

EFFECT OF CAD/CAM NASOALVEOLAR MOLDING APPLIANCE ON CORRECTION OF THE NASAL DEFORMITY IN COMPLETE BILATERAL CLEFT LIP AND PALATE

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ABSTRACT

INTRODUCTION: Cleft lip and palate (CLP) affects about 1.5 per 1000 live births (250,000 new cases per year) worldwide. They can be either unilateral or bilateral, complete or incomplete. The bilateral cleft lip and palate (BCLP) deformity typically arises with a protrusive premaxilla. The nasal deformity includes deficient columella, with flared lateral alar cartilages which usually require additional surgeries to improve the nasal symmetry. NasoAlveolar Moulding (NAM) technique, aims to align the alveolus, lip, and nose properly; reduce the severity of the nasal deformity, and lengthen the columella without surgery.

OBJECTIVES: The study aims to quantify the effect of NAM therapy, fabricated by CAD/CAM additive manufacturing, in the improvement of nasolabial deformity in terms of bialar width, columellar length and width in infants with complete BCLP.

MATERIALS AND METHODS: Ten infants with non-syndromic BCLP (age < 1 month) were selected. Impressions were obtained. The casts obtained from the impressions were scanned using a 3D laser scanner. Designing and 3D printing of the appliances were completed. The appliances were inserted and retained using surgical tapes. Nasal stents were incorporated 60 days after the start of the treatment. Nasal measurements were obtained before treatment and at the end of treatment (after four months).

RESULTS: Data was collected and statistically analyzed. After NAM therapy, there was a statistically significant increase in columellar length and a statistically significant decrease in both columellar width and bialar width.

CONCLUSIONS: CAD/CAM PNAM therapy has proved its effectiveness in BCLP by showing an improvement in the columellar and bialar presurgical presentation. CAD/CAM PNAM therapy should be considered a routine procedure in the treatment protocol for BCLP.

KEYWORDS: Cleft Lip and Palate, Nasoalveolar Molding, CAD/CAM, Columella.

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INTRODUCTION

Cleft lip and palate (CLP) affects about 1.5 per 1000 live births (250,000 new cases per year) worldwide. They can be either unilateral or bilateral, complete, or incomplete (1,2). CLP represents a major public health problem due to the possible associated morbidity, multifactorial etiology, and the extensive multidisciplinary commitment required for intervention and management (3,4).

Several risk factors are found to cause orofacial cleft (OFC). These include geographic factors, race, family history, gender, exposure to risk factors in pregnancy, such as alcohol consumption and tobacco smoking (2,3), poor nutrition (4), viral infections, drugs and also teratogens in the workplace and home (5,6). Recent studies show that obesity during pregnancy may be related to CLP (6).

The bilateral cleft lip and palate (BCLP) deformity arises with a protruded or deviated premaxilla. The nasal deformity involves a broader nasal base than normal, along with the absent or deficient columella, which is the greatest challenge in treatment (7,8).

Management of CLP is a long term process that begins in infancy and continues in adulthood. Throughout life, many surgical procedures are undergone by these

patients. Despite various advances in surgery, patients with CLP still require certain orthopedic corrections before surgery (9,10).

The theory of presurgical nasoalveolar molding (PNAM) treatment is based on Matsuo's concept that the nasal cartilage is still developing and is easily molded during the first six weeks of life due to high levels of maternal oestrogen making the tissues softer. This lasts until 3 to 4 months of age (11).

The first PNAM was designed by Grayson, including a stent that extended from the anterior flange of an acrylic plate to correct the nostril shape and to mold the cleft alveolar segments (12). Nasal alveolar molding is used to reshape the nasal cartilage and mold the maxillary arch before cleft lip repair and primary rhinoplasty. The benefits include improvement of dental arch form and nasal tip and alar symmetry, which benefit both function and esthetics (12,13). As a result, the changes associated with PNAM therapy help decrease the complexity of subsequent surgeries (14).

