Original Article

Three-Dimensional Digital Evaluation of Maxillary Arch Changes after using Nasoalveolar Molding Devices in Unilateral Complete Cleft Lip and Palate Patients

Chantadilok W, DDS[1], Pisek P, DDS, MSc, FRCD, MOrth RCSEd, PhD[1], Manosudprasit A, DDS, MSD, CAGs[1], Chowchuen B, MD, MBA[2], Manosudprasit A, DDS, DScD, CAGs[1], Manosudprasit M, DDS, MDS, FRCDT[1]

[1] Division of Orthodontic, Department of Preventive Dentistry, Faculty of Dentistry, Khon Kaen University, Khon Kaen, Thailand
[2] Division of Plastic Surgery, Department of Surgery, Faculty of Medicine, Khon Kaen University, Khon Kaen, Thailand

Background: Cleft lip and palate is one of the most frequent congenital craniofacial anomalies. This defect affects aesthetic, speech, occlusion, and also psychological problems. A lot of techniques have been introduced to improve the position of the facial and oral malformations. Pre-surgical nasoalveolar molding device (PNAM) was used to decrease of the alveolar cleft width. The common method for evaluating the effects of this device is performed via palatal cast analysis with two or three dimensionally analyzed.

Objective: This study aimed to evaluate the three-dimensional changes to maxillary arches after using PNAM in unilateral complete cleft lip and palate (UCLP) patients before primary lip repair.

Materials and Methods: The samples were taken from twenty infants treated with the Khon Kaen University-PNAM (KKU-PNAM). Dental casts were obtained at two points time, i.e. pre-treatment (T1) and post-treatment (T2), they were digitized using a 3D intraoral scanner (3Shape's R700 Scanner, Copenhagen K, Denmark). The three-dimensional models were evaluated for variations in dimension with OrthoAnalyzer™ software. For statistical analysis, paired t-test was used to compare the differences between treatment periods. Descriptive analysis and intra-class correlations were employed to characterize data.

Results: After treatment with the KKU-PNAM in UCLP patients, the results showed a significant decrease in the width between the anterior part (AG-AL; $p<0.001$) and inter-canine area (CG-CL; $p<0.001$). However, posterior arch width, length and height of both greater and lesser segments (PG-PL, AL/PG-PL, DG/CG plane and DL/CL plane; $p<0.001$ and AG/PG-PL; $p = 0.008$) had significantly increased. The intra-class correlation coefficient between the reproduced landmarks, twice repeated by the same operator, were greater than 0.914.

Conclusion: From the current study, the alveolar molding effect of the KKU-PNAM appeared to mainly decrease the anterior region of the arch, namely the area most affected by cleft lip and palate.

Keywords: 3D analysis, Cleft lip, Cleft palate, Nasoalveolar molding, Maxillary arch

J Med Assoc Thai 2019;102(Suppl.5): 27-33
Website: http://www.jmatonline.com

Cleft lip and palate is one of the most frequent congenital craniofacial anomalies of the head and neck influencing physical appearance and impacting the psychosocial development of an individual. This defect affects speech, hearing, appearance and also psychology, often leading to long-lasting adverse outcomes amid health and social composition(1). The primary characteristics and appearances in unilateral cleft lip and palate (UCLP) include any or all of the following: a shorter and asymmetry position of the columella; displacement of the lower lateral cartilage, asymmetric nasal tip combined with obtuse vestibular dome, a flattened alar of the nose, uneven size of the nostrils, deviated nasal-septum, maxillary retrusion, presence of nasolabial fistula and separated segments of the alveolar ridge(2,3).

A lot of techniques have been introduced over the centuries to improve and redirect the position of the nose as well as the cleft segments. Treatment of cleft lip and palate depends on the cleft type and its severity. Pre-surgical nasoalveolar molding (PNAM) is a device accepted as a novel option for the correcting of nose and lip shape, as well as the alveolar ridge segment position prior to primary lip repair. Hence, the main objective of this device is to reduce the severity of the initial cleft deformity. This enables the oral surgeon to repair the lip with minimal soft tissue tension. Moreover, the objective of PNAM utilization includes the decreasing of the alveolar cleft width- bringing the lip segments together(4).

