

# Pre-Surgical Nasoalveolar Molding Technique: A Literature Review

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Cleft lip and palate patients have many defects particularly nasal deformities. The nasoalveolar molding (NAM) technique is an adjunctive treatment, which not only corrects deviated alveolar segments but also addresses nasal deformity before cheiloplasty. NAM technique is claimed to facilitate primary surgical correction and to provide favorable esthetic outcomes. However, there is limited evidence to confirm the special benefits of NAM technique since so far there have been no truly long term controlled clinical trials to evaluate outcomes of treatment based on pre-surgical NAM technique. NAM technique can aid surgeons in their primary repairs of nasal deformities but there should be concern about cost-risk benefits and ability of parents to manage home care. Further studies based on properly designed and managed long-term clinical trials are still needed for reaching consensus on special benefits of NAM technique compared with other treatment protocols.

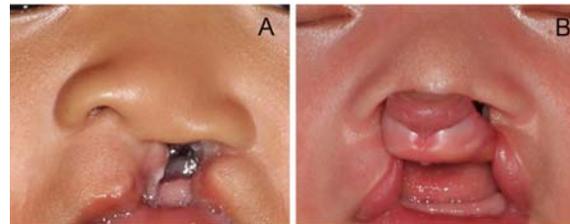
**Keywords:** Nasoalveolar molding, NAM, Cleft lip and palate

*J Med Assoc Thai* 2014; 97 (Suppl. 10): S17-S24

**Full text. e-Journal:** <http://www.jmatonline.com>

Treatment of cleft lip and cleft palate is very challenging. This condition is the most common of congenital craniofacial malformations. The birth incidence is higher in Asian and Caucasian than African populations<sup>(1)</sup>. Facial esthetics, functional defects and psychological problems affect cleft patients, so a multidisciplinary team approach is needed to care for these patients<sup>(2)</sup>. The orthodontist is one of the team involved in this treatment from birth to adulthood<sup>(3)</sup>.

Impaired facial esthetics is one of the main concerns. In unilateral cleft lip and palate patients, the clinical features are nasal asymmetry and deformity of lower alar cartilage on cleft side. Note: a typical condition of unilateral cleft lip and palate (UCLP) (Fig. 1A). The nasal tip, columella and philtrum deviate to the non-cleft side. Alveolar segments displace to abnormal positions with the greater segment deviating laterally and the lesser segment often deviating medially. However, there is wide variation of alveolar segment deviation among newborns with oral clefts. The gap width between the alveolar segments varies in severity. In bilateral cleft lip and palate patients (BCLP), (Fig. 1B) there is nasal deformity but more symmetry



**Fig. 1** (A) Unilateral cleft lip and palate deformity. (B) Bilateral cleft lip and palate deformity.

than unilateral cleft lip and palate. The lower alar cartilages are flat or concave and flared. The nasal tip is depressed and cannot migrate upward leading to short columella and philtrum. The nostrils also are deformed being wider and decreased in height. There is a protruded premaxilla and deviation of the lateral segments behind the premaxilla<sup>(4)</sup>.

The nasoalveolar molding (NAM) technique was developed in order to provide pre-surgical correction of nasal deformities for both UCLP and BCLP as an advance on use of the conventional pre-surgical orthopedics (CPSO)<sup>(5-8)</sup>, largely limited to reduction of lip and alveolar clefts.

## Indications and contra-indications for application of NAM technique

### Indications<sup>(9-12)</sup>

- Unilateral or bilateral cleft lip with or without

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palate

- Nasal deformity and asymmetry
- Short and/or deviated columella
- Alveolar segments malposition
- Neonatal cleft patients
- Co-operative parents or caregivers

### ***Contra-indications and disadvantages of NAM technique***

Contra-indications and disadvantages for use of NAM technique are related to those that apply to CPSO.

