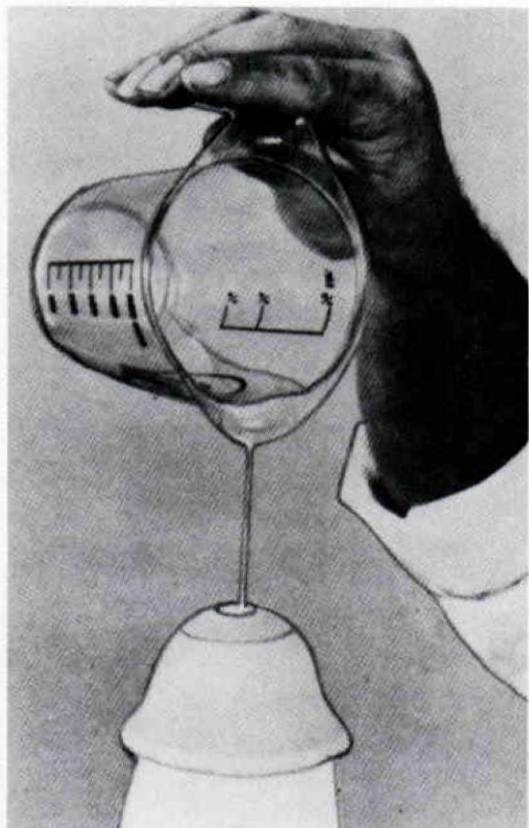


Figure 2: The liquid component mixture is poured into the opening at the top of the distal pad mold.

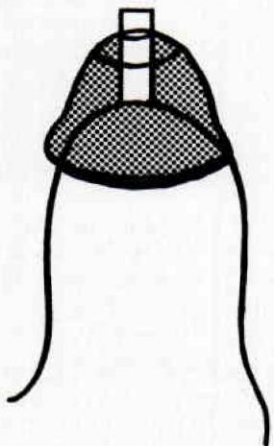


Figure 3: To create a pull sockhole, a polyethylene tube is placed through the opening in the distal end pad mold.

If the silicone gel liner is fabricated immediately after the end-bearing cushion, the ORTHOSIL will chemically bond to itself. ORTHOSIL will not adhere to itself after about three hours, when the vulcanization process has been completed. If you want to bond another layer of silicone to an existing one, a special bonding agent 617H46 must be painted on the surface.

In preparation of the gel insert, six layers of elastic stockinette are used in the layup and then an outer PVA bag is applied. Use only 623T13 Elastic Stockinette for fabrication of the silicone gel liner. Only this elastic stockinette has been specially woven and treated to be compatible with ORTHOSIL silicone gel. The elasticity of the stockinette allows stretch circumferentially, but not lengthwise.

Weigh out and mix thoroughly nine parts to one respectively of 617H43 ORTHOSIL Silicone Gel and ORTHOSIL Catalyst. A special caucasian pigment paste is available for ORTHOSIL. Only this pigment can be used with ORTHOSIL. Immediately pour the silicone mixture into the opening of the PVA bag. Do not evacuate the air from the layup before pouring in the silicone gel. Squeeze the bulk of the ORTHOSIL into the layup at the distal end of the model. Tie off the PVA bag around the polyethylene piece, still found in the distal end pad, and turn on a light vacuum. Invert the plaster positive model to a position of about 130° to allow the air to be evacuated ahead of the gel (Figure 4). Distribute the mixture slowly, and return the cast to a vertical position.

When the silicone gel begins to vulcanize, distribute the mixture to the bony prominences or any other areas that require extra padding. Once vulcanization begins, the silicone gel mixture does not shift easily and it will remain where it is distributed when fully vulcanized.

At a room temperature of 70°F the vulcanization process should be completed in about two hours. The silicone gel liner can be removed and sprinkled with talcum powder on the inside and outside. The proximal brim should be trimmed using a pair of sharp scissors, as sanding will expose fibers of the stockinette (Figure 5).

