Evaluation of preoperative naso-alveolar molding in correction of unilateral complete cleft lip and palate associated with nasal deformity

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Received 12 May 2021
Revised 12 Jun 2021
Accepted 24 Jun 2021
Published 31 March 2022

Pan Arab Journal of Rhinology
2021, 11:110–117

Objectives
Complete cleft lip and palate (CLP) is a common congenital middle-third facial defect, which has considerable medical, economic, social, and psychological consequences for the affected individuals and their families. Many surgical techniques had evolved for correction, but the displacement of the lower lateral nasal cartilage is considered a challenge for the surgeon. Preoperative naso-alveolar molding (NAM) aims at alignment of tissues, thus improving the surgical outcome. The aim of the current study was to assess the outcome of the use of NAM as a presurgical orthodontic modality for the treatment of patients with unilateral complete CLP associated with nasal deformity.

Patients and methods
This prospective controlled study was conducted on 16 randomly selected patients with unilateral complete CLP associated with nasal deformity. They were divided randomly into two equal groups. One group included eight patients who underwent presurgical NAM therapy, and the other one included eight patients who underwent surgical repair only as a control.

Results
A statistically significant difference was found regarding the hemicolumellar height ratio. Although alar base width values were slightly smaller in presurgical NAM therapy group, no statistically significant difference was found for the alar base width values or the domal angles.

Conclusion
Presurgical NAM proved superior postsurgical nasal symmetry compared with controls regarding the nostril height. The parents of patients with unilateral complete CLP associated with nasal deformity should be counselled to have presurgical NAM to improve the surgical outcome.

Keywords:
cleft lip, cleft palate, orthodontics

Pan Arab J Rhinol 11:110–117
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Introduction

Cleft lip and palate (CLP) deformity is a congenital middle-third facial defect; its incidence is common and has a worldwide prevalence, but it differs from one country to the other. According to the WHO, one infant in every 600 is born worldwide presenting this defect, which has considerable medical, economic, social, and emotional consequences for the affected individuals and their families [1].

Male children are more affected than female children [2]. Other factors that affect the incidence of CLP include the socioeconomic status and age of the parents. Lower socioeconomic status individuals are at a higher risk for developing CLP, which is most likely related to poorer nutrition at the lower end of the economic scale [3]. Parental age has been linked to an increased occurrence of CLP, with the father's age being more significant than the mother's age. However, the risk is higher when both parents are over the age of 30 years [4].

The upper lip development starts at the fourth week of gestation by fusion of the maxillary process with the lateral and medial nasal prominences and is completed within 3 weeks. Failure of fusion between the central and lateral parts of the upper lip results in cleft lip on one or both sides. Cleft lip may extend deeply into the maxilla and the primary palate, resulting in cleft of the alveolus and CLP [5].

Many techniques have been explored to improve the presurgical and surgical protocols to obtain the most aesthetic and stable result for patients with CLP.

Presurgical orthodontics has been introduced for correction of the cleft lip deformity. The goal of such treatment is to re-align the bony elements of the cleft to facilitate surgical repair [6]. With more attention directed toward the associated nasal deformity,

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appliances have been designed to mold the alar cartilage before surgical correction with the objective of improving the surgical outcome [7].

Naso-alveolar molding (NAM) is an orthodontic intervention modality that attempts at reducing the nasal deformity associated with cleft lip by reducing the alveolar gap through realigning the bony elements (alveolar ridges and lower maxilla) of the cleft as well as active molding and repositioning of the alar cartilage. While the bony alignment improves, the overlying soft tissues will follow [6,8,9]. Moreover, NAM takes the advantage of cartilage plasticity in repositioning the splayed lower lateral cartilage and thus improves the nasal element of the final surgical outcome [10].

The aim of the current study was to assess the outcome of using NAM as a presurgical orthodontic modality for the treatment of patients with unilateral complete CLP associated with nasal deformity in comparison with surgical repair only without preoperative NAM.

Patients and methods

Patients recruitment

This prospective controlled study was conducted on 16 randomly selected patients with unilateral CLP associated with nasal deformity presenting to the Pediatric Otorhinolaryngology Outpatient Clinic in a Tertiary Care Hospital at Cairo, Egypt (blinded for peer review).

