UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU

ARÓN ALIAGA DEL CASTILLO

Anterior open bite treatment with bonded spurs associated with build-ups versus conventional bonded spurs: a randomized clinical trial

Tratamento da mordida aberta anterior com esporão colado associado a build-ups versus esporão colado convencional: um ensaio clínico randomizado

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Orientador: Prof. Dr. Guilherme Janson

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ABSTRACT

ABSTRACT

Anterior open bite treatment with bonded spurs associated with build-ups versus conventional bonded spurs: a randomized clinical trial

Introduction: The aim of this 2-arm parallel randomized clinical trial was to compare the dentoskeletal and dental arches changes after anterior open bite early treatment with bonded spurs associated with posterior build-ups versus conventional bonded spurs. **Methods:** Patients between 7 and 11 years old with anterior open bite were prospectively and randomly allocated to two groups. The experimental group consisted of patients treated with bonded spurs associated with posterior build-ups. The comparison group comprised patients treated with conventional bonded spurs. Lateral headfilms and digital dental models were obtained at pretreatment (T1) and after 12 months of treatment (T2). The primary outcomes were the change in overbite, gonial and mandibular plane angles, and molars vertical development. Randomization was performed using the web site www.randomization.com. Blinding was applicable for outcome variables assessment only. Intergroup comparisons were performed with t tests or Mann-Whitney U tests ($P<0.05$). **Results:** The experimental group included 24 patients (17 female; 7 male, mean age 8.22 ± 1.06) and the comparison group included 25 patients (14 female; 11 male, mean age 8.30 ± 0.99). After 12 months, all patients showed improvements. The groups showed similar increases of the overbite and similar dentoskeletal and dental arches changes. The experimental group showed statistically significant smaller vertical development of the maxillary first molar than the comparison group. The groups showed statistically significant differences for the intermolar distances. The maxillary intermolar distance decreased in the experimental group and increased in the comparison group, while the mandibular distance increased in the experimental group and decreased in the comparison group. **Conclusions:** Similar overbite increases, dentoskeletal and dental arches changes were observed in both groups after 12 months of treatment. Although bonded spurs associated with build-ups showed significant smaller vertical development of the maxillary molars, it did not produce greater counter-clockwise rotation of the mandible than conventional bonded spurs. A slight decrease in the maxillary intermolar distance and a slight increase in the mandibular intermolar distance could be expected with bonded spurs associated with posterior build-ups, while the opposite behavior could be expected when conventional bonded spurs are used. **Registration:** This trial was registered at

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Keywords: Open Bite; Orthodontic Appliances; Orthodontics, Interceptive; Dental Models

RESUMO

RESUMO

Tratamento da mordida aberta anterior com esporão colado associado a build-ups versus esporão colado convencional: um ensaio clínico randomizado

Introdução: O objetivo deste ensaio clínico randomizado, em paralelo, foi comparar as alterações dentoesqueléticas e dos arcos dentários após o tratamento precoce da mordida aberta anterior com esporão colado associado a build-ups versus esporão colado convencional. **Métodos:** Pacientes entre 7 e 11 anos de idade com mordida aberta anterior foram prospectiva e aleatoriamente alocados em um dos dois grupos de estudo. O grupo experimental foi composto por pacientes tratados com esporão colado associado a build-ups e o grupo controle foi composto por pacientes tratados apenas com esporão colado. Telerradiografias laterais e modelos de estudo digitais foram obtidos ao início (T1) e após 12 meses do tratamento (T2). As variáveis primarias foram as alterações no trespasse vertical anterior, nos ângulos goníaco e mandibular e no desenvolvimento vertical dos molares. A randomização foi realizada no site www.randomization.com. O cegamento foi possível apenas para a avaliação das variáveis resultado. As comparações intergrupos foram realizadas com o teste t ou U de Mann Whitney, e com o teste Chi-quadrado ($P<0.05$). **Resultados:** 24 pacientes (17 mulheres, 7 homens; idade média 8,22 ± 1,06) foram incluídos no grupo experimental e 25 pacientes (14 mulheres, 11 homens; idade média 8,30 ± 0,99) foram incluídos no grupo controle. Após 12 meses, todos os pacientes apresentaram melhorias. Ambos os grupos apresentaram um aumento similar do trespasse vertical anterior e similares alterações dentoesqueléticas e nos arcos dentários. O grupo experimental apresentou desenvolvimento vertical do molar superior significantemente menor que o grupo controle. Os grupos apresentaram diferenças significantes na alteração das larguras intermolares. A largura intermolar superior diminuiu no grupo experimental e aumentou no grupo controle, enquanto a largura intermolar inferior aumentou no grupo experimental e diminuiu no grupo controle. **Conclusões:** Similares aumentos do trespasse vertical anterior, alterações dentoesqueléticas e dos arcos dentários foram observadas em ambos os grupos após 12 meses de tratamento. Embora o esporão colado associado a build-ups demonstrou um desenvolvimento vertical dos molares superiores significantemente menor, não demonstrou uma rotação mandibular maior do que o esporão colado convencional. Uma leve diminuição da largura intermolar superior e um leve aumento da largura

intermolar inferior pode ser esperado com o esporão colado associado a build-ups; enquanto, o oposto pode ser esperado com o esporão colado convencional. **Registro:** O ensaio clínico foi registrado no site Clinicaltrials.gov com número de identificação NCT03702881. **Protocolo:** O protocolo não foi publicado. **Financiamento:** O presente trabalho foi realizado com apoio da Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – Brasil (CAPES) – Código de Financiamento 001; e dos processos nº: 2017/06440-3, 2018/05238-9 e 2018/24003-2, Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP).

Palavras-chave: Mordida Aberta; Aparelho Ortodôntico; Ortodontia Interceptora; Modelos Dentários.

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LIST OF ABBREVIATIONS AND ACRONYMS

T1	Pretreatment.
T2	After 12 months of treatment.
CAPES	Coordenação de Aperfeiçoamento de Pessoal de Nível Superior.
FAPESP	Fundação de Amparo à Pesquisa do Estado de São Paulo.
RCT	Randomized Clinical Trial.
CONSORT	Consolidated Standards of Reporting Trials.
SNA	SN to NA angle.
Co-A	Condylion to A-point distance.
SNB	SN to NB angle.
Ar-Go	Articulare to gonion distance.
Ar.Go.Me	ArGo to GoMe angle.
Co-Gn	Condylion to gnathion distance.
ANB	NA to NB angle.
SN.GoGn	SN to GoGn angle.
SN.PP	SN to PP angle.
N.S.Gn	SN to SGn angle.
AFH	Nasion to menton distance.
PFH	Sella turcica to gonion distance.
LAFH	ANS, anterior nasal spine to menton distance.
Mx1.NA	Maxillary incisor long axis to NA angle.
Mx1-NA	Distance between most anterior point of crown of maxillary incisor and NA line.

Mx1-PP Perpendicular distance between incisal edge of maxillary incisor and palatal plane.

Mx6-PP Perpendicular distance between mesial cusp of maxillary first permanent molar and palatal plane.

Md1.NB Mandibular incisor long axis to NB angle.

Md1-NB Distance between most anterior point of crown of mandibular incisor and NB line.

Md1-GoMe Distance between incisal edge of mandibular incisor and mandibular plane.

Md6-GoMe Distance between mesial cusp of mandibular first permanent molar and mandibular plane.

Mx Maxillary.

Md Mandibular.

1 central incisor.

6 First molar.

3 Canine.

ICC Intraclass Correlation Coefficient.

BSBU Bonded spurs associated with build-ups.

BS Bonded spurs.

AOB Anterior open bite.

DAVD Dentoalveolar vertical development.

3-3 Intercanine distance.

6-6 Intermolar distance.

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1 INTRODUCTION

1 INTRODUCTION

Anterior open bite malocclusion is defined as the lack of contact between the incisal edges of the anterior teeth.[1] It directly affects esthetics and produces functional problems during feeding and pronunciation of some words, exposing patients to psychosocial issues.[1,2] Its etiology is multifactorial and includes the association of environmental and genetic factors.[1,3,4] Deleterious habits as pacifier, thumb sucking, tongue trust and mouth breathing are considered the most involved environmental factors that contribute to this malocclusion.[3,5]

The treatment of anterior open bite in children focuses in the interruption of deleterious habits allowing vertical dentoalveolar development of anterior teeth without interferences.[6] Some treatment approaches include fixed or removal palatal cribs,[7-14] fixed spurs,[15-17] or bonded spurs in the palatal and lingual surfaces of maxillary and mandibular incisors, respectively.[12,14,17] They keep tongue pressure away from the anterior teeth and serve as a reminder to discontinue other oral habits. Their effects are similar from those reported after palatal crib therapy[12,18] and include increases in dentoalveolar vertical development and lingual tipping of incisors.[14,17] Contrary to the idea of being an invasive approach, they show easy patient´s acceptance and adaptability.[15,17,19] Some of the advantages of bonded spurs include easy installation and no laboratory preparation need.[17]

Commonly, anterior open bite is associated to a vertical growth pattern,[3,5,20] and the severity of this association could increase with age,[21] if the malocclusion is not early corrected.[20,22] Thus, some protocols associate therapies to correct deleterious habits and produce control of the vertical dimension.[23] Among these protocols, bonded spurs associated with vertical chincup have demonstrated efficiency in open bite correction[24,25] and a significant decrease of the gonial angle.[24]

Posterior build-ups have been reported as an efficient associated therapy that provides counter clockwise rotation of the mandible because of its bite-block effect after anterior open bite treatment in adults.[26] They could be considered as an alternative for vertical control during anterior open bite early treatment when associated with bonded spurs. Nevertheless, no studies evaluating this association

has been reported. Therefore, the aim of the present randomized clinical trial was to compare the dentoskeletal and dental arches changes after anterior open bite treatment with bonded spurs associated with build-ups versus conventional bonded spurs.

2 ARTICLES

2 ARTICLES

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

ARTICLE 1 - Dentoskeletal changes in open bite patients treated with bonded spurs associated with posterior build-ups versus conventional bonded spurs: a single-center, randomized clinical trial

ARTICLE 2 - Dental arches changes after open bite treatment with bonded spurs associated with posterior build-ups and conventional bonded spurs: a randomized clinical trial

2.1 ARTICLE 1

Dentoskeletal changes in open bite patients treated with bonded spurs associated with posterior build-ups versus conventional bonded spurs: a single-center, randomized clinical trial.

ABSTRACT

Introduction: The aim of this 2-arm parallel randomized clinical trial was to cephalometrically compare the dentoskeletal effects of bonded spurs associated with posterior build-ups versus conventional bonded spurs in the early treatment of anterior open bite malocclusion. **Methods:** Patients between 7 and 11 years old with anterior open bite were prospectively and randomly allocated into two groups. The experimental group consisted of patients treated with bonded spurs associated with posterior build-ups. The comparison group comprised patients treated with conventional bonded spurs. Lateral headfilms were obtained at pretreatment (T1) and after 12 months of treatment (T2). The primary outcomes were the change in overbite, gonial and mandibular plane angles, and molars vertical development. Randomization was performed using the web site www.randomization.com. Blinding was applicable for outcome assessment only. Intergroup comparisons were performed with t tests or Mann-Whitney U tests ($P<0.05$). **Results:** The experimental group included 24 patients (17 female; 7 male, mean age 8.22 ± 1.06) and the comparison group included 25 patients (14 female; 11 male, mean age 8.30 ± 0.99). Baseline demographic and cephalometric characteristics were similar between groups. After 12 months, all patients showed improvements. Both groups showed similar improvements of the overbite and mandibular vertical development; and similar slight decreases of the gonial and mandibular plane angles. The experimental group showed statistically significant smaller vertical development of the maxillary first molar than the comparison group. The other dentoskeletal variables showed similar changes without statistically significant differences between groups. No serious harm was observed other than plaque accumulation around the spurs. **Conclusions:** Similar overbite increases and dentoskeletal changes were observed in both groups after 12 months of treatment. Although the experimental group showed significant smaller vertical development of the maxillary molars, it did not produce greater counter-clockwise rotation of the mandible than the comparison group. **Registration:** This trial was registered at

Clinicaltrials.gov with the identifier NCT03702881. **Protocol:** The protocol was not published. **Funding:** This study was financed in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – Brasil (CAPES) – Finance Code 001; and by grant #: 2017/06440-3, 2018/05238-9 and 2018/24003-2, São Paulo Research Foundation (FAPESP).

Keywords: Open Bite; Orthodontic Appliances; Orthodontics, Interceptive.

INTRODUCTION

Anterior open bite malocclusion is considered a challenge for orthodontists.[1,2] It affects esthetics and produce functional problems that could reflect in psychosocial issues.[2,3] It´s prevalence in the mixed dentition is around 17%[4] and has a multifactorial etiology involving the interaction of environmental and genetic factors.[2,4] Environmental factors include deleterious habits as pacifier, thumb sucking, tongue trust and mouth breathing.[4,5] Greater the influence of environmental factors, better will be the prognosis if the causal factor is eliminated.[2,5]

Several protocols have been proposed as early treatment and mostly focus in the interruption of deleterious habits allowing vertical dentoalveolar development of anterior teeth without interferences.[6-9] Among these protocols, bonded spurs have been studied because of its practicality that includes low cost, small size, esthetics, no need of laboratory preparation, easy installation and reduced chair time.[10-12] They effectively correct the anterior open bite by keeping tongue pressure away from the anterior teeth and serve as a reminder to cease other oral habits. Their effects include increases in dentoalveolar vertical development and palatal and lingual tipping of maxillary and mandibular incisors, respectively.[10-12]

Anterior open bite is commonly related to a vertical growth pattern and increase in the lower anterior face height.[4,5,13] Thus, some protocols associate therapies that correct the habits and control the vertical dimension.[14-18] One of these protocols, bonded spurs associated with chincup, demonstrated efficiency in open bite correction[16,17] and a significant decrease of the gonial angle.[16] However, it depends on the patient's collaboration.

The use of posterior build-ups (2-3 mm bonded resin blocks in the maxillary molars) with orthodontic fixed appliances for anterior open bite treatment in adults have been reported as practical, efficient and stable treatment option that provides counter clockwise rotation of the mandible because of its bite-block effect.[19] Then, it could be thought that the association of bonded spurs with posterior build-ups would produce vertical control during anterior open bite early treatment. Nevertheless, no studies evaluating this association has been reported.

