Porous Plastic Laminates for Upper-Extremity Prostheses

JAMES T. HILL, C.E., B.S.[1] AND
FRED LEONARD, PH.D.[2]

THE problem of perspiration and its removal from the amputee's arm and leg stumps encased in sockets has engaged the attention of the doctor and limb fitter for as long as limbs have been fitted.

In the early days of leather prostheses, a few months of wear during the summer were sufficient to cause the leather to rot and degrade because of perspiration. Since it was not possible to wash leather prostheses easily, severe hygienic problems were created. Efforts to coat leather with plastic films to overcome this difficulty were only partially successful for, in many instances, the adhesion of the coating was poor and frequent re-coatings were necessary. With the development of the all-plastic arm, it became possible to wash the socket thoroughly and virtually eliminate the hygienic problem. However, because the plastic did not permit diffusion of water vapor, sweat gathered profusely in the socket and became a source of discomfort and irritation. Efforts to permit diffusion of sweat by drilling gross holes in the plastic socket were not very successful. Although this practice permitted greater removal of sweat than in undrilled prostheses, the strength characteristics were seriously affected when a sufficient number of holes were cut to permit adequate removal. In addition, there still remained between the holes impervious plastic which could block large numbers of sweat pores—approximately 155 per square centimeter on the forearm (1)—and permit puddling between the plastic and the stump.

It appeared that for optimum socket ventilation a porous-plastic socket should be developed which contained a large number of interconnnected pores. Such a socket should permit rapid diffusion of sweat with minimal blocking of sweat pores. The porous laminate envisioned would consist of a layered fabric resin composite with unbridged voids between the filler strands. Such material should be easily cleaned by soaking in detergent, followed by flushing with water. The following design criteria were outlined for the desired socket material:

1. The socket material should have a uniform distribution of minute pores which would result in high porosity without blockage of sweat pores.
2. It should be easily cleaned.
3. Porous socket fabrication should conform as closely as possible with well-known fabrication techniques current in the practice of upper-extremity prosthetics.

Procedures for preparing porous upper-extremity prostheses were developed, utilizing the design criteria as a guide.

In general, the method comprised the use of a solvent or diluent with an epoxy resin. After initial cure had occurred, the solvent was permitted to evaporate by removal of the outer polyvinyl-alcohol (PVA) bag.

A series of experiments determined the combination of diluent, curing rate, and other factors necessary to produce a laminate with the optimum ratio between porosity and strength *(3, 4).* Evaluation at New York University indicated that the procedure initiallv developed by the Army Prosthetics Research

[1] Chief, Process Engineering Section, U.S. Army Prosthetics Research Laboratory, Walter Reed Army Medical Center, Washington 12, D. C.

[2] Scientific Director, APRL, WRAMC, Washington 12, D.C.

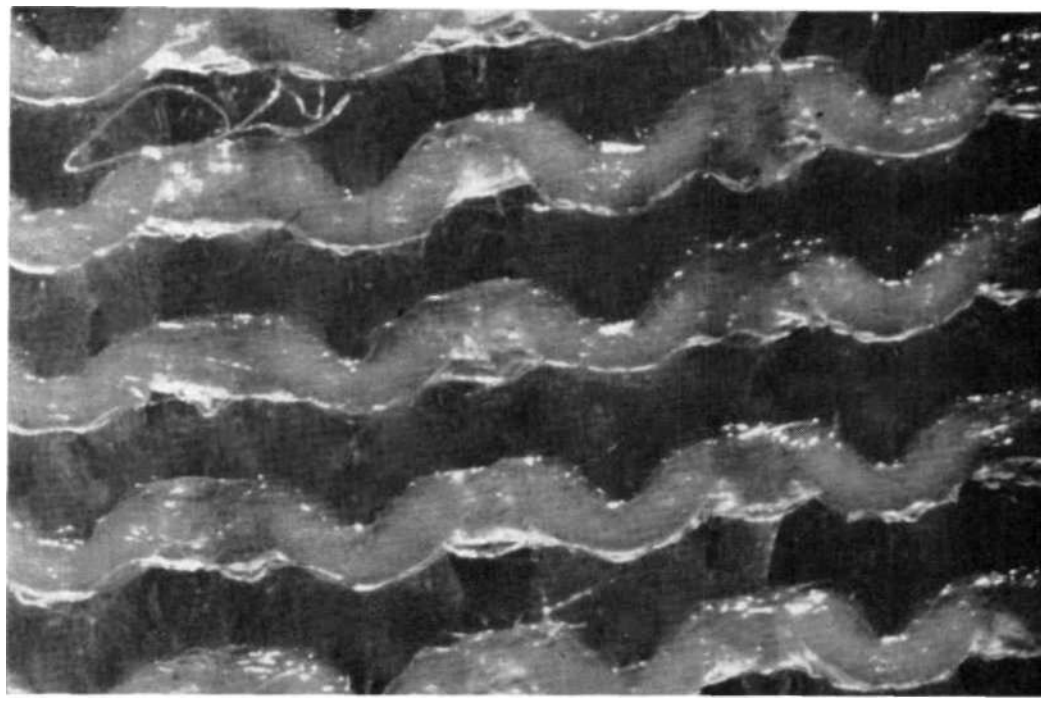

Fig. 1. Porous epoxy laminate made in accordance with the procedure developed at the Army Prosthetics Research Laboratory. Magnification approximately 21X. Courtesy *Veterans Administration Prosthetics Center.*

Laboratory produced a satisfactory material insofar as porosity and strength were concerned but that use of the conventional stockinet as filler produced rough surfaces that made cleaning difficult. Subsequent experiments at the Army Prosthetics Research Laboratory showed that this problem could be overcome by using a nylon stockinet of 200-denier Banlon knit (Fig. 1) for the outer and inner layers of the laminate and by the reapplication of a PVA bag at a critical time in the curing process. Further testing and development resulted in a practical technique which is described in detail in a manual prepared by the Army Prosthetics Research Laboratory *(2).* Sockets fabricated in accordance with this manual have smooth surfaces and high porosities. Patients fitted with porous sockets have reported a definite increase in comfort as a result of improved ventilation *(6).*

Laboratory tests have shown that porous epoxy laminates are not as strong in compression and tension as nonporous laminates, but that resistance to impact loads appears to increase with the porosity and reach a maximum at approximately 17 per cent of effective porosity.[3] In practice, the combination of physical properties possessed by the porous laminate which has been developed is satisfactory for use in arm prostheses. Experiments in the use of porous laminates for lower-extremity prostheses are under way.

