

Clinical Evaluation of an Acrylic Latex Material Used as a Prosthetic Skin on Limb Prostheses¹

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Clinical evaluation of new devices and techniques, whether conducted formally or informally, is a necessary step in the evolution of a device or technique from the idea stage to widespread use on patients. In some cases, manufacturers conduct their own clinical evaluations by distributing the devices to selected orthotists-prosthetists and requesting their opinion after fitting a number of cases. In other instances the developer may have a great amount of clinical experience with the device and therefore not go outside for an evaluation. Government agencies usually require a formal evaluation that consists of a protocol involving a recommended number of patients, an even geographic distribution of patients, initial and follow-up data collection forms, a pre-determined time table, and a final report.

Evaluations are particularly difficult in the field of orthotics and prosthetics because laboratory, or bench testing, is usually inadequate inasmuch as patient reactions cannot be obtained. Furthermore, there are usually so many dependent variables involved in prosthetics and orthotics application that a scientific study is impractical, if not impossible.

This is a result of a formal clinical evaluation of an acrylic latex prosthetic skin

developed for the Veterans Administration by Fred Leonard, Ph.D. at George Washington University for use over limb prostheses. The evaluation was a function of the AAOP Research Evaluation Committee.

The Need for a Prosthetic Skin

One of the stated advantages of modular endoskeletal prostheses is that the foam cover is soft, pliable, and "lifelike." Unfortunately, problems associated with the foam cover have been one of the major contraindications for using endoskeletal prostheses. Foam covers are very soft and pliable, but tear easily, stain easily, absorb water, and are not flesh colored. Cosmetic hosiery must be worn over the foam to protect it and to provide a flesh color, but the hosiery needs to be replaced frequently because it also tears, stains, and absorbs water. Owing to these problems endoskeletal prostheses are provided only to patients who consider cosmesis extremely important and who will not be participating in activities that tend to harm the foam cover, such as sports, working in dirty areas, working near water, and kneeling. In the past few years development of a prosthetic skin to protect the foam cover has been a high pri-

ority. In the past, a number of major chemical companies were contacted by the National Academy of Sciences, and government agencies concerning this problem, but until now no solution was forthcoming.

The Acrylic Latex Prosthetic Skin

The acrylic latex prosthetic skin developed by Dr. Leonard consists mainly of Hycar liquid latex pigment and a diluent (water), which is applied by either a brush or spray.

Tests undertaken at George Washington University showed that the material did coat the surface of the foam satisfactorily leaving a texture that was not unlike that of human skin. In tests comparing foam coated with the acrylic latex to uncoated foam, the coated foam did not appear to change in hue after one hundred and sixty hours of exposure to ultraviolet light, whereas the uncoated foam changed from yellow to a brownish hue rather rapidly. The material also displayed a high resistance to staining, and it was recommended that methanol or soap and water be used to clean the material. The stress-strain properties of the acrylic latex material proved to be greater than that of the underlying foam substrate. Further tests indicated that the peel strength of the coating is greater on a urethane foam than on vinyl foam.

Need for a Clinical Evaluation

Although laboratory results on the prosthetic skin sounded promising, a number of questions remained unanswered. Past experiences have demonstrated that laboratory testing of materials can often be misleading and that clinical evaluation of a technique or device is necessary to determine practicality, if for no other reason. In this case, it had not been demonstrated that the

material would be sufficiently flexible, yet strong enough, to function about the knee joint in above-knee prostheses. Preliminary testing of the material at Rancho Los Amigos Hospital suggested that the original technique for coating above-knee prostheses with the acrylic latex prosthetic skin was unsatisfactory and that a new technique needed to be developed. Other areas that required investigation under clinical conditions were patient acceptance, fabrication time, cost effectiveness, durability for use with endoskeletal upper-limb prostheses, chemical handling problems, and uses of the material in other areas of orthotics and prosthetics.

Fabrication Technique

The acrylic latex material is available in one-quart containers in three different base colors. Combinations of the base colors can provide very accurate color matching for each patient. A shade guide (Fig. 1) is provided which contains seven different color swatches along with instructions for combining the base colors to obtain the shades shown. The shade guide should be used in the same way that color swatches are used for cosmetic gloves on prosthetic hands. The proper shade is determined during patient evaluation and casting, using both sunlight and interior lighting to determine a good compromise in color. The darker color is always added to the lighter color because it is easy to make the material darker but very difficult to make it lighter after it has been made too dark. Between 200 and 300 grams is usually sufficient to cover a below-knee prosthesis (Fig. 2).

