Case Report

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Nasoalveolar molding combined with an extra-oral strap in a patient with a bilateral complete cleft lip and palate: a case report

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Cleft lip and/or palate are craniofacial development deformities. The goal of using Nasoalveolar molding (NAM) is to facilitate the treatment of extreme cases to generate better outcomes. This article provides an overview of a case of a 4-day old female patient with a bilateral complete cleft lip and palate, treated with a passive obturator and CMU-NAM II (Chiang Mai-Nasoalveolar Molding II) with an extra-oral strap, while correcting the premaxilla into the midline position. This process took 4 months and 14 days. During this time, the patient was followed up every 2 weeks for adjusting the devices before performing cheiloplasty. After cheiloplasty, an obturator was fabricated and followed up every 2 months until the palate was repaired. After the follow-up period, satisfactory results were obtained. The patient is well-sucking, and has no issues pertaining to choking while milk-feeding. The shape of the nose was similar to a normal appearance with reduced cleft gaps.

Keywords: cleft lip and/or palate, nasoalveolar molding, strap

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Introduction

Cleft lip and cleft palate are facial and upper jaw malformations. This condition is the sixth most common among the top seven congenital malformations in Thailand, with the highest incidence in the Northeast [1, 2]. The reported incidence ranges from 1.01–2.68 cases per 1,000 newborns, classified into cleft lip, cleft palate, and cleft lip with cleft palate per 1,000 newborns: 0.16–0.90 cases, 0.07–0.95 cases, and 0.25–0.90 cases, respectively [3]. Several studies have classified the factors that cause the condition into three main categories: genetic factors, environmental factors that affect organogenesis, especially in the first trimester of pregnancy, such as smoking, drinking, malnutrition, and vitamin deficiencies, especially folic acid, or exposure to certain medications [4-6], and genetic factors combined with environmental factors. Genetic factor analysis revealed that more than half of the cleft lip and palate cases were not related to a syndrome. In contrast, 30% of the patients with cleft lip and palate have a disorder associated with the syndrome of another disease [7].

In cleft lip and palate cases, breastfeeding difficulties are common due to the lip and palate openings, because air will pass through these openings, making it impossible to generate negative pressure inside the mouth. Therefore, the suction efficiency is lost. Sucking takes a longer time. In some cases, milk may be aspirated

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into the respiratory tract, causing respiratory and middle-ear infections [8]. Furthermore, a cleft causes an abnormal alignment of the ridges of the upper jaw, a flattened nasal cavity, and an abnormal shape of the nasal cartilage. Moving the bony ridges of the upper jaw premaxilla into the appropriate alignment with the remaining lateral ridges by minimizing protrusion and twisting of the premaxilla, as well as adjusting the shape of the nose to be as close to normal as possible, will help the plastic surgeon perform the nose and lip surgery better and easier, reducing the time and number of revision surgeries needed to correct the nose and lips after treatment [9].

This article presents a case report on the treatment procedures and clinical outcomes of a patient with bilateral complete cleft palate treated using a passive obturator and using Chiang Mai-Nasoalveolar Molding II (CMU-NAM II), together with an extra-oral strap and correcting the alveolar bone deflection using a plaster strip to pull the premaxilla to the middle of the face.

Case report

A 4-day-old Thai female patient, born at Vachira Phuket hospital, was referred from the neonatal intensive care unit with a breastfeeding problem. At that time, the patient was being fed using an orogastric tube. The patient was healthy, the third child, and had a bilateral complete cleft lip and palate. The family history revealed that there was no genetic history of cleft palate. The birth was normal, the birth weight was 2,690 grams, and the gestational age at birth was 38 weeks. The father was a hired worker, and the mother was a housewife, 51 and 34 years old, respectively. The mother received folic acid at approximately the 4th month of pregnancy. There was no history of taking other drugs during pregnancy. There was no history of drinking alcohol, smoking, or related syndromes. Examination of the child's oral cavity revealed that the premaxilla and prolabium protruded forward and were twisted 45^{o} to the left. There was a gap in contact between the mouth and nasal passages on both sides. The left tip of the nose was attached to the prolabium. There was a small section of columella. The side of the nostrils flared out. The right alveolar cleft was wider than the left (Figures 1, 2).



Figure 1 4-day-old baby girl with a bilateral complete cleft lip and palate



Figure 2 Study of the Model (4 days of age)

The treatment plan was to create a passive obturator so that the patient could suckle the breast well and become used to inserting the apparatus. A plaster strip was applied outside the mouth, together with traction, to divert the premaxilla to the midline of the face to restructure the nose and alveolar bone before cheiloplasty using CMU-NAM II and sending the patient for cheiloplasty, together with passive obturator insertion until the cleft palate closure surgery. The patient was continuously followed up and underwent oral health assessments, and saw a speech therapist.

