SABRINA TAILANE BATISTA LOPES

NAM E QUEILOPLASTIA PROMOVEM SIMETRIA NA FACE E ARCO SUPERIOR EM PACIENTES COM FENDA UNILATERAL COMPLETA

Faculdade de Odontologia

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NAM E QUEILOPLASTIA PROMOVEM SIMETRIA NA FACE E ARCO SUPERIOR EM PACIENTES COM FENDA UNILATERAL COMPLETA

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Ata da Comissão Examinadora para julgamento de Monografia da aluna **SABRINA TAILANE BATISTA LOPES**, do Curso de Especialização em Ortodontia, realizado no período de 11/02/2019 a 26/02/2022.

Aos 25 dias do mês de fevereiro de 2022, às 09:45 horas, por meio da plataforma virtual Zoom, reuniu-se a Comissão Examinadora, composta pelos professores Soraia Macari (orientadora), Henrique Pretti e Rodrigo Xavier Silveira de Souza. Em sessão pública foram iniciados os trabalhos relativos à Apresentação da Monografia intitulada **"NAM e queiloplastia promovem simetria na face e arco superior em pacientes com fenda unilateral completa"**. Terminadas as arguições, passou-se à apuração final. A nota obtida pela aluna foi 99,5 (noventa e nove e meio) pontos, e a Comissão Examinadora decidiu pela sua **APROVAÇÃO**. Para constar, eu, Soraia Macari, Presidente da Comissão, lavrei a presente ata que assino, juntamente com os outros membros da Comissão Examinadora. Belo Horizonte, 25 de fevereiro de 2022.

Profa. Soraia Macari

Orientador

Prof. Henrique Pretti

Prof. Rodrigo Xavier Silveira de Souza

Dedico este trabalho a Deus por sua fidelidade desde sempre e para sempre. Aos meus pais, Sebastião que estará sempre em meu coração, Tânia minha maior fonte de apoio, meu irmão Dú e meu marido Caio por acreditarem em mim, e meus afilhados Benjamim, Melany e João Gabriel.

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“Guardemos firme a confissão da nossa esperança, pois fiel é aquele que fez a promessa.” – Hb. 10: 23

RESUMO

As fissuras congênitas de lábio e/ou palato, também conhecidas como fenda labial, fenda labiopalatina e fenda palatina, fazem parte de um conjunto de doenças que afetam a cavidade oral e os lábios. As causas ainda são desconhecidas, mas podem estar relacionadas a fatores genéticos e ambientais. As fendas orofaciais estão dentre as malformações crânio-faciais mais comuns presentes desde o nascimento. O bebê afetado precisará desde o seu nascimento até a sua vida adulta de acompanhamento e tratamento com equipes multidisciplinares, e dentre eles o tratamento ortodôntico é fundamental. O modelador nasoalveolar (NAM) consiste em uma placa intraoral onde o intuito é de diminuir a gravidade da deformidade da fenda original, no pré-cirúrgico e permitir que o cirurgião obtenha um melhor reparo do alvéolo, lábio e nariz nos pacientes que possuem a fissura. Sendo assim, o objetivo do seguinte trabalho é de avaliar o resultado do uso do NAM e da queiloplastia na obtenção da simetria facial e da maxila em bebês fissurados tratados na Faculdade de Odontologia da Universidade Federal de Minas Gerais, por meio de análise de imagens fotográficas realizadas durante os atendimentos clínicos num período de pré-cirúrgico, cirúrgico e pós-cirúrgico, além de modelos digitais moldados antes do tratamento e pós o uso do NAM.

Palavras-chave: Moldagem nasoalveolar. Fissura labiopalatina. Queiloplastia.

ABSTRACT

NAM and chiloplasty promote face and upper arch symmetry in patients with complete unilateral cleft.

Congenital cleft lip and/or palate, also known as cleft lip, cleft lip and palate, and cleft palate, are part of a set of diseases that affect the oral cavity and lips. The causes are still unknown, but they may be related to genetic and environmental factors. Orofacial clefts are among the most common craniofacial malformations present from birth. The affected baby will need, from birth to adulthood, follow-up and treatment with multidisciplinary teams, and among them, orthodontic treatment is essential. The Nasoalveolar Modeler (NAM) consists of an intraoral plate whose purpose is to reduce the severity of the deformity of the original cleft, in the pre-surgical period and allow the surgeon to obtain a better repair of the alveolus, lip and nose in patients with cleft. Therefore, the objective of the following work is to evaluate the result of using NAM and cheiloplasty in obtaining facial and maxillary symmetry in cleft babies treated at the Faculty of Dentistry, Federal University of Minas Gerais, through photographic image analysis performed during clinical care in a pre-surgical, surgical and post-surgical period, in addition to molded digital models before treatment and after the use of NAM.

Keywords: Nasoalveolar molding. Cleft lip and palate. Cheiloplasty.

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1 INTRODUÇÃO

As fendas orofaciais não sindrômicas, como a fenda labial, fenda labiopalatal e fenda palatina, compreendem um conjunto de doenças que afetam a cavidade oral e os lábios. As causas ainda são desconhecidas e tal alteração pode causar efeitos na fala, audição, aparência e cognição do indivíduo, o que pode levar a resultados contrários para a saúde e integração social. Entende-se que crianças que são afetadas pelas fendas orofaciais precisam de cuidados multidisciplinares que vão desde o nascimento até a idade adulta, afinal, tem maior morbidade e mortalidade ao longo da vida, quando comparado com crianças não afetadas (MOSSEY *et al*., 2009).

As fissuras congênitas de lábio e/ou palato, são as malformações Crânio-faciais mais comuns ao nascimento. No geral, a incidência de fenda labial com ou sem fenda palatina é de aproximadamente 1 para 1000 e varia com a raça afetando principalmente os asiáticos, depois os caucasianos e então os africanos, do sexo masculino (2:1) já a incidência de fenda palatina isolada é de aproximadamente 1 para 2500, é uniforme e afeta diferentes etnias, onde as meninas são mais afetadas. Enquanto no Brasil a incidência é de 1:650 nascidos vivos (BEZERRA *et al*.,2020; FREITAS e SILVA *et al*., 2008; WORLEY *et al*., 2018).

