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PRS GLOBAL OPEN

ORIGINAL ARTICLE
Pediatric/Craniofacial

# Surgical Nasoalveolar Molding: A Rational Treatment for Bilateral Cleft Lip Nose and Systematic Review

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**Background:** The purpose of this study was to evaluate the surgical outcome after using primary surgery to address bilateral cleft lip nose and palate deformities. In addition, the authors performed a systematic review to evaluate the effects of the nasoalveolar molding on non-syndromic bilateral cleft lip and palate.
**Methods:** A prospective cohort study on a surgeon's surgical outcome of 25 consecutively performed primary bilateral cleft lip nasal deformity repairs was conducted and a systematic review of the literature for studies published until December 2019 was done to evaluate the effect of presurgical NAM on nasolabial aesthetics and alveolar gap.
**Results:** Since 2014, 25 consecutive patients with complete bilateral cleft have undergone primary anatomical repair of the cleft nasal deformity using primary cheilorhinoplasty. The average columella length was 4.3 ± 1.3 mm. The average ratio of the columella height to nasal height was 0.48 mm 1 year postoperatively and 0.52 mm 5 years postoperatively. Statistically significant differences have been observed between the pre and postoperative alveolar and palatal gaps after using primary cheiloplasty or bilateral lip adhesion. After systematic literature searching, 14 identified studies were qualified for the final analysis, which included 433 patients. The overall study quality according to Oxford CEBM and GRADE scale was low.
**Conclusions:** The results of this study suggest that the proposed primary cheilorhinoplasty is a good alternative to improve nose appearance and alveolar gap in patients with primary bilateral cleft lip nose and palate deformity. Based on the available scientific evidence, definitive conclusions about the effectiveness of presurgical Naso Alveolar Molding on nasolabial aesthetics cannot be drawn. Quality of the included articles were too low to make a conclusion. *(Plast Reconstr Surg Glob Open 2020;8:e3082; doi: 10.1097/GOX.0000000000003082; Published online 24 September 2020.)*

## INTRODUCTION

Bilateral cleft lip nose and palate deformity management is challenging. The midline structure is distorted with protruded premaxilla and a small prolabium, including an absent or short columella and deformed alar cartilage. Different techniques have been published with their own advantages and disadvantages. McComb,[1] Trott and Mohan,[2] and Mulliken[3] reported successful outcomes of their synchronous lip and nose repair at bilateral primary lip repair. The main limitations associated with these techniques are the increased rate of recurrence (McComb), sacrifice of nose tissue and visible scars (Mulliken), and extended skin incisions (Trott and Mohan).

The V-Y composite flap technique was first described by Potter[4] in 1954 and has been used by different authors for secondary cleft nose repair.[5,6] The usefulness of this method in primary unilateral cleft lip nose repair is not well described in the literature.

Nevertheless, the V-Y method leaves a straight scar in the lateral segment of the closure, which may create a lateral scar contracture of the vestibule. Berkeley, in 1959,[7] and, later, Nakajima and Yoshimura,[8] described the use of Z plasty to elongate the nasal vestibule, and this concept was included in the V-Y-Z technique to prevent lateral scar contracture.[9,10]

Different studies have been conducted to evaluate the efficacy of the presurgical nasoalveolar molding treatment on patients with non-syndromic cleft lip and palate most

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*Received for publication April 18, 2020; accepted July 13, 2020.*



DOI: 10.1097/GOX.0000000000003082

**Disclosure:** *The authors have no financial interest to declare in relation to the content of this article.*

of them in unilateral forms. The heterogeneity of these studies limits the construction of scientific evidence of the effect of NAM in bilateral cleft lip and palate. The last meta-analysis published by Hosseini in 2017 concluded that there is limited evidence to support the short- or long-term effectiveness of presurgical NAM in cleft lip and palate patients.[11]

Dr. Rossell-Perry's proposed method has been named as the "Surgical Naso Alveolar Molding" because the surgical technique acts in a similar form as the presurgical NAM: the vestibule of the nose is expanded, and the premaxila and alveolar cleft segments are aligned.[10]

The objective of the present study was to evaluate the nasal and maxillary arch form after undergoing cheiloplasty or lip adhesion in patients with complete bilateral cleft lip nose and palate.

In addition, a systematic review was performed to evaluate surgical effects using orthopedic NAM in patients with bilateral cleft lip nose.

