A Long Term Study on Treating Velopharyngeal Insufficiency By Teflon Injection

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Thirty-five individuals with velopharyngeal insufficiency, including eight with failed pharyngeal flaps, were treated with injectable Teflon and followed postoperatively for an average of three years. The patients' speech and voice quality were evaluated pre- and postoperatively, and an outcome was judged successful only if there was total elimination of the preoperative symptoms of hypernasality and inappropriate nasal air emission. All patients were evaluated preoperatively with cinefluorography, and an attempt was made to obtain serial postoperative films in order to determine the stability of the Teflon pad with time.

An overall success rate of 74% was achieved. Success for patients with VPI, excluding those patients with pharyngeal flaps was 78%. In treating the failed pharyngeal flap cases we achieved a 62% success rate. The stability of the implanted Teflon was assessed over time as determined from measurements made on patients who received two or more postoperative cine films. Statistical analysis revealed no significant change in thickness of the pad over a period of time. Our conclusions are that with careful case selection, the injectable Teflon procedure is safe, effective and that the implant remains stable with time.

KEY WORDS: Velopharyngeal Insufficiency, Teflon, speech, hypernasality, nasal emission, cinefluorography

Introduction

With modern surgical techniques, the majority of infants with cleft palate have adequate velopharyngeal function for normal speech after the primary surgical procedure. However, there remain a large number of individuals born with cleft palate who do not achieve successful velopharyngeal closure following primary palatal repair. In addition, there are those who manifest symptoms of velopharyngeal insufficiency (VPI) due to such conditions as an abnormally deep nasopharynx, short palate, anomalies of the cervical vertebrae and anomalies in the point of insertion of the levator palatini muscles. These individuals often present a problem in diagnosis and subsequent management.

Of the numerous secondary procedures for correcting VPI, the technique of augmenting the posterior pharyngeal wall has received and continues to receive considerable attention. Such augmentation has been attempted by the implantation in the posterior pharyngeal wall of a number of different materials.
including paraffin (Eckstein, 1904), cartilage (Hagerty and Hill, 1961), and silicone (Blocksma, 1963) to name several. The basic intent of this type of procedure is to construct a pad or bulge in the posterior pharyngeal wall at approximately the level of the atlas against which the velum can make contact. The resultant reduction in the depth of the nasopharynx provides a smaller velar port area to be obturated during the production of speech.

Teflon has been used as an implant material since 1962, when Arnold first injected it into the lateral portion of a paralyzed vocal cord. Shortly thereafter, Lewy et al., (1965) reported the injection of Teflon into the posterior pharyngeal wall of a 15-year-old female who had a history of hypernasal speech and nasal air escape. They reported that voice quality improved following the implant. Bluestone et al., (1968) reporting on a series of 12 patients, noted that all had improvement in their nasality ratings with five of the patients having speech approximating normalcy. In 1969, Blocksma and Braley surveyed several hundred surgeons by a mail questionnaire. Of the 378 who responded, 47 reported performing retropharyngeal implantation on 372 patients, only 33 of whom had been treated by the Teflon injection technique. These 378 respondents reported that, of the 10 materials used in pharyngeal wall implants, there was a failure rate in long-term retention ranging from zero to 100% with Teflon having the zero percent failure rate. Since that time, most of the reported studies on retropharyngeal wall implants have used the injectable Teflon material technique.

In 1972, Sturim and Jacobs presented a comprehensive report on 23 patients with velopharyngeal insufficiency treated by Teflon injection who were studied for one year postoperatively. They reported that, of their 23 patients, 12 were considered to have good results, 10 were improved and one was unchanged. In 1977, Smith and McCabe reported on a series of 80 patients treated with Teflon injection for minimal velopharyngeal insufficiency. They found that 60% were judged postoperatively to have good voice quality and 19% had improved voice with less marked hypernasality. Keuhn and Van DeMark (1978) assessing the postoperative results of 69 patients treated with injectable Teflon concluded that velopharyngeal competency for speech improves as a function of time but that subjects demonstrating preoperative gaps of two millimeters or more should not be considered for the implant technique.

