UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU

DEMI LISBÔA DAHÁS JORGE

**Three-dimensional evaluation of conventional anterior open bite
treatment with bonded spurs associated with build-ups versus
conventional bonded spurs: a randomized clinical trial
with 24-month follow-up**

**Avaliação tridimensional do tratamento da mordida aberta anterior
com esporão colado associado à build-ups versus esporão colado
convencional: um ensaio clínico randomizado de 24 meses**

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Orientador: Prof. Dr. Guilherme Janson

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ABSTRACT

ABSTRACT

Three-dimensional evaluation of conventional anterior open bite treatment with bonded spurs associated with build-ups versus conventional bonded spurs: a randomized clinical trial with 24-month follow-up

Objective: To compare the dentoalveolar effects of early treatment of anterior open bite with bonded spurs associated with build-ups versus conventional bonded spurs by three-dimensional superimposition of digital models after 24 months. **Material and Methods:** Fifty patients between 7 and 11 years of age with anterior open bite were prospectively and randomly assigned to one of two study groups. The experimental group (G1) consisted of 25 patients treated with bonded spurs associated with build-ups. The control group (G2) consisted of 25 patients treated with conventional bonded spurs. Digital dental models, acquired from intraoral scanning of the dental arches, were captured at baseline (T1) and after 24 months of treatment (T2). Superimposition of the T1 and T2 digital models was performed in the 3D SlicerCMF program, based on landmarks and regions of interest. Three-dimensional linear distances and the amount of directional changes in each plane of the 3D space (x, y, and z axes: lateral-lateral or transverse, anteroposterior or sagittal and superior-inferior or vertical, respectively) were measured. When normality was verified, intergroup comparisons were performed with t tests ($P<0.05$). **Results:** G1 included 22 patients and the G2 comprised 24 patients. After 24 months of treatment patients showed improvements in the overbite and there was no statistically significant intergroup difference in maxillary central and lateral incisors and molar changes. **Conclusions:** Both protocols showed similar 3D changes in maxillary incisors and molars after 24 months of treatment. Superimposition of digital dental models showed similar extrusion, medial and forward displacement of the maxillary incisors and similar extrusion, buccal and forward displacement of the maxillary molars for both groups, after 24 months of treatment. A treatment period of 24 months of AOB provides greater efficiency than a 12-month period.

Keywords: Open bite, mixed dentition, orthodontic appliances.

RESUMO

RESUMO

Avaliação tridimensional do tratamento da mordida aberta anterior com esporão colado associado à build-ups versus esporão colado convencional: um ensaio clínico randomizado de 24 meses

Objetivo: Comparar os efeitos dentoalveolares do tratamento precoce da mordida aberta anterior com esporão colado associado a build-ups versus esporão colado convencional através da sobreposição tridimensional de modelos digitais, após 24 meses. **Material e Métodos:** Cinquenta pacientes entre 7 e 11 anos de idade com mordida aberta anterior foram prospectiva e aleatoriamente alocados em um dos dois grupos de estudo. O grupo experimental (G1) consistiu de 25 pacientes tratados com esporão colado associado a build-ups. O grupo comparação (G2) consistiu de 25 pacientes tratados apenas com esporão colado. Modelos de estudo digitais, adquiridos a partir do escaneamento intraoral dos arcos dentários, foram obtidos ao início do tratamento (T1) e após 24 meses (T2). A sobreposição dos modelos digitais foi realizada no programa 3D SlicerCMF, baseada em pontos e regiões de interesse no palato. Foram mensuradas as distancias lineares tridimensionais e a quantidade de alterações direcionais em cada plano do espaço 3D (eixos x, y, e z: latero-lateral ou transversal, anteroposterior ou sagital e superior-inferior ou vertical, respectivamente). Verificada a normalidade, comparações intergrupos foram realizadas com o teste t ($P < 0.05$). **Resultados:** O G1 incluiu 22 pacientes e o G2 incluiu 24 pacientes. Após 24 meses de tratamento, os pacientes mostraram melhorias na sobremordida e não houve diferença estatisticamente significativa. **Conclusões:** Ambos os protocolos mostraram alterações 3D semelhantes nos incisivos e molares superiores após 24 meses de tratamento. Na sobreposição dos modelos foi observada semelhante extrusão, deslocamento medial e anterior dos incisivos e similar extrusão deslocamento vestibular e anterior dos molares superiores para ambos os grupos, após 24 meses de tratamento. Um período de tratamento de 24 meses no tratamento da mordida aberta anterior oferece maior eficiência que um tratamento de 12 meses.

Palavras-chave: Mordida aberta, dentição mista, aparelho ortodôntico.

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LIST OF ABBREVIATION AND ACRONYMS

ABNT	Associação Brasileira de Normas Técnicas
FAPESP	São Paulo Research Foundation
AOB	Anterior Open Bite
ROI	Region of Interest
1RL	Right-left displacement of the mean between right and left maxillary permanent central incisors
2RL	Right-left displacement of the mean between right and left maxillary permanent lateral incisors
6RL	Right-left displacement of the mean between right and left maxillary permanent molars
1AP	Antero-posterior displacement of the mean between right and left maxillary permanent central incisors
2AP	Antero-posterior displacement of the mean between right and left maxillary permanent lateral incisors
6AP	Antero-posterior displacement of the mean between right and left maxillary permanent molars
1SI	Superior-inferior displacement of the mean between right and left maxillary permanent central incisors
2SI	Antero-posterior displacement of the mean between right and left maxillary permanent lateral incisors
6SI	Antero-posterior displacement of the mean between right and left maxillary permanent molars
13D	3D displacement of the mean between right and left maxillary permanent central incisors

23D	3D displacement of the mean between right and left maxillary permanent lateral incisors
63D	3D displacement of the mean between right and left maxillary permanent molars
1VL	Vestibular-lingual inclination of the mean between right and left maxillary permanent central incisors
2VL	Vestibular-lingual inclination of the mean between right and left maxillary permanent lateral incisors
6VL	Vestibular-lingual inclination of the mean between right and left maxillary permanent molars
1MD	Mesiodistal angulation of the mean between right and left maxillary permanent central incisors
2MD	Mesiodistal angulation of the mean between right and left maxillary permanent lateral incisors
6MD	Mesiodistal angulation of the mean between right and left maxillary permanent molars
OP	Mean of right and left occlusal plane
mm	Millimeters
°	Degree

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1 INTRODUCTION

1 INTRODUCTION

Anterior open bite (AOB) is defined as the absence of overbite between the maxillary and mandibular incisors, and its treatment is considered challenging. (JANSON; VALARELLI, 2014; NGAN; FIELDS, 1997; NIELSEN, 1991) Has a multifactorial etiology, where the interaction of genetic and environmental factors are observed and the greater the influence of environmental factors are, the better orthodontic treatment is. (JANSON; VALARELLI, 2014) This condition compromises esthetics and functional problems, leaving the patient in an uncomfortable situation. (PITHON; DOS SANTOS; LIMA SANTOS; AGUIAR SALES LIMA *et al.*, 2016; VALARELLI; JANSON, 2014)

On mixed dentition, its prevalence is around 17%, and if it's not intercepted early, the severity can get worse with age. (COZZA; BACCETTI; FRANCHI; MCNAMARA, 2006; JANSON; VALARELLI, 2014) The deleterious habits, such as finger or pacifier sucking, tongue interposition and mouth breathing are the most frequent environmental factors of this malocclusion. (JANSON; VALARELLI, 2014) However, only the existence of the deleterious habit does not guarantee the installation of this malocclusion, but rather the duration (how long it is exerted), intensity (amount of force developed) and frequency (number of times exerted per day) at which the habit is performed. (GRABER; RAKOSI; PETROVIC, 1997. p.484-5)

Several early treatments has been studied, and the ones that show the best efficiency focused on the interruption of deleterious habits allowing vertical dentoalveolar development of anterior teeth. (COZZA; BACCETTI; FRANCHI; MUCEDERO *et al.*, 2005; COZZA; MUCEDERO; BACCETTI; FRANCHI, 2007; DA SILVA FILHO; GARIB; LARA, 2015; PEDRIN; ALMEIDA; ALMEIDA; ALMEIDA-PEDRIN *et al.*, 2006) Among these treatments protocols on the mixed dentition, the largest number of studies reported showed the use of fixed palatal cribs (CANUTO; JANSON; DE LIMA; DE ALMEIDA *et al.*, 2016; COZZA; BACCETTI; FRANCHI; MCNAMARA, 2006; COZZA; BACCETTI; FRANCHI; MUCEDERO, 2007; COZZA; MUCEDERO; BACCETTI; FRANCHI, 2007; DA SILVA FILHO; GARIB; LARA, 2015; GIUNTINI; FRANCHI; BACCETTI; MUCEDERO *et al.*, 2008; INSABRALDE; DE

ALMEIDA; HENRIQUES; FERNANDES *et al.*, 2016; LEITE; MATIUSSI; SALEM; PROVENZANO *et al.*, 2016; MUCEDERO; FRANCHI; GIUNTINI; VANGELISTI *et al.*, 2013; SLAVIERO; FERNANDES; OLTRAMARI-NAVARRO; DE CASTRO *et al.*, 2017; TORRES; ALMEIDA; ALMEIDA-PEDRIN; PEDRIN *et al.*, 2012; VILLA; CISNEROS, 1997) or removable. (DA SILVA FILHO; GARIB; LARA, 2015; ERBAY; UGUR; ULGEN, 1995; PEDRIN; ALMEIDA; ALMEIDA; ALMEIDA-PEDRIN *et al.*, 2006; SANKEY; BUSCHANG; ENGLISH; OWEN, 2000; SUBTELNY; SAKUDA, 1964; TORRES; ALMEIDA; DE ALMEIDA; ALMEIDA-PEDRIN *et al.*, 2006) Bonded spurs also has been studied and its effectiveness resembles that of the fixed palate grid, in addition to some other advantages such as small size, does not require the need for a laboratory step, low cost, more aesthetic, easy installation, reduced chair time, more practical and easy patient's acceptance and adaptability. (CANUTO; JANSON; DE LIMA; DE ALMEIDA *et al.*, 2016; CASSIS; DE ALMEIDA; JANSON; ALIAGA-DEL CASTILLO *et al.*, 2018; CASSIS; DE ALMEIDA; JANSON; DE ALMEIDA-PEDRIN *et al.*, 2012; INSABRALDE; DE ALMEIDA; HENRIQUES; FERNANDES *et al.*, 2016; JANSON; VALARELLI, 2014; LEITE; MATIUSSI; SALEM; PROVENZANO *et al.*, 2016)

Associated therapies that promote the control of vertical development in cases of anterior open bite has been developed and studied, as this malocclusion is often related to the pattern of vertical growth, with increase and rotation of the mandibular antero-inferior facial height. (CANGIALOSI, 1984; JANSON; VALARELLI, 2014; NAHOUM; HOROWITZ; BENEDICTO, 1972; NIELSEN, 1991; SANKEY; BUSCHANG; ENGLISH; OWEN, 2000) Among these efficient therapies, most of them generate an intrusion of the posterior teeth, producing a counterclockwise rotation of the mandible. (AKYALÇIN, 2007; ALBOGHA; TAKAHASHI; SAWAN, 2015; CARANO; MACHATA; SICILIANI, 2005; COZZA; BACCETTI; FRANCHI; MUCEDERO, 2007; DEFRAIA; MARINELLI; BARONI; FRANCHI *et al.*, 2007; DOSHI; BHAD, 2011; ERBAY; UGUR; ULGEN, 1995; FERREIRA; ALMEIDA; TORRES; ALMEIDA-PEDRIN *et al.*, 2012; ISCAN; AKKAYA; KORALP, 1992; ISCAN; DINCER; GULTAN; MERAL *et al.*, 2002; KILIARIDIS; EGERMARK; THILANDER, 1990; KUSTER; INGERVALL, 1992; SANKEY; BUSCHANG; ENGLISH; OWEN, 2000; SCHULZ; MCNAMARA; BACCETTI; FRANCHI, 2005) However, the major disadvantage of these therapies is that they either require great patient cooperation, also are anti-aesthetic and unhygienic.

