Palatoplasty Outcomes in Nonsyndromic Patients With Cleft Palate: A 29-Year Assessment of One Surgeon's Experience

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Abstract: The primary objective of cleft palate repair is velopharyngeal competence without fistula. The reported incidence of fistula and velopharyngeal insufficiency (VPI) is variable. Our purpose was to assess the senior surgeon's 29-year palatoplasty experience with respect to incidence of fistula and VPI. Our hypotheses were that VPI is related to (1) age at palatoplasty, (2) cleft palate type, and (3) VPI and palatal fistula incidence decrease with the surgeon's experience. We reviewed the records of all children with cleft palate treated by the senior author between 1976 and 2004. Cleft palate was categorized according to Veau. Palatoplasty was performed on 449 patients, using a 2-flap technique with muscular retropositioning. The mean age at palatoplasty was 11.6 ± 4.9 months (range, 7.0–46.4 months). The incidence of palatal fistula was 2.9%, and velopharyngeal sufficiency was found in 85.1% of patients. We found a significant association between age at palatoplasty and VPI ($P = 0.009$, odds ratio, 1.06 [95% confidence interval, 1.02–1.10]). Velopharyngeal insufficiency was also associated with the Veau hierarchy ($P = 0.001$). Incidence of VPI was independent of surgeon experience ($P = 0.2$). In conclusion, the incidence of palatal fistula was low. Velopharyngeal insufficiency was associated with increasing age at palatoplasty and with the Veau hierarchy.

Key Words: Velopharyngeal insufficiency, fistula, velopharyngeal incompetence, palatoplasty, cleft palate, Veau classification

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Although many methods have been described to close a palatal cleft, all share the common goal of establishing a competent velopharyngeal sphincter. Palatoplasty success is measured by both the structural and functional integrity of the repaired palate.[1] Loss of structural integrity after palatoplasty results in a fistula. Palatal fistula is evident shortly after palatoplasty and, depending on the size of the defect, may affect velopharyngeal competence and speech. The reported incidence of fistula ranges from 4.7% to 60%.[2–7] In contrast, the functional outcome of palatoplasty is not evident until the infant is older. Velopharyngeal insufficiency (VPI), the audible hallmark of a nonfunctional palate, is failed velopharyngeal sphincter closure and is characterized by hypernasal resonance and decreased intraoral pressure for pressure-dependent consonants during speech.[8] The reported frequency of VPI is 5% to 30%.[4,9–16]

Surgeons are obligated to intermittently and critically assess their results and redirect treatment protocols accordingly. Nevertheless, the wide variability of published outcomes underscores the lack of standardization that permeates the literature and limits meaningful interpretation of results.[17] At the most basic level, some studies fail to stratify outcomes by cleft severity or other important patient variables (eg, hearing, syndromic association). A more pervasive problem is the definitional and nosological inconsistencies between surgeons and centers. Although there are several comparative studies, most are limited by the inclusion of multiple surgeons, institutions, and operative techniques.[4,11,16,18] There are few clinical audits documenting the long-term results of cleft palate repair by 1 surgeon using 1 technique.[10,13–15]

The purpose of this study was to determine if age at palatoplasty, type of cleft, or surgical experience is associated with palatoplasty outcome (ie, fistula, VPI). To reduce confounding variables, we analyze the senior surgeon's 29-year experience at a single institution using 1 palatoplasty technique.

MATERIALS AND METHODS

Patient Population

After approval by the institutional review board of the Committee on Clinical Investigation, we identified and reviewed the charts of all patients with cleft palate repaired by the senior author at the Children's Hospital Boston between 1976 and 2004. We included those patients who were at least 4 years of age at the time of this review. Four years was chosen because children with velopharyngeal sufficiency at age 4 years are unlikely to subsequently develop VPI, and children younger than 4 years are often unable to cooperate for appropriate speech assessment.[13,19] Exclusion criteria were submucous cleft palate, identified syndrome, Robin sequence, and hearing loss (sensorineural or persistent conductive hearing loss despite tympanostomy). Data collected included date of birth, sex, cleft palate type (classified according to Veau:[20] I [soft palate], II [hard/soft palate extending to the incisive foramen], III [unilateral complete cleft lip/palate], and IV [bilateral complete cleft lip/palate]), age at palatoplasty, postoperative speech assessments, and need for a secondary operation to correct VPI. Palatal fistulas were recorded (nasal-alveolar and anterior palatal fistulas intentionally not repaired [Pittsburgh types VI and VII[21]], and bifid uvula [Pittsburgh type I] were excluded[2]).