If actual prosthetist working time is considered, the man-hours required for fabrication of porous laminates are somewhat longer than those required for the conventional plastic laminates. Depending on the technique employed, the porous laminating process may take up to one-and-one-half times as long as the conventional technique.

The components of the liquid resin system may elicit allergic reactions in certain sensitive individuals. Therefore, fabrication should take place in a well-ventilated area and protective gloves should be used in preparing the layup.

[3] Effective porosity is the ratio of the quantity of water that flows through the laminate to the amount that flows through the stockinet alone.

Xo stump dermatitis or other adverse reactions have been reported from the use of the porous laminates to date.

Because the socket is porous, it is necessary that it be cleaned thoroughly and often in order to preclude an accumulation of foreign matter in the pores of the wall. It is recommended that ordinary soap and water be used for this cleaning.

Porous laminates may be considered for application to all upper-extremity amputation levels from below-elbow to shoulder-disarticulation. The technique is of particular value whenever perspiration presents a significant problem.

EPOXY-RESIN MIXTURE

The following epoxy-resin system has been found to produce a satisfactory porous laminate:

		Parts by weight
Epoxy resin	ERL 2795[4] or Epon 815[5]	65
Curing Agent	Versamid 140[6]	35
Solvent	Trichloroethylene	43

The "pot life" of the liquid resin mixture resulting from this formulation is never less than 30 minutes and usually considerably longer.

The individual limb fitter can best determine the actual amount of resin mixture required for a particular lamination. Appendix A (page 29) contains a table which may serve as a guide in determining the correct amounts of materials for various applications.

FABRICATION

Briefly described here is the fabrication of a double-wall, below-elbow, porous prosthesis, utilizing a plaster-of-Paris (or wax) buildup; this account is followed by a brief description of the fabrication of a single-wall, below-elbow, porous prosthesis, based on the Mylar[7] cone method.[8]

DOUBLE-WALL, BELOW-ELBOW, POROUS PROSTHESIS

For the fabrication of a double-wall, below-elbow, porous prosthesis, the stump model is prepared in accordance with common practice (9). As shown in Figure 2A, the model is then placed in a vise, distal end up, and coated with a lacquer such as Hi-Glo.[9] When this coating has dried, a moistened sheet of PVA is stretched over the model and tied at the base (Fig. 2B). The next step in preparing the layup is to cut one length of tubular Banlon stockinet with a 200-denier weave[10] and three lengths of tubular orthopedic stockinet so that each is at least 6 inches longer than the stump model (Fig. 2C). The end of each piece of stockinet is sewed in a curve to match the distal end of the model, and the excess stockinet is trimmed at the sewed end. The Banlon stockinet is turned inside out and pulled down over the model (Fig. 2D). Two of the orthopedic stockinets are pulled down over this. Then the remaining piece of stockinet is turned inside out and pulled down over the layup. The stockinet is smoothed, pulled down tightly, and tied at the base.

A PVA pressure sleeve is now prepared in the usual manner, pulled down snugly over the layup, and tied at the base rod (Fig. 3A). The layup is ready for impregnation, and it is time to mix the resin.

To measure the ingredients for the resin mixture, it is well to balance a disposable container, such as a paper cup, on a scale. The resin, curing agent, and solvent are then put in the cup in the proper amounts by weight. By referring to the table contained in Appendix A (page 29), it can be seen that the following quantities should be sufficient for a short below-elbow socket:

ERL 2795 (resin)	45.5 grams
Versamid 140 (curing agent)	24.5 grams
Trichloroethylene (solvent)	30.0 grams

[4] Bakelite Chemical Division, Union Carbide Chemical Company, New York, N. Y.

[5] Shell Chemical Company, New York, N. Y.

[6] General Mills Chemical Division, Kankakee, 111.

[7] DuPont Corporation Trademark.

[8] Both accounts compiled for CPRD, NAS-NRC, from *A Manual for the Preparation of Above and Below Elbow Porous Prostheses (2),* published by the U. S. Army Prosthetics Research Laboratory, Walter Reed Army Medical Center, Washington 12, D. C.

[9] Western States Lacquer, Dallas, Tex.

[10] Wm. H. Horn and Bros., Philadelphia, Pa.

