

PONTIFÍCIA UNIVERSIDADE CATÓLICA DE MINAS GERAIS
Programa de Pós-graduação em Odontologia

Carolina Morsani Mordente

**AVALIAÇÃO TRIDIMENSIONAL DO COMPLEXO NASO-MAXILAR-VIAS AÉREAS
SUPERIORES APÓS EXPANSÃO RÁPIDA DA MAXILA EM PACIENTES
PORTADORES DE FISSURA LÁBIOPALATINA:
uma comparação entre diferentes disjuntores**

Belo Horizonte
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Orientador: Prof. Dr. Ildeu Andrade Junior

Coorientador: Prof. Dr. Dauro Douglas Oliveira

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**Aos meus pais e à Bárbara,
pelo amor incondicional e por tornarem possível a
realização deste sonho.**

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RESUMO

Objetivos: O objetivo deste estudo retrospectivo foi comparar, por meio de tomografia computadorizada de feixe cônico (TCFC), as mudanças que ocorreram no complexo naso-maxilar-vias aéreas superiores de pacientes com fissura lábiopalatina unilateral (FLPU) após expansão rápida da maxila (ERM) com quatro diferentes disjuntores. **Material e Métodos:** 40 pacientes com FLPU (idade média, 11.1 ± 2.2 anos), deficiência transversa da maxila e que realizaram ERM foram divididos nos seguintes grupos: (I) Hyrax, (II) Disjuntor em leque Borboleta, (III) iMini Molar e (IV) iMini Pré-molar. TCFC foram obtidas antes (T0) e após 3 meses da ERM (T1). As seguintes variáveis foram avaliadas: largura maxilar anterior e posterior total (LAT e LPT), no lado fissurado (LALF e LPLF) e não fissurado (LALNF e LPLNF), volume da passagem de ar nasal (VPN), orofaringe (VOF) e fissura alveolar (VFA), além da área axial mínima da orofaringe (AOF). **Resultados:** A análise intragrupo revelou um significativo aumento no VPN em I e III, mas na comparação intergrupo, houve apenas diferença estatística entre II e III. Nenhum grupo apresentou mudanças significativas no VOF. A única correlação encontrada entre o aumento da largura maxilar total e volume das vias aéreas foi entre LAT e VOF em II. Nesse grupo também foi encontrado uma expansão significativamente maior na LALNF que na LALF, enquanto nos outros a expansão ocorreu de forma simétrica. Todos apresentaram um aumento significativo no VFA, e nenhuma diferença foi encontrada entre eles. **Conclusões:** Somente os disjuntores Hyrax e iMini Molar aumentaram significativamente o VPN. Nenhum deles foi capaz de modificar significativamente o VOF. Houve uma correlação positiva entre as mudanças na LAT e no VOF. O Borboleta foi o único que mostrou diferença significativa na largura maxilar entre os lados fissurado e não fissurado, apresentando uma maior expansão na LALNF que LALF. O VFA aumentou em todos os grupos, mas nenhuma diferença foi encontrada entre eles.

Palavras-chave: Cavidade nasal. Fissura palatina. Orofaringe. Técnica de expansão palatina. Tomografia computadorizada de feixe cônico.

ABSTRACT

Objectives: The objectives of this retrospective study was to compare, by means of cone beam computed tomography (CBCT), the nasomaxillary complex and upper airway changes that occur in cleft lip and palate (CLP) patients after rapid maxillary expansion (RME) with four different expanders. **Material and Methods:** 40 unilateral CLP patients (mean age, 11.1 ± 2.2 years) with transverse maxillary deficiency that underwent RME were divided into the following groups: (I) Hyrax, (II) Fan-type, (III) iMini Molar and (IV) iMini Premolar. CBCT images were taken prior to RME (T0) and after the removal of the expander (T1). The following variables were analyzed: anterior and posterior maxillary width (AMW and PMW), anterior and posterior maxillary width in the cleft (AWCS and PWCS) and non-cleft sides (AWNCS and PWNCS), nasal passage (NP), oropharyngeal (OP) and alveolar cleft (AC) volume, and OP minimum axial area. **Results:** The intra-group analysis showed a significant increase in the NP volume in groups I and III, but in the inter-group comparison revealed a significant difference only between II and III. None of them showed significant changes in the OP volume. The only correlation between the increase in the maxillary width and upper airway changes was found between the AMW and OP variables in group II. There was a symmetric expansion of both cleft and non-cleft segments in all groups, except for II, that presented a greater increase in the AWNCS than AWCS. All expanders significantly increased the AC volume and no difference was found among them. **Conclusions:** Hyrax and iMini Molar were the only expanders to significantly increase the NP volume. None of them significantly modified the OP airway. There is a positive correlation between the changes in the AMW and OP volume. The Fan-type was the only expander that showed significant difference in the maxillary width between the cleft and non-cleft segments, presenting a greater increase in the last one. The alveolar cleft volume significantly increased in all groups and no significant difference was found among them.

Keywords: Cleft palate. Cone-Beam computed tomography. Nasal cavity. Oropharynx. Palatal expansion technique.

LISTA DE ABREVIATURAS

AC – Alveolar cleft

AMW – Anterior maxillary width

AOF – Área axial mínima da orofaringe

AWCS - Anterior maxillary width in the cleft side

AWNCS - Anterior maxillary width in the non-cleft side

CBCT - Cone beam computed tomography

CLP – Cleft lip and palate

ERM – Expansão rápida da maxila

FEM – Finite element model

FLP – Fissura lábiopalatina

FLPU – Fissura lábiopalatina unilateral

FT - Fan-type

HE – Hyrax

ICC – Intraclass correlation coefficient

iMini Molar – Inverted Mini-Hyrax with bands on first molars

iMini Premolar – Inverted Mini-Hyrax with bands on the first bicuspids

LAT – Largura maxilar anterior total

LALF – Largura maxilar anterior no lado fissurado

LALNF – Largura maxilar anterior no lado não fissurado

LF – Lado fissurado

LNf – Lado não fissurado

LPT – Largura maxilar posterior total

LPLF – Largura maxilar posterior no lado fissurado

LPLNF – Largura maxilar posterior no lado não fissurado

NP – Nasal passage

OP – Oropharynx

OSA – Obstructive sleep apnea syndrome

PMW – Posterior maxillary width

PWCS - Posterior maxillary width in the cleft side

PWNCS - Posterior maxillary width in the non-cleft side

RME – Rapid maxillary expansion

TCFC – Tomografia computadorizada de feixe cônico

TPA – Transpalatal arch

UCLP – unilateral cleft lip and palate

VFA – Volume da fissura alveolar

VOF – Volume da orofaringe

VPD – Velopharyngeal dysfunction

VPN – Volume da passagem de ar nasal

SUMÁRIO

1 INTRODUÇÃO.....	21
2 OBJETIVOS.....	23
2.1 Objetivo geral.....	23
2.2 Objetivos específicos.....	23
3 MATERIAL E MÉTODOS.....	24
3.1 Amostra.....	24
3.2 Grupos.....	24
3.3 Protocolo de cimentação, ativação e contenção.....	27
3.4 Exame tomográfico.....	28
3.5 Método de análise.....	28
3.6 Métodos de medida.....	29
3.6.1 <i>Medidas lineares maxilares</i>	30
3.6.2 <i>Medidas das vias aéreas superiores</i>	31
3.6.3 <i>Medida da fissura alveolar</i>	33
3.7 Análise estatística.....	34
4 ARTIGOS	35
4.1 Artigo 1.....	35
4.2 Artigo 2.....	57
5 CONSIDERAÇÕES FINAIS.....	77
REFERÊNCIAS.....	79
ANEXO.....	82

1 INTRODUÇÃO

A fissura lábio palatina (FLP) é uma má formação congênita e representa uma das anomalias craniofaciais mais comuns (SHAPIRA et al., 1999), afetando um em 700 nascimentos (MOSSEY et al., 2011). Nos casos unilaterais, ela provoca ruptura na integridade dos tecidos do lábio e palato, dividindo a maxila em dois segmentos distintos: um maior, no lado não fissurado (LNF), e um menor, no lado fissurado (LF) (SILVA FILHO; RAMOS; ABDO, 1992). Por esse motivo, cirurgias plásticas reparadoras são realizadas já nos primeiros anos de vida (KOSOWSKI et al., 2012). Tais procedimentos cirúrgicos geram um tecido cicatricial que exerce pressão sobre os segmentos maxilares, podendo levar à aproximação dos mesmos na região anterior do arco (SUBTENLY, 1966). Como consequência, esses pacientes normalmente apresentam deficiência transversa da maxila, sobretudo em sua região anterior (SUBTELNY, 1957; WADA; MIYAZAKI, 1976; TOWNEND, 1980; SILVA FILHO et al., 1998). Devido ao grande impacto da FLP sobre o complexo naso-maxilar, eles também normalmente apresentam-se com dimensões das vias aéreas superiores reduzidas e adenóides aumentadas se comparados com indivíduos normais (IMAMURA et al., 2002). Também são encontrados elevados índices de respiração oral, ronco e hipopnéia durante o sono (ROSE et al., 2002).

Para a correção da atresia maxilar e mordida cruzada em pacientes com FLP, a expansão rápida da maxila (ERM) é frequentemente indicada como parte do tratamento ortodôntico, sendo capaz de promover melhora significativa na dimensão transversa do arco maxilar (CAPELOZZA FILHO; DE ALMEIDA; URSI, 1994). Devido à deformidade óssea, é esperado que o mecanismo de interação entre as forças de expansão e a resistência à expansão nos segmentos fissurado e não fissurado seja diferente (GAUTAM; ZHAO; PATEL, 2011). Estudos clínicos e com elementos finitos demonstram uma expansão assimétrica dos mesmos durante a ERM (SUBTENLY; BRODIE, 1954; ISAACSON; MURPHY, 1964; PAN et al., 2007). No entanto, não existe na literatura um consenso sobre qual dos segmentos é mais lateralmente deslocado. Sabe-se ainda que a ERM tem um importante impacto na geometria e função da cavidade nasal, promovendo o deslocamento lateral de suas paredes e com isso facilitando o fluxo de ar pelas vias aéreas superiores (HERSHEY; STEWARD; WARREN, 1976; HARTGERINK; VIG; ABBOTT, 1987; TRINDADE et al., 2010). No entanto, esse procedimento tem a desvantagem de

aumentar as dimensões do defeito ósseo pré-existente, podendo influenciar no planejamento clínico e prognóstico das cirurgias de enxerto ósseo secundário (LONG; SPLANGER; YOW, 1995). Sendo assim, uma vez que vários tipos de disjuntores são disponíveis para a ERM, aqueles que promovem um menor aumento na fissura alveolar deveriam ser preferidos.

Os efeitos da ERM na maxila e nas vias aéreas superiores têm sido estudados a partir de vários métodos, como radiografias laterais e anteroposteriores, rinometria acústica e tomografia computadorizada multislice (BUCCHERI; DILELLA; STELLA, 2004; HABERSACK et al., 2007; TRINDADE et al., 2010). Avanços recentes em tomografia computadorizada de feixe cônico (TCFC) e softwares relacionados, têm possibilitado a realização do diagnóstico e plano de tratamento de maneira mais acurada em pacientes com FLP, devido à alta qualidade das imagens geradas (YOSHIHARA et al., 2012). Estudos anteriores têm mostrado que a partir da TCFC é possível visualizar cavidades como estruturas sólidas, permitindo medidas volumétricas com mínimo erro (ABOUDARA et al., 2009). Menor custo, tempo de aquisição e dose de radiação têm tornado a TCFC um método cada vez mais utilizado (LUDLOW et al., 2006).

Diversos disjuntores são utilizados para a ERM. Entre eles podemos citar: (1) Hyrax (BIEDERMAN, 1968); (2) Haas (HAAS, 1961); (3) disjuntor “em leque” Borboleta (SILVA FILHO et al., 2002); (4) Mini Hyrax Invertido, com um parafuso menor do que o convencional, que possibilita seu posicionamento em uma região mais anterior (BARTOLOMEO, 2010; FIGUEIREDO, 2011); (5) disjuntor Mini Hyrax Invertido associado a uma barra transpalatina, confeccionado com o intuito de estabilizar o arco na região posterior e direcionar a força ortopédica para a região anterior da maxila (ROMUALDO, 2012). Diante das várias opções citadas acima, evidências científicas acerca dos efeitos de cada disjuntor tornam-se necessárias. Elas são capazes de auxiliar os ortodontistas clínicos na escolha pelo aparelho capaz de trazer maiores benefícios para cada um de seus pacientes.