Although the literature is generally supportive of the Teflon injection technique, there appear to be several areas of uncertainty or contradiction with respect to which patients will optimally benefit from this procedure. The problems in comparing the literature appear to be related to such factors as the criteria for patient selection, the definition of a successful outcome and the fate of the individual’s speech as well as the fate of the pad created by the implanted material with time. The purpose of this paper is to report on the outcome of a longitudinal study of 35 patients in whom Teflon injection was used to treat velopharyngeal insufficiency. Specifically, this study has attempted to address the following questions:

1. What are the criteria to be used in selecting patients for the Teflon injection procedure?
2. What was the long term outcome on the patient’s speech?
3. What has been the long term stability of the implanted Teflon?
4. Did the patient’s age or etiology of their VPI affect the success rate of the procedure?
5. What were the medical complications of the procedure?
6. For those patients who were not improved by one injection, were additional implants successful?
7. What can be done for those patients who fail to respond to this technique?
8. For patients with a failed pharyngeal flap, can Teflon satisfactorily reduce the size of the lateral ports allowing for normal speech?

Sample

The 35 patients included in this study were selected without regard to the etiology of their velopharyngeal insufficiency. The group was made up of 21 males and 14 females. The mean group age at the time of first injection
was 14 years with a range of four to 41 years. Twenty-five of the patients (12 with repaired cleft palate) had symptoms of VPI but had not undergone any secondary surgical procedures. Eight patients had been previously treated by a pharyngeal flap but still demonstrated hypernasality and nasal air emission. The two other patients included in the study had unusual medical conditions which led to VPI.

**Group 1-General VPI:** The criteria for selecting the 25 patients (15 males and 10 females) for Teflon injection versus other more traditional surgical procedures consisted of the following as determined by lateral cineradiographic analysis: (1) the existence of good velar movement during the production of connected speech, (2) appropriateness of the velar movement pattern to the speech sample, (3) a residual gap of 1 cm or less. This group of 25 patients consisted of three individuals with repaired cleft lip and palate, nine with repaired cleft palate, three with submucous cleft palate, and ten individuals who had or developed VPI from causes other than cleft of the palate. The mean group age was 10.5 years with a range of four to 22 years.

**Group 2-VPI Persisting after pharyngeal flap:** Eight patients had undergone pharyngeal flap procedures at least one year earlier for velopharyngeal insufficiency but continued to demonstrate inadequate closure. In these cases, panendoscopy proved to be a valuable diagnostic technique in determining the side of inadequacy as well as the optimal site for the implant. This group consisted of four males and four females. The mean age was 19 years with a range of 11 to 32 years.

**Group 3-Other:** Two adult males who did not fall into our previously stated categories were nonetheless treated by the implant procedure as our clinical judgment suggested that this procedure had a greater chance of success over other alternatives. One patient was a 24-year-old male with a life-long history of hypernasality and inappropriate nasal air emission secondary to mild dysarthria. The other was a 41-year-old male whose entire hard palate and upper jaw had been ablated because of osteogenic sarcoma. The structures had been reconstructed with a forehead flap. The soft palate was intact and mobile, but was retracted anteriorly by scar.

**Method**

**Preoperative Speech and Voice Assessment**

All 35 patients demonstrated consistent hypernasal voice quality and consistent inappropriate nasal air emission during conversational speech as determined by two speech pathologists. Objective quantification of the consistency of each patient’s hypernasality was determined by using the Cul-de-sac Test (Bzoch, 1979). This measure involves alternately pinching the nares closed and then leaving them open while the patient produces consonant-vowel-consonant words in which only non-nasal oral consonants are used. This procedure is carried out on 10 different words and any shift in resonance on a given word is evaluated as hypernasal. This provides a readily reproducible index of any change in the frequency of hypernasality over time. The assessment of inappropriate nasal air emission was also determined by two speech pathologists. Objective quantification was then established by determining the number of times a small paper paddle held under the nares moved while the patient produced 10 words containing 20 non-nasal plosive sounds. The success or failure of the Teflon procedure was dependent on the total elimination of these two clinical symptoms from the patient’s speech.

Patients with severe articulation disorders were not selected for this procedure as it is known that abnormal compensatory articulation habit patterns could affect our clinical tests for hypernasality and nasal emission.

