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## RESEARCH ARTICLE

### PREFERRING NASO ALVEOLAR MOULDING – PRESENT SCENARIO

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#### ABSTRACT

**Background:** Naso Alveolar Moulding (NAM) is an effective and successful procedure enabling the presurgical approximation of the alveolar segments to increase the overall procedural success in cleft lip/palate (CL/P) cases. Even though it has become routine at certain centers in western countries, the preference still remains evasive in India. **Objectives:** The study aimed at assessing the preference for NAM among the CL/P surgeons in India and evaluating the technical considerations in the fabrication of NAM appliance. The study also assessed the preference of Pedodontists in the multidisciplinary CL/P team. **Methods:** CL/P surgeons associated with Smile Train across India were approached for evaluating the preference of NAM in their daily practice and their opinions on the technical aspects of performing NAM were collected through the questionnaire. A total of 190 questionnaires were prepared out of which 40 were filled through direct personal interview and 150 were sent and collected via mail. The results were analyzed using NPar tests and chi square tests. Results: Among the 107 respondents, 63.6 % preferred PSIO and 59.8 % preferred NAM. Ninety two percent of the surgeons prefer NAM being done by Pedodontists and 81.3% opined that Pedodontists should be a part of CL/P team. All the results were statistically significant. **Conclusion:** From the study we conclude that, NAM is a preferred technique in cases especially with wide clefts. The age of initiation of moulding and regular follow up adjustments are instrumental in ensuring success of NAM.

## INTRODUCTION

Orofacial clefts are among the most common congenital disorders worldwide having a significant impact on the health, development, quality of life, survival of affected individuals and their families, even in settings where specialized, early care is widely available and accessible.<sup>[1]</sup> World-wide a prevalence of approximately 1 in 700 children (Mossey and Little, 2002) being born with CL/P each year, remains the best estimate to date (Mossey and Modell, 2012). Cleft lip with or without cleft palate show a sevenfold range from 3.4 to 22.9 per 10,000 live births, while reports of isolated cleft palate only range from 1.3 to 25.3 per 10,000 live births, a 20-fold variation (Mossey et al., 2009).<sup>[1]</sup> United States Bureau of Census (2001) quotes that an infant affected with cleft is born each 2.5minute<sup>[2]</sup> with Asians exhibiting the maximum incidence of cleft palate followed by Caucasians and Africans. As per the incidence in India over 28,600 infants are born every year with cleft lip/ palate which means 78 affected infants are born every day, or 3 infants with clefts born every hour.<sup>[5]</sup> CL/P present with separated lip segments and significant abnormality of the nasal structure with wide nasal base and depressed, concave lower lateral nasal cartilage. There is projection and outward rotation of the pre-maxilla along with retro-positioning of the anterior maxillary wall on the affected side thus widening cleft between the non-joined

segments. Nasal asymmetry occurs due to a shortened columella pulling the nose to the unaffected side and unopposed pull of the orbicularis oris muscle causing flattening of nasal tip and inferior displacement of the soft triangle. The nasal septum is twisted, slanted and dislocated out of the vomerine groove twisting the nasal tip and the alar cartilage will be dislodged from its normal anatomical position. Intra-orally, the alveolar segments are displaced to abnormal positions with the medial surface of the greater segment rotated laterally and the lesser segment collapsed medially.<sup>[4-8]</sup> The basic treatment objective for the CL/P patient is restoring the normal anatomy of the alveolar and nasal components which requires multiple surgical procedures from birth to maturity and frequent outpatient attendances. The major hard and soft tissue abnormalities observed in these patients makes it highly desirable to restore the correct skeletal, cartilaginous and soft tissue relationships pre-surgically.<sup>[10]</sup> Many techniques to realign or approximate lip and alveolar segments collectively called as "Pre surgical infant orthopedics (PSIO)" has been employed since 1950 as an adjunct to surgical correction of protruding pre-maxilla. The original research on the neonatal molding of the nasal cartilage was performed for the first time by Matsuo and Hirose. However, in 1993, Grayson introduced a highly effective version of cartilage molding which came to be known as Naso-alveolar moulding.<sup>1</sup> The basic principle of NAM is that the

cartilages in the newborn baby is moldable because of the estrogen received from the mother during first month after birth which in turn increases the level of hyaluronic acid that inhibits intercellular matrix linkage of nasal cartilage making it soft with high plasticity. [9] Even though Pre-surgical Orthopedic movements of jaw segments have become routine at certain centers but the long-term results of these and most importantly how much it is preferred by the cleft lip and palate surgeons prior to the surgeries is yet to be evaluated fully in India. This study was conceptualized with the prime aim of assessing the popularity and acceptance of NAM among cleft lip and palate surgeons with reference to the important technical aspects involved in carrying out the procedure in infants and fabrication of the appliance and also to assess the preference to a Pedodontist performing the procedure.