The foam cover that is to be coated with the acrylic latex material should be finished as smoothly as possible. One cosmetic stocking⁴ should be pulled snugly over the prosthesis and foam cover, an overhand knot is put in the stocking








SHADE GUIDE FOR ACRYLIC LATEX COATING.						
						
#1	#2	#3	#4	#5	#6	#7
BASE	Mix: 3 PARTS #1 1 PART #5	Mix: 2 PARTS #1 2 PARTS #5	Mix: 1 PART #1 3 PARTS #5	BASE	Mix: 1 PART #5 3 PARTS #7	BASE

Fig. 1. Shade Guide. The shade guide uses flesh colors ranging from very light Caucasian to dark Negroid. The color is matched to the patient's skin and mixed according to the directions. Before this acrylic latex was available, color matching an endoskeletal prosthesis was a difficult and expensive process.

about the prosthesis, and the assembly is suspended in a well ventilated area for ease of application and drying (Fig. 3) as well as fume removal.

Acrylic latex can be painted on without dilution. If it is to be sprayed on it should be diluted with water. Before applying the acrylic latex to the prosthesis, the sock is dampened with water. The acrylic



Fig. 2. Mixing the acrylic latex. The proper color is determined by matching the shade guide to the patient's skin. Instructions on the shade guide (Fig. 1) explain the proper ratios to mix. About 200-300 grams of acrylic latex are required to coat a below-knee prosthesis. (Courtesy of the Veterans Administration Prosthetic Center).

latex is painted on as smoothly as possible to avoid streaks. Each coat takes approximately two hours to dry, but this time can vary widely depending upon factors such as heat, ventilation, and humidity. The second and third coats of acrylic latex can be applied without any treatment to the initial layer. However, if streaking or uneven surfaces appear on any layer they should be sanded smooth before the next layer is applied. A total of three or four layers of acrylic latex material is used depending upon the preference of the prosthetist.

The best finish is obtained when the final layer is sprayed on with a conventional spray gun (Fig. 4A). When a spray gun is not used the final layer should be smoothed with a wet finger, similar to smoothing plaster, approximately thirty minutes after it has been applied (Fig. 4B). After the final layer has been applied it is preferable to allow the prosthesis to dry over night. In this study the actual labor involved in applying the acrylic latex prosthetic skin varied from 45 to 90 minutes.

The prosthetic skin is finished by either trimming it with a sharp knife at the proximal edge of the socket, pulling it



Fig. 3. One dampened cosmetic stocking is pulled over the SACH foot and foam cover (in the example, a Hydra-cadence cover is shown). The stocking is tied at the top and suspended. The acrylic latex is then painted, on, using smooth, even strokes. Each layer should be sanded lightly when drying is uneven before application of the next coat. Three or four coats are required, with a drying time of one to two hours between coats. (Courtesy of the Veterans Administration Prosthetics Center).

back slightly and gluing it down with contact cement or, when an insert is used, lapping it over the top of the socket and gluing it to the inside edge of the socket (Fig. 5).

The patient is instructed to clean the prosthesis with soap and water or with alcohol whenever it picks up dirt. The patient should also be told that, although this material is much more resistant to ultraviolet rays than foam, prolonged exposure to direct sunlight may darken the color.

The prosthetic skin is waterproof. If the patient is to wear the prosthesis in or

near water, he should make sure that there are no peeling or open areas in the skin which would allow water into the prosthesis, because once water gets into the foam it will not dry out satisfactorily. In addition, if a colored sock worn over the prosthesis gets wet, the dye from the sock may stain the prosthetic skin permanently.

Evaluation Plan

The evaluation protocol stated that the acrylic latex prosthetic skin would be applied to a minimum of sixty prostheses with a minimum follow-up of two months per prosthesis. The evaluators would consist of twelve certified prosthetists chosen in a manner to provide a wide geographic distribution, a variety of clinical settings (VA and non-VA), and a variety of climates. The project coordinator would be responsible for holding the initial planning meeting, contacting the prosthetist-evaluators and maintaining control of the evaluation forms. A timetable was established that set the total length of the project at thirteen months.