Sendo assim, este trabalho tem como objetivo comparar as alterações que ocorreram no complexo naso-maxilar-vias aéreas superiores de pacientes com fissura lábiopalatina unilateral (FLPU) após ERM com quatro diferentes disjuntores.

2 OBJETIVOS

2.1 Objetivo geral

Avaliar e comparar, por meio de TCFC, as mudanças que ocorreram no complexo naso-maxilar-vias aéreas superiores de pacientes com fissura FLPU após expansão rápida da maxila (ERM) com quatro diferentes disjuntores.

2.2 Objetivos específicos

Avaliar e comparar as mudanças geradas pelos quatro disjuntores nas seguintes medidas:

- a) largura maxilar anterior e posterior no LF;
- b) largura maxilar anterior e posterior no LNF;
- c) volume da passagem de ar nasal;
- d) volume da orofaringe;
- e) área axial mínima da orofaringe;
- f) volume da fissura alveolar.

3 MATERIAL E MÉTODOS

O protocolo da pesquisa foi aprovado pelo Comitê de Ética em Pesquisa da Pontifícia Universidade Católica de Minas Gerais (CAAE: 08111612.5.0000.5137), Belo Horizonte, Brasil.

Todos os pacientes e responsáveis foram esclarecidos sobre o estudo por meio do Termo de Consentimento Livre e Esclarecido.

3.1 Amostra

A amostra foi proveniente do banco de dados do Departamento de Ortodontia da Pontifícia Universidade Católica de Minas Gerais, Belo Horizonte, Brasil. Ela consistiu de 40 pacientes (23 homens e 17 mulheres) entre 8 e 14 anos (idade média 11.1 ± 2.2 anos) portadores de FLP transforame unilateral. Todos receberam tratamento na Clínica de Ortodontia da instituição.

Os pacientes atenderam aos seguintes critérios de inclusão: (1) presença de FLP transforame unilateral; (2) maior atresia maxilar na região anterior que posterior definida clinicamente, que os levaram a se submeter à ERM; (3) TCFC antes e após 3 meses de contenção da ERM; e (4) idade entre 8 e 14 anos. Os critérios de exclusão foram: (1) presença de síndrome associada; (2) lesões cariosas ativas; (3) doença periodontal ativa; e (4) tratamento ortodôntico prévio à ERM.

3.2 Grupos

A amostra foi dividida em quatro grupos com 10 pacientes, de acordo com o tipo de disjuntor utilizado para a ERM: (I) Hyrax, (II) Borboleta, (III) Mini Hyrax Invertido com bandas nos primeiros molares (iMini Molar) e (IV) Mini Hyrax Invertido com bandas dos primeiros pré-molares associado a uma barra transpalatina (iMini Pré-molar). A distribuição dos grupos pela idade, gênero e lado da fissura encontra-se na Tabela 1.

Tabela 1: Distribuição dos grupos pela idade (anos), gênero e lado da fissura.

Grupos	Idade		Gênero		Lado da Fissura	
	Média	DP	M	F	D	E
Hyrax	11.3	2.4	7	3	4	6
Borboleta	10.5	1,8	6	4	2	8
iMini Molar	10.4	2.4	7	3	3	7
iMini Pré-molar	12.3	2.3	3	7	4	6

DP, Desvio padrão; M, Masculino; F, Feminino; D, Direito; E, Esquerdo.

Fonte: Dados da pesquisa.

O disjuntor Hyrax foi confeccionado com o parafuso da marca Leone (Florença, Itália), posicionado anteroposteriormente na região de molares decíduos ou pré-molares, bandas nos primeiros molares permanentes e extensões de fio 0.9mm apoiadas nas superfícies palatinas dos caninos e molares decíduos ou pré-molares (Figura 1).

Figura 1: Disjuntor Hyrax.

Fonte: Arquivo pessoal.

O disjuntor Borboleta foi confeccionado com o Expansor Ortodôntico em Leque (Morelli, Sorocaba, São Paulo, Brasil) o qual apresenta uma dobradiça posterior. O aparelho também é composto por extensões de fio 0.9mm apoiadas nas superfícies palatinas dos molares decíduos ou pré-molares e partes em acrílico, o que o torna dentomucossuportado (Figura 2).

Figura 2: Disjuntor Borboleta.



Fonte: Arquivo pessoal.

O disjuntor iMini Molar foi confeccionado com o mini parafuso Variety Expander (Dynaflex, Sait Ann, Missouri, EUA) posicionado anteroposteriormente na região de caninos. As extensões provenientes do parafuso contornam a superfície palatina dos dentes posteriores até as bandas nos primeiros molares permanentes (Figura 3).

Figura 3: Disjuntor iMini Molar.



Fonte: Arquivo pessoal.

O disjuntor iMini Pré-molar também foi confeccionado com o mini parafuso importado Variety Expander, da marca Dynaflex, Sait Ann, Missouri, EUA, posicionado anteroposteriormente na região de caninos. As extensões provenientes do parafuso contornam a superfície palatina dos caninos até as bandas nos primeiros pré-molares. Uma barra transpalatina confeccionada com fio 0.9mm

soldada em bandas nos primeiros molares permanentes ainda estava presente (Figura 4).

Figura 4: iMini Pré-molar.



Fonte: Arquivo pessoal.

Todos os disjuntores foram confeccionados pelo mesmo profissional técnico responsável pela confecção dos aparelhos ortodônticos do Mestrado em Ortodontia da Pontifícia Universidade Católica de Minas Gerais.

3.3 Protocolo de cimentação, ativação e contenção

Os disjuntores foram cimentados com o cimento Ultra Band-Lok Blue (Reliance Orthodontics Products, Itasca, Illinois, EUA). As bandas receberam jateamento prévio com óxido de alumínio (partículas de 50 micrômetros) para aumento da retenção. Resina composta (Z 100tm Restorative, 3M ESPE, Dental Products, Saint Paul, Minnesota, EUA) foi colocada unindo as extensões dos disjuntores à superfície palatina dos dentes que não receberam banda.

O protocolo de ativação foi meia volta no parafuso por dia ($\frac{1}{4}$ de volta pela manhã e $\frac{1}{4}$ de volta à noite). A ativação foi realizada até que fosse obtida a sobrecorreção da atresia maxilar, representada pela oclusão da cúspide palatina do primeiro molar permanente superior com a ponta da cúspide vestibular do primeiro molar permanente inferior quando os disjuntores Hyrax e iMini Molar foram utilizados. A sobrecorreção quando os disjuntores Borboleta e iMini Pré-molares foram utilizados, foi obtida quando a cúspide palatina do primeiro pré-molar superior passava a ocluir com a ponta da cúspide vestibular do primeiro pré-molar inferior.

Os pacientes foram avaliados semanalmente. Após a fase de ativação, o disjuntor foi travado com fio de latão 0.7mm e mantido cimentado durante três meses, como contenção, sem que nenhuma intervenção ortodôntica fosse realizada. Com o objetivo de evitar recidiva, a partir deste momento, o aparelho foi substituído por uma barra transpalatina com extensões anteriores de fio 0.9mm, até que a próxima etapa do tratamento ortodôntico fosse iniciada.

3.4 Exame tomográfico

Os pacientes foram submetidos à TCFC antes da disjunção (T0), e após 3 meses de contenção da ERM (T1). Para a realização da segunda TCFC, o disjuntor foi removido, e só depois do exame a barra transpalatina foi instalada. As imagens foram adquiridas no tomógrafo i-CAT (Imaging Sciences International, Hatfield, Pennsylvania, EUA) com FOV (Field of View) de toda a região do crânio, voxel de 0,3 mm e tempo de exposição de 40 segundos.

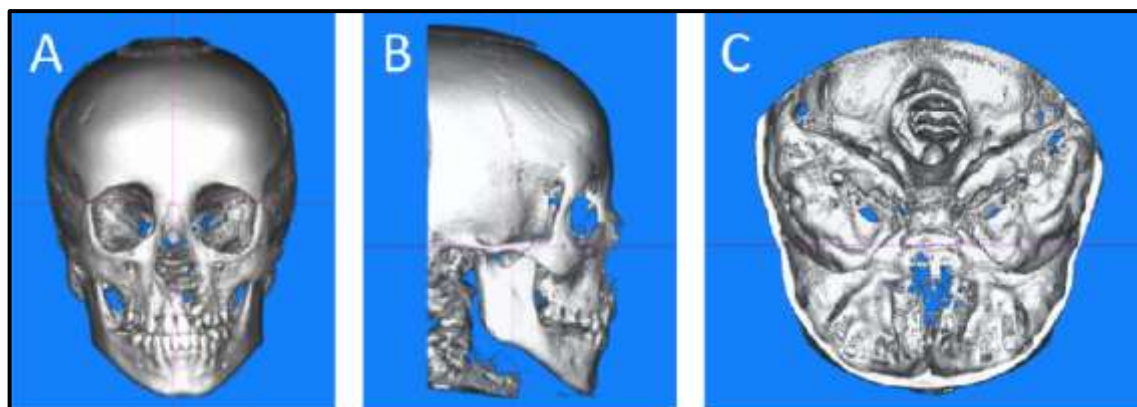
3.5 Método de análise

Todas as imagens tomográficas foram analisadas utilizando os programas Dolphin Imaging (versão 11.5, Dolphin Imaging & Management Solutions, Chatsworth, California) e ITK-SNAP (versão 2.4, Penn Image Computing and Science Laboratory, Philadelphia, PA), no Departamento de Ortodontia da Case Western Reserve University, Cleveland, Ohio.

Antes da realização das medidas no programa Dolphing Imaging, as 80 tomografias foram orientadas nos 3 planos do espaço, para que fossem feitas com o crânio de todos os pacientes em uma mesma posição.

Na vista coronal, as suturas frontozigomáticas esquerda e direita foram alinhadas paralelas ao solo, utilizando o ponto mais medial das mesmas como referência. Sagitalmente, a orientação foi feita posicionando o Plano de Frankfurt paralelo ao solo. Na vista axial, a crista galli e o ponto cefalométrico básion (ponto mais baixo na margem anterior do forame magno) foram alinhados perpendiculares ao solo (Figura 5).

Figura 5: Orientação do crânio nas vistas (A) coronal, (B) sagital e (C) axial.



Fonte: Arquivo pessoal.

3.6 Medidas

As medidas foram realizadas por um único examinador (C.M.) devidamente calibrado, que desconhecia o grupo e o momento da aquisição das tomografias (T0 ou T1). Todas as medidas, os programas e as ferramentas dos programas utilizadas encontram-se listados no Quadro 1.

Quadro 1: Medidas, programas e ferramentas utilizadas.

(continua)

<i>Medidas lineares maxilares</i>	<i>Programa/Ferramenta</i>
Largura maxilar anterior no lado fissurado (LALF)	Dolphing Imaging "Digitize/Measurement"
Largura maxilar anterior no lado não fissurado (LALNF)	Dolphing Imaging "Digitize/Measurement"
Largura maxilar anterior total (LAT)	Dolphing Imaging "Digitize/Measurement"
Largura maxilar posterior no lado fissurado (LPLF)	Dolphing Imaging "Digitize/Measurement"
Largura maxilar posterior no lado não fissurado (LPLNF)	Dolphing Imaging "Digitize/Measurement"
Largura maxilar posterior total (LPT)	Dolphing Imaging "Digitize/Measurement"
<i>Medidas das vias aéreas superiores</i>	<i>Programa/Ferramenta</i>
Volume da passagem de ar nasal (VPN)	Dolphing Imaging "Sinus/airway analysis"
Volume da orofaringe (VOF)	Dolphing Imaging "Sinus/airway analysis"

(conclusão)

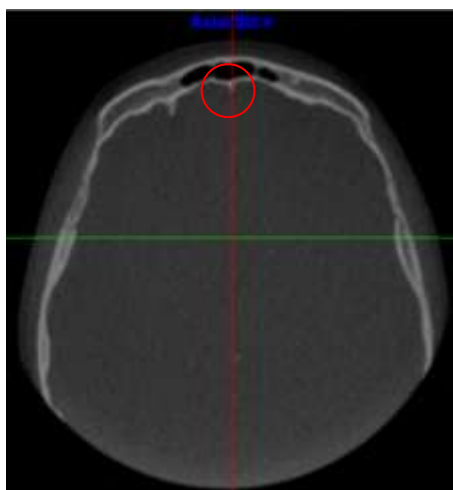
<i>Medidas das vias aéreas superiores</i>	<i>Programa/Ferramenta</i>
Área axial mínima da orofaringe (AOF)	Dolphing Imaging “Sinus/airway analysis”
<i>Medida da fissura alveolar</i>	<i>Programa/Ferramenta</i>
Volume da fissura alveolar (VFA)	ITK-SNAP “Volumes and Statistics”

Fonte: Elaborada pela autora.

