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The Surgical Nasoalveolar Molding: A Rational Treatment for Unilateral Cleft Lip Nose Deformity and Literature Review

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Background: The purposes of this study were to evaluate surgical outcomes after primary surgery to address unilateral cleft lip, nose, and palate deformities and to perform a review of the literature to evaluate the effects of nasoalveolar molding (NAM) plus primary surgical repair on nonsyndromic unilateral cleft lip and palate.

Methods: A cohort study of 37 primary complete unilateral cleft lip nasal deformity repairs was performed by a single surgeon. The outcomes were anthropometric measurements of the repaired lip, nose, and alveolar cleft width at the age of 1 and 5 years. A review of the literature was performed for studies published until March 2020 to evaluate the effect of presurgical NAM on nasolabial aesthetics.

Results: Statistically significant differences were observed between pre- and postoperative columellar angle and alveolar cleft width. A total of 308 studies were identified, and 8 were included in the final analysis of 684 patients. The overall study quality was low according to the Oxford Centre of Evidence-Based Medicine, and GRADE level of evidence was low.

Conclusions: Primary cheilorhinoplasty alone is a good approach to improve nose appearance and alveolar gap in patients with unilateral cleft lip nose and palate deformity. Definitive conclusions about the effectiveness of presurgical NAM cannot be drawn. Available scientific evidence is not sufficient to demonstrate that combined use of presurgical nasoalveolar molding and primary surgery provides better nasolabial aesthetic outcomes than does primary surgery alone.
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INTRODUCTION

Different strategies, including presurgical orthopedics and primary rhinoseptoplasty, have been proposed to improve the quality of the primary repair by treating underlying skeletal deformities, at least partially. The principle of nasal cartilage molding was first described by Matsuo et al[1] in 1989. Ten years later, Grayson et al[2] published their work using presurgical nasoalveolar molding (NAM), a passive appliance that allowed them to mold the alveolar segment and nose deformity.

Different studies have been conducted to evaluate the efficacy of the presurgical NAM treatment on patients with nonsyndromic unilateral cleft lip nose and palate. The heterogeneity of these studies limits the construction of scientific evidence of the effect of NAM. Some of them reported good outcomes; however, some disadvantages and complications have been described. The main complications associated with this technique are irritation or ulceration of the mucosa and gingival tissue, inflammation of the tissues, notching, infection, temporary airway obstruction, and facial growth disturbance.[3–5]

The proposed method has been named as "surgical nasoalveolar molding" because the surgical technique acts in a similar manner as presurgical NAM: the vestibule

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of the nose is expanded with alveolar cleft segment alignment.[6]

The purpose of this study was to evaluate the long-term surgical outcomes after using primary surgery without presurgical NAM to address unilateral cleft lip nose and palate deformities. In addition, a review of the studies published until March 2020 was conducted to evaluate the effect of presurgical NAM on nasolabial aesthetics.

MATERIALS AND METHODS

A cohort of 37 nonsyndromic, primary complete unilateral cleft lip nasal deformities repaired by a single surgeon (P.R.P.) were analyzed under general anesthesia immediately before the surgery for cleft lip, cleft palate, and alveolar cleft repair at the age of 3 months and 1 and 5 years. The parents of each child were informed about the nature of the surgical techniques used, and the parents provided signed consent before the surgery. The inclusion criteria were as follows:

(a) Nonsyndromic complete unilateral cleft lip and palate.
(b) Primary cheiloplasty performed at the age of 3 months by the same surgeon (P.R.P.).
(c) Postoperative nasal stent use for 6 months.
(d) Pre- and postoperative anthropometric measurements at the age of 3 months and 1 and 5 years.

