UNIVERSIDADE FEDERAL DE MINAS GERAIS
Faculdade de Odontologia
Colegiado de Pós-Graduação em Odontologia

José Dilson Alves de Oliveira Júnior

ABORDAGENS NO TRATAMENTO DE FISSURAS LABIOPALATINAS: *INTEGRAÇÃO DE MÍDIAS SOCIAIS, TECNOLOGIAS 3D E TÉCNICAS CIRÚRGICAS*

Belo Horizonte
2025

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Orientadora: Profa. Dra. Soraia Macari
Coorientadora: Profa. Dra. Carina Cristina Montalvany Antonucci

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FOLHA DE APROVAÇÃO

ABORDAGENS NO TRATAMENTO DE FISSURAS LABIOPALATINAS: INTEGRAÇÃO DE MÍDIAS SOCIAIS, TECNOLOGIAS 3D E TÉCNICAS CIRÚRGICAS

JOSÉ DILSON ALVES DE OLIVEIRA JÚNIOR

Tese submetida à Banca Examinadora designada pelo Colegiado do Programa de Pós-Graduação em ODONTOLOGIA, como requisito para obtenção do grau de Doutor em ODONTOLOGIA, área de concentração CLÍNICA ODONTOLÓGICA.

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"Não é o que você faz, mas quanto amor você dedica no que faz que realmente importa.”

Madre Teresa de Calcutá

RESUMO

A fissura labiopalatina é uma malformação congênita que afeta funções vitais e requer tratamento multidisciplinar do nascimento ao longo da vida. Esta tese conecta, em 3 artigos científicos distintos, a importância das mídias sociais (artigo 1), o tratamento pré-cirúrgico com tecnologia 3D (artigo 2) e técnicas de cirurgia primária no tratamento dessa malformação. Os objetivos de cada artigo foram: (1) analisar a qualidade e o conteúdo dos vídeos relacionados a fissura labiopalatina no YouTube™ e TikTok™. (2) Avaliar a diferença entre o planejamento virtual e os resultados clínicos no tratamento de fissuras labiopalatinas utilizando placas do protocolo do Moldelador Nasoalveolar (NAM) fabricadas por engenharia reversa. (3) Comparar os resultados estéticos das técnicas cirúrgicas de Millard e Fisher em bebês com fissura labiopalatina unilateral. A metodologia utilizada em cada artigo foram: (1) foi realizada uma busca no YouTube™ e TikTok™ utilizando palavras-chave específicas. Os vídeos foram avaliados usando uma lista de verificação preparada por especialistas em fissura labiopalatina, focando em parâmetros como visualizações, curtidas, comentários e o conteúdo fornecido. (2) Foram avaliados 36 bebês não sindrômicos com fissuras transforame completas unilaterais ou bilaterais. Modelos virtuais foram criados e placas NAM foram fabricadas utilizando impressão 3D. As medições foram comparadas entre os planejamentos virtuais e os resultados clínicos. (3) Foram analizadas e comparadas fotografias pós-operatórias de 40 bebês, divididos igualmente entre as duas técnicas, utilizando a escala de classificação modificada proposta por Mortier e Anastassov, que atribui pontos a elementos anatômicos do triângulo nasolabial (lábio vermelho, lábio branco, cicatrizes e nariz). Como resultado de cada artigo, observou-se que: (1) os vídeos do YouTube™ apresentaram qualidade moderada, enquanto os vídeos do TikTok™ foram predominantemente de baixa qualidade; (2) o NAM reduziu significativamente as larguras das fissuras e aumentou as dimensões do arco maxilar; no entanto, foram observadas discrepâncias significativas entre o planejamento virtual e os resultados clínicos. (3) o teste do qui-quadrado revelou uma associação estatisticamente significativa na estética nasal entre os grupos Millard e Fisher, sem diferença significativa para os demais elementos anatômicos. Como conclusão de cada artigo, vimos que: (1) os vídeos do YouTube™ e TikTok™ são predominantemente de baixa qualidade, tornando-os inadequados como ferramentas educacionais para pacientes com Fissura Labiopalatina em seu tratamento multidisciplinar; (2) o NAM é eficaz na redução da fissura e melhoria do arco, mas as discrepâncias entre o planejamento virtual e os resultados reais destacam a necessidade de atualizar os algoritmos de crescimento para maior precisão; (3) as técnicas de Millard e Fisher oferecem resultados estéticos comparáveis, apesar da técnica de Fisher demonstra superioridade significativa na estética nasal. A tese destaca a importância dessas abordagens multidisciplinares e integradas.

Palavras-chave: fissura labiopalatina; moldagem nasoalveolar; mídias sociais, procedimentos de cirurgia plástica.

ABSTRACT

Approaches to the treatment of cleft lip and palate: integration of social media, 3D technologies, and surgical techniques.

Cleft lip and palate is a congenital malformation that affects vital functions and requires multidisciplinary treatment from birth throughout life. This thesis connects, in 3 distinct scientific articles, the importance of social media (article 1), pre-surgical treatment with 3D technology (article 2), and primary surgical techniques in the treatment of this malformation. The objectives of each article were: (1) to analyze the quality and content of videos related to cleft lip and palate on YouTube™ and TikTok™; (2) to evaluate the difference between virtual planning and clinical outcomes in the treatment of cleft lip and palate using plates from the Nasoalveolar Molding (NAM) protocol manufactured by reverse engineering; (3) to compare the aesthetic outcomes of the Millard and Fisher surgical techniques in infants with unilateral cleft lip and palate. The methodology used in each article: (1) a search was conducted on YouTube™ and TikTok™ using specific keywords. The videos were evaluated using a checklist prepared by cleft lip and palate specialists, focusing on parameters such as views, likes, comments, and the content provided; (2) 36 nonsyndromic infants with complete unilateral or bilateral transforamen clefts were evaluated. Virtual models were created, and NAM plates were fabricated using 3D printing. Measurements were compared between virtual planning and clinical outcomes; (3) postoperative photographs of 40 infants, equally divided between the two techniques, were analyzed and compared using the modified classification scale proposed by Mortier and Anastassov, which assigns points to anatomical elements of the nasolabial triangle (red lip, white lip, scars, and nose). As results of each article, it was observed that: (1) YouTube™ videos presented moderate quality, while TikTok™ videos were predominantly of low quality; (2) NAM significantly reduced cleft widths and increased the dimensions of the maxillary arch; however, significant discrepancies were observed between virtual planning and clinical outcomes. (3) the chi-square test revealed a statistically significant association in nasal aesthetics between the Millard and Fisher groups, with no significant difference for the other anatomical elements. As conclusions of each article, we found that: (1) YouTube™ and TikTok™ videos are predominantly of low quality, making them unsuitable as educational tools for patients with cleft lip and palate in their multidisciplinary treatment; (2) NAM is effective in reducing the cleft and improving the arch, but discrepancies between virtual planning and actual results highlight the need to update growth algorithms for greater accuracy; (3) the Millard and Fisher techniques offer comparable aesthetic results, although the Fisher technique demonstrates significant superiority in nasal aesthetics. The thesis highlights the importance of these multidisciplinary and integrated approaches.

Keywords: cleft lip and palate; nasoalveolar molding; social media; plastic surgery procedures.

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LISTA DE ABREVIATURAS E SIGLAS

NAM	Modelador nasoalveolar (do inglês "Nasoalveolar Molding")
UCLP	Fissura Labiopalatina Unilateral (do inglês "Unilateral Cleft Lip and Palate")
BFLP	Fissura Labiopalatina Bilateral (do inglês "Bilateral Cleft Lip and Palate")
CAD	Desenho Assistido por Computador (do inglês "Computer-Aided Design")
3D	Tridimensional
CLP	Fissura Labiopalatina (do inglês "Cleft Lip and Palate")
SPSS	Pacote Estatístico para as Ciências Sociais (do inglês "Statistical Package for the Social Sciences")
UFMG	Universidade Federal de Minas Gerais
CAAE	Certificado de Apresentação para Apreciação Ética
STL	Stereolithography (formato de arquivo usado para impressão 3D)
MADs	Dimensões do Arco Maxilar (do inglês "Maxillary Arch Dimensions")
ICC	Coeficiente de Correlação Intraclasse (do inglês "Intraclass Correlation Coefficient")
RE	Engenharia Reversa (do inglês "Reverse Engineering")
ANOVA	Análise de Variância (do inglês "Analysis of Variance")

SUMÁRIO

1 CONSIDERAÇÕES INICIAIS

A fissura de lábio e palato refere-se à falta de fusão entre os segmentos maxilares direito e/ou esquerdo durante a embriogênese. A deformidade congênita resultante leva à malformação do terço médio e inferior da face e resulta em incapacidades funcionais, como alimentação, fala e audição, além de afetar a saúde psicológica e a qualidade de vida dos pacientes (Roth, 2021; Breh *et al.*, 2022).

As fissuras de lábio e/ou palato afetam aproximadamente 1/650 nascidos vivos no mundo e 1/924 no Brasil, sendo que a maioria das fissuras é unilateral e não sindrômica (Mossey; Modell, 2012; Jayashree, 2013; Roth, 2021; Silva *et al.*, 2021).

Atualmente, o diagnóstico da fissura labiopalatina é realizado ainda na fase uterina por meio de ultrassonografia morfológica (Parthofer *et al.*, 2023). Indivíduos que nascem com essa condição necessitam de um tratamento multidisciplinar abrangente, envolvendo múltiplas especialidades (Parthofer *et al.*, 2023). Nesse cenário, muitos pacientes com fissura labiopalatina e seus familiares enfrentam diversas incertezas em relação às fases do tratamento, necessitando de informações precisas sobre sua condição (Powell; Bien; Cohen; Barta, 2023; Sunkara; Powell; Quick; Landis, 2023).

Embora tradicionalmente seja responsabilidade de profissionais de saúde e organizações fornecerem esclarecimentos sobre o tratamento, a facilidade do acesso à internet tornou-se a principal referência não apenas para dados médicos, mas também para buscar diagnósticos ou tratamentos antes mesmo de procurar uma avaliação profissional (Korkmaz; Buyuk, 2020; Anderson; Monica, 2021; Kılınç, 2022; Powell; Bien; Cohen; Barta, 2023).

Nos últimos anos, as mídias sociais, como YouTube™ e TikTok™, têm se tornado importantes fontes de informação para pacientes e profissionais de saúde (Anderson; Monica, 2021; Massarat; Risa; Navid, 2023). No entanto, a qualidade e a confiabilidade das informações disponíveis nessas plataformas são frequentemente questionáveis (Korkmaz; Buyuk, 2020; Kılınç, 2022; Freire; Sanchez; Suarez; Joves *et al.*, 2023).

Estudos indicam que muitos vídeos sobre saúde nessas plataformas contêm informações incorretas ou desatualizadas, o que pode levar a mal-entendidos e práticas inadequadas (Hassona *et al.*, 2016; Kılınç, 2022; Meade; Dreyer, 2022). Portanto, é crucial analisar criticamente esses conteúdos para garantir que pacientes

e suas famílias recebam informações precisas, úteis e que as levem o mais cedo possível ao melhor tratamento para cada caso.

O tratamento das fissuras labiopalatinas é um processo complexo e requer a colaboração de cirurgiões plásticos, ortodontistas, fonoaudiólogos, psicólogos e outros profissionais de saúde ao longo de várias fases do desenvolvimento do paciente, iniciando-se ao nascimento, com a ortopedia pré-cirúrgica, e podendo se estender ao longo da vida (Dean; Wainwright; Doringo; Teichgraeber *et al.*, 2019; Hattori; Pai; Saito; Chou *et al.*, 2023; Parthofer *et al.*, 2023).

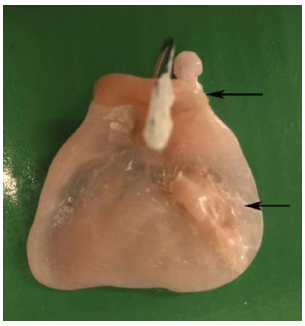
O modelador nasoalveolar (NAM) é um tratamento ortopédico pré-cirúrgico para os tecidos duros e moles de bebês com fissura labiopalatina. Esta técnica utiliza o alto grau de plasticidade da cartilagem nasal e a moldabilidade dos segmentos ósseos alveolares durante os 2 a 3 meses iniciais de vida para aproximar os segmentos labiais e alveolares fissurados, remodelar a cartilagem nasal e melhorar a estética nasal e facial antes da cirurgia primária (Aslan, 2018; Ahmed, 2019; Abd *et al.*, 2020).

O NAM tradicional, introduzido por Grayson *et al.* em 1993, consiste em uma placa acrílica de moldagem intraoral na qual os segmentos alveolares maiores e menores da fenda palatina/labial são aproximados nos casos unilaterais e a pré-maxila nos bilaterais, por meio de ajustes semanais no acrílico e colocação de stents intranasais associados à placa, compostos por fio de arame forrado com acrílico, empregados para levantar e moldar a cartilagem nasal (Kapadia *et al.*, 2020).

Os estudos anteriores sobre NAM mostraram excelentes resultados no crescimento e desenvolvimento ósseo e na redução da fenda alveolar (El-Ghafour, 2009; Neha, 2017; Abd *et al.*, 2020), e que o uso de NAM pode reduzir significativamente a necessidade de cirurgias secundárias e melhorar a simetria nasal e labial (Grayson *et al.*, 1999; Santiago *et al.*, 1998; Maull *et al.*, 1999).

Apesar das vantagens do NAM em reduzir o número de correções cirúrgicas secundárias e custos associados, ele tem sido desafiado por sua carga de cuidados e consultas frequentes, pois o dispositivo original é construído manualmente após a primeira consulta. Em alguns casos, várias impressões do defeito da fenda intraoral são necessárias para ajustar as placas conforme o desenvolvimento alveolar da criança. Isso demanda várias visitas para remoldagem, gerando abandono do tratamento por muitas famílias devido à falta de recursos e tempo (Roth, 2021) (Figura 1).

Figura 1 - Aparelho de modelagem com setas mostrando áreas de adição de material de silicone



Fonte: NEHA *et al.*, 2017, p.120.

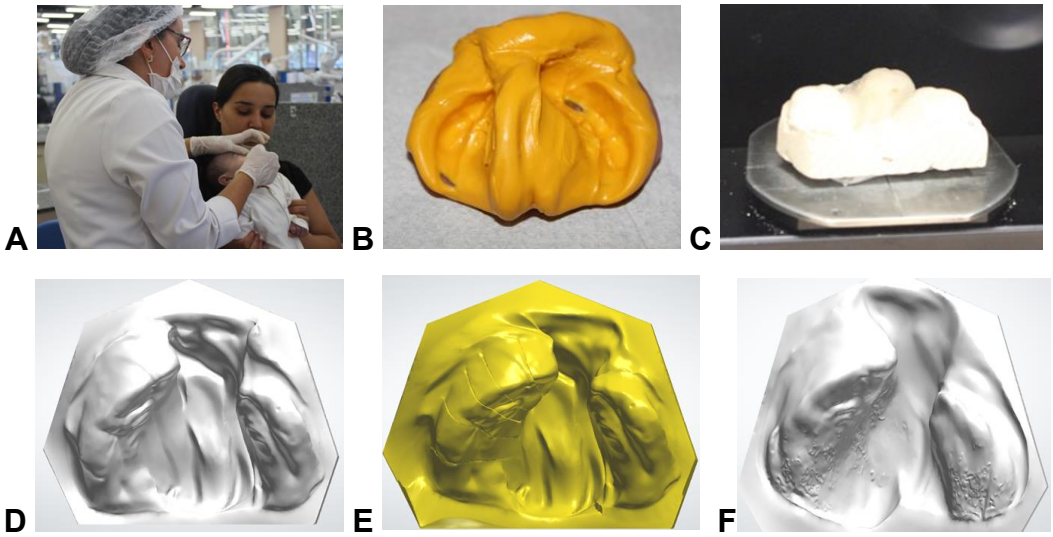
Os elásticos ortodônticos são colocados nos botões de retenção, acessórios acrílicos posicionados anteriormente no aparelho. O aparelho é mantido no lugar com elásticos bilaterais colados nas bochechas (Figura 2) (Kapadia *et al.*, 2020). Consultas semanais seguem para adição sequencial do material de reembasamento à base de silicone e recorte do acrílico onde necessário para moldar o alvéolo e acompanhar o crescimento (Neha *et al.*, 2017).

Figura 2 – Aparelho de moldagem nasoalveolar com stent nasal com elásticos bilaterais colados nas bochechas

Fonte: Fonte: NEHA et al., 2017, p.121.

O NAM confeccionado por meio da engenharia reversa torna esse método menos complicado, pois emprega software de engenharia e sistemas de prototipagem, com geração do modelo digital seguido pelo planejamento virtual via web e obtenção dos modeladores (Abbott *et al.*, 2012; Andrade, 2021; de Souza *et al.*, 2023) (Figura 3).

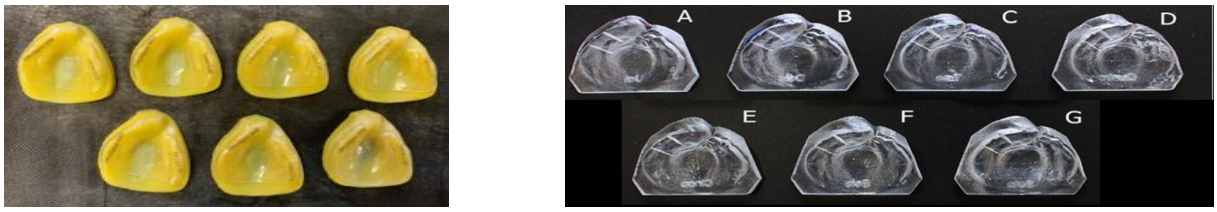
Figura 3: Protocolo NAM engenharia reversa:



Legenda: A – Moldagem da cavidade oral do bebê; B – Molde em silicone; C – Modelo em gesso; D – Modelo escaneado (STL); E – Planejamento virtual; F – Modelo real escaneado feito ao final do tratamento

Fonte: Universidade Federal de Minas Gerais, 2023.

Figura 4: Modelos físicos impressos e sequenciais que foram utilizados como base para confeccionar as placas modeladoras (A – G).



Fonte: Universidade Federal de Minas Gerais, 2023.

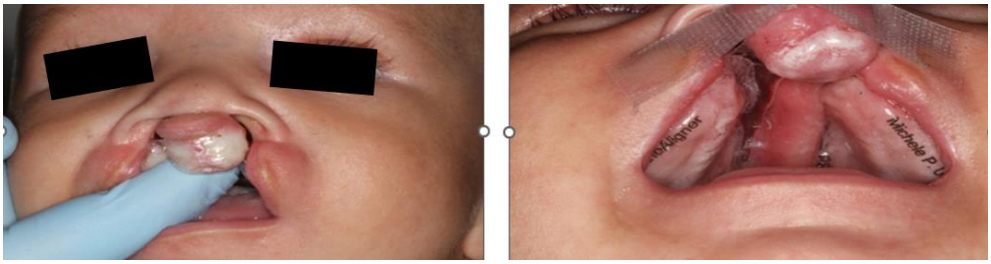
O elevador nasal é adicionado manualmente junto à primeira placa NAM, assim como as fitas horizontais para aproximação dos lábios e tração da columela. A base do elevador é colocada no domus nasal e tracionada com elástico 3/16” médio e fita transpore hipoalergênica (3M, St Paul, MN) para fixar o elevador nasal na testa do bebê. Essa mesma fita, com maior espessura, é utilizada para tracionar e unir o lábio do bebê, passando pela metade da bochecha, pelos lábios fissurados até a outra metade (Figura 4).

