AD

TECHNICAL REPORT 6803

FABRICATION TECHNIC FOR AN INFLATABLE NECK SPLINT

Reported by:

Mary H. Yeakel, Major, AMSC
Douglas K. Ousterhout, Captain, MC

May 1968

U.S. ARMY MEDICAL BIOMECHANICAL RESEARCH LABORATORY
WALTER REED ARMY MEDICAL CENTER
Washington, D.C. 20012

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Project 3A025601A821 00 095

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ABSTRACT

The technic for fabricating a latex inflatable bladder to be used in conjunction with the commercially available Myo Cervical Collar has been described in detail. The latex material used is one which is simple to manipulate and possesses excellent physical properties for this type of application. Due to the dynamic nature of this appliance, a rather small assortment of sizes of both collars and inflatable bladders can be shelf stocked for ready availability to meet patient requirements.

BACKGROUND

Various appliances have been described for use in the treatment of cervical scar contracture following split thickness skin grafting of the neck[1-3] in an attempt to maintain the extension and cosmesis which the surgical procedure has accomplished. It is generally felt that the appliance must fulfill two objectives: 1. maintain the head in extension and 2. apply light pressure to the grafted area for at least six months. Although several commercial neck braces are available for immobilizing the head in extension, they do not directly provide any method for applying pressure to the grafted area.

This paper describes the technic for fabricating an inflatable bladder used in conjunction with a Myo Cervical Collar in an attempt to provide a dynamic splint which can be fabricated and stocked prior to patient need, and obviates the major shortcomings of previosuly described cervical splints. Choice of the proper size collar and inflatable bladder permits rapid fitting of a perfectly adapted, dynamic splint which can be easily fitted in the operating room, at the bedside or in the physician's office.

APPLIANCE DESIGN

Head extension is maintained by choosing the proper size (small, medium, large) Myo Cervical Collar and adjusting it for the desired amount of extension and patient comfort. The anterior portion of the patient's mandible should extend well over the upper edge of the collar, otherwise the mandible will tend to slide inside the collar when the patient is lying supine in bed. After the collar has been fitted, a bladder is chosen which is just slightly wider than the collar. The air inlet valve is placed through the opening made in the collar for this purpose. The collar and the bladder are then repositioned against the patient's neck. When the collar is securely fastened, the bladder is inflated to the desired air pressure. The amount of pressure is determined by the patient.