In 1993, Grayson et al invented the pre-surgical

Correspondence to:
Manosudprasit A.
Division of Orthodontic, Department of Preventive Dentistry, Faculty of Dentistry, Khon Kaen University, Khon Kaen 40000, Thailand.
Phone & Fax: +66-43-202863
E-mail: agg441@hotmail.com

How to cite this article: Chantadilok W, Pisek P, Manosudprasit A, Chowchuen B, Manosudprasit A, Manosudprasit M. Three-Dimensional Digital Evaluation of Maxillary Arch Changes after using Nasoalveolar Molding Devices in Unilateral Complete Cleft Lip and Palate Patients. J Med Assoc Thai 2019;102;Suppl.5: 27-33.

nasoalveolar molding (PNAM) appliance with an oral stent extended from the labial vestibule flange and acrylic plate in order to correct nostrils shape and size; and additionally, to mold the cleft alveolar segments and reduce alveolar width[4,5]. PNAM devices represent a paradigm shift in thinking from traditional methods. This appliance was developed and modified by many centers in order to increase efficiency for maximizing treatment outcomes[6]. In 2012, Khon Kaen University Cleft Lip and Palate Center, Thailand, designed a new PNAM device where by separating the appliance into 3 parts: extraoral strapping, an active alveolar molding plate and nasal molding device. (Figure 1)[7].

The most common method for evaluating and estimating the effects of PNAM in cleft lip and palate patients is performed via palatal cast analysis. This method may be analyzed two or three dimensionally[8]. This technique has been widely applied for the evaluation of results obtained from infant orthopedics; however, the evaluation of three-dimensional relationships is a superior method to compare the precise changes in the point-to-point measurement of a series of dental models prior to, during and post device implementation[9]. Consequently, the purpose of this study was to observe the three-dimensional changes in the maxillary arch of the unilateral completed cleft lip and palate in patients post KKU-PNAM implementation.

Materials and Methods

Study design

The present research is a prospective clinical study.

Participants

The study sample comprised of dental models taken from twenty infants of both genders with complete unilateral cleft lip and palate attending the Center of Cleft Lip and Cleft Palate and Craniofacial Deformities, Khon Kaen University under the Tawanchai Royal Grant Project. The treatment plan indicated the use of the pre-surgical nasoalveolar molding device prior to cheiloplasty

Inclusion criteria

Good general health without any systemic disease, disability or other syndromes, and parents willing to participate in the study having signed their informed consent.

Exclusion criteria

Patients exhibiting a systemic disease, disability or other syndrome; parents denying participation in the study or not giving their informed consent; or incomplete medical and dental models in accordance with the research protocol.

Procedure

Subjects' parents were instructed on how to utilize the KKU-PNAM appliance and advised to encourage their infant to wear the device. The treatment begins by using extra-oral strapping combined with nasal molding device. Two week later, patients are recalled to take an impression for construction of an alveolar molding plate. The appliance is worn 24 hours a day except during cleaning and/or feeding. The parents are instructed to turn traction screw twice a day for molding the maxillary arch. The entire sample fulfilled all eligibility criteria and underwent impression-taking at two time points during the initial visit (T1) as well as post KKU-PNAM implementation prior to primary lip surgery (T2). Maxillary casts were constructed via direct impression with fast-setting type alginate, then filled with white plaster, and trimmed to form a proper base. Commercial intraoral scanner (Trios® Digital impression solution) was employed to construct a three-dimensional model with data collected and kept in an appropriate file. The digital casts were subsequently measured via the 3D OrthoAnalyzer™ (3Shape, Copenhagen, Denmark). Reference points (Figure 2 and Table 1) and distance measurements (Figure 3 and Table 2) were based on the anatomic landmark of the dent alarch as described by Seckel et al with certain modifications identified and digitized amid the 3D model[10,11]. Moreover, the superimposition and color coding diagrams were constructed by employing the same software to confirm the statistically analyzed results.

The reproducibility of the landmark localizations was investigated twice by the same operator within a 1 month interval.