3.6.1 Medidas lineares maxilares

Antes da realização das medidas, foi determinada uma linha média craniana, representada pela linha perpendicular ao solo passando pela cripta frontal, na vista axial (Figura 6).

Figura 6: Linha média craniana.



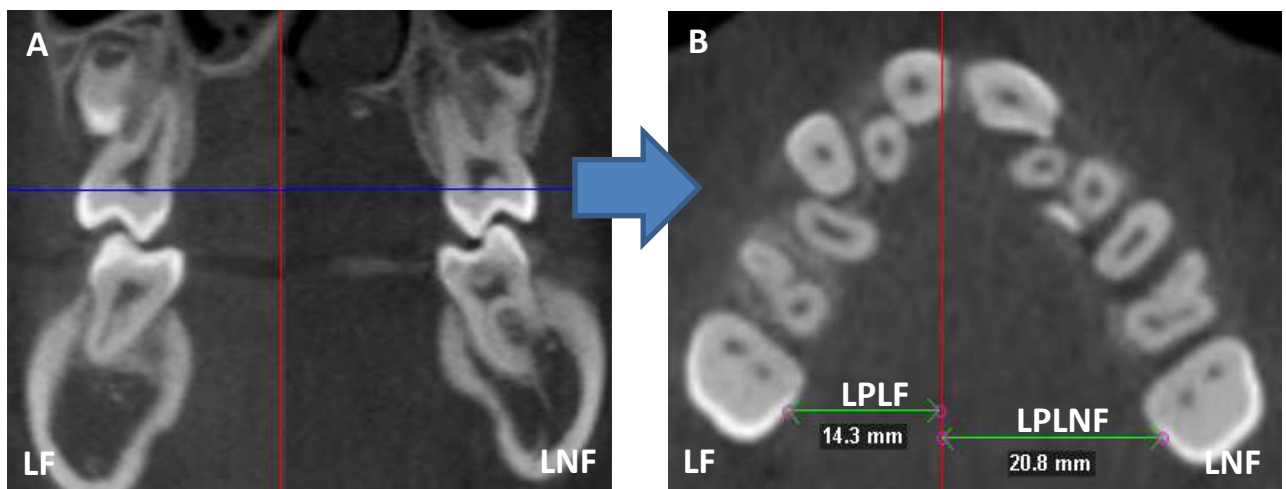
A linha vermelha representa a linha média craniana, que intercepta a cripta frontal (circulada em vermelho).

Fonte: Arquivo pessoal.

- a) **Largura maxilar anterior no lado fissurado (LALF):** o corte coronal que mostrou a maior secção da coroa do dente anterior (primeiro molar decíduo ou primeiro pré-molar) no lado fissurado foi selecionado. Em seguida, o corte axial passando pela junção amelocementária da superfície palatina de cada um foi selecionado. Neste corte, a distância entre o ponto mais medial da face palatina da coroa dentária e a linha média craniana foi mensurada;
- b) **Largura maxilar anterior no lado não fissurado (LALNF):** realizada da mesma forma da LALF, porém no lado não fissurado;

- c) **Largura maxilar anterior total:** soma da LALF e LALNF;
- d) **Largura maxilar posterior no lado fissurado (LPLF):** realizado da mesma forma da LALF, porém na região do primeiro molar permanente (Figura 7);
- e) **Largura maxilar posterior no lado não fissurado (LPLNF):** realizada da mesma forma LPLF, porém no lado não fissurado (Figura 7);
- f) **Largura maxilar posterior total:** soma da LPLF e LPLNF.

Figura 7: Obtenção da largura maxilar posterior no lado fissurado (LPLF) e não fissurado (LPLNF).



A, corte coronal selecionado; a linha azul passa pela junção amelocementária na superfície palatina de cada primeiro molar permanente; B, corte axial determinado pela linha azul, onde a distância entre o ponto mais medial da face palatina da coroa dentária e a linha média craniana foi mensurada.

Fonte: Arquivo pessoal.

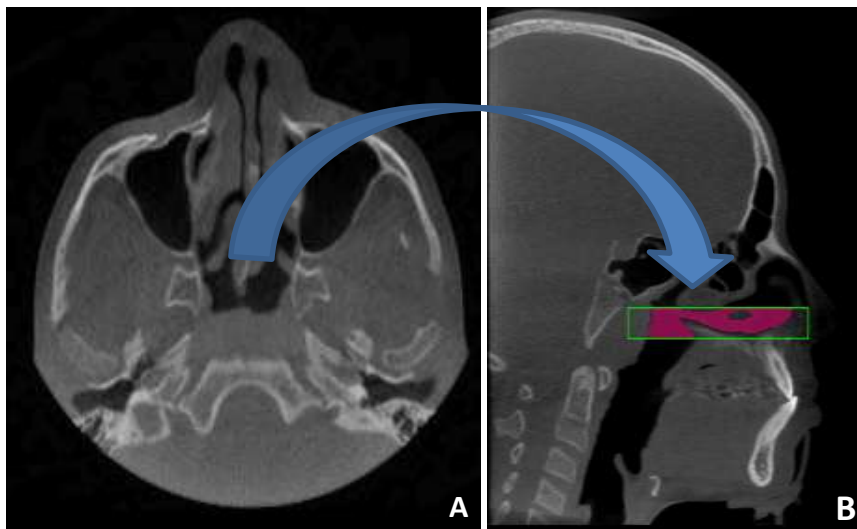
3.6.2 Medidas das vias aéreas superiores

Antes da realização das medidas, foram identificados os limites superior e inferior da passagem de ar nasal (PN) e orofaringe (OF), conforme mostrado no Quadro 2 e Figuras 8 e 9 (EL; PALOMO, 2010). Como a orofaringe trata-se de uma estrutura cilíndrica, também foi calculada através do programa sua área axial mínima (AOF), ou seja, sua área de maior constrição axial (Figura 9).

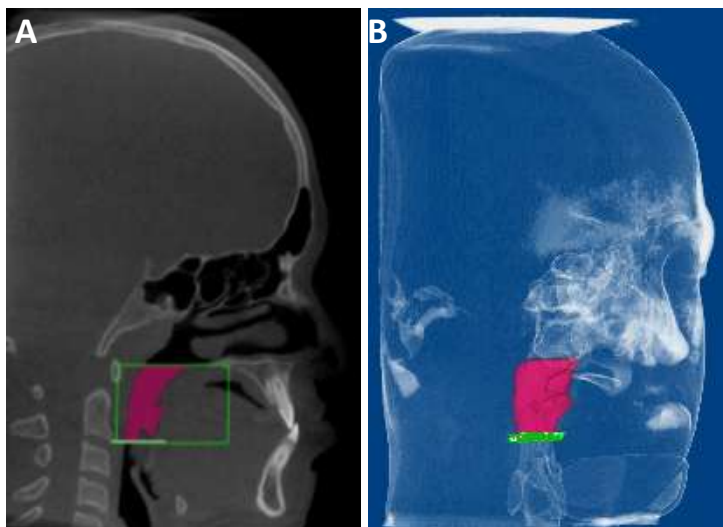
Quadro 2: Limites da passagem de ar nasal e orofaringe.

Estruturas	Limite Superior	Limite Inferior
Passagem de ar nasal (PN)	Corte axial anterior à fusão do septo nasal à parede posterior da faringe.	Plano que passa pelas espinhas nasais anterior e posterior (plano palatino).
Orofaringe (OF)	Plano palatino.	Plano paralelo ao plano palatino, passando pelo ponto mais ântero-inferior da segunda vértebra cervical.

Fonte: Elaborada pela autora.

Figura 8: Limites superior (A e B) e inferior (B) da passagem de ar nasal.

Fonte: Arquivo pessoal.

Figura 9: Limites superior e inferior da orofaringe (A e B).

A linha branca em A e a secção verde em B representam a área axial mínima da orofaringe.

Fonte: Arquivo pessoal.

A colocação de “Seed Points” selecionou todo o volume dentro dos limites estabelecidos para a PN e OF, e o uso da opção “Update Volume” calculou o volume total das estruturas. O uso da opção “Enable Minimum Axial Area” gerou a AOF.

3.6.3 Medida da fissura alveolar

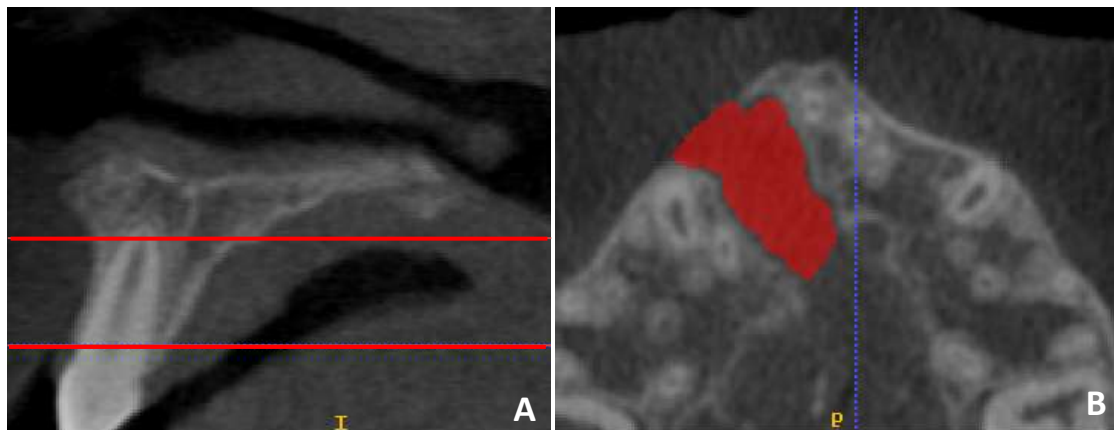
Antes da realização das medidas, foram identificados os limites superior e inferior da fissura alveolar (FA), conforme mostrado no Quadro 3 e Figura 10 (OBEROI et al., 2009).

Quadro 3: Limites da fissura alveolar.

<i>Estrutura</i>	<i>Limite Superior</i>	<i>Limite Inferior</i>
<i>Fissura alveolar (FA)</i>	Plano paralelo ao solo passando pelo ponto A.	Plano paralelo ao solo passando pelo ponto mais inferior do processo alveolar vestibular na região dos incisivos.

Fonte: Elaborada pela autora.

Figura 10: Limites superior, inferior (A) e anteroposterior (B) da fissura alveolar.



Fonte: Arquivo pessoal.

A região da FA foi demarcada e preenchida em cada corte axial dentro de seus limites superior e inferior a partir da opção “Paintbrush Tool” e seu volume foi calculado a partir da opção “Volumes and Statistics”.

3.7 Análise estatística

Todas as medidas foram repetidas pelo mesmo examinador em 20 tomografias escolhidas de forma aleatória após um intervalo de duas semanas. A reprodutibilidade intraexaminador foi testada através do *intraclass correlation coefficient* (ICC). Os resultados variaram de 0.97 a 0.99 para todas as medidas, exceto para VPN, cujo resultado foi de 0.87, indicando uma alta reprodutibilidade das variáveis analisadas nesse estudo.

O teste D'Agostino e Pearson demonstrou que os dados das medidas avaliadas apresentaram distribuição normal. O teste t pareado foi utilizado para avaliar se havia diferença em relação à idade entre os pacientes dos quatro grupos. O teste qui-quadrado foi utilizado para avaliar se havia diferença em relação ao gênero e lado da fissura entre os pacientes dos quatro grupos. Para a avaliação intra-grupos, o teste t pareado foi utilizado, avaliando a existência de diferenças entre T0 e T1 para cada uma das medidas em cada grupo. Para a avaliação inter-grupos, o teste ANOVA um critério seguido pelo teste post hoc de Bonferroni foi utilizado, verificando a existência de diferenças na variação entre T0 e T1 de cada medida entre cada um dos grupos. O teste de correlação de Pearson foi utilizado para avaliar a existência de correlação entre LAT e VPN, VOF, AOF, e entre LPT e VPN, VOF, AOF. O teste t pareado foi utilizado para avaliar a existência de diferenças na variação entre T0 e T1 entre LALF e LALNF, bem como entre LPLF e LPLNF, em cada um dos aparelhos. O nível de significância foi estabelecido em 5% e as análises foram realizadas por meio do software GraphPad Prism 5.01 (San Diego, CA, EUA).

