Silicone Implants for Velopharyngeal Incompetence: A Progress Report

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Nasal emission in speech secondary to inadequate velopharyngeal valving is most commonly observed in patients who have had a cleft palate repair. It is also observed where the palate is congenitally deficient in length, where the palate's musculature is inactive, where the pharyngeal vault is excessively deep, or where the pharyngeal muscle motion is poor. In an attempt to correct this condition we have implanted in the posterior pharynx an inert silicone, Silastic[1], to narrow the velopharyngeal orifice. Having reported earlier on the tissue tolerance of Silastic in experimental animals (*12*) and on the use of various forms of Silastic as pharyngeal implants (*3*), we present this paper as a progress report and evaluation of recent results.

The pharyngoplasty concept is indeed old. Passavant in 1879 is said to have first elevated a pharyngeal flap to decrease nasal emission (*2*). In 1900 Gersuny (*5*) injected vaseline into the posterior pharynx with good speech results, but with disaster overtaking these patients from embolic phenomena. Eckstein (*4*) in 1904 injected paraffin into the posterior pharyngeal wall with apparent success, and in 1912 Hollweg and Perthes (*7*) reported transplantation of autogenous costal cartilage behind the mucous membrane and musculature of the posterior pharyngeal wall through a cervical approach behind the sternocleidomastoid muscle. Von Gaza (*13*) in 1926 reported good speech improvement with five fat grafts using an external approach.

Lando (*9*) in 1950 is credited with having introduced homogenous cartilage through the transoral route into the posterior pharynx wall with good speech results. But Hagerty and Hill (*6*) made the most significant contribution in this field when they traced the history of posterior pharyngeal implant with accuracy and reported in excellent detail twenty cartilage grafts to the posterior pharynx wall transorally in post-operative cleft palate patients. Their results indicated that foreward displacement of the pharyngeal wall is an effective procedure for improving velopharyngeal contact and speech.

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[1] Silastic is the trade name for silicone rubber manufactured by Dow Corning Corporation, Midland, Michigan.

Implant Materials

Pharyngeal implant tissues, both homogenous and autogenous, have exhibited a tendency to absorb. We implanted two dermofat grafts from the buttocks with fair initial results but with ensuing absorption. A preserved cartilage graft to the posterior pharynx gave an excellent primary speech result but there was absorption after one year and a resulting loss of speech correction. In a patient with polydactylism, two supernumerary digits were amputated, divested of skin and nail, and placed in the pervertebral pharyngeal space with good early speech correction. But an inert implant, we believed, would avoid the disadvantage of absorption.

The silicones seem to approach being the perfect inert substitute for autogenous tissue, having distinct advantages over any other plastic material. Silastic has the low density and softness of normal soft tissue. It is virtually free from tissue reaction and allergic response, is readily available in medical grade in various forms, and it can be shaped and worked without special equipment (*1*). Chemically, the silicone rubbers are polymers of dimethylsiloxane to which fillers may be added to vary consistency and increase strength. Cross-linkages occur between chains of polymers and the result is silicone rubber (see Figure 1). Dow Corning has carefully labelled non-toxic polymers "medical grade" but *it is important to remember that not all silicone rubbers are tolerated in tissue.* We have used the following types of Silastic as pharyngeal implants, all of which can be autoclaved.

A. Solid: medical Silastic 372 (medium) or S-6508 (soft)
B. Shredded: medical Silastic 372 (medium)

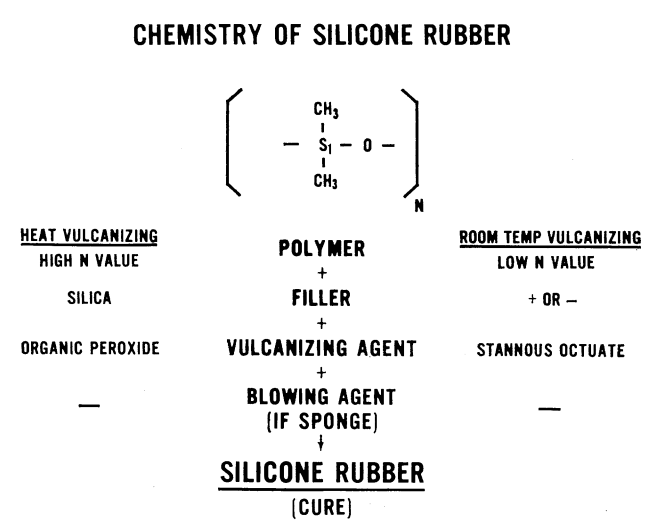

FIGURE 1. Silicone rubbers are polymers of dimethylsiloxane with a catalyst activating cross-linkage between molecules.

