

# Effect of Relaxing Incisions on the Maxillary Growth after Primary Unilateral Cleft Palate Repair in Mild and Moderate Cases: A Randomized Clinical Trial

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**Background:** The purpose of this study was to evaluate the association between the use of relaxing incisions and maxillary growth disturbance after primary palatoplasty in patients with unilateral cleft lip and palate.

**Methods:** This is a prospective, randomized, double-blind controlled trial study with ethical committee approval between 2 groups of patients with unilateral cleft lip and palate who were operated on using the two-flap and one-flap techniques from 2008 to 2011. Two groups of patients with unilateral cleft lip and palate were operated on using the mentioned techniques by the Outreach Surgical Center Program Lima since 2008. Data collection was accomplished by evaluation of maxillary arch dimensions and dental arch relationships (scored using the 5-year-olds' index).

**Results:** The mean score for the 5-year-olds' index was 2.57 for two-flap technique and 2.80 for one-flap technique without statistical significant differences ( $P=0.71$ ). Our comparative study did not find statistically significant differences in maxillary arch dimensions between the studied techniques for unilateral cleft palate repair. Good levels of agreement were observed according to the  $\kappa$  statistics.

**Conclusions:** The results arising from this clinical trial do not provide statistical evidence that one technique let us obtain better maxillary development than the other at 5 years. The use of relaxing incisions was not associated with maxillary growth impairment. A technique with limited relaxing incisions does not have better maxillary growth. Additional longer term study is necessary to confirm this preliminary report. (*Plast Reconstr Surg Glob Open* 2017;5:e1201; doi: 10.1097/GOX.0000000000001201; Published online 16 January 2017.)

No consensus has been reached regarding the etiology of maxillary growth restriction in patients with a cleft palate after primary palatoplasty. Other authors have indicated that there is a lack of evidence demonstrating an association between growth restriction and various potential etiologic factors.<sup>1-3</sup> Systematic reviews have concluded that well-designed, randomized clinical trials are required to further investigate the association between primary palatoplasty and facial growth disturbance.<sup>2,4,5</sup>

It has been suggested that the main factor responsible for growth inhibition is the primary palatoplasty itself.<sup>5,6</sup> Several protocols for primary cleft palate repair have been developed in consideration of the concerns about subsequent maxillary growth, which have influenced the selection of surgical techniques.<sup>4,5,7</sup> However, other authors have suggested that it is the timing of hard palate closure, instead of the type of surgical technique, that determines postoperative growth.<sup>2,8-10</sup> In addition to the surgical technique and patient age at the time of cleft palate repair, other factors that have been associated with the inhibition of the maxillary growth in patients with a cleft palate include genetic facial pattern, severity of the cleft, presurgical management, surgeon's skills, previous cleft lip repair, alveolar repair, and overall treatment protocol.<sup>6,11-15</sup> Limited evidence has suggested that the use of surgical relaxing incisions during primary palatoplasty is particularly detrimental to maxillary growth.<sup>2,16</sup> However, no properly designed study has been performed to demonstrate an association between these incisions and subsequent growth.

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The purpose of the current study was to evaluate the association between the use of relaxing incisions and maxillary growth disturbance after primary palatoplasty in patients with unilateral cleft lip and palate by conducting a well-designed and well-controlled long-term study. A surgical technique developed by the author (P.R.P.) called the “one-flap palatoplasty”<sup>17</sup> represents a good model to study the association between relaxing incisions and subsequent growth, when compared with the conventional “two-flap palatoplasty.”<sup>18</sup>

## MATERIALS AND METHODS

This is a prospective, randomized, single-blind controlled trial study with a parallel design comparing 2 groups of patients with unilateral cleft lip and palate who underwent either the two-flap or one-flap method of cleft palate repair from 2008 to 2011. All patients diagnosed with a unilateral cleft palate underwent surgery at approximately 12 months of age, based on the Outreach Surgical Center Program Lima protocol. Cleft lip repair was performed in all patients at approximately 3 months of age using 1 of the 2 techniques according to our usual surgical protocol: upper rotation advancement plus double unilimb Z-plasty or triple unilimb Z-plasty. None of the patients underwent alveolar bone grafting, secondary palatoplasties, or orthodontic treatment. All operations were performed by the same plastic surgeon (P.R.P.).

