# Effectiveness of the Nasal Creator Device after Cheiloplasty in Patients with Cleft Lip and Palate as Measured by 3D Stereophotogrammetry

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*Objective: To evaluate nostril morphology post-cheiloplasty after patients with unilateral cleft lip and palate (UCLP) use of the nasal creator device. Study Design: This is a prospective study. Sixteen patients with non-syndromic UCLP treated at Khon Kaen University underwent cheiloplasty and then wear the nasal creator device for 6 months. Three-dimensional images were taken, from which 5 lines and 8 landmark points were evaluated prior to (T0) and 1 day (T1), 1 month (T2), 3 months (T3), and 6 months (T4) after cheiloplasty. A Repeated Measure ANOVA was used to evaluate nostril changes between time periods and a paired t-test was used to compare values between the affected and non-affected side at T4 (P < .05). Results: On the affected side, the nostril height significantly increased from T0 (2.46±0.89 mm) to T4 (4.22±1.03 mm), and the nostril width significantly decreased from T0 (9.46±2.57 mm) to T4 (7.34±1.41 mm). On the non-affected side, the nostril height significantly increased from T0 (3.39±0.78 mm) to T4 (4.65±1.07 mm), and the nostril width was not significantly different from T0 (6.00±1.25 mm) to T4 (6.59±0.95 mm). The alar base width was not significantly different between T0 (30.18±2.72 mm) and T4 (29.82±1.69 mm). Nostril height and width were not significantly different by T4 when comparing the affected and non-affected sides. Conclusion: Using nasal creator device for 6 months significantly increased the nostril height and decreased nostril width and alar base width after cheiloplasty.*

*Keywords: cheiloplasty, unilateral cleft lip and palate, nasal creator device, 3D stereophotogrammetry*

## INTRODUCTION

Cleft lip and palate (CLP) is the most common structural abnormality to affect children in the embryonic period. Incidence is about 2.49:1,000 in the Northeast of Thailand.1,2 CLP occurs when the maxillary process and the medial nasal process fail to fuse in the 4th to 8th week of development. This can result in discrepancies and displacement of the nasomaxillary complex, along with the upper lip, alveolus, palate, and nose and can adversely affect respiration, mastication, swallowing, and speech.3-5

Patients with unilateral cleft lip and palate (UCLP) have nasal asymmetry due to a shortened columella, downturned nose tip, flat and elongated alar base, and missing nasal floor on the affected side.6 Research on satisfaction with overall facial appearance, in addition to upper lip, profile, and anterior teeth, of patients with unilateral cleft lip and palate has shown that the nose is considered least satisfactory.7 To correct the nasal deformity, a procedure is carried out to move the alar cartilage to a normal position, improving the normal vault and shape of the cartilage.8 A preoperative nasoalveolar molding (PNAM) and a nasal retainer are used to resolve nasal morphology.9 Nevertheless, after cheiloplasty, there is some relapse

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in alar cartilage position due to scar contraction.8 Therefore, post-operative maintenance of the corrected nose shape calls for using the nasal retainer for 3-6 months.10,11 In 2018, nasal creator device was designed and manufactured by Khon Kaen University Cleft Lip and Palate Center (Figure 1A, 1B, 1C, 1D). The device is made from medical silicone, and it is user friendly, esthetic, reasonably priced, and has been developed for self-retention and with available sizes according to patients' needs.

Therefore, this study used 3D stereophotogrammetry in order to evaluate the effectiveness of the nasal creator device in stabilizing shape of nostril in patients with UCLP who have undergone cheiloplasty. The outcomes of this study can be used as baseline information informing the design of future protocol.

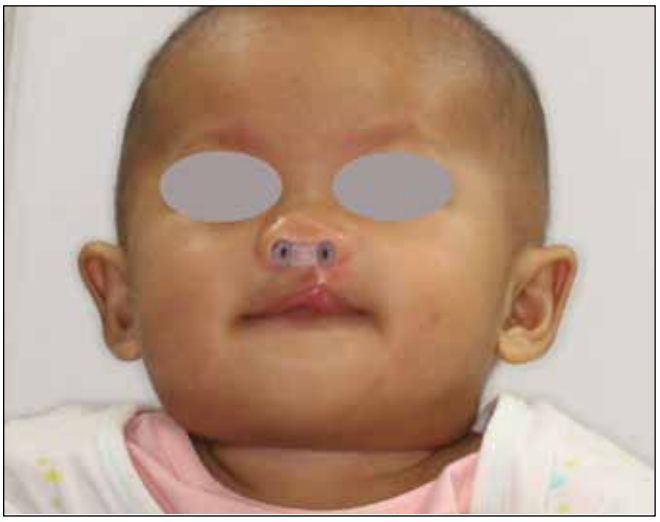
## MATERIALS AND METHOD

### Study population

This study was approved by the Ethics Committee for Human Research, Khon Kaen University (HE611596, IRB00001189).