C. Sponge, coarse: S-9711
D. RTV Fluid: S-5392 with stannous octuate catalyst

Method

Twenty-seven patients received implants. These patients ranged in age from three to 31 years; the mean age was 10.3 years.

In 10 patients of the series the Silastic pharyngeal implant was utilized alone. In the remaining 17 patients, simple suture of separated posterior palatal muscle bundles augmented the velopharyngeal closure.

The following techniques were used for the various types of implants.

Solid Silastic. Implants of this material were carved in various sizes prior to surgery, with preference for a virtually oval implant having well-rounded margins and deep grooves on the posterior surface to help hold it fixed in the tissues. Implants were carved to a thickness of 6 to 10 mm and inserted through a vertical incision on the lateral posterior pharyngeal wall into a pocket prepared *beneath* the pharyngeal musculature (Figure 2). A solution of 1% Xylocaine with 1:100,000 epinephrine was injected for hemostasis, and the wound closed with 4-0 chromic sutures. The implant was placed just above the level of the atlas tubercle.

Shredded Silastic. This medium is merely the solid variety put through a shredding machine at the Dow Corning Corporation plant. We reasoned that this material placed in a posterior pharyngeal pocket would remain better fixed in position by invading fibroblasts. The shredded silicone rubber did prove difficult to handle but could be packed successfully into a pocket beneath the posterior pharyngeal musculature in sufficient quantity to give adequate correction.

Coarse Sponge Silastic. The sponge Silastic was inserted in a similar location utilizing a similar technique.

RTV Fluid Silastic. This fluid Silastic was administered by simple injection just above the atlas level. To about 10 cc RTV Fluid we added 2 to 3 drops of stannous octuate catalyst (all previously autoclaved) and stirred it briefly. The activated fluid was transferred rapidly to a 10 cc B–D Lok Control Syringe with metal rings. About 4 to 7 cc of the material was then injected through a ⅌17 angled needle or inserted through a polyethelene catheter into a previously prepared pocket. The "set-up time" varied with the batch but averaged around 10 minutes (Figures 3 and 4).

Results

Of the 27 patients receiving implant, 81% displayed no tissue reaction (Table 1). The oldest implant was free from reaction after 25 months.

The solid Silastic implants have been well tolerated and have given, in general, a fairly good speech correction. We have not seen any migration of the implants to date, but movement in the prevertebral space over a