Preoperatively, all patients underwent the following measurements, as shown in Figure 1:

(a) Columellar angle: This is measured using a transparent protractor as described by Fisher, considered as the angle of deviation from the sagittal plane.[7]

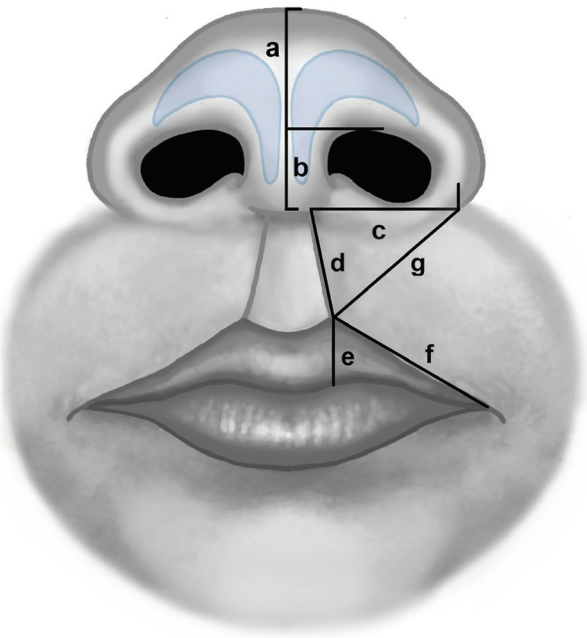

Fig. 1. Standard anthropometric measurements: (a) nostril dome height; (b) columella length; (c) alar width; (d) lip height; (e) vermilion height; (f) lip width; (g) nasal base width.

(b) Alveolar cleft width: This is the distance measured between points A (gingival ridge of the cleft, crest of the alveolar ridge) and B (most dorsal point of the premaxilla contour, medial segment).

During follow-up, all patients were subjected to the following measurements on both sides of the nose using a caliper (Vernier):

(a) Columellar angle (described above).
(b) Alveolar cleft width (described above).
(c) Nostril dome height: Measured from the lateral border at the base of the columella to the highest point on the nasal dome on each side.
(d) Columellar length: Measured from the lateral border at the base of the columella to the highest point of the nostril at the same level.
(e) Nasal base width: Measured from the lateral border at the base of the columella to the most lateral point of the ala in a line perpendicular to the axis of the columella.
(f) Alar base position: The distance from the alar base to the peak of the Cupid's bow on each side.
(g) Lip height: The distance from the lateral border at the base of the columella to the peak of the Cupid's bow on each side.
(h) Vermilion height: The distance from the peak of the Cupid's bow to the same position over the red line on each side.
(i) Lip width: The distance from the peak of the Cupid's bow to the oral commissure on each side.

These measurements were performed on both the cleft and noncleft sides of the nose using a caliper (Vernier).

All patients underwent primary cheilorhinoplasty, including the following procedures[8,9]:

(a) Primary cheiloplasty using triangular method (Pool's modification, Figs. 2, 3).
(b) Primary rhinoplasty using the V–Y–Z method[9] (Figs. 2, 3).
(c) Primary alveolar cleft repair at 5 years and autologous bone graft during the mixed dentition period.

We did not perform any type of presurgical management for any of the patients. Complications were recorded as descriptive data.

Statistical Analysis

Since the normality assumption was not met, nonparametric Mann-Whitney *U* tests were used to assess statistical significance. The α error was set as $P < 0.05$, yielding a confidence level interval of 95%. Analyses were performed with SPSS v15.0 (SPSS Inc, Chicago, Ill.).

Parents of each child were informed about the nature of the surgical techniques used, and they provided signed consent before surgery.

Surgical Approach

Nose

Nose repair was based on vestibular lengthening using the V–Y–Z technique.[9] (**See Video 1**, which displays the

