SHAPE&ROLL PROSTHETIC FOOT MANUAL 3 – FABRICATION OF THE COSMETIC SHELL

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Abstract

Cosmetic appearance of a prosthetic foot is important for many lower limb prosthesis users, regardless of their income. The ultimate success or failure of a prosthetic foot design can be affected by its physical appearance. This technical note describes a method for manufacturing low-cost prosthetic foot shells from room temperature vulcanized (RTV) rubber materials. In particular, the paper describes how to (1) capture a negative mold of the dorsal shape of a physiologic foot using inexpensive materials, (2) create a plaster positive model of the foot from the dorsal negative mold, and (3) create an inexpensive three-piece mold for the simple production of prosthetic foot shells. Many of the techniques are well-known to sculptors. However, this work describes our adaptations of sculpturing techniques for the specific task of creating a prosthetic foot shell of uniform thickness. A method for creating a split-toe design is also included in the paper. This type of design is necessary for persons who want to wear thong sandals. General comments are included on materials that we have used in the development of a shell for our prosthetic foot, the Shape&Roll prosthetic foot. With appropriate materials and when embedding an inexpensive nylon stocking reinforcement, a strong, tear-resistant cosmetic foot shell can be fabricated.

Introduction

In most cultures, a difference from the average physical appearance, either due to trauma, disease or birth defect, is considered a deviation from the norm, i.e. an abnormality or a disability [1]. This classification is a social construct rather than a physiological characteristic, something better described as impairment [2]. Physical impairment can lead to body image disturbances and cosmetic concerns as a result [3]. Dillingham et al. [4] assessed prosthesis use and satisfaction over a ten-year period in persons with traumatic trans-tibial amputation. Of the seventy-eight persons interviewed, only 58% reported being satisfied with the appearance of their prosthesis. Murray and Fox [5] analyzed the relationship between body image and prosthesis satisfaction. Their results demonstrate a complex interaction of multiple factors and gender differences. For male users of lower limb prostheses, high functionality of the prosthesis correlated with a better body image. However, with the passing of time, males found their prosthesis less aesthetically pleasing. For female users, appearance was more highly correlated with a satisfactory body image than functionality. Unfortunately, studies analyzing the cosmetic concerns of persons with amputations in developing countries seem to be nonexistent. It is the authors' belief, however, that people in developing countries have similar concerns regarding cosmesis. Therefore, prosthesis users who wish to minimize the visible difference of their impairment may choose a cosmetic cover with the most natural look to facilitate mimicry of able-bodied persons [2, 6].

This technical note provides a fabrication method for a cosmetic prosthetic foot shell that is attractive due to its low cost, natural look, strength and durability, and straight-forward fabrication technique.

Methods

Capturing a negative model of the foot using clay

There are many ways to capture a negative model of the foot. We explored a variety of techniques and ultimately decided to use a method which utilizes pressure molding of clay against the foot to get an impression of its dorsal surface. This method seemed superior to others for our application because it was simple and inexpensive and because it uses materials that are widely available throughout the world. The following paragraphs describe the procedure in a step-by-step fashion.

We start by cutting a piece of wood, approximately 4 cm thick, that outlines a person's foot and demonstrates the desired foot shape, side, and size for the patients for whom the cosmetic foot cover will be made. The wooden footprint is placed on two adjacent sheets of thin rigid plastic (5 or 6 mm thick) such that the seam between the two sheets of plastic is directly under the lateral and medial malleoli. Once aligned as such, a marker is used to trace the outline of the wooden footprint onto the sheets of plastic. The plastic under the wood is then cut away resulting in two plastic pieces with a "hole" equivalent to the foot print when realigned to the same position. Next, the plastic pieces are realigned, with

the wooden footprint replacing the plastic that has been cut away. The person acting as the foot model places his/her foot onto the wooden footprint. A piece of dental floss or fishing line is cut and draped around the bottom of the wooden footprint and up both sides of the legs. The piece of floss or fishing line should pass over the centers of both malleoli (medial and lateral) and should line up with the seam between the plastic sheets. The ends of the floss or fishing line are held in place by a rubber band on the shank of the person's leg (Figure 1a). Throughout the molding procedure, the person's ankle should be held in a neutral position.

