The "Interface" in the Immediate Postsurgical Prosthesis[a]

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The Prosthetics Research Study initiated investigation of the immediate postsurgical prosthesis by using as the primary rigid dressing, a hard conventional plaster socket without compressible interface. Our first 16 below-knee amputations in 1964 were treated with only a nonadherent silk dressing and sterile five-ply wool stump stock covering the wound. The initial plaster socket was then applied in PTB configuration leaving the knee free to move. Formation of edema, partial wound separation, abrasions, and distal anterior stump irritation in several cases made it evident that tissue support was inadequate with the plaster socket alone. Mobilization of the knee joint proved to be detrimental since it adversely affected cast socket suspension no matter how carefully the cast socket was applied. As a result of this early experience, we modified the technique to provide controlled pressure on the soft tissues of the stump using a compressible interface between the rigid plaster-of-paris dressing and the stump. Appropriate pressure proved beneficial to wound healing and promoted early stump maturation. During the past 4 years we have investigated in depth the effects of pressure on stump tissues. Basic research and correlated clinical studies have provided significant data highly relevant to the wound healing process.

In essence an effective pressure interface agent combined with the rigid dressing immobilizes and supports the fresh operative wound, markedly limiting the development of postoperative edema, improving circulation, minimizing inflammation response, and promoting wound

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healing. Equally beneficial and advantageous are upright activities of the patient including controlled weight bearing through standing and walking early in the post-operative period. Detailed examination of these so-called "appropriate pressures" presents a number of important questions. How critical are these pressures? What are the desirable gradients? What variations can be tolerated to insure optimum healing, yet avoid tissue necrosis? What are the magnitudes of relatively constant or intermittent pressures and which is preferable? What are the volumetric stump changes in the immediate postsurgical period? What are the time requirements to achieve complete wound healing and stump maturation? The impressive clinical results obtained in our experience numbering well over 300 amputations provide some insight and conclusions which nevertheless require additional substantiating followup in the form of basic research studies. This investigation is continuing in our laboratory and by others. A preliminary report of such in-depth study of basic physiological questions derived through instrumentation was reported elsewhere and has provided some answers to the posed questions. In general our observations support the clinical requirements for an effective pressure interface agent between the amputation stump and immediate postsurgical rigid dressing.

OBJECTIVES

To achieve this desirable environmental factor, the ideal interface material should be compressible and maintain its elasticity over a predictable period of time. It should be capable of compensating for and adapting readily to volumetric stump changes if and when these occur. It should be controllable and adjustable manually through inflation or by other means to maintain the optimum pressure gradients in the postoperative period once these pressures are known and have been achieved. It should also be porous or ventilated to permit outflow of fluids and perspiration and have permeability for air circulation. Finally, it should be nonirritating to the skin and able to be sterilized.

Several materials or combinations of materials meeting the described requirements to varying extents were studied and clinically tested. They consisted of the following sterilized items (Fig. 1):

1. Inflatable rubber balloon or bladder.
2. Well-fluffed surgical gauze.
3. Lamb's wool.
4. Stryker gel pads.
5. Machinist's cotton waste.
6. Foam rubber.
7. Steel and brass wool.
8. Perforated Silastic foam pads.
9. Reticulated polyurethane distal pads.

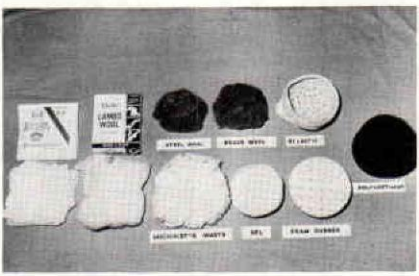

Figure 1

METHODS

Most of these materials were reasonably effective when properly applied. However, the various techniques of application required considerable judgment to estimate the proper quantity for any given case. Need for considerable skill in precise application technique of the surgical dressing and initial plaster wrap added another variable. Only three of the materials, Nos. 4, 8, and 9 were preformed and molded to stump contour thus assuring continuous uniformity of the pads and simplicity in their application.

