UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU

RODRIGO ALMEIDA NUNES TEIXEIRA

Comparison of cephalometric and nasal cavity changes between the expander with differential opening and the fan-type expander: a secondary data analysis from a randomized clinical trial

Comparação das alterações cefalométricas e da cavidade nasal entre o expansor maxilar com abertura diferencial e o com abertura em leque: análise secundária de um ensaio clínico randomizado

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ERRATA

Dedico este trabalho...

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O sucesso nasce do querer, da determinação e persistência em se chegar a um objetivo. Mesmo não atingindo o alvo, quem busca e vence obstáculos, no mínimo fará coisas admiráveis.

José de Alencar

ABSTRACT

Comparison of cephalometric and nasal cavity changes between the expander with differential opening and the fan-type expander: a secondary data analysis from a randomized clinical trial

Introduction: The aim of this study was to compare the cephalometric and nasal cavity skeletal changes between the expander with differential opening (EDO) and the fan-type expander (FE). **Methods:** This study was a secondary analysis of a previous randomized clinical trial. Forty-eight patients with posterior crossbite were randomly allocated into two study groups. Twenty-four patients (11 male, 13 female) with a mean initial age of 7.6 ± 0.9 years were treated with rapid maxillary expansion (RME) using the EDO. Twenty-four patients (10 male, 14 female) with a mean initial age of 7.8 ± 0.9 years were treated with the FE. Cone-beam computed tomography (CBCT) was performed before treatment and 1 to 6 months after the active phase of RME. Using frontal CBCT slices passing at the level of permanent first molars and deciduous canines, the width of the nasal cavity was measured in the lower, middle and upper thirds. Nasal cavity height was also evaluated in both regions. Cephalometric analysis was performed using Dolphin Imaging Software. Intergroup comparisons of interphase changes were performed using t or Mann-Whitney tests ($P<0.05$). **Results:** The two groups were similar regarding baseline data. EDO showed a greater transverse increase in the lower third of the nasal cavity in both canine ($P=0.007$) and molar regions ($P<0.001$). No intergroup difference was observed for changes in nasal cavity middle and upper widths and height. In FE group, a greater increase of SNA angle was observed after expansion compared to EDO group ($P=0.043$). Both expanders produced a similar downward rotation of the mandible (FMA, $P=0.850$). A greater palatal tip of maxillary incisors was observed in FE group ($P=0.041$). **Conclusions:** Both expanders produced similar vertical cephalometric changes. However, fan-type expanders caused a greater maxillary anterior displacement after expansion with a compensatory palatal tip of maxillary incisors compared to the expander with differential opening. Both expanders are effective in

transverse increase in the lower third of the nasal cavity compared to the fan-type expander, both at the anterior and posterior region of the maxilla.

Keywords: Orthodontics, interceptive. Palatal expansion technique. Orthodontic appliances. Cephalometry. upper airway

RESUMO

Comparação das alterações cefalométricas e da cavidade nasal entre o expansor maxilar com abertura diferencial e o com abertura em leque: análise secundária de um ensaio clínico randomizado

Objetivo: O objetivo desse estudo foi comparar os efeitos dento esqueléticos por meio de análise cefalométrica e as alterações na cavidade nasal entre o expansor maxilar com abertura diferencial e em leque, em pacientes ortodônticos na fase de dentadura mista por meio de tomografia computadorizada cone-beam (TCCB). **Material e métodos:** O estudo foi conduzido a partir de uma análise secundária de dados de uma amostra já existente obtida em um estudo clínico randomizado prévio. A amostra consiste em 48 pacientes, de ambos os sexos, idade entre 7 e 10 anos e com deficiência transversa da maxila. Os pacientes foram randomizados em dois grandes grupos experimentais. O primeiro grupo consiste em 24 indivíduos tratados com expansão rápida da maxila (ERM) com o expansor com abertura diferencial (GED). O segundo grupo é composto por 24 indivíduos tratados com o expansor com abertura em leque (GEL). A análise das alterações cefalométricas foi composta por 16 variáveis angulares e lineares e foi realizada no software Dolphin 3D (California, USA). As alterações nas vias aéreas foram avaliadas por meio da mensuração das distâncias entre as paredes da cavidade nasal, no mesmo software. As comparações intergrupos foram avaliadas por meio dos testes t ou Mann Whitney ($p<0,05$). **Resultados:** As medidas iniciais não obtiveram diferença entre os grupos. A análise cefalométrica demonstrou que os efeitos dentro esqueléticos foram semelhantes entre os dois expansores, exceto para SNA ($P=0,043$) e inclinação palatina dos incisivos superiores ($P=0,041$) que foram ligeiramente maiores no grupo GEL. Na avaliação da cavidade nasal, o grupo GED apresentou maior aumento transversal no terço inferior tanto na região anterior ($P=0,007$) quanto na região posterior ($P<0,001$). Não foram observadas diferenças intergrupos para as alterações na largura e altura média e superior da cavidade nasal. **Conclusões:** Ambos os expansores produziram efeitos dento esqueléticos e nas dimensões da cavidade nasal. O expansor em leque teve um leve aumento na inclinação do SNA e dos incisivos superiores palatinos comparado com o expansor diferencial. O expansor com abertura diferencial produziu

maior aumento no terço inferior da cavidade nasal em relação ao expansor tipo leque, tanto na região anterior quanto na posterior da maxila.

Palavras-chave: Ortodontia interceptora. Aparelhos ortodônticos. Técnica de expansão palatina. Cefalometria. Resistência das Vias Respiratórias. Apneia Obstrutiva do Sono.

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LIST OF ABREVIATIONS AND ACRONYMS

CBCT	Cone Beam Computed Tomography
EDO	Expander with Differential Opening
FE	Fan-type Expander
ICC	Intraclass Correlation Coefficient
RCT	Randomized Clinical Trial
RME	Rapid Maxillary Expansion

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1. INTRODUCTION

1. INTRODUCTION

Transverse maxillary constriction is a common condition in patients in the mixed dentition.(SILVA FILHO; CAPELLOZA FILHO; FORNAZARI; CAVASSAN, 2003) It is estimated that 13% of children in this phase have posterior crossbites.(ALMEIDA; PEREIRA; ALMEIDA; ALMEIDA-PEDRIN et al., 2011) This malocclusion may occur in primary dentition and perpetuate for the following stages, because will not selft-correct.(SILVA FILHO; GONÇALVES; MAIA, 1991) Maxillary constriction has a diverse etiology, including non-nutritive sucking habits, atypical phonation, atypical swallowing, oral breathing and genetic factors.(LOURENÇO BELLUZZO; FALTIN JUNIOR; LASCALA; BACCI et al., 2012) In orthodontics, the early treatment of posterior crossbite with rapid maxillary expansion (RME) is considered the gold standard.(PROFFIT, 2006) Dentoskeletal effects are well documented in the orthodontic literature.(BAZARGANI; FELDMANN; BONDEMARK, 2013; LAGRAVERE; MAJOR; FLORES-MIR, 2005)

According to the maxillary morphology, expansion may be required in different magnitudes in the posterior and anterior regions of the dental arch. Conventionally, the maxillary expander is composed by a single screw, centrally positioned on the palate.(HAAS, 1961) Expanders with fan-type opening (FE) have an anterior screw and a posterior hinge, and the dentoalveolar effects are greater in the intercanine region.(DORUK; BICAKCI; BASCIFTCI; AGAR et al., 2004) However, one third of patients with maxillary constriction have a greater transversal deficiency in the anterior width.(LOURENÇO BELLUZZO; FALTIN JUNIOR; LASCALA; BACCI et al., 2012) In these cases, a conventional expansion would overexpand the posterior region to correct the intercanine width and a only the fan-type expansion would not correct the posterior crossbite. In order to control the amount of expansion in the posterior and anterior regions of the dental arch, the expander with differential opening (EDO), composed of two independent screws, one anterior and one posterior, was recently presented.(GARIB; GARCIA; PEREIRA; LAURIS et al., 2014)

When compared to the conventional expander, the EDO is capable to promote a greater expansion in anterior region of dental arch and a similar molar expansion.(ALVES; JANSON; MCNAMARA; LAURIS et al., 2020) When compared to the FE, the EDO showed a greater expansion at the level of the maxillary second

deciduous and first permanent molars and a less correction of anterior width.(MASSARO; JANSON; MIRANDA; CASTILLO et al., 2020) Based on previous studies, the EDO proves to be an excellent choice of appliance for patients with maxillary constriction in different magnitudes in the anterior and posterior regions. The presence of two screws allows the orthodontist to individualize the amount of expansion in both intermolar and intercanine regions.(GARIB; GARCIA; PEREIRA; LAURIS et al., 2014)

In cephalometric studies, RME with conventional expander promotes immediate effects of maxilla lowering, with dental alveolar extrusion in the posterior region, mandible rotation in a clockwise direction, and anterior open bite.(HAAS, 1961) These changes are temporary and responsible for the effect of increasing the facial convexity and lower anterior facial height immediate after the expansion.(HAAS, 1980) However, in long term, these changes promoted by the RME do not produce significant changes in the anteroposterior and vertical relationships between maxilla and mandible.(LAGRAVERE; MAJOR; FLORES-MIR, 2005) When cephalometric compared with the conventional expander the FE showed similar skeletal effects.(ÇÖREKÇI; GÖYENÇ, 2013) There are no cephalometric studies comparing the effects of the conventional or the FE with the EDO expander.