The inclusion criteria were infants with complete unilateral CLP; infants' age ranged between 2 to 3 weeks; and nonsyndromic cleft cases.

The exclusion criteria were infants with incomplete cleft lip anomaly; syndromic cleft cases; infants in need for any other orthodontic treatment at time of NAM therapy; and infants who had any life-threatening conditions, such as severe heart diseases or any airway problems.

The patients were divided randomly into two equal groups. 'NAM group' included eight patients who underwent presurgical NAM therapy. 'Control group' included eight patients who underwent surgical repair without prior NAM therapy.

The study was approved by the hospital's Ethical and Research Committee. Written informed consents were obtained from all parents regarding the procedure and for participation in the study, with permission taken from the parents to publish eye-barred photographs of the infants enrolled in the study, as well as agreement of the parents for presurgical NAM therapy in NAM group.

Examination technique

A definite protocol for evaluation was followed in all patients. This included detailed history taking. Antenatal period was investigated for intake of medications. Complete general examination was carried by pediatrician to exclude any syndromes or life-threatening conditions. Otorhinolaryngological examination was done with full description of the CLP and preoperative photographing.

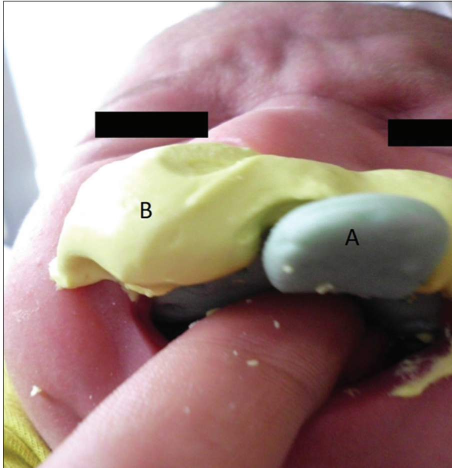
Frontal and basal view digital photographs were taken for all patients from the same distance and angle during neutral facial expression.

Naso-alveolar molding therapy

For impression taking, the infant was put in a lateral position by the surgeon to keep the tongue forward and fluids drain out of oral cavity. An intraoral impression tray was introduced in the mouth. By use of silicone-based material, the tray was seated until the impression material just reaches the posterior border of the hard palate (Fig. 1). Once impression material was set, the tray was removed. Oral cavity was then examined for residual impression material in the cleft region or nose.

The impression obtained was poured in a gypsum product, and the cast was used to fabricate the obturator. Heat-cure (auto polymerizing) acrylic resin was processed to fabricate the intraoral molding acrylic palatal plate of the molding prosthesis with 2–3-mm thickness to provide structural integrity. Nasal stent (Fig. 2) was constructed from 0.019-inch round stainless-steel self-retaining wire and secured to the labial flange of the appliance. It was extended forward and then curved backward in the form of swan neck to enter 3–4 mm past the nostril aperture. The swan neck shape provided access to tape the lip across the cleft. The wire extending into the nostril was curved back on itself to create a small loop for retention of the intranasal hard acrylic component of the nasal stent to provide form and support to the tissues. This hard acrylic component was shaped into a bilobed form, resembling a kidney. Finally, the superior aspect of the nasal stent was covered with a thin layer of soft liner to ensure positive elastic pressure to the internal tissues of the nasal dome. The upper lobe should be inserted into the nose and gently lifted toward the dome until a moderate amount of tissue blanching was evident. The appliance got finished and polished to ensure that all tissue borders were smooth, and the

Figure 1



Taking impression by intraoral impression tray (a) and impression taking material (b).

Figure 2

Naso-alveolar molding with nasal stent.

oral portion of the appliance that would be in contact with the tongue was given a high polish.

First stage involving alveolar molding alone started within 1 week from presentation and ranged for a mean of 40 days. It was done using the appliance without the nasal stent. Second stage involving nasal molding ranged for a mean of 47 days. It was done using a second appliance with nasal stent (Fig. 3). Meanwhile, the lip was taped throughout the procedure.

Regarding insertion appointment, the appliance was fitted carefully in infant oral cavity with the help of adhesive oral gel (denture adhesive), and then observation of the infant for a suitable period (few hours) was done till getting sure he/she was able to suckle without gagging or struggling before sending him/her home. Any necessary adjustments were made before leaving.