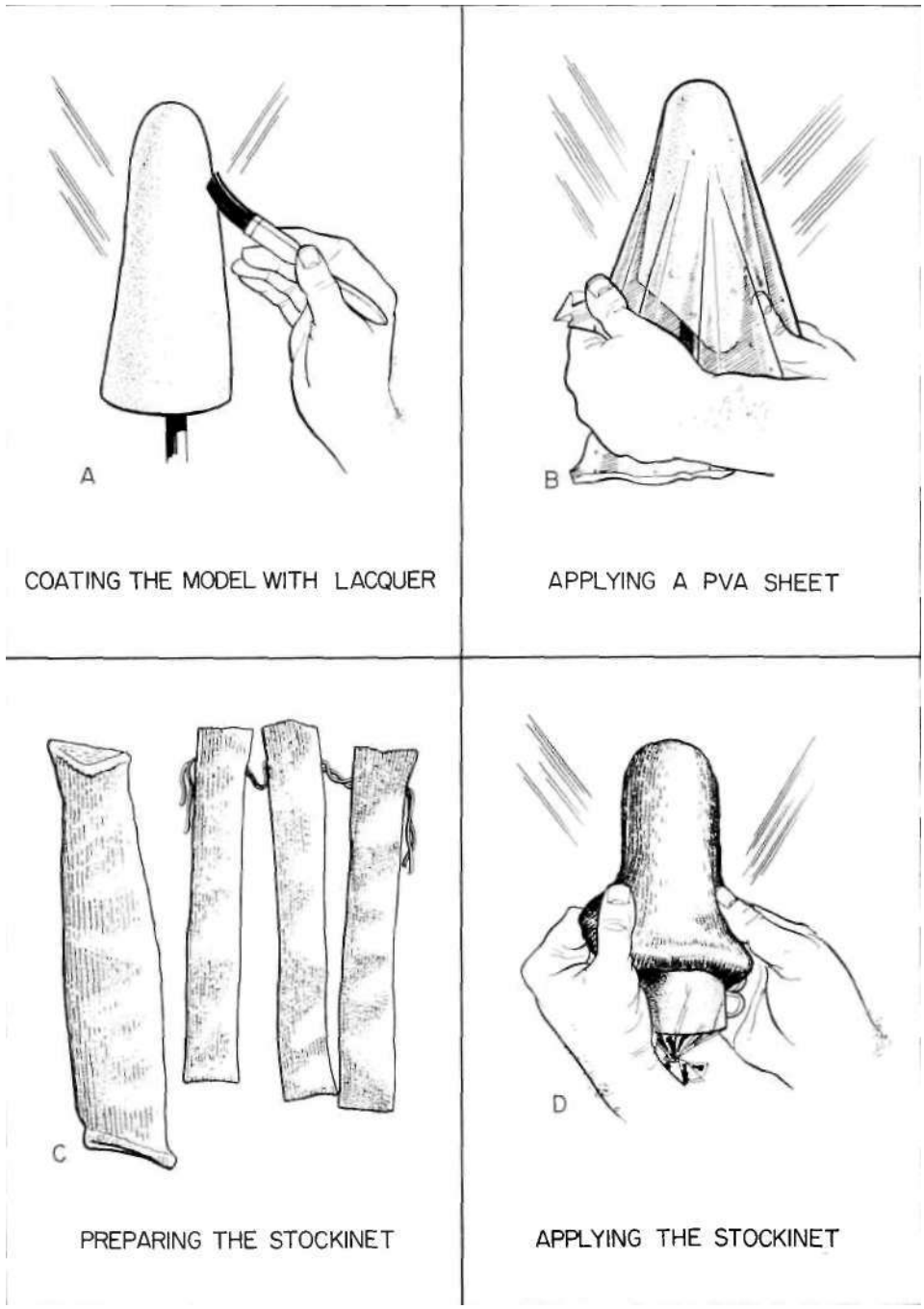

Fig. 2. Preparing the layup.

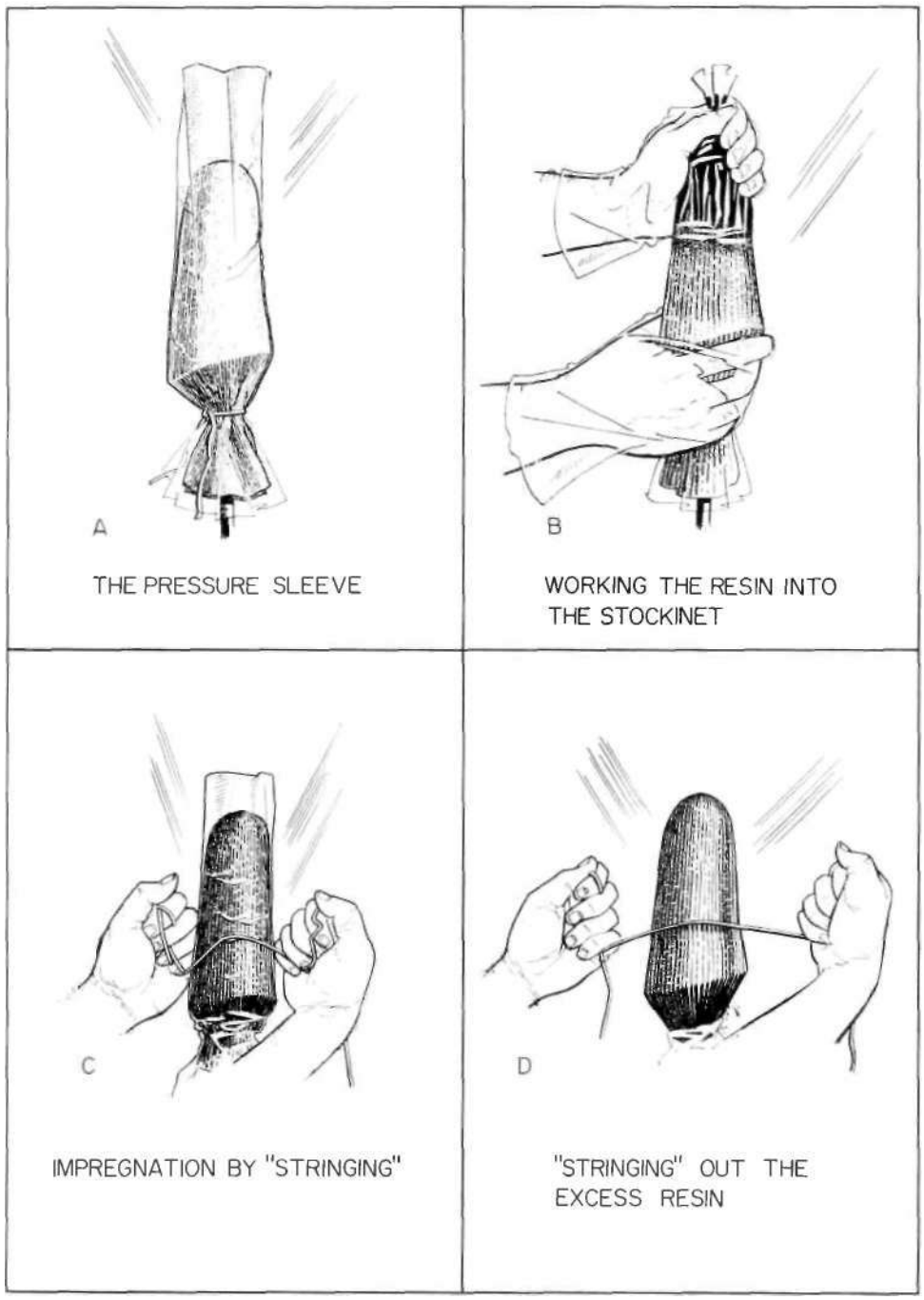

Fig. 3. Applying the resin mixture.

