

# Research Efforts in Improved Prosthetic Skin for Prostheses

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At the Conference on Cosmesis and Modular Limb Prostheses (1) on March 3-7, 1971, sponsored by the Committee on Prosthetics Research and Development of the National Academy of Sciences, it was agreed that modular, endoskeletal prostheses offer definite advantages over conventional crustacean prostheses in many ways, but the lack of a practical method of providing a good cosmetic finish has kept the idea from being accepted widely.

To investigate this matter further, an *Ad Hoc* Committee on Cosmesis for Endoskeletal Prostheses was appointed and the following people met in Annapolis, Maryland on July 19-20, 1971:

Fred Leonard, *Chairman*  
Cecil Benton  
Mary Dorsch  
Hector W. Kay  
Kenneth C. Kingsley  
Maurice A. LeBlanc  
Alvin L. Muilenburg  
Thomas Pirrello  
William F. Sauter  
A. Bennett Wilson, Jr.

At this meeting tentative specifications for a material suitable for

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prosthetic skin were drafted, and plans were outlined to recruit the assistance of appropriate chemical companies in developing it.

Tentative specifications, a brief description of the problem, and samples of PVC gloves have been discussed and given to about a dozen companies. The assistance given to this project by Dr. Leonard and the Army Medical Biomechanical Research Laboratory is greatly appreciated.

It is hoped that one of the chemical companies contacted will become interested in the problem and develop a superior prosthetic skin covering for endoskeletal limb prostheses. If this can be done, both the amputee and the clinician will be happier.

The memorandum addressed to organizations that may be interested in working on this problem and the tentative specifications follow this report as Appendixes A and B, respectively.

## **APPENDIX A**

**October 18, 1971**

### **Memorandum**

**From: Committee on Prosthetics  
Research and Development**

**Subject: Research in Prosthetic Skin  
for Endoskeletal Prosthesis**

Cosmetic gloves and leg covers for artificial limbs are presently made of polyvinyl chloride. This material has been used for many years, and while it is satisfactory in many respects, it has the disadvantages that it stains easily, discolors in sunlight, and lacks sufficient elasticity.

### **Efforts to Date**

The Army Medical Biomechanical Research Laboratory at Walter Reed Medical Center, under the guiding influence of Dr. Fred Leonard, has pioneered the research to date on the prosthetic skin material for artificial limbs. This work has centered around polyvinylchloride with different stabilizers and plasticizers as well as plasticizer-free, inherently flexible elastomers. To date no satisfactory material has been found. It is time to explore other materials, and to undertake basic research, if necessary, to develop a more ideal product.

Until now, our efforts have been "in-house" within the prosthetics field. At this point we feel we need to go out-of-house because our own manpower and technology are inadequate for the task.

### **State of the Art**

Current limb prostheses are exoskeletal in construction; they are made of rigid, laminated plastic shells integrated with metal joints. We are trying to replace these with newly developed endoskeletal prostheses, which have an internal skeletal structure covered with a soft foam and skin in an anatomical manner. These new prostheses are more acceptable to patients because they are soft and look more cosmetic in appearance with the mechanical parts covered.

We have the necessary components for the new endoskeletal prostheses, except for an acceptable prosthetic skin covering. This is the crucial link for the whole system and is where we need help.



## **Amputee Population**

There are about 300,000 amputees in the United States. Of this number, approximately 32 per cent are upper-limb losses.

## **Our Proposal**

Until now, we have been unable to interest major chemical companies in working on the prosthetic skin problem understandably because the commercial market is small. This project has become increasingly important, however, and we would like to solicit the assistance of chemical companies or other capable research facilities to undertake this work by supporting it with federal government funds available through this office.

A copy of the tentative specifications for the prosthetic skin, a sample of polyvinyl chloride cosmetic glove now in use, and other information are available for further study.

## **APPENDIX B**

**October 18, 1971**

### **TENTATIVE SPECIFICATIONS FOR PROSTHETIC SKIN FOR ENDOSKELETAL LIMB PROSTHESES**

**Ad Hoc Committee on Cosmesis  
for Endoskeletal Prostheses  
Committee on Prosthetics Research  
and Development  
National Research Council-National  
Academy of Sciences**

#### **I. SCOPE**

These specifications are for a material to be used as the outer cover of an endoskeletal artificial limb, i.e., to serve as the artificial skin.

(An endoskeletal artificial limb is comprised of the prosthetic skeleton—a metal tube and joints, the prosthetic soft tissue—a flexible plastic foam, and the prosthetic skin.)