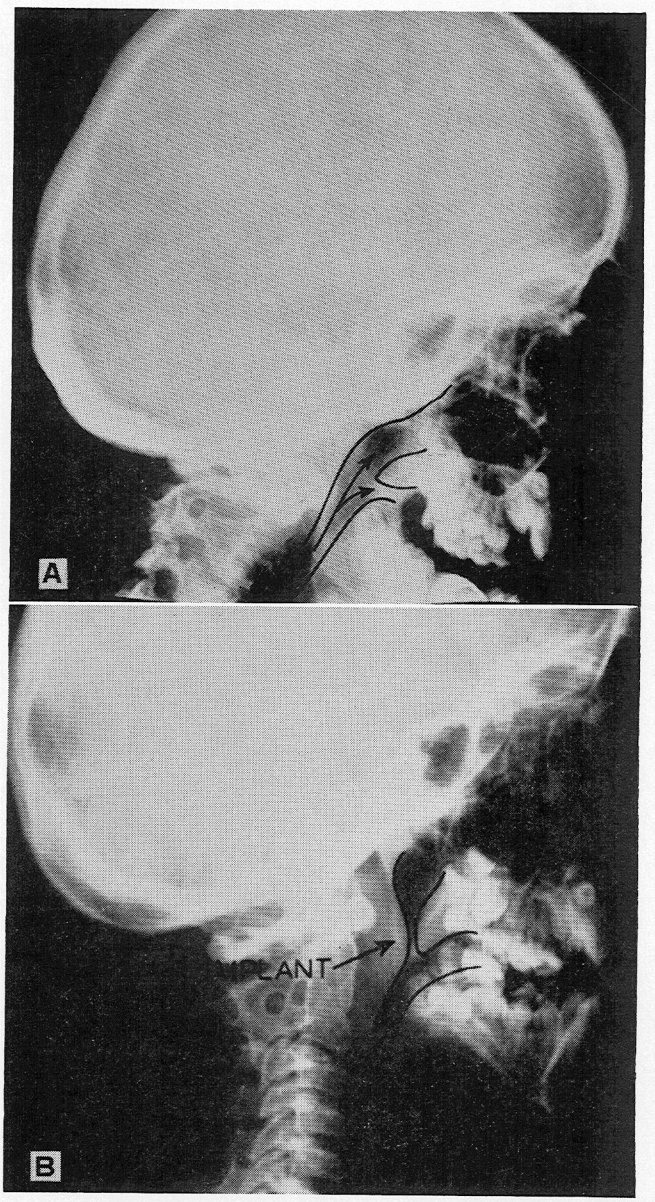

FIGURE 2A. Post-operative cleft palate with nasal emission during phonation.
FIGURE 2B. Silastic implant in position during phonation making possible complete closure of velopharyngeal orifice. A good speech result was obtained.

period of times remains a possibility. The oldest solid implant has been in position for a period of 24 months.

The shredded Silastic was well tolerated by tissue when fine shreds were used, but tended to extrude itself when coarse pieces were embedded.

In one case there was incomplete loss of the implant after two months with pieces extruded but no loss of speech correction. In another, a virtually complete loss of the shredded implant resulted in total loss of the speech correction 18 months after surgery. None of the fine shredded implants were extruded, but they did show some shrinkage into a firm, somewhat circular mass. The oldest shredded implant has been in position 26 months. Speech correction has been generally good in this group, and excellent in two cases.

The sponge Silastic was used in only one patient with excellent early results but with subsequent infection and extrusion after five months.

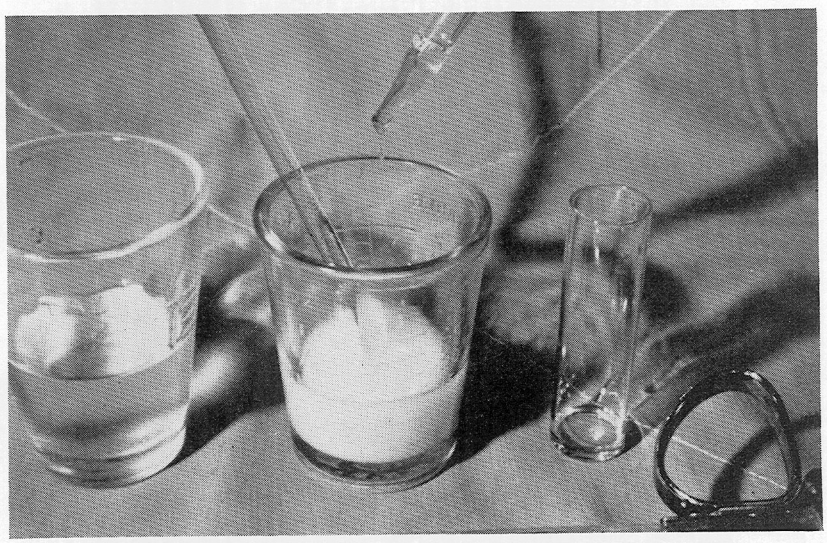

FIGURE 3A. Stannous octuate catalyst is added to RTV Fluid Silastic S-5392.

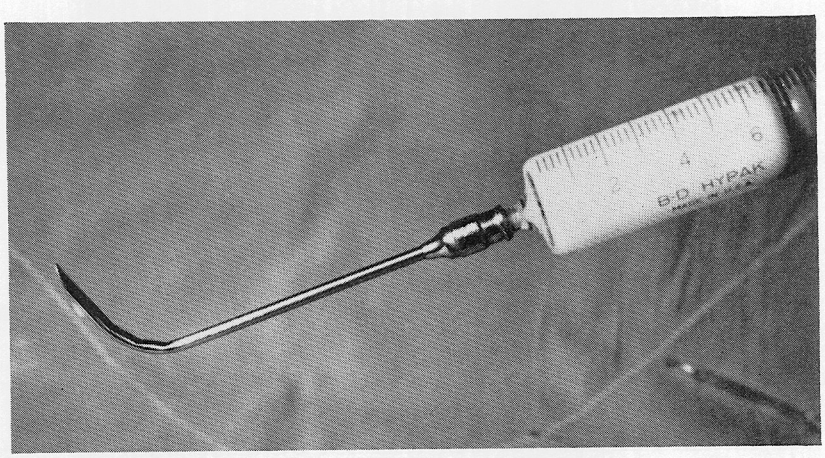

FIGURE 3B. The activated fluid is placed swiftly in a 10 cc syringe and injected.

