



# Efficacy of the nasal molding in patients with unilateral cleft lip and palate in newborn to 6-month-old patients

## *Eficacia del conformador nasal en pacientes con labio y paladar hendidos unilateral de recién nacidos a 6 meses*

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### ABSTRACT

**Objective:** The aims of this research were to assess and describe the clinical changes in the nostril that shows depression and asymmetry in patients with unilateral cleft lip and palate (UCLP) treated with presurgical nasoalveolar molding (PNAM) in the Center of Medical Specialties of the State of Veracruz (CEMEV). **Material and methods:** An observational, descriptive, longitudinal and prospective cohort study was carried out. 15 patients with ages between 0 and 6 months were part of the study. Measurements of t nostril height, nostril width, nasal basal width and columella length were performed at three times (T1, T2 and T3). **Results:** The vertical, horizontal and nostril base lengths showed a significant decrease in the initial measurement (T1), presenting a close similarity with the healthy nostril, with only 0.8 mm of difference with the healthy nostril in the vertical dimension ( $p \leq 0.000982$  t Wilcoxon); in a horizontal dimension, 5.02 mm ( $p \leq 0.000023$  t Student) and compared with the measurements of the nasal base it was found that at T3 it decreased 51%, ( $p \leq 0.00004$  t Student). This reflects the effectiveness of the nasal molding treatment for correcting the nasal asymmetry caused by a nasal, lip and alveolar cleft. **Conclusion:** Treatment with the PNAM is effective since it reduced by 50% at least nasal depression, compared with the initial and final measurements.

### RESUMEN

**Objetivo:** El propósito de este estudio fue evaluar y describir cuáles son los cambios clínicos del ala nasal que presenta depresión y asimetría en los pacientes con labio y paladar hendidos unilateral, tratados con el moldeador nasoalveolar prequirúrgico en el Centro de Especialidades Médicas del Estado de Veracruz. **Material y métodos:** Se realizó un estudio observacional, descriptivo, longitudinal y prospectivo, estudio de una cohorte. Se analizaron 15 pacientes, con edades comprendidas de 0 a 6 meses de vida. Se realizaron mediciones en tres tiempos (T1, T2 y T3) de la longitud de la ventana de la nariz en sentido horizontal, vertical, base de la nariz y longitud de la columela. **Resultados:** Las longitudes vertical, horizontal y base nasal, presentaron una notoria disminución en las medidas iniciales (T1) indicando una mejor similitud y semejanza con el ala nasal sana, tan solo 0.8 mm de diferencia con el ala nasal sana en sentido vertical ( $p \leq 0.000982$  t Wilcoxon); en sentido horizontal 5.02 mm ( $p \leq 0.000023$  t Student) y comparando las mediciones de la base nasal se encuentra que en T3 disminuyó en un 51% ( $p \leq 0.00004$  t Student). Esto hace referencia a que el tratamiento del conformador nasal es efectivo para la corrección de la asimetría nasal generada por las fisuras nasal, labial y alveolar. **Conclusión:** El tratamiento con el moldeador nasoalveolar prequirúrgico es efectivo al disminuir al menos un 50% la depresión nasal en las tres mediciones, comparando medidas iniciales y finales.

**Key words:** Unilateral cleft lip and palate, presurgical nasoalveolar molding, nasal asymmetry.

**Palabras clave:** Labio y paladar hendidos unilateral, moldeador nasoalveolar prequirúrgico, asimetría nasal.

### INTRODUCTION

Cleft lip and palate is a craniofacial congenital anomaly that afflicts patients both physically and functionally. Incidence is variable according to geographical location and it may be related to socioeconomic status, cultural level, health services and quality of policies in health care as well as literacy and ethnic group. Worldwide there is an incidence of 1:500<sup>1</sup> and in Mexico the incidence is 1:750 live newborns per year.<sup>2</sup>

Facial development occurs between the fourth and twelfth week of intrauterine life by fusion of five facial processes or prominences: frontonasal prominence

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and maxillary and mandibular prominences.<sup>3</sup> Lack of fusion between these processes is what causes lip, alveolar and palatal clefts. Risk factors during gestation are: intake of drugs such as diazepam and phenytoin, emotional disturbances, maternal age of more than 40 years, diabetes and methrorragia during the first trimester.<sup>4</sup>