Palatoplasty Technique

The operative technique in all patients was a 2-flap palatoplasty. Nasal lining dissected from the palatal shelves and vomerine flap(s)

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were used as indicated in complete clefts. The anteriorly displaced tensor and levator veli palatini muscles were incised from their abnormal attachment to the posterior palatine edge, dissected from the oral and nasal mucosa, retropositioned, and apposed. Other maneuvers to facilitate closure were dissection of the greater palatine arteries from the mucoperiosteal flaps, posterior ostectomy of the greater palatine foramina, and hamular fracture to free the tensor veli palatini tendon and facilitate posteromedial displacement of the velar muscles and mucoperiosteal flaps for a 3-layer soft palatal repair. A gauze palatal pack, soaked in balsam of Peru, was sutured to the alveolar ridges to support the mucoperiosteal flaps and minimize bleeding, pain, and dead space under the flaps.

Palatoplasty Outcome

Patients were followed up annually in our interdisciplinary cleft palate clinic. The senior author examined all the patients in conjunction with speech pathologists who specialize in cleft palate. The presence of a fistula, recorded by the senior author or any other observer (eg, dental, oral surgery), was recorded. The speech pathologist completed perceptual assessments on each patient using the Pittsburgh Weighted Values for Speech Symptoms Associated With Velopharyngeal Incompetence instrument.[22] Outcome measures were palatal fistula and VPI requiring a secondary operation.

Velopharyngeal function was classified as sufficient, borderline, or insufficient. Velopharyngeal insufficiency was characterized by moderate or severe hypernasal resonance, audible nasal emission, and decreased intraoral pressure. A tailored superiorly based pharyngeal flap[23,24] was recommended for patients with VPI or those with borderline velopharyngeal sufficiency despite speech therapy when speech posed a personal or social problem or both. Patients underwent multiview (lateral, frontal, and base) videofluoroscopy, sometimes combined with flexible fiberoptic nasopharyngoscopy. Patients for whom a pharyngeal flap was recommended, but not performed, were recorded as equivalent as having had a flap. The plastic surgeon and speech pathologist reviewed studies together before consideration of a pharyngeal flap.

Statistical Analysis

Patient characteristics were summarized and descriptive statistics compared among Veau palatal types. We calculated the incidences of palatal fistula and VPI requiring a secondary operation. Age at palatoplasty, a continuous variable, was compared among cleft palate types using 1-way analysis of variance. The incidences of palatal fistula and VPI were compared among cleft types using Fisher exact test and Bonferroni method to correct for multiple comparisons.

We next compared our binary outcome variables, fistula and VPI requiring a secondary operation, to the cleft type using Fisher exact test and to the age at palatoplasty using logistic regression. To evaluate for a possible association between surgeon experience and VPI requiring a secondary operation, we separated patients into quartiles based on year of palatoplasty: group 1 (1976–1990, n = 112), group 2 (1990–1995, n = 113), group 3 (1995–2000, n = 112), and group 4 (2000–2004, n = 112). All calculated P values were 2-tailed and considered significant if less than 0.05. Results were presented as odds ratios (ORs) and 95% confidence intervals (95% CIs) as a measure of association. Statistical analyses were performed using Stata version 8 (Statacorp, College Station, TX).

RESULTS

Veau Types

We included 449 patients in this review and summarized patient characteristics overall and by cleft type in Table 1. Veau III was the most common cleft type. There was a significant difference in sex distribution among cleft palate types: girls more commonly had a Veau I or II cleft, and boys more commonly had a Veau III or IV ($P < 0.001$). The mean age at palatoplasty was 11.6 ± 4.9 months (range, 7.0–46.4 months). There were no differences in age at palatoplasty among cleft palate types ($P = 0.8$).

Palatal Fistula

Palatal fistula was found in 13 patients (2.9%). Most were slitlike and found at the junction between the hard and soft palate. Eight additional patients (1.8%) were found to have a bifid uvula. Veau II and IV clefts had the highest incidence of fistula, but we found no significant differences among the cleft types ($P = 0.9$) (Fig. 1). Furthermore, we found no differences in the average age at palatoplasty between patients who did and did not have a fistula (10.4 ± 4.6 vs 10.3 ± 5.0 months, respectively; $P = 0.9$).

