Effects of Nasoalveolar Molding Therapy on Nasal and Alveolar Morphology in Unilateral Cleft Lip and Palate

Defne Keçik, DDS, PhD,* and Ayhan Enacar, DDS, PhD†

Objective: The objective of this study was to evaluate the effects of presurgical nasoalveolar molding (PNAM) therapy on nasal and alveolar tissues in patients with unilateral cleft lip and palate.

Patients and Methods: Twenty-two patients with a mean age of 23 days, having complete unilateral cleft lip and palate, were included in this prospective study. After the impressions were taken of the palatal and nasolabial regions separately, the maxillary and nasal plaster models were scanned for linear, angular, and area measurements before and after PNAM therapy. The distances between the identified landmarks were measured in the maxillary casts, and the distance and area measurements were performed for the nasal casts with the specified software called Image J developed by the National Institutes of Health. All subjects have undergone PNAM therapy for 6 months. The nasal and maxillary casts are scanned, and the images were evaluated using the software Image J. The alveolar segments should be approximated, and the cleft width and alar base of the affected side after PNAM should be reduced, and the nostril area of the maxillary and palatal casts should be increased. The columella deviation should be decreased.

Results: The decrease of the cleft width, arch length, and alar base width on the affected side and the deviation of the cleft were significant, in addition to the significant increase of the arch circumference and nostril area on the affected side (P < 0.001).

Conclusions: Presurgical nasoalveolar molding therapy is a significantly helpful treatment for patients with unilateral cleft lip and palate. The reduction in the alveolar cleft region and the nasal reshaping are favorable.

Key Words: Unilateral cleft lip and palate, nasoalveolar molding, dental cast measurements

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Cleft lip–cleft palate is one of the most common congenital craniofacial disorders caused by embryological defects encountered at the process of the formation and development of the facial structures between the fourth and eighth weeks of embryological development.1 Cleft lip and alveolus and palate deformity cause deficiency and disharmony of the midface in all 3 planes of space.2–4 Maxillary retrusion is a common phenomenon in patients with unilateral cleft lip and palate. Much of the growth disturbance of the maxillary skeleton mainly results from the surgical repair of the palate.3 Ross5 stated that excessive postoperative scar tissue formed by undermining of soft tissues could inhibit forward growth of the maxilla.

The essential treatment philosophy for the cleft lip alveolus and palate patients is to restore the normal anatomy and physiology of the stomatognathic system including the alveoli and nasal components. Because of the hard and soft-tissue deficiency and abnormality, the ideal treatment philosophy should be to achieve the satisfactory skeletal, cartilaginous, and soft-tissue relationship before surgical correction.

In unilateral cleft lip, nasal deformity, the lower lateral nasal cartilage on the cleft side is rotated inferiorly and depressed toward the cleft area. The columella is short and deviated.6,7 In the palatal region, the deviation of the nasal septum shifts the base of the nose to the unaffected side.

The concept of modern presurgical infant orthopedics began with McNeill’s8 studies and applied by many authors.9–20 Matsuo et al11 and Matsuo and Hirose22 were the first to apply the presurgical molding of the cleft in the nasal cartilage of the newborn, by placing a silicone stent inside the nostril to shape the nasal cartilage. Grayson et al23,24 have presented the presurgical nasoalveolar molding appliance that has a nasal stent attached to the acrylic alveolar molding plate to reshape the nasal cartilage and approximate the alveolar segments. In addition, the aim was to decrease the width of the alar base of the affected side and approximate the lip segments by placing an adhesive tape across the upper lip segments.25

The presurgical nasoalveolar molding system including adhesive tapes attached to the labial segments decreases the size of the cleft by approximating the alveolar segments, lengthens the columella, repositions the philtrum, reshapes the nasal cartilages, and enhances the depressed alar cartilage of the affected side in patients with unilateral cleft lip and palate.26–28 Nasoalveolar molding in unilateral cleft lip and palate is advantageous for the reduced need for alveolar bone grafting,25,29 giving the opportunity to perform primary gingivoperiosteoplasty at the time of lip repair as well as the reduction in the number and complexity of the minor soft-tissue revision surgeries required to maintain the acceptable nasolabial aesthetics.24 Because of the lack of statistical documentation of the effects of the nasoalveolar molding therapy throughout the literature, the purpose of our study was to evaluate the changes in the nasal, labial, and alveolar region with nasoalveolar molding therapy in patients with unilateral cleft lip–cleft palate deformity.