Specific objectives or hypotheses

The aim of this study was to compare the dentoskeletal changes of bonded spurs associated with posterior build-ups versus conventional bonded spurs in anterior

open bite early treatment. The null hypothesis tested was that there are no differences for the dentoskeletal effects between the groups.

METHODS

Trial design and any changes after trial commencement

This was a single-center, randomized clinical trial (RCT) with two-parallel arms, with a 1:1 allocation ratio. This RCT followed the CONSORT statement and guidelines,[20] and did not require changes in methods after trial commencement.

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 number 68551617.8.0000.5417 / 2.112.035). In addition, the protocol of this study was registered at Clinicaltrials.gov with the identifier NCT03702881

Patients were recruited at the Orthodontic Clinic of Bauru Dental School, University of São Paulo, Brazil, from June 2017 to April 2018. The selection criteria consisted on: patients between 7 to 11 years old, with erupted permanent first permanent molars, anterior open bite greater than 1 mm, with the maxillary and mandibular permanent central incisors fully erupted, no or mild crowding, and without the need of maxillary expansion. Children in the first transitional period were considered to be eligible for treatment when the maxillary lateral incisors were beginning to erupt and the maxillary central incisors still showed an open bite.[11,16] Children with previous orthodontic treatment, craniofacial anomalies or syndromes, tooth agenesis, loss of permanent teeth, severe crowding, maxillary constriction or posterior crossbite, were excluded.

Informed consent was obtained from the patients and their parents or legal guardians before their recruitment.

Interventions

Bonded spurs (Morelli, Sorocaba, SP, Brazil) were installed at the cervical and incisal portions of the palatal and lingual surfaces of the maxillary and mandibular incisors, respectively. The spurs were bonded using Transbond XT primer/adhesive system (3M Unitek, Monrovia, CA, USA). The positions for the spurs were chosen to

prevent possible future occlusal interferences.[11,16] The spurs were sharpened with a carborundum disk before bonding.[14]

The experimental group comprised patients treated with bonded spurs associated with posterior build-ups (2-3 mm bonded resin blocks) (Orthobite; FGM, Joinville, SC, Brazil). Posterior build-ups were cemented on the functional cusps of all maxillary posterior teeth to maintain the natural occlusal forces balance[19] (Fig 1A). The comparison group comprised patients treated only with bonded spurs (Fig 1B).

Digital lateral headfilms were obtained using Orthophos XG 3D (Dentsply Sirona, Bensheim, Germany) in centric occlusion and with lips at rest at pretreatment and after 12 months of treatment, for all patients.

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

The change in the overbite, gonial angle (Ar.Go.Me), mandibular plane angle (Sn.GoGn), and maxillary and mandibular molar vertical development (Mx6-PP, Md6-PP) were considered as primary outcome measurements

Secondary outcome measurements included the change in: maxillary and mandibular position and length, mandibular ramus height, sagittal discrepancy, palatal plane inclination, facial axis angle, anterior/posterior/lower anterior face heights, and inclination/position/height of maxillary and mandibular incisors.

The cephalometric variables (Table I) were digitally evaluated using Dolphin© Imaging Software (Version 11.5, Dolphin Imaging and Management Solutions, Patterson Dental Supply, Inc., Chastworth, CA, USA).[16] There were no outcome changes after trial commencement.

Sample size calculation

Sample size was calculated in order to provide 80% of test power, at a significance level of 0.05 to detect an intergroup difference of 1.5 mm in the overbite with a standard deviation of 1.69 mm, previously reported.[16] The minimal sample size required per group was 21 patients.

Interim analyses and stopping guidelines

Not applicable.

Randomization (random number generation, allocation concealment, implementation)

Randomization scheme was obtained by using the Web site Randomization.com ⟨http://www.randomization.com⟩.[21] This software generated the randomization list by using random block sizes, ensuring equal distribution in both groups. Then, 50 patients were randomized before trial commencement.

Allocation concealment was achieved with sequentially numbered, opaque, sealed envelopes, containing the treatment allocation cards. In addition, opacity was implemented by inserting the card with the assignment into foil. The envelopes were prepared before trial commencement. Patient´s name and baseline information were written on the envelope before opening it. All envelopes were torn open and then they were securely stored in a different location from the trial site.[22]

The generation of randomization list, allocation concealment, and implementation (enrollment of participants/treatment assignment/deliver intervention) were performed independently by different persons.[22]

Blinding

Blinding of either patient or operator was not possible, since both knew the type of appliance that was being installed. However, the assessment of the lateral radiographs was blinded because they were unidentified during the analysis.[23]

Statistical analyses (primary and secondary outcomes, subgroup analyses)

Lateral headfilms of 30% of the sample were randomly selected and retraced by the same examiner after a 30-day interval. Intraobserver reliability was assessed with the intraclass correlation coefficient (ICC).

Normal distribution was tested with Shapiro-Wilk test. Group comparison regarding sex was performed with Fisher´s exact test. Intergroup comparisons regarding age and cephalometric variables were performed with t tests or Mann-Whitney U tests, depending on normality. Statistical analyses were performed with SPSS software (Version 25; IBM, Armonk, NY, USA). Results were considered significant at $P< 0.05$.

RESULTS

Participant flow

One thousand and twenty-five children were assessed for eligibility; 969 were excluded because they did not meet the inclusion criteria, and 6 declined to participate. Fifty patients were randomized in a 1:1 ratio (Fig 2).

Baseline data

The groups showed similar characteristics regarding age and sex distribution and for all the variables obtained from the cephalometric analysis (Tables II and III; Fig 3A).

Number analyzed for each outcome, estimation and precision

One of the 25 (4%) patients, was lost to follow-up in the experimental group. Considering that the primary analysis was carried out on a per-protocol basis, 24 patients in the experimental group and 25 patients in the comparison group were analyzed in their original assigned groups.

The ICC values ranged from 0.886 (95% CI; 0.762, 0.945) to 0.996 (95% CI; 0.991, 0.998), demonstrating a very good intraexaminer reliability.[24]

All patients in both groups showed improvements, demonstrated by the decrease in their anterior open bite condition (overbite increase). After 12 months, the anterior open bite was corrected in 16 of the 24 (66.7%) patients in the experimental group and in 18 of the 25 (72%) patients in the comparison group.

Overall, both groups showed, numerically, similar changes after treatment (Table IV, Figs 3B and 4). For the primary outcomes, they showed similar increases of the overbite and mandibular vertical development; and similar decreases of the gonial and mandibular plane angles. The experimental group showed statistically significant smaller vertical development of the maxillary first molar than the comparison group.

For the secondary outcomes, the groups showed similar decreases of: maxillary protrusion, maxillo-mandibular sagittal relationship, maxillary incisor labial inclination and protrusion and mandibular incisor labial inclination (Table IV, Figs 3B and 4); and similar increases of: maxillary and mandibular lengths, ramus height, palatal plane inclination, anterior/posterior/lower anterior facial heights, maxillary incisor vertical development, mandibular incisor protrusion and vertical development.

Harms

No serious harm was caused to the participants of this study other than plaque accumulation around the spurs. The benefits and collateral effects of the two used protocols were already known from previous literature.[11,16,19] Eight of the 24 (33.3%) patients in the experimental group and 7 of the 25 (28%) patients from the comparison group still showed anterior open bite and continued with the appliances after this evaluation period.

DISCUSSION

Main findings in the context of the existing evidence and interpretation

Early treatment of anterior open bite malocclusion has been studied and several protocols exits to treat this condition.[10-12,14-17,25-28] However, randomized clinical trials evaluating conventional and new associated protocols are still necessary.[6-9]

Previous studies have reported the efficiency of bonded spurs alone for the early treatment of anterior open bite.[10-12] Some protocols associate the bonded spurs with chinchup with the intention to produce control of the vertical dimension[16,17]. Although a significant reduction of the gonial angle has been reported with this protocol, no significantly greater decrease of the mandibular plane angle were observed when compared to an untreated control group.[16,17]

Posterior build-ups have been reported as an effective alternative for anterior open bite in adults. When associated with orthodontic fixed appliances, they produce significant vertical control of posterior teeth and a consequent reduction on the mandibular plane angle; controlling therefore the vertical dimension.[19]

It could be thought that bonded spurs associated with posterior build-ups could produce a combined effect of elimination of deleterious habits, vertical control of posterior teeth and a consequent decrease of the mandibular plane angle in children with anterior open bite, as reported for adults. Nevertheless, these effects have not been previously evaluated. This is the first randomized clinical trial evaluating this protocol and comparing it with bonded spurs without any associated appliance.

The groups showed similar cephalometric characteristics at pretreatment (Table III, Fig 3A), eliminating the influence of any baseline factor on the treatment results. No differentiation between dental and skeletal open bites were performed during recruitment.[11] At this age range, anterior open bite malocclusion has mostly dentoalveolar origin caused by deleterious oral habits and anterior tongue posture

and/or thrusting.[2,4] The skeletal component might increase with age if the malocclusion is not early corrected.[1,29] All patients presented at least, one deleterious habit and they and their parents or legal guardians received instructions on interrupting them. No myofunctional therapy was performed during the orthodontic treatment period.

Although all patients improved after 12 months into treatment, 8 of the 24 patients in the experimental group and 7 of the 25 patients in the comparison group remained with anterior open bite. This could be related to the initial severity of anterior open bite that these patients may have and to the persistence of some deleterious habits,[11,12,16] so they would need treatment for longer than 12 months.

Both treatment protocols showed important improvements of the anterior open bite condition, evidenced clinically and cephalometrically (Table IV, Figs 3 and 4). The overbite improvement was expected because of the presence of bonded spurs in the palatal and lingual surfaces of the maxillary and mandibular incisors, respectively. The spurs prevented the thumb sucking, anterior posture and tongue thrusting, allowing the vertical development of the anterior teeth without interferences.[10-12,16,17]

Overbite increases between 3.07[10,12] to 4.26 mm[11] and between 4.52[17] to 5.23 mm[16] have been reported when bonded spurs alone or bonded spurs associated with chinchup are used, respectively. Based on this, the associated therapy seems to produce a numerically greater increase in the overbite. In the present study, the overbite increased 4.84 mm in both, the experimental and comparison groups (Table IV). The overbite increased similarly, independently of the presence of posterior build-ups.

Vertical development of maxillary molars in untreated open bite patients,[11,16,17] in patients with other type of malocclusion or normal occlusion,[30,31] with similar ages and follow-up, ranges from 0.64 to 0.90 mm.[11,16,17,30,31] The comparison group showed a value within this range, as expected since patients on this group had no appliances in the posterior teeth. The experimental group showed statistically significant smaller vertical development of the maxillary first molar when compared to the comparison group (Table IV). This shows that posterior build-ups in children produced some vertical control only of the maxillary molar, observed in the cephalometric analysis. No significant difference was observed for the mandibular molars, reflecting no vertical control of these teeth. Contrary to the maxillary molar intrusion effect observed in adults,[19] no molar intrusion was present in this study. This could be expected, since patients were growing children, as evidenced by the increases observed in the facial

heights variables. Even when patients are treated with bonded spurs associated with vertical chincup,[16,17] or with bite blocks associated with vertical chincup,[18] some vertical development of molars is observed, because of the growth potential that children present.

The experimental and comparison groups showed similar slight decreases of the gonial (0.66º and 0.68º, respectively) and mandibular plane angles (0.18º and 0.32º, respectively) with no significant differences between them (Table IV). This study shows that a slight decrease in the gonial and mandibular plane angles could be expected after the use of bonded spurs, with or without the association with posterior build-ups. This effect has been reported in other studies using bonded spurs.[11,12] Contrarily, only one study showed an important increase of the mandibular plane angle after bonded spurs therapy.[10] This could be related to the inherent characteristics of the studied sample.

Although smaller vertical development of the maxillary molar was observed in the experimental group, it was not enough to produce statistically significant greater reduction of the gonial angle and counter-clockwise rotation of the mandible than the comparison group, as reported for the bonded spurs associated with vertical chincup therapy,[16,17] and when posterior bite blocks associated with vertical chincup is used.[18]

Greater and significant decreases on the gonial and mandibular plane angles have been reported after the use of vertical chinchup in patients with greater vertical skeletal open bite characteristics.[13] Nevertheless, one study that performed comparisons between bonded spurs and chincup as isolated therapies showed no differences for the decrease of the mandibular plane angle and their values were smaller than 0.54º.[12] This may be related to the mainly dentoalveolar origin of the open bite in the included patients and to patient´s compliance with the use of the chincup.[16]

Regarding the other cephalometric variables, no statistically significant differences were observed between groups (Table IV). The skeletal variables reflected the growth potential of the patients in both groups. The dentoalveolar variables showed that the improvement of the overbite on the experimental and comparison groups was associated to palatal inclination, retrusion and vertical development of maxillary incisors; and to lingual inclination, vertical development and slight protrusion of the mandibular incisors, as previously reported with this kind of therapies.[10-12,16,17]

The results of this study showed that the association of bonded spurs with posterior build-ups was not capable to produce a greater counter-clockwise rotation of

the mandible in children with anterior open bite when compared to bonded spurs alone. Further studies with longer follow-up periods and comparing the dentoskeletal effects of bonded spurs associated with posterior build-ups, bonded spurs associated with chincup, and bonded spurs alone, should be performed to complement the understanding of the effects of the different associated appliances.

Limitations

Ideally, open bite patients with greater vertical skeletal characteristics would be included. However, at this age range, the anterior open bite malocclusion has mainly a dentoalveolar origin, making it difficult to obtain an ideal sample.

Although improvements were observed in all patients, some patients in both groups remained with negative overbite. This could be attributed to the 12 months follow-up period that was not enough to close more severe anterior open bites. In addition, the persistent of deleterious habits and lack of cooperation of some patients may have played a role, as well.

Generalizability

The generalizability of the results of this study should be limited to anterior open bite patients with similar age ranges and similar initial dentoskeletal characteristics considered in this research.

CONCLUSIONS

- Both treatment protocols produced similar overbite increases and showed similar dentoskeletal changes after 12 months of treatment.
- Although the bonded spurs associated with posterior build-ups showed significantly smaller vertical development of the maxillary molars, it did not produce greater counter-clockwise rotation of the mandible when compared to conventional bonded spurs.