Velopharyngeal Insufficiency

Two-flap palatoplasty achieved a competent velopharyngeal sphincter in 85.1% of patients. The relationship between age at palatoplasty and the need for a pharyngeal flap is shown in Figure 2. Palatoplasty was performed before 11 months of age for most patients, and when done so, the incidence of VPI requiring a secondary operation was less than 12.5%. A higher VPI incidence was noted in 158 children who underwent palatoplasty at an older age (≥11 months). We found a significant association between age at palatoplasty and the presence of VPI requiring a secondary operation. Between 7.0 and 46.4 months of age, each additional

TABLE 1. Clinical Characteristics Overall and by Veau Palate Type

Patient Characteristic	All Patients (n = 449)	Veau I (n = 123, 27.4%)	Veau II (n = 36, 8.0%)	Veau III (n = 206, 45.9%)	Veau IV (n = 84, 18.7%)	P*
Age at cleft palate repair, mo						
Mean ± SD	11.6 (4.9)	11.1 (5.0)	11.0 (3.8)	11.9 (5.3)	11.7 (4.2)	0.8
Range	7.0–46.4	7.0–39.8	7.0–30.4	7.7–46.4	7.6–31.8	
Female sex, n (%)	203 (45.2%)	78 (63.4%)	24 (66.7%)	76 (36.9%)	25 (29.8%)	<0.001
Fistula, n (%)	13 (2.9%)	2 (1.6%)	3 (8.3%)	4 (1.9%)	4 (4.8%)	0.9
Need for pharyngeal flap due to VPI, n (%)	67 (14.9%)	6 (4.9%)	5 (13.9%)	36 (17.5%)	20 (23.8%)	<0.001

*Fisher exact test was used to test for differences in proportions among Veau groups for categorical variables, and 1-way analysis of variance was used to test for differences in mean age at cleft palate repair.

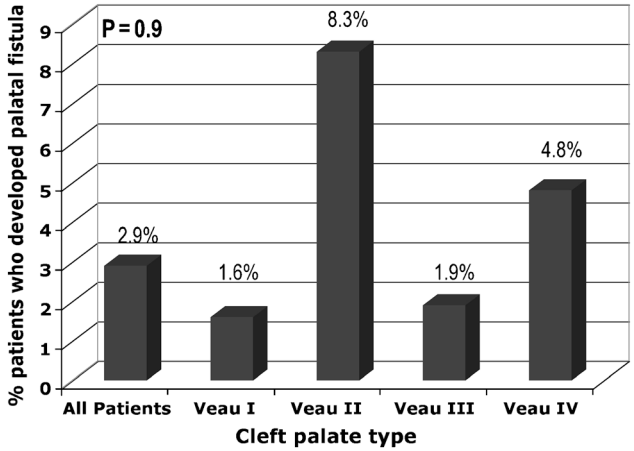

FIGURE 1. Palatal fistula incidence was 2.9%. Cleft palate without vomeric attachment (Veau II and IV) had the highest fistula incidence, although no significant differences were found among cleft palate types ($P = 0.9$).

month in age at palatoplasty was associated with a 6% increase in odds of VPI requiring a secondary operation ($P = 0.009$; OR, 1.06 [95% CI, 1.02–1.10]).

The need for a pharyngeal flap corresponded with the Veau hierarchy, and significant differences were found among cleft palate types ($P = 0.001$) (Fig. 3). Although patients with Veau IV were significantly more likely to need a pharyngeal flap than those with Veau I ($P < 0.01$, Bonferroni corrected; OR, 6.0 [95% CI, 2.3–15.8]), no differences were found as compared with Veau II and III ($P > 0.2$, Bonferroni corrected; OR, 2.0 [95% CI, 0.8–2.8]; and $P > 0.2$, Bonferroni corrected; OR, 1.5 [95% CI, 0.8–2.8], respectively), and no differences in need for a pharyngeal flap were found among Veau I, II, and III cleft palate ($P > 0.2$, Bonferroni corrected).

Surgeon Experience

We found no significant differences in palatal fistula or VPI incidences among patient quartile groups over the 29-year period ($P = 0.4$). However, the most recent quartile of patients had the lowest incidence of VPI requiring a secondary operation. Average age at palatoplasty became younger with each successive group (range of age in years: group 1 = 11.6 ± 3.9 [7.8–36.0], group 2 = 10.5 ± 5.2 [7.0–46.4], group 3 = 9.9 ± 5.1 [7.7–39.8], and group 4 = 9.5 ± 5.5 [7.0–37.5]).