Parents, especially mothers, were taught about how to insert, remove, and clean the appliance and the oral cavity at least once per day. Moreover, they were told to keep the infant wearing the mold all the time except at its cleaning time.

Periodic examination of the tissues and adjustment of the appliance was continued every week to mold the naso-alveolar complex into the desired shape and position.

Operative procedure

All patients had undergone Millard's technique[11] for primary repair at a mean age of 3.5 months under general anesthesia. Oral endotracheal intubation was done with fixation by medical silk tape to center of lower lip to avoid lateral distortion. Presurgical molding therapy using NAM was done in group 'A' only.

Marking of the patients was done by the tip of a needle dipped in methylene blue ink. Point 1 is at the mucocutaneous junction at the middle of the displaced Cupid's bow. Point 2 is at the height of the bow on the noncleft side. The distance between 1 and 2 determines the site of the bow height on the cleft side (point 3). Point 4 is the height of the Cupid's bow on the cleft side. The vertical length of the noncleft side (alar base to Cupid's bow) equals the normal length of the philtrum.

After markings, 0.5% lidocaine with 1: 200 000 epinephrine is injected in the planned dissection planes of the lip. Local injection is for maximizing homeostasis and facilitating dissection. The surgical steps are shown in Fig. 4.

The nasal deformity was dealt with by McComb nasal tip plasty [12], which concludes elevation of the nasal dome and rim. Cartilage from the cleft side was freed from the opposite side and then positioned and reshaped using nylon sutures.

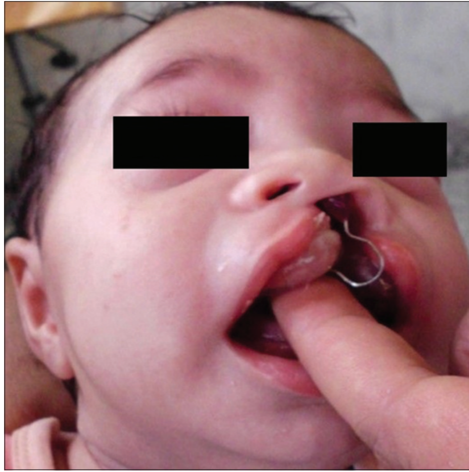
Postoperative care

Postoperative lactation was allowed without any semisolid food. Elbow immobilizers were used for 2 weeks. Gentle cleaning of suture line was instructed using saline-impregnated cotton swabs, followed by application of antibiotic cream. Topical silicone scar gel was advised to apply in one direction three times daily from the tenth day till the sixth month postoperatively.

Postoperative follow-up

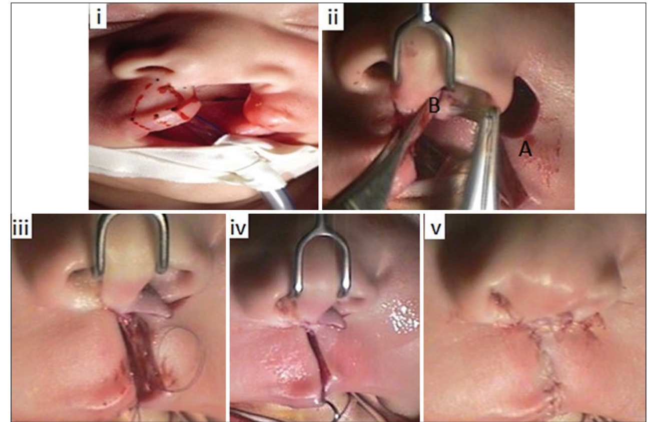
Postoperative photographs were obtained at the follow-up visits at 2 weeks, and first, second, fourth, and sixth months postoperatively. The latest photograph was used for assessment.

Figure 3



Naso-alveolar molding insertion.

Figure 4



(i) Intraoperative markings; (ii) the rotation flap (a), the remaining lip tissue is being sutured to the columella (b). (iii) Suturing of the muscles in the depth of the rotation incision. (iv) Suturing of the tip of the advancement flap to the upper end of the rotation incision. (v) Suturing of the skin.