MATERIALS AND METHODS

Twenty-two infants (12 boys and 10 girls) with complete unilateral cleft lip and palate were included in the study. The mean...
age of the infants were 23 days ranging from 2 to 42 days. The inclusion criteria were patients (1) having complete unilateral cleft lip and palate, (2) without any syndromic defect that would conjunct with cleft lip and palate, and (3) who had not received any maxillary orthopedic and nasoalveolar molding treatment. Principles outlined in the Declaration of Helsinki were followed.

After the clinical examination, the impression of the palatal area including the alveolar cleft region was taken with a silicone elastomeric impression material with an infant acrylic impression tray, then followed by taking the impression of the nasolabial region. The impression was obtained when the infant was awake, in prone position. The maxillary and nasal models were obtained. The nasoalveolar molding plate was constructed on these plaster models using acrylic resin. Soft denture liner (Ufi Gel Relining System; VOCO GmbH, Cuxhaven, Germany) was added on the appliance’s oral cavity side for preventing the soft tissues to be prevented from irritation and also for a better retention of the appliance. The appliance was supported with surgical adhesive tapes attached to both cheeks. The presurgical nasoalveolar molding plate is selectively ground for moving the alveolar segment to the desired area, and a soft acrylic liner is placed to the regions where the alveolar bone is to be reduced, weekly to reshape and direct the greater alveolar segment through the smaller segment, aiming to reduce the alveolar cleft width. The parents of the patients were informed to place an adhesive tape (Micropore Surgical Tape; 3M, St Paul, MN) on the lip segments to approximate the lip segments aiming to narrow the alar base of the cleft side. The nasal stent was placed on to reshape the nasal cartilages after 1 month of nasoalveolar molding appliance usage with adhesive tapes to obtain a narrowed alar base in this 1-month period and to avoid creating a giant nostril. The maxillary and nasolabial casts were obtained at the beginning (T0) and at the end (T1) of presurgical nasoalveolar molding therapy when the infants were 6 months old. The landmarks on the maxillary casts were marked with a 0.3-mm pencil on the conventionally used landmarks indicated by Friede et al, Seckel et al, and Peltomäki et al. In the nasal models, reference points were marked also with a 0.3-mm pencil. Maxillary and nasal models were scanned with a submentovertex technique in 1:1 ratio (HP Scanjet G4010 Photo Scanner; Hewlett-Packard, Palo Alto, CA).

The reference points marked on the maxillary casts and nasal casts were described in Figures 1 and 2A, respectively. In maxillary cast images, the cleft width (G-L), arch circumference (T-C-I-G + L-C’-T’), anterior arch width (C-C’), posterior arch width (T-T’), arch length (G to T-T’ perpendicular), and alveolar distance to midpoint (G to T-T’) were measured on the scanned image with the software program Image J (Image Processing and Analysis in JAVA) developed by the National Institutes of Health (Fig. 1; Table 1).

In the images of nasal structure, (1) alar width of the noncleft side (lac-sn), (2) alar width of the cleft side (sn-lac’), (3) total alar base (lac-lac’), (4) columella deviation angle (angle between lac-lac’ and sn-pmr), (5) nostril area of the noncleft side, and (6) nostril area of the cleft side were measured using the same software. In the calculation of the nostril area of the cleft side, the alar base was set by drawing a line between the point of conjunction of the medial alar cartilage to the labial tissue and the point of the conjunction of the lateral alar cartilage to the labial tissue (lac’)(Fig. 2B; Table 1).

The reproducibility of the linear, angular, and area measurements on the maxillary and nasal casts made twice after 1 month was calculated using the same software. The reproducibility of the linear, angular, and area measurements on the maxillary and nasal casts was made twice after 1 month.
TABLE 1. Linear, Angular, and Area Measurements of Maxillary and Nasal Casts

<table>
<thead>
<tr>
<th>Measurements</th>
<th>Landmarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary cast measurements</td>
<td></td>
</tr>
<tr>
<td>(1) Cleft width</td>
<td>G–L</td>
</tr>
<tr>
<td>(2) Arch circumference</td>
<td>T-C-I-G + L-C’-T’</td>
</tr>
<tr>
<td>(3) Anterior arch width</td>
<td>C-C’</td>
</tr>
<tr>
<td>(4) Posterior arch width</td>
<td>T-T’</td>
</tr>
<tr>
<td>(5) Arch length</td>
<td>G to T-T’ perpendicular</td>
</tr>
<tr>
<td>(6) Alveolar distance to midpoint</td>
<td>G to T-T’</td>
</tr>
<tr>
<td>Nasal cast measurements</td>
<td></td>
</tr>
<tr>
<td>(1) Alar width (unaffected side)</td>
<td>lac-sn</td>
</tr>
<tr>
<td>(2) Alar width (affected side)</td>
<td>sn-lac’</td>
</tr>
<tr>
<td>(3) Total alar base</td>
<td>lac-lac’</td>
</tr>
<tr>
<td>(4) Columella deviation angle</td>
<td>Angle between lac-lac’ and sn-prn</td>
</tr>
<tr>
<td>(5) Nostril area (nonleft side)</td>
<td>The area of the unaffected nostril</td>
</tr>
<tr>
<td>(6) Nostril area (left side)</td>
<td>The area above mac-lac’ line</td>
</tr>
</tbody>
</table>