The maxillary constriction is generally associated with a predominantly oral breathing.(GALEOTTI; FESTA; VIARANI; D'ANTÒ et al., 2018; MELSEN; ATTINA; SANTUARI; ATTINA, 1987) The lowering of the tongue for air passage during oral breathing cause an imbalance between facial muscles that has as consequence the transverse maxilla deficiency.(GARIB; SILVA FILHO; JANSON, 2010) The RME, indicated for correction of this morphology, also has an impact on the adjacent maxilla craniofacial structures.(SILVA FILHO; CAPELLOZA FILHO; FORNAZARI; CAVASSAN, 2003) As a consequence of this change in the maxillary transverse dimension, increases in the volume of upper airways was previously reported.(CAPPELLETTE; ALVES; NAGAI; FUJITA et al., 2017; COMPADRETTI; TASCA; BONETTI, 2006)

Rapid maxillary expansion increases the space of nasal cavity, decreasing airway resistance and consequently improving breathing.(ALYESSARY; OTHMAN; YAP; RADZI et al., 2019) Therefore, the RME may has a positive impact in young patients presented with Obstructive Sleep Apnea Syndrome (OSAS).(CAMACHO;

CHANG; SONG; ABDULLATIF et al., 2017) The term OSAS describes a syndrome of upper airway dysfunction during sleep which is characterized by increased upper airway resistance and pharyngeal collapsibility and is associated with snoring and/or increased work of breathing while the child is sleeping.(JOOSTEN; LARRAMONA; MIANO; VAN WAARDENBURG et al., 2017) Individuals who have this type of breathing disorder usually have clinical signs including snoring, mouth breathing, daytime sleepiness, recurrent airway infections, otitis, sleep disorders, nocturnal enuresis, frequent nightmares and behavioral disorders such as irritability, anxiety, difficulty in consolidation of memory and concentration reduction. All of these characteristics are detrimental to the child's development.(BUCCHERI; CHINÈ; FRATTO; MANZON, 2017)

It is well accepted in the scientific community that the RME, in addition the correction of maxillary morphology and posterior crossbites, also has positive results in improving OSAS and general health of patients.(EICHENBERGER; BAUMGARTNER, 2014) Through fluid dynamics analysis of air passage in patients undergoing RME, previous studies showed that ventilation conditions of nasal airways improved after RME, and pressure in three parts of pharyngeal airway decreased during inspiration, consequently decreasing chances of obstruction.(GHONEIMA; ALBARAKATI; JIANG; KULA et al., 2015; IWASAKI; SAITOH; TAKEMOTO; INADA et al., 2013; IWASAKI; TAKEMOTO; INADA; SATO et al., 2014; IWASAKI; YANAGISAWA-MINAMI; SUGA; SHIRAZAWA et al., 2019)

As is already known, depending on the position of the screw in the expansion appliance, there is a difference in the amount of expansion between the anterior and posterior region. Therefore, this difference may also be present in the change in upper airway dimension. The conventional expander and the FE had similar effects on the nasal airway immediately after expansion. However, increases in the nasal volume were more stable in the conventional group.(SÖKÜCÜ; DORUK; UYSAL, 2010) In long term, the nasal cavity and maxillary widths were more expanded in the RME group.(ÇÖREKÇI; GÖYENÇ, 2013) There are no studies comparing the changes in upper airway dimensions including the EDO expander.

With the greater importance that literature has given to upper airways and OSAS treatment, there is a need to explore these characteristics that have not been previously evaluated. Through three-dimensional Cone Beam Computed Tomography

(CBCT) assessment, it will be possible to evaluate the upper airways with higher quality. The CBCT analysis provides an accurate for improved understanding of airway anatomy, pathology and upper airway mechanics.(OSORIO; PERILLA; DOYLE; PALOMO, 2008)

There are still no reports in the literature comparing the skeletal effects and the changes in the dimensions of the upper airways between the FE and the EDO. There are also no studies comparing skeletal changes of the maxilla and mandible between these two types of expander. Is there a cephalometric difference in the effects of the EDO and FE? Are the changes in the nasal cavity similar in the two expanders? No previous study has compared FE and EDO maxillary expanders by cephalometry analysis and nasal cavity dimensions.

2. ARTICLES

2. ARTICLES

The articles presented in this thesis were written according to the American Journal of Orthodontics and Dentofacial Orthopedics instructions and guidelines for article submission (Annexes).

2.1 Article 1 - Cephalometric evaluation of the expander with differential opening and the fan-type expander: a secondary data analysis from an RCT

2.2 Article 2 - Comparison of nasal cavity changes between the expander with differential opening and the fan-type expander: a secondary data analysis from an RCT

2.1 Article 1

Cephalometric evaluation of the expander with differential opening and the fan-type expander: a secondary data analysis from an RCT

ABSTRACT

Introduction: This study aimed to compare the sagittal and vertical cephalometric changes between the expander with differential opening (EDO) and the fan-type expander (FE). **Methods:** This study comprised CBCT-derived cephalometric images from forty-eight patients from a previous randomized clinical trial. The sample was randomly allocated into two groups. Twenty-four patients (11 male, 13 female, mean age 7.6 ± 0.9 years) were treated with rapid maxillary expansion (RME) using EDO. Twenty-four patients (10 male, 14 female, mean age 7.8 ±0.9 years) performed RME using FE. Cephalometric analysis was performed before treatment and 1 to 6 months after the active phase of RME using Dolphin Imaging Software. Intergroup comparisons of interphase changes were performed using t and Man-Whitney tests (P<0.05). **Results:** In FE group, a greater increase of SNA angle was observed after expansion compared to EDO group (P=0.043). Both expanders produced a similar downward rotation of the mandible (FMA, P=0.850). A greater palatal tip of maxillary incisors was observed in FE group (P=0.041). **Conclusions:** Both expanders produced similar vertical cephalometric changes. However, fan-type expanders caused a greater maxillary anterior displacement after expansion with a compensatory palatal tip of maxillary incisors compared to the expander with differential opening.

Keywords: Orthodontics, interceptive; Palatal expansion technique; Orthodontic appliances; Cephalometry

INTRODUCTION

Rapid Maxillary Expansion (RME) is a routine procedure to treat maxillary constrictions and posterior crossbites.[1,2] RME performed in the mixed dentition is reliable causing both transversal skeletal and dental effects.[3-5] RME has the advantages of adequate efficacy and efficiency, improving nasal respiration and decreasing symptoms of obstructive sleep apnea.[6,7] On the other hand, RME cause some vertical collateral effects including the clockwise mandibular rotation and a overbite decrease.[8]

When the maxillary constriction is concentrated in the canine region, the fan-type expander (FE) is a treatment alternative to conventional RME expanders. Using FE, the expansion effects occurs mainly in the intercanine region while the intermolar distance increase is negligible.[9,10] A previous study reported that the skeletal expansion was greater in the anterior region of the maxilla with FE.[11] On the other hand, the expander with the differential opening (EDO) permit to achieve a greater expansion in the anterior region of the dental arch compared to the intermolar expansion that also increases.[12,13] A recent three-dimensional study demonstrated that EDO promoted a greater maxillary lateral displacement than FE.[14]

Conventional RME expanders, including Haas-type and Hyrax expanders, showed a slight anterior displacement of maxilla.[15,16] RME also promoted an immediate effect of down and backward rotation of the mandible.[8,17] These mandibular position changes produced an increase of the anterior facial height and an extrusion of the posterior anchorage teeth and a decreased in the overbite were also reported as immediate RME effects.[18,19]

The cephalometric effects of FE comprised a significant forward displacement of the maxilla and a downward displacement of the mandible.[20] The palatine and mandibular plane rotated downward after FE expansion with no differences compared with conventional expanders.[21] The EDO cephalometric changes have not been previously reported.

Considering that FE and EDO cause different degrees of expansion in the posterior region of the maxillary dental arch, molar extrusion and vertical effects of RME might be different between the expanders. In addition, there is an assumption that differences in the expander designs may influence the anteroposterior position of

the maxilla. Therefore, this study aimed to compared cephalometric changes between the expander with differential opening (EDO) and the fan-type expander (FE). The null hypothesis is that both expanders present similar cephalometric effects.

MATERIAL AND METHODS

Trial design

A secondary data was obtained from a previous randomized clinical trial (RCT) registered at Clinicaltrials.gov (NCT03705871). This study was developed according to the Consolidated Standards of Reporting Trials (CONSORT) statement and guidelines. The Research Ethics Committee of Bauru Dental School, University of Sao Paulo approved the present study (protocol number: 35403520.0.0000.5417)

Participants, eligibility criteria and settings

The sample was recruited from November of 2017 to June of 2018 for a previous randomized clinical trial at the Orthodontic Clinic of Bauru Dental School, University of São Paulo, Brazil.[9,14] The eligibility criteria were patients from both sexes with age varying from 7 to 11 years with Class I and II malocclusions and posterior crossbites. Patients with craniofacial syndromes, clinical absence of maxillary deciduous canine and history of previous orthodontic treatment were excluded. Forty-eight patients composed the final sample (n=48).

Interventions

Patients were randomized into two study groups with a 1:1 allocation ratio design. EDO group comprised of twenty-four patients (11 male, 13 female, mean initial age of 7.6 ± 0.92 years) treated with the expander with differential opening (Figure 1A). The protocol activation was standardized in two-quarter turns in the morning and two-quarter turns in the evening for both screws during six days. For an additional four-day period, only the anterior screw was activated following the same protocol. The total amount of expansion was 4.8mm in the posterior screw and 8mm in the anterior screw.

FE group included twenty-four patients (10 male, 14 female, mean initial age of 7.8 ± 0.96 years) treated with the fan-type expander (Figure 1B). The screw was

activated two-quarter turns in the morning and two-quarter turns in the evening for ten days. The total amount of screw opening was 8mm.

After the active phase, in both groups, the expanders were maintained in the oral cavity for 6 months as a retention. CBCT exams were performed before (T1) and 1 to 6 months after expansion (T2). The tomographic exams were adjusted following the ADALAIP principles of low radiation dose using a 0.3 mm voxel size, FOV of 17x12 cm, 90Kvp, 7mA with a 17.5 seconds of exposure time.[22]

The CBCT images were standardized with the Frankfurt plane parallel to the horizontal plane in the lateral view. In a frontal view, the median sagittal plane was positioned perpendicular to the horizontal plane. In the axial view, the plane passing through the center of the foramen magnum and at the Crista Galli was placed perpendicular to the horizontal plane.

CBCT-derived cephalometric images were obtained and analyzed using Dolphin 3D Imaging 11.5 software (Patterson Dental Supply, Inc., Chatsworth, CA, USA). The cephalometric variables are presented in Table I.

Outcomes

The outcomes evaluated in this study were sagittal and vertical cephalometric variables.

Sample Size Calculation

A sample of 21 patients in each group was required to detect a minimum intergroup difference of 1° with a standard deviation of 1.13° for SN.GoGn angle[20], an alpha error of 5% and a test power of 80%.

Randomization

Computer-generated randomization was performed using the website Randomization.com (www.randomization.com). A different researcher prepared the allocation concealment with opaque, sealed and numbered envelopes before the trial commencement. One operator was responsible to open the envelopes and implementing the group allocation cards.

Blinding

For clinical procedures, blinding process was not possible once patients and the orthodontist were aware of the expander type that was used. However, all cephalometric images derived from CBCT scans were unidentified before analysis. Therefore, during the cephalometric analysis, the examiner was blinded.

Error study

The cephalometric analysis was repeated in 30 per cent of the sample after a 30-day interval. The examiner (R.T.) that performed the cephalometric analysis did not participate in any of the clinical procedures nor in the randomization process. The intra-rater error was calculated using Intraclass Correlation Coefficients (ICC) and Bland-Altman method.

Statistical Analyses

Normal distribution of variables was verify using Shapiro-Wilk test. Intergroup comparisons for initial age and sex ratio at baseline were performed using t-test and chi-square test, respectively. Intergroup comparisons of cephalometric changes were assessed using t and Mann-Whitney tests. The level of significance regarded was 5% with a 95% confidence interval. All statistical analyses were performed using Jamovi software, version 1.6.

RESULTS

Measurements showed an adequate reproducibility with ICC varying from 0.759 (Wits appraisal) to 0.982 (SN.GoGn angle). The variable with the greatest limits of agreement was the Wits appraisal (0.702 to 0.950). The variable with the smallest limits of agreement was IMPA (0.905 to 0.926).

There were no intergroup differences for sex and age distribution (Table II). The initial cephalometric variables were similar in both groups (Table III).

