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ORIGINAL ARTICLE

The surgical treatment of velopharyngeal insufficiency in patients with velo cardio facial syndrome

Tratamiento quirúrgico de insuficiencia velofaringea en pacientes con síndrome velo cardio facial

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Abstract

Introduction: *Velopharyngeal insufficiency (VPI) is the condition in which the velopharyngeal sphincter (VPS) cannot seal the communication between the nasal cavities and the remainder more inferiorly located vocal tract during speech. The most common craniofacial syndrome with VPI is the velocardio facial syndrome (VCFS). Surgical management of VPI involves the creation of a partial soft tissue closure of the velopharynx, such that even the attenuated function of the VPS is rendered sufficient to close the velopharynx completely, eliminating VPI.* **Objective:** *Describe the results of pharyngeal flap (PF) surgery in patients with VCFS and VPI.* **Material and methods:** *Ten-year retrospective review of cases of VCFS and VPI treated by PF surgery. All PF were individually planned according to findings of video nasopharyngoscopy (VNP) and multiplanar videofluoroscopy (MPVF). A total of 28 patients were included in the study group.* **Results:** *Nasal resonance was restored to normal limits in 27 patients. One patient presented with a dehiscence of the PF with persistent VPI.* **Conclusion:** *Customizing PF surgery according to individual clinical and imaging findings seems to provide the best prognosis for correcting VPI in patients with VCFS and VPI.*

Keywords: *Velo cardio facial syndrome. Velopharyngeal insufficiency. Surgery. Speech and language pathology. Cleft palate.*

Resumen

Introducción: *Insuficiencia velofaríngea (IVF) significa que el esfínter velofaríngeo (EVF) no logra sellar la comunicación entre cavidades nasales y tracto vocal situado inferiormente durante el habla. El síndrome más común con IVF es el síndrome Velo Cardio Facial (SVCF). El tratamiento quirúrgico de IVF requiere un cierre velofaríngeo de tal manera que sea suficiente para un sello adecuado, eliminando IVF.* **Objetivo:** *Describir los resultados de cirugía de colgajo faríngeo CF) en pacientes con SVCF e IVF.* **Material y Métodos:** *Revisión retrospectiva de 10 años reclutando casos de SVCF e IVF tratados quirúrgicamente con CF. El CF fue planeado individualmente conforme a los hallazgos de videonasofaringoscopia (VNF) y videofluoroscopia multiplanar (VFMP) en todos los casos. Un total de 28 pacientes fue incluido en el grupo de estudio.* **Resultados:** *La resonancia nasal fue restaurada dentro de limites normales en 27 pacientes. Un paciente presento dehiscencia del colgajo faríngeo con IVF persistente.* **Conclusión:** *El CF realizado conforme a hallazgos individuales clínicos y de imagen provee un óptimo pronóstico para corregir IVF en pacientes con SVCF e IVF.*

Palabras clave: *Síndrome velo cardio facial (SVCF). Ineficiencia velofaríngea (IVF). Paladar hendido (PH). Cirugía. Patología de habla y lenguaje.*

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Introduction

Normal resonance during speech is achieved by the coordinated closure of the VPS. The function of the VPS is to open, partially close or seal the communication between the nasal cavities and the inferior vocal tract, including the oral cavity and pharynx. The VPS is one of the two most important valves of the vocal tract; the other one is the glottis. Several muscles are responsible for VPS function during a speech, including the levator veli palatini, superior pharyngeal constrictor, and musculus uvulae[1-4].

Velopharyngeal sphincter (VPS) dysfunction results in excessive nasal resonance during a speech, that is, hypernasality. Also, VPS dysfunction can cause nasal emission or nasal turbulence during speech, specifically during the articulation of high oral-pressure consonants, including plosive and fricative phonemes[2,3].

Several disorders can affect the correct function of the VPS. Neuromuscular disorders, phonological disorders, radiation, and surgical treatments for pharyngeal neoplasias, adenoidectomy, surgical procedures, and obstructive sleep apnea. However, the most common etiology of VPS dysfunction is cleft palate (CP)[1,2].

The inability of the VPS to adequately balance resonance during speech is denominated as VPI. As mentioned herein, the cardinal signs of VPI are hypernasality and nasal emission. Hypernasality is considered the condition in which nasal resonance is abnormally high during speech. Nasal emission is perceptible nasal air turbulence during the articulation of phonemes which require high oral pressure (plosives and fricatives)[1,2].