by the same investigator. The differences between the 2 measurements were compared. The method of error (SE) was calculated using the formula according to Dahlberg’s formula; SE = \sqrt{\frac{\sum d^2}{2n}} / 2n, where d is the difference between 2 measurements of a pair and n is the number of duplicate determinations. Paired-samples test was used for statistical analysis, and the level of significance was used as P < 0.001.

RESULTS

All linear, angular, and area measurements had a coefficient of intrarater reliability between 0.59 and 0.85, 0.57 and 0.89, and 0.73 and 1.00, respectively; thus, these values were considered to have an insignificant effect on the measurements as far as reliability was concerned.

Considering the maxillary cast measurements, the cleft width (G–L) showed a significant decrease after nasoalveolar molding therapy (P < 0.001) (Table 2). Similarly, the difference between the pretreatment and posttreatment arch circumference (T-C-I-G + L-C’-T’) changes were significant (P < 0.001) (Table 2). The anterior (C-C’) and posterior (T-T’) arch widths did not show any significant difference before and after treatment (P > 0.001) (Table 2). Arch length (G to T-T’ perpendicular) and alveolar distance to midpoint (G to T-T’) showed significant differences before and after presurgical nasoalveolar molding therapy (P < 0.001) (Table 2).

When the nasal cast measurements were evaluated, the difference in the alar distance of the noncleft side (lac-sn) was not significant (P > 0.001) (Table 2). The alar distance of the cleft side (sn-lac’) reduced significantly with treatment (P < 0.001) (Table 2). The decrease in the total alar base (lac-lac’) and the increase in the columella deviation angle were found to be significant (P < 0.001) (Table 2). The nostril area of the noncleft side did not change significantly; however, the increase in the nostril area of the cleft side was statistically significant (P < 0.001) (Table 2).

DISCUSSION

For centuries, surgeons have dealt with the change of the unilateral cleft deformity. Presurgical orthopedic appliances have first been introduced by McNeill and developed with the acrylic obturator of Rosenstein and Jacobson the and pin-retained appliance of Latham et al. Although there is still a debate going on about the treatment philosophies of surgical correction with and without presurgical nasoalveolar molding, it is now recognized that presurgical infant orthopedics in unilateral cleft lip and palate is required for reducing the cleft width, approximating the lip segments, and improving the nasal symmetry by reshaping the nasal cartilages, therefore facilitating the achievement of surgical soft-tissue repair under minimal tension and optimal conditions for minimal scar formation. In addition, the number and complexity of minor soft-tissue revision

TABLE 2. Statistical Analysis of the Maxillary and Nasal Measurements (in Millimeters and Square Millimeters)

