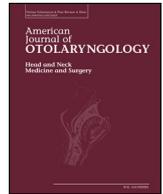




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# Novel treatment for mild and moderate velopharyngeal insufficiency using implantable AlloDerm for posterior pharyngeal wall augmentation and review of surgical repair techniques

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## ABSTRACT

**Purpose:** Mild and moderate velopharyngeal insufficiency is a relatively common structural defect of the velopharyngeal sphincter that occurs congenitally or secondarily to various medical conditions resulting in speech inadequacy. Currently, multiple surgical methods exist to treat mild and moderate velopharyngeal insufficiency; however, the revision rates are high and the outcomes are variable. This case series describes a novel technique using implantable AlloDerm to repair the posterior pharyngeal wall to treat mild and moderate velopharyngeal insufficiency.

**Materials and methods:** This paper presents four patients with mild or moderate velopharyngeal insufficiency who were treated with implantable AlloDerm in the posterior pharyngeal wall at a large, safety-net hospital in New England from 2000 to 2019. Additionally, a review of surgical repair techniques for velopharyngeal insufficiency was conducted with synthesis of a qualitative overview.

**Results:** There were sufficient follow-up data in three of these patients. All three reported subjective improvements in symptoms after the procedure. One patient had implant extrusion one month following the procedure with subsequent removal.

**Conclusion:** Ultimately, implantable AlloDerm for posterior pharyngeal wall augmentation is a useful, low risk method for treating mild to moderate velopharyngeal insufficiency.

## 1. Introduction

Velopharyngeal insufficiency (VPI) describes any structural defect of the velum or pharyngeal wall that prevents adequate closure of the sphincter between the oro- and nasopharynx. This is often secondary to insufficient tissue or mechanical interference, most commonly after cleft palate surgery [1]. About 20–42.5% of patients develop moderate to severe hypernasality after cleft palate repair [2,3]. Several factors determine the structural integrity of the velopharynx, including the length and mobility of the soft palate, movement of the lateral pharyngeal wall, and anterior movement of the posterior pharyngeal wall. Coordination of the soft palate with the pharynx is important for oronasal resonance. Inadequate function leads to VPI, which is a disorder related to speech intelligibility. Patients with VPI experience hypernasality and an increase in nasal air emission leading to a decrease in speech quality. This can lead to social and functional impairment [4].

VPI typically presents in children who have congenital, unrepaired cleft palate or have undergone primary surgery of the cleft palate which resulted in inadequate lengthening of the soft palate, scarring of the soft palate, or abnormal functioning of the levator musculature. Approximately 5–20% of cleft palate surgeries result in VPI [4]. Diagnosis begins with an evaluation by a speech-language pathologist (SLP) who can classify the disorder according to the Pittsburgh Weighted Speech Score (PWSS). PWSS quantitatively assesses five speech components commonly present in those with VPI. These include nasality, nasal emission, facial grimace, phonatory characteristics, and compensatory misarticulations. A score of 0 is interpreted as competent (no VPI), 1–2 is borderline competent (mild VPI), 3–6 is borderline incompetent (moderate VPI), and  $\geq 7$  is incompetent (severe VPI) [5]. Depending on severity of symptoms, video nasopharyngoscopy (VNP) and multiplanar videofluoroscopy (MPVF) are often utilized as subsequent diagnostic steps [6]. Depending on the degree of VPI and

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patient preferences, conservative management in collaboration with a SLP may be an initial step prior to surgical interventions.

Current surgical treatments for VPI are continually evolving and include pharyngoplasties, palate muscle repositioning, and posterior pharyngeal wall augmentation. Pharyngoplasties obstruct the nasopharyngeal port, and include techniques such as the pharyngeal flap pharyngoplasty and the sphincter pharyngoplasty. Palate muscle repositioning includes techniques such as the Furlow double-opposing z-platoplasty and the buccinator musculomucosal flap. Posterior wall augmentation utilizes alloplastic and autologous materials to create a closure of the velopharyngeal sphincter. In particular, posterior wall augmentation is generally reserved for mild to moderate VPI and offers a faster and potentially less morbid alternative to the technically challenging surgical treatments available.

