Use of digital tools for nasoalveolar modeling in patients with cleft lip and/or palate

Uso de herramientas digitales para el modelado nasoalveolar en pacientes con labio y/o paladar hendido

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Abstract:

Cleft lip and palate are the most frequent congenital craniofacial malformations, produced by failure in partial or complete fusion of the facial processes during embryonic development, of multifactorial origin that requires multidisciplinary treatment for its correction. Pre-surgical orthopedics includes therapies before the surgical treatment of this congenital disease. Nasoalveolar Molding (NAM) is one of them. Its principal purpose is to take advantage of the potential growth of newborns to stimulate the closure of the affected Nasoalveolar structures through intraoral and extraoral appliances. This article aims to highlight how the use of new technologies (3D printing, stereo-photogrammetry) has contributed to the medical area, especially in NAM therapy applied to patients with Cleft Lip and Palate (CLP), showing efficient results in the elaboration of appliances and giving more accurate measurements of the reduction of spaces between birth and after therapy.

Keywords:

Cleft lip and palate, Nasoalveolar molding, 3D printing, stereo-photogrammetry, pre-surgical therapy.

Resumen:

El labio y paladar hendido, es la malformación craneofacial congénita más frecuente, producida por falla en la fusión parcial o completa de los procesos faciales durante el desarrollo embrionario, de origen multifactorial que requiere el tratamiento multidisciplinario para su corrección. La ortopedia prequirúrgica incluye terapias previas al tratamiento quirúrgico de este mal congénito una de ellas es el Modelado Nasoalveolar (NAM) cuyo principal propósito es aprovechar el crecimiento potencial de los recién nacidos para estimular el cierre de las estructuras naso alveolares afectadas a través de aparatología intraoral y extraoral. El objetivo de este artículo es resaltar el uso de las nuevas tecnologías (Impresión 3D, estereofotogrametría) ha contribuido en el área médica, especialmente en la terapia NAM aplicada a pacientes con Labio y Paladar Hendido (LPH) mostrando resultados eficientes en la elaboración de aparatología y dando mediciones más precisas de la reducción de los espacios entre el nacimiento y después de la terapia.

Palabras Clave:

Labio y paladar hendido, Modelado Nasoalveolar, impresión 3D, estereofotogrametría, terapia prequirúrgica.

INTRODUCTION

Three-dimensional printing, known as additive manufacturing, is an advanced manufacturing technology. It is based on digital models of computer-aided design (CAD-CAM), using standardized materials to create custom 3D objects through specific automatic processes.[1,2] In the field of dentistry, its applications range from prosthodontics, oral and maxillofacial surgery and implantology, orthodontics, endodontics, and periodontics[3,4] 3D printing technologies can quickly accept data by rapidly manufacturing small and individual parts, new samples, products, molds and models in a complex way.[5] It has many advantages, such as high utilization of high-quality materials and resilience, economic benefits and low-scale

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production and demand. However, it has several disadvantages, such as the high cost of processing and material. However, 3D printing has generally been successfully applied in the dental field.[6,7]

CLEFT LIP AND PALATE

Cleft lip and palate, also known as cleft palate, is the most frequent congenital craniofacial malformation produced by failure in the partial or complete fusion of facial processes during embryonic development, affecting the jaws and soft tissues.[8,9] Several structures are involved, such as the lip, alveolar process, and hard and soft palate; therefore, it should be considered that it may occur in isolation, combined unilaterally or bilaterally.[9]

CLASSIFICATION

The classification of diseases allows us to unify medical criteria to understand them. Below are the most relevant and currently used. Different authors have classified cleft lip and palate. For example, the classification of lip and palate anomalies proposed by Victor Veau PhD. mentions four types of palate anomalies: Type 1 Cleft of the soft palate, type 2 Soft and hard cleft palate involving only the secondary palate, type 3 Unilateral: complete cleft from the uvula through the incisive hole and reaching one side of the premaxilla and type 4 Complete bilateral cleft from the uvula through the incisor and reaching both sides of the premaxilla.[10]