Next a large sheet of water-based clay should be prepared as well as several "ribs" cut from a large diameter PVC (polyvinyl chloride) tube. The "ribs" should be cut in various widths and lengths (see Figure 1c). One or both of the sides of the clay should be smooth and somewhat damp. The smooth side of the clay is applied to the dorsal surface of the foot and the clay is pressed against the forefoot and toes to secure a good impression of the foot. Another layer of clay is applied to the posterior aspect of the heel and is pressed against the skin to insure that the clay has been pressed tightly against the skin all around the foot. More layers of clay are applied to the foot to create a fairly thick layer of clay (roughly 2 cm) over the entire surface of the foot (Figure 1b). At this time, the PVC "ribs" should be applied to the clay model (Figure 1c) for reinforcement. These "ribs" should be applied to both the heel and forefoot sections of the mold, but should not cross the sections of clay directly beneath the malleoli. After the

“ribs” have been added to the mold, more clay should be applied (Figure 1d) to secure them in place. The PVC pieces are of utmost importance to give the block of clay the rigidity that is needed to prevent collapse of the clay negative model later. After a large amount of clay has been applied to the foot, with PVC “ribs” sandwiched between layers, the rubber band can be moved to release the dental floss or fishing line. The ends of the floss or fishing line are then pulled outward and down, cutting the clay in a plane that would go through both the medial and lateral malleoli (Figure 1e). This cut should also line up closely with the seam between the two sheets of plastic. The heel section of the mold should be slid backwards very carefully by pushing the posterior piece of plastic away from the heel of the foot. The anterior piece of plastic should be lifted upward and slightly anterior to remove it from the dorsal surface of the foot (Figure 1f). Inspect both halves of the negative mold. If either is unsatisfactory, remove the clay and remold. On a table top, the two pieces can be slid back together (Figure 1g). The seam between the clay pieces can be closed easily using a finger and pushing clay from one piece across the seam onto the other piece (Figure 1h). After the seams on both sides have been closed, the upper rim (where the leg came through) is leveled off using a knife (Figure 1i). After the top is leveled, another flat sheet of clay is applied to cap the top (Figure 1j). The seams around the edge of this sheet are then removed using the fingers and pushing clay from the sheet onto the clay mold. Next, the negative mold of the foot is tipped upside down on the table top and is secured to prevent it from moving (Figure 1k). The inner seams can now be carefully smoothed using the fingers (Figure 1l). The

longitudinal arch of the foot, if present, can be pushed outward using sweeping motions of the fingers if a wider base is required (The Shape&Roll Prosthetic Foot has a flat bottom and requires a certain minimum width in the area of the arch [7]. Other feet may not require this step). Undercutting of the clay under the toes can also be pressed out with a finger if a slightly taller cosmetic shell is required. Any desired modifications to the toes can be made easily to the negative clay model, although our experience showed that obtaining a good impression of the toes and leaving them unmodified gave the best final result. Confirm the quality of the negative mold before moving on. If there are problems, simply start over and press the clay against the foot again.

Creating a positive model of the foot

After a satisfactory negative mold of the foot has been produced and while it is still upside down, mix plaster and fill the mold (Figure 2a). Making sure that the intended bottom surface of the foot is level and pouring to an appropriate height inside the negative mold will lead to fewer modifications of the plaster model. Allow the plaster to harden and remove the clay from the outside. This positive model of the foot will have specific features that need to be modified. First, the top of the model (i.e. just above the ankle) should be cut and/or carved to meet the desired height of the shell and to create a flat, horizontal end (Figure 2b). The bottom edge (sole) of the foot will be sharp after pouring. This sharp edge should be filed down to create a smooth transition between the sides and bottom of the foot (Figure 2c). If the foot is too skinny, additional plaster can be added to the

model to bulk it out. However, this technique may result in the loss of skin details. Any other irregularities caused by imperfect molding of the foot should be corrected on the positive model.