Figura 5 - Fitas labiais tracionando os tecidos moles faciais da fissura e elevador labial tracionado por elástico e fita adesivado na testa do bebê.

Fonte: Universidade Federal de Minas Gerais, 2023.

Cada placa é trocada pela seguinte da sequência em casa, pelos próprios pais, após 7 dias de utilização (Figura 3). O paciente retorna após a utilização completa do ciclo (7 semanas) para moldagem final pré-cirúrgica. Os pais são orientados a contatar a equipe em caso de dúvidas, desadaptação da placa ou intercorrências, podendo agendar sessão para resolução (Ferreira, 2018; de Souza *et al.*, 2023) (Figura 5).

Figura 6 – Instalação e troca de placas sequenciais.



Fonte: Universidade Federal de Minas Gerais, 2023.

Atualmente, não existem algoritmos preditivos de crescimento que concedam ao operador a capacidade de automatizar o processo de manipulação dos modelos para deixar o resultado desejado. Cada participante com NAM tem características distintas de sua anatomia de fenda e, portanto, é difícil criar um algoritmo que possa explicar as grandes diferenças em cada caso (Ahhmed, 2019).

O design e a impressão 3D também têm o potencial de fortalecer os pontos fortes do tratamento NAM. O design virtual permite que o cirurgião veja o produto final antes de ser produzido. Depois que a impressão é feita e vazada, um técnico digitaliza o moldelo e o importa como um arquivo 3D para o software CAD, sobre o qual é feito planejamento do tratamento virtualmente e impressão dos modelos sequencias de cada etapa do tratamento, gerando as placas sobre esses modelos

(termoplastificação de acetato), como nos alinhadores ortodônticos (Jayashree, 2013; Grill, 2018; Ahmed, 2019; Roth, 2021; De Souza *et al.*, 2023).

O estudo dos parâmetros naturais de crescimento dos tecidos torna-se necessário para guiar os tratamentos pré e pós cirurgicos, podendo criar algoritmos para sequenciamento dos aparelhos NAM (De Souza *et al.,* 2023), permitindo melhor redirecionamento do crescimento e aproximação dos segmentos alveolares e labiais dos fissurados, além de remodelar a cartilagem nasal, melhorando a estética nasal e facial antes da cirurgia primária (Aslan, 2018; Ahmed, 2019; Abd, 2020).

Em seguida o bebê é submetido à cirurgia primária, a queiloplastia. E diversas técnicas têm sido desenvolvidas e aprimoradas ao longo dos anos, cada uma com suas vantagens e desvantagens. A escolha da técnica cirúrgica adequada é outro aspecto crítico no tratamento de fissuras labiopalatinas. A avaliação criteriosa e comparativa dessas técnicas é necessária para orientar a prática clínica e otimizar os resultados para cada paciente (Pradnyandari, 2023)

Entre as diversas técnicas cirúrgicas, se destacam as técnicas de Millard e Fisher como duas das mais amplamente utilizadas e estudadas. A técnica de Millard, introduzida por Ralph Millard, é conhecida por sua abordagem de rotação e avanço, que visa restaurar a continuidade do lábio superior e melhorar a simetria facial. É amplamente valorizada por sua capacidade de ajustar a altura do lábio e a forma do Arco do Cupido, resultando em uma aparência mais natural (Millard, 1957). No entanto, a técnica de Millard pode apresentar desafios em termos de cicatrização e simetria nasal (Pradnyandari, 2023).

Por outro lado, a técnica de Fisher, desenvolvida por David Fisher, utiliza a aproximação de subunidades anatômicas para reparar a fissura. Esta técnica é projetada para minimizar cicatrizes visíveis e melhorar a configuração fisiológica do lábio e do nariz, proporcionando resultados estéticos superiores em muitos casos (Fisher, 2005). A técnica de Fisher, no entanto, é mais complexa e requer um planejamento meticuloso e a utilização de até 25 marcadores operacionais para sua implementação, exigindo mais tempo e habilidade do cirurgião (Pradnyandari, 2023).

Uma conexão eficaz entre a informação acessível ao público, o avanço tecnológico das terapias pré-operatórias e a aplicação de técnicas de queiloplastia poderia proporcionar recomendações baseadas em evidências e apoiar tratamentos mais acessíveis, precisos e centrados no paciente.

Torna-se relevante, portanto, um estudo que vise integrar varáveis à nível de informação às famílias, analisando da qualidade dos conteúdos educacionais em mídias sociais, a importância da qualidade e adesão ao tratamento pré-cirúrgico, com a avaliação da aplicação de tecnologias 3D no planejamento e tratamento de fissuras labiopalatinas, e a importância da cirurgia associada para qualidade estética do resultado da queiloplastia. Essa abordagem amplia horizontes ao propor uma perspectiva multidisciplinar que une o ambiente digital, a engenharia biomédica, o refinamento e personalização das práticas cirúrgicas, contribuindo para o aprimoramento contínuo do cuidado oferecido a pacientes com fissuras labiopalatinas em âmbito global.

2 OBJETIVOS

2.1 Objetivo geral capítulo 1

Avaliar e comparar vídeos do YouTube™ e TikTok™ em termos de confiabilidade, qualidade, conteúdo e recursos específicos dos vídeos sobre a etiologia, cuidados e tratamento de pacientes com fissuras labioplatinas.

2.1.1 Objetivos específicos capítulo 1

- Avaliação de Métricas de qualidade audiovisual e veracidade das informações.
- Categorizar vídeos por fonte, objetivo e plataforma (YouTube e TikTok).
- Identificar temas principais e verificar informações baseadas em ciência.

2.2 Objetivo geral capítulo 2

Avaliar a diferença entre o planejamento virtual e os resultados clínicos reais obtidos com o uso de placas do protocolo NAM (Nasoalveolar Molding) construídas por meio de engenharia reversa.

2.2.1 Objetivos específicos capítulo 2

- Comparar as medidas dos modelos digitais (planejamento virtual) com os resultados clínicos reais após o uso das placas NAM.
- Verificar a precisão dos métodos digitais na fabricação das placas NAM e sua influência na eficácia do tratamento.
- Avaliar a eficácia do protocolo NAM modificado com engenharia reversa em melhorar a simetria facial e reduzir a largura da fissura.
- Comparar a técnica tradicional de NAM com a técnica de engenharia reversa em termos de precisão, conforto e eficácia.
- Analisar a viabilidade clínica do uso de modelos digitais e impressão 3D na fabricação das placas NAM, incluindo a redução do tempo de fabricação e a necessidade de ajustes manuais.

2.3 Objetivo geral capítulo 3

Comparar a eficácia das técnicas de Millard e Fisher na correção estética e proporções faciais de bebês com fissura labiopalatina unilateral.

2.3.1 Objetivos específicos capítulo 3

- Avaliar o resultado estético pré e pós-operatórios nas proporções oral, nasal e facial.
- Analisar a estética do lábio vermelho, lábio branco, columela e a presença de cicatrizes.
- Comparar as diferenças nas mudanças estéticas faciais de bebês tratados com as técnicas de Millard e Fisher.

3 METODOLOGIA EXPANDIDA

A metodologia desta tese foi estruturada em três capítulos, cada um abordando aspectos distintos relacionados as etapas para o tratamento de fissura labiopalatina, utilizando diferentes abordagens metodológicas para responder às questões propostas.

Artigo 1: Avaliação da Qualidade de Vídeos Educacionais no YouTube™ e TikTok™ para Pacientes com Fissura Labiopalatina

1. Seleção dos Vídeos (Material e Métodos - Seleção de Vídeos)

O estudo começou com a coleta de vídeos das duas plataformas de compartilhamento de vídeo mais populares: YouTube™ (www.youtube.com) e TikTok™ (www.tiktok.com). A pesquisa foi realizada em 10 e 11 de janeiro de 2023, respectivamente.

- **Palavras-chave:** Para garantir uma busca relevante e abrangente, quatro palavras-chave ("cleft lip and palate and dentist", "cleft lip and palate dental care plan", "lip and palate and lip surgery", "dental treatment in a patient with cleft lip and palate") foram cuidadosamente selecionadas no Google trends, pois geraram os resultados mais significativos em ambas as plataformas:
- **Critério de Seleção:** Reconhecendo que a maioria dos usuários visualiza apenas os primeiros resultados de uma pesquisa online (DESAI et al, 2013), os pesquisadores selecionaram os primeiros 60 vídeos para cada palavra-chave em cada plataforma. Isso resultou em um total de 480 vídeos inicialmente selecionados (240 do YouTube™ e 240 do TikTok™).
- **Critérios de Inclusão**: Apenas vídeos nos idiomas inglês e espanhol foram incluídos na análise.
- **Critérios de Exclusão:** Não forneceram informações relacionadas à fissura labiopalatina, vídeos duplicados, continham publicidade.
- **Conduta da Pesquisa:** Devido às dinâmicas e naturezas diferentes das plataformas, e à não padronização dos filtros de busca, as pesquisas foram conduzidas sem que os pesquisadores estivessem logados em suas contas.

Além disso, os históricos de busca e cookies foram excluídos previamente para evitar qualquer viés nos resultados apresentados pelas plataformas.

- **Amostra Final:** Dos 480 vídeos inicialmente selecionados, 177 foram excluídos devido aos critérios de exclusão, resultando em uma amostra final de 303 vídeos avaliados (172 do YouTube™ e 131 do TikTok™).

2. Análise dos Vídeos (Material e Métodos - Análise de Vídeos)

A informação de cada vídeo selecionado foi rigorosamente avaliada utilizando uma lista de verificação (checklist) desenvolvida por especialistas em fissura labiopalatina. Esta lista de verificação foi preenchida em formulários do Google Forms para facilitar a coleta e organização dos dados. Parâmetros Gerais Registrados para cada vídeo: título do vídeo, data de upload, país de origem, idioma, número de visualizações, duração (em minutos), número de comentários, número total de "curtidas" (likes) e "não curtidas" (dislikes), tempo desde o upload (em anos).

- **Categorização por Fonte do Vídeo:** Os vídeos foram classificados em quatro grupos principais com base na sua origem:
    - Mídia: Vídeos apresentados por uma fonte de notícias ou mídia identificada.
    - Individual: Vídeos apresentados por um indivíduo.
    - Organização Acadêmica/Saúde: Vídeos apresentados por uma conferência acadêmica, grupo de pesquisa ou organização médica.
    - Consumidor: Vídeos que endossavam e/ou promoviam a venda de um produto/serviço.
- **Categorização por Gerador da Informação:** A pessoa ou entidade que gerou a informação no vídeo foi categorizada em: dentista clínico, dentista especialista, equipe (staff), educadores, médico, caridade/ONG (Organização Não Governamental), programas de televisão.
- **Classificação do Objetivo Principal do Vídeo:** O propósito principal de cada vídeo foi investigado e classificado em quatro categorias:

- Educar: O vídeo informa/ensina sobre o tópico, incluindo informações baseadas em evidências.
- Opinião: O vídeo retrata a perspectiva de um indivíduo ou organização sobre o assunto.
- Apresentação Acadêmica: O vídeo é uma apresentação para um público acadêmico (ex.: anais de conferências).
- Comercial: O vídeo promove produtos ou serviços de uma empresa ou indivíduo. A classificação do objetivo foi baseada no assunto que estava predominantemente em foco.

- **Análise de Conteúdo da Informação:** Uma análise detalhada foi realizada sobre o conteúdo das informações fornecidas nos vídeos, abrangendo os seguintes tópicos:
  - Etiologia da Fissura Labiopalatina
  - Período gestacional.
  - Prevalência.
  - Classificação da fissura
  - Tratamento médico/cirúrgico.
  - Tratamento odontológico (diagnóstico pré-natal, amamentação, dieta, alterações orais e da dentição, uso do modelador nasoalveolar - NAM, fitas nasais e elevadores, e próteses obturadoras de palato).
  - Outros assuntos.
- **Pontuação de Veracidade do Conteúdo:** A veracidade de cada informação presente nos vídeos foi pontuada em uma escala:
  - 0: O vídeo não forneceu informações sobre a veracidade do seu conteúdo.
  - 1: Conteúdo incorreto (Fake news).
  - 2: Conteúdo desatualizado.

- 3: Conteúdo correto.

- **Avaliação da Qualidade Audiovisual**: A qualidade audiovisual dos vídeos foi avaliada seguindo os critérios de Sorensen *et al.* (2014):
  - Boa: Vídeos com visuais claros, texto, gráficos profissionais ou efeitos, sem dificuldade em compreender a fala ou a música.
  - Moderada: Vídeos caseiros, com qualidade razoável e clareza de texto média, fala difícil de entender e áudio ou sons de fundo que distraem.
  - Ruim: Vídeos borrados, granulados, com visuais difíceis de entender e/ou sem áudio.
- **Avaliação da Qualidade do Conteúdo:** A avaliação da qualidade do conteúdo foi realizada conforme Hegarty *et al.* (2017):
  - Excelente: Vídeos com excelente qualidade e fluidez, contendo a maioria das informações relevantes e muito úteis para os pacientes.
  - Moderada: Vídeos com qualidade moderada e fluidez subótima, nos quais algumas informações importantes foram discutidas adequadamente, mas outras foram mal discutidas, e que foram de alguma forma úteis para os pacientes.
  - Ruim: Vídeos com baixa qualidade e fluidez, nos quais algumas informações foram listadas, mas a maioria estava ausente, e que não foram úteis para os pacientes.

3. Medição da Confiabilidade (Material e Métodos - Análise de Vídeos)

Para garantir a confiabilidade dos dados coletados, foi realizada uma calibração inter e intra-avaliadores.

- Avaliadores: Duas dentistas pediátricas experientes foram selecionadas para a avaliação dos vídeos.
- Processo de Calibração:
  - Inicialmente, um checklist detalhado foi desenvolvido por especialistas em fissura labiopalatina, abordando tópicos relevantes como etiologia,

período gestacional, prevalência, classificação da fissura, tratamento médico/cirúrgico e tratamento odontológico.

- As avaliadoras participaram de uma sessão de treinamento inicial para garantir uma compreensão uniforme dos critérios de avaliação.
- Os primeiros dez vídeos de cada plataforma (YouTube™ e TikTok™) foram avaliados independentemente por ambas as avaliadoras.
- O coeficiente Kappa foi calculado para determinar o grau de concordância entre as duas avaliadoras, resultando em um valor de 0,99, indicando uma excelente concordância.
- Após um intervalo de duas semanas, os mesmos dez vídeos foram reavaliados pelas mesmas avaliadoras para verificar a consistência das classificações ao longo do tempo. Novamente, altos valores de Kappa foram obtidos, confirmando a consistência das classificações individuais.
- Após os testes e retestes, as avaliadoras discutiram quaisquer discrepâncias restantes e ajustaram os critérios do checklist para garantir classificações consistentes e confiáveis para todos os vídeos subsequentes. Esses passos asseguraram que as classificações dos vídeos foram realizadas de forma consistente e confiável, garantindo a validade dos resultados do estudo.

4. Análise Estatística (Análise Estatística)

A análise estatística dos dados foi crucial para identificar padrões e diferenças significativas entre as plataformas e variáveis estudadas.

- Software: Os dados foram organizados e analisados estatisticamente usando Microsoft Excel (Microsoft) e o Statistical Package for Social Sciences (SPSS for Windows, versão 21.0, IBM Inc., Armonk, NY, EUA).
- Caracterização dos Recursos de Vídeo: A distribuição de frequência dos dados foi determinada, e as porcentagens para as variáveis categóricas foram calculadas para caracterizar os recursos de vídeo.
- Testes Estatísticos:

- Análise de Variância (ANOVA) de uma via e testes de Kruskal-Wallis: Utilizados para comparar os parâmetros dos vídeos entre vídeos de conteúdo informativo bom, moderado e ruim.
- Teste Qui-quadrado de tendência linear: Empregado para determinar o resultado da plataforma (TikTok™ ou YouTube™) e a variável qualitativa nominal politômica.

- Nível de Significância Estatística: A significância estatística foi estabelecida em $p < 0,05$, o que significa que um resultado com p-valor abaixo de 0,05 foi considerado estatisticamente significativo.

Essa metodologia robusta permitiu aos pesquisadores analisar uma vasta quantidade de vídeos de forma sistemática e objetiva, fornecendo insights valiosos sobre a qualidade das informações disponíveis nas redes sociais para pacientes com fissura labiopalatina.

Artigo 2: Estudo Comparativo Entre Planejamento Virtual e Resultados Clínicos da Modelagem Nasoalveolar em Pacientes com Fenda Labiopalatina

1. **Amostra**:
   - 25 lactentes com fissuras transforame completas (15 unilaterais e 10 bilaterais), tratados entre 2022 e 2024 no Centro de Ortodontia da UFMG.
   - Critérios de inclusão: lactentes com idade entre 0 e 3 meses, sem síndromes ou doenças sistêmicas.
2. **Procedimentos**:
   - Moldagem inicial com silicone de adição para obtenção de modelos em gesso.
   - Digitalização dos modelos com scanner 3Shape R700™ e planejamento virtual utilizando o software OrthoAnalyzer™.
   - Impressão 3D das placas NAM sequenciais, com ajustes progressivos de 0,5 mm por etapa.

- Substituição das placas pelos pais a cada 7 dias, com retorno após 7 semanas para avaliação final.

3. **Medições**:
   - Avaliação das dimensões do arco maxilar (largura, comprimento e altura) em três momentos: inicial (T1), final do planejamento virtual (T2) e resultado clínico (T3).
   - Utilização de pontos de referência e técnicas de medição baseadas nos estudos de El-Ghafour (2020) e Tankittiwat (2021).
4. **Confiabilidade**:
   - Calibração dos examinadores para garantir consistência nas medições.
   - ICC calculado para avaliar confiabilidade intra e interexaminador.
5. **Análise Estatística**:
   - Testes ANOVA, Kruskal-Wallis e Tukey para comparar diferenças entre os momentos T1, T2 e T3.
   - Nível de significância definido em $p<0,05$.

Artigo 3: Análise Comparativa do Resultado Estético da Queiloplastia por meio das Técnicas Millard e Fisher no Tratamento de Fenda Labiopalatina Unilateral

Este estudo foi concebido como um clínico, transversal e comparativo, buscando analisar os desfechos estéticos de duas técnicas cirúrgicas para fissura labial unilateral.

1. Local do Estudo e Aprovação Ética: A pesquisa foi conduzida em um ambiente clínico especializado, o Hospital da Baleia, localizado em Belo Horizonte, Brasil. Antes do início da coleta de dados, o protocolo do estudo obteve a aprovação necessária de dois comitês de ética em pesquisa: o Comitê de Ética da Faculdade de Odontologia da UFMG (sob o número CAAE: 65707222.2.0000.5149) e o Comitê de Ética do próprio Hospital da Baleia (sob o número CAAE: 65707222.2.3001.5123). Adicionalmente, para garantir a conformidade ética e a proteção dos participantes,

todos os responsáveis legais pelos lactentes envolvidos foram detalhadamente informados sobre os objetivos, procedimentos e possíveis implicações da pesquisa, e assinaram o Termo de Consentimento Livre e Esclarecido (TCLE).

