# Presurgical nasoalveolar molding therapy in cleft lip and palate individuals: Case series and review

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## Abstract

The nasoalveolar molding (NAM) therapy is advocated to reduce the severity of alveolar cleft and nasal deformity. NAM therapy has demonstrated to be an effective method for reducing cleft and improve nose anatomy. This paper presents a case report of three cleft lip and palate individuals treated with NAM therapy. Furthermore, the paper highlights the advantages of NAM therapy along with an enumeration of literature suggesting in favor of NAM therapy and otherwise. Regardless of controversies and divergent views involved with NAM therapy, the immediate success of NAM therapy facilitating primary lip repair surgery cannot be under-emphasized.

Key words: Cleft lip and palate, nasoalveolar molding, presurgical treatment

## **INTRODUCTION**

Cleft lip and palate (CLP) is one of the most common congenital birth defects with the greatest incidence among Asians (2.1 cases/1000 live births). CLP is a multi-factorial birth disorder that can be associated with hereditary factors and environmental factors; folic acid deficiency, maternal smoking, alcohol consumption, and medications.<sup>[1]</sup>

Nasoalveolar molding (NAM) is a presurgical infant orthopedics technique that reduces the severity of the cleft and nasal deformity before the lip and palate surgery.<sup>[2]</sup> The principle of NAM is based on the breakdown of the intercellular matrix of nasal cartilage

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due to the abundance of hyaluronic acid during infant's first 6-8 weeks. During this period, there are high levels of maternal estrogen in fetal circulation, which triggers an increase in hyaluronic acid.<sup>[3]</sup> Furthermore, according to Hamrik's chondral modeling hypothesis, NAM is thought to simulate immature nasal chondorblasts producing the interstitial expansion, which in turn improve nasal morphology.<sup>[4]</sup> Various devices such as a palatal obturator, nasal conformers, articulation development prosthesis, palatopharyngeal obturator, and palatal lift are used as non-surgical therapies to improve cleft deformity.

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Three cases of CLP infants treated with NAM therapy are presented with following primary objectives;

- On alveolar segments,<sup>[5,6]</sup>
  - Reduction of severity of cleft of alveolar segments.
  - Alignment of lesser and greater alveolar segments.
  - Approximation of alveolar cleft without maxillary arch constriction.
- On lips,<sup>[2,7]</sup>
  - Nonsurgical columella lengthening.
  - Approximation of lip segments prior to surgery to reduce tension in the lip tissues and hence minimize lip scar.
  - Medialization of the premaxilla (in bilateral cleft lip [BCLP]) along the midsagittal plane and hence aide surgeon to form uniform Cupid's bow.
- On nose,
  - Reduction of nasal tip width.
  - Improve nasal tip projection.
  - Decrease nasal alar base width.
  - Improve nostril shape.

## **CASE REPORTS**

Cases 1 and 2 are isolated unilateral CLP (UCLP) and case three is BCLP.

#### Cases 1 and 2

Two infants, a female child, the age of 21 days, and a male child of 24 days were referred to Cleft and Craniofacial Centre, KK Women's and Children's Hospital, Singapore. On clinical examination, the patient's showed complete UCLP. On the first visit, lip taping (1/4 inches) (3M Steri-Strip<sup>™</sup>, Neuss, Germany) was done and instructions were given to parents about lip taping, and advised to continue lip taping for 2 weeks. On the second visit, palate impression was made with alginate impression material (Jeltrate°, Dentsply, DeTrey GmbH, Konstanz, Germany). The impression was poured using Type IV dental stone, and the cast was made ready of



Figure 1: Pretreatment extra- and intra-oral photos of unilateral cleft lip and palate individual

fabrication of NAM plate. The acrylic plate of 2 mm thickness was constructed with polymerizing resin (self-cure) and 0.036" TMA wire extension arm having a nasal stent. NAM plate was inserted into the patient's mouth with nasal stent gently resting beneath the nasal dome. The oral cavity was carefully examined for sore points and soft tissues blanching. Sufficient relief was provided for frenal attachment. For retention purpose, adhesive cream (Polident, GalxoSmithKline) was applied onto the NAM plate and held in place for about 50-60 sec for the cream to form a protective layer around the plate. The two active ingredients in the cream; gantrez salt, which holds the dentures firmly to the gums, and sodium carboxymethyl cellulose, which seals off the area, and prevents food from getting in between the gums and NAM plate.

