

# Presurgical Nasoalveolar Molding Therapy Using Figueroa's NAM Technique in Unilateral Cleft Lip and Palate Patients: A Preliminary Study

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**Objective:** The objective of the study was to evaluate the results of nasoalveolar molding (NAM) in the treatment of patients with unilateral cleft lip and palate using a modified technique in a South Indian population. **Study design:** The design was a prospective study with blinded measurements. The sample constituted 10 complete unilateral cleft lip and palate (UCLP) patients who underwent NAM therapy by the same operator. Direct extra and intra oral anthropometric measurements were done using a digital vernier caliper before and after NAM therapy. A photographic evaluation was also done to rate the nasal deformity post NAM therapy. The differences between measurements were statistically analyzed using paired t tests. **Results:** The extra oral measurements revealed a statistically significant increase in bi-alar width, columellar length and width. The intraoral measurements demonstrated a statistically significant reduction in anterior alveolar cleft width. There was also a significant increase in arch width and greater and lesser segments length. All cases were rated as improved by the surgeons in photographic analysis. **Conclusion:** The study has quantitatively shown that the modified NAM therapy improved nasal asymmetry by columellar lengthening and effectively molded the maxillary alveolar arch.

**Key words:** Nasoalveolar molding, unilateral cleft lip and palate, pre surgical orthopedics.

## INTRODUCTION

Surgical repair of cleft lip is performed within the first few months of life. Many a times some cleft teams advocate NAM therapy prior to surgical procedure to reduce the severity of the defect as the segments are brought closer and facilitate better primary lip repair. Nasal extensions incorporated into these appliances helps to mold the nasal structures and to attain nasal symmetry which decrease the need for extensive secondary nasal procedures<sup>1-6</sup>. Hence nasal molding in conjunction with the alveolar molding is becoming popular among cleft teams. The rationale behind nasal molding or remodeling treatment is based on researches that indicate the nasal cartilage is moldable within the first 6 weeks of life<sup>7</sup>.

Presurgical neonatal nasal remodeling with an infant plate was first described by Dogliotti *et al*<sup>8</sup>. The first treatment protocol for nasoalveolar molding (NAM) was described and popularized by Grayson *et al* (1993)<sup>2</sup>. A modification to the original NAM technique was described by Figueroa and Polley<sup>9</sup> (2006; Figueroa, Indo Cleft Meeting Course Bangalore, India, 2012). In this modification the nasal stents are introduced from the beginning of treatment and is not delayed for the alveolar gap to get reduced. The intraoral plate is fabricated with light cure orthodontic resin. A .028 or .030 inch (0.7mm or 0.8mm) stainless steel wire embedded in the plate is used to support the nasal stent. The wire has a U-loop used to adjust and activate the nasal stent. The plate does not depend on taping for its retention, instead relining the plate for the close fitting to the palatal tissues and denture adhesive are used to hold the appliance in position. Lip taping can be done to assist with approximation of the lip elements. This study describes our experience with the modified Figueroa NAM technique (Bennun<sup>10</sup>, 2006; Indo Cleft course, Bangalore, 2012; Gomez<sup>11</sup>, 2012) in a south Indian population as an important adjunctive treatment to improve nose symmetry prior to primary lip repair in patients with UCLP.

## MATERIALS AND METHOD

The investigation was conducted on patients reporting to the Department of Orthodontics and the Craniofacial Unit in Yenepoya Dental College, Yenepoya University, Mangalore, between December 2010 and December 2012. The protocol was approved by the ethical committee of Yenepoya University.

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NAM therapy with Figueroa's modification was performed on ten complete UCLP patients (5 girls and 5 boys). Isolated cleft lip patients were excluded from the study. All of the children were of south Indian descent and were less than 3 months of age. The parents were instructed on cleft management and the various stages of treatment. For the NAM procedure they were familiarized with the appliance and its use and care. The need for periodic follow up was emphasized.

