COSMETIC COVERS FOR LOWER-LIMB PROSTHESES

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ABSTRACT

A soft cosmetic cover for use with modular endoskeletal prostheses is discussed. The reverse molding procedure, which is used to make a mirror image of a unilateral amputee's remaining anatomical limb, is described. This process reduces the time required to fabricate a cosmetic cover since no mechanical or artistic shaping is required to match the prosthetic limb to the anatomical limb. The resultant cover is composed of a lightweight (3 lb./cu. ft.) open-celled urethane foam which produces its own high-density, scuff resistant, and water resistant skin. This cosmetic cover greatly facilitates fabrication and increases efficiency in the production of modular endoskeletal prostheses for lower-limb amputees.

INTRODUCTION

Historically, the development of prosthetic limbs emphasized either cosmetic appearance or restoration of lost function. Advances aimed toward fulfilling either of these objectives were critically limited by the lack of surgical knowledge, which resulted in more than 75 percent fatalities of all surgery being performed. Very few survivors of amputation surgery had stumps which could be fitted with an artificial limb, since the amputation technique (using boiling oil and crushing the soft tissue to control bleeding) resulted in stumps with no weight-bearing ability.

However, many noteworthy advances have been made in the areas of surgery and amputee rehabilitation. These advances have spawned new teams of physicians, prosthetists, therapists, and recently engineers who
have created a series of ever improving prosthetic appliances and amputee management techniques. These advances are summarized in References 1-5 and provide interesting insight into the evolutionary process which has resulted in a new generation of appliances. Simultaneously, these new appliances satisfy the need for a unit which replaces lost functions and provides a cosmetically acceptable appearance.

Accepting the CPRD design criteria which define the concept of total cosmesis, an endoskeletal modular prosthetic system has been developed for the lower limb. This new prosthetic system represents a merger of the materials technologies which resulted from the aerospace program with the knowledge paradigm associated with the prosthetics industry. By utilizing the endoskeletal weight-bearing-system concept in the prosthesis, a unit with improved function was achieved, but the innovations (6) did not produce a cosmetically acceptable system.

However, since the endoskeletal load-bearing system provides the load-bearing, jointed mechanism which is necessary for good function, the cosmetic requirements for the cosmetic cover were reduced to:

1. provide an easily cleaned surface,
2. provide a wear-resistant surface,
3. be able to be colored to match the skin tone of the amputee,
4. have no offensive odors,
5. have a natural texture, and
6. maintain flexibility at the joints after repeated flexures.

COSMETIC COVER DEVELOPMENT AND FABRICATION

The above criteria can be satisfied through the development of a cover which is fabricated from one of the new flexible polymeric foam systems. After evaluating several systems, a flexible urethane foam which generates its own thin, high density surface (approximately 60 Pcf.) was selected as the basic material for development. This open-celled foam system has an average density of 3–4 lb./cu. ft. and is manufactured commercially by Flexible Products Co. in Marietta, Georgia. The self-skinning characteristics provide a surface which is easily cleaned, abrasion resistant, and puncture resistant. Moreover, the foam system can be pigmented prior to the foaming process to produce a prosthetic appliance cover which matches the color of the patient's anatomical limb.

The urethane foam also meets the fourth design criterion once the gas which is generated in the foaming process is forced out of the foam. This is accomplished either by kneading the cover several times after the foam has cured or by placing the cured cover in a polyethylene bag and evacuating it.

The toughness and the thinness of the surface skin provide this foam with the characteristics which are necessary to satisfy the sixth design criterion. As long as the cover is not exposed to excessive heat, above 250
deg. F, or open flame, it has an expected life of more than 12 months; as a component in an experimental hip-disarticulation prosthesis, the foamed cover has undergone a 6-month clinical test without visible signs of failure due to flexure at the knee or hip joint.

In order to satisfy the fifth criterion and produce a cover which reproduces the anatomical characteristics of a unilateral amputee's leg, an inversion casting process has been developed which produces a well-shaped replica of the remaining limb without time-consuming sculpting. The steps involved in the process are presented in the following outline:

1. The patient's limb is coated with a thin layer of low viscosity (on the order of 50 centipoise) silicone oil.
2. One layer of cotton orthopedic stockinet is stretched over the limb.
3. The stockinet is coated with Liquid RTV silicone rubber.
4. Two layers of Banlon Orthopedic stockinet are pulled over the silicone-rubber-covered limb. This must be accomplished before the RTV vulcanizes.
5. A second layer of RTV is spread over the Banlon stockinet.
6. A nylon hose, preferably a panty hose, is pulled over the second layer of RTV, and the excess rubber is scraped off with the fingers so that the mesh of the hose is exposed at all points. It is this step which gives the foamed cover its texture so the texture of the hose is particularly important.
7. The mold is then permitted to vulcanize; this may require from 15-45 min. depending on the type of RTV employed and the amount and type of catalyst used.
8. The vulcanized rubber mold is then removed from the patient's limb by grasping the uppermost portion of the mold and pulling it over itself in the same manner that one removes a sock.
9. The tubular mold is then turned right side out again and the nylon stocking is removed. Care must be taken not to dislodge large pieces of the RTV. This will occur if the RTV has not been adequately wiped from the surface as described in step 6. If it does occur, the hose removal should be halted and fine sandpaper (180 grit) used to remove the excess RTV so that the nylon hose is exposed; then the hose may be removed with no damage to the mold.

The mold is then turned inside out so that the cotton stockinet is on the outside of the mold. This process produces a mirror image of the anatomical limb and is used to form the foam around the endoskeletal weight-bearing system.

To finish the construction of the cosmetic cover, the mold is suspended and the foam is measured, tinted, and mixed according to the manufacturer's instructions, and poured into the mold. Approximately 20 minutes after the pour, the one-piece cover which can undergo large
excursions as experienced at the knee may be stripped off of the mold in
the same manner in which the mold was removed from the anatomical
limb.

It should be noted that this system may be foamed directly around the
pylon system, poured, and reamed out to fit over an endoskeletal sys-
tem.

**SUMMARY**

The merger of aerospace materials technology with a knowledge of
prosthetics has resulted in the development of a novel cosmetic cover
which, when combined with an endoskeletal weight-bearing system, can
provide an amputee with a cosmetically acceptable appliance which
satisfies all of the cosmetic requirements set forth by CPRD.