A etiologia das fissuras lábiopalatinas parece ser um assunto controverso e não se encontra evidentemente estabelecida, existem indícios de que dois fatores (genéticos e ambientais) estão relacionados, podendo atuar isoladamente ou em associação. Sendo assim, a formação da fissura pode ser a resposta de uma associação de fatores genéticos e ambientais e pode ocorrer em momentos distintos durante a gestação, o que pode afetar diferentes locais da estrutura craniofacial e dentofacial (AKCAM *et al*., 2010; FREITAS e SILVA *et al*., 2008; WORLEY *et al*., 2018).

As deformidades de lábio e palato podem afetar funções e alterar o desenvolvimento psicológico, fisiológico e a adaptação social. Segundo Cerqueira *et al*., (2005), é importante que o bebê ao nascer com tal malformação tenha um acompanhamento precoce por uma equipe multiprofissional, com abordagem

interdisciplinar e tratamento integral que vai desde o nascimento até a vida adulta, propiciando ao fissurado o necessário ajustamento social.

A técnica para modelagem de bebês nascidos com fissura labiopalatina foi descrita por Grayson *et al*. em 1993. A modelagem nasoalveolar (NAM) consiste em uma placa de moldagem feita de acrílico autopolimerizável intraoral com stents nasais, cujo objetivo é diminuir a gravidade da deformidade da fenda original, no pré-cirúrgico e permitir que o cirurgião obtenha um melhor reparo do alvéolo, lábio e nariz (SHETYE; GRAYSON., 2017).

Há uma rotação externa da pré-maxila no lado afetado o que leva a deformação das estruturas nasais em casos de fenda labiopalatina unilateral. O que leva a um deslocamento da ponta nasal inferior e seu achatamento, o desvio do septo nasal muda a columela e a base nasal para o lado não afetado, além disso, a cartilagem alar é comprimida e girada inferiormente devido a sua deformação (KINOUCHI *et al*., 2018).

Estudos mostram que a pré-maxila se encontra protruída no lado não afetado e a abertura da narina se encontra na posição mais horizontal, a cúpula nasal é deprimida, a columela do lado afetado é curta e o septo nasal se encontra desviado para o lado não fissurado (NUR YILMAZ; GERMEÇ ÇAKAN, 2018).

Sendo assim o objetivo desse seguinte estudo é avaliar o uso do NAM nessa população específica para analisar seu benefício durante o tratamento antecipado, além da queiloplastia na obtenção da simetria facial e da maxila por meio de fotografias e modelos digitais avaliados em diversos tempos.

2 REVISÃO DE LITERATURA

As fendas orofaciais, abrangendo o lábio leporino (com ou sem fenda palatina) ou apenas fenda palatina, estão classificadas dentro dos defeitos congênitos mais conhecidos e possuem alta prevalência. Ao nascer, o bebê com esta alteração, provavelmente terá dificuldades durante sua fala, alimentação, inclusive pode apresentar anomalias dentais, perda da audição, além de problemas sociais e psicológicos (SETÓ-SALVIA; STANIER, 2014).

As fissuras orofaciais compreendem um defeito comum ao nascimento e ocorre em aproximadamente 1 em 600 nascidos vivos nos Estados Unidos. Sua prevalência varia entre 1,5 e 25/10.000 nascimentos, com uma média de 1 em 700 recém-nascidos. Sendo assim, 80 a 85% dos casos de fenda labial são unilaterais, sendo que 33% afetam o lado esquerdo. Sabe-se que mundialmente, as fendas lábiopalatinas são mais comuns em homens e a fenda palatina mais comum entre as mulheres. Entretanto, a frequência de crianças nascidas com fenda labial, fenda lábiopalatina e apenas fenda palatina, ainda é desconhecida em algumas partes do mundo (ABBOTT, 2014; MOSSEY *et al*., 2009; SETÓ-SALVIA; STANIER, 2014).

As causas da fissura lábio palatina podem estar relacionadas a fatores genéticos, como variantes de genes herdados da mãe ou do pai, ou desenvolver uma suscetibilidade maior em desenvolver uma fenda. Embora, durante as primeiras semanas de gravidez, a maioria dos casos de fenda lábiopalatina está envolvida com fatores ambientais e genéticos (SETÓ-SALVIA; STANIER, 2014).

Alguns estudos sugerem que fatores ambientais podem estar relacionados à fenda labiopalatina, e tem sido pesquisado a exposição da mãe à fumaça do tabaco, álcool, má nutrição, infecção viral, medicamentos e teratógenos, no início da gravidez (MOSSEY *et al*., 2009).

Com relação aos fatores genéticos, a fenda labial com ou sem fenda palatina é listada como uma característica de mais de 200 síndromes genéticas específicas, e a fenda palatina é registrada como um componente de mais de 400 dessas doenças. As taxas de concordância para fenda labial, fenda lábiopalatina e fenda palatina, são maiores em pares de gêmeos monozigóticos do que em pares dizigóticos. Entende-

se que as anomalias tenham causas heterogêneas, afinal, o agrupamento familiar e a concordância registrada em gêmeos com lábio leporino com ou sem a presença de fenda palatina, ou com fenda palatina apenas, são específicos para cada defeito (MOSSEY *et al*., 2009).

O reparo cirúrgico das fissuras labiopalatinas tem como objetivo primário restaurar, ao mais normal possível, a forma orofacial do indivíduo. O processo alveolar, os ossos pré-maxilar e maxilar formam a base do lábio que recobre e são alterados nessa população, o que dificulta o reparo da fenda (BHUTIANI *et al*., 2020).

O NAM que é uma intervenção precoce, pré-cirúrgica, indicada em pacientes com fissuras lábiopalatinas, onde o intuito é de diminuir a gravidade da deformidade da fenda inicial através de uso de fita adesiva, aparelho e acessório, é uma técnica nova e normalmente iniciada em recém-nascidos, com aproximadamente, um a dois meses de idade (SISCHO *et al*., 2012).

