Three Dimensional Evaluations of Nose and Lip Morphology Changes after Presurgical Nasoalveolar Molding in Complete Unilateral Cleft Lip and Palate Infants

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This present study aimed to evaluate the changes of nose and upper lip morphology after using Khon Kaen University forehead-supported presurgical nasoalveolar molding appliance (KKU PNAM) in unilateral cleft lip and palate (UCLP) patients by three dimensional (3D) Stereophotogrammetry. Twelve infants with UCLP were treated with the KKU PNAM. Measurements using 3D facial images were performed at initial visit (T1) and before cheiloplasty (T2). Starting age of treatment was 5 to 60 days and period of treatment was 66 to 132 days. Paired sample t-test was used to compare the differences between pre- and post-therapy measurements. After the KKU PNAM treatment, significant changes were observed in the measurements at T2 compared to T1 ($p<0.05$). There were significant increases in nostril height on the cleft side, columella length, columella angle and nose protrusion. Alar base deviation and nostril width on the cleft side were significantly reduced. Moreover, the vermillion gap was also significantly decreased. In conclusions, infants with KKU PNAM offered a significant decrease in cleft lip distance and improved nose morphology which possibly could improve the surgical outcomes of primary lip and nasal reconstruction.

Keywords: *Unilateral cleft lip and palate, Presurgical nasoalveolar molding, 3D Stereophotogrammetry*

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Cleft lip and palate are the most common craniofacial birth defects affecting roughly 1.5/1,000 newborns globally[1]. Grayson et al[2] designed the presurgical nasoalveolar molding (PNAM) to aid improvement of nostril shape, supported by an intraoral obturator which intended to mold the cleft alveolar segments, and to reduce the alveolar cleft width. Berggren et al[3] and Abdiu et al[4] reported development of the nasal alar elevator using a similar treatment objective to the PNAM. In 2012, Khon Kaen University Cleft Lip and Palate Center modified PNAM from Doruk and Kilic called extraoral nasal molding appliance (ENMA)[5] which incorporates the benefits of both Grayson's and Berggren-Abdiu's appliances and created the Khon Kaen University PNAM appliance (KKU PNAM)[6].

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In the past few years, 3D technology has evolved rapidly in dentistry. The evolution of 3D digital photo cameras (stereophotogrammetry) can be used to capture multiple images of the soft tissue surface of the face with correct geometry and texture information[7]. Singh et al[8,9] evaluated 3D changes in nasal morphology in patients with unilateral cleft lip and palate (UCLP) treated with PNAM using digital stereophotogrammetry to capture 3D facial images. However, this method is still not widely used due to the high expenses[10]. The purpose of this present study was to evaluate 3D changes of nose and upper lip morphology after treating UCLP patients with the KKU PNAM.

Material and Method

Study population

This present study consisted of 12 infants (3 boys and 9 girls) with complete UCLP whom sought care at the Tawanchai Cleft Center of the Faculty of Medicine, Khon Kaen University. Patients with systemic diseases, general disabilities, craniofacial or other syndromes were excluded from the study. Patients

who had received cheiloplasty and closed to normal position of lip, nose and alveolar cleft gap ≤2 mm were also excluded. The average age of the patients when starting KKU PNAM therapy was 27 days (range 5 to 60 days) (Table 1).

Treatment protocol of the study

The treatment protocol of the present study was adapted from Manosudprasit et al[6]:

Visit 1

1.1) History taking, clinical examination, diagnosis and treatment plan.

1.2) Advising treatment process to parents and obtaining the consent form.

1.3) Taking records at initial visit including:

1.3.1) Taking three dimensional surface images by the Morpheus 3D scanner; and

1.3.2) Taking impression for study model.

1.4) Applying lip strapping and forehead type of nasal molding device (Fig. 1).

1.5) Providing lip strapping kit to parents, and giving an advice on oral hygiene care, how to use and take care of devices.