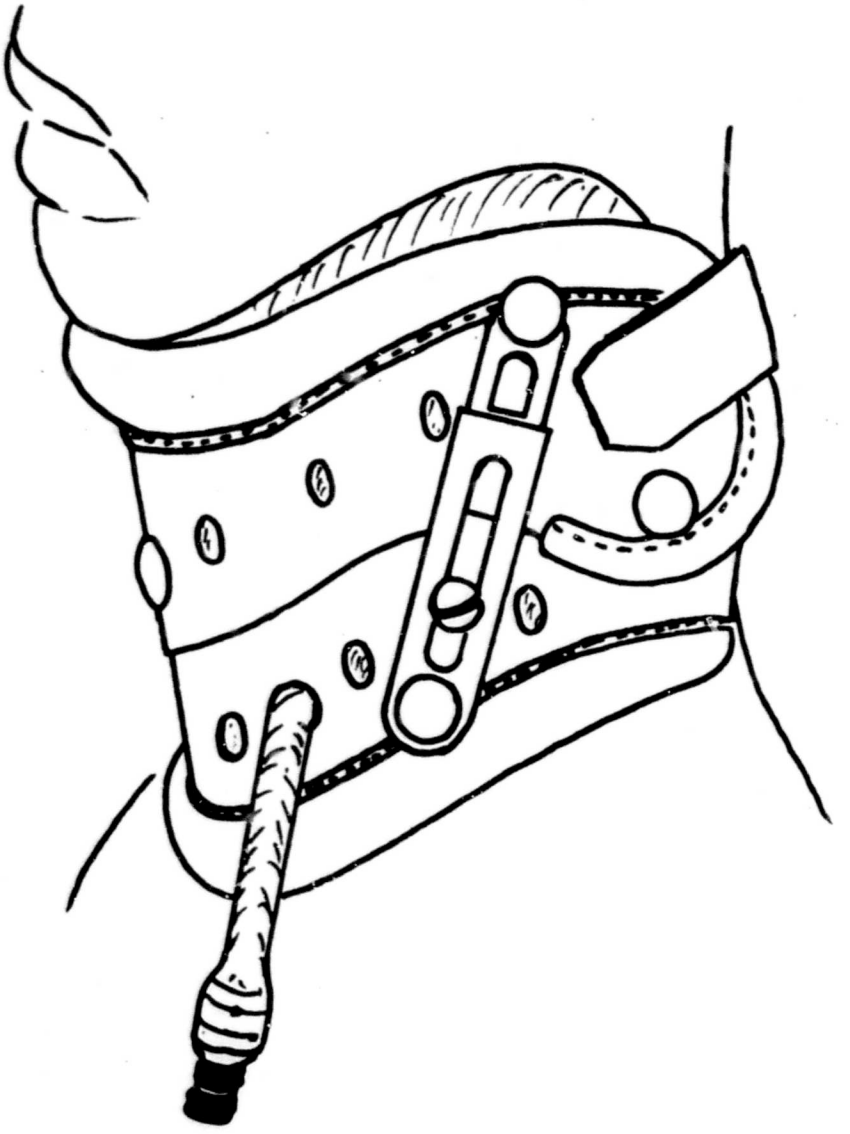

Fig. 1

FABRICATION OF THE LATEX BLADDER

PREPARATION OF LATEX AND COAGULANT

The material used in the fabrication of the bladder is a terpolymer elastomer which was developed at this laboratory.[4] This terpolymer is 90 parts butyl acrylate, 7.5 parts methyl methacrylate, and 2.5 parts methacrylamide latex compounded with 37 parts of polyethylmethacrylate as a reinforcing agent. In addition, 1.765 parts of formaldehyde added during the compounding procedure has the effect of producing a tightly knit or cross-linked material. All of the compounding ingredients are available commercially; however, the fabricator must be very careful in following the basic compounding formula of 100 parts terpolymer latex, 37 parts polyethylmethacrylate and 1.765 parts of formaldehyde to make all calculations on the basis of total solids of each material. The following is a typical example of a compounding problem:[5]

> 1500 ml of a 37% total solids terpolymer latex is to be compounded. To determine the amount of total rubber solids in this terpolymer latex, the following calculations are performed:
>
> 1500 x .37 x 1.02 = 567 gm rubber solids
> .37 = % total solids in latex
> 1.02 = density of the terpolymer latex
>
> To the terpolymer latex is added with gentle stirring 37 parts of the polyethylmethacrylate filler whose volume is determined as follows:
>
> $$\frac{567 \times .37}{.45 \times 1.06} = 440 \text{ ml polyethylmethacrylate filler latex}$$
>
> 567 = gm rubber solids in 1500 ml terpolymer latex
> .37 = parts of filler to be added
> .45 = per cent of total solids in polyethylmethacrylate latex
> 1.06 = density of polyethylmethacrylate latex

Therefore 440 ml of the 45% total solids polyethyl-methacrylate filler latex is added to the terpolymer latex.

1.765 parts of formaldehyde are then added whose volume is determined as follows:

$$\frac{567 \times .01765}{.37 \times 1.08} = 25.0 \text{ ml of 37\% Formalin}$$

567 = gm rubber solids in terpolymer latex
.01765 = parts of formaldehyde to be added
.37 = per cent formaldehyde in formalin solution
1.08 = density of formalin solution

Therefore 25.0 ml of 37% formalin solution is added to the above mixture with gentle stirring. After 5 minutes of additional stirring, the compounded latex is ready for use.

A coagulant is necessary for priming the dipping model for deposition of the compounded latex. The coagulant solution is made by thoroughly mixing 20 gm of calcium nitrate with 80 gm of denatured alcohol.

