

Original Article

A Modified Naso-Alveolar Molding Device for Unilateral Cleft Lip and Palate

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Abstract

Objective: Naso-alveolar-molding(NAM) is used to reshape the nasal cartilage and mold the maxillary alveolar arch before surgical cleft/lip repair. The study aimed to modify the conventional-NAM-device to lessen the severity of cleft lip/palate deformity and make the overall procedure simpler and beneficial, with fewer hospital recall visits.

Methods: Sixty-six patients with unilateral cleft lip/palate were selected: 21 males and 12 females were fitted with a conventional-NAM-device, whereas 18 males and 15 females were fitted with a modified-NAM-device. The inter-alveolar gap ranged between (14.5 and 13.5)mm. A presurgical-NAM-device was applied in the second week after the birth. Standardized parameters of cleft lip/palate were measured on the cast. Nostril width, columellar height, and columellar angle were measured on photographs. The number of recall visits was recorded. The modified device was similar to the conventional-NAM-device. However, the nasal stent was made of acrylic and separated from the plate. The thickness of the acrylic stent ranged from 10 to 3mm. The thicker and heavier acrylic was placed on the bigger arch side, and the thin part was placed on the small arch side.

Results: A difference was observed between the conventional and modified device in the time taken to reduce the inter-alveolar-gap. Additionally, with the modified device there were fewer recall visits to the hospital. Furthermore, when the conventional NAM was compared with the modified device, the latter showed a significant improvement regarding the patients' outcome (One-way-ANOVA or Kruskal-Wallis).

Conclusions: The modified device is an effective and non-invasive device for accelerating the alignment of the alveolar segments to create the foundation upon which excellent lip/primary nasal surgery results can be achieved. This modification made the procedure more beneficial and simpler for the patient and parents. At the same time, recall visits were reduced by half when compared to those required for the conventional device.

Keywords: *Unilateral cleft lip and palate, Pre-surgical infant orthopedics, Pre-surgical nasoalveolar molding.*

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Introduction

Cleft lip-palate (CLP) is a facial malformation that disturbs esthetics, speech, and hearing¹. Cleft lip and palate is one of the most common congenital disabilities. About 60-80% of CLP cases occur in males². In general, unilateral complete cleft abnormalities include lip, nostril, and alveolus disruption, as well as ill-defined cupid's bow and philtral ridge, unusual smallness of the lip, and hypertrophied frenum of the vermilion. Meanwhile, nasal deformities include squashed and flared nostril openings on the cleft side, creating distorted columella towards the affected side. In addition, the anterior nasal spine will be deviated towards the normal side, forming an asymmetrical tip of the nose^{3,4}.

The surgical management of cleft lip/ palate has been documented since 317 AD⁵. From the 1800s to the 1900s, many surgical techniques were developed. Nowadays, the focus has shifted to achieving precise closure of the muscles with superior esthetic results. To further recuperate the esthetic, the pre-surgical orthopedic concept was established as early as the 18th century^{6,7}. The pre-surgical device delivers a coalescent cleft with a well-shaped alveolar arch form. This configuration of the alveolar segments will build the foundation for good lip symmetry since it will reduce tension during the primary surgery without scar formation⁸. The effectiveness of the NAM starts in the first six weeks of life since there is a high level of maternal estrogen in the fetal circulation, which will activate hyaluronic acid. Accordingly, this hyaluronic acid modifies the cartilage elasticity, ligament, and connective tissue by breaking down the inter cellular matrix⁹. The conventional NAM device described by Grayson et al. (1999)¹⁰ has been used for many years for patients with unilateral cleft lip and palate. This conventional NAM necessitates weekly hospital visits for about 3-5 months^{11,12}. However, many patients come from far-off places and cannot easily make the frequent visits for the adjustment required as mandatory by the original protocol. Thus, a modified NAM device was fabricated with a shorter recall period. This article describes use of the modified-device device to reduce unilateral cleft lip and palate abnormality through simpler and easier procedures and with fewer recall visits than conventional devices.

Patients and methods

Fabrication of the conventional NAM device:

For each device, undercuts on the stone cast were wax-blocked to prevent the device from locking on the cast.

Then, hard acrylic was applied on the palate and alveolar ridge to prepare the molding plates. Afterwards, a pin-shaped handle was made at a 45-degree angle to the palate. The plate was 2–3 mm in thickness for structural integrity. After curing, a notch was created 3mm from the tip of the handle to hold the elastics. Finally, all surfaces were smoothed to prevent ulceration. Before delivery, all surfaces were checked again for any roughness.