The contra-indications include<sup>(13)</sup>:

- Sick or unwell baby
- Position of lip and alveolar ridge is in close to normal position
- Patient cannot adapt to NAM appliance
- Non-cooperative parents and caregivers
- Long distance with costs for parents to bring child to clinic

preparing for and making the NAM appliance

The disadvantages include<sup>(14)</sup>:

- The appliance is complex
- Time consuming
- Expensive
- Burden on the parents and caregivers

### **Treatment objectives of NAM technique**

- To reduce severity of initial alveolar cleft deformities<sup>(11,12)</sup>
- To correct or reduce nasal deformity (nasal cartilage, nasal tip projection, alar base, position of columella and philtrum)<sup>(9)</sup>
- To increase columella length<sup>(9)</sup>
- To align and approximate alveolar segments<sup>(9)</sup>
- To facilitate surgical operation by providing minimal cleft deformity<sup>(11,12)</sup>
- To reduce the likelihood of further nasal surgery<sup>(10)</sup>
- To minimize surgical scar formation<sup>(9)</sup>
- To improve long-term nasal esthetics<sup>(10)</sup>
- To reduced need for secondary alveolar bone grafts if gingivoperiosteoplasty is included in the treatment<sup>(10)</sup>

### **Pre-surgical nasoalveolar molding technique**

There are numerous claims that treatment of cleft lip and palate during neonatal life needs pre-surgical orthopedic treatment and surgical correction of clefts. NAM is an adjunctive treatment to aid primary

surgical reconstruction. NAM was developed not only to correct deviated alveolar segments but also to address nasal deformity before primary reconstruction. Due to infant cartilage becoming stiffer as the baby grows, NAM should start as soon as possible. Matsuo et al suggested that deformation of nasal cartilage, like auricular cartilage, is also correctable but this cannot be done after three months based on their observations of ability of early correction of auricular deformities without surgery<sup>(15,16)</sup>. They suggested that this neonatal moldability of cartilage depends on stimulation of hyaluronic acid secretion. Although this suggestion has often been cited, so far there has been no confirmation of what is a complex bio-molecular mechanism.

Grayson et al<sup>(9,10)</sup> introduced a pre-surgical NAM appliance for UCLP and BCLP. The difference between conventional pre-surgical orthopedic treatment and NAM is the latter's inclusion of a nasal stent. This component is a projection of acrylic<sup>(9,10)</sup> or wire<sup>(11,12)</sup> from the labial flange of intra-oral acrylic plate to the inside of nose beneath apex of alar cartilage on cleft side. There is one nasal stent in UCLP and two nasal stents in BCLP. The tip of nasal stent is a kidney shape with acrylic resin covered with a layer of soft silicone. This provides gentle molding of the lower lateral alar cartilage and nasal tip. In BCLP, there is also a prolabium depressor connected between nasal stents for lengthening the deficient columella.

NAM has different techniques and designs. Grayson et al<sup>(9-12)</sup> suggested that the nasal stent is added when the alveolar cleft gap is reduced to at least 5-6 mm. However, the nasal stent can be added at the beginning of treatment<sup>(17,18)</sup>. This method provides early nasal cartilage molding but there is risk of undesired large circumferential alar wall and alar base<sup>(9)</sup>. Grayson and Maull<sup>(11)</sup> reduced the bulk of the original appliance and incorporated 0.036-inch round stainless steel wire instead of acrylic to connect the nasal stent to the intraoral component. Bennun and Figueroa<sup>(19)</sup> presented a Dynamic Pre-surgical Nasal Remodeling (DPNR). The force generated during oral functions applies pressure to the nasal cartilage through the nasal stent, which incorporates a spring. Monasterio et al<sup>(20)</sup> proposed a very different design of nasal stent without intraoral appliance. They used a simple hook design as a nasal elevator attached to the forehead and could be delivered at the first consultation.

As with use of the CPSO, surgical adhesive tape is usually incorporated in the NAM technique. Taping across the cleft will bring cleft lip segments

closer together, also reducing the nasal alar base width and up-righting the inclined columella in (UCLP)<sup>(9,11)</sup>. The columella and prolabium also may be lengthened in (BCLP)<sup>(9,11)</sup>. Moreover, this can secure the appliance to the mouth and approximate the alveolar cleft segments<sup>(9-12)</sup>.

The duration of NAM treatment may occupy a period of three months before first surgery through weekly<sup>(10)</sup> or biweekly adjustment<sup>(21)</sup>. It may take one to two additional months for bilateral clefts<sup>(12)</sup>. However, the timings for surgery could vary depending on the severity of initial cleft deformity, clinician's experience and parent education and co-operation.

#### **Commentary on effects of nasoalveolar molding technique**

The NAM technique was developed as an advance on use of CPSO appliance to focus on correction of nasal deformities for both unilateral and bilateral cleft lip and palate. This technique is claimed to provide several beneficial outcomes.

