

# Effects of Nasoalveolar Molding on Lip Gap in Infants with Unilateral Cleft Lip: Experience from a Single Centre in Hong Kong

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## Abstract

**Background:** The introduction of the pre-surgical nasoalveolar molding (NAM) to approximate lip gap prior to the definitive primary surgical repair has revolutionized cleft care. It is only until recent years that the techniques of NAM application has been modified to optimize its effectiveness and subsequently results in its more widespread use. However, while most studies focus on the NAM's effect in improving nasal symmetry and reduction of alveolar gap, there is limited literature describing its effect on soft tissue approximation such as the lip gap. In this study, we aim to investigate if NAM would effectively reduce the lip gap in patients with complete unilateral cleft lip and palate.

**Methods:** We prospectively recruit non-syndromic patients with complete unilateral cleft lip and palate undergoing primary cleft lip repair in our center from January 2011 to August 2015. Patients who presented to our center beyond the first two weeks of life were excluded. The NAM was fitted to all the patients within the first two weeks of life with subsequent regular clinical follow up to ensure compliance and for device adjustment. A frontal view 2D clinical coloured photograph was taken prior to the NAM fitting for documentation. The lip gap: mouth width ratio was then measured and calculated from the photograph (pre-NAM). Direct anthropometric measurements were once again taken at the time of the primary cleft lip operation when the patient is fully anaesthetized (post-NAM). The pre-NAM ratio was then analyzed with post-NAM ratio.

**Results:** 23 patients were recruited (5F:18M) (13 left: 10 right), their pre-NAM lip gap: mouth width ratio were compared with their post-NAM lip gap: mouth width ratio. There was statistically significant reduction in the ratios between the two groups (p < 0.05).

**Conclusions:** There is statistically significant reduction of the lip gap: mouth width ratio (p < 0.05) when comparing the pre-NAM group with the post-NAM group. We can therefore postulate that NAM is effective in reducing the soft tissue gap in the lip gap in patients with complete unilateral cleft lip and palate.

Keywords: Naso-Alveolar Molding; Complete Unilateral Cleft Lip and Palate; Lip Gap

## Introduction

Prior to the era of widespread NAM usage, parents with infants with unilateral cleft lip (with or without cleft palate) were often instructed to begin the lip taping protocol soon after birth to diminish the soft tissue tension across the cleft (Figure 1). Lip taping protocol entails approximating the two sides of the cleft lip using a short strip of micropore or duoderm. However, its compliance is often doubtful at times, feeding and drooling would often necessitate frequent re-taping of the strip by the caregivers at home, and the infants would often only be seen by the surgeon again a week prior to the definitive lip repair surgery at about 12 weeks of age, making the evaluation of its compliance and effectiveness difficult.

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Figure 1: Lip taping to close the lip gap.

Since Grayson., *et al.* [1] designed the first pre-surgical nasoalveolar molding (NAM) appliance with a nasal stent to correct the nostril shape and reduce alveolar width in 1999, numerous modifications have been widely adopted in different parts of the world. The Chang Gung Craniofacial centre in Taiwan, Betty., *et al.* [2] has simplified the NAM appliance in 1998 and the application of this device has shown to improve nasal symmetry in infants with unilateral cleft lip and palate in both short and long term follow up study, Betty., *et al.* [2] and Liou., *et al.* [3]. In most of the time, the NAM appliance would be used in conjunction with the lip taping protocol in infants with complete unilateral complete cleft lip with/without cleft palate in order to narrow the lip gap. As the effective application of the NAM appliance would require frequent periodic review and adjustment of the device, the compliance to the pre-op lip taping protocol with the NAM appliance would be ensured. While the techniques and efficacy of the NAM appliance in narrowing the alveolar cleft width and improving nasal symmetry is well established by Betty., *et al.* [2] and Liou., *et al.* [3], objective data of the NAM protocol on reducing soft tissues cleft such as the lip gap is scanty.

This study focuses on the analysis of treatment outcomes of the application of the NAM appliance together with the lip taping protocol in infants with complete unilateral cleft lip and palate in terms of narrowing the lip gap before primary surgery.

## Methods

Between January 2011 and August 2015, infants with complete unilateral cleft lip and cleft palate were prospectively recruited into our study. Pre-surgical nasoalveolar molding was offered at the initial consultation, the theoretical basis of such device and the follow up clinic schedule were explained to the parents by a paediatric orthodontist. For those who had received antenatal counselling in our centre, the use of the pre-surgical nasoalveolar molding and lip taping within the first week of life as an adjuvant therapy to facilitate the overall management of cleft care was also explained to the parents after the diagnosis of fetal cleft lip was made. Patients with incomplete or micoform cleft lip, bilateral cleft lip and patients who were presented late (> one month old at time of presentation) to our center were excluded in our study.