To this resin mixture should be added an appropriate pigment; for example, 2.5 grams of Caucasian epoxy pigment or 3.5 grams of Negroid epoxy pigment (Appendix A, page 29). The pigment is stirred into the mixture until it is uniformly blended.

The resin mixture is poured into the open end of the PVA sleeve and worked down into the stockinet. Twisting the end of the sleeve (Fig. 3B) develops considerable force and aids in the impregnation.

When the stockinet is fully impregnated, the PVA sleeve is pulled down, and the excess resin is "strung" down to the proximal end of the layup (Fig. 3C). Next, the PVA sleeve is cut and removed from the layup. Care should be exercised not to spill the excess resin contained in the bottom of the sleeve. The sleeve and the excess resin are discarded. Spilled resin may be cleaned off with isopropyl alcohol or trichloroethylene. The layup is "strung" with a heavy string until no further excess resin appears (Fig. 3D).

The layup is now placed for 30 minutes in a pre-heated oven set at 115 deg. F (47 deg. C), for what is known as the pre-cure. During this stage, the solvent evaporates from the layup, leaving it porous.

Upon completion of the pre-cure, the layup is removed from the oven, and the oven is set at 212 deg. F (100 deg. C) for the cure. At this step in the procedure, the solvent has evaporated and the resin has gelled slightly. If any areas of the laminate contain excess resin, the excess is "strung" to the proximal end. When the oven has reached a temperature of 212 deg. F (100 deg. C), the laminate is placed back in the oven for one hour. During this hour, the laminate will be cured sufficiently to permit the buildup for the outer socket.

At the end of the hour, the laminate is removed from the oven, and the oven is set at 115 deg. F (47 deg. C).

As soon as the laminate is cool enough to handle, a sheet of Saran-Wrap or rubber sheeting is placed over the laminate as a separating medium. This sheet will facilitate the release of the outer socket which is to be laminated over the inner shell.

For the forearm buildup, plaster of Paris is considered preferable rather than wax, for the reason that wax may enter the pores of the prosthesis. The buildup is done in the usual manner (Fig. 4A). After the plaster has hardened, the paper cone is removed and the plaster of Paris is shaped to the desired contour. Any plaster on the knurled surface of the wrist unit is removed. The plaster is coated with Hi-Glo or some similar lacquer. A PVA sleeve is prepared, moistened, pulled down over the buildup, and trimmed at the wrist unit (Fig. 4B).

Next, a piece of Banlon stockinet and a piece of orthopedic stockinet are cut, each about 3 to 5 inches longer than the layup. Another piece of orthopedic stockinet is cut, a little more than double the length of the layup. (Additional lengths of stockinet may be used if additional strength is desired.)

The Banlon stockinet is turned inside out, pulled 1 to 2 inches over the distal end, and tied at the wrist unit (Fig. 4C). Excess stockinet that is proximal to the wrist unit is trimmed off.

The short piece of orthopedic stockinet is pulled over the longer piece so that both pieces meet at one end. The other end of the short piece should extend just past the middle of the longer piece.

These pieces of stockinet are extended and slipped, double end first, down over the wrist unit until the double thickness covers the entire layup (Fig. 4D). The double thickness of stockinet is tied at the wrist unit and pulled down and tied at the proximal end. The Banlon stockinet should be on the inside.

Two PVA pressure sleeves are now prepared in the usual manner, with the shiny surface of the material on the inside. One sleeve is set aside to be used later. The other is pulled down snugly over the layup and tied to the base rod at the proximal end.

Resin and pigment are mixed in the manner described previously. For a short or medium below-elbow forearm, the following quantities should be sufficient:

ERL 2795	68 grams
Versamid 140	37 grams
Trichloroethylene	45 grams
Pigment	As required to match the previous mixture.

