Influence of nasoalveolar molding on skeletal development in patients with unilateral cleft lip and palate at 5 years of age

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Introduction: The aim of this retrospective study was to assess the influence of presurgical nasoalveolar molding (NAM) on skeletal development in patients with operated unilateral cleft lip and palate at 5 years of age. **Materials:** Lateral cephalometric radiographs of 26 unilateral cleft lip and palate patients who had undergone presurgical NAM (NAM group) and 20 unilateral cleft lip and palate patients who did not have any presurgical NAM (non-NAM group) were analyzed. The radiographs were digitally traced using Quick Ceph Studio software (version 3.5.1.r (1151); Quick Ceph Systems, San Diego, Calif). Independent samples *t* tests were performed for statistical analysis. **Results:** No significant differences were observed in sagittal and vertical skeletal measurements between the NAM and non-NAM groups. **Conclusions:** NAM resulted in no significant difference in skeletal development in unilateral cleft lip and palate patients compared with those without NAM in early childhood. (Am J Orthod Dentofacial Orthop 2018;153:489-95)

Patients with unilateral cleft lip and palate have different characteristics in their craniofacial morphology when compared with patients without clefts. Patients with unilateral cleft lip and palate have a shorter maxilla in a retrusive position,[1-4] backward rotation of the mandible with an increased gonial and mandibular plane angle,[1-3] increased anterior facial height,[1,3] and decreased posterior facial height.[1,2] The type and timing of primary and secondary surgical interventions and morphogenetic pattern may cause these differences in craniofacial morphology between patients with and without clefts.[5-8]

Treatment of unilateral cleft lip and palate is a challenge in regard to outcomes in facial esthetics. Varying treatment procedures and surgical techniques are used to obtain better results, both functionally and esthetically, in the facial morphology of patients with unilateral cleft lip and palate. One such example is presurgical nasoalveolar molding (NAM), a type of passive infant orthopedics technique. It has been introduced to simplify primary repair and improve postsurgical esthetics.[9] The aims of presurgical NAM in patients with unilateral cleft lip and palate are to align the displaced alveolar segments into normal positions, to reduce the width of the cleft, to correct the malpositioned nasal cartilage, to increase columella length, and to improve the symmetry of the nostrils.[9-12] Approximation of the cleft segments by presurgical NAM in patients with unilateral cleft lip and palate has been suggested to minimize lip tension and reduce scar formation after cheiloplasty. Given this effect, this brings to mind the following questions. Does presurgical NAM have an effect on the craniofacial development in patients with unilateral cleft lip and palate? Does this treatment modality lead to maxillary retrusion?

There are several reports showing the effects of presurgical NAM on the soft tissues of craniofacial morphology in patients with unilateral cleft lip and palate in the short term[10,13-16] and the long term.[17-20] Most of these have focused on nasal esthetics and development.[10,14-19]

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Impacts of presurgical orthopedics on facial growth have been investigated in several studies.[21-23] Bongaarts et al[21] investigated the effect of infant orthopedics on facial growth in a prospective randomized clinical trial. They emphasized that the results are valid only for the passive type of appliance, and it is impossible to draw conclusions about appliances with extensions for nasal molding. In addition, studies by Hsieh et al[22] and Lee et al[23] did not give clear information on the impact of the presurgical NAM on facial development because presurgical NAM treatment was not isolated from gingivoperiosteoplasty.

Therefore, the aim of this study was to investigate the absolute effect of presurgical NAM on skeletal development in patients with unilateral cleft lip and palate in early childhood. The null hypothesis was that presurgical NAM in unilateral cleft lip and palate patients does not result in maxillary retrusion.

MATERIAL AND METHODS

This retrospective controlled study included 46 lateral cephalometric radiographs of patients with operated complete unilateral cleft lip and palate. Ethical approval for the study was obtained from Hacettepe University in Ankara, Turkey (reference number: GO 15/190-37). The number of subjects was based on an a priori sample size calculation from a previous study evaluating the effects of gingivoperiosteoplasty and NAM on facial growth in unilateral cleft lip and palate patients.[20] Based on mean values of SNA of 77.59° ± 5.17° in subjects receiving gingivoperiosteoplasty and NAM, and 80.63° ± 3.99° in subjects receiving NAM without gingivoperiosteoplasty, it was found that a minimum of 18 subjects in each group were needed for a significance level of 5% and a power of 80%.

The archives of the Department of Orthodontics at Hacettepe University were searched for cleft lip and palate patients at the Research and Application Center for the Treatment of Cleft Lip and Palate and Craniomaxillofacial Deformities evaluated between January 2010 and January 2014. Ninety-four white patients with cleft lip and palate were examined for eligibility. Thirty-six patients were eliminated because of having bilateral cleft lip and palate (32 patients), cleft palate (2 patients), or cleft lip and alveolus (2 patients). Fifty-eight patients had complete unilateral cleft lip and palate. Of these 58 patients, 46 were selected based on the following inclusion criteria: (1) complete unilateral cleft lip and palate without Simonart's band, (2) no other associated craniofacial anomalies, (3) no previous orthodontic treatment, (4) primary surgical interventions by the same operator, (5) similar timing of primary surgical interventions, (6) no gingivoperiosteoplasty, and (7) lateral cephalometric radiographs at 5 years of age. All patients included in this study were confirmed by the geneticist of the cleft center to be nonsyndromic. All patients had "NAM is needed" note in their medical files. Figure 1 shows the flow diagram of the sample with the reasons for exclusion.

Patients with unilateral cleft lip and palate were divided into 2 groups: 26 unilateral cleft lip and palate patients who had undergone NAM before cheiloplasty (NAM group) and 20 unilateral cleft lip and palate patients who had not received NAM before cheiloplasty (non-NAM group). There were 2 main reasons why some patients did not receive NAM. Some families could not afford the NAM treatment; socioeconomic factors, income level, living in another city (distance from the clinic), and high numbers of clinic visits (once a week) were reported as reasons not to accept the presurgical treatment. In addition, patients who had been referred to the clinic at older ages were not offered the NAM treatment.

All patients had received cheiloplasty and palatoplasty. Lip repair was done at approximately 3 to 4 months of age with the modified Millard procedure. The hard palate was repaired at approximately 12 months of age by using a 2-flap palatoplasty.

The presurgical NAM therapy in this study was begun during the first or second weeks after birth and continued for approximately 3 to 4 months under close supervision of the same orthodontist (M.A.). The presurgical NAM technique consisted of an acrylic molding plate and a nasal stent.[9] Acrylic resin was selectively removed, and soft acrylic material was sequentially added to the molding plate to align the cleft segments and to close the cleft gap. Adjustment of the presurgical NAM appliance was done at 1-week intervals. At the same time, adhesive tape over the lip was placed to join the labial segments. Once the cleft gap was reduced to 5 mm, a nasal stent, constructed with 0.036-in round stainless steel wire and covered with hard and soft acrylic at the most superior part, was added to the plate and adjusted weekly until the time of the cheiloplasty at approximately 3 to 4 months of age.

Age and sex distributions for the groups are shown in Table I.

The lateral cephalometric radiographs were digitized and analyzed using Quick Ceph Studio software (version 3.6.1.r [1151]; Quick Ceph Systems, San Diego, Calif) by an author (A.A.) and reviewed by the senior investigator (M.A.) to check the accuracy of landmark identification. Cephalometric measurements and their descriptions are given in Figure 2. Seven angular (SNA, maxillary depth, SN-palatal plane, maxillary height, SNB, FMA, and ANB)