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original article

Comparison of post-surgical soft tissue changes between bilateral cleft patients treated with and without a modified nasoalveolar molding appliance: A cohort study

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Keywords
Bilateral cleft lip/palate
Nasoalveolar molding (NAM)
Surgical lip closure

Summary

Introduction > The advantages of nasoalveolar molding (NAM) treatment for cleft lip and palate (CLP) patients have been well documented. A modified design for bilateral CLP was introduced.
Aims > This paper aimed to: 1- quantify the soft tissue changes after applying modified NAM treatment to these patients; and 2-compare post-surgical changes to a control group where no NAM was used.
Material and methods > At a tertiary care paediatric hospital, a historical cohort group of complete BCLP patients (n = 15) was compared to a prospectively collected group of complete BCLP patients who underwent NAM therapy (n = 15). In the NAM group (mean age: 1.1mos $\pm$ 0.2), a new modification of the NAM appliance was implemented. In the control group (mean age: 5mos $\pm$ 0.2), no NAM treatment was adopted prior to lip closure surgery. Soft tissue nasolabial segments were measured on initial (T1), post-NAM (T2) and 3 months post-surgery (T3) photographs; measurements were analysed statistically.
Results > In the NAM group, cleft size was reduced by 68 to 70% in 4–5 months and all measurements improved between T1 and T2. Columellar crest inclination decreased by 74%, columellar length increased by 184%, nostril and bialar widths decreased by 36% and 16%, respectively. The lip philtrum was elongated by 49.5%. At T3, all soft tissue variables statistically improved better in NAM versus non-NAM groups.
Conclusion > The modified NAM appliance provided improved results of lip approximation and nasal measurements compared to non-NAM treatment.

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Introduction

Achieving a functional and aesthetic outcome of lip repair in cleft lip and palate (CLP) patients has always been a challenging initial surgery. Factors such as nasal asymmetry, columellar deficiency and deformation of the nasal cartilage contribute to this complexity [1]. Presurgical orthopaedics in infants was developed to improve the position of the clefted segments, initially the lips, and facilitate their surgical approximation. The nasal deformity was addressed to shape the nostrils with two silicone tubes [2], a method refined by Grayson and Maull [3,4] to the current "nasoalveolar molding'' (NAM) appliance, which consists of an intraoral appliance with nasal stents extending intranasally.

The NAM assembly allows targeted force application to mold the alveolus, shape the nasal cartilage and in bilateral (B) CLP conditions, lengthen the columella. Accordingly, the width of the cleft and premaxillary protrusion are reduced, the arch shape is improved, symmetry between the lateral nasal cartilages is enhanced, and projections of the nasal tip and of the columellar length are increased [5–11]. Reported benefits of aligning the tissues by the NAM appliance before primary lip/nose repair include improved lip and nasal form, more stable results, less scar tissue, and reduced number of surgical revisions for excessive scar tissue, oronasal fistulas, nasal, and labial deformities [7,12–14]. All these beneficial NAM outcomes are increased if the treatment is started as soon as possible, ideally before 1 month of age [15,16]. However, despite these encouraging benefits, alveolar molding is still not widely applied because of inexperience, unavailability, and associated complications. These latter include irritation or ulceration of the oral mucosa or gingiva because of pressure from the molding plate [17] and common breakdown of the frenum attachments and the anterior premaxilla during retraction of the molding plate [4]. Excessive force on the nasal lobe could also result in nasal tip inflammation. One of the reported complications is skin irritation of the cheeks caused by fast or imprudent removal of the tapes [17]. In addition, some authors rated the prevalence of side effects: tissue irritation (> 10%), compliance issues (30%), and instability of the appliance (26%) [18]. Difficulty of appliance placement by the parents and poor compliance also led to loss of valuable treatment time.

These concerns along with disparities among operators have prompted modifications of the original design. Patil and Nimbalkar-Patil [19] avoided the vertical taping of the premaxilla to the oral plate by activating the appliance through relining and wire bending the columellar portion of the nasal stent to lengthen the columella in B CLP patients with severe premaxillary protrusion and complete loss of columella. Nagraj et al. [20] and Subramanian et al. [9] used a more resilient TMA wire to fabricate a nasal stent with a double loop technique that can be adjusted chair side. They stated that the modified appliance helps to reduce the number of follow-up visits, reduces appointment time, and facilitates better patient/parent compliance.