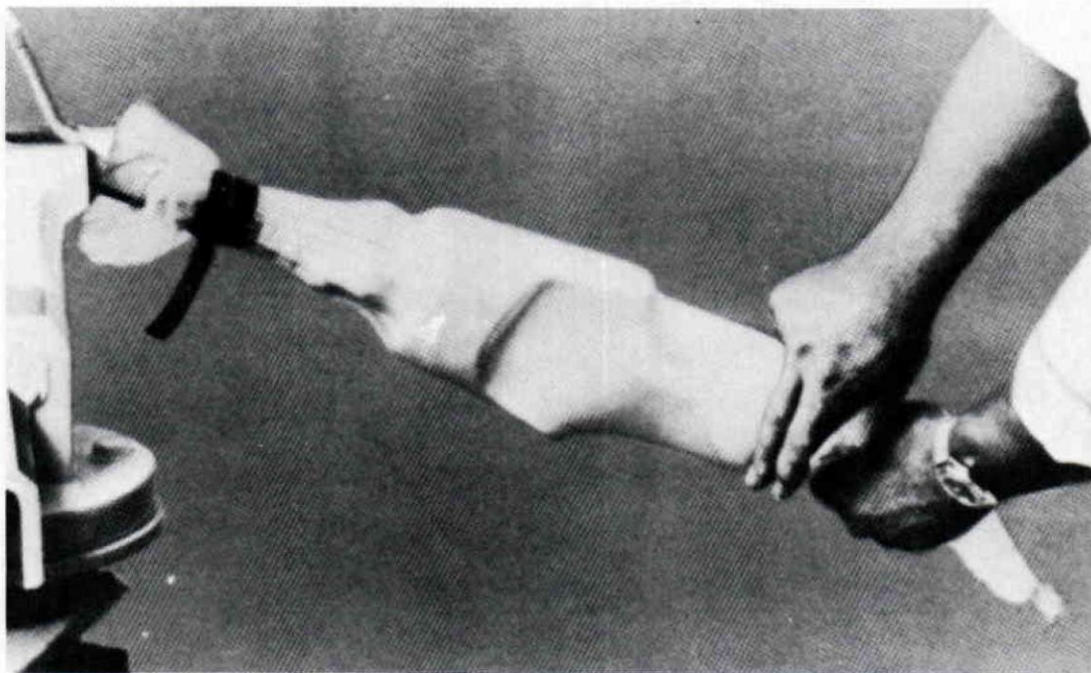


Figure 4: Invert the positive model to allow air to evacuate ahead of the gel.

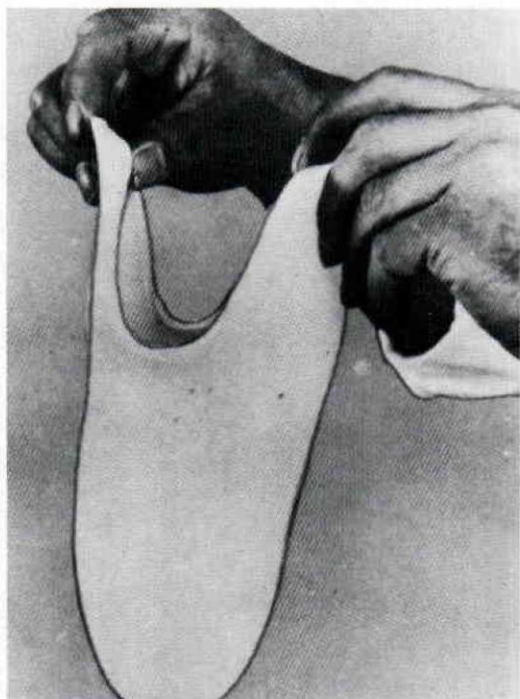


Figure 5: The completed gel insert should be trimmed with a pair of scissors to avoid a rough finish.

ORTHOSIL silicone gel can be used for custom padding too. It could be especially useful as a toe filler for amputations of the forefoot. It can be used for an endbearing cushion in a Symes socket, and for ischial seats and anterior above knee socket brims, virtually anywhere where pressure points could cause problems.³ When fabricating pads, prepare the plaster positive model in the same manner as stated previously, and use silicone spray as a parting agent.

SUMMARY

The many unique properties of silicone gel have been found to be of great benefit to amputees whose residual limbs have a large amount of scar tissue, skin grafts, or minimal tissue covering the skeleton. Silicone gel has also been used in sports prostheses, where greater stress is placed on the residual limb than in normal daily activities (sports such as hiking, skiing, racquetball, and tennis).

With the development of ORTHOSIL silicone gel and the accompanying 623T13 elastic stockinette, the fabrication process for padding and soft insert liners is relatively quick and easy. The lamination technique does not require the use of leather, and the problems of migration, sealing, and bonding are eliminated.

ORTHOSIL silicone gel should prove to be beneficial in fitting special problem cases.

NOTES

¹Holmgren, G., "The Interface Between the Body and the Above-Knee Prosthesis," *Prosthetics and Orthotics International*, 3(1):31-36, April, 1979.

²Graves, C.P., Jack M., "The Selectively Placed Silicone Gel Liner System for PTB Prostheses," *Orthotics and Prosthetics*, Vol. 34, No. 2, pp. 21-24, June, 1980.

³Potter, C.O., John W., and Sockwell, Jack E., "Custom-Foamed Toe Filler for Amputation of the Forefoot," *Orthotics and Prosthetics*, Vol. 28, pp. 57-60, September, 1974.

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