

# Early cleft management: The case for nasoalveolar molding

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**T**he aim of this Point/Counterpoint article is to discuss the value of nasoalveolar molding (NAM) therapy as part of the treatment protocol for infants born with cleft lip and palate. To better understand the debate over NAM and the valuable impact it can have in the management of an infant born with a cleft, the psychosocial, anatomic, and surgical challenges associated with clefts will be reviewed. A comparison of NAM to previous presurgical infant orthopedic techniques will then be presented. An appraisal of the NAM literature will be offered.

## PSYCHOSOCIAL, ANATOMIC, AND SURGICAL CHALLENGES

The birth of a child with a cleft can be a traumatic challenge for families. They might experience profound feelings of disappointment, helplessness, anxiety, and fear. The nose, lips, and maxillary arch of the newborn are often severely distorted and asymmetric. In babies with unilateral cleft lip and palate (UCLP), the asymmetric nostrils, deviated septum, and distorted maxillary arch form are the primary reconstructive challenges. Multiple nasal surgical revisions are often indicated to approximate nasal symmetry because existing surgical techniques for managing the nasal deformity are lacking. In bilateral cleft lip and palate (BCLP), the deficient columella and ectopic premaxilla are the primary reconstructive challenges. Multiple nasal surgeries resulting in excessive scarring at the columella-prolabial junction and lack of nasal projection often result.

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## PRESURGICAL INFANT ORTHOPEDICS BACKGROUND

The desire to reduce the surgical challenges of cleft lip and palate are not new; reports have been found as far back as the 16th century describing retraction of the ectopic and protrusive premaxilla in BCLP patients.<sup>1</sup> This is early evidence of surgeons' attempts to reduce the severity of the deformities before the primary surgical repair to achieve a better outcome. The same principle is true in orthodontics. Treating a milder case is easier than treating a more complex case and often leads to a better result. As clinicians strived for improved clinical outcomes, the field of presurgical infant orthopedics (PSIO) emerged. Several PSIO techniques have been described, such as maxillary plates,<sup>2</sup> the Latham device,<sup>3</sup> lip taping,<sup>4</sup> lip adhesion,<sup>5</sup> and NAM.<sup>6</sup> It is important to understand that PSIO is an umbrella term that covers any treatment of an infant's cleft deformity before the definitive primary lip surgery. We do not judge the efficacy of all functional appliances, for example, based on the results of any single appliance; rather, each functional appliance should be evaluated on its own merit. We make this same distinction with the umbrella term PSIO, to avoid misjudging NAM based on studies of alternative (non-NAM) PSIO techniques.

It has been shown in a randomized controlled clinical trial (Dutchcleft) that non-NAM forms of PSIO, specifically the intraoral molding plate, offer no measurable advantage or disadvantage in terms of facial growth, facial appearance, maternal satisfaction, maxillary arch dimensions, feeding, weight, length, or occlusion, relative to infants treated without the PSIO device.<sup>7-12</sup> NAM was not studied in this trial.

## NAM BACKGROUND

In 1984, Matsuo et al<sup>13</sup> described a technique to nonsurgically correct congenital auricular deformities, taking advantage of the plasticity of infant cartilage thought to be the result of elevated levels of circulating maternal estrogen in the infant's bloodstream. They applied this concept to the management of the cleft nasal deformity with good results, but the technique depended on an intact nasal floor.<sup>14</sup> As the plasticity

of the cartilage fades over the first 6 months of age, a state of elasticity eventually sets in, maintaining the shape of the nasal cartilage at that point.