The treatment during the first visit, i.e., history taking, clinical examination, and taking photographs, was performed at the dental department. The parents were informed of the treatment plan during the patient's initial visit and provided informed consent for using the clinical photographs in the publication. The parents received counseling to relieve their concerns at each follow-up visit, and were directed to register in the Beautiful Smile, Beautiful Voice Project for cleft lip and palate patients. Before taking an impression, the patient abstained from milk for at least 3 h.

The impression was taken in the neonatal intensive care unit using an acrylic tray with a fast-hardening alginate for a passive obturator (Figure 3). The thickness of the obturator was ~2 mm. A hole was drilled in the front of the obturator to allow the floss to be attached to the outside of the mouth, and to prevent the apparatus from slipping inside. The obturator was applied with micropore tape wrapped around the premaxilla, pulling it to the right to be in line with the center of the face as much as possible, and the mouth was covered with an adhesive bandage. The length of the strap was equal to the outer corners of both eyes. The first layer of tape was applied on both cheeks as a pad, before attaching the strap by sticking one end over the pad and squeezing the cheeks together while pulling the strap; the other end was placed on the opposite side of the cheek, so the strap rested on the lips and gums (Figures 4, 5). While applying the strap, the patient's cheeks were squeezed together with moderate force, and then the hand was released, allowing the strap to be pulled back, causing pressure. The mother was adviced on how to remove, put on, and clean the obturator, including how to make and use the pull tabs to divert the premaxilla and strap, and how to breastfeed by having the mother try to feed the patient. The emphasis on posture while suckling was to keep the head at 45° (semi-upright position) to reduce the chance of aspiration. After the follow-up appointment the next day, the patient was observed to be able to suckle well. There was no wound in the mouth, however, the parents did not tighten the strap and divert the premaxilla to the center of the face. Instructions about how to perform this method were repeated and monitored for two more weeks.



Figure 3 Impressions of the patient at the neonatal intensive care unit





Figures 4–5 The patient with a passive obturator, extra-oral strap, and using tape traction to move the premaxilla toward the midline

After inserting a passive obturator for ~1 month, an impression was taken using alginate for making CMU- NAM II in the operating room. An appointment was made for inserting an active obturator using the CMU-NAM II tool (Figure 6). A nose-tip pusher was made using a 0.9 mm round stainless-steel wire that was attached to the plate at both sides of the cleft to push up the flat nose tip and to resist the pressure from the belt outside the mouth. The wire was bent so that the end of the coil was folded into both nostrils to form the core of the nasal bulb. The inner end of the wire was covered with hard acrylic, and the outer layer was covered with a tear-shaped soft liner, with the convex top pointing toward the core and tilted forward to push the tip of the nose up. This action made the tip of the nose slightly pale.

Micropore tape was wrapped in the premaxilla position, and the strap was attached outside the mouth as before (Figure 7). It was important to ensure that no part of the apparatus interfered with the baby's suckling and did not press against the tissue around the mouth. The parents were instructed in how to remove the appliance,

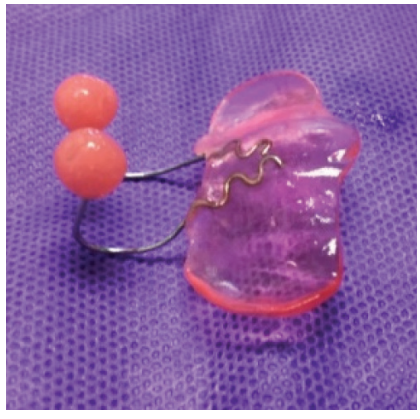


Figure 6 Chiang Mai-Nasoalveolar Molding II (CMU-NAM II)



Figure 7 The patient after inserting the CMU-NAM II and extra-oral strap

and that the baby had to wear it all the time, taking it off was allowed only when washing it with clean water every day. The parents had the patient try suckling, and follow-up appointments were made every 2 weeks. At every follow-up visit, the size of nasal bulb was increased to adjust the size and shape of the nose and bend the wire higher along with inserting the strap outside the mouth continuously until the nose structure and cleft size were close to normal. While inserting the instrument, the nose was adjusted slightly higher than normal to compensate for the recovery from pulling on the wound after the surgical suture.

At the follow-up, it was observed that the premaxilla had shifted to the center and the protrusion had decreased. The prolabium enlarged in the middle and approached the cleft lip on both sides. A longer columella, a prominent nasal tip, and a narrowed alveolar cleft gap were noted (Figures 8-10). The patient was referred for cheiloplasty when the patient was 5 months and 15 days old. After cheiloplasty, (Figure 11), the patient was followed-up after 3 weeks for taking the impressions and making a passive obturator for the patient before palatoplasty at the age of 1 year and 3 months. The treatment results were satisfactory (Figure 12). The patient was continuously followed up, and received an oral health assessment every 3 months, and went to see a speech therapist at the age of 1 year 9 months. The treatment process of the bilateral complete cleft lip and palate of the patient is summarized in Table 1.