DIPPING MODELS

The dipping models were made from 3/32" sheet aluminum cut in a kidney-shaped pattern 8-3/4" in length. (See Fig. 2)

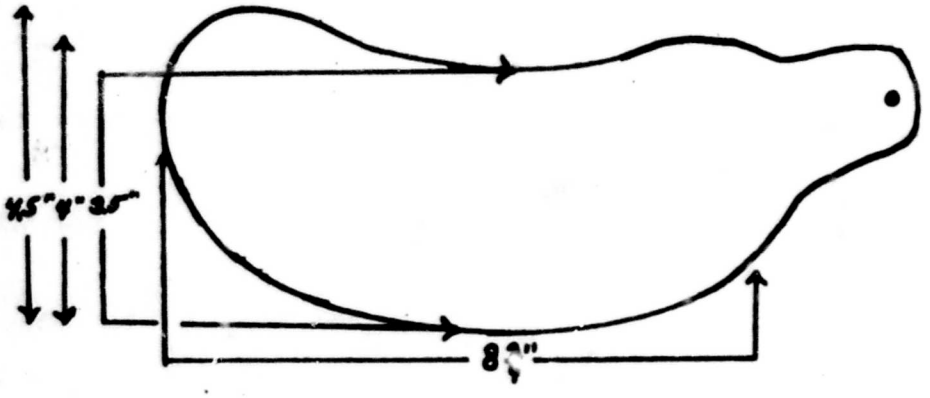

Fig. 2

One end was extended beyond the 8-3/4" length to provide a handle for holding the model while it is suspended in the latex terpolymer. A small hole drilled in the handle allows for a hook to be inserted for supporting the model during oven curing. After all sharp edges have been removed, the model is shaped to the contour of the neck. This will help to prevent the concave surface of the finished bladder from folding and creasing when it is fitted to the convex contour of the neck. Three bladder widths of 3.5", 4" and 4.5" were found to be an adequate assortment of sizes for an adult patient population.

A dipping model is also needed for fabrication of the filling tube into which a metal air valve will be placed. (Fig. 3).

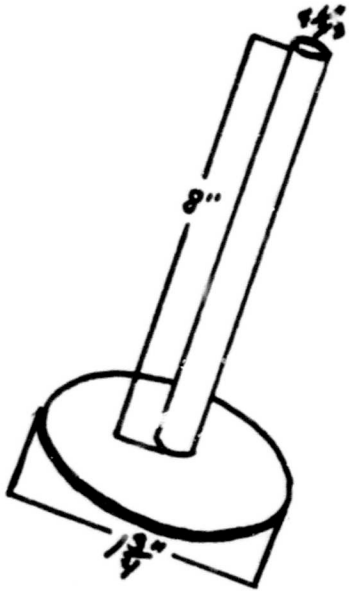

Fig. 3

This model is made from a 1/4" diameter metal rod with a 1-3/4" diameter metal disc soldered to one end. The disc is necessary to provide a collar on the tube for attaching the tube to the bladder.

BLADDER FABRICATION

A polytetrafluoroethylene (TFE) spray, dry release agent is applied to both dipping models. The model for the filling tube is then placed in a 100°C oven for approximately ten minutes. Preheating this model prior to dipping it in the terpolymer latex prevents shrinking and cracking of the latex film during the curing phase at the rather severe angle where the metal disc and rod have been soldered together. Preheating the bladder model is not necessary. The bladder model is dipped into the coagulant and air dried for several minutes to allow the excess coagulant to drip off. With a wire hook inserted into the handle, the model is then smoothly dipped into the liquid terpolymer where it is suspended for 90 seconds. (Fig. 4).