Nasoalveolar molding (NAM) has been used to allow for nasal molding and lengthening of the columella during the presurgical period. Nonsurgical elongation of the columella is very important in achieving satisfactory

surgical results (15,16). Reduced scar formation improves the facial esthetics.

In the year 2013, Punga and Sharma conducted a study to compare the effect of appliances with and without nasal stents. The results showed that nasal stents resulted in a significant increase in columellar length and a decrease in the bi-alar width which was not significant (17).

In the year 2015, Rau et al performed a study to evaluate the nasal measurements before and after NAM treatment. They found a significant elongation of the columella with improvement of nasal symmetry in BCLP, thus reducing tissue tension and improving surgical outcomes (18). These results were similar to those obtained by Lee et al in the year 2008 (19).

Computer-assisted design and computer-aided manufacturing (CAD/CAM) technology have recently influenced many fields of medicine (20). Intraoral plates can be produced virtually by using CAD/CAM technology. This enables the plates to be produced with high accuracy and with standardized dimensions (21,22). It also simplifies the appliance fabrication process and saves the clinic time in making adjustments (23,24).

A CAD/CAM system consists of three phases: scanning, designing, and manufacturing. The scanning device converts the shape of the stone model into three dimensional (3-D) units of information (voxels). The computer translates this information into a 3-D map (point cloud). The operator designs the restoration using the software and saves it in the form of standard tessellation language (STL) file which is then transferred to the manufacturing machine, whether it is a milling machine or a 3D printer (25).

In the year 2016, Ritschl et al compared the results of nasal measurements in infants before and after NAM treatment. The study was conducted on two groups, one group received NAM constructed using the conventional technique, while the other group received NAM designed and manufactured using CAD/CAM. The results showed an improvement in nasal measurements and nasal asymmetry in both groups. However, this study was conducted on infants with unilateral CLP (21).

The objective of this study is to quantify the effect of the NAM appliance, which is fabricated by CAD/CAM, in the improvement of nasolabial deformity in terms of bialar width, columellar length and width in infants with complete BCLP. The null hypothesis was that the presurgical NAM appliance in BCLP patients does not affect the nasolabial deformity.

MATERIALS AND METHODS

Ten infants with complete BCLP (age < 1 month) who presented to the Maxillofacial Department, Faculty of Dentistry, Alexandria University, were selected for this study. The inclusion criteria were as follows: 1) Complete BCLP. 2) no other congenital malformations or systemic diseases, 3) newborn to 1-month-old.

The parents were informed about the treatment procedures, and informed consent was filled out following the regulation of the Ethics Committee in the Faculty of Dentistry, Alexandria University.

Impression procedures

An impression of the intraoral cleft defect was made using vinyl polysiloxane impression material (3M ESPE, Express STD, USA). The maxillary impression was taken in a clinical setting that was prepared to handle airway emergencies if encountered. The impression was obtained with the infant fully awake and with no premedications or anesthesia. The impression adequately covered the anatomy of the upper gum pads and palatal shelves and included the vestibular folds. The impression was poured with dental stone to obtain accurate casts.

Fabrication of the NAM appliance

The stone cast data of each infant was acquired by a 3D laser scanner (Ceramill, AmannGirrbach, Germany). After the digitalization of the model cast, the first step was to define the parts of the maxillary seating surface for the plate. The intraoral plate was designed followed by the retentive buttons, which were oriented 40° downward to the occlusal plane. Two separated geometries were created in separate lay-ups and then integrated to form the appliance. The virtually designed NAM plate was saved as an STL file and ready for plate manufacture.

The NAM plate and retentive buttons were printed using a 3D printing machine (Ceramill, AmannGirrbach, Germany) that guaranteed high precision. The appliance was polished to ensure that all the borders are smooth before being delivered to the infant.