2. População do Estudo e Seleção da Amostra: A amostra do estudo foi determinada por conveniência, composta por 40 lactentes diagnosticados com fissura labiopalatina unilateral não sindrômica. Todos os participantes tinham idade entre 3 e 6 meses no momento da realização da cirurgia, período considerado adequado para a intervenção. Foram estabelecidos critérios de exclusão rigorosos para garantir a homogeneidade da amostra, excluindo pacientes com síndromes genéticas associadas à fissura e aqueles que já haviam sido submetidos a qualquer correção cirúrgica secundária prévia do lábio e/ou nariz.

3. Grupos de Estudo e Intervenção Cirúrgica: Os 40 lactentes elegíveis foram divididos equitativamente em dois grupos (n=20 em cada grupo), correspondendo à técnica cirúrgica utilizada:

- Grupo 1: Lactentes operados utilizando a técnica de Millard.
- Grupo 2: Lactentes operados utilizando a técnica de Fisher.

Todas as cirurgias foram realizadas por um único cirurgião experiente, garantindo a padronização técnica e minimizando o viés de diferentes habilidades operatórias. As intervenções ocorreram em um período de dois anos, entre 2022 e 2024, no mesmo centro cirúrgico, e seguiram um protocolo padronizado para os procedimentos pré e pós-operatórios.

4. Coleta de Dados e Avaliação Estética: A avaliação dos desfechos estéticos baseou-se em análises fotográficas. As fotografias foram capturadas por um único pesquisador, utilizando uma câmera digital de alta resolução, assegurando a consistência na técnica de imagem. As imagens focavam especificamente na vista frontal da região da boca e nariz (triângulo nasolabial). Duas séries de fotografias foram obtidas:

- T0: Tomadas imediatamente antes da cirurgia, servindo como registro da condição inicial dos pacientes.
- T1: Realizadas 6 meses após a cirurgia, permitindo a avaliação dos resultados estéticos após o período de cicatrização e recuperação inicial.

A comparação dos resultados estéticos pós-operatórios foi de natureza qualitativa, focando na avaliação da simetria e proporção entre o lado da fissura e o lado não afetado. Essa avaliação foi conduzida por dois cirurgiões-dentistas independentes e previamente calibrados, para garantir a objetividade e a concordância nas análises. Foi utilizada uma escala de classificação modificada proposta por Mortier e Anastassov (referenciada como Tabela 1 no artigo), que permite atribuir pontuações a elementos anatômicos específicos do triângulo nasolabial: lábio vermelho, lábio branco, cicatrizes e nariz.

5. Análise de Confiabilidade dos Avaliadores: Análises estéticas qualitativas foram conduzidas por dois cirurgiões-dentistas calibrados. Para avaliar a confiabilidade intraexaminador, cada examinador repetiu as medições em 20% das amostras após um intervalo de uma semana. O coeficiente de correlação intraclasse (ICC) foi calculado para avaliar a consistência das medições realizadas pelo mesmo examinador em momentos diferentes. Para padronizar os resultados, foram calculados o valor médio e o desvio padrão para cada critério, resultando em um valor de 0,95, indicando excelente concordância. Para a avaliação da confiabilidade interexaminador, ambos os examinadores mediram os mesmos 20% das amostras, e o ICC foi calculado para avaliar a consistência entre os dois examinadores, confirmando a consistência das avaliações individuais (0,95)

6. Análise Estatística: Foi utilizado o teste de Shapiro-Wilk para avaliar normalidade dos dados e o teste qui-quadrado para determinar a significância das diferenças entre os grupos. Este teste foi aplicado para avaliar a associação entre a técnica cirúrgica (Millard vs. Fisher) e as avaliações estéticas dos diferentes elementos anatômicos (lábio vermelho, lábio branco, cicatrizes e, crucialmente, o nariz), buscando identificar se havia uma diferença estatisticamente significativa nos resultados estéticos entre as duas técnicas

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Cada capítulo foi desenvolvido com rigor metodológico, garantindo a validade e confiabilidade dos dados coletados e analisados, contribuindo para uma compreensão abrangente dos diferentes aspectos do tratamento de fissura labiopalatina.

- **4 RESULTADO, DISCUSSÃO E CONCLUSÃO**

Os resultados, discussões e conclusões estão apresentados dentro dos três artigos científicos completos que compõem esta tese, seguindo a ordem dos objetivos específicos.

5 ARTIGO 1

Artigo publicado - Dental Press Journal of Orthodontics – 2024

Os vídeos do YouTube™ e do TikTok™ são úteis como ferramentas educacionais para pacientes com fissura

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ORIGINAL ARTICLE

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Are YouTube™ and TikTok™ videos useful as educational tool for patients with cleft lip and palate?

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ABSTRACT

Objective: To evaluate the quality of YouTube™ and TikTok™ videos as educational tools for patients with cleft lip and palate (CLP) as regards their care, and multidisciplinary treatment. **Methods:** Videos were searched on YouTube™ and TikTok™ using four keywords. The reliability and quality of the first 60 videos for each keyword and platform were analyzed. The following variables were analyzed: the source, distribution, and purpose of the videos, the general and audiovisual quality of the videos, and their main subject. The study's covariates were cleft classification, dental treatment, pre-surgical orthopedic treatments, surgical and medical treatments. **Results:** Of the 480 videos selected, 303 videos were evaluated (177 excluded due to the exclusion criteria). TikTok™ emerged as the most frequently accessed platform, recording a greater number of views and likes. YouTube™ stood out for its availability of longer and more comprehensive videos, in terms of content. On YouTube™ the majority of videos were produced by academic/health and medical organizations, predominantly aimed at educational purposes; whereas on TikTok™ prevailed the production of individual and personal content geared toward informational purposes. On both platforms, the videos proved to be of low quality. YouTube™ videos from individual sources and organizations were associated with medium and low quality, respectively. Additionally, YouTube™ videos of shorter duration were of lower quality. TikTok™ videos had lower overall quality, especially those produced individually, regardless of associations. **Conclusions:** YouTube™ and TikTok™ exhibited predominantly low-quality videos, suggesting they are not suitable as educational tools to guide patients with CLP for their multidisciplinary treatment.

Keywords: Cleft lip. Cleft palate. Social media. Treatment outcome. Dental health education. Health care.

RESUMO

Objetivo: Avaliar a qualidade dos vídeos do YouTube™ e TikTok™ como ferramentas educacionais para pacientes com fissura labiopalatina (FLP), no que diz respeito aos cuidados e tratamento multidisciplinar. **Métodos:** Vídeos foram pesquisados no YouTube™ e TikTok™ utilizando quatro palavras-chave. A confiabilidade e qualidade dos primeiros 60 vídeos para cada palavra-chave e plataforma foram analisadas. As variáveis analisadas foram: fonte, distribuição e propósito dos vídeos, qualidade geral e audiovisual dos vídeos, e seu principal assunto. As covariáveis do estudo foram classificação da fissura, tratamento odontológico, tratamentos ortopédicos pré-cirúrgicos, tratamentos cirúrgicos e médicos. **Resultados:** Dos 480 vídeos selecionados, 303 foram avaliados (177 excluídos devido aos critérios de exclusão). O TikTok™ emergiu como a plataforma mais frequentemente acessada, registrando um maior número de visualizações e curtidas. O YouTube™ destacou-se pela disponibilidade de vídeos mais longos e mais abrangentes em termos de conteúdo. No YouTube™, a maioria dos vídeos foi produzida por organizações acadêmicas/saúde e médicas, predominantemente com fins educacionais, enquanto no TikTok™ prevaleceu a produção de conteúdo individual e pessoal, voltado para fins informativos. Em ambas as plataformas, os vídeos mostraram-se de baixa qualidade. Vídeos do YouTube™ de fontes individuais e organizações foram associados a qualidade média e baixa, respectivamente. Além disso, vídeos do YouTube™ de menor duração apresentaram qualidade inferior. Vídeos do TikTok™ tiveram qualidade geral inferior, especialmente aqueles produzidos individualmente, independentemente de associações. **Conclusão:** YouTube™ e TikTok™ exibiram predominantemente vídeos de baixa qualidade, sugerindo que não são adequados como ferramentas educacionais para orientar pacientes com FLP em seu tratamento multidisciplinar.

Palavras-chave: Fissura labial. Fissura palatina. Mídias sociais. Resultado do tratamento. Educação em Saúde Bucal. Atenção à saúde.

INTRODUCTION

Cleft lip and palate is a congenital deformity that occurs due to lack of fusion between the maxillary segments and/or palate during embryogenesis, and affects approximately 1/650 live births worldwide,[1,2] and 1/1,924 in Brazil.[3] Individuals affected by clefts require multidisciplinary treatment, beginning at birth and possibly extending throughout life.[4,5] The procedures cover a variety of interventions, from pre-surgical orthopedic treatments, such as nasoalveolar molding (NAM),[4,6] and even corrective surgeries, including palatoplasty and cheiloplasty, as well as oral and maxillofacial procedures in adulthood.[5] Furthermore, they may need dental and orthodontic treatments, speech therapy, and otorhinolaryngology, among others.[5]

In this scenario, many patients with cleft lip and palate, along with their families, face several uncertainties regarding the treatment stages, requiring accurate information about their condition.[7,8] While it has traditionally been the responsibility of healthcare professionals and organizations to provide information about treatment, the ubiquity of Internet access means that the majority of the world's population has a wide range of information sources available. The Internet has become the main reference not only for medical data, but for different areas of the health system,[9-16] and also to search for diagnoses or treatments before even seeking a professional evaluation.[7, 17-19] Despite the potential benefits

of on-line health information, where everyone can share their opinions, the diversity of this content on the Internet ranges from professional information to patients' personal experiences.[20,21] This makes the possibility of spreading misinformation and erroneous content a concern,[18,19] as patients may not have the necessary skills to evaluate medical information and associate it with their health status.[19,21]

Among the most widely used social networks on the Internet are YouTube™ and TikTok™.[17,22] YouTube™ is the video-sharing platform of choice, and has become a phenomenon for commercial and personal content distribution, as well as for social media, due to its ability to provide visual and audio information. It is now the second most popular website in the world after Google, with more than a billion users.[17,22] In addition to having diverse video content, YouTube™ also allows access to a wide variety of health-related videos.[19] TikTok™, a popular social media video-sharing platform, was launched in 2016 and quickly rose to prominence in the market. In 2018 and 2019, it won the title of most downloaded application, with 800 million active users globally, registering billions of videos viewed daily.[17,22] Due to its time restriction for videos, ranging from 15 seconds to 3 minutes, TikTok™ stands out as an active learning tool thanks to its short, condensed, and fun approach.[23] However, the reliability, accuracy, and scientific validity of information, especially related to health, raise doubts, since videos

uploaded to these platforms do not undergo peer review.[18,23] Therefore, the present study aimed to evaluate and compare YouTube™ and TikTok™ videos as educational tools for patients with cleft lip and palate, in terms of reliability, quality, content, and specific features of the videos, concerning the etiology, their care, and multidisciplinary treatment.

MATERIAL AND METHODS

VIDEO SELECTION

It is worth noting that this study did not require approval from the ethics committee, as it contains public data. Two video-sharing sites, YouTube™ (www.youtube.com) and TikTok™ (www.tiktok.com), were used to conduct a search on January 10 and 11, 2023, respectively, for videos containing information for cleft lip and palate, using the following keywords: "cleft lip and palate and dentist", "cleft lip and palate dental care plan", "lip and palate and lip surgery" and "dental treatment in a patient with cleft lip and palate", as they are the terms that generated the most results in both platforms. The videos were searched using combinations of the four keywords for each platform. More than 95% of people view only the first 60 videos in an online search.[20] In this way, the first 60 results for each keyword on each platform were selected, using videos in English and Spanish as inclusion criteria, totaling 480 videos (240 on each platform).

The exclusion criteria were: information unrelated to cleft lip and palate, duplicate videos and videos containing advertising.[19] As the dynamics and nature of the two platforms are different, the search filters are not standardized, and therefore the search histories and cookies were excluded in advance[18], the platforms were accessed without logging in.

VIDEO ANALYSIS

The information from the videos was evaluated using a checklist prepared by experts in cleft lip and palate, and filled out on Google Forms. For each video, information about its title, upload date, country of origin, and language was extracted, and the following general parameters were recorded: (1) number of views; (2) duration (minutes); (3) number of comments; and (4) total number of "likes" and "dislikes", and (5) time since upload (years). The videos were also categorized according to their source, into four basic groups: (1) media (video presented by an identified news source/media), (2) individual (video presented by an individual), (3) academic/health organization (video presented by an academic conference, research group, or medical organization), and (4) consumer (video endorsing and/or promoting the sale of a product/service). The videos were distributed concerning the person who generated the information: (1) clinical dentist, (2) specialist dentist, (3) staff, (4) educators, (5) doctor, (6) charity/NGO, and (7) television programs.

The main objective of the videos was also investigated and categorized into four headings: (1) educate (the video informs/teaches about the topic, which includes evidence-based information), (2) opinion (video that portrays the perspective of an individual or organization on the subject), (3) academic presentation (video of a presentation for an academic audience, e.g. conference proceedings), and (4) commercial (video that promotes the product(s) of a company or individual). The objective classification was based on the subject that was predominantly in focus.

An analysis was also carried out regarding the content of the information provided in the videos: (1) etiology, (2) gestational period, (3) prevalence, (4) classification of the cleft (Lahshal, Spina, or Veau),[24,25] (5) medical/surgical treatment, (6) dental treatment (prenatal diagnosis, breastfeeding, diet, oral and dentition changes, information on the use of nasoalveolar molding (NAM), nasal taper and elevators, and palate obturator prostheses), and (7) other matters. The videos were scored according to the veracity of each information present: (0) the video did not provide information regarding the veracity of its content, (1) incorrect content (Fake news), (2) content out of date, and (3) correct content. The videos were searched on YouTube™ and TikTok™ using combinations of the keywords, resulting in the 60 videos analyzed.

The reliability and quality of these videos were assessed. The variables analyzed included the source, distribution, and purpose of the videos, general and audiovisual quality, and the main subject. The covariates of the study were the classification of the cleft, dental treatment, pre-surgical orthopedic treatments, and surgical and medical treatments.

The audiovisual quality of the videos followed the criteria according to Sorensen et al.[26] Videos that included clear visuals, text, professional graphics, or effects, and that caused no difficulty in understanding spoken words and music were rated as good. Home videos, videos with fair quality and average text clarity, difficult-to-understand speech, and distracting audio or sounds in the background were rated as moderate. Videos that were blurry, grainy, with hard-to-understand visuals, and/or had no audio were rated as poor. The content quality assessment was carried out according to Hegarty et al.[27] Videos with excellent quality and flow, containing most of the relevant information and that were very useful to patients were classified as excellent. Videos with moderate quality and suboptimal flow, in which some important information was discussed adequately, but others were poorly discussed, and that were somewhat helpful to patients, were classified as moderate. Videos with poor quality and flow, in which some information was listed but mostly

missing, as well as videos that were of no use to the patients, were rated as poor. Interaction index formulas were calculated for each video to assess the level of interaction, using the number of likes, dislikes, and total views, according to Hassona et al.[28]

To measure the reliability of the videos, an inter- and intra-rater calibration was performed on the first ten videos from both platforms (YouTube™ and TikTok™). Two experienced pediatric dentists (A.V.M.V. and K.R.J.C.) were selected for the evaluation. Initially, a detailed checklist was developed by experts in cleft lip and palate, containing relevant topics such as etiology, gestational period, prevalence, cleft classification, medical/surgical treatment, dental treatment, and other topics. The raters then participated in an initial training session, to ensure a uniform understanding of the evaluation criteria. The first ten videos from each platform were evaluated independently by both raters using the developed checklist. The Kappa coefficient was calculated to determine the degree of agreement between the two raters, resulting in a value of 0.99, indicating excellent agreement. After a two-week interval, the same ten videos were re-evaluated by the raters to check the consistency of the ratings over time, and again, high Kappa values were obtained, confirming the consistency of the individual ratings. Following the test and

retest ratings, the raters discussed any remaining discrepancies and adjusted the checklist criteria, to ensure consistent and reliable ratings of all subsequent videos. These steps ensured that the video ratings were performed consistently and reliably, ensuring the validity of the study results.

STATISTICAL ANALYSIS

The Kappa coefficient was used to assess agreement between reviewers. Data organization and statistical analysis were performed using Microsoft Excel (Microsoft) and the Statistical Package for Social Sciences (SPSS for Windows, version 21.0, IBM Inc., Armonk, NY, USA). To characterize the video resources, the frequency distribution of the data was determined, and the percentages for the categorical variables were calculated. One-way analysis of variance and Kruskal-Wallis tests were used to compare video parameters among videos of good, moderate, and poor informative content. The chi-square test of the linear trend was used to determine the platform outcome (Tiktok™ or YouTube™) and the polytomous nominal qualitative variable. Statistical significance was set at $p < 0.05$.

RESULTS

Of the 480 videos selected (4 keywords, the first 60 videos, and 2 platforms), 177 were excluded due to the exclusion criteria. In total, 303 videos were evaluated, 172 from the YouTube™ platform and 131 from TikTok™. For YouTube™ videos, variables such as the number of views, likes, and dislikes; the number of comments; and the number of years since the videos were uploaded, were evaluated (Fig 1). The same variables were evaluated for TikTok™, except for dislikes (Table 1). Furthermore, for TikTok™ videos, the number of saves that the video received was evaluated (Table 1). TikTok™ videos, although they had been uploaded for fewer years, had a higher number of views, likes, and comments, when compared to YouTube™ (Table 1).

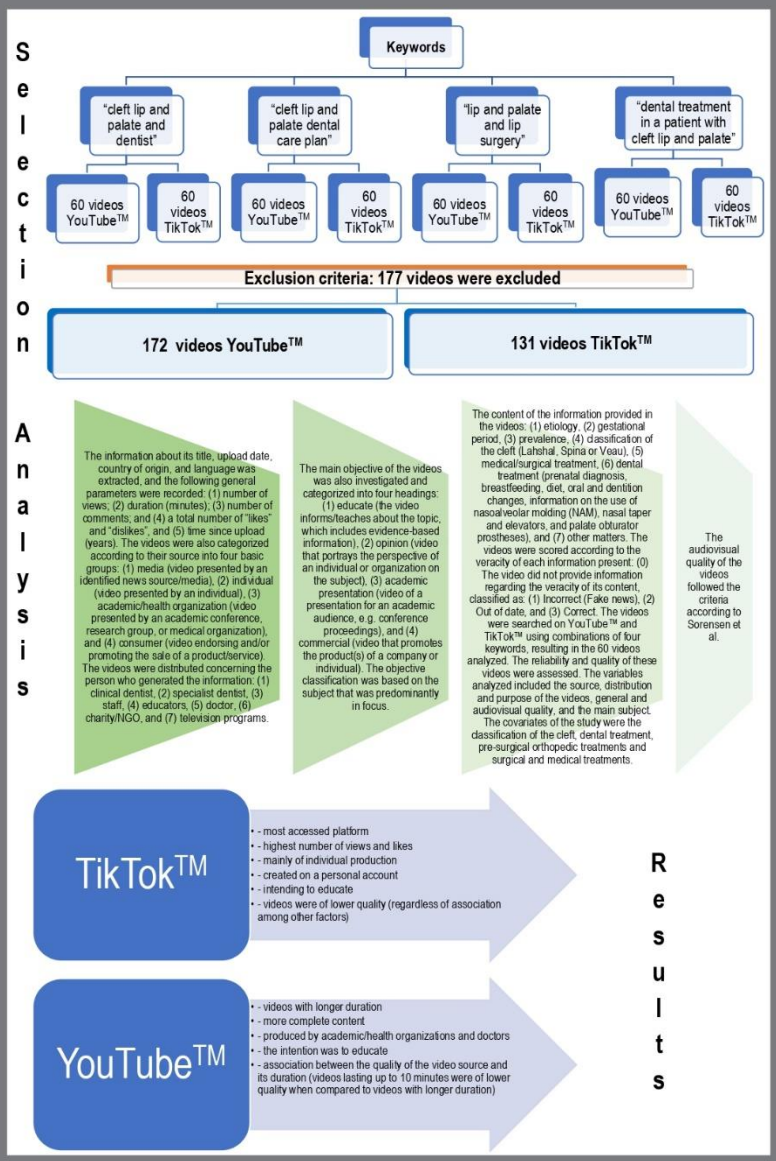

Figure 1: The schematic chart summarizes the video selection, analysis, and main findings.