If a split-toe design is not required, the positive model can be used after modifications and smoothing. If the split-toe design is desired, a hole should first be drilled at the junction between the first and second toes, i.e. where the tube-strap of the thong sandal would rest (Figure 2d). Next a hacksaw blade can be used to cut down the crease between the two toes and toward the center of the hole that was drilled (Figure 2e). The blade or a thin knife can be used to widen the cut between the first and second toes by scraping multiple times down the sides of the original cut. The top, bottom, and anterior edges of the cut should also be smoothed around by carving with a knife or a small file. We have found this method to be much easier and more reliable than placing clay between the toes during the negative impression stage. The result of the modifications should be a smooth positive model of the foot made of plaster (Figure 2f).

Making a three-piece mold for prosthetic foot shells

To fabricate a shell, a three-piece mold is required: Pieces 1 and 2 are two parts of a negative mold for the plaster positive whose fabrication we have described above. Piece 3 is the inner core, or spacer, of the mold required to create the void typical for shells. The creation of these three required pieces is described in the following paragraphs. The challenge one faces is to create a unified wall

thickness of the prosthetic foot shell, to prevent weak spots and subsequent failure of the shell.

We have found that the thickness of the prosthetic foot shell can be controlled closely by connecting the three mold pieces to a rigid plastic bowl. To create such a bowl, the plaster positive is wrapped in cellophane plastic (such as plastic food wrap). The wrapped positive is placed onto the wooden piece used previously and some additional pieces of plastic (each piece about 5-6 mm thick) cut slightly larger than the wooden piece (Figure 3a). Clay is placed around the foot (except for the top surface, i.e. the cross-section of the ankle) in a layer that is at least 3 cm thick (Figure 3b). The clay is also placed in such a way that its circumference is always expanding as it goes down toward the table, thus leaving no undercuts and facilitating removal after drape forming. A piece of cloth is placed over the clay to protect it from melting during the draping process. A thick piece of polypropylene plastic is then drape molded over the cloth to create the bowl (Figure 3c). After the plastic has cooled, it can be removed and the outer edges can be trimmed. The clay can be removed and reused.

For the next steps, the plaster positive should be dried thoroughly and should be sealed with several coats of lacquer if polyurethane rubber materials will be used to create the three piece mold. A light “coat” of polymer-based clay can also be rubbed onto the plaster positive model of the foot to seal it. Bear in mind that such coatings will remove skin details of the foot. Water-based clay should not be

used for this step as it reacts with the polyurethane rubber and interferes with its curing. If silicone materials are used for pieces 1 and 2, drying and sealing the plaster are not necessary. The following methods will be explained assuming that polyurethane rubber materials will be used for all three pieces of the mold.

After the bowl has been fabricated, the first piece of the three piece mold can be created. The bowl and plaster positive should first be sprayed with a parting agent designed for use with the polyurethane rubber materials. Next, the plaster positive is placed upside down into the bowl and a weight is placed on the plantar surface at the heel to prevent it from tipping. The positioning of the foot with respect to the bowl should be similar to that in which the bowl was thermoformed, although now both pieces are upside down when compared with the thermoforming step. Additionally, the mold should be set up such that the plantar surface of the plaster positive is level. At this time, a polymer-based clay funnel is connected between the most posterior edge of the heel and the side of the bowl. This funnel will be used later to fill the mold. Next, the polyurethane rubber materials are mixed thoroughly per manufacturer's recommendations and poured carefully, to avoid air bubbles, into the bowl up to the middle of the toes and the heel (Figure 3d). The amount of material poured at this stage is important because it sets the location of the seam of the prosthetic foot shell. The ideal location of the seam is at the largest circumference of the positive foot model. Having the seam at that location reduces the degree of undercutting and allows for easier removal of the foot shells from the mold during production. After the

polyurethane rubber material has cured, the weight on the plantar side of the heel is removed and a parting agent is sprayed onto the entire plantar surface of the plaster model, the cured polyurethane rubber, and the remaining inside of the bowl. More polyurethane rubber material is mixed and is poured in until the level is above the plantar surface of the foot by approximately 3 cm, thus embedding the plaster positive completely. Dip a dry strap into the liquid polyurethane mix and clamp it at the anterior and posterior ends of the bowl using binder clips (Figure 3e). The strap should be approximately 70 cm long and its middle portion should be dipped into the polyurethane mix. Make sure that this strap does not come in contact with the plaster positive. A piece of plywood is cut and placed onto the liquid polyurethane mix such that it will float on the top of the liquid polyurethane rubber without touching the sides of the bowl (Figure 3f). The liquid polyurethane rubber is now allowed to cure according to the manufacturer's recommended set-up time. During foot shell production, the strap can be used to pull the mold apart from the bowl. The plywood piece is used to distribute stress evenly across the mold when clamped for filling (see later steps in the process).