After patient selection the following pre NAM records were acquired:

- Case history
- Maxillary dental cast for intra oral measurements
- Photographs (Extra oral frontal, profile, submental and intra oral occlusal view)
- Extra oral anthropometric measurements

After the initial evaluation by the multidisciplinary cleft-craniofacial team, impression (Aquasil soft putty/ Regular set, Dentsply) were taken to fabricate the Figueroa NAM appliance. A palatal plate was made of light-cured resin (Triad, Dentsply, York, PA) (Fig.1) with a.030 inch (0.8mm) stainless steel orthodontic wire embedded into the plate before curing. On the day of delivery, the wire is measured and an adjustment loop is bent towards the middle. The distal aspect of the wire located into the cleft nostril is bent with a retentive loop. Light-cured resin is placed, shaped and cured over the retentive loop and forms the nasal stent. It is placed inside the cleft nostril, below the dome of the alar cartilage lifting it. The appliance is retained with denture paste adhesive (Fig.2). The patient is seen weekly for adjustments to the molding plate by selectively removing hard acrylic in the medial aspect of the lesser and greater segments and adding soft tissue conditioner on the lateral aspects to narrow the alveolar and palatal clefts.

The treatment was continued until the columella was sufficiently lengthened, the nasal tip moved towards the midline and the alveolar cleft narrowed. After NAM therapy, another set of intraoral casts and extra oral anthropometric measurements<sup>12</sup> were obtained.

The extra oral measurements (Table 1) were obtained with a vernier digital caliper accurate to 0.01 mm manually stabilizing the head of the child. The child is made to sit in the lap of the assistant in such a way that the right hand holds the temple region and the left hand to hold the lower jaw gently trying to achieve the best stabilized position. Extra oral measurements (Fig. 3) included bi-alar width, columellar width and length. The following intra-oral measurements (Table 2) were performed on maxillary casts: Anterior alveolar cleft width, arch width, greater and lesser segment length (Fig.3). A photographic evaluation was also done to rate the degree of nasal severity before and after NAM. Power point slides of the before and after NAM photographs (fig.4) were shown to the 3 surgeons of our cleft-craniofacial team who were asked to rate if the after NAM photograph demonstrated no change, worsening, or improvement with respect to overall nasal form and ease of future primary lip surgery. Post NAM lip repair was done by modified millard technique.

The measurements of the maxillary cast were completed and repeated three times by the same observer on three different occasions at an interval of one week. The observer was also blinded to the previous completed measurements. The measurements were tabulated in a spreadsheet and SPSS 17.0 software (SPSS Inc., Chicago, IL) was used to perform statistical analyses. An intraclass correlation coefficient was initially calculated. If the coefficient was greater than .75, the three repeated measurements were averaged. Means and standard deviations were then calculated. Paired *t* tests were used to test the differences of the measurements taken before and after therapy. Finally, various correlation coefficients were calculated.

Fig 1 a. Graysons appliance b. Figueroa's appliance



Table-1 Descriptions of the parameters used for intra oral cast measurements

Measurements	Descriptions
Columellar width (fig.3-b)	Distance between the most lateral points at the base of the columella
Columellar length (fig.3-a)	The length of the columella
Bi-alar width	Distance between the most lateral aspect of the right and left alare.

Fig 2 Patient with Figueroa's appliance



Fig 3 a. Columella length b. Columella width c. Arch Width d. Greater Segment Length e. Lesser Segment Length f. Anterior alveolar cleft width