The subjects were 16 patients aged 3-9 months who had been treated at KKU Cleft Lip and Palate Center from March 2019 to March 2020. All patients participating in this study were selected by consecutive sampling. Patients with a systemic disease that could interfere with soft tissue healing with associated craniofacial malformations or other syndromes, or who had already received cheiloplasty were excluded from the study. Cheiloplasty was executed by a consistent group of surgeons at Srinagarind hospital. After cheiloplasty, the patients were required to wear nasal creator device approximately 24 hours per day except when cleaning for 6 months (Figure 2). Their parents could remove and insert this device directly with no special equipment required. The devices require the same method of cleaning as a bottle of milk.

**Figure 2: Nasal creator device worn by patient with UCLP**



### Data collection and measurement

Three-dimensional surface images were evaluated prior to (T0) and 1 day (T1), 1 month (T2), 3 months (T3), and 6 months (T4) after cheiloplasty. The tools used to create 3D facial photographs were a 3D optical scanning system (Morpheus 3D; Morpheus Co, Gyeonggi, Korea) combined with Facemaker computer software (Facemaker;

**Figure 1: The nasal creator device. A, Front view. B, Side view. C, Package. D, Available sizes**

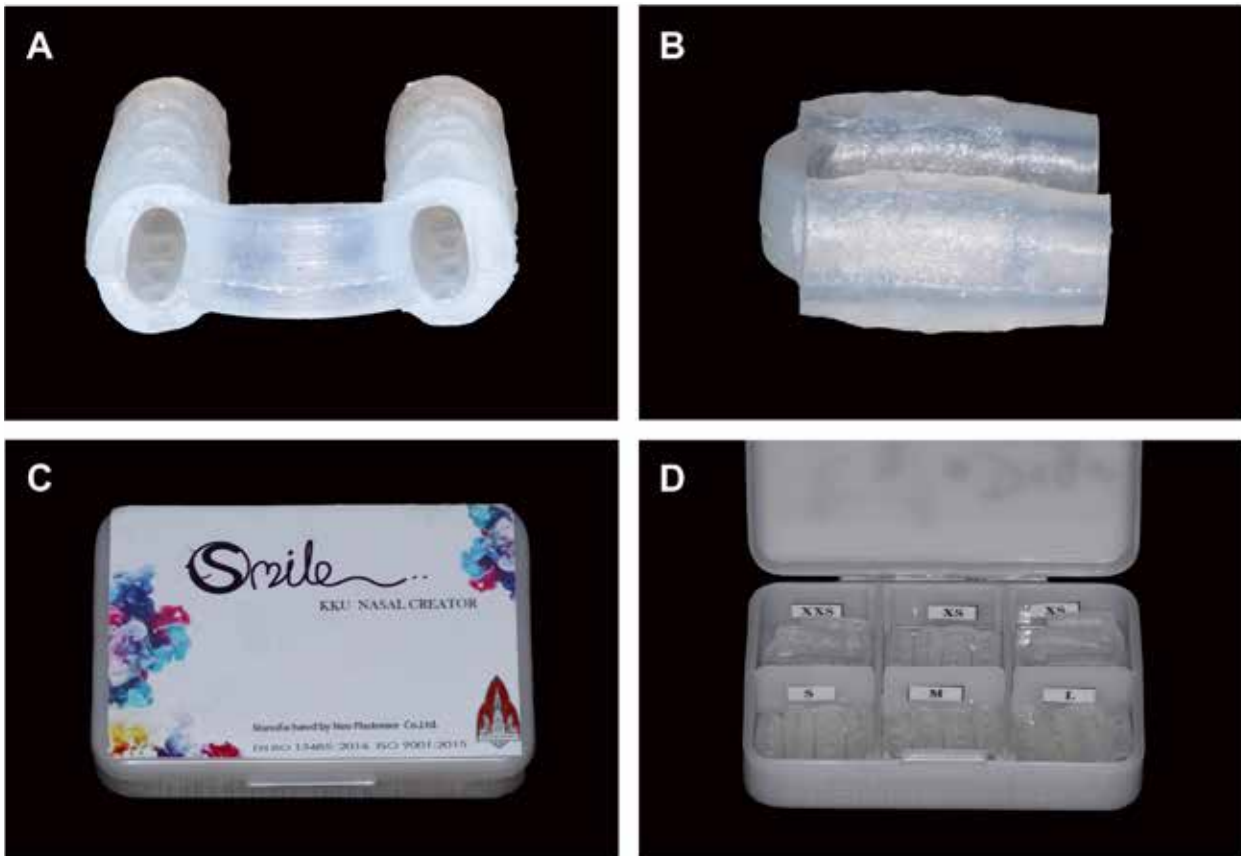


**Figure 3: Landmark positioning on three-dimensional surface images and measurements. A and B, Before cheiloplasty. C and D, After cheiloplasty and using nasal creator device for 6 months**

