UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU

OLGA BENÁRIO VIEIRA MARANHÃO

Dentoalveolar and skeletal changes after 2-year anterior open bite treatment with bonded spurs associated with build-ups versus conventional bonded spurs: a randomized clinical trial

Alterações dentoalveolares e esqueléticas após 2 anos de tratamento da mordida aberta anterior com esporões colados associados a build-ups versus esporões colados: um ensaio clínico randomizado

BAURU
2021

OLGA BENÁRIO VIEIRA MARANHÃO

Dentoalveolar and skeletal changes after 2-year anterior open bite treatment with bonded spurs associated with build-ups versus conventional bonded spurs: a randomized clinical trial

Alterações dentoalveolares e esqueléticas após 2 anos de tratamento da mordida aberta anterior com esporões colados associados a build-ups versus esporões colados: um ensaio clínico randomizado

Tese constituída por artigo apresentada à Faculdade de Odontologia de Bauru da Universidade de São Paulo para obtenção do título de Doutor em Ciências no Programa de Ciências Odontológicas Aplicadas, na área de concentração Ortodontia.

Orientador: Prof. Dr. Arnaldo Pinzan

BAURU

2021

Benário Vieira Maranhão, Olga

Dentoalveolar and skeletal changes after 2-year anterior open bite treatment with bonded spurs associated with build-ups versus conventional bonded spurs: a randomized clinical trial / Olga Benário Vieira Maranhão. – Bauru, 2021.

93 p. : il. ; cm.

Tese (Doutorado) – Faculdade de Odontologia de Bauru. Universidade de São Paulo

Orientador: Prof. Dr. Arnaldo Pinzan

Comitê de Ética da FOB-USP
Registro **CAAE: 19700919.2.0000.5417**
Data: **21 de Novembro de 2019**

Universidade de São Paulo
Faculdade de Odontologia de Bauru

Assistência Técnica Acadêmica

Serviço de Pós-Graduação

FOLHA DE APROVAÇÃO

Tese apresentada e defendida por
OLGA BENÁRIO VIEIRA MARANHÃO
e aprovada pela Comissão Julgadora
em 20 de janeiro de 2022.

Prof.ª Dr.ª **RITA DE CÁSSIA MOURA CARVALHO LAURIS**
HRAC

Prof.ª Dr.ª **KARINA MARIA SALVATORE DE FREITAS**
UNINGÁ

Prof.ª Dr.ª **DANIELA GAMBA GARIB CARREIRA**
FOB-USP

Prof. Dr. **ARNALDO PINZAN**
Presidente da Banca
FOB - USP

Profª. Drª. **Izabel Regina Fischer Rubira de Bullen**
Presidente da Comissão de Pós-Graduação

Al. Dr. Octávio Pinheiro Brisolla, 9-75 – Bauru-SP – CEP 17012-901 – C.P. 73
e-mail: posgrad@fob.usp.br – Fone/Fax (0xx14) 3235-8223
http://www.fob.usp.br

DEDICATÓRIA

Dedico este trabalho às pessoas que mais me incentivam: meus pais (Bárbara e Alexandre) e minha irmã Ana Rosa. Obrigada pela força e amor sem medidas.

AGRADECIMENTOS

Em uma jornada como esta, acadêmica, longa, cansativa e que exige muito de quem resolve estar envolvida, é impossível obter êxito sozinha. Agradeço a todos que contribuíram de alguma forma na construção da minha formação acadêmica:

Agradeço primeiramente a ***Deus****, por sempre me manter em pé e me acolher na fé em todos os momentos difíceis e provações*

*Aos meus pais (****Bárbara*** *e* ***Alexandre****) pelo amor sem medidas, apoio, palavras de carinho e educação. Sem o suporte desse casal maravilhoso eu jamais teria chegado até aqui. Sou grata aos dois por terem acreditado nos meus sonhos e objetivos, e por nunca desistirem de mim. Gratidão por sempre terem dado a força que eu precisava para ir mais longe, e por terem trilhado todo este caminho ao meu lado (mesmo quando a distância física nos separava). Obrigada por me ensinarem desde cedo a importância de ter empatia, de tratar o outro com carinho e respeito e a valorizar o estudo/educação. Esses valores são a base da minha vida como dentista e docente.*

À minha irmã ***Ana Rosa****, que também é minha melhor amiga, incentivadora e confidente. Obrigada pelas palavras de incentivo nos momentos em que eu me sentia incapaz ou desgastada demais para seguir em frente. Minha conquista de hoje também é dela! Tenho sorte de ter um núcleo familiar que emana tanto amor e apoio.*

À toda minha família pelo carinho e torcida ao longo de todos esses anos de estudos e abdicação. Agradeço especialmente aos meus

*padrinhos **Silenice e Damião**, que também são como pais para mim, e que sempre me deram suporte através do seu amor e fé.*

*Aos meus amigos da família Norte/Nordeste pela parceria durante minha jornada acadêmica em Bauru e por dividirem comigo as alegrias e dificuldades da formação acadêmica. Obrigada pelos momentos de alegria, companheirismo e conversas. Me orgulho de todos vocês **Anna Clara, Lucas, Carol, Kalil, Jeff, Rod, Helô, Mari Petri, Everardo e Mari Pordeus**. Dentro desse grupo, agradeço especialmente à Anna Clara e Lucas por toda a acolhida durante o ano de 2021, por me receberem com tanto carinho e vivenciarem comigo meus desafios e conquistas: tornaram tudo muito mais leve!*

*Aos meus amigos de Natal, principalmente **Aura, Anny, Carmem, Larissa, Vanessa Maisel** e **Reinaldo** por serem presentes na proximidade e na distância, pelo cuidado e torcida. Sorte a minha de ter conhecido pessoas tão incríveis e generosas.*

Às minhas turmas de mestrado e doutorado por estarem ao meu lado, pelo aprendizado diário, pelas risadas e choros que vieram ao longo da nossa formação. Chegamos no mestrado com muito desejo de aprender, sonhos e dúvidas; e estamos saindo como pessoas diferentes, mais maduras, com mais conhecimento e um grupo de amigos incrível.

*Aos meus amigos e colegas da Ortodontia, que chegaram através das turmas de mestrado e doutorado ao longo dos anos. Com eles aprendi muito sobre ortodontia, mas principalmente convivi com pessoas com diferentes histórias de vida e pensamentos. Agradeço especialmente à **Henrique Eto, Paula Cotrim, Thagid Yasmin** e **Lorena Vilanova** por terem sido calouros e veteranas tão incríveis e amigos. Ficarão*

guardados no meu coração com muito carinho, e sempre serão bem-vindos em minha cidade querida para nossos reencontros.

*À **Aron e Demi** pela parceria nesta pesquisa. Tive a sorte de ter esses dois amigos incríveis, parceiros, dedicados e inteligentes durante a elaboração e andamento desta tese de doutorado. Trabalhar com pessoas tão corretas e tranquilas é inspirador e me ensina muito diariamente. A vocês, toda minha admiração e carinho.*

*A **Dr. Guilherme Janson** por todos os ensinamentos durante os anos que fui sua aluna. Quem foi aluno do mesmo tem muitas histórias para contar a respeito dos seminários de artigo, das qualificações em inglês e sobre seu famoso jeito exigente na docência. Além dessas histórias, tenho uma gratidão enorme por todo o conhecimento que recebi nesse caminho. Hoje em dia entendo muito mais cada cobrança e exigência. Com certeza encerro agora meu ciclo como pós-graduanda com uma visão mais ampla a respeito da ciência, do ensino e da Ortodontia. Mesmo após nos deixar de forma tão prematura, Dr. Guilherme continua presente aqui... não apenas nesta tese ou na Ortodontia da FOB-USP, mas também no pensamento de todos os alunos que ele ajudou a formar ao longo de sua vida. Obrigada por ter me escolhido como orientada e por ter feito parte da minha história, "Big Boss"!*

*À **Dra. Daniela Garib** por ser um exemplo de professora, mulher e ortodontista. Sempre me inspirou ao longo desses anos, e recentemente me acolheu com um carinho e cuidado imenso após a perda do meu orientador. Serei imensamente grata por todos os ensinamentos e pela empatia que tem comigo.*

*Ao **Dr. Arnaldo Pinzan** por me receber nesses últimos meses como sua orientada, me ajudando a finalizar (junto com Dra. Daniela) a pesquisa que Dr. Guilherme me confiou. Gratidão por seu acolhimento, pelas conversas, sugestões e preocupação comigo. Jamais irei esquecer!*

*Aos professores Dr. **José Fernando Castanha Henriques,** Dr. **Marcos Roberto de Freitas e** Dr. **Renato Rodrigues de Almeida** pelos ensinamentos e suporte durante minha jornada na formação ortodôntica e acadêmica.*

Aos pacientes que fizeram parte desta pesquisa e aos seus responsáveis, pela confiança em nosso trabalho e por contribuírem com a ciência. Gratidão por terem proporcionado que este trabalho se tornasse realidade.

*Aos funcionários do departamento de Ortodontia da FOB-USP: **Cléo Vieira, Daniel Selmo, Sérgio Vieira, Vera Purgato e Wagner Baptista** por toda a ajuda e incentivo ao longo dos últimos anos.*

*À **Coordenação de Aperfeiçoamento de Pessoal de Nível Superior** – Brasil (CAPES) – Código de financiamento 001 pelo apoio na elaboração do presente trabalho.*

*À **Faculdade de Odontologia de Bauru, Universidade de São Paulo** por fornecer o suporte físico para minha formação acadêmica.*

"O que sabemos é uma gota; o que ignoramos é um oceano"

Isaac Newton

ABSTRACT

DENTOALVEOLAR AND SKELETAL CHANGES AFTER 2-YEAR ANTERIOR OPEN BITE TREATMENT WITH BONDED SPURS ASSOCIATED WITH BUILD-UPS VERSUS CONVENTIONAL BONDED SPURS: A RANDOMIZED CLINICAL TRIAL

Anterior open bite is a malocclusion commonly related to increased antero-inferior facial height, and consequently, some early treatment protocols associate appliances that allow the vertical development of anterior teeth with devices that control the vertical dimension. Studies regarding the treatment of anterior open bite associating build-ups with bonded spurs have been recently reported. The aim of the present study was to compare, after 24 months, the dentoalveolar and skeletal effects of the interceptive treatment of anterior open bite. Initially, 50 patients, aged between 7 and 11 years, with anterior open bite were included, into two groups: experimental, with 25 patients treated with bonded spurs associated with build-up; and control, with 25 patients treated only with bonded spurs. Lateral headfilms and digital models were obtained at the initial (T1) and at the end of treatment (T2). Shapiro-Wilk tests were used to test normal distribution and sex distribution was analyzed with Fisher exact test. Intergroup comparisons were performed with the t test, and intragroup comparisons with the dependent t test, respectively ($P<0.05$). Both groups presented similar results regarding dental and cephalometric variables. The 24-month treatment time was more effective in the treatment of more severe anterior open bites than 12 months of treatment.

Keywords: Open bite, mixed dentition, bonded spurs, build-ups.

RESUMO

Alterações dentoalveolares e esqueléticas após 2 anos de tratamento da mordida aberta anterior com esporões colados associados a build-ups versus esporões colados: um ensaio clínico randomizado

A mordida aberta anterior é uma má oclusão comumente relacionada ao aumento da altura facial ântero-inferior, e em razão disto alguns protocolos de tratamento precoce associam aparelhos que permitem o desenvolvimento vertical dos dentes anteriores com dispositivos que geram controle da dimensão vertical. Recentemente foram relatados estudos associando build-ups com esporões linguais para o tratamento da mordida aberta anterior. O objetivo do presente trabalho foi comparar, após 24 meses, os efeitos dentoalveolares e esqueléticos do tratamento interceptivo da mordida aberta anterior. Foram incluídos inicialmente 50 pacientes, entre 7 e 11 anos, com mordida aberta anterior, distribuídos em dois grupos: experimental, com 25 pacientes tratados com esporão colado associado a build-up; e controle, com 25 pacientes tratados apenas com esporões colados. Foram obtidas telerradiografias em norma lateral e os modelos digitais no início (T1) e ao final do tratamento (T2). O teste de Shapiro-Wilk foi usado para avaliar a distribuição normal, enquanto o teste exato de Fisher foi aplicado para avaliar a distribuição dos sexos. As comparações intergrupos foram realizadas com o teste t, e as intragrupos com teste t dependente, respectivamente ($P<0.05$). Os dois grupos apresentaram resultados semelhantes em relação às variáveis dentárias e cefalométricas. O período de 24 meses de tratamento foi mais eficaz para o tratamento de mordidas abertas anteriores mais severas em relação a 12 meses de tratamento.

Palavras-chave: Mordida aberta, dentadura mista, esporão colado, build-ups.