## MATERIALS AND METHODS

**Subjects:** The subjects of the study were Surgeons associated with Smile Train who are actively involved in CL/P rehabilitation in affected children.

**Study Design:** The study was initiated following the approval from institutional ethical committee. It was a questionnaire Survey which began in the month of March, 2017 and was completed by April 30, 2017. The prepared questionnaire included covering letter and the body. The covering letter included the details of the student, the Guide and the institution, title of the study and its purpose. It was a modest introduction to the study and humble invitation to the eminent surgeons for participating in the study.

The body of the questionnaire consisted of:

Totally 22 questions of which 12 questions were open ended questions and 10 questions were closed ended questions. Open ended questions included the age at which NAM is to be performed, the choice of material for recording the impression and fabricating the appliance, timing of recall appointments and most importantly, opinion of the surgeons about the participation of Pedodontist in the comprehensive cleft lip and palate team. Closed ended questions were to assess whether NAM is used prior to surgery, the technique of NAM followed, the design of the appliance, method of traction, adverse reactions and their remedies and the grading of outcome of NAM. Hundred and fifty questionnaires were sent via mails to the cleft lip and palate surgeons across India associated with Smile Train and 40 questionnaires were filled through direct interview with the surgeons in Bhagwaan Mahaveer Jain Hospital and other centers in Bangalore and Dakshina Kannada region. To improve the response to the mailed questionnaires, reminders were sent after 2 weeks and then again after 3 weeks of sending the first mail. Statistical analysis was performed using NPar tests and chi square tests

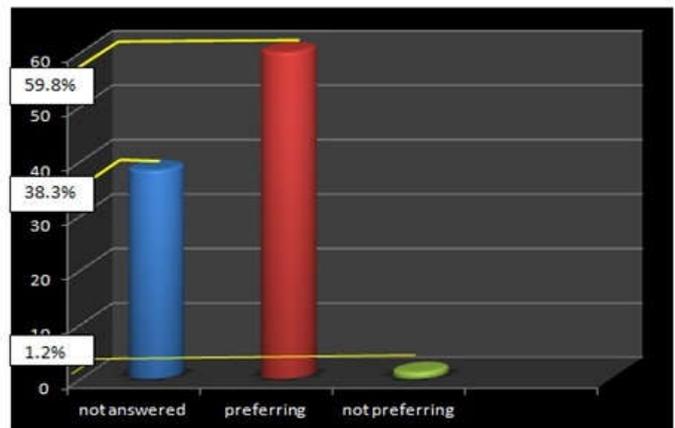
## RESULTS

We were able to collect responses of 107 surgeons from various rehabilitation centers across India actively involved in the care of affected children. Chi square test was used to estimate the level of significance. Out of these 107 respondents, 63.6 % of surgeons prefer pre-surgical infant orthopedic procedures in their patients ( $P$  VALUE = 0.005). (Table 1) Among the various infant orthopedic procedures, NAM is preferred by 59.8 % of the surgeons.

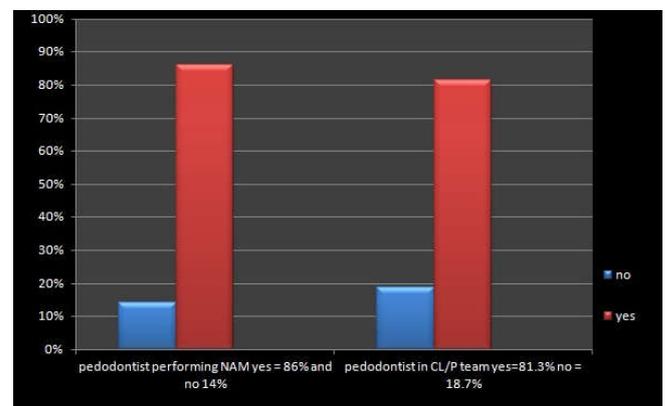
( $P$  VALUE= 0.000) (Graph 1) One interesting and most inspiring observation was that 92% of surgeon propose NAM procedure can be done by Pedodontist ( $P$  VALUE= 0.000) along with other specialists including Prosthodontists and Orthodontists and 81.3% of the Surgeons prefer having a Pedodontist in the cleft lip and palate team (Graph 2). The study also assessed the technical aspects of carrying out Naso alveolar molding in the child. The age at which most of the surgeons (60 %) preferred NAM was within one month, the other preferences being within 3 months and beyond 3 months. (Graph 3) Impression material of choice was silicone putty material by 42% and alginate by 21.4 % of the respondents. Special labs were preferred for fabrication of appliance by 38.3% and their own clinical setting by 25.2% of the respondents. Material of choice for fabrication of appliance was invariably soft self-cure acrylic and the technique preferred was mostly Figueroa's by 44.9% followed by Grayson's by 27.1% and Liou's method by 2.8% of the respondents (Graph 4).