## **II. REFERENCE DOCUMENTS**

A. "Tentative Specifications—Glove, Cosmetic, Adult-Size—for Use with Mechanical Hand for Upper Extremity Amputees," VA-PSAS Specification NO. U58-2T, December 31, 1958.

B. Report of the CPRD Conference on Cosmesis and Modular Limb Prostheses held on March 3-7, 1971.

C. Various ASTM Standard Tests.

## **III. REQUIREMENTS**

### **A. Appearance**

1. The material shall be capable of being formed to exhibit:

a. Realistic texture and appearance of human skin.

b. No evidence of mold-parting lines or other unnatural areas such as bubbles, flaws, nicks, and cuts.

2. The material shall be translucent and capable of being colored by incorporation of colors into it and tinted by external application of colors.

3. The colors shall not rub off or migrate from their point of application.

### **B. Mechanical Properties**

1. The ultimate tensile strength shall be not less than 5,000 pounds per square inch. Refer to test method ASTM D412-66.

2. The tensile strength at 100-per cent elongation shall be no

greater than 50 pounds per square inch. Refer to test method ASTM D412-66.

3. The elongation at break shall be not less than 800 per cent. Refer to test method ASTM D412-66.

4. The material shall exhibit a knotty-type of tear. The tear resistance shall be not less than 200 pounds per inch. Refer to test method ASTM D624-54, Die "C".

5. The fatigue life when the material is in tension from 0 to 300 per cent elongation shall be at least 300,000 cycles without physical change.

6. The material shall have no creep for a period of 24 hours under a load equivalent to 5 per cent of the ultimate tensile strength. Refer to test method ASTM D674-56 (1961).

7. The material shall exhibit resistance to abrasion as specified in the test method in Section IV.

#### *C. Physical Properties*

1. The material shall exhibit only slightly visible color change over a period of 72 hours under an S-1 mercury arc lamp. Refer to test method ASTM D795-65T, Procedure A.

2. The resistance to stain shall meet the criterion specified in the test method in Section IV.

3. The material shall exhibit a permanently dry feel.

4. The material shall not have an offensive odor after preparation for use.

5. When delivered, the material shall be nontoxic and non-allergenic and shall not cause dermatitis.

6. The material shall be self-ex-

tinguishing and shall not support combustion. Refer to test method ASTM D1692-59T.

#### *D. General*

1. The material shall be capable of being formed rapidly, economically and without shrinkage into thin, hollow shapes—such as a hand containing all skin details—by low pressure casting or dipping techniques.

2. Exposure to water or recommended cleaning solutions—e.g., soaps and detergents, alcohol, acetone, and petroleum hydrocarbons—shall not cause whitening or other change in color or change in mechanical and physical properties during the first year of wear.

3. The material shall not lose any of its mechanical or physical properties or otherwise deteriorate when stored in unsealed cardboard cartons at temperatures of  $-20$  to  $+120$  deg. F. and ambient humidities for one year. For example, there shall be only slightly visible color change and no evidence of exudation under these circumstances.

4. The mechanical and physical properties shall not change when the material is exposed to temperatures up to 180 deg. F. for 24 hours.

5. The material shall be chemically compatible with materials normally in contact with it.

#### **IV. TEST METHODS NOT OTHERWISE SPECIFIED**

##### *A. Abrasion Resistance Test*

Abrasion resistance shall be determined by placing a piece of the material approximately 2 in. by 8 in. on a Gardner single-brush washability machine (Gardner Labora-



tory, Inc., Bethesda, Maryland) or similar device. The brush assembly shall be modified to accommodate the abrading material over a slightly curved surface with a total weight of one pound. The abrading material shall be various fabrics of Dacron, nylon, wool, and cotton as well as the skin material itself. The skin material in contact with the abrading material shall be cycled 10,000 times with no deleterious effects, e.g., tear, holes, or tackiness.

#### B. Stain-Resistance Test

Stain resistance shall be determined by applying a stain to a swatch of the material for a period of 24 hours. The stain shall then be

removed by a recommended cleaning solvent. There shall be no visual evidence of stain remaining or discoloration of the material. The stain shall be any one of which the wearer might be expected to encounter during a day, e.g., ball-point ink, food, carbon paper, etc.

Note: All tests shall be conducted at  $75 \pm 2$  deg. F. and  $50 \pm 2$  per cent relative humidity unless otherwise specified.

#### Reference

1. Committee on Prosthetics Research and Development, *Cosmesis and Modular Limb Prostheses—A Report of a Conference*, National Academy of Sciences, Washington, D.C. 1971.