LIST OF ILLUSTRATIONS

Article 1

Article 2

LIST OF TABLES

Article 1

Article 2

TABLE OF CONTENTS

1 INTRODUCTION

1 INTRODUCTION

Anterior open bite is a malocclusion characterized by the lack of contact between the incisal edges of the upper and lower anterior teeth, in a vertical analysis.[1-3] This alteration is considered one of the most difficult to treat, due to the difficulty in the bite closure with orthodontic mechanics, and also consequently to it reduced and doubtful stability.[4] In addition, this malocclusion generates alterations in swallowing and phonation, which are harmful to patients in the functional and psychosocial aspects.[2, 3, 5]

The prevalence of anterior open bite in mixed dentition ranges from 17%, and its etiology is multifactorial, with environmental and genetic involvement.[2, 6, 7] Among the most common environmental factors are deleterious oral habits, which consists in thumb sucking, pacifier sucking, tongue thrusting and mouth breathing.[4, 8, 9] The involvement of environmental factors improves treatment prognosis when the causal factor is eliminated; in addition, the association of intensity, frequency and duration of the habit (Graber's Triad) directly influences the severity of malocclusion.[10]

Anterior open bite is classified as dental and skeletal. In the first situation, malocclusion is the result of interruption of the vertical development of the incisors and canines, which may or may not involve the alveolar component.[2, 4, 6, 11] In skeletal patients, however, there is a counterclockwise rotation of the palatal plane and clockwise rotation of the mandibular plane, which results in maxillomandibular divergence. In addition, it is also possible to find a deficient development of the mandibular ramus, which results in opening of the gonial angle and clockwise rotation of the mandible.[3, 4, 12]

Early treatment of anterior open bite in mixed dentition has been shown to be effective and is focused at interrupting deleterious oral habits, which allows the reestablishment of dentoalveolar development in the anterior region. The palatal crib is one of the most studied appliances, and it can be fixed or removable, with or without an expander screw for slow maxillary expansion (in the removable crib) or associated with the quadrihelix (in the fixed crib).[13-19] Besides, the installation of bonded spurs on the palatal and lingual surfaces of the upper and lower incisors is another alternative, which has been shown to be similarly effective to the fixed palatal crib. This appliance

is also more accepted by the patients during chewing, which is an important factor when deciding on the treatment plan for patients with anterior open bite.[19]

Dental open bite is usually associated with a pattern of vertical growth and increased anterior-inferior facial height.[4, 6, 20] When diagnosis and treatment are not performed early, skeletal involvement becomes more present. Thus, therapy associated with the control of the vertical dimension has been considered. Some of them are based on the use of devices such as: the Frankel-4 function regulator;[21] bionator for open bite [17, 22] associated or not with high traction extra buccal arch; posterior bite blocks of different thickness[23, 24] associated with chincup,[25] with magnets,[25, 26] or appliances activated by elastic springs;[25, 27] maxillary rapid or slow appliances associated with chincup;[20] rapid molar intrusion appliances[26]

Regardless of the choice of the appliance, the purpose of indicate these consists in promote the intrusion of the posterior teeth and, consequently, the counterclockwise rotation of the mandible. The palatal crib or spurs can also be associated with the chincup, and the second one can produce a significant decrease in the gonial angle.[28] Despite the effectiveness of these treatment options, some disadvantages may difficult it clinical application, such as the fact that they depend on the patient compliance (chincup, functional appliances or removable posterior bite blocks), are unhygienic (fixed posterior bite blocks) or have a more difficult installation.[29, 30] Therefore, it is essential to associate accessories, appliances and mechanics that are well accepted by patients, hygienic and easy to install to control the vertical dimension during the correction of anterior open bite.

Build-ups (2 to 3mm resin stops bonded to the functional cusps of upper molars) have been shown to be an efficient and stable option for the correction of anterior open bite when combined with fixed orthodontic appliance.[31] The bite closure occurs as consequence of the upper molars and counterclockwise rotation of the mandible in the permanent dentition, so its effect is similar to posterior bite blocks.[31]

It is speculated that the use of spurs bonded to anterior teeth associated with build-ups bonded in deciduous first and second molars, and permanent first molars, in mixed dentition, would be able to close the anterior open bite and also to control the vertical development of posterior teeth (in comparison to conventional bonded spurs only). This effect could result in a clockwise rotation of the mandible in response to the intrusion of the upper molars, which would consists in an alternative to vertical control, minimizing the need of patient compliance during treatment. However, there is still a

lack of researches that assesses the effects of bonded spurs associated with build-ups during mixed dentition.[32-34]

Although the efficiency of different appliances and protocols including associated therapies has been studied, most studies only perform a 12-month assessment. Thus, there is still a lack of properly randomized clinical trials evaluating treatment alternatives regarding associated therapies for the correction of anterior open bite in mixed dentition.[32-34] A greater follow-up is necessary due to the inclusion of severe open bites in the which 12 months are not enough to obtain a satisfactory result. This could explain the 86.7% efficiency reported in similar protocols (spurs associated with chincup).[28] It is expected that with longer follow-up time, efficiency will also be greater; as result of allowing the closure of the bite in the most severe cases.

Consequently, the aim of the present study is to compare the dentoalveolar and skeletal effects of early treatment of anterior open bite with bonded spurs associated with build-ups versus conventional bonded spurs after 24 months.

2 ARTICLES

2.1 ARTICLE 1

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

Dentoalveolar changes promoted by anterior open bite treatment with bonded spurs associated with build-ups versus conventional bonded spurs during 24 months: a randomized clinical trial

Authors:

Olga Benário Vieira Maranhão
Department of Orthodontics, Bauru Dental School, University of Sao Paulo, Brazil

Aron Aliaga-Del Castillo
Department of Orthodontics, Bauru Dental School, University of Sao Paulo, Brazil

Demi Lisbôa Dahás Jorge
Department of Orthodontics, Bauru Dental School, University of Sao Paulo, Brazil

Silvio Augusto Bellini-Pereira
Department of Orthodontics, Bauru Dental School, University of Sao Paulo, Brazil

Daniela Gamba Garib
Department of Orthodontics, Bauru Dental School, University of Sao Paulo, Brazil

Arnaldo Pinzan
Department of Orthodontics, Bauru Dental School, University of Sao Paulo, Brazil

Guilherme Janson
Department of Orthodontics, Bauru Dental School, University of Sao Paulo, Brazil

DENTOALVEOLAR CHANGES PROMOTED BY ANTERIOR OPEN BITE TREATMENT WITH BONDED SPURS ASSOCIATED WITH BUILD-UPS VERSUS CONVENTIONAL BONDED SPURS DURING 24 MONTHS: A RANDOMIZED CLINICAL TRIAL

Abstract:

Objective: To compare the dentoalveolar effects of early treatment of the anterior open bite with bonded spurs associated with build-ups versus conventional bonded spurs after 24 months. **Material and methods:** Fifty patients, between 7 and 11 years of age (32 female and 18 male), with open bite malocclusion were randomly assigned into two groups. The experimental group initially comprised 25 patients treated with bonded spurs associated with build ups. The comparison group initially comprised 25 patients treated only with bonded spurs. The measurements were performed on digital dental casts, obtained with TRIOS® intraoral scanner (3Shape A/S, Copenhagem, Dinamarca) at baseline (T1) and after 24 months of treatment (T2). Overbite, overjet, vertical development of incisors and first permanent molars, maxillary and mandibular arches perimeter and length, palatal depth, inter-canine and inter-first permanent molar width were measured at T1 and T2. Shapiro-Wilk tests were used to test normal distribution and sex distribution was analyzed with Fisher exact test. Intergroup comparisons regarding age, primary and secondary outcome measurements were performed with t or Mann-Whitney U tests, depending on normal distribution. The SPSS software (version 25; IBM, Armonk, NY) was used to perform the statistical analyses at a significance level of $P<0.05$. **Results:** During treatment, 3 patients in the experimental and 1 in the comparison group were lost. After 24 months, similar results were found in both groups. The overbite increased and the open bite remained in only one patient in the comparison group. **Conclusions:** Both groups presented similar results regarding overbite improvement and dental arch dimensional changes. The use of build-ups did not produce greater molar vertical development restriction after 24 months of treatment. A treatment time of 24 months was more efficient to correct severe anterior open bite patients than 12 months.

Keywords: Open bite, mixed dentition, bonded spurs, build-ups.

INTRODUCTION:

Anterior open bite is one of the most challenging malocclusions to treat and is characterized by the absence of incisal edges contact, which results in negative overbite.[1] The stability and prognosis are related to patient's age at the beginning of treatment and open bite severity (prevalence of dental or skeletal factors)[2]. The lack of incisal contacts affects patient's esthetics, swallowing, phonation and causes psychosocial problems.[1,3]

The etiology of this malocclusion is multifactorial and involves environmental and genetic factors.[1,4] Understanding of the main etiological factors of anterior open bite provides better resources for treatment and stability. The most common environmental factors are deleterious oral habits, such as digital sucking, pacifier sucking, tongue interposition and mouth breathing.[2,5,6] The prevalence of this malocclusion is high in the mixed dentition (17%), and is directly related to this environmental etiology.[1,4] Because of this high prevalence, it is important to understand the better treatment resources to correct an anterior open bite.

Early treatment of this malocclusion during the mixed dentition has been shown to be effective and its focused in interrupting oral deleterious habits.[7,8] Fixed or removable palatal crib is one of the most used and studied appliances for open bite correction, and can be associated with an expander screw or quadrihelix for maxillary expansion.[9-13] Another alternative is bonded spurs to the palatal and lingual surfaces of the incisors, which presents similar effectiveness as the palatal crib[12] (Fig. 1).

Usually, an open bite is associated with a vertical growth pattern and increased anterior face height.[2,4,14] When diagnosis and treatment are not performed early, the skeletal involvement becomes more significant. Thus, open bite treatment associated with vertical dimension control has been considered. It can be performed with appliances such as the function regulator Fankel-4,[15] posterior bite blocks associated with headgear,[16] open bite bionator associated or not with an extraoral appliance[17] or molar intrusion appliances.[18] However, they present some disadvantages which interferes in clinical application, such as patient compliance needs (headgear, functional and removable appliances), the hygiene difficulties (fixed bite blocks) or prolonged clinical time of installation.[18,19]

Build-ups (2 to 3mm resin stops bonded to the functional cusps of maxillary molars) have been an efficient and stable option for anterior open bite correction, when

associated with fixed orthodontic appliances.[20] Bite closure occurs through intrusion of the maxillary molars and counterclockwise rotation of the mandible in the permanent dentition, so its effect is similar to posterior bite blocks.[20] It is speculated that the use of spurs bonded to the anterior teeth associated with build-ups on the first and second deciduous molars, and first permanent molars, in the mixed dentition, would be able to close an anterior open bite and also control the vertical dimension of the posterior teeth, in comparison to bonded spurs alone (Figs. 2A and B).

Although the efficiency of many appliances and protocols including associated therapies has been studied, most studies only report 12-month follow-ups, showing 66.7% to 86.7% of efficiency reported in similar protocols.[10,13,21-23] It is expected that with longer follow-up the efficiency will also be higher due to the longer treatment time necessary to close more severe open bites. Thus, the aim of the present study was to compare the dentoalveolar effects of early treatment of anterior open bite with bonded spurs associated with build-ups versus conventional bonded spurs alone, after 24 months.

MATERIAL AND METHODS:

Trial design and any changes after trial commencement

The study consisted in a single randomized clinical trial with two groups constructed by patients randomized in a 1:1 allocation ratio. The RCT followed the Consolidated Standards of Reporting Trials statement and guideline.

Participants, eligibility criteria and settings:

The RCT was approved by the Ethics in Research Committee of Bauru Dental School, University of São Paulo, Brazil (protocol nº CAAE 19700919.2.0000.5417). The protocol of this RCT was registered at Clinicaltrials.gov with identification number NCT03702881.

At the beginning of the research, informed consent was obtained from all patients and their parents/legal guardians.

Patients' selection was conducted at Bauru Dental School, University of São Paulo, Bauru from June 2017 to April 2018. Inclusion criteria consisted of individuals of both sexes from 7 to 11 years of age, in the mixed dentition, with first molars and central incisors fully erupted, anterior open bite greater than 1 mm (dental or skeletal), without indication of maxillary expansion and only mild crowding. Patients with

unerupted permanent first molars and incisors, previously submitted to orthodontic treatment, with dental agenesis or tooth loss, moderate or severe dental crowding, posterior crossbite, craniofacial anomalies or syndromes, and with systemic or neurological diseases were excluded.

Intervention:

After random allocation, the bonded spurs (Morelli Ortodontia, Sorocaba, São Paulo, Brazil) were previously sharpened with carborundum disk and installed by one operator at the cervical of the palatal and lingual surfaces of all maxillary and mandibular incisors with Transbond XT light cure orthodontic adhesive (3M Unitek, Monrovia, Calif). In the experimental group, resin build ups (Ortho bite; FGM, Joinville, Santa Catarina, Brazil) with 2-3mm thickness were also bonded on the functional cusps of the maxillary molars (first permanent or second deciduous molars). The comparison group had only the spurs bonded.

After 12 months of treatment, the build ups were removed consequently to reestablishment of the vertical dimension, due to occlusal contacts between the opposing deciduous canines. However, the bonded spurs were maintained in both groups as active retention in patients in whom the open bite was completely closed, and to complete bite closure in cases with more severe open bite malocclusion.

The dental arches were digitized before treatment and after 24 months of treatment with a TRIOS® intraoral scanner (3Shape A/S, Copenhagen, Denmark). The pretreatment measurements were performed by one operator (S.A.B.P) and the 24-month measurements were performed by a second operator (O.B.V.M).

Outcomes (primary and secondary) and any changes after trial commencement

The primary outcomes were changes in overbite after treatment. The secondary outcomes were: overjet, vertical development of incisors and first permanent molars, maxillary and mandibular arches perimeter and length, palatal depth, inter-canines and inter-first permanent molars widths.

Measurements of primary and secondary outcomes were analyzed with OrthoAnalyzer® (3Shape A/S, Copenhagen, Denmark) software. There were no changes after trial commencement.

Sample size calculation

The sample size calculation considered an 80% of test power at a significance level of 0.05 to find a minimum intergroup difference of 1.5 in overbite measurement with a standard deviation of 1.69mm.[21] Consequently, a minimum sample size of 20 patients in each group was necessary.

Interim analyses and stopping guidelines

Not applicable.