4 ARTIGOS

4.1 Artigo 1

Three-dimensional analysis of the upper airway in cleft lip and palate patients after rapid maxillary expansion with four different expanders

Artigo a ser submetido ao periódico *American Journal of Orthodontics and Dentofacial Orthopedics (Qualis A1)*, cujas normas para submissão de artigos podem ser visualizadas no endereço eletrônico: <http://www.ajodo.org/authorinfo>.

Three-dimensional analysis of the upper airway in cleft lip and palate patients after rapid maxillary expansion with four different expanders

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ABSTRACT

Objectives: To evaluate, by means of cone beam computed tomography (CBCT), the anterior and posterior maxillary width (AMW and PMW), nasal passage (NP) and oropharyngeal (OP) volume changes that occur in unilateral cleft lip and palate (CLP) patients after rapid maxillary expansion (RME) with four different expanders. **Methods:** 40 unilateral CLP patients (mean age, 11.1 ± 2.2 years) with transverse maxillary deficiency that received RME were divided into the following groups: (I) Hyrax, (II) Fan-type, (III) iMini Molar and (IV) iMini Premolar. CBCT images were taken before (T0) and 3 months after RME (T1). **Results:** The intra-group analysis showed a significant increase in the NP volume in groups I and III, but in the inter-group comparison revealed a significant difference only between II and III. None of them showed significant changes in the OP volume. The only correlation between the increase in the maxillary width and upper airway changes was found between the AMW and OP variables in group II. **Conclusions:** Hyrax and iMini Molar were the only expanders to significantly increase the NP volume. None of them significantly modified the OP airway. There is a positive correlation between the changes in the anterior maxillary width and OP volume.

INTRODUCTION

Cleft lip and palate (CLP) is one of the most frequent craniofacial anomalies worldwide and affects approximately one in every 700 live-births.¹ CLP has a significant impact on the nasomaxillary complex and frequently leads to nasal deformities such as septum deviation, nostril atresia, and turbinates' hypertrophy. All these anatomical alterations reduce the internal dimensions of the nose, increase resistance to respiratory airflow, and produce mouth breathing.^{2,3} The scar tissue from the primary surgeries required in most CLP patients commonly causes a transverse maxillary deficiency, especially at the anterior region and a rapid maxillary expansion (RME) is often part of the orthodontic treatment of these individuals.⁴⁻⁷

RME was first introduced by Angell in the 19th Century, and its effects over the maxilla and as a treatment for respiratory disturbances have been described in the literature.⁸⁻¹¹ RME has an important impact on the upper airway dimension due to the transverse movement of the nasal lateral walls that pulls away the nasal turbinates in relation to the nasal septum.¹² Furthermore, RME also affects the position of the mandible, which may change the size and volume of the oropharyngeal (OP) airway.¹³

The effects of RME over the upper airways have been studied with various research methods such as lateral and anteroposterior cephalometric radiographs,^{14,15} acoustic rhinometric exams^{12,16} and multislice computed tomography.^{17,18} Recent advances in Cone Beam Computed Tomography (CBCT) and related softwares have made the diagnosis and treatment planning of CLP patients more accurate due to the higher quality of the images.¹⁹ Previous studies have confirmed that it is possible to visualize and measure the upper airway as a solid structure, allowing volumetric measurements with minimal error.²⁰ Lower costs, shorter scanning time and consequently lower radiation doses have made CBCT technology the preferred method to assess the airways.²¹ However, there is a lack of CBCT studies assessing the volumetric changes in the nasal and oropharyngeal airways during the orthodontic treatment of CLP patients.

The objectives of this retrospective study were to evaluate the maxillary width, nasal passage (NP) volume and OP airway minimum axial area and volume changes after RME and, to compare the results of four different expanders in CLP patients.

MATERIAL AND METHODS

Forty unilateral CLP patients (23 male and 17 female), aging from 8 to 14 years old (mean age of 11.1 years $\pm$ 2.2) participated in this study. All participants received treatment at the orthodontic clinic of the Pontifical Catholic University of Minas Gerais and all CBCT scans evaluated were obtained from the existing patient database. Sex and age distributions for all groups are shown in Table I. The institutional review board on research ethics of our University approved this study and signed informed consents were obtained from all patients and their parents prior to the study.

The sample inclusion criteria were: (1) complete unilateral CLP patients that received RME as an initial part of their comprehensive orthodontic treatment; (2) greater anterior than posterior transverse maxillary deficiency before RME; and (3) age between 8 and 14 years old. The following exclusion criteria were adopted: (1) presence of active caries lesions; (2) signs of active periodontal disease; (3) orthodontic treatment before RME; and (4) other associated craniofacial syndromes. The stage of cervical maturation of all patients was evaluated and they ranged from CS2 and CS4.

The sample was distributed into 4 groups of 10 patients each, according to the type of expander used: Hyrax (HE), Fan-type (FT), Inverted Mini-Hyrax with bands on first molars (iMini Molar), or Inverted Mini-Hyrax supported on the first bicuspid (iMini Premolar). The HE is a tooth-borne appliance with the jackscrew (Leone Orthodontics and Implantology, Firenze, Italy) located at first deciduous molars or first premolars region (Fig 1A). The FT (Morelli Ortodontia, Sorocaba, SP, Brazil) is a tooth and tissue-borne appliance presenting a hinge at the first permanent molars region to restrain posterior expansion (Fig 1B). The iMini molar expander is also a tooth-borne appliance with a Mini Hyrax screw (DynaFlex, Saint Ann, MO, EUA), located at the anterior region of the arch with its arms bent posteriorly and soldered to the first permanent molar bands (Fig 1C). Finally, on the iMini premolar expander, the reduced size Hyrax screw is also located anteriorly, but the arms were soldered to first premolar bands and it was used associated with a transpalatal arch (TPA) attached to the first permanent molars (Fig 1D). The same lab technician fabricated all expanders.

A pre-treatment CBCT scanning (T0) was obtained as part of the initial orthodontic records of the patients, in substitution to all conventional radiographs. Each expander was cemented with a fluoride releasing cement (*Ultra Band-Lok*, Reliance Orthodontic Products, Inc., Itasca, IL), and the activation regimen was established at 2 turns/day until the required expansion was achieved. After the 3-month retention period, the expander was removed, a post-expansion CBCT scanning (T1) was acquired and a TPA presenting anteriorly extending arms was immediately inserted to serve as a retainer until the next phase of the orthodontic treatment was initiated. Obtaining the T1 CBCT was justified because of its importance for adequate secondary bone graft surgical planning.

The same radiology technician obtained all tomographic scans using an iCat machine (Imaging Sciences International, LLC, Hatfield, PA), adjusted to 23x17 cm fov, 0,3 mm of voxel and a 40 seconds of exposure time. All measurements were performed by the same operator who was properly calibrated and blind to the group status. The changes in the maxillary width and upper airway (T0 to T1) were analyzed with the 11.5 Dolphin Imaging software (Dolphin Imaging & Management Solutions, Chatsworth, CA). The images of each patient's head were oriented in all 3 planes of space using the frontal, right lateral and superior views. In the frontal view, the head was positioned with the line connecting both right and left fronto-zygomatic sutures parallel to the floor. In the right lateral view, the Frankfort horizontal line was also positioned parallel to the floor. Finally, in the superior view, the line connecting Crista Galli and Basion was aligned parallel to the mid-sagittal plane and perpendicular to the ground.

The following measurements were performed to evaluate the upper airway dimensions, as previously described by El and Palomo²² (Figs 2 and 3):

1. Nasal passage volume: the NP airway inferior limit was defined as the palatal plane (ANS-PNS) extending to the posterior wall of the pharynx. The superior limit was defined as the last tomographic slice before the nasal septum fused with the posterior wall of the pharynx. The superior border of the NP was determined on the axial slice first and then it was reflected to the sagittal plane (Fig 2).

2. Oropharynx volume: defined as the volume of the pharynx between NP inferior limit and the plane parallel to the palatal plane that passes from the most anteroinferior point of the second cervical vertebrae (Fig 3A);

3. Oropharynx minimum axial area: the most constricted cross sectional area of OP, defined by the software (Fig 3);

Once each airway had been defined, the Dolphin software allowed the selection of the airway by defining a threshold range of CT units that characterized all air spaces of the head and neck regions. We arbitrarily standardized the threshold range from 25 to 35 units (0-200 units were available) observing which unit provided the most comprehensive airway selection without adding or leaving out upper airway space. OP and NP volumes and minimal cross sectional area of the OP were obtained by using the Sinus/airway analysis, Boundary Position, Seed Point, Update Volume and Enable Minimum Axial Area options.

To assess the anterior maxillary width, a coronal cut that best showed the crown of each anterior tooth (first deciduous molar or first premolar) was selected. The axial plane that passes through the cement-enamel junction on the palatal surface of each tooth was determined. The distance between the median point of the palatal surface of the dental crown and a median line was measured on this cut. The values for right and left sides were summed and represented the anterior maxillary width (AMW). The same protocol was repeated to determine the posterior maxillary width (PMW) using the first permanent molars as references (Fig 4). The midline was determined by a line perpendicular to the ground that intersected the frontal crypt, seen on axial slices.

Statistical analysis

All measurements were repeated in 20 random CBCT scans after a two-week interval. Calibration of the operator was tested with the intraclass correlation coefficient (ICC). The results varied from 0.97 to 0.99 for all measurements, except for the NP volume, which was 0.87, indicating a high reproducibility and reliability of all variables.

D'Agostino and Pearson tests indicated normal distribution of all variables analyzed. The Paired t test was used to evaluate possible differences in patients' age and the Qui-square test analyzed differences in the patients' gender and cleft side among the groups. The Paired t test was also used to evaluate intra group changes from T0 to T1 for all expanders individually. The One-way ANOVA followed by Bonferroni's post hoc test were used to evaluate if there were differences from T0 to

T1 in all variables among the expanders. The Pearson Correlation test was applied to assess the correlations between the changes at AMW and PMW and at the airway. The level of significance was set at 5% and the GraphPad Prism 5.01 software (GraphPad Software, San Diego, CA) was used for all statistical tests.

RESULTS

All groups were matched on age, sex, and cleft side.

No significant differences ($p>0.05$) were found in patients' age, gender and cleft side among the groups (Table 1).

A significant increase in the NP volume was found in the Hyrax and iMini Molar groups.

The Hyrax and iMini Molar groups (Tables II and IV) showed a significant increase ($p<0.05$) in NP volume. The intergroup evaluation demonstrated that a significant difference was found only between FT and iMini Molar groups (Table VI), with the greatest increase in the iMini Molar group (1423 mm^3), and the smallest in the FT group (112 mm^3) [Tables III and V, respectively].

None of the groups showed significant changes in the OP volume and minimum axial area.

The OP volume and minimum axial area increased in the Hyrax and iMini Molar groups and decreased in the Fan-type and iMini Premolar groups, but these changes were not statistically significant ($p>0.05$) [Tables II to V]. There is no significant intergroup difference (Table VI).

The maxillary width significantly increased in all groups, except for the PMW with the iMini Premolar expander.

All groups showed a significant increase ($p<0.05$) in the anterior maxillary width, with no intergroup differences (Tables II to VI). The posterior maxillary width significantly increased in all groups ($p<0.05$), except for the iMini Premolar expander ($P > 0.05$) (Table VI).

A positive correlation was found between the increase in anterior maxillary width and OP changes.

The only correlation found between the maxillary width and airway volume changes was registered in the FT group between the AMW and OP volume and minimum axial area changes (Table VII).

DISCUSSION

The transverse skeletal and morphological effects of RME have been investigated in non-cleft and cleft patients using different diagnostic methods.^{11-18,23} This craniofacial anomaly has a major impact on the nasomaxillary complex and may affect craniofacial development and compromise airway function.^{2,3,6} However, there is a lack of CBCT studies that quantify and compare the volumetric changes in the upper airway post RME in CLP patients, especially evaluating the efficacy of different types of expanders.