Table 1: Descriptive analysis of the investigated data (n = 303).

Platform	YouTube™					TikTok™					
Variables	Minimum	Maximum	Average	Median	Standard deviation	Minimum	Maximum	Average	Median	Standard deviation	P value
Views	33	1,297,646.0	34,216.7	3,612.5	119,174.041	100	50,600,000.0	786,980.95	6,529	5,264,481.142	**0.001**
Likes	0	7,303.0	252.99	29.5	746,909.0	0	1,400,000.0	31,925.0	952	153,493.145	**0.000**
Dislikes	0	9.0	0.16	0.0	1.2	0	14.0	443.43	25	2,114.914	0.897
Comments	0	38.9	17.19	2.0	38,936.0	0	2,598.0	30.16	0	249,795.0	**0.000**
Years since upload	1	20.0	4.42	3.0	3.65	0	4.0	1.06	1.00	1.03	**0.000**
Saved	-	-	-	-	-	0	2,598.0	30.16	0	7,487.0	-

Kolmogorov-Smirnov test, Mann-Whitney test.

Videos in English and Spanish were evaluated, of which 284 videos (93.7%) were in English and only 19 (6.3%) were in Spanish. Figure 2A illustrates the continent of origin of TikTok™ and YouTube™ videos, but in 52.8% of the videos it was not possible to identify the origin. Most of the videos posted on the topic came from Anglo-Saxon America (22.1%) and Asia (21.5%). Regarding the country of origin, in most videos, it was not possible to identify the country, but the highest frequency of publications was from the United States (20.8%), India (17.8%), and Saudi Arabia (0.9%) (data not shown).

The source of the videos, their distribution, and their objectives differed statistically between the studied platforms (Table 2). On YouTube™, there was a predominance of videos made by organizations, carried out by doctors, and with an educational goal (Table 2). On TikTok™, the prevalence was of videos of personal stories, made by laypeople providing personal information (Table 2).

Table 2: Variables evaluated in the videos (n = 172 YouTube™ / n = 131 TikTok™) and main themes treated in the YouTube™ (n = 172) and TikTok™ videos (n = 131).

Platform	YouTube™	TikTok™	
Variable	n (%)	n (%)	P-value
Video source			
Media	5 (2.9)	2 (1.5)	0.000
Individual users	61 (35.5)	126 (96.2)	
Organization	94 (54.7)	2 (2.3)	
Consumer	12 (7.0)	0 (0.0)	
Video distribution			
Clinical dentist	13 (7.6)	8 (6.1)	0.000
Specialist dentist	45 (26.2)	27 (20.6)	
Individual users	21 (12.2)	77 (58.8)	
Educators	12 (7.0)	2 (1.5)	
Doctor	72 (41.9)	14 (11.7)	
Charity/non-governmental organizations (NGOs)	9 (5.2)	3 (2,3)	
TV program	0 (0.0)	0 (0.0)	
Purpose of the video			
To educate	76 (44.2)	51 (38.9)	0.001
Opinion	51 (29.7)	78 (59.5)	
Academic presentation	13 (7.6)	0 (0.0)	
Commercial	32 (18.6)	2 (1.5)	
Main theme			
Etiology	50 (29.1)	3 (2.3)	0.000
Gestational period when the cleft lip occurred	4 (2.3)	3 (2.3)	
Prevalence	0 (0.0)	3 (2.3)	
Medical treatment	47 (27.3)	29 (22.1)	
Dental treatment	24 (14.0)	28 (21.4)	
Other matters	43 (25.0)	58 (44.3)	

Chi-square test for trend.

The main themes covered in the videos were significantly different when the platforms were compared to each other (Table 2). The themes of etiology, gestational period in which the cleft occurs, and medical treatment were more prevalent in YouTube™ videos when compared to TikTok™ (Table 2). The three main topics most covered in descending order on YouTube™ were: etiology, medical treatment, and other subjects

(personal stories); while on TikTok™, other subjects (personal stories) were among the most discussed topics, followed by medical and dental treatment (Table 2).

Figure 2B demonstrates that among the main topics related to dental treatment in individuals with cleft lip and palate, it was found that only 35.5% of YouTube™ videos presented scientifically based topics on prenatal diagnosis, breastfeeding, diet, oral changes, and dentition. On TikTok™, many of the videos did not present information or there was a predominance of videos with individuals reporting their personal experiences (Fig 2B).

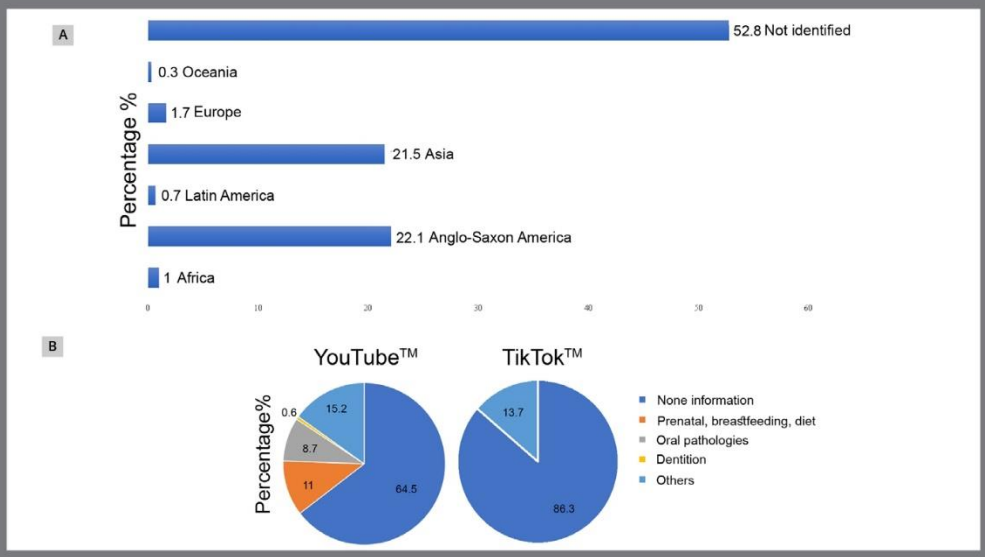

Figure 2: A) Data in percentage (%) of the continent of origin of TikTok™ and YouTube™ videos on cleft lip and palate (n = 303). **B)** Percentage (%) of subjects about dental treatment in TikTok™ and YouTube™ videos.

Information from videos on both platforms was categorized as non-existent, correct, incorrect, and outdated (Table 3). Except for the content of the videos containing information on the use of NAM, nasal taper, nasal elevator, and palate obturator prostheses, where there was no statistical difference between YouTube™ and TikTok™; other subjects —such as cleft classification, general information, dental treatment in individuals with clefts, and surgical medical treatment— differed statistically from each other; with YouTube™ presenting videos with more correct information when compared to TikTok™ (Table 3). YouTube™ showed no videos with incorrect information, while TikTok™ showed 1.5% erroneous information regarding general information. YouTube™ had a greater amount of outdated content when compared to TikTok™ videos (Table 3). The vast majority of videos did not provide information about cleft classification; however, 14 YouTube™ videos and one TikTok™ video addressed cleft classification; however, only 8.2% of the videos cited some type of diagnostic criteria, namely Lahshal (2.9%), Spina (4.1%), and Veau (1.2%).

On both platforms, the general quality of the videos was classified as low, although the audiovisual quality was moderate (Table 3). Only the general quality of the videos differed statistically between YouTube™ and TikTok™, the latter having lower quality videos (Table 3).

Table 3: Information provided in YouTube™ (n = 172) and TikTok™ (n = 131) videos, and general and audiovisual quality of videos concerning cleft lip and palate in YouTube™ (n = 172) and TikTok™ (n = 131) videos.

Platform	YouTube™	TikTok™	P-value
Type of information	n (%)	n (%)	
Cleft classification			
The video does not provide the information	158 (91.9)	130 (99.2)	0.003
Incorrect (Fake News)	0 (0.0)	0 (0.0)	
Correct	14 (8.1)	1 (0.8)	
Outdated	0 (0.0)	0 (0.0)	
General information			
The video does not provide the information	94 (54.7)	122 (93.1)	0.000
Incorrect (Fake News)	0 (0.0)	2 (1.5)	
Correct	74 (43.0)	7 (5.3)	
Outdated	4 (2.3)	0 (0.0)	
Dental treatment in individuals with cleft			
The video does not provide the information	133 (77.3)	123 (93.9)	0.000
Incorrect (Fake News)	0 (0.0)	0 (0.0)	
Correct	35 (20.3)	8 (6.1)	
Outdated	4 (2.3)	0 (0.0)	
Use of NAM plates, taper, nasal elevator and palate obturator prosthesis			
The video does not provide the information	142 (82.5)	105 (80.2)	0.532
Incorrect (Fake News)	0 (0.0)	0 (0.0)	
Correct	28 (16.3)	26 (19.8)	
Outdated	2 (1.2)	0 (0.0)	
Surgical medical treatment			
The video does not provide the information	121 (70.3)	118 (90.1)	0.000
Incorrect (Fake News)	0 (0.0)	0 (0.0)	
Correct	48 (28.0)	11(8.4)	
Outdated	3 (1.7)	2 (1.4)	
Overall quality			
High	44 (25.6)	2 (1.5)	0.000
Average	57 (33.1)	34 (26.0)	
Low	71 (41.3)	95 (72.5)	
Audiovisual quality			
Good	41 (23.8)	10 (7.6)	0.241
Moderate	73 (42.4)	86 (65.6)	
Bad	58 (33.7)	35 (26.7)	

Chi-square test for trend.

Bivariate analyses were carried out to evaluate the association between the general quality of the video and independent variables, such as the source, distribution, and objective of the video (Tables 6 and 7). Only on YouTube™ the video source was associated with quality, in which videos from individual sources presented medium quality and videos from organizations were mostly of low quality (Table 4). On TikTok™, there were no significant associations, although it was possible to observe that individually produced videos were of low quality (73%), as were personally distributed videos (77.9%) (Table 4).

Table 5 demonstrates the associations between the general quality of the video with the subject covered and the duration time, the latter being categorized as up to 10 minutes and over 10 minutes for YouTube™, and up to 1 minute and over 1 minute for TikTok™. Only the subject of etiology was associated with high quality, while prevalence, medical and dental treatment, and individual reports were associated with low quality, the latter having the highest incidence among videos from both platforms (Table 5). The duration of the videos varied greatly, depending on the platform, with shorter duration videos being found in TikTok™ than in YouTube™ videos (Table 5). The duration time was categorized, and it was observed that on TikTok™ 75.6% of the videos were less than 30 seconds long, 22.1% were between more than 30 seconds and less than 2 minutes, and only 2.3% of the videos were more than 2 minutes long (data not shown).

Table 4: Association between quality of YouTube™ videos and information from videos about cleft lip and palate, and association between quality of TikTok™ videos and information from videos about cleft lip and palate.

YouTube™			
Variable	**High**	**Medium**	**Low**
Video Source n (%)**			
Media	2 (28.6)	2 (28.6)	3 (42.9)
Individual users	20 (10.7)	52 (27.8)	115 (61.5)
Organization	21 (21.6)	33 (34.0)	43 (44.3)
Consumers	3 (25.0)	4 (33.3)	5 (41.7)
Video distribution n (%)**			
Clinical dentist	0 (0.0)	2 (25.0)	6 (75.0)
Specialist dentist	1 (3.7)	10 (37.0)	16 (59.3)
Individual users	1 (1.3)	16 (20.8)	60 (77.9)
Educators	0 (0.0)	1 (50.0)	1 (50.0)
Doctors	0 (0.0)	5 (35.7)	9 (64.3)
Charity/non-governmental organizations (NGOs)	0 (0.0)	0 (0.0)	3 (100)
Television program	0 (0.0)	0 (0.0)	0 (0.0)
Purpose of the video n (%)**			
Educate	20 (15.7)	47 (37.0)	60 (47.2)
Opinion	16 (12.4)	33 (25.6)	80 (62.0)
Academic presentation	3 (23.1)	4 (30.8)	6 (46.2)
Commercial	7 (20.6)	7 (20.6)	20 (58.8)
TikTok™			
Variable	**High**	**Medium**	**Low**
Video Source n (%)**			
Media	0 (0.0)	1 (50.0)	1 (50.0)
Individual	2 (1.6)	32 (25.4)	92 (73.0)
Organization	0 (0.0)	1 (33.3)	2 (66.7)
Consumer	0 (0.0)	0 (0.0)	0 (0.0)
Video distribution* n (%)			
Clinical dentist	0 (0.0)	2 (25.0)	6 (75.0)
Specialist dentist	1 (3.7)	10 (37.0)	16 (59.3)
Individual users	1 (1.3)	16 (20.8)	60 (77.9)
Educators	0 (0.0)	1 (50.0)	1 (50.0)
Doctors	0 (0.0)	5 (35.7)	9 (64.3)
Charity/non-governmental organizations (NGOs)	0 (0.0)	0 (0.0)	3 (100)
Television program	0 (0.0)	0 (0.0)	0 (0.0)
Purpose of the video n (%)**			
Educate	1 (2.0)	17 (33.3)	33 (64.7)
Opinion	1 (1.3)	17 (21.8)	60 (76.9)
Academic presentation	0 (0.0)	0 (0.0)	0 (0.0)
Commercial	0 (0.0)	0 (0.0)	2 (100.0)

*Pearson chi-square test. ** Chi-square test for trend. ***Fisher exact test.

YouTube™ videos were longer and more complete in terms of information, in which 38.4% of the videos were less than 2 minutes long, 29.1% were between 2 and 5 minutes long, 11.6% were between 6 and 10 minutes, 13.4% lasted between 11 and 20 minutes, and 11% lasted more than 40 minutes, with a duration extending to more than an hour (data not shown). Although there was a divergence in the length of videos between the platforms, and the fact that 73.4% of TikTok™ videos showed low quality in videos up to 1 minute, only on YouTube™ there was an association between video duration and quality, with 50% of the videos of up to 10 minutes being of low quality (Table 5).

Table 5: Association between overall quality of the videos and the theme and time duration of the video.

Variable	High	Medium	Low	P-value
Theme of the video n (%)**				
Etiology	27 (50.9)	17 (32.1)	9 (17.0)	0.00
Gestational period	0 (0.0)	4 (57.1)	3 (42.9)	
Prevalence	0 (0.0)	0 (0.0)	3 (100)	
Classification of cleft	5 (45.5)	5 (45.5)	1 (9.1)	
Medical treatment	11(14.5)	28 (36.8)	37 (48.7)	
Dental treatment	4 (7.7)	21 (40.4)	27 (51.9)	
Other (ex. self-report)	3 (3.0)	16 (15.8)	82 (81.2)	
Time duration YouTube™* n (%)				
Up to 10 minutes	24 (17.6)	44 (32.4)	68 (50.0)	0.00
More than 10 minutes	20 (55.6)	13 (36.1)	3 (8.3)	
Time duration TikTok™* n (%)				
Up to 2 minute	2 (1.6)	32 (25.0)	94 (73.4)	0.17
More than 2 minute	0 (0.0)	2 (66.7)	1 (33.3)	

*Pearson chi-square test **Chi-square test for trend ***Fisher exact test.

DISCUSSION

This study aimed to evaluate the content of YouTube™ and TikTok™ videos in the treatment of individuals with cleft lip and palate. The study revealed that TikTok™ was the most accessed platform, with the highest number of views and likes. On the other hand, YouTube™ presented videos with longer duration and more complete content. On YouTube™, the majority of videos were produced by academic/health organizations and doctors, with the intent to educate. In contrast, on TikTok™, the videos were mainly of individual production, created on personal accounts, also intending to educate. YouTube™ videos showed an association between the quality of the video source and its duration, videos lasting up to 10 minutes were of lower quality when compared to videos with longer duration, while TikTok™ videos were of lower quality, regardless of association among other factors.

The role of social media in health is complex and multifaceted, covering different areas of health and knowledge. It may have advantages, obstacles, and the necessity for quality oversight. Social networks are freely accessible to the public, enabling a diverse range of individuals —including nonspecialists, health professionals, and researchers— to share personal experiences and scientifically-based content, respectively. Social media is present in various aspects of global health

including improving healthcare disaster decision-making during the COVID-19 pandemic, cardiovascular healthcare, pregnancy care, nutrition, and obesity. There can be benefits to discussing healthcare on social media, and the healthcare professionals need to be engaged with social media.[9-16] In this way, the current research sought to assess and compare YouTube™ and TikTok™ videos as educational resources for patients with cleft lip and palate, focusing on their reliability, quality, content, and particular attributes related to the cause, management, and interdisciplinary treatment.

This study showed that TikTok™ stood out as the most frequently accessed platform, accumulating the highest number of views and likes, although a lower quality of content was perceived. These findings are in line with the conclusions of Meade and Dreyer,[23] who identified low-quality content and reliability in videos on TikTok™ related to orthodontic retention. On the other hand, YouTube™ stood out for presenting longer and more comprehensive videos in terms of content. Contrary to the results of this study, Korkmaz and Buyuk[19] analyses of videos on YouTube™ related to cleft lip and palate treatment revealed that the majority were classified as a moderate quality in terms of information, although they were not considered an entirely reliable source for patients.