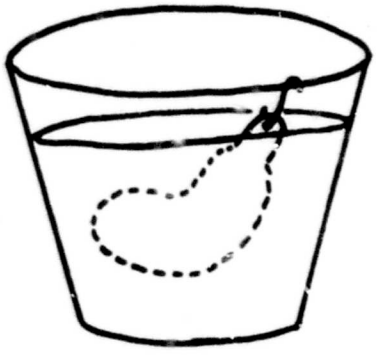

Fig. 4

This dwell time provides a film thickness of 13 mils + 2 mils; less dwell time will create a thinner film and vice versa. The terpolymer coated model is carefully removed and immediately freely suspended in a 60°C oven to cure for one hour.

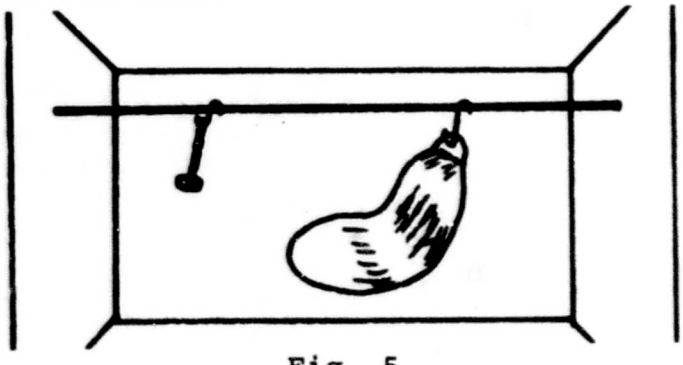

Fig. 5

The filling tube model is removed from the oven and the same procedure is followed except that the excess coagulant must be rapidly blotted off around the periphery of the metal disc and then immediately submerged in the terpolymer latex for a 90 second dwell. If these steps are not completed rapidly, the model may cool off to such an extent that shrinkage and cracking of the film will occur as the terpolymer cures.

During the oven cure, the milky white appearance of the terpolymer will be lost and the film will become translucent as the water is driven off.

For ease in removing the film from the models, they should be immersed in water for approximately ten minutes. The water, in this case, will be partially resorbed into the film and act as a plasticizer permitting greater ease in removing the cured terpolymer latex from the dipping models. When the film has been carefully removed from the dipping model, it must be placed in water for at least 18 hours to leach or wash out all of the soap, coagulant, and any other impurities which might be present in the film. The gusset (end closure) is formed on the same dipping model, however, the film is cast on only one half of the model. (Fig. 6).

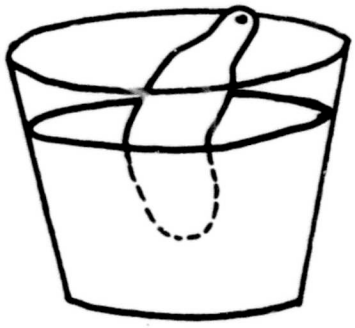

Fig. 6

This "half" bladder will be used in sealing the open end of the full size bladder.

Using a sharp knife or scalpel, the terpolymer is cut away from the bottom portion of the metal disc on the filling tube dipping model (Fig. 7)

Fig. 7

and the film is gently slipped over the end of the rod. (Fig. 8)

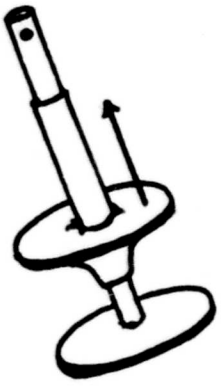

Fig. 8

After these three parts have been thoroughly washed of impurities, they are air dried for approximately one hour. An attempt should be made to prevent the sides of the latex parts from touching during air drying and the final oven cure, since they will tend to adhere to each other quite tenaciously. This can be done by using spring binder clips to which a wire hook has been attached and suspending the bladder parts from a wire or string - "clothes line fashion." After this air cure, the three

latex parts - the full size bladder, half bladder, and air inlet tube - are placed in an air circulating oven at 100°C for the final thirty minute cure. Upon removal from the oven, the parts are ready to be assembled to form the inflatable bladder.

