The Application of Ionomer Resins in Definitive Below Knee Prostheses: A Limited Study

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INTRODUCTION

For the past 30 years, polyester resins have been the material of choice for socket fabrication and exoskeletal lamination for all types of prostheses.[1] Without question, these thermosetting plastics have proven to be strong, durable, and effective for such application, and, at the time of their introduction, thermosetting plastics provided a quantum leap forward from the age of wood. The advent of plastics allowed for a more hygienic and less bulky prosthesis. More importantly, lamination provided a medium for duplicating a modified replica of the patient's residual limb. Thus, a more intimate fitting socket with greater weight-bearing characteristics was possible. In fact, the use of thermosetting resins continues today as the accepted state-of-the-art.

As with any material, the polyester resins have certain characteristics which are not ideally suited for all situations. With this as a basis, the University of Texas Health Science Center at Dallas, in conjunction with the Dallas Rehabilitation Institute, began investigating the use of alternative materials for definitive prosthetic design. One of the most attractive substitutes appeared to be thermoplastics. A clinical study was undertaken to evaluate the group of thermoplastics known as ionomer resins and their role in definitive prosthetic application, as opposed to the polyester resins in use today.

Thermosetting Resins

As indicated, thermosetting resins such as 4110 laminac have many positive attributes when used in the prosthetic arena. Some of the negative characteristics which prompted the investigation into other materials are equally impressive. The toxicity of the fumes given off during the lamination stage is certainly a matter of concern. The ability to modify a socket fabricated from polyester resin to accommodate residual limb change or pressure on bony prominences is essentially limited to grinding away an area for relief, or adding material to reduce socket dimensions. The cured polyester resin also is fairly rigid in nature—a factor which formed the major emphasis for research into the area of alternative materials.

Ionomer Resins

The thermoplastics which were utilized in this particular study of prosthetic application are classified as ionomer resins. The resins are based on copolymers of ethylene and methacrylic acid, which are partially reacted with metallic salts to form ionic crosslinks between acid groups of single chain or between neighboring chains.[2] The name Surlyn® is the registered trademark of the ionomer resins produced by DuPont and was the material used in the fabrication of the prosthetic sockets. Some of the characteristics which made Surlyn® an attractive option for prosthetic use are as follows:

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Clarity

Surlyn® is virtually transparent even in thicknesses up to ¼ inch. This allows the prosthetist to evaluate socket fit visually while the patient is standing with full weight bearing on the residual limb (Figure 1).

Adjustability

The nature of ionomer resins is compatible with heat induced molding which greatly facilitates modifications to the socket. Areas of pressure over bony anatomical structures are simply heated and relieved with no adverse affect on integrity or clarity of material. Surlyn® may also be buffed, sanded, drilled, and riveted in the same manner as the laminates.

Ease of Fabrication

Surlyn® comes in a sheet form and is heated and softened in an oven to allow drape vacuum forming. Unlike other thermoplastics, Surlyn® can be formed directly over a wet cast with no need for a lacquer coating or nylon stocking interface. This differs greatly from polycarbonates which require prefabrication dehydration and a dry cast for good results. Additionally, no post-fabrication curing is required to drive off skin irritating styrene gas, as in the case of polyester resin which has a greater than 25 percent flexible resin content. Additional fabrication time is required, however, in the case of long below knee and Symes level amputations because of the need to weld the posterior seam of the Surlyn® socket.

Flexibility

This factor has proven to be the most significant advantage of ionomer resins from the patient's standpoint. Sockets fabricated from Surlyn® have much greater flexibility than those fabricated from polyester resin. Patients report that the socket feels more like a part of them and is appreciably more comfortable. The exact deformation occuring in the socket during ambulation has not been quantitatively measured at this point, but clinical trials indicate that anatomical weight-bearing surfaces are not adversely affected by the dimensional changes.

Clinical Applications

Initially, the ionomer resin sockets were used only as "test" sockets prior to fabrication of an intermediate or definitive prosthesis. Later, use broadened to include intermediate prostheses, and eventually definitive application. The move toward definitive use was prompted by the patients themselves. Those who had been wearing intermediate prostheses made of Surlyn® complained of the rigidity of the laminated socket when their permanent prosthesis was delivered. This provided a significant clue as to the direction which should be taken in regard to providing a more comfortable definitive prosthesis.