A greater increase in SNA angle was observed after expansion in FE group compared to EDO group (P=0.043). Both expanders produced a similar and slight downward rotation of the mandible (FMA, P=0.850). A greater palatal tip of maxillary incisors was observed in FE group (P=0.041) (Table IV).

DISCUSSION

CBCT-derived cephalometric images were obtained from a previous randomized clinical trial that evaluated the three-dimensional changes of FE and EDO expanders.[9] Therefore, a new radiation exposure was not necessary. CBCT scans can reproduce conventional cephalometric images with similar precision and accuracy.[23] The landmark placement in lateral cephalometric images reconstructed from CBCT scans showed reliability in previous studies.[24,25] In our study, the intra-rater agreement of cephalometric variable measurements were adequate (ICC varying from 0.759 to 0.982) with acceptable limits of agreement.[26,27]

FE promoted a greater forward displacement of the maxilla (SNA, *P*=0.043) when compared with EDO. These outcomes are in agreement with previous showing a slight maxillary advancement after expansion with FE.[14,20,21] The forward displacement of the maxilla after expansion was also reported for different RME appliances.[2,5,8,28] FE and EDO expanders have different design of transversal expansion.[9,14] While FE concentrate the force in the anterior region of the midpalatal suture, EDO seems to distribute the strain in the entire anteroposterior dimension of the midpalatal suture. On the occlusal plane, different patterns of lateral rotation of the hemi-maxilla is expected for FE and EDO expanders.[20] The V shape opening of the midpalatal suture and the center of rotation of the hemi-maxilla are probably different for both types of expander (Figure 2). FE might produce a center of rotation located at the posterior region of the maxilla close to the tuberosity (Figure 2A). The presence of the pterygoid process articulating with the maxillary tuberosity might create a movement of the maxilla toward anterior as a reaction. EDO might produce a combined rotation and translation of the hemi-maxillas. With the center of rotation located outside the maxilla toward posterior (Figure 2B), the reactional movement of maxilla forward would be smaller compared to FE.

After RME, maxilla show a downward movement, rotating the mandible toward inferior and posterior and increasing the lower anterior face height (LAFH) and.[28-30] FE and EDO groups demonstrated similar vertical changes. Both appliances increased similarly the anterior facial height (0.31 and 1.18mm) and the mandibular plane angle (1.18 and 0.32 degrees) producing a slight decrease of SNB angle (-0.81 and -0.22 degrees). Previous studies also reported a clockwise rotation of the mandible causing

an increase in the vertical dimensions immediately after RME.[28,30,31] These vertical effects were temporary with conventional RME expanders.[32,33] A study by Doruk et al.[20] showed that FE produced less vertical changes of the mandible compared to conventional expanders explained by a negligible expansion in the molar region, which might be associated with less molar extrusion during expansion.[9,20]

The palatal tip of maxillary incisors after RME had been reported in previous studies.[28,30,34] In this study, the maxillary incisors showed a greater palatal tip in the FE group compared to EDO group (1.PP, *P*=0.041). The expansion design of FE concentrating the effects in the intercanine region induces more expansion at the dentoalveolar level.[20] The greater dental expansion and buccal inclination in the canine region after FE[14] might produce an increase of the anterior arch perimeter allowing for a greater palatal tip of maxillary incisors. The greater palatal inclination of maxillary incisors in FE group might also be a compensatory mechanism of the skeletal maxillary advancement observed in this group. The mandibular incisors showed a similar changes in EDO and FE groups, which is in agreement with previous studies with conventional expansion.[19,21]

The absence of a conventional expander group was a limitation of this study. Further studies should compare the sagittal and vertical effects of EDO and conventional RME expanders. A short-term cephalometric evaluation was performed in this study. Future studies might evaluate if short-term differences are stable in the long-term. In conclusion, FE caused a greater maxillary anterior displacement compared to EDO that might be advantageous in Class III patients. Future studies comparing FE, EDO and conventional expanders before Class III early treatment with facemask therapy should be performed.

CONCLUSIONS

The null hypothesis was rejected. Fan-type expanders caused a greater maxillary anterior displacement with a compensatory palatal tip of maxillary incisors inclination compared to the expander with differential opening. Both expanders produced similar vertical cephalometric changes.

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FIGURE LEGENDS

Figure 1 – (A) Maxillary expander with differential opening. (B) Fan-type expander.

Figure 2 – (A) Center of rotation (CR) of the maxilla using the fan-type expander. (B) CR of the maxilla using the expander with differential opening.

