

# Evidence-Based Medicine: Cleft Palate

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**Learning Objectives:** After studying this article, the participant should be able to: 1. Describe the incidence of cleft palate and risk factors associated with development of an orofacial cleft. 2. Understand differences among several techniques to repair clefts of both the hard and soft palates. 3. Discuss risk factors for development of postoperative fistulas, velopharyngeal insufficiency, and facial growth problems. 4. Establish a treatment plan for individualized care of a cleft palate patient.

**Summary:** Orofacial clefts are the most common congenital malformations of the head and neck region, and approximately three-quarters of these patients have some form of cleft palate deformity. Cleft palate repair is generally performed in children between 6 and 12 months of age. The goals of palate repair are to minimize the occurrence of fistulas, establish a normal velopharyngeal mechanism, and optimize facial growth. This Maintenance of Certification review discusses the incidence and epidemiology associated with cleft palate deformity and specifics associated with patient care, including analgesia, surgical repair techniques, and complications associated with repair of the cleft palate. (*Plast. Reconstr. Surg.* 139: 191e, 2017.)

The correction of cleft deformities is a hallmark of the service that plastic surgeons provide daily to those afflicted with life-changing injuries and congenital anomalies. Although the incidence of clefting varies from state to state and from nation to nation, approximately one in 690 infants is born in this country with an orofacial cleft.<sup>1</sup> Roughly three-quarters of these individuals have some form of overt cleft palate deformity; in the United States, 5.9 per 10,000 live births present with cleft palate alone, 5.6 present with clefts of the lip and palate, and 3.1 present with cleft lip alone.<sup>2</sup> Internationally, the rate of cleft palate alone is similar, averaging 4.5 cases per 10,000 live births, but varying from as low as 1.5 in Cuba to as high as 13.3 in Finland.<sup>3</sup>

Major congenital malformations are found in roughly one-quarter of patients with cleft lip and palate and up to half of those presenting with cleft palate alone.<sup>4,5</sup> The nomenclature here can be confusing, as they are defined as nonisolated, when at least one unrelated defect is present; isolated, when no major defects are present; and syndromic, when a genetic cause has been identified.<sup>2</sup>

This epidemiologic terminology conflicts with the common surgical practice of designating an isolated cleft palate as simply a palatal deformity without an associated cleft lip, and regardless of the presence of other malformations.<sup>6</sup> Because of the high rate of syndromes in patients with cleft palate alone, genetic evaluation is recommended for these families.<sup>7</sup> A recent systematic review suggests that the presence of other congenital anomalies is a more important predictor of a genetic condition, as almost all syndromic patients present in this manner. Therefore, all such patients should also undergo genetic consultation.<sup>5</sup>

Evidence continues to accrue in support of multiple risk factors associated with cleft development. These include folic acid deficiency (odds ratio [OR], 4.36),<sup>8</sup> tobacco use (OR, 1.48),<sup>9-12</sup> alcohol consumption (OR, 1.28),<sup>12</sup>

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obesity (OR, 1.26),<sup>12</sup> stressful events (OR, 1.41),<sup>12</sup> low zinc levels (OR, 1.82),<sup>12</sup> fever during pregnancy (OR, 1.30),<sup>12</sup> topiramate use,<sup>13–16</sup> and potentially amoxicillin exposure.<sup>17</sup> Folic acid supplementation was noted to be a protective factor.<sup>9,12,18</sup> Although previous studies suggested a correlation with corticosteroid use, more recent data do not support this hypothesis.<sup>19,20</sup>

## LITERATURE SEARCH AND ASSESSMENT

A search of the PubMed database was performed for the purposes of this review. All studies presenting under the search phrase or PubMed Medical Subject Headings term “cleft palate” qualified for evaluation. The investigation was limited to original articles published since the last Maintenance of Certification in Plastic Surgery article in 2012.<sup>21</sup> Further limitation was made to human studies and those written in the English language. All abstracts were evaluated, and pertinent publications were assigned a level of evidence rating as determined by the American Society of Plastic Surgeons Evidence Rating Scale for Therapy (Table 1). Appropriate studies were subsequently indexed to subcategories, including epidemiology, analgesia, surgical technique, fistula development, velopharyngeal insufficiency, facial growth, and sleep apnea.

## ANALGESIA

The goals of analgesia following cleft palate repair are to provide long-acting pain relief and simultaneously minimize the risks of respiratory depression, airway obstruction, and difficulty swallowing. With the aim of decreasing intravenous

opioid administration, Chiono et al. examined the efficacy of bilateral suprazygomatic maxillary nerve blocks before palatoplasty. In a prospective, randomized, double-blind study, the authors demonstrated that blockade of the maxillary nerve with 0.15 ml/kg of 0.2% ropivacaine was superior to saline controls in decreasing the overall dosage of intravenous morphine within the first postoperative 48 hours.<sup>22</sup> The effect of acetaminophen was similarly evaluated in a randomized placebo-controlled trial. Those receiving intravenous acetaminophen (at the time of surgery and every 6 hours thereafter) had the lowest rates of opioid requirement. In addition, patients taking oral acetaminophen fared better than the control group, who received oral and intravenous placebos.<sup>23</sup>

Jha et al. conducted a prospective, randomized, double-blinded trial on 50 patients comparing bupivacaine (2 mg/kg) against ketamine (0.5 mg/kg) infiltration of the surgical-site during palate repair. Although both groups had similar analgesic efficacy up to 12 hours, the ketamine group had improved pain relief at 24 hours. Those treated with ketamine also had a significantly lower need for rescue analgesics, decreased levels of sleep disturbance, and less dysphagia.<sup>24</sup> Acting as both a local analgesic and *N*-methyl-D-aspartate receptor antagonist to combat central sensitization, ketamine has shown similar effectiveness in children undergoing adenotonsillectomy.<sup>25</sup>

As noted in a previous review, a prospective randomized study documented the efficacy of steroids in reducing airway distress. Dexamethasone (0.25 mg/kg), administered for three doses over 24 hours, was compared to placebo and found to decrease the incidence of postoperative airway distress and fever. It did not, however, increase the risk of fistula formation or the time of discharge for patients.<sup>26</sup>