Besides the abnormal nasal resonance, VPI during phonological development can be associated with articulation disorders which are considered compensatory behaviors. These articulation patterns affect not only the VPS but the entire vocal tract. For example, plosive sounds can be substituted by glottal stops. These articulation errors are referred to as compensatory articulation (CA) patterns. It has been reported that CA occurs because, in some cases of VPI, the mechanoreceptors in the oral and nasal cavities send feedback of air pressure imbalance, which is automatically compensated with an increase in airflow from the lungs[5].

Thus, patients with VPI can present with normal articulation placement. In these cases, surgical treatment for restoring the normal function of the VPS is indicated. When VPI occurs with associated CA, treatment must include surgery and speech and language pathology (SLP) intervention[6,7].

In patients with CP, early surgical treatment can restore the function of the VPS, but the treatment is not successful in every case. Persistent VPI following surgical treatment of CP occurs in 20-40% of the cases. Rigorous diagnostic evaluation and surgical planning reduce the rate of VPI[8-10].

Another variable that must be considered when patients with CP are being evaluated is if the case is an isolated malformation or a malformation as a feature of a syndrome. The diagnosis and treatment plan significantly differs in cases of syndromic CP as compared to non-syndromic CP[11-13].

Diagnosis and treatment of patients with CP and persistent VPI require a transdisciplinary approach. SLP, psychology, medical genetics, cytogenetic, plastic and reconstructive, and otolaryngology evaluations are essential in developing an effective diagnosis and treatment plan[9,11,12].

The optimal approach for an adequate assessment of the function of the VPS during speech is the combination of VNP and MPVF[12]. VNP provides direct internal visualization of the anatomy during articulation. MPVF enhances a three-dimensional assessment allowing an external planar view through anatomy rendered translucent and making possible actual size measurements of the structures at rest and during speech. These imaging procedures should not be considered as options but as complementary[12].

The most common syndrome with VPI is velocardiofacial syndrome (VCFS)[13,14]. VPI in cases of VCFS can occur with a palatal cleft. The cleft can be total, subtotal or submucous. The most common presentation in cases of VCFS is the submucous CP (SCP)[13,14].

Several reports demonstrate that the most effective surgical procedure for correcting VPI in cases of VCFS is the PF[15-18]. Furthermore, PFs customized according to imaging findings provide a significantly higher success rate[11,12].

The purpose of this paper is to describe our experience in correcting VPI in cases of VCFS.

Materials and methods

A retrospective nonrandomized review of selected cases of VCFS with VPI operated on by a single surgeon using a specific surgical technique for a customized PF was carried out at the Corewell Health William Beaumont University Hospital, Royal Oak, Michigan, United States of America. The review included cases operated on from 2012 to 2022.

All cases of VCFS were diagnosed by constitutional single nucleotide polymorphism–chromosomal microarray with VPI.

This study was approved by the Internal Review Board of the Hospital.

Each patient was evaluated by the transdisciplinary team of the Ian Jackson Craniofacial and CP Clinic of the Hospital.

Video nasopharyngoscopy (VNP) and MPVF were performed in all cases.

A total of 28 cases with complete preoperative and postoperative studies were recruited and reviewed in detail. All patients were preoperatively and postoperatively evaluated by the same clinician (first author). All surgical procedures (PF) were performed by a single surgeon (second author).

The age of the patients at the time of surgery ranged from 5 to 14 years of age. The median age was 7 years of age.

Individualized preoperative planning was performed, customizing the PF according to imaging findings of VNP and MPVF. Polysomnography was indicated when clinical data of sleep-disordered breathing were documented. Because of the frequency of medialization of the internal carotid arteries (ICA´s) as a feature of VCFS[11,13,19,20], a computed tomography scan of the neck with contrast was performed for assessing the anatomical course of the ICA's in every case before any surgical procedure involving the pharynx.

For customizing the PF in each case, the findings of VNP and MPVF were considered.