Three-dimensional technology through computer-assisted design and computer-aided manufacturing was applied in the pre-surgical cleft treatment. Studies by Yu et al. [21] and Shen et al. [22] showed that this method leads to a more efficient and predictable NAM treatment with a potential decrease in cost. A preliminary prospective study by Ritschl et al. [23] highlighted that there is no difference in the efficiency and presence of complications between NAM produced manually and NAM fabricated with three-dimensional technology.

The persistent difficulties encountered by the parents to position the NAM appliance and the irritation caused by the tape, especially at the surfaces of the philtrum and the two segments of the upper lip, were addressed by our team through specific modifications incorporated in a novel design of the NAM appliance. Thereby, the aims of this paper were to: 1- quantify the soft tissue changes after applying NAM treatment to these patients, and 2- compare these changes to a control group where no NAM was used after lip closure surgery.

Material and methods

This study was approved by the Institutional Review Board (IRB #: BIO-2018-0045) of the American University of Beirut.

Design and setting

Patients were recruited from the Department of Orthodontics and Dentofacial Orthopaedics at the American University of Beirut Medical Center (a tertiary care paediatric hospital). 30 infants (males and females) diagnosed with a complete BCLP, with an age range between 0.9 months and 5.2 months were enrolled. Before patients' recruitment in the study and usage of their information and images for publication purposes, written informed consent was obtained from their parents.

Included in the NAM group were infants with non-operated BCLP, age ranging between 3 and 8 weeks with no associated syndromes.

As for the control group (non-NAM), non-syndromic BCLP infants treated surgically between the age of 4 and 6 months were selected.

Interventions

Two BCLP patient groups were considered: the NAM group (age: 1.1 $\pm$ 0.2 months) treated with a modified NAM appliance prior to surgical lip closure, recruited between 2017 and 2020, and a control non-NAM group (age: 5 $\pm$ 0.2 months) treated surgically by the same surgeon prior to the implementation of the usage of the NAM therapy, between years 2013 and 2016 (historical cohort). Patients in the NAM group were seen every two weeks for an average period of 18 $\pm$ 2 weeks to evaluate progress and adjust the appliance.

All patients were operated by the same surgeon who has an experience in treating cleft lip and palate patients for more than 20 years. The first group was treated at a period where the NAM was not yet introduced to the treating centre. Once an expert orthodontist started to apply the NAM therapy, all operated cleft lip patients started to follow that protocol. This explains the difference in the recruitment time of the patients between the two groups. Patients in the NAM group were seen every two weeks for an average period of 18 $\pm$ 2 weeks to evaluate progress and adjust the appliance.

Description of the modified NAM

The modification of the NAM appliance encompassed the two nasal stents to lift up the nostrils and two additional Constrictive Alar Pads (CAP) (*figure 1*). These latter were introduced to help in compressing the flattened ala and decrease the inter-alar width, in addition to the better stability of the appliance in the mouth. The CAP are made with a 0.036-inch (0.8-mm) stainless steel wire and the alar pads in acrylic. A helix incorporated on each side of the CAP is activated at each appointment. The original acrylic bulbs, on which the elastics and the cheek adhesive tapes are attached for appliance retention, are replaced by two horizontal stainless-steel arms emerging from the acrylic body of the appliance. These arms are less bulky and enhance retention symmetry by providing two points of application for the elastics instead of one. To elongate the philtrum and retract the premaxilla, the adhesive tape on the philtrum was replaced by an acrylic bar activated on one side by a Nickel Titanium closed coil extended from the right ascending arm of the nasal stent to the acrylic bar. The retractive force of the bar is activated by adding an elastic from a hook soldered at the left ascending arm to a series of buttons incorporated in the acrylic bar: if more activation is needed, the elastic will be extended to a further button. The described design of the acrylic bar aims to provide continuous force application to the philtrum and to allow easier insertion of the appliance by the parents.