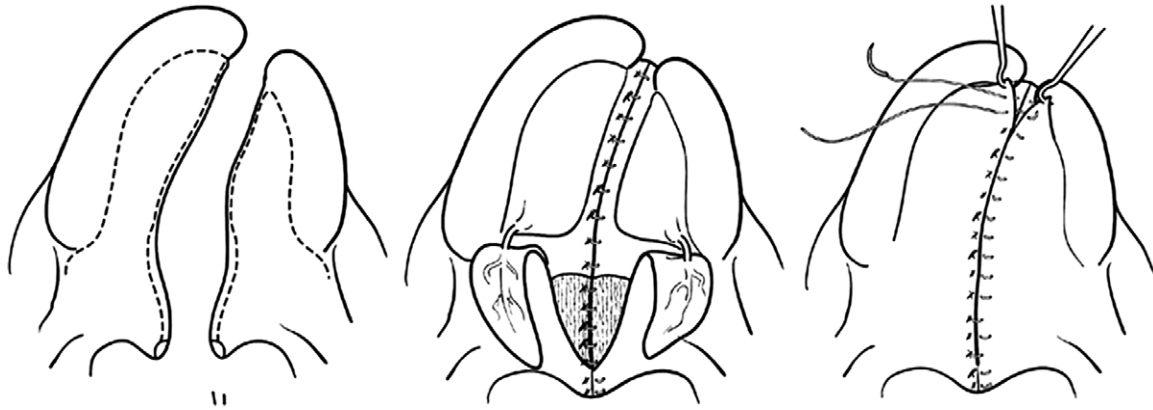
## SURGICAL TECHNIQUES

### Nomenclature

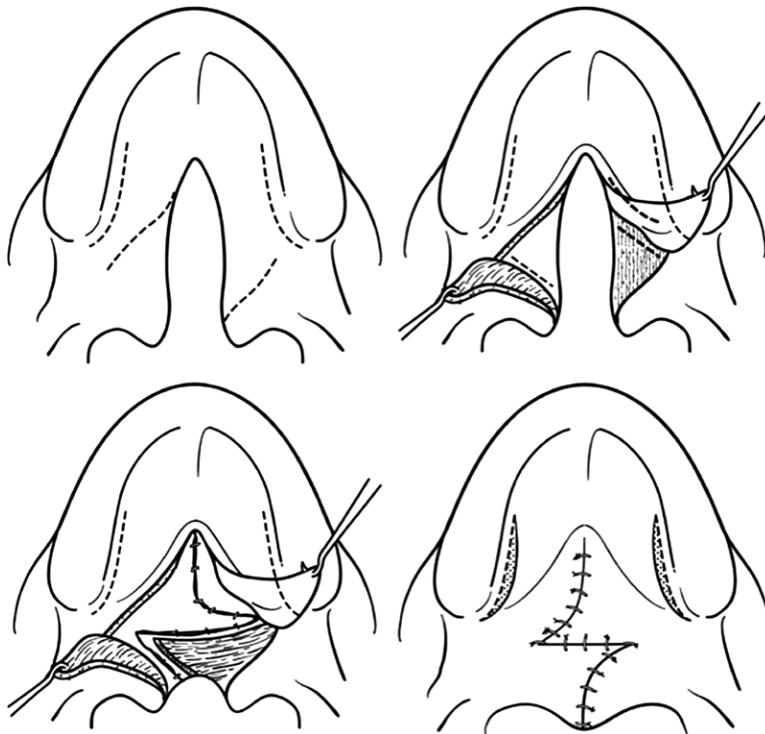
A survey of cleft surgeons revealed that the Bardach two-flap palatoplasty with intravelar veloplasty and the Furlow double-opposing Z-plasty were the two most commonly used palate repair procedures (Figs. 1 and 2), accounting for 87 percent of all cases.<sup>27</sup> Potentially because of advancements in the field, notable confusion exists in the nomenclature used for cleft palate repair. For instance, the terms Bardach palatoplasty and von Langenbeck repair describe a surgical approach to the hard palate but do not elucidate the soft palate

**Table 1. American Society of Plastic Surgeons Evidence Rating Scale for Therapy**

Level of Evidence	Qualifying Studies
I	High-quality, multicenter or single-center, randomized controlled trial with adequate power; or systematic review of these studies
II	Lesser-quality, randomized controlled trial; prospective cohort study; or systematic review of these studies
III	Retrospective comparative study, case-control study, or systematic review of these studies
IV	Case series
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research, or “first principles”



**Fig. 1.** Bardach two-flap palatoplasty. Bilateral mucoperiosteal flaps based on the greater palatine vessels are elevated from the hard palate. The flaps are then reapproximated at the midline, allowing closure of defects along the anterior aspect of the hard palate. [Reprinted from van Aalst JA, Kolappa KK, Sadove M. MOC-PSSM CME article: Nonsyndromic cleft palate. *Plast Reconstr Surg.* 2008;121(Suppl):1–14.]



**Fig. 2.** Furlow double-opposing Z-plasty. Bilateral musculomucosal flaps are elevated and mobilized in two opposite Z-plasties of the oral and nasal mucosa, resulting in a reorientation of the palatal musculature into a more transverse orientation. The Z-plasties also serve to lengthen the soft palate. [Reprinted from van Aalst JA, Kolappa KK, Sadove M. MOC-PSSM CME article: Nonsyndromic cleft palate. *Plast Reconstr Surg.* 2008;121(Suppl):1–14.]

reconstruction performed (i.e., Kriens intravelar veloplasty, radical intravelar veloplasty, double-opposing Z-plasty). Similarly, the classic Furlow palatoplasty was described as a double-opposing Z-plasty of the soft palate and direct closure of

the hard palate without the use of relaxing incisions.<sup>28</sup> However, in common practice, a Furlow palatoplasty is now synonymous with an approach to the soft palate without providing insight into hard palate closure. Given such inconsistencies,

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this review separates management of the hard and soft palates for the purpose of clarity.

### Hard Palate Repair

Commonly cited procedures for repair of the hard palate include a Bardach two-flap approach, von Langenbeck bipediced flaps, and the Veau-Wardill-Kilner pushback technique<sup>7</sup> (Figs. 1, 3, and 4). These methods have been criticized for the extensive use of incisions, wide subperiosteal undermining, and exposure of raw bone, which potentially increase scarring and impair maxillary growth.

In contrast, others have advocated minimizing incisions and avoiding bone exposure to optimize facial development. As noted, Furlow described direct repair of the hard palate mucosa without relaxing incisions in his original article on double-opposing Z-plasty.<sup>28</sup> However, direct repair techniques remain somewhat limited in their scope. When attempting closure of the hard palate with dissection through the cleft site only, one study noted that relaxing incisions were necessary in 42 percent of cases.<sup>29</sup> Pan et al. similarly advocated a minimal-incision palatoplasty with extensive lateral dissection across the alveolus to allow for additional mucosal mobilization. This procedure could not be universally applied but was successfully performed in 78 percent of cases, with a fistula rate of 7.6 percent.<sup>30</sup>

Since introduction of the vomerine flap in 1934 by Pichler,<sup>31</sup> numerous international institutions have adopted its use for hard palate closure, arguing that this method theoretically improves facial growth by minimizing scarring

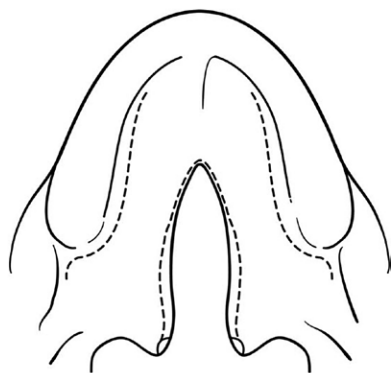
in growth-sensitive areas of the palate.<sup>32,33</sup> Several studies have shown favorable results in these patients.<sup>34–36</sup> A systematic review on this subject, however, noted that all studies assessed were retrospective and nonrandomized, with contradictory results. Thus, no definitive conclusions regarding the effects of this technique on maxillary growth could be made.<sup>37</sup>

Several flaps have been suggested to help prevent fistulas and minimize the exposure of raw bone surfaces. Among these, the buccinator musculomucosal flap (or buccal flap) has shown promise. One group described use of this flap for coverage of exposed bone following asymmetric repair of the hard palate, in which the noncleft side was elevated and mobilized to the opposite side.<sup>38</sup> This flap has also been used bilaterally for successful palatal lengthening.<sup>39</sup>