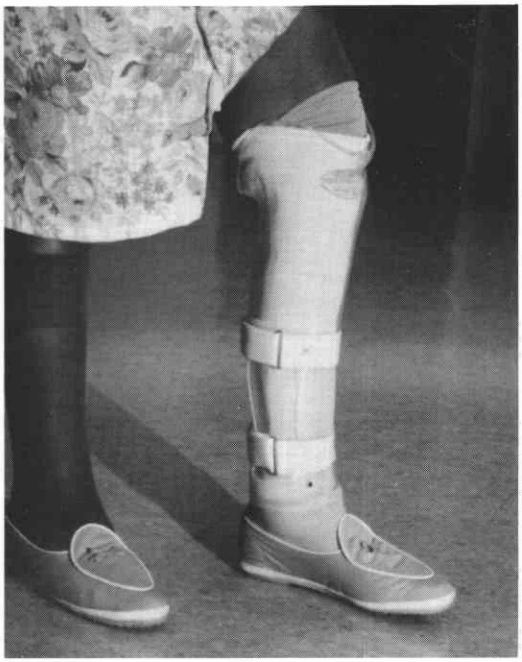

Figure 1. Symes amputee with clear Surlyn® prosthesis.

FABRICATION PROCEDURE

Though the technique is very similar to standard vacuum forming of orthotic devices, some specific steps are employed when making the definitive prostheses. To prepare the Symes cast for vacuum forming, the Symes foot retainer is attached to the modified positive model with plaster, using the vertical fabrication jig for alignment. A small hole is drilled into the popliteal area and the patellar bar of the cast to assure a good vacuum in these depressions. A piece of cotton stockinette is stapled above the trimline and stretched over the cast mandrel and

the holes in the hand drape pipe. Pressure sensitive tape is used to hold the stockinette in place on the pipe.

The thickness and dimension of the Surlyn® sheet to be used will vary according to type of prosthesis (i.e., Symes or BK) and the size of the patient. Most Symes casts require no more than a 24″ × 24″ sheet of $^3/_{16}$″ Surlyn® (for the lighter or less active patient $^1/_8$″ Surlyn® may be sufficient). The sheet is heated on a teflon rack for approximately seven minutes in a 350°F oven. The heated sheet is draped over the cast and sealed down the posterior side with the vacuum turned on. Excess plastic is cut away and trimmed almost flush with the socket before it is allowed to completely cool, eliminating the need for excessive grinding. Once cool, the posterior seam is grooved in preparation for welding. Three welds are run over the entire seam. The socket is then removed from the cast and trimmed. The foot is attached and the prosthesis is ready for fitting and delivery.

The below knee prosthesis is fabricated in the same manner one would fabricate a thermoplastic test socket. It is frame draped with a 12″ × 12″ sheet of $^1/_2$″ Surlyn.® Care must be taken to not create webs below the trimline. It is then formed onto the Berkley alignment fixture for dynamic alignment. The socket may be permanently incorporated into an endoskeletal system or be finished in an exoskeletal manner using acrylic resin for the outside lamination. Using acrylic resin will not impair the flexibility of the socket to the extent that polyester resin will.

CLINICAL RESULTS

The fittings of the ionomer resin sockets for definitive use began in April, 1982. Of the ten patients who were definitively fitted with Surlyn,® eight were Symes level amputees. The remaining two patients were below knee amputees (Figure 2).

In the Symes amputee group, five of the eight patients experienced failure of the prosthesis at the ankle/foot juncture (Figure 3). The shortest use time until breakage was 14 days and the longest was five months, with a mean of 11 weeks for the group experiencing breakage. Two of these patients were refitted with a second Surlyn® definitive, one of which failed again after two months, while the other prosthesis continued to function one year after a modified ankle/foot juncture was devised (Figure 4). The modification made was one of reinforcing the distal end of the socket with glass cloth adhered with acrylic resin.

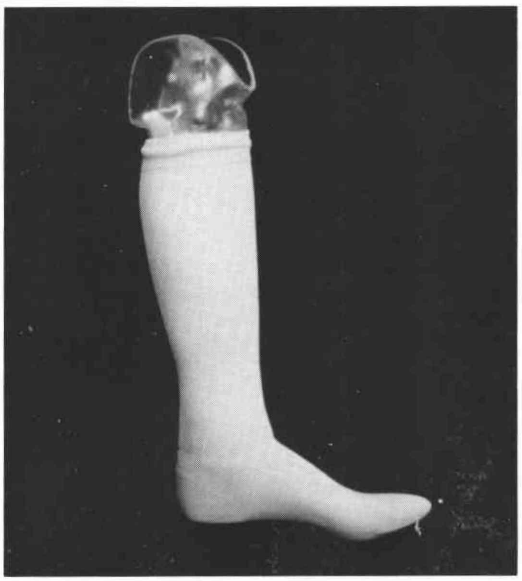

Figure 2. Below knee type prosthesis with ionomer resin socket.