#### ***Nasal esthetics***

In cases of UCLP, NAM provides pre-surgical lower nasal cartilage correction. Grayson et al<sup>(9-12)</sup> stated that the nasal deformity was reduced and nasal esthetics improved because the NAM brought the deviated columella and philtrum towards the midline in unilateral cleft cases. In addition, symmetrical contouring of the nasal cartilages was gained from a decrease in the nasal alar base width, improved nasal tip projection and reduction in the width of the nasal tip. However, NAM only improves nasal form and symmetry but the nose may still show slight asymmetry before primary surgical correction<sup>(22)</sup>.

Complete BCLP of the newborn presents generally greater deformities than UCLP. There is variable flattening and flaring of nasal alar wings, shortening of the nasal columella with collapse of nasal tip, shortened lip philtrum, and often with degrees of asymmetry of these structures. Application of NAM is intended to reduce such deformities in preparation for surgical repair<sup>(23,24)</sup>.

The application of NAM technique has been reported based on small sample sizes and no comparisons with outcomes of alternative treatments<sup>(25-28)</sup>. Although, these studies showed trend of clinical nasal improvement compared with baseline conditions, the significance of any lasting changes has, as yet, not been confirmed because of lack of proper controlled clinical trials.

Significant post-surgical improvement of nasal morphology has been reported. However, symmetry between affected and unaffected was not always achieved. Pai et al<sup>(25)</sup> also reported significant improvement of nasal form based on better sample size (57 patients). However, most reports<sup>(25,26)</sup> have not provided comparisons of NAM outcomes with outcomes using controls, such as neonates treated with only a CPSO appliance or without any pre-surgical intervention.

Most reports of NAM treatment are based on the short-term, but the long-term outcomes will tell the true story of treatment benefits. Maull, Grayson, Cutting et al<sup>(28)</sup> noted that evaluation of the superior benefits of NAM (as with evaluation of any treatment method) would require review at adolescence, despite calling their report "long term" but only to approximately 4.5 years of age. The same team has more recently<sup>(29)</sup> reported longer term (average age 9 years) follow-ups of UCLP subjects comparing progress outcomes of 25 NAM subjects with 10 subjects treated only by surgery. Their NAM group showed greater improvement. However, it must be noted that the small sample sizes hardly justify drawing statistically valid conclusions. Again, the same team reviewed use of NAM for BCLP up to adolescence finding satisfactory comparison of naso-labial form with an age-matched non-cleft group. This is an impressive finding but must be viewed with some reserve because it lacked comparison with control groups treated by methods other than NAM<sup>(27)</sup>.

Another example of the difficulty in accepting reports labeled "long-term outcome" is the report of Clark, Teichgraeber, Fleshman et al<sup>(30)</sup> who, although comparing NAM (20 patients) and non-NAM (5 patients) treatments had only follow-up ages ranging from 2.6 to 10 years of age. Although no measured differences were found comparing the two treatment groups, the small sample sizes did not permit any valid comparisons.

Both CPSO treatment and NAM aim to improve nasal esthetics, but NAM offers potential benefits. Besides, improved nasal tip projection and alar cartilage symmetry, nasoalveolar molding can lengthen the columella<sup>(31)</sup>. This is very necessary especially in BCLP, which normally presents deficient collumella length. However, this technique needs weekly adjustment and more compliance than conventional pre-surgical orthopedic treatment.

#### ***NAM technique and the alveolar cleft***

The NAM appliance has the intraoral

component, which serves as alveolar molding. With the intraoral appliance and adhesive tape, the deviated alveolar segments can be aligned and approximated, as has been a common observation with the application of conventional intraoral pre-surgical orthopedic molding. The use of NAM has been linked to pre-surgical preparation for gingivoperiosteoplasty (GPP) as part of the primary surgical closure following NAM, and as a claimed avoidance of the need for the now commonly employed secondary alveolar bone grafting. The Grayson-Cutting group have produced two reports on long-term outcomes of GPP following NAM treatment, one relating to UCLP<sup>(32)</sup>, and the other for BCLP<sup>(33)</sup>. There are no comparable long-term studies of NAM linked to GPP showing equivalent success to secondary bone grafts. Two reports have been found of similar studies of shorter duration, both studies reporting dissatisfaction with outcomes of GPP when combined with NAM<sup>(34,35)</sup>.