ASSEMBLY

Using the closed end as a guide, the bladder is folded in half and the open end is cut to match the closed end. (Fig. 9)

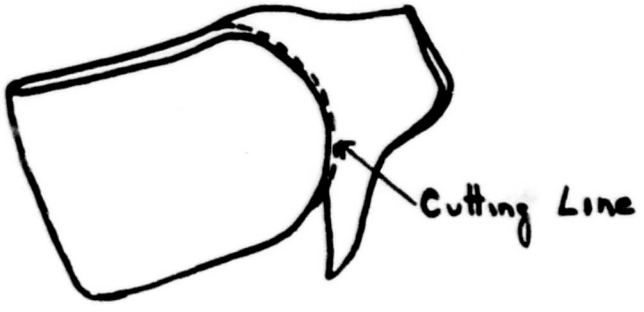

Fig. 9

Although the air inlet tube can be placed in any position on the anterior wall of the bladder, we have found that it is much easier for the patient to inflate the appliance if it is located near the center. A 5/16" hole is cut in the anterior wall with a hand punch or cork borer. A thin film of the liquid

terpolymer latex is spread on the collar of the air filling tube and the tube is drawn through the opening from the inside of the bladder to the outside. (Fig. 10).

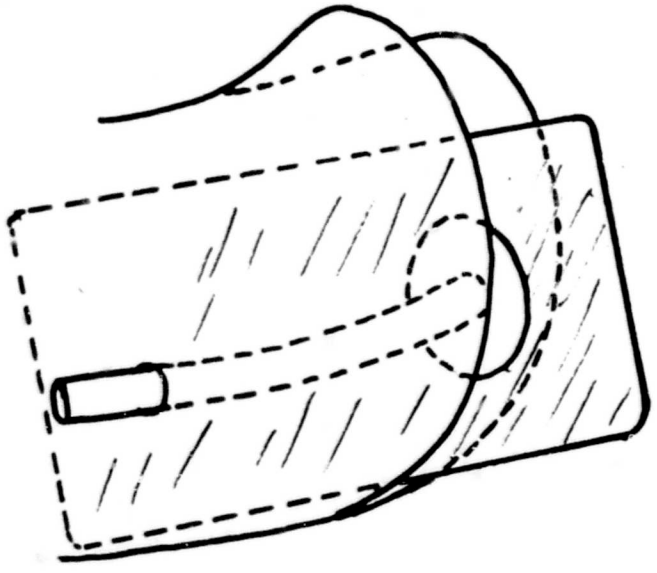

Fig. 10

A small piece of polyethylene film (4" x 4") is put between the air inlet tube collar and the inside posterior wall of the bladder to prevent the anterior and posterior walls from accidentally being glued to each other. Two aluminum plates approximately 3" square, one of which has a hole 5/16" in diameter in its center through which the air inlet tube can protrude, are placed over the collar area. Two or three thicknesses of fabric or gauze should be placed between the posterior wall of the bladder and the aluminum plate prior to applying pressure to the plates. The

fabric will provide a more even distribution of pressure while preventing the possibility of cutting the latex bladder when pressure is applied to the metal plates. Gentle pressure is applied to the metal plates for approximately four hours in a bench vise, "C" clamp, lock grip pliers, etc. (Fig. 11).

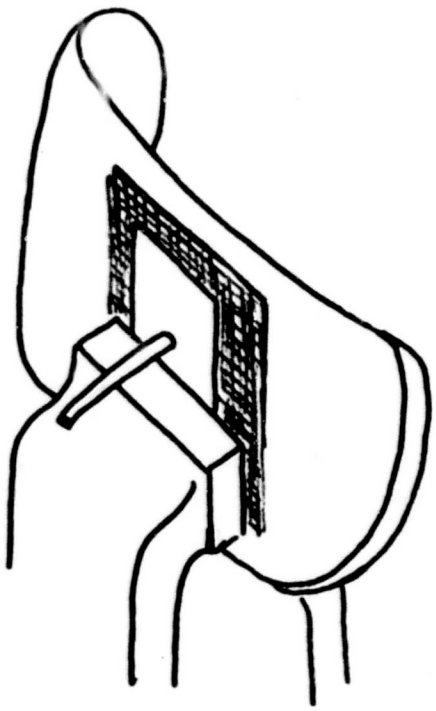

Fig. 11

When the bladder is removed from the vise, the metal plates, polyethylene film and fabric are removed.