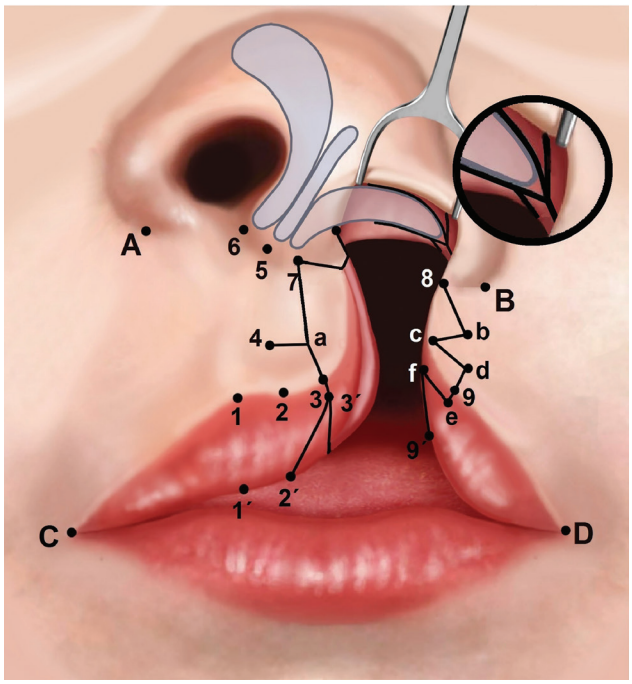

Fig. 2. Modified Pool's and V–Y–Z rhinoplasty techniques for unilateral cleft lip repair (preoperative view). Circle, V–Y–Z rhinoplasty; (1) and (3), peak of the Cupid's bow; (2), Cupid's bow (middle point); (1′), (2′), and (3′), similar as points 1, 2, and 3 but located over red line; (4), central point between supralabium and infralabium; (5), midpoint of the lip columellar crease; (6) and (7), lateral junction of the columella border and lip columellar crease; (8), intersection of the subalare crease and medial border of the lateral lip; (9), white roll (ends point); (9′), Same as point 8 but located over red line; (A, B), alar bases; (C, D), oral commissures.

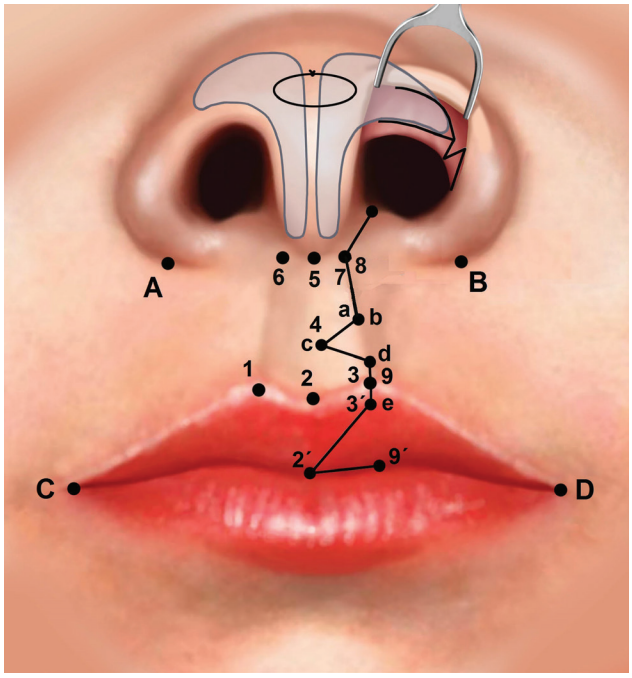

Fig. 3. Modified Pool's and V–Y–Z rhinoplasty techniques for unilateral cleft lip repair (postoperative view; numbers are the same as in Fig. 2).

Fig. 4. Preoperative view of a 3-month-old infant with complete unilateral cleft lip and palate.

V–Y–Z surgical technique for primary complete cleft lip nose repair.) This method expands the nasal vestibule in a way similar to how a presurgical orthopedic molds the nose (Figs. 4–7). A skin incision along the marginal and intercartilaginous borders was used to create a composite flap (vestibular skin and alar cartilage) in a V form. The lateral Z plasty additionally lengthens the vestibule and prevents lateral scar contracture. Two transcutaneous interdomal sutures were placed first using PDS 5/0 (**Video 1**). All incisions were closed using transcutaneous absorbable stitches (polyglactin 910). The use of these sutures in combination with the V–Y–Z method allowed us to achieve the following 2 objectives: (1) repositioning the alar cartilage and lengthening the columella at the cleft side and (2) decreasing the space created by surgical dissection, which reduces the risks of postoperative bleeding and hematoma formation. Nasal packing was used inside the operated nostril in all the cases to prevent bleeding and was removed the next day.

