ASSESSMENT OF MAXILLARY ARCH CHANGES AND NASOLABIAL ESTHETICS FOLLOWING PRIMARY LIP REPAIR IN PATIENTS WITH COMPLETE UNILATERAL CLEFT LIP AND PALATE USING NASOALVEOLAR MOLDING THERAPY

THANAPORN PATTANAWASIN

A Thesis Submitted to the Graduate School of Naresuan University
in Partial Fulfillment of the Requirements
for the Master of Science Degree in Dentistry
2025

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Thesis entitled "Assessment of maxillary arch changes and nasolabial esthetics following primary lip repair in patients with complete unilateral cleft lip and palate using nasoalveolar molding therapy"

by Thanaporn Pattanawasin

has been approved by the Graduate School as partial fulfillment of the requirements for the Master of Science Degree in Dentistry of Naresuan University

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Keywords	Cleft lip, Cleft palate, Nasoalveolar molding, Nasolabial, Primary lip repair, 3D model

ABSTRACT

Background: Complete unilateral cleft lip and palate (UCLP) is characterized by pronounced facial asymmetry resulting from maxillary arch displacement and nasolabial deformity. Presurgical nasoalveolar molding (NAM), combined with primary lip repair, aims to guide maxillary growth and enhance nasolabial symmetry. However, the combined effects on three-dimensional (3D) maxillary arch development and nasolabial esthetics remain insufficiently explored. This study aimed to evaluate 3D changes in maxillary arch morphology and nasolabial esthetic outcomes following primary lip repair in patients with complete UCLP.

Methods: This retrospective-prospective cohort study comprised two parts.In the maxillary arch morphology component, 25 infants with complete UCLP underwent modified NAM therapy prior to primary lip repair. Digital maxillary models were obtained at two time points: T1 (on the day of primary lip repair, aged 3–6 months) and T2 (on the day of palate repair, aged 9–18 months). Three-dimensional linear and angular measurements were conducted to assess transverse, sagittal, and vertical dimensional changes. Paired t-tests or Wilcoxon signed-rank tests were used based on data distribution, with a significance threshold of $p < 0.05$. Morphological changes were visualized via digital model superimposition using stable posterior maxillary landmarks.In the nasolabial esthetics component, 22 infants with complete UCLP who had undergone NAM therapy before primary lip repair were included. Nasolabial esthetics were evaluated using nasal and perioral symmetry indices, along with the Asher–McDade rating scale. Standardized two-dimensional facial photographs were taken post-primary lip repair 1-4 weeks (Tn1) and at the 6 month follow-up (Tn2). Symmetry ratios were measured using ImageJ software, based on predefined anatomical landmarks and reference planes. All measurements were performed by calibrated, blinded examiners. Intra- and inter-rater reliability were assessed using intraclass correlation coefficients (ICC). Perceptual esthetics were evaluated by three independent plastic surgeons, with repeated ratings to ensure reliability.

Results: In the maxillary arch morphology analysis, significant changes were observed in the transverse and sagittal dimensions. The anterior cleft width significantly decreased (mean difference = -0.95 mm, p = 0.001), while the anterior and posterior arch widths significantly increased (mean differences = 1.81 mm and 0.99 mm, respectively). Both greater and lesser segment lengths increased, and medial rotation of the greater segment was noted. Vertical dimension changes were not significant. Superimposition revealed medial movement of the greater segment and cleft gap narrowing.In the nasolabial esthetics analysis, significant improvements were found between Tn1 and Tn2. Nasal symmetry parameters improved, demonstrating better transverse and vertical nasal symmetry and midline alignment. In the perioral region, philtrum height symmetry significantly increased, while cupid's bow width, inter-commissure distance, and vermillion height ratios remained stable. These results indicate marked improvement in nasal symmetry and selective enhancement in perioral symmetry, with stable transverse oral dimensions during early growth.

Conclusions: Primary lip repair promotes coordinated early skeletal and soft tissue adaptation, evidenced by significant maxillary arch remodeling and nasolabial symmetry improvement. The strong interrelationship between skeletal development and soft tissue esthetics emphasizes the importance of integrated early cleft management.

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Thanaporn Pattanawasin

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CHAPTER I

INTRODUCTION

Background and rationale for the study

Orofacial clefts are one of the most common congenital anomalies. The prevalence of orofacial clefts such as cleft lip and cleft palate in Thailand was 2.14 per 1,000 live births (1). The form and severity of cleft lip and palate vary widely (2, 3). The notable clinical feature of unilateral cleft lip and palate is asymmetry of the face caused by displacement of the anterior part of the maxillary arch (4) and larger clefts have been associated with more severe nasolabial deformities (2).

Cleft lip and palate (CLP) infants need treatment by the multidisciplinary team to restore normal anatomy and function by improving dentition, speech, swallowing, hearing, and psychosocial issues (5-7). The treatment for patients born with completed unilateral cleft lip and palate should start with nasoalveolar molding (NAM) to guide the maxillary growth and reduce the severity of the initial cleft deformity (8-10). Moreover, NAM was found to be an efficient way to enhance nasal symmetry and was able to repair the inadequate nasal cartilage before surgical repair of the lip (11). The unilateral deformity of the lip and nose displays a special challenge to the surgeon in achieving symmetry (12). Nowadays, there are different types of NAM techniques with different mechanics to achieve different objectives (13). Pattanalak Center uses NU-NAM (Naresuan University nasoalveolar molding) which was modified from NAM used at Chang Gung Memorial Hospital (14, 15). After finishing using NAM, the next procedure is cheiloplasty or primary lip repair for rehabilitation of the normal anatomy of the lip by reduction of lip gap and other abnormal appearances of the lip such as large or protruding lip (16). However, the severity of scar contraction after primary lip repair may restrict following growth of the maxillary arch and affect the benefits of using NAM (9).

For evaluating the maxillary arch change, linear measurements in dental casts have been used frequently (17). Recently, there is three-dimensional analysis offers much more information, and three-dimensional images reduce human measurement errors and may be examined and studied at any time (18).

As part of the evaluation of nasolabial esthetics, there are many methods used in previous studies. Some studies measure directly on patients. For indirect measurement techniques involve evaluating the symmetry of the nasolabial region using nasal cast, two-dimensional photographs, and three-dimensional stereophotographs. Moreover, many authors reported about esthetic perception by using the Asher-McDade rating scale or other rating scales.

Most of the studies relating to the unilateral cleft lip and palate are mainly focused on the effectiveness of NAM, especially the change of maxillary arch dimensions. Moreover, most studies focus on evaluating nasolabial esthetics on only nasal symmetry, perioral symmetry or perception. Just a few studies investigated both the maxillary arch developed and nasolabial esthetics after primary lip repair in unilateral cleft lip and palate using NAM. Thus, this clinical study aims to evaluate three-dimensional changes in the maxillary arch dimensions between pre and post-primary lip repair and to evaluate nasolabial esthetics after primary lip repair and six months of follow-up in complete unilateral cleft lip and palate patients.

Research questions

1. What are the maxillary arch dimensions and nasolabial esthetics after primary lip repair in complete unilateral cleft lip and palate patients?

2. Are there any differences in the maxillary arch dimensions in complete unilateral cleft lip and palate patients who received NAM between pre and post-primary lip repair?

3. Are there any differences in nasolabial esthetics in complete unilateral cleft lip and palate patients after primary lip repair and six months of follow-up?

4. Are there any correlations between maxillary arch dimensions and nasolabial esthetics after primary lip repair in complete unilateral cleft lip and palate patients?

Research objectives

1. To describe the maxillary arch dimensions and nasolabial esthetics after primary lip repair in complete unilateral cleft lip and palate patients.

2. To evaluate three-dimensional changes of the maxillary arch dimensions in complete unilateral cleft lip and palate patients who received NAM between pre and post-primary lip repair.

3. To evaluate the symmetry and perception of nasolabial esthetics in complete unilateral cleft lip and palate patients after primary lip repair and six months of follow-up.

4. To describe the correlations between maxillary arch dimensions and nasolabial esthetics after primary lip repair in complete unilateral cleft lip and palate patients.

Research hypotheses

1. There are change of the maxillary arch dimension after primary lip repair in complete unilateral cleft lip and palate infants.

2. There are more symmetry and perception of nasolabial esthetics in complete unilateral cleft lip and palate infants after primary lip repair.

3. There are correlations between maxillary arch dimensions and nasolabial esthetics after primary lip repair in complete unilateral cleft lip and palate patients.

Expected results

1. To consider the change of the maxillary arch dimension after primary lip repair in complete unilateral cleft lip and palate infants.

2. To consider more symmetry and perception of nasolabial esthetics in complete unilateral cleft lip and palate infants after primary lip repair.

3. To consider the correlations between maxillary arch dimensions and nasolabial esthetics after primary lip repair in complete unilateral cleft lip and palate patients

Scopes of the study

This clinical study is designed to investigate and evaluate the development of maxillary arch dimensions and nasolabial esthetics after primary lip repair in complete unilateral cleft lip and palate infants at the Faculty of Dentistry, Naresuan University and Pattanalak Center, Naresuan University.

Keywords

Cleft lip, Cleft palate, Nasoalveolar molding, Nasolabial, Primary lip repair, 3D model

CHAPTER II

LITERATURE REVIEW

Among congenital anomalies in neonates, craniofacial abnormalities are one of the most frequent. The most prevalent congenital abnormality of the head and neck is cleft lip and palate combined. Clefts can be categorized as syndromic or non-syndromic. Typically, CLP are not syndromic; only 10% of infants with CLP will also have a related condition. But in infants affected by cleft lip (CL) who do not have cleft palate (CP), 30% will have an associated syndrome (3). CLP can vary widely in form and severity (2, 3).

Clinical feature in a patient with unilateral cleft lip and palate (2, 4, 5, 12)

The clinical features of patients with unilateral cleft lip and palate are described as follows:

- Alveolar part: greater alveolar segment protrusive and deviated toward the unaffected side.

: lesser alveolar segment always be missing alveolar bone and soft tissue because of a cleft.

- Nasal part : widened and asymmetric nasal tip

: asymmetric with widened nostril on the cleft side

: caudal septum and columella deviate toward the unaffected side.

: the alar of the nose on the cleft side is enlarged and depressed.

- Lip part : separated lip segments

Figure 1 Patient with unilateral cleft lip and palate

Source: Grayson BH and Maull D (2)

The treatment of patients with cleft lip and palate

Patients with CLP are treated with many procedures goal of restoring the congenital abnormality anatomically, functionally, and aesthetically (6, 19, 20). Recent years have seen a significant evolution due to improved surgical procedures, timing, and the integration of presurgical orthopedics (20). The treatment modalities in the management of unilateral cleft lip and palate are listed in Table 1 (21).

Table 1 The treatment modalities of unilateral cleft lip and palate in the first year of life (21)

Timing	Procedures
Neonatal/Before cleft lip repair	Presurgical infant orthopedics (22)
3-6 months of age	Cleft lip repair (23, 24)
9–12 months of age	Cleft palate repair (25)

Presurgical infant orthopedics

Presurgical orthopedics was introduced in 1950 by McNeil as the appliance for controlling the alignment and correction of maxillary arch segments in cleft patients (26).

NAM appliance is the new appliance introduced by Grayson et al. that is used as presurgical orthopedics for reducing the severity of the initial cleft space and deformity at the lip, maxillary arch, and nose, before primary lip repair, tip rhinoplasty and palatoplasty (2, 15, 27, 28). NAM comprises a variety of devices and protocols (28).

Type of NAM

The NAM is classified into active or passive depending on the forces required.

1. Active appliances - Active appliances have mechanical that apply traction to the alveolar segments to move them into the normal position by using components such as elastic chains, screws, or plates (20).
2. Passive appliances - Passive appliances deliver no force to the alveolar segments. The plates have just maintained the distance between the two maxillary segments and mold the alveolar segments in an expected position (20).

Examples of NAM techniques

Nowadays many modified appliances are used for different objectives such as: Modified presurgical NAM technique (14) and NU-NAM (15)

A modified presurgical NAM consists of a molding plate with nasal stent (Figure 2A) and extra-oral taping. This molding plate was created using maxillary models that had all undercuts blocked out with wax. A nasal stent wire (0.032-inch TMA) was embedded into the plate and bent wire into a coil in the middle with a bean shape in an acrylic nasal bulb. An acrylic nasal bulb is coated with soft acrylic to prevent irritation. Whereas NU-NAM uses a stainless steel wire (0.036-inch) and a hard acrylic only to construct an acrylic nasal bulb. The plate was placed in the mouth and the nasal stent soft acrylic was placed in the medial alar wall of the nose on the affected side. Extra-oral taping requires one steri-strip to be placed from one side of the cheek to the other (Figure 2B). The adjustment was done once every 2 weeks to activate the nasal bulb instead of once a week.

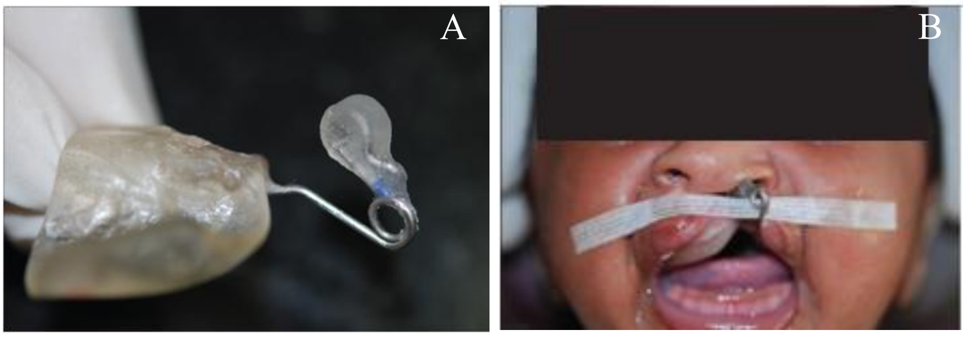

Figure 2 (A) Modified nasoalveolar molding with acrylic nasal bulb (B) Infant with nasoalveolar molding device and extraoral taping

Source: Subramanian C.S., et al. (14)

Figure 3 (A) NU-NAM (B) Infant with NU-NAM and extraoral taping

Source: Chaisooktaksin N., et al. (15)

The principal objectives and goals of NAM

The goals of NAM are to minimize the severity of the initial cleft deformity, to restore normal anatomical relationships by the approximation of labial and alveolar segments, and to optimize nasal form before surgery (2, 28). The NAM induced lip segments moved closer almost in contact at rest, also facilitating more symmetrical lower lateral alar cartilages and adequate nasal mucosal lining. Moreover, the objectives of NAM include molding the protruded premaxillary segment into normal alignment, reducing in width of the alveolar cleft segments, and also improving the shape of the maxillary arch (2, 27). The short-term effect of using NAM facilitates the task of plastic surgeons in performing primary lip repair and palatoplasty (29). However, there are arguments that NAM cannot be considered as having obvious long-term negative or positive effects on skeletal or soft tissue facial growth (28) so the long-term effects of NAM after surgical repairs are still controversial (9). Bongaarts et al. reported that NAM therapy has only a temporary effect on the maxillary arch, with no observable effect on the arch dimensions or the contact and collapse in the long-term (30). Clark et al. suggested that there was a long-term clinical improvement in nasal and lip anatomy after NAM therapy but no effect on dental arch and occlusion (31). Although there are no long-term effects in some studies, some suggest that using NAM can improve arch symmetry and stability and may prevent arch collapse in the long-term (9). The different outcomes of long-term effects in many studies may be caused by different types of NAM.

Benefits of NAM techniques

NAM technique has various benefits. NAM can be used for re-contouring the nasal cartilage on the defective side more symmetrical and columella lengthening can be done. Also, NAM can be used to mold and retract the protruded alveolar process of the maxillary arch before primary lip repair. Moreover, the effect that reducing the cleft size may promote bone formation and subsequently reduce the need for the secondary alveolar bone graft (14, 28, 32). After finishing treatment by NAM, the severity of cleft deformities is lessened, this enables the surgeon to repair the lip with minimal soft tissue tension (33). But benefits in the long-term are still controversial.

Risks of NAM techniques

There are some complications due to using NAM therapy. There are some studies (2, 20, 28, 34) reported the complications associated with NAM that can be categorized into three groups (34).

1. Soft tissue complications

The most common problem caused by using NAM is irritation of the oral mucosal or gingival tissue (2). The complications involve oral mucosal ulceration, bleeding, tissue fungal infections, and tissue irritation. Oral mucosa may be ulcerated caused by improper flanges or under-relieved areas of the acrylic molding plate and also by excessive activation of the internal surface of the appliance. Moreover, candidal infection may be the result of NAM full-time wearing due to plate contact with the oral microflora all day without being cleaned regularly (34).