NAM procedures:

a) Alveolar molding:

The appliance was then secured extraorally to the cheeks and bilaterally by surgical tapes (3M Micropore, USA.) that have orthodontic elastic bands (ORMCO Z-pack elastics, Mexico) looped at one end. The elastics inner diameter (0.25 in, wall thickness-heavy) was stretched approximately three times their resting diameter for proper activation force. Skin barrier tapes were applied to the infants' cheeks to reduce irritation. Active lip taping was applied to approximate the lip segments towards each other.

The parents were instructed to keep the plate in the oral cavity for 24 hours and to remove it only for daily cleaning at least once. They were provided with detailed instructions on the proper method of lip taping along with taping materials.

b) Nasal molding:

After 60 days from the beginning of the treatment, active nasal molding was done by incorporation of the nasal stent component of the NAM appliance. The nasal stent was constructed of 0.7 mm round stainless steel wire and had the shape of a "Swan Neck" (26).

The stent was attached to the labial flange of the oral molding plate. The wire extended forwards and then curved backward to create a small loop for retention of the intranasal portion of the nasal stent and entering 3–4 mm past the nostril aperture. The hard acrylic component was shaped into a bi-lobed form that resembles a kidney. A layer of soft denture liner (Coe-Soft, CG America Inc., USA) was added to cover the superior aspect of the nasal stent to ensure positive pressure to the internal tissues of the dome lifting the nostril apex and defining the top of the columella (Fig.1). Nasal measurements, including bialar width, columellar length, and width, were taken with a digital caliper before and after NAM treatment (Fig.2,

Table 1). Photographs before and after treatment were also obtained.

Table (1): Nasal measurements

Measurements	Descriptions
(a) Columellar length	Distance from the most superior point to the most inferior point of the columella.
(b) Columellar width	Narrowest width of the columella as a transverse measurement
(c) Bi-alar width	The measurement between the right and left most lateral point of the ala of the nose



Figure (1): NAM appliance with nasal stents in place. Orthodontic elastics and surgical tapes are used.

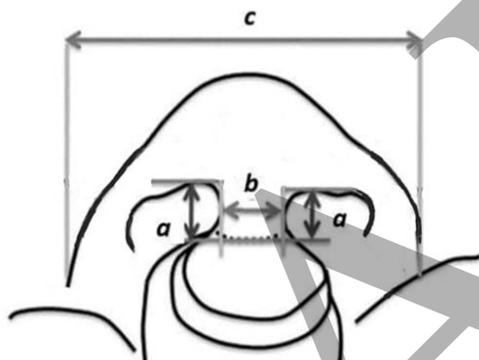


Figure (2): Basal view showing the nasal measurements.

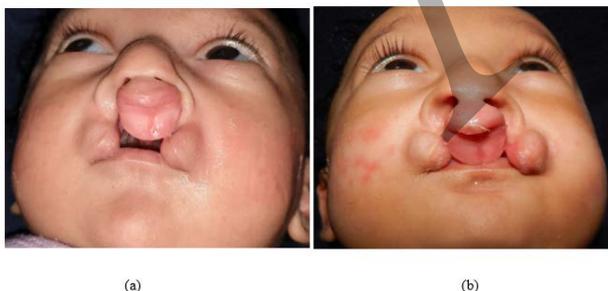


Figure (3): Photographs of the basal view showing the progress of nasal molding. (a) Before treatment. (b) During treatment.

Statistical analysis

- Data were collected and entered to the computer using SPSS (Statistical Package for Social Science) program for statistical analysis (ver 21) (27).
- Data were entered as numerical or categorical, as appropriate.

- Kolmogorov-Smirnov test of normality revealed significance in the distribution of most of the variables, so the non-parametric statistics was adopted (28).
- Data were described using minimum, maximum, mean, standard deviation and 95% CI of the mean, (29) median and inter-quartile range.
- Comparisons were carried out among related-samples by Friedman’s test “alternative to the one-way ANOVA with repeated measures” (30).
- An alpha level was set to 5% with a significance level of 95%, and a beta error accepted up to 20% with a power of study of 80%.