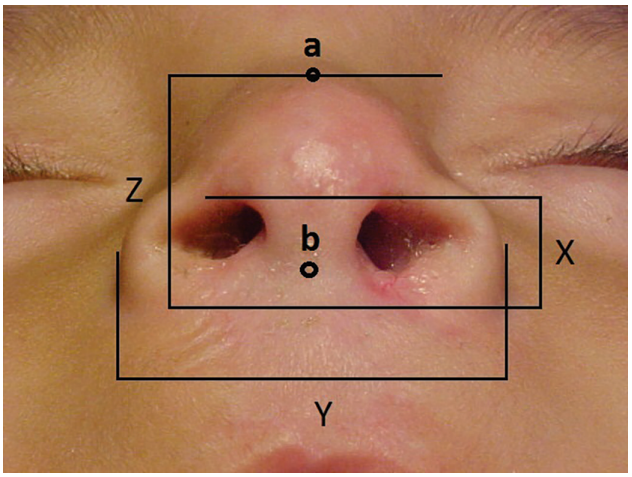


**Fig. 1.** Standard anthropometric measurements. (x) Columellar height. (y) Alar base width. (z) Nasal height. (a) Pronasale. (b) Subnasale.

## METHODS

### Observational Study

This is a prospective cohort, single-arm plus control group study of one surgeon's outcome of 25 consecutive primary complete bilateral cleft lip nasal deformity repair procedures. Nineteen patients received primary surgery alone as treatment of the bilateral cleft lip nose deformity. Six patients received bilateral lip adhesion according to Randall's technique[12] due to severe malposition of the premaxilla and primary surgery around 3 months later. Severe bilateral cleft lip and palate has been defined as a bilateral cleft lip with alveolar gap wider than 1 cm (in 1 or 2 sides).[13]

#### Inclusion Criteria

The inclusion criteria were non-syndromic complete bilateral cleft lip and palate patients who underwent the procedure between 2014 and 2015 at Los Andes Clinic in Lima, Perú. Additionally, anthropometric measurements of the nose and alveolar cleft were performed at 1 and 5 years postoperatively.

#### Exclusion Criteria

The exclusion criteria included syndromic patients, mild forms of bilateral cleft lip and palate (incomplete cases), and a short-term follow up (less than 5 years).

#### Nasal Outcomes Measurements

Anthropometric nose measurements at the time of alveolar cleft closure (5 year-olds) were compared with a control group of 28 incomplete cleft palate patients without a cleft lip.

The patients comprised an age-matched group received at our center for incomplete cleft palate repair during the time of the study.

The nasal profile was evaluated using the following parameters (Fig. 1):

a) Columellar height (x)

b) Ratio columellar height (x)/alar base width (y)

c) Ratio columellar height (x)/nasal height (z) (representing nose projection).

These measurements were performed by physical examination under general anesthesia using the Vernier caliper at 1 and 5 years postoperatively at the time of cleft palate repair and alveolar cleft repair, respectively.

#### Alveolar Gap Measurements

Serial dental casts were obtained from each BCLP child pre and postoperatively at the time of cheiloplasty (3 months), cleft palate repair (1 year), and alveolar cleft repair (5 years). The alginate impression procedure (Alginot, Kerr, Romulus, Mich.) was performed and measurement of the alveolar gap on each side was compared pre and post treatment (Fig. 2).

Postoperative analysis of the alveolar gap were performed using the following landmarks:

a) Alveolar gap: The width of the alveolar gap is the distance between point A and B.

Point A: On the gingival ridge of the cleft (crest of the alveolar ridge).

Point B: The most dorsal point of the premaxila contour.

#### Surgical Technique

These patients had had primary cheilorhinoplasty, including the following procedures:

a) Primary rhinoplasty based on bilateral medial mobilization of the lateral alar crus and vestibular lengthening using the V-Y-Z technique (Figs. 3, 4)[10];

b) Bilateral lip adhesion for severe bilateral cleft lip and palate forms; Any patient with a cleft width more than 1 cm received presurgical management with surgical lip adhesion based on Randall's technique. (Figs. 5–7);

c) Straight line bilateral cheiloplasty as described by Chen P.[14]

Vestibular skin incisions along the marginal and intercartilaginous borders were performed, creating a composite flap (vestibular skin and alar cartilage) in a V form, and