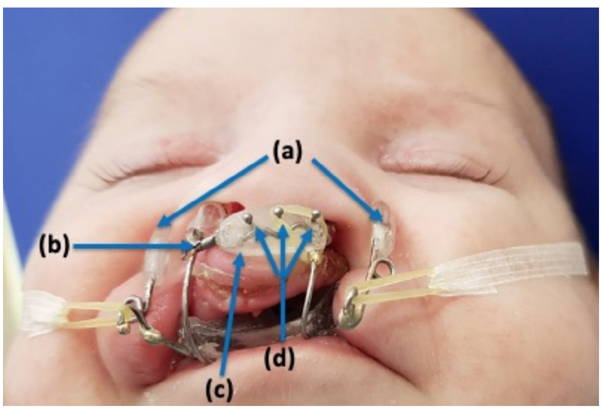

FIGURE 1

Modified Naso-Alveolar Molding appliance inserted in the mouth of a bilateral Cleft Lip and Palate patient. a: constrictive Alar Pads to compress the ala and decrease alar width and provide more stability of the appliance; b and c: Nickel Titanium coil and acrylic bar to retract the premaxilla and increase the columellar length; d: buttons to place the elastic (shown in the figure) for activation of the acrylic bar

Main outcome measures

Soft tissue nasolabial segments were measured on pre-NAM (T1), post-NAM (T2) and 3 months post-surgery (T3) photographs. The measurements included bialar width, cleft size and columellar length (*figure 2A*); nostril height, nostril width, length of the ala and length of the upper lip (*figure 2B*); nasal-ala slope angle and columellar angulation (*figure 2C*).

Photographs were taken at every visit following standardized guidelines. Measurements were made using the ImageJ

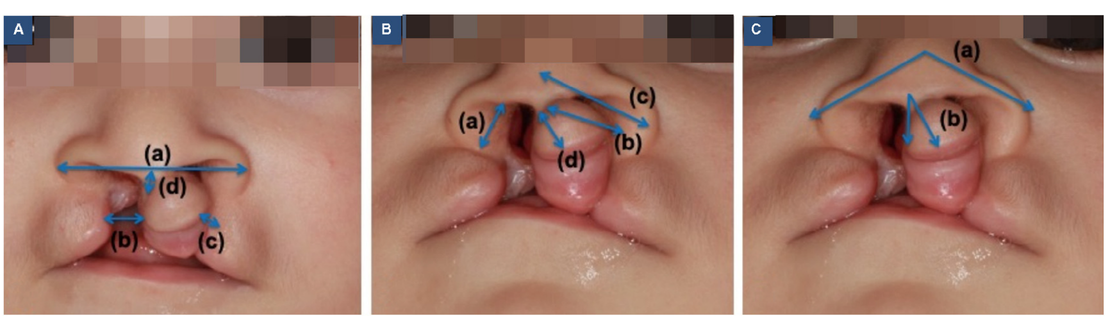

FIGURE 2

A. Bialar width. a: widest distance between the most lateral points of the lateral alae; Cleft size; b and c: largest distance between the clefted segments; Columellar length; d: distance along the crest of the columella between columella base to a horizontal line connecting the most superomedial points of inner nostrils. B. Nostril height. a: distance from the highest point on the upper inner rims of the nostrils to the alar base line; Nostril width; b: distance from the midpoint of the lateral surfaces of the columellar crest to the mid-point of the inner rim of lateral ala; Length of the ala; c: distance between the facial insertion point of the alar base and the pronasale. Length of upper lip; d: distance between the base of the nose (subnasale) and the inferior part of the upper lip (upper lip stomion). C. Nasal-ala slope angle. a: angle formed between the two slopes tangent to the alae on each side. Columellar angulation; b: angle formed between the long axis of the crest of the columella and a facial medial vertical line

software *(National Institutes of Health, Bethesda, Maryland, USA)* after calibration of photographs. All measurements were made by one investigator (*Initials*) and repeated on 10 randomly selected photographs by another (*Initials*).

Statistical analysis

The repeated measures were evaluated with the two-way mixed effects intra-class correlations for absolute agreement on single measures. Descriptive statistics for all measurements at baseline (T1) and 3-months post-surgery (T3) were generated for both groups, in addition to the post-NAM time point (T2) in the NAM group. The Shapiro-Wilk test showed that the data were normally distributed ($P > 0.05$).