Figure 1A

Figure 1B

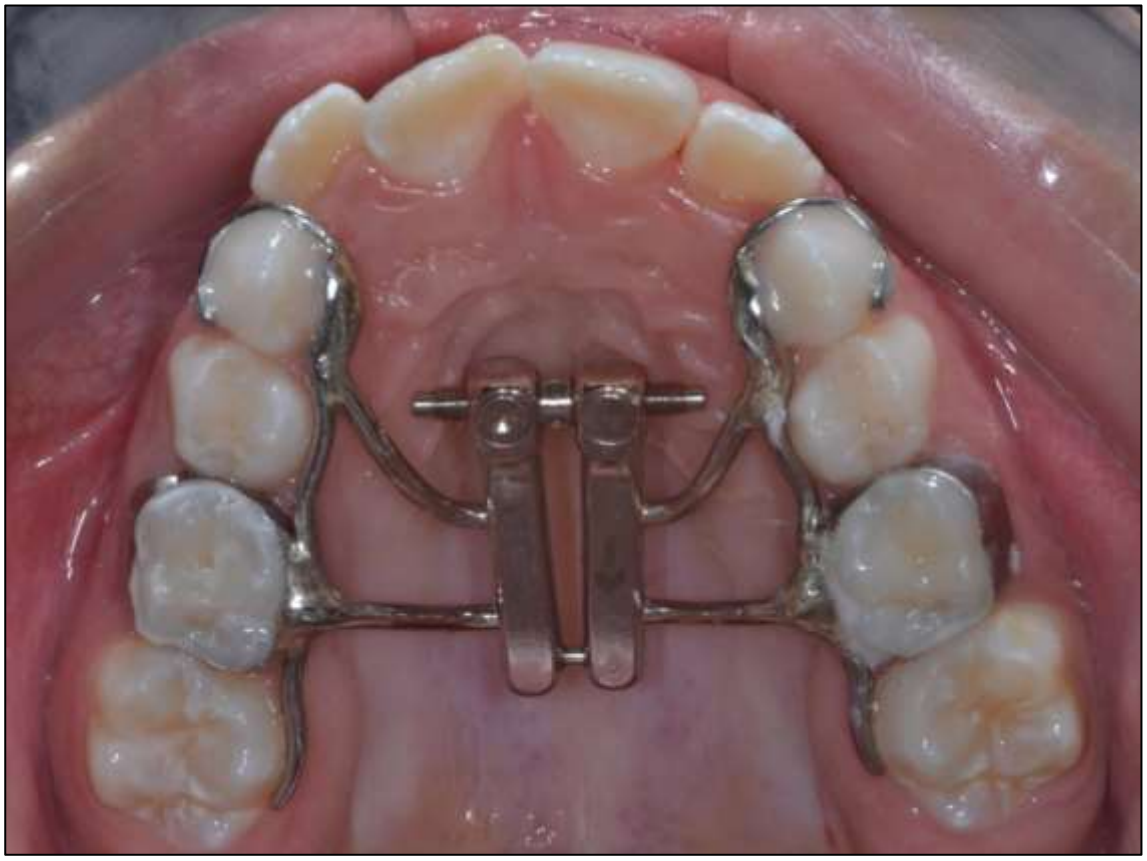

Figure 2A

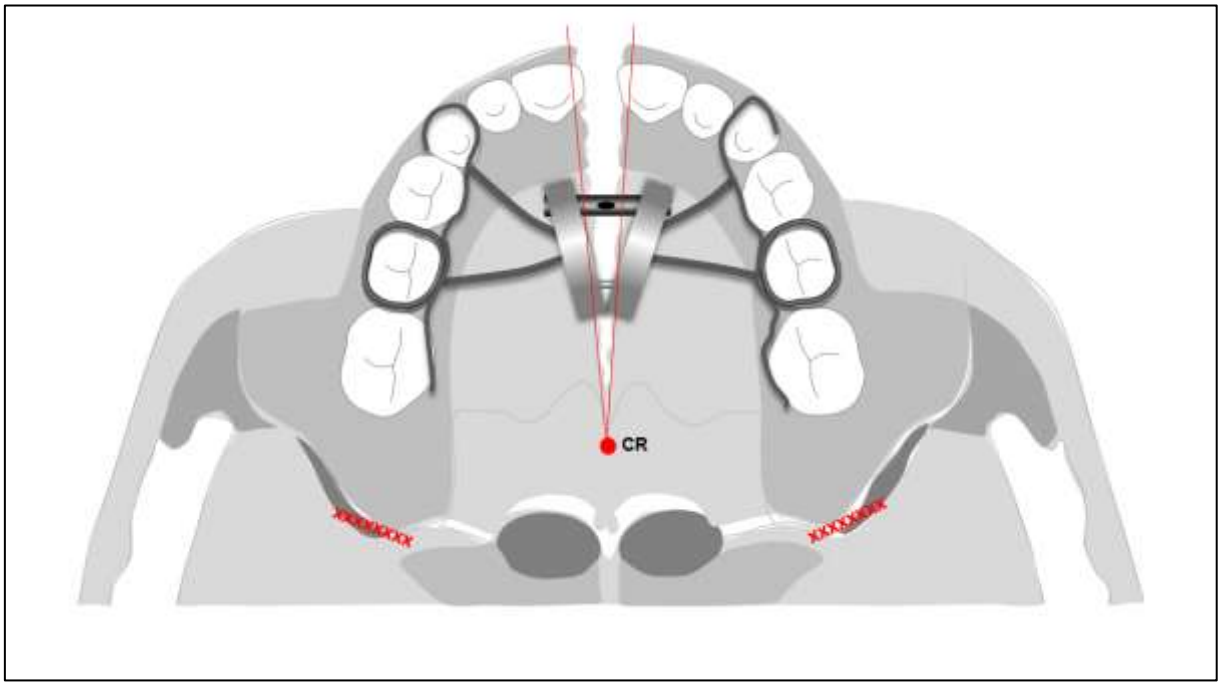

Figure 2B

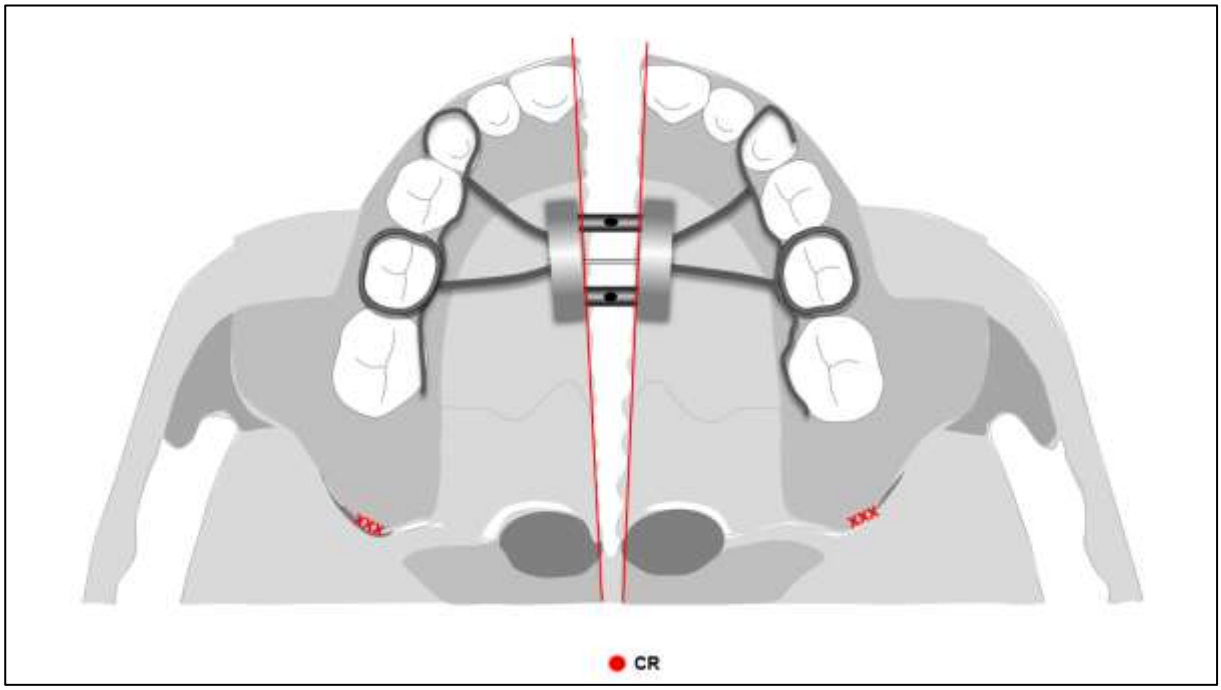

Table I - Skeletal and dentoalveolar cephalometric variables description.

Variables	Description
Maxillary Skeletal Component	
SNA (º)	SN to NA angle
A-N perp (mm)	A-point to N-perp distance
Midface Length (CoA) (mm)	Condylion to A-point distance
Mandibular Skeletal Component	
SNB (º)	SN to NB angle
Pg-N perp	Pogonion to N-perp distance
Mandibular Length (Co-Gn) (mm)	Condylion to Gnathion distance
Maxillomandibular Relationship	
Wits Appraisal (mm)	Distance between mandible and maxilla in relation to the occlusal plane
ANB (º)	NA to NB angle
Vertical Component	
SN.GoGn (º)	SN to GoGn angle
FMA (º)	Frankfurt plane to Mandibular plane angle
Lower Anterior Facial Height (LAFH) (mm)	ANS to menton
Maxilla Dental Relationship	
1.PP (º)	Maxillary incisor longa axis to NA angle
Mx1-NA (mm)	Distance between maxillary incisal to NA.
Mandible Dental Relationship	
IMPA (º)	Incisor mandibular plane angle
Md1-NA (mm)	Distance between mandibular incisal to NA

Table II - Intergroup comparison of age and sex (Mann-Whitney tests and Chi-square test, respectively).

Variable		**EDO Group**		**FE Group**		***P***
		n=24		**n=24**		
		Mean	**SD**	**Mean**	**SD**	
Initial age (years)		7.62	0.92	7.83	0.96	0.448
Sex	M	11		10		0.771
	F	13		14		

Table III - Intergroup comparison of starting forms (t tests).

Cephalometric variables	**EDO Group**		**FE Group**		**95% Confidence Interval**	***P***
	n=24		**n=24**			
	Mean	**SD**	**Mean**	**SD**		
Maxillary Skeletal Component						
SNA	83.9	4.27	82.8	3.26	-1.034, 3.376	0.291
A-Nperp	3.37	2.50	2.57	2.98	-0.802, 2.394	0.321
Co-A	81.1	3.04	81.4	3.97	-2.425, 1.683	0.718
Mandibular Skeletal Component						
SNB	79.2	3.88	78.3	3.52	-1.249, 3.057	0.402
PG-Nperp	-1.60	5.22	-2.50	5.46	-2.605, 3.597	0.749
Co-Gn	105	4.43	106	6.20	-3.618, 2.643	0.755
Maxillomandibular Relationship						
ANB	4.79	2.76	4.53	2.28	-1.207, 1.732	0.721
WITS	-1.53	2.32	-1.02	2.42	-1.896, 0.862	0.455
Vertical Component						
SNGo.Gn	33.9	4.69	33.9	5.72	-2.316, 2.049	0.903
FMA	26.5	4.53	26.0	4.01	-2.052, 4.586	0.446
LAFH	63.0	4.76	62.4	3.87	-3.067, 3.009	0.985
Dental Relationship						
1.PP	113	7.03	114	4.82	-1.979, 2.987	0.685
U1-NA	3.25	2.82	3.70	1.98	-1.866, 3.174	0.604
IMPA	89.3	4.80	89.8	5.66	-4.637, 2.370	0.518
L1-NB	4.89	1.88	4.58	2.04	-1.866, 0.966	0.526

Table IV - Intergroup comparison of interphase changes (t or Mann-Whitney tests).

Cephalometric variables	**EDO Group**		**FE Group**		**95% Confidence Interval**	***P***
	n=24		**n=24**			
	Mean	**SD**	**Mean**	**SD**		
Maxillary Skeletal Component						
SNA	0.09	1.58	1.13	1.05	-1.900, -1.585	0.043*
A-Nperp	0.68	1.25	0.79	0.88	-0.732, 0.524	0.740
Co-A	0.79	1.57	1.30	1.09	-1.288, 0.280	0.202
Mandibular Skeletal Component						
SNB	-0.81	1.55	-0.22	1.25	-1.407, 0.224	0.151
Pg-Nperp	-0.50	2.28	-0.76	2.28	-1.066, 1.583	0.696
Co-Gn	0.48	1.44	0.47	1.22	-0.766, 0.783	0.983
Maxillomandibular Relationship						
ANB	0.90	1.50	1.33	1.24	-1.219, 0.378	0.294
WITS	0.65	1.56	1.31	1.62	-1.572, 0.272	0.163
Vertical Component						
SNGo.Gn	1.18	2.30	0.32	1.52	-0.282, 1.982	0.138
FMA	0.48	1.67	0.57	1.52	-1.015, 0.840	0.850
LAFH	0.31	2.43	1.18	1.66	-2.065, 0.349	0.159
Dental Relationship						
1.PP	-0.97	1.86	-2.29	2.42	0.052, 2.564	0.041 †
U1-NA	-0.71	0.66	-1.00	1.15	-0.256, 0.832	0.293
IMPA	-1.16	2.11	-1.32	2.11	-1.064, 1.390	0.791
L1-NB	-0.22	0.73	-0.19	0.53	-0.410, 0.400	0.840

* Statistically significant at *P*<0.05 (t tests).

† Statistically significant at *P*<0.05 (Mann-Whitney test).

2.2 Article 2

Comparison of nasal cavity changes between the expander with differential opening and the fan-type expander: a secondary data analysis from an RCT

ABSTRACT

Introduction: The aim of this study was to compare the nasal cavity skeletal changes between the expander with differential opening (EDO) and the fan-type expander (FE). **Methods:** This study was a secondary analysis of a previous randomized clinical trial. Forty-eight patients with posterior crossbite were randomly allocated into two study groups. Twenty-four patients (11 male, 13 female) with a mean initial age of 7.6 ± 0.9 years were treated with rapid maxillary expansion (RME) using the EDO. Twenty-four patients (10 male, 14 female) with a mean initial age of 7.8 ± 0.9 years were treated with the FE. Cone-beam computed tomography (CBCT) was performed before treatment and 1 to 6 months after the active phase of RME. Using frontal CBCT slices passing at the level of permanent first molars and deciduous canines, the width of the nasal cavity was measured in the lower, middle and upper thirds. Nasal cavity height was also evaluated in both regions. Intergroup comparisons of interphase changes were performed using t or Mann-Whitney tests (P<0.05). **Results:** The two groups were similar regarding baseline data. EDO showed a greater transverse increase in the lower third of the nasal cavity in both canine (P=0.007) and molar regions (P<0.001). No intergroup difference was observed for changes in nasal cavity middle and upper widths and height. **Conclusions:** Both expanders are effective in promoting an increase of the nasal cavity skeletal dimensions. The expander with differential opening produced a greater transverse increase in the lower third of the nasal cavity compared to the fan-type expander, both at the anterior and posterior region of the maxilla.

Keywords: Palatal expansion technique, posterior crossbite, upper airway, cone beam computed tomograph

INTRODUCTION

Transverse maxillary constriction is a frequent condition in the mixed dentition with a prevalence rate of 17% at 7 years of age.[1] Pre-adolescent treatment of posterior crossbite can be performed with rapid maxillary expansion (RME).[2-4] In the mixed dentition, the conventional Haas-type expander produced a nasal and maxillary width increase.[5] The skeletal effect of RME in the mixed dentition was approximately 50% of the amount of screw expansion.[6] Conventional RME expanders also caused a maxillary downward displacement, increasing the nasal cavity height.[7,8]

The maxillary constriction and posterior crossbites were associated with a predominantly oral respiration and sleep disorders in pediatric patients.[9-11] The RME procedure has the advantage of influencing the maxilla craniofacial structures increasing the nasal cavity dimensions.[12] Increases in the volume of upper airways after RME was previously reported.[5,12] RME increased the space of nasal cavity, decreasing airway resistance and improving nasal respiration.[13] RME also improved Obstructive Sleep Apnea Syndrome (OSAS) in pediatric patients decreasing the apnea-hypopnea index (AHI) and increasing blood oxygen saturation.[14,15]

According to the morphology of the maxillary constriction, different amount of expansion might be required in the anterior and posterior regions of the dental arch.[16] The fan-type expander (FE) have an anterior screw and a posterior hinge producing greater increases in the intercanine region. In the molar regions, the fan-type expander produced only a negligible expansion.[17,18] Fan-type expanders are indicated for maxillary constrictions located in the canine region with adequate intermolar width.[19]

The expander with differential opening (EDO) is composed of two screws located in the anterior and posterior regions of the palate.[20] The EDO promoted a greater orthopedic and dental changes in the anterior region of the maxilla than the conventional expander.[21] When compared with the FE, EDO showed a greater expansion in the posterior region of the maxillary dental arch.[18] EDO is indicated when transverse deficiency is observed in both molar and canine regions, however a greater amount of expansion is needed in the canine region. No previous study evaluated the changes in the nasal cavity dimensions after RME with EDO and FE expanders. between the FE and EDO. The null hypothesis is that both expanders present similar increases in the width and height of the nasal cavity.

Therefore, the aim of this study was to compare the nasal cavity dimensional changes between the FE and EDO. The null hypothesis is that both expanders present similar increases in the width and height of the nasal cavity.