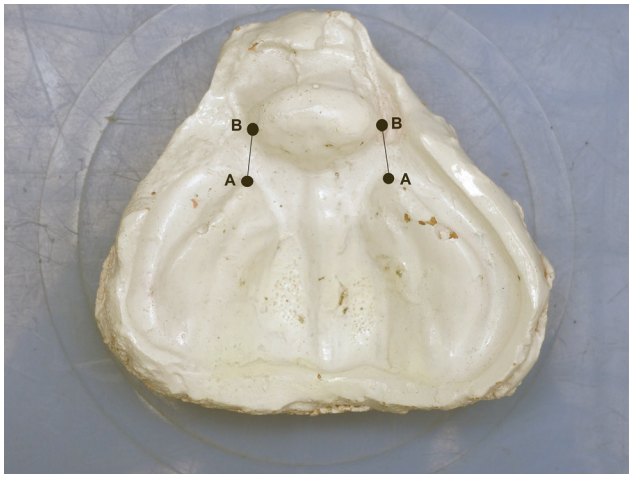


**Fig. 2.** Alveolar gap measurement using Vernier caliper.

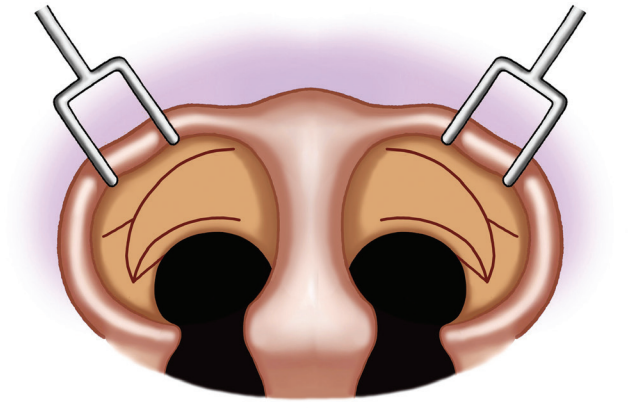

**Fig. 3.** The V-Y-Z technique for complete bilateral cleft lip nose repair.

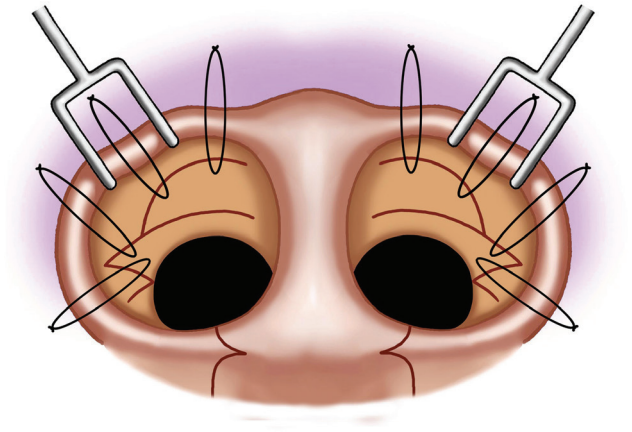

**Fig. 4.** The V-Y-Z closure using transcutaneous stitches with bilateral medial V-Y plasty plus lateral Z plasty components.

the 2 limbs of the lateral Z plasty were incised and elevated using fine scissors. The bilateral cartilage structures of the nose tip were dissected using this incision, degloving the alar cartilages at the nasal tip level. Next, the composite

**Fig. 5.** Preoperative view of a 1-month-old patient with severe complete bilateral cleft lip and palate.

**Fig. 6.** Postoperative view of the patient (3 months) shown in Figure 4 after undergoing lip adhesion first (1-month-old).

flap was displaced medially on both sides, and the lateral incision is closed in a Z plasty form.

All incisions were closed using transcutaneous stitches, as in Figure 4. We used 5-0 polyglycolic acid sutures through the skin starting inside the nose, then coming out at the level of the supraalar crease, returning through the same hole and finally coming out inside the nose and tying the sutures (Fig. 4).

The V-Y-Z method allows the repositioning of the alar cartilage and lengthening of the columella on both sides. Lateral Z plasty prevents scar contracture of the vestibular incisions.

**Fig. 7.** Postoperative view of the patient (1 year) shown in Figure 4 after undergoing primary rhinocheiloplasty using the proposed technique.

The nasal floor was repaired bilaterally using proper location of the alar and shortening of the nasal base width. During cheiloplasty, the levator labii superioris alaequae nasi and orbicularis oris muscles were repositioned and sutured at the midline level.

Nasal packing is recommended to prevent postoperative bleeding and should be removed the next day. Postoperative nostril stenting is used to prevent scar contracture of the vestibular incisions during 6 months. This device is used only to prevent vestibular scar contracture and synechias.

### Statistical Analysis

Mann–Whitney *U* test, a nonparametric test was used to assess the statistical significance. The alpha error was set as $P < 0.05$, yielding a confidence level of 95%. Standard software (SPSS v15.0; SPSS Inc, Chicago, Ill.) was utilized for data analysis. Parents of each patient were informed of the nature of the surgical techniques used and granted signed consent before surgery.

### Systematic Review Study

We conducted a systematic review of the literature based on a specific protocol developed and piloted following the guidelines outlined in the PRISMA-P statement[15] and registered in PROSPERO (CRD42019134146).

The eligibility criteria were (based on the PICOS):

- Participants, children born with non-syndromic complete bilateral cleft lip and palate.
- Intervention: presurgical nasoalveolar molding plus primary cheilorhinoplasty.
- Comparison: primary cheilorhinoplasty.
- Outcomes: any outcome relevant to the proposed treatments.
- Study design: any prospective and retrospective follow-up, cohort studies, case series and randomized control studies related to NAM appliance outcomes on the bilateral cleft lip and palate.