Em 1980, foi proposto inicialmente por Matsuo e colaboradores, a ideia de expansão não cirúrgica do tecido do revestimento nasal por meio de um dispositivo de moldagem nasal. Este método de modelador nasoalveolar pré-cirúrgico (NAM) teve sua publicação na década de 1990 por Grayson *et al*., o qual tornou-se um método padrão de fisioterapia pré-cirúrgica para pacientes que apresentam deformidade nasal em associação à fenda labial. O tratamento com o NAM antecedendo a cirurgia promoveu a correção da cartilagem nasal deformada, além de ter sido um meio eficaz na melhora da simetria nasal (BARRY; DEIRDRE, 2005; KUO *et al*., 2018; LIOU *et al*., 2004).

De acordo com ABD EL-GHAFOUR *et al*., (2020) em 1686 deu-se início à ortopedia infantil pré cirúrgica onde eram realizados ensaios para retrair a pré maxila em pacientes com fissuras labiopalatinas bilaterais. Ao longo do tempo, em 1844 pesquisadores usaram fitas adesivas para esticar os segmentos labiais, 1950 Mc Neil usou placas vestibulares para moldar os segmentos no local desejado, em 1989 Matsuo *et al*. usaram tubos de silicone para remodelar a narina, sendo os primeiros a descreverem o método não cirúrgico para correção de deformidade nasal e após vários estudos, em 1993 Grayson e colaboradores incorporaram um stent nasal à placa intraoral para remodelar a cartilagem nasal denominando-o de modelador nasoalveolar (NAM). Já no ano de 2006 Figueroa e Polley usaram uma placa intraoral

realizada com resina acrílica fotopolimerizável e com a era da ortodontia digital, em 2011 Yu e colaboradores criaram o CAD/NAM (computer-aided design / nasoalveolar molding) onde um software é utilizado para produzir vários modelos impressos em 3D, incluindo a sequência das etapas de ativação (ABD EL-GHAFOUR *et al*., 2020; MONASTERIO *et al*., 2013).

Tem-se usado a ortopedia pré-cirúrgica para alinhar e aproximar os segmentos alveolares maxilares no pré-operatório, o que facilita os reparos cirúrgicos primários realizados em pacientes fissurados. Sendo assim, o objetivo principal do NAM pré-cirúrgico é diminuir a gravidade da deformidade da fenda além de, proporcionar ao cirurgião a obtenção de um melhor reparo do alvéolo lábio e nariz. Sabe-se que o NAM pré-cirúrgico aumenta significantemente a simetria do nariz, e esse aumento da simetria é mantido na primeira infância em longo prazo (BARRY; DEIRDRE, 2005; LIOU *et al*., 2004; MAULL *et al*., 1999; PRADIP; BARRY, 2017).

De acordo com o estudo de Kuo *et al*., (2018), o NAM é utilizado com frequência na instituição no pré-operatório dos pacientes com fenda labial unilateral tanto completa quanto incompleta que apresente deformidade nasal grave.

Há poucas complicações graves relacionadas ao uso do NAM. O problema mais comum encontrado é a irritação da mucosa oral, tecido gengival ou mucosa nasal, devido à pressão excessiva causada pelo aparelho. Enquanto os benefícios são diversos, auxilia no alinhamento adequado do alvéolo, lábio e nariz, o que ajuda o cirurgião a obter um melhor resultado da cirurgia (BARRY; DEIRDRE, 2005; PRADIP; BARRY, 2017).

Mancini escreveu um trabalho (2018) onde, o objetivo do estudo foi quantificar as alterações nasais em bebês fissurados tratados com NAM e queiloplastia e grupo controle não fissurados. A morfologia nasal pós-cirúrgica foi comparada aos controles não fissurados e concluiu-se que comparando os dois grupos a forma nasal foi corrigida com hipercorreção da projeção da ponta nasal, ângulo da columela e larguras externas nasais.

Um estudo conduzido na Clínica Ortodôntica do Tokushima University Hospital, Tokushima, Japão entre 1997 e 2012 avaliou a eficácia do NAM pré-cirúrgico em pacientes com fissura nasal unilateral, onde dos 29 pacientes 13 foram tratados com

dispositivos palatinos com stents nasais e 16 que eram do grupo controle, tratados sem stents nasais ou fitas cirúrgicas. O autor sugere que a terapia com stent nasal é eficaz não apenas para indução do crescimento alveolar dentário, mas também como tratamento ortodôntico pré-cirúrgico para melhora da forma nasal e do resultado do tratamento após a cirurgia primária do lábio (KINOUCHI *et al*., 2018).

Em outro estudo em modelos onde investigou-se a eficiência do NAM em pacientes com fissura labiopalatina bilateral e comparou com bebês saudáveis da mesma idade, cujo desenvolvimento nasal era normal. Os resultados mostraram que comparando os dois grupos, a remodelagem da cartilagem foi eficaz e o NAM alongou significativamente o comprimento da columela e aumentou a altura da narina (GRILL *et al*., 2019).

4 METODOLOGIA / RESULTADOS E DISCUSSÃO

O seguinte trabalho será apresentado em formato de artigo.

Title: **NAM and cheiloplasty promote symmetry in the face and maxillary arch in patients with cleft**

Keywords: Cleft lip and palate; Nasoalveolar Molding; Arch length; Arch perimeter; Facial symmetry.

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AUTHOR CONTRIBUTIONS

Tania Mara de Souza Ianni, conception and design, drafting and critical revision of manuscript, final approval of the version to be published, agreement to be accountable for all aspects of the work; Sabrina Tailane Batista, conception and design, drafting and critical revision of manuscript, final approval of the version to be published, agreement to be accountable for all aspects of the work; Rodrigo Xavier da Silveira de Souza, conception and design, drafting and critical revision of manuscript, final approval of the version to be published, agreement to be accountable for all aspects of the work; Sérgio Edriane Rezende, conception and design, interpretation of data, critical revision of manuscript, final approval of the version to be published, agreement to be accountable for all aspects of the work; Tatiana Fernandes Araújo Almeida,

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DISCLOSURES

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ABSTRACT

Objective: This study evaluated the effect of nasoalveolar molding (NAM) and cheiloplasty to obtain symmetry of the face and maxillary arch.