We would like to note that although rating scales for assessing various dimensions of speech (articulation, resonance, and intelligibility) continue to be employed as research tools, we do not find them useful in terms of comparing results across studies. Although such tools are in fact a valid research method, their clinical applicability is often limited by time and staff.

**Radiographic Procedures**

Presurgical lateral cinefluorographic films were made on all patients except the eight who had a pharyngeal flap. Postsurgical films were obtained on 16 of the 27 patients without pharyngeal flaps. The speech samples con-
sisted of several sentences of increasing length. The sentence “In the evening Connie watches TV with me” was selected for detailed analysis because normative data on velopharyngeal function for 100 normal speakers exist for this sentence (Bzoch, 1968). The production of the speech sample required approximately one minute of fluoroscopy which resulted in no more than 4.9 Rads of localized radiation exposure to the patient. The site where the best attempt at closure was observed provided the basis for suggesting the optimal injection site of the Teflon material. Postsurgical films were obtained to assess location, size, and positional stability of the Teflon implant. For all films, tracings of the pertinent structures were made from the cinefluorographic image as projected on the screen of a Moviola Console Editor.

Presurgical Measurements: Velar function was assessed radiographically for each subject, and judgments were made by two speech pathologists relative to our previously stated criteria for velar function. From the presurgical film tracings the palatal plane was drawn as a line of reference. Parallel to the palatal plane a measurement was made from the tuberosity of the atlas to the anterior margin of the posterior pharyngeal wall. This measure served as a referant for assessing the amount of anterior displacement of the posterior wall following the Teflon implant. The size of the gap was measured at the point where the optimal attempt for closure was observed (Figure 1).

Postsurgical Measurements: Evaluation of velar movement and its appropriateness to the speech sample was again determined. From the postsurgical film tracings the amount of anterior displacement of the posterior pharyngeal wall was measured in the manner described under presurgical measurements (Figure 2). This measure was used to determine stability of the Teflon pad over time for those patients who had received more than one postoperative cine evaluation.

Surgical Procedure

Injectable Teflon paste consists of Teflon particles 50 to 100 microns in diameter suspended in glycerine resulting in a consistency similar to that of toothpaste. Teflon particles of this size are too large to be phagocytized and carried off in the lymphatics. After injection, the glycerine is absorbed leaving the Teflon particles to be individually encapsulated in scar. All injections were carried out by the senior author (L.T.F.).

Although the cinefluorographic film was always reviewed to determine the optimal level for advancing the posterior pharyngeal wall, in practice the injections were made as high as possible above the atlas for all patients.

1 The Teflon paste was supplied by the Ethicon Company of Somerville, New Jersey.
in this study. Adherence of mucosa directly to the basiocciput, and the presence of an adenoid pad limits higher injection and upward migration of the Teflon bulge. The pad, therefore, generally tends to enlarge inferiorly over the atlas as the material is injected. With the velum lifted on a ribbon retractor, injections were made at four to six sites transversely across the posterior pharynx to produce a ridge. The needle was moved in and out to infuse Teflon paste submucosally to submuscularly but not into the prevertebral fascia. A variable amount of Teflon was injected producing a transverse ridge which the relaxed velum would barely fall back against as determined from visual inspection while the patient was under anesthesia.

In the eight cases who had pharyngeal flaps, preoperative examination by indirect visual examination using a laryngeal mirror, oral panendoscopy, or both, identified the side and contour of the lateral port which did not close. Teflon paste was then injected posteriorly and laterally to just close the port.

The standard Lewy syringe devised for vocal cord injections and a long 19 gauge needle were used for injecting the Teflon material. Several of our early efforts to conduct the procedure under local anesthesia proved to be both inaccurate for the surgeon and uncomfortable for the patient, and subsequently general endotracheal anesthesia was used. Bluestone et al., (1968), also reported similar difficulties when conducting the procedure under local anesthesia.

In 17 of the 35 cases one injection procedure did not produce satisfactory results. For 10 of these 17 patients the procedure was repeated, and eight of these were successful. In the two cases where a second injection was unsuccessful, a third implant was also unsuccessful.