MATERIAL AND METHODS

Trial Design

This study comprised a secondary data analysis from a previous randomized clinical trial (RCT). The trial had a 1:1 allocation ratio design and was registered at Clinicaltrials.gov (NCT03705871). The Consolidated Standards of Reporting Trials (CONSORT) statement and guidelines were followed with no changes after trial commencement. Ethical approved was obtained from the Research Ethics Committee of Bauru Dental School, University of Sao Paulo (protocol number: 35403520.0.0000.5417)

Participants, eligibility criteria and settings

Patients with Class I and II malocclusions and posterior crossbites from both sexes with age varying between 7 and 11 years were recruited at the Orthodontic Clinic of Bauru Dental School, University of São Paulo, Brazil. The sample selection was performed from November 2017 to June 2018 for a previous randomized clinical trial.[18,22] The exclusion criteria were Class III malocclusion, craniofacial syndromes, clinical absence of maxillary deciduous canines and history of previous orthodontic treatment. The final sample size was composed of forty-eight patients (n=48).

Interventions

The EDO group included 24 patients (11 male, 13 female) with a mean initial age of 7.6 ± 0.92 years, treated with the expander with differential opening (Figure 1A). Both expanders screws were concurrently activated two-quarter turns in the morning and two-quarter turns in the evening for 6 days. For an additional period of 4 days, only the anterior screw was activated following the same protocol. The amount of expansion was 4.8 mm in the posterior screw and 8 mm in the anterior screw.

The FE group included 24 patients (10 male, 14 female) with a mean initial age of 7.8 ± 0.96 years, treated with the expander with fan-type opening (Figure 1B). The

screw activation comprised two-quarter turns in the morning and two-quarter turns in the evening for 10 days, resulting in an expansion of 8 mm in the screw. In both groups, the expander was maintained in the oral cavity for 6 months as a retention.

CBCT exams were obtained before treatment (T1) and 1 to 6 months after the active phase of RME (T2). The image acquisition protocol was 90Kvp, 7mA, FOV 17x12cm, 17.5 seconds of exposure time and voxel size of 0.3mm. The acquisition protocol was adjusted to decrease the radiation exposure as much as possible without compromising image assessment.[23]

In the Dolphin 3D Imaging 11.5 software (Patterson Dental Supply, Inc., Chatsworth, CA, USA), all CBCT scans were standardized with the Frankfurt plane parallel to the horizontal plane and the median sagittal plane perpendicular to the horizontal plane. In the axial view, the plane passing through the center of the foramen magnum and at the Crista Galli was placed perpendicular to the horizontal plane.

Two coronal sections were obtained for each patient at T1 and T2. The anterior coronal section passed at the root canal of the right maxillary deciduous canine (Figure 2A). The posterior coronal section passed at the center of the palatine root canal of the right permanent maxillary first molar (Figure 2B).

The nasal cavity widths at the lower, middle and upper thirds were measured according to a previous study.[24] The nasal height was measured from the upper to the lower limits of the nasal cavity middle region as shown in Figure 2C.

Outcomes

The outcomes evaluated in this study were changes in the nasal cavity width and height after RME.

Sample Size Calculation

The sample size calculation was performed considering an alpha error of 5% and test power of 80%. For a standard deviation of 1.08mm in the lower third of the nasal cavity[24] and considering a minimum difference of 1 mm between groups, a sample of 19 patients was required for each group.

Randomization

The randomization was performed using the website Randomization.com (www.randomization.com). Allocation concealment was achieved with opaque, sealed and numbered envelopes, containing the group allocation cards. The randomization, allocation concealment and implementation processes were conducted by different researchers.

Blinding

CBCT images were de-identified before analysis. However, approximately 50% of the post expansion CBCT scans were performed with the expander in the oral cavity. Therefore, the examiner was not completely blinded to the type of expander.

Error study

All measurements were performed by the same examiner (R.T.) and 30 per cent of the sample was evaluated twice after a 30-day interval. The examiner has not participated in any of the clinical steps nor in the randomization process. The intra-rater error was calculated using Intraclass Correlation Coefficients (ICC) and Bland-Altman method.

Statistical Analyses

Shapiro-Wilk tests was used to verify the normal distribution of the variables. Intergroup initial age and sex ratio at baseline were assessed with t-test and chi-square test, respectively. Intergroup comparison for nasal cavity changes was performed using t or Mann-Whitney tests. The level of significance regarded was 5%. All statistical analyses were performed using Jamovi software, version 1.6.

RESULTS

Measurements showed an excellent reproducibility[25] with ICC varying from 0.923 (Anterior Nasal Height) to 0.991 (Posterior Lower Width). The variable with the greater limit of agreement was the Anterior Nasal Height (0.712 to 0.942). The variable with the smallest limit of agreement was the Posterior Lower Width of the nasal cavity (0.956 to 0.991).

Groups were similar regarding sex and age distribution (Table I). Pre-expansion (T1) variables were comparable in both groups (Table II). FE and EDO caused an increase in the nasal cavity widths and height in both anterior and posterior regions (Table III). The EDO promoted a significantly greater increase in the lower third of nasal cavity when compared to the FE at both anterior (mean difference of 0.66 mm; P=0.007) and posterior (mean difference of 1.11 mm; P<0.001) maxillary regions (Table III).

DISCUSSION

This study evaluated secondary outcomes of a previous randomized clinical trial.[22] CBCT images previously showed an adequate accuracy and reliability for measuring the nasal cavity dimensions.[26] The nasal cavity has several morphological irregularities that make measurements challenging.[27] On the other hand, measurement standardization and CBCT image sharpness allowed the performance of reliable measurements.[28] Our results showed an acceptable degree for intra-rater agreement with acceptable limits of agreement.[25,29] The CBCT scans were acquired for a previous study and the image acquisition protocol was adjusted to decrease the radiation exposure as much as possible without compromising the image quality.[23] One methodological limitation of this study was that post expansion CBCT images was not blinded because some patients have not removed the expander before the T2 CBCT exam. For this reason, results should be considered with caution.

Previous studies evaluating the effect of RME on the nasal cavity used conventional Haas-type and Hyrax expanders.[30-32] Conventional RME expanders produced a significant increase in the nasal cavity transverse dimensions with a greater increase in the lower portion of nasal cavity. The influence of EDO and FE in

the nasal cavity width and height was not previously described. In this study, both expanders promoted an increase in the nasal cavity dimensions. However, the EDO produced a greater transverse increase in the anterior and posterior regions of the lower third of the nasal cavity (Table III). The EDO increased the lower third of the nasal cavity more than the FE by 30% and 90% in the anterior and posterior region, respectively. These results are in accordance with a recent study reporting that EDO produced a greater transverse maxillary expansion compared with the FE.[22] The possible explanation for differences in nasal cavity transverse increase between both expanders is the activation of posterior screw in EDO that might have produced a greater opening of the midpalatal suture.

The height of nasal cavity increased after RME with no intergroup differences (Table III). These outcomes are in agreement with previous studies with conventional expanders that found an increase in the in the nasal cavity height.[26,30] Rapid maxillary expansion rotates the maxillary halves toward lateral displacing the hard palate downward.[8] The inferior displacement of the palatal shelves after expansion was also observed in animal studies.[33] The lower movement of the hard palate elongate the nasal cavity height. Both types of expanders, EDO and FE, caused the same previously reported outcomes.

The nasal cavity width and height increase after RME might influence the functional aspects of respiration and quality of sleep. The limitation of this study was that only a morphological assessment was performed. Studies with acoustic rhinomanometry showed that nasal airway resistance decreased after RME.[12,34,35] The increases in the nasal cavity dimensions can restore a normal nasal airflow causing an improvement of child general health.[36,37]

The nasal cavity enlargement after RME also influence more serious disorders as pediatric obstructive sleep apnea (OSA).[38,39] RME provided at least a 50% reduction in the AHI and an improvement of mean oxygen saturation in children with OSA.[15] The reduction of AHI index after RME was stable in the long-term.[40] EDO produced a greater increase of nasal cavity width than FE. Therefore, EDO might be more beneficial to pediatric patients with oral respiration and obstructive sleep apnea compared to FE. These assumptions should be confirmed in future studies comparing the functional parameters after RME with EDO and FE.

CONCLUSIONS

The expander with differential opening caused a greater increase in the lower level of the nasal cavity compared to fan-type expander both at the anterior and posterior regions. The increase in the middle and upper nasal widths and nasal height were similar between both expanders.

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FIGURE LEGENDS

Figure 1 – (A) Maxillary expander with differential opening. (B) Fan-type expander.

Figure 2 – (A) CBCT coronal section at the level of maxillary deciduous canine. (B) Coronal section at the level of permanent maxillary first molar. (C) Nasal cavity widths and height.