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REFERENCES

1. Nielsen IL. Vertical malocclusions: etiology, development, diagnosis and some aspects of treatment. Angle Orthod 1991;61:247-260.
2. Ngan P, Fields HW. Open bite: a review of etiology and management. Pediatr Dent 1997;19:91-98.
3. 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;144:872-878.
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;128:517-519.
5. Janson G, Valarelli F. Open-bite malocclusion: treatment and stability. Ames, IA: John Wiley & Sons, Inc; 2014.
6. Lentini-Oliveira DA, Carvalho FR, Rodrigues CG, Ye Q, Prado LB, Prado GF et al. Orthodontic and orthopaedic treatment for anterior open bite in children. Cochrane Database Syst Rev 2014:CD005515.
7. Feres MF, Abreu LG, Insabralde NM, Almeida MR, Flores-Mir C. Effectiveness of the open bite treatment in growing children and adolescents. A systematic review. Eur J Orthod 2016;38:237-250.
8. 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.
9. 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.
10. 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.
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;149:847-855.

12. 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;88:684-691.
13. Iscan HN, Dincer M, Gultan A, Meral O, Taner-Sarisoy L. Effects of vertical chincap therapy on the mandibular morphology in open-bite patients. Am J Orthod Dentofacial Orthop 2002;122:506-511.
14. Justus R. Correction of anterior open bite with spurs: long-term stability. World J Orthod 2001;2:219-231.
15. 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;129:418-423.
16. 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;142:487-493.
17. Insabralde NM, de Almeida RR, Henriques JF, Fernandes TM, Flores-Mir C, de Almeida MR. Dentoskeletal effects produced by removable palatal crib, bonded spurs, and chincup therapy in growing children with anterior open bite. Angle Orthod 2016;86:969-975.
18. Turkkahraman H, Cetin E. Comparison of two treatment strategies for the early treatment of an anterior skeletal open bite : Posterior bite block-vertical pull chin cup (PBB-VPC) vs. posterior bite block-high pull headgear (PBB-HPH). J Orofac Orthop 2017;78:338-347.
19. Vela-Hernandez A, Lopez-Garcia R, Garcia-Sanz V, Paredes-Gallardo V, Lasagabaster-Latorre F. Nonsurgical treatment of skeletal anterior open bite in adult patients: Posterior build-ups. Angle Orthod 2017;87:33-40.
20. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ et al. CONSORT 2010 Explanation and Elaboration: Updated guidelines for reporting parallel group randomised trials. J Clin Epidemiol 2010;63:e1-37.
21. Pandis N. Randomization. Part 1: sequence generation. Am J Orthod Dentofacial Orthop 2011;140:747-748.

22. Pandis N. Randomization. Part 3: allocation concealment and randomization implementation. Am J Orthod Dentofacial Orthop 2012;141:126-128.
23. Pandis N. Blinding or masking. Am J Orthod Dentofacial Orthop 2012;141:389-390.
24. Koo TK, Li MY. A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. J Chiropr Med 2016;15:155-163.
25. Huang GJ, Justus R, Kennedy DB, Kokich VG. Stability of anterior openbite treated with crib therapy. Angle Orthod 1990;60:17-24.
26. 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;129:734-739.
27. Meyer-Marcotty P, Hartmann J, Stellzig-Eisenhauer A. Dentoalveolar open bite treatment with spur appliances. J Orofac Orthop 2007;68:510-521.
28. Slaviero T, Fernandes TM, Oltramari-Navarro PV, de Castro AC, Conti F, Poleti ML et al. Dimensional changes of dental arches produced by fixed and removable palatal cribs: A prospective, randomized, controlled study. Angle Orthod 2017;87:215-222.
29. Graber TM, Rakosi T, Petrovic AG. Dentofacial orthopedics with functional appliances. 2nd ed. St Louis, MO: Mosby; 1997. p.484-5.
30. Iseri H, Solow B. Continued eruption of maxillary incisors and first molars in girls from 9 to 25 years, studied by the implant method. Eur J Orthod 1996;18:245-256.
31. Buschang PH, Carrillo R, Liu SS, Demirjian A. Maxillary and mandibular dentoalveolar heights of French-Canadians 10 to 15 years of age. Angle Orthod 2008;78:70-76.

FIGURE LEGENDS

Fig 1. A, Protocol including bonded spurs associated with posterior build-ups. B, Protocol including conventional bonded spurs.

Fig 2. CONSORT (Consolidated Standards of Reporting Trials) Flow diagram.

Fig 3. Superimposition of average cephalometric tracings for the experimental (red color) and comparison (black color) groups at pretreatment (A) and after 12 months of treatment (B).

Fig 4. Superimposition of average cephalometric tracings for the experimental (A) and comparison (B) groups. Black color, pretreatment; red color, after 12 months of treatment.

Fig 1.

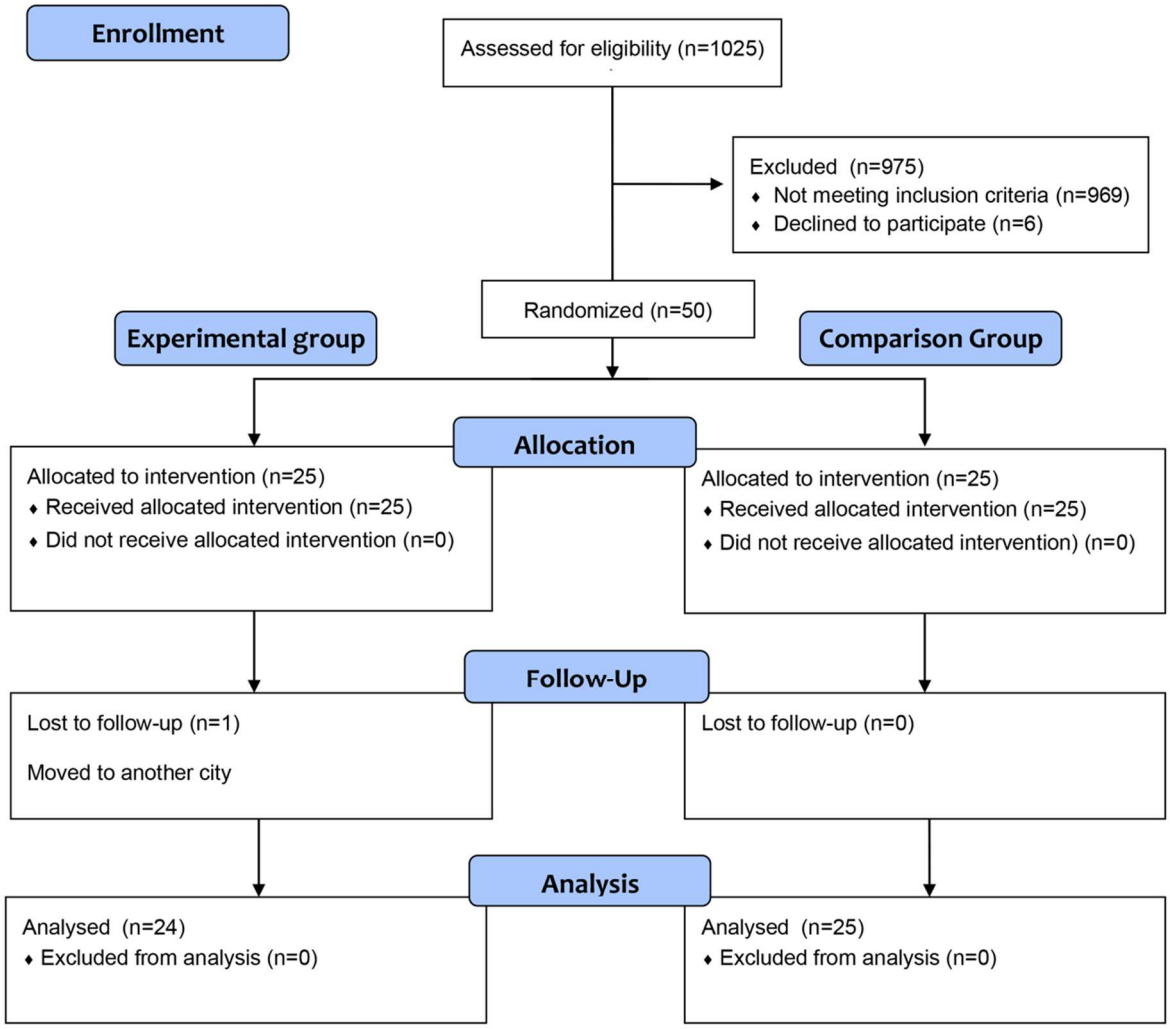
Enrollment
Assessed for eligibility (n=1025)
Excluded (n=975)
Not meeting inclusion criteria (n=969)
Declined to participate (n=6)
Randomized (n=50)
Experimental group
Comparison Group
Allocation
Allocated to intervention (n=25)
Received allocated intervention (n=25)
Did not receive allocated intervention (n=0)
Allocated to intervention (n=25)
Received allocated intervention (n=25)
Did not receive allocated intervention) (n=0)
Follow-Up
Lost to follow-up (n=1)
Moved to another city
Lost to follow-up (n=0)
Analysis
Analysed (n=24)
Excluded from analysis (n=0)
Analysed (n=25)
Excluded from analysis (n=0)

Fig 2.

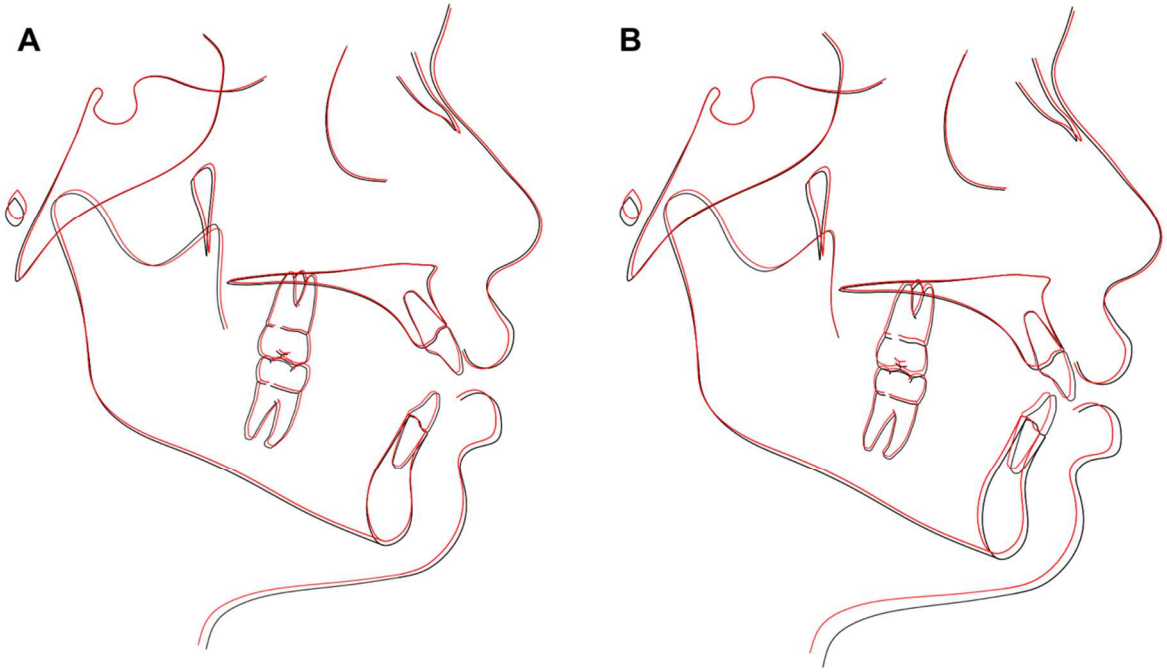

Fig 3.

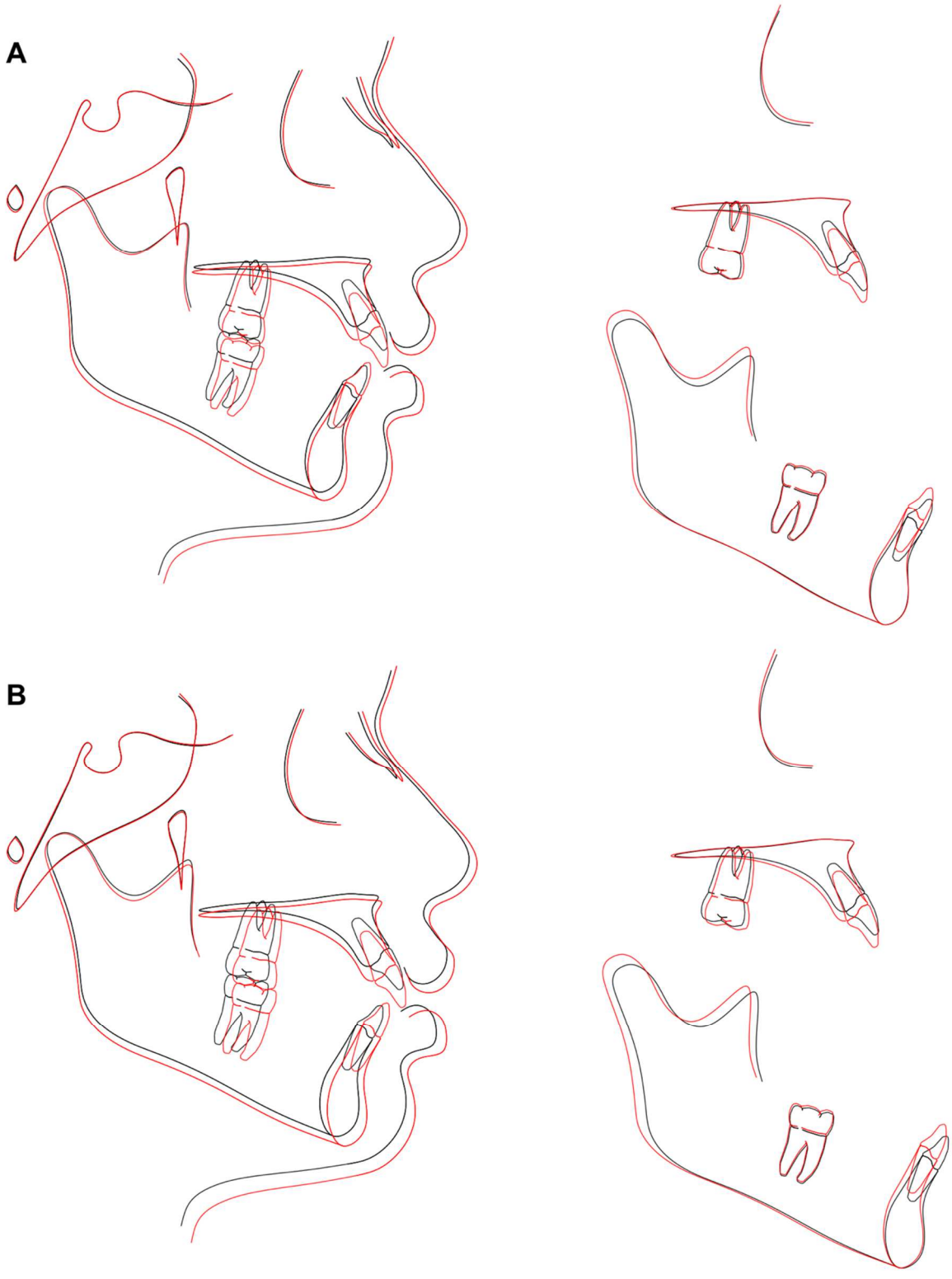

Fig 4.