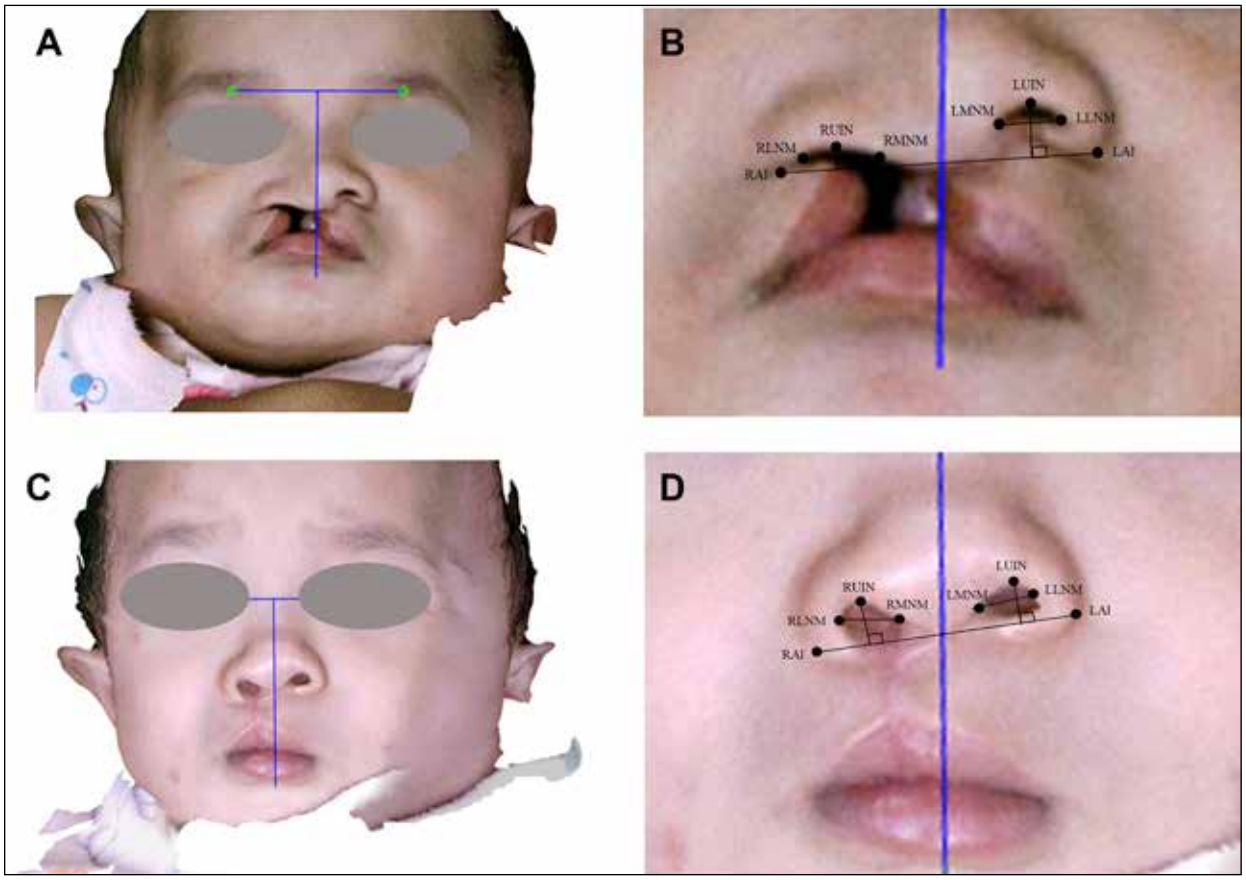



**Table 1: The description of 8 Landmark points**

| Landmarks | Point | Location |
|---|---|---|
| RAI | Right alare | The most infero-lateral point on the right alar contour |
| LAI | Left alare | The most infero-lateral point on the left alar contour |
| RUIN | Right upper inner rim of the nostril | The midpoint on the inner rim of the nostril on the right side |
| LUIN | Left upper inner rim of the nostril | The midpoint on the inner rim of the nostril on the left side |
| RMNM | Right medial nostril margin | The most medial nostril margin on the right side |
| LMNM | Left medial nostril margin | The most medial nostril margin on the left side |
| RLNM | Right lateral nostril margin | The most lateral nostril margin on the right side |
| LLNM | Left lateral nostril margin | The most lateral nostril margin on the left side |

Morpheus).12 For this study, 5 lines, including alar base width, nostril height on the right and left sides, and nostril width on the right and left sides, are drawn from 8 landmark points (Table 1, 2).13,14 The five linear measurements were made directly on each three-dimensional surface image, as shown below (Figure 3).

**Table 2: The 5 lines detected in this study**

| Landmarks | Line |
|---|---|
| RAI-LAI | Alar base width |
| RUIN□RAI-Lal | Nostril height on the right side |
| LUIN□RAI-Lal | Nostril height on the left side |
| RLNM-RMNM | Nostril width on the right side |
| LLNM-LMNM | Nostril width on the left side |

## Statistical analysis

SPSS (Statistical Package for Social Sciences for Windows; IBM Corp., Armonk, New York), Version 22, was used in data analysis. A Repeated Measure ANOVA was used to evaluate nostril changes between time periods, and a paired t-test was used to compare values from the affected and non-affected side at T4. Results were considered significant at $P < 0.05$.

The Intraclass Correlation Coefficient (ICC) was calculated to assess intra-examiner reliability for all 3D images, with repeated assessment by the same examiner after 1 month. Substantial reproducibility was found, with ICC values ranging from 0.850 to 0.986.