Figure 1A

Figure 1B

Figure 2A

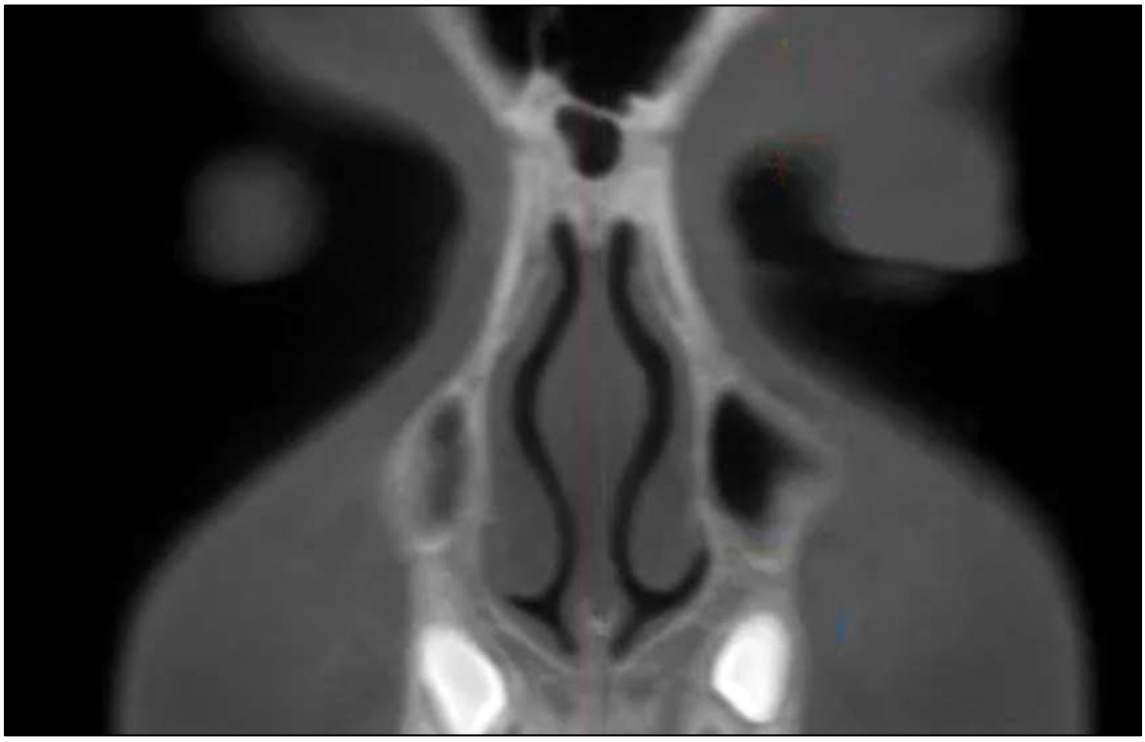

Figure 2B

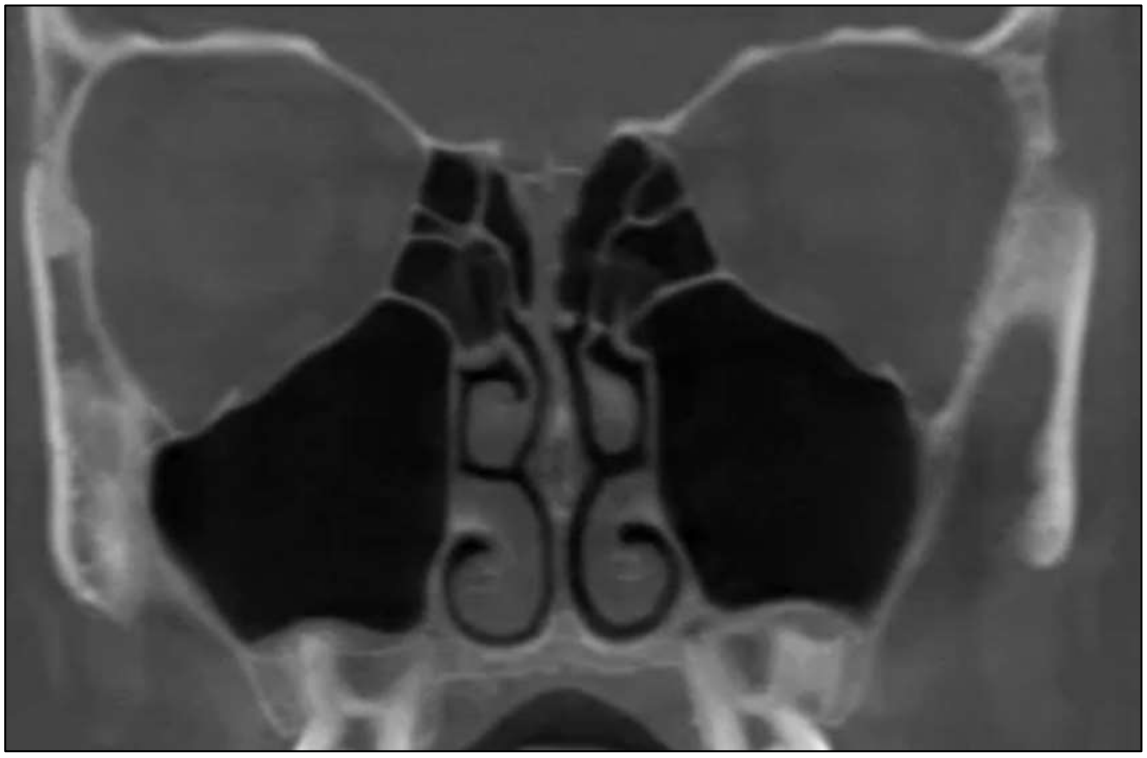

Figure 2C

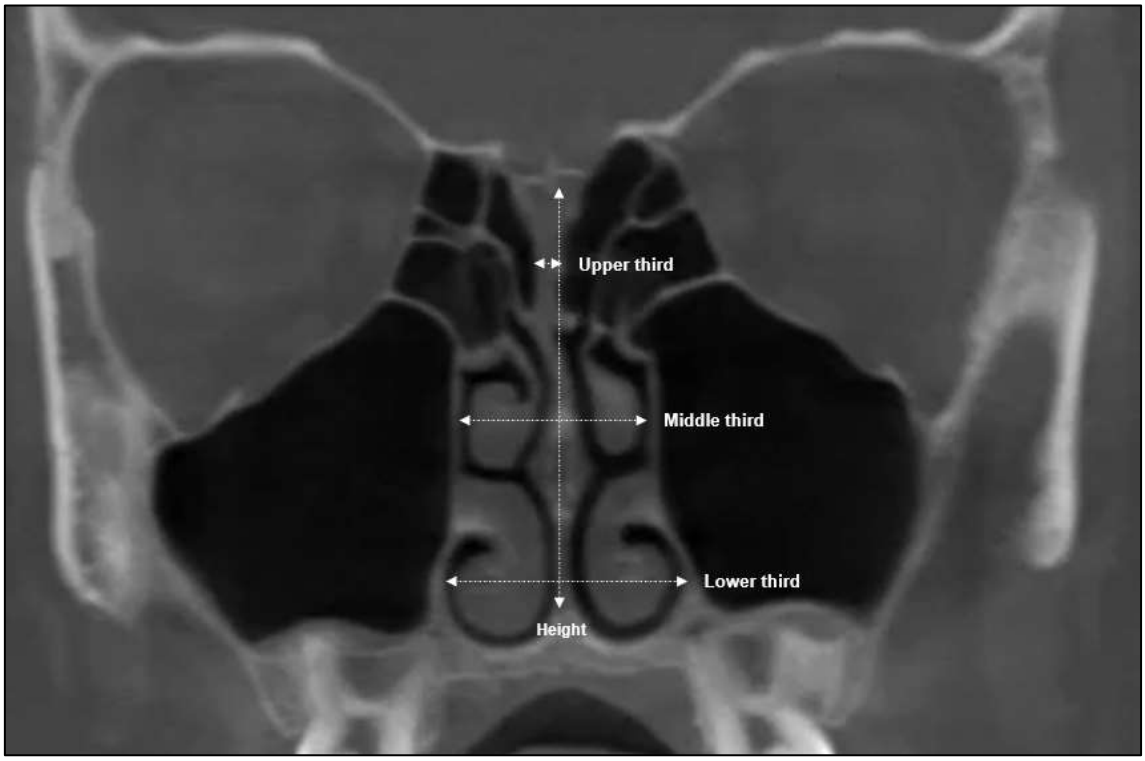

Table I - Intergroup comparison of age and sex (Mann-Whitney tests and Chi-square test, respectively).

Variable		**EDO Group**		**FE Group**		***P***
		n=24		**n=24**		
		Mean	**SD**	**Mean**	**SD**	
Initial age (years)		7.62	0.92	7.83	0.96	0.448
Sex	M	11		10		0.771
	F	13		14		

Table II - Intergroup comparison of starting forms (t or Mann-Whitney tests).

Linear distances	EDO Group n=24		FE Group n=24		95% Confidence Interval	*P*
	Mean	**SD**	**Mean**	**SD**		
Anterior Region						
Upper width	10.32	2.83	10.75	1.84	-1.780, 0.991	0.568
Middle width	21.11	1.78	19.73	1.52	-0.567, 1.360	0.412
Lower width	22.02	1.69	21.38	1.31	-0.211, 1.540	0.133
Height	31.42	2.39	31.51	1.99	-1.500, 0.800	0.458
Posterior Region						
Upper width	3.61	0.80	4.16	0.92	-0.800, 0.099	0.090
Middle width	20.18	2.61	21.11	2.32	-2.540, 0.336	0.130
Lower width	26.45	2.20	25.98	1.82	-0.677, 1.670	0.399
Height	31.74	3.83	31.93	2.66	-1.900, 1.000	0.688

Table III - Intergroup comparison of interphase changes (t or Mann-Whitney tests).

Linear distances	EDO Group n=24		FE Group n=24		95% Confidence Interval	*P*
	Mean	SD	Mean	SD		
Anterior Region						
Upper width	1.53	1.55	1.19	0.87	-0.300, 0.800	0.363
Middle width	2.19	1.08	1.63	0.69	-4.480, 0.900	0.056
Lower width	2.76	0.89	2.10	0.74	0.188, 1.140	0.007*
Height	1.04	1.55	0.72	0.76	-0.300, 1.100	0.326
Posterior Region						
Upper width	0.33	0.46	0.13	0.20	-0.009, 0.409	0.061
Middle width	1.02	0.72	0.62	0.58	-4.460, 0.800	0.057
Lower width	2.33	0.76	1.22	0.54	0.727, 1.500	<0.001†
Height	1.26	1.55	1.49	1.13	-1.000, 0.500	0.470

* Statistically significant at $P<0.05$ (t tests).
† Statistically significant at $P<0.05$ (Mann-Whitney test).

3. DISCUSSION

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Methods

This study evaluated secondary outcomes of a previous randomized clinical trial.(MASSARO; GARIB; CEVIDANES; JANSON et al., 2021) Therefore, a new radiation exposure was not necessary. The CBCT scans were acquired and the image acquisition protocol was adjusted to decrease the radiation exposure as much as possible without compromising the image quality.(OENNING; JACOBS; PAUWELS; STRATIS et al., 2018) CBCT-derived cephalometric images were obtained from a previous randomized clinical trial that evaluated the three-dimensional changes of FE and EDO expanders.(MASSARO; JANSON; MIRANDA; ALIAGA-DEL CASTILLO et al., 2021) CBCT images previously showed an adequate accuracy and reliability for measuring the nasal cavity dimensions.(WEISSHEIMER; DE MENEZES; MEZOMO; DIAS et al., 2011) The nasal cavity has several morphological irregularities that make measurements challenging.(PARKS, 2014) On the other hand, measurement standardization and CBCT image sharpness allowed the performance of reliable measurements.(NIU; MADHAN; CORNELIS; CATTANEO, 2021) CBCT scans can reproduce conventional cephalometric images with similar precision and accuracy.(KUMAR; LUDLOW; MOL; CEVIDANES, 2007) The landmark placement in lateral cephalometric images reconstructed from CBCT scans showed reliability in previous studies.(CEVIDANES; OLIVEIRA; MOTTA; PHILLIPS et al., 2009; CHANG; HU; LAI; YAO et al., 2011) Our results showed an acceptable degree for intra-rater agreement with acceptable limits of agreement.(KOO; LI, 2016; PANDIS, 2021)

Cephalometric changes

FE promoted a greater forward displacement of the maxilla and a greater palatal tip when compared to EDO group. These outcomes are in agreement with previous showing a slight maxillary advancement after expansion with FE and a palatal tip of maxillary incisors after RME.(ADKINS; NANDA; CURRIER, 1990; ÇÖREKÇI; GÖYENÇ, 2013; DORUK; BICAKCI; BASCIFTCI; AGAR et al., 2004; MASSARO; GARIB; CEVIDANES; JANSON et al., 2021; SARVER; JOHNSTON, 1989; WERTZ,