Both platforms, characterized by their dynamicity, reflected constantly evolving research results, shaped by continuous changes in audience interests and viewing patterns. It is important to highlight that variables such as viewing rate, likes, and dislikes may be susceptible to manipulation. Although the keywords were selected based on Google Trends, aiming to identify the most used terms, it is important to bear in mind that different sets of keywords can lead to the discovery of different videos.[19]

The videos on both platforms were predominantly in English, with no specific indication of their geographic origin. Consistent with the present results, previous studies found that patient education materials provided by cleft lip and palate teams, as well as personal videos shared on online platforms, were more available in English than in Spanish.[7,8]

On YouTube™, the videos were mostly produced by academic/health organizations and doctors, with the aim of educating; whereas on TikTok™, the video production was individual and personal, intending to give an opinion. Ideally, videos with greater educational content should be more suitable for the patient; however, it was found that on YouTube™, individual videos of lower quality had greater potential for user engagement.[20] The patient often lacks the intrinsic ability to evaluate

the quality of the video. At the same time, the quality of the content does not always extend to medical videos from reputable entities created for educational purposes.[20] The use of social media is one of the most common activities on the Internet, and has become more widespread with the increased use of mobile devices, providing a new dimension through which to access and provide health-related information for both doctors and patients.[18] In this sense, health professionals must be cautious when directing their patients to the appropriate use of YouTube™ and TikTok™ videos.[19,28,29]

In the study conducted by Korkmaz and Buyuk,[19] a notable interest in videos related to cleft lip and palate treatment was found among users. The number of views of these videos reached significant levels, and the public regularly expressed their engagement through comments, sharing information, and personal experiences. In this study, when comparing videos on cleft lip and palate treatment on both platforms, it was observed that YouTube™ videos were more extensive and comprehensive in terms of information, containing topics related to breastfeeding, prenatal care, diet, changes in oral health, and dentitions. By contrast, on TikTok™, we found no videos that addressed the topic in depth. However, it is important to highlight that this type of subjective opinion present on social media can lead to inherent risks for

the patient's health.[20] The presence of incorrect information can compromise patients' decision-making, discouraging the search for appropriate treatment or wrongly directing them to care alternatives that are not supported by science.[20]

Regarding the quality of the videos found, it was observed that the majority of TikTok™ videos were of significantly low quality. Although a clear association between the information contained in cleft lip and palate videos and the overall quality of TikTok™ videos was not identified, those containing personal opinions consistently demonstrated lower quality, when compared to videos for educational, academic, and commercial purposes. In the study conducted by Meade and Dreyer,[23] which evaluated the reliability and quality of TikTok™ videos concerning orthodontic retention, it was found that the majority of videos were of low content and produced by laypeople, indicating that videos originating from this platform had little useful educational value for the viewer.

In the current study, in YouTube™ videos, quality was significantly associated with the video source and its duration. In contrast to the findings of this study, Hassona et al.[28] analyzed videos on YouTube™ as a source of information regarding oral cancer, and found no significant association between the usefulness of the video, the viewing rate, viewer interaction, and video duration.

Regarding the platform, the current study corroborates with findings from Kilinç,[18] which also found that videos on TikTok™ displayed lower quality and less reliable information, when compared to videos on YouTube™. Although many videos on TikTok™ are newer than those on YouTube™, they have demonstrated greater audience appeal. Notably, while similar numbers on YouTube™ were expressed in tens, on TikTok™, they reached hundreds of thousands. This can be interpreted as a rapid and widespread dissemination of misinformation to the public, which can be critical for public health.[30,31]

Videos are classified on platforms based on audience and interaction assessments. Videos of medium to long duration, posted outside business hours and during business days, as well as those that use subjective language, associated with less popular events, and including temporal indications, are more likely to attract views, likes, and comments. Furthermore, the incorporation of negative or low-arousal emotions emerges as an effective strategy to arouse general interest in a video on the platform.[32] In this way, useful videos may not be ranked first in the viewing list and, therefore, may not be watched by viewers.[28]

An inherent limitation of this study is the lack of validated tools in the literature, given their innovative nature. This made it impossible to perform a multinomial regression analysis. Furthermore, the number of videos evaluated and the inconclusive results due to lack of content may be a limitation of this study. However, bivariate analyses have already presented important results regarding the provision of information and its quality regarding the topic, raising a warning about reliable search sources. This reinforces the need for control by health professionals, institutions, and organizations that provide assistance and scientific information when promoting quality content, sending useful videos, and guiding patients to reliable sources of information, in addition to all oral and written guidance and information given to patients and guardians.[8] It also confirms the need for more studies on the topic, to standardize analyses to investigate the quality of knowledge on the treatment of cleft lip and palate on different social platforms, as well as the development of guidelines to guide the most necessary and useful information for everyone.

Social media platforms must provide clear, accessible, evidence-based public health information.[33] YouTube™ and TikTok™ offer significant opportunities for disseminating health information, creating new data sources, and enhancing public health literacy.[9] In this context, social media sites are key institutions shaping modern life, making it essential to provide health-promoting policies, programs, and information to optimize public health.[34] Although there is evidence that indicates discordance in patients' and professionals' motives and use of social media in health care,[35] as both social media present in this study continue to grow as platforms for health information, it is essential to prioritize accuracy and reliability to enhance patients' self-care abilities and promote public health.[36] Cleft lip and palate are one of the most prevalent craniofacial anomalies worldwide, affecting about 1 in every 650 live births globally[2] and 1 in every 1924 live births in Brazil,[3] patients must have accurate access to information on social media.

Social media has enormous potential in teaching-learning processes, but one cannot expect immediate social changes.[37] Social media platforms, through the dissemination of content in video format, demonstrate a remarkable ability to improve epidemiological disease surveillance, enable large-scale communication, promote health education, facilitate knowledge translation, and foster collaboration between

health professionals,[38] primarily in low and middle-income countries.[39] The spread of misinformation or inadequately communicated information can contribute to the adoption of harmful health behaviors and trigger adverse health outcomes among consumers, as well as potentially incite hysteria and chaos.[20,39] Organizations that employ social media platforms must prioritize the provision of information that is accurate, of adequate duration, and easy to understand.[40] The active promotion of credible social media sites by government entities, healthcare professionals, and researchers, combined with educational initiatives on the appropriate use of social media, can significantly contribute to mitigating the harmful effects of misinformation.[40,41] On the other hand, as verified in the present study, several elements may be present in the videos of these platforms that tend to harm the implementation of learning experiences, such as: the lack of reliable content, and high-quality videos, among others, including the presence of elements that lead to destruction, such as advertisements and warnings; the lack of a filter system; the search for and organization of information; mechanisms that attest to the veracity of information, such as mandatory literary references; or the lack of tools that have been validated in prior literature.[31]

CONCLUSION

YouTube™ and TikTok™ exhibited predominantly low-quality videos, which might suggest they are not suitable as educational tools to guide patients with cleft lip and palate in their multidisciplinary treatment. Healthcare practitioners, educational institutions, and professional associations must bear the duty of enhancing the quality of the content of YouTube™ and TikTok™ videos regarding the treatment of patients with cleft. The creation and dissemination of high-quality educational content by uploading valuable and, ideally, peer-reviewed videos is crucial to enhance evidence-based public health, while also guiding patients towards trustworthy sources of information.

AUTHORS' CONTRIBUTIONS

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6 ARTIGO 2

Artigo em submetido – Revista Plos One – Julho/2025

Comparative Study Between Virtual Planning and Clinical Outcomes of Nasoalveolar Molding in Patients with Cleft Lip and Palate

Abstract

Introduction: Cleft lip and palate are the most prevalent craniofacial anomalies worldwide, which can be diagnosed via morphological ultrasonography and treated early with techniques such as nasoalveolar molding (NAM), optimizing facial symmetry, using virtual planning methods, including scanning, reverse engineering, and 3D printing. **Aim:** To evaluate the difference between virtual planning and actual outcomes obtained with the NAM protocol appliances. **Methodology**: This retrospective, single-blind parallel group study was conducted at the Orthodontic Center of Universidade Federal de Minas Gerais involving 25 infants with complete transforamen clefts (15 unilateral and 10 bilateral), treated with the modified NAM protocol between 2022 and 2024. Data were collected at three moments points: initial (M1), end of virtual planning (M2), and clinical outcome (M3). Cleft width measurements were used both unilaterally and bilaterally according to the definitions by El-Ghafour (2020) and Tankittwat (2021). tests ANOVA, Kruskal-Wallis, and Tukey were applied, with 5% significance level. **Results**: The NAM treatment reduced the anterior cleft width from 11.21 mm to 8.433 mm and the posterior from 18.23 mm to 14.83 mm in unilateral clefts, while increasing the intercanine width from 28.92 mm to 32.42 mm. In bilateral clefts, it reduced the narrow cleft width from 12.14 mm to 7.99 mm and the intercanine region from 26.02 mm to 24.94 mm. All these results presented were statistically significant ($p<0.05$). **Conclusion**: The study confirms the effectiveness of NAM in improving facial structures in cleft lip and palate, but highlights the need to enhance simulations due to discrepancies between virtual plans and actual results.

Introduction

Cleft lip and palate is the most prevalent craniofacial anomaly worldwide, affecting approximately 1 in every 650 live births globally (PUTRI et al., 2024). This condition presents diverse morphological variations and was first categorized in 1972 by Spina et al., based primarily on the anatomical relationship with the incisive foramen. This classification remains the most widely adopted both clinically and in the literature (BREH et al., 2022).

Currently, the diagnosis of cleft lip and palate is performed in utero through morphological ultrasonography (PARTHOFER et al., 2023). Following diagnosis, children born with this condition require comprehensive multidisciplinary treatment involving multiple specialties (PARTHOFER et al., 2023). This treatment begins at birth with feeding plates and pre-surgical

orthopedics and continues into adulthood, aiming to improve the quality of life for these individuals (BREH et al., 2022).

Among existing pre-surgical techniques, the adjunctive Nasoalveolar Molding (NAM) therapy employs orthopedic techniques to mold the alveolar ridges, which, collectively, also support the remodeling of facial cartilages and soft tissues (DE SOUZA et al., 2023). This technique was first described in the literature in 1993 by Grayson (2023) as a pre-surgical treatment aimed at improving functional and aesthetic outcomes throughout the patient's life.

The NAM technique can be applied to patients with unilateral and bilateral clefts involving the alveolar ridge area. It is estimated that NAM therapy can reduce the cleft's width by approximately 5 millimeters, while also uniting labial segments, increasing the columella angle, and promoting facial symmetry (DE SOUZA et al., 2023; ABBOTT, 2012).

Traditional NAM, introduced in 1993, involves the use of an intraoral acrylic molding plate designed to approximate the larger and smaller alveolar segments of the palate/lip cleft, as well as the premaxilla in bilateral cases (GRAYSON et al., 1993). Approximation is achieved through weekly adjustments of the plate, which also includes intranasal stents—acrylic-coated wires—used to lift and shape the nasal cartilage (GRAYSON et al., 2001).

In contrast, Reverse-Engineered NAM is an innovative approach that leverages scanning and 3D printing technologies to create customized oral aligners digitally designed for greater precision (DE SOUZA et al., 2023). This technique allows for the production of aligners that better fit the patient's specific anatomical needs, improving treatment efficacy and providing a more comfortable fit (DE SOUZA et al., 2023).

Additionally, this approach enables more spaced-out consultations, as the software generates a sequence of 7 plates (1 per week) for consecutive use over a 7-week period (DE SOUZA et al., 2023). After completing the final plate, which corresponds to the planned result, another consultation is scheduled, eliminating the need for weekly adjustments (DE SOUZA et al., 2023).

For the fabrication of Reverse-Engineered NAM aligners, a plaster model is crafted from the infant's impression and then scanned to develop a virtual plan, producing sequential plates to induce specific movements (DE SOUZA et al., 2023).

Several orthodontic studies have already evaluated the accuracy of measurements obtained from digital models compared to physical models (UNNIKRISHNAN et al., 2024). These studies show that digital models are clinically valid, acceptable, and provide a faster acquisition process (UNNIKRISHNAN et al., 2024; SINGH; TRIPATHI; RAI, 2024).

However, one of the challenges identified is the accuracy of virtual model planning used for fabricating sequential plates (CUNHA et al., 2021). Concerns have been raised about the possibility of virtual planning altering the dimensions of original models, which could impact treatment efficacy (MOREIRA et al., 2014). Therefore, it is crucial to validate the accuracy of digital methods and compare them with actual clinical outcomes to ensure treatment effectiveness (MOREIRA et al., 2014).

As there is currently no specific research comparing the accuracy of digital models in newborns affected by cleft lip and palate treated with aligner plates, the objective of this study was to assess the discrepancies between virtual planning and the actual clinical results obtained with NAM protocol plates constructed through reverse engineering. The aim is to achieve greater planning precision and develop more accurate algorithms in plate sequencing.

Materials and Methods

This retrospective, parallel-group study was conducted at the Orthodontics Center of the Federal University of Minas Gerais (UFMG) and approved by the Research Ethics Committee of the UFMG School of Dentistry (CAAE: 65707222.2.00 00.5149) and registered in Registro Brasileiro de Ensaios Clínicos (REBEC: ID RBR-38trvv9). The sample consisted of 25 non-syndromic infants, of which 15 had complete unilateral transforamen clefts and 10 had complete bilateral transforamen clefts. All participants were from a convenience sample, derived from the population undergoing treatment/follow-up by the NAM project from the Faculty of Dentistry, Federal University of Minas Gerais. They were treated with the modified reverse-engineering NAM protocol, conducted between 2022 and 2024.

Inclusion criteria were infants aged 0 to 3 months with complete unilateral or bilateral transforamen clefts requiring therapy with sequential NAM plates. Exclusion criteria included infants with other types of clefts, systemic diseases or syndromes, incomplete documentation, and those who did not adhere to the use of the device.

Eligible infants were assigned to treatment with the UFMG reverse-engineering NAM protocol, consisting of the following steps: initial molding, digitization and planning, 3D printing, installation of nasal elevator and lip tapes, and plate replacement. In the initial molding stage, trays that best fit the baby's arches were selected. In addition to pre-fabricated trays, custom trays of various proportions were made to cover the widest range of size and shape variations.

Intraoral impressions of the maxilla were made with addition silicone, a hypoallergenic material. The patient was positioned on the mother's lap, fully awake, with the face at a higher

level than the rest of the body and facing the dentist. The impression time was 1 minute. The molding material was then introduced into the upper arch with the selected tray to reproduce the entire area of the alveolar ridge and cleft palate. The obtained mold was cast with type III stone plaster.

In the digitization and planning stage, the model was scanned to obtain the digital model (3Shape R700TM Orthodontic Scanner) for virtual case planning. The planning software (OrthoAnalyzerTM - 3Shape) utilized reverse engineering (RE) techniques.

For the creation of sequential models, the larger segment of the maxilla was divided into four parts corresponding to the regions of the deciduous tooth germs (first molar, second molar, canine, and incisors). The smaller segment remained as a single unit. This division allowed for the appropriate contouring of the larger segment, reducing the cleft width.

The smaller segment was expanded to correct the existing atresia. After obtaining this final ideal model, the software generated seven more intermediate models, which presented the necessary changes for the patient's initial alveolar ridge to reach the shape of the final ideal model, with a maximum progressive movement of 0.5 mm at each stage (Ferreira, 2018).

Subsequently, the digital models were printed using rapid prototyping systems (Eden 500 printer for Stratasys – Holtzman, Rehovot, Israel) to later obtain the molding plates. The plates were produced by thermoforming acetate plates based on the obtained models. The nasal elevator was manually added to the first NAM plate, along with horizontal tapes for lip approximation and columella traction. The base of the elevator was placed on the nasal dome and tractioned with a medium 3/16” elastic and hypoallergenic tape to secure the nasal elevator to the baby's forehead. This same tape, with a greater thickness, was used to traction and unite the baby's lip, placing it from the middle of one cheek, passing through the cleft lips to the middle of the other cheek.

To ensure that the virtual guidelines do not allow distortions, the laboratory validates its system with the National Health Surveillance Agency, both the software used for planning and the printer used for prototyping. The printing standard is LCD Stereo Lithography, with resolution: 49.8µm (Z resolution: 10-200µm). The system undergoes periodic reviews and control of the "validated" status according to the Change Control procedure CAP.V.RQ.09 - Change Control (RQ09 CAP5) for any modifications or implementations that may be necessary. The executed test protocols provide documented evidence that the system operates according to the expected results specified in the tests and the system is suitable for its intended use.

Each plate was replaced by the next in the sequence at home by the parents after 7 days of use. The patient returned only after completing the cycle (7 weeks), when the final pre-surgical molding was performed. Parents were instructed to contact the clinic whenever there were any doubts, plate maladaptations, or any complications, and could schedule a session to resolve the issue if necessary.

The evaluated STL models included the initial models sent for planning (M1), the final STL models of the virtual planning (M2), and the final STL model of the clinical outcome (M3), which is the scanned/digitized model from the molding after using the cycle of alveolar ridge movement plates – pre-surgical molding.

The difference between the initial and final measurements of the virtual planning was compared with the difference between the initial and final measurements of the clinically obtained outcome on the ridge and cleft of the infants.

Two previously calibrated evaluators performed all measurements of maxillary arch dimensions (MADs) on the digital models, collected at the beginning (M1), end of virtual planning (M2), and after treatment (real final) (M3). The data were analyzed using the Materialise 3-matic software, with a precision of 0.01 mm.

The examiners participated in training sessions to familiarize themselves with the reference points and specific measurement techniques of the study. During training, the examiners practiced identifying the reference points and performing measurements on the digital models. Each examiner independently performed measurements on a randomly selected set of digital models. The measurements included all specified dimensions (width, length, and height).

The measurement results were compared between the examiners. Discrepancies were discussed and resolved, focusing on identifying and correcting possible sources of error. Based on the discussion, adjustments were made to the measurement techniques. The examiners repeated the measurements on the same models to verify consistency.

For intra-examiner reliability assessment, each examiner repeated the measurements on 20% of the models after a one-week interval. The intraclass correlation coefficient (ICC) was calculated to assess the consistency of measurements performed by the same examiner at different times. For inter-examiner reliability assessment, both examiners measured the same 20% of the models, and the ICC was calculated to assess consistency between the two examiners. To

standardize the results, the mean value and standard deviation were calculated for each criterion, resulting in a value of 0.95, indicating excellent agreement.

The entire calibration process, including measurement results and ICC values, was documented for future reference and to ensure study transparency. The measurements included cleft widths, arch widths, anteroposterior measurements, premaxillary width, alveolar length, and arch depth. The measurements used for unilateral analysis were based on the points and measurements from the study by El-Ghafour (2020), as shown in Tables 1, 2, and Figure 1.

Table 1. Points for Unilateral Analysis

Points	Description
G	Anterior point of the larger segment: The anterior end of the larger segment along the crest of the alveolar boné
L	Anterior point of the smaller segment: The anterior end of the smaller segment along the crest of the alveolar ridge
C	Canine tip of the larger segment: The intersection of the anterolateral groove and the crest of the alveolar ridge of the larger segment
C'	Canine tip of the smaller segment: The intersection of the anterolateral groove and the crest of the alveolar ridge
T	Tuberosity point of the larger segment: The posterior limit of the crest of the alveolar ridge of the larger segment
T'	Tuberosity point of the smaller segment: The posterior limit of the crest of the alveolar ridge of the smaller segment
C	Palatal point of the larger segment: The point at the intersection between the C-C' line and the cleft margin of the larger segment
c'	Palatal point of the smaller segment: The point at the intersection between the C-C' line and the cleft margin of the smaller segment
T	Posterior palatal point of the larger segment: The point at the intersection between the T-T' line and the cleft margin of the larger segment
t'	Posterior palatal point of the smaller segment: The point at the intersection between the T-T' line and the cleft margin of the smaller segment
Y	Y point: Intersection of the perpendicular line from point G to the T-T' line
N	N point: Intersection of the perpendicular line from point L to the T-T' line

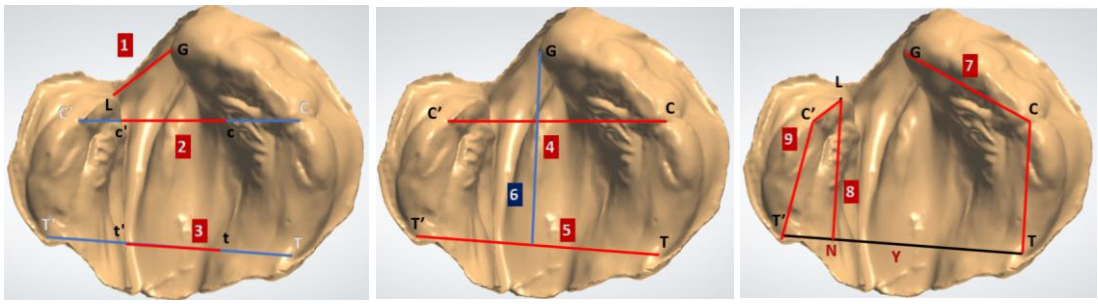
Source: EL-GHAFOUR, 2020, p. 6.