### Soft Palate Repair

Renewed focus has recently been placed on the quality of the repair of the soft palate and, in particular, its musculature. In 1969, Kriens first described the intravelar veloplasty, in which the palatine musculature is released from the posterior edge of the hard palate and reapproximated at the midline<sup>40</sup> (Fig. 5). Although the Kriens intravelar veloplasty remains a common approach for reconstruction of the levator sling, the Furlow palatoplasty and radical intravelar veloplasty procedures have gained increasing popularity.<sup>27,41</sup> To gauge the efficacy of these methods, Timbang et al. conducted a systematic review comparing the results of double-opposing Z-plasty against straight-line intravelar veloplasty repairs.<sup>42</sup> Although the authors concluded that there was a higher rate of secondary operations for velopharyngeal insufficiency in straight-line repairs, the study itself was criticized for failing to account for an evolution in the practice of muscle reconstruction, culminating in the radical intravelar veloplasty popularized by both Sommerlad and Cutting.<sup>43,44</sup>

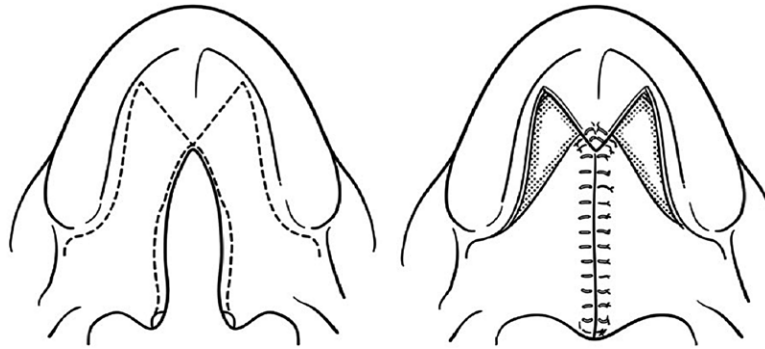
The radical intravelar veloplasty procedure advocates a more aggressive separation of the levator muscle from tensor attachments, typically by performing a tensor transection, which releases the anterior tethering of the levator sling and allows for more optimal repositioning.<sup>32,44</sup> Sommerlad et al. specifically favor use of an operating microscope to optimize visualization during the procedure and document excellent results, albeit with a steep learning curve.<sup>45,46</sup>



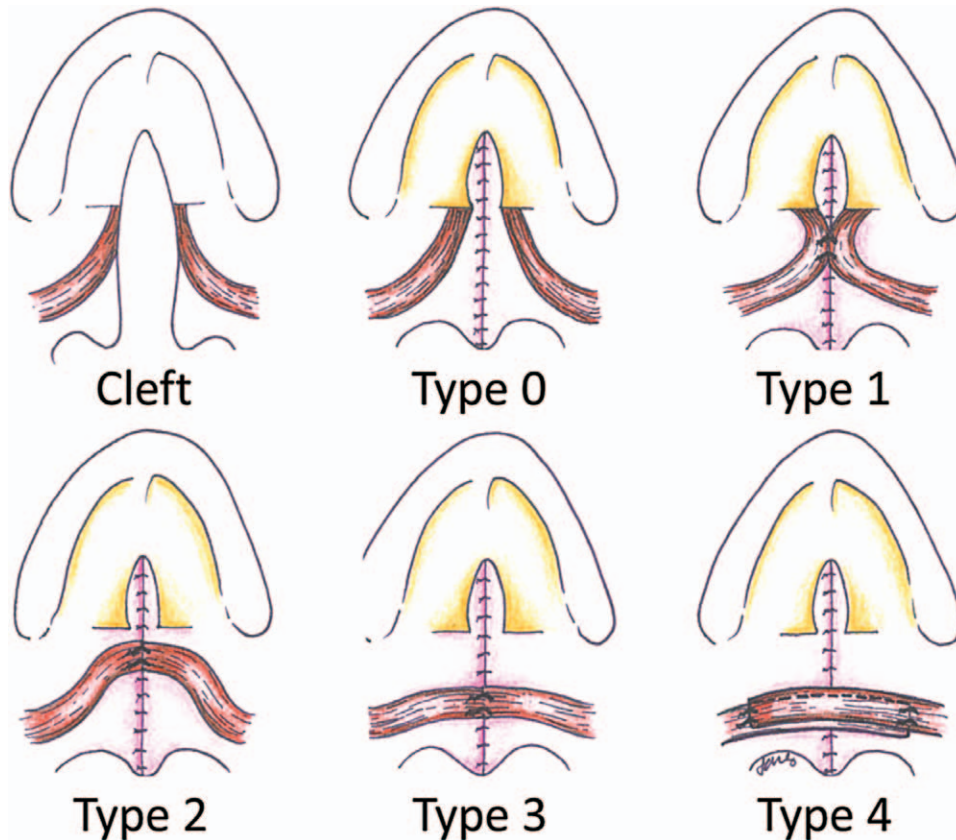
**Fig. 3.** Von Langenbeck palatoplasty. Markings are shown of the lateral relaxing incisions, which allow creation of bipediced flaps for closure of the cleft. This technique permits limited closure of anterior palatal defects and is best used when no cleft of the alveolus is present. [Reprinted from van Aalst JA, Kolappa KK, Sadove M. MOC-PSSM CME article: Nonsyndromic cleft palate. *Plast Reconstr Surg.* 2008;121(Suppl):1–14.]

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**Fig. 4.** Veau-Wardill-Kilner pushback palatoplasty. Similar to the Bardach technique, mucoperiosteal flaps are based on the greater palatine vessels and elevated over the hard palate. To obtain palatal lengthening, the flaps are then “pushed back” in a V-Y fashion. However, this procedure may leave behind more significant areas of exposed bone than the other procedures described. [Reprinted from van Aalst JA, Kolappa KK, Sadove M. MOC-PSSM CME article: Nonsyndromic cleft palate. *Plast Reconstr Surg.* 2008;121(Suppl):1–14.]



**Fig. 5.** Classification of intravelar veloplasty procedures. Type 0, no muscle repair; type I, no muscle dissection with midline reapproximation; type II (Kriens intravelar veloplasty), release of muscle fibers from the posterior edge of the hard palate without detachment of the tensor tendon; type III (radical intravelar veloplasty), levator fibers are released from anterior attachments with tensor transection, repositioned, and reapproximated at midline; type IV (overlapping intravelar veloplasty), levator fibers are dissected free from other muscles, repositioned, overlapped, and tightened. (Classification scheme adapted and updated from Andrades P, Espinosa-de-los-Monteros A, Shell DH, et al. The importance of radical intravelar veloplasty during two-flap palatoplasty. *Plast Reconstr Surg.* 2008;122:1121–1130.)

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Nguyen et al. performed a comparison of speech results from four separate intravelar veloplasty approaches.<sup>47</sup> The study assessed velopharyngeal function in those without intravelar veloplasty reconstruction (type 0), Kriens intravelar veloplasty (type II), radical intravelar veloplasty (type III), and a newly described overlapping intravelar veloplasty (type IV)<sup>48</sup> (Fig. 5). The overlapping intravelar veloplasty group demonstrated significantly better velopharyngeal function at 3 years when evaluated against the others. A notable trend toward more aggressive management of the levator yielding better speech results was also suggested by the authors.<sup>47</sup> The surgery involves a soft palate procedure consisting of a radical separation of the levator muscle from its surrounding components (Fig. 6), dissection to the origins of the levator at the skull base, followed by overlapping and tightening of the levator sling (Fig. 7)—a technique that is supported by computational models for optimization of velopharyngeal closure.<sup>49,50</sup> The mucosa is then closed with a single oral Z-plasty (Fig. 8). This is the author's preferred method of palate repair. (See Video, Supplemental Digital Content 1, which displays dissection of the hard palate with a modified two-flap palatoplasty technique. This video is available in the "Related Videos" section of the full-text article on PRSJJournal.com or at <http://links.lww.com/PRS/B914>. See Video, Supplemental Digital Content 2, which shows dissection of the soft palate and components separation of the muscle of the velum. This video is available in the "Related Videos" section of the full-text article on PRSJJournal.com or at <http://links.lww.com/PRS/B915>. See Video, Supplemental Digital Content 3, which demonstrates overlapping intravelar veloplasty and closure of the oral mucosa. This video is available in the "Related Videos" section of the full-text article on PRSJJournal.com or at <http://links.lww.com/PRS/B916>.)