Visit 2

2.1) After 2 weeks, the devices would be adjusted.

2.2) Taking impression for working model and then constructing active alveolar molding plate.

2.3) Inserting active alveolar molding plate and advising parents to activate the retraction screw with rate twice a day.

2.4) Applying lip strapping and forehead type of nasal molding device.

Visit 3

3.1) Following-up every 2 to 4 weeks (making new devices if the active alveolar molding plate is activated to close but alveolar cleft width is still wide).

3.2) About 2 to 3 months after the treatment, treatment outcomes would be assessed.

3.3) Taking records before referring the patients for cheiloplasty including:

3.3.1) Taking three dimensional surface images by the Morpheus 3D scanner; and

3.3.2 Take impression for study model.

Visit 4

4.1 Refer for cheiloplasty and gingivoperio steoplasty.

Table 1. Demographics data

Demographic data	Complete UCLP patients (n = 12)
Gender, n (%)	
Males	3 (25)
Females	9 (75)
Age at start of treatment, range (Mean ± SD) (days)	5 to 60 (27.4±18.4)

Fig. 1 A Neonate with the KKU PNAM in position.

Data collection and measurements

3D facial photographs of the patients were created by a 3D optical scanning system (Morpheus 3D; Morpheus Co, Gyeonggi, Korea) combined with Facemaker® computer software (Facemaker, Morpheus). All landmarks were digitized by the same investigator. Measurements of nose and upper lip in 3D surface images were performed at the initial visit (T1) and after using the KKU PNAM (T2) in order to evaluate changes of nose and upper lip morphology.

The measurements included alar base width (ABW), alar base deviation (ABD), nostril width on the cleft side (NWC), nostril height on the cleft side (NHC), columella length (CL), columella angle (CA),

nose protrusion from submersible (NPS), and vermillion gap (VG) (Table 2, Fig. 2).

Statistical analyses

SPSS version 16® (Statistical Package for Social Sciences for Windows) was used in data analyses. The changes of nose and upper lip morphology between T1 and T2 were presented as means and standard deviations (SD). The paired *t*-test was used to evaluate changes in the measurement lines. All *p*-values were two-tailed with 95% confidence intervals.

This research project was approved by the Ethics Committee on Human Research, Khon Kaen University (HE592130).

Results

Each measurement was made on 3D facial photographs at the initial visit (T1) and post treatment (T2) with the KKU PNAM (Fig. 3).

The changes of nose morphology

Changes in nose and lip morphology measurements from T1 to T2 are displayed in Table 3.

Discussion

In the year 2005, Doruk and Kilic[5] used an orthopedic plate with their extra oral nasal (elevator) molding appliance (ENMA). It consisted of a headband supported a nasal stent which made from 0.8 mm stainless steel incorporating a helical spring. The KKU PNAM adopted a modified system consisting of three parts. First, the nasal elevator or lift was applied to both nostrils for better control of columella shape and to reduce over correction of septal deviation from a one-sided nasal elevator. Second, a traction screw was incorporated in the alveolar molding plate which would accelerate the alveolar gap closing due to daily home activation. Grayson et al[2] designed the PNAM which consisted of an intraoral obturator aiming to reduce the alveolar cleft width. However, their appliance was bulky when inserted into mouth and difficult to breast-feed a baby compared to the KKU PNAM. Third, a protocol was developed, in which only strapping and nasal molding device were used for the first 2 weeks then the alveolar molding plate was added later. Our protocols were inspired by Berggen et al[3], followed-up by Abdiu et al[4], who developed the nasal alar elevator with lip tape which have been used since 1996, and Monasterio et al[11], reported the use of nasal elevator with elastic connection to a plastic base taped to the baby's forehead together with DynaCleft® labial strapping and without intra-oral plate. In a clinical trial, Monasterio et al. found that their treatment results compared closely with their use of the Grayson PNAM. They claimed simplicity of their appliance with benefits over Grayson's PNAM, including: being less invasive because there is no need to produce an expensive custom-made molding appliance; easy handling for parents; and do not require a dental specialist. Unlike Grayson's PNAM, the KKU alveolar molding plate and the nasal retractor are separate, and being easy to fabricate from a simple forehead impression[5].