Confirming the reports of other investigators (Smith and McCabe, 1972; Ward, Stoudt and Goldman, 1967), complications resulting from the injections were minimal. All of our patients experienced a sore throat, a stiff neck, and some had a low grade fever. In one patient, the Teflon bolus extruded two weeks after injection. One patient experienced postoperative nausea and vomiting, dark urine and elevated enzymes suggestive of malignant hyperthermia but recovered without sequelae. One patient with anterior displacement of the posterior pharyngeal wall below the level of the atlas developed objectionable snoring and obstructive sleep apnea. This was caused by airway obstruction as the base of the tongue contacted the posterior pharyngeal wall during sleep. Resection of the Teflon inferior to the atlas, leaving the upper portion of the pad intact, relieved his symptoms without altering velopharyngeal competence.
There were no chronic infections and no identifiable acute infections. There were no deaths. Later surgical exposure of the injected material (three pharyngeal flap elevations and one partial Teflon pad excision) produced no problems with infection.

Results and Discussion

Speech

No attempt was made to scale the “goodness” or to subjectively scale degree of improvement of each individual’s speech and voice characteristics. The criteria for a successful outcome were the total elimination of hypernasal voice quality and total elimination of inappropriate nasal air emission during speech. Anything other than total elimination of the patient’s symptoms was counted as a failure. A 74% success rate (26 of 35) was achieved in this study. The disposition of the nine failures is discussed under the appropriate groups below. The 26 successful patients have been followed postoperatively for a mean of 36 months (range one to 96 months) with a median of 27.5 months. It is to be noted that an injection may not produce immediate elimination of the patient’s VPI, probably because of the inflammation, tissue distortion, and edema in the acute post-injection period. In this series, the 26 patients who were successes could achieve closure by two to three months after their final injection. None of these individuals, to our knowledge, has experienced any return of their preoperative symptoms.

Groups 1 and 3. VPI: Table 1 summarizes the success of the implant procedure relative to the size of the existing velopharyngeal gap for each of the five etiological categories. The overall success rate for these groups was 21 of the 27 patients or 78%. Fifteen successes were achieved with one injection, while six required two procedures.

Our success of 78% compares to Sturim and Jacob’s (1972) study in which they report finding a “good” speech result in 56% of their subjects following the Teflon implant. These authors define “good” as “... verbal communication which did not call attention to itself”. Although it is difficult to interpret Smith and McCabe’s (1977) data, they report “good voice quality” following Teflon injection in 60% of their sample. It is not clear whether this rating of “good voice quality” implies a total elimination of nasal air emission and a restoring of nasal resonance balance to normalcy. More recently, Keuhn and Van Demark (1978) used five judges to rate pre- and postoperative speech samples for their patients on a five point scale. Our interpretation of their results is that 64% of their patients were rated postoperatively as having, “... acceptable velopharyngeal competency for speech”.

We believe that there are several possible explanations that might account for our success rate which is higher in this group than has been reported in the literature to date. Judicious patient selection criteria were employed which emphasized good velar mobility and appropriate movement patterns of the velum relative to the speech sample as seen on lateral cineflouroscopy. Further, only patients without gross compensatory articulation patterns and with normal intelligence were selected for the implant technique.

Of the six failures in these two groups, four received one injection and two received three injections. Three, including one patient who had three injections and the patient whose Teflon was extruded, were subsequently successfully treated with a pharyngeal flap procedure. Two were lost to follow-up before additional injections could be carried out, and one was determined to be untreatable by any further means.

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Group 2. VPI After Pharyngeal Flap: Eight patients who had been previously treated by a pharyngeal flap but who demonstrated hypernasality and nasal air emission a year or more after the flap were considered as candidates for lateral port reduction by Teflon injection. Five (62%) were successfully treated, and three were failures.

Our success rate of 62% compares to the experience of Sturim and Jacob (1972) in treating three failed pharyngeal flap cases in which they report improved speech results for all three cases. In contrast to our definition of success, they define an “improved” result as “... hypernasality decreased and concomitant verbal communication skills improved but some residual degree of distortion was still apparent.” Three of the successes were achieved with one implant and two required two procedures. Of the three failures, one subsequently had a total revision of the pharyngeal flap, and two were lost to follow-up without further treatment.