Surgical maneuvers to assist in closure of the palate have been elucidated in a number of studies. To optimize tension-free closure of the soft palate, Pan et al. described wide dissection of the tissues extending to the choanae, releasing mucosa off the pterygoid and palatine bones.<sup>30</sup> Mendonca et al. sought to assess the effectiveness of different surgical maneuvers to provide maximal mobility of the oral mucosa. They noted that release of the dense fibrous attachments overlying the palatine aponeurosis was the most effective method of providing laxity at the hard/soft palate junction.<sup>51</sup>

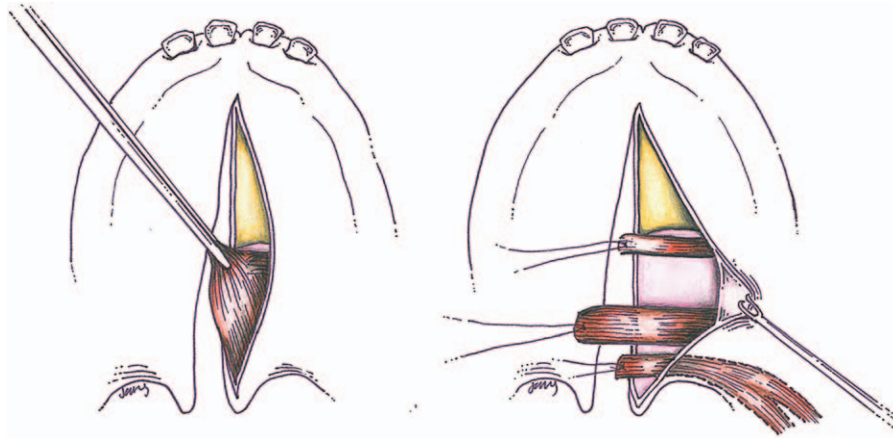
### Reconstruction of the Tensor Veli Palatini

Eustachian tube dysfunction is a nearly ubiquitous problem suffered by children born with cleft palate. In one classic report, infants with cleft palate were noted to have a 97 percent incidence of otitis media with effusion within the first 2 years of life.<sup>52</sup> Because of concern that tensor transection at the time of levator reconstruction may exacerbate ear problems, Cutting has championed a tensor tenopexy, in which the tendon is sutured directly to the hamulus. Flores et al. evaluated three sets of patients: those who underwent no tensor transection, those who underwent tensor transection, and those who underwent tensor tenopexy. By age 7, they found a significantly increased need for myringotomy tubes in the tensor transection group compared with the other cohorts. The study also noted a trend toward better results in the tensor tenopexy group.<sup>53</sup> Another team performed a prospective, randomized, controlled trial of patients who underwent either tensor tenopexy or tensor transection. After 1 year of close follow-up with otoscopy, tympanometry, and audiometry, they found no evidence that tensor tenopexy improved hearing loss or decreased eustachian tube dysfunction.<sup>54</sup>

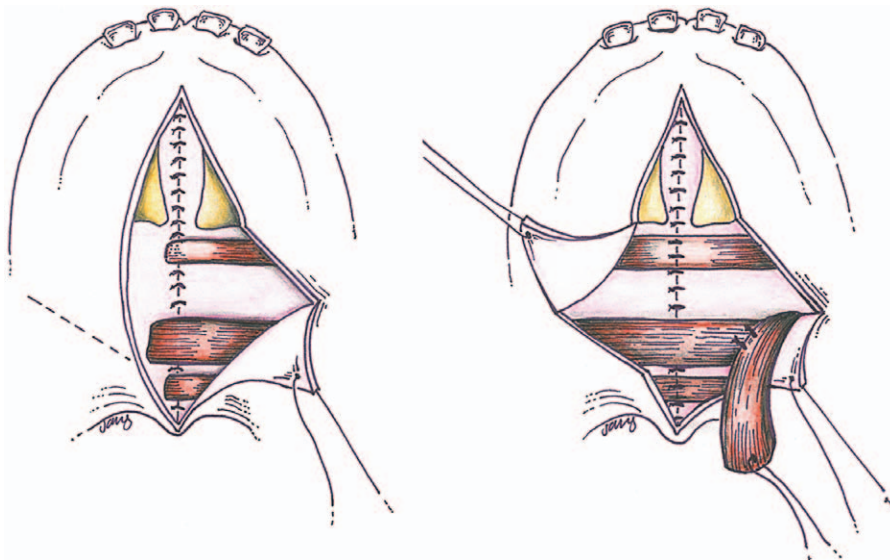
### FISTULA

A systematic review focusing on the development of postpalatoplasty fistulas identified an overall incidence of 8.6 percent.<sup>55</sup> There was no significant association with the repair technique. However, the severity of the cleft was a notable factor in fistula formation, as those presenting with cleft lip and palate (Veau class III/IV, 17.9 percent) had a higher fistula rate than in cleft palate alone (Veau class I/II, 5.4 percent)<sup>55</sup> (Table 2). A second systematic review had similar results, with an overall incidence between 7.87 and 9.81 percent. Again, it was seen that fistula rates were significantly lower in patients with cleft palate alone (Veau class I/II, 2.6 to 4 percent) compared with patients with unilateral cleft lip and palate (Veau class III, 11.62 to 13.71 percent).<sup>42</sup> Jackson et al. described a 30-year experience with a modified Furlow palatoplasty and also found a strong correlation with cleft type and fistula development. Although the overall incidence was 5.2 percent, the odds of developing an oronasal fistula were five times higher with a bilateral cleft lip and palate than with cleft palate alone.<sup>56</sup>

Given recent interest in the use of acellular dermal matrix to prevent or correct fistula formation following palatoplasty, a systematic review was



**Fig. 6.** Woo components separation palatoplasty (with overlapping intravelar veloplasty). Part I: dissection (see Video, Supplemental Digital Content 2, <http://links.lww.com/PRS/B915>). (Left) The Veau cleft muscle (a conglomeration of the tensor, levator, palatopharyngeus, and palatoglossus muscles) is initially dissected free from the oral and nasal mucosa. (Right) The Veau cleft muscle is then separated into its requisite components. The anterior edge of the levator is released from the aponeurosis of the tensor (along with any attached musculature). The palatoglossus and palatopharyngeus muscles are separated as a unit from the posterior edge of the levator. The levator is then free to be bluntly dissected deep down to its origins at the petrous portion of the temporal bone. These procedures must be performed carefully, as the muscle elements are not readily separated without dissection to their origins, making this an initially challenging endeavor.