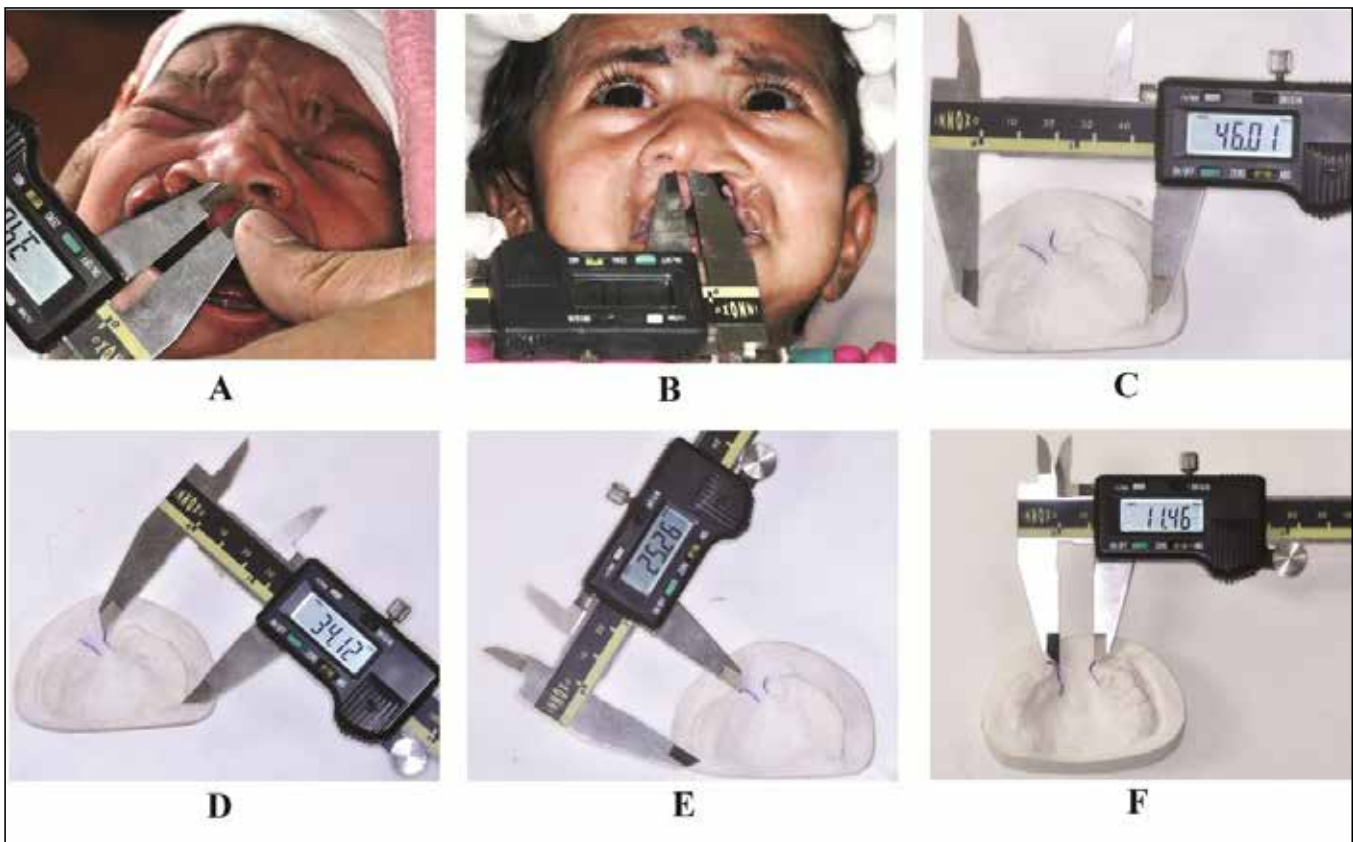


Table 2. Descriptions of the parameters used for intraoral cast measurements

Measurements	Descriptions
Anterior alveolar cleft width (fig.3-f)	Distance between the most anterior aspects of the alveolar ridges
Arch width (fig.3-c)	Distance between widest curvature of the maxillary alveolar arches
Greater Segment length (fig.3-d)	Distance between the most prominent point from the anterior aspect to the most prominent point of the posterior aspect of the greater segment.
Lesser segment length (fig.3-e)	Distance between the most prominent point from the anterior aspect to the most prominent point of the posterior aspect of the lesser segment.