The maxilla forms most of the nasal cavity lateral walls. Thus, an increase in nasal cavity volume would be an expected RME effect.²⁴ The series of events that cause this expansion is mainly a triangular¹⁴ or parallel²⁵ opening of the median palatal suture, which increases the nasal floor width and the nasal cavity volume. The results of this study showed a significant increase in the NP volume in the Hyrax and iMini Molar groups. However, the intergroup analysis showed significant differences only between FT and iMini Molar groups, which presented the smaller and greater increase, respectively. These findings suggested that RME might be able to improve the breathing pattern in CLP patients by reducing nasal resistance when the expansion of the posterior part of the maxilla is not restricted when FT and iMini-premolar expanders are used. However, our results did not show any correlation between the increase in PMW and the changes in the NP volume. Further studies are necessary to confirm such anatomical and functional correlations.

A previous study¹² used acoustic rhinometry to assess the nasal cavity volume changes in CLP patients with the Hyrax expander and found a significant increase post RME. Thus, only 58% of the patients presented any RME's beneficial effect in respiratory terms. These findings demonstrated that it is not possible to extrapolate the positive results observed in the group as a whole to individual patients. The RME's beneficial effect was 14% considering the whole group in their study. Since they used acoustic rhinometry, it's difficult to compare their results with ours. In the present experiment, the NP volume increased approximately 12,6% in the Hyrax group, 1,5% in the FT, 26,1% in the iMini Molar and 6,3% in the iMini Premolar group.

CLP patients may present velopharyngeal dysfunction (VPD), and consequently they are unable to completely close the nasal airway when they speak.

²⁶ Secondary surgical procedures to correct VPD, such as the pharyngeal flap, alter de nasopharyngeal airspace, increase nasal airway resistance, decrease airway size, and increase the prevalence of mouth breathing.³ Furthermore, a question is raised: although improving CLP patient's occlusion when performing RME, aren't we worsening the VPD at the same time? Further studies are necessary to confirm such correlation.

Maxillary constriction might also play a role in the pathophysiology of obstructive sleep apnea syndrome (OSA) because maxillary constriction is associated with a lower posture of the tongue that could result in narrowing of the oropharynx airway, which is an important risk factor for developing OSA. RME has been proposed as a treatment modality for OSA based on the hypothesis that the airway volume increases after maxillary expansion because the tongue would reposition more anteriorly in the oral cavity.²⁷ A previous RME study¹³ with non-cleft patients reported that the mandibular position changes in different directions, which may affect the OP airway size, shape, and volume. However, other studies evaluated OP airway in patients with maxillary constriction treated with RME and concluded that RME did not significantly affect the pharyngeal dimensions.^{28,29} This study confirms such findings and also did not find significant changes in the OP volume and minimum axial area in all groups.

A possible limitation of this retrospective study was the absence of control over tongue position when the CBCT images were taken. The position of the tongue and soft tissues are important anatomic factors that affect the shape and size of the oropharynx airway volume.³⁰ Because of exact matching by age and sex, and the standardized imaging protocol (scans taken during the same period of time by the same operator with the same instructions to the patients), possible confounding effects of tongue-position changes (changes in tongue length and height) might be minimized. Further studies should be performed to assess those changes. From our results, we found that RME treatment for orthodontic purposes is not an effective method to increase the oropharynx airway volume of unilateral CLP patients with maxillary constriction, no matter what kind of expander is chosen. It was found a positive correlation between the anterior maxillary expansion and OP volume and minimum axial area changes in the Fan-type group. However, since the intra-group analysis did not show significant changes, this information might not have clinical relevance.

Clinically, the kind of expander to treat CLP patients' maxillary transverse deficiency is determined by the orthodontist's preference and should be based on the patients' specific needs. The results of this study showed that if a greater increase in the NP volume is required, the Hyrax and iMini Molar expanders should be chosen. However, we found that RME is not an effective method to increase OP airway volume of CLP patients, no matter what expander is chosen.

CONCLUSIONS

- a) the Hyrax and iMini Molar were the only expanders to significantly increase the nasal cavity volume;
- b) RME did not increase the volume of the oropharyngeal airway.

FIGURES

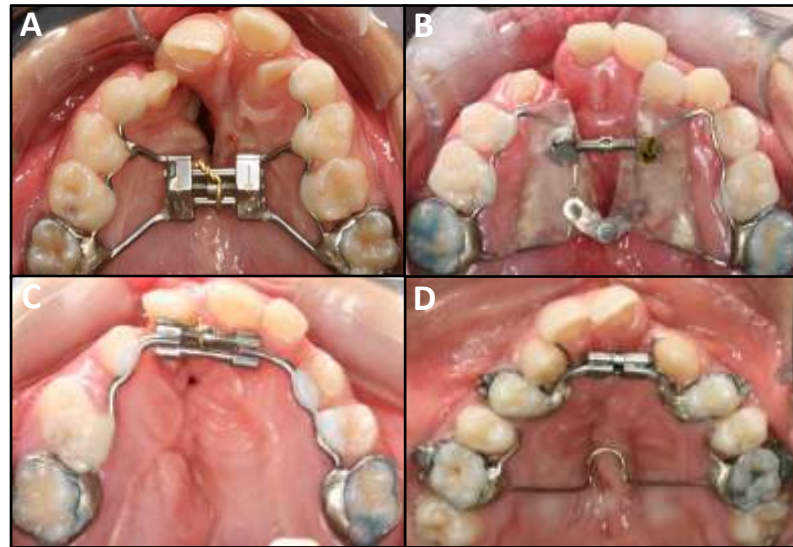


Fig 1. Rapid maxillary expanders evaluated: **A**, Hyrax; **B**, Fan-type; **C**, iMini Molar and **D**, iMini Premolar.

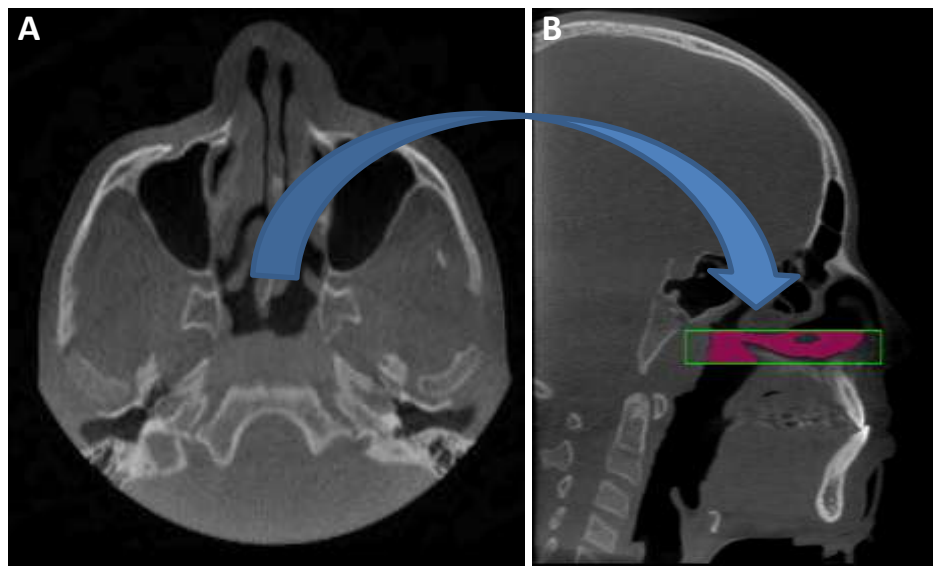


Fig 2. Limits of the nasal passage: **A**, determination of the last axial slice before the fusion of the nasal septum with the pharyngeal posterior wall; **B**, the reflection of that slice in the sagittal plane defines the upper limit, and the palatal plane determines the lower one.

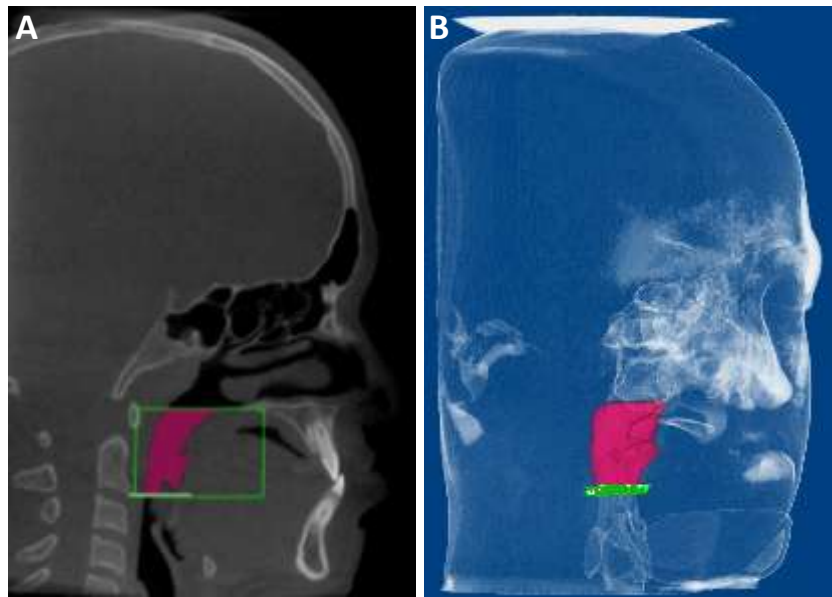


Fig 3. Oropharynx volume limits and minimum axial area: **A**, upper limit, palatal plane extended to the pharyngeal posterior wall, and lower limit, plane parallel to the palatal plane intersecting the lower and most anterior point in the second cervical vertebra; the horizontal white line represents the most constricted axial area (minimum axial area); **B**, 3D view of the oropharynx where the green plane represents its minimum axial area determined by the software within its limits.

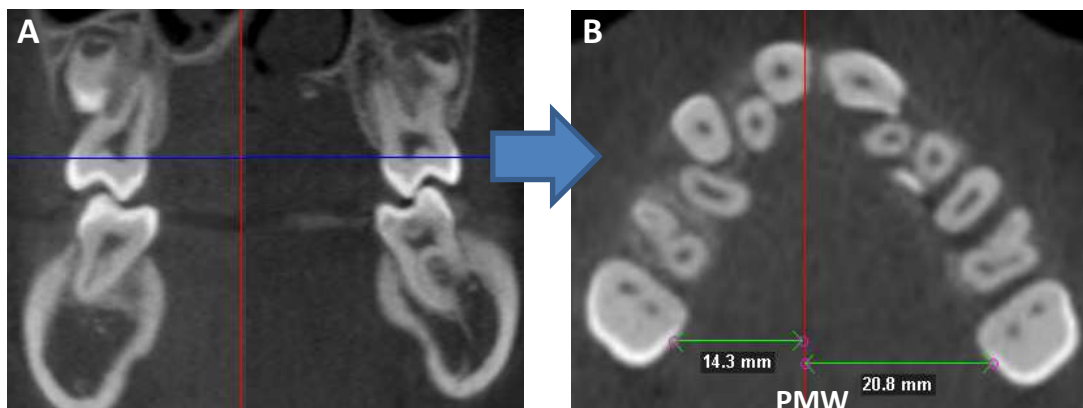


Fig 4. Maxillary posterior width: **A**, selection of the coronal slice that best shows the crown of each posterior tooth. In this patient, this cut was the same for both sides. The blue line intersects the cement-enamel junction on the palatal surface of these teeth; **B**, axial cut determined by the blue line on the coronal slice where the distance of the median point of the palatal surface of the dental crown and a median line was measured. The values for right and left sides were summed and represent the PMW.

TABLES

Table I. Age (in years), gender and cleft side distribution and comparison among all groups tested.

Group	Age		P value*	Gender		P value**	Cleft side		P value**
	Mean	SD		M	F		RS	LS	
Hyrax	11.1	2.4	ns	7	3	ns	4	6	ns
Fan-type	10.5	1.8		6	4		2	8	
IMini molar	10.5	2.4		7	3		3	7	
IMini premolar	12.5	2.3		3	7		4	6	

M, male; F, female; RS, right side; LS, left side.

* P value obtained with ANOVA One Way; **P value obtained with Qui-square test; ns, non-significant.

Table II. Comparison of the variables from T0 to T1 on the Hyrax group.