Postoperative case evaluation

The following lines were plotted on the photograph (Fig. 5). Line 1 (basal line) is a basal horizontal line across the base of the nose and was used as the foundation for measurements. Line 2 (central line) is a vertical line in the middle of the columella and was used as the central vertical reference. Lines 3 and 4 (lateral lines) are two vertical lines drawn at the lateral-most point of the alae. These lines were used to assess the width of the alar base on both the cleft and normal sides. Lines 5 and 6 (hemicolumellar lines) are two vertical lines starting from the dome of the nostril running parallel to line 2 and perpendicular to and ending at line 1. These lines were used to assess the hemicolumellar length on both the cleft and normal sides. Lines 7 and 8 (domal angle lines) are two lines starting from the upper end of lines 5 and 6 correspondingly and passing laterally along the free margin of the nostril. These lines were used to assess the domal angle between the medial and lateral crura of the alar cartilage and determining the shape and orientation of the nostril. Lines 9 and 10 (alar base width lines) are two horizontal lines extending from the midline (line 1) to the lateral-most points of the alar base (lines 3 and 4). These lines were used to assess the difference in alar base width between the cleft and normal sides. Angular measurement was done after obtaining linear measurements. The angles between lines 6 and 8 and lines 7 and 5 were measured. These angles represent the domal angle to compare the cleft side drooping of the lateral crus with the normal side.

Assessment of the results was done through panel evaluation in addition to measurements after magnification of the basal view. The panelists were asked to assess the nasal symmetry regarding the nostril shape, whether rounded, oval, or flat; nasal webbing; presence of indentation; deformity of the ala; and degree of resemblance of a normal nostril.

Statistical methods

All the collected data were statistically described in terms of mean ± SD, median, and range. Comparison between the study groups was done using Mann–Whitney U test for independent samples. *P* values less than 0.05 was considered statistically significant. All statistical calculations were done using computer program SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, Illinois, USA) release 15 for Microsoft Windows.

Results

The ratio of the hemicolumellar height between the cleft side/normal side was more symmetrical in the NAM group than in the control group (Table 1). The difference was statistically significant (*P*=0.046).

The alar base width values were slightly lower in the NAM group than in the control group (Table 2). However, the ratio of the alar base width between the cleft side/normal side in both groups was statistically insignificant (*P*=0.561).

Domal angle differences between the cleft side/normal side in both groups (Table 3) was statistically insignificant (*P*=0.205).

Panel assessment of the sixth month postoperative photograph was done (Figures 6, 7). Three rhinoplasty surgeons who did not participate in the current work were enrolled. All of them were asked to assess

Table 1 Descriptive and statistical analysis of the hemicolumellar heights and the ratio between cleft and normal sides' heights in both groups

Groups	Cleft side	Normal side	Cleft/normal ratio
Control			
Mean	0.538	0.845	0.615
N	8	8	8
SD	0.2484	0.1953	0.1343
Minimum	0.3	0.7	0.5
Maximum	1.1	1.2	0.9
Median	0.445	0.76	0.566
NAM			
Mean	0.451	0.606	0.738
N	8	8	8
SD	0.1531	0.1594	0.1002
Minimum	0.3	0.4	0.6
Maximum	0.8	0.9	0.8
Median	0.41	0.58	0.78
Total			
Mean	0.494	0.726	0.676
N	16	16	16
SD	0.2043	0.2118	0.1308
Minimum	0.3	0.4	0.5
Maximum	1.1	1.2	0.9
Median	0.41	0.7	0.652
Mann-Whitney *U*	25.5	9.5	13
Wilcoxon *W*	61.5	45.5	49
Z	−0.686	−2.37	−1.995
P	0.493	0.018	0.046

NAM, naso-alveolar molding

Table 2 Descriptive and statistical analysis of the alar base width and the ratio between cleft and normal sides' widths in both groups

Groups	Cleft side	Normal side	Cleft/normal ratio
Control			
Mean	2.254	2.114	1.08
N	8	8	8
SD	0.3587	0.4222	0.131
Minimum	1.9	1.4	1
Maximum	2.9	2.8	1
Median	2.25	2.14	1.05
NAM			
Mean	1.231	1.114	1.12
N	8	8	8
SD	0.2352	0.2531	0.111
Minimum	0.8	0.8	1
Maximum	1.6	1.6	1
Median	1.26	1.09	1.11
Total			
Mean	1.743	1.614	1.1
N	16	16	16
SD	0.6039	0.6162	0.119
Minimum	0.8	0.8	1
Maximum	2.9	2.8	1
Median	1.73	1.505	1.06
Mann-Whitney *U*	0	1	26.5
Wilcoxon *W*	36	37	62.5
Z	−3.363	−3.256	−0.582
P	0.001	0.001	0.561