Study design: Prospective longitudinal clinical study

Setting: Single-institution academic tertiary care center

Methods: 26 babies with complete unilateral cleft, received treatment with NAM therapy through reverse engineering. Patients were molded in 2 stages: before treatment (T1) and after use of NAM (T2); and photographed in 3 stages: T1, T2 and after cheiloplasty (T3). The digital models were used to measure the arch perimeter (AP), maxillary arch length (AL), and labial frenulum angle in relation to the midline of the maxilla (LFA). The photographs were used to quantify the columella angle (CA), nasal width/intercanthal length ratio (NB/ILR) and mouth width/interpupillary distance ratio (MW/IDR).

Results: There was a significant increase in AP (T1: 70.26mm±4.895 versus T2: 76.61mm±5.888) and AL (T1: 24.71mm±2.185 versus T2: 27.44mm±2.734), and a reduction in the LFA (T1: 101.5°±8.05 versus T2: 94.8°±5.426). A significant increase in the CA angle was observed between T1 (45.14°±12.67) versus T2 (59.59°±10.46), T1 versus T3 (78.38°±14.33) and T2 versus T3; and reduction in the NB/ILR between T1 (1.52mm±0.18) versus T2 (1.4mm±0.12), T1 versus T3 (1.16mm±0.08) and T2 versus T3.

Conclusion: There was maxillary growth and remodeling of the arch segments, contributing to a reduction in the extension of the cleft. The NAM protocol proved to be effective in improving facial symmetry and the alveolar process in cleft babies.

Keywords: Cleft lip and palate; Nasoalveolar Molding; Arch length; Arch perimeter; Facial symmetry.

INTRODUCTION

Patients with unilateral cleft palates have anatomical changes in the nose and maxilla, in the transverse, sagittal and vertical planes [1]. Abnormal nasal morphology with alar width inclination and columella tissue deficiency is a common condition that can compromise the results of first repair surgery [2]. Seeking better bone and cartilage relationships before surgical intervention is highly desirable. Since the 1950s, different techniques have been presented to bring soft and hard tissue closer together [3, 4]. The Nasoalveolar Molding (NAM) technique is a treatment modality described by Grayson & Cutting (1993) [5], which seeks to alleviate asymmetries and cleft severity before surgery [6-8], while promoting important modifications on immature nasal cartilage, taking advantage of its malleability [9, 10].

The clinical benefit of NAM therapy is hotly debated. [11-14]. The diversity of study models, evaluation times, size and heterogeneity of the samples, different protocols performed and poor detailed descriptions of the methods make it difficult to safely evaluate studies that use the NAM protocol [13]. Among the methods used by studies to assess the effects of NAM therapy are the use of two-dimensional images [7, 10, 14-16] and even three-dimensional records [17-23]. Results of the studies have shown improvement in the aesthetics of the nose, lip, alveolar bone, palate and nasal wings [14]. In addition, NAM therapy has been shown to decrease surgical scars associated with columella reconstruction [24]. Treatment with NAM seems to be a promising technique that deserves further study, making use of both two- and three-dimensional analyses, whose methodological consistency may confirm its benefits [3, 12, 25, 26].

The aim of this study was to evaluate the effectiveness of NAM therapy and cheiloplasty on the conformation of the maxillary arch and facial symmetry in patients with unilateral cleft palate, through measurements in photographs and digital scans.

METHODS

In this prospective trial from January 2017 to January 2020, twenty-six babies of both genders (18 boys and 8 girls), aged up to one month, presenting no syndromic unilateral cleft lip and palate, with scheduled cheiloplasty surgery, were included in this prospective trial. All participants were from a convenience sample, derived from the population undergoing treatment/follow-up by the NAM project of the Faculty of Dentistry, Federal University of Minas Gerais, Brazil. This study is in accordance with the Declaration of Helsinki and was approved by the Research Ethics Committee of the Faculty of Dentistry, Federal University of Minas Gerais, and registered under number: CAAE 10111619.1.0000.5149. Parents/guardians of eligible children were invited to participate in the research and instructed about the treatment, acceptance being granted by signing an informed consent form.

A limitation of the NAM protocol is the need for frequent visits to the pediatric clinic during treatment [23]. In this study, we had understandable absences of some patients due to the distance from where they lived, which caused the non-acquisition of the facial photographs of 8 patients from this sample (Figure 1).

Treatment with NAM using the reverse engineering technique

For the manufacture of plates used in the reverse engineering NAM protocol [27], in the first visit, a highly accurate impression was performed on the upper arch of

children with addition silicone (ESPE XT, 3M Health Care, Minnesota, USA) using acrylic pediatric trays. This treatment time was defined as T1.

After molding, virtual models were obtained through digital scanning using the Orthoanalyzer software (3Shape, Copenhagen, Denmark) for making the NAM plates. In these models, the fabrication of the devices was conducted to gradually approximate the alveolar bone segments.

Upon receiving the plates, those responsible were carefully instructed as to their use and weekly changes. To help close the cleft, 6 mm x 100 mm tapes (Steri strip, 3M Health Care, Minnesota, USA) were installed on the upper lip, below the alar width, joining the two segments affected by the cleft, since the beginning of therapy (T1). Nasal stent with tape support on the child's forehead was incorporated at the start of treatment.

After the use of the plates, and prior to cheiloplasty surgery, new molding and scanning procedures were performed to verify the success of the treatment. Treatment time was called T2.