Postoperative nostril stenting was used to prevent scar contracture of the vestibular incisions for 6 months. This device is used only to prevent vestibular scar contracture and synechiae. We used manually custom-made acrylic stents. They are safe, convenient, and economical and can be easily removed, cleaned, and maintained using tape. Nasal obstruction was prevented by drilling a hole through the device. Most patients tolerate this device well. We do not use sutures to maintain the stent in place, as they can lead to a reaction and/or infection.

Nasal Septum

The caudal portion of the nasal septum correction was done primarily by suturing the nasolabial muscles to the base of the septum during primary cheiloplasty (muscular septoplasty). The nasal fascicle of levator labii superioris alaeque nasi muscle laterally pulls the caudal septum and is repositioned fully to correct this segment of the nasal septum. Definitive correction of the posterior septum is performed at a later age if necessary.

Fig. 5. Postoperative view of the infant shown in Figure 4 after undergoing lip and nasal repair using the modified Pool's and V–Y–Z technique (at the age of 1 year).

Fig. 6. Preoperative view of a 3-month-old infant with complete unilateral cleft lip and palate.

Fig. 7. Postoperative view of the infant shown in Figure 6 after undergoing lip and nasal repair using the modified Pool's and V–Y–Z technique (at the age of 1 year).

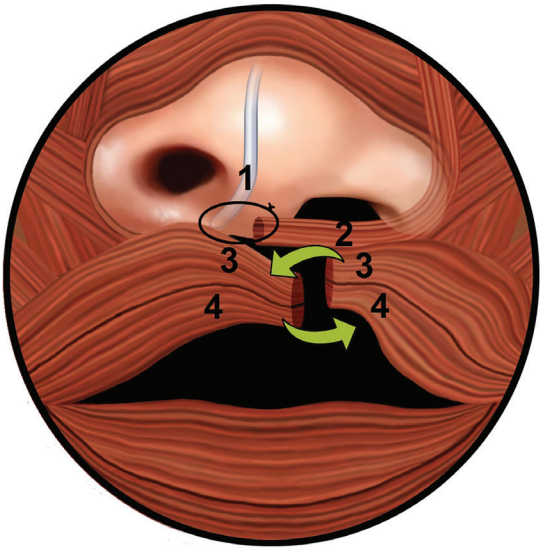

Fig. 8. Unilateral cleft lip muscular repair technique. 1, Caudal septum; 2, nasal fascicle of levator labii superioris alaeque nasi muscle; 3, marginal fascicle of orbicularis oris muscle; 4, peripheral fascicle of orbicularis oris muscle. Green arrows: At the vermilion level, the marginal fascicle of the orbicularis oris is sutured in a border-to-border form. Then, a transposition of the orbicularis oris fascicles is performed in an overlapping form to create the philtral column.

Lip and Nasal Floor

Primary cheiloplasty was performed using a modification of Pool's technique.[8] This technique is based on 2 unilimb Z-plasty methods (lip and vermilion), one advancement from the cleft side, and a columellar base flap (Figs. 4–7). The orbicularis oris and nasal fascicle of levator labii superioris alaeque nasi muscles are released from the upturned insertion and repaired. The orbicularis oris muscle is repaired in a border-to-border fashion, and the levator alaeque nasi is transposed and sutured to the caudal septum (Fig. 8). The repaired muscles of the upper lip modify the caudal septum and cleft segments as a surgical orthopedic (surgical NAM concept).[9]

The nasal floor is repaired using the upper portion of the lateral lip segment and the base of the ala. The alar base and piriform margin are released by a lateral lip incision in combination with an upper buccal sulcus incision and supraperiosteal dissection over the maxilla. The structural support of the anterior segment of the nasal floor is provided by the muscular repair of the upper lip (Fig. 8). A review of the literature based on a specific protocol developed was registered in PROSPERO (CRD42019134146), and the review was conducted and piloted following the guidelines outlined in the PRISMA-P statement.[10]

The PICOS-based eligibility criteria were the following:

- Participants: Children born with nonsyndromic unilateral cleft lip and palate.
- Intervention: Presurgical NAM plus primary cheilorhinoplasty.
- Comparison: Primary cheilorhinoplasty.
- Outcome: Long-term nasolabial aesthetic.