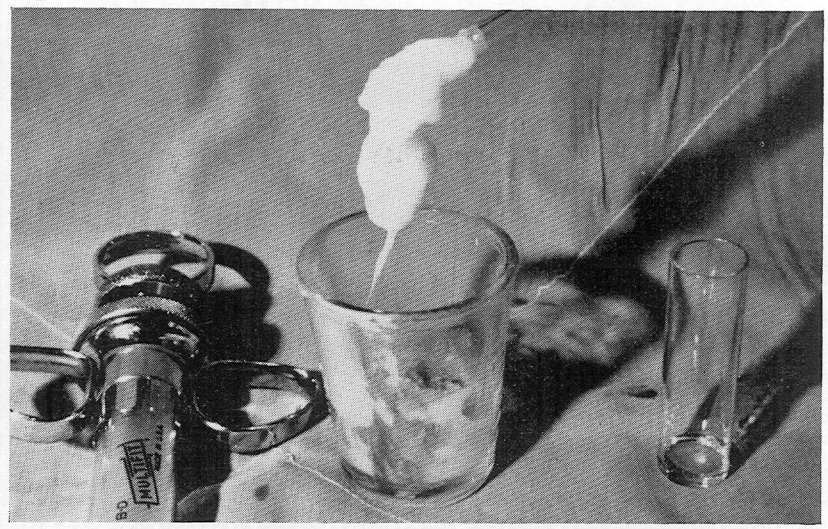

FIGURE 3C. After 10 minutes the fluid has vulcanized into a rubbery mass well tolerated by tissues.

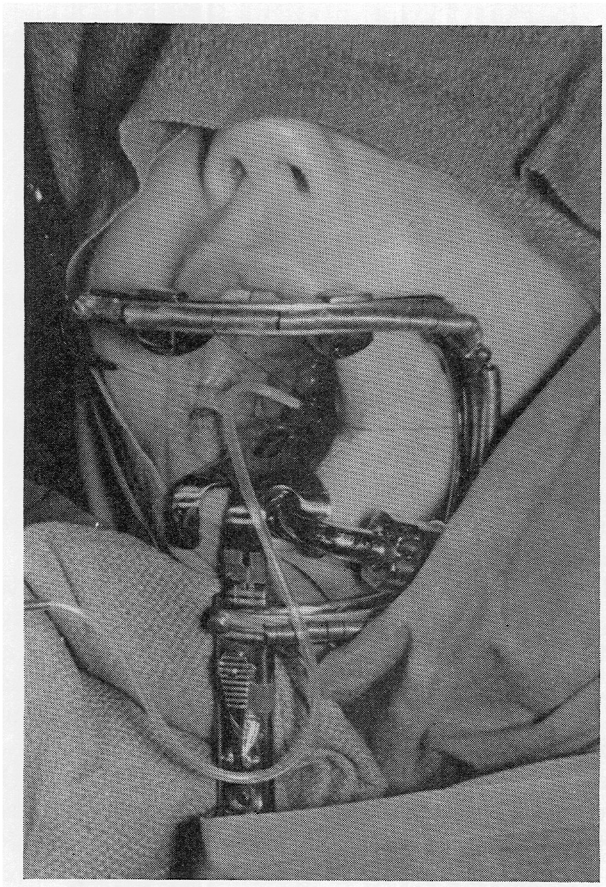

FIGURE 4. Injection of activated fluid Silastic into previously prepared pocket using polyethylene tube.

TABLE 1. Incidence of tissue reaction to various types ot implants.

Type of Implant	*N*	*Tissue Reaction*
Solid	5	0
Shredded	9	2 partial loss
Sponge	1	1 complete loss
Fluid	12	2 complete loss
Total	27	5

TABLE 2. Speech ratings after implant.

Ratings	*N*
Excellent (near normal)	3
Good (some degree of residual nasal emission)	13
Fair (moderate improvement)	7
Failures (no improvement)	4
Total	27

Pre-operative speech characterized by severe nasal emission recurred. We agreed to a second correction using the RTV.

Evaluation of the fluid Silastic seven months post-operatively showed no reaction and a satisfactory speech correction.