Variables	T0		T1		Mean of differences	P value
	Mean	SD	Mean	SD	T1 – T0	
AMW (mm)	22.02	3.15	26.69	3.36	4.67	<0.05
PMW (mm)	31.71	2.46	36.39	2.50	4.68	<0.05
NP volume (mm ³)	6738	1798	7588	1970	850	<0.05
OP volume (mm ³)	11127	3622	12290	5593	1163	ns
OP minimum area (mm ²)	187.2	83.67	211.4	99.48	24.2	ns

P value obtained with Paired t test: T0 versus T1; SD, standard deviation; ns, not significant (P >0.05).

Table III. Comparison of the variables from T0 to T1 on the Fan-type group.

Variables	T0		T1		Mean of differences	P value
	Mean	SD	Mean	SD	T1 – T0	
AMW (mm)	21.57	3.12	27.27	3.54	5.70	<0.05
PMW (mm)	33.13	3.24	35.23	2.57	2.10	<0.05
NP volume (mm ³)	7331	3318	7443	3041	112	ns
OP volume (mm ³)	12273	2167	11627	4018	-646	ns
OP minimum area (mm ²)	211.2	108.3	186.9	65.60	-24.3	ns

P value obtained with Paired t test: T0 versus T1; SD, standard deviation; ns, not significant (P >0.05).

Table IV. Comparison of the variables from T0 to T1 on the iMni Molar group.

Variables	T0		T1		Mean of differences	P value
	Mean	SD	Mean	SD	T1 – T0	
AMW (mm)	21.77	2.90	26.45	3.48	4.68	<0.05
PMW (mm)	33.17	2.29	38.35	2.83	5.18	<0.05
NP volume (mm ³)	5440	2246	6863	3182	1423	<0.05
OP volume (mm ³)	8947	4146	11901	10638	2954	ns
OP minimum area (mm ²)	127.2	45.82	190.5	127.1	63.3	ns

P value obtained with Paired t test: T0 versus T1; SD, standard deviation; ns, not significant (P >0.05).

Table V. Comparison of the variables from T0 to T1 on the iMni Premolar.

Variables	T0		T1		Mean of differences	P value
	Mean	SD	Mean	SD	T1 – T0	
AMW (mm)	22.93	1.99	26.79	2.50	3.86	<0.05
PMW (mm)	36.00	2.94	35.93	2.78	-0.07	ns
NP volume (mm ³)	8743	2325	9296	2897	553	ns
OP volume (mm ³)	12200	4505	12068	5973	-132	ns
OP minimum area (mm ²)	174.4	132.4	146.0	93.35	-28.4	ns

P value obtained with Paired t test: T0 versus T1; SD, standard deviation; ns, not significant (P >0.05).

Table VI. Comparison of variables' changes (T1 –T0) among all expanders.

Variables	Hyrax		Fan-type		iMini Molar		iMini Premolar		P value
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
AMW (mm)	5.70	2.89	4.68	1.60	4.67	0.87	3.86	1.42	ns ^{1,2,3,4,5,6}
PMW (mm)	5.18	1.78	2.10	1.25	4.68	1.05	-0.07	0.21	p<0.05 ^{1,2,3,5,6} n.s. ⁴
NP volume (mm ³)	112	681.2	1423	1261	850	937.9	553	1091	p<0.05 ¹ ns ^{2,3,4,5,6}
OP volume (mm ³)	-646	3603	2954	8684	1163	4272	-132	3144	ns ^{1,2,3,4,5,6}
OP minimum area (mm ²)	-24.3	109.6	63.3	144.4	24.2	94.5	-28.4	73.4	ns ^{1,2,3,4,5,6}

P value obtained with one way ANOVA followed by the Bonferroni post hoc test to compare the pairs: ¹ Fan-type versus iMini Molar; ² Fan-type versus Hyrax; ³ Fan-type versus iMini premolar; ⁴ iMini molar versus Hyrax; ⁵ iMini Molar versus iMini premolar; ⁶ Hyrax versus iMini Premolar; ns, not significant (p>0.05).

Table VII. Evaluation of the correlation among AMW and NP volume, OP volume, OP minimum area and among PMW and NP volume, OP volume, OP minimum area.

Variables		NP volume (P value)	OP volume (P value)	OP minimum área (P value)
Hyrax	AMW	ns	ns	ns
	PMW	ns	ns	ns
Fan-type	AMW	ns	<0.05 (r 0.68)	<0.05 (r 0.77)
	PMW	ns	ns	ns
iMini-Molar	AMW	ns	ns	ns
	PMW	ns	ns	ns
iMini-Premolar	AMW	ns	ns	ns
	PMW	ns	ns	ns

P value obtained with Pearson correlation test; r, Pearson's correlation coefficient; ns, not significant (P >0.05).

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4.2 ARTIGO 2

Maxillary segmental response and alveolar cleft changes following rapid maxillary expansion in cleft lip and palate patients: a comparison of four different expanders

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Maxillary segmental response and alveolar cleft changes following rapid maxillary expansion in cleft lip and palate patients: a comparison of four different expanders

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ABSTRACT

Objectives: To analyze, by means of cone beam computed tomography (CBCT), the transverse changes in the cleft and non-cleft maxillary segments and the volumetric changes in the alveolar cleft defect that occur in unilateral cleft lip and palate (UCLP) patients after rapid maxillary expansion (RME) with four different expanders. **Methods:** 40 UCLP patients (mean age, 11.1 ± 2.2 years) with transverse maxillary deficiency that received RME were divided into the following groups: (I) Hyrax, (II) Fan-type, (III) iMini Molar and (IV) iMini Premolar. CBCT images were taken before (T0) and 3 months after RME (T1). **Results:** All groups showed a significant increase in the anterior maxillary width. Only the iMini Premolar group did not show a significant expansion in the posterior maxillary width. When the transverse expansion in the cleft and non-cleft sides was compared, the Fan-type group was the only one to show a significant difference, with a greater expansion in the non-cleft side. A significant increase in the alveolar cleft volume was found in all groups, but there was no significant intergroup difference. **Conclusions:** All expanders significantly expanded the anterior region of the maxilla and, consequently, increased the alveolar cleft volume. There was a symmetric expansion between cleft and non-cleft sides in all groups, but the Fan-type one.

INTRODUCTION

Cleft lip and palate (CLP) is one of the most frequent craniofacial anomalies worldwide.¹ In unilateral cases, it can completely cleave lip and palate, dividing the maxilla into two well distinguished segments: a major one (non-cleft side) and a minor one (cleft side).² The early surgical correction initiates a molding action over the maxillary arch and each segment can be displaced toward each other.³ In unilateral CLP (UCLP) patients, a differential collapse of the lateral maxillary segments can cause an asymmetric transverse maxillary deficiency.^{4,5}

Rapid maxillary expansion (RME) is a well-known therapy for correcting the maxillary deficiency.⁶ Many different expanders have been developed to improve the efficiency of the maxillary expansion and to prevent post expansion relapse.^{7,8} Their effects have been demonstrated to be dental, based on increasing interdental distances and teeth axial inclination, and skeletal, based on enlargement of the maxillary base, widening of the nasal cavity, and increasing of maxillary sinus volume.^{9,10}

With the missing midpalate and anatomical deformity of the maxillary bone in the CLP patient, it can be expected that the interaction mechanism between the expansive force and resistance to expansion would be different on cleft and non-cleft maxillary segments.¹¹

Previous clinical^{6,12} and finite element model (FEM)^{11,13-15} studies have shown an asymmetric response of the maxillary segments to expansion forces. However, there is no consensus in the literature about which segment is more laterally displaced.

Moreover, RME plays a role to restore the normal maxillary transverse dimension in cleft patients, which is an essential condition for alveolar bone grafting.^{16,17} However, it can widen the alveolar cleft defect, which may be a negative factor for bone graft success.^{3,18} Since there is several different types of expanders available to perform the RME, those which promote the smallest increase in the alveolar cleft dimension should be chosen.

The dentoskeletal effects of RME have been researched with various techniques such as lateral and anteroposterior cephalometric radiographs^{19,20} and multislice computed tomography.²¹ Recent advances in cone beam computed tomography (CBCT) and related softwares have made the diagnosis and treatment

planning of CLP patients more accurate due to the high-quality images.^{22,23} However, most of the RME studies have not taken into account the volumetric changes of the alveolar cleft defect.

The objectives of this study were (1) to assess the transverse changes in the cleft and non-cleft maxillary segments and (2) to evaluate the volumetric changes in the alveolar cleft defect that occur after RME with four different expanders in UCLP patients.

MATERIAL AND METHODS

Forty UCLP patients (23 male and 17 female), aging from 8 to 14 years old (mean age of 11.1 years $\pm$ 2.2) participated in this study. All participants received treatment at the orthodontic clinic of the Pontifical Catholic University of Minas Gerais and all CBCT scans evaluated were obtained from the existing patient database. Sex and age distributions for all groups are shown in Table I. The institutional review board on research ethics of our University approved this study and signed informed consents were obtained from all patients and their parents prior to the study.

The sample inclusion criteria were: (1) complete UCLP patients that received RME as an initial part of their comprehensive orthodontic treatment; (2) greater anterior than posterior transverse maxillary deficiency before RME; and (3) age between 8 and 14 years old. The following exclusion criteria were adopted: (1) presence of active caries lesions; (2) signs of active periodontal disease; (3) orthodontic treatment before RME; and (4) other associated craniofacial syndromes. The stage of cervical maturation of all patients was evaluated and they ranged from CS2 and CS4.

The sample was distributed into 4 groups of 10 patients each, according to the type of expander used: Hyrax (HE), Fan-type (FT), Inverted Mini Hyrax with bands on first molars (iMini Molar), or Inverted Mini-Hyrax supported on the first bicuspid (iMini Premolar). The Hyrax expander is a tooth-borne appliance with the jackscrew (Leone Orthodontics and Implantology, Firenze, Italy) located at first deciduous molars or first premolars region (Fig 1A). The FT (Morelli Ortodontia, Sorocaba, SP, Brazil) is a tooth and tissue-borne appliance presenting a hinge at the first permanent molars region to restrain posterior expansion (Fig 1B). The iMini molar expander is also a tooth-borne appliance with a Mini Hyrax screw (DynaFlex, Saint Ann, MO, EUA), located at the anterior region of the arch with its arms bent posteriorly and soldered to the first permanent molar bands (Fig 1C). Finally, on the iMini premolar expander, the reduced size Hyrax screw is also located anteriorly, but the arms were soldered to first premolar bands and it was used associated with a transpalatal arch (TPA) attached to the first permanent molars (Fig 1D). The same lab technician fabricated all expanders.

A pre-treatment CBCT scanning (T0) was obtained as part of the initial orthodontic records of the patients, in substitution to all conventional radiographs.

Each expander was cemented with a fluoride releasing cement (*Ultra Band-Lok*, Reliance Orthodontic Products, Inc., Itasca, IL), and the activation regimen was established at 2 turns/day until the required expansion was achieved. After the 3-month retention period, the expander was removed, a post-expansion CBCT scanning (T1) was acquired and a TPA presenting anteriorly extending arms was immediately inserted to serve as a retainer until the next phase of the orthodontic treatment was initiated. Obtaining the T1 CBCT was justified because of its importance for adequate secondary bone graft surgical planning.

The same radiology technician obtained all tomographic scans using an iCat machine (Imaging Sciences International, LLC, Hatfield, PA), adjusted to 23x17 cm fov, 0,3 mm of voxel and a 40 seconds of exposure time. All measurements were performed by the same operator who was properly calibrated and blind to the group status. The changes in the maxillary width (T0 to T1) were analyzed with the 11.5 Dolphin Imaging software (Dolphin Imaging & Management Solutions, Chatsworth, CA). The images of each patient's head were oriented in all 3 planes of space using the frontal, right lateral and superior views. In the frontal view, the head was positioned with the line connecting both right and left fronto-zygomatic sutures parallel to the floor. In the right lateral view, the Frankfort horizontal line was also positioned parallel to the floor. Finally, in the superior view, the line connecting Crista Galli and Basion was aligned parallel to the mid-sagittal plane and perpendicular to the ground.