RESULTS

1. **Columellar length:** Friedman test showed a statistically significant increase in the median values and interquartile ranges of the columellar length on both the right and left sides between the start (T0) and end of the treatment period (T1) using the NAM appliance (p=0.000*) (Table 2).

Table (2): Shows the columellar length on the right and left side before and after NAM treatment.

	Right side	Left side
Columellar length (T0)		
-n	10	10
-Min-Max	0.00-2.00	0.00-2.00
-Mean ± Std. Deviation	0.80±0.63	0.70±0.67
-95% CI for mean	0.3476-1.2524	0.2172-1.1828
-Median (IQR)	1.00* (0.00-1.00)	1.00* (0.00-1.00)
-KS test of normality	D=0.324,p=0.004*	D=0.272,p=0.035*
Columellar length (T1)		
-n	10	10
-Min-Max	2.00-4.00	2.00-4.00
-Mean ± Std. Deviation	3.00±0.47	2.65±0.67
-95% CI for mean	2.6628-3.3372	2.1716-3.1284
-Median (IQR)	3.00 ^b (3.00-3.00)	2.75 ^b (2.00-3.00)
-KS test of normality	D=0.400, p=0.000*	D=0.234, p=0.127 NS
Columellar length change (T1 vs T0)		
-n	10	10
-Min-Max	1.00-3.00	1.00-3.00
-Mean ± Std. Deviation	2.20±0.63	1.95±0.69
-95% CI for mean	1.7476-2.6524	1.4599-2.4401
-Median (IQR)	2.00 (2.00-3.00)	2.00 (1.50-2.00)
-KS test of normality	D=0.324, p=0.004*	D=0.271, p=0.036*
Test of significance Friedman Test p value	$\chi^2_{(Fr)}(df=2)=19.419$ p=0.000*	$\chi^2_{(Fr)}(df=2)=18.588$ p=0.000*

*: Statistically significant (p<0.05)

2. **Columellar width:** Friedman test showed a statistically significant decrease in the median values and interquartile ranges of the columellar width between the start (T0) and end of the treatment period (T1) using the NAM appliance (p=0.000*) (Table 3).

Table (3): Shows the columellar width before and after NAM treatment.

Columellar width (T0)	
-n	10
-Min-Max	5.00-7.00
-Mean ± Std. Deviation	5.55±0.76
-95% CI for mean	5.0049-6.0951
-Median (IQR)	5.00 ^a (5.00-6.00)
-KS test of normality	D=0.365, p=0.000*
Columellar width (T1)	
-n	10
-Min-Max	4.00-6.00
-Mean ± Std. Deviation	4.60±0.70
-95% CI for mean	4.0998-5.1002
-Median (IQR)	4.50 ^b (4.00-5.00)
-KS test of normality	D=0.305, p=0.009*
Columellar width change (T1 vs T0)	
-n	10
-Min-Max	-1.50-0.00
-Mean ± Std. Deviation	-0.95±0.37
-95% CI for mean	-1.2139--0.6861
-Median (IQR)	-1.00 (-1.00--1.00)
-KS test of normality	D=0.454, p=0.000*
Test of significance Friedman Test p value	$\chi^2_{(Fr)}(df=2)=16.788$ p=0.000*

*: Statistically significant (p<0.05)

3. **Bialar width:** Friedman test showed a statistically significant decrease in the median values and interquartile ranges of the bialar width between the start (T0) and end of the treatment period (T1) using the NAM appliance (p=0.000*) (Table 4).