The inclusion criteria were any prospective and retrospective follow-up, cohort study, case series, and randomized control studies related to NAM appliance nasolabial aesthetic outcomes for unilateral cleft lip and palate. The studies were restricted to English. The exclusion criteria were animal studies, (non-)reviews, and meta-analysis.

The research question was: "Does the presurgical NAM plus primary cheilorhinoplasty provide better nasolabial aesthetic outcomes than primary cheilorhinoplasty alone in patients with unilateral cleft lip and palate?" The MeSH terms used for data searching were nasoalveolar molding AND cleft lip OR cleft palate. PubMed, Embase, and Cochrane Library databases were electronically searched from 1998 to March 7, 2020, by 2 physicians. For search strategy purposes, titles were screened first to exclude nonrelevant studies. Then, abstracts were evaluated to exclude studies that did not meet the inclusion criteria. Eight articles were selected after reviewing the full-text versions based on the eligibility criteria. Study quality assessment was performed independently according to the Oxford Center of Evidence-Based Medicine (CEBM) level of evidence classification and GRADE scale. Disagreements were resolved by discussion or consultation between these reviewers.

RESULTS

Cohort Study

Since 2014, 37 patients with complete unilateral cleft and palate underwent primary anatomical repair of the cleft lip nose deformity using primary cheilorhinoplasty and were followed until the age of 5 years. The demographic characteristics of the studied patients were 59.45% men and 40.54% women; 32.43% right side and 67.56% left side; cleft width range, 5–18 mm (mean, 8.91 mm); and mean follow-up time of 5.3 years. Statistically significant differences were observed between pre- and postoperative columellar angles and alveolar cleft widths ($P = 0.000$) (Table 1). There were no statistically significant differences between the cleft and noncleft nostril dome heights, alar base positions, columellar lengths, and lip and vermilion heights at the age of 1 and 5 years (Table 2; Figs. 4–7, 9–16). Differences between lip widths on cleft and noncleft sides were observed at 1 and 5 years postoperatively ($P = 0.000$) (Table 2).

Literature Review

Initially, 308 studies were identified, but only 8 met the inclusion criteria. These studies were published between 1998 and 2020 and recruited 684 patients with unilateral cleft lip and palate. Two prospective studies[11,12] and 6 retrospective studies were included.[13–18] Two studies did not find differences between the 2 groups (NAM + primary surgery versus primary surgery alone), and 6 studies reported better nasolabial aesthetic outcomes. However, the overall study quality according to Oxford CEBM level of evidence and GRADE scale was low (Table 3).

DISCUSSION

Cleft lip nose deformity management considers presurgical NAM, primary cheilorhinoplasty, and postoperative nasal stents as standard management of nose correction.[19] However, different studies (including meta-analyses) have described a lack of scientific evidence supporting the use of NAM for cleft lip nose repair.[20–22] A Taiwanese group from Chang Gung University conducted several studies concerning the effect of NAM on patients with cleft lip nose and palate. They demonstrated a short-term effect and stated that only surgery may guarantee a long-term effect.[18]

Based on the available scientific evidence and our experience during the last 20 years, good nose symmetry and alveolar cleft improvement can be obtained using an adequate surgical technique without presurgical treatment regardless of the severity of the cleft, as demonstrated in the present study (Tables 1 and 2; Figs. 4–7, 9–16). Similar outcomes have been reported by different authors. Adali et al[23] reported that there was no evidence that presurgical orthopedics produced any significant effect on arch form. The Dutchcleft studies concluded that presurgical orthopedics do not improve dental occlusion.[24,25]

One of the few studies comparing the use of NAM plus surgery against primary surgery alone was the retrospective study published by Chang et al.[17] They concluded that

Table 1. Preoperative and Postoperative Comparisons Using the Proposed Method (n = 37)