Table I. Cephalometric variables.

Cephalometric variables		
Maxillary skeletal components		
SNA	(°)	SN to NA angle
Co-A	(mm)	Condylion to A-point distance
Mandibular skeletal components		
SNB	(°)	SN to NB angle
Ar-Go	(mm)	Articulare to gonion distance
Ar.Go.Me	(°)	ArGo to GoMe angle
Co-Gn	(mm)	Condylion to gnathion distance
Maxillomandibular component		
ANB	(°)	NA to NB angle
Vertical components		
SN.GoGn	(°)	SN to GoGn angle
SN.PP	(°)	SN to PP angle
N.S.Gn	(°)	SN to SGn angle
AFH	(mm)	Nasion to menton distance
PFH	(mm)	Sella turcica to gonion distance
LAFH	(mm)	ANS, anterior nasal spine to menton distance
Dental relationship		
Overbite	(mm)	Distance between incisal edges of maxillary and mandibular central incisors, perpendicular to occlusal plane.
Maxillary dentoalveolar components		
Mx1.NA	(°)	Maxillary incisor long axis to NA angle
Mx1-NA	(mm)	Distance between most anterior point of crown of maxillary incisor and NA line
Mx1-PP	(mm)	Perpendicular distance between incisal edge of maxillary incisor and palatal plane
Mx6-PP	(mm)	Perpendicular distance between mesial cusp of maxillary first permanent molar and palatal plane
Mandibular dentoalveolar components		
Md1.NB	(°)	Mandibular incisor long axis to NB angle
Md1-NB	(mm)	Distance between most anterior point of crown of mandibular incisor and NB line
Md1-GoMe	(mm)	Distance between incisal edge of mandibular incisor and mandibular plane
Md6-GoMe	(mm)	Distance between mesial cusp of mandibular first permanent molar and mandibular plane

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

Table II. Intergroup comparisons for age and sex.

Variable	Experimental Group (n=24)		Comparison Group (n=25)		
	Mean	**SD**	**Mean**	**SD**	**P**
Age (y)	8.22	1.06	8.30	0.99	0.787†
Sex	n	%	n	%	
Female	17	70.8	14	56.0	
Male	7	29.2	11	44.0	0.377‡

† t test; ‡ Fisher´s exact test.

Table III. Intergroup comparison at pretreatment (T1).

Variable	Experimental Group (n=24)		Comparison Group (n=25)		Mean			
	Mean	SD	Mean	SD	Difference	95% CI		P
Maxillary skeletal component								
SNA (º)	83.19	2.67	83.65	3.89	-0.46	-2.38	1.47	0.636†
Co-A (mm)	74.40	3.51	74.60	3.16	-0.20	-2.11	1.72	0.838†
Mandibular skeletal component								
SNB (º)	79.00	3.40	79.50	3.06	-0.50	-2.35	1.36	0.594†
Ar-Go (mm)	33.88	4.05	34.42	3.57	-0.54	-2.73	1.65	0.622†
Ar.Go.Me (º)	129.95	6.01	131.48	5.20	-1.53	-4.76	1.70	0.345†
Co-Gn (mm)	95.65	4.86	96.57	4.86	-0.92	-3.71	1.87	0.509‡
Maxillomandibular component								
ANB (º)	4.20	1.79	4.14	1.81	0.06	-0.98	1.09	0.914†
Vertical component								
SN.GoGn (º)	34.47	5.29	34.42	4.34	0.05	-2.73	2.82	0.865‡
SN.PP (º)	-0.43	3.11	-0.99	3.43	0.56	-1.32	2.44	0.553†
N.S.Gn (º)	67.00	3.66	67.16	3.01	-0.17	-2.09	1.75	0.861†
AFH (mm)	98.60	5.09	99.38	5.50	-0.78	-3.83	2.27	0.609†
PFH (mm)	41.80	3.79	42.31	3.41	-0.51	-2.58	1.56	0.621†
LAFH (mm)	56.11	3.42	56.92	4.33	-0.81	-3.06	1.44	0.472†
Dental relationship								
Overbite (mm)	-4.45	1.49	-4.36	1.65	-0.09	-1.00	0.82	0.843†
Maxillary dentoalveolar component								
Mx1.NA (º)	27.85	5.08	29.28	5.24	-1.42	-4.39	1.55	0.490‡
MX1-NA (mm)	4.54	1.81	5.46	2.12	-0.92	-2.05	0.22	0.110†
Mx1-PP (mm)	21.18	2.57	21.74	2.85	-0.56	-2.12	1.00	0.474†
Mx6-PP (mm)	16.96	1.64	17.10	2.65	-0.14	-1.41	1.13	0.828†
Mandibular dentoalveolar component								
Md1.NB (º)	27.84	4.32	29.60	5.84	-1.75	-4.72	1.21	0.240†
Md1-NB (mm)	4.82	1.36	5.56	1.84	-0.74	-1.67	0.19	0.118†
Md1-GoMe (mm)	31.56	2.20	32.31	2.54	-0.75	-2.12	0.61	0.273†
Md6-GoMe (mm)	24.37	2.12	24.50	1.99	-0.13	-1.31	1.05	0.827†

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

Table IV. Intergroup comparison for treatment changes (T2-T1).

Variable	Experimental Group (n=24)		Comparison Group (n=25)		Mean Difference	95% CI		P
	Mean	SD	Mean	SD				
Maxillary skeletal component								
SNA (º)	-0.65	0.86	-0.35	1.01	-0.30	-0.84	0.24	0.274†
Co-A (mm)	1.37	1.04	1.25	1.07	0.11	-0.49	0.72	0.705†
Mandibular skeletal component								
SNB (º)	-0.16	1.08	0.32	0.98	-0.49	-1.08	0.11	0.105†
Ar-Go (mm)	0.50	1.35	0.26	1.69	0.25	-0.64	1.13	0.575†
Ar.Go.Me (º)	-0.66	2.19	-0.68	1.73	0.02	-1.11	1.15	0.970†
Co-Gn (mm)	2.29	0.96	2.68	0.90	-0.38	-0.92	0.15	0.155†
Maxillomandibular component								
ANB (º)	-0.49	0.87	-0.68	0.95	0.19	-0.34	0.71	0.473†
Vertical component								
SN.GoGn (º)	-0.18	1.37	-0.32	1.37	0.15	-0.64	0.93	0.712†
SN.PP (º)	0.15	0.82	0.16	0.66	0.00	-0.43	0.43	0.993†
N.S.Gn (º)	0.12	0.83	-0.23	1.04	0.35	-0.19	0.89	0.202†
AFH (mm)	2.11	0.96	2.39	1.13	-0.28	-0.88	0.32	0.354†
PFH (mm)	1.31	1.32	0.78	1.22	0.53	-0.20	1.26	0.153†
LAFH (mm)	0.55	0.81	0.74	1.07	-0.19	-0.73	0.36	0.498†
Dental relationship								
Overbite (mm)	4.84	1.76	4.84	1.41	0.00	-0.92	0.91	0.865‡
Maxillary dentoalveolar component								
Mx1.NA (º)	-5.50	4.72	-5.43	3.97	-0.07	-2.57	2.44	0.957‡
MX1-NA (mm)	-0.24	1.17	-0.36	1.13	0.12	-0.54	0.78	0.720†
Mx1-PP (mm)	2.75	1.06	2.92	0.99	-0.17	-0.76	0.42	0.564†
Mx6-PP (mm)	0.12	0.38	0.82	0.37	-0.70	-0.92	-0.49	<0.001‡*
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)	0.12	0.72	0.06	0.87	0.06	-0.40	0.52	0.806†
Md1-GoMe (mm)	2.40	0.69	2.24	0.89	0.16	-0.30	0.62	0.484†
Md6-GoMe (mm)	0.51	0.58	0.36	0.82	0.14	-0.27	0.56	0.484†

† t test; ‡ Mann-Whitney U test; Mx, Maxillary; Md, mandibular; 1, central incisor; 6 first molar.
*Statistically significant at $P<0.05$

2.2 ARTICLE 2

Dental arches changes after open bite treatment with bonded spurs associated with posterior build-ups and conventional bonded spurs: a randomized clinical trial

ABSTRACT

Introduction: The purpose of this single center, 2-arm parallel, randomized clinical trial was to compare the effects on the dental arches after anterior open bite treatment with bonded spurs associated with posterior build-ups versus conventional bonded spurs. **Methods:** Patients with ages from 7 to 11 years old with anterior open bite were prospectively and randomly allocated to one of the study groups. One group was treated with bonded spurs associated with posterior build-ups (BSBU) and the other solely with bonded spurs (BS). Digital dental models acquired by intraoral scanning were obtained at pretreatment (T1) an after 12 months of treatment (T2). The change on the overbite was considered as the primary outcome. The website site www.randomization.com was used to obtain the randomization list. The outcomes were blindly assessed. Comparisons between groups were performed with t or Mann-Whitney U tests ($P<0.05$). **Results:** Twenty-four patients (mean age 8.22 ± 1.06; 7 male and 17 female) were included in the BSBU group, and 25 patients (mean age 8.30 ± 0.99; 11 male and 14 female) were included in the BS group. After the follow-up period, all patients improved their initial conditions. The overbite increased approximately 4 mm in both groups. They showed similar anterior dentoalveolar vertical development and similar increases of incisor and molar heights. In addition, they should similar changes of incisor and molar buccolingual inclination and of the arch perimeters and lengths. The groups showed statistically significant differences for the intermolar distances. The maxillary intermolar distance decreased in the BSBU group and increased in the BS group, while the mandibular distance increased in the BSBU group and decreased in the BS group. **Conclusions:** BSBU and BS protocols demonstrated improvements with similar effects on the dental arches, after twelve months of treatment. A slight decrease in the maxillary intermolar distance and a slight increase in the mandibular intermolar distance could be expected with BSBU, while the opposite behavior could be expected when solely BS are used. **Registration:** This

trial was registered at Clinicaltrials.gov (identifier NCT03702881). **Protocol:** The protocol of this study was not published. **Funding:** This research was financed in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – Brasil (CAPES) – Finance Code 001; and by grant #: 2017/06440-3, 2018/05238-9 and 2018/24003-2, São Paulo Research Foundation (FAPESP).

Keywords: Dental Models; Open Bite; Orthodontics, Interceptive.

INTRODOUCTION

Anterior open bite (AOB) malocclusion has a multifactorial etiology where genetic and environmental factors could be involved.[1,2] In the mixed dentition, AOB malocclusion has a prevalence of 17%, [2]has mainly a dentoalveolar origin[1,2] and it could be caused by environmental factors that could include deleterious habits and mouth breathing. Among the deleterious habits; thumb sucking, pacifier, and tongue thrust are the most common.[2,3]

One of the main objectives of AOB malocclusion treatment is to interrupt the deleterious habits, eliminate the interferences and permit vertical development of the anterior teeth. Different treatment approaches have been described to treat this malocclusion.[4-7] Bonded spurs have been reported as an efficient alternative treatment in the mixed dentition, they have easy installation and eliminate the need of a laboratorial phase. [8-10] Their effects are similar to those produced by the palatal crib and include AOB reduction and vertical development of anterior teeth. [8-10] They satisfactorily reduce the AOB since they act as a reminder to stop the oral deleterious habits that patients with this malocclusion usually have.

Some treatment protocols integrate therapies that provide habits interruption and control of the vertical dimension[11-15] since AOB is usually associated with a vertical growth pattern.[3] In this regard, the vertical chincup has been reported as an associated therapy to bonded spurs showing AOB correction with gonial[13,14] and mandibular plane angle reduction.[14] However, the use of vertical chincup depends on patient compliance.[13]

One alternative that reported a significant vertical control during AOB treatment in adults uses bonded resin blocks in the maxillary molars, also known as posterior build-ups, associated with fixed orthodontic appliances.[16] After this treatment modality; intrusion of maxillary molars and a significant counter clockwise rotation of the mandible was observed, demonstrating its vertical control potential.[16] Thus, the association of bonded spurs and posterior build-ups may be an alternative for AOB treatment. Nevertheless, no studies evaluating this association in children has been reported.

Over the years, the studies have mainly focused on the evaluation of the cephalometric changes of different treatment modalities. Although the cephalometric evaluation brings a perspective of the skeletal and dentoalveolar changes, it does not show what happens in the dental arches in terms of arch dimensional changes and

incisor crown height increase. One study has performed conventional evaluations after crib therapy on dental models.[17] and only one randomized clinical trial reported the effects of AOB early treatment on the dental arches comparing fixed and removable palatal cribs using digital analysis of dental models.[18] However, no studies have evaluated the dental arches changes after AOB treatment with bonded spurs neither alone nor associated to other therapy.

Specific objectives or hypotheses

This randomized clinical trial aimed to compare the changes on dental arch dimensions after anterior open bite treatment with bonded spurs associated with posterior build-ups (BSBU) and bonded spurs alone (BS). The null hypothesis tested was that there are no differences for the dental arches changes between the BSBU and the CBS therapies.