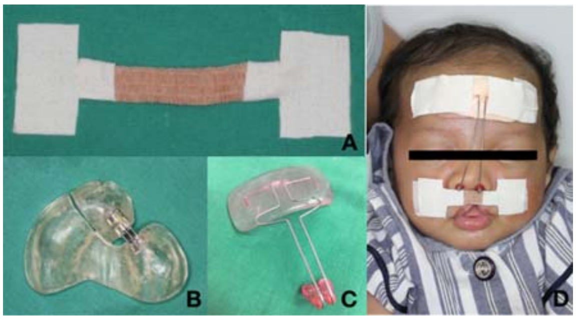

Figure 1. KKU-PNAM appliance.
A = extraoral strapping, B = an active alveolar molding plate, C = nasal molding device and D = a patient wearing the KKU-PNAM device.

Statistical analysis

The differences in outcome measurements prior to treatment (T1) and preceding cheiloplasty (T2) were analyzed using program SPSS for Windows version 23.0 with paired t-test. All *p*-values were two-tailed with 95% confidence intervals. Differences between the reproduced data were assessed with intra-class correlation coefficients (ICCs).

Study protocol was reviewed and approved by The Ethics Committee in Human Research, Khon Kaen University (KKUEC) (protocols No. HE602315).

Results

Subjects' general characteristics are displayed in Table 3. Twenty UCLP subjects consisting of 9 males (45%)

and 11 females (55%) were included. Affected cleft sides were 14: left side (70%) and 6: right side (30%). The average age of patients at the beginning stage was 18 days (range 2 to 55 days) with average duration of treatment prior to patient referral to receive cheiloplasty at 116.15 days (range 49 to 213 days).

Descriptive data of the changes in seven measurements at pre-treatment and post-treatment are presented in Table 4. Normality testing employed to determine normal distribution of data took the form of the Shapiro-Wilk test which revealed that all data was normally distributed.

Paired t-test comparison amid pretreatment (T1) and post-treatment (T2) measurements are presented in Table 5. Subsequent to treatment with the KKU-PNAM among UCLP patients, the results showed a significant decrease in the width dimension between the anterior part (AG-AL; $p<0.001$) and inter-canine area (CG-CL; $p<0.001$). Significant increases to posterior arch width, height, and length were observed in both greater and lesser segments (PG-PL, AL⊥PG-PL, DG⊥CG plane and DL⊥CL plane; $p<0.001$ and AG⊥PG-PL; $p = 0.008$).

The respective intra-class correlation coefficients incorporating 95% CI were calculated. A summary is shown in Table 6 revealing that all values were greater than 0.914. All variable levels were of a sufficiently substantial level in accordance with the guideline given by Shrout[12].

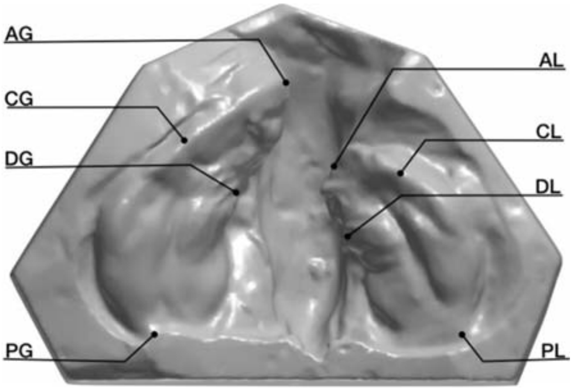

Figure 2. Reference points used in the present study.

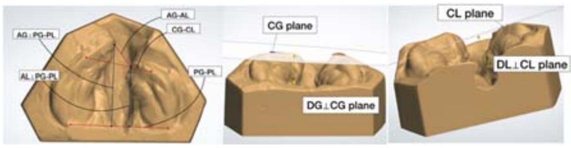

Figure 3. 3D distance measurements demonstrated on a computer screen.