<table>
<thead>
<tr>
<th>Measurements</th>
<th>T0</th>
<th>SD</th>
<th>T1</th>
<th>SD</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary cast measurements</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1) Cleft width</td>
<td>12.81</td>
<td>3.44</td>
<td>4.45</td>
<td>1.30</td>
<td>0.000</td>
</tr>
<tr>
<td>(2) Arch circumference</td>
<td>53.67</td>
<td>6.87</td>
<td>64.87</td>
<td>6.38</td>
<td>0.000</td>
</tr>
<tr>
<td>(3) Anterior arch width</td>
<td>32.00</td>
<td>2.06</td>
<td>34.44</td>
<td>2.57</td>
<td>0.549</td>
</tr>
<tr>
<td>(4) Posterior arch width</td>
<td>35.04</td>
<td>2.31</td>
<td>35.84</td>
<td>2.06</td>
<td>0.873</td>
</tr>
<tr>
<td>(5) Arch length</td>
<td>24.38</td>
<td>1.85</td>
<td>20.80</td>
<td>1.59</td>
<td>0.000</td>
</tr>
<tr>
<td>(6) Alveolar distance to midpoint</td>
<td>–3.72</td>
<td>2.23</td>
<td>5.78</td>
<td>3.18</td>
<td>0.000</td>
</tr>
<tr>
<td>Nasal cast measurements</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1) Alar width (unaffected side)</td>
<td>9.12</td>
<td>2.76</td>
<td>10.76</td>
<td>2.63</td>
<td>0.258</td>
</tr>
<tr>
<td>(2) Alar width (affected side)</td>
<td>19.83</td>
<td>3.42</td>
<td>13.83</td>
<td>2.42</td>
<td>0.000</td>
</tr>
<tr>
<td>(3) Total alar base</td>
<td>31.76</td>
<td>3.79</td>
<td>22.17</td>
<td>2.83</td>
<td>0.000</td>
</tr>
<tr>
<td>(4) Columella deviation angle</td>
<td>53.12</td>
<td>5.27</td>
<td>78.19</td>
<td>4.74</td>
<td>0.000</td>
</tr>
<tr>
<td>(5) Nostril area (nonleft side)</td>
<td>12.86</td>
<td>3.59</td>
<td>14.39</td>
<td>3.23</td>
<td>0.372</td>
</tr>
<tr>
<td>(6) Nostril area (left side)</td>
<td>18.49</td>
<td>4.36</td>
<td>22.68</td>
<td>3.97</td>
<td>0.000</td>
</tr>
</tbody>
</table>

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surgies required in maintaining the nasolabial aesthetics as growth and development continues are reduced, \(^{13}\) as well as the need for secondary alveolar bone grafting \(^{29}\) and overall treatment costs. \(^{27}\)

Several methods for the analysis of the upper jaws of cleft patients have been developed. Measurements have been directly on plaster casts or on cast photocopics. \(^{34-36}\) These methods are found to be relevant to morphologic scientific research. The measurements taken are usually distances and areas \(^{35,34}\) and slopes and angles, \(^{37}\) or by means of stereophotogrammetry. \(^{37,38}\)

In the current study, the effects of nasoalveolar molding appliance on the nasal, labial, and alveolar processes were investigated. To decrease the source of variability, only nonsyndromic patients with complete unilateral cleft lip and palate were included in this study. According to alveolar measurements with presurgical nasoalveolar molding therapy, the significant decrease in the cleft width and increase in the arch circumference enhance the bone structure to improve surgical outcome, diminish the tension of the repaired upper lip on the alveolar bones, and carry out gingivoperiosteoplasty, which were consistent with the findings of Stellzig et al. \(^{38}\) The insignificant difference in the anterior and posterior arch widths were also in harmony with the findings of Stellzig et al. \(^{38}\)

Hotz and Gnonski \(^{39}\) focused on the problem of growth in patients with unilateral cleft lip and palate and stated that there is a high correlation between maxillary measurements at birth and anterior cleft width at 6 months of age. In addition, anterior cleft width before lip surgery was strongly associated with maxillary arch conditions at birth by setting the most favorable time of lip closure dependent on anterior cleft reduction.

It is obvious that the presurgical nasoalveolar molding appliance prevents tongue intrusion into cleft area based on the significant decrease in the cleft width. This is supported by the study of Mishima et al, \(^{40}\) who have evaluated the effects of Hotz plate in patients with unilateral cleft lip and palate, specifying that the simulation of the growth of the segments in the Hotz plate–applied patients is larger than the patients who were not treated with the appliance. In our study, the alveolar distance, revealing the protrusion of the premaxilla, decreased significantly with the nasoalveolar molding therapy. This finding was in accordance with the study of Mishima et al, \(^{40}\) who indicated that the sagittal gap between the 2 alveolar segments was smaller in the patients treated with Hotz plate.

In our study, with respect to the arch width, the stability of the anterior and posterior arch widths indicated that the molding plate prevented the tongue to intrude into the cleft and diverging of the alveolar segments. Huddart \(^{17}\) compared the palatal width of patients with unilateral cleft lip and palate whom were applied orthopedic appliances with that of patients with unilateral cleft lip and palate without orthopedic appliances and noted that the palatal width increased in infants with unilateral cleft lip and palate without orthopedic appliances, but did not change in infants with unilateral cleft lip and palate with orthopedic appliances, similar to the findings of our study.