A similar conclusion applies to GPP combined with CPSO for UCLP and can be assumed also for BCLP. In an early and important review (reported in 1987) Ross concluded that “early repair of the cleft alveolus by any means has a detrimental effect on maxillary growth”. This conclusion came from unsatisfactory outcomes reported from several major cleft palate centers which had initially trialed primary bone grafting, whether by placing bone in the cleft site or by GPP, and that included pre-surgical orthopedics<sup>(36)</sup>.

A difficulty in judging the evidence for success of any form of alveolar bone grafting for cleft is determining the criteria for that success. Usually this is the greater the bone-fill the better, but also to be considered is the question of: How much bone-fill is essential to avoid the need for repeat of the graft are the objectives of the graft in relation to what future treatment is planned for the graft site. Criteria for a “successful” bone graft may vary according to how much bone-fill is required for continuing treatment at the graft site. Keeping in mind costs and benefits in different treatment options, criteria may be different for different treatment disciplines such as orthodontics, and fixed and removable prosthodontics.

#### **Complications with application of NAM technique**

Grayson and Maull<sup>(11)</sup> noted complications mainly of irritation from uneven pressure of the appliance on nasal and oral mucosa and on the cheeks where tape is attached. They also advised precautions to avoid the possibility of the appliance being dislodged into the mouth with risk of airway obstruction. Problems

of carer compliance in managing home care may also contribute to such complications<sup>(37)</sup>.

#### **Is nasoalveolar molding efficacious?**

“Efficacious” means “effective as a treatment”. This question was asked by Abbot and Meara (2012)<sup>(38)</sup> when they attempted a systematic review to provide an answer with a checking of the available literature dealing with NAM applied to UCLP. These authors concluded “high-level evidence” of effectiveness was lacking. Van der Heijden, Dijkstra, Stellingsma et al (2013)<sup>(14)</sup> in their extensive literature review noted lack of adequate reporting, low levels of evidence but suggesting that further research may provide more encouragement for use of NAM appliance. These two reviews supported the conclusions of the earlier systematic review of Uzel and Alparslan (2011)<sup>(39)</sup>.

As noted by Uzel and Alparslan<sup>(39)</sup>, the standard approach to determining treatment effectiveness in medical research is the randomized clinical trials (RCTs). The absence of RCTs in the field of cleft palate care is not surprising. There is little if any possibility of establishing such trials simply because of the variables, such as among any cleft group, whether UCLP or BCLP, with separate treatment and control group comparisons, number of subjects required and retained for such a trial, long follow-up period required, maintenance and processing of appropriate clinical records, study costs, and so on.

Uzel and Alparslan<sup>(39)</sup> also reported a systematic review of long-term outcomes following different types of presurgical orthopedics including NAM. These authors were searching for any report of an RCT, which is the gold standard for any method of testing treatment outcomes. Among publications up to 2009, these authors did not find any reported RCTs on the use of NAM that met the gold standards for objective clinical evidence of real evidence of efficacy. They suggested there is evidence on the improvement of nasal symmetry in patients with UCLP using NAM appliances. It must be noted that, although these same authors stated the need for RCTs. Grayson and Garfinkle recently also supported the need for RCTs<sup>(40)</sup>.

Chang, Por, Liou et al<sup>(41)</sup> reported on rare example of an attempt at what could be regarded as a prospective controlled clinical trial that included use of NAM. It compared treatment outcomes of four separate treatment regimes for four groups of 16 to 23 subjects up to 5 years of age: (1) primary rhinoplasty, (2) nasoalveolar molding alone (no rhinoplasty), (3) nasoalveolar molding with primary rhinoplasty, and (4)

nasoalveolar molding with primary rhinoplasty and with overcorrection. Bilateral nostril stents were used postoperatively for all four, subject groups. Perhaps as might be expected, there was a progressive improvement of assessed outcomes from Group 1 to Group 4. Such comparisons of treatment regimes are a necessary part of a controlled clinical trial. This study could be considered important because of one essential control which was that all surgery was carried out by one surgeon. However, this study also revealed one of the potential variables in answering the question: Was the surgical technique used identical for the whole period of 12 years during which clinical records were collected? Although there was no definitive answer to this question, it was stated in the report that the surgeon involved in the present study used “four different techniques in the search for the perfect nasal repair after a follow-up of 5 years”.

Earlier in 1999, Bennun, Perandones, Sepliansky et al<sup>(31)</sup> reported a prospective controlled clinical trial comparing small UCLP groups treated with and without NAM and both with the same lip repair, and with a non-cleft group. Greater improvement among the NAM group at 6 years of age was claimed. However, a difficulty with all such studies is finding a method of measurement comparisons that will objectively distinguish differences of soft tissue features of the nose shape and columella height comparing different treatment groups.