The initial evaluation meeting took place in Washington, D.C. September 21, 1977. At this meeting it was decided that evaluators would be recruited by inserting an information bulletin in the registration packet of all prosthetists attending the 1977 National meeting of the American Orthotics and Prosthetics Association in San Francisco, and the bulletin would be printed in the *Almanac*. The twelve facilities and prosthetists chosen to participate were:

Albuquerque Prosthetics, Albuquerque, New Mexico, Robert Bush, C.P.O.

Duke University Medical Center, Durham, North Carolina, Bert Titus, C.P.O.

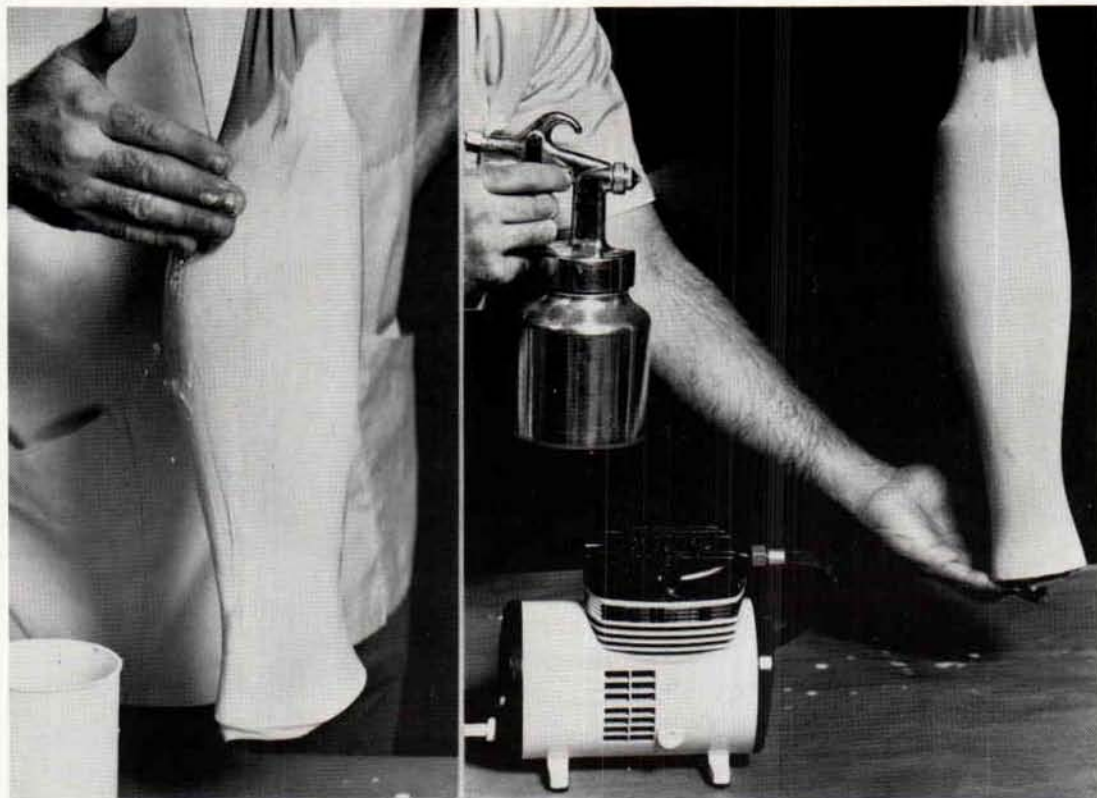


Fig. 4. The last coat can be finished in two ways: Left, about 30 minutes after painting the partially dried latex can be smoothed with dampened fingers or, right, the latex diluted with water can be applied with a spray gun. About six hours (or overnight) are needed for the skin to dry completely. (Courtesy of Veterans Administration Prosthetics Center).

Empire Orthopedic Laboratories,
Syracuse, New York, Kurt Marschall,
C.P.

Fitzsimmons Army Medical Center,
Denver, Colorado, Robert Schleiser,
C.P.O.

J.E. Hanger, Orlando, Florida, Hugh
Panton, C.P.O.

J.E. Hanger, Philadelphia, Pennsylv-
ania, Charles Wright, C.P.

Hittenbergers, Inc., San Jose, Califor-
nia, John Kintz, C.P.O.

Koeber's Prosthetic and Orthotic Lab-
oratories, Chicago, Illinois, Joseph
Smerko, C.P.

Lambert's Limbs and Braces, New Or-
leans, Louisiana, Claude Lambert,
C.P.O.