1970) The forward displacement of the maxilla after expansion was also reported for different RME appliances.(BUCCI; D'ANTÒ; RONGO; VALLETTA et al., 2016; HAAS, 1965; WEISSHEIMER; DE MENEZES; MEZOMO; DIAS et al., 2011; WERTZ, 1970) FE and EDO expanders have different design of transversal expansion.(MASSARO; GARIB; CEVIDANES; JANSON et al., 2021; MASSARO; JANSON; MIRANDA; ALIAGA-DEL CASTILLO et al., 2021) The expansion design of FE concentrating the effects in the intercanine region induces more expansion at the dentoalveolar level.(DORUK; BICAKCI; BASCIFTCI; AGAR et al., 2004) While FE concentrate the force in the anterior region of the midpalatal suture, EDO seems to distribute the strain in the entire anteroposterior dimension of the midpalatal suture. In the occlusal plane, different patterns of lateral rotation of the hemi-maxilla is expected for FE and EDO expanders.(DORUK; BICAKCI; BASCIFTCI; AGAR et al., 2004)

The V shape opening of the midpalatal suture and the center of rotation of the hemi-maxilla are probably different for both types of expander. FE might produce a center of rotation located at the posterior region of the maxilla close to the tuberosity. The presence of the pterygoid process articulating with the maxillary tuberosity might create a movement of the maxilla toward anterior as a reaction. EDO might produce a combined rotation and translation of the hemi-maxillas. With the center of rotation located outside the maxilla toward posterior, the reactional movement of maxilla forward would be smaller compared to FE. The greater dental expansion and buccal inclination in the canine region after FE(MASSARO; GARIB; CEVIDANES; JANSON et al., 2021) might produce an increase of the anterior arch perimeter allowing for a greater palatal tip of maxillary incisors. The greater palatal inclination of maxillary incisors in FE group might also be a compensatory mechanism of the skeletal maxillary advancement observed in this group. The mandibular incisors showed a similar changes in EDO and FE groups, which is in agreement with previous studies with conventional expansion.(ÇÖREKÇI; GÖYENÇ, 2013; FARRONATO; MASPERO; ESPOSITO; BRIGUGLIO et al., 2011)

After RME, maxilla show a downward movement, rotating the mandible toward inferior and posterior and increasing the lower anterior face height (LAFH) and.(BYRUM, 1971; SARVER; JOHNSTON, 1989; WERTZ, 1970) FE and EDO groups demonstrated similar vertical changes. Both appliances increased similarly the anterior facial height and the mandibular plane angle producing a slight decrease of SNB angle. Previous studies also reported a clockwise rotation of the mandible

causing an increase in the vertical dimensions immediately after RME.(LEONARDI; ABOULAZM; GIUDICE; RONSIVALLE et al., 2021; SARVER; JOHNSTON, 1989; WERTZ, 1970) These vertical effects were temporary with conventional RME expanders.(CHANG; MCNAMARA; HERBERGER, 1997; GARIB; HENRIQUES; JANSON; FREITAS et al., 2005) A study by Doruk et al.(DORUK; BICAKCI; BASCIFTCI; AGAR et al., 2004) showed that FE produced less vertical changes of the mandible compared to conventional expanders explained by a negligible expansion in the molar region, which might be associated with less molar extrusion during expansion. (DORUK; BICAKCI; BASCIFTCI; AGAR et al., 2004; MASSARO; JANSON; MIRANDA; ALIAGA-DEL CASTILLO et al., 2021)

The palatal tip of maxillary incisors after RME had been reported in previous studies.(ADKINS; NANDA; CURRIER, 1990; SARVER; JOHNSTON, 1989; WERTZ, 1970) In this study, the maxillary incisors showed a greater palatal tip in the FE group compared to EDO group. The expansion design of FE concentrating the effects in the intercanine region induces more expansion at the dentoalveolar level.(DORUK; BICAKCI; BASCIFTCI; AGAR et al., 2004) The greater dental expansion and buccal inclination in the canine region after FE(MASSARO; GARIB; CEVIDANES; JANSON et al., 2021) might produce an increase of the anterior arch perimeter allowing for a greater palatal tip of maxillary incisors. The greater palatal inclination of maxillary incisors in FE group might also be a compensatory mechanism of the skeletal maxillary advancement observed in this group. The mandibular incisors showed a similar changes in EDO and FE groups, which is in agreement with previous studies with conventional expansion.(ÇÖREKÇI; GÖYENÇ, 2013; FARRONATO; MASPERO; ESPOSITO; BRIGUGLIO et al., 2011)

Nasal Cavity Changes

Conventional RME expanders produced a significant increase in the nasal cavity transverse dimensions with a greater increase in the lower portion of nasal cavity .Previous studies evaluating the effect of RME on the nasal cavity used conventional Haas-type and Hyrax expanders.(CALDAS; TAKESHITA; MACHADO; BITTENCOURT, 2020; CORDASCO; NUCERA; FASTUCA; MATARESE et al., 2012; MASPERO; GALBIATI; DEL ROSSO; FARRONATO et al., 2019) The influence of

EDO and FE in the nasal cavity width and height was not previously described. In this study, both expanders promoted an increase in the nasal cavity dimensions. However, the EDO produced a greater transverse increase in the anterior and posterior regions of the lower third of the nasal cavity. The EDO increased the lower third of the nasal cavity more than the FE by 30% and 90% in the anterior and posterior region, respectively. These results are in accordance with a recent study reporting that EDO produced a greater transverse maxillary expansion compared with the FE.(MASSARO; GARIB; CEVIDANES; JANSON et al., 2021) The possible explanation for differences in nasal cavity transverse increase between both expanders is the activation of posterior screw in EDO that might have produced a greater opening of the midpalatal suture.

The nasal cavity width and height increase after RME might influence the functional aspects of respiration and quality of sleep. The limitation of this study was that only a morphological assessment was performed. Studies with acoustic rhinomanometry showed that nasal airway resistance decreased after RME.(COMPADRETTI; TASCA; BONETTI, 2006; HERSHEY; STEWART; WARREN, 1976; SCHÜTZ-FRANSSON; KUROL, 2008) The increases in the nasal cavity dimensions can restore a normal nasal airflow causing an improvement of child general health.(MCNAMARA; LIONE; FRANCHI; ANGELIERI et al., 2015; PIRELLI; FIASCHETTI; FANUCCI; GIANCOTTI et al., 2021) The height of nasal cavity increased after RME with no intergroup differences. These outcomes are in agreement with previous studies with conventional expanders that found an increase in the in the nasal cavity height.(MASPERO; GALBIATI; DEL ROSSO; FARRONATO et al., 2019; WEISSHEIMER; DE MENEZES; MEZOMO; DIAS et al., 2011) Rapid maxillary expansion rotates the maxillary halves toward lateral displacing the hard palate downward.(WERTZ, 1970) The inferior displacement of the palatal shelves after expansion was also observed in animal studies.(STARNBACH; BAYNE; CLEALL; SUBTELNY, 1966) The lower movement of the hard palate elongate the nasal cavity height. Both types of expanders, EDO and FE, caused the same previously reported outcomes.

The nasal cavity enlargement after RME also influence more serious disorders as pediatric obstructive sleep apnea (OSA).(MACHADO-JÚNIOR; ZANCANELLA; CRESPO, 2016; MARINO; RANIERI; CHIAROTTI; VILLA et al., 2012) RME provided at least a 50% reduction in the AHI and an improvement of mean oxygen saturation in

children with OSA.(CAMACHO; CHANG; SONG; ABDULLATIF et al., 2017) The reduction of AHI index after RME was stable in the long-term.(PIRELLI; SAPONARA; GUILLEMINAULT, 2015) EDO produced a greater increase of nasal cavity width than FE. The nasal cavity width and height increase after RME might influence the functional aspects of respiration and quality of sleep. Studies with acoustic rhinomanometry showed that nasal airway resistance decreased after RME.(COMPADRETTI; TASCA; BONETTI, 2006; HERSHEY; STEWART; WARREN, 1976; SCHÜTZ-FRANSSON; KUROL, 2008) The increases in the nasal cavity dimensions can restore a normal nasal airflow causing an improvement of child general health.(MCNAMARA; LIONE; FRANCHI; ANGELIERI et al., 2015; PIRELLI; FIASCHETTI; FANUCCI; GIANCOTTI et al., 2021) Therefore,

Limitations

The limitation of this study was the absence of a conventional expander group and only a morphological assessment was performed. In conclusion, FE caused a greater maxillary anterior displacement compared to EDO that might be advantageous in Class III patients. Future studies comparing FE, EDO and conventional expanders before Class III early treatment with facemask therapy should be performed. EDO might be more beneficial to pediatric patients with oral respiration and obstructive sleep apnea compared to FE. These assumptions should be confirmed in future studies comparing the functional parameters and the sagittal and vertical effects of EDO and conventional RME expanders.

4. CONCLUSIONS

4. CONCLUSIONS

The null hypothesis was rejected. Fan-type expanders caused a greater maxillary anterior displacement with a compensatory palatal tip of maxillary incisors inclination compared to the expander with differential opening. Both expanders produced similar vertical cephalometric changes.

The expander with differential opening caused a greater increase in the lower level of the nasal cavity compared to fan-type expander both at the anterior and posterior regions. The increase in the middle and upper nasal widths and nasal height were similar between both expanders.

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ANNEXES

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PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Expansor maxilar com abertura diferencial versus com abertura em leque: uma avaliação cefalométrica e de vias aéreas

Pesquisador: Rodrigo Almeida Nunes Teixeira

Área Temática:

Versão: 1

CAAE: 35403520.0.0000.5417

Instituição Proponente: Universidade de Sao Paulo

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 4.209.386

Apresentação do Projeto:

Trata-se de um projeto intitulado "Expansor maxilar com abertura diferencial versus com abertura em leque: uma avaliação cefalométrica e de vias aéreas", tendo como responsável principal Rodrigo Almeida Nunes Teixeira, e equipe de pesquisa composta por Camila da Silveira Massaro e Daniela Gamba Garib. Trata-se de uma dissertação de mestrado na qual os pesquisadores pretendem comparar os efeitos dento esqueléticos e as alterações nas vias aéreas superiores do expansor maxilar com abertura diferencial e em leque, em pacientes ortodônticos na fase de dentadura mista por meio de tomografia computadorizada cone -beam (TCCB). O estudo será conduzido a partir de uma análise secundária de dados de uma amostra já existente obtida em um estudo clínico randomizado prévio (CAAE 71648917.6.0000.5417). Esses dados estão nos prontuários que se encontram arquivados no arquivo de Documentação da Disciplina de Ortodontia da FOB-USP. A amostra consiste na análise de prontuários de 48 pacientes, de ambos os sexos, com idade entre 7 e 10 anos e com deficiência transversa da maxila. Os pacientes foram randomizados em dois grandes grupos experimentais. O primeiro grupo consiste em 24 indivíduos tratados com expansão rápida da maxila (ERM) com o expansor com abertura diferencial (GED). O segundo grupo é composto por 24 indivíduos tratados com o expansor com abertura em leque (GEL). Em 12 pacientes de cada grupo (subgrupos imediatos), a TCCB foi realizada antes do início do tratamento (T1) e imediatamente após a ERM (T2). Nos demais 12 pacientes de cada grupo (subgrupos tardios), a TCCB foi obtida em T1 e 6 meses após a ERM (T3).