The assessment of changes of lip/nose morphology using PNAM can be done in many ways. Previous literature had reported many methods of measurement. Pai et al[12] measured directly from photos, whilst Ezzat et al[13] and Gomez et al[14] used digital photographic measurements of casts. Measurements from photos are easy and convenient but do not provided 3D morphology of the patient and

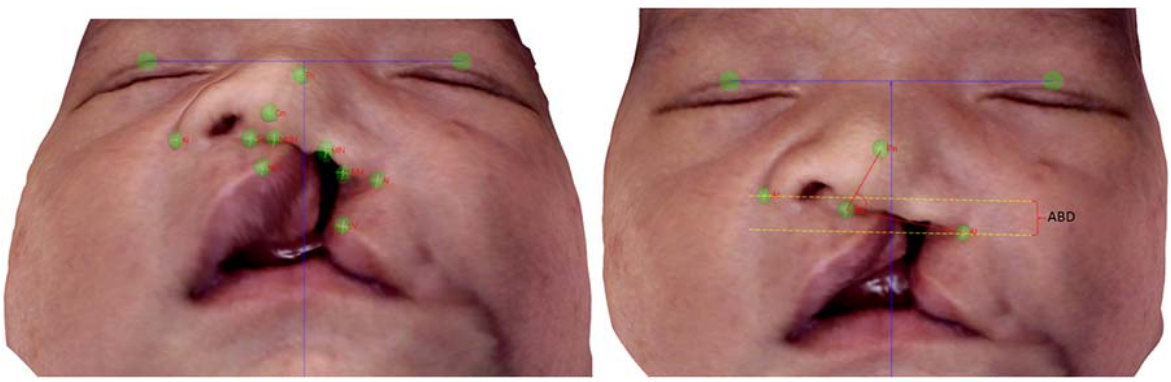

Fig. 2 Location of nose and upper lip landmarks and measurement lines.

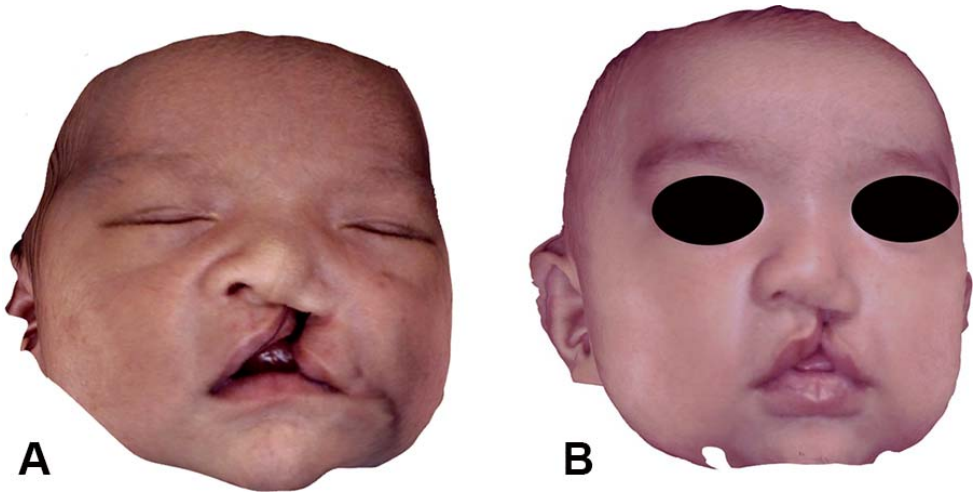

Fig. 3 (A) Before treatment at the age of 3 days, (B) After complete KKU PNAM at 102 days of age.