To assess the anterior maxillary width in the cleft side (AWCS), a coronal cut that best showed the crown of each anterior tooth (first deciduous molar or first premolar) was selected. Then, the axial plane that passes through the cement-enamel junction on the palatal surface of each tooth was found. The distance between the median point of the palatal surface of the dental crown and a median line was measured on this cut and represented the AWCS. The same was repeated for the other side and represented the anterior maxillary width in the non-cleft side (AWNCS). The same protocol was also repeated to determine posterior maxillary width in the cleft (PWCS) and non-cleft side (PWNCS) using the first permanent molars as references (Fig 2). The midline was determined by a line perpendicular to the ground that intersected the frontal crypt, seen on axial slices.

The changes in the alveolar cleft (T0 to T1) were analyzed with the 2.4 ITK-SNAP software (Penn Image Computing and Science Laboratory, Philadelphia, PA).

The alveolar cleft superior limit was defined as the line parallel to the ground passing through the point A and the inferior limit as a line also parallel to the ground passing through the most inferior point of the buccal alveolar crest at the superior central incisors region, chosen in sagittal slices.²³ The alveolar cleft region was painted in all axial slices within these limits using the 'Paintbrush Tool' and the volume was calculated using the "Volumes and Statistics" option.²⁴

Statistical analysis

All measurements were repeated in 20 random CBCT scans after a two-week interval. Calibration of the operator was tested with the intraclass correlation coefficient (ICC). The results varied from 0.97 to 0.99 for all measurements, except for the NP volume, which was 0.87, indicating a high reproducibility and reliability of all variables.

D'Agostino and Pearson tests indicated normal distribution of all variables analyzed. The Paired t test was used to evaluate possible differences in patients' age and the Qui-square test analyzed differences in the patients' gender and cleft side among the groups. The Paired t test was also used to evaluate intra group changes from T0 to T1 for all expanders individually. The One-way ANOVA followed by Bonferroni's post hoc test were used to evaluate if there were differences from T0 to T1 in all variables among the expanders. The Paired t test was applied to evaluate if there was significant difference in the changes from T0 to T1 between AWCS and AWNCS, and PWCS and PWNCS for all expanders individually. The level of significance was set at 5% and the GraphPad Prism 5.01 software (GraphPad Software, San Diego, CA) was used for all statistical tests.

RESULTS

All groups were matched on age, sex, and cleft side.

No significant differences ($p>0.05$) were found in patients' age, gender and cleft side among the groups (Table 1).

There was a significant increase in the anterior region of the maxilla in all groups, with no intergroup difference.

A significant increase in the anterior maxillary dimension (AWCS and AWNCS) was observed in all groups (Tables II to V), but no significant intergroup difference was found (Table VI).

The FT group showed a greater anterior expansion in the non-cleft side.

The maxillary segments (AWCS and AWNCS) showed a symmetric expansion in all groups, except in the FT one, where the non-cleft side expanded more than the cleft side ($P < 0.05$) [Table VII].

The iMini Premolar group showed the smallest posterior expansion, while the Hyrax and iMini Molar the greatest ones.

A significant increase in the posterior maxillary width was observed in the Hyrax and iMini Molar groups (Tables II to IV). There was smaller posterior expansion in the FT and iMini Premolar groups, the latter being insignificant.

No significant intergroup difference was found among the groups when the cleft and non-cleft posterior expansion was compared.

The PWCS and PWNCS changes were compared in all groups and the findings did not show any significant difference (Table VIII).

A significant increase in the alveolar cleft volume was found in all groups, but there was no significant intergroup difference.

The alveolar cleft volume significantly increased in all groups (Hyrax: 92.4mm³; FT: 109.0mm³; iMini Molar: 78.9mm³; iMini Premolar: 169,1mm³) [Tables II to V]. The iMini Premolar group showed the greatest increase and the iMini Molar the smallest one. However, no significant intergroup difference was found (Table VI).

DISCUSSION

Maxillary transverse deficiency is a frequent malocclusion in CLP patients and an asymmetric collapse of the cleft and non-cleft segments, with a greater constriction in the anterior region, is common characteristics in these individuals.^{4,5} To solve this problem many different expanders have been developed, with the goal to provide a greater anterior than posterior maxillary expansion without widening the alveolar cleft defect.^{7,8} The objectives of this study were to evaluate four different appliances regarding the maxillary segments and cleft defect changes.

The results showed that all expanders significantly increased the anterior region of the maxilla, at the cost of widening the alveolar cleft defect. When the cleft and non-cleft segments of the anterior part of the maxilla were evaluated, we found a symmetric response to the expansion forces, except in the FT group, where there was a greater anterior expansion in the non-cleft side. The greatest posterior maxillary expansion was achieved by the Hyrax and iMini Molar groups and the smallest one in the iMini Premolar. When the posterior expansion of the maxillary segments was analyzed, a symmetric expansion was observed in all groups.

It seems to have a controversy in the literature regarding the expansion of the cleft and non-cleft sides of the maxilla. Previous studies have reported an asymmetric expansion, with greater expansion in either the cleft side¹³ and the non-cleft side.^{11,15} These might be due to the fact that they used different methods, as FEM and 2D, and samples not homogenous. Moreover, an implant study suggested that the response of the maxilla to the RME procedure is unpredictable in nature,⁶ especially in UCLP patients, with the absence of thru midpalate and the deformity of the maxillary bone.¹¹

Despite the capacity of the RME to correct the transverse maxillary deficiency, it is evident that the separation of the maxillary halves caused by the incidence of the orthopedic forces significantly increases the alveolar cleft dimension.^{13,18} Although previous studies have already volumetrically measured this cleft defect^{16,25} ours is the first one to volumetric calculate how much it increases during the RME and with different expanders. The results showed that the alveolar cleft volume significantly increase in all groups (Hyrax: 13,99%; FT: 20,36%; iMini Molar: 15,29%; iMini Premolar: 29,02%). Therefore, the orthodontist and the surgeon must be aware of

this information when planning an interdisciplinary treatment for UCLP patients who require further alveolar bone graft.

Clinically, the decision of using one of these expanders to treat CLP patients relies on the orthodontist's preference and on the patients' specific needs. If both anterior and posterior expansion is required, the Hyrax and iMini Molar should be chosen. If a greater anterior than posterior expansion is necessary, the FT or iMini Premolar is the most indicated. However, the cleft and non-cleft sides may expand symmetrically, which in most cases is not clinically desirable. Furthermore, the results of this study showed that the increase in the alveolar cleft volume is unavoidable, no matter what expander is chosen.

CONCLUSIONS

- a) all expanders significantly increase the anterior region of the maxilla;
- b) the Hyrax and iMini Molar expanders showed the greatest posterior maxillary expansion, and the iMini Premolar the smallest one;
- c) the cleft and non-cleft sides in the anterior and posterior region of the maxilla presented a symmetric expansion in all groups, except in the anterior region in the FT one;
- d) the alveolar cleft volume significantly increased in all groups.

e) FIGURES

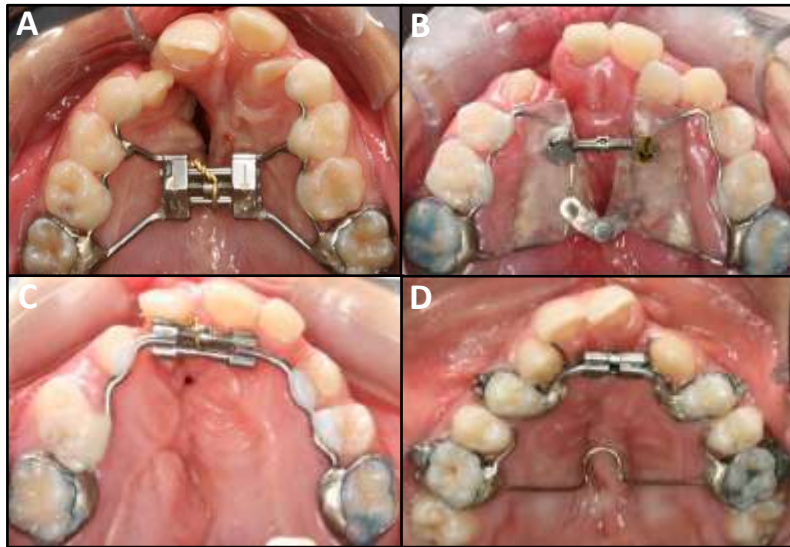


Fig 1. Rapid maxillary expanders evaluated: **A**, Hyrax; **B**, Fan-type; **C**, iMini Molar and **D**, iMini Premolar.

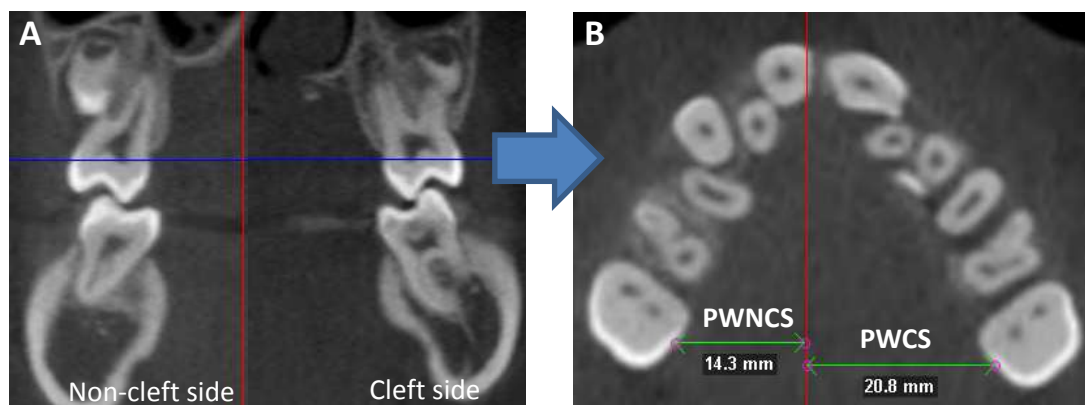


Fig 2. Maxillary posterior width in the non-cleft (left) and cleft (right) sides: **A**, selection of the coronal slice that best shows the crown of each posterior tooth. In this case this cut was the same for both sides. The blue line intersects the cement-enamel junction on the palatal surface of these teeth; **B**, axial cut determined by the blue line on the coronal slice where the distance of the median point of the palatal surface of the dental crown and a median line was measured.

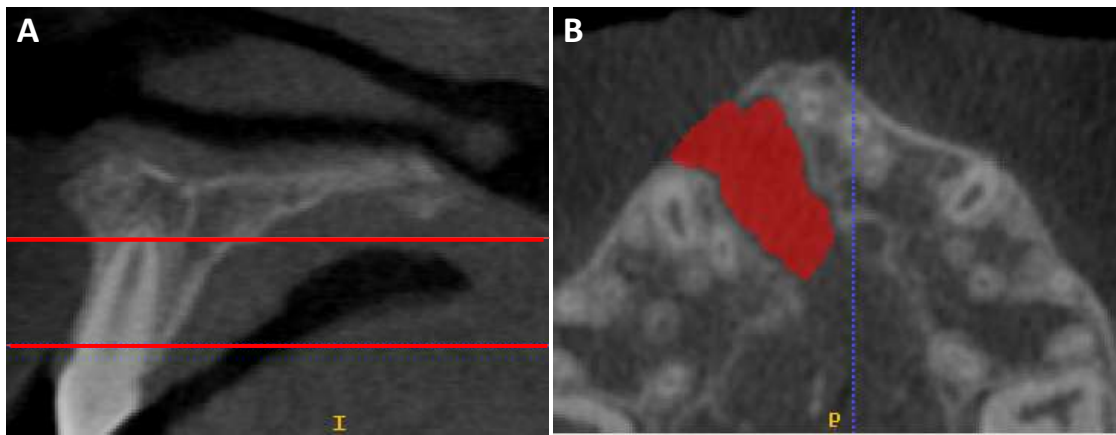


Fig 3. Limits of the alveolar cleft: **A**, the superior limit was defined as the line parallel to the ground passing through the point A and the inferior limit as the line also parallel to the ground passing through the most inferior point of the buccal alveolar crest at the superior central incisors in the sagittal view. **B**, in every slice within these limits the alveolar cleft was painted and then its volume was calculated.

TABLES

Table I. Age (in years), gender and cleft side distribution and comparison among all groups tested.

Group	Age		P value*	Gender		P value**	Cleft side		P value**
	Mean	SD		M	F		RS	LS	
Hyrax	11.1	2.4		7	3		4	6	
Fan-type	10.5	1.8		6	4		2	8	
IMini molar	10.5	2.4	ns	7	3	ns	3	7	ns
IMini premolar	12.5	2.3		3	7		4	6	

M, male; F, female; RS, right side; LS, left side.