### Participants

This trial included Peruvian infants with nonsyndromic complete unilateral cleft lip and palate who were otherwise healthy. Only children with mild or moderate unilateral cleft lip and palate were included in this study because severe cases require a relaxing incision on the cleft side (according to our usual surgical protocol).<sup>17,19</sup>

Patients with severe unilateral cleft lip and palates were excluded from both groups. The cleft palate severity was classified according to the cleft palate index described by the author.<sup>19,20</sup>

This index is calculated as the width of the cleft (cleft severity) divided by the sum of the width of the 2 palatal segments (tissue deficiency) measured at the level of the junction of the hard and soft palates. Based on the index, we categorized the cleft palate severity as follows: mild = index less than 0.2, moderate = index of 0.2 to 0.4, and severe = index more than 0.4. The cleft palate index was measured while the patients were receiving general anesthesia at the time of their cleft palate surgery.

### Assessment Time

The patients in both groups were followed longitudinally for 5 years. The outcomes were assessed at just 1 time, when the children were 5 years old.

### Interventions

#### *Two-flap Palatoplasty*

The two-flap palatoplasty group underwent Bardach’s two-flap palatoplasty<sup>18</sup> plus the Sommerlad type of intravelar veloplasty<sup>21</sup> and unilateral uvuloplasty.<sup>22,23</sup>

#### *One-flap Palatoplasty*

The one-flap palatoplasty group underwent one-flap palatoplasty as follows. After placing the patient in the supine position with the neck extended, the Dingman mouth gag was applied and the proposed incision location was marked with methylene blue. Local anesthetic was infiltrated into the palatal tissues with 2% lidocaine with epinephrine 1:200,000 at a dose of 0.5 mL/kg. After 5 to 7 minutes, the incisions were made with a number 15 blade after the markings. The unilateral uvuloplasty technique was used, retaining the larger of the 2 hemiuvulae and excising the smaller one.<sup>22</sup> Mucoperiosteal flaps were devised using cautery on the noncleft side. The incision ran along the edge of the palate, over the gingiva, and just medial to the line of dental eruption, as in the alveolar extension palatoplasty of Carstens.<sup>24</sup> Mucoperiosteal flap elevation began at the anterior-most portion of the hemipalate and continued up to the palatal pedicle. The neurovascular bundle was then mobilized by blunt dissection to further loosen it from the greater palatine foramen. The palatal mucoperiosteum on the cleft side was elevated through the medial incision to avoid placing the closure under any tension. Muscle repair was performed using the intravelar veloplasty technique as described by Sommerlad.<sup>21</sup>

After this was completed, the mucosa was carefully closed using absorbable 5-0 suture to achieve border-to-border edge approximation.

The one-flap palatoplasty differed from the two-flap technique by the use of a relaxing incision on the cleft side only. Extension of the subperiosteal dissection was the same in both groups. The soft palate surgical treatment was likewise identical with both techniques.

### Outcomes

The evaluated outcomes were dental arch relationships and maxillary arch dimensions.

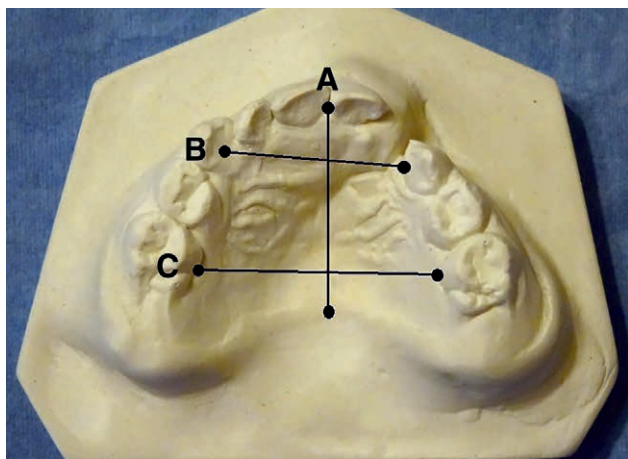
Dental casts were obtained from each patient after their surgery when they were 5 years old. Alginate impressions (Alginot; Kerr, Romulus, Mich.) were obtained while the patients were under general anesthesia. Dental arch relationships were assessed using the 5-year-olds’ index, as described by Atack et al<sup>25</sup> in 1997. This index considers 5 groups of outcomes, rated from 1 (“excellent”) to 5 (“very poor”). Maxillary arch dimensions were measured and compared between groups. The following measurements were made on the maxillary arch casts (Fig. 1): (1) intercanine distance = distance between the canine mesiobuccal cusp tips, (2) intermolar distance = distance between the second molar mesiobuccal cusp tips, and (3) maxillary length = distance in the midline from a point between the incisors to the posterior border of the maxilla.