Further complicated on extraoral soft tissue during extraoral surgical tape is used to align alveolar segments and induce the lip segments together is irritation on the cheek (34). Grayson and Maull suggest using skin barrier tape as a base before tape elastic retraction attachment for reducing skin irritation (2).

Nasal soft tissue may have complications. If there is more force application on some part of the nasal stent or place nasal stent is incorrectly positioned, it may cause inflammation of the intranasal epithelium (20), mega-nostril, columellar tearing, or bleeding (28, 34)

2. Hard tissue complications

Modifying the process of the internal surface of the appliance to approximate the alveolar greater and lesser segments, the lesser segment might rotate excessively so as to approach the major segment perpendicularly, resulting in an asymmetric T-shaped configuration (34). Moreover, the adverse effects include maxillary constriction, the formation of anterior and posterior crossbites, and a decrease in the size of the upper arch (28).

3. Compliance complications

The successful therapy involves a considerable commitment on the part of parents/caregivers (34). Loss of valuable treatment time if parent's compliance is poor (20). Moreover, some studies reported that there is a risk of molding plate dislodgement which may obstruct the airway (2, 20).

Primary lip repair

Primary lip repair is a surgical technique to reduce deformities in cleft patients. The most common age for surgical treatment is between 3 and 6 months old (24). The goals of primary lip repair are rehabilitation for normal anatomy, esthetic, and function of the upper lip; correction of the deformities of the nose, reconstruction of the nasal floor, and optimal alignment of the maxillary segments (16). Thus facial appearance improvement has a better psychological impact on the child and family (24). The greater amount of scar formation following lip and palate surgery may cause increased tension of scar tissue resulting in greater anterior arch constriction (9). Some studies reported that surgical repair of the lip, palate, or both has been implicated in causing midfacial retrusion (35) and maxillary arch collapse that may lead to dental crossbite (9).

Nasal conformer

Post-primary lip repair, nasal conformers (retainers) are commonly used to retain the nostril shape (11, 36) and protected postoperative relapse (37). There are many types of nasal conformers have been developed (36) (38). The general designs consist of a flexible stent made from medical silicone placed in the nasal vestibule for 3-6 months (38, 39). One defect of the nasal conformers is the need for adhesive tape to hold it in the nasal vestibule, the tape may lead to skin irritation and then following to poor compliance (37).

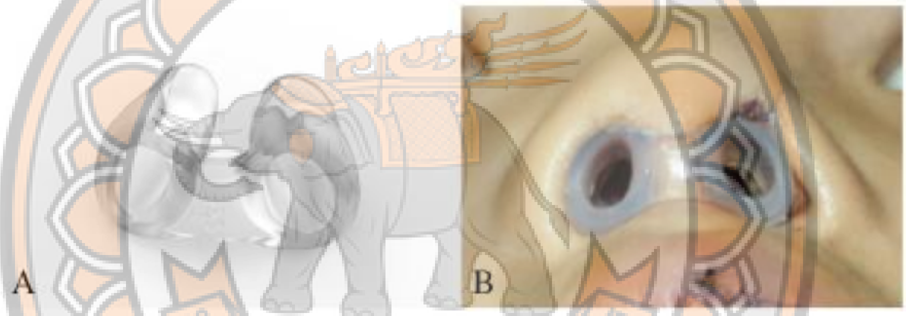

Figure 4 (A) Nasal conformer (B) Application of the nasal conformer

Source: Zhang S., et al. (37)

Palatoplasty/Palatal repair

The palatoplasty is surgery that closure the soft and hard palate and improves speech (40). The surgical techniques of modern palatoplasty will be concerned with speech development and midfacial skeletal growth. There are differences of opinion of time to palatoplasty but many studies and NUCCC accept at 9 to 12 months of age (25, 41).

The maxillary arch morphology

Some studies evaluate the maxillary arch morphology after primary lip repair (9, 16, 31, 35). Most of the studies that reported on the long-term effect of NAM focused on nasolabial appearance but few studies specifically reported on the long-term effect of NAM and used direct anthropometry to measure on dental cast or two-dimensional measurement on images (9, 31). One study reported the effect of NAM that a significant reduction in the cleft gap, and prevention of arch collapse, leads to improved, stable, and symmetric arch form at 6 years of age (9). However, the other one suggests that there was no statistically significant difference in the long-term three-dimensional anthropometric measurements on the dental arch between the NAM group and the non-NAM group (31).

Evaluating maxillary arch morphology

There are many methods for evaluating maxillary arch morphology following cleft repair.

1. Direct anthropometry on maxillary dental casts

Shetty et al. investigate the long-term effect of presurgical NAM on the growth of the maxillary arch by using a sliding caliper for linear anthropometric measurements on dental casts (9).

Figure 5 Direct linear anthropometric measurements on the maxillary arch

Source: Shetty V., et al. (9)

Dental cast analysis is simple but appears to be insufficient for observing some 3-dimensional (3D) morphologic changes and growth of cleft segments (42).

2. Three-dimensional measurement on digital models using the software

3D imaging of digital models is gaining more acceptance as an alternative to use of traditional plaster models. There are several advantages of digital models over plaster models such as reduced storage requirements, and easier viewing and retrieval. Moreover, digital models are fully calibrated so that the results are always 1:1 in real life that can using software that comes with many different features can be useful for deciding on treatment plans. So this method is much easier, less time-consuming, and has a reduced error of measurement compared to conventional procedures on plaster models (16).

Chaisooktaksin et al. evaluate the three-dimensional changes in maxillary alveolar morphology after using modified NAM in patients with complete unilateral cleft lip and palate. They conclude that the modified NAM was an effective device for reducing the alveolar cleft width while improving the alignment of alveolar cleft segments (15).

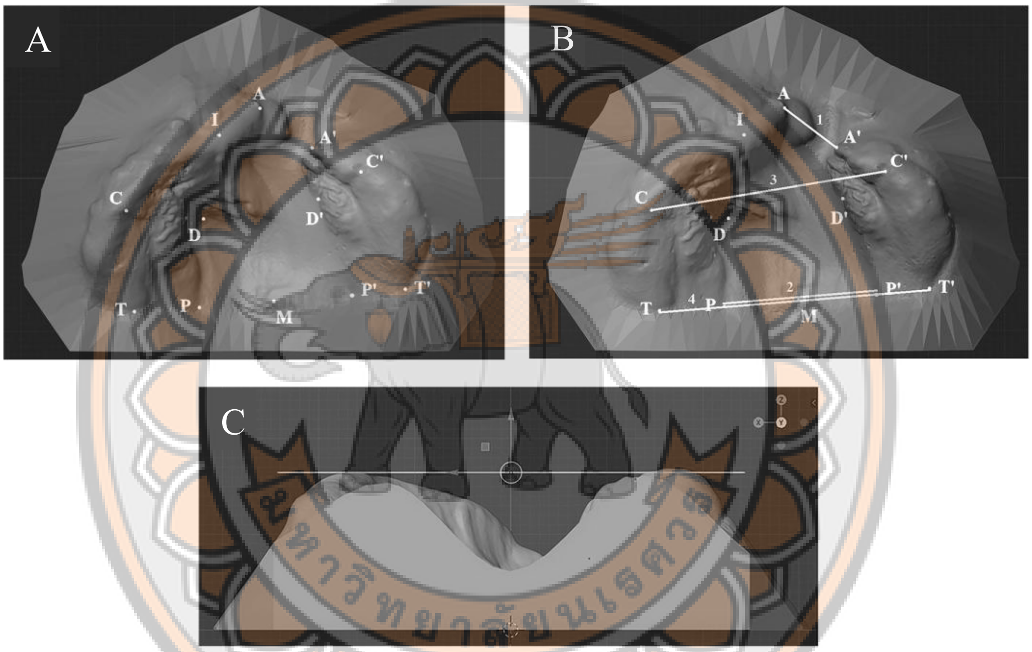

Figure 6 (A) Positioning of reference points for the measurement on 3D model (B) Transverse measurements (C) Horizontal reference plane on 3D model

Source: Chaisooktaksin N., et al. (15)

Braumann et al. analyze the growth of the edentulous maxilla of patients with complete unilateral cleft lip and palate and incomplete unilateral cleft lip and palate using a 3D digitizing system (43).

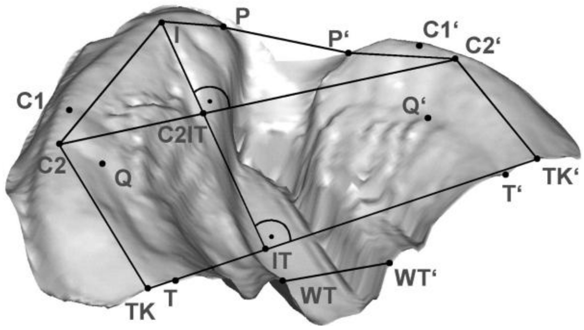

Figure 7 Measurements on 3D digitized and reconstructed surface of the upper jaw

Source: Braumann B., (43)

Baek et al. observe the alveolar molding (AM) effect and growth of UCLP patients using 3D analysis. The 3D models were constructed using a laser scanning machine and 3D software (42).

Today, there are many intraoral scanners and model scanners available on the market, such as the iTero system, CEREC system, Lava C.O.S system, Planscan system, TRIOS system, and 3Shape scanner (15, 16, 33, 44-46).

However, there are some studied reported factors such as illuminance and color temperature that can affect the trueness and precision of intraoral scanners (44).

The nasolabial appearance

Facial appearance plays an important role in social interactions and influences a person's perception of others and the quality of life (QoL) of the affected person (19). Cleft surgery aims to correct the deformity's functional and esthetics deficiencies (47). Patients with clefts who have nasolabial asymmetry have been observed to have lower esthetics scores (19).

Evaluating nasolabial esthetic

There are many methods for evaluating nasolabial aesthetics outcomes following cleft repair (28).

1. Direct anthropometry

Some studies use direct measurements of patients such as:

Mishra et al. evaluate the role of presurgical NAM in the correction of cleft lip nasal deformity for patients with unilateral and bilateral clefts of the lip. On measurements of different nasal parameters before and after lip repair, they measured on patients directly. These measurements included the height of the nostril, width of the nostril, perimeter of the alar rim, and length of the columella (48).

Suri et al. evaluate quantitative differences in presurgical presentations of alveolar alignment and nostril anatomy of infants with BCLP treated with NAM from those treated with maxillary infant orthopedics only (IO). They measure the nasal-alveolar features on anesthetized infants just before beginning surgery (49).

2. Indirect anthropometry

2.1 Nasal cast

Al-Qatami et al. compare the nasal form of unilateral cleft lip and palate patients treated with presurgical NAM therapy, primary lip-nose surgery, and postsurgical nostril retainer with patients treated with presurgical NAM and primary lip and nose surgery alone. They used anthropometric measurements on nasal cast for an accurate duplicate of the patient's three-dimensional nasal structure (50).

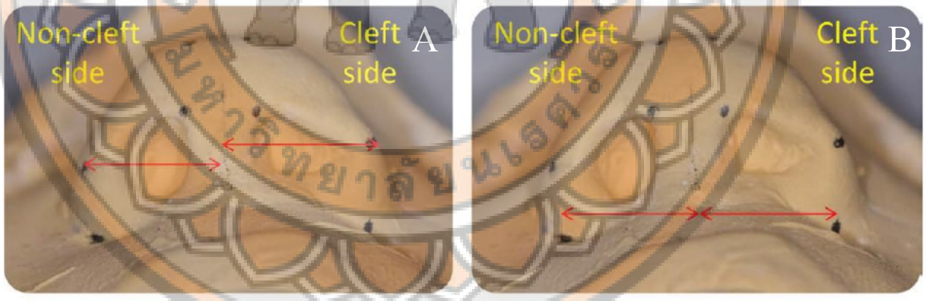

Figure 8 (A) Measurement of alar width at maximum convexity (B) Measurement of total alar base width

Source: Al-Qatami F., et al. (50)

2.2 Two-Dimensional (2D) photographs

Most of the studies use indirect measurements from 2D photographs because easy to perform and applicable in daily practice (51).

Pai et al. assess nostril symmetry and alveolar cleft width in infants with unilateral cleft lip and palate following presurgical NAM. They collect the nostril width on the affected and nonaffected side, nostril height on the affected and nonaffected side, columella—nasal base angle, and width of the alveolar cleft by measurements from the 2D photos. Nostril width and height data were used to calculate a ratio of affected to nonaffected side (52)

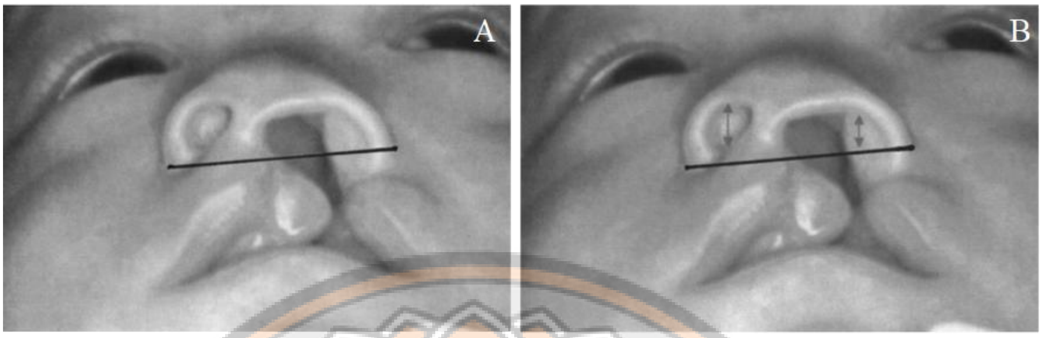

Figure 9 (A) Reference line connecting right and left alar bases (B) Height of nostril on each side

Source: Pai B.C.-J., et al. (52)

Nakamura et al. evaluated and compared preoperative and short-term postoperative nasal forms after NAM therapy followed by primary lip repair for patient with complete unilateral cleft lip and palate. The nostril height and width ratio, ratio of the height of the top of the alar groove, and curvature of the appropriate circle of the nasal ala were evaluated using color photographs (53).

2.3 Three-Dimensional (3D) stereophotographs

Nowadays the evaluation of nasolabial aesthetics by 3D stereophotogrammetry and laser surface scanning represent more developed procedures for facial anthropometric measurements (54).

Waewsanga et al. evaluate nostril morphology post-cheiloplasty after patients with unilateral cleft lip and palate use the nasal creator device by using three-dimensional surface images. They found that the nasal creator device can provide better esthetic outcomes, reduce the severity of nostril deformity, and may decrease nose revision surgery (39).

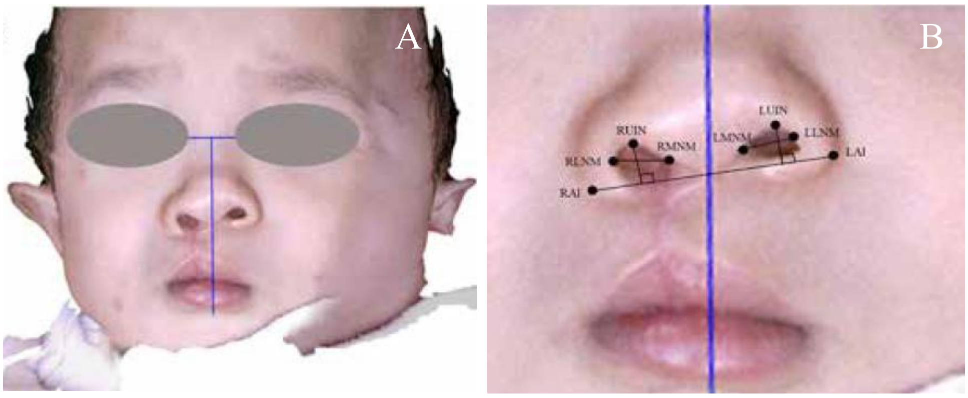

Figure 10 (A) 3D photographs in frontal views

(B) measurement on 3D photographs

Source: Waewsanga S., et al. (39)

Kumjan et al. assess the treatment outcomes of unilateral cleft lip and palate after primary surgery on nasolabial soft tissue of children ages 4-5 years old as compared with unaffected children. They measured on 3D images taken by a Morpheus 3D Scanner and measured by the Morpheus 3D program (55).