Parents were demonstrated regarding the insertion and removal of NAM plate and were told to apply the fresh cream once daily. The appliance was activated once in 2 weeks and during every activation schedule, the nasal stent's extension arm was activated for the correction of nasal projection, and also, nasal bulb or stent was increased in size for correction of nostril size. Furthermore, any trauma or sore points were evaluated along with evaluation of patient's compliance and parents' co-operation. The activation schedule continued until the time of primary lip repair, which is about 4 months.

Results achieved after NAM therapy were narrower lip gap, an approximation of lesser and greater alveolar segments, and correction of the droopy nostril. This aforementioned correction not only enabled better esthetic results after surgery but also reduced tissues tension and scar formation postsurgery [Figures 1-8].

#### Case 3

A male child, aged 18 days, with BCLP, was reported to the above-mentioned institution. On examination, he showed



Figure 2: Photos showing nasoalveolar molding plate along with lip taping



Figure 3: Photos showing post nasoalveolar molding therapy with approximation of lip width and improved nasal shape



Figure 4: Photos showing post primary lip repair surgery



Figure 5: Pretreatment extra- and intra-oral photos of unilateral cleft lip and palate individual



Figure 7: Photos showing post nasoalveolar molding therapy with approximation of lip width and improved nasal shape

complete BCLP with procumbency of the premaxilla. On the first visit, the parents were instructed to apply tape across the cheek such that premaxilla is pushed backward. Six weeks was the time taken by the premaxilla to move backward, once it was ascertained that premaxilla had moved sufficiently, the impression of the maxilla was made for the fabrication of NAM plate. The NAM plate was fitted, and a nasal stent was adjusted such that nostrils were molded. After 5 months, the promulgated objectives of NAM plate were achieved. The patient was subjected to



Figure 6: Photos showing nasoalveolar molding plate along with lip taping



Figure 8: Photos showing post primary lip repair surgery

primary lip repair, and post-surgical results were pleasing [Figures 9-12].

## **DISCUSSION**

Through this case report series, emphasizes is laid on the fact that NAM therapy is advantageous in both UCLP and BCLP individuals. Our technique of NAM therapy is



Figure 9: Pretreatment extra- and intra-oral photos of bilateral cleft lip and palate individual



Figure 11: Photos showing post nasoalveolar molding therapy with approximation of lip width and improved nasal shape

simple, efficient, quick, and precise without burdening the parents and the child. The plate is devoid of any retentive arms and additional retention elastics. This modification of removing the additional arms simplifies the plate and also makes the plate less bulky. However, the retention of the plate is obtained from the adhesive cream that is applied over NAM plate.

Skin irritation, especially on cheeks, can be reduced by applying skin barrier tapes (DuoDERM Extra Thin<sup>®</sup>, Convatec, Bristol-Myers Squibb Company, USA). It is also recommended to apply the dermal cream (ABC Derm, Perioral Cream, Bioderma Laboratoire Dermatologique, Lyon, France) to reduce skin irritation. We recommend over correction of nostril as nostril shape relapse is anticipated (width, 10%; height, 20%; and angle of columella, 4.7%) at one year of age,<sup>[8]</sup> moreover nasal conformers (Nostril Retainer<sup>®</sup>, Koken Co. Ltd., Tokyo, Japan) are recommended for at least 6-month posttreatment.<sup>[9]</sup>



Figure 10: Photos are showing nasoalveolar molding plate along with lip taping



Figure 12: Photos showing post primary lip repair surgery

Presurgical orthopedic devices and their application are controversial as two schools of thoughts predominate on the application of NAM therapy. One school, proponents of NAM therapy believe that NAM is effective and makes a significant difference in the management of CLP individuals. However, the second school of thought does not associate with all the objectives of NAM. We have enumerated studies in relation to the benefit of NAM and also, those studies which reveal otherwise [Tables 1 and 2].

## CONCLUSION

NAM therapy has been demonstrated to be an effective method for reducing cleft and improve nose anatomy. Regardless of controversies and divergent views involved with NAM therapy, the immediate success of NAM therapy facilitating primary lip repair surgery cannot be under-emphasized.