### Sample Size Calculation

The sample size estimation was based on the study having a power of 0.8, a two-sided level of significance of 0.05, and an estimated  $\kappa$  of 0.8. It was estimated that 70 patients were required in each group.

### Randomization

Each patient was randomized to undergo either one-flap palatoplasty or two-flap palatoplasty. The type of random-



**Fig. 1.** Measurement of the maxillary arch dimensions. A, Inter-molar distance: distance between the second molar mesiobuccal cusp tips. B, Intercanine distance: distance between the canine mesiobuccal cusp tips. C, Maxillary length: a midline from a point between the incisors to the posterior border of the maxilla.

ization was blocked randomization, which is recommended for smaller randomized controlled trials. Sequence generation for the randomized group allocation was accomplished through the use of computer-generated random numbers. A block size of 6 and allocation ratio of 2:1 were used. The group assignment was protected in a sealed envelope, which was opened by the surgeon just before surgery.

#### Blinding

Outcome assessment of the patients operated on was performed by 3 evaluators who were blinded to the group assignment. They scored all dental models obtained from the patients at 5 years of age. The evaluators were dentists from a local cleft program the patients attended during the postoperative period.

#### Adherence

We scheduled subsequent lip/nose revision and/or alveolar cleft closure surgery when the patients were 5 years old to enhance adherence and optimize follow-up of the patients enrolled in the study.

#### Statistical Analysis

We used the nonpaired *t* test to assess whether there were statistically significant differences between the 2 methods. An  $\alpha$  error of less than or equal to 0.05 was used to indicate statistical significance. All confidence intervals are described at 95%. The data were analyzed with SPSS 15.0 software (SPSS, Chicago, Ill).

The 5-year-olds' index used a categorical scale, which required the use of  $\kappa$  statistics to analysis the observers' performance.  $\kappa$  statistics were calculated to assess the reliability within observers. The overall  $\kappa$  for interexaminer agreement was determined using an Excel spreadsheet (Microsoft Corporation, Redmond, Wash.).

#### Ethics

This study was approved by our ethical committee. The parents of all children who underwent surgery received

complete information about the nature of this study and signed the informed consent form. Declaration of Helsinki has been followed in this study.

## RESULTS

Patients with unilateral cleft lip and palate were recruited from February 2008 to May 2011, and follow-up was extended until July 2016. The participant flow diagram is presented in Figure 2. There were 70 patients in the final one-flap palatoplasty group and 72 patients in the final two-flap palatoplasty group. Characteristics of the included subjects (sex, cleft side, cleft lip repair technique, and cleft severity) are presented in Table 1.

The mean score for the 5-year-olds' index was 2.57 in the two-flap technique group and 2.80 in the one-flap technique group; these scores were not significantly different ( $P = 0.71$ ; Table 2; Figs. 2, 3). None of the patients developed a group 5 dental arch relationship (poorest dental arch relationship). Reverse overjet with average inclined or proclined incisors (group 4 of the 5-year-olds' index) was observed in 10 of the 144 patients (6.94%; Fig. 4).

There were no statistically significant differences in maxillary arch dimensions between the 2 groups (Table 3).

Good levels of agreement were observed within and between observers for the 5-year-olds' index according to the  $\kappa$  statistic values (0.78–0.92; Table 4).

An equal number of postoperative palatal fistulas were observed in both groups ( $n = 2$ ; 2.85%). All fistulas were asymptomatic and located in the middle third of the palate.