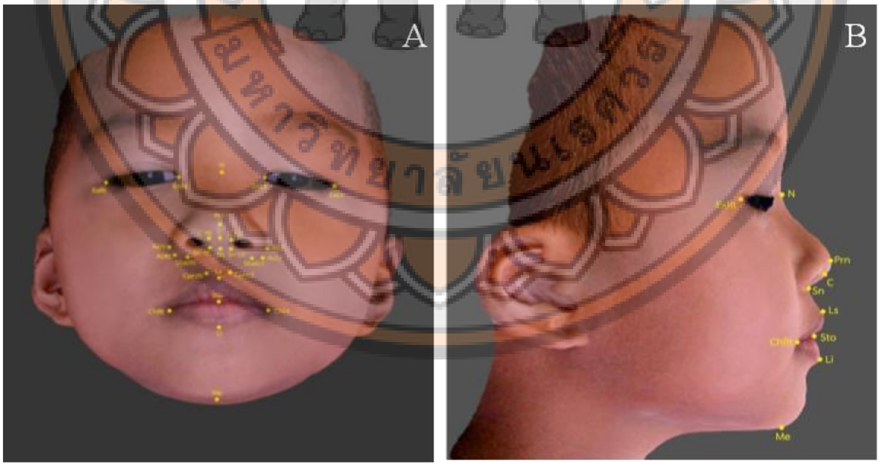

Figure 11 (A) 3D photographs in frontal views

(B) 3D photographs in lateral views

Source: Kumjan N., et al. (55)

Jahanbin et al. evaluate the effect of immediate versus delayed addition of the nasal stent to the NAM plate on the nose shape and alveolar cleft area in unilateral cleft lip and palate infants. The linear, angular, and area measurements were evaluated on the cleft side and compared with the noncleft side on 3D photo. Using 3D scanning of the entire face using Proface software to create 3D photos (56).

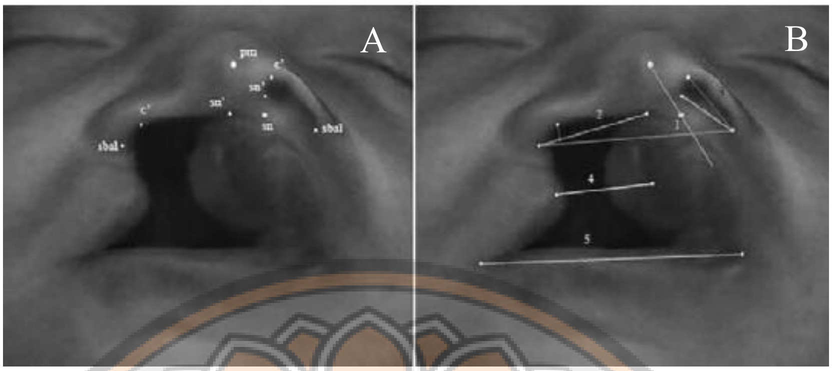

Figure 12 (A) Landmarks (B) Measurement from 3D photo

Source: Jahanbin A., et al. (56)

Kurnik et al. used both standardized clinical photographs and 3D images to assess nasal appearance following NAM and primary surgical repair for the treatment of unilateral cleft lip and palate (57).

The study by Shetty et al. evaluates nasal linear anthropometric measurements on nasal casts. However, there are some limitations of sliding calipers on plaster models for indirect anthropometry can be arduous and time-consuming. It limited evaluation to include only linear measurements without angular measurements were considered (54).

2.4 Other method

2.4.1 The Asher-McDade rating scale

The Asher-McDade scale is the method created by Asher-McDade et al. in 1991. There are 5-point ordinal scales (1=very good appearance, 2=good, appearance, 3=fair appearance, 4=poor appearance, 5=very poor appearance) are used to score the vermilion border, nasal form, nasal symmetry, and nasal profile on cropped 2D photographs (58).

Dogan et al. evaluate and compare the perception of nasolabial aesthetics by experienced professionals, inexperienced professionals, cleft patients, and laypersons in children with unilateral cleft lip and palate using the Asher-McDade Scoring System (59).

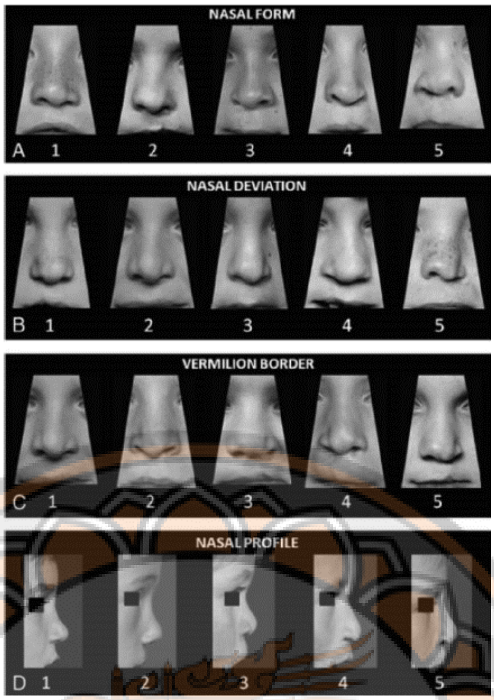

Figure 13 Asher-McDade Scoring System

Source: Dogan E., et al. (59)

Nayak et al. need to accurately compare the effect of NAM on nasolabial aesthetics, so they choose the Asher-McDade rating scale, a widely used validated scale in the studies. This scale assesses the frontal and lateral views of the nasolabial area without confounders such as other symmetries or lack of symmetry in the patient's face (60).

2.4.2 Other rating systems

Recently, in 2017 Mosmuller et al. developed the Cleft Aesthetic Rating Scale (CARS) which is a simple and reliable photographic reference scale for the assessment of nasolabial appearance in complete unilateral cleft lip and palate patients. There are 10 selected photographs of the nose and lip were used to create a sliding photographic scale. For the nose, scores ranged from A to E, and for the lip the scores ranged from 1 to 5 (Figure 6), representing a very good to very poor appearance, respectively (51).

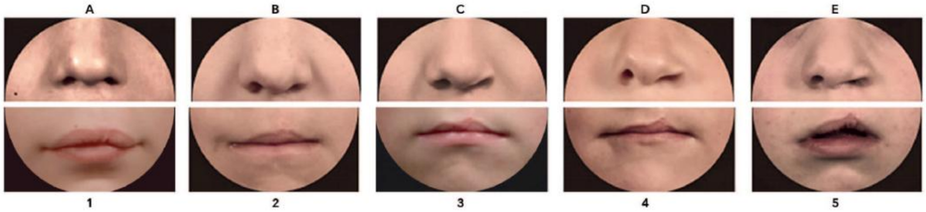

Figure 14 The Cleft Aesthetic Rating Scale

Source: Mosmuller D.G., et al. (51)

CHAPTER III

RESEARCH METHODOLOGY

Study design

The present research is a retrospective-prospective cohort study.

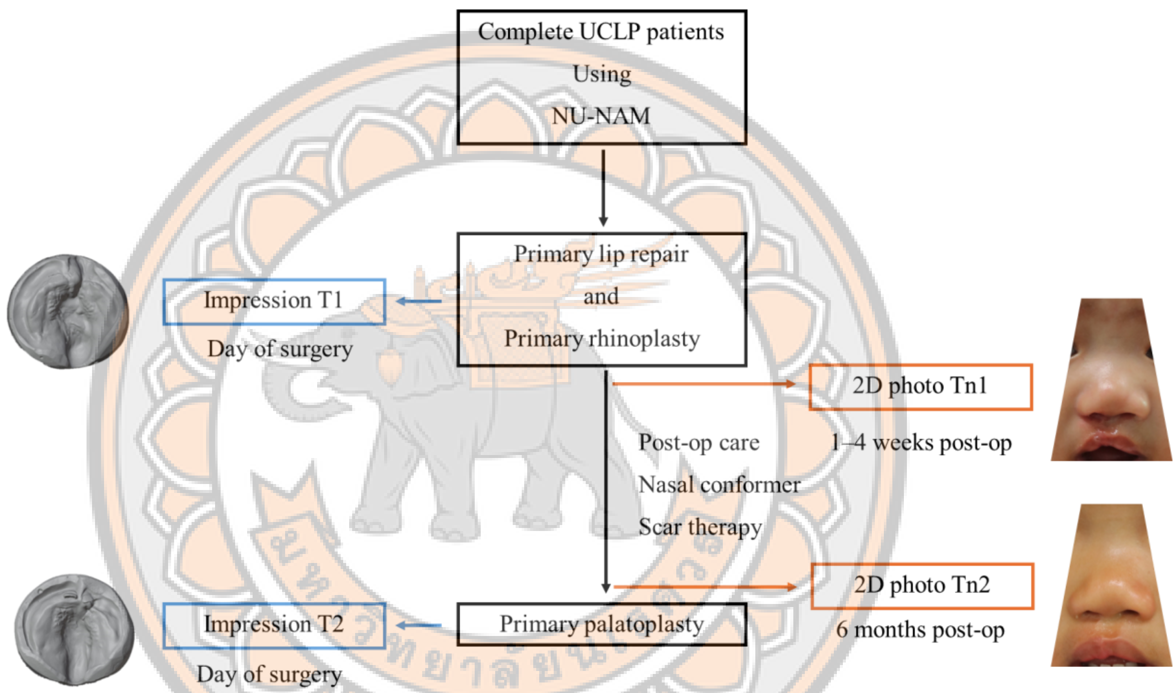

Figure 15 Research conceptual framework

NU-NAM treatment protocol

NU-NAM technique

The NAM used at the Faculty of Dentistry, Naresuan University, is NU-NAM. The NU-NAM has been modified from the NAM used in Chang Gung Memorial Hospital (Modified presurgical NAM) (14). NU-NAM comprises a passive alveolar molding plate with a nasal stent and extra-oral taping. There are differences between NU-NAM from the original, the nasal stent is made from stainless wire (0.036-inch) and both the molding plate and the nasal bulb are constructed from hard acrylic only The extra-oral taping is one long tape (3M Steri-Strip™, Micropore™ or

Transpore™). Skin barrier tapes (Tegaderm™) are used for relieving irritation on the cheeks. Additionally, NU-NAM can be inserted at the first visit.

At the first appointment, there were following procedures, history taking, extra-oral, and intra-oral clinical examinations were performed. The parents were informed about the treatment process and they signed a consent form. If the patient has good general health, NU-NAM therapy can start immediately.

The first recall visit is 1 week after insertion to check the parents' or caretakers' cooperation. If they can place the appliance and labial taping, later recall will be extended to 2-4 week intervals until the time for primary lip repair. Each recall visit only needs the nasal stent wire adjustment and does not need grinding acrylic from the molding plate because there is no acrylic in the medial aspect of the lesser and greater segments.

NU-NAM treatment was finished when the alar was overcorrected, the columella height of the nose was sufficiently lengthened and then the infant was prepared for primary lip repair and primary rhinoplasty. The impression of the maxillary arch was taken when finishing NU-NAM treatment on the day of primary lip repair for a study model (T1)

Figure 16 NU-NAM

Figure 17 NU-NAM application

Primary lip repair and primary rhinoplasty technique

After NAM treatment, all patients are referred for primary lip repair and primary rhinoplasty by a single surgeon (Assistant Professor Saran Worasakwutiphong) using modified rotational advancement of Noordhoff's technique and the Tajima procedure with overcorrection of the cleft nostril. After primary lip repair and primary rhinoplasty (about 9-12 month-old), all the patients are considerably referred for palate repair. The impression of the maxillary arch was taken on the day of palate repair at the age of 9-18 months for a study model (T2).

Figure 18 Primary lip repair and primary rhinoplasty technique

Nasal conformer protocol

After primary lip repair and primary rhinoplasty, the patients were advised to use nasal conformers to maintain nostril symmetry after surgery for at least 6 months.

Figure 19 Nasal conformer application

Samples

Samples size calculation

The sample size was calculated by using the G*Power 3.1 program (Heinrich Heine Universitat, Dusseldorf, Germany) to determine the minimum sample size. The effect size is 0.64 from the study of Pai et al. (48). The results revealed that 22 patients were required for a study with a power of 0.80 and an alpha of 0.05 and considering a drop-out rate of 10% then total sample size is 25 (58).

Inclusion criteria

1. Infants with completed unilateral cleft lip and palate who received and completed NAM treatment at the Faculty of Dentistry, Naresuan University by one orthodontist (Assistant Professor Ratchawan Tansalarak) and received and completed primary lip repair at the Faculty of Medicine, Naresuan University by one plastic surgeon (Assistant Professor Saran Worasakwutiphong) from March 2014 through December 2025
2. Infants with completed unilateral cleft lip and palate who have good general health without any syndrome, other congenital deformities, or systemic disease

3. Available clinical records and maxillary models and 2D facial imaging for analysis at four time points (pre-primary lip repair (Age between 3-6 months); T1, post-primary lip repair (Age between 9-18 months); T2, 1-4 weeks after primary lip repair; Tn1 and 6 months after primary lip repair; Tn2)

Exclusion criteria

1. Incomplete clinical records, maxillary models or 2D photographs
2. Patients who do not receive treatment at the Faculty of Dentistry, Naresuan University