## RESULTS

**Table 3: Demographic data**

| Gender (n) | Left UCLP | Right UCLP | Total |
|---|---|---|---|
| Male | 5 (83.3%) | 1 (16.7%) | 6 (37.5%) |
| Female | 8 (80%) | 2 (20%) | 10 (62.5%) |
| Total | 13 (81.2%) | 3 (18.8%) | 16 |
| | Mean±SD | Minimum | Maximum |
| Age (months) | 5.5±1.93 | 3 | 9 |
| Weight (before cheiloplasty) (kg) | 7.89±1.79 | 4.5 | 11 |
| Height (before cheiloplasty) (cm) | 70.38±7.78 | 58 | 83 |

Abbreviations: UCLP, unilateral cleft lip and palate

This study was performed on 16 subjects, including 6 males and 10 females. The age range was 3 to 9 months before cheiloplasty, with a mean age of 5.5 months. The study sample's demographic data is shown in Table 3.

**Table 4 Linear measurements of nostril morphology prior to (T0), 1 day (T1), 1 month (T2), 3 months (T3), and 6 months (T4) after cheiloplasty**

| Nostril morphology | T0 (Mean±SD) | T1 (Mean±SD) | T2 (Mean±SD) | T3 (Mean±SD) | T4 (Mean±SD) | P-value | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | T0-T1 | T0-T2 | T0-T3 | T0-T4 | T1-T2 | T1-T3 | T1-T4 | T2-T3 | T2-T4 | T3-T4 |
| Nostril height (mm) | | | | | | | | | | | | | | | |
| affected side | 2.46±0.89 | 5.16±1.39 | 4.59±1.35 | 4.02±1.61 | 4.22±1.03 | .000* | .000* | .010* | .005* | .672 | .129 | .250 | .111 | 1.000 | 1.000 |
| non-affected side | 3.39±0.78 | 5.06±1.48 | 4.76±1.47 | 4.32±0.78 | 4.65±1.07 | .002* | .021* | .003* | .011* | 1.000 | .354 | 1.000 | 1.000 | 1.000 | 1.000 |
| Nostril width (mm) | | | | | | | | | | | | | | | |
| affected side | 9.46±2.57 | 6.40±1.29 | 6.50±1.41 | 6.25±1.36 | 7.34±1.41 | .004* | .013* | .006* | .036* | 1.000 | 1.000 | .678 | 1.000 | .101 | .074 |
| non-affected side | 6.00±1.25 | 5.87±1.36 | 5.81±0.89 | 6.18±0.87 | 6.59±0.95 | 1.000 | 1.000 | 1.000 | 1.000 | 1.000 | 1.000 | 1.000 | 1.000 | .411 | 1.000 |
| Alar base width (mm) | 30.18±2.72 | 25.14±1.66 | 27.17±2.28 | 28.34±2.37 | 29.82±1.69 | .000* | .015* | .058* | 1.000 | .000* | .000* | .000* | .043* | .000* | .016* |