METHODS

Trial design and any changes after trial commencement

This study was conducted as a 2-arm parallel, single-center, randomized clinical trial (RCT) with a 1:1 allocation ratio. The Consolidated Standards of Reporting Trials guidelines[19] were followed to perform this study. No changes in methods were required after trial commencement.

Participants, eligibility criteria, and settings

Approval by the Ethics in Research Committee of Bauru Dental School, University of São Paulo, Brazil was obtained for this study (protocol number 68551617.8.0000.5417 / 2.112.035). The protocol was registered at Clinicaltrials.gov (identifier NCT03702881)

Patients´ recruitment was performed at the Orthodontic Clinic of Bauru Dental School, University of São Paulo, Brazil, from June 2017 to April 2018. The participants´ selection criteria included: age between 7 to 11 years old, presence of erupted permanent first permanent molars, anterior open bite greater than 1 mm, maxillary and mandibular permanent central incisors fully erupted, no or mild crowding, and no the need of maxillary expansion. Children in the first transitional period were considered eligible for treatment when the maxillary lateral incisors were beginning to erupt and the maxillary central incisors still showed an open bite.[9,13] Exclusion criteria included:

children with previous orthodontic treatment, craniofacial anomalies or syndromes, tooth agenesis, loss of permanent teeth, severe crowding, maxillary constriction or posterior crossbite.

Informed consent was signed by all patients and their parents or legal guardians before their recruitment.

Interventions

The cervical portion of the palatal surfaces of the maxillary incisors and the incisal portion of the lingual surfaces of the mandibular incisors were pumiced, rinsed, dried, and acid etched with 37% phosphoric acid. The etched surfaces were subsequently rinsed and carefully dried. Then, bonded spurs (Morelli, Sorocaba, SP, Brazil) were installed in all patients of both groups using Transbond XT primer/adhesive system (3M Unitek, Monrovia, CA, USA). The regions for bonding the spurs were selected to avoid possible future occlusal interferences.[9,13] A carborundum disk was used to sharpen the spurs before bonding.[11]

Posterior build-ups (2-3 mm bonded resin blocks) (Orthobite; FGM, Joinville, SC, Brazil) were cemented on the functional cusps of the maxillary posterior teeth, only in the BSBU group. The build-ups were cemented in all maxillary posterior teeth present to maintain the occlusal balance[16] (Fig 1A) The BS group included patients treated solely with bonded spurs (Fig 1B). The treatment follow-up in both groups was 12 months.

Digital dental models, acquired from intraoral scanning (TRIOS3; 3Shape, Copenhagen, Denmark), were obtained at pretreatment and after 12 months of treatment, for all patients.

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

Primary outcome was the change in the overbite. The changes in the other variables: overjet, anterior dentoalveolar vertical development, crown heights of incisors and permanent first molars molars, bucco-lingual inclinations of incisors and permanent first molars, arch dimensions (perimeter, arch length and palatal depth) and transverse distances, were considered as secondary outcomes (Table I, Figs 2-4).

The variables obtained from digital dental models (Table I, Figs 2-4) were analyzed using the OrthoAnalyzer 3D© software (3Shape, Copenhagen, Denmark).[18,20,21] There were no outcome changes after trial commencement.

Sample size calculation

Sample size calculation was performed considering a significance level of 0.05, a test power of 80%, and an intergroup difference of 1 mm in the overbite with a standard deviation of 1.1 mm, obtained from a pilot study. A minimal amount of twenty patients was required in each group.

Interim analyses and stopping guidelines

Not applicable.

Randomization (random number generation, allocation concealment, implementation)

The randomization list was generated using random block sizes in the web site Randomization.com ⟨http://www.randomization.com⟩.[22] This ensured patient´s allocation in both groups with a 1:1 ratio. Allocation concealment involved sequentially numbered, sealed and opaque envelopes, containing the treatment allocation cards. The card with the assignment treatment was inserted into foil, giving an additional opacity. The envelopes were prepared before trial commencement. Before open the envelope, the patient´s name and baseline information were written on its external surface. After, the envelopes were torn open and then were stored in a secured place different from the trial site.[23] One person generated the randomization list, the allocation concealment was performed by a second person; and the implementation (enrollment of participants/treatment assignment/deliver intervention) was done for a third person.[23]

Blinding

Since the operator and patients were aware about the type of appliance that was being installed, double blinding was not possible. Nevertheless, the digital dental models were unidentified and assessed by another collaborator, ensuring a blinding evaluation.[24]

Error study

The digital dental models (T1 and T2) of 15 patients randomly selected, were re-assessed by the same examiner after one month. The intraclass correlation coefficient (ICC) was used to evaluate the intra-examiner reliability.

Statistical analyses (primary and secondary outcomes, subgroup analyses)

All statistical analyses were performed using the SPSS software (Version 22; IBM, Armonk, NY, USA). After the evaluation of normal distribution with Shapiro-Wilk test, intergroup comparisons were performed with t tests or Mann-Whitney U tests, depending on normality. The Fisher´s exact test was used to compare sex distribution between groups. The statistical significance was set at $P< 0.05$ for all variables.

RESULTS

Participant flow (include flow diagram, early stopping and time periods)

During recruitment, one thousand and twenty-five children were assessed for eligibility. From these 1025, 969 did not meet the selection criteria and were excluded; and 6 declined to participate in the study. Then, fifty patients were randomized considering a 1:1 ratio (Fig 5).

Baseline data

At pretreatment, the groups showed similar age and sex distribution (Table II). The groups were comparable regarding almost all the evaluated variables (Table III), with exception of the mandibular intercanine distance (measured at the cusp level) that showed a statistically significant smaller value in the BSBU group when compared to the BS group (-0.69 mm).

Number analyzed for each outcome, estimation and precision, subgroup analyses

The BSBU group had one patient lost to follow-up. All patients, in the BSBU and BS groups showed decreases of the anterior open bite. A per-protocol basis was considered to perform the primary analysis. Then, 24 patients in the BSBU group and 25 patients in the BS group were analyzed in their original groups.

Intra-examiner reliability was considered as very good to excellent since the ICC values ranged from 0.965 (95%CI; 0.929, 0.983) to 0.999 (95% CI; 0.999, 1.000).[25]

After the 12 months follow-up period, 8 of the 24 patients of the BSBU group and 7 of the 25 patients of the BS group still had some AOB.

Similar treatment changes were observed in both groups (Table IV). The overbite increased approximately 4 mm in both groups. In addition, they showed similar

maxillary and mandibular anterior dentoalveolar vertical development and similar increases in the clinical crown heights of incisors and molars.

The maxillary and mandibular incisors, and maxillary molars showed lingual inclination while the mandibular molars showed buccal inclination. The maxillary and mandibular arch perimeter and arch length decreased while the palatal depth increased, similarly, in both groups.

Both groups showed increases in the maxillary intercanine distance and decreases in the mandibular intercanine distances (Table IV). The only significant differences between groups were found for the intermolar distances. The maxillary intermolar distances decreased in the BSBU group and increased in the BS group, while the mandibular intermolar distance (evaluated at the cervical level) increased in the BSBU group and decreased in the BS group.

Harms

The participants of this study were not exposed to serious harms. The benefits and side effects of bonded spurs and posterior build-ups have been previously reported.[9,13,16] The patients that showed anterior open bite after 12 months of follow-up continued with bonded spurs for longer time.

DISCUSSION

Main findings in the context of the existing evidence and interpretation

Several studies have evaluated the effects of different treatment approaches for the early correction of AOB malocclusion, using lateral cephalograms. They bring important information about how treatment affects the skeletal growth and the dentoalveolar development.[4-15,26,27] A complementary analysis should include the assessment of the dimensional changes on the dental arches. Nevertheless, few studies reporting this type of assessment after AOB treatment, have been reported.[17,18]

Treatment effectiveness has been reported after AOB treatment with posterior build-ups associated with orthodontic fixed appliances in adults.[16] However, its efficiency in children and their effects on the dental arches has not been evaluated.

The analysis of digital dental models obtained by intraoral scanning of the dental arches or by physical dental models scanning, are considered as a good alternative to evaluate treatment changes.[28] In the assessment of AOB treatment changes, it allows the evaluation of specific tooth areas that are sometimes difficult to visualize in lateral

cephalograms because of the superimposition of dental structures. Regarding AOB, only two studies have reported the treatment changes assessment after crib therapy on dental models. One included patients between 6 to 18 years old and had a follow-up of only 3.9 months and performed a manually assessment,[17] and the other included patients between 7-10 years old followed-up by 12 months and performed the assessment of digitized dental models.[18] The present study could be considered the first randomized clinical trial evaluating the dimensional changes of the dental arches after AOB early treatment with BSBU and BS alone using digital dental models obtained by intraoral scanning.

At pretreatment, similar mean ages and sex distribution was observed between groups (Table II). In addition, the groups showed similar AOB mean values and very similar dimensions of the dental arches with exception of the mandibular intercanine distance, that was smaller in the BSBU group than in the BS group (Table III). This was an inherent characteristic of the groups and did not interfere with the treatment changes comparisons.

After 12 months into treatment, the overbite presented similar increases in both groups, demonstrating that both treatment protocols are effective in reducing the AOB condition during this follow-up period (Table IV), as expected since they involved the use of bonded spurs. The dentoalveolar effects of bonded spurs include AOB correction by vertical development and some palatal and lingual inclination of maxillary and mandibular anterior teeth, respectively.[8-10,13,14]

The amount of AOB correction observed in this study (4.19 for the BSBU and 4.38 mm for the BS) was slightly greater than those reported for fixed or removable palatal cribs treatment (3.51 to 3.88) in patients with a similar age range and evaluated by dental models.[18] This demonstrates that either palatal cribs or bonded spurs produces similar improvements in the overbite. The overjet showed a minimal increase in both groups, as observed for fixed palatal crib therapy.[17,18] The overjet minimal changes reflects the changes on the buccolingual inclination of incisors and arch lengths,[17] that will be mentioned below.

The anterior dentoalveolar vertical development, evaluated as the distances from points located on the anterior alveolar processes to the occlusal plane, were similar between groups (Table IV). This study showed greater values (2.49 mm in the BSBU and 2.24 mm in the BS) for the maxillary anterior dentoalveolar vertical development than a previous study (0.84 mm for the fixed palatal crib and 1.34 mm for

the removable palatal crib).[18] In addition, the maxilla showed greater values of anterior dentoalveolar vertical development than the mandible, as previously reported.[18] The maxillary incisor crown heights increased similarly in both groups (1.17 mm, BSBU; 0.96 mm, BS). These increases were greater for the maxillary than the mandibular teeth, following a similar behavior as the dentoalveolar vertical development. It should be noted that the increases of the incisors crown heights were smaller than the anterior dentoalveolar vertical development. It reflects that during AOB treatment with these appliances, anterior dentoalveolar vertical development with some minimal eruption of the anterior teeth should be expected, as previously reported.[18]

No increase or a significant smaller increase of molar crown heights was expected in the BSBU group because of the presence of the posterior build-ups.[16] However, both groups showed slight increases with no significant differences between them (Table IV). This demonstrated that build-ups showed no significant vertical control of posterior teeth in the BSBU group, and this could be explained due to the vertical development that patients have since they were growing. This is also observed in cephalometric studies that evaluated associated therapies to control the vertical dimension in growing children.[13-15] The increases on molar crown heights observed in this study were smaller than 0.5 mm. Then, these results should be carefully interpreted.

The maxillary and mandibular incisors showed palatal and lingual inclination, respectively (Table IV), as previously demonstrated.[17,18] and as usually observed in cephalometric studies.[8-10,13,14] Both groups showed lingual inclination of maxillary molars and buccal inclination of mandibular molars. This behavior was reported also for untreated patients and are an expected effect of growth and development.[29] Although the BSBU group showed numerically greater values for these variables than the BS group, there were no significant difference between them. This demonstrated that BSBU does not significantly alter the buccolingual inclination of posterior teeth in children, as speculated for AOB treatment in adults.[16]

The arch perimeters and lengths decreased similarly in both groups (Table IV). This was reported for crib therapy, as well.[17,18] After AOB treatment with bonded spurs, greater arch perimeter decreases should be expected in the mandibular arch than in the maxilla. This should be considered during treatment planning.[17] Because of the age of the patients, the slight decreases on arch length was expected, as reported for normal growth.[30,31] The palatal depth showed a slight increase after treatment,

independently of the protocol used. It could be related to the decrease in the maxillary perimeter and length observed after treatment.

The groups only showed statistically significant differences for the changes on the intermolar distance. The maxillary intermolar distance decreased in the BSBU and increased in the BS group. The increase in the BS group was expected, as previously reported after crib therapy,[18] and described as normal growth.[32] The decrease in the BSBU group could be related to the numerically, but no statistically significant, greater lingual inclination of maxillary molars that the BSBU group showed.

The mandibular intermolar distance increased in the BSBU and decreased in the BS group (Table IV). Smaller increases of intermolar distances have been reported for the mandible in this age rage as normal growth.[32] A previous study reported decrease of the mandibular intermolar distance, measured at the cervical level, after crib therapy.[18] This slight decrease could be associated to the numerically, but not statistically significant, greater mandibular arch length decrease that BS group showed in comparison with the BSBU group.

This study shows that similar amount of correction and similar changes on the dental arches should be expected after AOB treatment with BSBU or with BS alone, with exception for the transverse distances. No significant vertical control of posterior teeth with BSBU therapy was observed after a 12-month follow-up period. More studies evaluating the dental arches changes after AOB early treatment with different appliances should be performed to compare our results with.

Limitations

Ideally, our groups should be compared with a group of untreated AOB patients with similar age range in order to confirm if the observed changes on dental arches dimensions are significantly different from those caused by growth and development in untreated patients. Nevertheless, it was not possible due to ethical reasons. Nevertheless, future non-randomized studies including historical controls with untreated AOB, should be planned.

Some patients in both groups still had some AOB and continued with treatment for more time. This has been reported in previous studies and could be related to an association of various factors as the short follow-up period, and persistence of oral habits, among others.[9,10,13] Further studies should be performed to evaluate the effects of these treatment protocols during a longer treatment follow-up.