**Table 1. Preference of Presurgical orthopedic procedure by the surgeons**

PSIO	Frequency	Percent
0 (preferring)	39	36.4
1 (not preferring)	68	63.6
Total	107	100.0



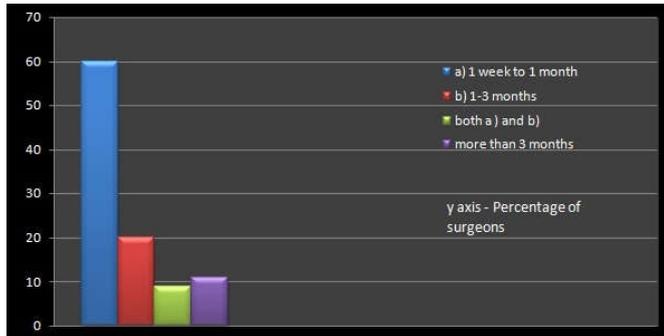
**Graph 1. Preference of Nasoalveolar moulding procedure by the surgeons – original pic**



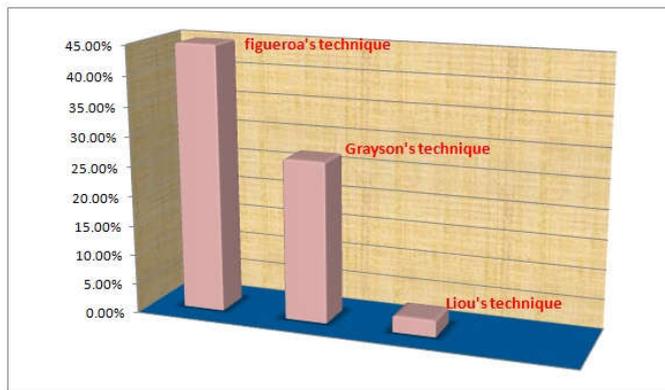
**Graph 2 . Preference to pedodontist in performing NAM and inclusion of Pedodontist in the multidisciplinary team – original pic**

Extra oral strapping device is mostly preferred (59.8%) for retention of the appliance. Nasal conformers are not preferred. Duration preferred for the NAM procedure was mainly 3-4 months. Mostly the recall appointments are given once in two weeks by most of the surgeons. Among the modifications of the conventional techniques, one technique preferred was that

proposed by Dr. Krishna Shama Rao, Dr. Vikram Shetty and Dr. Ajay Bajaj. Adverse effects noted due to wear of the appliance included soreness, ulcers, nasal ulcerations etc and remedies preferred by surgeons in such cases included mainly the moisturizing gels like Aloe Vera gels and adhesive tapes. Thirty six percent of respondents have observed good cooperation from the parents of children and 32% have told that the parents are mostly cooperative but not always. The surgeons who prefer NAM have mostly rated the procedure as yielding good results, excellent results and average results by 39%, 29% and 5% of the respondents respectively.



**Graph 3. Age of the child to start Nasoalveolar moulding as preferred by the surgeons – original pic**



**Graph 4. Depicting the percentage of surgeons preferring various techniques of NAM –original pic**

## DISCUSSION

In India, the incidence of cleft lip/ palate is estimated to be one in 500 live births.<sup>[16]</sup> In a country like India where the annual birth rates are very high, such large incidence would mean a good proportion of the population being affected. This fact in itself is sufficient to draw our attention towards studies regarding the plethora of deformities and other problems in the child associated with CLP and more importantly the comprehensive management of these problems. According to Rubin et al (2015), obtaining an aesthetic and functional primary surgical repair in patients with complete CL/P can be challenging due to tissue deficiencies and alveolar ridge displacement.<sup>[14]</sup> Patients with wider and more severe clefts generally have more pronounced naso-labial stigmata that tend to worsen with growth.<sup>[15]</sup> Apart from the obvious aesthetic defect and functional problems, there is an array of underlying defects that may not manifest at initial examination but are bound to surface sooner or later. Grayson (1999) proposed that although plastic surgery has made great advances in the area of cleft surgery, surgical repair alone cannot solve the multiple problems encountered with the deformities of the cleft.<sup>1</sup> In