**RESULTS**

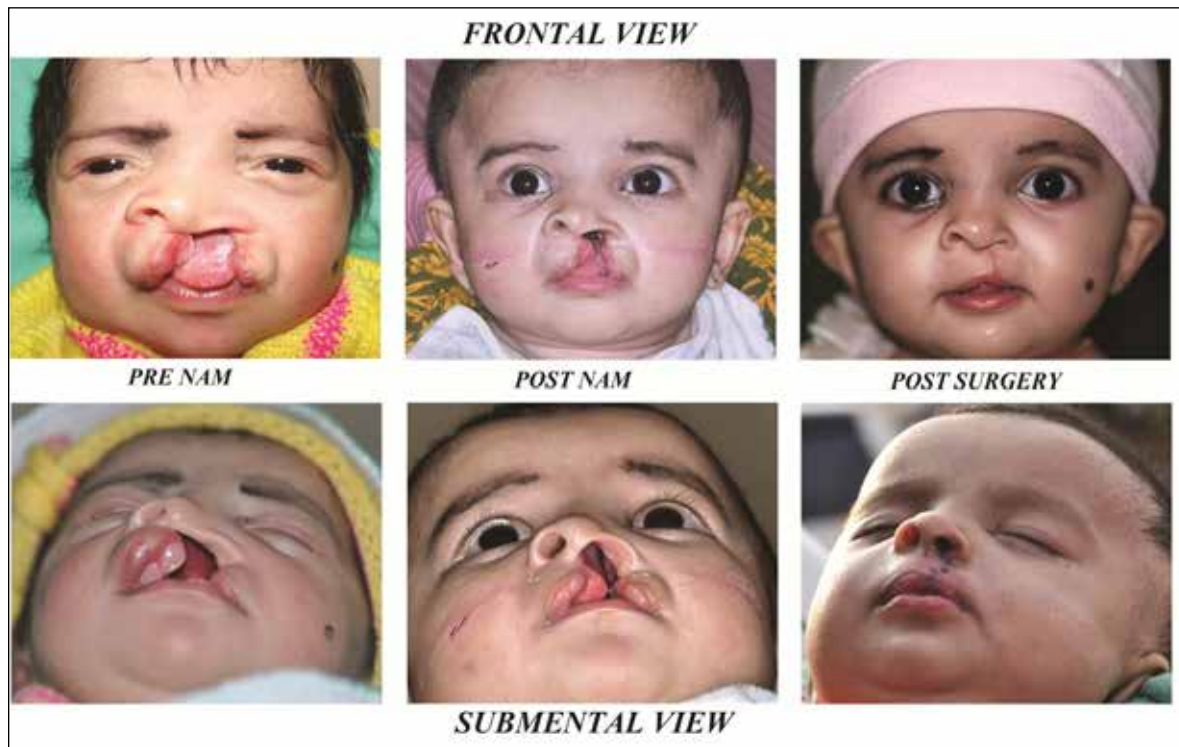
The study demonstrated significant changes in the nasal and palatal measurements after NAM as shown on Tables 3 and 4. The mean intraclass correlation coefficient was .997, and consistently ranged from .995 to .999. Therefore, the three repeated measurements were averaged. The mean and standard deviation of the differences before and after NAM therapy were then calculated for each measurement.

The extraoral measurements (Table 3) revealed a statistically significant increase in bi-alar width, columellar length and width.

The intraoral measurements (Table 4) revealed a statistically significant reduction of the anterior alveolar cleft width. There was also a significant increase in maxillary arch width and greater and lesser segments length.

On photographic evaluation all the cases post NAM were rated as improved by the surgeons. Thus the overall nasal appearance was improved by the technique. A case report is illustrated in Figure 5.

**Fig 4 Power point slides for photographic evaluation of the before and after NAM photographs**



**Table 3. Paired sample test- Extra oral measurements**

	Mean Pre	Standard Deviation	Mean Post	Standard Deviation	T	P
Bi alar Width Pre - Bi alar Width Post	27.66	4.46	30.97	4.0499	-10.14	<.001
Columella width Pre - Columella width Post	5.39	1.772	6.61	1.6622	-14.74	<.001
Columella length Pre - Columella length Post	2.21	1.280	4.81	1.728	-7.87	<.001