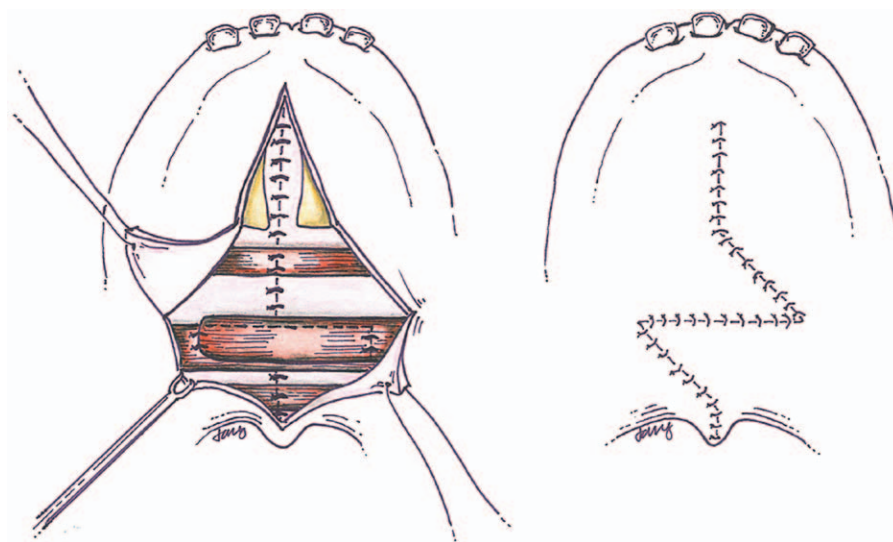
**Fig. 7.** Woo components separation palatoplasty (with overlapping intravelar veloplasty). Part II: Z-plasty. (Left) The nasal mucosa is closed with a straight-line incision. The oral Z-plasty is then marked and incised. (Right) The Z-plasty flaps facilitate visualization and access for muscle reconstruction. The tensor aponeurosis and palatopharyngeus/palatoglossus are each sutured together at the midline. The end of one levator muscle is then anchored to the base of the opposite site.

conducted on its effectiveness in fistula prevention in both primary palatoplasty and secondary fistula repair. Although the overall fistula rate was lower

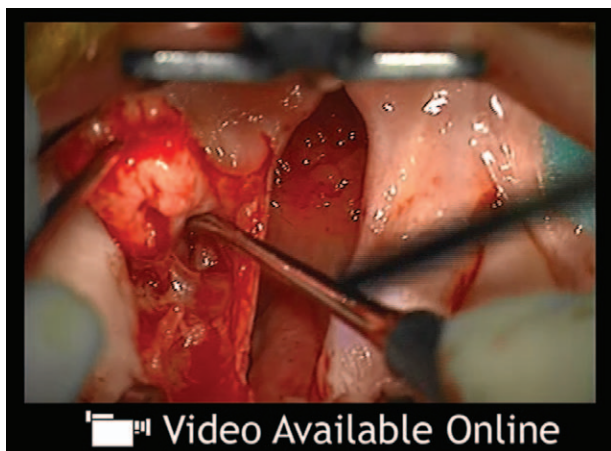
in both of the acellular dermal matrix groups, the authors concluded that the literature consisted primarily of retrospective, nonrandomized studies

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**Fig. 8.** Woo components separation palatoplasty (with overlapping intravelar veloplasty). Part III: closure (see Video, Supplemental Digital Content 2, <http://links.lww.com/PRS/B915>). (Left) The other end of the levator is then sutured to the base of its counterpart of the overlapping intravelar veloplasty. Additional tightening of the levator sling (to the surgeon's satisfaction) is the norm. (Right) The oral Z-plasty flaps are transposed and the mucosa is closed. On completion of this technique, the appearance resembles that of a Furlow palatoplasty.



Video Available Online

**Video 1.** Supplemental Digital Content 1 displays dissection of the hard palate with a modified two-flap palatoplasty technique. This video is available in the "Related Videos" section of the full-text article on PRSJournals.com or at <http://links.lww.com/PRS/B914>.



Video Available Online

**Video 2.** Supplemental Digital Content 2 shows dissection of the soft palate and components separation of the muscle of the velum. This video is available in the "Related Videos" section of the full-text article on PRSJournals.com or at <http://links.lww.com/PRS/B915>.

of Level IV or lower, and were therefore unable to recommend its routine clinical use.<sup>57</sup>

### SPEECH DEVELOPMENT AND VELOPHARYNGEAL INSUFFICIENCY

The development of velopharyngeal insufficiency following cleft palate repair has traditionally

been documented between 15 and 30 percent.<sup>58</sup> In contrast, Sullivan et al. specified that the incidence of velopharyngeal insufficiency was less than 12.5 percent when palatoplasty was performed before 11 months of age,<sup>59</sup> and Mahoney et al. described an overall rate of 10.3 percent over a 10-year period.<sup>60</sup>

It is widely accepted that reconstruction of the levator veli palatini (accomplished with intravelar

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**Video 3.** Supplemental Digital Content 3 demonstrates overlapping intravelar veloplasty and closure of the oral mucosa. This video is available in the “Related Videos” section of the full-text article on PRSJournals.com or at <http://links.lww.com/PRS/B916>.

**Table 2. Veau Cleft Classification**

Class	Description of Cleft
I	Soft palate only
II	Soft and hard palate to the incisive foramen (secondary palate only)
III	Unilateral cleft lip and palate
IV	Bilateral cleft lip and palate

veloplasty) is critical to the development of normal resonance during speech. However, a prospective randomized trial published in 1989 comparing the results of Kriens intravelar veloplasty (Fig. 5) to no-levator reconstruction showed no benefit from intravelar veloplasty.<sup>61</sup> Since then, the radical intravelar veloplasty (with transection of the tensor veli palatini and levator repositioning) has been advocated with notable improvement in speech outcomes, with rates as low as 4 to 7 percent cited.<sup>32,41</sup> Indeed, when one study recently compared radical intravelar veloplasty to a non-intravelar veloplasty group, the rate of velopharyngeal insufficiency was significantly improved with muscle repair.<sup>62</sup>

Rather than an end-to-end repair of the muscle, the Furlow double-opposing Z-plasty achieves both an overlap of the palatine musculature and lengthening of the soft palate in an ingenious geometric overlay of musculomucosal flaps<sup>28</sup> (Fig. 2). Jackson et al. reviewed a 30-year experience with a modified Furlow palatoplasty technique. In their study of 559 patients who received speech evaluation after age 5, the rate of velopharyngeal insufficiency was 8.1 percent. A competent

velopharyngeal mechanism was seen in 72.4 percent, whereas 21.5 percent had borderline results.<sup>56</sup>

Besides surgical technique, additional factors have been associated with the development of velopharyngeal insufficiency. Most institutions reported a higher rate of velopharyngeal insufficiency with more severe clefts.<sup>32,59,60</sup> Mahoney et al. identified male sex, shorter palate length, and larger cleft width as independent predictors of poorer speech outcomes.<sup>60</sup> An evaluation of 1300 patients at the Bremer Klinik in Germany found a significant correlation between the rate of velopharyngeal insufficiency and the surgeon performing the procedure.<sup>58</sup>

### Age at Surgery

Sullivan et al. noted a significant association between age at the time of surgery and the need for surgical management of velopharyngeal insufficiency.<sup>59</sup> Similarly, patients who underwent cleft palate repair with double-opposing Z-plasty before 18 months of age were seen to have better speech outcomes compared with those receiving surgery later. When findings from Pittsburgh Weighted Speech Scale scores were broken down into their nasality, emission, and articulation components, the presence of compensatory misarticulation was recognized to be the primary culprit for these lower scores.<sup>56</sup> These findings are corroborated by a prospective, longitudinal study that looked at the degree of speech development and the timing of surgery. Their analysis found that those individuals who were less lexically advanced (less than five words) and younger (mean age, 11 months) had overall better speech outcomes than those who were more advanced in speech and older (mean age, 14 months).<sup>63</sup>