## DISCUSSION

Even when the hypothesis is commonly accepted that surgery itself is primarily responsible for the facial growth disturbance after primary palatoplasty, the exact etiology of this disturbance is by no means established. This has led to the use of a variety of surgical protocols for cleft lip and palate management at different institutions, but the optimal strategy remains unknown. Since the report published by Gillies and Fry<sup>26</sup> in 1921, various studies have noted that inhibition of maxillary development in patients who have undergone cleft palate repair is an important issue. Because of the small growth disturbance observed in patients with a cleft palate who have not undergone surgery, iatrogenic factors have been considered potentially relevant.

The prevalence of secondary maxillary hypoplasia associated with cleft lip and palate repair varies among studies, with reports of approximately 25% to 60% of cleft lip/palate patients developing a dentofacial deformity requiring orthognathic correction.<sup>27–29</sup> In the current study, only 6.94% of patients with unilateral cleft lip and palate were noted to have maxillary hypoplasia at the age of assessment (5 years old); however, this percentage may increase as skeletal maturation occurs.

Various factors have been associated with maxillary hypoplasia, including congenital hypoplasia, primary cheiloplasty, disturbed blood supply, subperiosteal dissection of the mucoperiosteal flaps, minimization of the denuded

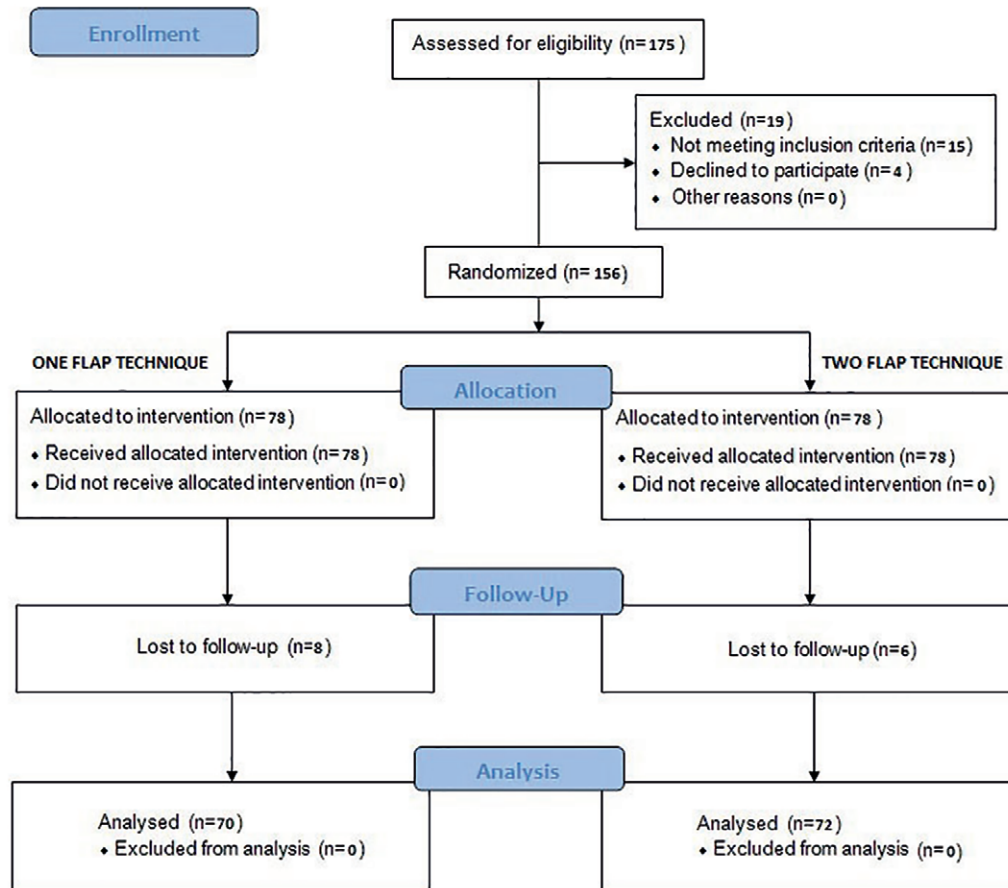


Fig. 2. Participant flow diagram.