Analysis of digital maxilla models

To assess the maxillary changes, the digital models were and the measurements of the perimeter, length of the maxillary arch and the angle of the labial frenulum in relation to the midline of the maxilla were taken. The images obtained from the models were oriented so that the occlusal plane was parallel to the computer screen where a millimeter screen was superimposed so that measurements could be

performed (Figure 2). To perform these measurements, the following reference points were established (Figure 2):

- LF (Labial Frenulum) - Point corresponding to the center of the edge at the level of the labial frenulum.
- RPP (Right posterior point) - Most posterior point in the center of the right-side edge.
- LPP (Left posterior point) - Most posterior point in the center of the left-side edge.
- PCP (Posterior center point) - Point that corresponds to half the distance between the RPP and LPP points.

From these reference points, the following measures were taken:

- Arch perimeter: Size in millimeters (mm) of the line that goes around the entire edge from RPP to LPP, passing through the center of the edge.
- Arch length: distance (mm) between the LF and PCP points.
- Angle of the labial frenulum in relation to the midline of the maxilla: angle (°) formed between the line of the arch length (LF and PCP) and the posterior line of the ridge (RPP and LPP), on the cleft side.

Photographic analysis of facial symmetry

The evaluation of changes in facial symmetry was performed through photographs in frontal and basilar positions, using a camera with a 100 mm macro lens (Canon EOS Rebel T3i, Japan). The child remained on the guardian's lap and the camera was fixed on a tripod at a constant distance for all shots (40 cm). The camera was positioned perpendicular to the child for the frontal photo. For basic photography,

the camera was positioned so that the tip of the nose was between the eyebrow line and the upper eyelid.

The images were taken from 18 children (14 boys and 4 girls) at three different times: beginning treatment with NAM (T1), final treatment with NAM/before cheiloplasty surgery (T2) and after surgery (T3). The following measures were taken:

- Columella Angle: Angle formed between the nasal reference line (the line connecting the left and right alar width) and the line that passes through the center of the columella, starting at the alar width to the apex of the nose, measured on the side affected by the cleft.
- Nasal width/intercanthal length ratio: Ratio between the nasal reference line and the mean between the left and right eye widths.
- Mouth width/interpupillary distance ratio: Ratio between the distance of the two labial commissures and the distance between the centers of the ocular pupils.

Angular and linear measurements in the photographs were performed using the ImageJ software (National Institute of Mental Health, Bethesda, Maryland, USA), performed by the same dentist, trained for this purpose. In order to minimize possible errors in measurements of three-dimensional structures in a two-dimensional manner, the measures were expressed in the form of ratio [28] (Figure 3).

Statistical analysis of photographs and digital models was conducted using the GraphPad Prism 8.0 software (GraphPad Prism Version 8.0 for Mac, La Jolla, California, USA). The data from the digital models was submitted to the t-student statistical test ($P<0.05$), and the data obtained from the analysis of the photographs was submitted to the one-way ANOVA statistical test ($P<0.05$). Pearson´s correlation was performed among the variables.

RESULTS

There was good adherence and acceptability of the protocol by the families in the treatment with NAM. The average length of treatment with NAM was 4.88 months. In this research there was no adversity or damage to the studied patients.

The analysis of the digital models of the 26 patients (Figure 1) to verify changes in the maxillary arch showed the following results:

- Arch perimeter: A significant increase in perimeter T1 (70.26 mm ± 4.895) versus T2 (76.61 mm ± 5.888) of approximately 6.35 mm was observed, as seen in Figure 2-A.
- Arch length: Figure 2-B shows a significant increase in the length of the maxillary arch T1 (24.71 mm ± 2.185) versus T2 (27.44 mm ± 2.734) of 2.73 mm.
- Angle of labial frenulum in relation to the midline of the maxilla: As seen in Figure 2-C, there was a significant reduction in the angle of the labial frenulum in relation to the midline of the maxilla T1 (101.5° ± 8.05) versus T2 (94.8° ± 5.426) of 6.7°.

The analysis of the photographs of the 18 participants (Figure 1) to evaluate the effect in obtaining facial symmetry showed the following results:

- Columella Angle: In the columella angle between the initial consultation T1 (45.14° ± 12.67) versus the consultation before surgery T2 (59.59° ± 10.46), there was an increase of 14.45°, showing the verticalization of this angle. When comparing the initial consultation T1 (45.14° ± 12.67) versus the post-surgical assessment T3 (78.38° ± 14.33), there was an even greater verticalization of 33.24°. Comparing the final

appointment for therapy with NAM (T2) and the post-surgical appointment (T3), there was a verticalization of the columella of 18.79°, as shown in Figure 3-A.

- Nasal width/intercanthal length ratio: Figure 3-B showed a significant reduction in the nasal width/intercanthal length ratio between T1 (1.52 ± 0.18) versus T2 (1.4 ± 0.12) of 0.12 mm, bringing this ratio closer to the value of 1. The comparison between the initial consultation T1 versus the post-surgical evaluation T3 (1.16 ± 0.08), showed an even greater reduction of 0.36, bringing this ratio closer to the value of 1. In the comparison of the evaluation at the end of NAM therapy (T2) versus postsurgical (T3), a reduction of 0.24 was observed.
- Mouth width/interpupillary distance ratio: There was no significant change in mouth width/interpupillary distance, as seen in Figure 3-C.

Correlation among the variables of the digital models and photographic analysis was verified in the period pre-NAM and post-NAM treatment, but not after cheiloplasty (Figure 4).

DISCUSSION

Surgical treatment of patients with cleft lip and palate is challenging [2]. In addition to nasal asymmetry and cleft lip, the maxillary alveolar structure may also be split. The repair of these tissues by primary surgical intervention is a great opportunity to deconstruct the stigma that this adversity produces. The idea of improving symmetry of the upper arch through NAM [5] and enhancing symmetry of the immature nasal cartilage through nasal stents before surgery [10, 29], aims to facilitate surgical intervention. In this context, the evaluation of the changes that the NAM protocol promotes in nasal and maxillary symmetry seeks to confirm its importance, providing

evidence for choosing the best treatment available for these children. This study found that the treatment with NAM through the reverse engineering technique, redirected maxillary and facial growth towards a better balance of the affected structures in patients with complete unilateral cleft lip and palate. The treatment provided improvement in the maxillary arch, allowing its adequate growth with an increase in perimeter and length, as well as a reduction in the angle of the labial frenulum in relation to the midline of the maxilla. Treatment with NAM, associated with cheiloplasty surgery, provided prominent balance on the face as perceived through the significant increase in the columella angle and reduction in the nasal width/intercanthal length ratio.