As per previously reported protocols have described, the following actual size measurements from MPVF were performed: distance between the tip of the uvula or the most inferior palatal border when the uvula was not identified and the hard palate at rest; distance between lateral pharyngeal walls (LPW) at rest; distance between LPW during the best articulation placement possible of the repetition of a standardized speech sample including plosive and fricative phonemes in combination with high and low vowels. Other pharyngeal features were assessed, including the adenoid pad, the shape of LPW during speech, the direction of velum motion, the percentage of VPS gap expressed as the size of the gap, presence, absence of location of Passavant's ridge[11-13]. Radiation dosage was obtained in all cases following MPVF. The dosage was below 9 mSv in every case. About these data, the American Association of Physicists in Medicine (AAPM) released a statement that risks of medical imaging at patient dosage <50 mSv for single procedures may be non-existent[11,12,21].

Video nasopharyngoscopy (VNP) findings were also analyzed as described in previous reports, including VPS closure pattern, velar movement during the speech sample expressed as a percentage, adenoid size, pharyngeal tonsils size, epiglottis, and vocal cords[11,12].

The length and width of the flap were customized according to the actual size measurements of the MPVF. The length was also corroborated intraoperatively using a long hypodermic needle and a laryngoscopy mirror.

Tonsillectomy and adenoidectomy (T & A) were performed in every case in preparation for PF surgery. There was a window of 6 months between both procedures in every case.

All cases were operated on following the technique described by SA Tatum et al.[11,19]. All patients were operated by a single surgeon. The PF position and width were determined according to the findings of VNP and MPV. The PF is intended to be as short a musculo-mucosal flap as possible, leaving a small donor site which resulted in less discomfort and, most importantly, no circumferential narrowing of the pharynx postoperatively. The palate was not split but retracted anteriorly and superiorly to provide adequate exposure for the surgery. The nasopharynx was visualized with an angled mirror as necessary during the procedure. The height of the flap pedicle was planned based on the positions of the hard palate, soft palate, and maximal movement of the lateral pharyngeal walls. The position of the base of the pedicle was then identified on VNP using specific reference points of anatomy common to the VNP and MPVF.

The length of the flap was determined by measuring the distance from the midsection of the soft palate-the likely insertion point of the flap into the palate-to the posterior pharyngeal wall using the hypodermic needle on a hemostat. The needle was passed through the velum until it touched the posterior pharyngeal wall at the expected height of the pedicle. A measurement was made based on the length of the needle from its tip to the proximal aspect at the oral surface of the palate. Both the length and width of the flap were increased by 2–4 mm to compensate for the expected shrinkage of the flap with harvesting.

Once this length was determined, the transverse dimension of the flap was marked with needlepoint cautery and a marking pen. This dimension was marked with a few dots along the entire length of the flap to prevent inadvertent narrowing of the flap along its length. The incisions on the posterior wall were extended down through the constrictor musculature with a scalpel.

Table 1. Nasometry normative data (MN%)

n = 20	
Males	**Females**
X = 26.71	X = 29.50
SD = 4.15	SD = 3.01
Ref = 18-35%	Ref = 23-36%

n: sample size; X: mean; SD: standard deviation; Ref: reference range. All subjects studied for this normative study exhibited normal (balanced) resonance during the speech and no history of velopharyngeal malformations or diseases as demonstrated by perceptual and intraoral examination by two experienced independent examiners. The nasometry was performed by having the subjects read aloud "The Rainbow Passage" (RP). All subjects were adults >18 years of age and <65 years of age.

Table 2. Preoperative MN

n = 28	
Range	**54-98%**
X	77.99
SD	5.40

n: sample size; X: mean; SD: standard deviation. Preoperatively, all patients presented with nasal emission. The nasal emission was not phoneme specific in any of the cases. A total of 20 patients demonstrated consistent nasal emission, and eight patients exhibited inconsistent nasal emission. Perceptually, 23 patients exhibited moderate hypernasality. Hypernasality was considered severe in five cases.

The dissection was extended through the visceral fascia leaving the alar fascia intact. The superiorly based myomucosal flap was then elevated in an inferior to the superior direction in the retropharyngeal space. Blunt dissection was performed as much as possible to elevate the flap off the alar fascia. The flap is elevated up to the previously planned height. Bipolar cautery was favored for hemostasis and was applied as little as possible to prevent the narrowing of the flap.

A transverse incision was then made on the nasal surface of the soft palate beginning above the base of the uvula, approximately 8-10 mm superior to the free edge, extending laterally to slightly greater than the expected width of the flap. Laterally, this is done with a needle tip cautery bent with two 90° angles. Centrally this is done with the angled Beaver palate knife.