Table 1. Characteristics of the Studied Patients

Characteristics (n)	Two Flaps (72)	One Flap (70)	P*
Gender, n (%)			
Male	39 (54.16)	43 (61.42)	0.44
Female	33 (45.83)	27 (38.57)	
Cleft side, n (%)			
Right	26 (36.11)	28 (40)	0.57
Left	46 (63.88)	42 (60)	
Cleft's severity, n (%)			
Mild	20 (27.77)	17 (24.28)	0.17
Moderate	52 (72.22)	47 (67.14)	
Cleft lip surgical technique, n (%)			
A	22 (30.55)	23 (32.85)	0.65
B	50 (69.44)	47 (67.14)	

\*Chi-square test.

A, upper rotation advancement + double unilimb Z-plasty; B, triple unilimb Z-plasty.

bone, surgeon's skills, patient age at the time of cleft palate repair, type and severity of the cleft, surgical technique, and use of relaxing incisions.<sup>6,11-15</sup>

Some previous studies have noted that the main factors are the primary lip and palate repairs.<sup>12,30-34</sup> However, the potential role of the various other factors makes it difficult to evaluate the association between types of surgical techniques (such as the use of relaxing incisions) and maxillofacial growth disturbance. These confounding factors are the main limitations of using observational studies to provide valid scientific evidence of associations.

Primary cheiloplasty and palatoplasty lead to the formation of scar tissue at the surgical site and cause dynamic and static disturbances that can have negative consequences on maxillary growth. This is why some authors suggest that surgery and the resulting incisions and scars are the main reasons for growth disturbances of the maxilla. A study published by Koberg and Koblin<sup>16</sup> observed that Veau's push-back and Langenbeck's techniques with relaxing incisions were the most detrimental to facial growth. A recent study by Odom et al<sup>35</sup> did not observe an association between the development of class III incisal relationship and the type of palatal incisions in patients with isolated cleft palate repair, when evaluated after long-term follow-up.

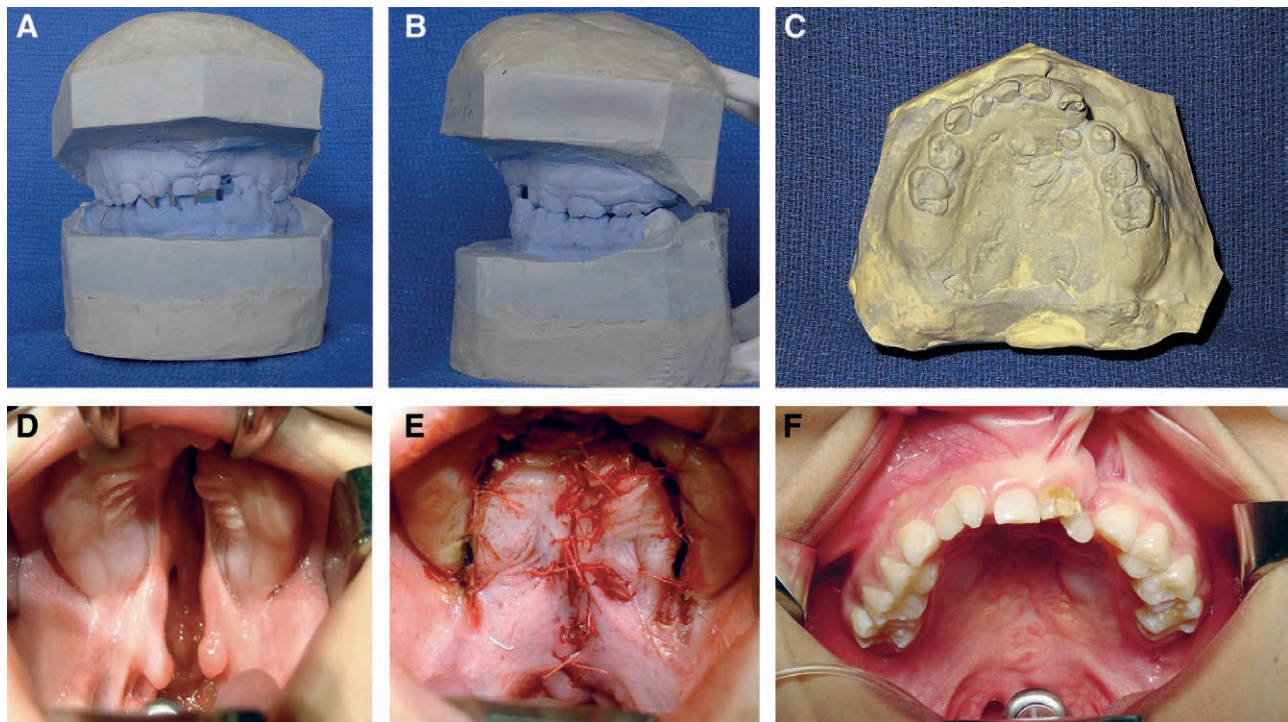
To overcome the drawbacks of observational studies, a few clinical trials have been performed during recent years. Fudalej et al<sup>36</sup> compared the outcomes of a group of 25 patients who underwent one-stage repair with those of a control group who underwent the two-flap technique and noted small differences between groups. In the clinical trial by Richard et al<sup>3</sup> of 47 patients who underwent 2 different two-stage techniques, no demonstrable differences in facial growth were observed at 4 to 7 years of age. Wada et al<sup>37</sup> conducted a clinical trial comparing different techniques against a control group who underwent the two-flap method and observed better maxillary growth using two-stage palatoplasty closing the hard palate when the patients were 5 years old.