TREATMENT SUCCESS RELATED TO THE SIZE OF THE GAP BEFORE TREATMENT

As can be seen in Table 1, there appeared to be no relationship between preinjection gap size and success. These findings differ from those reported by Blocksma and Braley (1969) who suggested that gap size should not exceed three-four millimeters. Keuhn and Van Demark (1978) report their highest success in patients with a gap of two millimeters or less. Our experience to date neither contradicts nor supports the statement of Ward et al. (1967) that there appears to be no limit to the size of the gap that can be successfully treated. We have no data for gaps over one centimeter. It is not clear why we had a lower success rate in the mid-gap range (three-eight millimeters), but we would conclude that it is attributable to variables other than gap size.

In preoperatively determining velar mobility and size of the velopharyngeal gap, we would disagree with Kuehn and Van Demark (1978) who suggested using the lateral still X-ray technique for preoperatively evaluating patients before a Teflon procedure. There is a large body of evidence that concludes that velopharyngeal function during sustained speech sounds for both normal and clinical subjects is not predictive of velopharyngeal function during speech (Bjork and Nylen, 1963; Shelton et al., 1964; Benson, 1972). Further, Williams and Eisenbach (1981) in a clinical sample, have reported finding an error rate of approximately 30% when comparing decisions of velopharyngeal closure made from the limited information provided by lateral still X-rays to the information obtained from lateral cinefluorography. Perhaps the wide range of differences noted in the literature suggesting the maximum size of the gap that can be successfully treated are due, in part, to the radiographic technique used and the speech sample employed in the initial appraisal of the subjects' velopharyngeal function.

TREATMENT SUCCESS RELATED TO ETIOLOGY

Our success rate for patients with repaired cleft palate was 75% (9/12). This compares favorably to the findings of Ward et al. (1967) who reported “excellent” or “good” results in 80% (4/5). However, our results contrast sharply with Sturim and Jacob (1972) who reported finding “good” results in only 36% (4/11) of their patients with repaired cleft palate. Their low success rate might be attributed, in part, to the fact that they did not reject patients preoperatively because of poor levator activity. Our success rate of 100% (3/3) in treating subjects with submucous cleft compares to the Ward et al. (1967) success rate of 88% (7/8) for this group. Our success rate of 80% (8/10) for the mixed cases of VPI not secondary to clefts compares with that reported by Ward et al. (1967) who achieved 60% (3/5) in non-cleft patients described as having “short palates”. Our success with this VPI group is higher than that of Sturim and Jacob (1972), who reported eight “good” results from a group of 12 individuals (67%) with VPI in the absence of any previous cleft.

Our generally higher success rates regardless of the etiology of the VPI may be attributed in part to our emphasis on presurgically determining the existence of velar mobility and appropriate velar movement during connected speech.

TREATMENT SUCCESS RELATED TO THE AGE OF THE PATIENT

Table 2 presents a summary of the success rate relative to the age of the patient and etiology of the VPI. Because of the small number of patients in each of the four age
groups, tests of difference were not carried out. However, our success rate in children under 11 was 88% compared to 60% in patients 12 and older. These findings agree with Blockma’s (1971) contention that younger patients are better candidates for pharyngeal implants than are older patients. However, it remains unclear to us why the procedure should not be equally successful in the older patient who meets stringent preoperative selection criteria.

**Implant Stability Related to Time**

Only 10 of our patients had two or more postoperative cines. The data on these subjects are presented without regard to the procedure’s ultimate success or failure as determined by the speech criteria. As can be seen in Table 3 the average time between the first and second postoperative cines was over three years. Although the mean difference in anterior displacement of the posterior pharyngeal wall suggests a decrease over time, there were in fact only three of the 10 patients who demonstrated a decrease while the other six remained essentially stable. A t-test for related data, as described by Weiner (1979), failed to reveal a significant difference at the 5% level of confidence ($t=1.406, p=.096$). This lack of a significant difference suggests that the thickness of the Teflon pad remains stable over time.