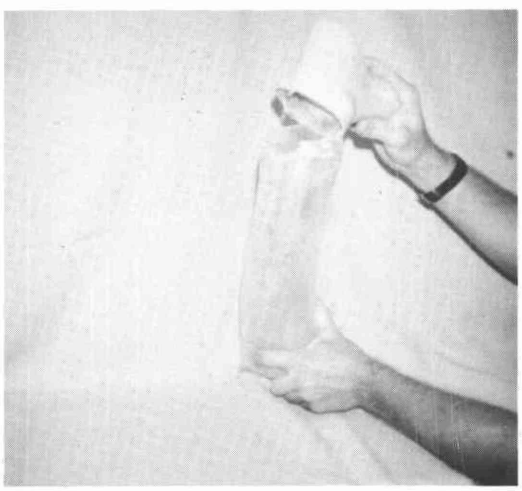

Figure 3. Stress fracture at ankle/foot juncture of Symes prosthesis.

This same method has since been used on two other prostheses in the Symes group. However, over a period of one year, both of these prostheses failed at a level just proximal to where the glass cloth reinforcement stopped. The re-

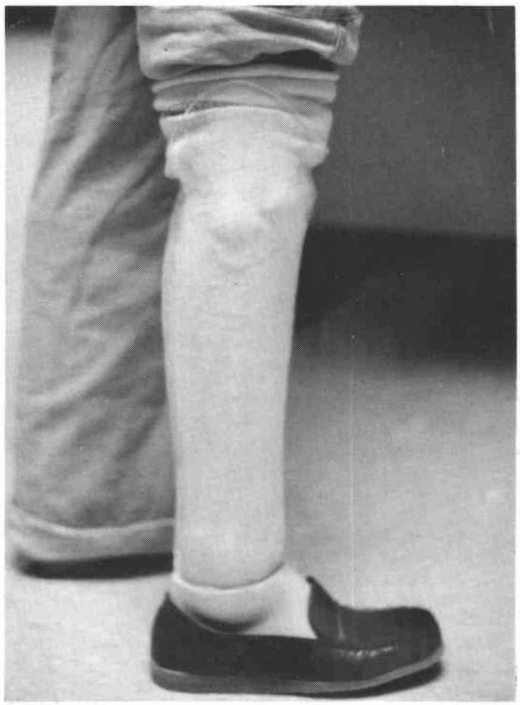

Figure 4. Closed socket design type now being used with reinforced ankle. Suspension is provided by a closed-cell polyethylene shim or pad encompassing the leg proximal of the malleoli and retained in place with a cast sock. Prosthetic socks are worn beneath the shim as usual.

maining patient in this group was an elderly lady who is a limited household ambulator and has experienced no known problems to this date.

One of the two below knee patients wore his Surlyn® socket prostheses for 11 months before a crack developed. That patient weighed in excess of 230 pounds and participated in sports on a routine basis. His socket developed a crack in the proximal posterio-lateral corner which eventually migrated down the posterior wall. He was subsequently refitted with a polyester laminate socket. The other BK amputee was a 110 pound woman in her twenties who continues to ambulate with her Surlyn® socket prosthesis one year and seven months after fitting.

CONCLUSION

As indicated by Stills and Wilson,[3] Surlyn® may not be ideal for applications where high unit stresses are anticipated. Although this seems to have been borne out in this initial group of patients, we still believe that ionomer resins might play an important role in definitive prosthetic fittings. This may be accomplished by reinforcement at crucial stress points, a variation in the ionomer resin itself, or by finding a different material that is better suited to long term stresses. The frame type design being used in the above knee Scandinavian socket may also hold significant promise in a below knee configuration.

The potential benefits of ionomer type resins to the amputee population are too great to dismiss without further evaluation and clinical analysis. It is hoped that others in our profession will actively participate in seeking viable materials for definitive socket application.

REFERENCES

[1] Aylesworth, R. Dean, ed., *Manual of Upper Extremity Prosthetics,* Artificial Limbs Project, University of California, Los Angeles, 1952.

[2] DuPont, E.I. De Nemours and Company (Inc.), *Surlyn® Ionomer Resins Industrial Extrusions Manual,* p. 3.

[3] Stills, Melvin, and A. Bennett Wilson, Jr., *A New Material in Orthotics Prosthetics,* Vol. 34, No. 3, pp. 29–37, September 1980.