**Table 2. Comparisons of 2 Methods of Unilateral Cleft Palate Repair According to the Dental Arch Relationship at 5 Years Old: Outreach Surgical Center Lima 2008 to 2016**

	Two Flaps (Mean)	SD	95% CL	One Flap (Mean)	SD	95% CL	P*
5-y-olds' index	2.57	1.0877058	1.822598–2.677402	2.8	1.911993	1.840532–2.939468	0.71

\*t test.

CL, confidence limit.



**Fig. 3.** A, Two-flap case, anteroposterior view: this is judged as a good result (group 2 of 5-y-olds' index). B, Two-flap case, lateral view: this is judged as a good result (group 2 of 5-y-olds' index). C, Two-flap case, maxillary arch dimensions. Intermolar distance, 34 mm (A); intercanine distance, 28 mm (B); maxillary length, 29 mm (C). D, Preoperative view of a male patient with complete unilateral cleft lip and palate. E, Postoperative view of the same patient operated on using the two-flap method. F, Five-year-old postoperative view of the patient.

In that study, the patients were randomly assigned to 4 experimental groups, but the number of unilateral cleft lip and palate patients was small (14 vs 16 patients in the treatment and control groups, respectively).

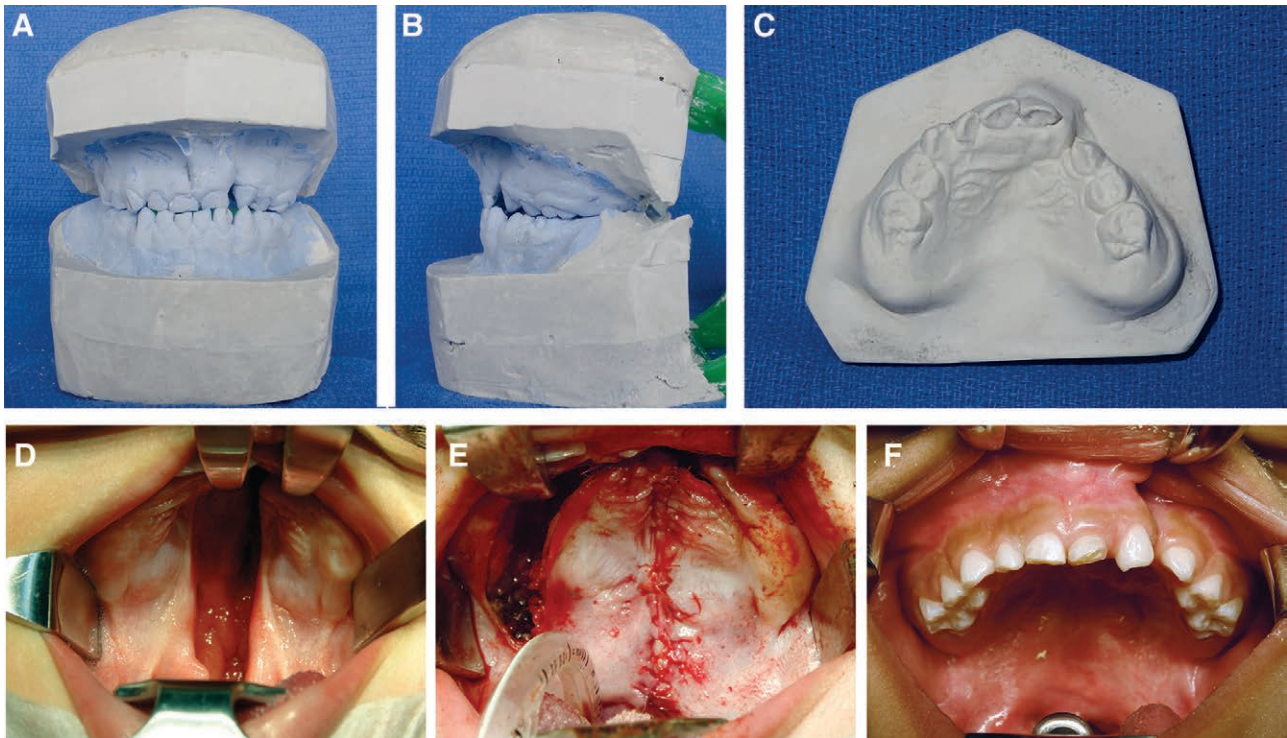
Thus, the statistical power of the study was low, so the validity of the conclusions is limited. A meta-analysis by Nollet et al<sup>38</sup> observed improved dental arch relationships with delayed palate closure compared with early closure. Finally, a multicenter clinical trial study (from Denmark, Finland, Norway, Sweden, and the United Kingdom) known as the SCANDINAVIAN CLEFT study included 3 clinical trials of primary surgery for unilateral cleft lip and palate that compared dental arch relationships at 5 years of age.<sup>39</sup> The results did not provide any statistical evidence that 1 surgical technique for cleft palate repair was superior to the others.

To our knowledge, the results presented here represent the first attempt to evaluate prospective data regarding the effect of relaxing incisions on the development of maxillary segments. The one-flap technique is a good model to use to study the association between relaxing incisions and maxillary growth because 1 side of the pal-