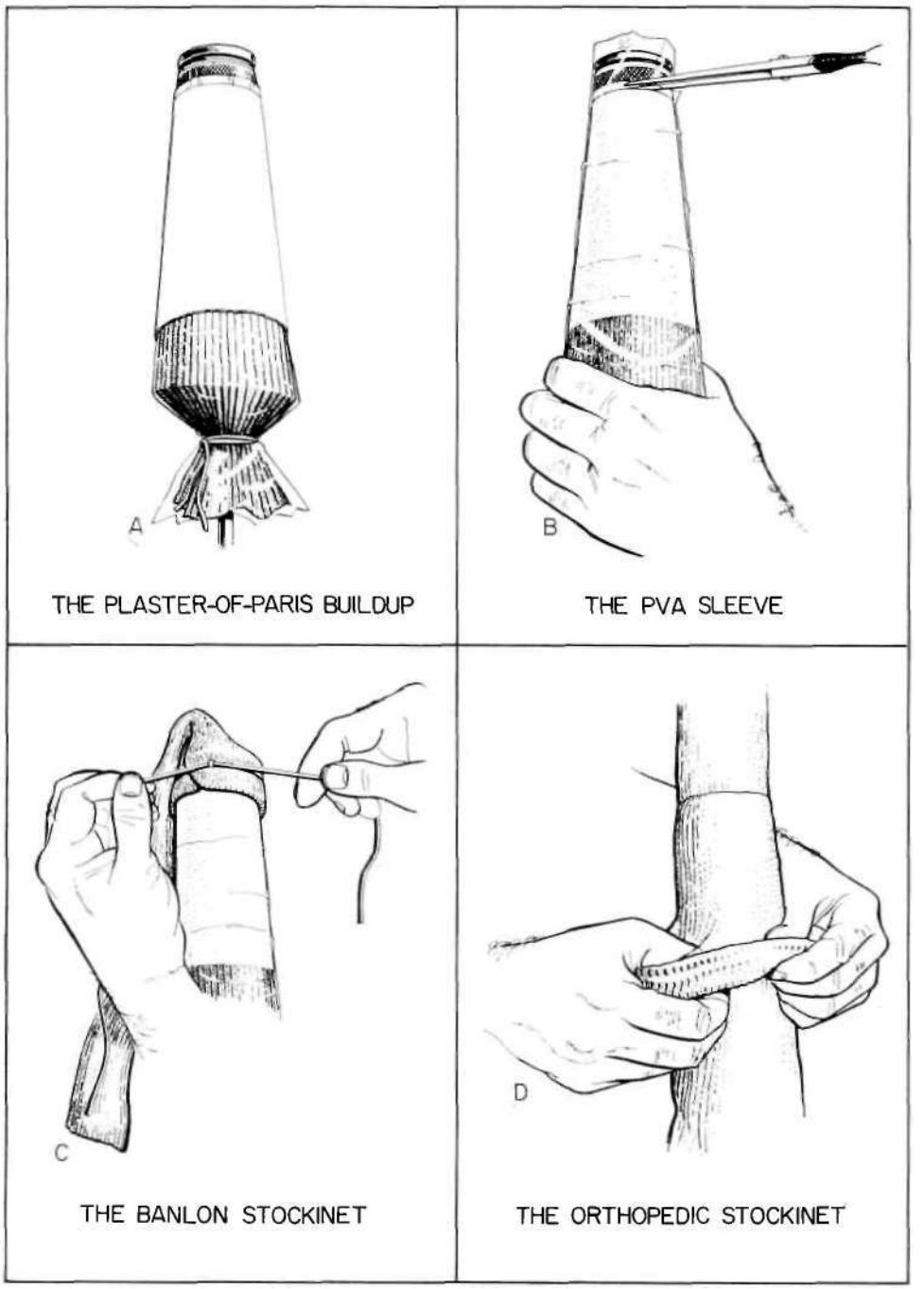

Fig. 4. The forearm buildup.

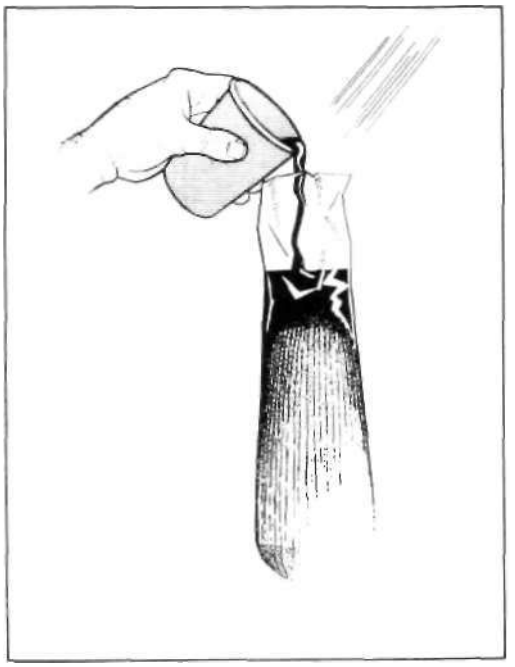

Fig. 5. Impregnating the forearm layup.

The resin is poured into the pressure sleeve (Fig. 5) and worked into the stockinet. When the stockinet is fully impregnated, the pressure sleeve is pulled down as far as possible, and the excess resin is "strung" down from the layup.

After the layup has been thoroughly "strung" down, the PYA sleeve is stripped off and discarded. The layup is "strung" once more to remove all excess resin.

There may be considerable resin in the stockinet around the base rod. This excess resin should be absorbed in the scrap stockinet wrapped around the base, so that it will not be drawn back into the laminate during the cure.

For the pre-cure, the layup is now placed for 30 minutes in a pre-heated oven set at 115 deg. F (47 deg. C), allowing the solvent to evaporate.

While the pre-cure is taking place, the second PVA pressure sleeve previously prepared should be moistened by wrapping it in a damp towel for 10 to 15 minutes. The next step in the procedure gives the prosthesis a smooth surface, and it is essential that the PYA sleeve be thoroughly moistened.

Upon completion of the pre-cure, the layup is removed from the oven. The moistened PVA sleeve is pulled down until the entire layup is in contact with the sleeve. Light contact pressure is most desirable, for this will result in a smooth surface without reducing the porosity. It is important that the sleeve slide easily over the layup; otherwise, the force and pressure may cause pooling of the resin. At this point in the procedure, there should be no pools of resin on the stockinet. If there are, they should be "strung" out.

The PVA sleeve is taped around the wrist unit (Fig. 6); any severely undercut areas should also be taped.

The layup is now placed for one hour in an oven pre-set at 212 deg. F (100 deg. C). During this period the PVA sleeve shrinks around the layup, giving the surface a smooth gloss and aiding in molding the undercuts. At the end of

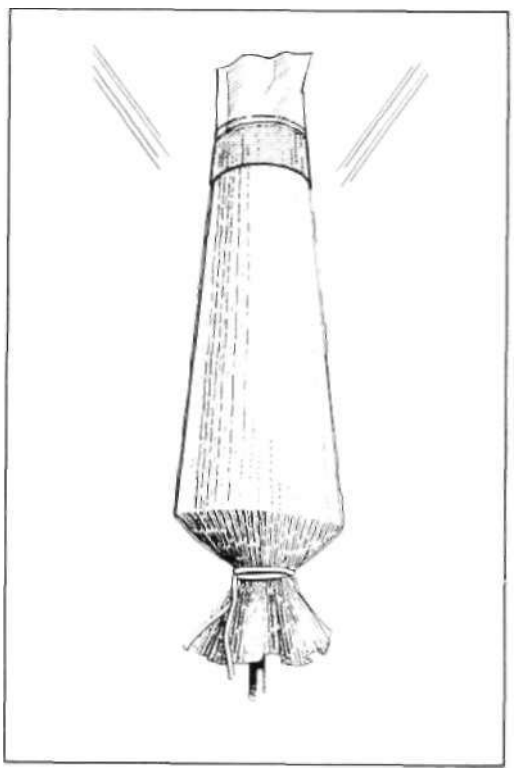

Fig. 6. Molding the surface.

the hour, the laminate is removed from the oven and the PVA sleeve is stripped off. At this point the laminate should be firm and free from tackiness.