Table 2. Measurements for Unilateral Analysis

Category	Measurements	Description
Cleft widths	1	Anterior cleft width: Distance between points G and L
	2	Canine cleft width: Distance between points c and c'
	3	Posterior cleft width: Distance between points t and t'
Arch widths	4	Intercanine region width: Distance between points C and C'
	5	Posterior arch width: Distance between points T and T'
Anteroposterior measurements	6	Larger segment position: Distance between points G and Y
	7	Larger segment length: Distance between points G and C plus distance between points C and T
	8	Smaller segment position: Distance between points L and N
	9	Smaller segment length: Distance between points L and C' plus distance between points C' and T'

Source: EL-GHAFOUR, 2020, p. 6.

Figure 1 – Reference points and measurements on the maxillary model used in the present study



Elaborated by the author, 2024.

The measures used for the bilateral analysis were based on the points and measures from the study by Tankittiwat (2021) (TABLES 3 and 4 and FIGURE 2).

Table 3 – Points for Bilateral Analysis

Points	Description
I	Incisal point: The point on the alveolar crest where the incisive papilla and labial frenum meet
P	Right premaxillary point: Lateral end of the premaxilla at its widest dimension (right)
P'	Left premaxillary point: Lateral end of the premaxilla at its widest dimension (left)
C	Right cusp point: Intersection of the alveolar ridge crest and the lateral groove (right)
C'	Left cusp point: Intersection of the alveolar ridge crest and the lateral groove (left)
L	Most anterior point of the alveolar crest of the right lateral segment
L'	Most anterior point of the alveolar crest of the left lateral segment
T	Most posterior point of the right maxillary tuberosity
T'	Most posterior point of the left maxillary tuberosity

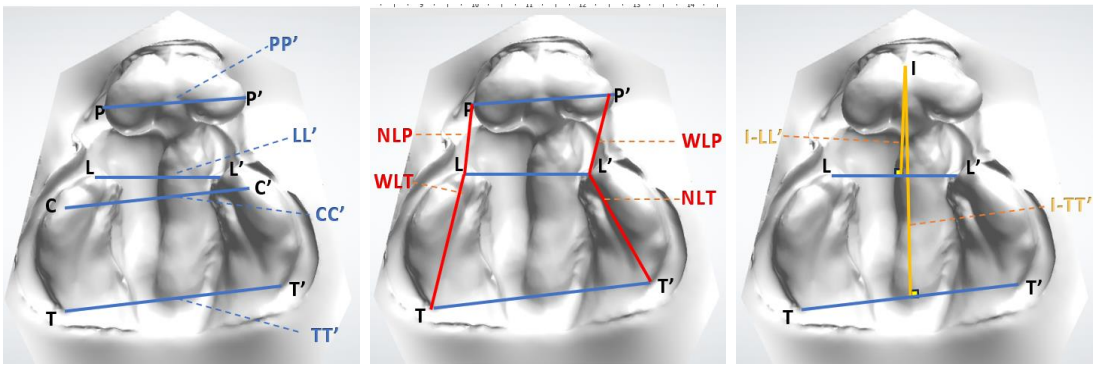
Source: TANKITTIWAT, 2021, p. 3

Table 4 - Linear Measurements for Bilateral Analysis: Width, Length, and Height

Measurement	Description
WPL	Wide cleft width: Distance between the lateral end of the premaxilla and the most anterior point of the lateral segments on the wider side
NPL	Narrow cleft width: Distance between the lateral end of the premaxilla and the most anterior point of the lateral cleft
PP'	Premaxillary width: Distance between the left and right lateral edges of the premaxilla
LL'	Anterior arch width: Distance between the most anterior point of the alveolar crest of the left and right lateral segments
CC'	Intercanine arch width: Distance between the left and right canine points
WLT	Wide alveolar length: Distance from the most anterior point of the lateral segment to the most posterior point of the maxillary tuberosity on the wider side of the cleft
NLT	Narrow alveolar length: Distance from the most anterior point of the lateral segment to the most posterior point of the maxillary tuberosity on the narrower side of the cleft
TT'	Posterior arch width: Distance between the most posterior left and right points on the maxillary tuberosity
I-TT'	Arch depth: Distance between the incisal points perpendicular to the posterior arch width
I-LL'	Premaxillary protrusion: Distance between the incisal points perpendicular to the anterior arch width

Source: TANKITTIWAT, 2021, p. 4

Figure 2 - Reference points and measurements of width and length dimensions in the maxillary models used in the present study.



Elaborated by the author, 2024.

Statistical Analysis

The statistical analysis was conducted using SPSS (Statistical Package for the Social Sciences) version 21.0. Variables were assessed for normality using the Shapiro-Wilk test. The comparison of proportions between the two groups will use the Student's t-test or Mann-Whitney tests to compare differences between groups. All tests were considered statistically significant at a p-value < 0.05.

Results

The results in patients with unilateral cleft lip and palate highlight several statistically significant measures ($p < 0.05$), which are essential for understanding the treatment's efficacy (TABLES 5, 6, 7, and 8).

Table 5. Descriptive statistics from the different experimental groups of patients with unilateral lip and palate cleft (mm).

Measure	1	2	3	4	5	6	7	8	9
					Inicial				
Number of values	15	15	15	15	15	15	15	15	15
Minimum	7.3	8	12.3	22.4	30.7	19.7	17	15.5	19
25% Percentile	9.2	11.5	14.5	27.1	33	22.4	29	18.7	23.1
Median	11.5	12.6	18.3	28.5	34.7	26.9	33.6	20.7	24.7
75% Percentile	11.8	14	21.9	31	37.2	29.2	34.6	23.8	26.6
Maximum	17.7	17.6	25.4	33.8	41.6	31	41.1	25.4	28
Range	10.4	9.6	13.1	11.4	10.9	11.3	24.1	9.9	9
					Final real results				
Number of values	12	12	12	12	12	12	12	12	12
Minimum	3	4.9	7.8	23.3	30.6	21.2	27	15.1	19

25% Percentile	6.05	8.6	12.83	30.75	33.03	24.03	30.43	17.13	21.45
Median	8.45	10.85	15.15	32.4	34.7	26.1	38.1	19.7	28.4
75% Percentile	11.08	12.88	17.55	35.15	38.8	28.48	43.53	22.1	32.94
Maximum	13	13.9	19.5	37.6	45.1	34.3	51.8	23.1	40.6
Range	10	9	11.7	14.3	14.5	13.1	24.8	8	21.6

	Final virtual results								
Number of values	15	15	15	15	15	15	15	15	15
Minimum	7.2	7	11.3	23.8	29.3	19.6	16.2	16.8	19.7
25% Percentile	8.8	9.2	15.1	25.5	32.1	22.9	28.8	18.8	22.4
Median	10.5	12.2	18	28.6	36	25.1	33.1	20	24.6
75% Percentile	11.7	14.2	21.3	30.2	37.3	29.5	36.8	23.8	26.8
Maximum	18	16.5	25.7	34.6	40.3	31.7	39.6	33.3	32.2
Range	10.8	9.5	14.4	10.8	11	12.1	23.4	16.5	12.5

Table 6. Comparisons between initial and real final results and initial and final virtual results after the use of NAM in patients with unilateral lip and palate cleft (mm).

	Measure		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Groups	**Inicial**	Mean	11.21	12.63	18.23	28.92	35.11	26.1	32.18	21.15	24.59
		Std. Deviation	2.705	2.339	4.191	3.017	3.087	3.48	5.841	2.921	2.344
		Std. Error of Mean	0.6983	0.6038	1.082	0.779	0.797	0.8986	1.508	0.7543	0.6053
	Final real	Mean	8.433	10.58	14.83	32.42	35.91	26.21	37.48	19.5	28.05
		Std. Deviation	3.122	2.761	3.408	3.709	4.077	3.609	7.807	2.67	6.895
		Std. Error of Mean	0.9012	0.7972	0.9839	1.071	1.177	1.042	2.254	0.7708	1.99
	Final virtual	Mean	10.81	12	18.15	28.34	34.91	25.69	31.65	21.94	24.84
		Std. Deviation	2.951	2.692	4.042	3.096	3.171	3.794	6.66	4.397	3.261
		Std. Error of Mean	0.7619	0.695	1.044	0.7993	0.8186	0.9797	1.72	1.135	0.842
Comparison	**Inicial x Final real**	*P* value	**<0.0001 ******	0.1177	**0.0368 ***	**0.0180 ***	0.4449	0.8975	0.0652	0.0616	**<0.0001 ******
	Inicial x Final virtual	*P* value	0.2464	0.0613	0.8306	0.1684	0.7415	0.5247	0.5538	0.3996	0.6952
	Final real x Final virtual	*P* value	0.0537	0.1887	**0.0317 ***	**0.0046 ****	0.4818	0.7195	**0.0465 ****	0.1043	0.1227

* Student T test

Table 7. Descriptive statistics from the different experimental groups of patients with bilateral lipa and palate cleft.

Measure	WPL	NPL	PP	LL	CC	WLT	NLT	TT	I-TT	I-LL
					Inicial					
Number of values	10	10	10	10	10	10	10	10	10	10
Minimum	8.7	3.2	16.3	14.3	21.8	15.5	13.7	28	29	14.3
25% Percentile	10	8.7	17.68	16.65	23.23	17.98	17.78	29.93	33.98	15.38
Median	12.75	11.75	19.75	19.15	24.45	19.65	20.65	32.05	39.05	18.45
75% Percentile	14.43	16.4	20.93	20.83	28.8	22.3	22.38	36.5	41.93	23.23
Maximum	20.8	18.8	24.1	22.7	34.5	28.5	26.9	43.2	42.8	24.8
Range	12.1	15.6	7.8	8.4	12.7	13	13.2	15.2	13.8	10.5
					Final real					
Number of values	10	10	10	10	10	10	10	10	10	10
Minimum	7.3	0	16	12.4	20.6	11.7	11.5	20	24.9	9.6
25% Percentile	8.525	4.225	17.05	14.2	22.05	15.88	14.45	28.05	26.45	15.45
Median	11.55	8.65	21.2	15.7	23.7	17.35	16.15	29.85	28.95	17.3
75% Percentile	13.93	12.78	22.23	18.43	26.65	21.28	22.55	36.95	32.55	18.25
Maximum	15.6	14	25.4	20.9	33.3	22.4	24.9	45.6	38.5	18.4
Range	8.3	14	9.4	8.5	12.7	10.7	13.4	25.6	13.6	8.8
					Final virtual					
Number of values	10	10	10	10	10	10	10	10	10	10
Minimum	6.4	2.8	16.3	13.2	21.8	14.2	13.5	26.9	25.1	12.3
25% Percentile	7.725	3.1	17.45	14.23	23.53	18	14.73	28.98	27.78	13.28
Median	9.3	8.35	19.6	18.95	24.25	18.85	19.8	30.55	32	14.8
75% Percentile	10.98	10.1	20.83	20.23	27.2	21.48	22.5	36.23	33.6	16.93
Maximum	13.3	12.9	24.3	21.8	32.9	25.5	26	43.7	36	18.5
Range	6.9	10.1	8	8.6	11.1	11.3	12.5	16.8	10.9	6.2

Table 8. Comparisons between initial and real final results and initial and final virtual results after the use of NAM in patients with bilateral lip and palate cleft.

	Measure		WPL	NPL	PP	LL	CC	WLT	NLT	TT	I-TT	I-LL
Groups	**Inicial**	Mean	13.04	12.14	19.57	18.69	26.02	20.45	20.31	33.6	37.52	19.19
		Std. Deviation	3.458	4.869	2.348	2.633	4.235	3.645	3.553	5.082	4.946	3.692
		Std. Error of Mean	1.094	1.54	0.7425	0.8326	1.339	1.153	1.123	1.607	1.564	1.168
	Final real	Mean	11.37	7.99	20.49	16.2	24.94	18.12	17.77	32.25	29.8	16.39
		Std. Deviation	2.908	4.704	3.112	2.881	4.316	3.388	4.611	7.957	4.196	2.738
		Std. Error of Mean	0.9197	1.488	0.9841	0.911	1.365	1.071	1.458	2.516	1.327	0.8658
	Final virtual	Mean	9.54	7.71	19.47	17.89	25.62	19.38	19.28	32.7	30.91	15.09
		Std. Deviation	2.24	3.621	2.37	3.015	3.571	3.028	4.167	5.673	3.503	2.077

		Std. Error of Mean	0.7084	1.145	0.7495	0.9535	1.129	0.9574	1.318	1.794	1.108	0.6567
Comparison	**Inicial x Final real**	*P* value	0.1208	**0.0367** *	0.1994	**0.0065** **	**0.0291** *	**0.0142** *	**0.0154** *	0.3188	**0.0012** **	**0.0420** *
	Inicial x Final virtual	*P* value	**0.0293** *	**0.0007** ***	0.1582	0.3108	0.2849	0.2518	0.3373	0.1555	**<0.0001** ****	**0.0011** **
	Final real x Final virtual	*P* value	0.1323	0.8831	0.4204	0.2163	0.7056	0.3921	0.4523	0.8858	0.5289	0.2471

* Student T test

In patients with unilateral clefts, the real treatment showed a reduction in the anterior cleft width from 11.21 mm to 8.433 mm ($p < 0.0001$) and in the posterior cleft width from 18.23 mm to 14.83 mm ($p = 0.0368$). The intercanine region width increased from 28.92 mm to 32.42 mm ($p = 0.0180$). The length of the larger segment increased from 32.18 mm to 37.48 mm ($p = 0.0465$), and the length of the smaller segment increased from 24.59 mm to 28.05 mm ($p < 0.0001$).

Comparison between final real and virtual values in unilateral cases showed significant differences in the intercanine region width ($p = 0.0046$) and the length of the larger segment ($p = 0.0465$).

In patients with bilateral clefts, the real treatment resulted in a reduction of the narrow cleft width (NPL) from 12.14 mm to 7.99 mm ($p = 0.0367$). The intercanine region width (CC) decreased from 26.02 mm to 24.94 mm ($p = 0.0291$), and the length of the wide segment (WLT) reduced from 20.45 mm to 18.12 mm ($p = 0.0142$).For virtual planning in bilateral cases, the narrow cleft width (NPL) showed a significant difference between the initial and final virtual values ($p = 0.0007$).

Discussion

The findings of this study offer an analysis of the effectiveness of nasoalveolar molding (NAM) using reverse engineering techniques in patients with unilateral and bilateral cleft lip and palate. The comparison between clinical outcomes and virtual planning reveals valuable insights into the accuracy and efficacy of these approaches.

In the study, several measurements showed significant discrepancies between clinical results and virtual planning. Measure 4, which assessed intercanine width, showed a clinically significant increase, but virtual planning did not adequately predict this change. Similarly,

Measure 7, referring to the length of the larger segment, presented a clinically significant increase that differed from what was virtually predicted. In bilateral patients, NPL stood out for a notable difference between virtual and real results.

Furthermore, some significant changes were not captured by virtual planning. Clinically, Measure 1, which analyzed the width of the anterior cleft, showed a significant reduction, and Measure 9, referring to the length of the smaller segment, showed a significant increase. On the other hand, Measure 3, which evaluated the width of the posterior cleft, showed a clinically significant decrease. However, virtual planning underestimated this these changes.

In contrast, the CC' measure, which analyzed intercanine width in bilateral patients, was accurately reflected in virtual planning, as well as the WLT and NLT measures, which evaluated segment lengths in bilateral patients, were adequately captured by virtual planning.

The significant reduction in the anterior and posterior cleft width after actual treatment is consistent with previous studies that highlight the effectiveness of NAM in decreasing cleft width. Grayson et al. (1993), Grayson et al. (2001) and Tankittiwat (2021) reported substantial improvements in facial symmetry and premaxilla position with the use of NAM.

However, the discrepancy between the actual final values and those predicted virtually suggests that virtual planning may underestimate the reduction observed clinically. Studies such as De Souza et al. (2023) and Abbott e Meara (2012) also point to the need for continuous improvements in virtual planning algorithms to better predict actual outcomes.

In unilateral results, the measure that assesses the width of the intercanine region showed a significant increase after actual treatment, with a notable difference between the actual and virtual final values. This finding suggests that virtual planning may not adequately predict the expansion observed clinically. Previous studies, such as those by Aslan et al. (2018), El-Ghafour (2020) and De Souza et al. (2023) have also reported similar discrepancies, the need for adjustments in virtual models to better capture clinical changes.

The lengths of the major and minor segments showed significant increases after actual treatment, with considerable differences between the actual and virtual final values. These findings align with studies that emphasize the importance of NAM in promoting vertical growth of alveolar structures (El-Ghafour (2020); Tankittiwat (2021); Breh, 2022; De Souza et al., 2023). However, an underestimation by virtual planning of the clinically observed growth was noted.

In bilateral results, measures evaluating cleft width showed significant reductions after the actual treatment, with virtual planning partially capturing these reductions. Previous studies,

such as those by Grayson et al. (1993), Grayson et al. (2001), and Tankittiwat (2021), have also reported significant improvements in cleft width with the use of NAM.

The measure assessing the width of the intercanine region showed a significant reduction after actual treatment, with virtual planning adequately capturing this change. This finding suggests that, for some measures, virtual planning can be accurate, but improvements are still needed to capture all nuances of clinical changes, as concluded by studies such as De Souza et al. (2023) and Aslan et al. (2018).

The segment lengths showed significant reductions after the actual treatment, with virtual planning adequately capturing these changes. These findings are aligned with studies that highlight the effectiveness of NAM in modifying and redirecting the growth of alveolar ridges (Breh, 2022; De Souza et al., 2023).

The findings of this study align with existing literature emphasizing the efficacy of NAM in modifying nasolabial and alveolar structures in patients with cleft lip and palate (GRAYSON et al., 1993; GRAYSON et al., 2001; EL-GHAFOUR, 2020; TANKITTIWAT, 2021; BREH et al., 2022; DE SOUZA et al., 2023).

Despite the observed discrepancy between virtual and clinical outcomes, this study provided a real growth pattern through the redirection of NAM plates, which can already be used to update the growth algorithm based on average values, particularly for unilateral patients.

According to Singh, Tripathi, and Rai (2024), advancements in computational algorithms may enable the integration of intraoral scan data with information from other medical imaging modalities, such as computed tomography, magnetic resonance imaging, or ultrasound, to support the virtual planning of NAM therapy, taking into account other tissues such as skeletal structures.

Future studies should focus on developing virtual planning methods based on the growth patterns of normotypical infants and validating these methods in larger and more diverse samples.