such cases, acceptable facial esthetics can be achieved by employing simple, cost effective procedures like pre-surgical infant orthopedics that has been employed since the 1950s as an adjunctive neonatal therapy for the correction of CL/P. The traditional orthopedic approaches failed to address the deformity of the nasal cartilages in unilateral, as well as bilateral, clefts of the lip and palate and the deficiency of columella tissue in infants with bilateral clefts. NAM represents a paradigm shift from the traditional methods of pre-surgical infant orthopedics and has almost become the synonym for Pre surgical infant orthopedic procedures( PSIO).<sup>[19]</sup> It includes two concepts - Passive molding using customized plates of acrylic guiding the development of the alveolus<sup>[12]</sup> so as to achieve selective repositioning of the alveolar segments as well as the surrounding soft tissue by molding the alveolar processes and the deformed nasal cartilages and lengthening of the deficient columella.<sup>[10,13]</sup> the second one is negative sculpturing through series of alterations made to the tissue side of NAM plate by adding up or removal of acrylic in required regions to obtain required alignment of the alveolar and nasal parts.<sup>[12]</sup> NAM mainly utilizes the malleability of immature nasal cartilage and its ability to maintain a permanent correction of its form. Hence the advantages of Pre-surgical Infant Orthopedics can be considered from a soft tissue perspective as well as from the usual osseous perspective. It facilitates nonsurgical elongation of the columella in bilateral cleft lip and palate through the application of tissue expansion principles by gradual elongation of the nasal stents and the application of forces that are applied to the lip and nose. NAM also eliminates surgical scars associated with traditional columella reconstruction, has reduced the number and cost of revision surgical procedures, and reduced the need for secondary alveolar bone grafts.<sup>[20]</sup> The principal objective of pre-surgical NAM is to reduce the severity of the initial cleft deformity which enables the surgeon to enjoy the benefits associated with repair of an infant who presents with a minimal cleft deformity. Lip segments that are almost in contact at rest, symmetrical lower lateral alar cartilages, and adequate nasal mucosal lining, which permits postsurgical retention of the projected nasal tip, reduction in the width of the alveolar cleft segments until passive contact of the gingival tissues is achieved are the outcomes of an ideal NAM procedure. The advantages of NAM itself increases its popularity and various studies shows its wide spread application.

In the current study the overall preference for the PSIO procedure among CL/P surgeons in India is 63.6% with a preference of 59.8 % for NAM. This is in accordance to Sandy et al (1998) showing 47-51% of neonates treated United Kingdom using pre-surgical appliances and In the United States and Canada, 71% of centers reported using some form of pre-surgical molding before bilateral cleft lip surgery, with naso alveolar molding being the most popular at 55% of those using this treatment according to Tan *et al.* (2012).<sup>[21,22]</sup> Ideally PNAM should begin as early as possible to increase the permanence of nasal improvement. In our study, the most preferred timing for NAM is within 1 month after birth (60%) which is in accordance to Bennum *et al.* who proposed early (before 15 days old) PNAM treatment resulted in improved nasal morphology and Matsuo *et al.* (1984) who determined that ideal cartilage molding can happen in first 6 weeks of life. For recording the impression, the use of fast setting color-timed alginate has been suggested in cleft infants, which has the advantage of recording the details even in the presence of