### FACIAL GROWTH

Roughly 25 percent of individuals with repaired unilateral cleft lip and palate require orthognathic surgery after completion of skeletal growth.<sup>64,65</sup> In contrast, classic studies have shown that unoperated cleft patients have normal facial growth into adulthood.<sup>66,67</sup> Maxillary deficiency following repair of orofacial clefts is thought to be related to an intrinsic primary defect and also caused by scarring from surgical reconstruction. In fact, infants with cleft lip and palate have been shown to have a deficiency in the volume of maxillary alveolar bone compared with normal controls.<sup>68</sup> Concerns have been raised that the degree of restriction and scarring associated with lip and palate repair have a significant impact on facial growth. A preponderance

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of the literature describes a characteristic growth inhibition of the maxilla of cleft lip and palate patients, particularly during adolescence.<sup>69–71</sup>

### Staging of Repair

Staging of the operative repair is not commonly performed in the United States. In fact, a recent survey noted that 88 percent of cleft surgeons practice a one-stage cleft palate repair.<sup>27</sup> Nonetheless, concern over a limitation in facial growth has led some to advocate a staged repair of the palate, with initial repair of the velum followed by a delayed reconstruction of the hard palate. Supporters of this technique have noted significant improvement in growth of these patients compared with those having undergone single-stage repair.<sup>72</sup> However, as discussed in the previous review, conflicting evidence exists with respect to this issue. In prospective trials, Liao et al. showed a decrease in maxillary growth and protrusion with single-stage repair,<sup>73</sup> whereas De Mey et al. found no significant difference in maxillary projection at age 15 between a single-stage group and a two-stage Malek protocol. Moreover, anteroposterior growth after single-stage repair was not significantly different from noncleft controls.<sup>74</sup> With regard to speech, however, significant limitations in phonologic development have been identified with a two-stage reconstruction compared with single-stage palatoplasty.<sup>75,76</sup>

### OBSTRUCTIVE SLEEP APNEA

Although the strength of evidence remains weak, several studies have demonstrated an association between cleft palate deformity and an increased incidence of sleep apnea. Overall, 32 percent of patients with cleft palate at one center screened positively for obstructive sleep apnea when administered a questionnaire.<sup>77</sup> In a small cohort of patients, the identification of sleep apnea preoperatively was significantly associated with postoperative respiratory distress, the need for supplemental oxygen, and a lengthened hospital stay.<sup>78</sup> Robison and Otteson performed a retrospective analysis of 459 subjects with cleft palate undergoing sleep studies and reported an increased prevalence of sleep-disordered breathing and obstructive symptoms compared with controls.<sup>79</sup> MacLean et al. had similar findings in a prospective study of 50 patients, where 75 percent were reported to frequently snore or have heavy or loud breathing while asleep.<sup>80</sup> In this group, greater sleep disruption was associated with lower cognition scores, diminished quality of life, and poorer weight gain.<sup>81</sup>

### CONCLUSIONS

As we advocate for the increased use of evidence-based medicine, it is critical that surgeons not only consider the strength of the scientific evidence but also temper the data with the particular idiosyncrasies of their own practices, patient populations, and surgical proficiency. As each of our experiences is unique, it is essential that individual practitioners closely follow their own results and consider changes to surgical practice when the evidence suggests better outcomes are possible.

Based on a review of the most recent evidence on cleft palate, expecting families should be counseled on risk factors associated with orofacial cleft development. After delivery, infants with cleft palate alone and those presenting with other congenital anomalies should be referred for genetic consultation.

For intraoperative pain control, local infiltration with bupivacaine remains the gold standard, although evidence exists to support the use of maxillary nerve blocks and administration of intravenous acetaminophen perioperatively. Although little consensus information exists regarding the exact timing of cleft palate repair, the author advocates repair between 9 and 12 months of age, preferably before significant development of language (more than five words). Numerous techniques exist for cleft palate repair, with evidence arguing in favor of more radical approaches to reconstruction of the levator sling, either with radical intravelar veloplasty or with overlapping of the muscle with Z-plasty.

Fistula rates overall are 8.6 percent, with more severe clefts demonstrating a greater chance of this complication. Strong evidence does not yet exist for advocating two-stage palate repair, with one-stage reconstructions predominating in the United States. Obstructive sleep apnea should be watched for in all patients with cleft palate.