	Preoperative		Postoperative						
	3 mo		1 y			5 y			
Measurements, mm	Mean (SD)	CI	Mean (SD)	CI	*P**	Mean (SD)	CI	*P*†	*P*‡
Columellar angle, degrees	66.54 (16.180)	61.3–71.8	2.18 (1.742)	1.62–2.74	0.0001	2.35 (1.981)	1.71–2.99	0.0001	0.701
Alveolar cleft width	8.91 (3.914)	7.65–10.2	0.81 (1.178)	0.43–1.19	0.0001	0.51 (0.010)	0.51–0.53	0.0001	0.335
Wide clefts (n = 15) (>10 mm)	13.23 (2.176)	11.21–17.37	3.10 (1.116)	1.74–4.28	0.0001	1.55 (0.852)	0.42–2.56	0.0001	0.478
Narrow clefts (n = 25) (≤10 mm)	7.17 (2.346)	5.37–10.20	1.78 (1.165)	1.05–3.75	0.0001	0.46 (0.324)	0.32–2.01	0.0001	0.566

Mann-Whitney *U* test.
*Comparison between preoperative and postoperative measurements at 1 year.
†Comparison between preoperative and postoperative measurements at 5 years.
‡Comparison between postoperative measurements at 1 and 5 years.

Table 2. Postoperative Comparisons of the Noncleft and Cleft Sides Using the Proposed Method at the Age of 1 and 5 Years (n = 37)

	1 y					5 y				
	Noncleft Side		Cleft Side			Noncleft Side		Cleft Side		
Measurements, mm	Mean (SD)	CI	Mean (SD)	CI	*P**	Mean (SD)	CI	Mean (SD)	CI	*P*†
Nostril dome height	10 (3.333)	7.96–12	9.81 (1.090)	9.46–11.2	0.525	10.75 (0.967)	10.4–11.1	10.54 (1.002)	10.2–10.9	0.384
Nasal base width	12.45 (1.028)	12.1–12.8	12.75 (1.148)	12.4–13.1	0.518	13.73 (0.808)	13.5–14.2	13.27 (1.183)	12.9–13.7	0.397
Alar base position	13.75 (1.077)	13.4–14.1	13.89 (1.176)	13.5–14.3	0.634	14.64 (0.999)	14.3–15.0	14.78 (1.142)	14.4–15.3	0.600
Columellar length	4.64 (0.674)	4.42–4.86	4.48 (0.828)	4.21–4.75	0.432	6.29 (1.705)	5.74–6.84	6.13 (0.965)	5.82–6.44	0.540
Lip height	10.24 (1.038)	9.9–10.6	10.89 (1.086)	10.5–11.2	0.784	13.02 (0.853)	12.7–13.3	13.10 (1.007)	12.8–13.4	0.716
Lip width	12.29 (1.098)	11.9–12.6	11.18 (0.905)	10.9–11.5	0.0001	18.24 (1.583)	17.7–18.8	14.54 (1.178)	14.2–14.9	0.00003
Vermilion height	4.67 (0.837)	4.4–4.94	5.00 (0.869)	4.72–5.28	0.187	7.48 (0.828)	7.21–7.75	7.81 (0.925)	7.51–8.11	0.148

Mann-Whitney *U* test.
*Comparison between postoperative cleft and noncleft sides at 1 year.
†Comparison between postoperative cleft and noncleft sides at 5 years.

Table 3. Selected Articles, according to Inclusion Criteria and Used for Data Extraction to Evaluate the Effect of Nasoalveolar Molding (NAM) on Nasolabial Aesthetics