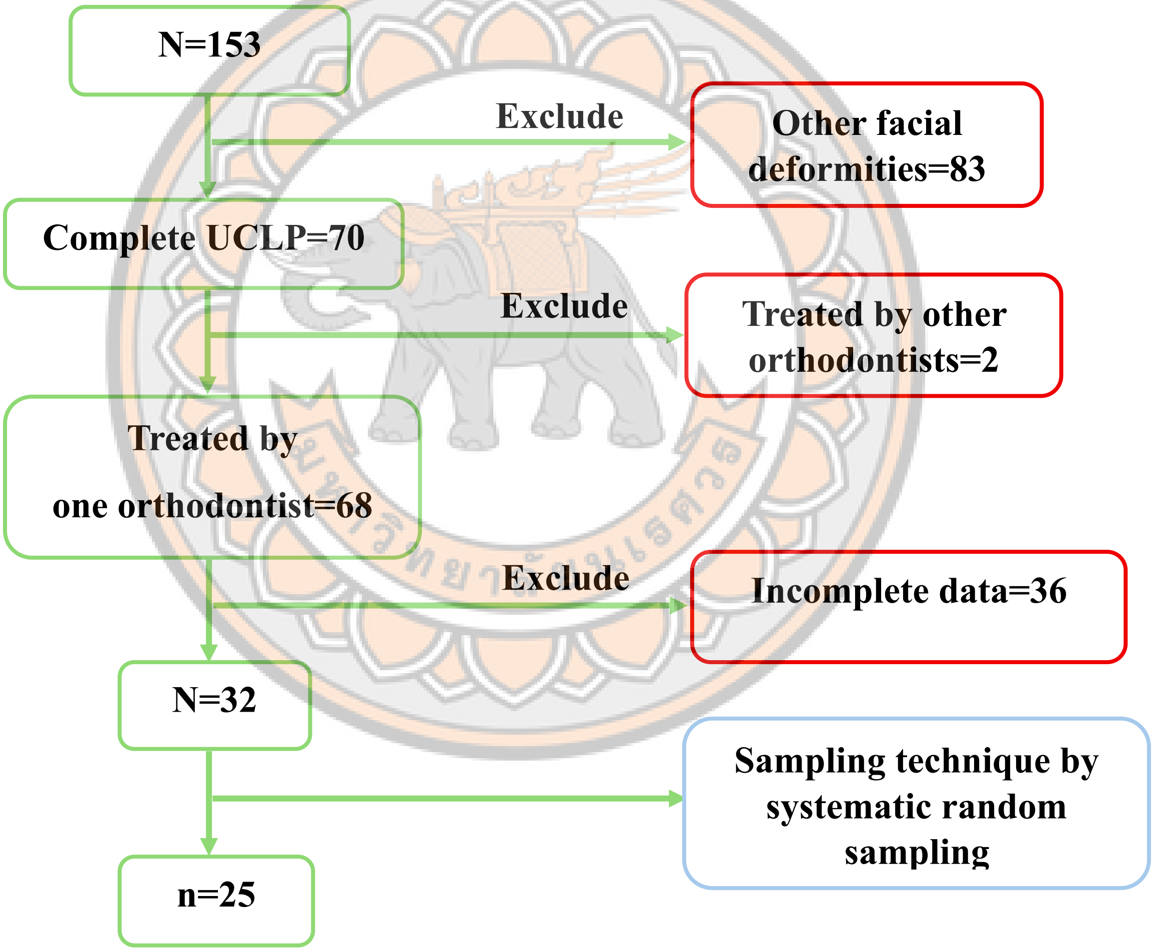

Figure 20 Flow diagram shows the patient selection process in part 1

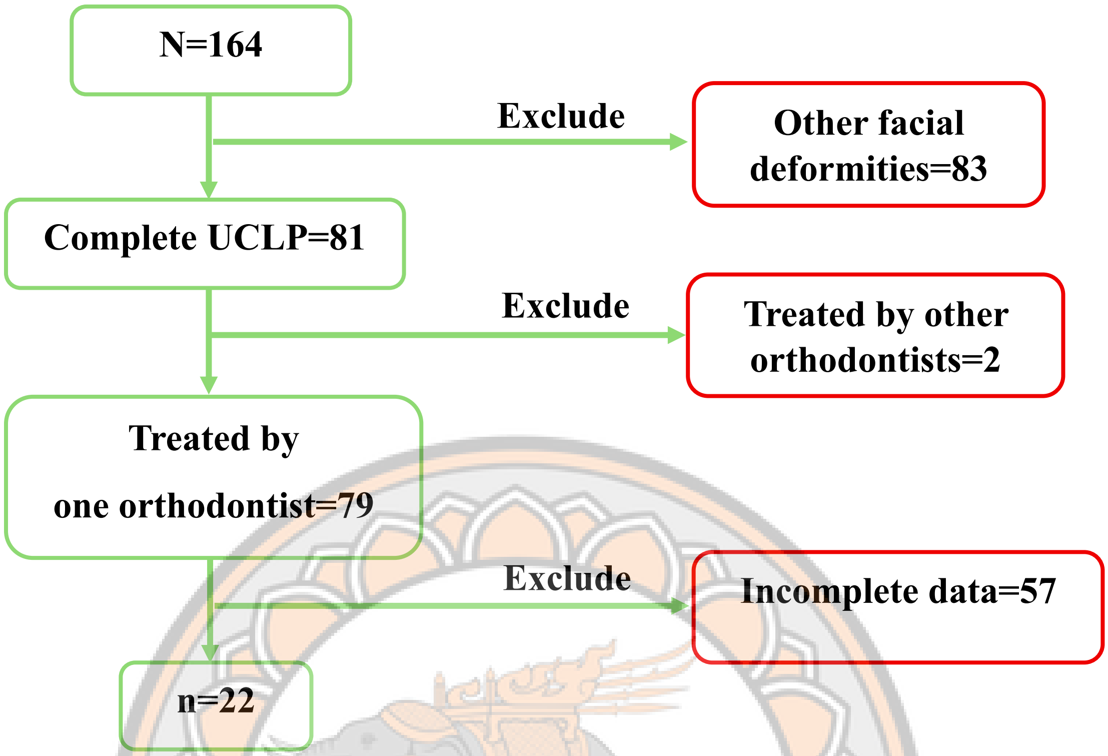

Figure 21 Flow diagram shows the patient selection process in part 2

Variables Part 1: Maxillary arch morphology change

Independent variable: NU-NAM

Dependent variable: Maxillary arch morphology changes

Confounding variables: Gender

Variation of individual growth pattern

Severity of scar contraction after primary lip repair

Complications

Materials and methods Part 1: Maxillary arch morphology change

Equipment and materials

1. iTero Element 2 Intraoral Scanner (Align Technologies, San Jose, CA/USA)
2. Blender software version 4.0.2 (Blender Foundation, Amsterdam, Netherlands)
3. Maxillary models; T1 and T2

Methods

All study models of the sample and five patients not included in this study were scanned with the intraoral scanner (iTero Element 2 Intraoral Scanner, Align Technologies, San Jose, CA/USA) by the main examiner (Thanaporn Pattanawasin). After the scanner's process is finished, the complete 3D model can be shown on the computer screen. Then export the 3D model in the stereolithography file format (.stl).

For blinding the examiner, all of the 3D model files were changed name into random coding numbers. And the calibration, five models that were not included in this study were imported into Blender software version 4.0.2 (Blender Foundation, Amsterdam, Netherlands) to calibrate the main examiner with the experienced standard examiner (Assistant Professor Ratchawan Tansalarak) and then evaluate the intra and inter-rater reliability before collecting data by using intraclass correlation (ICC) and accepted ICC > 0.75 (61).

One month after model scanning and data coding, all of the 3D models of samples were imported into Blender software for measurements by the main examiner (Thanaporn Pattanawasin). The reference points used in this study indicated by Chaisooktaksin et al. (15) were marked and defined on the 3D models using the Annotate Tool (Table 2 and Figure 21). Using the horizontal plane (HP) that passes through the canine point to evaluate the difference in the vertical plane (15). The reference points, a horizontal plane, and the linear and angular measurements shown in Table 2-3 and Figure 20-21 were measured via the Measure Tool in Blender software. The changes in measurements between T1 and T2 were compared. For visualization of morphological changes between two-time points, using the superimposition on tuberosity points (T, T') of 3D models because the distance between these landmarks seems to be the most stable (15).

Table 2 Definition of the reference points and reference planes (15)

Reference points	Definition
Incisal point (I)	The intersection of the crest of the alveolar ridge and the line drawn from the labial frenum to the incisive papilla
Anterior cleft point (GS-A) (LS-A’)	The anterior endpoint of the alveolar crest (at the most inferior, medial, midpoint of the alveolar crest) Where A is the anterior cleft point on the greater segment and A’ is the anterior cleft point of the lesser segment.
Canine points (GS-C) (LS-C’)	The intersection of the lateral sulcus and the crest of the alveolar ridge
Tuberosity points (GS-T) (LS-T’)	The posterior endpoint of the alveolar crest (intersection of the crest of the alveolar ridge with the outline of the tuberosity)
Posterior cleft points (GS-P)(LS-P’)	The intersection of the alveolar cleft margin with the plane that connects the tuberosity points
Deep cleft (GS-D) (LS-D’)	The deepest point of the cleft segment
M point	The midpoint of the line connecting the tuberosity point
Horizontal plane of the greater segment (HP)	The horizontal plane passing through the C point
Horizontal plane of the lesser segment (HP’)	The horizontal plane passing through the C’ point

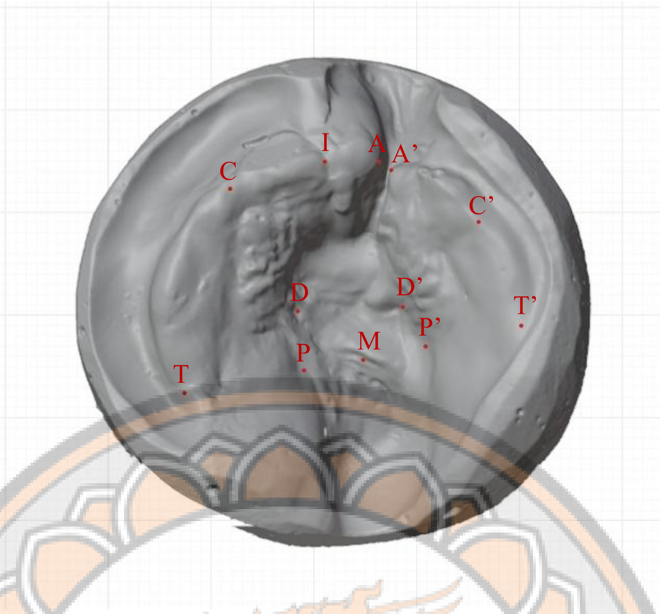

Figure 22 Positioning of reference points for the measurement (15)

Table 3 Abbreviations and definitions of measurements (15, 62, 63)

Measurements	**Definition**
A-A'	Anterior cleft width
P-P'	Posterior cleft width
C-C'	Anterior arch width
T-T'	Posterior arch width
A⊥T-T'	Length of the greater cleft segment
A'⊥T-T'	Length of the lesser cleft segment
D-HP	Height of the greater cleft segment (distance from the deepest point of the greater cleft segment perpendicular to the horizontal plane of the greater segment)
D'-HP'	Height of the lesser cleft segment (distance from the deepest point of the lesser cleft segment perpendicular to the horizontal plane of the lesser segment)
IMT angle	Greater segment rotation

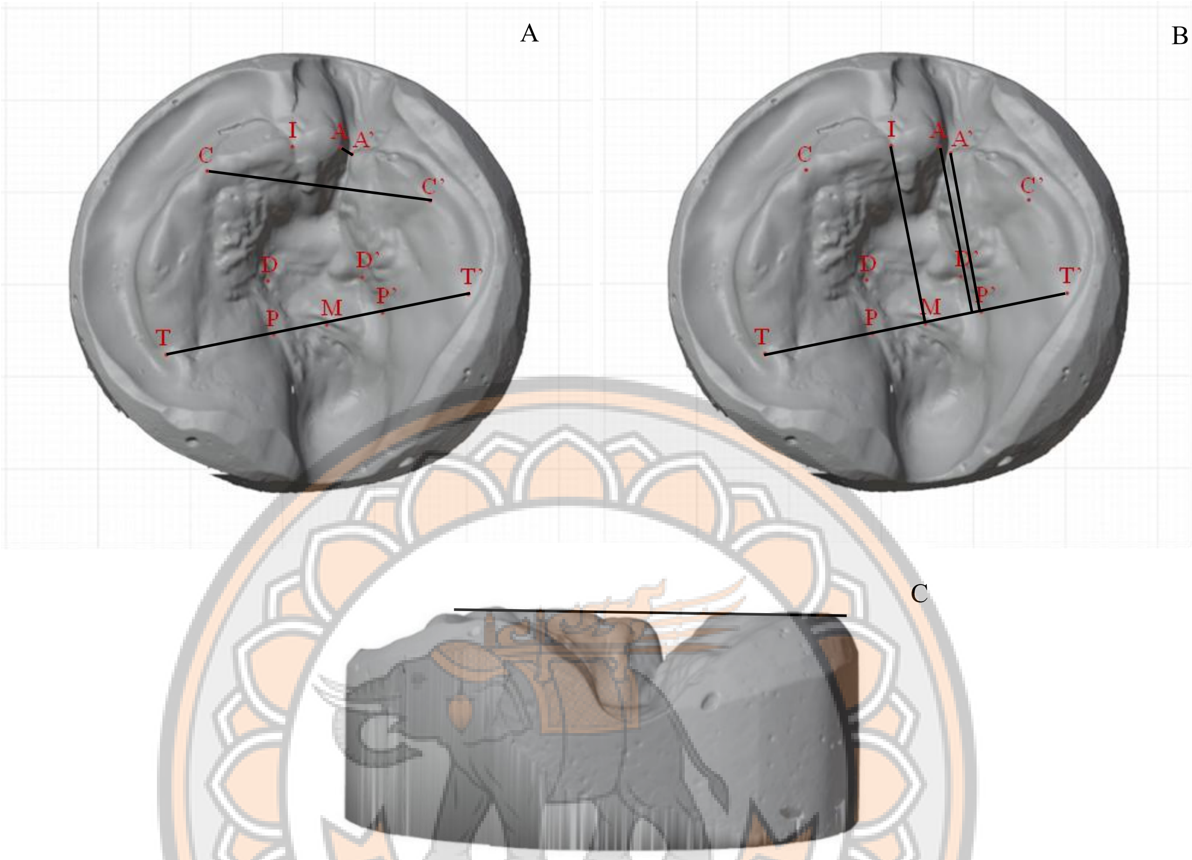

Figure 23 (A) Transverse measurements (B) Sagittal and angular measurements. 1, Anterior cleft width (A-A’); 2, Posterior cleft width (P-P’); 3, Anterior arch width (C-C’); 4. Posterior arch width (T-T’); 5. Length of the greater cleft segment (A⊥T-T’); 6. Length of the lesser cleft segment (A’⊥T-T’); 7. Greater segment rotation (IMT angle) (C) Horizontal reference plane (15)

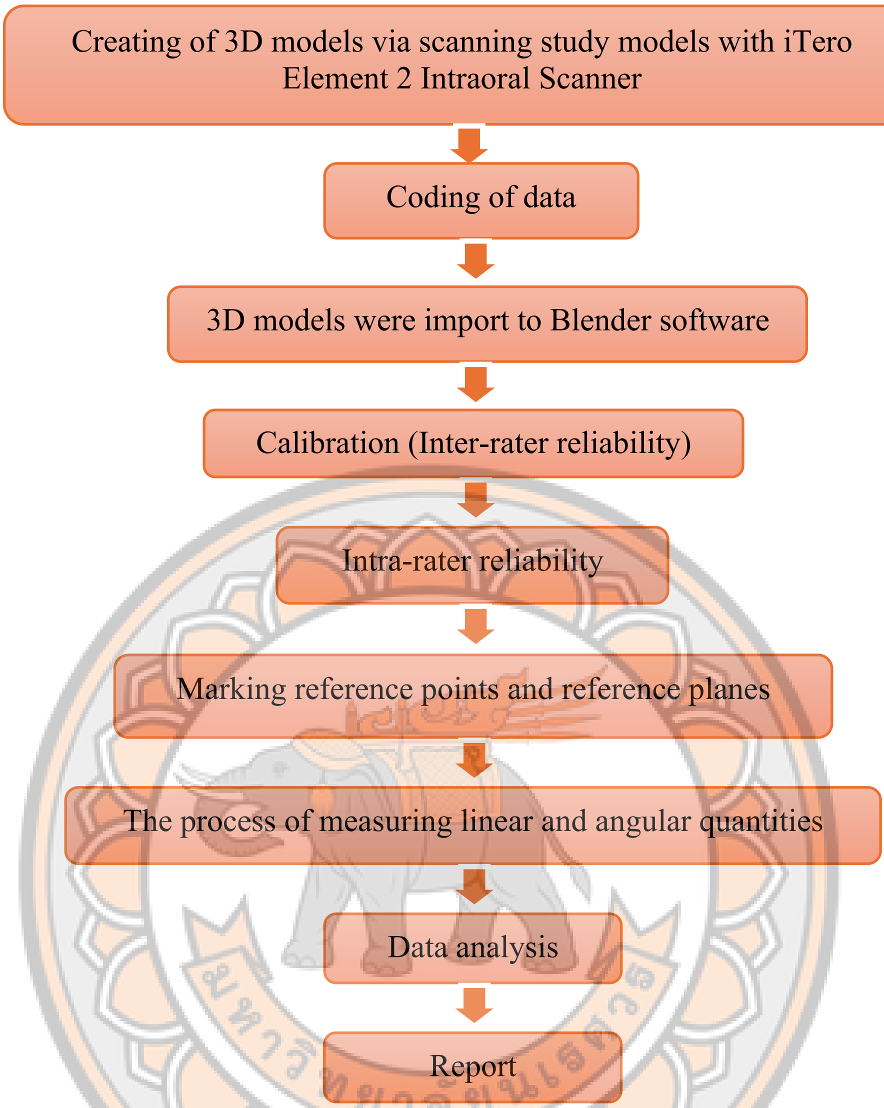

Figure 24 Flow diagram shows the research methods for maxillary arch morphology change

Variables Part 2: Nasolabial esthetics

Independent variable:	NU-NAM
Dependent variable:	Nasolabial esthetics (nasal symmetry, perioral symmetry, Asher-McDade rating scale)
Confounding variables:	Asymmetry of nasolabial before primary lip repair
	Gender
	Variation of individual growth pattern
	Severity of scar contraction after primary lip repair
	Nasal conformers compliance
	Complications

Materials and methods Part 2: Nasolabial esthetics

Equipment and materials

1. Digital camera
2. ImageJ software version 1.8.0 (The National Institute of Health (NIH), USA)

Methods

Nasolabial esthetics assessment in this study comprises of nasal component symmetry index, perioral component symmetry index, and Asher-McDade rating scale. The measurements in part of the nasal component symmetry index are nostril height ratio, nostril width ratio, alar base ratio, and columella length ratio. For the perioral component symmetry index, there are cupid's bow width ratio, inter-commissure width ratio, philtrum height ratio, and vermillion height ratio. The Asher-McDade rating scale was used for the evaluation of the perception of nasal form, nasal deviation, vermilion border, and nasal profile by other three plastic surgeons and repeated after one month to determine interrater and intrarater reliability.

Facial images were taken both in 2D by Digital camera. The facial images were taken from basal, frontal, and lateral views (right side).

For blinding the examiner, all of the 2D facial images were labeled with random coding numbers. And the calibration, five images that were not included in this study were imported into ImageJ software version 1.8.0 (The National Institute of Health (NIH), USA) to calibrate the main examiner with the experienced standard examiner (Assis. Prof. Saran Worasakwutiphong) and then evaluate the intra and inter-rater reliability before collecting data by using intraclass correlation (ICC) and accepted ICC > 0.75 (61).