Animal studies, systematic (and nonsystematic) reviews, and meta-analysis and case reports were excluded. The studies were restricted to English and no restrictions were applied regarding publication dates.

The research question was: does the presurgical NAM plus primary cheilorhinoplasty provides better nasal and alveolar gap outcomes than primary cheilorhinoplasty alone in patients with bilateral cleft lip and palate? The research terms used for data searching were: Nasoalveolar molding AND cleft lip and palate. Pubmed, Embase, and Cochrane Library databases were electronically searched up to December 31, 2019, by 3 authors (PRP, COF, and PDJ). For search strategy purpose, titles were screened first excluding non-pertinent studies. Then, abstracts were evaluated to exclude studies without inclusion criteria. Finally, the articles were selected after reviewing the full-text versions based on eligibility criteria. Study quality assessment was performed independently by the same authors according to the Oxford CEBM Level of Evidence classification and GRADE scale. Disagreements were resolved by discussion or consultation between these authors.

## RESULTS

### Observational Study

Twenty-five consecutive patients with primary bilateral cleft lip nasal deformities underwent surgery since 2014. The characteristics of the studied groups are presented in Table 1.

Postoperative nasal profiles comparison between operated and control group at 1 and 5 years old is presented in Table 2.

We found no statistically significant differences in the columellar height and columellar height to nasal height ratio between the cleft patients at 5 years old and control patients ($P = 0.134$) ($P = 0.328$) (Table 2).

The alar base width was significantly greater in the cleft group than in the normal group ($P < 0.001$) (Table 2).

Statistically significant differences were observed in relation to the alar base width and ratio of the columellar height to the alar base width between groups ($P = 0.002$) (Table 2). Statistically significant differences were observed between pre- and postoperatively alveolar gap measurements using lip adhesion and primary cheiloplasty ($P = 0.000$) (Tables 3, 4).

**Table 1. Characteristics of the Studied Groups**

| | Operated Group | Control Group |
|---|---|---|
| n | 25 | 28 |
| Age at the time of lip adhesion (n = 6) | 7.1 wk (range, 6–8 wk) | |
| Age at the time of primary cheilorhinoplasty (mean) | 4.2 mo (range, 3–5 mo) | — |
| Gender | | |
| Male | 16 (64%) | 8 (32%) |
| Female | 9 (36%) | 17 (68%) |

**Table 2. Postoperative Nasal Profile Comparison between Operative and Control Groups at 1 and 5 Years Old (n = 25)**

| Measurements, mm | One-year Follow-up (n = 25), Mean (SD) | Five-year Follow-up (n = 25), Mean (SD) | P* | Control Group (n = 28), mean (SD) | P† |
|---|---|---|---|---|---|
| Columella height | 4.30 (1.01) | 5.80 (1.02) | 0.428 | 4.80 (1.01) | 0.134 |
| Alar base width | 32.2 (1.48) | 35.40 (0.85) | 0.090 | 25.60 (1.32) | 0.001 |
| Ratio of columella height to nasal height | 0.48 (0.68) | 0.52 (1.17) | 0.317 | 0.51 (0.76) | 0.328 |
| Ratio of columella height to alar base width | 0.25 (0.83) | 0.30 (1.13) | 0.240 | 0.33 (0.94) | 0.002 |

Mann–Whitney *U* test.
*Comparison between postoperative follow-up at 1 year and 5 years.
†Comparison between postoperative follow-up at 5 years and in control group.

**Table 3. Alveolar Gap Comparisons from Lip Adhesion to Alveolar Cleft Closure (n = 6)**

| Side, mm | Before Lip Adhesion, Mean (SD) | Before Primary Cheiloplasty, Mean (SD) | Before Primary Palatoplasty, P* | Before Alveolar Cleft Closure, Mean (SD) | P† | Mean (SD) | P‡ |
|---|---|---|---|---|---|---|---|
| Right | 13.1 (0.79) | 5.8 (1.18) | 0.000 | 2.8 (0.95) | 0.000 | 1.3 (0.83) | 0.080 |
| Left | 13.3 (1.23) | 6.3 (1.54) | 0.000 | 3.0 (0.87) | 0.000 | 1.5 (1.00) | 0.120 |

Values are expressed as mean ± SD. Significance level was set as $P < 0.05$. Mann–Whitney *U* test. $P < 0.05$.
*Comparison between controls A and B.
†Comparison between controls B and C.
‡Comparison between controls C and D.