NAM, naso-alveolar molding.

the nasal symmetry of all patients and to give a percentage score representing the degree of similarity between the cleft side/normal side from their point of view. Photographs were randomly presented to each surgeon alone with blinding the groups they belonged to (Table 4). A statistically insignificant difference was noted between panel assessments of both groups (*P*=0.792).

Discussion

Each case of CLP deformity represents a new challenge for the surgeon. The aim is to restore the deformity both aesthetically and functionally. One of the problems to be faced is the position of the lower lateral nasal cartilage. The displacement of the lower lateral nasal cartilage leads to depression of the dome, increase of alar rim, oblique columella, and overhanging of the nasal apex [9].

Preoperative molding improves surgical repair outcome. It decreases the width of the initial cleft as well as improves the alignment of tissues. Thus, healing will occur under less tension, and scar tissue will be reduced. Eventually, the overall aesthetic outcome will improve [13].

Figure 5

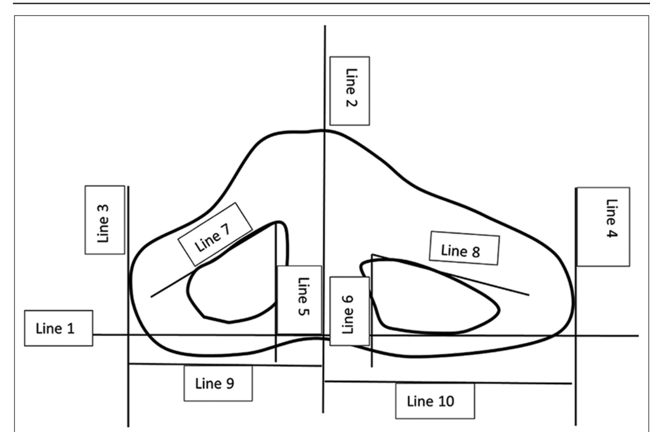
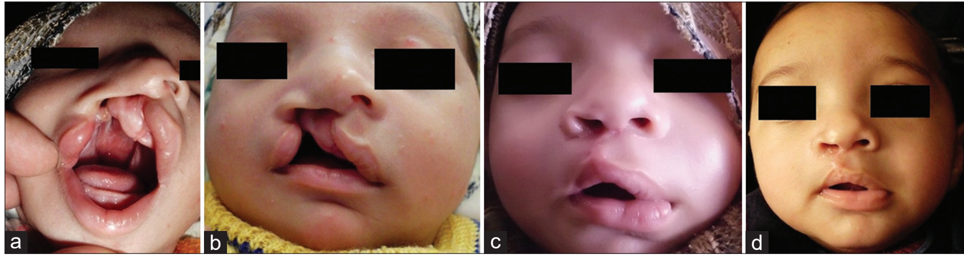


Diagram of the basal view of the nose. All lines are shown in numbers.

This study included 16 cases divided randomly into two equal groups. 'NAM group' included eight patients who underwent presurgical NAM therapy. 'Control group' included eight patients who underwent surgical repair without prior NAM therapy.

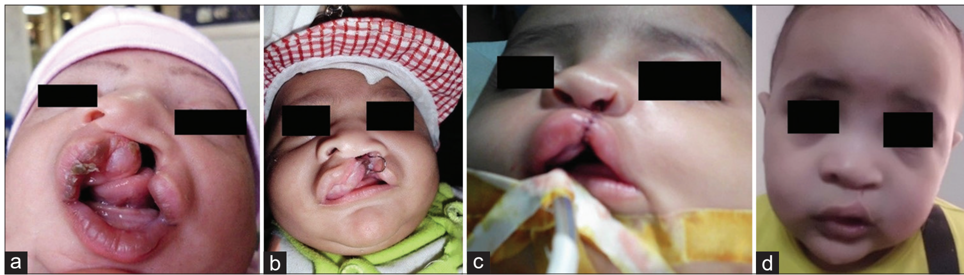
The ratio of the hemicolumellar height between the cleft side/normal side was more symmetrical in the NAM group than in the control group, with statistical significance (*P*=0.046). Presurgical NAM therapy increased the hemicolumellar height on the

Figure 6



Photographs of a child at (a) the time of presentation, (b) after NAM therapy, (c) first postoperative month, and (d) sixth postoperative month. NAM, naso-alveolar molding.