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A análise das alterações cefalométricas será composta por 16 variáveis angulares e lineares e será realizada no software Dolphin 3D (California, USA). As alterações nas vias aéreas serão avaliadas por meio da mensuração das distâncias entre as paredes da cavidade nasal, no software Dolphin 3D, e por meio da análise fluidodinâmica no software Mimics 13 (Materialise, BEL). As comparações intergrupos serão avaliadas por meio dos testes t ou Mann Whitney ($p<0,05$).

Objetivo da Pesquisa:

Hipótese:

A hipótese nula é de que não há diferença entre os efeitos obtidos com os dois protocolos de expansão.

Objetivo Primário:

O objetivo do presente estudo será comparar os efeitos dento esqueléticos e as alterações nas vias aéreas superiores da expansão rápida maxila realizada com o expansor com abertura diferencial e com o expansor com abertura em leque..

Avaliação dos Riscos e Benefícios:

Hipótese:

A hipótese nula é de que não há diferença entre os efeitos obtidos com os dois protocolos de expansão.

Objetivo Primário:

O objetivo do presente estudo será comparar os efeitos dento esqueléticos e as alterações nas vias aéreas superiores da expansão rápida maxila realizada com o expansor com abertura diferencial e com o expansor com abertura em leque..

Comentários e Considerações sobre a Pesquisa:

Trata-se de uma pesquisa bem interessante na qual com os resultados obtidos poderá se mostrar mais detalhes e diferenças dos efeitos dento esqueléticos produzidos pelo expansor maxilar com abertura diferencial e pelo expansor com abertura em leque além dos efeitos na dimensão das vias aéreas.

Considerações sobre os Termos de apresentação obrigatória:

Foram apresentados todos os documentos necessários para que seja avaliada a presente pesquisa. Ou seja: O projeto, carta de encaminhamento, orçamento, cronograma, folha de rosto, a justificativa para a dispensa do TCLE, o documento de aquiescência do departamento autorizado o

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uso dos prontuários e a autorização da pesquisadora Camila da Silveira Massaro, autorizando o pesquisador Rodrigo Almeida Nunes Teixeira, utilizar os dados de sua pesquisa registrada no CAAE 71648917.6.0000.5417.

Recomendações:

Não se aplica.

Conclusões ou Pendências e Lista de Inadequações:

Trata-se de uma pesquisa bem interessante na qual com os resultados obtidos poderá se mostrar mais detalhes e diferenças dos efeitos dento esqueléticos produzidos pelo expansor maxilar com abertura diferencial e pelo expansor com abertura em leque além dos efeitos na dimensão das vias aéreas. Os pesquisadores só irão trabalhar com prontuários e apresentaram todos os documentos necessários para que a pesquisa pudesse ser avaliada do ponto de vista ético. Apresentaram uma justificativa para a dispensa do TCLE que podemos considerar viável tendo em vista a particularidade desse período de isolamento social em função dessa pandemia do corona vírus. Dessa forma podemos aprovar o início da pesquisa.

Considerações Finais a critério do CEP:

Esse projeto foi considerado APROVADO na reunião ordinária do CEP de 05/08/2020, via Google Meet, devido à pandemia da COVID-19 e por orientações da CONEP, com base nas normas éticas da Resolução CNS 466/12. Ao término da pesquisa o CEP-FOB/USP exige a apresentação de relatório final. Os relatórios parciais deverão estar de acordo com o cronograma e/ou parecer emitido pelo CEP. Alterações na metodologia, título, inclusão ou exclusão de autores, cronograma e quaisquer outras mudanças que sejam significativas deverão ser previamente comunicadas a este CEP sob risco de não aprovação do relatório final. Quando da apresentação deste, deverão ser incluídos todos os TCLEs e/ou termos de doação assinados e rubricados, se pertinentes.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1577192.pdf	10/07/2020 14:34:56		Aceito
Outros	CHECKLIST.pdf	10/07/2020 14:32:27	Rodrigo Almeida Nunes Teixeira	Aceito

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Continuação do Parecer: 4.209.386

Outros	MODELO_TALE_CAAE_71648917600005417.pdf	10/07/2020 14:28:00	Rodrigo Almeida Nunes Teixeira	Aceito
Outros	MODELO_TCLE_CAAE_71648917600005417.pdf	10/07/2020 14:27:02	Rodrigo Almeida Nunes Teixeira	Aceito
Outros	Documento_anexo_dispensaTCLE.pdf	10/07/2020 14:21:23	Rodrigo Almeida Nunes Teixeira	Aceito
Outros	AUTORIZACAO_USO_AMOSTRA.pdf	10/07/2020 14:18:31	Rodrigo Almeida Nunes Teixeira	Aceito
Outros	AUTORIZACAO_USO_ARQUIVO.pdf	10/07/2020 14:17:40	Rodrigo Almeida Nunes Teixeira	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TERMO_DE_DISPENSA_TCLE_TALE.pdf	10/07/2020 14:15:00	Rodrigo Almeida Nunes Teixeira	Aceito
Projeto Detalhado / Brochura Investigador	PROJETO_CEP.pdf	10/07/2020 14:13:34	Rodrigo Almeida Nunes Teixeira	Aceito
Declaração de Pesquisadores	DECLARACAO_DE_COMPROMISSO_DO_PESQUISADOR_COM_OS_RESULTADOS.pdf	10/07/2020 14:12:52	Rodrigo Almeida Nunes Teixeira	Aceito
Declaração de Instituição e Infraestrutura	TERMO_DE_AQUIESCENCIA.pdf	10/07/2020 14:12:17	Rodrigo Almeida Nunes Teixeira	Aceito
Folha de Rosto	FOLHA_DE_ROSTO.pdf	10/07/2020 14:10:26	Rodrigo Almeida Nunes Teixeira	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

BAURU, 12 de Agosto de 2020

Assinado por:
Juliana Fraga Soares Bombonatti
(Coordenador(a))

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DISPENSA DE TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO (TCLE) E TERMO DE ASSENTIMENTO (TALE)

Solicitamos ao Comitê de Ética em Pesquisa, FOB-USP, a dispensa do Termo de Consentimento Livre e Esclarecido e Termo de Assentimento, do projeto de pesquisa **"Expansor maxilar com abertura diferencial versus com abertura em leque: uma avaliação cefalométrica e de vias aéreas"** de autoria de ***Rodrigo Almeida Nunes Teixeira*** sob a orientação *da* ***Prof. Dra. Daniela Gamba Garib***.

Tal solicitação justifica-se dentro dos conformes do inciso IV.8 da resolução do CNS n° 446/12, onde a dispensa do TCLE é considerada quando a sua obtenção signifique riscos substanciais ao participante da pesquisa. Durante a pandemia do corona vírus (COVID-19), a Organização Mundial da Saúde (OMS) reforça que as medidas de isolamento e distanciamento social ainda são as melhores alternativas para o combate da propagação do vírus. Um novo recrutamento destes pacientes que já foram tratados constituiria um maior risco de transmissão e propagação do vírus na comunidade. A amostra pretendida para a pesquisa em questão é de caráter retrospectivo, cujo pacientes já realizaram o tratamento ortodôntico planejado. Os prontuários contendo todos os exames complementares que serão analisados, estão sob os cuidados da disciplina de Ortodontia do Departamento de Odontopediatria, Ortodontia e Saúde Coletiva (autorização de uso em anexo).

Além disso, tomando como base o decreto governamental do estado de São Paulo número 65.044 da data de 03.07.2020, demais atividades que podem gerar aglomeração, como as atividades clínicas acadêmicas, estão suspensas. A partir disso, segundo novo calendário proposto pela Reitoria de Pós-graduação da USP, divulgado no dia 16.06.2020, fundamentado na proteção e na preservação da saúde da comunidade universitária e população, os atendimentos clínicos só serão previstos para janeiro de 2021. Segundo o Plano de Readequação para o ano acadêmico 2020 (PRAA-2020), divulgado no dia 03.07.2020, professores, servidores técnico-administrativos, pós-doutorandos, pós-graduandos e alunos de graduação devem seguir com o trabalho remoto até nova orientação da Reitoria.

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O estudo em questão será realizado a partir de uma análise de dados secundários de uma amostra já existente de uma pesquisa aprovada pelo comitê de ética da FOB-USP, sob CAAE 71648917.6.0000.5417. No TCLE e TALE da pesquisa anterior (anexos), já devidamente aprovados pelo CEP da FOB-USP e assinados pelos responsáveis e participantes, foi inserido que os exames complementares (tomografias) possibilitarão a avaliação dos efeitos do aparelho em toda a face.

Vale ressaltar que todos os indivíduos da pesquisa ou responsáveis legais assinam a "AUTORIZAÇÃO PARA DIAGNÓSTICO E/OU EXECUÇÃO DE TRATAMENTO ORTODÔNTICO" (modelo anexo) a qual aprova tanto a execução do tratamento, se necessário, quanto seu uso para "quaisquer fins de ensino e de divulgação em jornais e/ou revistas científicas do país e do exterior", desta forma aprova-se também o uso dos dados do seu prontuário para o ensino em pesquisas cientificas.

Os nomes e dados pessoais dos indivíduos não serão divulgados em nenhum momento, mantendo desta forma o sigilo profissional (Artigo 9º do Código de Ética Odontológico) e a privacidade dos participantes da pesquisa durante todas as fases e assumimos o compromisso de cumprir as exigências contidas na Resolução CNS Nº 466/12.

Bauru, 10 de julho de 2020.

Rodrigo Almeida Nunes Teixeira
Orientado

Daniela Gamba Garib
Orientador

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AUTORIZAÇÃO DE USO DE AMOSTRA PARA ANÁLISE DE DADOS SECUNDÁRIOS

Prezada Senhora Coordenadora,

Como parte da documentação solicitada por este Colegiado para a avaliação de projetos de pesquisas envolvendo seres humanos, eu, **Camila da Silveira Massaro**, regularmente matriculada no Programa de Ciências Odontológicas Aplicadas área de concentração Ortodontia, e responsável principal pela pesquisa: ***"Expansor maxilar com abertura diferencial versus com abertura em leque: um ensaio clínico randomizado"*** previamente aprovada pelo Comitê de Ética em Pesquisa da FOB-USP (CAAE 71648917.6.0000.5417), **autorizo** a utilização dos dados do projeto acima mencionado para o desenvolvimento do trabalho "**Expansor maxilar com abertura diferencial versus com abertura em leque: uma avaliação cefalométrica e de vias aéreas**" pelo mestrando e responsável principal do projeto de pesquisa **Rodrigo Almeida Nunes Teixeira.**

Atenciosamente,

Bauru, 10 de julho de 2020.

Camila da Silveira Massaro

Camila da Silveira Massaro
Doutoranda em Ortodontia
FOB-USP

Profª Drª Juliana Fraga Soares Bombonatti
Coordenadora do Comitê de Ética em Pesquisa-FOB-USP

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AUTHOR INFORMATION PACK

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