**Table 4. Alveolar Gap Comparisons from Primary Cheiloplasty to Alveolar Cleft Closure (n = 19)**

| Side, mm | Control A, Mean (SD) | Control B, Mean (SD) | P* | Control C, Mean (SD) | P† |
|---|---|---|---|---|---|
| Right | 7,0 (2.70) | 1,5 (2.02) | 0,001 | 0,9 (0.85) | 0.334 |
| Left | 7,1 (2.62) | 1,7 (0.79) | 0,001 | 1,1 (1.00) | 0,254 |

Values are expressed as mean ± SD. Significance level was set as $P < 0.05$. Mann–Whitney *U* test. $P < 0.05$. Control A, before primary cheiloplasty. Control B, before palatoplasty. Control C, before alveolar cleft closure.
*Comparison between controls A and B.
†Comparison between controls B and C.

Observed bad results and complications are presented in Table 5. Surgical outcomes are presented in Figures 5–13.

### Systematic Review

Flowchart of literature search and selection is presented in Figure 14. Initially 69 studies were identified and 229 were excluded as duplicates according to the exclusion criteria. Finally,14 full-text reports were included in the systematic review.

Finally, the overall study quality according to Oxford CEBM and GRADE level of evidence was low (Tables 6, 7).

## DISCUSSION

Different protocols for primary bilateral cleft lip nose have been described, and few studies have evaluated the effects of the primary rhinoplasty without presurgical management. Bilateral cleft lip nose deformity management considers presurgical nasal molding (NAM), primary rhinocheiloplasty, and postoperative nasal stents

**Table 5. Bad Results and Complications Associated with the V-Y-Z Technique for Primary Bilateral Cleft Lip Nose Deformity (n = 25)**

| Complication | n (%) |
|---|---|
| Asymmetry | 6 (24) |
| Granuloma | 4 (16) |
| Partial recurrence* | 3 (12) |
| Vestibular synechia | 2 (8) |
| Infection | 1 (4) |

*Partial recurrence is understood when significant changes are observed in comparison with the immediate postoperative period.

**Fig. 8.** Preoperative view of a 1.5-month-old patient with severe complete bilateral cleft lip and palate.

**Fig. 9.** Postoperative view of the patient (5 years) shown in Figure 7 after undergoing lip adhesion first (1 month-old) and nasal repair using the V-Y-Z technique and primary cheiloplasty (3 month-old).

**Fig. 10.** Postoperative view of the maxillary arch form of the patient shown in Figure 7 (5 years old).

as standard management of nose correction in patients with bilateral cleft lip nose.[16] Different studies (including meta-analysis) have described the absence of scientific evidence supporting the use of NAM for cleft lip nose repair.[11,17–19] Significant relapse of the deformity has been observed after using nasal moldings,[20] and good outcomes were observed only in combination with primary rhinoplasty.[21–23] The Taiwanese group from Chang Gung University demonstrated that nasal molding has a short-term effect, and only surgery may guarantee a long-term effect.[23]

Based on this scientific evidence and our experience during the last 20 years, we consider that good nose symmetry and premaxilla position can be obtained using an adequate surgical technique without presurgical treatments.

**Fig. 11.** Preoperative view of a 3-month-old patient with complete bilateral cleft lip and palate.

**Fig. 12.** Postoperative view of the patient (5 years) shown in Figure 10 after undergoing nasal repair using the V-Y-Z technique and primary cheiloplasty (3 months-old).

Marginal incisions with and without skin excision have been described by research groups such as Tajima and Maruyama[24] and Mulliken.[3] We have observed visible and poor scars, and the use of these incisions for columellar lengthening may produce a turned-up nose appearance.

Conservative treatment based on McComb principles for alar cartilage degloving and fixing using transcutaneous incisions was used with good short-term outcomes.[1] An unsatisfactory higher recurrence of the nasal deformity was observed after a long-term follow up.[25]

In the present study, significant differences were observed related to the gender of the studied groups.

**Fig. 13.** Postoperative view of the maxillary arch form of the patient shown in Figure 10 (5 years old).

Male gender was observed to be prevalent in the operated group. However, nose anthropometric measurement differences related to gender was not noted at this age.[26] Therefore, these differences between groups could not explain the observed outcomes. One limitation that should be considered in this study is that measurements were taken by only one observer.

The utility of the proposed technique for bilateral cleft nose deformity repair was confirmed in this study with non-statistically significant differences between the 2 groups regarding the postoperative columella length and ratio of the columellar height to nasal height (Table 2). The mean columellar height in our group of operated patients was 5.8 (1.022) mm, which is similar to the outcome obtained by Morovic and Cutting's group of patients (5.6 ± 1.4 mm).[27]

The alar base width in our group of operated patients was also similar to the outcome in Morovic and Cutting's group of patients (35.4 and 34.4 mm, respectively). The observed ratio of the columellar height to alar base width in our operated patients was similar to that reported by Chang et al[21] (0.30 versus 0.27, respectively). However, they used presurgical nasal molding, and a more aggressive surgical technique with skin excision (Mulliken).