Arch perimeter is considered one of the most important parameters for orthodontic diagnosis and treatment planning [30]. It is defined as the distance from the mesial surface of the first permanent molar around the dental arch to the same point on the opposite side. In this study, using the widths of this concept, we made an analogy to the dental arch perimeter to analyze the dimension and changes that occurred in the alveolar arch of babies with cleft lip and palate who used NAM as an early treatment. Maxillary arch perimeter, assessed using digital models, showed an increase after NAM therapy. This increase can be attributed to the continuous growth of the alveolar ridges, guided by the forces exerted by the devices of this therapy. This result corroborates with some studies found in the literature. [30, 31] that demonstrated an increase in the arch perimeter in this phase.

Guided by the concept of arch length, as a line that starts on the palatal surface of the central incisor, passing through the palatine raphe until it finds an imaginary line perpendicularly, that passes through the mesial surface of the first permanent molars, this measurement was performed in babies. Fitting this imaginary

line to the most posterior point of the ridge on the left and right sides, the length of the arch was measured. Thus, changes in the size of the maxillary arch, in the anteroposterior direction, before and after NAM therapy were evaluated. Our study demonstrated a significant increase in this measure, which is in disagreement with the findings by Khateeb et al. [30], who observed a decrease. This increase can be attributed to the large growth observed in the alveolar arches at this stage of childhood, and an increase in this measure is desirable for a therapy that guides growth without impeding the normal development of facial structures [31] . Further prospective studies are needed to clarify arch length behavior during the active phase of the NAM protocol.

In the angle of the labial frenulum in relation to the midline of the maxilla, a significant decrease was seen in this measure, showing a decrease in the width of the cleft. This dimensional change is particularly important when considering the difficulties encountered in bringing the ridge segments together, especially during surgical repair procedures [4]. These improvements reduce the perception of cleft severity, creating, especially among parents and caregivers, a more optimistic image of adversity, such as greater adherence to treatment [15]. Other authors have also reported a reduction in this measure, in varying amounts, probably due to factors such as cleft severity or age at treatment initiation [7, 32].

Up righting and increasing the extension of the columella before the lip repair surgery favors the surgical procedure, offering better surgical results [4, 5]. The findings of this study corroborate with other studies, [7, 30], showing, however, small quantitative discrepancies, probably due to differences in methodologies.

This study demonstrated that children who received NAM therapy obtained significant improvement in nasal symmetry. There was a reduction in the width of the

width of the nose with values that approached the intercantal width, which is desirable in a harmonic face. This significant reduction in the size of the slit-side nostril, in width, is in line with the findings of other researchers [7, 32] that met the goals of this therapy. The use of nasal stents also modifies this immature alar cartilage [29], contributing to the success of the therapy. The verticalization of the columella and the significant reduction in the angle of the labial frenulum in relation to the midline of the maxilla, observed in the analyzes of this study and in other investigations [7, 17], show a decrease in the width of the cleft lip and palate and can help reduce the number of soft tissue surgery revisions and grafts. These findings have a positive impact on surgical repair surgery.

In this study, we evaluated the changes that occurred in structures markedly affected by the cleft, such as the nose, lip and maxilla. Quantitative changes were observed in these structures, showing an increase in nasal verticalization and a decrease in the width of the cleft in the maxillary arch, achieved by NAM therapy. These changes improve facial esthetics and reduce the stigma of this adversity [15].

The distance between the labial commissures must present, in a harmonic face, the same values of the interpupillary distance, and when placed in the ratio form, they must approach the number one [33]. In this study, the changes caused by treatment with NAM therapy and even after lip repair surgery did not show significance in this measure. These results are positive, since the reduction of cleft in the lips and alveolar bone did not affect the width between the labial commissures, which would be an undesirable effect of this treatment.

The clinical benefits of therapy are widely discussed among researchers and clinicians [3, 13, 25, 26], and NAM is often associated with a positive change in nasal

esthetics and decreased cleft width [15, 22, 28]. In the present study, measurements of the maxilla and soft tissue structures of the face showed significant and important improvements in the treatment of patients with clefts. The reverse engineering technique overcame an important limitation in this therapy when compared to conventional NAM therapy: by delivering all the devices in a single consultation, so that they can be installed by the parents, the patient avoided the weekly visits for care, which had always been a difficulty in complying with the treatment. The results of the present study are useful to reinforce the importance of NAM therapy with professionals who develop treatment strategies in terms of aesthetic, anatomical and functional aspects. A consensus among researchers around the methodology, such as standardizing measurement times and outcome variables, may bring greater consistency to the evidence regarding the benefits of the NAM protocol, offering further improvements in this therapy and greater understanding of its strengths and limitations.

A limitation of this study was to determine the length and width of the maxillary arch, since there is no standardized methodology in the literature to perform these measurements in newborn babies.

CONCLUSION

Early non-surgical NAM treatment did not interfere with the growth of the perimeter and length of the babies' alveolar arch, allowing a normal development of this structure. NAM and cheiloplasty surgery proved to be effective, promoting maxillary symmetry and improving nasal symmetry, which makes the face more harmonious.

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Figure's Legends

Figure 1. CONSORT flow diagram.

Figure 2. Digital models analysis. A – Arch perimeter (mm). B – Arch length (mm). C – Angle of the labial frenulum in relation to the midline of the maxilla. n = 18 participants. T-student ($P<0.05$). * different from pre-NAM.

Figure 3. Photographic analysis. A – Columella angle measurement. B – Nasal base/intercantal length ratio measure. C - Mouth width/interpupillary distance ratio. n = 26 participants. One-way ANOVA test ($P<0.05$).* different from pre-NAM, # different from post-NAM.