Randomization (random number generation, allocation concealment, implementation)

Randomization was obtained in the Randomization.com web site (http://www.randomization.com).[24] Allocation concealment consisted in opening of opaque and sealed envelopes, numbered and sequenced according to the previously random number generation. Each envelope was sequentially opened after patient's recruitment. Before opening, each envelope was identified with patient's name and allocation data. Each patient was allocated into one of the two study groups and all envelopes were confidential and stored in a different place where the research was developed.[25]

The random number generation, allocation concealment methods and allocation were performed by three different investigators. Additionally, another researcher was responsible for the patient interventions.[25]

Blinding

The interventions developed in the present research did not allow a double-blind study because patients and operator were able to know which accessories were installed. However, bias was carefully avoided during participants randomization and allocation.

Statistical analysis

A single operator remeasured 30% of the sample of the digitized dental casts after a 30-day interval. Random and systematic errors were analyzed with Dahlberg´s formula[26] and paired t tests, respectively. Additionally, inter and intra-examiner calibration were evaluated with intraclass correlation coefficient (ICC).[27]

Shapiro-Wilk tests were used to test normal distribution of the variables and intergroup sex distribution was analyzed with Fisher exact test. Intergroup comparisons regarding age, primary and secondary outcomes measurements were performed with t or Mann-Whitney U tests, depending on normal distribution.

SPSS software (version 25; IBM, Armonk, NY) was used to perform the statistical analyses. The significance level was set at $P<0.05$.

RESULTS

Participant flow

In eligibility assessment 1025 children were evaluated, 969 were excluded based on inclusion and exclusion criteria, and 6 declined to participate. Initially, 50 patients were included and allocated in 1:1 ratio (Fig. 3).

Baseline data

Both groups were similar regarding age, sex distribution and most dental cast variables (Tables I and II). The initial mandibular inter-canine cervical distance was significantly larger in the comparison group (Table II).

Number analyzed for each outcome, estimation, and precision

Consequent to the COVID-19 pandemic, a few patients could not attend the final stage of the investigation. Three patients (12%) were lost in the experimental group and one (4%) in the comparison group, totalizing 22 in the experimental and 24 in the comparison group.

The ICC values ranged from 0.834 to 0.997 in the inter-examiner analysis, and from 0.835 to 0.999 in the intra-examiner correlation, which consists in excellent inter and intra-examiner reliabilities.[28]

There was no significant difference between both groups in the primary and secondary outcomes measures after treatment (Table III). The experimental and comparison groups presented overbite and overjet improvements (Table III). After 24 months of treatment, there were similar increases in clinical crown height of the maxillary and mandibular incisors and molars in both groups, which were numerically larger in the maxillary arch (Table III). Arch perimeter and length decreased in both arches, and the palatal depth increased similarly in the groups (Table III). There was

inter-canine width increase in the maxillary arch and intermolar width increase in both arches.

Harms

Some bonded spurs accidentally debonded during the treatment time. It occurred in 2.5% of experimental group patients, and in 5.3% in the comparison group. The spurs were bonded again, as soon as possible.

DISCUSSION

Main findings in the context of the existing evidence and interpretation

Most studies regarding dentoskeletal changes after open bite treatment are based on cephalometric analysis.[12,21-23] During the mixed dentition there is more dentoalveolar involvement in open bite malocclusion, so it is important to evaluate these changes with even more specific tools, such as digital models.[29] In digital models generated after intraoral scanning it is possible to measure the changes with more precision in relation to plaster models, because there are less distortions. The cephalometric analysis provides important outcomes regarding dental and skeletal changes, but it is still a bidimensional record. Dental casts enable three-dimensional visualization of dentoalveolar structures, which reduces the superimposition limitations of head-films. Measurements in digital models are also more precise in comparison to physical plaster models and easier to determine.[29]

At the pretreatment stage, both groups were comparable and similar in most variables (Tables I and II). Only the mandibular intercanine distance was significantly larger in the comparison group (Table II). This should not interfere with the comparison because the most important outcomes are the treatment changes.

During the 24-month evaluation period there was no significant difference in intergroup treatment changes (Table III). This study is a follow-up of a previous investigation which evaluated the treatment changes after 12 months.[22,23] During that period, the combination of bonded spurs and build ups provided smaller maxillary molar extrusion in relation to bonded spurs alone, although no significant counterclockwise mandibular rotation was observed.[22,23] However, at the 12-month observation stage, as the deciduous canines reestablished contacts, the build-ups had no more vertical effects and were removed. This probably explains why there were no more significant vertical intergroup differences in the treatment effects after 24 months.

Perhaps, the build-ups should have been increased after the 12-month period. This should be further investigated.

The spurs were maintained in both groups to investigate whether a longer treatment period would provide a greater treatment efficacy of these devices. After 12 months of treatment, the anterior open bite was corrected in 66.7% in the experimental group and in 72% in the comparison group.[23] After 24 months, 100% of the patients in the experimental group and 95.83% in the comparison group presented a positive overlap, demonstrating that some patients, especially those with a severe open bite, need a longer treatment time to close the bite.

There was a negative overlap in only 1 from 24 (4.16%) patients of the comparison group, after the 24-month treatment, however, there was a greater percentage of open bite closure in comparison to the 12-month evaluation period. In this patient, the deleterious sucking habit continued even with the bonded spurs installed, as reported by the patient's parents. A fixed palatal tongue crib or spurs soldered to a palatal arch might be necessary in these cases in order to effectively remove the habit.[13,30-33]

Most previous studies are not randomized clinical trials and usually present 12 months of treatment duration, which is not always enough to correct more severe cases.[8,12,21,34] Consequently, the percentage of open bite correction with bonded spurs either alone or associated with devices to control the vertical dimension varies from 47% to 86.7%.[12,13,21,23,34,35] It might be speculated that this percentage is not higher in consequence of persistent deleterious oral habits and a short treatment time in some cases.

The association between bonded spurs and vertical control is not widely reported in the literature. Besides build-ups, some studies used chin-cup associated with bonded spurs. Nevertheless, there was no significant restriction in molar vertical development with this association.[13,21,35]

At the end of 24 months both groups had similar treatment changes in the dental cast variables (Table III). The maxillary and mandibular arches presented vertical development. The negative values of the maxillary and mandibular dentoalveolar development show tooth extrusion in relation to the occlusal plane. There was also incisors and molars clinical crown extrusion in both groups. Dental extrusion is a desirable effect of bonded spurs.[8,12,22,23,36] This appliance provides tongue repositioning through a reflex arch that involves tongue contact with the spurs, pain

and pull back.[8] This mechanism avoids tongue interposition between the maxillary and mandibular incisors and consequently these teeth reestablish their normal vertical development, which closes the bite.[8]

At this stage, decreases in perimeter and arch length are consequences to posterior teeth mesialization to the leeway space in patients with or without malocclusion. After open bite correction this decrease is also expected consequent to the lingual and palatal incisor inclinations during treatment.[8,33,37]

The palatal depth increased after treatment in both groups probably because of normal eruption of molars and premolar, which were used as landmarks to define the occlusal plane (Table III). Maxillary canine and molars width also increased in both groups as consequence of normal occlusal development.[38,39] These variables increased in the maxillary arch and the mandibular intercanine distance decreased. This may be consequent to individual characteristics such as archwire format and degree of crowding.[40] Previous studies also reported increases in intercanine and intermolar distances in school children between 11 and 14 years of age.[40] It was also reported an increase in intermolar distance during normal development, until 14 years of age.[40,41] In general, orthodontic treatment is also responsible for increases in arch width.[40]

Limitation

This study had two groups of open bite patients orthodontically treated. It would be interesting to include a control group with untreated patients, although it is not ethically viable to keep patients without treatment for so long.

Generalizability

The results obtained are applicable to patients with similar characteristics of the investigated groups.

CONCLUSIONS:

- Both groups presented similar results regarding overbite improvement and dental arch dimensional changes;
- The use of build-ups does not produce significant vertical molar development restriction after 24 months of treatment;

- A treatment time of 24 months was able to correct 100% of patients presenting with anterior open bite in the mixed dentition.

Acknowledgment

The authors thank to Coordination of Higher Education Personnel Improvement – CAPES (Finance Code 001) and São Paulo Research Foundation – FAPESP (process number no. 2017/06440-3, no. 2018/05238-9 and no. 2018/24003-2,) for their financial support.

References

1. Ngan P, Fields HW. Open bite: a review of etiology and management. Pediatr Dent 1997;19:91-8.
2. Janson G, Valarelli F. Open-bite malocclusion: treatment and stability. Ames, IA: John Wiley & Sons, Inc; 2014.
3. 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;86:638-43.
4. 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 Dentofacial Orthop 2005;128:517-9.
5. Johnson ED, Larson BE. Thumb-sucking: literature review. ASDC J Dent Child 1993;60:385-91.
6. Peltomaki T. The effect of mode of breathing on craniofacial growth--revisited. Eur J Orthod 2007;29:426-9.
7. 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.
8. Meyer-Marcotty P, Hartmann J, Stellzig-Eisenhauer A. Dentoalveolar open bite treatment with spur appliances. J Orofac Orthop 2007;68:510-21.
9. Villa NL, Cisneros GJ. Changes in the dentition secondary to palatal crib therapy in digit-suckers: a preliminary study. Pediatr Dent 1997;19:323-326.
10. 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 Dentofacial Orthop 2006;129:418-23.
11. 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;28:610-7.
12. 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 Dentofacial Orthop 2016;149:847-55.

13. 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;86:969-75.
14. Sankey WL, Buschang PH, English J, Owen AH, 3rd. Early treatment of vertical skeletal dysplasia: the hyperdivergent phenotype. Am J Orthod Dentofacial Orthop 2000;118:317-27.
15. 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 Dentofacial Orthop 1995;108:9-21.
16. Iscan HN, Sarisoy L. Comparison of the effects of passive posterior bite-blocks with different construction bites on the craniofacial and dentoalveolar structures. Am J Orthod Dentofacial Orthop 1997;112:171-8.
17. Weinbach JR, Smith RJ. Cephalometric changes during treatment with the open bite bionator. Am J Orthod Dentofacial Orthop 1992;101:367-74.
18. Cinsar A, Alagha AR, Akyalcin S. Skeletal open bite correction with rapid molar intruder appliance in growing individuals. Angle Orthod 2007;77:632-9.
19. Carano A, Machata W, Siciliani G. Noncompliant treatment of skeletal open bite. Am J Orthod Dentofacial Orthop 2005;128:781-6.
20. 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.
21. 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 Dentofacial Orthop 2012;142:487-93.
22. Aliaga-Del Castillo A, Bellini-Pereira SA, Vilanova L, Miranda F, Massaro C, Arriola-Guillén LE et al. Dental arch changes after open bite treatment with spurs associated with posterior build-ups in the mixed dentition: A randomized clinical trial 2021;159:714-723. e711.
23. Aliaga-Del Castillo A, Vilanova L, Miranda F, Arriola-Guillén LE, Garib D, Janson G et al. Dentoskeletal changes in open bite treatment using spurs and posterior build-ups: A randomized clinical trial 2021;159:10-20.

24. Pandis N. Randomization. Part 1: sequence generation. Am J Orthod Dentofacial Orthop 2011;140:747-8.
25. Pandis N. Randomization. Part 3: allocation concealment and randomization implementation. Am J Orthod Dentofacial Orthop 2012;141:126-8.
26. Dahlberg G. Statistical methods for medical and biological students. New York: Interscience Publications; 1940.
27. Fleiss JL. Analysis of data from multiclinic trials. Control Clin Trials 1986;7:267-275.
28. Koo TK, Li MYJJocm. A guideline of selecting and reporting intraclass correlation coefficients for reliability research 2016;15:155-63.
29. Huanca Ghislanzoni LT, Lineberger M, Cevidanes LH, Mapelli A, Sforza C, McNamara JA, Jr. Evaluation of tip and torque on virtual study models: a validation study. Prog Orthod 2013;14-19.
30. 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 Dentofacial Orthop 2006;129:734-39.
31. Cozza P, Mucedero M, Baccetti T, Franchi L. Treatment and posttreatment effects of quad-helix/crib therapy of dentoskeletal open bite. Angle Orthod 2007;77:640-5.
32. Mucedero M, Franchi L, Giuntini V, Vangelisti A, McNamara JA, Jr., Cozza P. Stability of quad-helix/crib therapy in dentoskeletal open bite: a long-term controlled study. Am J Orthod Dentofacial Orthop 2013;143:695-703.
33. 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.
34. Leite JS, Matiussi 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;86:734-39.
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;6:684-91.

36. Justus R. Correction of anterior open bite with spurs: long-term stability. World J Orthod 2001;2:219-31.
37. 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 chincup. Orthod Craniofac Res 2018;21:104-11.
38. Abdulmawjood AA, Ahmed MK, Al-Saleem NJIOJ. Palatal depth and arch parameter in class I open bite, deep bite and normal occlusion 2005;1:26-31.
39. Šlaj M, Ježina MA, Lauc T, Rajić-Meštrović S, Mikšić MJTAO. Longitudinal dental arch changes in the mixed dentition 2003;73:509-14.
40. Ward DE, Workman J, Brown R, Richmond SJTAO. Changes in arch width: a 20-year longitudinal study of orthodontic treatment 2006;76:6-13.
41. Moorrees CF, Chadha JMJTAO. Available space for the incisors during dental development-a growth study based on physiologic age 1965;35:12-22.

Figure legends

Figure 1. A, Bonded spurs (Source: File of the Orthodontic clinic at Bauru Dental School-USP). B, Orthodontic fixed appliance associated with build-ups to correct anterior open bite (source: Vela-Hernández, 2017)[20]

Figure 2A. Treatment protocol with bonded build ups in posterior tooth.

Figure 2B. Treatment protocol with bonded spurs only.