A two-way mixed ANOVA with time (T1/T3) as a within-group factor and treatment group (NAM/Control) as a between-group factor was used to compare both groups at baseline and after surgery. All variables presented a non-significant time x group interaction and subsequently simple main effects were reported. In the NAM group, one-way repeated-measures analysis of variance (Anova) followed by post-hoc multiple comparisons was used to analyse the difference in measurements between the three time points. The absolute and relative (T1-T3/T3) differences between T1 and T3 were compared between the 2 groups using an independent t test. In addition, in the NAM group, the absolute and relative changes between T1 and T2 (T1-T2/T2) and T2 and T3 (T2-T3/T3) were compared using a paired t test.

The level of significance was set at 0.05. The Statistical Package for Social Sciences software (version 24.0; IBM Corp., Armonk, NY, USA) was used for statistical analysis.

Results

Difference between NAM and non-NAM groups

The intraclass correlation coefficients gauging reliability of all measurements between operators were high, ranging from 0.865 to 0.961. No statistically significant differences were observed in the gender ($\chi^2 = 0.158$, $P = 0.691$) and cleft type ($\chi^2 = 0.619$, $P = 0.431$) distribution for both groups. The cleft size at baseline was 9.36 ± 1.92 mm in the NAM group, and 8.29 ± 1.74 mm in the control, the difference being statistically non-significant ($P = 0.151$).

Descriptive statistics of all variables in both groups at T1 and T3 are listed in *table I*. At T1, all measurements were similar for the 2 groups except for the right nostril that was significantly larger in the NAM group (12.75 ± 1.02 mm) compared to the Non-NAM group (9.3 ± 2.17 mm) and the left nostril that was longer in the NAM group by 0.61 mm on average ($P = 0.041$).

At T3, there was a statistically significant difference in all linear measurements between both groups except for nostril width on

Table I

Descriptive statistics and comparison between measurements at T1 and T3 (*n* = 30).

	T1				T3			
	NAM (*n* = 15)	Non-NAM (*n* = 15)	Two-way mixed Anova	NAM (*n* = 15)	Non-NAM (*n* = 15)	Two-way mixed Anova		
	Mean (SD)	Mean (SD)	F	*P* value	Mean (SD)	Mean (SD)	F	*P* value
Nostril height R	3.63 (0.72)	3.59 (0.88)	0.015	0.902	6.47 (0.64)	4.75 (0.83)	32.451	< 0.001**
Nostril height L	3.28 (0.67)	2.67 (0.71)	4.691	0.041*	6.17 (0.68)	3.86 (0.83)	55.196	< 0.001**
Nostril width R	12.75 (1.02)	9.3 (2.17)	24.843	< 0.001**	7.12 (0.65)	7.12 (1.3)	0	0.984
Nostril width L	11.31 (1.63)	10.23 (2.44)	1.614	0.217	6.82 (0.72)	7.57 (1.11)	3.863	0.062
Alar length R	18.18 (1.46)	16.55 (1.42)	7.747	0.011	13.69 (1.14)	14.34 (1.25)	1.768	0.197
Alar length L	17.65 (1.96)	16.57 (1.92)	1.854	0.187	13.99 (1.39)	14.55 (1.55)	0.872	0.361
Bialar width	32.53 (3.81)	30.73 (2.4)	1.908	0.181	24.84 (1.71)	26.98 (1.93)	8.263	0.009**
Columellar length	1.78 (0.63)	1.66 (0.62)	0.196	0.662	5.21 (0.57)	3.58 (0.78)	34.38	< 0.001**
Naso-alar slope angle	126.9 (9.37)	125.67 (9.73)	0.099	0.756	108.87(5.52)	116.76 (8.47)	7.329	0.013*
Columellar angulation	16.83 (7.61)	16.65 (7.24)	0.004	0.95	2.59 (1.01)	6.9 (3.4)	17.751	<0.001**
Upper lip length	5.05 (1.3)	4.75 (0.82)	0.467	0.501	8.28 (0.44)	6.55 (0.78)	44.645	<0.001**

T1: Baseline; T3: Post-surgery; R: Right; L: Left; SD: Standard deviation; SE: Standard error.
*Significant at $P < 0.05$.
**Significant at $P < 0.01$.

Table II
Comparaison of absolute and relative changes between NAM and control groups (*n* = 30).