Using the open end of the bladder as a guide, the gusset portion is cut so that it will extend inside the bladder at least 3/4" toward the bladder center following the contour of the periphery of the open end of the bladder. (Fig. 12).

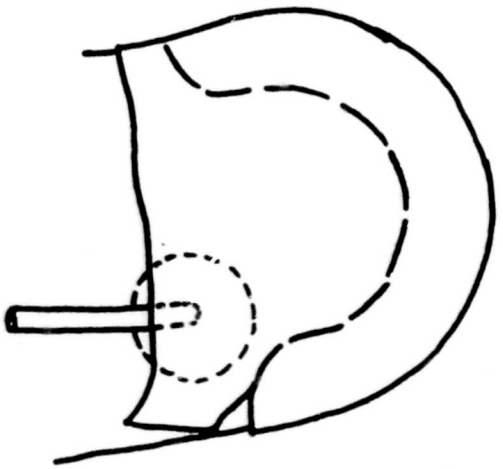

Fig. 12

Care must be taken to be sure that the air inlet valve will not be accidentally occluded by the gusset when the bladder is sealed. When the gusset is placed in position between the anterior and posterior walls of the bladder, it should protrude approximately 1/8" beyond the cut edge of the bladder so that a good edge seal and smooth end surface can be obtained. A film of terpolymer is applied to the contact surfaces and the gusset is slipped in position inside the end of the bladder. (Fig. 13). Two pieces of polyethylene

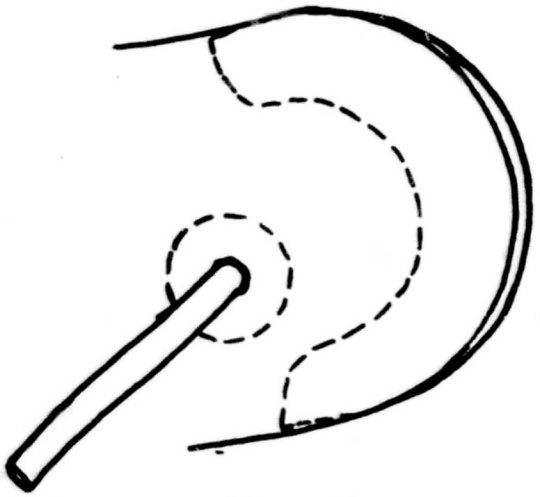

Fig. 13

film are placed over the area and several thicknesses of fabric or gauze are placed over the polyethylene film. Two aluminum plates of sufficient size to cover the entire area are placed against the fabric and pressure is applied for at least four hours.

Insertion of the air valve into the filling tube can now be started.

The length of the air filling tube is optional. Approximately one inch seems to be quite satisfactory. A thin coat of liquid terpolymer is applied to the base of the metal air valve. (Fig. 14).

Fig. 14

The air filling tube is stretched open with a suitable instrument such as a half round needle nose pliers and the valve is slipped into the filling tube. When the filling tube is properly positioned around the valve, a film of terpolymer is applied to the surface. Three individual pieces of thread are taken around the valve base, tied securely, and another coat of terpolymer is applied. (Fig. 15). This will help to prevent the

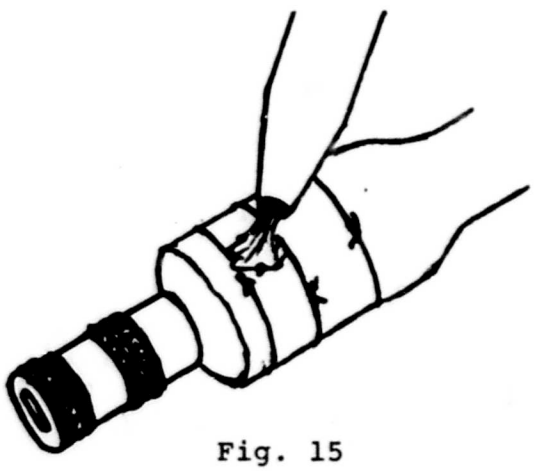

Fig. 15

valve from being accidentally dislodged from the inlet tube and also will insure an air tight seal.