Orthomedics, Inc., California, Frank
Moos, C.P.O., Dan Snelson, C.P.,
Richard Voner, C.P.O., and Lennart
Rosenquist, C.P.

Stonecipher Prosthetics, Arcadia, Cal-
ifornia, John Stonecipher, C.P.

United Prosthetics, Boston, Massa-
chusetts, Joseph Martino, C.P.O.

The evaluation coordinator, Carlton
Fillauer, sent a letter to each evaluator
which stated the protocol, namely that



Fig. 5. The prosthetic skin is adhered to the socket by gluing the top one-half inch to the socket with rubber cement. When an insert is used, the prosthetic skin can be folded over the trim line and glued inside the socket.

each prosthetist should fit a minimum of five patients with prostheses using the prosthetic skin and should complete the initial evaluation form and three follow-up forms for each patient over a two-month period. Mr. Fillauer also provided the evaluators with the acrylic latex material and an instruction manual which was prepared by Bert Koralnik, C.P. and John Fanelli of the Veterans Administration Prosthetic Center. A letter was sent to the chiefs of the V.A. Clinics in which the participating prosthetists attended (appendix) in order to explain the purpose of the evaluation.

The Method

The acrylic latex prosthetic skin was applied to a total of fifty-two prostheses on fifty-one patients, one being a bilateral. Twenty-two patients were from V.A. clinics. Forty-nine of the 51 patients were followed for periods ranging from

two to four months; incomplete information was provided on the remaining three patients. All of the information in this report will therefore be based upon the forty-nine patients who had complete follow-up. An Initial Evaluation form and three Follow-up forms (Figs. 7 and 8) were completed by the evaluator over a two-month clinical trial period. Pertinent data from these forms are summarized in this report.

TABLE 1
Patient Information

Total Number of Patients	48 (one bilateral B/K)
Number of V.A. Patients	22
Types of Prostheses:	
Below-knee	33
Above-knee	11
Knee disarticulation	1
Hip disarticulation	1
Symes'	1
Above-elbow	<u>2</u>
Total Number of Prostheses	49

Distribution of Patients by Level of Amputation

The acrylic latex material that was used during the evaluation was provided by the project coordinator, and was a pre-mixed Caucasian colored acrylic latex that was the consistency of a latex paint. Pigment, a color chart, and directions for varying the color of the material to match the skin of the patient were also provided. In all cases the acrylic latex was painted on a Bock cosmetic stocking and allowed to dry for one to three hours. Usually from three to four coats were required and, in some cases, two stockings were used to provide a heavy duty cover. Only Otto Bock and U.S. Manufacturing Company foams were used during the evaluation.

TABLE 2

EVALUATION REPORTS RECEIVED

<i>FACILITY</i>	<i>Initial</i>	<i>Second</i>	<i>Third</i>	<i>Fourth</i>
Albuquerque Prosthetics	4	4	4	4
Duke Medical Center	6	6	6	6
Empire Orthopaedic Laboratories	6	6	6	6
Fitzsimmons Army Medical Center*	5	4	4	4
J.E. Hanger - Orlando	11	11	11	11
J.E. Hanger - Philadelphia	1	1	1	1
Hittenbergers, Inc.	1	1	0	0
Koeber's P & O Labs	4	4	4	4
Lamberts Limbs-Braces	4	4	4	4
Orthomedics*	4	4	4	3
Stonecipher Prosthetics	5	5	5	5
United Prosthetics*	<u>1</u>	<u>0</u>	<u>0</u>	<u>0</u>
GRAND TOTAL	52	50	49	48

*One failure experienced — no further reports on this case.

Thirty-three below-knee prostheses were coated with the acrylic latex prosthetic skin. Eleven above-knee prostheses were covered with the prosthetic skin although, in most cases, only the shank was covered. These included Hydracadence, U.S.M.C. modular, IPOS, and Bock endoskeletal systems. In addition, one knee-disarticulation (OHC four bar knee), one hip-disarticulation, and one Symes' prosthesis were covered with the prosthetic skin. Two endoskeletal above-elbow prostheses were also included. Although no complete failures were experienced in the below-knee prostheses, one failure occurred on an above-knee prosthesis and one on the hip-disarticulation prosthesis due to lack of flexibility at the knee. A recommended procedure for applying the prosthetic skin to extend over the knee joint had not been developed, and therefore each prosthetist was left on his own when applying the prosthesis to this group of patients.