McNeil<sup>5</sup> and Burston<sup>6</sup> in England introduced the concept of early maxillary orthopedics for cleft treatment during the fifties. In 1984 Matsuo et al<sup>7-9</sup> used cartilage-modeling techniques during the neonatal period to correct congenital deformities of cleft lip and nostrils. It wasn't until 1999 that Grayson<sup>10</sup> described the presurgical nasoalveolar molding (PNAM), a well-accepted technique since it adequately molds the wing of the nose and gives it a more esthetic and functional form through modeling and changing the position of the immature and malleable nasal cartilages thus accomplishing an enlargement of the columella.<sup>11-14</sup>

Nasal stents are devices that were designed under the biological basis of Roux theory<sup>15</sup> that states that there is an intimate relationship between form, structure and function. This concept was later introduced by Dr. Moss in the 60's under his theory of functional matrix.<sup>16</sup> This is the reason why before cheiloplasty, nasal molding modifies alar base depression caused by the cleft thus improving the tip of the nose and elongating the columella when used in early stages. Besides, they are also used in the subsequent stage of a primary rhinoplasty for relapse prevention in the recently molded wing of the nose while keeping the airway permeable and preventing the formation of surgical adhesences due to nasal secretions and scarring.<sup>12,13</sup>

Early orthopedics must be managed in the three dimensions of space: vertical, sagittal and transverse. The nasal stent should be inserted in an obturator that stimulates the palatal processes and brings them together due to the presence of the acrylic and muscular forces. As a result nasal molding occurs and deformation of the nasal wall is reduced since the device stimulates and repositions the soft tissues and nasal cartilages.<sup>17-19</sup> By bringing together the palatal processes, arch form is improved as well as tongue position; intraoral pressure is balanced and modification of the nasal tissues is facilitated in order to improve the results in the surgical primary closure of the lip. To achieve all this, a great deal of cooperation from the parents is required as well as a good fabrication procedure and placement of the device from the professional.<sup>18</sup>

The present study aimed to assess and describe the clinical changes in the nasal wing that presents

depression and asymmetry in patients with unilateral cleft lip palate at the Clinic of Craniofacial Anomalies of the CEMEV.

## MATERIAL AND METHODS

Before beginning with data collection the study was reviewed and approved by an ethics committee assigned to it by the Head of Teaching of CEMEV. For conducting this study a sample of 15 patients with diagnosis of cleft lip and palate with ages between newborn and 6 months of age who attended the Center of Medical Specialties of the State of Veracruz (CEMEV) in the Clinic of Craniofacial Anomalies (CACF) for a period of 6 months was conformed. The inclusion criteria were: patients of both genders, patients with ages between newborn and 6 months old, patients with unilateral CLP who had depression of the nasal wing, parents wishing to cooperate in this study and who signed the informed consent, patients who received care in the CACF. The exclusion criteria were: patients who due to the distance of their residence could not attend regular appointments and fortnightly controls, patients who had already undergone cheiloplasty, patients with craniofacial syndromes, patients who did not require shaping of the nasal wing, patients with a prognosis of short life expectancy. The elimination criteria were: patients with a maximum of 2 missed appointments fortnightly, patients who did not follow the indications for use and those who did not show commitment with treatment.

Thursdays are the days for reception of patients with a diagnosis of CLP. Sample selection was made and the informed consents were signed. The clinical charts and photographs were obtained. In the same appointment an impression with condensation silicone was taken and a Friedman plate with hard auto-curable acrylic was initially constructed. A button was adhered to the plate with an angulation of 45°. Two Transpore® tapes were attached to the plate and then adhered to the cheeks with an angle of 45° to help hold the plate and direct the stimulation forces for the lip and palate fissure. Once the cleft has a width of less than 5 mm the PNAM is constructed (*Figures 1 and 2*). The PNAM has a wire that at its distal end has a ball of hard acrylic coated with soft acrylic for not tearing the soft tissues and that extends from the Friedman plate to the afflicted nostril. Fortnightly controls should be done to adapt the obturator or Friedman plate and/or the nasal stent. It was instructed to use Corega® or Fixodent® for plate fixation and for directing adequately the forces to the plate. Additionally, placement, use and

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