Conventional device insertion and adjustment visits

Once the device was ready to be worn, a few drops of denture adhesive paste were used for retention. Then the device was inserted by sliding one side in first and then the other. Afterward, the elastics were attached to the handle and stretched as far as possible. Parents were instructed to regularly replace elastics with new ones to guarantee the device's effectiveness by preserving the tension. The device was used 24 hours a day and only removed for cleaning. Weekly adjustments were required for maximum effectiveness. The areas of adjustment are the labial flange and the palate adjacent to the cleft area. For adjustments, the hard acrylic was removed in the area of growth, and a soft denture liner was added to provide pressure for resorption to guide the growth. Once inter-alveolar gap closure to approximately 5 mm was achieved, a nasal stent was fabricated and attached to the vestibular shield of the device. The nasal stent was made of an orthodontic wire curved into a raised small ball to match the other nostril's shape. The nasal stent was adjusted weekly to direct cartilage growth by elevating the orthodontic wire.

Fabrication of the modified-device

As with the conventional NAM device, undercuts on the stone cast were blocked, then hard acrylic was used to make a plate with the same thickness and pin-shaped handle.

Similarly, a notch was made 3 mm away from the tip of the handle to hold the elastics. However, the nasal stent was not attached to the plate. Instead, a separate nasal stent made of hard acrylic was fabricated. The nasal stent was rectangular, with two hollow circles on each side to attach the tape. The thickness of acrylic ranged from 10 to 3 mm. The thicker and heavier acrylic is placed on the bigger arch side, and the thin part is placed on the small arch side. The soft denture liner was attached to the skin side of the acrylic to prevent trauma and irritation to the skin. A handle was attached to acrylic and extended to the nostril to elevate it to mirror

the adjacent shape. The upper half of the handle was lined with a soft liner to prevent trauma to the nostril tissue.

Modified device insertion and adjustment visits

The plate was inserted by sliding one side in first and then the other. Then, the elastics were attached to the handle and stretched in the same way as with the conventional NAM. However, the labial portion was removed. Furthermore, more acrylic was removed on the tissue side of the plate in the area of growth to make more space for the alveolar arch to move. Adjustments were made to the plate every two weeks. While for the nasal stent, the acrylic handle attached to the nasal stent was extended into the nostril and curved to mirror the adjacent normal nostril's shape.

Similarly to the conventional procedure, a soft liner was placed in the acrylic nasal stent and was replaced every two weeks. When the nasal stent was positioned correctly, the tapes were adhered to both openings of the stent on each side and adhered to the cheeks. Afterwards, another tape was placed horizontally, extending from the right cheek to the left cheek to secure the nasal stent. The anti-sensitive tapes were replaced daily by the parents, and they were instructed on how to use, clean and replace the nasal stent.

Procedure

Sixty-six patients with unilateral (CLP) were selected, comprising 21 males and 12 females, for treatment with the conventional NAM device, while 18 males and 15 females were selected for treatment with a modified device via the pre-surgical NAM device, which was applied in the second week after the birth. Patients with life-threatening syndromes and respiratory difficulty were not considered. Informed consent was obtained from each case. After the clinical examination, an impression was taken using heavy-body silicone elastomeric material. Infant acrylic impression trays were used. During the impression, the infant was held upside down with the neck extended for maximum exposure to visualize the posterior extent of the tray. This position controls the flow of the impression material. During the procedure, the infants were actively crying, meaning they had normal breathing and no choking. Impressions were poured into dental stone to obtain a precise cast.

Methods

Standardized cleft lip and palate parameters were measured on the cast and photographs. The inter-alveolar gaps ranged from 14.5 mm to 13.5 mm before

using the device. Maxillary casts were used to measure the interalveolar cleft gap. Photographs with standard anterior position were taken before and after treatment with constant magnification. The photographs measured the columellar deviation angle, nostril width and height, and soft tissue cleft width. Linear measurements were done directly using a ruler; however, a goniometer was used to measure the columellar angle.

Statistical analysis

The Stat Graphics Plus Version 5.1 program was used to analyze the data. For parametric data, one-way ANOVA was used to measure the differences between the treated samples and controls. While Kruskal–Wallis test was used for non-parametric data, and the differences were detected using notched box and whisker plots.