Discussion

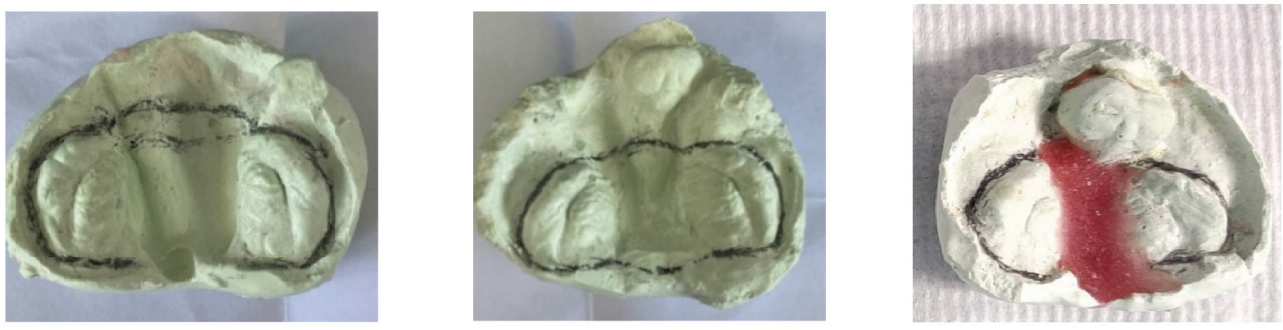
Cleft lip and palate are abnormalities of the upper jaw bone and face. A nasal molding device is a treatment option used to make the surgery more effective, especially in patients with more severe anomalies, for which surgical suture correction by plastic surgery alone may not be sufficient. For patients with very severe deformities, reshaping the nose and dilating the fissure side of the nostrils before surgery can improve balance and obtain a near-normal columella length, and reduce wound retention compared with surgical correction alone. Therefore, it is recommended to restructure the nose by aligning the maxillary curve in cases with a complete cleft. There are many nasoalveolar molding patterns, such as the KORAT-NAM, Khon Kaen University nasoalveolar molding (KKU-NAM), and CMU- NAM. In the present case, where the patient had quite severe abnormalities, a device called CMU-NAM II



Figure 8 Premaxilla position after inserting the CMU-NAM II



Figure 9 Extra-oral photographs taken prior to cheiloplasty (4 months of age)



a b c

Figure 10 Study models. a. 4 days of age, b. 1 month of age, c. 5 months of age



Figure 11 Extra-oral appearance one month after cheiloplasty (6 months of age).



a b c

Figure 12 Extra-oral appearance after cheiloplasty. a. 8 months of age, b. and c. 1 year and 10 months of age

Table 1 Treatment process in a bilateral complete cleft lip and palate patient

Visit	Treatment
1	1.1) History taking, clinical examination, taking photographs, and developing a treatment plan. 1.2) Explain the treatment processes to the parents and have the consent form signed.
2	2.1) Take impressions for the study model. 2.2) Insert a passive obturator. 2.3) Apply an extra-oral strap and divert the premaxilla to the center of the face. 2.4) Give advice on oral hygiene care, how to use and take care of the devices, and the breastfeeding position. 2.5) Follow up after 1 day, assess the use of the obturator and the outcomes of the extra oral strap, and then follow up every 2 weeks (take records)
3	3.1) Take the impressions for the working models and then construct the nasoalveolar molding (CMU-NAMII) 3.2) Insert the CMU-NAMII, apply the extra-oral strap and divert the premaxilla to the center of the face. 3.3) Advise the parents to use the device. 3.4) Follow up every 2 weeks (take records and increase the device to adjust the size of the nasal bulb). 3.2) Approximately 4 months after treatment, assesstreatment outcomes, and take records before referring the patients for cheiloplasty.
4	Cheiloplasty
5	5.1) Follow up at 3 weeks after cheiloplasty and take records. 5.2) Take an impression for the study model and insert the passive obturator. 5.3) Recall and assess the treatment outcomes every 1–2 months until the palate was repaired. 5.4) Provide oral hygiene instructions.
6	6.1) Take records and refer the patients for palate repair at the age of 1 year 3 months. 6.2) Follow up every 3 months (take care of oral hygiene) and send to see a speech therapist at age 1 year 9 months.

developed by Chaiworawitkul [10-12] was used to restructure the nose and upper jaw bone. CMU-NAM is claimed to decrease the complexity of making devices. There are 3 types; CMU NAM I for use with a unilateral complete cleft lip and palate, CMU-NAM II for use with a bilateral complete cleft lip and palate, and CMU NAM III for use with a cleft nose and lip that does not include the palate.