One month after data collecting and coding, all of the 2D images of samples were imported into ImageJ software for measurements by the main examiner (Thanaporn Pattanawasin) for assessing the nasal component symmetry index and perioral component symmetry index. The reference points used in this study indicated by Waewsanga et al. (39), Pai et al. (52), Kumjan et al. (55), Vyas et al. (64), Bagante et al. (65) were marked and defined on the images using the Lable Tool

Using the horizontal plane (HP) that passes through the right alar (AlRt) and left alar (AlLt) points and midline (vertical) that passes through the Ls point as a reference plane (52). The reference points, a horizontal plane, a vertical plane, and the linear and angular measurements shown in Table 4-5 and Figure 23-24 were measured via the Length, Straight Tool in ImageJ software. The changes in measurement ratio between Tn1 and Tn2 were compared.

Table 4 Definition of the reference points and reference planes (nasolabial) (39, 52, 55, 64, 65)

Reference points	Definition
Right alar (AlRt)	The most lateral point on the nasal alar on the right side
Left alar (AlLt)	The most lateral point on the nasal alar on the left side
Right alar base (AbRt)	The most inferolateral point on the nasal alar on the right side
Left alar base (AbLt)	The most inferolateral point on the nasal alar on the left side
Right nostril dome (NdRt)	The highest point of the nostril on the right side
Left nostril dome (NdLt)	The highest point of the nostril on the left side
Right nostril lower border (NlRt)	The lowest point of the nostril on the right side
Left nostril lower border (NlLt)	The lowest point of the nostril on the left side
Farthest medial nostril (FmRt),(FmLt)	The point farthest medial of the nostril
Farthest lateral nostril (FlRt),(FlLt)	The point farthest lateral of the nostril
Top point of the columella (C)	The midpoint of the columella crest at the level of the nostril top points

Reference points	Definition
Right top point of the columella (CRt)	The top point of the columella crest on the right side
Left top point of the columella (CLt)	The top point of the columella crest on the left side
Subnasale (Sn)	The junction between the lower border of the nasal septum, the partition that divides the nostrils, and the cutaneous portion of the upper lip in the midline
Right crista philter (CphRt)	The point on the crest of the philtrum on the right side, the vertical groove in the median portion of the upper lip, just above the vermilion border
Left crista philter (CphLt)	The point on the crest of the philtrum on the affected side, the vertical groove in the median portion of the upper lip, just above the vermilion border
Labiale superius (Ls)	The midpoint of the vermilion border of the upper lip
Right cheilion (ChRt)	The most lateral point on the right side of closed lips
Left cheilion (ChLt)	The most lateral point on the non-affected side of closed lips
Stomion (Sto)	The midpoint of the labial fissure when the lips are closed naturally
Lower border right (LRt)	The lower border of upper lip at point on the crest of the philtrum on the right side
Lower border left (LRt)	The lower border of upper lip at point on the crest of the philtrum on the left side
Horizontal reference plane (HP)	The horizontal plane passing through the AlRt and AlLt points

Reference points	Definition
Midline	The vertical plane passing through the Ls point

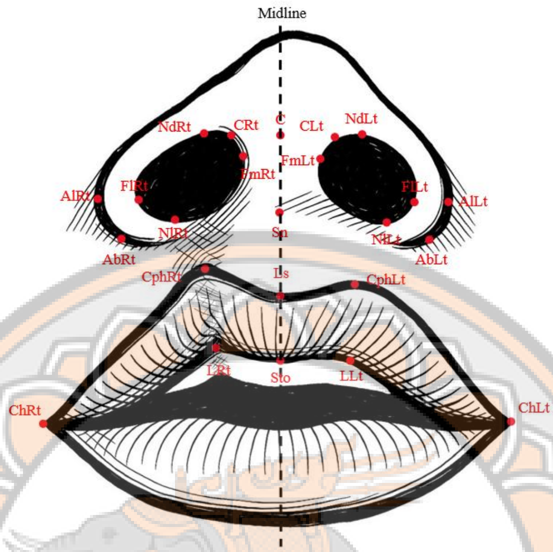

Figure 25 Positioning of reference points for the 2D distance measurement (39, 52, 55, 64, 65)

Table 5 Definition of 2D distance measurement ratio of nasolabial appearance (39, 52, 55, 64, 65)

Measurements	Definition
1) AlRt-midline/AlLt-midline	Alar ratio
2) AbRt-midline/AbLt-midline	Alar base ratio
3) NdRt-NlRt/ NdLt-NlLt	Nostril height ratio
4) FlRt-FmRt/ FmLt-FlLt	Nostril width ratio
5) CRt⊥AlRt-AlLt/ CLt⊥AlRt-AlLt	Columella length ratio
6) CphRt-midline/ CphLt -midline	Cupid's bow ratio
7) ChRt-midline/ ChLt-midlinr	Inter-commissure width ratio
8) CphRt⊥AlRt-AlLt/ CphLt⊥AlRt-AlLt	Philtrum height ratio
9) CphRt-LRt/ CphLt-LLt	Vermillion height ratio

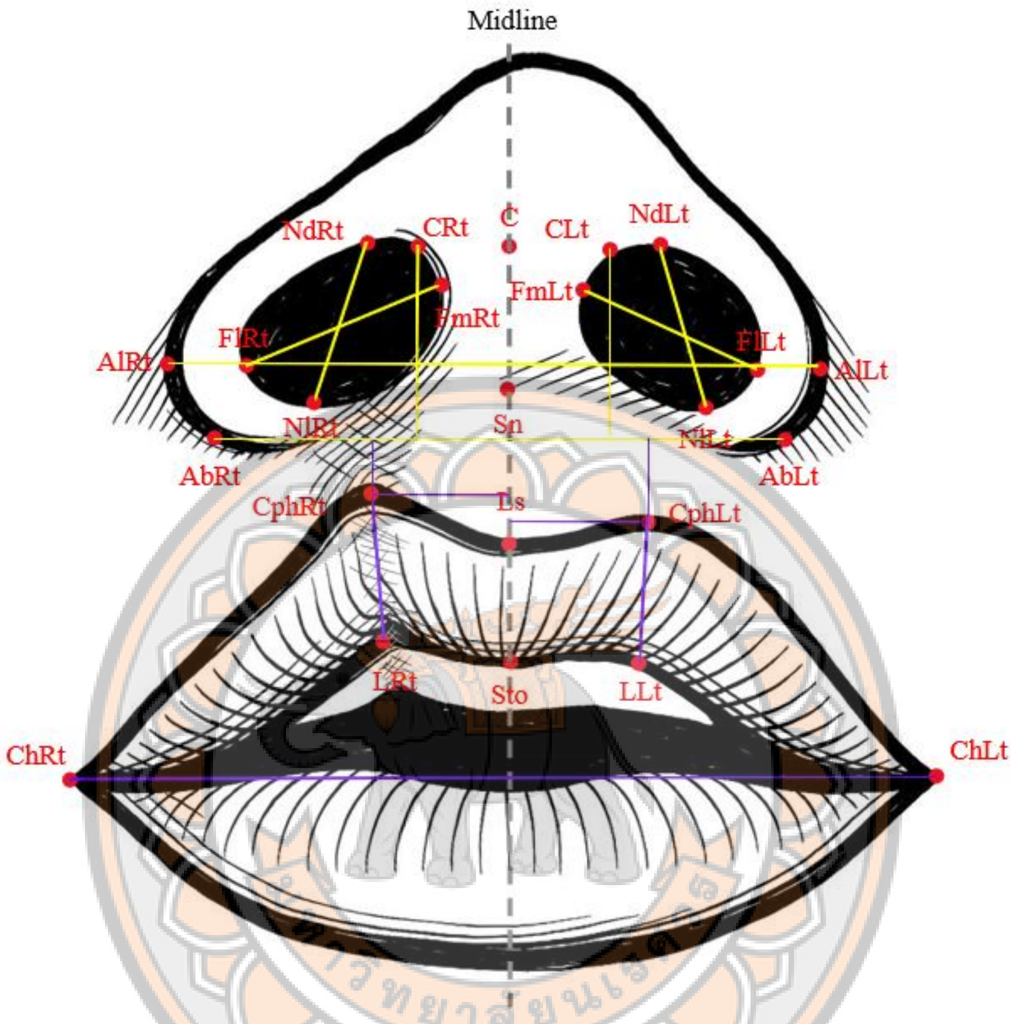

Figure 26 Measurements for nasal symmetry index and perioral symmetry index (39, 52, 55, 64, 65)

For evaluation of the perception of nasal form, nasal deviation, vermilion border, and nasal profile, use the Asher-McDade rating scale by other plastic surgeons. Choose and crop the 2D facial images in frontal and lateral views. Then the examiners evaluated each picture and scored 5-point ordinal scales (1=very good appearance, 2=good, appearance, 3=fair appearance, 4=poor appearance, 5=very poor appearance)

Figure 27 Asher-McDade rating scale

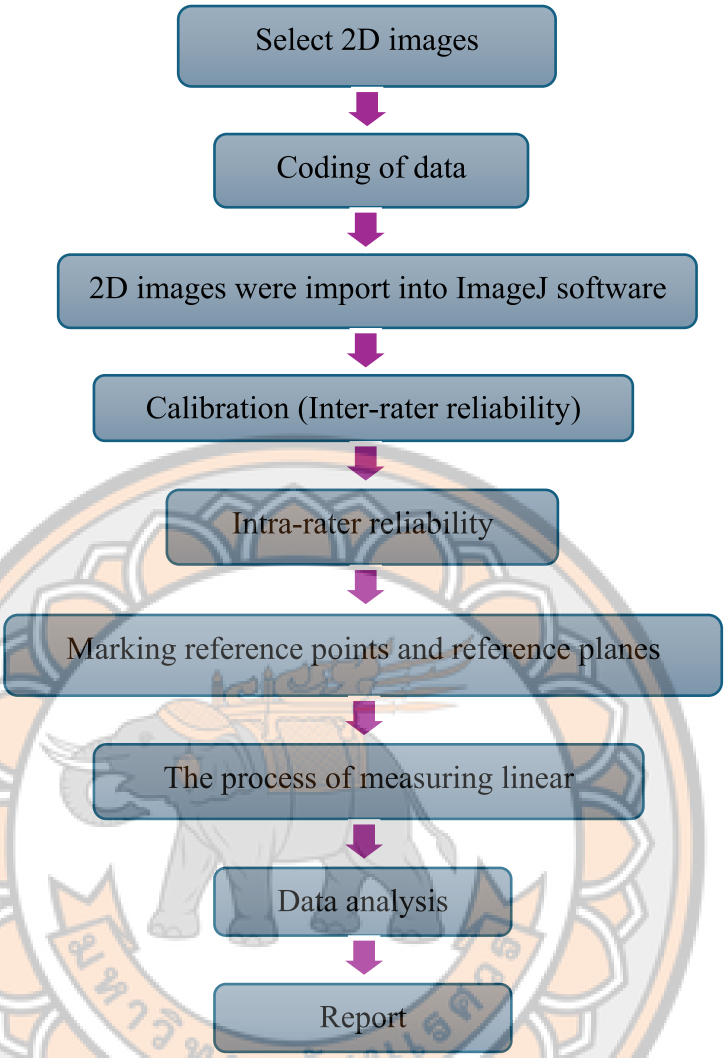

Figure 28 Flow diagram shows the research methods for nasolabial esthetics assessment

Analyses of the data

The statistics were calculated by using an SPSS program (IBM SPSS Statistics for Windows, Version 17.0; IBM Corp, NY, USA).

Using descriptive statistics (mean, standard deviation) to identify maxillary arch dimensions and nasolabial esthetics after primary lip repair. For analytical statistics, the change in measurements between T1 and T2 was compared by using a paired student's *t*-test or Wilcoxon signed-rank test.

For analytical statistics of nasolabial esthetics after primary lip repair, the ratio difference (nasal symmetry, perioral symmetry) between Tn1 and Tn2 using a paired student’s *t*-test or Wilcoxon signed-rank test. The Wilcoxon signed-rank was used to analyze Asher-McDade rating scale.

For analytical statistics of correlations between maxillary arch dimensions and nasolabial esthetics after primary lip repair using Pearson’s r test test. The p-values less than 0.05 were considered statistically significant.

CHAPTER IV

RESULTS AND DISCUSSION

Results

Part 1: Maxillary arch morphology change

Patient Characteristics and Clinical Data

A total of 25 infants diagnosed with non-syndromic complete unilateral cleft lip and palate were included in this study. The study population consisted of 17 males (68%) and 8 females (32%), demonstrating a higher proportion of male patients. The mean birth weight of the cohort was 3000.8 ± 295.7 grams.

Regarding cleft laterality, left-sided clefts were more prevalent, occurring in 18 infants (72%), while right-sided clefts were observed in 7 infants (28%), consistent with the known epidemiological predominance of left-sided unilateral clefts.

With respect to treatment timing, the mean age at the first NAM appointment was 22.04 ± 23.31 days, indicating that most patients commenced presurgical orthopedic therapy within the neonatal period. Primary lip repair (T1) was performed at a mean age of 120.72 ± 26.05 days, while the post primary lip repair follow-up assessment (T2) was conducted at a mean age of 350.52 ± 55.93 days, corresponding to approximately six months after primary lip repair.

The initial alveolar cleft width prior to treatment demonstrated a mean value of 9.84 ± 3.66 mm, indicating substantial inter-individual variability in the severity of the initial cleft deformity. A summary of patient demographic characteristics, cleft morphology, and treatment milestones is presented in Table 6.

Table 6 Demographic and clinical characteristics of infants with complete unilateral cleft lip and palate (N=25)

Characteristic	n (%)	Mean ± SD	Median(IQR)
Gender			
Male	17 (68)	-	-
Female	8 (32)	-	-
Cleft Side			
Left	18 (72)	-	-
Right	7 (28)	-	-
Birth weight (g)	25 (100)	3000.8 ± 295.7	-
Initial cleft width (mm)	25 (100)	9.84 ± 3.66	-
Age at treatment milestones (days)			
First NAM appointment	25 (100)	22.04± 23.31	12(28-9)
Primary lip repair (T1)	25 (100)	120.72 ± 26.05	109(136-102)
Post- primary lip repair (T2)	25 (100)	350.52 ± 55.93	331(350.5-322)

SD = Standard Deviation; IQR = Interquartile Range

Maxillary arch changes between T1 and T2

Inter-rater reliability was assessed to determine the consistency of measurements and ratings between independent evaluators. The calculated intraclass correlation coefficients (ICC) for inter-rater agreement ranged from 0.797 to 1.000, indicating very good reliability across all evaluated parameters. These results demonstrate a high level of consistency between examiners and confirm the robustness of the measurement protocol.

Intra-rater reliability analysis was performed to evaluate the stability and reproducibility of repeated measurements by the same examiner. The ICC values ranged from 0.976 to 1.000, reflecting nearly perfect reliability according to the criteria proposed by Rankin and Stokes (66). This finding indicates excellent measurement consistency and minimal intra-observer variability throughout the data acquisition and analysis process.

Three-dimensional quantitative analysis of the digital maxillary models demonstrated significant morphological changes between the primary lip repair (T1) and the post-primary lip repair follow-up (T2), as summarized in Table 7.

In the transverse dimension, a statistically significant reduction in anterior cleft width was observed, with a mean decrease of 0.95 ± 1.28 mm ($p = 0.001$). In contrast, posterior cleft width exhibited a slight increase (mean change: 0.25 ± 2.16 mm); however, this difference was not statistically significant ($p = 0.567$). Both anterior and posterior maxillary arch widths increased significantly over time. Specifically, the anterior arch width increased by 1.81 ± 2.94 mm ($p = 0.005$), while the posterior arch width increased by 0.99 ± 2.04 mm ($p = 0.023$), indicating transverse expansion of the maxillary arch following primary lip repair.

In the sagittal dimension, significant elongation of both alveolar segments was detected. The greater segment length increased by a mean of 1.09 mm ($p = 0.043$), and the lesser segment length increased by 1.76 mm ($p = 0.001$), demonstrating forward dimensional growth of both maxillary segments between T1 and T2.

With respect to vertical changes, no statistically significant differences were identified. The vertical height of the greater segment increased by 0.46 ± 2.18 mm ($p = 0.288$), while the lesser segment height increased by 0.17 ± 1.83 mm ($p = 0.649$), suggesting relative vertical stability of the maxillary segments during the post-primary lip repair period.