Results

The conventional NAM device improved the cleft lip and palate within three months, as shown in Figure 1. The modified device showed better cleft width and nasal architecture results with fewer recall visits (Figure 2). The effects of the conventional and the modified device were measured on photographs and the cast, as shown in (Figures 3 and 4). The means of measurements, which indicated the improvements achieved through treatment of the 33 selected patients fitted with the conventional NAM device, were compared with the means of measurements for the modified device; data are shown in Table 1. The mean values revealed statistical differences between the conventional and the modified device. The records showed that the mean inter alveolar gap was decreased by about 8.0 mm in the patients fitted with the conventional device. However, in patients fitted with the modified device, the interalveolar gap decreased by about 10.4 mm.

Similarly, the mean nostril width decreased by about 0.81 mm in patients fitted with the conventional devices. However, the mean nostril width decreased by about 1.75 mm in patients fitted with the modified device. Furthermore, the mean columellar height increased by about 0.4 mm in patients fitted with conventional devices. However, the mean columellar height increased by about 0.65 mm in patients fitted with the modified device. The mean columellar angle was increased by about 17° degrees in patients fitted with conventional devices, whereas the modified device increased the columellar angle by about 22° degrees. Moreover, the mean number of recall visits was 15 visits for patients receiving the conventional treatment, while patients fitted with the modified device required only six visits to finish the treatment.

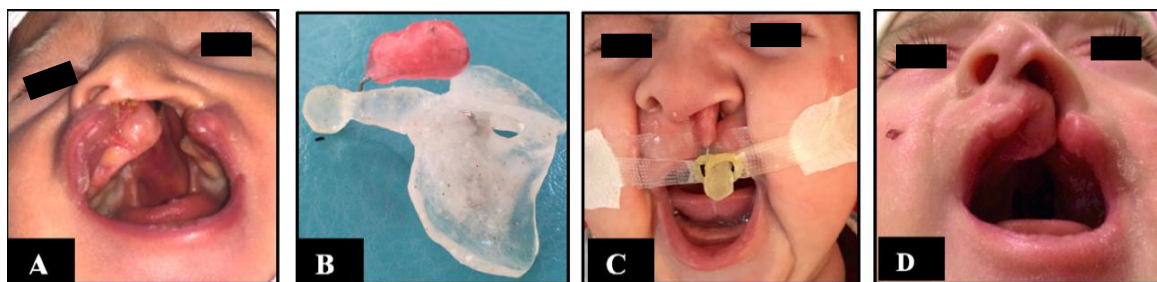


Figure 1: Conventional NAM device. A: Before use of the conventional device. B: Conventional NAM device. C: Conventional NAM placed and fastened with strips and elastics. D: after the use of the conventional NAM device.

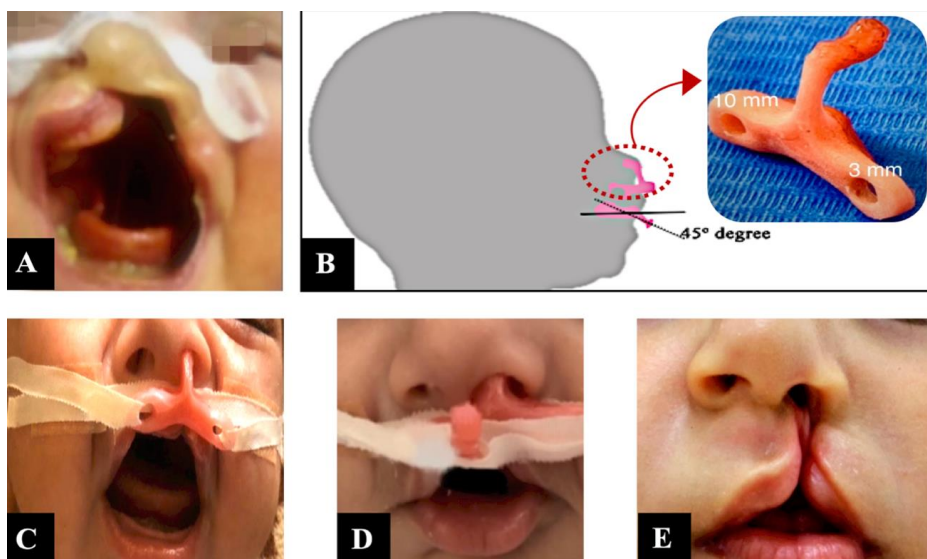


Figure 2. The modified device. A: Before the use of the modified device. B: The modified device with nasal stent dimensions. C: Modified nasal stent placed and fastened with strips and elastics. D: The modified device with a nasal stent in place. E: After the use of the modified device and nasal stent.