AlloDerm, an acellular dermal matrix, has been shown to alleviate tension and reinforce tight closures during surgery [5]. AlloDerm has also been shown to regenerate tissue and minimize scarring [7]. A prior study demonstrated safety and efficacy of the AlloDerm material in revision pharyngoplasty for the treatment of persistent VPI [8]. This case series describes a novel treatment for mild and moderate VPI using implantable AlloDerm for posterior nasopharyngeal wall augmentation.

## 2. Materials and methods

This study was declared exempt by the Boston Medical Center and Boston University Medical Campus Institutional Review Board (IRB). A record review was conducted of all patients who received posterior wall augmentation for treatment of VPI with implantable AlloDerm at a large, safety-net hospital in New England from 2000 to 2019. A total of four patients were included in this study (two males, two females) who underwent the procedure with ages ranging from 23 to 43-years-old at the time of the procedure. One patient had two AlloDerm procedures completed, although there were no available data on the first procedure. Data were abstracted as available, including age at the operation, relevant medical history, preoperative VPI symptoms, prior imaging and SLP appointments, length of surgery, amount of AlloDerm injected, follow-up time, and subjective results and complications following surgery. A summary of each patient's course was formulated based on the available information.

## 3. Results

### 3.1. Patient 1

Patient 1 was a 29-year-old female with a surgical history notable for cleft palate repair at the age of 3. The patient's preoperative VPI symptoms included regurgitation of liquids and a hypernasal voice. The distance between her soft palate and pharyngeal wall, calculated in the Swallowtail application, was 1.34 cm at rest and 1.17 cm at maximum soft palate displacement. Minimal nasal reflux was noted on modified barium swallow testing. Pre-operative speech and swallow assessment by a SLP was notable for mild to moderate hypernasality.

During the procedure, an incision was made in the posterior pharyngeal wall and a 4 × 7 cm thin (0.53–1.02) AlloDerm, as well as a 4 × 7 cm thick (1.04–2.28) AlloDerm broken into 2 strips of 1 × 4 cm, was inserted through an incision in the posterior pharyngeal wall. The total procedure time was 45 min.

The patient reported that she and her family noticed an improvement in hypernasality following the procedure. She was seen one month after her procedure and reported snoring and difficulty blowing her nose that started two weeks after the procedure; these were thought to be secondary to wound healing. She did not attend her follow-up SLP appointment.

### 3.2. Patient 2

Patient 2 was a 23-year-old female with a history notable for severe closed head injury following a motor vehicle accident with subsequent tracheostomy and then decannulation. The patient's preoperative VPI symptoms were hypernasal speech and spastic dysarthria without nasal regurgitation. Modified barium swallow was completed. Preoperative speech and swallow assessment were notable for severe spastic-apraxic dysarthria characterized by spastic hypernasal speech (absent velopharyngeal closure).

During the procedure, an incision was made in the posterior pharyngeal wall and a 4 × 7 cm thick (1.04–2.28) AlloDerm was inserted through the incision in the posterior pharyngeal wall. The total procedure time was 68 min.

She reported that she and her family noticed a subjective improvement in hypernasality of around 30% following the procedure. However, one month following the procedure, the patient's implant had extruded and was subsequently removed. The patient was then seen two months following the original procedure by a SLP, who noted the same preoperative assessment as prior to the original procedure.

### 3.3. Patient 3

Patient 3 was a 43-year-old male with a surgical history of a right acoustic neuroma excision who developed post-operative right vocal cord immobility and VPI due to cranial nerve X palsy. The patient had received prior right-sided vocal fold injection laryngoplasty and palatoplasty using AlloDerm in the past. The patient's preoperative VPI symptoms were hypernasality and hoarseness, which were noted in the preoperative SLP appointment.

Of note, the patient received a right-sided vocal fold injection laryngoplasty at the time of posterior pharyngeal wall augmentation. One milliliter of AlloDerm was injected into Passavant's Ridge. The total procedure time was 100 min.

The patient reported improvement in hypernasality and communicative behaviors. Swallowing was judged to be within normal limits at a follow-up SLP appointment one month after the procedure.