*Statistically significant differences between times (in row)

**Table 5 UCLP nostril morphology measurements at T4 comparing affected and non-affected sides**

| Variable (mm) | Affected side | Non-affected side | Paired differences (95% CI) | | | |
|---|---|---|---|---|---|---|
| | Mean±SD | Mean±SD | Mean±SD | Lower | Upper | P Value |
| Nostril height | 4.22±1.03 | 4.65±1.07 | -0.56±1.26 | -1.23 | 0.11 | 0.097 |
| Nostril width | 7.34±1.41 | 6.59±0.95 | 0.73±1.81 | -0.23 | 1.69 | 0.127 |

Abbreviations: T4, 6 months after cheiloplasty; UCLP, unilateral cleft lip and palate; CI, confidence interval.

On the affected side, the nostril height showed a significant increase from T0 to T4 and the nostril width showed a significant decrease from T0 to T4. On the non-affected side, the nostril height showed a significant increase from T0 to T4 and the nostril width was not significantly different from T0 to T4. The alar base width was not significantly different between T0 and T4 (Table 4). Patients with UCLP' nostril height on their affected side (4.22±1.03 mm) was not significantly different from nostril height on their non-affected side (4.65±1.07 mm) by 6 months after cheiloplasty (T4) (P = 0.097), and nostril width was also not significantly different by T4 when comparing the affected (7.34±1.41 mm) and non-affected sides (6.59±0.95 mm) (P = 0.127) (Table 5).

## DISCUSSION

Prior to cheiloplasty, the study sample's mean weight were 7.89 kg and mean height were 70.38 cm which conformed to the Thai standard. Male infants had a weight range of 6.3-8.4 kg and height range of 62.4-69.2 cm, and female infants had a weight range of 5.8-7.9 kg and height range of 60.9-69.1 cm.15 This confirmed that all subjects are in normal growth and development.

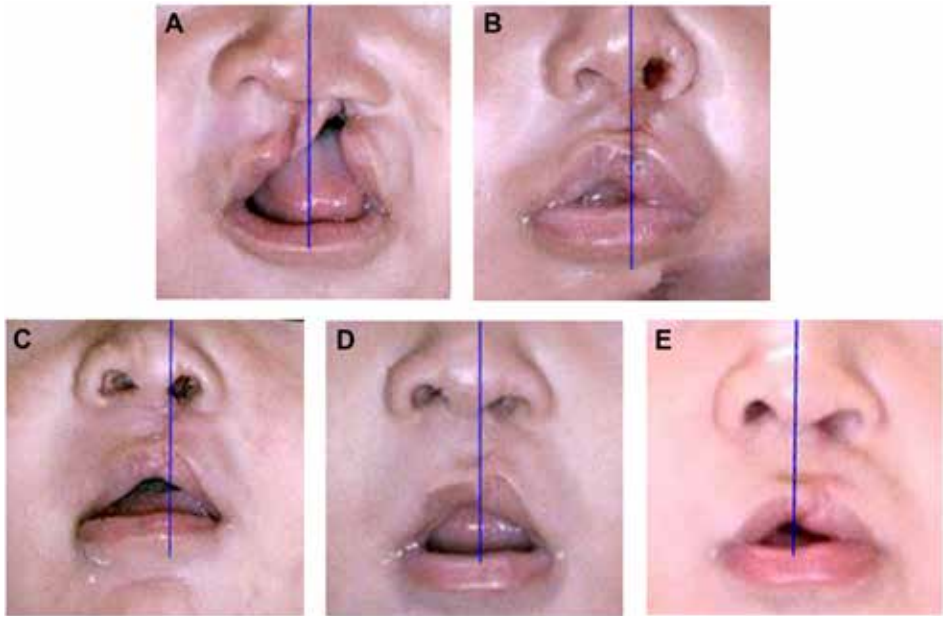
The lip repair operation, cheiloplasty, relieves increasing lip pressure that is found to be harmful to craniofacial growth.16,17 However, some relapse in the position of the alar cartilage occurs owing to scar contraction or tissue memory. As a result, several authors have recommended the use of postoperative nasal stent after cheiloplasty, enabling maintenance of the corrected nasal position and improving the results of the operation by limiting the effects of scar contracture, breaking off any memory of the displaced lower lateral cartilage, and generally guiding development.8,10,18-20 It is suggested that the nasal stent be placed immediately after the operation, as immediate postoperative placement helps the nasal cartilage to heal in the corrected position and leads to a more satisfactory nostril shape in the long-term.8,21 Several studies have shown that long-term use of the nasal retainer, 24 hours per day outside of daily cleaning for 3-6 months, sustains the corrected nasal cavity.6,8,9,10,18,19,22