saliva, being comfortable to the patient, easy manipulation, being inexpensive, and preventing respiratory arrest. Elastomeric putty has the advantage of not extruding deep into the undercut areas in the region of cleft and also resist tearing during removal.<sup>[23]</sup> Invariably all the clinicians prefer soft self-cure acrylic for fabricating the appliance. Since its introduction by Grayson, NAM has undergone modification several times. The original technique introduced by Grayson involved the initiation of nasal molding once the alveolar segments have been approximated to 6 mm which increased the number of appointments resulting in excess financial burden on the parents. Grayson has also proposed a weekly follow-up in the patients as the molding of cartilage can be effectively done during the first 6 weeks of the infants' life with selective adjustment of the appliance in each visit. In Figueroa and Liou techniques, nasal stent is introduced along with the alveolar molding appliance in the first appointment itself. This has facilitated simultaneous and mutually dependent nasal and alveolar molding that is found to restore the esthetics better. In our study, majority of the surgeons have preferred Figueroa's technique (44.9%). Talmant *et al.* developed a nearly identical technique, but all molding was performed post-surgically. Suri and Tompson proposed a modified muscle-activated maxillary orthopedic appliance; Retnakumari *et al.* described alveolar molding appliance with expansion screw; dynamic pre-surgical nasal remodeling intraoral appliance was designed by Bennun and Figueroa; extra-oral nasal molding appliance by Doruk and Kiliç and self-retentive appliance with orthodontic wire was used by Singh et al.

The most common complication following wear of the appliance is irritation to the oral mucosal or gingival tissue. Intraoral tissues may ulcerate from pressure or rubbing. Common areas of breakdown are the frenum attachments, the anterior pre-maxilla, and the posterior fauces as the molding plate is retracted. However, the use of NAM has been controversial and has polarized professionals in the field of craniofacial rehabilitation, challenging the established standards of care.<sup>[23]</sup> NAM proponents say that the technique reduces the severity of the cleft (e.g., nasal defect, cleft size) thereby improving the future surgical results and minimizes scarring and Lee *et al.* (2004) proved that mid-facial growth in the sagittal and vertical plane was not affected by NAM and gingivoperiosteoplasty.<sup>[24]</sup> Ezzat C F *et al.* (2006) found that Pnam therapy improved nasal symmetry and helped normalize the dental alveolar arch.<sup>[25]</sup> Several short-term (4 months to 1 year) and long-term (4.5 to 9 years) studies like Maull et al., 1999; Ezzat et al., 2007; Jaeger et al., 2007; Barillas et al., 2009 etc indicate that NAM significantly improves nasal symmetry over surgery alone.<sup>[23]</sup> According to Hotz et al (1979) controversy still exists over whether or to what extent pre-surgical infant orthopedic treatment in CL/P makes sense. First of all, not all kinds of early orthopedic approaches are equivalent and comparable. Furthermore, long term evaluation of the effect of early orthopedic procedures can only be of value if the concomitant surgical interventions are performed with the same technique, the same timing and, if possible, by the same surgeon.<sup>[18]</sup> Berkowitz (2009) argues that NAM plus gingivoperiosteoplasty compromises future facial growth. Other opponents also suggest that NAM places an extra emotional burden on the family system, which already must adapt to having a newborn with a birth defect and that without parent /caregiver compliance the procedure is an additional burden on the family.<sup>[23]</sup> The frequent appointments associated with NAM have decreased its preference among

surgeons in CL/P as indicated in the study even though more number of surgeons have supported the procedure. Lack of awareness among the parents combined with the extra burden of follow-up visits; make the procedure less accepted by the parents of the children who are made aware of the surgical aspects better. NAM being a highly technique sensitive procedure depends on the follow-up adjustments of the appliance to get the desired approximation of the alveolar segments. The parents should be properly educated regarding the importance of NAM especially in the cases with large cleft where it will be difficult to surgically approximate the segments, so that they are motivated enough to bring their children for the regular follow-up visits till the desired result is obtained. In this regard the Smile Train project has succeeded in providing adequate care to children affected with CL/P who belong to lower strata of society all around the world. The drawback of the current study is the small sample size from which the results have been derived. The study can be further improvised with larger sample size and by collecting the data through direct personal interview with the cleft lip and palate surgeons across India.

## Conclusion

PNAM has been proved to be an effective adjunctive therapy for reducing hard and soft tissue cleft deformity before surgery, but its preference remains questionable. The present study showcases the current scenario of Naso Alveolar molding in India. Pre-surgical naso-alveolar molding with primary retrograde nasal reconstruction improves the quality of the reconstructive outcome and decreases the number of surgical procedures. Generally, the acceptance of naso-alveolar molding has been slow in the Indian scenario because of the lack of sufficient resources, poor background of the parents and lack of awareness among the general public regarding the procedures. The present study shines light on the slow yet steady increase in the preference for the procedure. The study shows immense scope for Pedodontists in the field of comprehensive cleft lip/ palate management. A vast majority of surgeons preferred the Pedodontists doing NAM on the child besides other specialists. Thus the current study is a wake up call for the fellow Pedodontists to be actively involved in the comprehensive CL/P management team.

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**Conflict of interest:** None

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