Resin stops of approximately 2-3 millimeters, bonded to the functional cusps of the upper molars, also known as posterior build-ups, has been shown to be a good alternative for vertical control of the posterior teeth and as an adjunct for the treatment of anterior open bite in permanent dentition, due to its effects of unblock the occlusion and intrusion of the molar and consequent counterclockwise rotation of the mandible. Some advantages include that it is noninvasive therapy and does not depend on patient collaboration. (VELA-HERNANDEZ; LOPEZ-GARCIA; GARCIA-SANZ; PAREDES-GALLARDO *et al.*, 2017)

It can be speculated that the use of bonded spurs associated with build-ups on the first and second deciduous molars and permanent molars, instead of chincup, would produce vertical control during anterior open bite early treatment without the need of patient collaboration. If this vertical control real happens in mixed dentition, it could be thought that this can be a valid method to vertical control of posterior teeth, reducing the need for patient cooperation to produce this effect. However, there are no studies in the literature evaluating the effects of bonded spurs associated with build-ups. (FERES; ABREU; INSABRALDE; ALMEIDA *et al.*, 2016; FERES; ABREU; INSABRALDE; DE ALMEIDA *et al.*, 2017; LENTINI-OLIVEIRA; CARVALHO; RODRIGUES; YE *et al.*, 2014; PISANI; BONACCORSO; FASTUCA; SPENA *et al.*, 2016)

The effectiveness of anterior open bite treatment in mixed dentition has been studied over an average treatment interval of 12 months, obtaining 86.7% of efficiency. (ALBOGHA; TAKAHASHI; SAWAN, 2015; CARANO; MACHATA; SICILIANI, 2005; CASSIS; DE ALMEIDA; JANSON; DE ALMEIDA-PEDRIN *et al.*, 2012; COZZA; BACCETTI; FRANCHI; MUCEDERO, 2007; INSABRALDE; DE ALMEIDA; HENRIQUES; FERNANDES *et al.*, 2016; LEITE; MATIUSSI; SALEM; PROVENZANO *et al.*, 2016; PEDRIN; ALMEIDA; ALMEIDA; ALMEIDA-PEDRIN *et al.*, 2006; SANKEY; BUSCHANG; ENGLISH; OWEN, 2000; TORRES; ALMEIDA; DE ALMEIDA; ALMEIDA-PEDRIN *et al.*, 2006; TORRES; ALMEIDA; ALMEIDA-PEDRIN; PEDRIN *et al.*, 2012) Perhaps a longer treatment time is required for the most severe anterior open bite cases. In addition, most studies assess the effectiveness of anterior open bite treatment based on cephalometric superimposition.(DEFRAIA; MARINELLI; BARONI; FRANCHI *et al.*, 2007; PEDRIN; ALMEIDA; ALMEIDA; ALMEIDA-PEDRIN *et al.*, 2006; TORRES; ALMEIDA; DE ALMEIDA; ALMEIDA-PEDRIN *et al.*, 2006;

WEINBACH; SMITH, 1992) There was only one study that evaluated study models but their superimposition was not performed.(SLAVIERO; FERNANDES; OLTRAMARI-NAVARRO; DE CASTRO *et al.*, 2017)

Therefore, the purpose of this study was to perform a 24-month follow-up of a randomized clinical trial to compare the three-dimensional dentoalveolar changes of anterior open bite treatment with bonded spur associated with build-ups versus conventional bonded spurs.

2 ARTICLE

2 ARTICLE

The article presented in this Dissertation was formatted according to the American Journal of Orthodontics and Dentofacial Orthopedics instructions and guidelines for article submission.

ABSTRACT

Objective: To compare the dentoalveolar effects of early treatment of anterior open bite with bonded spurs associated with build-ups versus conventional bonded spurs by three-dimensional superimposition of digital models after 24 months. **Material and Methods:** Fifty patients between 7 and 11 years of age with anterior open bite were prospectively and randomly assigned to one of two study groups. The experimental group (G1) consisted of 25 patients treated with bonded spurs associated with build-ups. The control group (G2) consisted of 25 patients treated with conventional bonded spurs. Digital dental models, acquired from intraoral scanning of the dental arches, were captured at baseline (T1) and after 24 months of treatment (T2). Superimposition of the T1 and T2 digital models was performed in the 3D SlicerCMF program, based on landmarks and regions of interest. Three-dimensional linear distances and the amount of directional changes in each plane of the 3D space (x, y, and z axes: lateral-lateral or transverse, anteroposterior or sagittal and superior-inferior or vertical, respectively) were measured. When normality was verified, intergroup comparisons were performed with t tests ($P<0.05$). **Results:** G1 included 22 patients and the G2 comprised 24 patients. After 24 months of treatment patients showed improvements in the overbite and there was no statistically significant intergroup difference in maxillary central and lateral incisors and molar changes. **Conclusions:** Both protocols showed similar 3D changes in maxillary incisors and molars after 24 months of treatment. Superimposition of digital dental models showed similar extrusion, medial and forward displacement of the maxillary incisors and similar extrusion, buccal and forward displacement of the maxillary molars for both groups, after 24 months of treatment. A treatment period of 24 months of AOB provides greater efficiency than a 12-month period. **Registration:** This trial was registered at Clinicaltrials.gov (Identifier: NCT3702881). **Protocol:** The protocol was not published. **Funding:** This trial was financed in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – Brasil (CAPES), Finance Code 001; and by grants: number. 2017/06440-3, number. 2018/05238-9 and number. 2018/24003-2, São Paulo Research Foundation (FAPESP).

INTRODUCTION

Anterior open bite (AOB), defined as a vertical malocclusion where there is a lack of contact between the maxillary and mandibular incisors, consequently presenting a negative vertical overlap, is easy to identify, but its treatment is considered challenging if the malocclusion is not early intercepted.¹⁻³ Generally, this condition compromises esthetics and generates functional problems, such as speech and eating difficulties, which most often subject the patient to uncomfortable situations and psychosocial problems.^{4,5}

Its prevalence in the mixed dentition is around 17% and its severity can get worse with age if this malocclusion is not intercepted early.^{3,6} The most frequent environmental factors are deleterious habits, such as finger and/or pacifier sucking, tongue interposition and mouth breathing.^{3,27} The genetic component is limited to an unfavorable vertical growth pattern.²⁸

Several protocols have been studied in the mixed dentition which are focused on the interruption of deleterious habits, such as fixed or removable palatal cribs.^{6,8-12} Lingual bonded spurs have also been studied and its effectiveness resembles that of the fixed palatal crib, in addition to some other advantages such as small size, does not require laboratory work, low cost, more esthetic, easy installation, reduced chair time, more practical and easy patient acceptance and adaptability.¹¹⁻¹³

AOB patients usually present a vertical growth pattern and accentuated anterior face height, therefore, associated therapies that promote control of vertical development have been developed and studied.^{3,6,13-16} It has been reported that the use of bonded spurs associated with high pull chin cup are efficient in AOB correction.^{13,15} However, the major disadvantage of this protocol is that it requires great patient cooperation, are anti-esthetic and unhygienic.

Posterior build-ups associated with orthodontic fixed appliances for AOB treatment has been reported and has been shown to be a good alternative for vertical control of the posterior teeth and provides a counterclockwise rotation of the mandible.¹⁷ In the mixed dentition, it can be speculated that the use of bonded spurs associated with build-ups on the first and second deciduous molars and permanent molars, instead of a chin cup, would produce vertical control during anterior open bite early treatment without the need of patient compliance.

Most studies in the literature evaluated the effectiveness of treating anterior open bite in the deciduous and mixed dentition over an average treatment interval of

12 months, obtaining 86.7% of efficiency.^{12,13,15,16,18-23} This is probably because there is a need for longer treatment time in the most severe anterior open bite cases. In addition, most studies assess the effectiveness of anterior open bite treatment based on cephalometric superimposition.^{16,22,24,25} There was only one study that evaluated study models but their superimposition was not performed.²⁶

Specific objectives or hypotheses

For this reason, the purpose of this study was to perform a 24-month follow-up of a randomized clinical trial to three-dimensionally compare the dentoalveolar changes promoted by treatment of anterior open bite with bonded spur associated with build-ups versus conventional bonded spurs. The null hypothesis tested was that both therapies produce similar 3D changes on the maxillary incisors and molars after 24 months of treatment.

MATERIAL AND METHODS

Trial design

This was a parallel-group clinical trial study, composed of patients randomly allocated with a 1:1 ratio. No changes to the methods after trial commencement occurred. The study was approved by the Ethics in Research Committee of Bauru Dental School, University of São Paulo, Brazil (protocol number CAAE: 19700919.2.0000.5417). Informed consent was obtained from the patients and their parents or legal guardians before their recruitment. The protocol of this study was registered at Clinicaltrials.gov with the NCT03702881 identifier.

Participants

Eligibility Criteria

The following selection criteria were applied: patients ranging from 7 to 11 years of age, in the mixed dentition, with maxillary and mandibular permanent incisors and molars fully erupted, anterior open bite (AOB) equal or greater than 1mm, absence of/or mild crowding, without the need of maxillary expansion and presence of nonnutritive sucking habits and/or tongue interposition. Exclusion criteria consisted in patients with craniofacial anomalies or syndromes, tooth agenesis, loss of permanent teeth, severe crowding, maxillary constriction, previous orthodontic treatment or posterior crossbite.

Consecutive patients, within the inclusion criteria, were selected at the Orthodontic Clinic of Bauru Dental School, University of São Paulo, Brazil, from June 2017 to April 2018.

Interventions

Bonded spurs (Morelli, Sorocaba, SP, Brazil) were installed at the cervical and incisal portions of the palatal and lingual surface of the maxillary and mandibular incisors, respectively, in all 25 patients of the experimental group (G1) using Transbond XT prime/adhesive system (3M Unitek, Monrovia, Calif. - Fig.1A). Posterior build-ups of 2-3 mm thickness (Orthobite, FGM, Joinville, SC, Brazil) were also bonded on the functional cusps of all maxillary posterior teeth to maintain balanced occlusal forces. Only bonded spurs were bonded in all 25 patients of the comparison group, in the same way as in G1. In both groups, the spurs were sharpened with a carborundum disk before bonding (Fig. 1B).

All patients and parents received instructions to assist in giving up the deleterious habit. After 12 months, the build-ups were removed from G1, maintaining only the bonded spurs in both groups. After 24 months, the bonded spurs were removed from both groups. Digital dental models were obtained with intraoral scanning (TRIOS, 3Shape A/S, Copenhagen, Denmark), at pretreatment and after 24 months, for all patients. Dental model three-dimensional intergroup comparisons were performed at (T1) and after 24-month follow-up (T2).

Outcomes

Superimpositions of maxillary digital dental models were performed based on regions of interest located on the palate. A 3D Slicer software, version 4.11 was used. Download of SlicerCMF and Q3DC extensions were necessary to perform the superimposition steps.²⁹ Models based on “.stl” file format were necessary for the superimpositions.

Superimposition Steps

Model Orientation: Firstly, all T1 and T2 maxillary models were three-dimensionally oriented using Slicer software's transforms tool. 3D coordination on the occlusal view was accomplished by centering the midpalatal raphe. In the frontal and sagittal view, the occlusal plane (plane through the maxillary first molars mesiobuccal

cuspid tips and canine cuspid tips) was leveled with the horizontal plane. This “T1 oriented” and “T2 oriented” models were created and saved on ‘.vtk’ file format and were used for the next steps.

Approximation of T2 to T1 models: Approximation is necessary to decrease 3D rotation and was performed in one step: the T2 model was approximated to the T1 model with the “SlicerCMF fiducial registration”. Four landmarks were placed on the mesiobuccal cuspid tips of the maxillary first permanent and deciduous molars, on both models (Fig. 2). In cases where the deciduous molars were not present, landmarks were placed on the buccal cuspid tips of the permanent molars, with a total of 2 landmarks per molar. Thus, the software computed and created the approximated model, saved as “T2apT1”.

