Association Between Palatal Index and Cleft Palate Repair Outcomes in Patients With Complete Unilateral Cleft Lip and Palate

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**IMPORTANCE** This study evaluates a technique to estimate cleft severity and tissue hypoplasia in patients with cleft palate. Current classifications are limited to the morphologic characteristics of the clefts. A new classification is proposed in relation to the palatal index, which allows more individualized surgical attention for the cleft palate.

**OBJECTIVE** To evaluate the relationship of palatal index and cleft palate repair surgical outcomes (palatal fistula and velopharyngeal insufficiency) in patients with unilateral cleft lip and palate.

**DESIGN, SETTING, AND PARTICIPANTS** Retrospective study performed by the Outreach Surgical Center Program Lima, Lima, Perú, of surgical outcomes of 152 consecutive pediatric patients, aged 12 to 15 months, with nonsyndromic unilateral complete cleft lip and palate treated during from 2001 to 2007. Findings were obtained at 1 to 5 years' follow-up.

**INTERVENTIONS** Palatoplasty using the 2-flap technique plus intravelar veloplasty. Palate index was measured preoperatively with the patient under general anesthesia.

**MAIN OUTCOMES AND MEASURES** Postoperative analysis via the χ² test to assess the statistical significance of association between the palatal index and surgical outcomes.

**RESULTS** Palatal fistula rates correlated directly with the cleft severity, as estimated by the palatal index ($P = .01$), but there was no association between postoperative velopharyngeal insufficiency and palatal index ($P = .76$).

**CONCLUSIONS AND RELEVANCE** The palatal index was a good predictor of fistula development in the studied group. There was an association between the cleft severity and tissue deficiency (estimated using this index) and presence of palatal fistula. Further long-term study is needed to evaluate the relationship between the palatal index and maxillary growth.

**LEVEL OF EVIDENCE** 4.
The current classifications for cleft lip and palate are descriptions of the anatomic components involved in the cleft, but they do not consider the severity of its distortion. The Kernahan and Stark classification and diagram (Kernahan-Stark) is one of the most widely used around the world. This diagram shows which anatomic segment is involved but not how severely it is affected. Another system is the Veau classification, which is the simplest and most utilitarian method of evaluation, but it includes the same limitations as the Kernahan-Stark.

In 2005, one of us (P.R.-P.) presented a new cleft classification and subsequently published the classification of severity and diagram for cleft description (the clock diagram), which includes the palatal index, a more complete method of evaluation of the cleft palate. We use the palatal index to classify cleft palate deformity and select a proper surgical technique based on the severity of the cleft palate and tissue deficiency. This index is the proportion between the width of the cleft (cleft severity) and the sum of the width of the 2 palatal segments (tissue deficiency) measured at the level of the hard and soft palate junction (Figure 1). The index indicates the amount of soft tissue available for palatal flaps and its relation to the width of the cleft to be repaired. Based on these measurements, the index classifies 3 degrees of severity for the cleft palate: mild (palatal index of 0-0.2), moderate (0.2-0.4), and severe (>0.4) (Figure 2).

Some studies have examined the association between tissue deficiency and the incidence of fistula and velopharyngeal insufficiency (VPI). Muzaffar et al. report that wider clefts or those involving the complete cleft palate result in higher fistula rates. Cohen et al. found the same results in their study using the Veau classification to estimate severity of the cleft palate. However, these classifications estimate only the severity of the cleft (anatomic segment involved or width of the cleft) without considering the tissue deficiency, as the palatal index does. The specific aim of the present study is to examine whether there are associations between the palatal index and some cleft palate repair surgical outcomes (palatal fistula and VPI) in patients with unilateral cleft lip and palate.

## Methods

Because this was an observational retrospective study, institutional review board approval was waived. The study involved 152 consecutive patients with nonsyndromic unilateral complete cleft lip and palate repaired by the Outreach Surgical Center Program Lima during the years 2001 to 2007. All patients underwent a 2-flap palatoplasty plus Sommerlad-type intravelar veloplasty at age 12 to 15 months. All procedures were performed by the same plastic surgeon (P.R.-P.).

The palatal index was obtained preoperatively with the patient under general anesthesia using a measuring tape and registered in a format. As shown in Figure 1, the cleft palate was estimated by comparing the cleft’s width (X) with the summed width of both palatal segments (Y1 + Y2), where X represents the cleft width measured in millimeters at the hard palate posterior border level, and Y1 and Y2 represent the palatal segment diameter (right and left) measured also in millimeters at the same level as X.