After the polyurethane has completely cured, the strap can be pulled to remove the plantar surface part of the negative mold. Remove the plaster positive carefully.

Bolts with matching T-nuts should be located for the next steps. To create the inner piece of the mold, i.e. the piece that creates the void of the shell, two holes

are drilled through the plastic bowl using a bit with a diameter that will allow the bolts to slide through. The location of these holes should be on the bottom of the bowl and positioned as shown in Figure 3g. The bolts are connected to the T-nuts and tightened as tightly as possible using fingers only to avoid excessive deformation of the T-nut into the plastic. Next, a small tube of polymer-based clay is placed around the T-nuts, without touching them, and against the bottom surface of the bowl (Figure 3g). This tube of clay represents the thickness of the shells at their openings. Making this part of the shells thicker will help to prevent tearing when taking prosthetic feet in and out of the shells. To create a uniform thickness shell, polymer-based clay is rolled between two pieces of steel or aluminum of the desired thickness (Figure 3h). These pieces are cut and molded into both the dorsal and plantar sections of the negative polyurethane rubber mold (Figure 3i), leaving a hole at the funnel location to allow liquid polyurethane to enter the mold. The mold is closed, clamped together, and filled with properly mixed polyurethane rubber material (Figure 3j). After the appropriate amount of time has been allowed for curing, the plantar part of the negative mold is removed, revealing the inner piece of the three-piece mold (Figure 3k). The material that setup inside the funnel and against the heel of the inner piece is cut off with a sharp knife and the clay is removed from the mold. All of the pieces are cleaned thoroughly. We now have a three piece mold for a shell with uniform wall thickness (Figure 3l), consisting of a plantar piece, a dorsal piece embedded into a bowl and a spacer that can be screwed to the bowl and thus kept in proper alignment.

Making a prosthetic foot shell

To make a prosthetic foot shell, it is extremely important first to spray all molding surfaces with a parting agent. After this step is completed, a small amount of polyurethane material is mixed and painted or slathered onto the inner piece of the mold with a brush or by hand. A nylon stocking of approximate color of the skin tone of the user is pulled over the inner piece and this piece is bolted to the bowl. If the mold has a split toe design, the nylon should be cut in this area so that the stocking does not fill the void between the “big toe”-part and the “rest of the toes”-part of the inner piece. The plantar piece of the mold can be clamped together with the bowl and a larger batch of polyurethane can be mixed. This polyurethane material can be dyed to the approximate skin tone of the end user. Pour polyurethane slowly into the mold to minimize air bubbles. Air bubbles reduce the quality of the shell (mechanical and cosmetic) and are not desired. After the material cures, the clamp can be removed and the mold can be pulled apart using the straps. It is easiest to remove the bolts holding the inner piece first and allowing all rubber pieces to exit the bowl. The shell with its embedded inner piece can be separated from the other pieces and then removed from the inner piece using a smooth shoe horn. The T-nuts inside the inner piece should not be used in conjunction with bolts and a vice to remove the inner piece from the shell. Doing so can result in failure of the inner piece of the mold. The newly created shell will look similar to that shown in Figure 4a. The funnel part and other excess rubber at the seams can be trimmed with a scalpel or sharp knife.

Creating shells with the split toe, as mentioned earlier, allow the use of thong sandals (Figure 4b), which are prominent in many countries.

Discussion

Moisture problems with polyurethane

Polyurethane is a moisture-sensitive material and as such must be handled with care to prevent the formation of bubbles on the surface of the rubber piece. The main goal is to limit the exposure of the two-part material to humidity in the room and to properly dry all surfaces that will come into contact with the rubber during the curing process. The insides of any containers used for mixing as well as the surfaces of the molds themselves should be thoroughly dried before mixing and pouring. It is important to close the polyurethane containers after each use as quickly as possible to reduce the moisture impact of the environment on the polyurethane quality. This step helps to reduce the amount of moisture absorbed by the polyurethane and will prolong its shelf life.