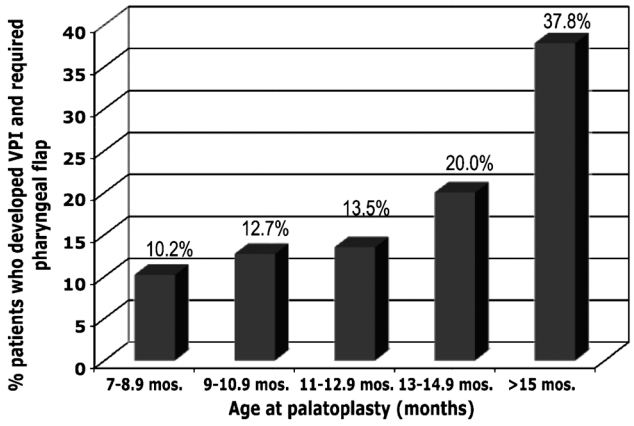

FIGURE 2. Age at palatoplasty compared with percentage of patients who developed VPI and required a secondary operation.

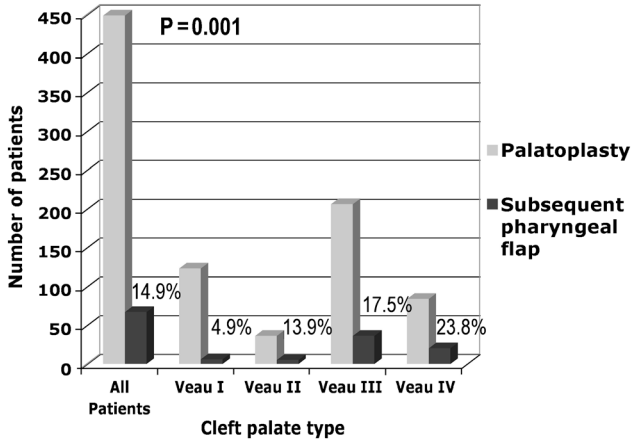

FIGURE 3. Veau cleft palate type compared with VPI. Percentage indicates number of patients who had VPI and required secondary operation per total number of patients as categorized by Veau cleft type. Need for a secondary operation varied significantly among cleft types ($P = 0.001$); Veau IV patients were more likely to need a pharyngeal flap as compared with Veau I ($P < 0.01$, Bonferroni corrected; OR, 6.0 [2.3–15.8]), although not when compared with Veau II and III ($P > 0.2$). No differences in VPI incidence were found among Veau I, II, and III ($P > 0.2$).

DISCUSSION

The palatoplasty results of this large single-surgeon series of nonsyndromic patients demonstrate several important findings. Our reported VPI incidence requiring a second operation, 14.9%, is similar to other reports (4.6%–26.4%).[6,10,11,13,16,25–27] Such comparisons are problematic, however, because many of these investigations differ significantly in palatoplasty technique, age at palatoplasty, threshold for recommendation of a secondary operations, and patient exclusion.[12,15] The association between palatoplasty technique and incidence of VPI is unclear. We previously compared the 2-flap palatoplasty technique, described in this article, with the von Langenbeck method and found no difference in VPI incidence.[19] However, double-opposing Z-plasty has been reported to result in VPI and a secondary operative incidence as low as 7.2%.[4,12] Lower incidences of VPI have been reported by some authors,[4,13,15] but there was a correspondingly higher fistula incidence. It is possible that attempts to improve velar functioning by more extensive dissection increase the likelihood of developing a fistula.

This study confirms that age at palatoplasty is a significant factor in achieving velopharyngeal sufficiency. This finding is consistent with our prior observation[19] and those of others[28,29] that velopharyngeal competence is attained more often in infants who undergo cleft palate repair between 7 and 11 months of age. We compared age at palatoplasty and risk of VPI and demonstrated a significantly increased odds of VPI with each month in advanced age at time of palatoplasty. Our analysis did not extrapolate to repairs done before 7 months of age, but the benefit of such early palatoplasty regimens has not been established.[12,13,29,30] Age at palatoplasty must be considered in relation to age of speech sound production and articulation.[17,29] Spoken words typically begin at approximately 12 months of age. Although most children in our

series were repaired before 12 months of age, palatoplasty was quite late in several instances. Advanced age at palatoplasty, often among foreign-born adopted patients with a first language other than English, deserves more investigation.[31]

We found VPI incidence requiring a secondary operation to follow the Veau hierarchy with progression in cleft severity associated with poorer speech outcome. These findings are in confirmation of other studies.[6,26,32] However, other reports have found the highest VPI incidences in "isolated cleft palate," which corresponds with Veau I and II.[4,12,13,33] The basis for these inconsistent observations is unclear, but may be related to a lack of a unified classification of cleft palate. Distinction between Veau I and II is important as palatal vomeric attachment has been shown to be critical in achieving velopharyngeal sufficiency.[19] Although many classification systems have been proposed, we prefer the Veau classification because of its simplicity, ease of comparison, and association with functional outcome.