### 3.4. Patient 4

Patient 4 was a 36-year-old male with a history of traumatic brain injury, quadriplegia, and surgical interventions for multiple joint contractures. Preoperative VPI symptoms were not available and there was no SLP or imaging data on the patient pre- or post-procedure in the electronic medical record. The patient received an AlloDerm implant, but was lost to follow-up thereafter.

## 4. Discussion

There is no consensus regarding surgical treatment for VPI, and there is less information on the treatment for mild and moderate VPI. Currently, most surgical procedures to treat VPI have high revision and complication rates. Our results demonstrate an alternative treatment option with implantable AlloDerm for mild and moderate VPI, which is safe and effective in a series of patients.

In three patients who received the procedure and in which there were follow-up data, there was a subjective improvement in symptoms including hypernasality. Unfortunately, this improvement was not sustained in one patient due to implant extrusion. Extrusion is a post-operative complication that has been reported across a wide range of implant materials, and is more often seen in alloplastic implants [9]. Fortunately, repeat posterior wall augmentation can be safely performed after a prior extrusion or treatment failure with satisfactory results and low morbidity.

Limitations of this study include a limited sample size of four patients and a lack of complete data for each patient, including some

relevant follow-up data. Future studies should examine long-term follow-up data to assess the continued impact and success of AlloDerm for posterior pharyngeal wall augmentation.

## 5. Mild to moderate VPI treatments

### 5.1. Posterior pharyngeal wall augmentation

Posterior pharyngeal wall augmentation involves decreasing the anterior-posterior diameter between the velum and posterior pharyngeal wall at the C2 level. This procedure is indicated for small gaps (> 50% closure), VPI grades 2 or 3, and retained soft palate and lateral wall mobility. Complications with these materials include postoperative neck pain, occult retropharyngeal fluid collection, migration and foreign body reactions. Recently, grafts have gained popularity due to less foreign body reactions, although they can still be associated with obstructive sleep apnea (OSA), fat embolism, or injury to the carotid artery. Many materials have been used, including fat, silicone, cartilage, gortex, calcium hydroxyapatite, polytetrafluoroethylene (Teflon), and others [10]. Although posterior wall augmentation with these materials has distinct advantages in comparison to other surgeries, they have a high overall revision rate of 18.6% [4].

Amongst the autologous implants, the most well studied material for VPI is autologous fat, which can be injected in various locations including the velopharynx. However, there are still relatively few studies reporting on isolated posterior pharyngeal wall augmentation with improvement rates ranging from 53% to close to 100% [11,12]. The main drawback for fat grafts has been resorption, which has been reported in 30–80% of cases [13]. The use of cartilage for posterior pharyngeal wall augmentation has been described by Denny et al. who found that of the 20 patients studied, five patients had complete elimination of audible nasal emissions, four patients had no change, and 11 patients had improvements without eliminating their VPI [14]. It has been reported that cartilage is better tolerated compared to other materials, but has a high rate of late resorption [15]. Although both fat and cartilage are effective implant materials, often times multiple procedures may have to be performed to ensure long-lasting results [14,16].

In a retrospective study of 111 patients, Lypka et al. described posterior pharyngeal wall augmentation using silicone, gortex block, rolled gortex, and cartilage [9]. Silicone and rolled gortex had the highest extrusion rates [9]. 64 of the 88 patients evaluated had normal speech following the operation, 22 were mildly improved, and two patients had no improvement [9]. In a larger study examining calcium hydroxyapatite, Munson and Ward found that in a series of 17 patients, all patients reported improvements in hypernasality, and PWSS reached at least borderline competent levels in 89% of isolated VPI patients and 50% of cleft palate patients [17]. Sipp et al. described seven pediatric patients treated with calcium hydroxyapatite for posterior pharyngeal wall augmentation. Four patients had a satisfactory result, while three patients who had preexisting craniofacial abnormalities experienced treatment failures [18]. No major complications were reported [18]. Brigger et al. also utilized hydroxyapatite for posterior wall augmentation and reported success in a series of eight patients with four treatment failures, which were partially attributed to increased baseline severity of preoperative VPI [19]. In a case series of 50 pediatric patients, Cofer et al. used a tissue filler of dextranomer and hyaluronic acid copolymer to treat VPI and found that hypernasality was reduced in 93% of patients, nasal grimace was resolved in 83% of patients, and audible nasal emission was resolved in 96% of patients [20]. Minor complications reported included snoring (16%), severe neck pain (14%), OSA (4%), and gingivostomatitis (2%) [20]. Furlow et al. described 35 patients treated by posterior pharyngeal wall augmentation using polytetrafluoroethylene [21]. The overall success rate was 74% and the implant remained stable over time.