Two aspects of the incision ensure that the flap acquires its proper position and width even after it is inserted into the palate. First, the position of the lateral aspect of the palatal incision will dictate the position for the lateral aspects of the flap once inset. Thus, the incision should remain straight, not following the curvature of the free edge of the soft palate along the palatopharyngeal fold. An incision that follows the downward curvature of the palate will effectively place the flap lower than its planned height, regardless of the position of the pedicle. Second, the width of the incision will also dictate the width of the inset flap, regardless of the harvested width of the flap. Thus, the width of the palatal incision should be at least as wide as the needed width of the flap and, practically speaking, a few millimeters wider. Respecting these two related concerns in creating the palatal incision maintains the height and width of the flap as previously planned.

Angles scissors were then used to create a pocket through this incision into the substance of the soft palate extending close to the junction of the hard and soft palate. Care was taken to ensure that a single, confluent pocket was created, devoid of septations, to accept the flap. 2-0 chromic gut sutures on a tapered needle were passed through the oral mucosa of the soft palate near the junction of the hard and soft palate through the pocket, brought out through the nasal surface incision, and passed through the inferior edge of the flap–muscle layer first.

The sutures were then passed back through the flap-mucosal layer first, through the soft palate pocket and back out through the oral mucosal layer, creating a horizontal mattress. Usually, four such sutures were equally placed along the soft palate and inferior edge of the flap from one corner to the next (sometimes, three and five sutures were used, depending on the dimensions of the flap and the patient's anatomy). Like the width of the nasal surface palate incision, most lateral sutures are key because their placement defines the width of the flap. It is also notable here that no attempt should be made to place these lateral-most sutures any further lateral than necessary. This results in attempting to stretch the flap further than its width will allow, creating tension and a likelihood for dehiscence of these critical lateral sutures. The surgeon should simply trust and utilize the measurements of needed width and the widths of the flap and palatal incisions created to this point rather than seeking even greater width through the wider-than-needed placement of the lateral sutures.

The flap was pulled into the pocket of the soft palate when the sutures were gently tightened and tied. Good apposition of the flap to the palate is observed with the mirror as sutures are gently pulled into position.

All patients presented with VPI, as demonstrated by SLP evaluation of speech and resonance. Also, all cases exhibited abnormal mean nasalance (MN), as demonstrated by nasometry. The nasometry was performed according to the protocol previously reported[11] (Tables 1 and 2).

Preoperatively all patients exhibited nasal emission, twenty patients exhibited consistent nasal emission, and eight patients exhibited inconsistent nasal

emission. None of the patients presented with phoneme-specific nasal emission.

A total of 23 patients presented with moderate hypernasality, and five exhibited severe hypernasality. None of the patients presented with mild hypernasality.

A total of 20 patients exhibited CA. SLP intervention was necessary before the imaging procedures to achieve the best possible articulation placement for the repetition of the speech sample. The speech sample used has been reported previously[12].

Computed tomography (CT) scan of the neck with contrast demonstrated unilateral medialization of ICA in eight patients. None of the patients demonstrated bilateral medialized ICA's. The location and depth of the ICA, as demonstrated by the imaging procedure, were carefully considered before T & A and PF surgery. It should be noted that the eight cases in which the medialization was demonstrated by a CT scan exhibited pulsations on the posterior pharyngeal wall during VNP.

None of the patients presented with clinical data suggestive of sleep-disordered breathing following T & A.

All cases had a periodic follow-up from 6 months to 4 years.

Postoperative SLP evaluation of speech and resonance, nasometry and VNP was performed in all cases. To avoid unnecessary radiation exposure, MPVF was performed only in cases with consistent data of postoperative VPI.

Successful correction of VPI was considered as the condition in which MN scores were within reference values, and postoperative VNP demonstrated complete occlusion of both portals of the PFs during adequate articulation placement.

Results

One patient presented with persistent nasal emission postoperatively. Moreover, MN persisted unchanged. Perceptually, hypernasality persisted as moderate. VNP 2 months postoperatively demonstrated total dehiscence of the flap.

Twenty-seven patients demonstrated the absence of nasal emission postoperatively. MN was within normal limits as per the normative study previously reported (Table 3).

Perceptually, 27 patients demonstrated normal nasal resonance during speech.