ate does not require a lateral surgical incision. This differs from the two-flap technique, which includes the use of a relaxing incision on the cleft side. The use of the one-flap technique was compared with the conventional two-flap technique in a previous study that showed no statistically significant differences between the techniques with respect to the development of palatal fistulas or velopharyngeal insufficiency.<sup>17</sup>

We used the 5-year-olds' index described by Atack et al<sup>25</sup> as a growth indicator to assess the relationship between the dental arches around the beginning of mixed teething. This method, based on the Goslon index developed by Mars et al,<sup>40</sup> enables preliminary detection of alterations arising from primary palatoplasty. The 5-year-olds' index is not a predictive measure of ultimate maxillary growth in patients with a unilateral cleft lip and palate; therefore, the obtained results should be validated at the time of permanent dentition. Growth cannot be assessed until maturity.

The current study demonstrated no statistically significant differences between the 2 surgical techniques with respect to dental arch relationships or maxillary arch dimensions.



**Fig. 4.** A, One-flap case, anteroposterior view: this is judged as a good result (group 2 of 5-y-olds' index). B, One-flap case, lateral view: this is judged as a good result (group 2 of 5-y-olds' index). C, One-flap case, maxillary arch dimensions. Interincisor distance, 34 mm (A); intercanine distance, 27 mm (B); maxillary length, 29 mm (C). D, Preoperative view of a female patient with complete unilateral cleft lip and palate. E, Postoperative view of the same patient operated on using the one-flap method. F, 5.8-y-olds' postoperative view of the patient.

**Table 3. Comparisons of 2 Methods of Unilateral Cleft Palate Repair According to the Maxillary Arch Dimensions at 5 Years Old: Outreach Surgical Center Lima 2008 to 2016**

Maxillary Arch Dimensions (mm)	Two Flaps (Mean)	SD	One Flap (Mean)	SD	95% CL	P*
Interincisor distance	27.64	1.574802	27.32	1.867444	26.78928–28.08755	0.926
Intermolar distance	35.32	1.320186	35.92	1.207963	34.69250–36.27939	0.662
Maxillary length	29.64	2.135798	30.02	2.038807	29.03301–30.49942	0.67

\*t test.