Different studies have reported an increased alar base width after primary bilateral cleft lip and palate repair (observed in this study).[25,27] This unfavorable outcome may be related to the development of hypertrophic scars due to tension of the closure or facial muscle action and could be easily corrected later. Based on these findings, we may conclude that bilateral vestibular lengthening enables columellar lengthening and nasal tip projection and symmetry, as demonstrated in this study.

The main complications of this surgical technique included: skin dimples and granulomas (both related to the transcutaneous stitches, all of them temporarily), scar contractures, vestibular synechia, asymmetries, hypertrophic scars, and nasal deformity recurrence (Table 3). Nose asymmetries are common (24% of the operated patients) and probably related to the skeletal asymmetry. Due to the use of extended incisions over the nasal vestibule, the risk of scar contracture and vestibular synechia must be considered. Patients must use postoperative nasal retainers for 6 months to prevent this serious complication.

Any severe form of bilateral cleft lip and palate requires presurgical management to prevent complications like wound dehiscence or premaxilla malposition. NAM (nasoalveolar molding) is used with this purpose to mold nasal cartilages, premaxila, and alveolar ridges. However, some studies have been reported limitations using NAM as lack of scientific evidence, costs, irritation of the lip and nasal tissues, risk of aspiration, mucosal ulceration, dental caries, nasal and intraoral bleeding, fungal infection, dental caries, loss of follow-up, facial growth compromise, and airway obstruction.[28–30]

Surgical methods for protruding premaxilla management are effective and good alternative when the use of non-surgical methods is not possible. Lip adhesion represents an alternative to be used in severe bilateral cleft lip management.

The surgical adhesion and primary cheiloplasty mold the underlying bony structures, reduce tension for lip closure, and allow us to reposition the alar base, as we observed in this study (Tables 3, 4). There were no cases of lip dehiscence in this group of patients independently of the severity of the clefts (mean: 13 mm). The main limitation is the requirement of additional surgical and anesthetic times with its associated complications and expenses.

NAM therapy has been extensively studied as presurgical treatment of cleft lip and palate deformities and more than 300 papers have been published since 1998. Based on the scientific method, a prospective study between 2 or more randomized groups and blinded assessment is necessary to demonstrate the efficacy and utility of any therapy. From the 69 reviewed articles, only 14 were selected for the study, as they have answered the research question associated to a good level of evidence. This proves the lack of existing literature regarding bilateral cleft lip and palate.

Included studies in this systematic review are retrospectives (except 1) and observational associated with increased rate of bias. Only 1 prospective cohort study is published and has only 8 patients. Most of the studies (except 2) have a small number of patients (<25), limiting the validity of their obtained conclusions. Additionally, only 7 studies have a control group.

Six of the 14 studies do not have control groups and the other 6 studies have evaluated their outcomes only after NAM treatment.

Five studies aimed to evaluate the effects of the nasoalveolar molding in patients with bilateral cleft lip and palate and compare them with healthy infants. Most of them have been observed post-treatment changes using NAM in BCLP patients, improving the nasal shape by molding the cartilages and decreasing the cleft gap, however, the used retrospective observational method is limited to evaluate efficacy.[31–35]