* P value obtained with ANOVA One Way; **P value obtained with Qui-square test; ns, non-significant.

Table II. Comparison of the variables from T0 to T1 on the Hyrax group.

Variables	T0		T1		Mean of differences	P value
	Mean	SD	Mean	SD	T1 – T0	
AMWCS (mm)	11.34	1.82	13.43	1.82	2.09	<0.05
AMWNCS (mm)	10.96	2.61	13.50	2.18	2.54	<0.05
PMWCS (mm)	16.30	2.22	18.57	2.25	2.27	<0.05
PMWNCS (mm)	15.27	1.81	17.47	1.89	2.20	<0.05
Alveolar cleft volume (mm ³)	660.1	260.7	752.5	269.7	92.4	<0.05

P value obtained with Paired t test: T0 versus T1; SD, standard deviation; ns, not significant (P >0.05).

Table III. Comparison of the variables from T0 to T1 on the Fan-type group.

Variables	T0		T1		Mean of differences	P value
	Mean	SD	Mean	SD	T1 – T0	
AMWCS (mm)	11.22	2.42	13.65	2.64	2.43	<0.05
AMWNCS (mm)	10.35	1.70	13.62	1.77	3.27	<0.05
PMWCS (mm)	16.97	2.55	17.92	2.19	0.95	<0.05
PMWNCS (mm)	16.16	1.23	17.31	0.86	1.15	<0.05
Alveolar cleft volume (mm ³)	535.2	154.4	644.2	157.5	109.0	<0.05

P value obtained with Paired t test: T0 versus T1; SD, standard deviation; ns, not significant (P >0.05).

Table IV. Comparison of the variables from T0 to T1 on the iMini Molar group.

Variables	T0		T1		Mean of differences	P value
	Mean	SD	Mean	SD	T1 – T0	
AMWCS (mm)	11.36	2.48	13.82	2.99	2.46	<0.05
AMWNCS (mm)	10.41	2.32	12.62	2.85	2.21	<0.05
PMWCS (mm)	16.78	1.77	19.54	1.94	2.76	<0.05
PMWNCS (mm)	16.39	1.98	18.85	2.18	2.46	<0.05
Alveolar cleft volume (mm ³)	515.9	175.5	594.8	175.5	78.9	<0.05

P value obtained with Paired t test: T0 versus T1; SD, standard deviation; ns, not significant (P >0.05).

Table V. Comparison of the variables from T0 to T1 on the iMini Premolar group.

Variables	T1		T2		Mean of differences	P value
	Mean	SD	Mean	SD	T1 – T0	
AMWCS (mm)	12.36	3.54	14.20	3.00	1.84	<0.05
AMWNCS (mm)	12.16	2.79	13.99	2.30	1.83	<0.05
PMWCS (mm)	18.02	2.50	18.02	2.42	0.00	ns
PMWNCS (mm)	17.98	1.54	17.91	1.39	-0.07	ns
Alveolar cleft volume (mm ³)	582.6	383.1	751.7	474.8	169.1	<0.05

P value obtained with Paired t test: T0 versus T1; SD, standard deviation; ns, not significant (P >0.05).

Table VI. Comparison of variables' changes (T1 –T0) among all expanders.

Variables	Hyrax		Fan-type		iMini Molar		iMini Premolar		P value
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
AMWCS (mm)	2.09	1.33	2.43	1.63	2.46	0.97	1.84	1.11	n.s. ^{1,2,3,4,5,6}
AMWNCS (mm)	2.54	1.38	3.27	1.43	2.21	1.38	1.83	0.99	ns ^{1,2,3,4,5,6}
PMWCS (mm)	2.27	1.24	0.95	0.70	2.76	1.09	0.00	0.24	p<0.05 ^{1,2,5,6} ns ^{3,4}
PMWNCS (mm)	2.20	1.52	1.15	0.81	2.46	1.38	-0.07	0.28	p<0.05 ^{5,6} ns ^{1,2,3,4}
Alveolar cleft volume (mm ³)	92.4	91.0	109.0	50.4	78.9	64.0	169.1	146.8	ns ^{1,2,3,4,5,6}

P value obtained with one way ANOVA followed by the Bonferroni post hoc test to compare the pairs: ¹ Fan-type versus iMini Molar; ² Fan-type versus Hyrax; ³ Fan-type versus iMini premolar; ⁴ iMini molar versus Hyrax; ⁵ iMini Molar versus iMini premolar; ⁶ Hyrax versus iMini Premolar; ns, not significant (p>0.05).

Table VII. Comparison of the anterior maxillary width changes (T1 – T0) between the cleft and non-cleft sides in all expanders.

Groups	AMWCS (T2 – T1)		AMWNCS (T2 – T1)		Mean of differences	P Value
	Mean	SD	Mean	SD	T1 – T0	
Hyrax	2.09	1.33	2.54	1.38	0.45	ns
Fan-type	2.43	1.63	3.27	1.43	0.84	<0.05
IMini Molar	2.46	0.97	2.21	1.38	-0.25	ns
IMini Premolar	1.84	1.11	1.83	0.99	-0.01	ns

P value obtained with Paired t test: T0 versus T1; SD, standard deviation; ns, not significant (P >0,05).

Table VIII. Comparison of the posterior maxillary width changes (T1 – T0) between the cleft and non-cleft sides in all expanders.

Groups	PMWCS (T2 – T1)		PMWNCS (T2 – T1)		Mean of differences	P Value
	Mean	SD	Mean	SD	T1 – T0	
Hyrax	2.27	1.24	2.20	1.52	-0.07	ns
Fan-type	0.95	0.70	1.15	0.81	0.20	ns
IMini Molar	2.76	1.09	2.46	1.38	-0.30	ns
IMini Premolar	-0.00	0.24	-0.07	0.28	-0.07	ns

P value obtained with Paired t test: T0 versus T1; SD, standard deviation; ns, not significant (P >0,05).

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5 CONSIDERAÇÕES FINAIS

Esta linha de pesquisa se iniciou em 2009 pelos Profs. Dauro Douglas Oliveira e Ildeu Andrade Jr., diante da necessidade de se corrigir a atresia maxilar presente em boa parte dos pacientes portadores de FLP atendidos no Centro de Tratamento e Reabilitação de Anomalias e Deformidades Craniofaciais (CENTRARE - PUC Minas). Frente à dificuldade de se obter a correção da dimensão transversal maxilar destes pacientes, principalmente na região anterior do arco, 3 questionamentos surgiram: (1) O disjuntor tipo Hyrax é eficaz na expansão da região anterior do arco, uma vez que é citado na literatura como o aparelho mais utilizado? (2) O disjuntor tipo Haas Borboleta realmente promove uma maior expansão anterior do arco? (3) Qual seria uma alternativa clínica para obtenção da expansão anterior, sem prejudicar a manutenção de uma higienização satisfatória, já que o Haas Borboleta é composto por uma volumosa parte em resina acrílica?

Devido a estas questões, houve a idéia de se utilizar um disjuntor menor, facilitando a higienização e possibilitando o posicionamento do parafuso em uma região mais anterior do arco maxilar. Por isto, o disjuntor Mini Hyrax Invertido começou a fazer parte das opções de tratamento dos pacientes portadores de FLP, promovendo resultados bastante satisfatórios. Logo, estudos vêm sendo desenvolvidos em nossa Universidade para verificar a eficácia deste novo disjuntor. O presente estudo ainda visou comparar os efeitos desse aparelho com aqueles encontrados com o uso dos disjuntores Haas Borboleta e Hyrax.

Clinicamente, a decisão de qual disjuntor utilizar depende da preferência do Ortodontista e das características de cada paciente, devendo ser considerados os aspectos dentoalveolares, as vias aéreas superiores e a fissura alveolar.

Em relação aos fatores dentoalveolares, se expansão anterior e posterior forem requeridas, tanto o Hyrax como o iMini Molar podem ser utilizados. Se maior expansão anterior que posterior for necessária, tanto o Borboleta quanto o iMini Pré-molar podem ser escolhidos. Esta decisão deve ser tomada com base na necessidade de manutenção da dimensão transversa posterior e comprometimento do conforto do paciente durante esta fase do tratamento. Já em relação ao volume da passagem de ar nasal, se a ERM for realizada visando um aumento nessa dimensão, o Hyrax e o iMini Molar devem ser escolhidos. Eles foram os únicos que provocaram esse efeito, e nenhuma diferença foi encontrada entre eles. Os efeitos

dos disjuntores sobre a orofaringe e a fissura alveolar não mostraram ter capacidade de influenciar essa escolha, uma vez que nenhum deles alterou significativamente essas estruturas.

A amostra do presente estudo é inferior ao necessário de acordo com o cálculo amostral realizado. No entanto, é bastante homogênea, uma vez que todos os pacientes apresentam FLP transforame unilateral e a faixa de idade entre os grupos não possui diferença estatisticamente significativa. É importante salientar a dificuldade de se selecionar uma amostra com estas características específicas, mesmo em grandes centros de tratamento de pacientes portadores de FLP. Pode-se dizer também que há muito poucos estudos na literatura que utilizaram TCFC para avaliar os efeitos da ERM no volume das vias aéreas superiores e fissura alveolar em pacientes com FLP e ainda compararam os efeitos de diferentes disjuntores. A grande precisão das TCFCs contribui para a confiabilidade dos resultados (YOSHIHARA et al., 2012) e permite melhor avaliação do paciente para obtenção do diagnóstico e planejamento seguros.

Apesar de algumas limitações, o estudo respondeu aos objetivos propostos. Todavia, trabalhos futuros são necessários para continuar compreendendo os efeitos desses aparelhos na ERM em pacientes portadores de FLP. Dessa forma, buscamos encontrar o aparelho capaz de trazer os maiores benefícios para cada um destes pacientes, que já possuem um elevado comprometimento psicossocial.

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ANEXO A – Cópia da aprovação do Comitê de Ética da PUC Minas

COMISSÃO NACIONAL DE ÉTICA EM PESQUISA



PARECER CONSUBSTANCIADO DA CONEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: AVALIAÇÃO DAS ALTERAÇÕES DIMENSIONAIS DA FISSURA ALVEOLAR E VIAS AÉREAS SUPERIORES APÓS EXPANSÃO RÁPIDA DA MAXILA EM PACIENTES PORTADORES DE FISSURA LÁBIO PALATINA

Pesquisador: Ildeu Andrade Júnior

Área Temática: Área 8. Pesquisa com cooperação estrangeira.

Versão: 3

CAAE: 08111612.5.0000.5137

Instituição Proponente: Pontifícia Universidade Católica de Minas Gerais - PUCMG

Patrocinador Principal: Financiamento Próprio

COMPROVANTE DE ENVIO DO PROJETO

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: AVALIAÇÃO DAS ALTERAÇÕES DIMENSIONAIS DA FISSURA ALVEOLAR E VIAS AÉREAS SUPERIORES APÓS EXPANSÃO RÁPIDA DA MAXILA EM PACIENTES PORTADORES DE FISSURA LÁBIO PALATINA

Pesquisador:

Versão: Ildeu Andrade Júnior

CAAE: 3

08111612.5.0000.5137

Instituição Proponente: Pontifícia Universidade Católica de Minas Gerais - PUCMG

DADOS DO COMPROVANTE

Número do Comprovante: 037701/2012

Patrocinador Principal: Financiamento Próprio

3

Dados do Projeto de Pesquisa

Título da Pesquisa: AVALIAÇÃO DAS ALTERAÇÕES DIMENSIONAIS DA FISSURA ALVEOLAR E VIAS AÉREAS SUPERIORES APÓS EXPANSÃO RÁPIDA DA MAXILA EM PACIENTES PORTADORES DE FISSURA LÁBIO PALATINA

Pesquisador: Ildeu Andrade Júnior

Área Temática: Pesquisas com coordenação e/ou patrocínio originados fora do Brasil, excetuadas aquelas com copatrocínio do Governo Brasileiro;

Versão: 3

CAAE: 08111612.5.0000.5137

Submetido em: 24/10/2012

Instituição Proponente: Pontifícia Universidade Católica de Minas Gerais - PUCMG

Situação: Aprovado

Localização atual do Projeto: Pesquisador Responsável

Patrocinador Principal: Financiamento Próprio