Generalizability

The results of this clinical trial may be only generalized to patients with similar initial dentoalveolar and dental arch dimensions characteristics with ages between 7 to 11 years old.

CONCLUSIONS

- Both treatment protocols showed similar overbite increases, anterior dentoalveolar vertical development, clinical crown height increases, similar buccolingual inclination changes of incisors and molars, similar palatal depth increases, and similar decreases of the arch perimeters and lengths.
- No significant restriction of molar crown height increase was observed in the BSBU group.
- The BSBU group showed a slight decrease in the maxillary intermolar distance and a slight increase in the mandibular intermolar distance, while the opposite behavior was observed in the BS group.

ACKNOWLEDGMENTS

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REFERENCES

1. Ngan P, Fields HW. Open bite: a review of etiology and management. Pediatr Dent 1997;19:91-98.
2. 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;128:517-519.
3. Janson G, Valarelli F. Open-bite malocclusion: treatment and stability. Ames, IA: John Wiley & Sons, Inc; 2014.
4. Lentini-Oliveira DA, Carvalho FR, Rodrigues CG, Ye Q, Prado LB, Prado GF et al. Orthodontic and orthopaedic treatment for anterior open bite in children. Cochrane Database Syst Rev 2014:CD005515.

5. Feres MF, Abreu LG, Insabralde NM, Almeida MR, Flores-Mir C. Effectiveness of the open bite treatment in growing children and adolescents. A systematic review. Eur J Orthod 2016;38:237-250.
6. 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.
7. 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.
8. 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.
9. 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;149:847-855.
10. 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;88:684-691.
11. Justus R. Correction of anterior open bite with spurs: long-term stability. World J Orthod 2001;2:219-231.
12. 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;129:418-423.
13. 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;142:487-493.
14. Insabralde NM, de Almeida RR, Henriques JF, Fernandes TM, Flores-Mir C, de Almeida MR. Dentoskeletal effects produced by removable palatal crib, bonded spurs, and chincup therapy in growing children with anterior open bite. Angle Orthod 2016;86:969-975.

15. Turkkahraman H, Cetin E. Comparison of two treatment strategies for the early treatment of an anterior skeletal open bite : Posterior bite block-vertical pull chin cup (PBB-VPC) vs. posterior bite block-high pull headgear (PBB-HPH). J Orofac Orthop 2017;78:338-347.
16. 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.
17. 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.
18. Slaviero T, Fernandes TM, Oltramari-Navarro PV, de Castro AC, Conti F, Poleti ML et al. Dimensional changes of dental arches produced by fixed and removable palatal cribs: A prospective, randomized, controlled study. Angle Orthod 2017;87:215-222.
19. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ et al. CONSORT 2010 Explanation and Elaboration: Updated guidelines for reporting parallel group randomised trials. J Clin Epidemiol 2010;63:e1-37.
20. Massaro C, Miranda F, Janson G, Rodrigues de Almeida R, Pinzan A, Martins DR et al. Maturational changes of the normal occlusion: A 40-year follow-up. Am J Orthod Dentofacial Orthop 2018;154:188-200.
21. Alves ACM, Janson G, McNamara JA, Jr., Lauris JRP, Garib DG. Maxillary expander with differential opening vs Hyrax expander: A randomized clinical trial. Am J Orthod Dentofacial Orthop 2020;157:7-18.
22. Pandis N. Randomization. Part 1: sequence generation. Am J Orthod Dentofacial Orthop 2011;140:747-748.
23. Pandis N. Randomization. Part 3: allocation concealment and randomization implementation. Am J Orthod Dentofacial Orthop 2012;141:126-128.
24. Pandis N. Blinding or masking. Am J Orthod Dentofacial Orthop 2012;141:389-390.
25. Koo TK, Li MY. A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. J Chiropr Med 2016;15:155-163.
26. Huang GJ, Justus R, Kennedy DB, Kokich VG. Stability of anterior openbite treated with crib therapy. Angle Orthod 1990;60:17-24; discussion 25-16.

27. 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;129:734-739.
28. Aragon ML, Pontes LF, Bichara LM, Flores-Mir C, Normando D. Validity and reliability of intraoral scanners compared to conventional gypsum models measurements: a systematic review. Eur J Orthod 2016;38:429-434.
29. Sayania B, Merchant M, Josephs P, Chung CH. Changes in the buccolingual inclination of first molars with growth in untreated subjects: A longitudinal study. Angle Orthod 2017;87:681-687.
30. Moorrees CF, Gron AM, Lebret LM, Yen PK, Frohlich FJ. Growth studies of the dentition: a review. Am J Orthod 1969;55:600-616.
31. Bishara SE, Jakobsen JR, Treder J, Nowak A. Arch length changes from 6 weeks to 45 years. Angle Orthod 1998;68:69-74.
32. Bishara SE, Jakobsen JR, Treder J, Nowak A. Arch width changes from 6 weeks to 45 years of age. Am J Orthod Dentofacial Orthop 1997;111:401-409.

FIGURE LEGENDS

Fig 1. A, Bonded spurs associated with posterior build-ups. B, Bonded spurs.

Fig 2. Measurements of: overbite and overjet (A), vertical development (B and C), and clinical crown heights of incisors (D and E) and molars (F-I).

Fig 3. Buccolingual inclinations (A) of incisors (B and C) and molars (D and E) in relation to the occlusal plane.

Fig 4. Arch perimeter (A and B), arch length (C and D), palatal depth (E), intercanine and intermolar distances (F and G).

Fig 5. Consolidated Standards of Reporting Trials (CONSORT) Flow diagram.

Fig 1.

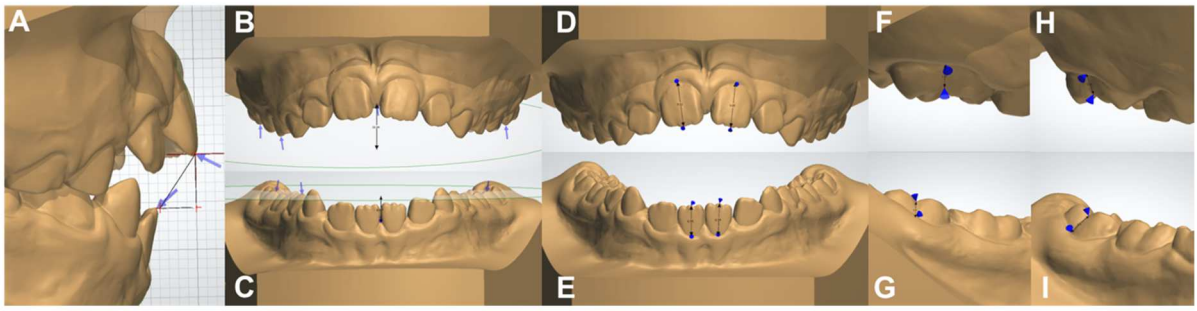

Fig 2.

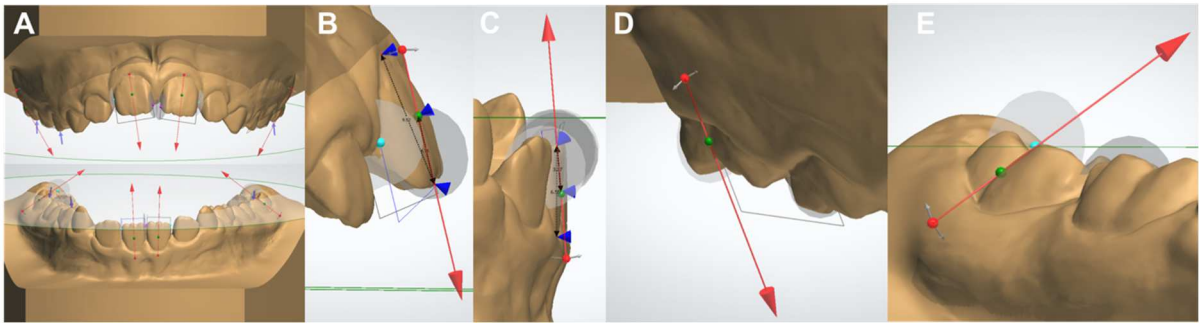

Fig 3.

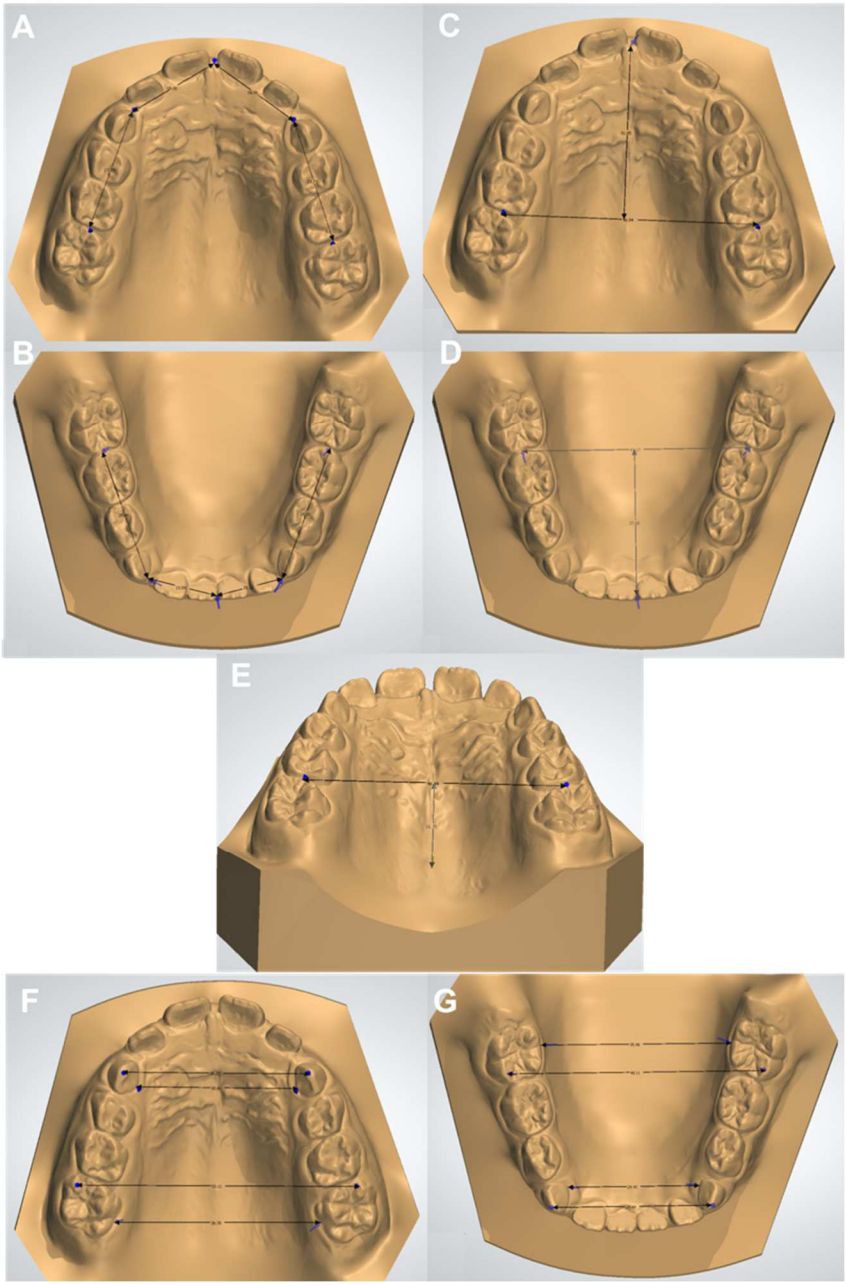

Fig 4.

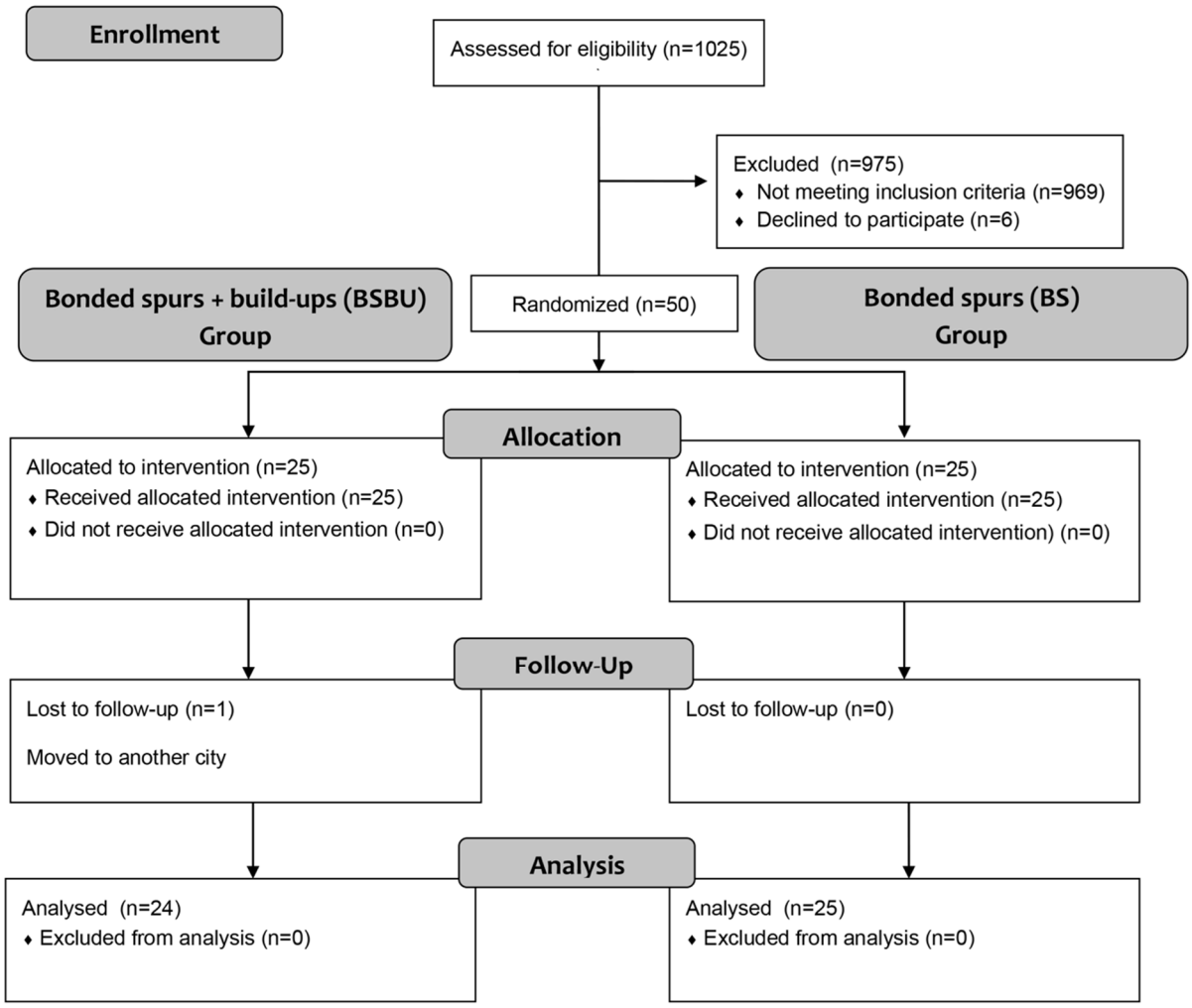
Enrollment
Assessed for eligibility (n=1025)
Excluded (n=975)
♦ Not meeting inclusion criteria (n=969)
♦ Declined to participate (n=6)
Bonded spurs + build-ups (BSBU) Group
Randomized (n=50)
Bonded spurs (BS) Group
Allocation
Allocated to intervention (n=25)
♦ Received allocated intervention (n=25)
♦ Did not receive allocated intervention (n=0)
Allocated to intervention (n=25)
♦ Received allocated intervention (n=25)
♦ Did not receive allocated intervention) (n=0)
Follow-Up
Lost to follow-up (n=1)
Moved to another city
Lost to follow-up (n=0)
Analysis
Analysed (n=24)
♦ Excluded from analysis (n=0)
Analysed (n=25)
♦ Excluded from analysis (n=0)

Fig 5.