With this understanding of cartilage plasticity and the ability to permanently modify its shape, the concept of NAM was created. The NAM appliance consists of a removable alveolar molding plate made of orthodontic acrylic or Biocryl (Great Lakes Orthodontics, Tonawanda, NY) from a dental cast of the infant's maxilla. The nasal stent is bent at the end of a 0.032-in stainless steel wire that is embedded into the anterior portion of the alveolar molding plate. The nasal stent and the intraoral molding plate are adjusted weekly or biweekly to gradually correct the nasal and alveolar deformities, giving rise to the name *nasoalveolar molding*. The objectives of NAM are to provide symmetry to severely deformed nasal cartilages, achieve projection of the flattened nasal tip, provide nonsurgical elongation of the columella, improve alignment of the alveolar ridges, and reduce the distance between the cleft lip segments. NAM can be applied to the entire range of cleft deformities, including complete clefts without an intact nasal floor. A more complete description of the theory, fabrication, and biomechanics of NAM is available.<sup>15</sup>

#### DISADVANTAGES OF NON-NAM PSIO

The primary shortfall of all PSIO techniques other than NAM is that they neglect to address the nasal cartilage deformity during the period of cartilage plasticity. Failure to correct the severe nasal cartilage deformity during this period often results in the need to perform more surgical revisions.<sup>16,17</sup>

Lip taping or surgical lip adhesion alone can be a disadvantage for patients with BCLP. If control of the alveolar segments is not achieved, the premaxilla can descend vertically, and the anterior aspect of the posterior alveolar segments can collapse palatally. This can result in an impinging deepbite of the premaxilla, arch-form collapse, and incoordination with the mandibular arch. In addition, the malpositioned premaxilla can render fistula closure difficult. A persistent fistula can affect the production of speech and allow oral contents to enter the nasal cavity. These conditions will present challenges for surgical reconstruction, orthodontic management, and speech therapy. Another disadvantage of surgical lip adhesion is the increased trauma, morbidity, and associated surgical costs for the patient and family.

Yet another disadvantage occurs with the use of pin-retained PSIO, such as the Latham device. This procedure is associated with increased costs and morbidity because of the invasiveness of appliance insertion,

removal, and sometimes sedation anesthesia. In addition, it fails to address the nasal cartilage deformity.

#### ADVANTAGES OF NAM

The practice of NAM not only avoids most of the disadvantages mentioned above but also offers some significant benefits to the patient, the caregiver, and society. Five recent systematic reviews addressing the issue the NAM concluded that whereas high-level evidence is lacking to definitively support NAM, there is a trend toward a positive clinical effect.<sup>18-23</sup> Dozens of articles have been published about the use of NAM in both UCLP<sup>24-51</sup> and BCLP<sup>16,26,30,32,35,37,45,46,52-57</sup> patients. The overwhelming majority report positive effects, and none report any negative effects.

For the sake of brevity, we will review 2 articles with the longest follow-up periods. In patients with UCLP, Barillas et al<sup>40</sup> showed that nasal cartilages were more symmetric in infants treated with NAM than in those treated with surgery alone. This improvement was observed at 9 years of age. In 2011, Garfinkle et al<sup>53</sup> reported near-normal anthropometric nasal measurements for patients with BCLP treated with NAM compared with a noncleft sample up to age 12 years. Interestingly, the study showed that after NAM and the primary lip and nose surgery, the measures of nasal growth proceeded in parallel with the noncleft population.

The advantages of NAM might also include psychosocial benefits to the infant's family. We are currently participating in a multicenter study sponsored by the National Institutes of Health to evaluate caregivers' responses to NAM. The preliminary findings indicate that the frequent visits for NAM adjustments reduce caregivers' anxiety and lead to a sense of empowerment. These changes arise as the caregiver develops increased skill in managing the NAM appliance, observes improvement in the baby's appearance, and receives support and counseling from weekly visits to the cleft team.

A recent survey of surgeons from the American Cleft Palate and Craniofacial Association showed that they expected to achieve better nasolabial outcomes for infants with clefts that are mild rather than severe. Although blinded to treatment group, the surgeons identified the NAM patients as having mild deformities and the non-NAM treated patients as having more severe deformities. Furthermore, they selected infants who had been treated with NAM as those who would be less likely to require secondary revisions.

NAM might also reduce the overall cost of cleft care by reducing the number of secondary nasal revisions. A retrospective study regarding the cost of care at New

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