\*p<.05

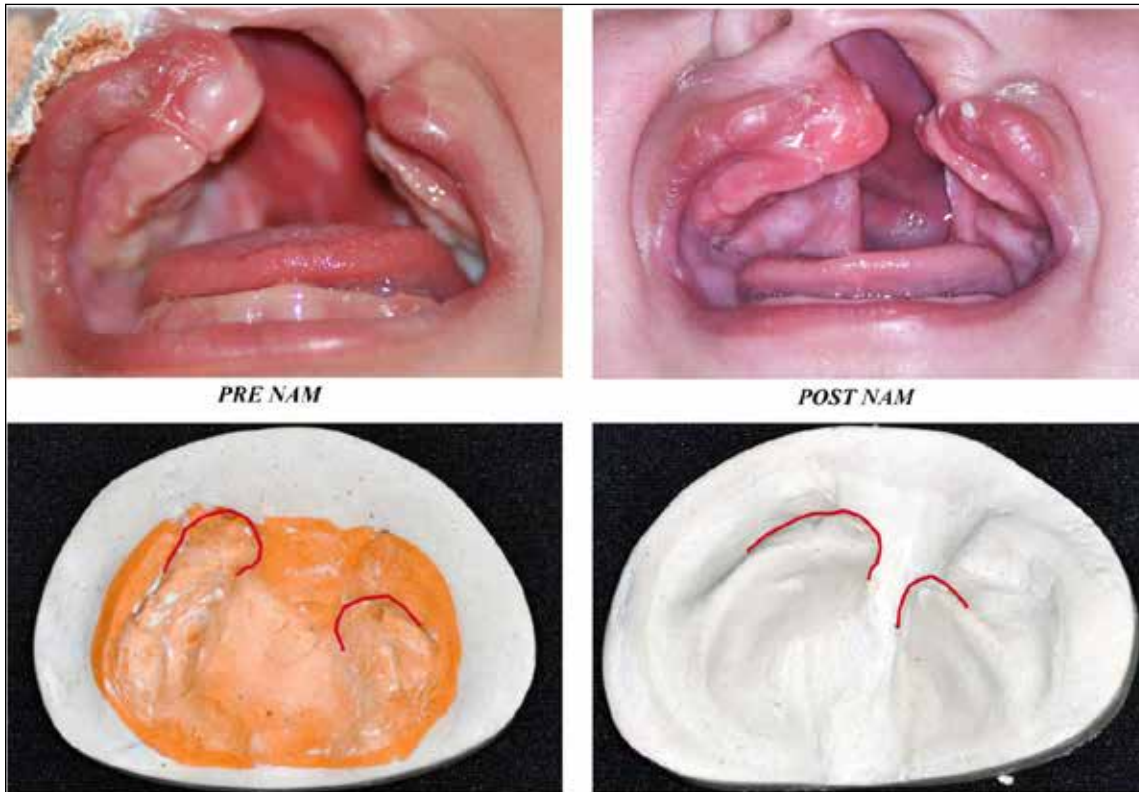
**Table 4. Paired Samples Test- Intra oral measurements**

	Mean Pre	Standard Deviation	Mean Post	Standard Deviation	T	P
Intersegment distance Pre - Intersegment distance Post	12.778	6.0464	8.77	5.157	5.172	.001
Arch width Pre - Arch width Post	40.33	4.821	42.231	5.3534	-2.136	.061
Greater segment length Pre - Greater segment length Post	27.32	5.191	29.77	5.775	-4.524	.001
Lesser segment length Pre - Lesser segment length Post	20.65	4.252	24.75	5.116	-4.328	.002

\*p<.05



Fig 5. Pre , Post NAM , Post surgery and 3 years post surgery comparison extra oral photographs of a unilateral cleft lip & palate case



## DISCUSSION

Evaluation of the extra oral features revealed that NAM therapy using the Figueroa technique significantly improved the nasal symmetry, length and width of the columella and the Bi-alar width. Lengthening of the columella in a superior and medial direction increased the height of the nostril and resulted in improvement of nasal form. The maxillary cast measurement revealed significant reduction of the anterior alveolar cleft width in all the cases. There was also a significant increase in the maxillary arch width along with greater and lesser segments length. It was noted that the bi-alar width increased along with the arch width and length of the greater and lesser segments. It appears that the appliance didn't disturb the transverse growth of the nose and maxilla and thus NAM therapy mainly acted through redirection of the alveolar segments and not by restricting its growth.

The photographic analysis was done to evaluate the eyeball perception about the results in surgeons view. The surgeons rated all cases as having a more favorable situation for primary lip repair after NAM therapy. The ratings indicated that the surgeons preferred a NAM treated case rather than a non treated case adding to the significance of the therapy. The mean starting age for presurgical nasoalveolar molding therapy was 40.6 days. This is near the end of the ideal cartilage-molding period as reported by Matsuo and Hirose<sup>2</sup> who determined it to be within the first 6 weeks of life. The average length of therapy was 132 days. Several studies<sup>13-25</sup> have documented the favorable changes in nasal form and anterior maxillary cleft after NAM therapy in the treatment of the patients with UCLP. Figueroa modification of NAM therapy enabled placement

of nasal stent at the initial appointment taking advantage of the early molding capability of the nasal cartilages. Incorporation of the adjustment loop in the nasal stent facilitated adjustments and more control over the stent. In addition the plate didn't require any extra oral taping for its retention thus avoiding excessive taping of the face. In our hands this modification to the original technique has demonstrated practical clinical advantages. These advantages of Figueroa's modification encouraged us to do more on this technique rather than Grayson's technique. The complication of mega nostrils due to early incorporation of the nasal stent was not noticed in any of our cases. A follow up clinical evaluation of 3 years post surgery was done in three patients. The columella (Deviation and length) correction and nasal tip projection achieved by NAM enabled the surgeons to accomplish a good columella and nasal tip projection post lip repair. These features remained stable 3 years post surgery. However the alar shape achieved by the NAM therapy was not seen to be stable post surgery which is also observed in the follow ups. This may be due to the lack of primary nasal repair which is preferred to be done along with primary lip repair as suggested by Grayson<sup>5</sup>. The surgeons in our centre adopt modified Millard's technique for lip repair which gives an excellent result in all the cases. The alveolus was well approximated and the primary teeth had erupted in the follow up patients.