Registration based on palatal regions of interest: to obtain registration based on the palatal regions of interest (ROI), the “T1_oriented” and “T2apT1” models were necessary. Using the “ROI registration”, four lateral and one central landmark were used to define the regions of interest on the palate in the T1 and reproduced in the T2apT1 model (Fig.3). Anterior and posterior lateral landmarks were placed in the angle formed between the top and the base of the palate on the right and left sides. Horizontal lines, perpendicular to the midpalatal raphe, one passing through the middle of the occlusal surface of the first deciduous molars or premolars, and the other passing between the first permanent and second deciduous molars defined the anterior and posterior limits, respectively. The central landmark was in the midpalatal raphe, equidistant to the two previously described horizontal lines. ROI with 15 to 20 mm radius were created on both models.³⁰ The software automatically computed and registered the models. Then, the “T2T1_reg_palatal” registered model with its registration matrix was created.

Measurements: Using the Q3DC extension, landmarks were placed on the T1 and T2_reg_palatal models. These landmarks were placed on the T1 model and were reproduced on the T2_reg_palatal model. These landmarks were located on the incisal edge and gingival limit of the maxillary permanent incisors and on the mesio-buccal cuspid tips and upper and lower limit of the mesiobuccal sulcus of the maxillary molars (Fig.4). Three-dimensional linear distances were obtained: left-right ([+] for lateral and [-] for medial), antero-posterior ([+] for forward and [-] for backward movement), superior-inferior ([+] for extrusion and [-] for intrusion), and 3D displacements. Also, the angle between two lines (vestibulo-lingual inclination ([+] for vestibular inclination

and [-] for lingual inclination), mesiodistal angulation ([+] for mesial angulation and [-] for distal angulation) and occlusal plane angulation ([+] for clockwise rotation and [-] for counterclockwise rotation) were automatically obtained by the software.^{30,31}

Any changes to trial outcomes after the trial commenced, with reasons:

There were no outcome changes after trial commencement.

Sample size

a. How sample size was determined.

Calculation of sample size was based on the ability to detect a clinically relevant difference with a test power of 80%, at a significance level of 0.05. In this way, to detect an intergroup difference of 1.5mm in the overbite with a standard deviation of 1.69 mm,¹³ at least 20 patients per group were required. To compensate for sample attrition, 25 patients per group were enrolled.

b. When applicable, explanation of any interim analyses and stopping guidelines.

Not applicable.

Randomization

Sequence generation

Patients were randomly designated to two groups: Group 1 (experimental/G1) was composed of 25 patients treated with bonded spurs associated with posterior build-ups, and Group 2 (comparison/G2) was composed of 25 patients treated only with bonded spurs, ensuring equal distribution in the 2 groups. Randomization was obtained by using the website Randomization.com (<http://www.randomization.com>).³²

Allocation

Allocation was achieved with numbered, sealed opaque envelopes containing the treatment allocation cards, prepared before trial beginning. All envelopes were torn open and were securely stored in a different location from the trial site.³³

Implementation

Before opening the envelope, the baseline information was written on the outside and the practice manager was responsible for opening the next envelope in sequence and implementing the randomization process.

Blinding

There was no blinding to treatment allocation, considering that both patient and operator knew which type of appliance was being installed, however, appraisal of the digital dental models was blinded, because they were unidentified during analysis.³⁴

Method error

Thirty percent of the sample (15 patients) were remeasured after 30 days, by the same operator (D.D) to assess the methodology error.

Statistical methods

Normality distribution analysis was performed using Shapiro-Wilk test. Group comparisons were performed with t or Mann-Whitney U tests, depending on data normality. Group comparability regarding age and sex distribution was investigated using t and Fisher exact tests, respectively. Statistical analyses were performed with SPSS software (Version 22; IBM, Armonk, NY). Results were considered significant at $P < 0.05$.

RESULTS

Participants flow

A total of 1025 patients in the mixed dentition were assessed for eligibility, where: 969 were excluded because they did not match the eligibility criteria and 6 declined to participate (Fig.5). Therefore, 50 patients were selected and randomized into a 1:1 ratio.

The random errors ranged from 0.02 mm (2SI) to 0.59 mm (2RL) and from 0.11° (OP) to 3.18°(2BL) for linear and angular measurements, respectively. None of the variables had significant systematic error (Table I).

Due to absence of normal distribution, Mann-Whitney U tests were necessary for the variables: central incisors right-left displacement, central incisors antero-posterior displacement, central incisors supero-inferior displacement, central incisors

3D displacement, central incisor buccolingual displacement, molar buccolingual displacement and molar mesiodistal displacement (Table II).

Baseline data

The groups showed similar age and sex characteristics distribution and initial overbite values (Table III).

Number analyzed for each outcome, estimation, and precision

After 12 months of treatment, only one patient (4%) of the experimental group was lost because she moved to another city. However, in the 24-month follow-up stage, due to Covid-19 pandemic, contacts of another 2 (12%) patients of the experimental group and 1 patient (4%) from the comparison group were lost, totalizing 22 in the experimental and 24 in the comparison group (Fig. 5).

Clinically, decrease of anterior open bite during the 24-month treatment interval was observed in all patients of both groups. The groups showed numerically similar 3D changes, however, a statistically significant difference on mesiodistal angulation of lateral incisors was found because the laterals moved laterally in the experimental and mesially in the comparison group (Table IV).

The central and lateral incisors showed a medial trajectory, in both groups (Table IV). The molars presented similar buccal displacements in the groups. There were similar and forward displacements of the central and lateral incisors, and molars mesial movement in both groups. The central and lateral incisors and the molars had proportionally and similar decreasing extrusion in both groups. There was no significantly different intergroup 3D displacement, vestibulo-lingual inclination, mesiodistal angulation changes of the incisors and molars, and rotation of the occlusal plane, which was clockwise.

Harms

Some bonded spurs were lost during the 24-month period, accidentally debonding, showing breakdown rates of 2.5% and 5.3%, in G1 and G2, respectively. All of them were bonded again as soon as possible. Bonded spurs can sporadically fall off and be aspirated or swallowed, and this needs to be considered and informed to the patient and respective parents.¹³

DISCUSSION

Main findings in the context of the existing evidence and interpretation

Several AOB early treatment protocols have been studied and compared.^{6,11-13,15,16,26,35,36} In the mixed dentition, the AOB has predominantly dentoalveolar characteristics, and is usually accompanied by deleterious habits and/or anterior tongue thrust. Therefore, therapies aimed to interrupt the deleterious habit, allowing vertical development of the anterior teeth, can correct the overbite and provide occlusal stability.^{13,37,38}

Despite some studies reported the effects of bonded spurs on early treatment of anterior open bite, only one¹³ was associated with vertical development control.^{3,11-13,15,38} However, there is no trial that associated posterior build-ups with bonded spurs in the mixed dentition. Therefore, this was the first randomized clinical trial that compared the effect of BS associated with build-ups with BS alone in AOB treatment. It could be speculated that this association with posterior build-ups for 12 months could eliminate the deleterious habits and provide vertical control of the posterior teeth. Also, most studies in the literature evaluated the effectiveness of early treatment of AOB over an average treatment interval of 12 months, reporting 53.8¹² to 86.7%¹³ of efficiency in closing the bite. The reason for this rather low effectiveness in closing the bite may be the small treatment time for the most severe AOB cases, associated with accentuated vertical skeletal characteristics. Therefore, an extended treatment time of 24-month was essential to investigate the dentoskeletal effects and its influence on treatment efficiency.

The use of 3D digital models to evaluate dentoalveolar changes is considered a better method than cephalometric evaluation, due the difficulties of defining landmarks of the incisors overlap, associated with the limitations of a 2D evaluation.²⁶ Superimposition of 3D digital models offers a risk-free imaging technique, is more informative, with less limitations when compared with cephalometric superimposition, and offers great opportunities for the assessment of tooth movement.³⁹ The palatal rugae has been described as a stable reference during facial growth, primarily in the transverse and sagittal planes.^{30,40-43} Despite there is an urgent need for high quality studies testing several techniques of maxillary superimposition, it can be considered that using two-thirds of the third rugae is a reliable method.³⁹

The number of preparation steps (pre-orientation, orientation, and approximation) of digital dental models to generate the registration model, refines the

process of superimposition technique, which is an advantage and showed more reliability, reducing 3D errors. Studies with ROI on the palate tend to show reliability and good intra examiner reproducibility.^{30,39} However, the patients were in the mixed dentition. There are still no studies that evaluated superimposition of digital dental models in AOB patients in the mixed dentition. Consequently, there were some limitations and difficulties encountered by the operators.

Pretreatment overbite of the experimental and comparison groups were of -4.45 and -4.36mm, respectively (Table III). After 12 months of treatment, 16 out of 24 patients (66.7%) in the experimental group and 18 out of 25 patients (72%) in the comparison group had the AOB closed, presenting a positive overlap. The posterior build-ups were then removed from the experimental group, leaving these patients only with bonded spurs. After 24 months, the bonded spurs were removed and 22 out of 22 (100%) in the experimental group and 23 out of 24 (95,83%) in the comparison group presented a positive overlap.

Only 1 from 24 (4.16%) patients of the comparison group, presented a negative overlap after the 24-month treatment, however, when compared with the 12-month evaluation period, there was a greater percentage of open bite closure. In this patient, there was continuity of the deleterious sucking habit, even with the bonded spurs installed, as reported by the patient's parents. Perhaps, in these cases, to effectively remove the habit, it may be necessary to use a fixed palatal tongue crib or spurs soldered to a palatal arch.^{11,12,36}

The increase in overbite in patients treated only with bonded spurs have ranged from 3.07^{12,35} to 4.26mm.¹¹ When bonded spurs were associated with chincup, the increase ranged from 4.52¹⁵ to 5.23mm,¹³ in 12 months. In this trial, after 24-month, the overbite increased 6mm in the experimental and 5.91mm in comparison group (Table III). Therefore, it can be concluded that the overbite had similar increases, independently of posterior build-ups. However, the amount of overbite increase was greater in the 24-month treatment period.

Medial displacements of the central and lateral maxillary incisors occurred and explain the usual closure of the midline diastema, also favored by eruption of the maxillary permanent canines, at this stage⁴⁴ (Table IV). Buccal molar displacement is most likely due to the occlusal contacts between the build-ups and the opposing teeth, which produced a buccal vector. Forward displacement of the central and lateral incisors may be consequent to leveling the accentuated curve of Spee of the maxillary

arch, which is very accentuated in open bite patients. As the curve is leveled, the teeth crowns will need more space to be accommodated in a straight line and will consequently mesialize.³ Mesial molars movement would probably be consequent to use of the leeway space as the second deciduous molars are exfoliated.^{11,13,36,44,45}

Clinically, similar decrease of anterior open bite was observed in both treatment protocols. In the experimental group there was 3.13 mm of extrusion of the maxillary central incisors and 3.03 mm in the comparison group, which are similar to previous studies^{11,13,14,21} (Table IV). This shows that the decrease of AOB by maxillary incisors extrusion corresponds to an average of 3.08mm in two years of treatment. However, complete closure of the open bite will also depend on some extrusion of the mandibular incisors.²⁶

Molars extrusion were of 0.98 and 1.08 mm in the experimental and comparison groups, respectively (Table IV). The posterior build-ups were not effective in controlling their vertical development during the treatment period of 12 months.⁴⁶ When the build-ups were removed after 12 months, they had no more vertical effect because the opposing deciduous canines were already in contact. Therefore, obviously, no further vertical effect would be expected in the remaining 12 months of the treatment period, until completion of the 24-month period.

The maxillary central and lateral incisors were palatally tipped, which is usually expected during open bite closure in the mixed dentition.^{3,45,47} The molars also experienced palatal tipping, which may be explained by contact of the build ups with the opposing teeth buccal cusps, generating a palatal tipping force on these teeth. However, this has to be further investigated.