Concerning lip anomalies, we have four types too. Complete cleft lip, when there has been a fusion of the upper jaw process with the labial philtrum and the floor of the nose has not formed; incomplete cleft lip, when there is a partial fusion of the maxillary process with the labial philtrum, the floor of the nose is closed, but when there is a partial fusion of the maxillary process with the labial philtrum, the floor of the nose is closed, but the orbicular muscle of the lips is not accurately oriented in circle; scar cleft lip, when there is a complete fusion of the maxillary process with the labial philtrum, but there is a small scar-shaped cleft in the labial red roll, and bilateral cleft lip when there is no fusion of the labial philtrum with the two upper jaw processes.[10]

In 1992, Doctors Davis and Ritchie made a classification respecting the alveolar zone that includes three groups:

Group I: Prealveolar clefts, which can be unilateral, medium, or bilateral.

Group II: Postalveolar clefts, which can affect the soft palate, soft and hard palate (the alveolar ridge is intact), or submucous cleft palate.

Group III: Alveolar clefts, which can be unilateral or bilateral.[11]

The embryogenic classification of Stark and Kernahan in 1958 said that clefts can be of the primary paladar:

Unilateral: Total and subtotal

Medium: Total (absent premaxilla)

Subtotal: (rudimentary premaxilla) and bilateral: Total and subtotal. The clefts of the secondary palate can be Total, Subtotal, and submucosa, and finally, mixed clefts are

Unilateral, Medium, and bilateral which are able to be Total and subtotal.

The classification respects the alveolar zone by Kernahan and Stark, who in 1972 classified the clefs of the primary palate (Subtotal, unilateral, and bilateral) and the clefs of the secondary palate in (Subtotal, total) Unilateral (Subtotal, total) and Bilateral.[12]

The literature states that the etiology of cleft palate is multifactorial and may be affected by genetic and environmental causes. Factors such as smoking, alcoholism, nutritional deficiencies of the mother, and age of both mother and father are also considered.[13,14]

Research indicates that 3% of newborns have some type of genetic malformation, while this figure is 1% for live births only. Latin American collaborative study of congenital malformations ECLAMC reported a global rate of 10.49 x 10,000 for this condition, with a higher incidence and prevalence in Bolivia, Ecuador, and Paraguay. In Mexico, the incidence varies between 1/2000 and 1/5000 births per year. Epidemiological reports show that more than half of all cases are mixed (or combined) clefts between the lip and palate, and 25% of cases can occur bilaterally.[15,16]

A study of cleft lip cases in Mexico, reported by the General Directorate of Epidemiology of the Ministry of Health in 2015, states that 60% of new cases are in men, while the remaining 40% are in women. It should be mentioned that 70% of the cases described are isolated congenital malformations, but in the remaining 30% are associated with more than 320 syndromes recorded.[17]

It is vitally important to understand that this condition requires interdisciplinary support for its treatment, and it can extend to the patients' first years of life.[4]

NASOALVEOLAR MOLDING

Pre-surgical orthopedics in patients with cleft lip and, or palate includes any treatment before lip surgery in patients with this congenital disease.[15] This began in the 1950s with McNeil's proposal to use a series of devices to approximate the alveolar segments to facilitate surgical cleft repair. However, other authors state that their goal is to harness the intrinsic development potential of the patient at an early age to repair this malformation.[15]

According to Matsuo *et al.* The atrial cartilage could be shaped with permanent results if treatment starts within the first 6 weeks of life. During this period, maternal estrogens in fetal circulation trigger an increase in hyaluronic acid, which alters the elasticity of the cartilage ligament and connective tissue by breaking down the intracellular matrix.[18]