**Success of the Implant Technique Related to the Experience With the Technique**

As all 35 patients in this study were under the operative care of one surgeon (L.T.F.), we were able to evaluate the success rate of the procedure relative to the increase in operative experience. For our sample the first 18 patients underwent a total of 30 injection procedures with a patient success rate of 67% (12/18) but an injection success rate of only 40% (12/30). The final 17 patients received a total of 17 injections, which resulted in a
success rate both per patient and per injection of 82% (14/17). It is apparent that, in the last half of this series, our experience with the technique resulted in more effective treatment of individual patients as well as in a higher success rate per injection procedure.

Conclusions

There are several secondary surgical techniques available for the correction of velopharyngeal insufficiency. Although several studies have been conducted to evaluate the pharyngeal wall implant procedure using Teflon, little information has been available relative to long-term evaluation of either the technique or of the Teflon material. The results of this long-term study would suggest the following:

1. With careful patient selection emphasizing good velar mobility and appropriateness of the velar movement patterns for speech as determined by cinefluorography, the implant technique resulted in the total elimination of hypernasality and inappropriate nasal emission in 78% of the cases.

2. In this study patients without pharyngeal flap who were successfully treated demonstrated velopharyngeal closure two to three months postoperatively. To our knowledge none have experienced any return of their preoperative speech symptoms.

3. Measurements made of the Teflon pad from serial cinefluorographic films demonstrated no significant change in thickness with time.

4. The etiology of the VPI did not appear to be an important variable with respect to patient selection or to treatment success. In addition we found that patients between four and 11 years of age were more often successfully treated than were our older patients.

5. Medical complications were minimal. No deaths, chronic or acute postoperative infections were experienced. One patient experienced symptoms suggestive of malignant hyperthermia and another appears to have had a previously undiagnosed problem of sleep apnea unmasked.

6. If success was not achieved after two injections, further injections did not prove helpful.

7. For those patients who failed to achieve success by the implant procedure, no clinically significant limitations were encountered when another secondary procedure (pharyngeal flap) was performed.

8. In cases of a failed pharyngeal flap, lateral port reduction by injecting Teflon resulted in successfully treating 62% of the patients.

In addition to the original questions stated in the introduction our results would suggest that the size of the velopharyngeal gap in individuals with an otherwise functional velum did not appear to be critical to a successful outcome although our experience has been limited to the treatment of velopharyngeal gaps of one centimeter or less. The maximum gap that can be successfully treated has yet to be identified.

Summary

In summary, we believe that this study has further defined the efficacy of the pharyngeal wall implant technique as a clinically useful means for treating selected cases of velopharyngeal insufficiency. Although the concept of pharyngeal wall implants is not new, general acceptance has been delayed primarily for two reasons: 1) the lack of a physiologically compatible implant material and 2) the failure to identify the critical variables for selecting patients suitable for this procedure. This study, as well as others, would suggest that Teflon is a suitable implant material permitting the procedure to be tailored to the individual's specific problem. However, it is not our intention to imply that the success or failure of a pharyngeal wall implant is dependent upon injectable Teflon per se but, rather, that any implant material that is shown to be physiologically compatible and stable deserves consideration. Perhaps newer implant materials and refinement of the technique such as the Proplast pharyngeal wall implant (Wolford, 1980) will stimulate further interest and use of the implant procedure. In addition, we believe that this study has shown that, with the establishment of a stringent rationale for patient selection, a high degree of success can be expected.

In using the injectable Teflon, there are
several apparent advantages. Generally there is only a short period of anesthesia and only an overnight hospitalization with lower cost to the patient. If the injection is unsuccessful it can be repeated, and prior injections do not preclude further surgical procedures such as a pharyngeal flap. The procedure does not appear to alter the velopharyngeal closure mechanism and should not interfere with midfacial growth. The single major disadvantage is that the injection is "blind" and an error in placement involving intracorotid injection could be fatal. Not all VPI patients are candidates for this procedure, and the preoperative evaluation must include, in addition to diagnostic speech studies, a cine or videofluoroscopic evaluation of velopharyngeal function.

We are concerned with the apparent abandonment of the technique because of difficulties in the approval of specific injectable implant materials. We feel that there are a number of individuals who can be treated simply and effectively by the implant procedure and it is incumbent upon the professions to further development and approval of an injectable implant material.

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