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After obtaining informed consent from the parents, 2-dimensional coloured clinical photos of the patient's cleft lip and nose were taken at both a frontal view within the first week after birth by the paediatric orthodontist. The NAM appliance would be started within the first week of consultation. Lip taping using a standard 10mm micropore strip would be commenced simultaneously with the NAM appliance. The two sides of the cleft lip would be approximated as much as possible after the insertion of the NAM plate and micropore strip would be taped across the cleft lip to close the soft tissue lip gap. Two pieces of duoderm would also be applied onto the cheek to protect the cheek from skin irritation due to the frequent taping and re-taping of the micropore strip. Parents are instructed to keep the NAM appliance (Figure 2) and the lip taping on the patients for at least 20 hours a day, seven days a week to increase its effectiveness. Their techniques in the application, cleaning and removal of the NAM appliance and lip taping were reviewed weekly by the specialty nurses. We followed the Grayson's techniques in which a period of alveolar molding (duration of 6 - 8 weeks) is followed by the subsequent nasal molding (duration of 6 - 8 weeks) after the alveolar cleft has been reduced. Regular monitoring and fine adjustment of the NAM appliance by a paediatric orthodontist were carried out to detect pressure marks or other irritation on skin or mucosa.



Figure 2: Nasoalveolar molding.

Treatment was continued until the definitive primary cleft lip repair at 12 to 14 weeks of life. After the patient was fully anaesthetised and relaxed prior to the operation, various anthropometric measurements including the soft tissue lip gap, lip length, mouth width, columellar height and nostril width were measured using the Vernier calipers.

The pre-NAM ratio of the lip gap: mouth width was calculated based on the measurement from the frontal view photo. The post-NAM ratio of the lip gap: mouth width was calculated based on the intra-operative anthropometric measurement just prior to the primary cleft lip surgical repair.

## Results

23 (F : M = 5 : 18) (left: right = 13 : 10) non-syndromic infants undergoing primary cleft lip repair for unilateral complete cleft lip and palate in our hospital from 2009 to 2015 were recruited. All the patients received pre-surgical naso-alveolar molding (NAM) with no complications.

All patients received primary cleft lip repair at a mean age of 3.3 months (range: 2.9 - 4 months).

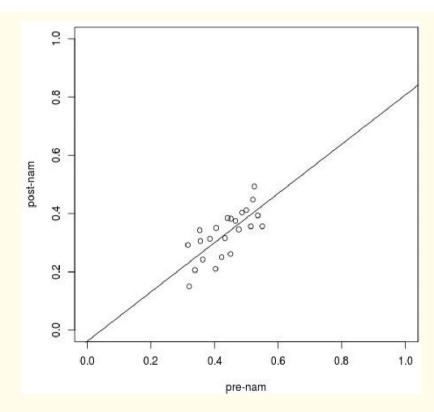
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The results are as followed:

In the pre-NAM group, the mean lip gap: mouth width ratio is 0.435 (range - 0.32 to 0.55).

In the post-NAM group, the mean lip gap: mouth width ratio is 0.33 (range - 0.15 to 0.49).

There is statistically significant reduction (p = 0.0000000989) in the lip gap: mouth width ratio between the pre-NAM group and the post-NAM group (Figure 3).



*Figure 3:* Correlation diagram showing the pre-NAM and the post-NAM lip gap : mouth width ratio (p < 0.05).

#### Discussion

Our findings showed that there is a statistically significant reduction in the lip gap: mouth width ratio between the pre-NAM group and the post-NAM group (p < 0.05) in patients with complete unilateral cleft lip and palate.

Complete unilateral cleft lip and palate often presents as a surgical challenge at the time or primary cleft lip repair as the lip gap is often wider than isolated cleft lip and would therefore potentially results in poorer scarring secondary to tension. The use of pre-surgical or-thodontics techniques have been introduced in the recent decades to overcome these problems. The use of naso-alveolar molding (NAM) was first introduced by Grayson in the early 1990s to utilize the early plasticity of the nasal cartilage when the serum maternal estrogens is still high, and the application of NAM should ideally starts within the first two weeks of life, with frequent adjustment of the device in the following weeks in order to obtain optimal results.

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It is only until the recent years, with the modifications of the NAM techniques by the Chang Gung group that the use of NAM has slowly becoming more widespread in Asia. In Hong Kong, we are the first center to pioneer the use of pre-surgical orthodontics for patients with unilateral cleft lip and palate in 2011. While the efficacy of NAM device in terms in narrowing of the lip gap has been well established, e.g. Andrea., *et al.* [4], the evaluation of the treatment outcome often relies on sophisticated 3D imaging technique which is labour intensive and expensive.

In our study, only 2D clinical photos were taken, no bulky equipment was needed; and we are able to overcome the issue with the difference in scale when taking the photo by comparing the ratio of lip gap: mouth width instead of the absolute value of the lip gap in the pre-NAM and post-NAM group. Furthermore, this can also eliminates the "4D" effect of the growing infant, which is the normal soft tissue growth during the time period when the pre-NAM photo was taken and when the post-NAM measurements were made.

One major limitation of our study is that in real life, the lip gap refers to a 3-dimensional distance, therefore we might have underestimated the lip gap in the pre-NAM group when we are only using the measurements based on a 2D clinical photograph. This potential bias would likely results in the underestimation rather than the overestimation of the lip gap in the pre-NAM group, which means our findings might potentially underestimated the difference between the lip gap: mouth width ratio between the two groups.

# Conclusions

Our results have shown a statistical significant reduction in the lip gap: mouth width ratio between the pre-NAM and the post-NAM groups, we conclude that the use of pre-surgical naso-alveolar molding in complete unilateral cleft lip and palate patients are effective in reducing the lip gap: mouth width ratio.

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