The RTV fluid Silastic was simplest to insert but most difficult to control. By adding a small amount of barium to one quantity of the fluid Silastic we observed its dissemination downward along the prevertebral fascia in post-operative lateral pharyngeal x-rays. In later work a small pocket was formed by enucleation scissors dissection and the RTV fluid deposited by ℀17 polyethelene catheter. Of the 12 patients treated by this method, two achieved an excellent speech result. Six were improved, but exhibited articulation defects and residual nasal emission, and four were rated as failures. Of the latter, two extruded the implant: one after four months with a severe case of measles, and one after six months with no known cause (Table 2).

In general, the patients respond swiftly to the interest of the surgeon and his team in improved attitudes and social adjustment. Psychological improvement was generally out of proportion to the degree of speech correction, many of these patients losing a good deal of shyness and introversion. Where excellent correction was obtained, personality improvement was dramatic.

Speech measurement was difficult for us to achieve accurately and objectively. We did not have the facilities to conduct complicated analyses comparable to those of Hagerty and Hill (*6*). Our chief objective was the elimination of characteristic nasal emission in speech, turning to the speech therapist for correction of persistant habitual articulation errors.

Routine lateral pharyngeal x-ray films and tape recordings obtained before and after surgery assisted in assessing results.

Discussion

It is important to note that foreign body reactions have disturbed the early favorable speech results in five out of 27 patients in this series. It is reasonable to expect additional rejection reactions in the future. The routine use of Silastic in the posterior pharynx as a corrective procedure in velopharyngeal incompetence is not deemed advisable and further observation is necessary to determine the extent of its future usefulness.

The implant technique of bringing the posterior pharyngeal wall forward has usefulness that appears limited to those patients with good lateral pharyngeal motion or good palatal motion. There must be at least a limited amount of muscular valving activity to take advantage of the anterior projection created by the implant or little improvement can be anticipated. The posterior pharyngeal flap has a definite usefulness where the palate is immobile and the pharyngeal vault very deep (*10*). The Hynes pharyngoplasty has proved extremely useful in cases that require narrowing of the pharyngeal isthmus not greater than one centimeter (*8*).

More than ever a study of this group of patients emphasized the necessity for a technically excellent, atraumatic primary cleft palate repair employing a method that yields as little scar as possible. We agree heartily with Mr. J. P. Reidy when he states that the repair of a palatal cleft should be performed only by trained and experienced surgeons constantly in practice (*11*).

Summary

A study of 27 patients whose velopharyngeal incompetence was treated by a variety of retropharyngeal Silastic implants is presented. Speech improvement of various extents was observed in 23 of those patients. Foreign body reactions have occurred in five of the patients. The types of implants used were described in detail and limitations of the technique were discussed.

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Acknowledgments

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Editor's Note: Dr. Blocksma has requested that Dr. Peter Randall (University of Pennsylvania) comment about the preceding paper. The following are Dr. Randall's remarks.

This work by Dr. Blocksma is very interesting indeed. Posterior pharyngeal implants are not new, but the use of this new material opens up possibilities that may have considerable promise. Frankly, I am somewhat concerned about the possibility of this material migrating from the site of injection, but if it can be shown that it will stay pretty much where it is originally inserted and not erode the overlying mucosa, it may well prove to be a very simplified and effective method of treatment.

At first, I was delighted to see that this was being carried out in such a careful manner and in such competent hands, but then in the middle of Dr. Blocksma's presentation he mentioned a step which throws a monkey wrench into the entire project. It may be a little one, but I think we should be particularly careful of these things, and if possible avoid them at all costs.

In this project Dr. Blocksma is evaluating the effect of a single procedure on the improvement of speech. In his presentation he mentioned that on some of these patients he also carried out a modified palatalplasty as well. This was a minor procedure, but I think we should be very careful if we are evaluating a particular operation to keep this operation as "pure" as possible. In other words, we really cannot be sure if the improvement that he reports is due entirely to the implant, or due partially to the palatalplasty as well. So, I certainly hope that in the future he will try to do nothing more than the insertion of the implant so that we can judge this very fine series of patients in the best possible way.

I might add that this takes considerable intestinal fortitude because each patient is a separate individual with a severe problem, and any surgeon would want to do the most he possibly could for that person if they are undergoing a surgical procedure. We will certainly watch this work and look forward to hearing from Dr. Blocksma again.

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