Study	Sample Size/Treatment	Design	Evidence Level	Effect of Nasolabial Aesthetic	Follow-up
Singh et al[12]	15 patients treated with NAM + surgery and 10 controls	Prospective cohort study	2c	Columella and nasal tip similar to noncleft mean; labial tubercle similar to noncleft mean	37 wk
Barillas et al[16]	15 patients treated with NAM + surgery and 10 patients treated with surgery alone	Retrospective cross-sectional study	4	Greater degree of nasal symmetry in comparison with surgery group	9 y
Chang et al[17]	23 patients treated with rhinoplasty alone; 16 patients treated with NAM alone; 14 patients treated with NAM + rhinoplasty; 23 patients treated with NAM + rhinoplasty + overcorrection	Retrospective cross-sectional study	4	Best assessment using NAM + primary rhinoplasty + overcorrection	5 y
Clark et al[13]	20 patients treated with NAM + surgery and 5 patients treated with surgery alone	Retrospective cross-sectional study	4	No differences using long-term 3D anthropometric measurements in nasal and lip anatomy	5 y
Broder et al[11]	49 patients treated with NAM + surgery and 35 patients treated with surgery alone	Nonrandomized prospective multicenter study	2b	Clinicians' comparable outcomes between the 2 groups; Caregivers' better outcomes using NAM + surgery	After cleft palate surgery
Liang et al[18]	42 patients treated with NAM + surgery and 42 patients treated with surgery alone	Retrospective RCT study	2b	Nonstatistical differences between the 2 groups at 5 years	5 y
Kornbluth et al[15]	191 patients	Retrospective cohort multicenter study	4	Center using presurgical orthopedics achieved better nasolabial outcomes	6–12 y
Hosseinian et al[14]	11 patients treated with NAM + surgery; 12 patients treated with surgery alone	Retrospective cohort study	4	Less nasal asymmetry using NAM + surgery than surgery group alone	6–18 y

NAM plus primary rhinoplasty plus overcorrection provides better surgical outcomes than primary rhinoplasty alone at the age of 5 years.

The proposed technique for cleft lip nasal repair produces a surgical vestibular lengthening in a manner as similar as the presurgical NAM method without the cost and related complications observed with this presurgical treatment.

Rhinoplasty can also lead to complications due to the use of extended incisions over the nasal vestibule; the risks of scar contracture and vestibular synechia must be considered. Although this complication occurs infrequently, it is the most serious due to its effect on nasal function. Repairing severe vestibular synechia could be challenging for the surgeon, explaining why any patient treated with this type of surgical technique must use postoperative nasal retainers for 6 months to prevent this serious complication.

A recent comparative study published by the author found an increased rate of synechiae using the V–Y–Z technique in comparison with the McComb technique (4.16% versus 0%).[26] Based on the presented outcomes, the effectiveness of the proposed technique for unilateral cleft nose deformity repair without presurgical management was confirmed in this study.

Long-term significant changes were observed with regard to pre- and postoperative columellar angle and alveolar cleft lip, whereas nonstatistically significant differences were found between the cleft and noncleft sides regarding nostril dome height, nasal base width, alar base position, columellar length, lip height, and vermilion height (Tables 1 and 2; Figs. 4–7, 9–16). Observed differences in the lip width are associated with congenital hypoplasia on the cleft side of the lip. This condition has been reported by others.[27,28]

Fig. 9. Preoperative view of a 3-month-old infant with complete unilateral cleft lip and palate.

Fig. 11. Postoperative view of the infant shown in Figure 8 after undergoing cleft lip nose repair using the proposed technique (at the age of 5 years).

Fig. 10. Postoperative view of the infant shown in Figure 8 after undergoing cleft lip nose repair using the proposed technique (at the age of 1 year).

Fig. 12. Postoperative view of the alveolar cleft and maxillary arch form of the infant shown in Figure 8 after undergoing cleft lip nose repair using the proposed technique (at the age of 5 years).

Observed complications were low (5.4% of scar contracture and 2.7% of synechia) in comparison with similar studies, and all were well addressed without any additional surgery.[29,30] There were no cases of lip dehiscence in this group of patients independent of cleft severity (wider than 15 mm), illustrating that presurgical orthopedics are not necessary to prevent this complication.

Positive changes were observed for the alveolar cleft (Table 1). The primary surgery allowed us to correct the alveolar gap in a more physiological form (Figs. 12, 16). Changes in the alveolar gap width and transverse dental arch relationships have been described by different groups following primary cheiloplasty.[24,31,32] These authors reported that presurgical orthopedics had no lasting effect on arch form.

The main limitations of this observational study are uncontrolled confounding variables (surgeon performance, cleft's severity), the retrospective nature, and the lack of control group.

Different reviews and meta-analysis have been published during the last years addressing the effects of NAM in cleft lip and palate surgery.[33,34] A 2017 meta-analysis

Fig. 13. Preoperative view of a 3-month-old infant with complete unilateral cleft lip and palate.