Additionally, a statistically significant increase in the IMT angle was observed, with a mean change of 1.92° ± 4.17° ($p = 0.030$). This finding indicates a medial rotational movement of the greater segment, reflecting favorable rotational remodeling of the maxillary arch configuration following primary lip repair

Table 7 Changes in maxillary arch dimensions between T1 and T2 in infants with unilateral cleft lip and palate (N = 25)

Parameter	Mean ± SD		Mean Diff ± SD T2-T1	95% CI	p-value
	T1	T2			
Cleft width					
Anterior (A-A')	3.84 ± 2.49	2.89 ± 2.52	-0.95 ± 1.28	-1.48, -0.42	**0.001a**
Posterior (P-P')	11.81 ± 2.95	12.06 ± 4.06	0.25 ± 2.16	-0.64, 1.14	0.567b
Arch width					
Anterior (C-C')	27.43 ± 3.39	29.24 ± 3.70	1.81 ± 2.94	0.60, 3.03	**0.005b**
Posterior (T-T')	33.55 ± 2.51	34.54 ± 2.30	0.99 ± 2.04	0.15, 1.84	**0.023b**
Cleft segment dimensions					
Greater segment length	21.71 ± 2.69	22.80 ± 2.20	1.09 ± 2.55	0.04, 2.15	**0.043b**
Lesser segment length	19.13 ± 2.15	20.89 ± 2.07	1.76 ± 2.43	0.76, 2.77	**0.001b**
Greater segment height (D-HP)	8.61 ± 1.64	9.07 ± 1.68	0.46 ± 2.18	-0.44, 1.36	0.288a
Lesser segment height (D'-HP')	8.48 ± 1.58	8.65 ± 1.68	0.17 ± 1.83	-0.59, 0.92	0.649b
Greater segment rotation (IMT)	82.12° ± 5.45°	84.04° ± 6.11°	1.92° ± 4.17°	0.20, 3.64	**0.030b**

Note: All measurements are in millimeters except for the IMT angle (degrees).

T1 = at primary lip repair; T2 = at post primary lip repair.

Mean Diff = Mean difference; SD = Standard Deviation

Boldface indicates statistically significant values $p<0.05$; **a** Wilcoxon signed-rank test; **b** Paired t-tests

Digital superimposition analysis

Three-dimensional superimposition of the maxillary models at T1 (blue) and T2 (green), using posterior maxillary landmarks as reference points, revealed medial displacement and rotational remodeling of the anterior region of the greater segment (Figure 27). Additionally, increases in both anterior and posterior arch widths were evident, supporting the transverse dimensional changes demonstrated in the quantitative analysis. The superimposition also illustrated medial migration of the anterior maxillary segment, which was associated with a reduction in alveolar cleft width.

Figure 29 Superimposition of maxillary models at T1 and T2 using posterior maxillary reference landmarks (blue, T1; green, T2)

Part 2: Nasolabial esthetics

Patient Characteristics and Clinical Data

A total of 22 infants with non-syndromic complete unilateral cleft lip and palate (UCLP) were included in the nasolabial esthetic evaluation (Part 2 of the study). The study cohort comprised 16 males (62.5%) and 6 females (37.5%), demonstrating a male predominance. With respect to cleft laterality, left-sided clefts were observed in 16 infants (62.5%), while right-sided clefts were present in 6 infants (37.5%).

The mean birth weight of the infants was 2959.1 ± 318.6 grams. The mean initial alveolar cleft width prior to treatment was 9.53 ± 3.82 mm, indicating moderate to severe variability in cleft severity among the study population.

Regarding treatment timing, the mean age at the first NAM appointment was 21.90 ± 23.14 days, reflecting early initiation of presurgical orthopedic therapy. Post-primary lip repair 1-4 week (Tn1) was performed at a mean age of 160.00 ± 27.38 days, and post-primary lip repair 6 months follow-up assessment (Tn2) was conducted at a mean age of 338.77 ± 63.06 days, corresponding to approximately six months after primary lip repair.

A summary of the demographic and clinical characteristics of the infants included in the nasolabial esthetic analysis is presented in Table 8.

Table 8 Demographic and clinical characteristics of infants with complete unilateral cleft lip and palate (N=22)

Characteristic	n (%)	Mean ± SD	Median(IQR)
Gender			
Male	16 (62.5)	-	-
Female	6 (37.5)	-	-
Cleft Side			
Left	16 (62.5)	-	-
Right	6 (37.5)	-	-
Birth weight (g)	22 (100)	2959.1 ± 318.6	-
Initial cleft width (mm)	22 (100)	9.53 ± 3.82	-
Age at treatment milestones (days)			
First NAM appointment	22 (100)	21.90± 23.14	14(23-9)
Post-primary lip repair 1-4 weeks (Tn1)	22 (100)	160.00 ± 27.38	157.5(181-139)
Post-primary lip repair 6 months (Tn2)	22 (100)	338.77 ± 63.06	340.5(390-288.5)

SD = Standard Deviation; IQR = Interquartile Range

Changes in nasal and perioral symmetry between Tn1 and Tn2

Quantitative analysis of nasolabial symmetry parameters demonstrated significant improvements in multiple nasal and perioral ratios between post-primary lip repair (Tn1) and pre-palatoplasty (Tn2), as summarized in Table 9.

In the nasal region, statistically significant changes were observed across all major symmetry parameters. The alar ratio increased significantly from 0.97 ± 0.13 at Tn1 to 1.08 ± 0.11 at Tn2, with a mean difference of 0.11 ± 0.09 ($p < 0.001$). Similarly, the alar base ratio showed a significant increase of 0.12 ± 0.11 ($p < 0.001$). The nostril height ratio demonstrated a significant reduction (mean change: −0.17 ± 0.17, $p < 0.001$), indicating improved vertical nostril symmetry. In contrast, the nostril width ratio increased significantly by 0.20 ± 0.12 ($p < 0.001$), reflecting enhanced transverse nasal symmetry. The columella length ratio also decreased significantly (mean change: −0.18 ± 0.15, $p < 0.001$), suggesting improved midline nasal alignment and proportionality.

In the perioral region, significant improvement was observed in philtrum height symmetry, with the philtrum height ratio increasing by 0.09 ± 0.08 ($p < 0.001$). In contrast, no statistically significant changes were detected in the cupid's bow ratio (mean change: −0.48 ± 1.29, $p = 0.09$), inter-commissure width ratio (mean change: −0.00 ± 0.25, $p = 0.95$), or vermillion height ratio (mean change: 0.01 ± 0.15, $p = 0.86$), indicating relative stability of these perioral parameters during the follow-up period.

Overall, the results demonstrate significant improvements in nasal symmetry parameters and selective enhancement of perioral symmetry following primary lip repair and during subsequent growth, particularly in nasal morphology and philtral proportions, while transverse oral width and vermillion height remained relatively unchanged between Tn1 and Tn2.

Table 9 Changes in nasal and perioral symmetry between Tn1 and Tn2 in infants with unilateral cleft lip and palate (N = 22)

Parameter	Mean ± SD		Mean Diff ± SD T2-T1	95% CI	p-value
	Tn1	Tn2			
Nasal part					
Alar ratio	0.97 ± 0.13	1.08 ± 0.11	0.11 ± 0.09	0.06, 0.15	**<0.01**
Alar base ratio	0.97 ± 0.12	1.09 ± 0.15	0.12 ± 0.11	0.07, 0.18	**<0.01**
Nostril height ratio	1.10 ± 0.19	0.93 ± 0.13	-0.17 ± 0.17	-0.24, -0.09	**<0.01**
Nostril width ratio	0.98 ± 0.17	1.19 ± 0.23	0.20 ± 0.12	0.15, 0.26	**<0.01**
Columella length ratio	0.96 ± 0.12	0.78 ± 0.13	-0.18 ± 0.15	-0.24, -0.11	**<0.01**
Perioral part					
Cupid's bow ratio	2.30 ± 1.43	1.81 ± 1.28	-0.48 ± 1.29	-1.05, 0.09	0.09
Inter-commissure width ratio	1.02 ± 0.16	1.02 ± 0.16	-0.00 ± 0.25	-0.12, 0.11	0.95
Philtrum height ratio	0.88 ± 0.09	0.96 ± 0.08	0.09 ± 0.08	0.05, 0.12	**<0.01**
Vermillion height ratio	1.11 ± 0.15	1.12 ± 0.11	0.01 ± 0.15	-0.06, 0.07	0.86

Note: All measurements are in ratio.

Tn1 = at post-primary lip repair 1-4 weeks; Tn2 = at post-primary lip repair 6 months

Boldface indicates statistically significant values $p<0.05$ using paired t-tests

Changes in nasolabial perception assessed by the Asher–McDade rating scale

Perceptual assessment using the Asher–McDade rating scale revealed significant improvements in selected nasolabial features between Tn1 and Tn2 (Table10).

Median nasal form scores increased from 1 (IQR 1–2) at Tn1 to 2 (IQR 1–3) at Tn2, with a median difference of 1 (IQR 0–1.75), indicating a statistically significant change ($p = 0.016$). Similarly, nasal deviation scores increased significantly, with a median difference of 0.5 (IQR 0–1; $p = 0.005$).

For the vermilion border, a significant improvement was observed, with a median difference of −0.5 (IQR −1 to 0; $p = 0.009$). In contrast, changes in nasal profile did not reach statistical significance, showing a median difference of 0 (IQR −0.75 to 0; $p = 0.366$).

Table 10 Changes in nasolabial perception using Asher-McDade rating scale in infants with unilateral cleft lip and palate (N = 22)

Parameter	Median (IQR)		Difference (Tn2-Tn1) Median (IQR)	p-value
	(Tn1)	(Tn2)		
Nasal form	1 (1 to 2)	2 (1 to 3)	1 (0 to 1.75)	**0.016**
Nasal deviation	1 (1 to 2)	2 (1 to 2)	0.5 (0 to 1)	**0.005**
Vermilion border	2 (1.25 to 2.75)	1 (1 to 2)	-0.5 (-1 to 0)	**0.009**
Nasal profile	2 (1 to 2)	2 (1 to 2)	0 (-0.75 to 0)	0.366

Note: All measurements are in rating scale.

Tn1 = at post-primary lip repair 1-4 weeks; Tn2 = at post-primary lip repair 6 months

Boldface indicates statistically significant values $p<0.05$ using Wilcoxon signed-rank test

Correlation between maxillary arch dimensions and nasolabial esthetics

Correlation analysis revealed statistically significant moderate positive associations between maxillary arch dimensions and nasolabial symmetry parameters, as shown in Table 11, with consistent positive linear trends observed in the corresponding scatter plots (Figure 30).

Anterior arch width demonstrated a significant positive correlation with the philtrum height ratio ($r = 0.588$, $p = 0.034$), indicating that increased transverse development of the anterior maxillary arch was associated with improved philtral symmetry.

Vertical development of the greater maxillary segment showed significant positive correlations with both the columella length ratio ($r = 0.563$, $p = 0.045$) and the philtrum height ratio ($r = 0.623$, $p = 0.023$). Among these, the strongest association was observed between greater segment height and philtrum height ratio, suggesting a more pronounced influence of vertical maxillary growth on philtral morphology.

In addition, greater segment rotation was significantly correlated with the inter-commissure width ratio ($r = 0.60$, $p = 0.03$), indicating that rotational changes of the maxillary segment were associated with improved transverse perioral symmetry.

Overall, all correlations were positive and of moderate strength ($r \approx 0.56$–0.62), suggesting consistent but not exclusive relationships between maxillary morphology and nasolabial esthetic outcomes.

Table 11 Correlation between maxillary arch dimensions and nasolabial esthetics (Nasolabial symmetry ratio)

Maxillary arch dimension	Nasolabial symmetry ratio	Pearson Correlation	p-value
Anterior arch width	Philtrum height ratio	0.588	**0.034**
Greater segment height	Columella length ratio	0.563	**0.045**
Greater segment height	Philtrum height ratio	0.623	**0.023**
Greater segment rotation	Inter-commissure width ratio	0.60	**0.03**

Boldface indicates statistically significant values $p<0.05$ using Pearson Correlation

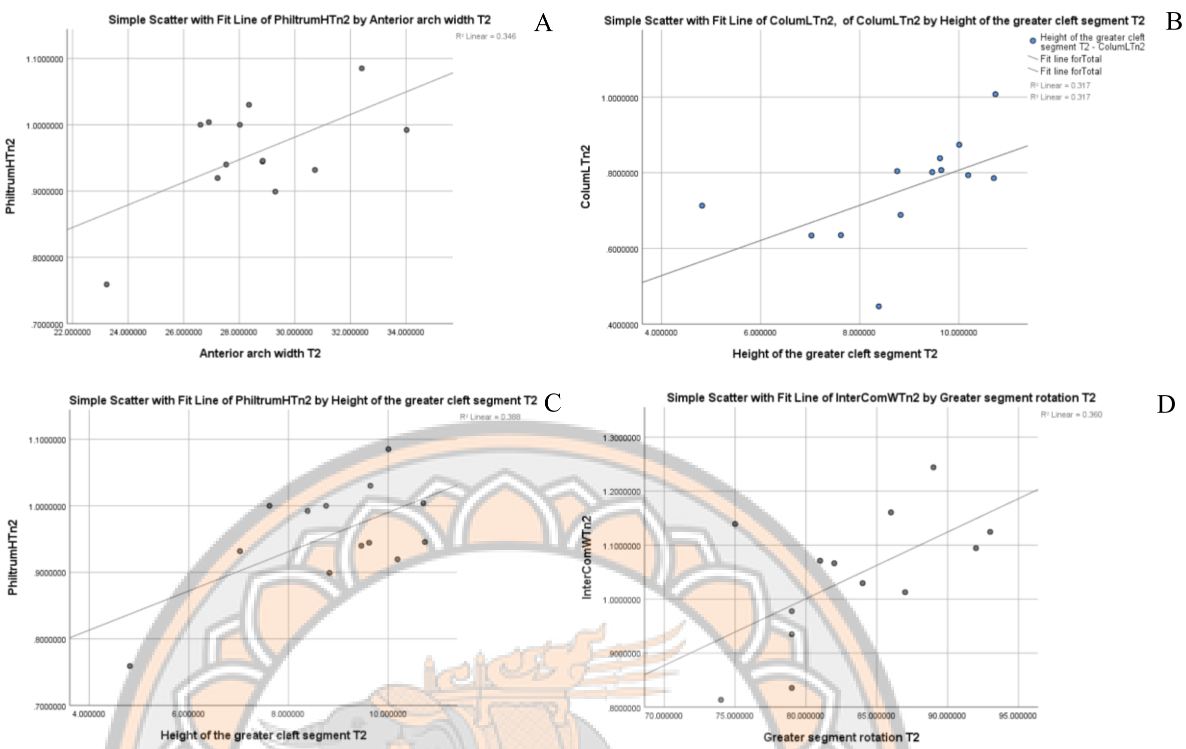

Figure 30 Scatter plots illustrating the correlations between maxillary arch dimensions and nasolabial symmetry parameters

(A) Relationship between anterior arch width and philtrum height ratio

(B) Relationship between greater segment height and columella length ratio

(C) Relationship between greater segment height and philtrum height ratio

(D) Relationship between greater segment rotation and inter-commissure width ratio

All plots include fitted linear regression lines demonstrating positive correlations.

Discussion

The management of CLP is directed toward the restoration of function, facial esthetics, and balanced craniofacial growth. Progress in surgical techniques, together with the incorporation of presurgical NAM, has contributed to improved early clinical outcomes in CLP patients (6, 19, 20). Primary lip repair, typically performed between 3 and 6 months of age (24), plays a critical role in reconstructing the lip and nasal structures (15), however, its long-term influence on maxillary growth remains a subject of ongoing debate. Excessive scarring following lip and palatal repair has been associated with maxillary arch constriction (9), midfacial retrusion (35), and the development of posterior crossbites (9). Consequently, a detailed understanding of early post-primary lip repair changes in maxillary morphology is essential for optimizing treatment strategies and improving long-term craniofacial outcomes.

Treatment protocols for CLP vary considerably across treatment centers (67), and multiple comparative studies have investigated the effects of different presurgical orthopedic approaches. Both passive alveolar molding (PAM) and NAM have been shown to effectively reduce anterior cleft width, with several studies reporting greater reductions following NAM compared with PAM (68). In addition, simplified techniques such as lip taping have been proposed as cost-effective alternatives, particularly in low-resource settings where access to specialized appliances may be limited (69).

Building upon the work of Chaisooktaksin et al. (15), the present study extends the evaluation of maxillary morphology beyond the pre-primary lip repair phase by examining changes occurring between primary lip repair and post-primary lip repair using three-dimensional digital models. Compared with conventional plaster casts, 3D digital analysis offers superior reproducibility, precision, and efficiency for longitudinal morphological assessment (70-74).