The laminate is now ready for the final cure. It is replaced in the oven, set at 212 deg. F (100 deg. C), for 75 minutes to complete the final cure.

While the plastic is still warm, the layup is cut to the desired length. The outer socket will separate easily from the inner socket. The plaster may be removed by striking the socket with a rubber mallet. If necessary, a chisel may be used to dig the plaster out of the distal end of the socket. Remaining PVA film can be stripped off by hand or dissolved with hot water.

The prosthesis is held firmly on the amputee's stump, and the trim line is marked, after which the socket is removed and trimmed in the usual manner. After the socket and the forearm have been properly aligned, the edges are sanded and bonded together with liquid epoxy resin (ERL 2795, 65 parts; Versamid 140, 35 parts) (Fig. 7). The bond may be cured with a heat gun, or the prosthesis may be placed for one hour in an oven set at 212 deg. F (100 deg. C).

Fig. 7. Bonding the socket and forearm.

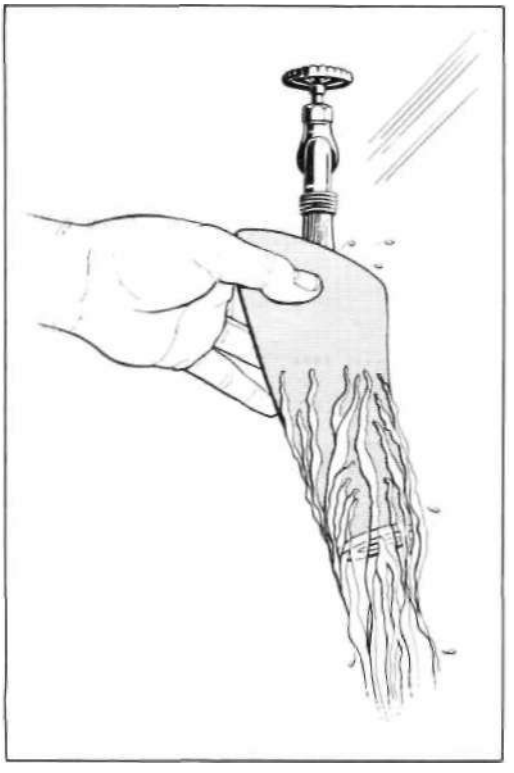

Fig. 8. Testing the porosity.

The porosity of the finished prosthesis can be tested by holding it under a water tap and allowing the water to run through the prosthesis (Fig. 8). If the prosthesis has been prepared properly, the laminate should show a uniform porosity.

The prosthesis is now ready to be harnessed in the usual manner.

SINGLE-WALL, BELOW-ELBOW, POROUS PROSTHESIS (MYLAR CONE METHOD)

For the fabrication of a single-wall, below-elbow, porous prosthesis, the stump model is prepared in the usual manner *(9),* placed in a vise, distal end up, and coated with lacquer. When the lacquer has dried, a moistened PVA sheet is pulled down over the stump model and tied at the base.

The stockinet layup, consisting of one length of tubular Banlon stockinet and three lengths

Fig. 9. The stockinet layup on the model. A PVA sheet is pulled down and tied at the base rod.

of tubular orthopedic stockinet, is prepared in the same manner as the stockinet layup for the socket of the double-wall prosthesis previously described.

When the stockinet layup is completed (Fig. 9), a sheet of PVA is pulled down over the layup and tied at the base rod. This PVA cover will protect the layup during subsequent steps.

Next, on an 8 in. X 12 in. sheet of Mylar (5-10 mils), a crayon mark is made halfway along one of the sides, about one-quarter in. from the edge. A second mark is made one-half in. inside the first mark. Then two final marks are made; one 3 in. above the first mark, the other 3 in. below the first mark. A curve is drawn from the edge of the Mylar sheet through the upper mark, through the inside mark, through the lower mark, and thence to the edge of the sheet. A cut is made along the