Figure 3. Consort flow diagram.

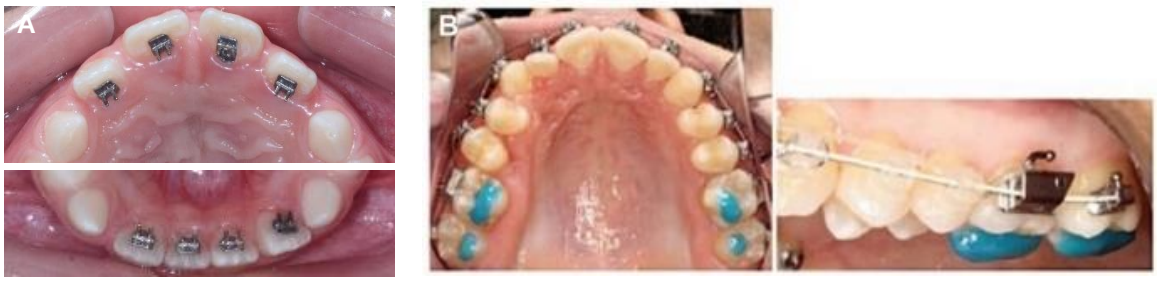

Figure 1.

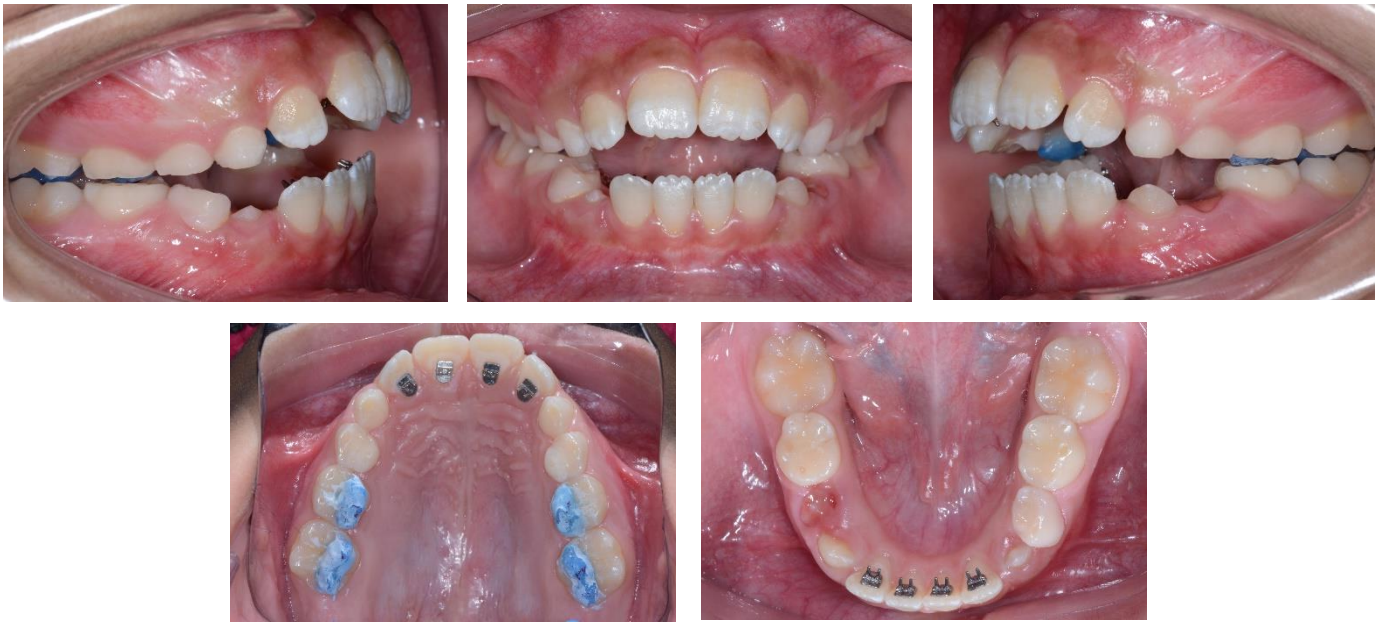

Figure 2A.

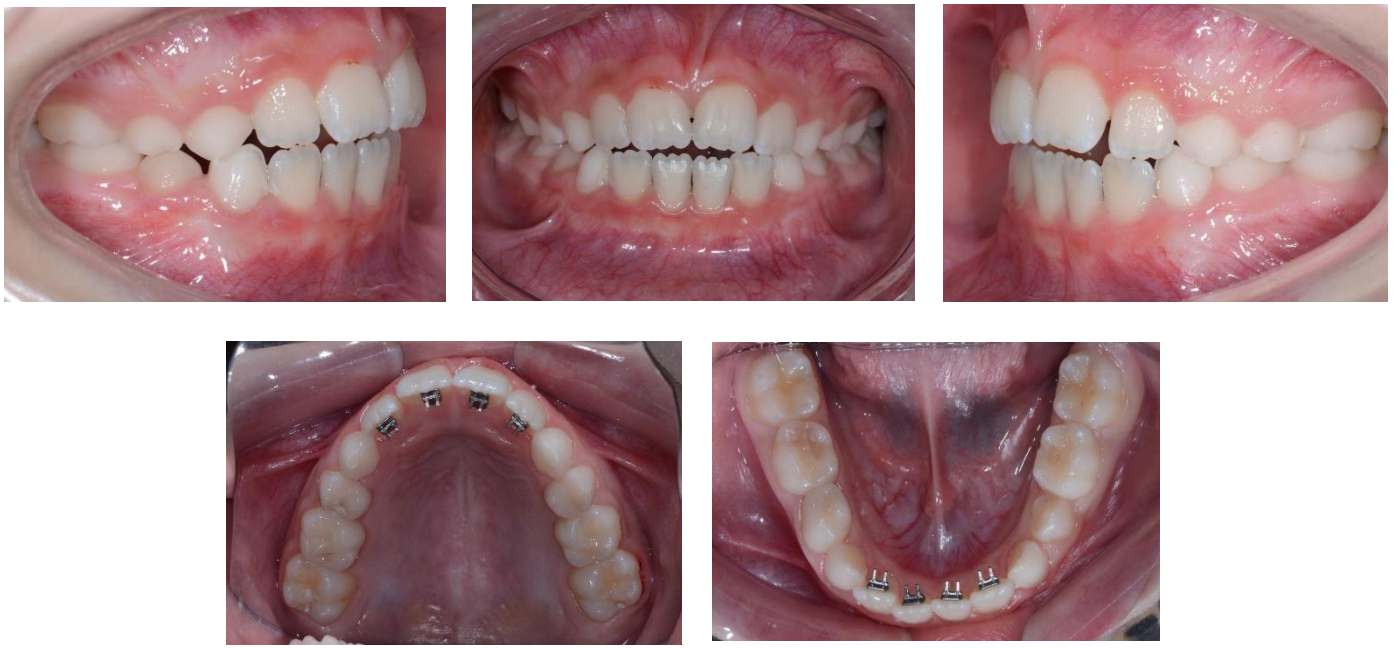

Figure 2B.

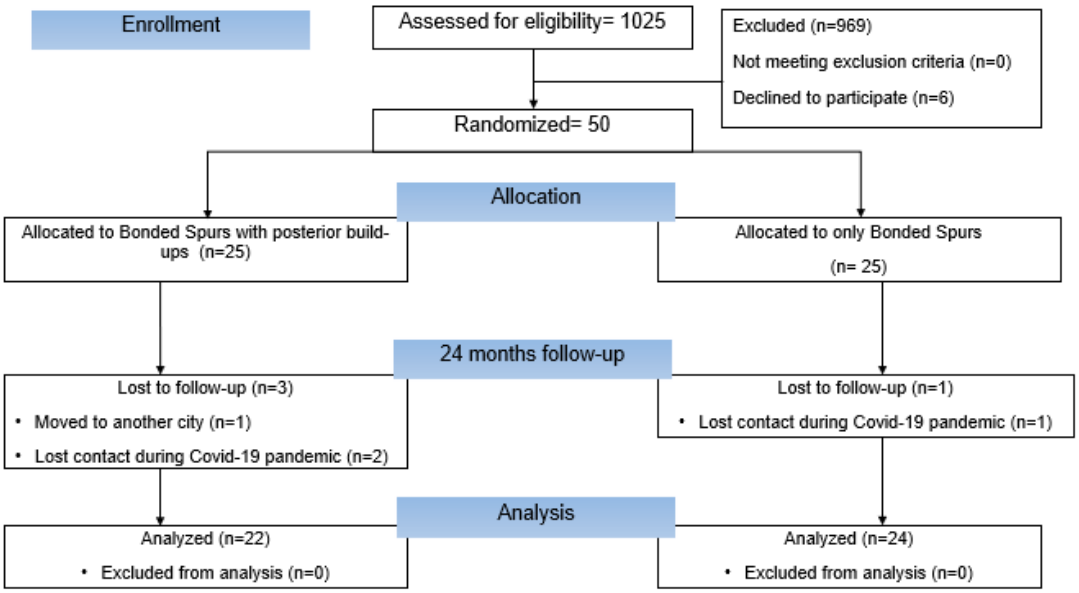
Enrollment
Assessed for eligibility= 1025
Excluded (n=969)
Not meeting exclusion criteria (n=0)
Declined to participate (n=6)
Randomized= 50
Allocation
Allocated to Bonded Spurs with posterior build-ups (n=25)
Allocated to only Bonded Spurs (n= 25)
24 months follow-up
Lost to follow-up (n=3)
• Moved to another city (n=1)
• Lost contact during Covid-19 pandemic (n=2)
Lost to follow-up (n=1)
• Lost contact during Covid-19 pandemic (n=1)
Analysis
Analyzed (n=22)
• Excluded from analysis (n=0)
Analyzed (n=24)
• Excluded from analysis (n=0)

Figure 3.

Table I. Intergroup comparison regarding age and sex distribution.

Variable	**Experimental Group (n=22)**		**Comparison Group (n=24)**		
	Mean	**SD**	**Mean**	**SD**	**P**
Age (years)	8.18	1.07	8.33	1.00	0.635†
Sex	n	%	n	%	
Female	15	68.2	14	58.3	
Male	7	31.8	10	41.7	0.552‡

† t test; ‡ Fisher exact test.

Table II. Intergroup comparison at pretreatment (T1).

Variable	Experimental Group (n=22)		Comparison group (n=24)		Mean difference	CI 95%		P
	Mean	SD	Mean	SD				
Dentoalveolar relationship								
Overbite	-4.01	1.47	-4.15	2.19	0.13	-0.93	1.20	0.920‡
Overjet	3.73	1.71	4.01	1.72	-0.28	-1.26	0.70	0.570†
Vertical development								
Mx dentoalveolar (mm)	9.02	1.50	8.97	1.92	0.04	-0.94	1.04	0.924†
Mx1 clinical crown height (mm)	8.14	1.43	8.09	1.31	0.04	-0.74	0.83	0.906†
Mx6 clinical crown height (mm)	3.36	0.54	3.12	0.63	0.24	-0.97	0.58	0.110‡
Md dentoalveolar (mm)	4.74	1.43	4.44	1.33	0.29	-0.49	1.09	0.455†
Md1 clinical crown height (mm)	7.08	1.08	6.99	0.83	0.08	-0.46	0.63	0.765†
Md6 clinical crown height (mm)	4.08	0.57	3.93	0.65	0.14	-0.20	0.50	0.401†
Arch dimensions								
Mx arch perimeter (mm)	75.95	3.82	77.32	3.42	-1.36	-3.45	0.71	0.194†
Mx arch length (mm)	27.98	1.77	28.81	1.85	-0.83	-1.87	0.21	0.222‡
Palatal depth (mm)	13.19	1.85	13.61	2.11	-0.42	-1.57	0.72	0.459†
Md arch perimeter (mm)	70.95	3.56	72.38	3.41	-1.42	-3.43	0.57	0.159†
Md arch length (mm)	24.76	1.64	25.64	1.67	-0.87	-1.83	0.07	0.071†
Width								
3-3 Mx Cusp (mm)	31.76	2.61	31.92	2.07	-0.16	-1.63	1.30	0.825†
3-3 Mx Cervical (mm)	25.63	2.33	26.09	1.81	-0.46	-1.76	0.83	0.474†
6-6 Mx Mesiobuccal Cusp (mm)	50.24	3.04	50.93	2.00	-0.68	-2.17	0.81	0.361†
6-6 Mx Cervical (mm)	36.42	2.81	36.38	2.36	0.03	-1.45	1.52	0.962†
3-3 Md Cusp(mm)	26.98	2.27	27.66	2.27	-0.68	-2.06	0.69	0.324†
3-3 Md Cervical (mm)	21.32	1.75	22.50	1.87	-1.17	-2.28	-0.07	0.037†*
6-6 Md Mesiobucal Cusp (mm)	45.49	2.61	45.67	2.16	-0.18	-1.56	1.19	0.786†
6-6 Md Cervical (mm)	33.88	2.59	34.32	1.83	-0.44	-1.72	0.84	0.493†

SD, standard deviation; CI, confidence interval; Mx, maxillary; Mx dentoalveolar, vertical development of maxillary anterior teeth measured from the contact point of central incisors to the occlusal plane; Mx1, maxillary incisor; Mx6, maxillary first molar; Md, mandibular; Md dentoalveolar, vertical development of mandibular anterior teeth measured from the contact point of central incisors to the occlusal plane; Md1, mandibular incisor; Md6, mandibular first molar.

Table III. Intergroup comparison of treatment changes after 24 months (T2-T1).