Table 1: The means of measurements achieved through treatment of patients with the conventional and the modified device.

Measurements	Conventional NAM device	The modified device	Unit
Inter-Alveolar Gap	8.0 ± 0.17 a	10.4 ± 0.11 b	mm
Nostril Width	0.81 ± 0.12 a	1.75 ± 0.08 b	mm
Columellar Height	0.40 ± 0.02 a	0.65 ± 0.02 b	mm
Columellar Angle	17 ± 1.21 a	22 ± 1.08 b	mm
Recall Visits	15 a	6 b	Number of visits

Numbers with different letters represent statistical differences within the Column (One-way ANOVA or Kruskal-Wallis test, $p < 0.05$, Mean ± S.E).

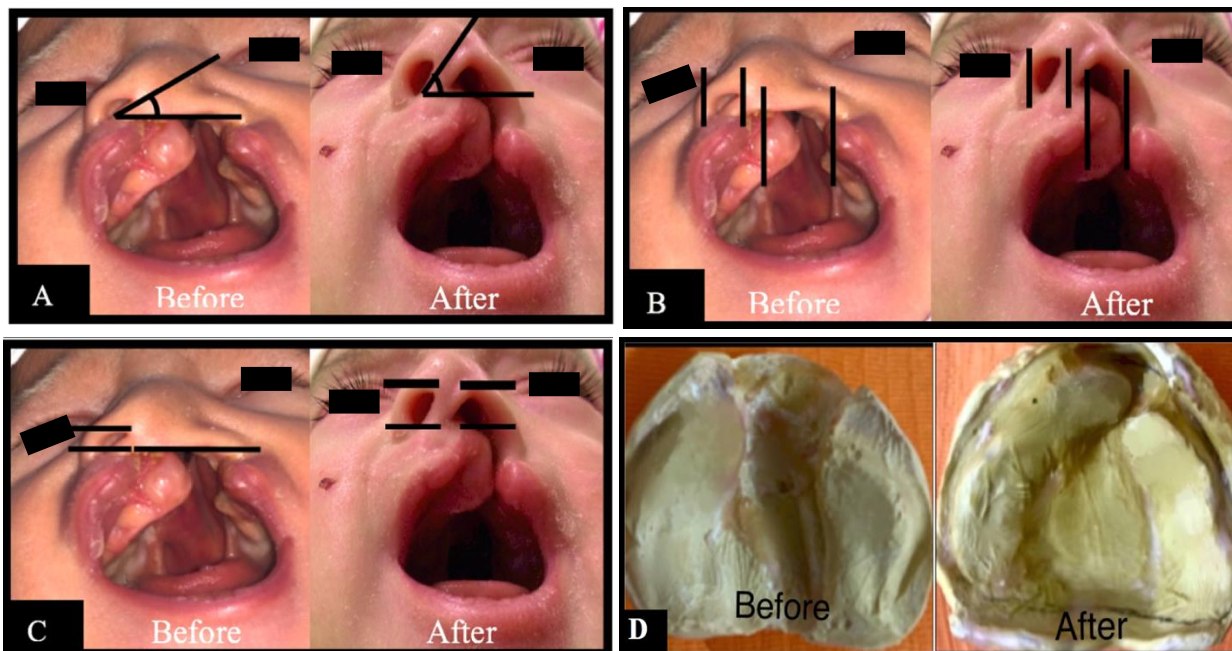


Figure 3: Conventional NAM device. A: The columellar angle. B: Measurements of the nostril width. C: Measurement of columellar height. D: Before and after cast.