As the bite was closed, the maxillary central and lateral incisors also experienced root distal angulation, which occurs due to closure of anterior diastemas as the bite closes and also due to the eruption pressure of the canines on the lateral incisor crowns.^{3,47-50} Only the experimental group lateral incisors behaved differently, experiencing root mesial angulation. This should be further investigated.

The molars had mesial angulation, which is consistent with their normal eruption path. Usually, they erupt with greater distal angulation, that gradually decreases.^{47,49} Because the maxillary occlusal plane is drawn from the first molars to the maxillary incisors, and the incisors had greater extrusion than the molars, it is obvious that the occlusal plane would experience a clockwise rotation.

Based on these results, it can be concluded that bonded spurs associated with posterior build-ups showed no significant clinical differences when compared with only bonded spurs on a 24-month treatment period. However, extending treatment time to 24-month proved to be necessary in cases where closure of anterior open bite, after 12-month of treatment, was not achieved, either due to the open bite severity or to persistent deleterious habits. If persistent deleterious habits are actually the cause, switch to a tongue crib or tongue spurs soldered to a palatal arch are recommended.

Limitations

Patients with greater vertical development should be included, however, selection of an ideal sample is limited because an AOB in the mixed dentition has basically a predominant dentoalveolar origin. Inclusion of an untreated control group would be ideal, however, keeping patients with an AOB without treatment in the mixed dentition for 24-months would not be possible due to ethical reasons. Evaluation of the mandibular arch would also be necessary to provide a better idea of the amount of vertical changes of the maxillary and mandibular incisors in open bite correction. However, a superimposition method for the mandibular arch has not been developed yet.

Generalizability

The generalizability of this trial might be limited to anterior open bite patients with similar age and dentoskeletal characteristics.

CONCLUSIONS

- Both protocols showed similar 3D changes in the maxillary incisors and molars;
 - Superimposition of digital dental models showed similar extrusion, medial and forward displacement of the maxillary incisors and similar extrusion, buccal and forward displacement of the maxillary molars for both groups after 24 months of treatment;
 - A treatment period of 24 months of AOB provides greater efficiency than a 12-month period.
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REFERENCES

1. Ngan P, Fields HW. Open bite: a review of etiology and management. *Pediatr Dent* 1997;19:91-98.
 2. Nielsen IL. Vertical malocclusions: etiology, development, diagnosis and some aspects of treatment. *Angle Orthod* 1991;61:247-260.
 3. Janson G, Valarelli F. Open-bite malocclusion: treatment and stability. Ames, IA: John Wiley & Sons, Inc; 2014.
 4. Pithon MM, Dos Santos CR, Lima Santos N, Aguiar Sales Lima SO, da Silva Coqueiro R, Dos Santos RL. Impact of malocclusion on affective/romantic relationships among young adults. *Angle Orthod* 2016;86:638-643.
 5. Valarelli FP, Janson G. O tratamento não cirúrgico da mordida aberta anterior no paciente adulto. *Ortho Sci., Orthod. sci. pract* 2014;7:252-270.
 6. Cozza P, Baccetti T, Franchi L, McNamara JA, Jr. Treatment effects of a modified quad-helix in patients with dentoskeletal open bites. *Am J Orthod* 2006;129:734-739.
 7. Graber TM, Rakosi T, Petrovic AG. Dentofacial orthopedics with functional appliances. 2nd ed. St Louis, MO: Mosby; 1997. p.484-5.
 8. Subtelny JD, Sakuda M. Open-bite: diagnosis and treatment. *Am J Orthod* 1964;50:337-358.
 9. Ozawa TO, Capelozza Filho L, Silva Filho OGd. Controle vertical em ortodontia com o uso de. *Ortodontia* 1998;31:81-90.
 10. Feres MF, Abreu LG, Insabralde NM, Almeida MR, Flores-Mir C. Effectiveness of the open bite treatment in growing children and adolescents. A systematic review. *Eur J Orthod* 2016;38:237-250.
 11. Feres MF, Abreu LG, Insabralde NM, de Almeida MR, Flores-Mir C. Effectiveness of open bite correction when managing deleterious oral habits in growing children and adolescents: a systematic review and meta-analysis. *Eur J Orthod* 2017;39:31-42.
 12. Pisani L, Bonaccorso L, Fastuca R, Spena R, Lombardo L, Caprioglio A. Systematic review for orthodontic and orthopedic treatments for anterior open bite in the mixed dentition. *Prog Orthod* 2016;17:28.
 13. Canuto LF, Janson G, de Lima NS, de Almeida RR, Cancado RH. Anterior open-bite treatment with bonded vs conventional lingual spurs: A comparative study. *Am J Orthod* 2016;149:847-855.
-

14. Leite JS, Matussi LB, Salem AC, Provenzano MG, Ramos AL. Effects of palatal crib and bonded spurs in early treatment of anterior open bite: A prospective randomized clinical study. *Angle Orthod* 2016;86:734-739.
 15. Cassis MA, de Almeida RR, Janson G, de Almeida-Pedrin RR, de Almeida MR. Treatment effects of bonded spurs associated with high-pull chincup therapy in the treatment of patients with anterior open bite. *Am J Orthod* 2012;142:487-493.
 16. Iscan HN, Dincer M, Gultan A, Meral O, Taner-Sarisoy L. Effects of vertical chincup therapy on the mandibular morphology in open-bite patients. *Am J Orthod* 2002;122:506-511.
 17. Insabralde NM, de Almeida RR, Henriques JF, Fernandes TM, Flores-Mir C, de Almeida MR. Dentoskeletal effects produced by removable palatal crib, bonded spurs, and chincup therapy in growing children with anterior open bite. *Angle Orthod* 2016;86:969-975.
 18. Pedrin F, Almeida MR, Almeida RR, Almeida-Pedrin RR, Torres F. A prospective study of the treatment effects of a removable appliance with palatal crib combined with high-pull chincup therapy in anterior open-bite patients. *Am J Orthod* 2006;129:418-423.
 19. Vela-Hernandez A, Lopez-Garcia R, Garcia-Sanz V, Paredes-Gallardo V, Lasagabaster-Latorre F. Nonsurgical treatment of skeletal anterior open bite in adult patients: Posterior build-ups. *Angle Orthod* 2017;87:33-40.
 20. Albogha MH, Takahashi I, Sawan MN. Early treatment of anterior open bite: Comparison of the vertical and horizontal morphological changes induced by magnetic bite-blocks and adjusted rapid molar intruders. *Korean J Orthod* 2015;45:38-46.
 21. Carano A, Machata W, Siciliani G. Noncompliant treatment of skeletal open bite. *Am J Orthod* 2005;128:781-786.
 22. Cozza P, Baccetti T, Franchi L, Mucedero M. Comparison of 2 early treatment protocols for open-bite malocclusions. *Am J Orthod* 2007;132:743-747.
 23. Sankey WL, Buschang PH, English J, Owen AH, 3rd. Early treatment of vertical skeletal dysplasia: the hyperdivergent phenotype. *Am J Orthod Dentofacial Orthop* 2000;118:317-327.
 24. Torres F, Almeida RR, de Almeida MR, Almeida-Pedrin RR, Pedrin F, Henriques JF. Anterior open bite treated with a palatal crib and high-pull chin cup therapy. A prospective randomized study. *Eur J Orthod* 2006;28:610-617.
-

25. Torres FC, Almeida RR, Almeida-Pedrin RR, Pedrin F, Paranhos LR. Dentoalveolar comparative study between removable and fixed cribs, associated to chincup, in anterior open bite treatment. *J Appl Oral Sci* 2012;20:531-537.
 26. Defraia E, Marinelli A, Baroni G, Franchi L, Baccetti T. Early orthodontic treatment of skeletal open-bite malocclusion with the open-bite bionator: a cephalometric study. *Am J Orthod* 2007;132:595-598.
 27. Weinbach JR, Smith RJ. Cephalometric changes during treatment with the open bite bionator. *Am J Orthod* 1992;101:367-374.
 28. Slaviero T, Fernandes TM, Oltramari-Navarro PV, de Castro AC, Conti F, Poleti ML et al. Dimensional changes of dental arches produced by fixed and removable palatal cribs: A prospective, randomized, controlled study. *Angle Orthod* 2017;87:215-222.
 29. Ioshida M, Muñoz BA, Rios H, Cevitanes L, Aristizabal JF, Rey D et al. Accuracy and reliability of mandibular digital model registration with use of the mucogingival junction as the reference. *Oral surgery, oral medicine, oral pathology and oral radiology* 2019;127:351-360.
 30. Garib D, Miranda F, Yatabe M, Lauris J, Massaro C, McNamara Jr J et al. Superimposition of maxillary digital models using the palatal rugae: does aging affect the reliability? *Orthodontics & craniofacial research* 2019.
 31. Yatabe M, Prieto JC, Styner M, Zhu H, Ruellas AC, Paniagua B et al. 3D superimposition of craniofacial imaging—The utility of multicentre collaborations. *Orthodontics & craniofacial research* 2019;22:213-220.
 32. Pandis N. Randomization. Part 1: sequence generation. *Am J Orthod* 2011;140:747-748.
 33. Pandis N. Randomization. Part 3: allocation concealment and randomization implementation. *American journal of orthodontics and dentofacial orthopedics* 2012;141:126-128.
 34. Pandis N. Blinding or masking. *Am J Orthod* 2012;141:389-390.
 35. Rossato PH, Fernandes TMF, Urnau FDA, de Castro AC, Conti F, de Almeida RR et al. Dentoalveolar effects produced by different appliances on early treatment of anterior open bite: A randomized clinical trial. *Angle Orthod* 2018.
 36. Justus R. Correction of anterior open bite with spurs: long-term stability. *World J Orthod* 2001;2:219-231.
-

37. Cozza P, Baccetti T, Franchi L, Mucedero M, Polimeni A. Sucking habits and facial hyperdivergency as risk factors for anterior open bite in the mixed dentition. *Am J Orthod* 2005;128:517-519.
 38. Cassis MA, de Almeida RR, Janson G, Aliaga-Del Castillo A, de Almeida MR. Stability of anterior open bite treatment with bonded spurs associated with high-pull chin cup. *Orthod Craniofac Res* 2018;21:104-111.
 39. Stucki S, Gkantidis N. Assessment of techniques used for superimposition of maxillary and mandibular 3D surface models to evaluate tooth movement: a systematic review. *Eur J Orthod* 2020;42:559-570.
 40. Almeida MA, Phillips C, Kula K, Tulloch C. Stability of the palatal rugae as landmarks for analysis of dental casts. *Angle Orthod* 1995;65:43-48.
 41. Choi J-I, Cha B-K, Jost-Brinkmann P-G, Choi D-S, Jang I-S. Validity of palatal superimposition of 3-dimensional digital models in cases treated with rapid maxillary expansion and maxillary protraction headgear. *Korean J Orthod* 2012;42:235-241.
 42. Miller R, Kuo E, Choi W. Validation of Align Technology's Treat IITM digital model superimposition tool and its case application. *Orthodontics & craniofacial research* 2003;6:143-149.
 43. Hoggan BR, Sadowsky C. The use of palatal rugae for the assessment of anteroposterior tooth movements. *Am J Orthod*, 2001;119:482-488.
 44. Moorrees CF, Grøn A-M, Le Bret LM, Yen PK, Fröhlich FJ. Growth studies of the dentition: a review. *Am J Orthod*, 1969;55:600-616.
 45. da Silva Filho O, RJ GG, Maia FA. Sucking habits: clinical management in dentistry. *The Journal of clinical pediatric dentistry* 1991;15:137-156.
 46. Aliaga-Del Castillo A, Vilanova L, Miranda F, Arriola-Guillén LE, Garib D, Janson G. Dentoskeletal changes in open bite treatment using spurs and posterior build-ups: A randomized clinical trial. *Am J Orthod*, 2021.
 47. van der Linden FP, Duterloo HS. Development of the human dentition: an atlas. HarperCollins Publishers; 1976.
 48. Rodrigues dAR, Ursi W. Anterior open bite. Etiology and treatment. *Oral health* 1990;80:27.
 49. Moyers RE. Standards of human occlusal development. 1976.
 50. Lindauer SJ, Rubenstein LK, Hang WM, Andersen WC, Isaacson RJ. Canine impaction identified early with panoramic radiographs. *The Journal of the American Dental Association* 1992;123:91-92.
-

FIGURE LEGENDS

Figure 1.: Experimental group (A) and comparison group (B).