The significant decrease in the cleft width (G-L) and the approximation of point G to T′T′ line and T′T′ perpendicular line by nasoalveolar molding therapy indicates the approximation and the proper alignment of the alveolar cleft segments, for the formation of a close-to-optimal dental arch curve. This leads to the reduction of the need for alveolar bone grafting as an outcome of gingivoperiosteoplasty. \(^{25}\)

With the alveolar segments in a better position and increased osseous bridges across the cleft, the adult teeth have a better chance of erupting in a good position and adequate periodontal support. \(^{41}\)

Of course, a three-dimensional description of arch change would be optimal. All techniques described could theoretically be used in 3 dimensions, yet the number of landmarks of occlusal plane in study casts could be increased by this way.

The unilateral cleft lip and alveolar deformity is associated with a significant abnormality in nasal cartilage morphology as well as the asymmetry of alar base and columella. With the presurgical nasoalveolar molding, the aim is to reform the nasal cartilage and correct the soft-tissue deformity while approximating and aligning the alveolar segments.

With the gradual adjustment of the nasal stent for 3 or 4 months, the depressed and concave alar cartilage is reshaped; an acceptable nostril formation is achieved; and with the application of the surgical tape applied to approximate the lip segments, the alar base of the defect side is shortened, and the columella asymmetry is reduced significantly similar to the statements of Grayson and Cutting, \(^{32}\) Maull et al., and Grayson et al. \(^{22}\)

Matsuo et al \(^{35}\) indicated that the high degree of plasticity in neonatal cartilage results from the high levels of hyaluronic acid, which is a component of proteoglycan aggregate of the intercellular matrix in the cartilage. Maternal estrogen increases the hyaluronic acid level, therefore increasing the cartilage plasticity in the neonate. \(^{35}\) Hyaluronic acid reduces cartilage, ligament, and connective tissue elasticity and increases the plasticity by breaking down the intercellular matrix. The maternal estrogen is higher immediately after birth and reduces within 6 weeks, and the cartilage becomes less plastic. \(^{44}\) That is the reason why the soft-tissue and alar cartilage molding therapy is more successful within the 3 to 4 months after birth. \(^{32,24,45}\) Similarly in our study, the morphologic change in the alar cartilages was higher during the first 3 months of the presurgical nasoalveolar molding therapy.

The alar width and the nostril area of the unaffected side remained unchanged during molding therapy; however, the nostril area and the alar width of the cleft side changed significantly. The increase in the nostril area of the cleft side was significant, despite the decrease in the alar width; with the reshaping effect of the nasal stent, the alar cartilages of the cleft side became nearly symmetrical to the noneleft side. The labial tape insignificantly reduced the alar width of the cleft side and the nasal stent protruded the alar cartilages, resulting in a better nostril formation.

The total alar base reduced significantly mostly because of the reduction in the nasal width of the cleft side by the help of adhesive labial tape, and the columella deviation angle increased significantly with the gradual activation of the nasal stent combined with the application of adhesive labial tape, similar to the findings of Grayson et al \(^{34}\) and Pai et al. \(^{46}\)

Similar to the findings of our study, Barillas et al \(^{47}\) had stated that the alar and septal cartilages were more symmetrical compared with the patients who have not undergone the nasoalveolar molding therapy. Maull et al. \(^{48}\) also found that children who had undergone presurgical nasoalveolar molding treatment had a significantly improved symmetry of the nose compared with the group who had undergone only alveolar molding. According to the observation of McComb and Coghlan, \(^{35}\) asymmetry in the unilateral cleft nose does not improve in time.

The weakness of this study was the absence of a control group. The comparison of the findings with a control group could have revealed more specific and reliable results; however, the ethical impossibility of taking impressions from a healthy newborn, thus the absence of a control group, caused the authors to evaluate the data only among the patients with cleft lip and palate who have undergone nasoalveolar molding therapy.

Nasal morphology has been evaluated by identifying landmarks on a two-dimensional photograph to make various linear and angular measurements. \(^{49-51}\) A three-dimensional surface data with laser light scanner are a more developed method for analyzing the cleft lip nose deformity; however, our method requires a simple,
practical, and economical way of evaluating the effects of nasoalveolar molding therapy for cleft lip–cleft palate deformity.

CONCLUSIONS

Our study gives the opportunity to evaluate the effects of presurgical nasoalveolar molding therapy on the alveolar processes and palatal region as well as the nasal tissues, alar cartilages, and labial segments. As interdisciplinary team–centered care for cleft lip and palate is indispensable; the presurgical nasoalveolar molding therapy allowing the growth of the alveolar processes in the right direction, thus improving the arch form, as well as reshaping the flattened nose into a more symmetrical shape and uprighting the columella are also benefited for reducing the need for secondary alveolar bone grafts, minimizing the extent of lip, nose, and alveolar complex surgeries and formation of scar tissue, with more stable postoperative results.

REFERENCES


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