The present findings demonstrated a significant reduction in anterior cleft width, accompanied by significant increases in both anterior and posterior arch widths during the early post-primary lip repair period. Sagittal elongation of both maxillary segments was also observed. Despite concerns that postoperative scar formation following primary lip repair and primary rhinoplasty may restrict maxillary growth, the increase in both greater and lesser segment lengths suggests that early surgical intervention did not inhibit sagittal maxillary development during this period. This may indicate that the potential restrictive effects of scar formation are either minimal or counterbalanced by intrinsic growth potential and the favorable alignment achieved through presurgical orthopedic and surgical interventions (75). These findings are consistent with previous reports describing transverse expansion and anterior maxillary growth following NAM and primary lip repair (9, 16). In contrast, vertical dimensions remained relatively stable, in agreement with earlier studies indicating minimal vertical maxillary changes during infancy (15, 35). Collectively, these results suggest that early post-primary lip repair morphological adaptations are more pronounced in the transverse and sagittal dimensions than in the vertical dimension.

A significant increase in the IMT angle indicated medial rotational remodeling of the greater segment. This change may reflect the combined effects of modified NAM therapy and the soft tissue forces introduced by primary lip repair, consistent with experimental and clinical evidence describing the influence of lip pressure and scar formation on maxillary morphology (35, 76-78). Such rotational remodeling may contribute to improved approximation and alignment of the alveolar segments during early development (68). While modified NAM likely plays a dominant role in preoperative segment positioning, the post-primary lip repair changes observed in this study may represent a synergistic interaction between presurgical orthopedic therapy and surgical intervention in shaping maxillary morphology (9). Although the absence of a control group limits causal interpretation, the consistent trends toward improvement across transverse, sagittal, and rotational dimensions provide important insight into early post-primary lip repair morphological adaptation.

From a clinical standpoint, the observed transverse widening, sagittal elongation, and segmental rotation may contribute to a more coordinated and harmonious maxillary arch form prior to palatoplasty (79). Improved alignment of the alveolar segments may facilitate subsequent surgical closure and reduce tissue tension during later procedures (33). Furthermore, early normalization of maxillary arch morphology may simplify future orthodontic management, although this potential benefit requires validation through long-term longitudinal studies (9).

In addition to these morphological improvements, the present findings may have important implications for treatment protocol optimization. Presurgical orthopedic intervention using modified NAM contributes to transverse expansion of the maxillary arch, facilitating soft tissue stretching and improving surgical conditions during primary lip repair. Increased transverse arch width may reduce tissue tension, thereby facilitating flap approximation and potentially minimizing the risk of tissue compromise during surgical closure.

At the same time, NAM reduces anterior cleft width through medial approximation and rotational alignment of the maxillary segments, resulting in a narrower cleft gap prior to surgery. This combination of transverse soft tissue expansion and cleft gap reduction creates a more favorable anatomical environment for primary lip repair and primary rhinoplasty, which may contribute to improved surgical precision and nasolabial esthetic outcomes.

These observations are consistent with long-term comparative studies demonstrating that the integration of presurgical NAM and primary rhinoplasty is associated with improved nasolabial esthetic outcomes compared with alternative treatment approaches (80). Taken together, these findings suggest that a treatment protocol incorporating modified NAM followed by primary lip repair and primary rhinoplasty may represent a favorable approach in early cleft management. However, given the multifactorial nature of treatment outcomes, further controlled and long-term studies are required to confirm its effectiveness and potential role as a standard treatment protocol.

In parallel with these skeletal adaptations, coordinated soft-tissue remodeling was also observed in the nasolabial complex during the early post-primary repair period. Quantitative analysis of nasolabial symmetry demonstrated significant improvements in multiple nasal and perioral parameters between post-primary lip repair 1-4 weeks (Tn1) and post-primary lip repair 6 months (Tn2), indicating early morphological adaptation of the nasolabial complex following primary lip repair. Significant improvements were observed in key nasal symmetry indices, including alar ratio, alar base ratio, nostril height ratio, nostril width ratio, and columella length ratio, reflecting progressive normalization of both transverse and vertical nasal morphology during early post-surgical growth. These findings are consistent with previous longitudinal and anthropometric studies, which have reported significant enhancement of nasal symmetry and nasal soft-tissue proportions following primary cleft lip repair in unilateral cleft populations (81-83) . Early postoperative remodeling of the alar base, nostril dimensions, and columellar alignment has been attributed to the combined effects of surgical reconstruction (81, 83), soft-tissue tension redistribution, scar maturation, and intrinsic growth potential of the nasal cartilaginous framework (81, 82).

In the perioral region, significant improvement in philtrum height symmetry was observed, while other perioral parameters, including cupid's bow ratio, inter-commissure width ratio, and vermillion height ratio, remained relatively stable during the follow-up period. This pattern suggests that midline vertical structures of the nasolabial complex, particularly the philtral region, may be more responsive to post-primary lip repair remodeling and growth compared with transverse oral dimensions. Similar findings have been reported in previous studies, in which philtral morphology and midline soft-tissue proportions demonstrated greater postoperative adaptability than lateral perioral structures (84). In contrast, the relative stability of vermillion height observed in the present study may reflect an early phase of postoperative adaptation followed by subsequent structural stabilization (85), in which initial surgical repositioning and soft-tissue remodeling are followed by the establishment of functional equilibrium. The relative stability of transverse oral width and vermillion height may further reflect early functional balance between muscular forces (81, 84), surgical repair, and maxillary growth constraints during infancy, resulting in maintenance of perioral transverse proportions once early postoperative adaptation has occurred.

Interpretation of nasal and perioral symmetry ratios was based on deviation from 1 as a representation of symmetry, as commonly applied in anthropometric and morphometric cleft studies (52, 81), where a ratio of 1 represents perfect symmetry between the cleft and noncleft sides. Accordingly, longitudinal changes between Tn1 and Tn2 were interpreted in terms of both the direction and magnitude of deviation from unity, reflecting dynamic morphological adaptation rather than static correction.

In the nasal region, the longitudinal changes in alar and alar base ratios reflected a pattern of transverse remodeling rather than simple linear normalization toward perfect symmetry. At Tn1, the cleft to noncleft ratios for both alar and alar base width were already close to 1, with the cleft side being slightly narrower than the noncleft side. By Tn2, these ratios shifted to values modestly above 1, indicating a relative transverse widening of the alar and alar base on cleft side over time. Although the ratios exceeded 1, both parameters remained within a range close to symmetry, suggesting reorganization of transverse nasal balance rather than deterioration of esthetic proportionality.

From a biological and biomechanical perspective, this pattern is consistent with the concept that postoperative nasal symmetry is dynamically influenced by scar contraction and differential growth forces. Chimruang et al. (86), in their systematic review and meta-analysis, emphasized that maintenance of nasal symmetry after primary lip repair is inherently challenged by postoperative scar contraction, which tends to distort nasal contours and promote relapse of asymmetry. Consequently, postoperative nasal conformers play a critical role in counteracting scar contraction by providing continuous mechanical support to the alar cartilage and nostril framework during the critical healing and remodeling phase. Their quantitative analysis further demonstrated that residual asymmetry commonly persists, with the cleft side nostril being on average wider and shorter than the noncleft side, while conformer use significantly improved nostril width and height ratios toward values closer to 1. These findings support the present observation that alar and alar base ratios remain near symmetry despite directional shifts, reflecting controlled remodeling rather than progressive deformity.

In contrast, the nostril height ratio demonstrated a different directional pattern. At Tn1, the cleft side tended to be slightly higher than the noncleft side, whereas at Tn2 the ratio shifted to values below 1, indicating a relative reduction in cleft side nostril height over time. This directional change suggests a minor relapse pattern with preservation of near symmetry but altered proportional dominance between sides. This dynamic remodeling pattern is consistent with longitudinal observations reported by Pai et al. (52), who demonstrated postoperative improvement in nasal symmetry followed by mild relapse during growth, reflecting ongoing developmental remodeling rather than static correction. Similar long-term trends have also been reported by Nayak et al. (87) , who observed progressive widening of nasal and alar base dimensions on the cleft side, together with reduction in nasal height and columellar length over time, attributing these changes to differential growth between the cleft and noncleft sides rather than failure of early intervention.

In the perioral region, the philtrum height ratio showed a significant shift toward 1, indicating partial improvement in vertical philtral symmetry, although complete normalization was not achieved. Other perioral parameters demonstrated relative stability, with non-significant changes in the cupid’s bow ratio, inter-commissure width ratio, and vermilion height ratio, suggesting maintenance of transverse and vermilion proportions during the early postoperative period. Collectively, these findings indicate selective normalization of specific nasal and midline perioral structures, while certain transverse and vertical asymmetries persist during early post-primary lip repair adaptation. This pattern is consistent with Yang et al. (81), , who reported progressive normalization of the crista philtri height ratio toward 1 and long term stability of labial variables, including labial width and lateral-oblique height, with no significant differences compared with the noncleft side.

From a biological and biomechanical perspective, the observed nasal symmetry improvements likely result from the interaction between surgical repositioning of the lip-nasal musculature, altered soft-tissue tension vectors, and underlying skeletal remodeling (85). In the present cohort, primary lip repair was performed in conjunction with primary rhinoplasty, allowing for early anatomical repositioning of the nasal cartilaginous framework and alar structures, which may generate balanced soft-tissue forces across the nasal base and columella, promoting symmetrical nasal growth and midline stabilization (82, 85). In addition, the integration of presurgical orthopedic management, such as NAM, may further contribute to early structural alignment, facilitating more symmetrical post-surgical adaptation of the nasolabial complex (83, 85).

In the present study, all patients were advised to use a nasal conformer following primary lip repair, which may have contributed to the favorable nasolabial esthetic outcomes observed. A recent systematic review and meta-analysis found that the use of postoperative nasal conformers in patients with unilateral cleft lip and palate was associated with improved nasal symmetry, with nostril width and height ratios generally closer to symmetry compared with controls, suggesting that conformers can support maintenance of nasal contour and reduce asymmetry during early healing and growth (86).

This objective enhancement of nasal symmetry is aligned with clinical evidence demonstrating that customized postsurgical nasal conformers are associated with improved symmetry between cleft and non-cleft sides, as shown in anthropometric comparisons at six months postoperative follow-up (83). Such improvements in nasal symmetry may result from the mechanical support provided by conformers, which help stabilize alar cartilage position and maintain nostril shape during scar maturation and soft-tissue remodeling (86).

Importantly, these objective symmetry gains correspond to perceptual esthetic improvements as measured by the Asher-McDade rating scale. The Asher-McDade system, a widely used ordinal scale evaluating components such as nasal form, nasal deviation, nasal profile, and vermilion border, has been shown to provide reliable nasolabial esthetic ratings in cleft populations, with nasal form and symmetry contributing significantly to overall aesthetic assessment (59, 88, 89). In the current cohort, significant increases in nasal form and nasal deviation scores and improvements in vermilion border perception between early and later postoperative time points suggest that the enhanced anatomical symmetry facilitated by conformer use translated into meaningful perceptual esthetic gains by expert raters (59).

Although findings from the systematic review indicate a trend toward improved nasal symmetry with conformer use, limitations such as heterogeneity in conformer types and retention protocols, as well as the absence of standardized subjective esthetic evaluations in many conformer studies (86), highlight the need for further research integrating both objective anthropometric measures and validated perceptual scales like the Asher-McDade rating system.

In addition to intrinsic biological and biomechanical factors, postoperative care protocols may also contribute to the observed stability of perioral proportions. At the Pattanalak Center, a standardized postoperative scar management protocol is implemented following primary lip repair, in which gentle circular massage of the surgical site is initiated two weeks postoperatively and performed four times daily for approximately five minutes per session. This intervention aims to promote scar softening, improve tissue elasticity, and reduce fibrotic contracture during the early healing phase. Such postoperative scar modulation may facilitate more uniform soft-tissue remodeling and contribute to symmetrical perioral proportions. Consequently, this protocol may partially explain the relative symmetry and stability of perioral ratios observed between Tn1 and Tn2 in the present cohort, particularly in parameters such as vermillion height and transverse oral dimensions. The integration of structured postoperative scar management with surgical reconstruction may therefore play an important role in optimizing early nasolabial esthetic outcomes and promoting stable soft-tissue adaptation during infancy.

Correlation analysis revealed significant moderate positive associations between maxillary arch development and nasolabial esthetics, supporting the concept of coordinated skeletal–soft tissue adaptation during early cleft repair. The observed associations were consistently positive, indicating that improvements in maxillary morphology were accompanied by corresponding enhancements in nasolabial symmetry. These findings are consistent with previous studies demonstrating associations between facial morphology and esthetic outcomes (88, 90).

Transverse expansion of the anterior maxillary arch was associated with improved philtral symmetry, suggesting that adequate anterior arch width may contribute to better soft tissue balance across the midline. This may be explained by the role of underlying skeletal support in guiding soft tissue contour and tension distribution in the upper lip region (90).

Notably, vertical development of the greater segment showed significant correlations with both columella length and philtrum height ratios, with the strongest relationship observed for philtral height. This finding highlights the importance of vertical skeletal growth in influencing midline nasal and philtral structures, possibly through its effect on nasal base support and soft tissue projection. Similar interdependence between skeletal and soft tissue morphology has been reported following primary lip repair (84, 88).

Furthermore, the significant association between greater segment rotation and inter-commissure width ratio underscores the role of three-dimensional segmental orientation in perioral esthetics. Rotational alignment of the maxillary segment may influence muscular balance and soft tissue positioning around the oral commissures, thereby contributing to transverse facial symmetry, consistent with previous findings (88, 91) .

Despite these significant findings, the strength of the correlations remained moderate, indicating that nasolabial esthetic outcomes are likely influenced by multiple interacting factors. Previous studies have shown that morphological variables alone explain only a limited proportion of esthetic variability, reinforcing the multifactorial nature of treatment outcomes (90). Factors such as surgical technique, scar formation, and intrinsic soft tissue characteristics may all contribute to the final esthetic result (84, 88).

Collectively, these findings reinforce the importance of early orthopedic and surgical interventions aimed at optimizing maxillary segment position in all three dimensions, namely transverse, vertical, and rotational to promote favorable nasolabial harmony (91). This is consistent with systematic reviews indicating that while interventions can significantly influence maxillary morphology, their impact on esthetic outcomes may vary (88, 90).

Clinically, these results indicate that early primary lip repair contributes not only to immediate esthetic reconstruction but also to progressive improvement in nasolabial symmetry during early growth. The observed enhancement of nasal symmetry parameters and philtral proportions suggests that early surgical intervention may establish favorable morphological conditions for subsequent developmental adaptation and later secondary procedures (84). Together, these findings emphasize the importance of comprehensive early management strategies that integrate presurgical orthopedics, precise surgical reconstruction, and longitudinal growth monitoring to optimize long-term nasolabial esthetic outcomes in patients with complete unilateral cleft lip and palate (85, 86).

Despite the clinical relevance and consistency of these findings, several limitations should be acknowledged. First, the absence of a control group without standardized postoperative nasal conformer use or scar management protocols limits the ability to draw causal inferences regarding the independent effects of these interventions on nasolabial esthetic outcomes. Second, the relatively short follow-up period restricts evaluation of long-term growth stability and the persistence of the observed skeletal and soft-tissue adaptations. Third, the observational study design without randomization limits the ability to isolate the individual contributions of presurgical orthopedics, surgical techniques, nasal conformer use, and postoperative scar management. Finally, although both objective anthropometric measurements and perceptual assessments were incorporated, inter-individual biological variability and growth-related differences may also influence outcomes.

Additionally, caregiver compliance, which plays a significant role in the effectiveness of both presurgical orthopedic therapy and postoperative care, was not quantitatively assessed in this study. Variations in adherence to appliance wear, nasal conformer use, and scar management protocols may have influenced the observed outcomes and should be considered when interpreting the results.

Therefore, future longitudinal controlled studies with larger sample sizes, standardized treatment protocols, appropriate control groups, and extended follow-up periods are required to validate these findings and to further clarify the long-term skeletal–soft tissue–esthetic interactions in the comprehensive management of unilateral cleft lip and palate. In addition, such studies should incorporate well-defined control groups and include comparisons between different presurgical orthopedic approaches, including various NAM techniques, to better understand their impact on treatment outcomes.