TABLE 3

Advantages

- Does not tear — extremely durable
- Matches skin color
- Not necessary to wear stocking over leg
- Washable with soap and water or methanol
- Retains soft, pliable texture of foam
- More resistant to ultra violet discoloration than foam

Disadvantages

- Drying time extends elapsed fabrication time by one day
- More difficult to make adjustments
- Foot may peel if worn barefoot, but it can be patched
- Can be stained by dye in sock if it gets wet
- Technique for covering the knee joint not preferred

Summary of Results

The time required to apply the prosthetic skin to a prosthesis was considered a problem by some of the prosthetists as it could delay the delivery time for the pros-

thesis by one day. The actual time spent by the prosthetist or technician in applying the material to the prosthesis, not including drying time, varied between 45 and 90 minutes. When drying time is included, this figure increases from six to twelve hours, as the prosthesis is generally left to dry over night.

Most of the color matching problems were caused because the prosthetist improperly mixed the materials. These problems were alleviated after the prosthetists became more familiar with the technique.

In one case the prosthetic skin wore out when the patient wore the prosthesis barefoot in the sand. Four other cases of peeling were reported, but none were considered serious.

One patient complained that the prosthetic skin was discolored from the dye in his sock after the sock got wet. The prosthetic skin has a tendency to pick up dirt but can be washed with soap and water. Many patients commented on the natural feel of the material and liked the ability to wash the prosthesis like their own limb. They also liked the fact that there was no need to wear stockings over the prosthesis.

In general, it was felt that the advantages of the prosthetic skin (durability, cosmesis, etc.) far outweighed the few problems that occurred during the evaluation, particularly for below-knee prostheses.

Conclusions and Recommendations

The final meeting of the evaluation coordinator, chairman of the AAOP Research Evaluation Committee, and three of the evaluators was held in Chattanooga, Tennessee on August 16, 1978. Specific conclusions and recommendations made were:

1. Based on the results of this evaluation the acrylic latex prosthetic skin was found to provide a superior coating for

foam covered endoskeletal prostheses when compared to previous methods, and therefore this material should be recommended for application on below-knee prostheses.

2. The acrylic latex material should be made available commercially to prosthetists, premixed in two or three base colors, and should be provided with a shade guide and a one page instruction sheet.

3. Further work is required to develop a technique for applying acrylic latex or a similar material on foam covers that extend above the knee and for other articulated prostheses, i.e., hip-disarticulation prostheses, above-elbow and shoulder-disarticulation prostheses. Although some of the evaluators felt they had succeeded in using this material over prosthetic knee joints, all felt that the techniques could be improved substantially. The greatest need for a prosthetic skin is for above-knee prostheses, and therefore the development of this technique should have a high priority.

Summary

The American Academy of Orthotists and Prosthetists Research Evaluation Committee conducted an evaluation of an acrylic latex material as a coating or skin for foam-covered endoskeletal prostheses. The material was originally developed at George Washington University with fiscal support from the VA. Twelve prosthetists from various parts of the United States participated. Each was requested to apply the prosthetic skin to five prostheses, including prostheses fitted to patients in their respective VA clinics. Complete follow-up information on forty-nine patients has been reported. Twenty-two of these patients were veterans treated in VA clinics throughout the country.

The prosthetic skin proved to be durable, washable, and cosmetic. It retained

the soft, flexible properties of the foam. Patients commented that it felt lifelike and appreciated not having to wear cosmetic stockings. The ability to wash the prosthesis was another advantage. The acrylic latex prosthetic skin was found to provide improved finish to below-knee prostheses when compared to previous methods.

Problems included difficulties in mixing the proper color, which was solved by changing the technique. Peeling was evident on five prostheses, but was not considered to be a deterrent to use of the covering. Problems associated with staining and ultraviolet discoloration were reported, but were not considered to be significant.

Application of the material varied between 45 and 90 minutes. Total drying time ranged from six to eight hours.

A technique for application of the material to above-knee prostheses needs to be developed further since participants in the evaluation project had mixed results when above-knee prostheses were involved.

Footnotes

¹This evaluation was conducted by the American Academy of Orthotists and Prosthetists and funded by Veterans Administration contract #V5244P-1583 in response to solicitation #5244-63-77.

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⁴Otto Bock Orthopaedic Industries, Minneapolis, Minnesota.