APPLICATION TECHNIQUES

Interface materials 2, 3, 5, and 6 were applied directly to the distal stump end over the nonadherent silk dressing and were held in place with the Orlon Lycra stump sock. Materials 4, 6, 7, and 8 were applied to the outside of the Orlon Lycra stump sock and retained in position with a thin one-ply cast sock. In addition, materials 4, 6, 7, and 9 were retained over the outside of the Orlon Lycra stump sock solely by the application of the elastic plaster wrap.

For evaluation purposes, materials 4, 6, and 7 were applied both with and without the thin cast sock to study the effect of an additional variable which proved negligible. One material, "Dri-Site" (Johnson and Johnson) was included in category number 6 (foam rubber) but only used directly over the nonadherent silk dressing over the wound.

RESULTS

Early consideration and attempts to introduce an adjustable inflatable balloon or bladder between the stump and the cast socket were abandoned since nonabsorbability of fluids presented serious problems in the form of unhealthy skin maceration, the result of insufficient porosity and poor air ventilation. Theoretical advantages of closed fluid or gas pressure systems are great. We intend to exploit this source of pressure management in future studies.

Fluffed gauze and machinist's waste provide some initial compressive quality which, however, is lost quickly when absorbed fluids dry into a hard, crusty, nonelastic mass.

Lamb's wool does not absorb or retain fluids due to its lanolin content. It allows secretions to pass through freely and to be absorbed by the rigid plaster dressing itself which acts similar to a sponge effect resulting in a relatively dry wound. However, the effective compression factors of lamb's wool are very low initially and we suspect shortly thereafter will become nonexistent.

Stryker gel pads lack the very basic requirement of porosity and being nonabsorbent permit skin maceration by restricting the outflow of fluids and causing the formation of additional moisture through perspiration. The elasticity of this material, however, is considered within an acceptable range. Stryker gel pads compared with other materials are expensive.

Foam rubber of various densities and porosities including related materials tends to create a relatively warm or hot environment, stimulating the formation of perspiration. Another basic inherent characteristic of foam rubber is the absorb-

ing and retaining of secretions which, of course, is not desirable. Perforations or vent holes provided are usually occluded when the initial plaster wrap is applied under necessary tension. Elasticity in various forms of foam rubber is excellent. "Dri-Site" (Johnson & Johnson), a wound dressing which behaves as its name implies, neither provides the required body uniformity nor sufficient compression.

The major difficulty experienced with steel and brass wool was in the form of occasional temporary wound and skin irritation as a result of suspected splinters which penetrated the Orlon Lycra stump sock during weight-bearing activities. Again a lack of uniformity also required skillful application into the rigid dressing. Elasticity was regulated by selection of material density.

The preformed foam pads consisting of a combination of Silastic 386 Foam Elastomer and Silastic 388 Denture Release were molded in four different sizes. The resulting end pads were uniform and simple to apply. Density was controllable by the mixture ratio of Silastic and resulted in excellent compression over the distal stump end. Nevertheless the inherent characteristics of the material, including occlusion of vent holes during application under tension, resulted in heat and accompanying perspiration. Also, manufacture of these pads was considered expensive and time consuming. The experience gained with this particular approach, however, set the stage for evaluating reticulated polyurethane foam.

Currently, the most suitable material is the reticulated (skeletonized) polyurethane foam of 20 pores per inch density. This material envelopes most of the desirable characteristics described earlier and has been clinically applied for more than 1 year on over 100 patients with remarkably good results.

MANUFACTURER'S DESCRIPTION OF POLYURETHANE

Polyurethane is produced of chemicals derived from petroleum

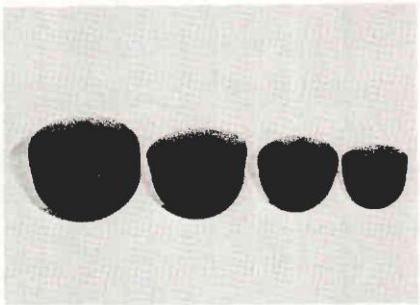

Figure 2

and is composed of 12-sided bubbles or cells that give it a foam-like appearance. Reticulation is the process of removing the walls of the cells. The remaining strands, thicker than were the cell walls, are left in a form that might be best described as a three-dimensional fish-net. Polyurethane foam has a temperature resistance up to 250 deg. F. and can be sterilized with boiling water, steam, or gas.