inherent photographic errors, especially distortion from pressure exerting on to soft tissue structure in case if impression was made. The effect of nasal impression pressure on the nose included increased nasal width whilst decreased nasal height. In this present study, we performed an indirect measurement on the infant's lips and nose using a 3D stereophotogrammetry. These photographic methods enable 3D reconstructions of the images of solid objects[15]. These techniques offer a number of distinct advantages, namely minimal invasiveness, rapid capture speeds (often under one second) without exposure to radiation, and the ability to archive images for subsequent analyses. In addition, a high degree of image precision and accuracy is possible for clinical use[16]. Dindaroglu et al[17] evaluated the accuracy of 3D stereophoto grammetry by comparing with direct anthropometry and digital photogrammetry methods. This study concluded that measurements using 3D stereophoto-grammetry were consistent with both direct anthropometric and 2D photogrammetric measurements with high intra-observer and inter-observer reproducibility. Ghoddousi et al[18] assessed the accuracy of measurements, recorded by 3D stereophotogrammetry, by comparing three methods of facial measurements, including: manual anthropometry; 3D stereophotogrammetry; and 2D photography. They concluded that the degree of accuracy of the 3D stereophotogrammetric system was very satisfactory and the variability of the 3D measurements was marginally less than that of the manual measurements and significantly less than that of the 2D measurements. In 1999, Maull et al[10] performed a study using 3D nasal casts of 20 UCLP patients after lip repair, 10 of whom had received the PNAM. A significant difference was found in the mean asymmetry index scores, indicating that 4.5 years after lip repair of the PNAM group, they remained more symmetrical than the control group. Moreover, Singh et al[8] evaluated 3D changes in nasal morphology in 10 patients with UCLP. Digital stereophotogrammetry was used to capture three-dimensional facial images, and x, y, and z coordinates of 28 nasal landmarks were digitized. This study indicated that bilateral nasal symmetry was improved after using the PNAM. Singh et al., in 2007[9], compared the 3D facial morphology in 15 UCLP patients surgically corrected after the PNAM and 10 non-cleft control subjects. They concluded that, at one month follow-up, 3D facial morphology in the treated UCLP patients was almost indistinguishable from the control group.

Changes of alar base width between the initial visit (T1) and at the end of treatment (T2) were maintained which could be attributed to natural growth. Singh et al[8] also reported no significant change in alar base width when utilizing digital 3D stereophoto grammetry to evaluate changes in nasal morphology in 10 UCLP patients undergoing Grayson PNAM therapy. Other studies have been controversial in their findings of changes in alar base width. Gomez et al[14], using digital photographic measurements of casts of nose and lips in 30 UCLP patients treated with Grayson PNAM for 100 days, found an increase in nasal width. On the other hand, Kecik and Enacar[19], using 3D imaging of casts, found a significant decrease in the total alar base width compared to before treatment.

Table 2. Definition of the measurement of nose and upper lip

Measurement (mm)	Definition
ABW	The measurement between the most infero-lateral points of the alar (Al-Al)
ABD	The difference between vertical levels of right and left alars
NWC	The direct distance between the most medial nostril margin and the most lateral nostril margin on the cleft side (MNM-LNM)
NHC	The distance from the midpoint on the inner rim of the nostril perpendicular to nostril width line on the cleft side (MIN-NWC)
CL	The distance between midline base of nose and the most antero-superior of the columella (Sn-Cm)
CA	Angular measurement between the columella axis and the base of nose on the cleft side (Pn-Sn-Al)
NPS	The measurement from subnasale to pronasale (Sn-Pn)
VG	The distance of the most medial point on the vermilion border to the most lateral point on the vermilion border on the cleft side (MV-LV)

Table 3. Differences of nose and lip morphology between pre- (T1) and post- (T2) KKU PNAM therapy for 12 subjects