To achieve retention of the nasal retainer, sometimes called a nostril retainer, nasal stent, or nasal conformer6,18,19,20-22, some studies have recommended using adhesive silicone or adhesive tape.23,24 Use of the imported nasal retainer at our center has had a number of disadvantages, including the expensive cost of importing the device and improper device sizes for our patients. Additionally, due to poor retention, micropore tape must be used with the imported device, leading to clinical problems such as esthetic issues and allergic reactions to the tape. Therefore, one of the properties of the nasal creator device used in this study is self-retention, decreasing the need for tape usage and the resulting allergies. The nasal creator device is made from medical silicone which can be easily manipulated and adjusted, reducing compressive force from the device relative to the hard-acrylic device.8 Moreover, it is prepared as a pre-form device and available in sizes covering all patients in a 3-12month age range.

In this study, the nostril height of the affected side significantly increased from T0 to T4 but decreased from T1 to T4. These results are in line with those of Pai et al. and Funayama et al 6,25, who

**Figure 4 Using nasal creator device with kinesiology tape. A, Frontal view. B, Submentovertex view. C, kinesiology tape.**


**Figure 5 Nostril morphology. A, Before cheiloplasty (T0). B, After cheiloplasty 1 day (T1). C, After cheiloplasty 1 month (T2). D, After cheiloplasty 3 months (T3). E, After cheiloplasty 6 months (T4).**



attributed that nostril height dramatically decrease 3 months after cheiloplasty and infants often unable to tolerate postoperative devices. Most parents or caregivers are shown to compromise by only using the nostril retainer when the infants are asleep or not using the device at all times. However, in some non-cooperative patients, parents were advised to apply kinesiology tape to gain more retention (Figure 4). Nevertheless, nostril height of the affected side was not significantly increased from T3 to T4. The nostril width on the affected side, increase from T3 to T4 and alar base width exhibited a significant increase from T1 to T4. There is some relapse in nostril width and alar base width in the first year after cheiloplasty.6,26,27 In the present study, patients with UCLP' affected and non-affected sides were compared at the final stage of evaluation (T4), and no significant difference between either nostril height or width was found. Hence, the present nasal creator device can improve the affected nostril so that it is closely in line with the non-affected nostril (Figure 5).

There was no complication among 16 patients following cheiloplasty and using nasal creator device for 6 months. But we found clinical problem in some patient with inadequate retention and kinesiology tape was need to be used. For this reason, it is necessary to develop a new version of the device.

Lip repair is essential in order to enhance patient with CLP's appearance, speech, occlusion, and quality of life. To sustain satisfactory results, clinicians should plan carefully and motivate the parents to use the device with their infants after lip repair. The findings from this study are important in determining further treatment protocol for patients with CLP, such as protocol involving the use of a nasal retainer for improving the affected nostril after cheiloplasty. The limitation of this study was small sample size and short-term evaluation. Also, the device in this study should be developed for better self-retention. Further studies are needed to include more subjects and long term follow up of more than 6 months to confirm that the results are not temporary.

## CONCLUSION

The nasal creator device used in this study for 6 months significantly increased the nostril height and significantly decreased the nostril width after cheiloplasty. These provide better esthetic outcome, reduce severity of nostril deformity, and may decrease nose revision surgery.

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