Table 1. Definition of reference points

Landmark	Description
PG	Posterior end of the alveolar cast in the greater segment
AG	Anterior endpoint of the alveolar crest in the greater segment
CG	Crossing point of the canine groove and alveolar ridge in the greater segment
DG	Deepest point of the cleft in the greater segment
PL	Posterior end of the alveolar cast in the lesser segment
AL	Anterior endpoint of the alveolar crest in the lesser segment
CL	Crossing point of the canine groove and alveolar ridge in the lesser segment
DL	Deepest point of the cleft in the lesser segment

Table 2. Definition of distance measurements amid the three-dimensional digital cast

Distances (mm)	Definition
AG-AL	Anterior transverse cleft gap between greater and lesser segments
CG-CL	Inter-canine width between greater and lesser segments
PG-PL	Posterior transverse distance between greater and lesser segments
AG⊥PG-PL	Length of greater cleft segment (distance from anterior endpoint to alveolar crest of greater segment perpendicular to posterior transverse line)
AL⊥PG-PL	Length of lesser cleft segment (distance from anterior endpoint to alveolar crest of lesser segment perpendicular to posterior transverse line)
DG⊥CG plane	Height of greater cleft segment (distance from deepest point in greater side perpendicular to the horizontal plane of crossing point of the canine groove and alveolar ridge on greater side)
DL⊥CL plane	Height of lesser cleft segment (distance from deepest point on lesser side perpendicular to the horizontal plane of crossing point of canine groove and alveolar ridge on lesser side)

In order to visualize the morphological changes in the maxillary dentoalveolar arch resultant of the molding effect of the KKU-PNAM appliance, the three-dimensional image surfaces of all consecutive models of each patient were automatically oriented and superimposed. Each graphic is demonstrated as a model superimposition (Figure 4A) and color code (Figure 4B). The reference points were oriented in a coordinated system employing the midpoint between posterior arch width (PG-PL) which plays a role as a stable point during treatment duration. From superimposition, yellow represents the pretreatment model and green mean the posttreatment model. From Figure 4A, the anterior part of the greater segment moved backward as an outcome of KKU-PNAM treatment. Accordingly, cleft gap was reduced, while the vertical and sagittal dimensions were normally developed. Distances between the surfaces were processed and demonstrated graphically via a color-map code indicating the degree of shape-change. Additionally, the color map was set to a range of 6 mm to -6 mm with red and blue indicating maximal distance changes. From Figure 4B which exhibits one of the sample models, the red area was expressed at the anterior ridge indicating deformity of the greater segment; this segment demonstrated most changes as opposed to the other treatment parts.

Table 3. General characteristics of participants

Demographics data	n = 20
Gender	
Males	9 (45%)
Females	11 (55%)
Type	
Right	6 (30%)
Left	14 (70%)
Age at initial stage (days)	2 to 55 (18±16.25)
Duration of treatment time (days)	49 to 213 (116.15±43.8)

Discussion

The study samples consisted of twenty Thai unilateral complete cleft lip and plated (UCLP) patients (9

Table 4. Descriptive data (n = 20)

Measurement	Mean	Median	SD	Min	Max	Range
Pre-treatment (T1)						
AG-AL	10.62	10.56	2.298	7.51	14.95	7.44
CG-CL	25.78	25.41	2.427	19.64	30.51	10.87
PG-PL	29.65	30.00	1.732	25.92	32.03	6.11
AG⊥PG-PL	22.46	22.30	2.345	18.46	26.96	8.50
AL⊥PG-PL	17.30	17.11	2.026	14.58	21.92	7.34
DG⊥CG plane	10.89	10.87	1.018	8.25	12.66	4.41
DL⊥CL plane	10.13	10.19	1.428	7.71	12.62	4.91
Post-treatment (T2)						
AG-AL	4.56	4.725	1.367	2.04	6.97	4.93
CG-CL	22.18	22.385	2.581	17.61	27.09	9.48
PG-PL	32.10	32.395	1.276	28.89	33.69	4.80
AG⊥PG-PL	23.72	23.57	2.510	18.04	28.62	10.58
AL⊥PG-PL	19.98	19.32	2.502	15.80	25.60	9.80
DG⊥CG plane	11.99	12.15	1.357	9.23	14.34	5.11
DL⊥CL plane	11.19	11.23	1.282	8.64	13.26	4.62