Figure 4. Pearson’s correlation test among photographic parameters and digital maxilla models analysis in the period pre-NAM and post-NAM treatment.

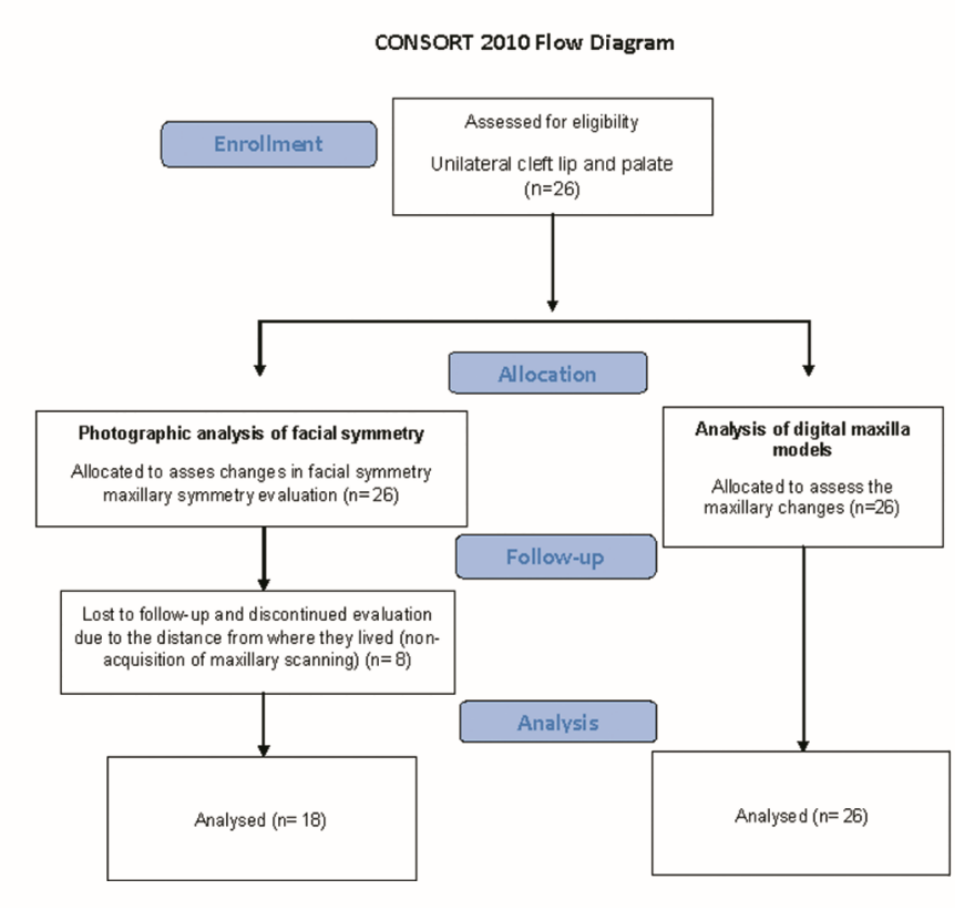
CONSORT 2010 Flow Diagram
Enrollment
Assessed for eligibility
Unilateral cleft lip and palate (n=26)
Allocation
Photographic analysis of facial symmetry
Allocated to asses changes in facial symmetry maxillary symmetry evaluation (n=26)
Analysis of digital maxilla models
Allocated to assess the maxillary changes (n=26)
Follow-up
Lost to follow-up and discontinued evaluation due to the distance from where they lived (non-acquisition of maxillary scanning) (n=8)
Analysis
Analysed (n=18)
Analysed (n=26)