After the metal plates are removed from the gusset area, it may be necessary to air cure the bladder for several more hours to insure complete evaporation of the water from the terpolymer latex which was used as the adhesive. The adhesive bond will be quite weak until this occurs. However, at this time the bladder should be gently inflated and those parts of the bladder which may have adhered to each other, due to some of the terpolymer having been forced into the bladder interior when pressure was applied to the gusset area, carefully separated. If there are any areas where a complete seal has not been obtained, a light application of the terpolymer should be applied. Air curing of the terpolymer latex will be complete when the milky white appearance has disappeared.

To be absolutely certain that the bladder is air tight, it should be inflated and held under water while gentle pressure is applied. Any tiny pinholes through which air is escaping must be sealed before the final finishing steps are started.

The tacky feel of the bladder and its strong tendency to adhere to itself can be obviated by forcing talcum powder into the bladder interior. With the air valve in the open position, the tip of a plastic squeeze bottle is placed in the valve stem and the talc is forced into the bladder. (Fig. 16).

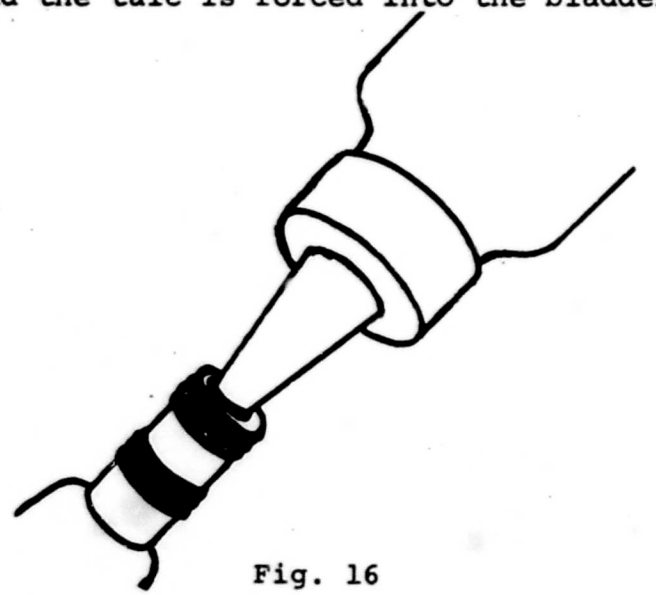

Fig. 16

Manipulation of the bladder will distribute the talc over the interior surface of the bladder. The exterior portion is powdered by putting talc on the hands and gently distributing it over the bladder surface.

Excess material such as droplets of terpolymer which may have formed during the dipping procedure and all rough surfaces can be removed by gently sanding with rotary equipment using an arbor and fine grit band.

DONNING THE APPLIANCE

A Myo Cervical Collar of appropriate size is fitted to the patient so that the desirable degree of neck extension is obtained. When the collar is adjusted, it is removed from the patient and a hole is cut or punched in the collar where the air inlet valve will protrude. The bladder is positioned on the collar with the air valve placed through the opening and the appliance fitted to the patient. Care should be taken to be sure that there are no creases or wrinkles in the bladder surface touching the skin. These will tend to cause blister formation over a period of several hours.

The bladder is inflated with a hand atomizer bulb adapted with a length of flexible tubing (Fig. 17a) which can be easily fitted over the valve stem or a threaded metal adaptor which can be screwed into the valve stem. (Fig. 17b).