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## REFERENCES

- Parker SE, Mai CT, Canfield MA, et al.; National Birth Defects Prevention Network. Updated National Birth Prevalence estimates for selected birth defects in the United States, 2004–2006. *Birth Defects Res A Clin Mol Teratol*. 2010;88:1008–1016.
- Mai CT, Cassell CH, Meyer RE, et al.; National Birth Defects Prevention Network. Birth defects data from population-based birth defects surveillance programs in the United States, 2007 to 2011: Highlighting orofacial clefts. *Birth Defects Res A Clin Mol Teratol*. 2014;100:895–904.
- Tanaka SA, Mahabir RC, Jupiter DC, Menezes JM. Updating the epidemiology of isolated cleft palate. *Plast Reconstr Surg*. 2013;131:650e–652e.
- Genisca AE, Frias JL, Broussard CS, et al.; National Birth Defects Prevention Study. Orofacial clefts in the National Birth Defects Prevention Study, 1997–2004. *Am J Med Genet A* 2009;149:1149–1158.
- Maarse W, Rozendaal AM, Pajkrt E, Vermey-Keers C, Mink van der Molen AB, van den Boogaard MJ. A systematic review of associated structural and chromosomal defects in oral clefts: When is prenatal genetic analysis indicated? *J Med Genet*. 2012;49:490–498.
- Lowry RB, Sibbald B. Updating the epidemiology of isolated cleft palate. *Plast Reconstr Surg*. 2014;133:67e–68e.
- van Aalst JA, Kolappa KK, Sadove M. MOC-PSSM CME article: Nonsyndromic cleft palate. *Plast Reconstr Surg*. 2008;121 (Suppl):1–14.
- Kelly D, O'Dowd T, Reulbach U. Use of folic acid supplements and risk of cleft lip and palate in infants: A population-based cohort study. *Br J Gen Pract*. 2012;62:e466–e472.
- Butali A, Little J, Chevrier C, et al. Folic acid supplementation use and the MTHFR C677T polymorphism in orofacial clefts etiology: An individual participant data pooled-analysis. *Birth Defects Res A Clin Mol Teratol*. 2013;97:509–514.
- Gunnerbeck A, Edstedt Bonamy AK, Wikström AK, Granath F, Wickström R, Cnattingius S. Maternal snuff use and smoking and the risk of oral cleft malformations: A population-based cohort study. *PLoS One* 2014;9:e84715.
- Honein MA, Devine O, Grosse SD, Reefhuis J. Prevention of orofacial clefts caused by smoking: Implications of the Surgeon General's report. *Birth Defects Res A Clin Mol Teratol*. 2014;100:822–825.
- Molina-Solana R, Yáñez-Vico RM, Iglesias-Linares A, Mendoza-Mendoza A, Solano-Reina E. Current concepts on the effect of environmental factors on cleft lip and palate. *Int J Oral Maxillofac Surg*. 2013;42:177–184.
- Holmes LB, Hernandez-Diaz S. Newer anticonvulsants: Lamotrigine, topiramate and gabapentin. *Birth Defects Res A Clin Mol Teratol*. 2012;94:599–606.
- Hernandez-Diaz S. Evidence accumulates on the association between topiramate use early in pregnancy and the risk of oral clefts. *Pharmacoepidemiol Drug Saf*. 2014;23:1026–1028.
- Margulis AV, Mitchell AA, Gilboa SM, et al.; National Birth Defects Prevention Study. Use of topiramate in pregnancy and risk of oral clefts. *Am J Obstet Gynecol*. 2012;207:405.e1–405.e7.
- Mines D, Tennis P, Curkendall SM, et al. Topiramate use in pregnancy and the birth prevalence of oral clefts. *Pharmacoepidemiol Drug Saf*. 2014;23:1017–1025.
- Lin KJ, Mitchell AA, Yau WP, Louik C, Hernández-Díaz S. Maternal exposure to amoxicillin and the risk of oral clefts. *Epidemiology* 2012;23:699–705.
- Wehby GL, Félix TM, Goco N, et al. High dosage folic acid supplementation, oral cleft recurrence and fetal growth. *Int J Environ Res Public Health* 2013;10:590–605.
- Skuladottir H, Wilcox AJ, Ma C, et al. Corticosteroid use and risk of orofacial clefts. *Birth Defects Res A Clin Mol Teratol*. 2014;100:499–506.
- Bay Bjørn AM, Ehrenstein V, Hundborg HH, Nohr EA, Sørensen HT, Nørgaard M. Use of corticosteroids in early pregnancy is not associated with risk of oral clefts and other congenital malformations in offspring. *Am J Ther*. 2014;21:73–80.
- Chepla KJ, Gosain AK. Evidence-based medicine: Cleft palate. *Plast Reconstr Surg*. 2013;132:1644–1648.
- Chiono J, Raux O, Bringuier S, et al. Bilateral suprazygomatic maxillary nerve block for cleft palate repair in children: A prospective, randomized, double-blind study versus placebo. *Anesthesiology* 2014;120:1362–1369.
- Nour C, Ratsiu J, Singh N, et al. Analgesic effectiveness of acetaminophen for primary cleft palate repair in young children: A randomized placebo controlled trial. *Paediatr Anaesth*. 2014;24:574–581.
- Jha AK, Bhardwaj N, Yaddanapudi S, Sharma RK, Mahajan JK. A randomized study of surgical site infiltration with bupivacaine or ketamine for pain relief in children following cleft palate repair. *Paediatr Anaesth*. 2013;23:401–406.
- Honarmand A, Safavi MR, Jamshidi M. The preventative analgesic effect of preincisional peritonsillar infiltration of two low doses of ketamine for postoperative pain relief in children following adenotonsillectomy: A randomized, double-blind, placebo-controlled study. *Paediatr Anaesth*. 2008;18:508–514.
- Senders CW, Di Mauro SM, Brodie HA, Emery BE, Sykes JM. The efficacy of perioperative steroid therapy in pediatric primary palatoplasty. *Cleft Palate Craniofac J*. 1999;36:340–344.
- Katzel EB, Basile P, Koltz PF, Marcus JR, Giroto JA. Current surgical practices in cleft care: Cleft palate repair techniques and postoperative care. *Plast Reconstr Surg*. 2009;124:899–906.
- Furlow LT Jr. Cleft palate repair by double opposing Z-plasty. *Plast Reconstr Surg*. 1986;78:724–738.
- Becker M, Hansson E. Low rate of fistula formation after Sommerlad palatoplasty with or without lateral incisions: An analysis of risk factors for formation of fistulas after palatoplasty. *J Plast Reconstr Aesthet Surg*. 2013;66:697–703.
- Pan BS, Rapp SJ, Vu A, Uribe-Rivera A, Billmire DA, Gordon CB. Evolution in minimal-incision palatoplasty: Surgical technique and outcomes in 67 consecutive cases. *Plast Reconstr Surg*. 2014;134:102–111.
- Pichler H. Operationen der angeborenen Lippen-Kiefer-Gaumenspalten. *Wien Klin Wochenschr*. 1934;47:70–72.
- Sommerlad BC. A technique for cleft palate repair. *Plast Reconstr Surg*. 2003;112:1542–1548.
- Agrawal K, Panda KN. Use of vomer flap in palatoplasty: Revisited. *Cleft Palate Craniofac J*. 2006;43:30–37.
- Ross RB. Growth of the facial skeleton following the Malek repair for unilateral cleft lip and palate. *Cleft Palate Craniofac J*. 1995;32:194–198.
- Brattström V, Mølsted K, Prahll-Andersen B, Semb G, Shaw WC. The Eurocleft study: Intercenter study of treatment outcome in patients with complete cleft lip and palate. Part 2: Craniofacial form and nasolabial appearance. *Cleft Palate Craniofac J*. 2005;42:69–77.
- Mølsted K, Brattström V, Prahll-Andersen B, Shaw WC, Semb G. The Eurocleft study: Intercenter study of treatment outcome in patients with complete cleft lip and palate. Part 3: Dental arch relationships. *Cleft Palate Craniofac J*. 2005;42:78–82.
- Lee YH, Liao YF. Hard palate-repair technique and facial growth in patients with cleft lip and palate: A systematic review. *Br J Oral Maxillofac Surg*. 2013;51:851–857.