Nose	Mean±SD	Range	95% CL	Change: Increase/ Decrease	*p*- value
Alar base width (ABW) (mm)	-0.59±1.96	-3.80 to 2.90	-1.84 to 0.66	No change	0.32
Alar base deviation (ABD) (mm)	-1.19±1.12	-3.00 to 0.40	-1.90 to -0.48	Decrease	0.004*
Nostril width on the cleft side (NWC) (mm)	-1.46±2.04	-4.40 to 2.30	-2.75 to -0.16	Decrease	0.03*
Nostril height on the cleft side (NHC) (mm)	2.16±1.40	0.60 to 5.20	1.27 to 3.05	Increase	0.002*
Columella length (CL) (mm)	1.53±1.56	0.30 to 5.40	0.55 to 2.52	Increase	0.002*
Columella angle (CA) (degree)	18.79±1.57	4.30 to 60.10	8.81 to 28.77	Increase	0.002*
Nose protrusion from subnasale (NPS) (mm)	1.80±1.25	0.10 to 3.80	1.02 to 2.58	Increase	0.000*
Vermillion gap (VG) (mm)	-5.15±3.58	-11.60 to 1.20	-7.43 to -2.87	Decrease	0.000*

* indicates a statistically significant difference ($p<0.05$)

Changes of nostril width on the cleft side in the present study were significantly decreased when treated with the KKU PNAM. This result concurs with many publications[8,13,19-21] which used different types of the PNAM. Pai et al[12], using measurements directly from photos of 57 mixed complete and incomplete UCLP treated with Grayson PNAM, reported a decrease in the width of the cleft nostril by 50% with improved symmetry after treatment with the PNAM. The finding of nostril height increase on the cleft side in the present study agrees with other studies using Grayson PNAM[12-14,20,21]. Columella length was increased in our study. This concurs with Liou et al[20] who studied 25 Taiwanese infants with UCLP treated with Grayson PNAM. They found that the columella length was significantly increased comparing to before PNAM treatment. After using the KKU PNAM in the present study, columella angle were significantly improved. This is consistent with Gomez et al[14], who reported correction of the deviation by 14.6° after using the PNAM. The improvement of angulation was also reported in others studies[12,13,19]. Meltzer et al.[22] suggested that this columella angle provides a rapid mean of assessing changes in nasal morphology as a result of PNAM.

The KKU PNAM increased nose protrusion (from subnasale to vertical tangent to nose tip) between T1 and T2. On the contrary, Singh et al[8] and Gomez et al[14] observed no significant changes at the tip of the nose (Prn-Sn). This might be due to the use of separate nasal molding of the KKU PNAM as opposed to using nasal molding device attached to the alveolar molding plate which might exert less force than the independent nasal elevator. Treatment with the KKU PNAM

produced a significant decrease in the soft tissue lip gap from T1 to T2. This result agrees with previous findings using PNAM with strapping from Ezzat et al[13] and Kecik and Enacar[19] who found a significant reduction in cleft width. Interestingly, Kirbschus et al[21] and Mishra et al[23] also found a significant reduction in cleft width, even though strapping was not incorporated in their PNAM system.

The limitations of this study may arise from the general limitations of all PNAM studies that have not yet provided sufficient evidence of long-term benefits for ULCP patients. There has been general criticism of the study methods examining the effects of PNAM that must also include the KKU PNAM. Grayson and Garfinkle[24], and Hathaway and Long[25] agreed in simultaneous publications in 2014 that, so far, there have been no randomized clinical trials that can provide adequate clinical evidence of special benefits of PNAM. These authors have expressed the need for such prospective clinical trials. Another limitation is that this present study had a relatively small number of patients so that its particular findings of changes of naso-labial morphology may not represent a substantial population of unilateral cleft lip and palate patients treated with the KKU PNAM.