With the assistance of the manufacturer, we overcame the early problem of shaping the material to stump contours. The performed reticulated distal pads in sizes of 3, 4, 5, and 6 in. are suitable for most if not all stump sizes, (Fig. 2, 3, 4, 5, and 6). After careful evaluation 20 pores per inch density appeared

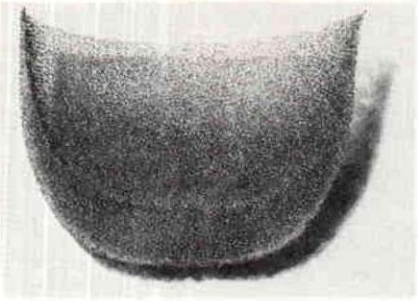

Figure 3

to be the most suitable. However, this does not imply that density of the foam is related to pore size. Our aim was for maximum pore size without sacrificing density or causing detrimental skin irritation due to coarseness of the material.

Aside from providing uniformity in each application, reticulated polyurethane distal pads provide the prosthetist with a greater range of safety over the critical distal-anterior stump margin than was before possible. They remove some of the guesswork and provide satisfactory results for individuals with less experience.

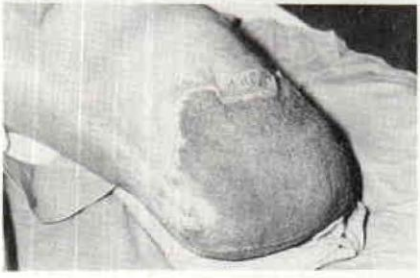

Figure 4

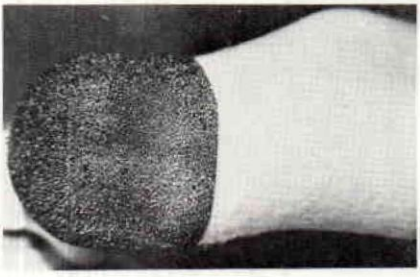

Figure 5

Figure 6

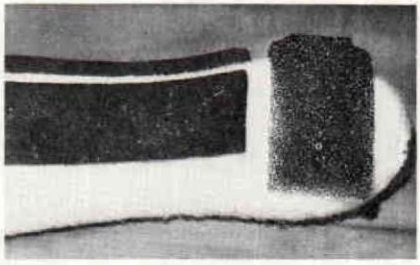

Figure 7

Reticulated polyurethane of the same density and porosity but in ½-in. thick sheet form is recommended as a compressive interface material for Syme and hip-disarticulation rigid dressings (Fig. 7 and 8).

Efforts are being made to substitute compressed polyurethane with identical density as felt for relief pads currently in use in the below-knee and Syme rigid dressings. Plans are to provide polyurethane relief pads with adhesive

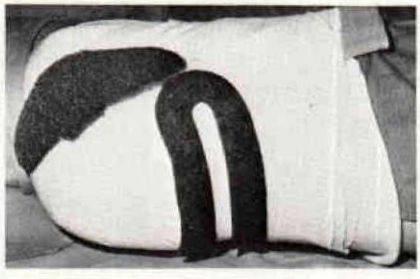

Figure 8

backing to eliminate the need for medical adhesive spray.

Aside from its many uses and applications in various industries and professions, it should be noted that reticulated polyurethane is also successfully used for conventional medical dressings.

SUMMARY

To achieve and maintain effective tissue support in a fresh amputation stump through controlled compression by means of an immediate postsurgical rigid dressing, an effective interface agent with certain fundamental and functional characteristics is required. Various types of interface materials have been evaluated both clinically and through instrumentation. The results obtained indicate the suitability of reticulated polyurethane foam, 20 pores per inch, which has the ideal characteristics of an effective interface material. Further use for this material in different forms and for related applications shows additional possibilities as a surgical dressing.

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