Figure 7



Photographs of a child at (a) the time of presentation, (b) after NAM therapy, (c) immediate postoperative, and (d) sixth postoperative month. NAM, naso-alveolar molding

Table 3 Descriptive and statistical analysis of the domal angles and the difference between cleft and normal sides' domal angles in both groups

Groups	Cleft side	Normal side	Difference
Control			
Mean	94.75	87.25	7.5
N	8	8	8
SD	6.409	8.972	8.88
Minimum	81	80	−8
Maximum	100	105	18
Median	97	84.5	8
NAM			
Mean	96.5	83	13.5
N	8	8	8
SD	8.767	13.763	7.559
Minimum	83	64	5
Maximum	107	100	24
Median	98.5	85	11
Total			
Mean	95.63	85.13	10.5
N	16	16	16
SD	7.473	11.436	8.548
Minimum	81	64	−8
Maximum	107	105	24
Median	97.5	84.5	10
Mann-Whitney *U*	26	26	20
Wilcoxon *W*	62	62	56
Z	−0.634	−0.632	−1.267
P	0.526	0.527	0.205

NAM, naso-alveolar molding.

cleft side, repositioned the depressed lower lateral cartilage, as well as improved the flat nasal tip and the inferior displacement of the soft triangle [10,13]. Pai *et al.*[14] reported a statistically significant difference in presurgical NAM patients' nostril height with better ratios. Moreover, similar results were described by Ezzat *et al.* [15]. Presurgical NAM therapy increased the cleft nostril height, thus improved the symmetry.

No statistically significant difference was found in the current work for alar base width between the cleft side/normal side in both groups. Comparable results were stated by Ezzat *et al.* [15]. On the contrary, Pai *et al.*[14] documented a statistically significant difference between the nostril width for the cleft side and the nonaffected side among both groups. Furthermore, Deng *et al.*[16] in 2005 reported statistically significant narrowing of the widths of cleft lip and dentoalveolar cleft after presurgical orthodontic treatment.

The difference between the domal angles of the cleft side/normal side in both groups was not statistically significant in this work. Singh *et al.*[17] opposingly reported reduction in domal angle and narrowing of the nostril on the cleft side in presurgical NAM patients.

One study on 20 cases of complete unilateral CLP in 2017 described a significant difference in the cleft side/normal side ratio of the nostril area, width, and height with NAM therapy [18].

Blind panel evaluation of both groups was performed by three surgeons. No preference was found to one

Table 4 Descriptive and statistical analysis of peer review in both groups

Groups	Peer 1 (%)	Peer 2 (%)	Peer 3 (%)	Score	
	50	60	60		
	75	60	80		
	90	100	90	Mean	63.13%
	60	80	70	*N*	8
Control	50	90	50	SD	16.00%
	20	60	40	Minimum	40.00%
	50	70	60	Maximum	93.30%
	50	60	40	Median	61.67%
	80	80	60		
	30	60	60		
	60	70	70	Mean	60.42%
	40	70	60	*N*	8
NAM	30	60	50	SD	12.53%
	80	80	80	Minimum	46.70%
	30	60	50	Maximum	80.00%
	80	60	50	Median	60.00%
				Mean	61.77%
				N	16
Total				SD	13.95%
				Minimum	40.00%
				Maximum	93.30%
				Median	61.67%
Mann-Whitney *U*					29.5
Wilcoxon *W*					65.5
Z					−0.263
P					0.792

NAM, naso-alveolar molding.

group over the other. However, Chang *et al*. [19] stated that better panel assessment scores were related to the presurgical NAM with primary rhinoplasty group than the rhinoplasty alone group.

Conclusion

Presurgical NAM proved superior postsurgical nasal symmetry compared with controls regarding the nostril height. The parents of patients with unilateral complete CLP associated with nasal deformity should be counselled to have presurgical NAM to improve the surgical outcome.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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