Conclusion

This study aimed to evaluate the effectiveness of KKU PNAM in treating 12 UCLP patients by 3D Stereophotogrammetry on pre-surgical changes of nose and upper lip morphology. Measurement changes between the initial and complete treatment indicates improvement in nasal and lip morphology which possibly could improve the surgical outcomes of primary lip and nasal reconstruction. However, this present study only demonstrated short-term nose and lip results. Further studies are needed to evaluate continuing and long-term controlled clinical trial outcomes after the treatment and to determine the frequency and severity of residual dental malocclusions, the number of nose and lip revisions, and the need for secondary bone grafting.

Remark

This patient's parents gave permission by signing the consent form for the use of all clinical photographs in this report for publication.

What is already known on this topic?

Previous studies have reported many methods of measurement to assess the effects of nasal-alveolar molding appliance. This is the first study to use3D morphology of the patients and inherent photographic errors.

What this study adds?

The present study was to evaluate the effectiveness of the KKU PNAM in treating UCLP patients by measuring the changes of nose and upper lip morphology using 3D Stereophotogrammetry to avoid any distortion caused by processing such as errors during facial impressions and during photographic conversion.

Acknowledgements

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Potential conflicts of interest

None.

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การเปลี่ยนแปลงรูปร่างจมูกและริมฝีปากภายหลังการปรับแต่งจมูกและสันเหงือกก่อนการทำศัลยกรรมในผู้ป่วยทารกปากแหว่งเพดานโหว่ด้านเดียวสมบูรณ์ ด้วยการประเมินแบบ 3 มิติ

มนเทียร มโนสุดประสิทธิ์, เอกสิทธิ์ มโนสุดประสิทธิ์, สิริญา ภัทรศิริพร

การศึกษานี้มีวัตถุประสงค์เพื่อประเมินการเปลี่ยนแปลงของรูปร่างจมูกและริมฝีปากบนภายหลังการปรับแต่งจมูกและสันเหงือกก่อนการทำศัลยกรรม ในผู้ป่วยปากแหว่งเพดานโหว่ด้านเดียวสมบูรณ์ ด้วยวิธีสเตอริโอโฟโตแกรมเมตรีแบบสามมิติ ทารกจำนวน 12 คน ได้รับการรักษาด้วยการดัดแปลงเครื่องมือ ปรับแต่งจมูกและสันเหงือก ก่อนการทำศัลยกรรมชนิดยึดบริเวณหน้าผากของมหาวิทยาลัยขอนแก่น (KKU PNAM) ทำการวัดโดยใช้ภาพถ่ายใบหน้าแบบ 3 มิติ ก่อนเริ่มการรักษา (T1) และก่อนการทำศัลยกรรมตกแต่งริมฝีปาก (T2) อายุเริ่มต้นก่อนการรักษาคือ 5-60 วัน และช่วงระยะเวลาของการรักษา 66-132 วัน สถิติแพร์ แซมเปิล ที เทสต์ ถูกนำมาใช้เพื่อเปรียบเทียบการวัดก่อนและหลังการรักษา หลังจากการรักษาด้วย KKU PNAM มีการเปลี่ยนแปลง อย่างมีนัยสำคัญทางสถิติในการวัดที่ T2 เมื่อเทียบกับ T1 ($p<0.05$) พบว่ามีการเพิ่มขึ้นอย่างมีนัยสำคัญทางสถิติของความสูงรูจมูกด้านรอยแยก ความยาวโคลัมเมลลา มุมโคลัมเมลลา และความยื่นของจมูก ขณะที่ส่วนเบี่ยงเบนฐานจมูกและความกว้างรูจมูกด้านรอยแยก มีค่าลดลงอย่างมีนัยสำคัญทางสถิติ นอกจากนี้ขนาดรอยแยกริมฝีปากบน มีค่าลดลงอย่างมีนัยสำคัญทางสถิติ โดยสรุปทารกที่รักษาด้วย KKU PNAM สามารถลดระยะทางของช่องว่างริมฝีปาก และทำให้รูปร่างจมูกดีขึ้น ซึ่งอาจจะสามารถช่วยให้ผลของการทำศัลยกรรมตกแต่งริมฝีปากและจมูกดีขึ้น