Table 5. Results of pair t-test

Parameters	Paired differences				t	*p*-value	Change
	Mean	SD	95% CI				
			Lower	Upper			
AG-AL	-6.060	1.715	5.25733	6.86267	-15.802	<0.001*	Decrease
CG-CL	-3.600	1.792	2.76115	4.43885	-8.982	<0.001*	Decrease
PG-PL	+2.451	1.858	-3.32092	-1.58108	+5.897	<0.001*	Increase
AG⊥PG-PL	+1.255	1.894	-2.14171	-0.36829	+2.962	0.008*	Increase
AL⊥PG-PL	+2.684	1.949	-3.59654	-1.77146	+6.156	<0.001*	Increase
DG⊥CG plane	+1.109	1.001	-1.57767	-0.64033	+4.953	<0.001*	Increase
DL⊥CL plane	+1.065	0.790	-1.43506	-0.69494	+6.023	<0.001*	Increase

Table 6. Intra-class correlation coefficients amid the reproductive data

Parameters	Intra-class correlation coefficients (95% CI)	
	Pretreatment (T1)	Posttreatment (T2)
AG-AL	0.993 (0.981 to 0.998)	0.978 (0.940 to 0.992)
CG-CL	0.990 (0.972 to 0.996)	0.989 (0.970 to 0.996)
PG-PL	0.996 (0.986 to 0.998)	0.914 (0.734 to 0.971)
AG⊥PG-PL	0.998 (0.994 to 0.999)	0.993 (0.981 to 0.998)
AL⊥PG-PL	0.998 (0.994 to 0.999)	0.995 (0.986 to 0.998)
DG⊥CG plane	0.945 (0.850 to 0.980)	0.973 (0.925 to 0.991)
DL⊥CL plane	0.987 (0.963 to 0.995)	0.985 (0.957 to 0.995)

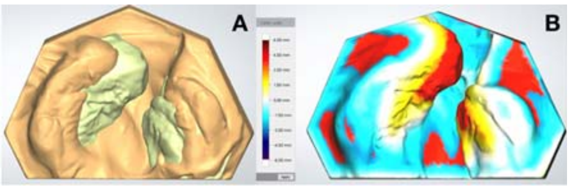

Figure 4. Superimposition (A) and color coding diagram (B).

male, 11 female) treated using KKU-PNAM therapy. Timing of cleft-defect repair also plays an essential role in treatment outcomes. All of the subjects in this study fell within the golden period (2 to 55 days) as indicated by Matsuo's study which claimed that cartilaginous and soft tissue is best molded within the first 3 to 4 months after birth; the earlier the intervention is begun-the better the results[13]. This correlates with a study by Shetty et al which made a comparison of the PNAM effect within earlier life versus treatment after this period, thus demonstrating that a favorable result was obtained when treatment was initiated within 1-month of life. Nevertheless, a desirable result was also achieved when treatment was begun within 5 months of life, but with less desirable results[14].

The three-dimensional digital imaging of dental casts is progressively gaining acceptance as an alternative to traditional direct measurement on plaster casts[15]. The recent study from Botticelli et al claimed that the laser-scanned digital cleft lip and palate models offer the potential for 3D analysis of arch dimension including linear, area, and ratio measurement[16]. In this study, we applied digital models for evaluation of dentoalveolar maxillary arch measurements in infants with unilateral complete cleft lip and palate post-treatment with the KKU-PNAM. With the three-dimensional digital image analysis described herein, it is possible to visualize treatment outcomes. The measuring points on a digital cast are simple to locate; even those points which are difficult to measure manually on a dental cast. Therefore, this technique displays advantages over the conventional method-especially with regards to error making amid measuring the vertical dimensions of the model.