Figure 1

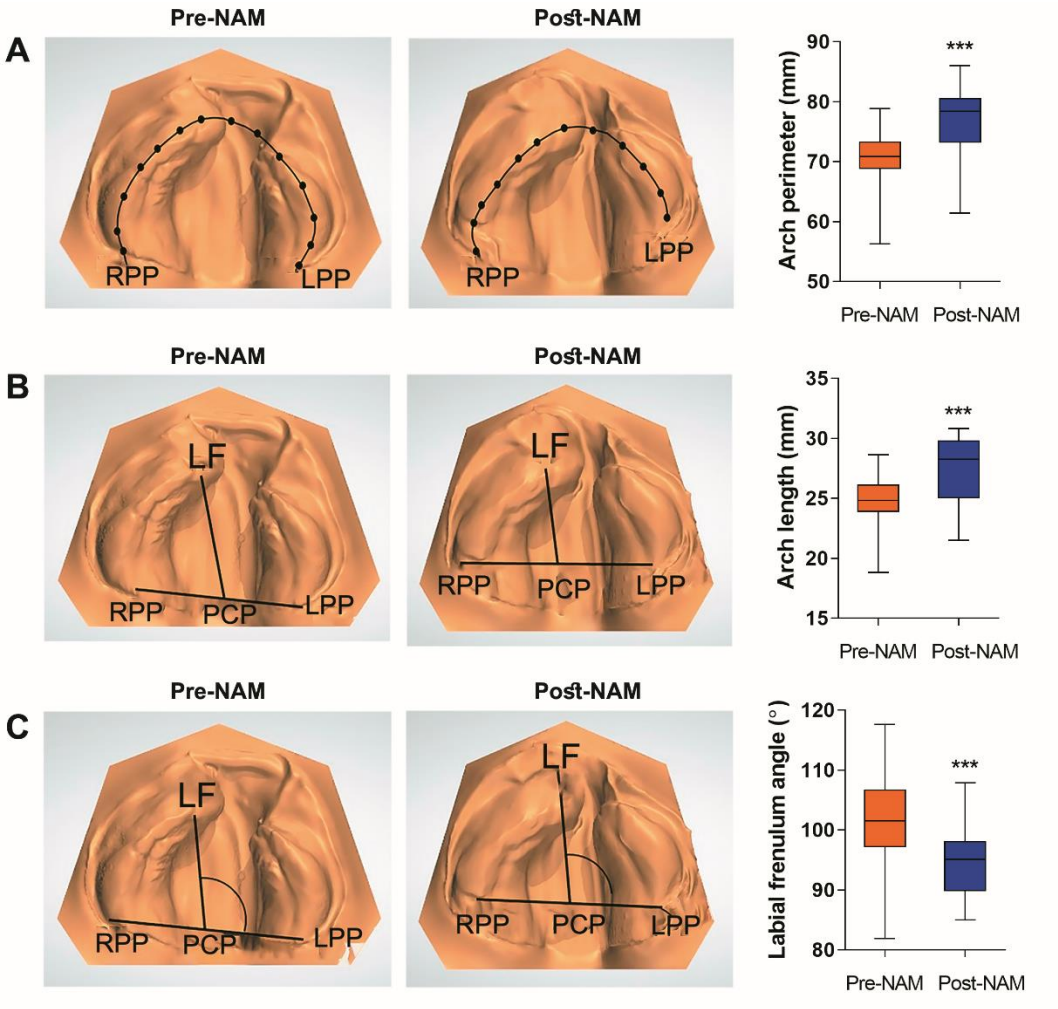

Figure 2

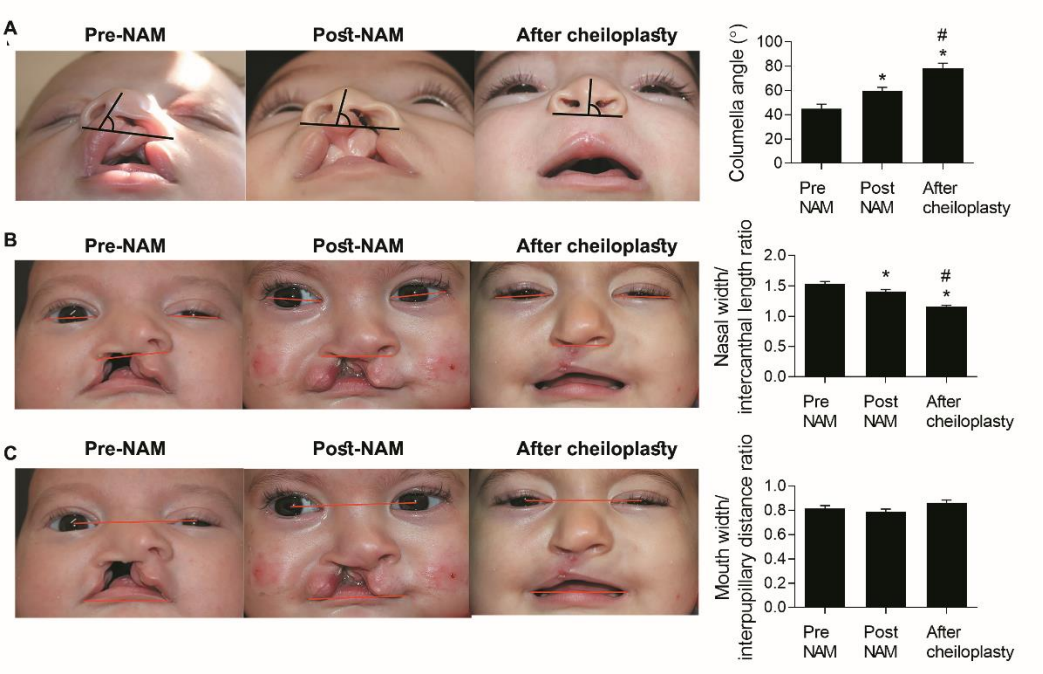

Figure 3

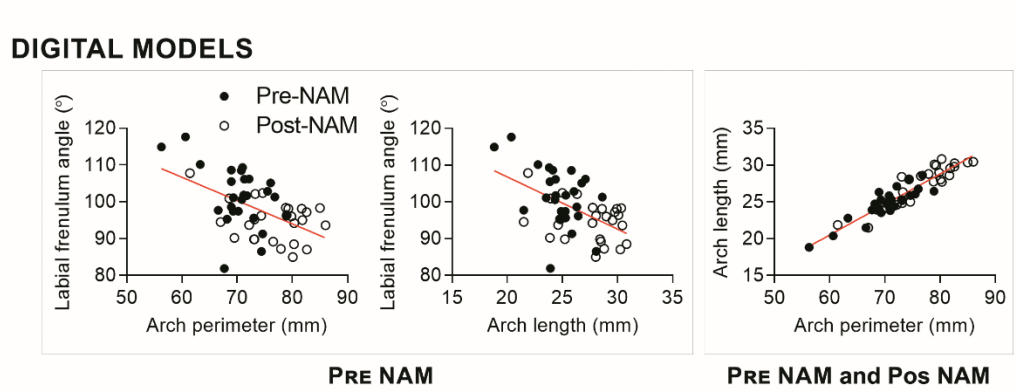
DIGITAL MODELS
Pre-NAM
Post-NAM
Labial frenulum angle (°)
Arch perimeter (mm)
Labial frenulum angle (°)
Arch length (mm)
Arch length (mm)
Arch perimeter (mm)
PRE NAM
PRE NAM and Pos NAM
PHOTOGRAPHIC ANALYSIS
Columella angle (°)
Mouth width / Interpupillary distance ratio
Columella angle (°)
Pre-NAM
Post-NAM
After Cheiloplasty
Nasal width / Intercanthal length ratio
PRE NAM
Pos NAM
DIGITAL MODELS X PHOTOGRAPHIC ANALYSIS
Pre-NAM
Post-NAM
Nasal width/ Intercanthal length ratio
Arch length (mm)
Mouth width / Interpupillary distance ratio
Arch length (mm)
Mouth width/ Interpupillary distance ratio
Arch perimeter (mm)
PRE NAM
Pos NAM

Figure 4

3 CONCLUSÃO

Conclui-se que o tratamento de pacientes fissurados unilaterais apresentam melhora no crescimento facial e maxilar, além de possibilitar a simetria dos mesmos, com o uso de NAM e queiloplastia.

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