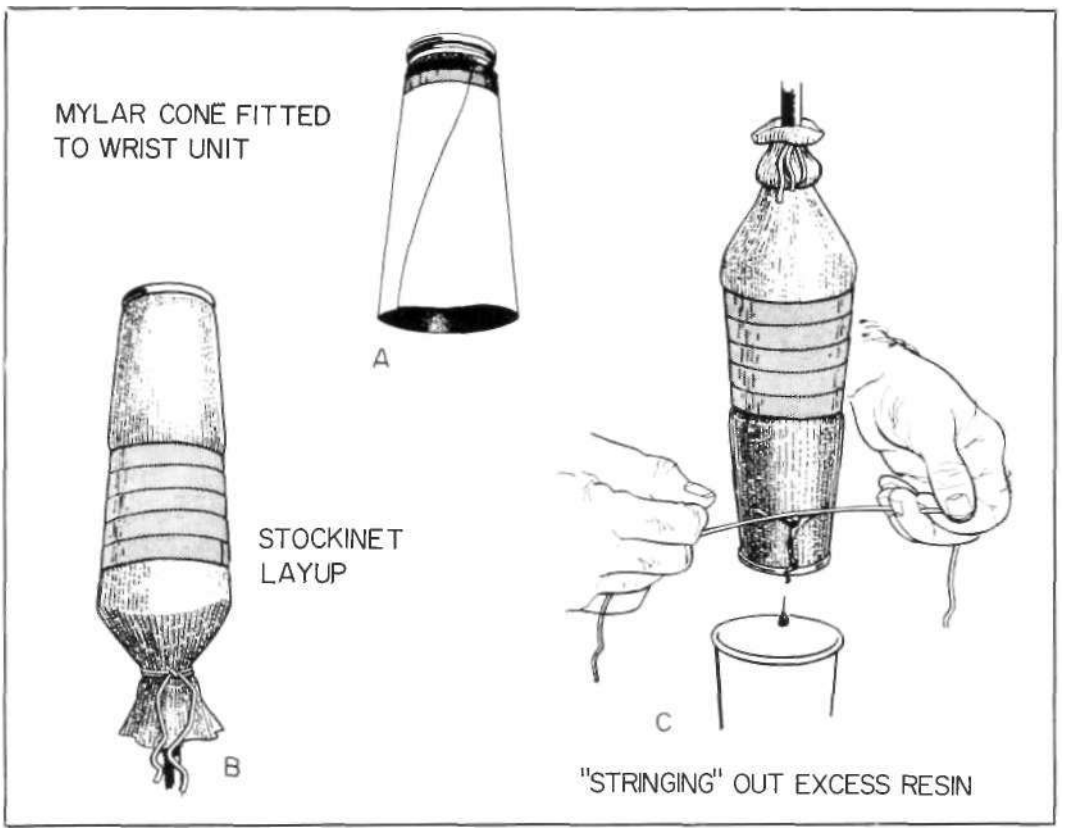

Fig. 10. The Mylar cone buildup and impregnation.

curve. This cut side will permit the standard adult wrist unit to fit squarely to the Mylar sheet when it is fitted into a cone (Fig. 10A). The wrist unit should be fitted a minimum distance into the cone.

The cone is placed over the stump model and adjusted so that the desired contour of the finished prosthesis will be obtained. Next, the prosthetist holds the cone and wrist unit in one hand, placing the unit flat on a table. With the other hand, he positions the stump model in the cone so that the distance between the elbow axis and the table surface corresponds to the required forearm length. The cone is adjusted at the proximal end, and the excess is trimmed off. The shortest cone that will give a desirable final shape to the forearm should be used, since it will provide the greatest bond area between the forearm and the socket. When the correct conical shape is obtained, the cone is closed with transparent tape, the proximal end of the cone is taped to the socket with transparent tape, the wrist unit is taped in place, all holes in the unit are closed with a sealer, and all seams are taped.

Next, a piece of orthopedic stockinet is cut so that it is at least 10 in. longer than twice the length of the layup. The stockinet is pulled down over the entire layup in such a manner that half of the stockinet extends above the wrist unit. The stockinet is tied at the wrist unit, and the extended half of the stockinet is pulled back down over the layup. The stockinet is pulled smooth and tied at the base rod.

The proximal edge of the Mylar is found by palpation, and a light line is drawn around the layup just distal to the edge of the cone. All the areas below this line are covered with masking tape (Fig. 10B).

A batch of resin is mixed as follows:

ERL2795	45.5 grams
Versamid 140	24.5 grams
Trichloroethylene	30 grams

Sufficient pigment is added to give a slight color to the batch.

The entire layup is inverted and brush-coated with this resin mixture. The excess resin is "strung" down toward the wrist unit (Fig. 10C).

Fig. 11. Sanding the porous cone.

The layup is now placed for 30 min. in a pre-heated oven set at 115 deg. F (47 deg. C) for the pre-cure. After the cone has been pre-cured for 30 min., the oven temperature is increased to 212 deg. F (100 deg. C) and the cone is cured for 30 min. at this temperature.

The layup is then removed from the oven, the masking tape is removed from the lavup, and the cone is separated from the inner socket. The Mylar sheeting is removed from inside the porous cone. The porous cone is sanded around the wrist unit until a smooth taper is obtained (Fig. 11).

With the table contained in Appendix A (page 29) as a guide, a 250-gram batch of resin mixture is prepared, including in it a suitable amount of pigment.

At this point the PVA sheet placed over the socket layup early in the procedure is removed, and a PVA sleeve is placed over the socket layup.

The inner socket layup is impregnated with resin in the usual manner. Excess resin is removed from the layup by "stringing," the PVA sleeve is removed from the layup, and any excess resin is "strung" out.

Now the porous cone is pulled down over the inner socket and aligned so that the wrist