Figure 2: Approximation of “T2_oriented” to “T1_oriented” models: landmarks located on “T1” (A) and “T2” models (B). Models approximation based on four tooth landmarks computed the “T2apT1” model (C-D).

Figure 3: Registration based on regions of interest on the palate. Landmarks located on “T1” (A) and “T2apT1” (B) models. Regions of interest of 15-20mm² on the palate (C-D). Model registration based on the ROI generated the “T2_reg” model (E-F).

Figure 4: Markups on T1 and T2 models.

Figure 5: Consort flow diagram

Fig.1.

Fig.2

Fig.4

Fig.5.

Table I: Method error (Dahlberg's formula and dependent t tests)

	Mean	SD	Mean	SD	Dahlberg	P
Right-Left Displacement						
1	-0.41	0.54	-0.44	0.57	0.14	0.494
2	-0.25	0.63	0.05	0.63	0.59	0.217
6	0.29	0.62	0.35	0.59	0.15	0.253
Antero-Posterior Displacement						
1	1.71	1.05	1.66	1.07	0.09	0.111
2	1.84	0.86	1.87	0.94	0.07	0.328
6	1.85	0.74	1.88	0.71	0.14	0.600
Supero-Inferior Displacement						
1	2.87	1.07	2.89	1.06	0.03	0.102
2	2.71	0.93	2.71	0.94	0.02	0.930
6	1.14	0.69	1.09	0.69	0.11	0.234
3D Displacement						
1	3.70	0.92	3.70	0.92	0.05	0.907
2	3.51	0.90	3.53	0.91	0.05	0.261
6	2.42	0.81	2.45	0.75	0.10	0.335
Vestibulo-lingual Angulation						
1	-4.50	3.78	-4.64	3.85	0.90	0.674
2	-5.62	7.36	-4.16	8.45	3.18	0.256
6	-2.25	3.02	-2.38	3.93	1.98	0.864
Mesiodistal Angulation						
1	0.47	2.82	-0.98	1.58	2.74	0.154
2	-1.53	4.53	-2.11	3.17	3.17	0.931
6	2.58	4.01	2.40	3.70	2.42	0.840
Occlusal plane Angulation						
OP	3.28	2.42	3.35	2.38	0.11	0.074

1 - mean between right and left maxillary permanent central incisors

2 - mean between right and left maxillary permanent lateral incisor

6 - mean of maxillary right and left first permanent molars

OP - mean of right and left occlusal plane

Table II: Results of normality test (Shapiro-Wilk)

	Experimental Group	Comparison Group
	P	P
Right-Left Displacement		
1	0.35	0.03*
2	0.23	0.13
6	0.89	0.30
Antero-Posterior Displacement		
1	0.22	0.02*
2	0.16	0.24
6	0.97	0.10
Supero-Inferior Displacement		
1	0.43	0.02*
2	0.36	0.23
6	0.36	0.11
3D Displacement		
1	0.30	0.01*
2	0.77	0.38
6	0.84	0.28
Vestibulo-lingual Angulation		
1	0.00*	0.07
2	0.13	0.29
6	0.00*	0.47
Mesiodistal Angulation		
1	0.09	0.67
2	0.08	0.25
6	0.00*	0.33
Occlusal plane Angulation		
OP	0.86	0.90

1 - mean between right and left maxillary permanent central incisors

2 - mean between right and left maxillary permanent lateral incisor

6 - mean of maxillary right and left first permanent molars

OP - mean of right and left occlusal plane

* Statistically significant at $P < 0.05$

Table III. Intergroup comparison of age and sex distribution and overbite values

Variable	Experimental Group (n=22)		Comparison Group (n=24)		P
	Mean	SD	Mean	SD	
Age (y)	8.18	1.07	8.33	1.00	0.635†
Sex	n	%	n	%	0.552‡
Female	15	68.2	14	58.3	
Male	7	31.8	10	41.7	
Overbite T1 (mm)	-4.52	1.48	-4.35	1.69	0.715†
Overbite T2 (mm)	1.48	1.11	1.56	1.17	0.823†
Overbite T2-T1 (mm)	6.00	1.79	5.91	1.75	0.855†

†, t test

‡, Fisher exact test

T1, Pretreatment

T2, After 24 months of treatment

T2-T1, Treatment changes

Table IV. 3D Changes, registration based on the ROI around the palate

	Experimental Group N=22		Comparison Group N=24					
	Mean	SD	Mean	SD	Mean Difference	95%CI		P
Right-Left Displacement								
1	-0.39	0.49	-0.44	0.51	0.05	-0.24	0.35	0.775†
2	-0.06	0.84	-0.53	0.75	0.47	-0.04	0.99	0.070‡
6	0.45	0.58	0.32	0.45	0.13	-0.18	0.43	0.416‡
Antero-Posterior Displacement								
1	1.80	1.39	1.43	1.07	0.38	-0.36	1.11	0.676†
2	1.98	1.02	1.87	1.00	0.12	-0.54	0.78	0.720‡
6	2.09	0.83	2.06	0.84	0.03	-0.47	0.53	0.902‡
Supero-Inferior Displacement								
1	3.13	0.96	3.03	1.81	0.11	-0.75	0.97	0.312†
2	2.79	1.13	2.34	1.24	0.45	-0.33	1.23	0.250‡
6	0.98	0.57	1.08	0.83	-0.09	-0.52	0.33	0.665‡
3D Displacement								
1	3.98	1.04	3.76	1.61	0.22	-0.60	1.03	0.235†
2	3.76	1.17	3.42	1.05	0.33	-0.39	1.06	0.356‡
6	2.58	0.76	2.62	0.75	-0.04	-0.49	0.41	0.867‡
Vestibulo-lingual Inclination								
1	-3.40	7.58	-4.92	5.50	1.51	-2.40	5.42	0.843†
2	-3.69	9.46	-1.47	6.75	-2.21	-7.47	3.04	0.399‡
6	-1.64	4.80	-1.31	2.73	-0.33	-2.63	1.96	0.416†
Mesiodistal Angulation								
1	0.72	4.02	0.70	2.72	0.02	-2.01	2.04	0.987‡
2	-2.20	6.20	1.76	4.93	-3.95	-7.56	0.34	0.033‡*
6	4.53	1.62	2.55	3.55	1.98	-3.03	7.00	0.792†
Occlusal plane Angulation								
OP	4.03	2.31	2.80	3.60	1.22	-0.60	3.05	0.184‡

1 - mean between right and left maxillary permanent central incisors

2 - mean between right and left maxillary permanent lateral incisor

6 - mean of maxillary right and left first permanent molars

OP - mean of right and left occlusal plane

† Mann-Whitney U test

‡ t test

* Statistically significant at $P < 0.05$

3 DISCUSSION

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Anterior open bite on mixed dentition has mostly dentoalveolar origin, is usually accompanied by deleterious habits and several early treatment protocols has been studied. (CANUTO; JANSON; DE LIMA; DE ALMEIDA *et al.*, 2016; CASSIS; DE ALMEIDA; JANSON; DE ALMEIDA-PEDRIN *et al.*, 2012; COZZA; BACCETTI; FRANCHI; MCNAMARA, 2006; INSABRALDE; DE ALMEIDA; HENRIQUES; FERNANDES *et al.*, 2016; JUSTUS, 2001; LEITE; MATIUSSI; SALEM; PROVENZANO *et al.*, 2016; PEDRIN; ALMEIDA; ALMEIDA; ALMEIDA-PEDRIN *et al.*, 2006; ROSSATO; FERNANDES; URNAU; DE CASTRO *et al.*, 2018; SLAVIERO; FERNANDES; OLTRAMARI-NAVARRO; DE CASTRO *et al.*, 2017) Thus, those therapies aim to provide the correction of overbite by the interruption of deleterious habit, allowing the vertical development of anterior teeth. (CASSIS; DE ALMEIDA; JANSON; ALIAGA-DEL CASTILLO *et al.*, 2018; CASSIS; DE ALMEIDA; JANSON; DE ALMEIDA-PEDRIN *et al.*, 2012; COZZA; BACCETTI; FRANCHI; MUCEDERO *et al.*, 2005)

The treatment of anterior open bite with bonded spurs associated with posterior build-ups was only reported on permanent dentition. (VELA-HERNANDEZ; LOPEZ-GARCIA; GARCIA-SANZ; PAREDES-GALLARDO *et al.*, 2017) Therefore, this was the first randomized clinical trial that compared this therapy with bonded spurs alone in early treatment of anterior open bite.

The effectiveness of anterior open bite early treatment has been evaluated on an average interval of 12 months, reporting 53.8 (LEITE; MATIUSSI; SALEM; PROVENZANO *et al.*, 2016) to 86.7% (CASSIS; DE ALMEIDA; JANSON; DE ALMEIDA-PEDRIN *et al.*, 2012) of efficiency. On this study, the extension of treatment time of 24-month was fundamental to evaluate the dentoskeletal effects and its influence on treatment efficiency.

Most of studies measured anterior open bite on lateral cephalograms, however, some limitations might be found due to the 2D evaluation. (SLAVIERO; FERNANDES; OLTRAMARI-NAVARRO; DE CASTRO *et al.*, 2017) Therefore, analyze dentoalveolar changes on 3D digital dental models has been considered better method than

cephalometric evaluation. (SLAVIERO; FERNANDES; OLTRAMARI-NAVARRO; DE CASTRO *et al.*, 2017)

It is important to mention that using the superimposition of digital dental models results in less limitations when compared to cephalometric superimposition because the first one provides a lot of useful information, a risk-free imaging technique and, mostly, a huge range of possibilities for the evaluation of tooth movement. (STUCKI; GKANTIDIS, 2020) In this context, as facial structures grows, the palatal rugae have been considered a stable reference during this process, mainly, in the transverse and sagittal planes (ALMEIDA; PHILLIPS; KULA; TULLOCH, 1995; CHOI; CHA; JOST-BRINKMANN; CHOI *et al.*, 2012; GARIB; MIRANDA; YATABE; LAURIS *et al.*, 2019; HOGGAN; SADOWSKY, 2001; MILLER; KUO; CHOI, 2003) The process of superimposition is refined due the number of preparation steps. This advantage provides more reliability, reducing 3D errors. The use of two-thirds of the third rugae is considered a reliable method. (GARIB; MIRANDA; YATABE; LAURIS *et al.*, 2019; STUCKI; GKANTIDIS, 2020)

After 12-month of treatment, 16 out of 24 (66.7%) patients in the G1 and 18 out 25 (72%) patients in G2 had the AOB closed, presenting a positive overlap. The posterior build-ups were removed from G1 leaving the groups equivalent in terms of therapy. On 24-month evaluation, 22 out 22 (100%) in the G1 and 23 out 24 (95.83%) in G2 presented positive overlap. Pretreatment overbite of the experimental and comparison groups were of -4.45 and -4.36mm, respectively (Table III).

On this 1 patient (4.16%) of G2 that presented negative overlap, the persistence of deleterious habit was reported by the patient's parents. However, when compared to 12-month evaluation, there was a greater closure of AOB. In cases like this, it may be necessary a more robust appliance such as fixed palatal crib or soldered spurs.(CANUTO; JANSON; DE LIMA; DE ALMEIDA *et al.*, 2016; JUSTUS, 2001; LEITE; MATIUSSI; SALEM; PROVENZANO *et al.*, 2016) A similar increase on overbite was clinically observed in both treatment protocols, undependable of posterior build-ups (Table III). Nevertheless, the closure of AOB was greater on 24-month evaluation then 12-month evaluation period.