Variable	Experimental Group (n=22)		Comparison Group (n=24)		Mean Difference	CI 95%		P
	Mean	SD	Mean	SD				
Dentoalveolar relationship								
Overbite	5.73	1.72	5.81	2.29	-0.08	-1.30	1.13	0.891†
Overjet	0.51	1.55	0.43	1.44	0.07	-0.81	0.97	0.857†
Vertical development								
Mx dentoalveoliar (mm)	-3.45	2.31	-3.09	1.75	-0.36	-1.54	0.81	0.535†
Mx1 clinical crown height (mm)	1.30	1.37	1.26	0.85	0.04	-0.65	0.73	0.590‡
Mx6 clinical crown height (mm)	0.65	0.36	0.68	0.33	0.24	-0.24	0.17	0.768†
Md dentoalveolar (mm)	-1.69	1.80	-0.94	1.51	-0.70	-1.70	0.20	0.121†
Md1 clinical crown height (mm)	0.87	0.73	0.83	0.52	0.04	-0.33	0.41	0.830†
Md6 clinical crown height (mm)	0.40	0.55	0.61	0.45	-0.20	-0.50	0.09	0.181†
Arch dimensions								
Mx arch perimeter (mm)	-2.85	2.52	-2.63	2.30	-0.21	-1.65	1.22	0.765†
Mx arch length (mm)	-0.80	1.76	-1.05	1.16	0.24	-0.63	1.12	0.574†
Palatal depth (mm)	0.61	0.89	0.66	1.28	-0.05	-0.71	0.61	0.877†
Md arch perimeter (mm)	-4.10	2.36	-4.64	1.96	0.53	-0.74	1.82	0.404†
Md arch length (mm)	-1.02	1.50	-1.61	0.83	0.58	-0.15	1.32	0.115†
Width								
3-3 Mx Cusp (mm)	1.09	1.61	1.77	2.04	-0.68	-2.39	1.03	0.417†
3-3 Mx Cervical (mm)	0.18	0.96	0.54	1.71	-0.35	-1.58	0.86	0.548†
6-6 Mx Mesiobuccal Cusp (mm)	1.38	1.14	1.04	0.93	0.34	-0.27	0.96	0.271†
6-6 Mx Cervical (mm)	0.29	0.87	0.37	1.17	-0.07	-0.69	0.54	0.801†
3-3 Md Cusp (mm)	-0.98	2.00	-0.81	1.93	-0.22	-4.96	4.52	0.925†
3-3 Md Cervical (mm)	-0.05	1.40	-1.14	2.02	1.09	-1.57	1.23	0.806†
6-6 Md Mesiobuccal Cusp (mm)	0.08	0.90	0.35	0.88	-0.27	-0.80	0.26	0.311†
6-6 Md Cervical (mm)	0.18	1.03	0.19	0.91	-0.01	-0.59	0.57	0.970†

SD, standard deviation; CI, confidence interval; Mx, maxillary; Mx dentoalveolar, vertical development of maxillary anterior teeth measured from the contact point of central incisors to the occlusal plane; Mx1, maxillary incisor; Mx6, maxillary first molar; Md, mandibular; Md dentoalveolar, vertical development of mandibular anterior teeth measured from the contact point of central incisors to the occlusal plane; Md1, mandibular incisor; Md6, mandibular first molar.

2.2 ARTICLE 2

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

Dentoskeletal changes after 2-year anterior open bite treatment with bonded spurs associated with build-ups versus conventional bonded spurs: a randomized clinical trial

Authors:

Olga Benário Vieira Maranhão
Department of Orthodontics, Bauru Dental School, University of Sao Paulo, Brazil

Aron Aliaga-Del Castillo
Department of Orthodontics, Bauru Dental School, University of Sao Paulo, Brazil

Demi Lisbôa Dahás Jorge
Department of Orthodontics, Bauru Dental School, University of Sao Paulo, Brazil

Daniela Gamba Garib
Department of Orthodontics, Bauru Dental School, University of Sao Paulo, Brazil

Arnaldo Pinzan
Department of Orthodontics, Bauru Dental School, University of Sao Paulo, Brazil

Guilherme Janson
Department of Orthodontics, Bauru Dental School, University of Sao Paulo, Brazil

DENTOSKELETAL CHANGES AFTER 2-YEAR ANTERIOR OPEN BITE TREATMENT WITH BONDED SPURS ASSOCIATED WITH BUILD-UPS VERSUS CONVENTIONAL BONDED SPURS: A RANDOMIZED CLINICAL TRIAL

ABSTRACT:

Objective: To compare the dentoskeletal changes of anterior open bite treatment in the mixed dentition with bonded spurs associated with build-ups versus conventional bonded spurs after a 24-month follow up. **Methods:** Fifty patients between 7 and 11 years of age (18 male, 32 female) were randomly assigned into two groups. The experimental group (n=25) was treated with bonded spurs associated with build-ups. The comparison group (n=25) was treated with bonded spurs only. Digital headfilms were obtained before treatment (T1) and after 2 years of treatment (T2). Measurements were performed using Dolphin Imaging software (version 11.5; Dolphin Imaging and Management Solutions, Chatsworth, Calif). The cephalometric variables consisted of maxillary and mandibular components, vertical components, overbite (primary outcomes), maxillary and mandibular dentoalveolar components. Intergroup comparisons were performed using t tests and Mann-Whitney U tests. The significance level regarded was $P<0.05$. **Results:** During the 24-month follow up, three patients in the experimental group and one in the comparison group were lost. Both groups presented similar overbite increase, vertical facial height increase and incisors and first molar extrusion. The success rate of AOB closure during the mixed dentition consisted in 100% in experimental group and 95.83% in comparison group. No significant differences between experimental and comparison group regarding treatment alterations. **Conclusions:** Both therapy demonstraded similar dentoskeletal changes. The occlusal build-ups were not an advantage to openbite correction after a 2-year followup.

Keywords: Open bite, mixed dentition, bonded spurs, build-ups.

INTRODUCTION:

Anterior open bite (AOB) consists of a malocclusion characterized by the lack of contact between incisal edges of maxillary and mandibular incisors, resulting in a negative overbite.[1] This alteration is more difficult to treat the older the patient and the

greater the negative overbite.[2] Anterior open bite might impair the smile esthetics, the speech, the swallowing and increase bullying problems.[1,3,4]

Environmental and genetic factors are involved in the etiology of anterior open bite.[1,5] The treatment success and stability are related to AOB etiology.[2] Deleterious oral habits, such as tongue interposition, pacifier sucking, mouth breathing and digital sucking are the most common environmental factors associated with anterior open bite.[2,6,7] Consequently, the prevalence of AOB during the mixed dentition is high (17%) and decreases as age increases.[5]

Fixed or removable palatal crib is commonly used in early treatment of anterior open bites during the mixed dentition.[8-12] The spurs bonded to palatal and lingual surfaces of incisors are also used to correct the negative overbite and tongue posture(Fig. 1).[11] The bonded spurs present similar outcomes compared to palatal cribs[12]. Bonded spurs are also more accepted by the patients and parents due to adequate esthetic and comfort.[11] Both palatal crib and bonded spurs can be associated with other appliances when patients present a posterior crossbite or a hyperdivergent growth pattern.[10,12]

The control of vertical dimension can be performed with removable or fixed appliances that result in molars intrusion or skeletal vertical growth control as headgears, biteblocks or chin cap.[13-15] Occlusal build-ups consisting of 2-3mm resin blocks can also be used associated with the palatal crib or bonded spurs.[16,17] The association of these blocks with orthodontic fixed appliance were described in the permanent dentition as an alternative to treat AOB and promote a counterclockwise rotation of mandible in adults.[18] A previous randomized clinical trial analyzed build ups associated with bonded spurs in the mixed dentition and observed a success rate of open bite closure of 66.7% after 12-month follow-up.[16,17] This low correction rate might have been associated with the short followup. Cases with more severe anterior open bite and prolonged oral deleterious habits should need a longer treatment time.[16,17]

Considering the hypothesis that longer treatment time could influence the frequency of open bite correction, the objective of this study was to compare the dentoskeletal changes of anterior open bite early treatment with bonded spurs associated with build-ups versus bonded spurs alone after 24 months. The null hypothesis tested was that both treatment protocols present similar dentoskeletal changes.

METHODS

Trial design and any changes after trial commencement

This research consisted in a single-center RCT with 1:1 allocation ratio and two arms. The study followed the Consolidated Standards of Reporting Trials statement and guideline. Because of ethical reasons, no control group without therapy was used.

Participants, eligibility criteria and settings

This study was approved by the Ethics in Research Committee of Bauru Dental School, University of São Paulo, Brazil (protocol nº CAAE 19700919.2.0000.5417). This RCT was registered at Clinicaltrials.gov with the identification number NCT03702881.

All patients and legal guardians/parents filled the informed consent before the study commencement. Patient's selection was conducted at Bauru Dental School, University of São Paulo, Bauru from June of 2017 to April of 2018. Individuals from 7 to 11 years of age of both sexes, in the mixed dentition with first molars and central incisor fully erupted and with anterior open bite greater than 1mm were included. The exclusion criteria consisted of moderate or severe incisor crowding, need of maxillary expansion, history of previous orthodontic treatment, permanent tooth loss or dental agenesis, systemic or neurological diseases and craniofacial anomalies.

Intervention

Spurs (Morelli Ortodontia, Sorocaba, São Paulo, Brazil) were bonded at the lingual surfaces of central and lateral maxillary and mandibular permanent incisors with Transbond XT light cure orthodontic adhesive (3M Unitek, Monrovia, Calif). In the experimental group, resin build-ups (Ortho bite; FGM, Joinville, Santa Catarina, Brazil) with 2-3 thickness were bonded on the functional cusps of the maxillary firs permanent or second deciduous molars. The thickness of these build-ups were controlled with a millimetric ruler to achieve a standardizations. The comparison group used the bonded spurs alone without the occlusal build-ups.

After 12-month followup the deciduous canines already presented the reestablishment of vertical contact. Consequently the 2-3mm resin build-ups could not be able to improve the vertical dimension and were removed. Experimental and comparison groups had the bonded spurs in the oral cavity until the complete anterior bite closure with an overbite of at least 2mm. In cases with a more severe AOB, the

bonded spurs were maintained as active retention until the end of the 24-month follow-up.

Before treatment and after 24 months of follow-up, digital headfilms were obtained with Orthophos XG 3D (Dentsply Sirona, Bensheim, Germany) for all patients.

Outcomes (primary and secondary) and any changes after trial commencement:

The primary outcome was the overbite changes. The secondary outcomes were the other cephalometric changes (Table I). Dolphin Imaging software (version 11.5; Dolphin Imaging and Management Solutions, Chatsworth, Calif) was used to perform all cephalometric measurements.

The overbite was cephalometrically determined as the distance in millimeters between the incisal edges of maxillary and mandibular central incisors.

Sample size calculation

A 80% of test power at a significance level of 0.05 to detect a minimum of 1.5mm in the overbite between both groups was considered with a standard deviation of 1.69mm.[19] A minimum sample size of 20 patients in each group was necessary.

Interim analyses and stopping guidelines

Not applicable.

Randomization (random number generation, allocation concealment, implementation)

The randomization was obtained using the Randomization.com web site (http://www.randomization.com).[20] Envelopes were identified with patient's name and allocation data. The patients were allocated into one of the two groups and the envelopes were stored in another place different from where the research was developed. The opaque and sealed envelopes, sequenced and numbered according to a random number generation were opened in allocation concealment.[21]

Three different investigators performed the random number generation, allocation concealment methods and allocation. The patients investigation was performed by another researcher.

Blinding

The patients and operator were not blinded for the type of therapy. Consequently, this RCT was not a double-blind study.

Statistical analysis

After 30-day interval, 30% of the sample were remeasured by a single operator. The interclass correlation coefficient (ICC) was used to inter and intraexaminer calibration.[22]

The normal distribution of the variables was evaluated using Shapiro-Wilk tests. The comparison of sex distribution between groups was analyzed using Fisher exact test. Depending on normal distribution, intergroup comparisons were performed using t tests or Mann-Whitney U tests.

To perform the statistical analyses, the SPSS software (version 25; IBM, Armonk, NY) was used. The significance level regarded was $P<0.05$.

RESULTS

Participant flow

Initially, 1025 children were evaluated in eligibility assessment. After applying the inclusion and exclusion criteria 969 were excluded, and 6 did not accepted to participate. Consequently, 50 patients were included and allocated into two groups with a 1:1 ratio (Fig. 3)

Baseline data

Both groups presented similar age, sex distribution and pretreatment cephalometric variables (Tables II and III).

Number analyzed for each outcome, estimation and precision

Some patients could not reach the final stage of the research as consequence of COVID-19 pandemic. In the experimental and comparison groups 12% (three patients) and 4% (one patient) were lost due to treatment interruption, respectively. The final sample consisted of 22 patients in the experimental group and 24 patients in the comparison group.

The ICC values ranged from 0.772 to 0.997 in interexaminer analysis and from 0.857 to 0.997 in intraexaminer evaluation, which demonstrates a very good reliability.

The AOB clinical closure after 24-month follow-up consisted in 100% in the experimental group and 95.8% in the comparison group.

There were no significant differences between experimental and comparison group for primary and secondary outcomes (Table IV). Both groups presented overbite improvement of approximately 6mm in 24 months (Table IV). The mandibular plane angle showed a slight counterclockwise rotation in both groups (Table IV). The vertical facial heights (AFH, PFH and LAFH) increased similarly in the experimental and comparison groups (Table IV). Incisors and first molars showed an extrusion during the followup that was similar in both groups (Table IV). A lingual inclination and retrusion of maxillary and mandibular incisors were observed similarly in both groups (Table IV).