The integration of advanced digital technologies with traditional clinical practices may provide a promising pathway for the treatment of cleft lip and palate, improving the quality of life for patients affected by this condition.

Conclusion

This study confirms the efficacy of reverse-engineered nasoalveolar molding (NAM) in the treatment of cleft lip and palate, demonstrating significant improvements in patients' facial structures. However, discrepancies between the outcomes predicted by virtual planning and the

actual clinical results highlight areas where algorithm improvements are needed to ensure more accurate predictions, thereby optimizing therapeutic planning.

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7 ARTIGO 3:

Artigo em submetido – Revista The Journal of Craniofacial Surgery– Julho/2025

Randomized Clinical Trial: Comparative Analysis of the Aesthetic Outcome of Cheiloplasty Using Millard and Fisher Techniques in the Treatment of Unilateral Cleft Lip and Palate

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Abstract

Background: Cleft lip and palate are among the most common congenital craniofacial malformations, affecting approximately 0.5 to 1.6 per 1000 live births globally. Beyond compromising facial aesthetics, these conditions significantly impact feeding, speech development, and psychosocial well-being. Surgical correction, known as cheiloplasty, is a critical intervention aimed at restoring both function and aesthetic appearance. Among the widely adopted techniques, the Millard ("rotation-advancement") and Fisher (triangular incision) methods offer distinct advantages and complexities, making the choice of technique pivotal for optimal patient outcomes. **Methods**: This retrospective cross-sectional comparative study was conducted at a specialized craniofacial surgery center, evaluating the aesthetic results of cheiloplasty in 40 non-syndromic infants (3 to 6 months old at the time of surgery) diagnosed with unilateral cleft lip and palate. The infants were equally divided into two groups (n=20 each): one treated with the Millard technique and the other with the Fisher technique. All surgeries were performed by a single experienced surgeon between 2022 and 2024, following a standardized protocol. Pre-operative (T0) and 6-month post-operative (T1) photographs were qualitatively assessed by two calibrated dental surgeons. The evaluation utilized a modified classification scale (Mortier and Anastassov) to compare anatomical elements of the nasolabial triangle, specifically the red lip, white lip, scars, and nose. Statistical analysis of the aesthetic outcomes was performed using the chi-square test. **Results**: The chi-square test revealed a statistically significant association ($p = 0.0342$) in the aesthetic evaluation of the nasal region between the Millard and Fisher groups, demonstrating the Fisher technique's superiority in nasal aesthetics. Conversely, for other anatomical elements—the red lip, white lip, and scars—no statistically significant difference was found between the two techniques ($p > 0.05$).

This suggests comparable outcomes for these specific components regardless of the surgical method. **Conclusion:** This study confirms that while both the Millard and Fisher techniques yield comparable aesthetic results for most facial elements (red lip, white lip, and scars) in unilateral cheiloplasty, the Fisher technique offers a significant advantage in achieving superior nasal aesthetics. These findings underscore that the selection of the surgical technique should be highly individualized, prioritizing nasal refinement where desired and aligning with the surgeon's expertise, thereby contributing to the continuous improvement and personalization of clinical practice in cleft lip repair.

Keywords: cleft lip surgery, cheiloplasty, Millard, Fisher

Introduction

Cleft lip and palate are among the most common congenital malformations, affecting approximately 0.5 to 1.6 per 1000 live births worldwide (Kemenkes RI, 2019). These malformations result from a failure in the fusion of facial processes during embryonic development, leading to an opening in the upper lip and/or palate, which can vary in severity and appearance (Worley ML, Patel KG, Kilpatrick LA, 2018). Cleft lip and palate not only compromise facial aesthetics but also affect functionality, including difficulties in feeding, speech, and psychosocial development (Vlahovic AM, Haxhija EQ, 2017).

Surgical correction of cleft lip and palate is a critical intervention aimed at restoring both function and aesthetic appearance. Millard advised postponing lip repair until at least 3 months of age and preferred to wait until 4 or 5 months when possible. At 3 months, the baby generally has adequate size and weight for anesthesia, the precision of the repair can be increased, and it allows time for parental acceptance of the cleft (BRICHACEK, 2021; MILLARD, 1976; KAPP-SIMON, 2004).

Roberts et al. (2020) showed, in their study, an updated view of practices and preferences in unilateral cleft lip surgery, highlighting the predominance of techniques with modifications and the role of adjuvant procedures (such as nasoalveolar molding (NAM) and rhinoplasty) in case management. However, challenges in adhering to these guidelines are notable in certain contexts.

Michael et al. (2023), in a retrospective study in Ibadan, Nigeria, observed that the median age for lip repair was 11 months, with a significant prevalence of late primary surgeries (after 12 months), especially for unilateral cleft lips (Hazard Ratio (HR) = 22.4; p = 0.005). This delay may be associated with a reduced perception of deformity severity or difficulties in accessing care, even when interventions are free.

Two of the widely used surgical techniques are the Millard and Fisher techniques. The Millard technique, also known as the "rotation-advancement technique," is widely recognized for its simplicity and effectiveness in restoring lip continuity (Swanson JW, 2021). On the other hand, the Fisher technique, which uses a triangular incision, is known for providing better aesthetic results in terms of nasal symmetry and scar quality (Swan MC, Fisher DM, 2021).

The choice of surgical technique can significantly influence aesthetic and functional outcomes, impacting patients' quality of life. Even with better aesthetic results (Swanson JW, 2021), the Fisher technique, compared to the Millard technique, is more complex and requires a greater number of operational markers, which can increase surgical time and the learning curve for surgeons (Swan MC, Fisher DM, 2021).

Comparing the results of different methods is complicated due to differences in patient age at the time of surgery, cleft measurements, and evaluation time (Zleckas et al., 2011), in addition to the technical bias of each surgeon.

Fujimoto et al. (2020) identified that Millard, with less tissue removal, remains globally popular due to this advantage. ElMaghraby et al. (2021) and Zaki et al. (2025) reinforced the aesthetic superiority of the scar with Fisher compared to Millard, despite greater tissue sacrifice for complex unilateral cleft lip cases. Suchyta et al. (2020) observed that the Fisher technique offers better aesthetic results for lay observers, without affecting nasal symmetry.

The continuous evolution of surgical approaches is further highlighted by Colin White et al. (2022), who described a unilateral lip revision technique that converts previous repairs performed by the Millard method to repairs based on Fisher's anatomical subunit technique. This approach aims to improve both aesthetic and functional outcomes, including simultaneous nasal correction, demonstrating the ongoing pursuit of enhanced results even in secondary cases.

This research aims to evaluate the facial aesthetic changes in infants with unilateral cleft lip and palate treated with the Millard and Fisher techniques by the same operator. The analysis will be based on pre- and post-operative photographs, with the objective of providing data that can assist in the choice of the most effective surgical technique.

Methodology

This retrospective cross-sectional comparative study is being conducted at a specialized craniofacial surgery center, Hospital da Baleia in Belo Horizonte, and has been approved by the Ethics Committee of the Faculty of Dentistry at UFMG (CAAE: 65707222.2.00 00.5149) and the Ethics Committee of Hospital da Baleia (CAAE: 65707222.2.3001.5123). All patient guardians were duly informed about the objectives and methods of the experiment and signed the Informed Consent Form.

The study sample, defined by convenience, consists of 40 infants diagnosed with non-syndromic unilateral cleft lip and palate, aged between 3 and 6 months at the time of surgery. Syndromic patients and those who underwent secondary surgical correction of the lip and/or nose were excluded. The infants were divided into two groups (n=20): group 1, comprising infants operated on using the Millard technique, and group 2, using the Fisher technique.

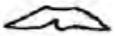
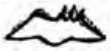
The surgeries were performed between 2022 and 2024 by an experienced surgeon at the same center, following a standardized pre- and post-operative treatment protocol.

Photographs were taken by the same researcher using a high-resolution digital camera, capturing a frontal view focusing on the mouth and nose region (nasolabial triangle) at two time points: T0—taken immediately before the surgery to document the patients' initial condition, and T1—taken 6 months after surgery to assess post-healing results.

The comparison of post-operative aesthetic outcomes was conducted based on qualitative evaluations between the cleft and normal sides, using the modified classification scale proposed by Mortier and Anastassov. This scale assigns points to anatomical elements of the nasolabial triangle (red lip, white lip, scars, and nose). The scale assigns points to each element, reflecting the level of correction of deformities.

The more difficult the correction of the secondary lip or nose deformity, the higher the total score. (Zleckas et al., 2011) (TABLE 1).

Tabel 1. Rating Scale

Anatomical Element	Assessment	Diagram	Points
Red lip (Vermilion)	Bulge		0.5
	Notch		0.5
	Lateral lip too thick		1
	Lateral lip too thin		3
	Defect of the vermilion border		0.5
White lip	Too short		1
	Too long		1
	Cupid's bow and philtrum too narrow or no Cupid's bow at all		4
	Cupid's bow and philtrum too wide		2
Scars	Straight, not on the philtrum border		1
	Straight, depressed		1
	Straight, prominent		1
	Medium quality scar		1
	Poor quality scar		2
Nose	Columella too short		0.5
	Visible subluxation or deviation of the septum		2
	Long sill		0.5
	Narrow sill		0.5
	Columellar base too wide		0.5
	Columellar base too narrow		0.5
	Insufficient wrapping of the ala		0.5
	Exessive wrapping of the ala		0.5
	Deformation of the upper part of the nostril rim		0.5
	Poor position of alar cartilage		1
	High position of the ala		0.5
	Low position of the ala		0.5
	Flat and hypoplastic ala		3

Source: (Zleckas et al., 2011, p.87)

Qualitative aesthetic analyses were conducted by two calibrated dental surgeons. To assess intra-examiner reliability, each examiner repeated measurements on 20% of the samples after a one-week interval. The intraclass correlation coefficient (ICC) was calculated to evaluate the consistency of measurements taken by the same examiner at different times. To standardize the results, the mean value and standard deviation were calculated for each criterion, resulting in a value of 0.95, indicating excellent agreement. For inter-examiner reliability assessment, both examiners measured the same 20% of the samples, and the ICC was calculated to assess consistency between the two examiners., confirming the consistency of individual ratings (0.95).

The Shapiro-Wilk test was used to assess the normality of the data, and the chi-square test was employed to determine the significance of differences between groups. This test was applied to evaluate the association between the surgical technique (Millard vs. Fisher) and the aesthetic assessments of different anatomical

elements (vermilion lip, white lip, scars, and, crucially, the nose), aiming to identify whether there was a statistically significant difference in aesthetic outcomes between the two techniques.

Results

The chi-square test revealed a statistically significant association in the aesthetic evaluation of the nasal region between the groups treated with the Millard and Fisher techniques ($p = 0.0342$) (FIGURE A, B e C). For the other anatomical elements assessed—red lip, white lip, and scars—no statistically significant difference was found between the techniques ($p > 0.05$) (TABLE 2).

Tabel 2. Mean score and standard deviation obtained from the variables of each anatomical element.

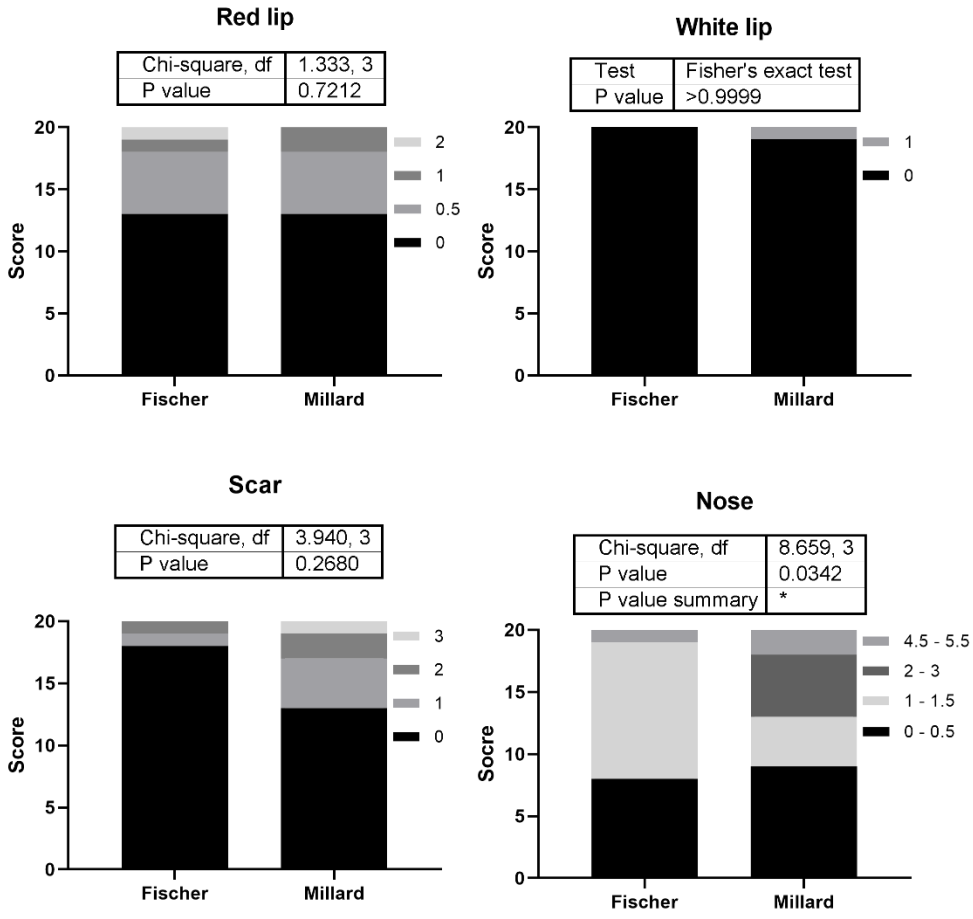
Anatomical Element	Surgical Technique	Score Mean(SD)	Signficance
Red lip	Fischer	0.275 (0.499)	NS
	Millard	0.225 (0.343)	
White lip	Fischer	0.000 (0.000)	NS
	Millard	0.050 (0.223)	
Scars	Fischer	0.150 (0.489)	NS
	Millard	0.550 (0.887)	
Nose	Fischer	1.000 (0.931)	NS
	Millard	1.650 (1.488)	

Kolmogorov-Smirnov; Nor significant (NS), n = 20 participants

Fig. A. Nose appearance after cleft lip repair according to the technique by Fischer

Fig. B. Nose appearance after cleft lip repair according to the technique by Millard

Fig C . Distribution of scores in the evaluation of each anatomical element in association with the surgical technique used (Millard or Fisher).



Chi-square test

Discussion

The results of this study indicate that there was no statistically significant difference between the Millard and Fisher techniques for the red lip, white lip, and scar

components; however, a significant difference was found in the aesthetic evaluation of the nose, favoring the Fisher technique.

ElMaghraby et al. (2021) and Zaki et al. (2025) demonstrated the superiority of the Fisher technique regarding scar quality, with a higher proportion of "good" scars (90% Fisher vs. 65% Millard) but without significant statistical differences in anthropometric measurements, such as lip height and width. In our study, although there was a trend toward better scar scores in the Fisher group, it did not reach statistical significance, corroborating findings that differences may be subtle or dependent on the sensitivity of the scales and the segment analyzed.

Previous studies, such as those by Swanson (2021) and Fujimoto et al. (2020), also report that the Millard technique involves less tissue removal and remains globally recommended for its lower surgical complexity, without evident direct functional impairments to the lip. The findings of this study reinforce the similarity in performance between the two techniques regarding lip components.

The statistically significant finding in this study, concerning the superiority of the Fisher technique for the nose, aligns with more recent literature. ElMaghraby et al. (2021) report better results in alar symmetry and contour with Fisher, a critical finding also detailed by Patel et al. (2019) and Suchyta et al. (2020), who identified Fisher as the preferred technique for nasal symmetry, especially in evaluations by laypersons and specialists.

Patel et al. (2019) describe that, while both techniques are satisfactory, Fisher ensures greater stability in nasal proportions, regardless of cleft severity, whereas Millard tends to exhibit more asymmetries in cases of complete cleft.

These findings are consistent with reports from White et al. (2022), whose Operation Rainbow Canada technique is based on the Fisher anatomical approach for unilateral cleft lip revision, emphasizing aesthetic improvements, particularly in nasal symmetry and scar positioning, further validating Fisher's prominence in nasal refinement.

On the other hand, Michael et al. (2023) focuses more on the epidemiological and temporal aspects of surgery, highlighting factors influencing surgical timing, which is relevant for surgical success but does not directly engage in aesthetic comparisons

between techniques. The methodological heterogeneity in existing studies (number of evaluators, scales used, segment analyzed, and definition of aesthetic success) complicates unequivocal comparisons, as suggested by reviews like Zaki et al. (2025).

This information converges toward a technical consensus: Fisher is the most indicated anatomical approach when nasal refinement and symmetry are priorities, while Millard is a valid and effective alternative, particularly for situations favoring simplicity or tissue preservation.

This study aims to serve as a foundation for future longitudinal research, including comparisons with other patient groups, such as those undergoing nasoalveolar molding (NAM) therapy. Continuous data collection and comparisons with different therapeutic approaches will enable a broader understanding of the best and most individualized methods for cleft lip and palate correction.

Conclusion

This study reveals that, although the Millard and Fisher techniques offer comparable aesthetic results for most facial elements in unilateral cheiloplasty, the Fisher technique demonstrates significant superiority in nasal aesthetics. This suggests that the choice between them should be individualized based on the priority of nasal refinement and the surgeon's expertise, contributing to the continuous improvement of clinical practice.

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8 CONSIDERAÇÕES FINAIS

Esta tese buscou integrar variáveis relacionadas à informação das famílias, qualidade dos conteúdos educacionais em mídias sociais, aplicação de tecnologias 3D no planejamento e tratamento de fissuras labiopalatinas, e a comparação de técnicas cirúrgicas (Millard e Fisher). Essa integração oferece uma abordagem abrangente e inovadora com o envolvimento de profissionais de saúde e organizações na criação de conteúdos precisos para mídias sociais, incentivo a adoção de tecnologias como o planejamento virtual e a impressão 3D, e a escolha entre as técnicas cirúrgicas baseada em uma avaliação cuidadosa das necessidades específicas de cada paciente, considerando os benefícios e desafios de cada abordagem.

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APÊNDICES

APÊNDICE A/ TCLE-Termo de Consentimento Livre e Esclarecido capítulo 2

Termo de Consentimento Livre e Esclarecido (TCLE)- Responsável pelo menor com fissuras lábio palatinas do projeto NAM

ESTUDO: Estudo Comparativo Entre Planejamento Virtual e Resultados Clínicos do Modelador Nasoalveolar em Pacientes com Fissura Labiopalatina

O menor de idade pelo qual o (a) senhor (a) é responsável está sendo convidado (a) a participar da pesquisa “Estudo Comparativo Entre Planejamento Virtual e Resultados Clínicos do Modelador Nasoalveolar em Pacientes com Fissura Labiopalatina”, de forma voluntária. Esta pesquisa consiste em analisar os modelos virtuais gerados antes e após o tratamento com o planejamento virtual, com a finalidade de otimizar o tratamento com as placas alinhadoras.

A participação do menor sob sua responsabilidade no estudo consistirá em seguir as orientações do uso da Placa Palatina NAM e trocá-la semanalmente, colocar as fitas adesivas fixadas nas bochechas, fazer colocação do stent nasal, filmagem e fotografias para avaliação da evolução do tratamento.