	Absolute change: T3-T1			Relative change:100*[(T3-T1)/T1]		
	NAM	Non-NAM	*t* test	NAM	Non-NAM	*t* test
	Mean (SD)	Mean (SD)	*P* value	Mean (SD)	Mean (SD)	*P* value
Nostril height R	2.84 (0.91)	1.16 (0.74)	< 0.001**	84.91 (43.01)	35.89 (23.66)	0.002**
Nostril height L	2.89 (0.66)	1.19 (0.42)	< 0.001**	93.68 (35.23)	47.68 (20.65)	0.001**
Nostril width R	−5.63 (0.87)	−2.17 (1.36)	< 0.001**	−44.06 (4.56)	−22.02 (9.48)	< 0.001**
Nostril width L	−4.49 (1.36)	−2.66 (1.47)	0.004**	−39.05 (7.38)	−24.36 (8.55)	< 0.001**
Alar length R	−4.49 (1.71)	−2.21 (1.21)	0.001**	−24.33 (7.88)	−13.11 (6.53)	0.001**
Alar length L	−3.65 (2.2)	−2.01 (1.26)	0.035*	−19.95 (10.56)	−11.78 (6.81)	0.035*
Bialar width	−7.69 (3.5)	−3.75 (1.86)	0.003**	−22.92 (8.18)	−12.01 (5.44)	0.001**
Columellar length	3.43 (0.63)	1.91 (0.39)	< 0.001**	234.42 (139.82)	129.39 (50.56)	0.028*
Naso-alar slope angle	−18.04 (6.75)	−8.91 (3.83)	0.001**	−13.98 (4.75)	−7.01 (2.72)	< 0.001**
Columellar angulation	−14.25 (6.54)	−9.75 (4.44)	0.061	−83.44 (7.42)	−58.43 (9.49)	< 0.001**
Upper lip length	3.22 (1.36)	1.8 (0.94)	0.007**	75.25 (50.55)	40.83 (24)	0.044*

T1: Baseline; T3: Post-surgery; R: Right; L: Left; SD: Standard deviation.
*Significant at $P < 0.05$.
**Significant at $P < 0.01$.

the right ($P = 0.984$) and left ($P = 0.062$) side, in addition to right and left alar lengths ($P = 0.197$ and $P = 0.361$ respectively).
Nostril height, columella length and lip length were significantly greater in the NAM group ($P < 001$), and bialar width was 2.14 mm greater for the Non-NAM group ($P = 0.009$). The naso-alar slop angle and columellar angulation were significantly smaller in the NAM group by 7.89 and 4.31 degrees respectively ($P = 0.013$ and $P < 0.001$) (*table I*).
When the absolute change (T3-T1) was compared between the two groups, all measurements were significantly different except for the columellar angulation ($P = 0.061$) and all without exception were different when the relative changes were compared (*table II*).

Differences between pre- and post-NAM

After NAM application, the cleft size was significantly reduced in all 15 patients, from 8.72 ± 3.55 mm at T1 to 2.78 ± 1.05 mm at T2 on the right and 6.42 ± 2.26 mm to 1.87 ± 0.81 mm on the left side ($P < 0.001$). All measurements displayed significant changes between T1, T2 and T3 (*table III*). Both the bialar width and the naso-alar slope angle decreased significantly from T1 to T2 ($P < 0.001$) and to T3 ($P = 0.006$). Columellar length increased through the time points, and the difference between T2 and T3 (0.77 mm) was nearly one third of the difference between T1 and T2 (2.69 mm). The same trend was found for the upper lip length, which increased 2.08 mm from T1 to T2, and nearly half this measure (1.15 mm) from T2 to T3 (*table III*).

TABLE III
Comparison of measurements in the NAM group between T1, T2 and T3 (*n* = 15).