Harms

During the treatment time, 2.5% patients in experimental group and 5.3% in comparison group had accidental spur debonding. The spurs were bonded again as soon as possible.

DISCUSSION

Main findings in the context of the existing evidence and interpretation

The anterior open bite has been studied and some early treatment protocols are described in the literature, such as the use of palatal crib, chincup associated therapy, posterior bite blocks, Frankel-4 regulator and spurs associated or not with build ups.[11,13-15,23] The cephalometric analysis is usually performed to evaluate the dentoskeletal changes during these therapies.[11,17,19] There are many studies regarding these alterations and protocols, although there are still a lack of randomized clinical trials in this field.

Most of studies regarding AOB early treatment presented shorter follow-ups at maximum 12-months [11,12,16,17,19,24] and were not randomized clinical trials.[11,19,24] Previous studies have evaluated the cephalometric changes after 12 months in this same sample.[16,17] The experimental group presented build-ups and bonded spurs, meanwhile the comparison group presented only the bonded spurs. At this stage, the open bite closure prevalence consisted of 66.7% to experimental group and 72% to

comparison group. After 12 months the build ups were removed. The bonded spurs were maintained to evaluate the anterior open bite correction in a longer follow up.

The present study showed that a follow-up longer than 12 months is important to improve the bite closure in severe open bite cases. Consequently, the AOB was clinically closed in 100% of the patients in the experimental group and in 95.8% in the comparison group after a 24-months follow-up. The anterior open bite was not completely closed in only one patient in the comparison group (4.16%), as consequence of deleterious oral habit persistence, although the openbite has decreased. A fixed palatal crib might be installed in these cases to interrupt the habit more efficiently and improve the bite closure.[12,25-27]

The frequency of AOB correction in this study was higher than previous studies. It was previously reported that AOB correction with bonded spurs alone or associated with appliances to promote vertical control varied from 47% to 86.7%.[11,16,17,19,24,28] This success rate might not be higher in consequence of the shorter treatment time and the persistence of deleterious oral habits.

After 24 months of treatment, both groups presented similar alterations, with no statistical significant differences (Table IV). The changes in maxillary, mandibular and maxillomandibular skeletal components represented the normal growth development of individuals with the same age evaluated in the present research.

Regarding the vertical components, the similarity between the experimental and comparison groups at posttreatment was expected. A counterclockwise rotation of the mandible was found in both groups. The anterior rotation of the mandible was described in previous studies of anterior open bite treatment with bonded spurs.[11,12,17] Consequently, the present data pointed that bonded spurs has no influence in skeletal vertical development.

The increase in overbite of 6.00 and 5.91 in experimental and comparison group, respectively, was higher than previously reported. The treatment with only bonded spurs presented an increase of overbite ranging from 3.07 to 4.84mm[11,17,24,28], meanwhile the association between bonded spurs and vertical dimension control with chincup or build ups ranged from 4.52 to 5.23.[12,17,19] In contrast, untreated patients with anterior open bite presented an increase in overbite ranging from 1.43 to 2.08 mm in a 12-month follow up, which was consequence of the spontaneous correction of the

malocclusion after the deleterious oral habits was removed.[11,12,19] The removal of deleterious habits and 12-month treatment are useful to correct smaller negative overbite discrepancies. The AOB correction in more severe cases needs longer treatment time.[16,17]

Regarding dentoalveolar component, the results represent the pattern of open bite closure. The correction of AOB with bonded spurs occurs through incisors vertical development and palatal/lingual inclination after the improvement in tong posture.[11,24] This alteration was previously reported,[11,12,19,24,28] although changes in incisors position in the present study were higher as consequence of the longer treatment time. There were maxillary and mandibular first permanent molars extrusion in both groups, which might be associated with the normal growth pattern of the sample.

Limitation:

The main limitation of this study is the lack of a nontreated control group in the evaluation. However, this group would have an ethical issue with no intervention for 24 months.

Generalizability

The results obtained during this follow-up represents patients with similar characteristics of the groups. Further studies might be performed with different groups at 24-months followup.

CONCLUSION

- The success rate of AOB closure after 24-month followup consisted in 100% in the experimental group and 95.8% in the comparison group
- The cephalometric changes were similar in both treatment modalities
- The use of build-ups did not presented significant vertical effects after 24-months followup

Acknowledgment

The authors thank to Coordination of Higher Education Personnel Improvement CAPES (Finance Code 001) and São Paulo Research Foundation – FAPESP (process number no. 2017/06440-3, no. 2018/05238-9 and no. 2018/24003-2,) for their financial support.

References

1. Ngan P, Fields HW. Open bite: a review of etiology and management. Pediatr Dent 1997;19:91-8.
2. Janson G, Valarelli F. Open-bite malocclusion: treatment and stability. Ames, IA: John Wiley & Sons, Inc; 2014.
3. Pithon MM, Dos Santos CR, Lima Santos N, Aguiar Sales Lima SO, Coqueiro RS, Dos Santos RL. Impact of malocclusion on affective/romantic relationships among young adults. Angle Orthod 2016;86:638-43.
4. Al-Bitar ZB, Al-Omari IK, Sonbol HN, Al-Ahmad HT, Cunningham SJ. Bullying among Jordanian schoolchildren, its effects on school performance, and the contribution of general physical and dentofacial features. Am J Orthod Dentofacial Orthop 2013;144:872-8.
5. 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 Dentofacial Orthop 2005;128:517-9.
6. Johnson ED, Larson BE. Thumb-sucking: literature review. ASDC J Dent Child 1993;60:385-91.
7. Peltomaki T. The effect of mode of breathing on craniofacial growth--revisited. Eur J Orthod 2007;29:426-9.
8. Villa NL, Cisneros GJ. Changes in the dentition secondary to palatal crib therapy in digit-suckers: a preliminary study. Pediatr Dent 1997;19:323-6.
9. 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 Dentofacial Orthop 2006;129:418-23.
10. 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;28:610-7.
11. 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 Dentofacial Orthop 2016;149:847-55.
12. 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;86:969-75.
13. 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 Dentofacial Orthop 1995;108:9-21.
14. Cinsar A, Alagha AR, Akyalcin S. Skeletal open bite correction with rapid molar intruder appliance in growing individuals. Angle Orthod 2007;77:632-9.
15. Iscan HN, Sarisoy L. Comparison of the effects of passive posterior bite-blocks with different construction bites on the craniofacial and dentoalveolar structures. Am J Orthod Dentofacial Orthop 1997;112:171-8.
16. Aliaga-Del Castillo A, Bellini-Pereira SA, Vilanova L, Miranda F, Massaro C, Arriola-Guillén LE et al. Dental arch changes after open bite treatment with spurs associated with posterior build-ups in the mixed dentition: A randomized clinical trial 2021;159:714-723. e711.
17. Aliaga-Del Castillo A, Vilanova L, Miranda F, Arriola-Guillén LE, Garib D, Janson G et al. Dentoskeletal changes in open bite treatment using spurs and posterior build-ups: A randomized clinical trial 2021;159:10-20.
18. 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.
19. 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 Dentofacial Orthop 2012;142:487-93.
20. Pandis N. Randomization. Part 1: sequence generation. Am J Orthod Dentofacial Orthop 2011;140:747-8.
21. Pandis N. Randomization. Part 3: allocation concealment and randomization implementation. Am J Orthod Dentofacial Orthop 2012;141:126-128.
22. Fleiss JL. Analysis of data from multiclinic trials. Control Clin Trials 1986;7:267-275.
23. Weinbach JR, Smith RJ. Cephalometric changes during treatment with the open bite bionator. Am J Orthod Dentofacial Orthop 1992;101:367-74.

24. Leite JS, Matiussi 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.
25. 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 Dentofacial Orthop 2006;129:734-9.
26. Mucedero M, Franchi L, Giuntini V, Vangelisti A, McNamara JA, Jr., Cozza P. Stability of quad-helix/crib therapy in dentoskeletal open bite: a long-term controlled study. Am J Orthod Dentofacial Orthop 2013;143:695-703.
27. 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.
28. 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;6:684-91.

Figure legends:

Figure 1. Open bite treatment with bonded spurs only.

Figure 2. Open bite treatment with bonded spurs associated with build-ups.

Figure 3. Consort flow diagram.

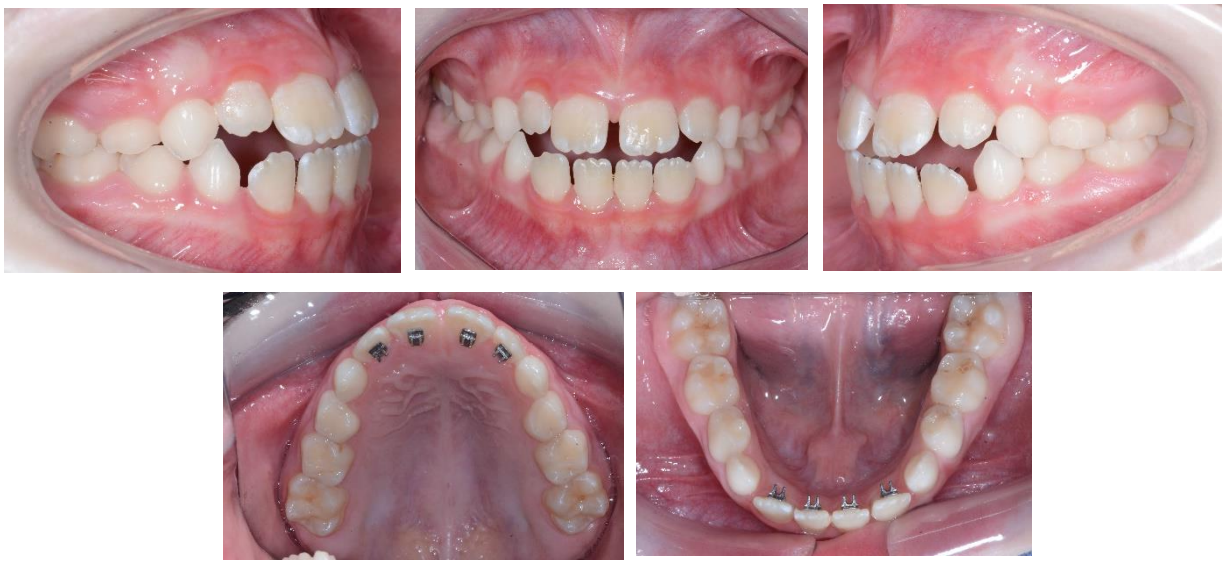

Figure 1.

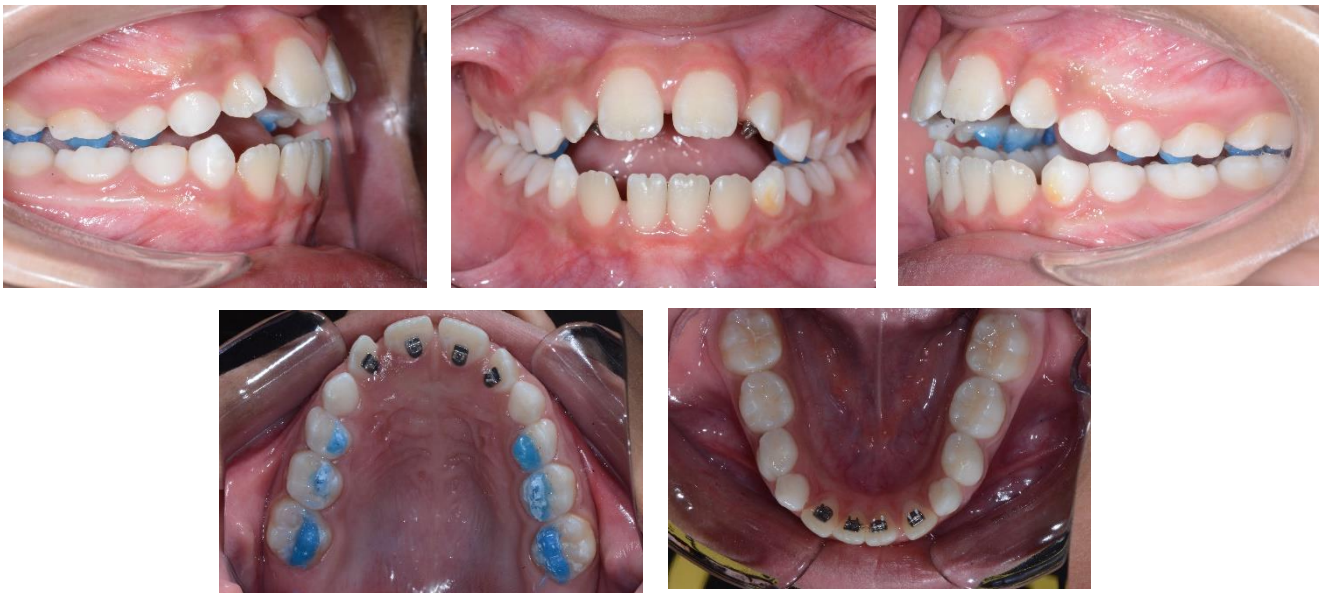

Figure 2.