None of the patients presented with clinical data of sleep-disordered breathing after at least 2 months postoperative follow-up. However, mild to moderate snoring was reported in all patients in the immediate postoperative period. Snoring was progressively decreasing by 2-4 months postoperatively. Five patients persisted with mild snoring, as reported by parents, 7 months postoperatively.

All patients were able to swallow liquids in the first 48 postoperative hours. The hospital length of stay ranged from 1 to 3 postoperative days.

Discussion

The results of this study support the previously reported statement that PF surgery seems to be the best option for correcting VPI in patients with VCFS[10,11,15-17].

The purpose of this study was to describe the results of a retrospective review of a series of cases of VCFS with VPI. All patients underwent T & A in preparation for velopharyngeal surgery, and all patients were operated on by a single surgeon using the surgical technique for tailoring the PF to match preoperative clinical and imaging findings.

Debate exists as to the optimal technique in velopharyngeal reconstruction. Syndromic cases, especially those occurring in the setting of VCFS, present with specific challenges which are not present in otherwise healthy patients. Patients with VCFS present with attenuated musculature of the VPS, resulting in poor lateral pharyngeal wall movement and thinner, less robust tissue planes for reconstruction. Platybasia is present in VCFS, and anecdotally it is recognized that this results in a deeper, wider velopharyngeal gap. Together these factors result in a much larger than usual velopharyngeal gap, weaker than usual tissue for reconstruction, and a need for a long and very wide, nearly obstructive flap in most cases. This markedly heightens the importance of choosing the optimal technique and taking care to tailor a reconstruction to this circumstance. The challenge is to both eliminate VPI and avoid nasal obstruction and sleep apnea[14].

Although it has been reported that not every case of VPI should be approached by PF surgery, several reports, including this one, support the statement that the best results for successfully correcting VPI in patients with VCFS can be achieved by this surgical procedure. In contrast, perhaps the less exacting challenge of reconstruction in the non-syndromic patient allows for success utilizing other techniques, including sphincter pharyngoplasty, primary or secondary intravelar veloplasty, primary of secondary Furlow's "Z" plasty, or injection of fat or synthetic materials. Nonetheless, to achieve the best postoperative results, every case of VPI should be analyzed individually, and the surgical procedure should be

Table 3. Postoperative MN

n = 28	
Range	20-74%
X	37.04
SD	4.10

n: sample size; X: mean; SD: standard deviation. A total of 27 patients demonstrated MN within normal limits postoperatively. The nasometry was performed 2 months postoperatively in all cases. Only one patient demonstrated abnormal MN. There was no difference between preoperatively and postoperatively measurements in this case. Nasal emission was eliminated postoperatively in 27 patients. One patient persisted with nasal emission postoperatively. Nasal emission was consistent in this case, and it did not change following the surgical procedure.

selected according to the specific clinical and imaging findings of each case.

The success rate for correcting VPI in this study group was 97%. Only one case persisted with VPI secondary to dehiscence of the flap from the palate. Despite the care taken in measurements of the flap, it was probably insufficient in length, and the flap was attached to the palate with mild tension, likely resulting in failure of the sutures.

This has led to the following understanding of surgical anatomy and subsequent changes to planning. First, although a high flap is desirable, based on the height of the greatest movement of the lateral pharyngeal walls in most cases, this does present challenges. The higher one climbs in the nasopharynx, the greater the distance between the posterior pharyngeal wall and the palate, which curves anteriorly to meet the hard palate. Thus, a high insertion point in the soft palate does require a longer flap. In addition, the anterior aspect of the soft palate, nearer to the hard palate, will not displace posteriorly. In contrast, the more central and inferior aspects of the soft palate will "give" posteriorly with gentle pressure. Thus, insertion of the flap into the lower regions of the palate will allow for some forgiveness of a flap that is minimally insufficient in length. We now accept that an incision only 1 cm above the free edge and the development of a pocket towards the poster hard palate edge still places the flap high enough and in an advantageous trajectory while also taking advantage of some give of the soft palate, as well as a deeper pocket with greater surface area for attachment. The pedicle is still placed as high as needed (most often at the lower aspect of the torus tuberous).