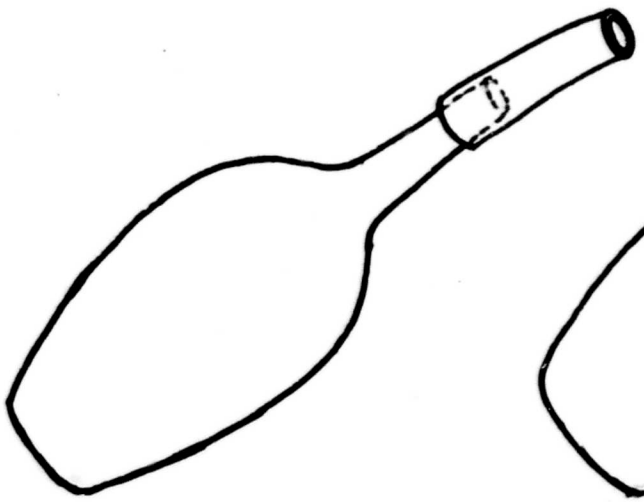

Fig. 17a

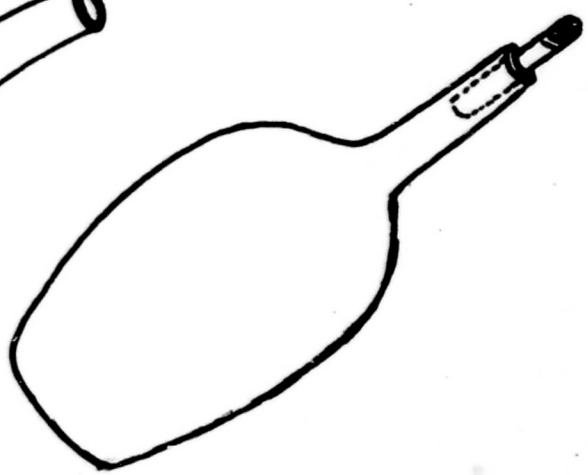

Fig. 17b

DISCUSSION

The technic for fabricating a latex inflatable bladder to be used in conjunction with the commercially available Myo Cervical Collar has been described in detail. Although the appliance described in this report has been designed for use as an adjunct to surgical prevention and treatment of cervical scar contracture,[6] the technic can be used equally well for other inflatable bladder designs.

The total fabrication time for this technic spans a period of two days, however, the initial steps of dipping, curing and removing the films from the models only requires approximately 1-1/2 hours and about twenty minutes of actual working time. Even with just one set of dipping models several parts can be fabricated in a one day period. The parts can be thoroughly washed overnight and the remaining fabrication procedures completed the second day.

The latex material used is one which is both simple to manipulate and possesses excellent physical properties for this type of application. If a puncture should occur in the bladder, a small amount of the liquid terpolymer latex can be applied to the area. Several hours of air curing will provide an excellent seal.

If necessary, the bladders can be sterilized by standard autoclave procedures. To insure internal sterilization of the bladder and to prevent it from bursting if a vacuum is employed, the air valve must be in the open position and the inlet tube in a flat, uncrimped position.

Because of the dynamic nature of this appliance, a rather small assortment of sizes of both the collars and the bladders can be shelf stocked for ready availability to meet patient requirements.

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MATERIALS

Terpolymer latex and polyethylmethacrylate (Polyderm)-

Polysciences, Inc.
2777 Philmont Ave.
Bethayres, Penna. 19006

Formaldehyde - chemical supply company.

Coagulant (calcium nitrate and denatured alcohol) -

chemical supply company

Air Valve #40-AS -

Halkey-Roberts Corporation
Spring Valley Avenue
Paramus, New Jersey 07652

Myo Cervical Collar - orthopedic supply company.

Release Agent - MS-122 Fluorocarbon -

Miller-Stephenson Chemical Co., Inc.
445 North Lake Shore Drive
Chicago, Illinois 60611

Atomizer Bulb -

The DeVilbiss Co.
Somerset, Penna. 15501

3/32" sheet aluminum

1/4" metal rod

Wire hooks

Thread

UNCLASSIFIED

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Walter Reed Army Medical Center
Washington, D.C. 20012

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Douglas K. Ousterhout, Captain, MC

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13. ABSTRACT

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