### Palatal Index: \( \frac{X}{Y1+Y2} \)

The presence of symptomatic palatal fistula was determined by physical examination 6 months to 1 year postoperatively. We excluded all the anterior fistulas because the alveolar cleft is not repaired primarily under our protocol. Velopharyngeal insufficiency following palat repair, characterized by a typical hypernasal speech, was determined by our speech pathologist (E.C.N.) at physical examination. The standardized speech evaluation parameters of Henningsson et al. were used to describe speech outcomes obtained at 1- to 5-year follow-up.

### Statistical Analysis

We use the \( \chi^2 \) test to assess the statistical significance of association between the palatal index and surgical outcomes. Significance was set at \( P < .05 \) and a confidence level of 95%. Data were analyzed with the Stata 11.0 software (StataCorp LP).

## Results

A total of 152 consecutive patients, aged 12 to 15 months (mean age, 12.8 months), were included in the study, 118 boys (77.6%) and 34 girls (22.4%) (male to female ratio, 3:8:1). All patients underwent 2-flap palatoplasty plus the Sommerlad-type intravelar veloplasty technique from 2001 to 2007 to correct unilateral complete cleft lip and palate (left to right ratio, 3:1:1). All procedures were performed by the same surgeon (P.R.-P.), and all patients were managed under the Outreach Surgical Center Program Lima protocol, including general anesthesia. The palatal index was registered preoperatively in all cases. We found statistically significant association between palatal index and presence of fistula, as evaluated at 6 months to
1 year postoperatively (\(P = .01\)). The fistula increased depending on the severity of the cleft. The proportion of fistula in the population was 8.6% (95% CI, 4.1%-13.1%) (Table). In contrast, we found no statistically significant association between palatal index and presence of postoperative hypernasality determined at 5-year follow-up (\(P = .76\)) (Table). We observed no association between the palatal index and VPI. The proportion of VPI in the population was 9.9% (95% CI, 5.2%-14.6%).

**Table.** Association Between Palatal Index and the Cleft Palate Surgical Outcomes Postoperative Fistula and VPI

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Severity of the Cleft, No. (%)</th>
<th>(P) Value (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fistula</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0</td>
<td>13 (100)</td>
</tr>
<tr>
<td>No</td>
<td>16 (11.5)</td>
<td>139 (100)</td>
</tr>
<tr>
<td>Total</td>
<td>16 (10.5)</td>
<td>152 (100)</td>
</tr>
<tr>
<td>VPI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1 (6.7)</td>
<td>15 (100)</td>
</tr>
<tr>
<td>No</td>
<td>15 (10.9)</td>
<td>137 (100)</td>
</tr>
<tr>
<td>Total</td>
<td>16 (10.5)</td>
<td>152 (100)</td>
</tr>
</tbody>
</table>

Abbreviations: NA, not applicable; VPI, velopharyngeal insufficiency.

\(^{a}\) Measured using the palatal index formula \(X/(Y_1 + Y_2)\) (see Figure 1).

**Discussion**

Current cleft classifications have some limitations in describing the cleft deformity. Traditional methods involve diverse cleft characteristics but are limited in their descriptions or are too cumbersome for application. Most utilitarian methods of cleft description, like Kernahan-Stark and the Veau classification, consider only the anatomic segment involved as a form of evaluation of the severity of the cleft. The evaluation of the cleft palate tissue deficiency is not considered in these classifications.

One of us (P.R.-P.) presented during the CLEFT 2005 conference in Durban, South Africa, a new classification system for cleft lip and palate, the palatal index, a system designed to estimate the secondary palate deformity by considering the cleft’s severity (width of the cleft) and the tissue deficiency (width of the palatal segments). To illustrate the differences between the palatal index and the currently used methods of cleft estimation, we provide 2 case examples. Figure 3 shows a complete cleft palate with a 21-mm cleft width. The palatal segment widths are 14 and 16 mm, right and left, respectively. The palatal index is 0.70 (21/30). Figure 4 shows another complete cleft palate but with a 25-mm cleft width and right and left palatal segment widths of 33 and 32 mm, respectively. The palatal index illustrated in Figure 4 is 0.38 (25/65).