	T1 Mean (SD)	T2 Mean (SD)	T3 Mean (SD)	Repeated-measures Anova		Tukey's Post hoc *P* value		
				F	*P* value	T1/T2	T1/T3	T2/T3
Cleft size R	8.72 (3.55)	2.78 (1.05)	–	57.118	< 0.001**	–	–	–
Cleft size L	6.42 (2.26)	1.87 (0.81)	–	65.199	< 0.001**	–	–	–
Nostril height R	3.63 (0.72)	5.93 (0.7)	6.47 (0.64)	106.144	< 0.001**	< 0.001**	< 0.001**	< 0.001**
Nostril height L	3.28 (0.67)	5.88 (0.69)	6.17 (0.68)	228.684	< 0.001**	< 0.001**	< 0.001**	< 0.001**
Nostril width R	12.75 (1.02)	8.05 (0.92)	7.12 (0.65)	295.516	< 0.001**	< 0.001**	< 0.001**	0.001**
Nostril width L	11.31 (1.63)	7.56 (0.93)	6.82 (0.72)	109.706	< 0.001**	< 0.001**	< 0.001**	0.001**
Alar length R	18.18 (1.46)	15.54 (1.52)	13.69 (1.14)	68.863	< 0.001**	< 0.001**	< 0.001**	0.002**
Alar length L	17.65 (1.96)	15.42 (1.33)	13.99 (1.39)	31.079	< 0.001**	< 0.001**	< 0.001**	0.007**
Bialar width	32.53 (3.81)	27.32 (2.6)	24.84 (1.71)	56.792	< 0.001**	< 0.001**	< 0.001**	0.006**
Columellar length	1.78 (0.63)	4.44 (0.56)	5.21 (0.57)	226.957	< 0.001**	< 0.001**	< 0.001**	< 0.001**
Naso-alar slope angle	126.9 (9.37)	111.93 (6.54)	108.87 (5.52)	78.604	< 0.001**	< 0.001**	< 0.001**	0.014*
Columellar angulation	17.17 (7.61)	4.26 (1.91)	2.59 (1.01)	50.735	< 0.001**	< 0.001**	< 0.001**	0.005**
Upper lip length	5.05 (1.3)	7.13 (0.8)	8.28 (0.44)	48.491	< 0.001**	< 0.001**	< 0.001**	0.004**

T1: Baseline; T2: Post-NAM, T3: Post-surgery; SD: Standard Deviation.
*Significant at $P < 0.05$.
**Significant at $P < 0.01$.

TABLE IV
Comparison of absolute and relative changes in the NAM group between T1, T2 and T3 (*n* = 15).

	ABSOLUTE				RELATIVE			
	T2-T1	T3-T2	Paired *t* test	(T1-T2)/T1	(T2-T3)/T2	Paired t test		
	Mean (SD)	Mean (SD)	t	*P* value	Mean (SD)	Mean (SD)	*t*	*P* value
Nostril height R	2.3 (0.79)	0.54 (0.29)	7.941	< 0.001**	68.16 (33.25)	9.47 (5.41)	6.587	< 0.001**
Nostril height L	2.61 (0.57)	0.28 (0.16)	15.377	< 0.001**	84.19 (30.46)	4.93 (3)	9.444	< 0.001**
Nostril width R	−4.7 (1.02)	−0.94 (0.65)	−8.835	< 0.001**	−36.7 (6.74)	−11.23 (6.75)	−7.318	< 0.001**
Nostril width L	−3.75 (1.32)	−0.74 (0.48)	−7.201	< 0.001**	−32.5 (8.32)	−9.53 (5.62)	−7.044	< 0.001**
Alar length R	−2.38 (1.43)	−1.84 (1.35)	−0.856	0.410	−13.28 (7.4)	−11.46 (7.86)	−0.539	0.601
Alar length L	−2.23 (1.2)	−1.42 (1.26)	−2.519	0.029*	−12.24 (6)	−9.06 (7.27)	−1.794	0.1
Bialar width	−5.21 (1.67)	−2.48 (2.12)	−6.284	< 0.001**	−15.76 (3.7)	−8.66 (6.78)	−4.531	0.001**
Columellar length	2.66 (0.72)	0.77 (0.35)	6.995	< 0.001**	184.47 (113.25)	17.87 (8.74)	5.044	< 0.001**
Naso-alar slope angle	−14.97 (5.55)	−3.07 (2.99)	−7.078	< 0.001**	−11.63 (3.97)	−2.67 (2.61)	−6.860	< 0.001**
Columellar angulation	−12.58 (5.59)	−1.67 (1.4)	−7.790	< 0.001**	−74.16 (6.96)	−37.06 (18.17)	−7.247	< 0.001**
Upper lip length	2.07 (1.11)	1.15 (0.94)	2.068	0.063	49.23 (40.76)	17.63 (16.09)	2.459	0.032*

T1: Baseline; T2: Post-NAM, T3: Post-surgery; SD: Standard Deviation.
*Significant at $P < 0.05$.
**Significant at $P < 0.01$.