This patient had a rather severe cleft. In addition, the position of the premaxilla deviated greatly from the center of the face, the nose was deformed and columella was short. CMU-NAM II and an extra-oral strap was used to restructure the nose and premaxilla before surgery to increase the effectiveness of the surgery. This treatment made the nose shape and the alignment of the maxillary bone close to normal and decreased the gap between the clefts, reducing the pulling force of the wound, resulting in a more esthetic appearance [11,13-14].

Studies have demonstrated that in addition to improving the shape of the lips and nose, using NAM also reduces the oronasal fistula. Furthermore, it can reduce the secondary alveolar bone graft by 60% [13]. NAM is most effective when performed between birth and ~3–4 months of age due to the high levels of hyaluronic acid in the developing nasal cartilage. Hyaluronic acid and proteoglycans increase the flexibility of cartilage, ligaments, and connective tissue. However, after the baby is ~6 weeks old, the level of hyaluronic acid decreases, thereby reducing the elasticity of the cartilage. Therefore, if the baby is healthy, the apparatus can be attached beginning at ~1–2 weeks old due to the soft nasal cartilage, making it easy to adjust its shape [15]. Matsuo and Hirose [16] reported that cartilage growth peaks in the first 6 weeks postpartum due to the presence of maternal estrogen levels that result in high levels of hyaluronic acid, therefore, it is suggested that a nasal restructuring tool should be used during this period [16-17]. Therefore, this patient was appointed to make the CMU-NAM at 1 month old.

In this case, an external strap was used to help press the protruding premaxilla into a normal alignment by fabricating the obturator to not cover the gingival ridge, which provided pressure and tension from the strap to the mouth to press and pull the ridge of the upper jaw in the desired direction. This is in line with Pool [18], who recommended using tape outside the mouth to reduce the cleft gap. In Thailand, when using the KKU-NAM technique, the strap has also been used in conjunction with a nasal molding device [19].

The CMU-NAM II does not obstruct a baby's natural suckling behavior. This tool makes it simple, saves time, and reduces tooling stress. However, after surgery, nasal flattening is common; the nasal width tends to increase, and columella length gradually decreases due to scar stretching [10-11]. It is recommended to have a device to support the nasal cartilage shape after surgery or after suture removal. For example, it is recommended to use a device called the Chiang Mai University-Nasal Stent (CMU Nasal Stent) or a device called a nasoform, which must be inserted all the time for the first 6–8 months, then the amount of time is gradually decreased to adjust the narrow and flat nostrils to return to a more normal shape and resist the pulling force of the scar after suturing and inserting a passive obturator to close the cleft palate while waiting for the sutures to close when the baby is ~1 year old [11]. In this patient, a nasoform was not inserted after lip suture surgery because the parents did not have time to follow up on the treatment. However, a passive obturator was inserted and followed up every 2 months until the palate was repaired.

Revision surgery is usually done between 3–6 months of age [20], depending on the maturity of

the body. The internationally accepted and commonly used rule is the “rule of 10”; i.e., at 10 weeks old the baby weighs 10 pounds (4.55 kg) and has a hemoglobin of 10 g [21-22]. In this patient, the patient was sutured at the age of 5 months and 15 days, weighing 5.68 kg.

The care of patients with cleft lips and/or cleft palates is an interdisciplinary approach [22] that requires coordination, consultation, joint planning, and referral for ongoing care. Vachira Phuket Hospital has a complete multidisciplinary team capable of providing excellent care for this group of patients. Parental acceptance and cooperation is one of the key factors related to treatment success [23], especially when applying nasoalveolar molding, an oral strap, and continuous follow-ups to increase the size of the nasal bulbs. Therefore, before treatment, parents must have a detailed understanding of the various steps and duration of treatment, including encouragement, compliments, and pointing out positive changes to understand and adjust to the child's abnormality. Because the parents of this patient understood and cooperated very well, the treatment results were satisfactory.

Conclusion

A patient with a bilateral complete cleft lip and palate was treated prior to cheiloplasty with a passive obturator and CMU-NAM II in combination with an extra oral strapping and pulling of the premaxilla position, making the nose and columella almost normal, narrowing the alveolar cleft gaps, and improving the esthetics of her facial appearance. However, a follow-up bone grafting surgery, soft tissue cosmetic surgery, orthodontics, and continuous follow-up of oral health and additional treatment by an interdisciplinary team are required to improve the patient’s quality of life.

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