Figures 3 and 4 represent the same types of clefts under current classifications (Veau class III), but their palatal indexes, and hence their surgical protocols and prognoses, are different under our palatal index classification. Even though Figure 4 shows a wider cleft, this cleft has a better index and prognosis. We may close this cleft without lateral raw surfaces, and the fistula rate is lower in this group. Despite the narrower cleft shown in Figure 3, the palatal segments are narrower too, and this cleft has a worse index and prognosis. We cannot close this cleft without lateral raw surfaces, and the fistula rate is higher in this group, as we conclude in the present study.

The main difference between current classifications and our palatal index is that the palatal index provides 2 fundamental pieces of information: extension of the cleft (cleft width) and tissue deficiency (palatal segment width). In 2005, Berkowitz et al described a method of tissue deficiency evaluation based on the ratio of the area of the cleft to that of the palatal segments, but their technique requires additional technology for estimation, and its application is related to the time of cleft palate closure. Our method is easier to perform and can be done intraoperatively before the surgery.

Some studies have evaluated the relationship between cleft severity and development of VPI based on the type of cleft. They have found that the vomer may therefore be a crucial feature. Cases in which the vomer is attached maintain more palatal length, which enhances the chance of effective closure during primary repair. In addition, those with an unat-
tached vomer may have hypoplastic musculature. Krause and colleagues have also shown a relationship between the extent of the cleft (according to a gradient from soft cleft palate through hard and soft cleft palate and unilateral cleft lip and palate to bilateral cleft lip and palate) and outcome, with the most extensive defect being the most likely to require a pharyngoplasty. However, none of these studies correlated cleft width and tissue deficiency with the development of VPI, as we consider in this study. In addition they considered all the types of cleft palates, including bilateral and isolated cleft palates.

This may be the reason for the differences between their studies and our study. Muzaffar et al (2001), Rohrich et al (1996), Schultz (1986), and Landheer et al (2010) have all reported a direct relationship between extent of clefting and fistula rate.

Phua et al (2008) found that severity of clefting had an effect on the incidence of fistulae. They observed a higher incidence of fistulae and VPI in bilateral cleft palate. However, they did not find higher rates of fistula in wider unilateral cleft palates. In a previous publication, one of us (P.R.-P.) estimated a much higher fistula and VPI rate related to the severe forms of cleft palate (73% of total fistulas and 49.5% of total VPI cases). However, that study considered a longer period (1996-2007) and included other types of clefts, like bilateral and isolated cleft palates, which are different pathologic entities with higher rates of complications.

A recent study by Yuan and colleagues in 2012 found different results, with low overall rates of fistulas for all type of clefts and higher VPI rates in patients with wider clefts. However, in their study the authors used current methods of evaluation (Veau classification and width of the cleft) and did not consider tissue deficiency. In addition, they considered all types of cleft palates (including isolated and bilateral cleft palates), which are different pathologic entities with higher rates of VPI.

**Figure 3. Complete Cleft Palate, Severe, Palatal Index 0.70**

A, Preoperative view showing a 21-mm cleft width and right and left palatal segment widths of 14 and 16 mm, respectively (palatal index, 0.70 [21/30]).

B, Postoperative view after repair using the 2-flap technique with raw lateral surfaces.

**Figure 4. Complete Cleft Palate, Moderate, Palatal Index 0.38**

A, Preoperative view showing a 25-mm cleft width and right and left palatal segment widths of 33 and 32 mm, respectively (palatal index, 0.38 [25/65]).

B, Postoperative view after repair using the 2-flap technique without raw lateral surfaces.
This may account for the difference from our results. Special attention is required for severe forms of bilateral and isolated cleft palates, for which a VPI surgery is often required.

These studies have described the association between the Veau classification (types II and IV) and VPI. This classification should be used as a predictor of VPI.

Supported by these findings, we propose herein a new classification, the palatal index, and accompanying surgical protocol for cleft palate. Since 2007 we have used this index and protocol for primary unilateral cleft palate repair:

- Mild (palatal index <0.2) (Figure 2A), raw area free palatoplasty;
- Moderate (palatal index, 0.2–0.4) (Figure 2B), 2-flap technique without raw lateral areas; and
- Severe (palatal index, >0.4) (Figure 2C), delayed hard palate closure.

**Conclusions**

The palatal index is a good predictor of fistula development in the studied group. We observed a direct relationship between cleft severity and tissue deficiency (estimated using this index) and presence of palatal fistula. Although the study population was not randomized, this study suggests that there is not a direct relationship between the degree of palatal index and VPI. Further long-term study is needed to evaluate the relationship between palatal index and maxillary growth.