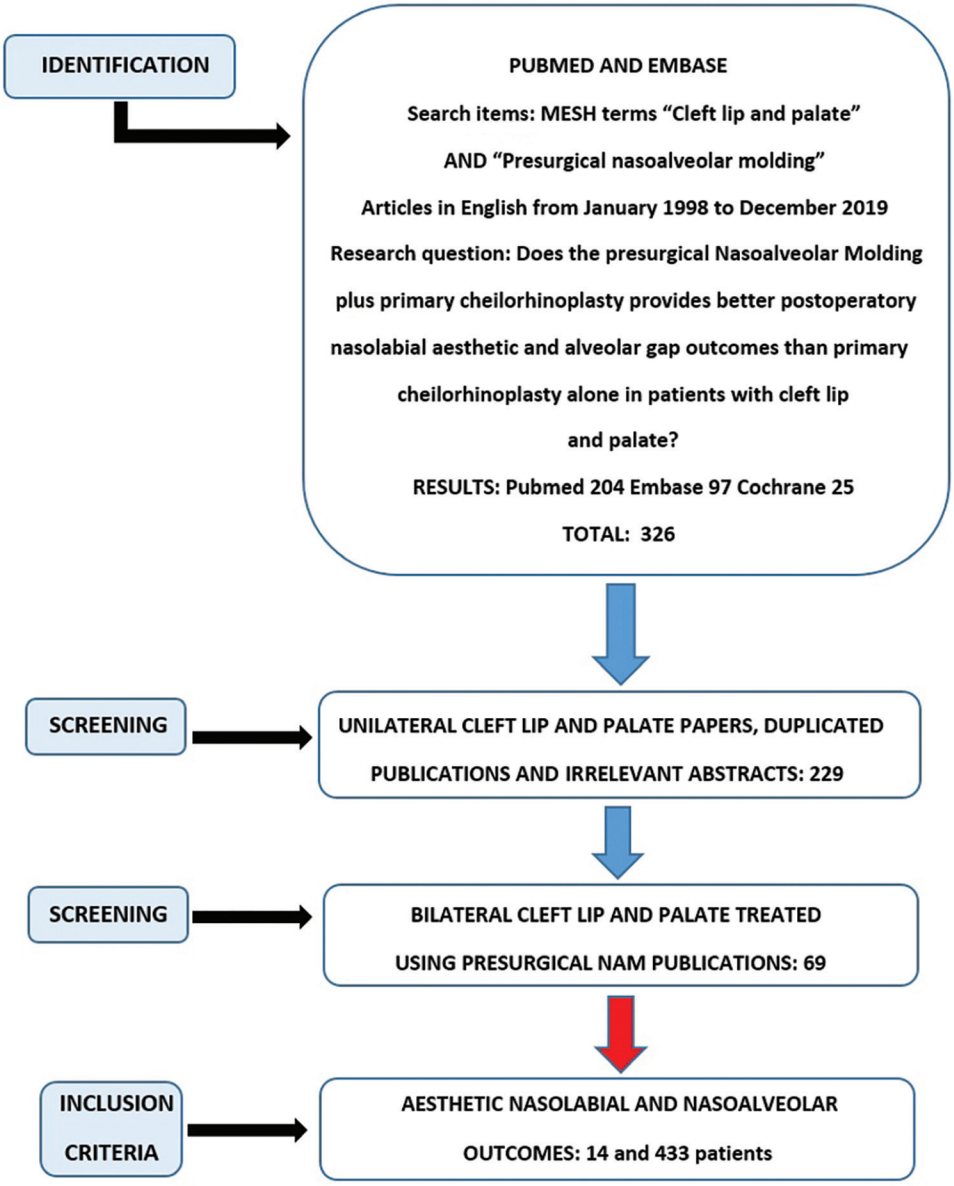


**Fig. 14.** Flowchart of literature search and selection.

Liao et al studied a sample of 58 patients, but their evaluation has been done after NAM treatment without control groups, and the outcomes should be measured after primary surgery.[34] The same situation has been observed with the studies by Grill et al, Isik et al, Rau et al, Li et al, and Spengler.[31,33,35–37]

In 2014, Li et al observed an elongation of the columella, elevation of the nasal tip, and nasal dome improvement in BCLP patients treated with modified NAM using screws. However, the number of studied patients is very small (8).[35]

Also, Grill et al[16] observed a statistically significant columella elongation, with an increase of 106.5% in BCLP using NAM. However, despite NAM treatment, the columella length did not reach the healthy cohort proportions at the time of lip closure. In addition, outcomes have been evaluated after NAM treatment and not after surgery, limiting their conclusions.[36]

Spengler et al and Mishra et al observed significant changes after using NAM therapy and concluded that the complexity of subsequent surgeries decreases and the number of secondary surgeries are reduced. However, their used samples are very small (8 and 6), limiting their conclusions.[37,38]

Meazzini et al and Garfinkle et al did a longer term follow up (13 years) and concluded improvement of nasal outcomes after NAM + primary rhinoplasty. However, despite the use of long term cohorts, the observational and retrospective nature of their studies is limited to demonstrate any efficacy. In addition, Garfinkle et al's study does not has control group since their compare outcomes versus Farkas studies.[22,39] Three studies observed columellar

**Table 6. Selected Articles, According to Inclusion Criteria and Used for Data Extraction to Evaluate the Effect of Nasoalveolar Molding (NAM) on Nasolabial Aesthetics and Alveolar Gap (Studies 1–7)**