Second, an attempt was made in this failed case to gain length by elevating higher into the nasopharynx. This was not successful because the craniocervical junction contours posteriorly away from the palate at this level, essentially deepening the nasopharynx. Thus, raising the flap more cephalad only results in moving the origin of the flap further from the point of insertion in the palate: negating the benefit of obtaining greater flap length. Indeed, it is only the initial position of the inferior transverse incision relative to the initial determination of the pedicle height that ultimately determines whether the flap will be of sufficient length.

In the end, adding 3-5 mms to the initially planned length of the flap has become the accepted technique in the authors' practice. This has not resulted in unacceptably large donor site defects; none have resulted in dysphagia.

In one other patient, central dehiscence of the flap from the nasal surface of the palate was noted on follow-up endoscopy. Fortunately, the lateral aspects of the flap had healed to the palate well, and there was no fistula in the palate itself. Thus, the width of the flap was sufficient. In addition, no air escape occurred in the slit-like opening between the flap and the nasal surface of the palate, VPI was corrected, and there was no impact on swallowing. Thus, there was no indication to correct this partial dehiscence.

In this case, the following point has been learned: the midline of the palate in occult submucous cleft may be quite thin, especially in the setting of VCFS and especially if no prior repair has been performed. Opening this central aspect of the nasal surface incision must be done with extreme care, avoiding the use of cautery. Similarly, a midline suture is not used in these patients as it is likely to pull through the palate. In these cases, two lateral sutures and two paramedian sutures are used. In placing the paramedian sutures, an attempt is made to pass the suture at least partially through the cleft muscle so that tissue of greater thickness and substance is used to fixate the flap centrally.

Performance of neck CT scan with contrast for assessing the anatomical course of the ICA's is an essential preoperative procedure in patients with VCFS undergoing any pharyngeal surgical procedure. In this study group, eight patients demonstrated unilateral medialization of the ICA. Although pulsations on the posterior pharyngeal wall were observed in all eight patients, the physical exam is not sufficient to rule out a carotid artery aberrancy. The anatomical course should be appropriately assessed by a CT scan. If carotid aberrancy is identified, the procedure may still proceed. The flap is raised over the carotid. The vessel is carefully lateralized, and the lateral pharyngeal wall mucosa is sewn to the lateral aspect of

the posterior pharyngeal wall, excluding the vessel from the surgical field.

Previous studies have reported success rates for correcting VPI ranging from 92 to 96% when PFs are performed with preoperative planning and anatomic information as provided by MPVF and VNP[11,12,22].

Besides the complication which precluded correction of VPI in one case as reported herein, other complications, including postoperative inferior displacement of the PF, shrinking or tubing of the PF, and total reabsorption of the flap have been mentioned in other studies[11,22].

Concerning shrinking or narrowing of the PF resulting in failure to restore VPS function during a speech, this complication has been frequently attributed to a technical error. However, other mechanisms of failure can be responsible for this complication. Despite adequate planning and surgical technique, the healing process can result in a flap being narrower than planned.

Future studies with larger study groups are necessary to continue studying the possible causes of failure to correct VPI in patients with VPI.

The limitations of this study should be highlighted. Although the study group was homogeneous and a single surgeon performed all the procedures, the number of cases was reduced to draw definitive conclusions, but the results of customizing PF surgery according to individual and imaging findings in patients with VCFS are promising.

Conclusion

Customizing PF surgery according to individual clinical and imaging findings seems to provide the best prognosis for correcting VPI in patients with VCFS and VPI. Syndromic patients may present with greater surgical challenges in terms of the quality of tissue for reconstruction and the larger dimensions of the gap in the VPS. Tailoring the height, width, and length of the flap based on VNP, MPVF, and intraoperative measurements is critical in syndromic patients. Tension in attaching the flap to the palate must be avoided. Therefore, an initial incision in the palate at roughly the junction of the middle and lower thirds is acceptable. And adding width and length to the initial measurements is expected to account for the shrinkage of the flap that occurs in harvesting. The central aspect of an unoperated palate with a submucous CP in a syndromic patient may be exquisitely thin. Care must be taken in creating the insertion pocket and fixating the flap in this region.

Performing T & A in preparation for PF surgery seems to prevent sleep-disordered breathing.

Preoperative assessment of the anatomical course of the ICA's is essential when pharyngeal surgical procedures are being scheduled in patients with VCFS and VPI.

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Conflicts of interest

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Ethical disclosures

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