Because of its undesirable reactivity with moisture, casting polyurethane rubber against a plaster positive model introduces difficulties. The plaster must be thoroughly dried and/or lacquered before polyurethane can be poured against it. Slow drying in a warm oven is preferred followed by the application of several coats of lacquer before polyurethane is applied to the plaster. Moisture in plaster is not a problem for silicone molding, however, because moisture is actually necessary for the curing of silicone. Therefore, the use of silicone rubber for the

fabrication of the dorsal and plantar portions of the negative mold may be preferable to polyurethane rubber.

Vacuuming bubbles from the liquid polyurethane material

The surface finish of the cosmetic shell can also be compromised by air bubbles in the final cure. Air is entrapped in the polyurethane during both mixing and pouring. Any two-part polyurethane rubber must be mixed thoroughly to ensure a consistent final cure. However, care must be taken not to trap air in the mix. The use of slow and gentle stirring motions will ensure that a minimum of air is entrapped during mixing. Additionally, after stirring is completed, the two part mix can be “de-gassed” using a vacuum chamber to yield excellent results.

Alternate funnel arrangement for reduction of trapped air bubbles (Figure 5).

During the pouring of the polyurethane into the mold, air bubbles often become trapped in the area of the posterior surface of the heel. Before the rubber starts to cure the mold can be tilted to allow bubbles to rise out into the funnel area. An alternate configuration of the funnel could be used to eliminate this step and allow bubbles to naturally come out of the mold. If the funnel is placed so that it connects to the most inferior aspect of the heel, the increased angle should allow for bubbles to float out of the funnel and away from the surface of the shell.

Lastly, the rim of the shell should be made thicker than the normal wall thickness to resist tearing around the opening of the shell. This increased thickness is

accomplished by placing a thicker rim of polymer-based clay around the top of the dorsal portion of the negative mold (see Figure 3g).

Cost estimates

In 2005, the approximate cost of fabricating the three-piece mold was $35-$60, depending on whether material was purchased in small or bulk quantities. The cost of fabricating each prosthetic foot shell was about $5. It is important to understand that this technique will be most cost effective in places where labor is inexpensive. Labor has not been factored into these estimates of mold and shell costs.

With simple and inexpensive materials, a cosmetically pleasing polyurethane prosthetic foot shell can be fabricated with a uniform wall thickness. Tests in our laboratory have shown that these shells (covering Shape&Roll prosthetic feet) are durable in fatigue experiments modeled after the ISO 10328 standard, with little wear seen after 2,000,000 cycles at the A80 loading levels.

Other promising techniques are also emerging for the fabrication of prosthetic foot shells. One recently developed technique by Edward Pennington-Ridge (Elegant Design and Solutions, Ltd) can be used to fabricate cosmetically appealing foot shells out of silicone sealant/caulking materials. A silicone foot shell (covering a Shape&Roll prosthetic foot) has also been fatigue tested in our laboratory, with some wear under the heel and forefoot sections after 2,000,000 cycles of loading at the A80 level. However, the silicone materials should be

easily repairable by the prosthesis users as wear occurs (Pennington-Ridge, personal communication). At this time, both methods (polyurethane and silicone shell fabrication techniques) seem appropriate for the production of a durable and cosmetically appealing prosthetic foot shells although field tests will be needed to verify these claims. Prosthesis fitting centers should choose the method they would like to use based on the available materials in their area, the skills their staff members can develop, and their perceived advantages and disadvantages of the different methods and materials.

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Figure Captions

Figure 1 – Photos illustrating a procedure for capturing a negative mold of a foot using clay and PVC pipe “ribs”. See text for details.

Figure 2 – Photos illustrating a procedure for creating a plaster positive model of the foot using the clay negative. See text for details.

Figure 3 – Photos illustrating the procedure for making a three-piece mold for production of prosthetic foot shells. See text for details.