Table (4): Shows the bialar width before and after NAM treatment

Bialar width (T0)	
-n	10
-Min-Max	28.00-37.00
-Mean ± Std. Deviation	33.40±2.80
-95% CI for mean	31.3993-35.4007
-Median (IQR)	34.00 ^a (31.00-35.00)
-KS test of normality	D=0.185, p=0.200 NS
Bialar width (T1)	
-n	10
-Min-Max	23.00-34.00
-Mean ± Std. Deviation	29.55±3.44
-95% CI for mean	27.0924-32.0076
-Median (IQR)	30.00 ^b (27.00-33.00)
-KS test of normality	D=0.152, p=0.200 NS
Bialar width change (T1 vs T0)	
-n	10
-Min-Max	-5.00 - -1.00
-Mean ± Std. Deviation	-3.85±1.20
-95% CI for mean	-4.7106 - -2.9894
-Median (IQR)	-4.00 (-5.00 - -3.50)
-KS test of normality	D=0.250, p=0.078 NS
Test of significance Friedman Test p value	$\chi^2_{(Fr)}(df=2)=20.000$ p=0.000*

*: Statistically significant (p<0.05)

DISCUSSION

Presurgical maxillary orthopedic treatment in infants with CLP aims to align the premaxilla and the maxillary segments into an almost normal form and anatomic relation before surgical lip repair. Several orthopedic appliances correct the alveolar segments but do not correct the nasal deformity or improve the nasal symmetry (31). Therefore, the use of PNAM appliance with the addition of the nasal stents in complete BCLP has resulted in an improvement in the nasal esthetics providing satisfactory

results after surgery. Nasal molding aims to centralize the nasal tip, correct symmetry and lengthen the deficient columella (32).

The concept of PNAM was based on Matsuo's concept, which stated that the high plasticity of the nasal cartilages in the six weeks after birth is due to the high levels of maternal oestrogen. This concept was applied by Grayson, who designed the first NAM appliance.

This study aimed to analyze the effects of CAD/CAM NAM on the presurgical presentations of the bialar and columellar anatomy to evaluate whether the anatomic interrelationships of this region were affected after nasal molding and columellar lengthening.

The use of CAD/CAM in the manufacture of the NAM appliance has simplified the designing and fabrication procedure, saved time and eliminated human errors. This resulted in minimal adjustments needed to be done chairside. The appliances were produced with higher precision and standardized dimensions, which was not possible with the conventional manual technique.

The results of the present study rejected the null hypothesis. Evaluation of the nasal measurements revealed that the CAD/CAM NAM therapy significantly improved the nasal esthetics. The bialar width was significantly decreased due to the effect of the nasal stents which pull the alae upwards. On the contrary, Punga & Sharma found no significant difference in the bi-alar width before and after NAM treatment (17).

The significant increase in columellar length indicates the high value of nasal stents in stretching of the deficient columella superiorly. The results of the study are consistent with Spengler et al (14), Lee et al (19), Punga & Sharma (17) and Rau et al (18).

In the year 2008, Lee et al reported an increase in columellar length and suggested that nonsurgical columellar elongation with NAM restored columellar length to normal by 3 years and therefore, the need for secondary nasal surgery was reduced (19).

The clinical effects of the tensional stresses applied by the nasal stents to the columella were shown by the inverse relationship between the columellar length and columellar width. These findings are similar to Suri et al in the year 2012 (33).

The results obtained from the NAM treatment also indicated an improvement in the nasal symmetry. According to Ritschl et al, nasal measurements and symmetry were improved using both conventional NAM and CAD/CAM NAM in unilateral CLP (21).

The results obtained from this study showed the effects of NAM on the improvement of nasal esthetics by the improvement of the nasal symmetry, correction of the bialar width, and elongation of the columella. In addition, the NAM appliance helped in the feeding of the infants, therefore, eliminating the need for a nasogastric tube for feeding and improving the quality of CLP management. This also encouraged the parents to be more compliant and to understand the importance of the appliance.

CONCLUSION

CAD/CAM PNAM therapy has proved its effectiveness in the presurgical management of BCLP by showing an improving the columellar and bialar presurgical presentations. The increase in the columellar length and decrease in the columellar width indicates the stretching

effect of the appliance on the columella. The straighter columella indicates the improvement in nasal symmetry. This made the subsequent nasal and lip repair surgery easier to perform with minimal tension and less scar formation. CAD/CAM PNAM therapy should be considered a routine procedure in the treatment protocol for BCLP.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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