Validity of RCTS requires consistency of treatment methods for comparative evaluations of treatment outcomes. Such consistency, even adopting the alternative of controlled clinical trials, is virtually impossible to attain or retain<sup>(40)</sup>. This is because of so many variables:

- The variation of primary cleft conditions even within one category such as UCLP,
- The important influence of primary surgery on ultimate outcomes,
- The wide range of surgical methods that are advocated by different surgeons, such as with and without pre-surgical NAM,
- In ability to start any trial with a sufficiently large sample of patients to enable satisfactory data collection for evaluations,
- In order to achieve satisfactory sampling, cases must be progressively accumulated over several years which greatly extends to time period for the trial,
- The necessity to maintain a consistent surgical treatment protocol for the period of collecting cases,

- The need for long-term review of effects of primary surgery from infancy through adolescence.

An example of this problem in drawing useful conclusions from a lengthy prospective clinical trial is illustrated in the reports of Dec, Sheyte, Grayson et al<sup>(32,33)</sup>. Although this team had the same surgeon for 19 years, he used a range of surgical repair techniques over that time.

### **Conclusion**

The effectiveness, and benefits of cleft lip and cleft palate care, rest primarily with what the surgeon is able to accomplish. Appreciation of the value of NAM must come primarily from the gain to surgeon in facilitating his/her cleft repairs, particularly of the neonates' nasal deformities. It must be assumed that some surgeons find the nasal esthetic outcomes for their patients have improved since adopting NAM treatment. However, as with reported experiences with CPSO and now with NAM treatment, there are surgeons who produce results that are judged to be of equal merit. While questions remain, about whether or not any form of pre-surgical orthopedics helps the surgeon and hence the patient, the controversies about what is “best practice” will remain. It must be said that despite lack of evidence for the nature of that “best practice”, the quality of cleft lip and palate care is demonstrating improvements.

### **Acknowledgement**

The authors wish to thank Associate Professor Keith Godfrey for his guidance and knowledge, which enabled us to develop this article. Thanks also to the Center of Cleft Lip-Cleft Palate and Craniofacial Deformities, Khon Kaen University in association with the “Tawanchai Project”.

### **Potential conflicts of interest**

None.

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## เทคนิคนาโซแอลวีโอดาร์โมลดึงก่อนการผ่าตัด

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ผู้ป่วยปากแหว่งเพดานโหว่มีความผิดปกติหลายอย่าง โดยเฉพาะอย่างยิ่งความพิการของรูปร่างจมูก เทคนิคนาโซแอลวีโอดาร์โมลดึงหรือแนมเป็นการรักษาเสริมอย่างหนึ่งที่ไม่เพียงแก้ไขสันเหงือกที่บิดเบี้ยวไป แต่ยังแก้ไขปัญหาความพิการของรูปร่างจมูกก่อนการทำศัลยกรรมเย็บริมฝีปาก เทคนิคแนมถูกอ้างว่าช่วยทำให้การศัลยกรรมแก้ไขทำได้ง่ายขึ้นและให้ผลของความสวยงามเป็นที่น่าพอใจ แต่อย่างไรก็ตามยังมีข้อจำกัดในแง่ของหลักฐานพิสูจน์ที่ยืนยันประโยชน์ของเทคนิคแนม เนื่องจากจนปัจจุบันนี้ไม่มีงานวิจัยเชิงทดลองทางคลินิกที่มีกลุ่มควบคุมและติดตามผลในระยะยาวอย่างแท้จริง เพื่อประเมินผลของการรักษาด้วยเทคนิคแนมก่อนการทำศัลยกรรม เทคนิคแนมสามารถช่วยคลายแพทย์ในการทำศัลยกรรมแก้ไขความพิการของรูปร่างจมูก แต่ควรพิจารณาความเสี่ยงและประโยชน์ที่ได้รับ รวมถึงความสามารถของผู้ปกครองที่จะจัดการผู้ป่วยที่บ้านได้ การศึกษาเพิ่มเติมที่ออกแบบการศึกษาอย่างเหมาะสมและติดตามผลทางคลินิกในระยะยาว ยังจำเป็นสำหรับการได้ข้อสรุปประโยชน์จากเทคนิคแนมเมื่อเปรียบเทียบกับการรักษาอื่นๆ

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