Maxillary incisors presented a medial displacement, which can be justified by midline diastema closure, also favored by normal maxillary canine eruption path (Table IV). (MOORREES; GRØN; LEBRET; YEN *et al.*, 1969) Also forward displacement of maxillary incisors was observed, which may be consequent to leveling the accentuated curve of Spee of the maxillary arch. Buccal and forward displacement of the maxillary molars are most likely due to the occlusal contacts between posterior build-ups and antagonistic teeth and using leeway space as the second deciduous molars are exfoliated. (CANUTO; JANSON; DE LIMA; DE ALMEIDA *et al.*, 2016; CASSIS; DE ALMEIDA; JANSON; DE ALMEIDA-PEDRIN *et al.*, 2012; DA SILVA FILHO; RJ; MAIA, 1991; JUSTUS, 2001; MOORREES; GRØN; LEBRET; YEN *et al.*, 1969)

Similar extrusion of maxillary incisors was observed in both treatment protocols (Table IV). The decrease of AOB by maxillary incisors extrusion corresponds to an average of 3.08mm in two years of treatment. However, some extrusion of the mandibular incisors are necessary to complete closure of open bite. (SLAVIERO; FERNANDES; OLTRAMARI-NAVARRO; DE CASTRO *et al.*, 2017) Thus, evaluation of the mandibular arch would also be necessary to provide a better idea of the amount of vertical changes of the maxillary and mandibular incisors in open bite correction.

On experimental group, molars extrusion was of 0.98 and on comparison group were 1.08 mm (Table IV). During the treatment period of 12-month, the posterior build-ups were not effective on vertical control. (ALIAGA-DEL CASTILLO; VILANOVA; MIRANDA; ARRIOLA-GUILLÉN *et al.*, 2020) Therefore, it is coherent that no further vertical effects were found on 24-months treatment period.

Due to the closure of anterior diastema as the bite closes, the maxillary central and lateral incisors had a root distal angulation. (JANSON; VALARELLI, 2014; LINDAUER; RUBENSTEIN; HANG; ANDERSEN *et al.*, 1992; MOYERS, 1976; RODRIGUES; URSI, 1990; VAN DER LINDEN; DUTERLOO, 1976) Mesial angulation of molars was consistent with their normal eruption path. Palatally tipping of maxillary incisors and molars occurred due open bite closure and probably by the contacts of the build-ups with the opposing teeth buccal cusps, respectively. (DA SILVA FILHO; RJ; MAIA, 1991; JANSON; VALARELLI, 2014; VAN DER LINDEN; DUTERLOO, 1976) This must be further investigated. The occlusal plane had a clockwise rotation.

The findings of this research showed that both protocols presented similar increase of anterior open bite, and no significant clinical differences were observed between therapies. However, extending treatment time to 24-month was essential to achieve the closure of anterior open bite in cases where this closure was not obtained, after 12-month of treatment.

4 CONCLUSIONS

4 CONCLUSIONS

The outcomes of this research lead to following conclusions:

- Both protocols showed similar 3D changes in the maxillary incisors and molars;
- Superimposition of digital dental models showed similar extrusion, medial and forward displacement of the maxillary incisors and similar extrusion, buccal and forward displacement of the maxillary molars for both groups after 24 months of treatment;
- A treatment period of 24 months of AOB provides greater efficiency than a 12-month period.

REFERENCES

REFERENCES

AKYALÇIN, Ç. A. A. R. Skeletal Open Bite Correction with Rapid Molar Intruder Appliance in Growing Individuals. **Angle Orthod**, 77, n. 4, p. 632-638, 2007.

ALBOGHA, M. H.; TAKAHASHI, I.; SAWAN, M. N. Early treatment of anterior open bite: Comparison of the vertical and horizontal morphological changes induced by magnetic bite-blocks and adjusted rapid molar intruders. **Korean J Orthod**, 45, n. 1, p. 38-46, Jan 2015.

ALIAGA-DEL CASTILLO, A.; VILANOVA, L.; MIRANDA, F.; ARRIOLA-GUILLÉN, L. E. *et al.* Dentoskeletal changes in open bite treatment using spurs and posterior build-ups: A randomized clinical trial. **Am J Orthod**, 2021.

ALMEIDA, M. A.; PHILLIPS, C.; KULA, K.; TULLOCH, C. Stability of the palatal rugae as landmarks for analysis of dental casts. **Angle Orthod**, 65, n. 1, p. 43-48, 1995.

CANGIALOSI, T. J. Skeletal morphologic features of anterior open bite. **Am J Orthod**, 85, n. 1, p. 28-36, Jan 1984.

CANUTO, L. F.; JANSON, G.; DE LIMA, N. S.; DE ALMEIDA, R. R. *et al.* Anterior open-bite treatment with bonded vs conventional lingual spurs: A comparative study. **Am J Orthod**, 149, n. 6, p. 847-855, Jun 2016.

CARANO, A.; MACHATA, W.; SICILIANI, G. Noncompliant treatment of skeletal open bite. **Am J Orthod**, 128, n. 6, p. 781-786, Dec 2005.

CASSIS, M. A.; DE ALMEIDA, R. R.; JANSON, G.; ALIAGA-DEL CASTILLO, A. *et al.* Stability of anterior open bite treatment with bonded spurs associated with high-pull chincup. **Orthod Craniofac Res**, 21, n. 2, p. 104-111, May 2018.

CASSIS, M. A.; DE ALMEIDA, R. R.; JANSON, G.; DE ALMEIDA-PEDRIN, R. R. *et al.* Treatment effects of bonded spurs associated with high-pull chincup therapy in the treatment of patients with anterior open bite. **Am J Orthod**, 142, n. 4, p. 487-493, Oct 2012.

CHOI, J.-I.; CHA, B.-K.; JOST-BRINKMANN, P.-G.; CHOI, D.-S. *et al.* Validity of palatal superimposition of 3-dimensional digital models in cases treated with rapid maxillary expansion and maxillary protraction headgear. **Korean J Orthod**, 42, n. 5, p. 235-241, 2012.

COZZA, P.; BACCETTI, T.; FRANCHI, L.; MCNAMARA, J. A., Jr. Treatment effects of a modified quad-helix in patients with dentoskeletal open bites. **Am J Orthod**, 129, n. 6, p. 734-739, Jun 2006.

COZZA, P.; BACCETTI, T.; FRANCHI, L.; MUCEDERO, M. Comparison of 2 early treatment protocols for open-bite malocclusions. **Am J Orthod**, 132, n. 6, p. 743-747, Dec 2007.

COZZA, P.; BACCETTI, T.; FRANCHI, L.; MUCEDERO, M. *et al.* Sucking habits and facial hyperdivergency as risk factors for anterior open bite in the mixed dentition. **Am J Orthod**, 128, n. 4, p. 517-519, Oct 2005.

COZZA, P.; MUCEDERO, M.; BACCETTI, T.; FRANCHI, L. Treatment and posttreatment effects of quad-helix/crib therapy of dentoskeletal open bite. **Angle Orthod**, 77, n. 4, p. 640-645, Jul 2007.

DA SILVA FILHO, O. G.; GARIB, D. G.; LARA, T. S. **Ortodontia interceptiva: protocolo de tratamento em duas fases**. Artes Médicas Editora, 2015. 8536701781.

DA SILVA FILHO, O.; RJ, G. G.; MAIA, F. A. Sucking habits: clinical management in dentistry. **J Clin Pediatr Dent**, 15, n. 3, p. 137-156, 1991.

DEFRAIA, E.; MARINELLI, A.; BARONI, G.; FRANCHI, L. *et al.* Early orthodontic treatment of skeletal open-bite malocclusion with the open-bite bionator: a cephalometric study. **Am J Orthod**, 132, n. 5, p. 595-598, Nov 2007.

DOSHI, U. H.; BHAD, W. A. Spring-loaded bite-blocks for early correction of skeletal open bite associated with thumb sucking. **Am J Orthod**, 140, n. 1, p. 115-120, Jul 2011.

ERBAY, E.; UGUR, T.; ULGEN, M. The effects of Frankel's function regulator (FR-4) therapy on the treatment of Angle Class I skeletal anterior open bite malocclusion. **Am J Orthod**, 108, n. 1, p. 9-21, Jul 1995.

FERES, M. F.; ABREU, L. G.; INSABRALDE, N. M.; ALMEIDA, M. R. *et al.* Effectiveness of the open bite treatment in growing children and adolescents. A systematic review. **Eur J Orthod**, 38, n. 3, p. 237-250, Jun 2016.

FERES, M. F.; ABREU, L. G.; INSABRALDE, N. M.; DE ALMEIDA, M. R. *et al.* Effectiveness of open bite correction when managing deleterious oral habits in growing children and adolescents: a systematic review and meta-analysis. **Eur J Orthod**, 39, n. 1, p. 31-42, Feb 2017.

FERREIRA, F. P. C.; ALMEIDA, R. R.; TORRES, F. C.; ALMEIDA-PEDRIN, R. R. *et al.* Evaluation of the stability of open bite treatment using a removable appliance with palatal crib combined with high-pull chincup. **Dental Press J Orthod**, 17, p. 52-60, 2012.

GARIB, D.; MIRANDA, F.; YATABE, M.; LAURIS, J. *et al.* Superimposition of maxillary digital models using the palatal rugae: does aging affect the reliability? **Orthod Craniofac Res**, 2019.

GIUNTINI, V.; FRANCHI, L.; BACCETTI, T.; MUCEDERO, M. *et al.* Dentoskeletal changes associated with fixed and removable appliances with a crib in open-bite patients in the mixed dentition. **Am J Orthod**, 133, n. 1, p. 77-80, Jan 2008.

GRABER, T. M.; RAKOSI, T.; PETROVIC, A. G. **Dentofacial orthopedics with functional appliances. 2nd ed.** St Louis, MO: Mosby, 1997. p.484-5.

HOGGAN, B. R.; SADOWSKY, C. The use of palatal rugae for the assessment of anteroposterior tooth movements. **Am J Orthod**, 119, n. 5, p. 482-488, 2001.

INSABRALDE, N. M.; DE ALMEIDA, R. R.; HENRIQUES, J. F.; FERNANDES, T. M. *et al.* Dentoskeletal effects produced by removable palatal crib, bonded spurs, and chincup therapy in growing children with anterior open bite. **Angle Orthod**, 86, n. 6, p. 969-975, Nov 2016.

ISCAN, H. N.; AKKAYA, S.; KORALP, E. The effects of the spring-loaded posterior bite-block on the maxillo-facial morphology. **Eur J Orthod**, 14, n. 1, p. 54-60, Feb 1992.

ISCAN, H. N.; DINCER, M.; GULTAN, A.; MERAL, O. *et al.* Effects of vertical chincap therapy on the mandibular morphology in open-bite patients. **Am J Orthod**, 122, n. 5, p. 506-511, Nov 2002.

JANSON, G.; VALARELLI, F. **Open-bite malocclusion: treatment and stability.** Ames, IA: John Wiley & Sons, Inc, 2014.

JUSTUS, R. Correction of anterior open bite with spurs: long-term stability. **World J Orthod**, 2, p. 219-231, 2001.

KILIARIDIS, S.; EGERMARK, I.; THILANDER, B. Anterior open bite treatment with magnets. **Eur J Orthod**, 12, n. 4, p. 447-457, Nov 1990.

KUSTER, R.; INGERVALL, B. The effect of treatment of skeletal open bite with two types of bite-blocks. **Eur J Orthod**, 14, n. 6, p. 489-499, Dec 1992.

LEITE, J. S.; MATIUSSI, L. B.; SALEM, A. C.; PROVENZANO, M. G. *et al.* Effects of palatal crib and bonded spurs in early treatment of anterior open bite: A prospective randomized clinical study. **Angle Orthod**, 86, n. 5, p. 734-739, Sep 2016.