The results concerning dentoalveolar arch changes in UCLP patients who received KKU-PNAM treatment were evaluated. In the transversal dimension, it was observed that the anterior cleft width (AG-AL) displayed a statistically significant decrease in all patients, which is in accordance with other researchers[9,17-19]. The anterior cleft deformity could be significantly decreased as a result of the extraoral lip strapping and the active alveolar molding plate, combined with a traction screw, followed by sequential plate changes ($p<0.001$*). Furthermore, from the inter-canine cleft width (CG-CL) measurement, the results observed a decrease in distance post-PNAM treatment coequal to anterior cleft width. Notwithstanding, these results are inconsistent with Mishima et al[17], whereby the same measurement increased. In this investigation, the posterior cleft width (PG-PL) of the dentoalveolar arch increased in the course of the two-time points. This result correlates with previous findings using the PNAM as stated by Mishima and Stellzig et al who established a significant increase in posterior cleft width[20].

In the current study, the length of the greater and lesser segments (AG/PG-PL and AL/PG-PL) increased. This implies that the maxillary segments have the potential to respond to the growth guidance provided by the PNAM appliance. Yet, these findings are not corroborated by the findings of Baek and Son in that when the length of the greater segment was reduced, the sagittal length of the greater segment increased subsequent to cheiloplasty, thus owing to later growth of the posterior alveolar segment[17,21]. Also, amid the vertical dimension, the depths of the alveolar cleft increased in both segments after treatment with the KKU-PNAM.

The superimposition and color-coding diagram in this study further confirm the clinical, and also, statistical outcomes. The color-coding presented the distances between surfaces, enabling one to state the sum of all morphological changes occurring in a given period of time. The additional benefits are to: motivate patients as they are able to visualize treatment progress, to compare the dentoalveolar arch between the beginning and end of treatment, and to evaluate cleft size prior to referring the patient for primary lip repair. For study limitations, certain confounding factors occurred between subjects, such as differing frequency of visits among subjects, duration of treatment, and age at the initial stage. Possible causes a rose from a variety of reasons ranging from socioeconomic status of caregiver, basic knowledge of parent, delays to - or poor referral systems, lack of awareness and cooperation in terms of wearing the appliance, and severity of cleft gap. Nevertheless, the true effect of the PNAM in regards doubt arising from distinguishing between therapeutic effects and natural adaptation is yet to be revealed due to the presentation of no control group, i.e. a subject group which did not receive treatment incorporating PNAM, as a consequence of ethic consideration.

Although the study demonstrated dentoalveolar arch changes post-PNAM treatment, it is important to determine the successful treatment outcome for each cleft patient; hence, the long-term benefits rendered by the KKU-PNAM protocol remain to be observed. Besides that, documentation relating to the three-dimensional imaging may serve to assist in further longitudinal studies by enabling follow-up of maxillary growth, modification to the treatment protocol, and observation of the desired outcomes.

Conclusion

The molding effect produced by the KKU-PNAM in unilateral complete cleft lip and palate patients evaluated and analyzed quantitatively using an accurate and reliable computer software program. The KKU-PNAM is an effective infant orthopedics treatment device in improving and molding maxillary arch shape. It reduces the severity of the cleft deformity-mainly at the anterior part of the maxillary arch. Moreover, more improved outcome could be achieved post-primary lip repair. A long-term evaluation and examination of the patients ought to be carry out to assess the profit of the treatment results.

What is already known on this topic?

Pre-surgical nasoalveolar molding is an appliance used among CLP patients prior to cheiloplasty. Numerous studies have reported on the measurements of the effects of various types of PNAM in relation to the maxillary arch. To date, the three-dimensional changes to the dentoalveolar arch post-treatment via the KKU-PNAM have not been studied.

What this study adds?

The present study aimed to evaluate the effectiveness of the KKU-PNAM in treating UCLP infants via the observation of 3D imagery changes to the dentoalveolar maxillary arches. Lastly, the findings of the current research are useful amid improving treatment protocol, modifying the PNAM device and possibly acting as a starting point for making comparisons of outcomes from various appliances among different centers.

Acknowledgements

This research was supported for publication by the Faculty of Dentistry, Khon Kaen University and the Center of Cleft Lip and Cleft Palate and Craniofacial Deformities, Khon Kaen University under the Tawanchai Royal Grant Project. The authors would like to sincerely thank all participants, their families, and the hospital staff who helped us carry out this study.

Potential conflicts of interest

The authors declare no conflicts of interest.

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