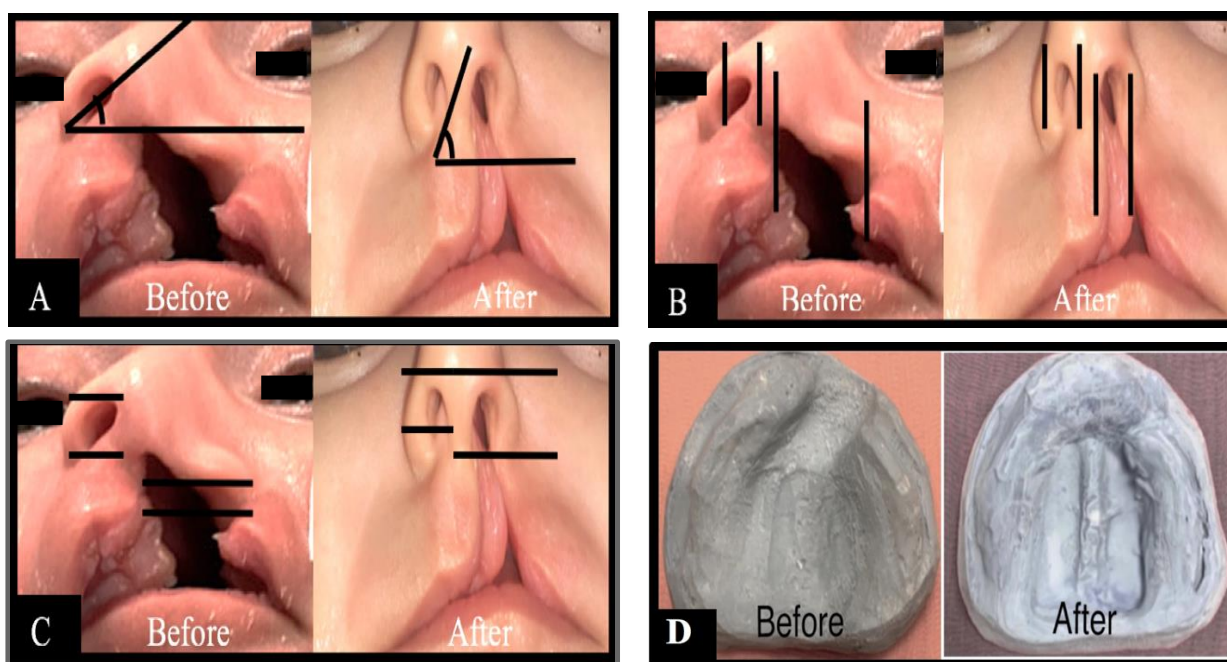


Figure 4: The modified device A: The columellar angle. B: Measurements of the nostril width. C: Measurement of the columellar height. D: Before and after cast.

Discussion

Over the last few decades, many studies have evaluated the NAM's effect on lessening the distance of displaced segments of the maxillary arch¹³. However, critics of the treatment have described its procedures as unnecessary, tedious, and costly. Furthermore, the use of the conventional device is very difficult for parents to manage; besides, it injures the oral mucosa. Consequently, many parents reject the use of this device.

In addition, due to deficiency of resources and the underprivileged backgrounds of the parents, acceptance of the molding arch pre-surgical treatment has been slow in Iraq, which further limits the effectiveness of the cleft team¹⁴. Accordingly, many other techniques have been invented to address these disadvantages. In this study, the modified version of Grayson's original protocol¹⁰ was found to be more time efficient, less tedious, and to increase the parents' support.

Furthermore, the treatment was started in the second week following the birth, which was found to achieve the maximum effect of the treatment. Relatedly¹⁵, it was demonstrated that the patient's age plays an important role in the device's success, as patients treated within the first month gained more benefit from the treatment than older patients.

In this study, the device had a separate nasal stent with a thick base to eliminate the need to fabricate complicated nasal stent wire and make it easier for parents to handle. The conventional NAM acts through the maxillary flanges, while with the modified device, the nasal stent with its thick base functions on the maxillary segments by pressing on the lip externally. Subsequently, this external force molds the alveolar arch inwards to the normal position. In comparison, when using the original technique by Grayson¹⁰, the external force is only applied through tape. However, tape and the nasal stent apply external force in the modified technique to accelerate the arch molding since the thick portion is applied on the larger arch side.

Furthermore, the conventional device caused nasal discomfort for the patient during feeding. Since slight intraoral movement of the plate occurs during feeding, this leads to slight movement of the nasal stent. Among patients treated with the modified device, this problem was diminished since the nasal stent was separate from the plate and securely attached to the lip and cheeks. Moreover, a study that compared the conventional NAM technique with NAM plus DynaCleft (separate nasal stent like a hook attached to the forehead)¹⁶ observed that both methods considerably lessened the cleft width and enhanced the nasal asymmetry, which indicates that the separate nasal stent will improve the overall outcome of the NAM device. However, it should be noted that the use of DynaCleft is expensive. Hence, in our treatment, acrylic material was used with a soft liner to make treatment more affordable for the parents. Additionally, when conventional NAM was compared with the modified device, the latter achieved better results regarding the patients' outcome.