Figure 4 – Prosthetic foot shell examples. The polyurethane can be dyed to different skin tones as shown in the lower photograph.

Figure 5 – Creating the fill hole in the position shown and filling in this orientation, should allow air to more easily escape the mold when filling with polyurethane.


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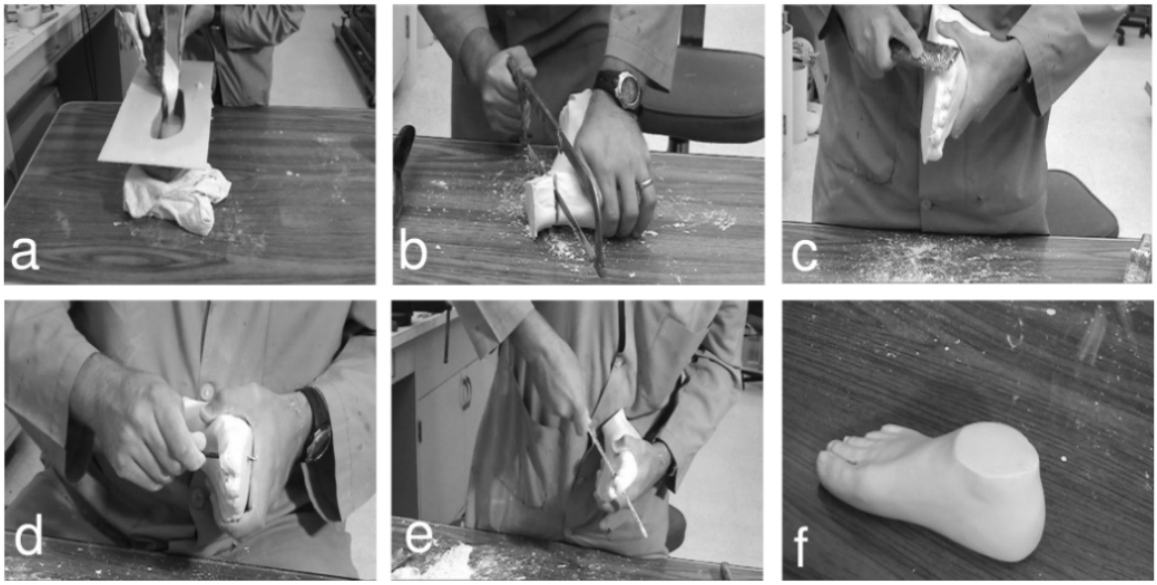
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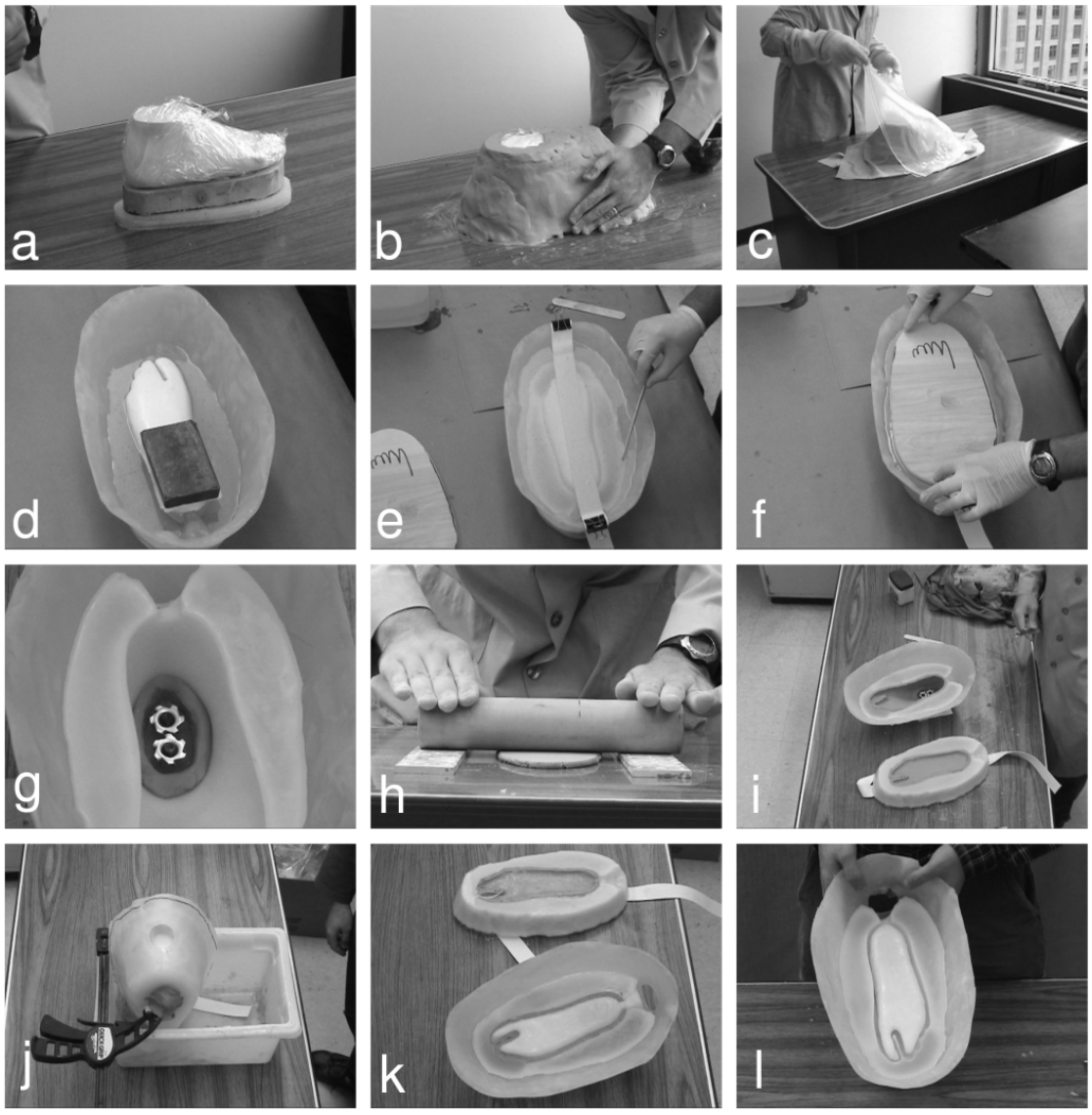
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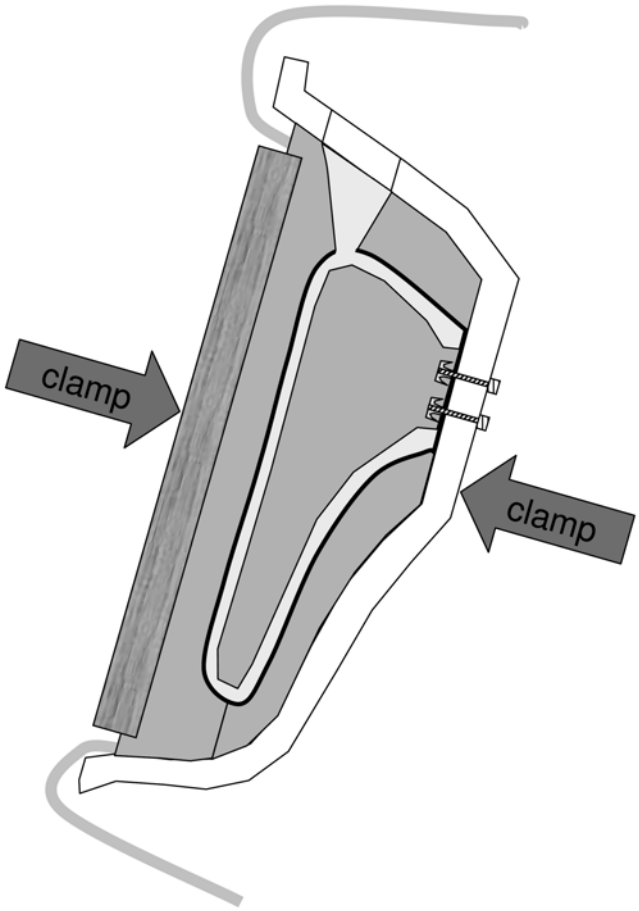
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