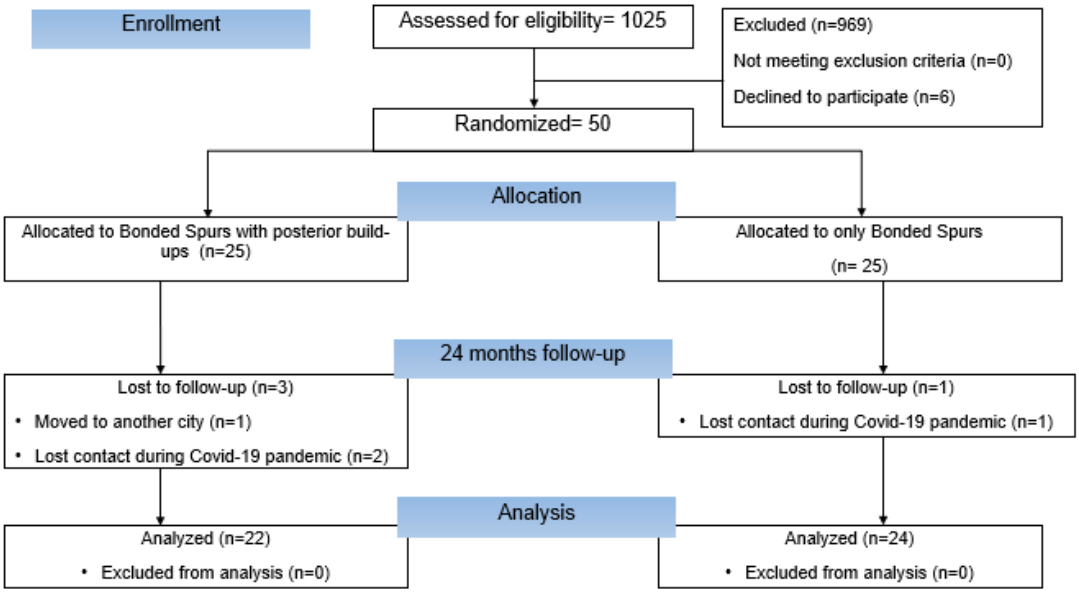
Enrollment
Assessed for eligibility= 1025
Excluded (n=969)
Not meeting exclusion criteria (n=0)
Declined to participate (n=6)
Randomized= 50
Allocation
Allocated to Bonded Spurs with posterior build-ups (n=25)
Allocated to only Bonded Spurs (n= 25)
24 months follow-up
Lost to follow-up (n=3)
• Moved to another city (n=1)
• Lost contact during Covid-19 pandemic (n=2)
Lost to follow-up (n=1)
• Lost contact during Covid-19 pandemic (n=1)
Analysis
Analyzed (n=22)
• Excluded from analysis (n=0)
Analyzed (n=24)
• Excluded from analysis (n=0)

Figure 3.

Table I. Cephalometric variables.

Variables	Definition
Maxillary and mandibular component	
SNA, º	SN to NA angle
Co-A, mm	Co to A point distance
SNB, º	SN to NB angle
Ar-Go, mm	Ar to Go distance
Ar.Go.Me, º	Ar-Go to mandibular plane distance
Co-Gn, mm	Co to Gn distance
ANB, º	NA to NB angle
Vertical component	
SN.Go.Gn, º	SN to GoGn distance angle
SN.PP, º	SN to palatal plane distance angle
N.S.Gn, ºNS.Gn	SN to SGn angle
AFH, mm	N to Me point distance
PFH, mm	S to Go distance
LAFH, mm	Anterior nasal spine to Me distance
Dentoalveolar relationship	
Overbite, mm	Distance of maxillary incisal edge to mandibular incisal edge, perpendicular to occlusal plane
Maxillary dentoalveolar component	
Mx1.NA, º	Maxillary incisor long axis to NA angle
Mx1-NA, mm	Distance between the most anterior central incisor labial surface to NA
Mx1-PP, mm	Distance between central incisor edge to palatal plane
Mx6-PP, mm	Distance between maxillary first molar mesiobuccal cusp to palatal plane
Mandibular dentoalveolar component	
Md1.NB, º	Mandibular incisor long axis to NB line distance angle
Md1-NB, mm	Distance between most labial mandibular incisor surface to NB
Md1-GoMe, mm	Distance between mandibular incisal edge to mandibular plane

Md6-GoMe, mm	Distance between mandibular first molar mesiobuccal cusp to mandibular plane

Mx1, maxillary incisor; Mx6, maxillary first permanent molar; Md1, mandibular incisor; Md6, mandibular first permanent molar.

Table II. Pretreatment characteristics of study groups.

Variable	Experimental (n= 22)		Comparison (n= 24)		
	Mean	**SD**	**Mean**	**SD**	**P**
Age (years)	8.18	1.07	8.33	1.00	0.635
Sex	n	%	n	%	
Female	15	68.2	14	58.3	
Male	7	31.8	10	41.7	0.552†

† t test.

Table III. Intergroup comparison at pretreatment (T1).

Variable	Experimental Group (n=22)		Comparison Group (n=24)		Difference			
	Mean	SD	Mean	SD	Mean	CI 95%		P
Maxillary skeletal component								
SNA (º)	83.14	2.72	83.69	3.96	-0.55	-2.56	1.45	0.581†
Co-A (mm)	74.62	3.24	74.69	3.19	-0.06	-1.98	1.84	0.942†
Mandibular skeletal component								
SNB (º)	79.05	3.49	79.51	3.12	-0.45	-2.42	1.51	0.645†
Ar-Go (mm)	33.95	4.11	34.42	3.64	-0.46	-2.77	1.84	0.686†
Ar.Go.Me (º)	130.2	6.21	132.02	4.5	-1.82	-5.02	1.38	0.259†
Co-Gn (mm)	95.82	4.82	96.6	4.95	-0.78	-3.69	2.12	0.621‡
Maxillomandibular component								
ANB (º)	4.09	1.83	4.17	1.83	-0.08	-1.17	1.00	0.878†
Vertical component								
SN.GoGn (º)	34.31	5.5	34.75	4.1	-0.43	-3.3	1.63	0.509‡
SN.PP (º)	-0.46	3.24	-0.77	3.33	0.31	-1.64	2.27	0.747†
N.S.Gn (º)	66.87	3.77	67.27	3.02	-0.39	-2.41	1.63	0.697†
AFH (mm)	98.76	4.92	99.32	5.61	-0.56	-3.71	2.58	0.721†
PFH (mm)	41.98	3.79	42.14	3.37	0.88	-2.28	1.97	0.884†
LAFH (mm)	56.18	3.48	56.96	4.41	-0.79	-3.17	1.58	0.505†
Dentoalveolar relationship								
Overbite (mm)	-4.52	1.48	-4.35	1.69	-0.17	-1.12	0.77	0.715†
Maxillary dentoalveolar component								
Mx1.NA (º)	28.27	5.09	29.1	5.27	-0.83	-3.91	2.25	0.767‡
MX1-NA (mm)	4.57	1.88	5.52	2.14	-0.94	-2.15	0.25	0.119†
Mx1-PP (mm)	21.16	2.57	21.85	2.84	-0.69	-2.30	0.92	0.394†
Mx6-PP (mm)	16.96	1.68	17.17	2.68	-0.21	-1.55	1.13	0.753†
Mandibular dentoalveolar component								
Md1.NB (º)	28.1	4.36	29.98	5.62	-1.88	-4.89	1.12	0.213†
Md1-NB (mm)	4.87	1.37	5.65	1.81	-0.78	-1.74	0.18	0.109†
Md1-GoMe (mm)	31.59	2.23	32.31	2.59	-0.72	-2.17	0.72	0.317†
Md6-GoMe (mm)	24.40	2.21	24.42	2.00	-0.02	-1.27	1.23	0.974†

† t test; ‡ Mann Whitney U test; Mx, maxillary; Md, mandibular; 1, central incisor; 6, first molar.

Table IV. Intergroups comparisons of treatments changes (T2-T1).

Variable	Experimental Group (n=22)		Comparison Group (n=24)		Difference			
	Mean	SD	Mean	SD	Mean	CI 95%		P
Maxillary skeletal component								
SNA (º)	-0.18	1.12	0.27	1.14	-0.46	-1.13	0.20	0.170†
Co-A (mm)	3.86	1.70	3.25	1.27	0.61	-0.27	1.50	0.169†
Mandibular skeletal component								
SNB (º)	0.65	1.19	1.15	1.41	-0.49	-1.27	0.29	0.212†
Ar-Go (mm)	4.86	2.4	3.73	2.48	1.12	-0.32	2.58	0.126†
Ar.Go.Me (º)	-1.47	2.36	-1.42	2.17	-0.04	-1.39	1.30	0.944†
Co-Gn (mm)	5.65	1.96	5.01	1.62	0.63	-0.42	1.70	0.235†
Maxillomandibular component								
ANB ()	-0.84	0.88	-0.85	0.83	0.00	0.50	0.51	0.972†
Vertical component								
SN.GoGn (º)	-0.55	1.38	-0.21	1.93	-0.33	-1.34	0.67	0.503†
SN.PP (º)	-0.82	1.71	0.65	1.87	0.16	-0.90	1.24	0.753†
N.S.Gn (º)	-0.41	1.02	-0.65	1.48	0.23	-0.52	1.00	0.537†
AFH (mm)	4.55	1.59	4.32	2.04	0.23	-0.86	1.33	0.670†
PFH (mm)	2.85	2.42	1.82	1.92	1.02	-0.26	2.32	0.116†
LAFH (mm)	2.21	1.20	2.20	1.59	0.00	-0.83	0.85	0.984†
Dentoalveolar relationship								
Overbite (mm)	6.00	1.79	5.91	1.75	0.09	-0.96	1.15	0.855†
Maxillary dentoalveolar component								
Mx1.NA (º)	-5.06	5.17	-5.54	4.88	0.47	-2.51	3.46	0.749†
MX1-NA (mm)	-0.44	1.58	-0.58	1.61	0.14	-0.81	1.09	0.939‡
Mx1-PP (mm)	3.7	1.46	3.60	1.75	0.10	-0.86	1.06	0.836†
Mx6-PP (mm)	1.11	0.65	1.32	0.75	-0.21	-0.63	0.21	0.318†
Mandibular dentoalveolar component								
Md1.NB (º)	-3.06	3.12	-3.11	3.36	0.05	-1.82	1.92	0.958†
Md1-NB (mm)	-1.17	3.84	-0.61	2.63	-0.55	-2.54	1.43	0.574†
Md1-GoMe (mm)	3.41	1.11	3.50	1.15	-0.08	-0.76	0.58	0.798†
Md6-GoMe (mm)	1.06	0.90	0.95	1.02	0.10	-0.46	0.68	0.704†

† t test; ‡ Mann Whitney U test; Mx, maxillary; Md, mandibular; 1, central incisor; 6, first molar.

3 DISCUSSION

3 DISCUSSION

The early treatment protocols of the anterior open bite has been studied and are described in the literature, although there are still a lack of randomized clinical trials in this field.[19, 21, 24, 30, 35] The cephalometric analysis is usually performed to evaluate the dentoskeletal changes during these therapies.[19, 28, 36] It is an important tool, although is also important to evaluate the dentoalveolar involvement in open bite malocclusion with 3D tools, such as digital models.[2] It is also possible to measure the dentoalveolar changes with more precision in digital models in relation to plaster models, because there are less distortions.

In addition to the lack of randomized clinical trials, most of studies regarding AOB early treatment present follow-ups at maximum 12-months [19, 28, 36-39] It was previously evaluated the cephalometric and dentoalveolar changes after 12 months in this same sample.[36, 39] At this stage, the open bite closure prevalence consisted of 66.7% to bonded spurs associated with build-ups group and 72% to only bonded spurs group.

The open bite closure previously found indicates that more severe open bites cannot be fully treated in only 12-month follow-up. In the present study, after 24-month follow-up the AOB was clinically closed in 100% of the patients in the experimental group and in 95.8% in the comparison group. Consequently, the overbite improvement consisted of 6.00 and 5.91 in experimental and comparison group, respectively. This increasement was higher than previously reported in studies with bonded spurs and vertical dimension control or with only build-ups [19, 28, 36-38, 40]

Even with the bonded build-ups, one patient in the comparison group (4.16%), did not present the AOB closure, which was consequence the deleterious oral habit persistence.[16, 33, 38, 41]

These founds are clinically important and present higher frequency of AOB correction than previous studies. Most studies reported an AOB correction ranged from 47 to 86.7% in cases with bonded spurs alone or associated with appliances to promote vertical control. [19, 28, 36, 37, 39, 40]

After the 12-month observation stage of the present study, as the deciduous canines reestablished contacts, the build-ups were removed and no significant vertical intergroups differences were found after 24 months. It should be further investigated if

the increase in build-ups heigh after the reestablishment of canines contacts would influence in vertical dimension control.

At the pretreatment stage, both groups were comparable and similar in most variables. Only regarding the dentoalveolar analysis the mandibular intercanine distance was significantly larger in the comparison group. In contrast, after 24 months both groups were similar in dentoalveolar and skeletal alteration, with no statistical significant differences.

After 24 months of treatment, both groups presented similar dentoalveolar and skeletal alterations, with no statistical significant differences. The skeletal alterations represented the normal growth development of individuals with the same age evaluated in the present research. The decreases in perimeter and arch length are consequences of the lingual and palatal incisor inclinations during treatment and also the molar mesialization to the leeway space.[33, 42, 43]

In the digital casts and cephalometric analysis there was incisors and molars clinical crown extrusion in both groups, which consists in a desirable effect of bonded spurs, and also was influenced by the normal growth pattern of the patients included.[3, 19, 43, 44]

4 CONCLUSIONS

4 CONCLUSIONS

The outcomes of this research lead to the following conclusions:

- The success rate of AOB closure after 24-month followup consisted in 100% in the experimental group and 95.8% in the comparison group
- Both groups presented similar results regarding overbite improvement
- The dentoalveolar and cephalometric changes were similar in both treatment modalities
- The use of build-ups did not presented significant vertical development restriction after 24-months followup.

REFERENCES

REFERENCES

1- Almeida RR, Ursi WJ. Anterior open bite. Etiology and treatment. Oral Health. 1990;80(1):27-31.