Table 1: Studies favoring NAM therapy						
Author and year	Objectives	Sample size	Results			
Maull <i>et al.</i> (1999) <sup>[10]</sup>	Long-term effectiveness of NAM	10 patients treated with NAM 10 patients treated with alveolar molding alone	Mean symmetry index for NAM group was 0.74, control group was 1.21 NAM statistically increases nasal symmetry			
Pai <i>et al.</i> (2005) <sup>[8]</sup>	Assess nostril symmetry and alveolar cleft width in infants with UCLP	57 patients treated with NAM	The improved symmetry of the nose in width, height, and columella angle as compared to presurgical status. At 1-year of age, there was relapse of nostril symmetry in width (10%), height (20%), and angle of columella (4.7%)			
Singh <i>et al.</i> (2005) <sup>[11]</sup>	To evaluate three- dimensional changes in nasal morphology in patients with UCLP	10 patients with UCLP treated with NAM	Nasal symmetry in patients was improved slight overcorrection of the alar dome on the cleft side using pressure exerted by the nasal stent is indicated to maintain the NAM result			
Spengler <i>et al.</i> (2006) <sup>[6]</sup>	Evaluate the effectiveness of NAM in BCLP patients	8 patients with BCLP of average age of 34.9 days	Intraoral measurements showed that there was a significant reduction in premaxillary protrusion and deviation and a significant reduction in the width of the larger cleft. Extra-oral measurements showed that there was significantly increase in the bi-alar width and columella length and width, as well as improved columella deviation and nostril height on both sides			
Baek and Son (2006) <sup>[12]</sup>	Observe the alveolar molding effect and growth of UCLP using 3-D analysis	16 Korean UCLP infants	Alveolar molding effects took place mainly in the anterior alveolar segment and growth took place mainly in the posterior alveolar segment and palatal segment			
Ezzat <i>et al.</i> (2007) <sup>[4]</sup>	Evaluation of the outcome of NAM	12 patients with UCLP treated from 1997 to 2003	Statistically significant decrease in both columella deviation and intersegment alveolar cleft distance ( <i>P</i> <0.05). Statistically significant increase in nostril height, maxillary, and columella width ( <i>P</i> <0.05)			
Aboul Hassan <i>et</i> <i>al.</i> (2010) <sup>[13]</sup>	Evaluate the outcome of NAM therapy in UCLP patients	15 patients of average age of 2 weeks with unilateral complete CLP	Statistically significant decrease in intersegment alveolar cleft distance (narrowing by more than 3.3 mm) and statistically significant increase in cleft nostril angle (improved by >25 degrees)			
Mishra <i>et al.</i> (2010) <sup>[14]</sup>	Evaluate the role of presurgical NAM in correction of cleft lip nasal deformity for patients with unilateral and bilateral clefts of the lip	17 patients of unilateral cleft nose deformity and 6 patients of bilateral cleft nose deformity. Patients were North Indians and are <1-year of age	Children treated with NAM had significantly lengthening of columella ( $P$ =0.02). Patients with unilateral cleft lip had more reduction in alveolar gap ( $P$ =0.08) than bilateral group ( $P$ =0.15). Nostril height was higher in experimental group than control group ( $P$ =0.18)			
ljaz (2009) <sup>[15]</sup>	Introduce an effective, simple and cost-effective NAM appliance	18 males and 14 females aged from 3 to 12 days	Average measurement of anterior cleft gap was reduced from 13.281 mm to 11.065 mm (2.215 mm, <i>P</i> <0.001). Average measurement of intercanine was reduced from 22.156 mm to 20.437 mm (1.718 mm, <i>P</i> <0.001). Changes to intermolar width was not statistically significant (0.156 m, <i>P</i> =0.604). Columella length was increased from 1.515 mm to 3.671 mm (2.156 mm, <i>P</i> <0.000). Alveolar segment was changed from 24.218° to 16.859° (7.359 degrees, <i>P</i> <0.000)			
Clark <i>et al.</i> (2011) <sup>[16]</sup>	Evaluate the long- term effectiveness of NAM in patients with UCLP	20 patients were in NAM group and 5 patients were in non- NAM group	Clinically, the improvement in the PNAM group was most evident in nasal and lip anatomy. However, there were no statistically significant differences between the 2 groups on each of the measurements on three-dimensional facial images and dental models			
Shetty <i>et al.</i> (2012) <sup>[5]</sup>	Compare the morphological changes of patients treated with NAM within 1-month of age and patients after 1-month of age	Group I consisted of 15 patients treated with NAM within 1-month of age Group II consisted of 15 patients treated with NAM between 1 and 5 months of age Group III was a control group which consisted of 15 children of 18 months old	Effects of NAM were most significant for group I. Group II benefited from NAM but to a certain extent. At 18 months, group I patients resembled closely to group III children			
Liao <i>et al.</i> (2013) <sup>[17]</sup>	Comparison of the outcome of Grayson and Figueroa NAM techniques	27 patients treated with Grayson technique. 31 received Figueroa technique	Both NAM techniques demonstrated positive effects on patients with complete BCLP. However, Figueroa technique is associated with fewer oral mucosal complications and more efficiency			
Rau <i>et al.</i> (2015) <sup>[18]</sup>	Grayson's NAM technique was analvzed	27 patients were analyzed before and after NAM	NAM is a suitable presurgical treatment modality. A positive effect has been seen in UCLP and BCLP infants, as compared with their birth status			