Fig. 15. Postoperative view of the infant shown in Figure 13 after undergoing cleft lip nose repair using the proposed technique (at the age of 5 years).

Fig. 14. Postoperative view of the infant shown in Figure 13 after undergoing cleft lip nose repair using the proposed technique (at the age of 1 year).

Fig. 16. Postoperative view of the alveolar cleft and maxillary arch form of the infant shown in Figure 13 after undergoing cleft lip nose repair using the proposed technique (at the age of 5 years).

by Hosseini et al[34] suggested further research to reach more relevant recommendations. Two recent reviews by Maillard et al[35] in 2017 and Liu et al[36] in 2018 concluded that the use of NAM offers positive aesthetical effects. This conclusion cannot be drawn from the present work due to the heterogeneity of the included studies and nonspecificity of the research questions.

A recent nonliterature review published by Esenlik et al[37] concluded that improved surgical outcomes, reduced burden of care, reduction in the need for revision surgery, and lower costs are proven benefits of this therapy. However, a nonreview of the literature is insufficient to reach at any conclusions about the therapeutic effects, and large clinical trials or meta-analyses are required for this purpose.

In the present review, 3 studies reported no differences between 2 groups with and without the use of NAM. Liang et al[18] compared 2 groups of patients in a randomized clinical trial: NAM plus primary cheiloplasty or primary cheiloplasty alone. None of these patients had primary rhinoplasty. The authors did not observe any differences between these groups after 5 years of follow-up. Their findings indicated that the improvement of the nasal symmetry obtained using NAM is temporary, and primary rhinoplasty is required to obtain satisfactory

long-term outcomes. This study had the best level of evidence (2b).

Clark et al[13] did not observe any differences between 2 groups of operated patients with and without NAM based on 3-dimensional facial images and dental models after 5 years of follow-up. The main limitations in this study were its retrospective design and small sample of patients (20 patients treated with NAM + primary surgery versus 5 patients treated with surgery alone).

Broder et al[11] published a nonrandomized prospective multicenter study comparing 2 groups of patients with unilateral cleft lip and palate treated using primary cheilorhinoplasty with and without NAM. Clinicians reported comparable outcomes between the 2 groups, and caregivers reported significantly better outcomes in facial appearance in their patients who underwent NAM.

The study conclusions may be biased due to the differences in cleft severity. Five studies (3 cohorts and 2 cross-sectional) reported improved nose symmetry using NAM. Four were retrospective observational studies.[12,14–17] Three were multicenter studies; however, due to uncontrolled retrospective nature of these studies, we were not able to associate surgical outcomes with a specific protocol. Singh et al[12] published a prospective cohort study comparing 1 group of patients with unilateral cleft lip and palate treated using primary cheilorhinoplasty plus NAM with a control group.

The main limitations in determining associations between the treatment and outcomes were a lack of randomization, distribution of the groups, and the small number of patients (15 versus 10), resulting in low statistical power. Most studies had a small number of patients.

Finally, the overall study quality according to Oxford CEBM level of evidence and GRADE scale was low, ranging between 2b and 4 (Table 3). None of the published studies at this time have been well designed to demonstrate an association between the use of NAM and better postoperative nasolabial aesthetic outcomes in comparison with primary cheiloplasty alone.

It is important to clarify that this study did not intend to compare the 2 types of study findings (cohort study and literature review), given the different designs. I personally do not use presurgical NAM in unilateral cleft lip and palate for 4 reasons: it is unnecessary (it is only an alternative), it has associated complications and increased costs, and there is a lack of scientific evidence for its use.

CONCLUSIONS

The results of this study and literature review suggest that primary cheilorhinoplasty alone is a good alternative to improve nose and maxillary arch appearance in patients with unilateral cleft lip nose and palate deformity. The available scientific evidence is not sufficient to demonstrate that the combined use of presurgical orthopedics and primary surgery achieves better outcomes than primary surgery alone. Based on this result, the use of presurgical orthopedics to improve skeletal deformity in patients with unilateral cleft lip and palate could still be considered as an alternative and not as a gold standard.

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PATIENT CONSENT

Parents or guardians provided written consent for the use of the patients' images.

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