2- Ngan P, Fields HW. Open bite: a review of etiology and management. Pediatr Dent. 1997;19(2):91-8.

3- Nielsen IL. Vertical malocclusions: etiology, development, diagnosis and some aspects of treatment. Angle Orthod. 1991;61(4):247-60.

4- Janson G, Valarelli F. Open-bite malocclusion: treatment and stability. Ames, IA: John Wiley & Sons, Inc; 2014.

5- Pithon MM, Dos Santos CR, Lima Santos N, Aguiar Sales Lima SO, Coqueiro RS, Dos Santos RL. Impact of malocclusion on affective/romantic relationships among young adults. Angle Orthod. 2016;86(4):638-43.

6- 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 Dentofacial Orthop. 2005;128(4):517-9.

7- Mossey PA. The heritability of malocclusion: part 2. The influence of genetics in malocclusion. Br J Orthod. 1999;26(3):195-203.

8- Johnson ED, Larson BE. Thumb-sucking: literature review. ASDC J Dent Child. 1993;60(4):385-91.

9- Peltomaki T. The effect of mode of breathing on craniofacial growth--revisited. Eur J Orthod. 2007;29(5):426-9.

10- Graber TM. Thumb and Finger-Sucking. Am J Orthod 1959:258-64.

11- Nahoum HI, Horowitz SL, Benedicto EA. Varieties of anterior open-bite. Am J Orthod. 1972;61(5):486-92.

12- Cangialosi TJ. Skeletal morphologic features of anterior open bite. Am J Orthod. 1984;85(1):28-36.

13- Villa NL, Cisneros GJ. Changes in the dentition secondary to palatal crib therapy in digit-suckers: a preliminary study. Pediatr Dent. 1997;19(5):323-6.

14- 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 Dentofacial Orthop. 2006;129(3):418-23.

15-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(6):610-7.

16-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 Dentofacial Orthop. 2006;129(6):734-9.

17-Cozza P, Baccetti T, Franchi L, Mucedero M. Comparison of 2 early treatment protocols for open-bite malocclusions. Am J Orthod Dentofacial Orthop. 2007;132(6):743-7.

18-Cozza P, Mucedero M, Baccetti T, Franchi L. Treatment and posttreatment effects of quad-helix/crib therapy of dentoskeletal open bite. Angle Orthod. 2007;77(4):640-5.

19-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 Dentofacial Orthop. 2016;149(6):847-55.

20-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(3):317-27.

21-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 Dentofacial Orthop. 1995;108(1):9-21.

22-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 Dentofacial Orthop. 2007;132(5):595-8.

23-Kiliaridis S, Egermark I, Thilander B. Anterior open bite treatment with magnets. Eur J Orthod. 1990;12(4):447-57.

24-Iscan HN, Sarisoy L. Comparison of the effects of passive posterior bite-blocks with different construction bites on the craniofacial and dentoalveolar structures. Am J Orthod Dentofacial Orthop. 1997;112(2):171-8.

25-Iscan HN, Akkaya S, Koralp E. The effects of the spring-loaded posterior bite-block on the maxillo-facial morphology. Eur J Orthod. 1992;14(1):54-60.

26-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(1):38-46.

27-Kuster R, Ingervall B. The effect of treatment of skeletal open bite with two types of bite-blocks. Eur J Orthod. 1992;14(6):489-99.

28-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 Dentofacial Orthop. 2012;142(4):487-93.

29-Carano A, Machata W, Siciliani G. Noncompliant treatment of skeletal open bite. Am J Orthod Dentofacial Orthop. 2005;128(6):781-6.

30-Cinsar A, Alagha AR, Akyalcin S. Skeletal open bite correction with rapid molar intruder appliance in growing individuals. Angle Orthod. 2007;77(4):632-9.

31-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(1):33-40.

32-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(3):237-50.

33-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(1):31-42.

34-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(1):28.

35-Weinbach JR, Smith RJ. Cephalometric changes during treatment with the open bite bionator. Am J Orthod Dentofacial Orthop. 1992;101(4):367-74.

36-Aliaga-Del Castillo A, Vilanova L, Miranda F, Arriola-Guillén LE, Garib D, Janson. Dentoskeletal changes in open bite treatment using spurs and posterior build-ups: A randomized clinical trial. 2021;159(1):10-20.

37-Leite JS, Matiussi 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(5):734-9.

38-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(6):969-75.

39-Aliaga-Del Castillo A, Bellini-Pereira SA, Vilanova L, Miranda F, Massaro C, Arriola-Guillén LE, et al. Dental arch changes after open bite treatment with spurs associated with posterior build-ups in the mixed dentition: A randomized clinical trial. 2021;159(6):714-23. e1.

40-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.

41-Mucedero M, Franchi L, Giuntini V, Vangelisti A, McNamara JA, Jr., Cozza P. Stability of quad-helix/crib therapy in dentoskeletal open bite: a long-term controlled study. Am J Orthod Dentofacial Orthop. 2013;143(5):695-703.

42-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 chincup. Orthod Craniofac Res. 2018;21(2):104-11.

43-Meyer-Marcotty P, Hartmann J, Stellzig-Eisenhauer A. Dentoalveolar open bite treatment with spur appliances. J Orofac Orthop. 2007;68(6):510-21.

44-Justus R. Correction of anterior open bite with spurs: long-term stability. World J Orthod. 2001;2:219-31.

APPENDIX

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

We hereby declare that we are aware of the articles “Dentoalveolar changes promoted by anterior open bite treatment with bonded spurs associated with build-ups versus conventional bonded spurs during 24 months: a randomized clinical trial” and “Dentoskeletal changes after 2-year anterior open bite treatment with bonded spurs associated with build-ups versus conventional bonded spurs: a randomized clinical trial” will be included in Thesis of the student Olga Benário Vieira Maranhão and may not be used in other works of Graduate Programs at the Bauru School of Dentistry, University of São Paulo.

Bauru, December 8st, 2021.

Olga Benário Vieira Maranhão
Author

Signature

Arnaldo Pinzan
Author

Signature

ANNEXES

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

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

PARECER CONSUBSTANCIADO DO CEP

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

Área Temática:

Versão: 2

CAAE: 19700919.2.0000.5417

Instituição Proponente: Faculdade de Odontologia de Bauru

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 3.717.939

Apresentação do Projeto:

O projeto é continuação de um projeto anterior já aprovado por este CEP (CAAE 68551617.8.0000.5417) visando acompanhar pacientes em tratamento ortodôntico com diferentes aparelhos por mais 12 meses, perfazendo um total de 24 meses de acompanhamento. São 50 participantes da pesquisa, entre 7 e 11 anos de idade. O grupo experimental consiste em 25 pacientes tratados com esporão colado associado a build-ups. O grupo controle consiste em 25 pacientes tratados apenas com esporão colado. Telerradiografias laterais e modelos de estudo digitais (adquiridos a partir do escaneamento dos arcos dentários) foram obtidos no início (T1) e serão obtidos após 24 meses de acompanhamento (T2).

Variáveis dentoalveolares e esqueléticas serão avaliadas a partir de telerradiografias no programa Dolphin®. Modelos de estudo serão analisados no programa Orthoanalyzer® para avaliar as alterações dentoalveolares em ambos os arcos dentários. Verificada a normalidade, comparações intergrupos serão realizadas com o teste t e as intragrupos com o teste t dependente, respectivamente ($P<0.05$).

Objetivo da Pesquisa:

Comparar os efeitos dentoalveolares e esqueléticos do tratamento precoce da mordida aberta anterior com esporão colado associado a build-ups versus esporão colado convencional após 24

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).

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

Continuação do Parecer: 3.717.939

meses.

Avaliação dos Riscos e Benefícios:

Riscos:

Durante a remoção do aparelho, o menor poderá sentir uma rápida pressão nos dentes onde estão os esporões, porém ao final da consulta o mesmo pode retomar sua rotina.

Benefícios:

1- Para o participante da pesquisa, correção da "mordida aberta anterior", auxiliando-o a não mais utilizar chupeta ou chupar o dedo, corrigindo a relação entre os arcos dentários.

2- Orientação para profissionais a respeito da forma mais estável e eficaz de tratamento.

Comentários e Considerações sobre a Pesquisa:

A pesquisa está embasada na literatura pertinente sobre os estudos que utilizaram aparelhos similares para a correção da mordida aberta anterior. A novidade é que será avaliada a efetividade da associação de esporões colados com levantes de mordida (build-ups), bem como uma comparação entre esta modalidade de tratamento e a utilização dos esporões colados em um acompanhamento de 24 meses no intuito de melhorar a correção em casos mais complexos, o que ainda não foi estudado.

A metodologia está descrita com detalhes suficientes e os exames complementares utilizados (fotografias, modelos de estudo advindos do escaneamento intraoral e radiografias) são imprescindíveis para averiguar o sucesso do tratamento e quantificar a correção da maloclusão. Há a garantia de tratamento efetivo ao participante.

Considerações sobre os Termos de apresentação obrigatória:

Foi encaminhado um ofício contendo as correções necessárias, que foram acatadas. Os documentos corrigidos e a carta de autorização para uso de dados de projeto anterior foram anexados no próprio ofício.

Recomendações:

Não há.

Conclusões ou Pendências e Lista de Inadequações:

Aprovado.

Considerações Finais a critério do CEP:

Esse projeto foi considerado APROVADO na reunião ordinária do CEP de 13/11/2019, com base

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 (verse).

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

Continuação do Parecer: 3.717.939

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_1413690.pdf	02/10/2019 17:25:14		Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	4_TCLE2.doc	02/10/2019 17:24:37	Olga Benário Vieira Maranhão	Aceito
Outros	Oficio_CEP.doc	02/10/2019 17:24:12	Olga Benário Vieira Maranhão	Aceito
Outros	9_Check_listCEP_2019.pdf	21/08/2019 21:14:59	Olga Benário Vieira Maranhão	Aceito
Outros	7_QuestionarioTecnicoPesquisador.pdf	21/08/2019 21:14:23	Olga Benário Vieira Maranhão	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	4_Termo_de_assentimento.doc	21/08/2019 21:13:15	Olga Benário Vieira Maranhão	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	4_TCLE.doc	21/08/2019 21:13:00	Olga Benário Vieira Maranhão	Aceito
Projeto Detalhado / Brochura Investigador	5_Projeto_Doutorado_CEP.docx	21/08/2019 21:12:02	Olga Benário Vieira Maranhão	Aceito
Outros	6_Anexo3.pdf	21/08/2019 21:11:03	Olga Benário Vieira Maranhão	Aceito
Outros	6_Anexo2.pdf	21/08/2019 21:10:45	Olga Benário Vieira Maranhão	Aceito
Outros	6_Anexo1.pdf	21/08/2019 21:10:28	Olga Benário Vieira Maranhão	Aceito
Orçamento	10_Orcamento.docx	21/08/2019 21:09:54	Olga Benário Vieira Maranhão	Aceito

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 (verse).

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

Continuação do Parecer: 3.717.939

Declaração de Pesquisadores	3_DeclaracaoCompromissoPesquisadorResultadosPesquisa.pdf	21/08/2019 21:05:48	Olga Benário Vieira Maranhão	Aceito
Declaração de Instituição e Infraestrutura	2_carta_de_encaminhamento_termo_de_aquiescencia.pdf	21/08/2019 21:05:14	Olga Benário Vieira Maranhão	Aceito
Cronograma	8_Cronograma.docx	21/08/2019 21:03:01	Olga Benário Vieira Maranhão	Aceito
Folha de Rosto	1_Folha_de_rosto_preenchida.pdf	21/08/2019 21:01:47	Olga Benário Vieira Maranhão	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

BAURU, 21 de Novembro de 2019

Assinado por:
Ana Lúcia Pompéia Fraga de Almeida
(Coordenador(a))

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 B. Patient´s informed consent.

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 que você participou anteriormente com Dr. Arón Aliaga Del Castillo (previamente aprovada pelo CEP sob CAAE 68551617.8.0000.5417), onde o aparelho foi colado na parte de trás dos seus dentes da frente (anteriores) junto com uma massinha nos dentes de trás em alguns casos. 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 uma lista de perguntas (questionário) sobre desconforto com o aparelho e melhorias na 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

Al. Dr. Octávio Pinheiro Brisolla, 9-75 – Bauru-SP – CEP 17012-901 – C.P. 73
e-mail: veragato@fob.usp.br – Fone/FAX (0xx14) 3235-8217
http://www.fob.usp.br

ANNEX C. Parents informed consent exoneration (front)

Universidade de São Paulo
Faculdade de Odontologia de Bauru

Departamento de Odontopediatria, Ortodontia e Saúde Coletiva

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) nos participantes da pesquisa entre 6 a 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. Será garantido o ressarcimento de despesas que o participante venha a ter em decorrência da participação na pesquisa, como transporte e alimentação, por exemplo (Resolução 466/2012). É 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 prevalecida, 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.

Rubrica do Participante da Pesquisa :

Al. Dr. Octávio Pinheiro Brisolla, 9-75 – Bauru-SP – CEP 17012-901 – C.P. 73
e-mail: veragato@fob.usp.br – Fone/FAX (0xx14) 3235-8217
http://www.fob.usp.br

ANNEX C. Parents informed consent exoneration (front)

Universidade de São Paulo
Faculdade de Odontologia de Bauru

Departamento de Odontopediatria, Ortodontia e Saúde Coletiva

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.

ANNEX C. Parents informed consent exoneration (verse)

Universidade de São Paulo
Faculdade de Odontologia de Bauru

Departamento de Odontopediatria, Ortodontia e Saúde Coletiva

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/0698/FOB**), previsto no item VII 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