Table I. Digital dental models variables.

Digital model variables		
Dental relationship		
Overbite	(mm)	Vertical distance between the mesiodistal midpoints of the incisal edges of the most erupted maxillary and mandibular central incisors (Fig 2A).[18,20]
Overjet	(mm)	Horizontal distance between the mesiodistal midpoints of the incisal edges of the most prominent maxillary and mandibular central incisors (Fig 2A).[18,20]
Vertical development		
Mx. and Md. anterior DAVD	(mm)	Vertical and perpendicular distance from the alveolar process at the level between central incisors contact or a middle point between them (in the presence of spaces) to the occlusal plane, in a frontal view. The occlusal plane was determined by a line passing through the mesiobuccal cusp tip of the right and left first permanent molars and the mesiobuccal cusp tip of the right deciduous first molar or first premolar, in the maxilla and in the mandible (Figs 2B and C).[18]
Mx1, Mx6, Md1, Md6 Heights	(mm)	Vertical distance between the incisal/occlusal and cervical limits of the tooth long axis buccal aspect of the central incisors and first permanent molars, respectively (Figs 2D-I). The means between the right and left sides were considered.[18,20]
Bucco-lingual inclinations		
Mx1, Mx6, Md1, Md6 Inclinations	(°)	Angle between the tooth long axis and the maxillary or mandibular occlusal plane (Fig 3A) Incisor long axis was represented by an arrow buccolingually and mesiodistally manipulated on the lateral and frontal views, respectively. On the frontal view, the arrow was mesiodistally manipulated to represent tooth angulation. On the lateral view, the arrow was buccolingually manipulated, representing crown torque.[21] The arrow should be tangent to the incisal half of the vestibular surface (Figs 3B and C). First permanent molar long axis was represented by an arrow, placed on the buccal groove, mesiodistally and buccolingually manipulated on the lateral and frontal (mesial/distal) views, respectively. On the lateral view, the arrow was mesiodistally manipulated to represent tooth angulation. On the mesial/distal views, the arrow was buccolingually manipulated, representing crown torque.[21] The arrow should be tangent to the occlusal half of the buccal groove (Figs 3D and E).
Arch dimensions		
Arch perimeter	(mm)	Measured as the sum of 4 segments: linear distance between the mesial aspects of the first permanent molar and deciduous canine; linear distance between the mesial aspects of the deciduous canine and the central incisor, measured on the right and left sides (Figs 4A and B).[18,21]
Arch length	(mm)	Measured perpendicularly in the horizontal plane from a line connecting the mesial aspects of the permanent first molars to a contact point between the central incisors or to a midpoint between them at the level of the gingival margin, in the absence of contact point (Figs 4C and D).[18,21]
Palatal depth	(mm)	Measured from a line passing through the mesial gingival papilla of the permanent first molars to the deepest point on the palate surface, perpendicularly to the arch length (Fig 4E).[20,21]
3-3cusp	(mm)	Inter-canine width at the level of the cus (Figs 4F and G).[18]
3-3cervical	(mm)	inter-canine width at the level of the palatal/lingual gingival margin midpoint (Figs 4F and G).[18,21]
6-6mesiobuccal cusp	(mm)	Inter-first permanent molars width at the level of the mesiobuccal cusp (Figs 4F and G).[18]
6-6cervical	(mm)	Inter-first permanent molars width at the level of the palatal/lingual gingival margin midpoint (Figs 4F and G).[18,21]

Mx, maxillary; Md, mandibular; DAVD, dentoalveolar vertical development; 1, central incisor; 6, first permanent molar; 3-3 inter-canine distance; 6-6, inter-first permanent molar distance.

Table II. Intergroup comparisons for age and sex.

Variable	Bonded spurs + build-ups (BSBU) Group (n=24)		Bonded spurs (BS) Group (n=25)		
	Mean	**SD**	**Mean**	**SD**	**P**
Age (y)	8.22	1.06	8.30	0.99	0.787†
Sex	n	%	n	%	
Female	17	70.8	14	56.0	
Male	7	29.2	11	44.0	0.377‡

† t test; ‡ Fisher´s exact test

Table III. Intergroup comparison at pretreatment (T1).

Variable	Bonded spurs + build-ups (BSBU) Group (n=24)		Bonded spurs (BS) Group (n=25)		Mean Difference	95% CI		P
	Mean	SD	Mean	SD				
Dental relationship								
Overbite	-4.02	1.47	-4.15	2.19	0.13	-0.95	1.21	0.920‡
Overjet	3.74	1.71	4.02	1.72	-0.28	-1.27	0.71	0.570†
Vertical development								
Mx dentoalveolar (mm)	9.02	1.50	8.98	1.93	0.05	-0.95	1.04	0.924†
Md dentoalveolar (mm)	4.74	1.44	4.44	1.34	0.30	-0.50	1.10	0.455†
Mx1 clinical crown height (mm)	8.15	1.44	8.10	1.32	0.05	-0.75	0.84	0.548‡
Mx6 clinical crown height (mm)	3.37	0.55	3.12	0.64	0.25	-0.10	0.59	0.155†
Md1 clinical crown height (mm)	7.09	1.08	7.00	0.84	0.08	-0.47	0.64	0.760‡
Md6 clinical crown height (mm)	4.09	0.58	3.94	0.65	0.15	-0.20	0.50	0.399†
Buccolingual inclinations								
Mx1 (º)	78.79	5.05	77.71	6.36	1.09	-2.22	4.40	0.511†
Mx6 (º)	62.98	7.23	62.20	5.26	0.78	-2.84	4.40	0.668†
Md1 (º)	76.38	6.93	78.50	6.06	-2.12	-5.85	1.62	0.617‡
Md6 (º)	35.82	4.52	34.19	4.57	1.63	-0.99	4.24	0.631‡
Arch dimensions								
Mx arch perimeter (mm)	75.95	3.83	77.32	3.42	-1.37	-3.45	0.72	0.194†
Md arch perimeter (mm)	70.95	3.56	72.38	3.42	-1.43	-3.43	0.58	0.159†
Mx arch length (mm)	27.98	1.78	28.82	1.85	-0.83	-1.88	0.21	0.115†
Md arch length (mm)	24.77	1.65	25.64	1.68	-0.88	-1.83	0.08	0.071†
Palatal depth (mm)	13.19	1.86	13.62	2.11	-0.43	-1.57	0.72	0.459†
Transverse distances								
3-3 Cusp Mx (mm)	31.77	2.61	31.93	2.08	-0.16	-1.63	1.31	0.825†
3-3 Cervical Mx (mm)	25.63	2.33	26.10	1.81	-0.47	-1.77	0.84	0.474†
3-3 Cusp Md(mm)	26.98	2.27	27.67	2.28	-0.69	-2.07	0.70	0.324†*
3-3 Cervical Md (mm)	21.33	1.76	22.50	1.87	-1.18	-2.28	-0.07	0.037†
6-6 Mesiobuccal Cusp Mx (mm)	50.25	3.05	50.93	2.01	-0.68	-2.18	0.81	0.361†
6-6 Cervical Mx(mm)	36.42	2.81	36.38	2.37	0.04	-1.46	1.53	0.962†
6-6 Mesiobucal Cusp Md (mm)	45.49	2.62	45.68	2.17	-0.19	-1.57	1.19	0.786†
6-6 Cervical Md(mm)	33.89	2.59	34.33	1.83	-0.44	-1.73	0.84	0.493†

‡ Mann-Whitney U test; † t test; Mx, Maxillary; Md, mandibular; 1, central incisor; 6 first permanent molar; 3-3, inter-canine distance; 6-6 inter-first permanent molar distance.
*Statistically significant at $P<0.05$

Table IV. Intergroup comparison for treatment changes (T2-T1).

Variable	Bonded spurs + build-ups (BSBU) Group (n=24)		Bonded spurs (BS) Group (n=25)		Mean			
	Mean	SD	Mean	SD	Difference	95% CI		P
Dental relationship								
Overbite	4.19	1.80	4.38	2.02	-0.19	-1.29	0.91	0.734‡
Overjet	0.23	1.18	0.07	1.23	0.16	-0.54	0.85	0.652†
Vertical development								
Mx dentoalveolar (mm)	-2.49	1.38	-2.24	1.12	-0.25	-0.97	0.47	0.509‡
Md dentoalveolar (mm)	-1.31	1.18	-1.55	1.17	0.25	-0.43	0.92	0.467†
Mx1 clinical crown height (mm)	1.17	0.97	0.96	0.76	0.21	-0.29	0.71	0.653‡
Mx6 clinical crown height (mm)	0.16	0.36	0.23	0.28	-0.06	-0.25	0.12	0.764‡
Md1 clinical crown height (mm)	0.79	0.44	0.75	0.53	0.04	-0.24	0.32	0.765†
Md6 clinical crown height (mm)	0.05	0.30	0.13	0.38	-0.08	-0.27	0.12	0.439†
Buccolingual inclinations								
Mx1 (º)	1.80	3.97	3.20	3.63	-1.40	-3.58	0.79	0.204†
Mx6 (º)	-2.17	4.21	-0.67	4.22	-1.51	-3.93	0.91	0.217†
Md1 (º)	-1.23	3.17	-0.64	5.17	-0.59	-3.07	1.89	0.719‡
Md6 (º)	0.49	3.57	0.15	2.16	0.34	-1.38	2.05	0.693†
Arch dimensions								
Mx arch perimeter (mm)	-0.54	1.20	-0.64	1.67	0.10	-0.74	0.94	0.815†
Md arch perimeter (mm)	-1.43	1.33	-1.34	1.95	-0.09	-1.05	0.87	0.850†
Mx arch length (mm)	-0.20	0.93	-0.43	0.85	0.23	-0.28	0.74	0.375†
Md arch length (mm)	-0.50	0.71	-0.60	0.95	0.10	-0.38	0.58	0.904‡
Palatal depth (mm)	0.38	0.46	0.59	0.88	-0.21	-0.62	0.19	0.164‡
Transverse distances								
3-3 Cusp Mx (mm)	-0.10	1.15	0.41	1.23	-0.51	-1.32	0.29	0.068‡
3-3 Cervical Mx (mm)	0.01	0.78	0.18	0.91	-0.17	-0.74	0.41	0.561†
3-3 Cusp Md (mm)	-0.86	1.20	-0.82	1.31	-0.04	-0.92	0.83	0.920†
3-3 Cervical Md (mm)	-0.37	0.65	-0.98	1.39	0.61	-0.19	1.40	0.127†
6-6 Mesiobuccal Cusp Mx(mm)	-0.27	0.74	0.23	0.67	-0.50	-0.90	-0.09	0.017†*
6-6 Cervical Mx(mm)	-0.34	0.79	0.14	0.74	-0.48	-0.92	-0.04	0.034†*
6-6 Mesiobucal Cusp Md (mm)	0.23	0.52	-0.02	0.53	0.25	-0.05	0.56	0.099†
6-6 Cervical Md(mm)	0.21	0.37	-0.06	0.50	0.27	0.02	0.53	0.036†*

‡ Mann-Whitney U test; † t test; Mx, Maxillary; Md, mandibular; 1, central incisor; 6 first molar; 3-3, inter-canine distance; 6-6 inter-first permanent molar distance. For the vertical development: negative values indicate an increase in the vertical development of the maxillary alveolar and mandibular alveolar variables, and positive values indicate increase in the clinical crown heights. For the buccolingual inclinations: negative values indicate buccal inclination of the maxillary incisor, lingual inclination of the mandibular incisor and lingual inclination of the maxillary and mandibular molars. For the arch dimensions, transverse distances and dental relationship, negative values indicate decreases and positive values indicate increases. *Statistically significant at $P<0.05$.

3 DISCUSSION

3 DISCUSSION

Various approaches have been reported for the early treatment of anterior open bite malocclusion. Nevertheless, there is a need of more randomized clinical trials comparing well established approaches versus new protocols with or without the association of different appliances to treat this malocclusion.[6,18,27-29]

The effects of these protocols are usually reported evaluating lateral cephalograms and show the effects of treatment evaluating skeletal and dentoalveolar variables on a sagittal and vertical perspectives.[7,8,12,14,15,17,24,25,30,31]

Nowadays, digital dental models acquired by intraoral scanning has become a routine exam in university and private clinics. This allows the evaluation of treatment changes on sagittal, vertical and transverse perspectives and without exposing the patient to more radiation. The measurements obtained from them have reported accuracy, reliability, and reproducibility.[32,33] Thus, it should be considered as an important complementary evaluation during anterior open bite early treatment.