38. Yang Z, Liu L, Fan J, Chen W, Fu S, Yin Z. Use of the buccinator musculomucosal flap for bone coverage in primary cleft palate repair. *Aesthetic Plast Surg*. 2013;37:1171–1175.
39. Mann RJ, Neaman KC, Armstrong SD, Ebner B, Bajnrauh R, Naum S. The double-opposing buccal flap procedure for palatal lengthening. *Plast Reconstr Surg*. 2011;127:2413–2418.
40. Kriens OB. An anatomical approach to veloplasty. *Plast Reconstr Surg*. 1969;43:29–41.
41. Andrades P, Espinosa-de-los-Monteros A, Shell DH IV, et al. The importance of radical intravelar veloplasty during two-flap palatoplasty. *Plast Reconstr Surg*. 2008;122:1121–1130.
42. Timbang MR, Gharb BB, Rampazzo A, Papay F, Zins J, Doumit G. A systematic review comparing Furlow double-opposing Z-plasty and straight-line intravelar veloplasty methods of cleft palate repair. *Plast Reconstr Surg*. 2014;134:1014–1022.
43. Nardini G, Flores RL. A systematic review comparing Furlow double-opposing z-plasty and straight-line intravelar veloplasty methods of cleft palate repair. *Plast Reconstr Surg*. 2015;135:927e–928e.
44. Cutting C, Rosenbaum J, Rovati L. The technique of muscle repair in the cleft soft palate. *Oper Tech Plast Reconstr Surg*. 1995;2:215–222.
45. Sommerlad BC. Surgery of the cleft palate: Repair using the operating microscope with radical muscle repositioning. The GostA approach. *B-ENT* 2006;2(Suppl 4):32–34.
46. Sommerlad BC. The use of the operating microscope for cleft palate repair and pharyngoplasty. *Plast Reconstr Surg*. 2003;112:1540–1541.
47. Nguyen DC, Patel KB, Skolnick GB, et al. Progressive tightening of the levator veli palatini muscle improves velopharyngeal dysfunction in early outcomes of primary palatoplasty. *Plast Reconstr Surg*. 2015;136:131–141.
48. Woo AS, Skolnick GB, Sachanandani NS, Grames LM. Evaluation of two palate repair techniques for the surgical management of velopharyngeal insufficiency. *Plast Reconstr Surg*. 2014;134:588e–596e.
49. Inouye JM, Pelland CM, Lin KY, Borowitz KC, Blemker SS. A computational model of velopharyngeal closure for simulating cleft palate repair. *J Craniofac Surg*. 2015;26:658–662.
50. Inouye JM, Perry JL, Lin KY, Blemker SS. A computational model quantifies the effect of anatomical variability on velopharyngeal function. *J Speech Lang Hear Res*. 2015;58:1119–1133.
51. Mendonca DA, Patel KB, Skolnick GB, Woo AS. Anatomical study of the effects of five surgical maneuvers on palate movement. *J Plast Reconstr Aesthet Surg*. 2014;67:764–769.
52. Paradise JL. Middle ear problems associated with cleft palate: An internationally-oriented review. *Cleft Palate J*. 1975;12:17–22.
53. Flores RL, Jones BL, Bernstein J, Karnell M, Canady J, Cutting CB. Tensor veli palatini preservation, transection, and transection with tensor tenopexy during cleft palate repair and its effects on eustachian tube function. *Plast Reconstr Surg*. 2010;125:282–289.
54. Tiwari R, Sharma RK, Panda NK, Munjal S, Makkar S. Tensor tenopexy: A clinical study to assess its effectiveness in improving eustachian tube function and preventing hearing loss in patients with cleft palate. *J Plast Reconstr Aesthet Surg*. 2013;66:e239–e245.
55. Hardwicke JT, Landini G, Richard BM. Fistula incidence after primary cleft palate repair: A systematic review of the literature. *Plast Reconstr Surg*. 2014;134:618e–627e.
56. Jackson O, Stransky CA, Jawad AF, et al. The Children's Hospital of Philadelphia modification of the Furlow double-opposing Z-palatoplasty: 30-year experience and long-term speech outcomes. *Plast Reconstr Surg*. 2013;132:613–622.
57. Aldekhayel SA, Sinno H, Gilardino MS. Acellular dermal matrix in cleft palate repair: An evidence-based review. *Plast Reconstr Surg*. 2012;130:177–182.
58. Schuster T, Rustemeyer J, Bremerich A, Günther L, Schwenzer-Zimmerer K. Analysis of patients with a cleft of the soft palate with special consideration to the problem of velopharyngeal insufficiency. *J Craniofac Surg*. 2013;41:245–248.
59. Sullivan SR, Marrinan EM, LaBrie RA, Rogers GF, Mulliken JB. Palatoplasty outcomes in nonsyndromic patients with cleft palate: A 29-year assessment of one surgeon's experience. *J Craniofac Surg*. 2009;20(Suppl 1):612–616.
60. Mahoney MH, Swan MC, Fisher DM. Prospective analysis of presurgical risk factors for outcomes in primary palatoplasty. *Plast Reconstr Surg*. 2013;132:165–171.
61. Marsh JL, Grames LM, Holtman B. Intravelar veloplasty: A prospective study. *Cleft Palate J*. 1989;26:46–50.
62. Doucet JC, Herlin C, Captier G, Baylon H, Verdeil M, Bigorre M. Speech outcomes of early palatal repair with or without intravelar veloplasty in children with complete unilateral cleft lip and palate. *Br J Oral Maxillofac Surg*. 2013;51:845–850.
63. Chapman KL, Hardin-Jones MA, Goldstein JA, Halter KA, Havlik RJ, Schulte J. Timing of palatal surgery and speech outcome. *Cleft Palate Craniofac J*. 2008;45:297–308.
64. Ross RB. Treatment variables affecting facial growth in complete unilateral cleft lip and palate. *Cleft Palate J*. 1987;24:5–77.
65. Oberoi S, Hoffman WY, Chigurupati R, Vargervik K. Frequency of surgical correction for maxillary hypoplasia in cleft lip and palate. *J Craniofac Surg*. 2012;23:1665–1667.
66. Bishara SE. Cephalometric evaluation of facial growth in operated and non-operated individuals with isolated clefts of the palate. *Cleft Palate J*. 1973;10:239–246.
67. Ortiz-Monasterio F, Rebeil AS, Valderrama M, Cruz R. Cephalometric measurements on adult patients with non-operated cleft palates. *Plast Reconstr Surg Transplant Bull*. 1959;24:53–61.
68. Dec W, Olivera O, Shetye P, Cutting CB, Grayson BH, Warren SM. Cleft palate midface is both hypoplastic and displaced. *J Craniofac Surg*. 2013;24:89–93.
69. Lissou JA, Weyrich C. Extent of maxillary deficiency in patients with complete UCLP and BCLP. *Head Face Med*. 2014;10:26.
70. Moreira I, Suri S, Ross B, Tompson B, Fisher D, Lou W. Soft-tissue profile growth in patients with repaired complete unilateral cleft lip and palate: A cephalometric comparison with normal controls at ages 7, 11, and 18 years. *Am J Orthod Dentofacial Orthop*. 2014;145:341–358.
71. Toro-Ibacache V, Cortés Araya J, Díaz Muñoz A, Manríquez Soto G. Morphologic variability of nonsyndromic operated patients affected by cleft lip and palate: A geometric morphometric study. *Am J Orthod Dentofacial Orthop*. 2014;146:346–354.
72. Gundlach KK, Bardach J, Filippow D, Stahl-de Castrillon F, Lenz JH. Two-stage palatoplasty, is it still a valuable treatment protocol for patients with a cleft of lip, alveolus, and palate? *J Craniofac Surg*. 2013;41:62–70.
73. Liao YF, Yang IY, Wang R, Yun C, Huang CS. Two-stage palate repair with delayed hard palate closure is related to favorable maxillary growth in unilateral cleft lip and palate. *Plast Reconstr Surg*. 2010;125:1503–1510.
74. De Mey A, Franck D, Cuyllits N, Swennen G, Malevez C, Lejour M. Early one-stage repair of complete unilateral cleft lip and palate. *J Craniofac Surg*. 2009;20(Suppl 2):1723–1728.
75. Willadsen E. Influence of timing of hard palate repair in a two-stage procedure on early speech development in Danish children with cleft palate. *Cleft Palate Craniofac J*. 2012;49:574–595.

76. Pradel W, Senf D, Mai R, Ludicke G, Eckelt U, Lauer G. One-stage palate repair improves speech outcome and early maxillary growth in patients with cleft lip and palate. *J Physiol Pharmacol.* 2009;60(Suppl 8):37–41.
77. Silvestre J, Tahiri Y, Paliga JT, Taylor JA. Screening for obstructive sleep apnea in children with syndromic cleft lip and/or palate. *J Plast Reconstr Aesthet Surg.* 2014;67:1475–1480.
78. Smith D, Abdullah SE, Moores A, Wynne DM. Post-operative respiratory distress following primary cleft palate repair. *J Laryngol Otol.* 2013;127:65–66.
79. Robison JG, Otteson TD. Increased prevalence of obstructive sleep apnea in patients with cleft palate. *Arch Otolaryngol Head Neck Surg.* 2011;137:269–274.
80. MacLean JE, Fitzsimons D, Fitzgerald DA, Waters KA. The spectrum of sleep-disordered breathing symptoms and respiratory events in infants with cleft lip and/or palate. *Arch Dis Child.* 2012;97:1058–1063.
81. Smith CB, Walker K, Badawi N, Waters KA, MacLean JE. Impact of sleep and breathing in infancy on outcomes at three years of age for children with cleft lip and/or palate. *Sleep* 2014;37:919–925.