| Study | Sample Size/Treatment | Design | Evidence Level | Effect of Nasolabial Aesthetic | Follow-up |
|---|---|---|---|---|---|
| Grill et al[36] | 19 BCLP patients treated using NAM; 32 healthy controls | Retrospective cohort study | 4 | NAM significantly elongated the columella length and nostril height before surgery. Nasal dimensions will not reach healthy proportions. | After NAM treatment |
| Meazzini et al[39] | 23 BCLP patients treated using NAM; 23 healthy controls | Retrospective cohort study | 4 | Nasal protrusion and length of the columella were very close to normal. Nasolabial angle and interalar width were still excessively wide compared to the noncleft sample. | 13 y |
| Isik et al[31] | 8 BCLP patients treated using NAM; No control group | Retrospective cohort study | 4 | NAM provides significant decreases in both alveolar and palatal cleft as compared with birth status. | After NAM treatment |
| Gong et al[32] | 19 BCLP patients treated using NAM; 21 BCLP patients treated without NAM | Retrospective cohort study | 4 | Computer-aided nasoalveolar molding can can reduce the cleft gap, correct the alveolar midline deviation, and retract the projection and outward rotation of the premaxila segment. | 6 mo |
| Rau et al[33] | 10 BCLP patients treated using NAM; No control group | Retrospective cohort study | 4 | Nasal and alveolar gap changes has been seen when compared with their birth status. | After NAM treatment |
| Chang et al[40] | 23 only rhinoplasty; 19 only NAM; 24 NAM + rhinoplasty; 25 NAM + overcorrection; 23 controls | Retrospective cross-sectional study | 4 | Presurgical nasoalveolar molding followed by primary rhinoplasty with overcorrection resulted in a nasal appearance that was closer to the patients without cleft lip. | 3 y |
| Li et al[35] | 9 BCLP patients using modified NAM | Retrospective cohort study | 4 | Modified NAM using screws correct nasolabial deformities and retract and centralize the premaxilla. | After NAM treatment. |

**Table 7. Selected Articles, According to Inclusion Criteria and Used for Data Extraction to Evaluate the Effect of Nasoalveolar Molding (NAM) on Nasolabial Aesthetics and Alveolar Gap (Studies 8–14)**

| Study | Sample Size/Treatment | Design | Evidence Level | Effect of Nasolabial Aesthetic | Follow-up |
|---|---|---|---|---|---|
| Liao et al[34] | 58 BCLP patients comparing 2 NAM methods; no control groups | Retrospective cohort study | 4 | Both methods improve nasal deformities and reduce alveolar gaps. | After NAM treatment |
| Garfinkle et al[22] | 77 BCLP patients treated using NAM + primary rhinoplasty; No control group | Cohort study | 4 | BCLP patients treated with NAM attained nearly normal nasal morphology in comparison with Farkas published outcomes. | 12.5 y |
| Mishra et al[38] | 6 BCLP patients treated using NAM vs No NAM group | Retrospective cross-sectional study | 4 | Nostril height and columella was larger in NAM group. Nostril width and alar perimeter did not change significantly. | 1 y |
| Meazzini et al[40] | 18 patients, NAM treated; 18 patients, no NAM; 40 healthy patients | Retrospective cross-sectional study | 4 | Columella length, nasal tip angle, and protrusion are improved close to normal. Nasolabial angle and interalar distances are wider in both samples. | 5 y |
| Lee et al[41] | 13 BCLP rhinoplasty; 13 NAM + rhinoplasty; 13 healthy patients | Retrospective cross-sectional study | 4 | Columellar length is restored to normal using NAM and reduced the need for secondary nasal surgery. | 3 y |
| Liou et al[42] | 22 patients NAM + primary surgery; no control group. | Retrospective cohort study | 4 | NAM + surgery lengthened the columella in BCLP patients. However, there was a relative relapse in columella length. | 3 y |
| Spengler et al[37] | 8 BCLP patients treated using NAM; no control group. | Prospective cohort study | 4 | NAM improves the nasal asymmetry and deficient nasal tip projection and forces the protruded premaxilla, improving the shape of the maxillary arch. | After NAM treatment |

elongation close to healthy patients after NAM treatment and primary surgery but using small samples and retrospective studies.[21,41,42]

Meazzini et al[40] conducted a study comparing 2 treatment protocols in patients with BCLP. The group of patients treated with NAM presurgically showed an improvement in nasal outcomes; however, interalar distance and nasolabial angle were far from normal.[26]

The level of evidence according to the Oxford CEBM classification was 4 for all papers. Qualification using GRADE scale was C (Low, 1 or more studies with severe limitations).

We can conclude that there is scarce evidence published on bilateral cleft lip and palate patients about long-term nose and maxillary arch morphology using NAM. 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 and alveolar outcomes in comparison with primary cheilorhinoplasty alone. Nevertheless, in the long term, insufficient evidence exists to support the superiority of NAM versus no NAM to assess nasal aesthetic and alveolar arch form. Definitely, more sustainable studies are needed to endourse nasoalveolar molding treatment as part of a protocol, regarding that its use is not extent of complications and its real benefit is not well known in the long term.

## CONCLUSIONS

The results of this study suggest that proposed primary cheilorhinoplasty (the surgical NAM) and surgical lip adhesion are good alternatives to improve nose appearance and alveolar gap in patients with primary bilateral cleft lip nose and palate deformity. Definitive conclusions about the effectiveness of presurgical Naso Alveolar Molding cannot be drawn. Available scientific evidence is not sufficient to demonstrate that the combined use of presurgical NAM and primary surgery provides better nose and alveolar gap outcomes than primary surgery alone.

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