The frequency of palatal fistula in our patients (2.9%) was less than other reports in the literature (4.7%–60%).[2–6,10,11,13,15] Nevertheless, numerical comparisons are of dubious value because few authors have used a standardized definition of palatal fistula.[2,21] Smith et al[21] proposed the Pittsburgh Fistula Classification System based on anatomic location. Inclusion of all fistula types, in reporting or assessment, could be misleading. For example, Cohen et al[2] excluded nasal-alveolar and anterior palatal fistulas (Pittsburgh types VI and VII), as these are often intentionally not repaired at the time of palatoplasty. We excluded Pittsburgh types VI and VII palatal fistulas. Nor did we include bifid uvula (Pittsburgh type I), because this does not seem to cause dyslalia, hypernasal resonance, or nasal air emission and therefore does not usually require repair.[34,35] There were 8 patients (1.8%) noted to have postoperative bifid uvula in our series. Rather than anatomic location, as used by the Pittsburgh classification, palatal fistulas may be best characterized by whether they are clinically important leading to nasal air emission, hypernasal resonance, decreased intraoral pressure, or regurgitation of fluid and food.

We did not find an association between the incidence of palatal fistula and cleft type or age at repair. The lack of significance in our series may have been due to the small number of palatal fistulas with limited power to detect differences. The highest incidence of fistula in our patients was in Veau II and IV clefts, although these differences were not significant. An association between fistula incidence and cleft type has been reported.[2,5–7,15] Other investigators have noted higher fistula incidences (32%–35%) with Veau IV clefts.[2,15] These clefts are wider at the junction of the hard and soft palate, a common location of fistula,[21] and are technically challenging to close. Similar to other investigations,[2,5] we found that age at palatoplasty was not predictive of fistula formation. However, this finding is not universal. Several reports have reported that fistula formation is more likely in older children undergoing palatoplasty.[3,7]

Because this investigation was of 1 surgeon's palatoplasty experience, we could evaluate the relationship between outcomes and volume. It is assumed that surgical experience builds and skills improve over time. Although we found no significant relationship between surgeon experience and the incidence of VPI, the lowest incidence was in our most recent patient group. Some have shown secondary palatal operative incidence to decrease with increasing surgical experience. Bearn et al[9] evaluated experience as it relates to cleft palate outcome by comparing low-volume and high-volume surgeons. High-volume surgeons were found to have significantly lower fistula and hypernasality incidences after palatoplasty when compared with low-volume surgeons. Sommerlad[15] found the need for a secondary operation to decrease significantly in his successive 5-year periods from 10.2% to 4.9% to 4.6%. Salyer et al[13] assessment of their experience showed that the proportion of patients with VPI fell, although not statistically significantly, over 2 decades from 11.0% to 6.4%. Witt et al[16] reported need for secondary palatal management to be 25%, and this decreased over time, although this was not statistically significant. Lower incidence of VPI over time may also be explained by the declining age at which palatoplasty is performed. Palatoplasty at a younger age over successive time periods was observed in our study and has been noted by others.[13–16] This temporal change in treatment plan likely resulted from an impression, corroborated by this analysis, that earlier palatoplasty yields improved functional outcomes.

Study Limitations

The strength of this study is that it represents a review of 1 surgeon's experience using a 2-flap palatoplasty technique. Although this eliminates the variability seen in other series, these results cannot be generalized to other surgeons or techniques. Although significant associations are described, no causative relationships can be claimed. The speech pathologists in our interdisciplinary clinic specialize in cleft pathology. Speech outcomes were obtained from qualitative descriptions by more than 1 speech pathologist, and interrater reliability was not evaluated. Speech pathologists may vary in their description of resonance, nasal emission, and intraoral pressure. Therefore, we evaluated functional outcome based on performing or recommending a secondary operation for correction of VPI. Secondary operative incidences are difficult to compare between surgeons and institutions because the threshold to perform such operations and inclusion/exclusion of patients varies.

CONCLUSIONS

This audit is of a large series of nonsyndromic patients with cleft palate who were treated by 1 surgeon using a 2-flap palatoplasty. We found a low incidence of palatal fistula (2.9%). The need for a secondary operation for VPI was associated with increasing age at palatoplasty (12.5% if closure was before 11 months) and followed the Veau hierarchy. These results reflect the importance of a close, long-term working relationship between the speech pathologist and plastic surgeon in an interdisciplinary cleft palate center.

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