The Nasoalveolar modeling described by Grayson *et al.* from 1993 onwards was supported by the publications by Matsuo in 1989 and 1991, who corrected non-surgically a congenital ear deformity, taking advantage of the plasticity of the cartilage of the newborn, which is due to the high levels of estrogen that continue to circulate in the bloodstream of the newborn and the

presence of hyaluronic acid, making non-surgical remodeling more effective the first 4 months of life under the principle that said elasticity decreases in the first 6 months of age making that the correction obtained is maintained permanently. The contributions of Nakajima in 1990 were also relevant as he successfully used nasal tablets for nose modeling after the first labial closure surgery.[18]

NAM's general objective is to reduce the severity of the cleft deformity before surgical repair using orthopedic appliances and taking advantage of the growth potential of the patients to achieve the objectives described in (Figure 1).[19-21] Likewise, this therapy can produce adverse situations. Figure 2[19-21] presents some of its main compilations.[22]

TRADITIONAL THERAPY

The technique described by Grayson consists of remodeling the alveolar plate in orthodontic acrylic or Biocryl, according to the plaster model of the patient's maxilla, to which the nasal conformer is attached, which consists of a piece of stainless steel wire 0.032 in thickness, coming from the anterior part of the alveolar plate.[22] Treatment begins approximately two weeks after birth, taking an impression with elastomeric material in an individual bucket while maintaining attention in managing the newborn's airway; to do so, an inverted position of the child is used so that the tongue is placed forward and allows the fluids to leave the oral cavity and with the advantage that being in hospital any emergency on the airway can be attended.[23] Figure 3[18] illustrates several examples of this apparatus.
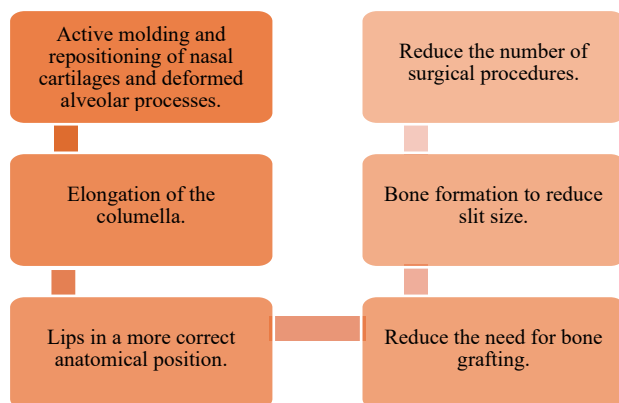

Figure 1. Nasoalveolar molding objectives. [19-21]

APLICATION OF 3D TECHNOLOGIES TO NAM THERAPY

3D photography, also known as stereo-photogrammetry, has been used to measure the progressive morphological changes quantitatively that occur during treatment. Computer-aided design and computer-aided manufacturing (CAD/CAM) adaptation to manufacture NAM appliances has resulted in an

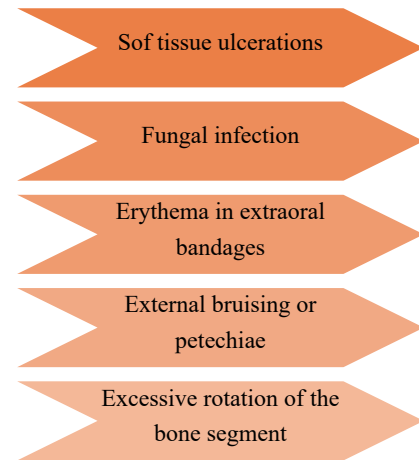inexpensive, efficient, and easier-to-use production mode than other production techniques.[1]

Figure 2. Main complications of NAM. [19-21]