NAM: Nasoalveolar molding, UCLP: Unilateral cleft lip and palate, BCLP: Bilateral cleft lip and palate, PNAM: Presurgical nasoalveolar molding

Table 2. Oldales not laveling NAM therapy						
Author and year	Objectives	Sample size	Results			
Prahl <i>et al.</i> (2001) <sup>[19]</sup>	Evaluate the effect of IO on maxillary dimensions in infants with UCLP	Sample size of ( $n$ =54). One group (IO+) wore passive maxillary plates during the first year of life, the other group (IO-) did not	IO only has a temporary effect on maxillary arch dimensions that does not last beyond surgical soft palate closure. Therefore, IO as a tool to improve maxillary arch form could be abandoned			
Prahl <i>et al.</i> (2003) <sup>[20]</sup>	To study the effect of IO on maxillary arch form and position of the alveolar segments	Sample size of ( $n$ =49). 24 (IO+) and 25 (IO-). One group (IO+) wore passive maxillary plates during the first year of life; the other group (IO-) did not	In both groups, there is no contact or overlap of maxillary segments. In time, collapse increases with no significant difference in the severity of collapse of observational period			
Konst <i>et al.</i> (2003) <sup>[21]</sup>	To investigate the effects of IO on the language skills of children with complete UCLP	At the ages of 2, 2 <sup>1</sup> / <sub>2</sub> , 3, and 6 years, language development was evaluated in 12 children (six IO and six non-IO). The participants had complete UCLP without soft tissue bands or other malformations	Children treated with IO during their first year of life produced longer sentences than non- IO children at the ages of 2½ and 3 years. At 6 years of age, both groups presented similar expressive language skills. Hence, IO treatment did not have long-lasting effects on language development			
Bongaarts <i>et al.</i> (2004) <sup>[22]</sup>	Evaluation of the effect of IO on the occlusion of the deciduous dentition in patients with UCLP	Children with complete UCLP ( <i>n</i> =54). Half of the patients was randomized to wear a plate till surgical closure of the soft palate (IO1), and the other half (IO2) did not have a plate	There were no significant differences found between the (IO+) and (IO-) groups for the 5-year-old index; the Huddart-score; and overjet, overbite, and sagittal occlusion			
Bongaarts <i>et al.</i> (2006) <sup>[23]</sup>	Evaluation of the effect of IO on maxillary arch dimensions in the deciduous dentition in patients with UCLP	Children with complete UCLP ( $n$ =54). Half of the patients (IO+) had a presurgical orthopedic plate until surgical closure of the soft palate at the age of 52 weeks; the other half (IO-) did not undergo presurgical orthopedics	There were no clinically significant differences found between (IO+) and (IO-) for any of the variables			
Bongaarts <i>et al.</i> (2009) <sup>[24]</sup>	To evaluate longitudinally the effect of IO on dentofacialcephalometric variables in UCLP patients from 4 to 6 years of age	54 children with complete UCLP. Half of the patients (IO+) had IO until surgical closure of the soft palate at the age of ±52 weeks; the other half (IO2) received no intervention	In the IO+ group, 21 patients were analyzed; in the IO- group, 20 patients were analyzed at age 4 and 22 at age 6. No differences were found between IO+ and IO-, except for two measurements: The interincisal angle was larger and the mentolabial angle was smaller in the IO+ group			

## Table 2: Studies not favoring NAM therapy

NAM: Nasoalveolar molding, IO: Infant orthopedics, UCLP: Unilateral cleft lip and palate

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#### **Conflicts of interest**

There are no conflicts of interest.

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