## 6. Mild to severe VPI treatments

Previously, the primary objective with VPI surgery was to create an ideal distance between the pharynx and soft palate during phonation. A positive correlation has been demonstrated between the change in closure grade and speech intelligibility [22]. However, managing VPI is not as simple as closing the physical defect due to the numerous factors that contribute to speech, including velopharyngeal closure patterns and variation in muscle insertion. In certain cases and with larger velopharyngeal gaps, it becomes necessary to perform more invasive methods of intervention to correct VPI. Surgery must not be aimed at simply closing the physical defect of the oropharynx, but may also need to address the release of abnormal muscle insertions and place them in a correct orientation in order to establish a dynamic sling. The levator veli palatini is the principal component for initiating and maintaining closure of the velopharynx through manipulation of the soft palate. Children with cleft palate are predisposed to abnormal levator muscle insertions at the level of the hard palate; therefore, surgery should aim at restoring the transverse orientation of the muscle in order to recreate the levator sling. There are many surgeries and variations that are used for the treatment of VPI with no current gold standard.

### 6.1. Pharyngeal flap procedure

The pharyngeal flap procedure is mainly indicated in patients with a large central gap (> 9 mm) with sagittal closure and adequate lateral pharyngeal wall movement [23]. Complications are associated with the size and placement of the graft, and include oronasal fistula, inadequate palatal lengthening, OSA, and persistent hypernasality [24]. Although pharyngeal flaps were performed relatively often in the past, recent evidence has shown a revision rate ranging from 6.1 to 20%; the flap procedure is more uncommon today, although it is still an effective treatment for VPI with good outcomes [4,25].

### 6.2. Sphincteroplasty

Sphincteroplasty is indicated in coronal closure patterns when there is relatively good movement of the soft palate with little to no movement of the lateral walls. It is also indicated in revision of primary pharyngeal flap surgery. Although it is associated with a higher revision rate (10.6% vs. 6.1%), sphincteroplasty is preferred over the pharyngeal flap because theoretically the innervation is kept intact allowing for a dynamic structure [4,25]. Early causes of failure, specifically poorer speech outcomes associated with this technique are a large central port, dehiscence, tight port and low flap inset along the posterior pharyngeal wall with attachment below C1. Although less likely to cause OSA than pharyngeal flap, one study found a significant reduction of slow-wave sleep quantity and increase in cortical microarousals [26]. Another study found an increase in apnea-hypopnea index, obstructive events per night and hypopneas [27].

### 6.3. Furlow double z-palatoplasty

The Furlow double z-palatoplasty is an adjunctive method to repair VPI after primary palatal repair, but is now commonly used in primary VPI management [28]. This involves transposing the abnormally inserted levator veli muscular into a more anatomic, posterior and transverse orientation. This method is associated with fewer complications than the pharyngoplasties and generally complications are secondary to inadequate lengthening of the soft palate. There have been various modifications, with varying results and revision rates, since the development of the technique, which is very popular for VPI treatment [29].

#### 6.4. Buccinator musculomucosal flap

The buccinator musculomucosal flap technique lengthens the velum in both primary palatoplasty and secondary VPI. Surgery involves dissecting the soft palate from the hard palate and using the buccal myomucosal flaps to fill in the defect, lengthening the palate up to 2.5 cm [30]. Bilateral flaps had a success rate of 85% [31]. The revision rate has been reported to be as high as 13.5% [32].

#### 7. Conclusion

Currently there is not a consensus regarding treatment for mild and moderate VPI due to the rates of complications and revisions. Therefore, we present this novel treatment as an alternative to current treatment options. Ultimately, augmenting the posterior wall using implantable AlloDerm is a useful, low risk method for treating mild and moderate VPI.

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#### Declaration of competing interest

None.

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