LENTINI-OLIVEIRA, D. A.; CARVALHO, F. R.; RODRIGUES, C. G.; YE, Q. *et al.* Orthodontic and orthopaedic treatment for anterior open bite in children. **Cochrane Database Syst Rev**, n. 9, p. CD005515, Sep 24 2014.

LINDAUER, S. J.; RUBENSTEIN, L. K.; HANG, W. M.; ANDERSEN, W. C. *et al.* Canine impaction identified early with panoramic radiographs. **Am J Orthod**, 123, n. 3, p. 91-92, 1992.

MILLER, R.; KUO, E.; CHOI, W. Validation of Align Technology's Treat IITM digital model superimposition tool and its case application. **Orthod Craniofac Res**, 6, p. 143-149, t 2003.

MOORREES, C. F.; GRØN, A.-M.; LEBRET, L. M.; YEN, P. K. *et al.* Growth studies of the dentition: a review. **Am J Orthod**, 55, n. 6, p. 600-616, 1969.

MOYERS, R. E. **Standards of human occlusal development.** 1976. 0929921038.

MUCEDERO, M.; FRANCHI, L.; GIUNTINI, V.; VANGELISTI, A. *et al.* Stability of quad-helix/crib therapy in dentoskeletal open bite: a long-term controlled study. **Am J Orthod**, 143, n. 5, p. 695-703, May 2013.

NAHOUM, H. I.; HOROWITZ, S. L.; BENEDICTO, E. A. Varieties of anterior open-bite. **Am J Orthod**, 61, n. 5, p. 486-492, May 1972.

NGAN, P.; FIELDS, H. W. Open bite: a review of etiology and management. **Pediatr Dent**, 19, n. 2, p. 91-98, Mar-Apr 1997.

NIELSEN, I. L. Vertical malocclusions: etiology, development, diagnosis and some aspects of treatment. **Angle Orthod**, 61, n. 4, p. 247-260, Winter 1991.

PEDRIN, F.; ALMEIDA, M. R.; ALMEIDA, R. R.; ALMEIDA-PEDRIN, R. R. *et al.* A prospective study of the treatment effects of a removable appliance with palatal crib combined with high-pull chin cup therapy in anterior open-bite patients. **Am J Orthod**, 129, n. 3, p. 418-423, Mar 2006.

PISANI, L.; BONACCORSO, L.; FASTUCA, R.; SPENA, R. *et al.* Systematic review for orthodontic and orthopedic treatments for anterior open bite in the mixed dentition. **Prog Orthod**, 17, n. 1, p. 28, Dec 2016.

PITHON, M. M.; DOS SANTOS, C. R.; LIMA SANTOS, N.; AGUIAR SALES LIMA, S. O. *et al.* Impact of malocclusion on affective/romantic relationships among young adults. **Angle Orthod**, 86, n. 4, p. 638-643, Jul 2016.

RODRIGUES, d. A. R.; URSI, W. Anterior open bite. Etiology and treatment. **Oral health**, 80, n. 1, p. 27, 1990.

ROSSATO, P. H.; FERNANDES, T. M. F.; URNAU, F. D. A.; DE CASTRO, A. C. *et al.* Dentoalveolar effects produced by different appliances on early treatment of anterior open bite: A randomized clinical trial. **Angle Orthod**, Jun 18 2018.

SANKEY, W. L.; BUSCHANG, P. H.; ENGLISH, J.; OWEN, A. H., 3rd. Early treatment of vertical skeletal dysplasia: the hyperdivergent phenotype. **Am J Orthod**, 118, n. 3, p. 317-327, Sep 2000.

SCHULZ, S. O.; MCNAMARA, J. A., Jr.; BACCETTI, T.; FRANCHI, L. Treatment effects of bonded RME and vertical-pull chincup followed by fixed appliance in patients with increased vertical dimension. **Am J Orthod**, 128, n. 3, p. 326-336, Sep 2005.

SLAVIERO, T.; FERNANDES, T. M.; OLTRAMARI-NAVARRO, P. V.; DE CASTRO, A. C. *et al.* Dimensional changes of dental arches produced by fixed and removable palatal cribs: A prospective, randomized, controlled study. **Angle Orthod**, 87, n. 2, p. 215-222, Mar 2017.

STUCKI, S.; GKANTIDIS, N. Assessment of techniques used for superimposition of maxillary and mandibular 3D surface models to evaluate tooth movement: a systematic review. **Eur J Orthod**, 42, n. 5, p. 559-570, 2020.

SUBTELNY, J. D.; SAKUDA, M. Open-bite: diagnosis and treatment. **Am J Orthod**, 50, n. 5, p. 337-358, 1964.

TORRES, F. C.; ALMEIDA, R. R.; ALMEIDA-PEDRIN, R. R.; PEDRIN, F. *et al.* Dentoalveolar comparative study between removable and fixed cribs, associated to chincup, in anterior open bite treatment. **J Appl Oral Sci**, 20, n. 5, p. 531-537, Sep-Oct 2012.

TORRES, F.; ALMEIDA, R. R.; DE ALMEIDA, M. R.; ALMEIDA-PEDRIN, R. R. *et al.* Anterior open bite treated with a palatal crib and high-pull chin cup therapy. A prospective randomized study. **Eur J Orthod**, 28, n. 6, p. 610-617, Dec 2006.

VALARELLI, F. P.; JANSON, G. O tratamento não cirúrgico da mordida aberta anterior no paciente adulto. **Ortho Sci., Orthod. sci. pract**, 7, n. 27, p. 252-270, 2014.

VAN DER LINDEN, F. P.; DUTERLOO, H. S. **Development of the human dentition: an atlas**. HarperCollins Publishers, 1976. 0061425850.

VELA-HERNANDEZ, A.; LOPEZ-GARCIA, R.; GARCIA-SANZ, V.; PAREDES-GALLARDO, V. *et al.* Nonsurgical treatment of skeletal anterior open bite in adult patients: Posterior build-ups. **Angle Orthod**, 87, n. 1, p. 33-40, Jan 2017.

VILLA, N. L.; CISNEROS, G. J. Changes in the dentition secondary to palatal crib therapy in digit-suckers: a preliminary study. **Pediatr Dent**, 19, n. 5, p. 323-326, Jul-Aug 1997.

WEINBACH, J. R.; SMITH, R. J. Cephalometric changes during treatment with the open bite bionator. **Am J Orthod**, 101, n. 4, p. 367-374, Apr 1992.

APPENDIX

**APPENDIX A- DECLARATION OF EXCLUSIVE USE OF THE ARTICLE IN
DISSERTATION/THESIS**

We hereby declare that we are aware of the article “THREE-DIMENSIONAL EVALUATION OF CONVENTIONAL ANTERIOR OPEN BITE TREATMENT WITH BONDED SPURS ASSOCIATED WITH BUILD-UPS VERSUS CONVENTIONAL BONDED SPURS: A RANDOMIZED CLINICAL TRIAL WITH 24-MONTH FOLLOW-UP” will be included in Dissertation of the student Demi Lisbôa Dahás Jorge and may not be used in other works of Graduate Programs at the Bauru School of Dentistry, University of São Paulo.

Bauru, January 19th, 2021

Demi Lisbôa Dahás Jorge
Author

Signature

Guilherme Janson
Author

Signature

ANNEXES

ANNEX A. Ethics Committee approval, protocol number 19700919.2.0000.5417 (front). **COMPROVANTE DE ENVIO DO PROJETO****DADOS DO PROJETO DE PESQUISA**

Título da Pesquisa: Alterações promovidas pelo tratamento da mordida aberta anterior com esporão colado associado a build-ups versus esporão colado convencional: um ensaio clínico randomizado, acompanhamento de 24 meses

Pesquisador: Olga Benário Vieira Maranhão

Versão: 2

CAAE: 19700919.2.0000.5417

Instituição Proponente: Faculdade de Odontologia de Bauru

DADOS DO COMPROVANTE

Número do Comprovante: 107179/2019

Patrocinador Principal: Financiamento Próprio

Informamos que o projeto Alterações promovidas pelo tratamento da mordida aberta anterior com esporão colado associado a build-ups versus esporão colado convencional: um ensaio clínico randomizado, acompanhamento de 24 meses que tem como pesquisador responsável Olga Benário Vieira Maranhão, foi recebido para análise ética no CEP USP - Faculdade de Odontologia de Bauru da USP em 26/08/2019 às 18:18.

Endereço: DOUTOR OCTAVIO PINHEIRO BRISOLLA 75 QUADRA 9
Bairro: VILA NOVA CIDADE UNIVERSITARIA **CEP:** 17.012-901
UF: SP **Município:** BAURU
Telefone: (14)3235-8356 **Fax:** (14)3235-8356 **E-mail:** cep@fob.usp.br

ANNEX A. Ethics Committee approval, protocol number 19700919.2.0000.5417 (front).

principal
 sair

Público
 Pesquisador
 Alterar Meus Dados

Olga Benário Vieira Maranhão - Pesquisador | V3.2
 Sua sessão expira em: 22min 45

Cadastros

DETALHAR NOTIFICAÇÃO

DADOS DA VERSÃO DO PROJETO DE PESQUISA

Título da Pesquisa: Alterações promovidas pelo tratamento da mordida aberta anterior com esporão colado associado a build-ups versus esporão colado convencional: um ensaio clínico randomizado, acompanhamento de 24 meses
Pesquisador Responsável: Olga Benário Vieira Maranhão
Área Temática:
Versão: 2
CAAE: 19700919.2.0000.5417
Submetido em: 02/10/2019
Instituição Proponente: Faculdade de Odontologia de Bauru
Situação da Versão do Projeto: Aprovado
Localização atual da Versão do Projeto: Pesquisador Responsável
Patrocinador Principal: Financiamento Próprio

Comprovante de Recepção: PB_COMPROVANTE_RECEPCAO_1413690

DADOS DA NOTIFICAÇÃO

Tipo de Notificação: Envio de Relatório Parcial
Detalhe:
Justificativa:
Data do Envio: 18/01/2021
Situação da Notificação: Em relatório

DOCUMENTOS DO PROJETO DE PESQUISA

Versão em Tramitação (E1) - Versão 3
 Emenda (E1) - Versão 3
 Documentos do Projeto
 Comprovante de Recepção - Submissão
 Cronograma - Submissão 1
 Declaração de Instituição e Infraestrutura
 Declaração de Pesquisadores - Submissão
 Folha de Rosto - Submissão 1
 Orçamento - Submissão 1
 Outros - Submissão 1
 Projeto Detalhado / Brochura Investigação
 TCLE / Termos de Assentimento / Justificativa
 Versão Atual Aprovada (PO) - Versão 2
 Projeto Completo

Tipo de Documento	Situação	Arquivo	Postagem	Ações
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HISTÓRICO DE TRÂMITES

Apreciação	Data/Hora	Tipo Trâmite	Versão	Perfil	Origem	Destino	Informações
N1	20/01/2021 19:42:48	Confirmação de Indicação de Relatório	2	Coordenador	USP - Faculdade de Odontologia de Bauru da USP	USP - Faculdade de Odontologia de Bauru da USP	
N1	20/01/2021 15:12:36	Indicação de Relatório	2	Secretária	USP - Faculdade de Odontologia de Bauru da USP	USP - Faculdade de Odontologia de Bauru da USP	
N1	20/01/2021 15:12:20	Aceitação do PP	2	Secretária	USP - Faculdade de Odontologia de Bauru da USP	USP - Faculdade de Odontologia de Bauru da USP	
N1	18/01/2021 20:57:58	Notificação enviada	2	Pesquisador	PESQUISADOR	USP - Faculdade de Odontologia de Bauru da USP	

LEGENDA:

(*) Apreciação
 PO = Projeto Original de Centro Coordenador
 E = Emenda de Centro Coordenador
 N = Notificação de Centro Coordenador
 POP = Projeto Original de Centro Participante
 Ep = Emenda de Centro Participante
 Np = Notificação de Centro Participante
 POC = Projeto Original de Centro Coparticipante
 Ec = Emenda de Centro Coparticipante
 Nc = Notificação de Centro Coparticipante

(*) Formação do CAAE
 Ano de submissão do Projeto Tipo do centro Código do Comitê que está analisando o projeto

n	n	n	n	n	n	a	a	.	d	v	.	t	x	x	x	.	i	i	i	i	i	i	
Sequencial para todos os Projetos submetidos para apreciação						Digito verificador		Sequencial, quando estudo possui Centro(s) Participante(s) e/ou Coparticipante(s)															

Voltar

ANNEX B. Informed consent form (To the minor's responsible).