3D PRINTING TO NAM THERAPY

Since 2011, the application of 3D printing in the medical field has grown at an unprecedented pace.[19] Rapid prototyping (RP) and additive manufacturing have enormous potential to increase technical refinement, accuracy, ease of use, and accessibility of medical devices compared to traditional manufacturing methods. Additive manufacturing allows the designer to have greater control over the interior of the object, allowing greater versatility and precision.[24]
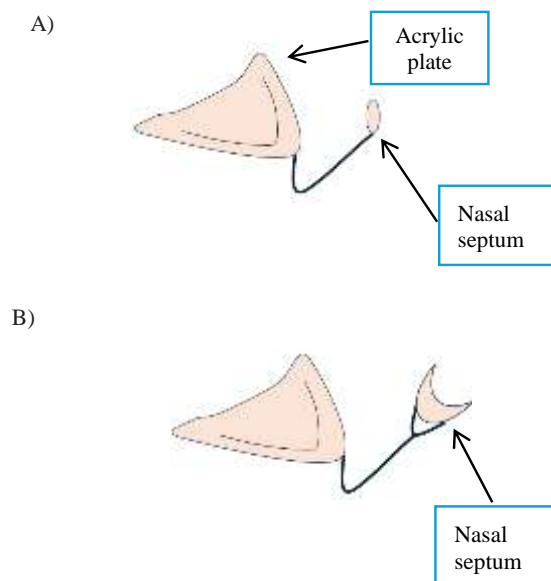

Figure 3. Examples of traditional appliances A) unilateral B) bilateral.[18]

In 2013, Gon and Yu manufactured NAM devices for patients with bilateral cleft lip and palate, and by using the Rapidform 2006 software, they aligned the alveolar segments, and the columellar length increased after therapy.[25] Later, Shen *et al.* conducted a study that showed 3D technology can significantly reduce the number of follow-up visits and device modifications, thus minimizing the care burden and costs associated with NAM treatment.[26,27] In 2017, Bauer *et al.* presented the RapidNAM system, which uses a "growth prediction factor" to project the patient's cleft growth and generate a series of molding plates based on these projections.[28] While Grill *et al.* used the RapidNAM system to generate a virtual series of molding plates at once using a single print. Compared to the manual CAD/CAM method, which takes up to 1.5 hours per plate, the RapidNAM system reported by Grill et al. created each plate in 10 to 15 minutes. In an additional lace nasal stent study, it can be automatically separated and inserted into a new intraoral molding plate, avoiding the need to create a new nasal stent for each new molding plate.[29]

APPLICATIONS OF 3D STEREOMETRY IN NAM THERAPY

3D or stereo-photogrammetry facial photography is a non-invasive method to obtain a high-precision three-dimensional reproduction of facial structures. The analysis with this 3D technology has yielded good initial results and is a valuable focus in the current development of facial morphology with clinical application.[29] Achieving precision is complex, and 3D technology allows better approaches. In this sense, the 3dMD facial system has accuracy with an average error of less than 0.2 mm, which makes the data reliable.[30]

The use of this digital tool has had few studies in patients, some of the most recent are, in 2007, Singh *et al.* used digital stereoscopy to collect 3D facial images of patients with unilateral cleft lip and, or cleft palate. They found that the patients' three-dimensional facial morphology with clefts after NAM therapy was "practically indistinguishable" from that of patients in the control group.[31] Meanwhile Staderini *et al.* describe the use of the 3dMD system to standardize the capture of 3D photographs of patients with unilateral cleft lip and, or cleft palate before and after the NAM treatment. The Geomagic Studio 2019 software to evaluate morphological changes. It selects the eyes and chin to calculate the asymmetry index and the plane of symmetry.[32]

CONCLUSION

Alveolar Nasus Molding treatment has been adopted as an effective pre-surgical alternative that reduces overall arch length, premaxial protrusion, nasal projection, columnar length, symmetry, and nasal width. The implementation of CAD/CAM computer-guided technological tools and stereo-photogrammetry for patients with CLP has benefited and optimized the development of orthopedic appliances that reduce the time and adjustment of these in the office; however, in underdeveloped countries, these technologies are not yet available, so conventional or manual techniques continue to be an actual valuable option for patients with this congenital disease. In turn, 3D photography helps analyze the progress and more accurate measurements of the morphological changes produced by these therapies. More rigorous trials are needed to adopt these techniques to improve this type of therapy, which reduces the adverse effects of this congenital condition.

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