Conclusions

This study concluded that the modified device improved the appliance's overall outcome, and better results were observed regarding such as reducing the interalveolar gap and nostril width with increasing columellar height. Additionally, the modified device required fewer recall visits to the hospital, which signifies that less time is

taken to reduce the inter-alveolar gap. Therefore, this study has shown that the modified device can significantly decrease cleft width and enhance the nasal architecture with fewer recall visits. Moreover, throughout the treatment and follow-up sessions, no complications were observed and the treatment was found to be simpler and more beneficial for patients and parents.

References

1. Jiménez-Castellanos E, Carmona A, Catalina-Herrera CJ, Jiménez-Castellanos J. Oral anatomical defects associated with cleft palate and cleft lip. *Eur J Anat.* 2020;8(3):137-41.
2. Tewfik TL, Karsan N, Kanaan A. Cleft lip and palate and mouth and pharynx deformities. *Drugs Dis.* 2015;15:1-12.
3. Retnakumari N, Divya S, Meenakumari S, Ajith PS. Nasoalveolar molding treatment in pre-surgical infant orthopedics in cleft lip and cleft palate patients. *Arch Med Health Sci* 2014;2(1):36-47.
4. Tsegga TM, Christensen CJ. Jaw and Dental Abnormalities. *Dent Clin North Am.* 2020;64(1):11-23.
5. Millard DR. *The Evolution in Cleft Craft: The Evolution of its Surgery.* 1st ed. Boston, Mass: Little Brown and Co. 1976(2):77-121.
6. Xiaoyu MA, Giacona MB. Nasoalveolar moulding as treatment for cleft lip and palate: A case report. *Columbia Dent Rev.* 2009;4(1):4-14.
7. Murthy PS, Deshmukh S, Bhagyalakshmi A, Srilatha K. Pre surgical nasoalveolar moulding: Changing paradigms in early cleft lip and palate rehabilitation. *J Int Oral Health.* 2013;(5):70-80.
8. Yang S, Stelnicki EJ, Lee MN. Use of nasoalveolar molding appliance to direct growth in newborn patient with complete unilateral cleft lip and palate. *Pediatr Dent.* 2022;25(3): 253-6.
9. Retnakumari N, Divya S, Meenakumari S, Ajith PS. Nasoalveolar molding treatment in pre-surgical infant orthopedics in cleft lip and cleft palate patients. *Arch Med Health Sci.* 2016;2(1):36-37.
10. Grayson BH, Santiago PE, Brecht LL, Cutting CB. Pre-surgical nasoalveolar molding in infants with cleft lip and palate. *Cleft Palate Craniofac.* 1999;21(36):486-488.
11. Bajaj A, Rao KS, Sharma SM, Shetty V. Modified pre-surgical nasoalveolar molding in the infants with complete unilateral cleft lip and palate: a stepwise approach. *J Maxillofac Oral Surg.* 2011;10(3):275-80.

12. Schiebl J, Bauer FX, Grill F, Loeffelbein DJ. RapidNAM: Algorithm for the semi-automated generation of nasoalveolar molding device designs for the pre-surgical treatment of bilateral cleft lip and palate. *IEEE Trans Biomed Eng.* 2019;22(6):277-282.
13. Lautner N, Raith S, Ooms M, Peters F, Hölzle F, Modabber A. Three-dimensional evaluation of the effect of nasoalveolar molding on the volume of the alveolar gap in unilateral clefts. *J Craniomaxillofac Surg.* 2020;48(2):141-47.
14. Heravi F, Ghoochani TZ, Jahanbin A, Askary A. Nasal elevation: A case report of a new approach in orthopedic treatment of infants suffering from cleft lip-palate. *Shiraz E-Med J.* 2019;20(12):1-6.
15. Shetty V, Vyas HJ, Sharma SM, Sailer HF. A comparison of results using nasoalveolar moulding in cleft infants treated within 1 month of life versus those treated after this period: Development of a new protocol. *Int J Oral Maxillofac Surg.* 2012;41(1):28-36.
16. Monasterio L, Ford A, Gutierrez C, Tastets ME, Garcia J. Comparative study of nasoalveolar molding methods: nasal elevator plus Dyna-Cleft(R) versus NAM-Grayson in patients with complete unilateral cleft lip and palate. *Cleft Palate Craniofac J.* 2013;50(5):548-54.