Universidade de São Paulo
Faculdade de Odontologia de Bauru

Departamento de Odontopediatria, Ortodontia e
Saúde Coletiva

Página 1 de 2

Termo de Consentimento Livre e Esclarecido (Ao responsável do menor)

O menor sob sua responsabilidade está sendo convidado a participar como voluntário da pesquisa intitulada "Alterações promovidas pelo tratamento da mordida aberta anterior com esporão colado associado a build-ups versus esporão colado convencional: um ensaio clínico randomizado, acompanhamento de 24 meses". Essa pesquisa científica será realizada por Olga Benário Vieira Maranhão, Doutoranda em Ortodontia na Faculdade de Odontologia de Bauru da Universidade de São Paulo, sob orientação do Prof. Dr. Guilherme Janson e terá como objetivo avaliar, por meio de modelos dentários e de radiografias, os efeitos dentários e esqueléticos após 24 meses de uso do esporão colado (aparelho fixo, dentro da boca, colado na parte de trás dos dentes anteriores) associado ou não a resinas nos dentes póstero-superiores (de cima e de trás, de acordo com o grupo sorteado) em indivíduos dos 8 aos 11 anos de idade. O aparelho tem a função de impedir a língua em se interpor entre os dentes da frente e auxiliará o menor a não mais utilizar chupeta ou chupar o dedo. A finalidade deste aparelho é proporcionar um bom relacionamento entre os arcos dentários, corrigindo a "mordida aberta anterior" presente. Você e o menor sob sua responsabilidade serão orientados durante todo o tratamento sobre os cuidados necessários e sobre eventuais questionamentos.

Será realizada a remoção do aparelho após 24 meses de tratamento, seguida pela realização da documentação (registro) do menor, que consistirá em: três fotografias extrabucais (frente, lateral, e do sorriso), cinco fotografias intrabucais (frontal, lateral direita, lateral esquerda, oclusal superior e oclusal inferior), radiografias (panorâmica, lateral, e periapicais dos dentes da frente) e digitalização (escaneamento) dos arcos dentários superior e inferior (dentes de cima e de baixo) com scanner digital. As documentações são necessárias para avaliar os efeitos do tratamento.

As tomadas radiográficas são procedimentos comuns realizados respeitando todas as medidas de segurança com a mínima exposição necessária aos raios-x. Fotografias são procedimentos rápidos e fazem parte da rotina odontológica. O procedimento de digitalização dos arcos dentários é um método simples e apresenta mínimo desconforto e nenhum risco para o menor. Se acontecer algum tipo de desconforto, o profissional saberá como aliviá-lo imediatamente.

Durante a remoção do aparelho, o menor poderá sentir uma rápida pressão nos dentes onde estão os esporões. Em seguida, será possível continuar a rotina normal de alimentação e higienização sem nenhum problema.

Na consulta de remoção do aparelho, será entregue um questionário para avaliar desconforto ou dor que o paciente possa ter sentido durante o tratamento, assim como o impacto deste tratamento na qualidade de vida do paciente. O questionário é simples e apresenta perguntas diretas que estão escritas de acordo com a faixa etária do menor. Deverá ser respondido pelo menor e entregue logo após a consulta, e em caso de dúvidas sobre como o questionário funciona, a pesquisadora responsável estará por perto para auxiliar.

O tempo total de tratamento será de 24 meses. Todos os procedimentos clínicos serão realizados pela própria pesquisadora responsável, na clínica de Ortodontia da Faculdade de Odontologia de Bauru, Universidade de São Paulo. Ao participar desta pesquisa, o menor sob sua responsabilidade apresentará como benefícios a gratuidade do planejamento ortodôntico, do tratamento das suas más oclusões (posicionamento incorreto dos dentes), do acompanhamento clínico, e, caso apresentem a necessidade de algum outro tratamento bucal, serão encaminhados para o sistema de Triagem da Faculdade de Odontologia de Bauru para serem posteriormente encaminhados a outros Departamentos. Se houver suspeita de qualquer alteração médica ou psicológica, os responsáveis serão orientados a buscar tratamento e acompanhamento adequado para o menor. Ao final do estudo, os participantes terão garantido o acompanhamento e/ou tratamento ortodôntico complementar (se necessário) e estarão dispostos aos melhores métodos preventivos, diagnósticos e terapêuticos que se demonstrarem eficazes, por parte da Instituição patrocinadora. Não será oferecida remuneração, auxílio para alimentação ou transporte até o local nos dias de atendimento. E garantida a indenização em casos de danos que ocorram decorrentes dos procedimentos empregados nesta pesquisa.

É importante que você saiba que tanto a privacidade do menor sob sua responsabilidade quanto a sua serão respeitadas. Ou seja, o nome do menor, o seu, ou qualquer outro dado que possa, de qualquer forma, identificá-los, será mantido em sigilo. Saiba também que o menor receberá um termo como este o convidando a participar desta pesquisa e que, caso ele recuse o convite, a vontade dele será prevaída, mesmo que o Sr(a) (pais/responsável legal) permita sua participação. O menor poderá deixar de participar da pesquisa a qualquer momento sem sofrer prejuízos, retirando, então, seu consentimento, sem precisar justificar.

As pesquisadoras envolvidas com a referida pesquisa são Olga Benário Vieira Maranhão e Demi Lisbôa Dahás Jorge e com elas você poderá manter contato via e-mail (olgamaranhao@hotmail.com ou demidahas@hotmail.com) ou telefone (84) 994077278/ (91) 981115553.

Rubrica do Participante da Pesquisa:

ANNEX B. Informed consent form (To the minor's responsible).

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Universidade de São Paulo
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É assegurado o esclarecimento de dúvidas durante toda pesquisa, bem como será garantido o livre acesso a todas as informações e esclarecimentos adicionais sobre o estudo.

Pelo presente instrumento que atende às exigências legais, o(a) Sr.(a) _____, responsável pelo menor _____, portador da cédula de identidade _____,

após leitura minuciosa das informações constantes neste TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO, devidamente explicada pelos profissionais em seus mínimos detalhes, ciente dos serviços e procedimentos aos quais será submetido, não restando quaisquer dúvidas a respeito do lido e explicado, DECLARA e FIRMA seu CONSENTIMENTO LIVRE E ESCLARECIDO concordando em participar da pesquisa proposta. Fica claro que o participante da pesquisa, pode a qualquer momento retirar seu CONSENTIMENTO LIVRE E ESCLARECIDO e deixar de participar desta pesquisa e ciente de que todas as informações prestadas tornar-se-ão confidenciais e guardadas por força de sigilo profissional (Art 9º do Código de Ética Odontológica).

Por fim, como pesquisador responsável pela pesquisa, DECLARO o cumprimento do disposto na Resolução CNS nº 466 de 2012, contidos nos itens IV.3 e IV.5.a e, na íntegra com a resolução CNS nº 466 de dezembro de 2012.

Por estarmos de acordo com o presente termo o firmamos em duas vias igualmente válidas (uma via para o participante da pesquisa e outra para o pesquisador) que serão rubricadas em todas as suas páginas e assinadas ao seu término, conforme o disposto pela Resolução CNS nº 466 de 2012, itens IV.3.f e IV.5.d.

Bauru, ____ de _____ de _____.

 Olga Benário Vieira Maranhão
 Pesquisadora responsável

 Assinatura do responsável pelo menor

O Comitê de Ética em Pesquisa – CEP, organizado e criado pela FOB-USP, em 29/06/98 (Portaria GD/0688/FOB), previsto no item VIII da Resolução nº 466/12 do Conselho Nacional de Saúde do Ministério da Saúde (publicada no DOU de 13/06/2013), é um Colegiado Interdisciplinar e Independente, de relevância pública, de caráter consultivo, deliberativo e educativo, criado para defender os interesses dos participantes da pesquisa em sua integridade e dignidade e para contribuir no desenvolvimento da pesquisa dentro de padrões éticos.

Qualquer denúncia e/ou reclamação sobre sua participação na pesquisa poderá ser reportada a este CEP:

Horário e local de funcionamento:

Comitê de Ética em Pesquisa

Faculdade de Odontologia de Bauru-USP - Prédio da Pós-Graduação (bloco E - pavimento superior), de segunda à sexta-feira, no horário das 13h30 às 17 horas, em dias úteis.

Alameda Dr. Octávio Pinheiro Brisolla, 9-75

Vila Universitária - Bauru - SP - CEP 17012-901

Telefone/FAX: (14) 3235-8356

e-mail: cep@fob.usp.br

ANNEX B. Informed consent form (To the minor).

Página 1 de 1

**Universidade de São Paulo
Faculdade de Odontologia de Bauru**

Departamento de Odontopediatria, Ortodontia e
Saúde Coletiva

Termo de Assentimento

Você está sendo convidado (a) a participar da pesquisa **“Alterações promovidas pelo tratamento da mordida aberta anterior com esporão colado associado a build-ups versus esporão colado convencional: um ensaio clínico randomizado, acompanhamento de 24 meses”**. Essa pesquisa será realizada pela Dra. Olga Benário Vieira Maranhão, aqui na Faculdade de Odontologia de Bauru da Universidade de São Paulo (FOB-USP) e consiste na continuação da pesquisa previamente aprovada pelo CEP e realizada pelo Arón Aliaga Del Castillo, sob CAAE 68551617.8.0000.5417. Caso concorde em participar, é importante que você saiba que os atendimentos serão aqui na clínica de Ortodontia desta faculdade (FOB-USP). Assim como você, o seu responsável também será informado sobre a sua participação neste estudo.

O aparelho que você utilizou para corrigir a mordida aberta anterior será removido e para isso será necessária a realização de alguns procedimentos. Mas não se preocupe, são todos seguros. Vamos tirar algumas fotos e fazer um exame para ver a posição dos seus ossos (radiografias). A remoção do aparelho é rápida e será seguida pela remoção do excesso de massinha (resina) que poderá ficar colado nos dentes neste momento. Durante a retirada do aparelho você sentirá uma pressão nos dentes, mas o procedimento é seguro e não causará problemas aos seus dentes.

Depois da remoção do aparelho você vai receber um questionário sobre desconforto com o aparelho e qualidade de vida que o tratamento trouxe a você. As perguntas são simples e estão escritas de uma forma que você consiga entender. Em caso de dúvidas sobre o questionário, pode perguntar à pesquisadora responsável.

Você não precisa participar da pesquisa se não quiser. Não terá nenhum problema e receberá atendimento da mesma forma. Se você não tiver o desejo de participar pode pintar a carinha triste.

Sendo assim, após me explicarem ou ter lido e entendido todas as informações deste texto, eu, _____ aceito participar da pesquisa **“Alterações promovidas pelo tratamento da mordida aberta anterior com esporão colado associado a build-ups versus esporão colado convencional: um ensaio clínico randomizado, acompanhamento de 24 meses”**, pintando a carinha feliz.

Entendi as coisas ruins e as coisas boas que podem acontecer.

Entendi que posso dizer “sim” e participar, mas que, a qualquer momento, posso dizer “não” e desistir e que ninguém vai ficar furioso.

Os pesquisadores tiraram minhas dúvidas e conversaram com os meus responsáveis.

Recebi uma cópia deste termo de assentimento e concordo em participar da pesquisa.

Bauru, ____ de _____ de _____.

Olga Benário Vieira Maranhão
Pesquisadora responsável

Assinatura do menor

SIM, CONCORDO

NÃO CONCORDO