A comparative study was done between Grayson's and Figueroa's NAM techniques by Liao et al<sup>27</sup>. The study was conducted on 63 patients with complete UCLP (31 patients Grayson's, 32 patients Figueroa's). Pretreatment and post treatment facial photographs and clinical charts were used to compare efficacy (nostril height

ratio, nostril width ratio, columellar angle), efficiency (molding frequency), and incidence of complications (facial irritation, mucosal ulceration). The result of the study indicated that the Grayson and Figueroa techniques did not differ in treatment efficacy for nostril height ratio and columellar angle. Although the Grayson technique was more effective for reducing nostril width ratio, it was less efficient (i.e., required more adjustments) and had a higher incidence of mucosal ulceration. They concluded that the two NAM techniques differed in efficacy, efficiency, and incidence of complications in patients with complete UCLP and understanding these differences may help surgeons and orthodontists in selecting the best technique for their own patient. During the course of our study we did not experience cases with mucosal irritation.

Gomez et al<sup>11</sup> did a study in thirty UCLP patients using the Figueroa's technique. Nasal casts were obtained before and after PNAM. Frontal and standardized digital photographs were taken from all casts, and a photographic analysis was performed. Significant reduction of cleft columella deviation with an increase in columella length, nostril height, and axial inclination on the cleft side were recorded. They concluded that a favorable reshaping of the nose after NAM was achieved resulting in an improvement in form before lip surgery. Our study evaluated both intra and extra oral changes in a south Indian population. Direct measurements of columella length, width and bi-alar width were obtained. All the parameters revealed a significant improvement. Our team (3 surgeons) rated the photographs after NAM therapy as more favorable for primary lip repair.

The NAM therapy has its own advantages and disadvantages as per our experience. Parental counseling and education is an important aspect of the therapy. Additional professional training of the operator is important irrespective of the specialty they are trained with as impression making itself causes life threatening issues to the infant. Most of the cleft parents are not self motivated for NAM therapy unless they understand its benefits. So motivation and appreciation has to be adopted throughout the treatment. One of the disadvantages of the therapy is the regular visits needed for checkups which require tremendous parent cooperation. We used to encourage the mother to feed the child with the appliance at the earliest. If the child gets depended on feeding with the appliance it's a definite boost up in parent's cooperation.

There were not many complications during the treatment except for a patient getting ulceration in the columellar region due to impingement of the nasal stent. The stent was discontinued for a while and readapted with a better coat of soft tissue liner in the nasal bulb.

The advantages definitely outweigh as seen in the results of the study. A patient with less severity in deformity is always preferred by the surgeons for a better finish and result. The institution of presurgical orthodontic treatment also requires an early appointment with orthodontics, which requires prompt referral system especially from the pediatricians and the surgeons along with the cooperation of the patient/parents in order to utilize the molding potential. We believe that the necessity of early referral could be justified by lowering the number of revisionary surgeries.

This study was a preliminary study to evaluate the clinical effectiveness of NAM therapy using the Figueroa technique in India. The small patient sample size (ten patients) may not provide

enough power to perform statistical analysis. However, the data obtained in this study could be used for sample-size calculations in future studies. Further, the results of the study demonstrates the effectiveness of the technique and the short term follow up clinical evaluation of the three patients was encouraging, but long term studies with larger numbers of patients are required to evaluate the long-term benefits of this approach.

## CONCLUSION

NAM therapy plays a significant positive role in the treatment of UCLP patients. It presents the surgeon, a cleft patient with less severity, decreasing the complexity of the primary lip repair. NAM therapy using the Figueroa modification to the original NAM technique is a useful adjunct in the treatment of UCLP patients with moderate to severe clefts and should be considered a viable option in the treatment protocol.

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