Você deverá conceder autorização do uso de informações dos prontuários do menor, autorizar a moldagem das arcadas, a confecção de fotos e vídeos, e autorizar o uso das imagens para fins científicos.

A pesquisa será realizada no Núcleo de Ortodontia da Faculdade de Odontologia da Universidade Federal de Minas Gerais (UFMG). A identidade do menor que você é responsável será total sigilo e será tratada com privacidade. Seu nome ou o material que indique sua participação não será liberado sem sua permissão. O menor sob sua responsabilidade poderá deixar de participar deste estudo a qualquer momento sem nenhum problema ou prejuízo na sua relação com os pesquisadores e a UFMG.

Antes de começar vamos explicar lhe explicar tudo para que fique tranquilo e despreocupado.

A moldagem será realizada com material odontológico hipoalergênico utilizado para moldagem de bebês. O tempo de moldagem ocorre em torno de 10 minutos. Há o risco de um desconforto no bebê ocasionado pelas moldagens para a confecção do NAM. Para minimizar o desconforto serão utilizadas moldeiras próprias para bebês e o procedimento realizado por profissional experimente..

O uso do NAM consiste em placas que serão confeccionadas a partir do escaneamento da moldagem. O uso da placa deverá ser realizado dia inteiro, realizando higienizações, e trocada pela placa seguinte semanalmente. A placa pode gerar desconforto ao menor sob sua responsabilidade. Orientações detalhadas serão fornecidas e qualquer dúvida ou desconforto que o participante estiver, o responsável deverá entrar em contato para receber orientações e atendimento, se necessário. Há o risco de um desconforto no bebê ocasionado pela presença do aparelho. Para minimizar estes acontecimentos a moldagem será sempre realizada pelo professor

orientador da clínica e a adaptação e ajuste do aparelho serão feitos por pessoa capacitada e treinada, utilizando material adequado. Mas, caso o desconforto ocorra, você deverá entrar em contato com algum dos pesquisadores para que este seja avaliado e tratado. Todas as medidas serão tomadas para minimizar as possibilidades de risco, como a padronização dos procedimentos e utilização de um material confiável.

Com esta pesquisa, o menor sob sua responsabilidade terá o benefício de ter um acompanhamento do tratamento objetivando melhora na alimentação, respiração, fonação, reposicionamento dos tecidos moles (lábios, gengiva), diminuição da fenda, reposicionamento do nariz, redução do número de cirurgias e melhora dos resultados estéticos e funcionais.

Em nenhum momento você ou o participante o qual você é responsável terão o nome divulgado, e mesmo com a publicação dos resultados, a sua identidade será preservada. Você não terá qualquer ônus ou ganho financeiro por participar da pesquisa, porém o menor sob sua responsabilidade será beneficiado recebendo o acompanhamento do tratamento. Caso sejam identificados e comprovados danos provenientes desta pesquisa, você tem assegurado o direito à indenização.

O material da pesquisa será arquivado pelo pesquisador responsável pela pesquisa em sua sala na Faculdade de Odontologia da UFMG sendo o período de arquivamento em torno de 5 anos, tempo previsto para o término da pesquisa.. O menor sob sua responsabilidade poderá deixar de participar deste estudo a qualquer momento, sem nenhum constrangimento ou prejuízo na sua relação com os pesquisadores e a UFMG. Em caso de qualquer dúvida deverá e/ou poderá entrar em contato a qualquer hora com os pesquisadores responsáveis Soraia Macari, ou José Dilson Alves de Oliveira Júnior (98) 988155623. Os pesquisadores responsáveis por este projeto podem decidir sobre a exclusão do menor sob sua responsabilidade do estudo por razões científicas, a respeito das quais você deverá ser devidamente informado.

TERMO DE LIVRE CONSENTIMENTO

Declaro que li e entendi as informações fornecidas nesse termo de consentimento. Tive a oportunidade de realizar perguntas e todas minhas dúvidas foram respondidas de forma satisfatória. Permito a utilização dos dados e resultados da pesquisa para divulgação e ensino, respeitando meu direito de não ser identificado. Este termo de consentimento está sendo assinado por mim em duas vias de igual teor e forma. Recebi uma via deste documento e outra via permaneceu com os pesquisadores.

Nome completo do participante sob sua responsabilidade

Local:_____ Data___/___/_____

_____

_____

Nome do responsável Assinatura

Documento apresentado:_____ N°:_____
Pesquisadores: Soraia Macari / Tel.:(31) 97048587/ José Dilson (98) 988155623
E-mail: soraiamacari@gmail.com / doutordilsonjunior@gmail.com

_____ _____
Assinatura do pesquisador responsável Assinatura do pesquisador auxiliar

Endereço: Av. Antônio Carlos, 6627. Faculdade de Odontologia. Campus Pampulha Sala 3204.

Em caso de dúvidas éticas o Comitê de Ética em Pesquisa (COEP – UFMG) coep@prpq.ufmg.br poderá ser contatado. Av. Presidente Antônio Carlos, 6627 – Unidade Administrativa II – 2º andar – Sala 2005 – Telefax: 3409 4592 – Belo Horizonte – MG

APÊNDICE B/ TCLE-Termo de Consentimento Livre e Esclarecido capítulo 3

Termo de Consentimento Livre e Esclarecido (TCLE)- Responsável pelo menor com fissuras lábio palatinas submetido à cirurgia de queiloplastia

ESTUDO: Comparação das Técnicas Cirúrgicas de Millard e Fisher no Tratamento de Fissuras Unilaterais Labiopalatinas: Uma Análise Estética e Proporcional Pré e Pós-Operatória através de Fotografias

O menor de idade pelo qual o (a) senhor (a) é responsável está sendo convidado (a) a participar da pesquisa “Comparação das Técnicas Cirúrgicas de Millard e Fisher no Tratamento de Fissuras Unilaterais Labiopalatinas: Uma Análise Estética e Proporcional Pré e Pós-Operatória através de Fotografias”, de forma voluntária. Esta pesquisa consiste em avaliar, através de fotografias e escaneamentos, a diferença nos resultados estéticos e proporcionais das técnica cirúrgica.

A participação do menor sob sua responsabilidade no estudo consistirá em fotografias e escaneamento facial para avaliação do pré e pós operatório.

Você deverá conceder autorização do uso de informações dos prontuários do menor, autorizar a confecção de fotos e vídeos e autorizar o uso das imagens para fins científicos.

A pesquisa será realizada no Hospital da Baleia. A identidade do menor que você é responsável será total sigilo e será tratada com privacidade. Seu nome ou o material que indique sua participação não será liberado sem sua permissão. O menor sob sua responsabilidade poderá deixar de participar deste estudo a qualquer momento sem nenhum problema ou prejuízo na sua relação com os pesquisadores e a UFMG.

Antes de começar vamos explicar lhe explicar tudo para que fique tranquilo e despreocupado.

As fotografias faciais serão realizadas após a anestesia geral, assim como o escaneamento, feito com o um aplicativo no celular, com duração média de 30 segundos. Após 6 meses serão realizadas novas fotografias a fim de compração.

Com esta pesquisa, o menor sob sua responsabilidade terá o benefício de ter um acompanhamento durante seus primeiros meses de crescimento. Esses ajudaram no tratamento de outros pacientes com fissuras.

Em nenhum momento você ou o participante o qual você é responsável terão o nome divulgado, e mesmo com a publicação dos resultados, a sua identidade será preservada. Você não terá qualquer ônus ou ganho financeiro por participar da pesquisa. Caso sejam identificados e comprovados danos provenientes desta pesquisa, você tem assegurado o direito à indenização.

O material da pesquisa será arquivado pelo pesquisador responsável pela pesquisa em sua sala na Faculdade de Odontologia da UFMG sendo o período de arquivamento em torno de 5 anos, tempo previsto para o término da pesquisa. O menor sob sua responsabilidade poderá deixar de participar deste estudo a qualquer momento, sem nenhum constrangimento ou prejuízo na sua relação com os pesquisadores e a

UFMG. Em caso de qualquer dúvida deverá e/ou poderá entrar em contato a qualquer hora com os pesquisadores responsáveis Soraia Macari, ou José Dilson Alves de Oliveira Júnior (98) 988155623. Os pesquisadores responsáveis por este projeto podem decidir sobre a exclusão do menor sob sua responsabilidade do estudo por razões científicas, a respeito das quais você deverá ser devidamente informado.

TERMO DE LIVRE CONSENTIMENTO

Declaro que li e entendi as informações fornecidas nesse termo de consentimento. Tive a oportunidade de realizar perguntas e todas minhas dúvidas foram respondidas de forma satisfatória. Permito a utilização dos dados e resultados da pesquisa para divulgação e ensino, respeitando meu direito de não ser identificado. Este termo de consentimento está sendo assinado por mim em duas vias de igual teor e forma. Recebi uma via deste documento e outra via permaneceu com os pesquisadores.

Nome completo do participante sob sua responsabilidade

Local:_____ Data___/___/_____

_____
_____
Nome do responsável Assinatura

Documento apresentado: _____
N°:_____

Pesquisadores: Soraia Macari / Tel.:(31) 97048587/ José Dilson (98) 988155623
E-mail: soraiamacari@gmail.com / doutordilsonjunior@gmail.com

_____ _____
Assinatura do pesquisador responsável Assinatura do pesquisador auxiliar

Endereço: Av. Antônio Carlos, 6627. Faculdade de Odontologia. Campus Pampulha Sala 3204.

Em caso de dúvidas éticas o Comitê de Ética em Pesquisa (COEP – UFMG) coep@prpq.ufmg.br poderá ser contatado. Av. Presidente Antônio Carlos, 6627 – Unidade Administrativa II – 2º andar – Sala 2005 – Telefax: 3409 4592 – Belo Horizonte – MG.

ANEXOS

ANEXO A/ Aprovação dos Comitês de Ética e Pesquisa

HOSPITAL DA BALEIA/ FUNDAÇÃO BENJAMIN GUIMARÃES

PARECER CONSUBSTANCIADO DO CEP

Elaborado pela Instituição Coparticipante

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação da proporção maxilo-mandibular e nasal de participantes com fissuras lábio palatinas comparado a participantes normotípicos

Pesquisador: SORAIA MACARI

Área Temática:

Versão: 1

CAAE: 65707222.2.3001.5123

Instituição Proponente: Hospital da Baleia/ Fundação Benjamin Guimarães

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 6.316.920

Apresentação do Projeto:

A pesquisa corresponde a um estudo experimental, longitudinal prospectivo, simples cego, quali e quantitativo, in vivo. Os procedimentos clínicos serão executados na clínica do Projeto de Extensão "NAM Nasoalveolar Modelador", no Hospital da Baleia, centro de referência a pacientes fissurados de Belo Horizonte – MG, e no ambulatório Neonatal do Hospital Risoleta Neves - MG.

Amostra de conveniência de 100 participantes divididos em 5 grupos.

Haverá uso de material biológico.

Objetivo da Pesquisa:

Objetivo geral: Analisar o crescimento maxilo-mandibular e nasal de participantes com fissuras lábio palatinas com e sem tratamento com NAM (moldador nasoalveolar). Analisar as possíveis proteínas envolvidas no processo de remodelação dos maxilares e nasal.

Objetivos específicos:

Endereço: Rua Juramento, 1464
Bairro: Saudade **CEP:** 30.285-000
UF: MG **Município:** BELO HORIZONTE
Telefone: (31)3489-1548 **Fax:** (31)3461-4840 **E-mail:** cep@hospitaldabaleia.org.br

1. Mensurar arcos dentários (maxila e mandíbula) de bebês normotípicos.
2. Comparar entre bebês normais e fissurados com e sem uso do NAM: as dimensões maxilares e mandibulares, proporção maxilo mandibular, quantidade de crescimento no sentido ântero-posterior, transversal e o perímetro da maxila e mandíbula; avaliação do crescimento nasal e da narina.
3. Analisar as proteínas associadas a remodelação maxilar e nasal antes e após uso do NAM.
4. Comparar as proteínas associadas à remodelação óssea maxilar de bebês normotípicos com bebês fissurados com e sem o uso do NAM.

Avaliação dos Riscos e Benefícios:

Riscos:

Procedimento do uso do NAM Engenharia Reversa; risco relacionado ao uso do tape, fita colocada nos lábios para estiramento da musculatura; procedimento para a coleta das amostras de saliva; procedimento de escaneamento facial e vídeos: os autores apresentaram os riscos de todas as etapas e as estratégias para minimizá-los de acordo.

Benefícios da pesquisa: Os resultados da pesquisa poderão gerar conhecimentos e propostas de terapias profiláticas que poderão prevenir futuras mordidas cruzadas anteriores ao longo da infância dos bebês.

Benefício direto aos participantes: acompanhamento do tratamento objetivando melhora na alimentação, respiração, fonação, reposicionamento dos tecidos moles (lábios, gengiva), diminuição da fenda, reposicionamento do nariz, redução do número de cirurgias e melhora dos resultados estéticos e funcionais.

Comentários e Considerações sobre a Pesquisa:

I. O presente estudo apresenta mérito científico, exequibilidade e justifica-se devido à necessidade de compreensão das dimensões maxilares e nasais de indivíduos fissurados, definindo parâmetros naturais de crescimento, a serem sequenciados nos aparelhos NAM, otimizando o tratamento e obtendo melhores resultados.

Entretanto, adequações devem ser feitas para a aprovação da emenda.

Considerações sobre os Termos de apresentação obrigatória:
Os 3 TCLE´s apresentados estão de acordo.

Não foi apresentado:
1- Termo de Anuência da Instituição Hospital da Baleia

Conclusões ou Pendências e Lista de Inadequações:
Pendências:
1- Termos de anuência: Hospital da Baleia (instituição)

Adequações:
1- Melhor estratificação dos critérios de inclusão.
2- Rever datas do cronograma a partir da liberação deste parecer.
3- Rever orçamento: análise estatística (não haverá custo?).
4- Adequar o TALE: erros de português e informações repetidas.

Considerações Finais a critério do CEP:
Sugerido dividir os critérios de inclusão de acordo com os 5 grupos que serão avaliados. Por exemplo: serão incluídos no grupo 1 recém-nascidos até 3 meses, de ambos os sexos, escolhidos aleatoriamente .....no grupo 2..... e assim por diante.

Diante do exposto, o Comitê de Ética em Pesquisa - CEP, de acordo com as atribuições definidas na Resolução CNS 466/2012 e na Norma Operacional nº001/2013 do CNS, manifesta-se por aguardar o atendimento às questões acima para emissão do seu parecer final.
De acordo com a resolução CNS 466/2012 e Norma Operacional nº 001/2013 do CNS, as pendências devem ser respondidas exclusivamente pelo pesquisador responsável no prazo de 30 dias, a partir da data de envio do parecer do CEP. Após esse prazo o protocolo será arquivado.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Outros	Emenda.pdf	23/02/2023 16:03:04	SORAIA MACARI	Aceito
Outros	Anuencia_coordenacao_CENTRARE.pdf	30/11/2022 10:04:25	SORAIA MACARI	Aceito
Outros	Anuencia_coordenacao_Risoleta_Neves.pdf	25/11/2022 15:46:50	SORAIA MACARI	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLEBiorrepositorioUFMG.pdf	22/11/2022 19:12:55	SORAIA MACARI	Aceito
Outros	Anuencia_uso_lab_3204.pdf	22/11/2022 19:10:31	SORAIA MACARI	Aceito
Outros	Anuencia_Nucleo_Ortodontico_assinada.pdf	22/11/2022 19:10:14	SORAIA MACARI	Aceito
Outros	Parecer_consubstanciado_CPGO_assinado.pdf	22/11/2022 19:09:38	SORAIA MACARI	Aceito
Outros	aprovacao_departamento.pdf	22/11/2022 19:08:53	SORAIA MACARI	Aceito
Outros	Uso_Imagens.pdf	22/11/2022 19:08:15	SORAIA MACARI	Aceito
Declaração de Manuseio Material Biológico / Biorepositório / Biobanco	Termo_de_Constituicao_de_Biorrepositorio.pdf	22/11/2022 19:07:37	SORAIA MACARI	Aceito
Outros	TCUD_ASSINADO.pdf	22/11/2022 19:07:11	SORAIA MACARI	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_ANEXO_C_sem_NAM.pdf	22/11/2022 19:06:26	SORAIA MACARI	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_ANEXO_B_normotpipico.pdf	22/11/2022 19:06:08	SORAIA MACARI	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_ANEXO_A.pdf	22/11/2022 19:05:50	SORAIA MACARI	Aceito
Projeto Detalhado / Brochura Investigador	Projeto.pdf	22/11/2022 19:05:35	SORAIA MACARI	Aceito

Situação do Parecer:
Pendente

Necessita Apreciação da CONEP:
Não

BELO HORIZONTE, 21 de Setembro de 2023

Assinado por:
IZABELLA NOBRE QUEIROZ
(Coordenador(a))

Endereço: Rua Juramento, 1464
Bairro: Saudade **CEP:** 30.285-000
UF: MG **Município:** BELO HORIZONTE
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RQU ACO Ver. 05/2019

Risoleta
Hospital Risoleta Tolentino Neves

PARECER DE PROJETO DE PESQUISA

Núcleo de Ensino, Pesquisa e Extensão (NEPE)

Hospital Risoleta Tolentino Neves

Belo Horizonte, 08 de fevereiro de 2023.

Processo Nº17/2022

Título do Projeto: Avaliação da proporção maxilo-mandibular e nasal de participantes com fissuras lábio palatinas comparado a participantes normotípicos.

Equipe de pesquisadores: José Dilson Alves de Oliveira Júnior (doutorando de Odondologia), Profa. Dra. Soraia Macari, Leniana Santos Neves e Prof. Dr. Henrique Pretti (Faculdade de Odontologia/UFMG), Aniella Peixoto Abbas Neves (Hospital Risoleta Tolentino Neves), Mariana Sisto Alessi (Hospital da Baleia)

Instituições envolvidas: Faculdade de Odontologia/UFMG, Hospital da Baleia, Hospital Risoleta Tolentino Neves

Parecer

A Comissão de Avaliação de Projetos de Pesquisa e Extensão (CAPPE/HRTN) posiciona-se favoravelmente à realização do projeto de pesquisa no Hospital Risoleta Tolentino Neves, com as seguintes sugestões e recomendações:

- Considerar inscrição no projeto de pesquisa no ReBEC (The Brazilian Registry of Clinical Trials) ao invés do Clinical Trials. Atualmente o registro de ensaios clínicos nacionais no "Clinicals Trials" tem sido remetido ao ReBEC.
- Encaminhar à CAPPE documento informando os dados sócio-demográficos que são coletados dos pacientes incluídos na pesquisa.
- **A coleta de dados poderá ser iniciada após aprovação do projeto no CEP/UFMG.**

VIGÊNCIA DO PARECER: Este Projeto tem validade de 05 (cinco) anos a partir da data do parecer final. O Relatório final das atividades com as publicações e produções científicas geradas a partir deste estudo deverá ser encaminhado ao NEPE após a conclusão do mesmo.

Rafael Calvão Barbuto
Coordenador do Núcleo de Ensino, Pesquisa e Extensão
HRTN/FUNDEP/UFMG

HRTN / FUNDEP
COLEGIADO DO NEPE

ANEXO B/ Registro Brasileiro de Ensaios Clínicos (ReBEC)