CL, confidence limit.

**Table 4. Levels of Agreement within and between Observers for the Index Scores of the 5-year-olds' Study Models**

Intraexaminer		
Examiner	κ Values	95% CL
A	0.78	0.68–0.84
B	0.86	0.76–0.94
C	0.92	0.86–0.96
Interexaminer		
Examiners	Evaluation	κ Values
A–B	1	0.82
A–B	2	0.78
A–C	1	0.8
A–C	2	1
B–C	1	0.78
B–C	2	1

CL, confidence limit.

These results are similar to those of most of the reviewed clinical trials. We may, thus, assume that there is no association between the use of relaxing incisions and subsequent

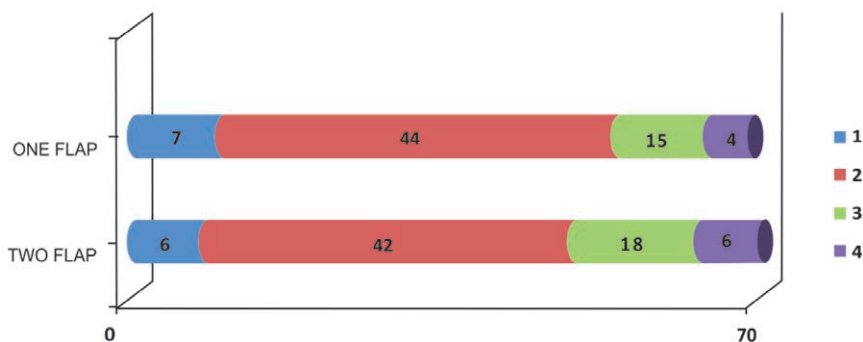
disturbance of maxillary growth. If the incisions affect maxillary growth, then, we should observe asymmetry between the cleft and noncleft side when comparing these techniques.

One of the concerns using the one-flap technique was asymmetric development of the maxillary arch; however, we did not observe this undesirable outcome in our study participants.

We found symmetrical development of the maxillary arch using both techniques. A good 5-year-olds' index score was observed in 86 of the 140 patients (61.42%) in this study. Only 10 of the 140 patients (6.94%) exhibited a group 4 dental arch relationship (Fig. 5).

In comparison with the U.K. Clinical Standards Advisory Group study (37% of 5-year-old patients had 5-year index scores of 4 or 5) and Sommerlad's consecutive series (reported as 10% scores of 4 or 5 using GOSLON scale), we obtained better outcomes.<sup>41,42</sup>

Generalization of our results may be limited because we evaluated only patients with mild or moderate unilateral cleft lip and palate. In our center, the surgical technique for



**Fig. 5.** Dental arch relationship evaluated with 5-y-olds' index in patients with unilateral cleft lip and palate operated on using 2 different methods.

severe disorders requires relaxing incisions on both sides to prevent the development of palatal fistulas. The percentage of patients lost to follow-up was small in this study (8.97%; 14/156), with little difference between groups (8 vs 6; Fig. 2). This minimized the risk of transfer bias. Performance bias (a common problem during surgical research) was avoided in this study because only 1 surgeon performed all operations. Blinding of the patients and surgeon was unfeasible, which was one of the main limitations of this study.

The utility of the two-flap technique is questionable because it provides similar surgical outcomes to those achieved with the one-flap technique but with additional surgical incisions and dissection.<sup>17</sup>

Based on our findings and the results of previous clinical trials, we may assume that secondary maxillary hypoplasia after unilateral cleft lip and palate repair is the result of the interaction of other factors, not only the use of relaxing incisions. Surgical protocols should, therefore, not be established by considering only a single factor, such as surgical incisions.

## CONCLUSIONS

The results of this clinical trial do not provide evidence that 1 technique for primary palatoplasty allowed us to achieve better dental arch relationships or maxillary arch dimensions than the other at 5 years of age. Thus, there seems to be no relationship between the use of relaxing incisions and maxillary growth impairment when patients are 5 years old. Additional longer term studies are necessary to confirm the results of this preliminary report.

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