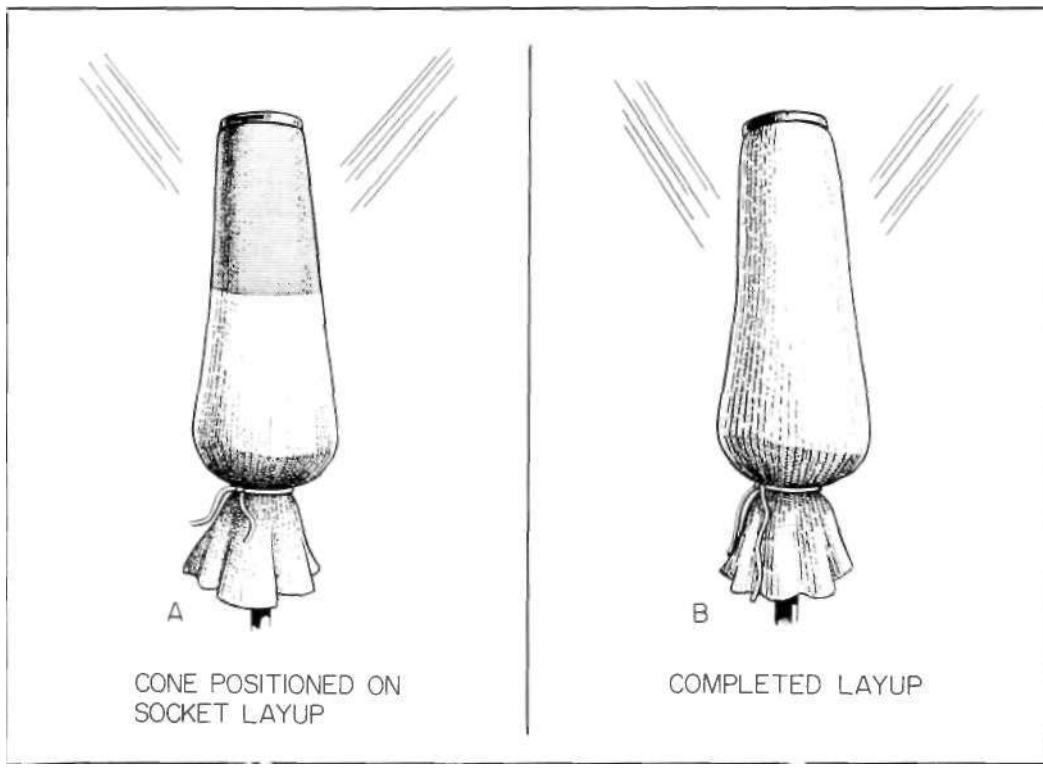

Fig. 12. Preparing the layup combining the socket and the porous cone

unit is in the proper position. The stockinet is tied at the base rod (Fig. 12A).

A piece of Banlon stockinet is cut so as to be 3 to 5 in. longer than the layup, and a piece of orthopedic stockinet is cut so as to be twice the length of the Banlon stockinet. One end of the Banlon stockinet is tied around the wrist unit. The orthopedic stockinet is pulled over the Banlon stockinet and tied at the middle around the wrist unit. (Additional layers of stockinet may be used if greater strength is required.) All layers of stockinet are pulled down over the layup and tied at the base rod (Fig. 12B).

The layup is now thoroughly impregnated with the remaining resin mixture, with the use of a PVA sleeve and "stringing." It is very important that all the excess resin be "strung" down toward the proximal end, so that there will be no pooling of resin when a PVA bag is pulled down in a subsequent step. A few pieces of scrap stockinet should be wrapped around the base pipe to absorb excess resin.

The layup is now placed for 30 min. in an oven pre-set at 115 deg. F (47 deg. C) for a pre-cure. While the layup is pre-curing, a PVA sleeve is prepared to fit the forearm. The PVA sleeve is wrapped in a moistened towel for 10 to 15 min. during the pre-cure. At the end of the pre-cure, the layup is removed from the oven and any excess resin is "strung" out. The oven temperature is increased to 212 deg. F (100 deg. C). Meanwhile, the moistened PVA sleeve is pulled down over the layup so that the entire laminate is in firm contact with the sleeve. If the sleeve is sufficiently moist, it will slide easily over the layup without causing any resin pools. However, if any resin pools do form, they should be "strung" out of the laminate. The PVA sleeve is taped around the wrist unit and any undercut areas to insure proper lamination.

The laminate is now placed for 60 min. in the oven, previously set at 212 deg. F (100 deg. C). At the end of 60 min., the laminate is removed from the oven and the PVA sleeve is stripped off. At this point, the laminate should be free from tackiness.

For the final cure, the laminate is replaced in the oven, still set at 212 deg. F (100 deg. C).

After the final cure, the laminate is removed from the oven and cut to the desired length. The laminate should separate easily from the mold.

The prosthesis is held firmly on the amputee's stump, and the trim line is marked. Then the socket is removed and trimmed in the usual manner.

POLYESTER-RESIN MIXTURE

Shortly after the initial success of the porous epoxy laminates, attempts were made to produce similarly porous polyester laminates. At first these attempts were unsuccessful. Although highly porous laminates were produced, their physical strengths were inadequate for prosthetic application.

However, because of significant improvements in the method of preparing porous epoxy laminates, particularly through the reapplication of a PVA bag at a critical time in the curing process, it was decided to reinvestigate the porous polyester system. The Army Prosthetics Research Laboratory has produced a series of cylindrical, porous polyester laminates which have shown when tested a strength sufficient for prosthesis (5). Preliminary results of the evaluation are promising. The fabrication procedures presently recommended are the same as have been described for porous epoxy laminates in this article and set forth in full in *A Manual for the Preparation of Above and Below Elbow Prostheses (2),* published by the Army Prosthetics Research Laboratory.

The following polyester-resin formulation is tentatively suggested for a medium below-elbow porous prosthesis:

Laminae 4110[11]	80 grams
Paraplex P-13[12]	20 grams
Luperco ATC[13] .	3 grams
Trichloroethylene .	43 grams
Naugatuck Promoter No. 3[14]...	6 drops
Polyester pigment . .	1 gram (or as required)

[11] American Cyanamid Company, Plastics Division, 30 Rockefeller Plaza, New York 20, N. Y.

[12] Rohm and Haas Company, Philadelphia 8, Pa.

[13] Wallace and Tiernan, Incorporated, Lucidol Division, 174 Military Road, Buffalo, N. Y.

APPENDIX A

RESIN MIXTURES REQUIRED FOR VARIOUS APPLICATIONS (2)

Amount of* Total Resin Mixture Needed	Amount of ERL 2795 Necessary	Amount of Versamid 140 Necessary	Amount of Trichloroethylene Necessary	Typical Applications
Grams	*Grams*	*Grams*	*Grams*	
50	23.0	12.0	15.0	
75	34.0	18.5	22.5	
100	45.5	24.5	30.0	Short BE
125	56.0	30.5	37.5	
150	68.0	37.0	45.0	Medium BE
175	79.5	43.0	52.5	
200	91.0	49.0	60.0	Long BE
225	102.5	55.0	67.5	
250	114.0	61.0	75.0	Long BE
275	125.0	67.0	83.0	
300	136.5	73.5	90.0	Shoulder

* Total resin mixture includes resin, curing agent, and solvent.

Color appropriate for the individual should be added to the resin mixture and stirred in until it is uniformly blended. For a 100-gram mixture, 1 to 4 grams of color is sufficient. Epoxy pigment, Caucasian, tan, No. 22826 (60% pigment) and epoxy pigment, Negroid, brown, No. 22831 (53% pigment) (Plastics Color Company, 22 Commerce Street, Chatham, N. J.) have been used successfully at New York University (7).

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