The absolute change in all measurements between initial and post-NAM (T2-T1) was significantly greater than the one between post-NAM and final time point (T3-T2) except for upper lip length (P = 0.063) and right ala length (P = 0.410). The same patterns were depicted when comparing the relative changes between the different time points except for both right and left ala lengths (P = 0.601 and P = 0.1 respectively) (*table IV*).

Discussion

This study emphasized the benefits of the NAM therapy in BCLP patients, previously reported in the literature, by comparing to a control group where no NAM intervention was applied. For better assessment of the changes after NAM and surgical intervention, previously reported and new naso-labial soft tissue variables were assessed.

In a comparative retrospective study, Suri et al. evaluated the quantitative differences in presurgical presentations of alveolar alignment and nostril anatomy of infants with BCLP treated with NAM from those treated with maxillary infant orthopaedics only (IO). They concluded that infants who received NAM had longer columellae and better-aligned alveolar segments than those who received only IO. Other nostril dimensions were not significantly different [24]. In our study, changes in key measurements demonstrated differences between T1 and T2 (nostril height, columellar length), but either small (columellar height) or no statistically significant differences (nostril height) between T2 and T3 (*tables II and III*), indicating that the major improvement followed the NAM therapy rather than the surgical intervention. These findings underscore the importance of NAM in facilitating the lip surgical lip closure, but also reflect the possible limitations of surgery without NAM, at least in complete clefts that include the nose. Analytical descriptions of the different parts of the NAM appliance underline their desirable design features, anatomic correlations, and clinical importance [25]. In this perspective, we introduced a new NAM modification for the treatment of BCLP that proved to be efficient in reshaping the different soft tissue segments of the lip and the nose for better surgical outcome, with easier manipulation of the appliance by the parents and less discomfort for patients.

The adhesive tapes were replaced by an acrylic bar activated by a closed NiTi coil and a removable elastic, which deliver a continuous and gentle force to retract the philtrum and elongate the columella. The results were further improved by adding the CAP that helped to mold and reshape both nasal ala. Post-surgical outcome of a patient treated with the modified NAM appliance is illustrated in *figure 3*. In addition, the outcome of another patient operated without the use of the appliance is shown in the *figure 4*. The anatomical aesthetic difference can be noticed between the final results of the surgery, especially at the level of symmetry of the nose and the shape of the upper lip. Our findings support the premise that the reshaping of the soft tissues after the use of the NAM therapy and its approximation to normal structures are better obtained if the intervention was done at an early age because of the easier malleability of the

FIGURE 3

A, B. Complete B CLP in 1-month-old boy with very short columella, wide cleft and everted premaxilla. C. Modified NAM appliance in the mouth. D, E. 5 months after NAM therapy, patient ready for primary surgical lip repair. The following changes can be noticed: columellar lengthening, retraction of premaxilla, and approximation of the lip segments for easier surgical closure. F, G. 3 months after lip closure. To note the improved symmetry in the nostrils, the adequate columellar length, and the reduced width of the nasal base

FIGURE 4

Extra oral before after surgical comparison showing the benefit for the symmetry of the nose and the shape of the upper lip

tissues. The major immediate advantage is related to better soft tissue conditions for the lip closure surgery by reducing the undue stretching of the lips with better approximating of the different segments. In addition, the reported easy manipulation and placement of the modified appliance by the parents and the absence of skin irritation at the level of the philtrum were additional benefits to be noted. Yet despite all the advantages of the new modification, further improvements can still be introduced. While reduced in size and number, tapes on the cheeks can contribute to skin irritation and could be overcome with additional design developments.

More accurate evaluation of soft tissue changes should be obtained through 3D images, not including 3D CBCT records with radiologic doses that would be harmful in such short intervals. Also, lager numbers of patients with longer follow-ups should improve the generalizability and predictability of results.

Conclusion

The modified NAM appliance design was found to yield the benefits intended by nasal alveolar molding of soft tissues through a greater decrease in bialar width, better achievement of nasal symmetry, as well as greater increase in columellar and upper lip lengths and nasal tip projection. Further research with a larger sample size might be needed to canvass the wider range of variation of the cleft conditions and formulate more generalizable conclusions.

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