CHAPTER V

CONCLUSIONS

This study demonstrated that primary lip repair in patients with complete unilateral cleft lip and palate is associated with significant early morphological adaptation of both the maxillary arch and the nasolabial complex. Three-dimensional quantitative analysis revealed marked transverse and sagittal maxillary changes between the primary lip repair stage (T1) and the post-primary lip repair follow-up (T2), including reduction of anterior cleft width, transverse expansion of the maxillary arch, sagittal elongation of both maxillary segments, and medial rotational remodeling of the greater segment, while vertical dimensions remained relatively stable. These findings indicate coordinated structural reorganization of the maxillary arch following primary lip repair.

Concurrently, adaptive remodeling of the nasolabial complex was observed between the early post-primary lip repair period (Tn1, 1–4 weeks) and the 6-month follow-up (Tn2). Changes in nasal morphology reflected dynamic proportional reorganization with preservation of near-symmetry, rather than uniform linear normalization toward perfect symmetry. Selective parameters, particularly nostril height and philtral proportions, demonstrated true improvement toward symmetry, whereas transverse oral width and vermilion dimensions remained relatively stable, indicating early stabilization of perioral transverse proportions during post-surgical growth.

Importantly, correlation analysis demonstrated significant associations between maxillary arch development and nasolabial esthetic outcomes, highlighting a close interrelationship between skeletal maxillary growth and soft-tissue nasolabial adaptation following primary lip repair. Transverse, vertical, and rotational changes of the maxillary segments were significantly correlated with key nasal and perioral symmetry parameters, supporting the concept of integrated craniofacial development in early cleft management.

Collectively, these findings indicate that primary lip repair, in combination with early orthopedic management, contributes not only to immediate esthetic reconstruction but also to coordinated skeletal–soft tissue adaptation during early growth. This integrated morphological response may establish favorable anatomical conditions for subsequent surgical procedures and long-term craniofacial development. The results underscore the importance of comprehensive early treatment strategies and longitudinal monitoring to optimize functional and esthetic outcomes in patients with complete unilateral cleft lip and palate.

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APPENDIX

Appendix A: The protocol approved by Naresuan University Institutional Review Board

COA No. 253/2024 AF 11/6.0

IRB No. P1-0120/2567

คณะกรรมการจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยนเรศวร

99 หมู่ 9 ตำบลท่าโพธิ์ อำเภอเมืองพิษณุโลก จังหวัดพิษณุโลก 65000 หมายเลขโทรศัพท์ 05596 8752

หนังสือรับรองโครงการวิจัยครั้งแรก

คณะกรรมการจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยนเรศวร ดำเนินการให้การรับรองโครงการวิจัยตามแนวทางหลักจริยธรรมการวิจัยในคนที่เป็นมาตรฐานสากล ได้แก่ Declaration of Helsinki, The Belmont Report, CIOMS Guideline และ International Conference on Harmonization in Good Clinical Practice หรือ ICH-GCP

ชื่อโครงการ : การประเมินการเปลี่ยนแปลงของสัณฐานกระดูกเบ้าฟันขากรรไกรบนและความงามจมูกร่วมริมฝีปากภายหลังการผ่าตัดริมฝีปากปฐมภูมิในผู้ป่วยปากแหว่งเพดานโหว่ข้างเดียวชนิดสมบูรณ์ด้วยการปรับจมูกและกระดูกเบ้าฟัน

ผู้วิจัยหลัก : ผศ.ทพญ.รัชวรรณ ตันศลารักษ์

สังกัดหน่วยงาน : คณะทันตแพทยศาสตร์

ผู้ร่วมวิจัย : จุฑารัตน์ ฉิมเรือง ศรัณย์ วรศักดิ์วุฒิพงษ์ ธนพร พัฒนวศิน

วิธีทบทวน : แบบเร่งรัด

รายงานความก้าวหน้า : ส่งรายงานความก้าวหน้าอย่างน้อย 1 ครั้ง/ปี หรือส่งรายงานฉบับสมบูรณ์หากดำเนินโครงการเสร็จสิ้นก่อน 1 ปี

เอกสารรับรอง

1. IF 01 Research Ethical Application (Secondary Research) เวอร์ชั่น 2.0 วันที่ 22 กรกฎาคม 2567
2. IF 02 Conflict of interest and Funding Form เวอร์ชั่น 1.0 วันที่ 20 มิถุนายน 2567
3. IF 05 ประวัติผู้วิจัย เวอร์ชั่น 1.0 วันที่ 20 มิถุนายน 2567
4. IF 06 งบประมาณของโครงการวิจัย เวอร์ชั่น 1.0 วันที่ 20 มิถุนายน 2567
5. Full Proposal Research เวอร์ชั่น 1.0 วันที่ 20 มิถุนายน 2567
6. Demographic data form เวอร์ชั่น 2.0 วันที่ 22 กรกฎาคม 2567

ลงนาม........................

(นายแพทย์สมบูรณ์ ตันสุภสวัสดิกุล)

ประธานคณะกรรมการจริยธรรมการวิจัยในมนุษย์

มหาวิทยาลัยนเรศวร

วันที่รับรอง : 25 กรกฎาคม 2567

วันหมดอายุ : 25 กรกฎาคม 2568

ทั้งนี้ การรับรองนี้มีเงื่อนไขดังที่ระบุไว้ด้านหลังทุกข้อ (ดูด้านหลังของเอกสารรับรองโครงการวิจัย)

นักวิจัยทุกท่านที่ผ่านการรับรองจริยธรรมการวิจัยต้องปฏิบัติดังต่อไปนี้

1. ดำเนินการวิจัยตามที่ระบุไว้ในโครงการวิจัยอย่างเคร่งครัด
2. ใช้เอกสารแนะนำอาสาสมัคร ใบยินยอม (และเอกสารเชิญเข้าร่วมวิจัยหรือใบโฆษณาถ้ามี) แบบสัมภาษณ์ และหรือแบบสอบถาม เฉพาะที่มีตราประทับของคณะกรรมการจริยธรรมในมนุษย์ มหาวิทยาลัยนเรศวรเท่านั้น และส่งสำเนาเอกสารดังกล่าวที่ใช้กับผู้เข้าร่วมวิจัยจริงรายแรกมาที่คณะกรรมการจริยธรรมการวิจัยในมนุษย์ เพื่อเก็บไว้เป็นหลักฐาน
3. รายงานเหตุการณ์ไม่พึงประสงค์ร้ายแรงที่เกิดขึ้นหรือการเปลี่ยนแปลงกิจกรรมวิจัยใด ๆ ต่อคณะกรรมการจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยนเรศวร ภายในระยะเวลาที่กำหนดในวิธีดำเนินการมาตรฐาน (SOPs)
4. ส่งรายงานความก้าวหน้าต่อคณะกรรมการจริยธรรมการวิจัยในมนุษย์ ตามเวลาที่กำหนดหรือเมื่อได้รับการร้องขอ
5. หากการวิจัยไม่สามารถดำเนินการเสร็จสิ้นภายในกำหนด ผู้วิจัยต้องยื่นขออนุมัติใหม่ก่อน อย่างน้อย 1 เดือน
6. หากผู้วิจัยส่งรายงานความก้าวหน้าหลังใบรับรองหมดอายุ และยังไม่ได้ใบรับรองฉบับใหม่ ผู้วิจัยจะต้องหยุดดำเนินการวิจัยส่วนที่เกี่ยวข้องกับการรับอาสาสมัครใหม่ นับตั้งแต่หลังวันใบรับรองหมดอายุจนกว่าจะได้รับใบรับรองฉบับใหม่
7. หากการวิจัยเสร็จสมบูรณ์ผู้วิจัยต้องแจ้งปิดโครงการตามแบบฟอร์มของคณะกรรมการจริยธรรมในมนุษย์ มหาวิทยาลัยนเรศวร

*รายชื่อของคณะกรรมการจริยธรรมการวิจัยในมนุษย์ (ชื่อและตำแหน่ง) ที่เข้าร่วมประชุม ณ วันที่พิจารณารับรองโครงการวิจัย (หากร้องขอล่วงหน้า)

Appendix B: The protocol approved by Naresuan University Institutional Review Board (extended)

COA No. 253/2024 AF 14/6.0
IRB No. P1-0120/2567

คณะกรรมการจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยนเรศวร
99 หมู่ 9 ตำบลท่าโพธิ์ อำเภอเมืองพิษณุโลก จังหวัดพิษณุโลก 65000 หมายเลขโทรศัพท์ 05596 8640

เอกสารรับรองโครงการวิจัย

คณะกรรมการจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยนเรศวร
ดำเนินการให้การรับรองโครงการวิจัยตามแนวทางหลักจริยธรรมการวิจัยในคนที่เป็นมาตรฐานสากล ได้แก่ Declaration of Helsinki, The Belmont Report, CIOMS Guideline และ International Conference on Harmonization in Good Clinical Practice หรือ ICH-GCP

ชื่อโครงการ : การประเมินการเปลี่ยนแปลงของสัณฐานกระดูกเบ้าฟันขากรรไกรบนและความงามจมูกร่วมริมฝีปากภายหลังการผ่าตัดริมฝีปากปฐมภูมิในผู้ป่วยปากแหว่งเพดานโหว่ข้างเดียวชนิดสมบูรณ์ด้วยการปรับจมูกและกระดูกเบ้าฟัน
ผู้วิจัยหลัก : ผศ.ทพญ.รัชวรรณ ตัณศลารักษ์
สังกัดหน่วยงาน : คณะทันตแพทยศาสตร์
ผู้ร่วมวิจัย : จุฑารัตน์ นิ่มเรือง ศรัณย์ วรศักดิ์วุฒิพงษ์ ธนพร พัฒนวศิน
วิธีทบทวน : รูปแบบเร่งรัด
รายงานความก้าวหน้า : ส่งรายงานความก้าวหน้าอย่างน้อย 1 ครั้ง/ปี หรือส่งรายงานสรุปผลการวิจัยหากดำเนินโครงการเสร็จสิ้นก่อน 1 ปี
เอกสารรับรอง

1. PF 01 Submission for Post Approval Report เวอร์ชั่น 1.0 วันที่ 8 มิถุนายน 2568

ลงนาม สมบูรณ์ ต้นสุภสวัสดิกุล

(..นายแพทย์สมบูรณ์ ต้นสุภสวัสดิกุล...)
ประธานคณะกรรมการจริยธรรมการวิจัยในมนุษย์
มหาวิทยาลัยนเรศวร

วันที่รับรอง	: 25 กรกฎาคม 2567
วันหมดอายุ	: 25 กรกฎาคม 2568
วันที่รับรองต่อเนื่องครั้งที่ 1	: 25 กรกฎาคม 2568
วันที่หมดอายุการรับรองครั้งที่ 1	: 25 กรกฎาคม 2569

ทั้งนี้ การรับรองนี้มีเงื่อนไขดังที่ระบุไว้ด้านหลังทุกข้อ (ดูด้านหลังของเอกสารรับรองโครงการวิจัย)

นักวิจัยทุกท่านที่ผ่านการรับรองจริยธรรมการวิจัยต้องปฏิบัติดังต่อไปนี้

1. ดำเนินการวิจัยตามที่ระบุไว้ในโครงการวิจัยอย่างเคร่งครัด
2. ใช้เอกสารแนะนำอาสาสมัคร ใบยินยอม (และเอกสารเชิญเข้าร่วมวิจัยหรือใบโฆษณาถ้ามี) แบบสัมภาษณ์ และหรือ แบบสอบถาม เฉพาะที่มีตราประทับของคณะกรรมการจริยธรรมในมนุษย์ มหาวิทยาลัยนเรศวรเท่านั้น
   และส่งสำเนาเอกสารดังกล่าวที่ใช้กับผู้เข้าร่วมวิจัยจริงรายแรกมาที่คณะกรรมการจริยธรรมการวิจัยในมนุษย์ เพื่อเก็บไว้เป็นหลักฐาน
3. รายงานเหตุการณ์ไม่พึงประสงค์ร้ายแรงที่เกิดขึ้นหรือการเปลี่ยนแปลงกิจกรรมวิจัยใด ๆ ต่อคณะกรรมการจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยนเรศวร ภายในระยะเวลาที่กำหนดในวิธีดำเนินการมาตรฐาน (SOPs)
4. ส่งรายงานความก้าวหน้าต่อคณะกรรมการจริยธรรมการวิจัยในมนุษย์ ตามเวลาที่กำหนดหรือเมื่อได้รับการร้องขอ
5. หากการวิจัยไม่สามารถดำเนินการเสร็จสิ้นภายในกำหนด ผู้วิจัยต้องยื่นขออนุมัติใหม่ก่อน อย่างน้อย 1 เดือน
6. หากผู้วิจัยส่งรายงานความก้าวหน้าหลังใบรับรองหมดอายุ และยังไม่ได้ใบรับรองฉบับใหม่
   ผู้วิจัยจะต้องหยุดดำเนินการวิจัยส่วนที่เกี่ยวข้องกับการรับอาสาสมัครใหม่
   นับตั้งแต่หลังวันใบรับรองหมดอายุจนกว่าจะได้รับใบรับรองฉบับใหม่
7. หากการวิจัยเสร็จสมบูรณ์ผู้วิจัยต้องแจ้งปิดโครงการตามแบบฟอร์มของคณะกรรมการจริยธรรมในมนุษย์ มหาวิทยาลัยนเรศวร

*รายชื่อของคณะกรรมการจริยธรรมการวิจัยในมนุษย์ (ชื่อและตำแหน่ง) ที่เข้าร่วมประชุม ณ วันที่พิจารณารับรองโครงการวิจัย (หากร้องขอล่วงหน้า)

Appendix C: Demographic data form

Demographic data form

Subject's name ………………………………………………………………………….

Subject information	
Gender	O Male O Female
Cleft side	O Right O Left
Date of birth (DD/MM/YY)	_ _/_ _/_ _
Date of the beginning of NAM treatment (DD/MM/YY)	_ _/_ _/_ _
Age at the beginning of NAM treatment (MM/DD)	_ _/_ _
Initial alveolar cleft gap (mm) T0	_ _
Complications	O Extra-oral O Cheeks …………………………………… O Lip ………………………………………… O Nose ………………………………………
	O Intra-oral O Labial/Buccal mucosa……………… O Palate …………………………………… O Alveolar ridges…………………………
Compliance (NAM)	O Broken appointment O Discontinued usage of NAM
Compliance (nasal conformer)	O Broken appointment O Discontinued usage of nasal conformer
Duration of treatment time (days)	_ _
Date of primary lip repair (DD/MM/YY)	_ _/_ _/_ _
Age at primary lip repair (months and days)	_ _/_ _
Date of palatoplasty (DD/MM/YY)	_ _/_ _/_ _
Age at palatoplasty (months or year)	_ _/_ _

Appendix D: Measurements data form for maxillary arch change

Measurements data form for maxillary arch change

Code No.

Date _ _ /_ _ / _ _

Measurements*	Value T1	Value T2
A-A’		
P-P’		
C-C’		
T-T’		
A⊥T-T’		
A’⊥T-T’		
D-HP		
D’-HP’		
IMT angle		

Appendix E: Measurements data form for nasolabial esthetics

Measurements data form for nasolabial esthetics

Code No.

Date _ _ /_ _ / _ _

Measurements*	Value TN1	Value TN2
1) AlRt-midline/AlLt-midline		
2) AbRt-midline/AbLt-midline		
3) NdRt-NlRt/ NdLt-NlLt		
4) FlRt-FmRt/ FmLt-FlLt		
5) CRt⊥AlRt-AlLt/ CLt⊥AlRt-AlLt		
6) CphRt-midline/ CphLt -midline		
7) ChRt-midline/ ChLt-midlinr		
8) CphRt⊥AlRt-AlLt/ CphLt⊥AlRt-AlLt		
9) CphRt-LRt/ CphLt-LLt		

Appendix F: Data form for Asher-Mcdade rating scale

Code No.

Date _ _ /_ _ / _ _

Score	1	2	3	4	5
Vermilion border					
Nasal form					
Nasal symmetry					
Nasal profile					

(1=very good appearance, 2=good, appearance, 3=fair appearance, 4=poor appearance, 5=very poor appearance)

BIOGRAPHY

BIOGRAPHY

Name-Surname	Thanaporn Pattanawasin
Address	10 Moo 3, Tha Ngam Subdistrict, In Buri District, Sing Buri Province 16110, Thailand
Work Place	Bueng Sam Phan Hospital Sub Samor Thod Sub-district, Bueng Sam Phan District, Phetchabun Province 67160, Thailand
Position	Dentist
Work Experiences	
2019 - Now	Dentist, Bueng Sam Phan Hospital Sub Samor Thod Sub-district, Bueng Sam Phan District, Phetchabun Province 67160, Thailand
Education Background	
2019	D.D.S., Naresuan University