Only two studies assessed the effects of palatal crib on dental arches dimensions.[13,34] Since bonded spurs are an efficient treatment alternative to palatal crib, the study of their effects in the dentoskeletal and dental arches variables are still necessary. Therefore, this could be considered as the first randomized clinical trial evaluating the early treatment of anterior open bite after bonded spurs with and without an associated appliance (posterior build-ups) assessing the dentoskeletal effects on lateral cephalograms and the dental arches dimensional changes on digital dental models.

Although differentiation of patients between dental and skeletal open bites was not performed during recruitment, the dentoskeletal vertical characteristics were similar between groups, eliminating any effect of pretreatment factors on the treatment changes evaluation. Ideally, patients with greater vertical growth should be included. However, anterior open bite malocclusion at the age range considered in this study has mainly a dentoalveolar origin.[1,17] Its association with a vertical growth could increase with age,[21] if the malocclusion is not early corrected.[20,22]

Similar changes on the dentoskeletal and dental arches variables were observed between groups. Contrary to the significant maxillary molar intrusion and counter clockwise mandibular rotation effects reported in adult patients with the use of posterior build ups,[26] this study showed that the bonded spurs associated with build-ups demonstrated a slight vertical development of the maxillary molar. Although this was significant smaller than that observed for the bonded spurs group, it did not produce a greater clockwise rotation of the mandible. The vertical development of molars could be expected because of the growth potential that patients had.[35,36] Even when vertical chincup is used associated with bonded spurs[24,25] or with posterior bite blocks,[31] vertical development of the molars could be expected.

The dental arches changes observed with both protocols were similar from those observed for palatal crib.[13,34] In addition, the maxillary intermolar distance decreased in the bonded spurs associated with bulid-ups group and increased in the bonded spurs group. Contrarily, the mandibular intermolar distance increased in the group that used build-ups and decrease in the other group. These minimal differences were related to the other dental arches dimensional changes and to normal growth.[13,34,37-39]

Even though both treatment protocols showed important overbite increases, some patients still presented anterior open bite after the 12-month follow-up period and continued treatment for a longer period of time. This has been previously reported,[12,14] and could be related to the persistence of some oral habits or to the short follow-up period. Future studies evaluating these and other appliances for a longer follow-up period should be performed.

4 FINAL CONSIDERATIONS

4 FINAL CONSIDERATIONS

Both treatment protocols showed overbite increases and similar dentoskeletal and dental arches changes.

Although bonded spurs associated with posterior build-ups showed significant smaller vertical development of the maxillary molars, it did not produce greater counter-clockwise rotation of the mandible than conventional bonded spurs.

A slight decrease in the maxillary intermolar distance and a slight increase in the mandibular intermolar distance could be expected with bonded spurs associated with posterior build-ups, while the opposite behavior could be expected after the use of conventional bonded spurs.

REFERENCES

REFERENCES

1. Ngan P, Fields HW. Open bite: a review of etiology and management. Pediatr Dent. 1997;19:91-98.

2. 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;144:872-878.

3. 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;128:517-519.

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

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

6. 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.

7. Huang GJ, Justus R, Kennedy DB, Kokich VG. Stability of anterior openbite treated with crib therapy. Angle Orthod. 1990;60:17-24.

8. 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;129:734-739.

9. Cozza P, Mucedero M, Baccetti T, Franchi L. Treatment and posttreatment effects of quad-helix/crib therapy of dentoskeletal open bite. Angle Orthod. 2007;77:640-645.

10. Giuntini V, Franchi L, Baccetti T, Mucedero M, Cozza P. Dentoskeletal changes associated with fixed and removable appliances with a crib in open-bite patients in the mixed dentition. Am J Orthod Dentofacial Orthop. 2008;133:77-80.

11. 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.

12. 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.

13. Slaviero T, Fernandes TM, Oltramari-Navarro PV, de Castro AC, Conti F, Poleti ML et al. Dimensional changes of dental arches produced by fixed and removable palatal cribs: A prospective, randomized, controlled study. Angle Orthod. 2017;87:215-222.

14. 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;88:684-691.

15. Justus R. Correction of anterior open bite with spurs: long-term stability. World J Orthod. 2001;2:219-231.

16. Meyer-Marcotty P, Hartmann J, Stellzig-Eisenhauer A. Dentoalveolar open bite treatment with spur appliances. J Orofac Orthop. 2007;68:510-521.

17. 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;149:847-855.

18. Koletsi D, Makou M, Pandis N. Effect of orthodontic management and orofacial muscle training protocols on the correction of myofunctional and myoskeletal problems in developing dentition. A systematic review and meta-analysis. Orthod Craniofac Res. 2018;21:202-215.

19. Araujo EA, Andrade I, Jr., Brito Gde M, Guerra L, Horta MC. Perception of discomfort during orthodontic treatment with tongue spurs. Orthodontics (Chic.). 2011;12:260-267.

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;118:317-327.

21. Graber TM, Rakosi T, Petrovic AG. Dentofacial orthopedics with functional appliances. 2nd ed. St Louis, MO: Mosby; 1997. p.484-5.

22. Iscan HN, Dincer M, Gultan A, Meral O, Taner-Sarisoy L. Effects of vertical chincap therapy on the mandibular morphology in open-bite patients. Am J Orthod Dentofacial Orthop. 2002;122:506-511.

23. 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;21:104-111.

24. 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;142:487-493.

25. Insabralde NM, de Almeida RR, Henriques JF, Fernandes TM, Flores-Mir C, de Almeida MR. Dentoskeletal effects produced by removable palatal crib, bonded spurs, and chincup therapy in growing children with anterior open bite. Angle Orthod. 2016;86:969-975.

26. 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.

27. Lentini-Oliveira DA, Carvalho FR, Rodrigues CG, Ye Q, Prado LB, Prado GF et al. Orthodontic and orthopaedic treatment for anterior open bite in children. Cochrane Database Syst Rev 2014:CD005515.

28. 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.

29. Feres MF, Abreu LG, Insabralde NM, Almeida MR, Flores-Mir C. Effectiveness of the open bite treatment in growing children and adolescents. A systematic review. Eur J Orthod. 2016;38:237-250.

30. 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;129:418-423.

31. Turkkahraman H, Cetin E. Comparison of two treatment strategies for the early treatment of an anterior skeletal open bite : Posterior bite block-vertical pull chin cup (PBB-VPC) vs. posterior bite block-high pull headgear (PBB-HPH). J Orofac Orthop. 2017;78:338-347.

32. Aragon ML, Pontes LF, Bichara LM, Flores-Mir C, Normando D. Validity and reliability of intraoral scanners compared to conventional gypsum models measurements: a systematic review. Eur J Orthod. 2016;38:429-434.

33. Camardella LT, Breuning H, de Vasconcellos Vilella O. Accuracy and reproducibility of measurements on plaster models and digital models created using an intraoral scanner. J Orofac Orthop. 2017;78:211-220.

34. 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.

35. Iseri H, Solow B. Continued eruption of maxillary incisors and first molars in girls from 9 to 25 years, studied by the implant method. Eur J Orthod. 1996;18:245-256.

36. Buschang PH, Carrillo R, Liu SS, Demirjian A. Maxillary and mandibular dentoalveolar heights of French-Canadians 10 to 15 years of age. Angle Orthod. 2008;78:70-76.

37. Moorrees CF, Gron AM, Lebret LM, Yen PK, Frohlich FJ. Growth studies of the dentition: a review. Am J Orthod. 1969;55:600-616.

38. Bishara SE, Jakobsen JR, Treder J, Nowak A. Arch width changes from 6 weeks to 45 years of age. Am J Orthod Dentofacial Orthop. 1997;111:401-409.

39. Bishara SE, Jakobsen JR, Treder J, Nowak A. Arch length changes from 6 weeks to 45 years. Angle Orthod. 1998;68:69-74.

APPENDICES

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

We hereby declare that we are aware of the article “Dentoskeletal changes in open bite patients treated with bonded spurs associated with posterior build-ups versus conventional bonded spurs: a single-center, randomized clinical trial” will be included in Thesis of the student Arón Aliaga Del Castillo and may not be used in other works of Graduate Programs at the Bauru School of Dentistry, University of São Paulo.

Bauru, March 03rd, 2020.

Aron Aliaga-Del Castillo _____
Author Signature

Guilherme Janson _____
Author Signature

_____ _____
Author Signature

_____ _____
Author Signature

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

We hereby declare that we are aware of the article “Dental arches changes after open bite treatment with bonded spurs associated with posterior build-ups and conventional bonded spurs: a randomized clinical trial” will be included in Thesis of the student Arón Aliaga Del Castillo and may not be used in other works of Graduate Programs at the Bauru School of Dentistry, University of São Paulo.

Bauru, March 03rd, 2020.

Aron Aliaga-Del Castillo _____
Author Signature

Guilherme Janson _____
Author Signature

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Author Signature

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Author Signature

ANNEXES

ANNEX A. Ethics Committee approval, protocol number 2.112.035 (front).

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

Plataforma Brasil

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Tratamento da mordida aberta anterior com esporão colado associado a build-ups versus esporão colado convencional: um ensaio clínico randomizado

Pesquisador: Arón Aliaga Del Castillo

Área Temática:

Versão: 1

CAAE: 68551617.8.0000.5417

Instituição Proponente: Universidade de Sao Paulo

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.112.035

Apresentação do Projeto:

Afirma o Pesquisador que devido à mordida aberta anterior estar comumente relacionada com o aumento da altura facial ântero-inferior, alguns protocolos de tratamento precoce associam aparelhos que permitem o desenvolvimento vertical dos dentes anteriores sem interferências (controle dos hábitos deletérios) com aparelhos que produzem controle da dimensão vertical. Recentemente, foi descrita a eficiência e a estabilidade de batentes de

resina nos dentes póstero-superiores (build-ups) associado ao aparelho fixo no tratamento da mordida aberta anterior. Desta forma, o objetivo proposto no presente estudo é comparar os efeitos dentoalveolares e esqueléticos do tratamento precoce da mordida aberta anterior com esporão colado associado a build-ups versus esporão colado convencional. Serão selecionados 60 participantes com faixa etária entre 6 e 11 anos de idade com má oclusão Classe I de Angle e mordida aberta anterior. Serão se forma prospectiva e aleatoriamente alocados em um dos dois grupos de estudo. O grupo experimental consistirá de 30 pacientes tratados com esporão colado associado a build-ups. O grupo controle consistirá de 30 pacientes tratados apenas com esporão colado. Telerradiografias laterais e modelos de estudo digitais serão obtidos ao início (T1) e após 12 meses do tratamento (T2). Variáveis dentoalveolares e esqueléticas serão avaliadas a partir de telerradiografias no programa Dolphin®. Modelos de estudo serão analisados no programa

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Telefone: (14)3235-8356 **Fax:** (14)3235-8356 **E-mail:** cep@fob.usp.br

ANNEX A. Ethics Committee approval, protocol number 2.112.035 (verso).

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

Continuação do Parecer: 2.112.035

Orthoanalyzer® para avaliar o
desenvolvimento vertical dentoalveolar anterior, inclinações dos dentes posteriores e dimensões do arco superior. 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:

Objetivo Primário:

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

Objetivo Secundário:

Comparar as larguras, perímetro e comprimento do arco superior, assim como a profundidade do palato no tratamento precoce da mordida aberta anterior com esporão colado associado a build-ups versus esporão colado convencional.

Avaliação dos Riscos e Benefícios:

Riscos:

Após a instalação do aparelho, o menor pode sentir algum tipo de desconforto, porém suportável, na região anterior da língua ou no dedo (se for o caso). Essa sensação é necessária pois é ela que reeducará o posicionamento da língua e/ou eliminará o hábito de sucção de chupeta ou do dedo.

Adicionalmente, o menor poderá ou não relatar desconforto durante a mastigação durante a primeira semana de uso do aparelho que irá diminuindo a partir da segunda semana de tratamento. Os participantes e seus responsáveis receberam orientações em relação aos cuidados na alimentação e na higienização com a finalidade de diminuir qualquer desconforto.

Benefícios:

O aparelho terá a função de impedir a língua se interpor entre os dentes da frente e auxiliará o menor a não mais utilizar chupeta ou chupar o dedo.

A finalidade deste aparelho será proporcionar um bom relacionamento entre os arcos dentários, corrigindo a "mordida aberta anterior" presente.

Consequentemente o participante obterá um melhor funcionamento do sistema mastigatório e uma melhora na estética do sorriso.

Comentários e Considerações sobre a Pesquisa:

Não há.

Considerações sobre os Termos de apresentação obrigatória:

Todos os documentos exigidos foram apresentados, inclusive o TCLE e Termo de Assentimento,

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Continuação do Parecer: 2.112.035

que se apresentam de forma clara e objetiva, informando aos participantes e seus representantes legais os procedimentos a que serão submetidos, bem como todas as demais informações pertinentes.

Recomendações:

Não há.

Conclusões ou Pendências e Lista de Inadequações:

Tendo em vista a apresentação de todos os documentos de forma correta, sou de parecer favorável a APROVAÇÃO do projeto de pesquisa.

Considerações Finais a critério do CEP:

Esse projeto foi considerado APROVADO na reunião ordinária do CEP de 07.06.2017, com base nas normas éticas da Resolução CNS 466/12. Ao término da pesquisa o CEP-FOB/USP exige a apresentação de relatório final. Os relatórios parciais deverão estar de acordo com o cronograma e/ou parecer emitido pelo CEP. Alterações na metodologia, título, inclusão ou exclusão de autores, cronograma e quaisquer outras mudanças que sejam significativas deverão ser previamente comunicadas a este CEP sob risco de não aprovação do relatório final. Quando da apresentação deste, deverão ser incluídos todos os TCLEs e/ou termos de doação assinados e rubricados, se pertinentes.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_916069.pdf	18/05/2017 13:00:31		Aceito
Outros	Carta_de_Encaminhamento.pdf	18/05/2017 12:31:14	Arón Aliaga Del Castillo	Aceito
Declaração de Pesquisadores	Declaracao_de_Compromisso.pdf	18/05/2017 12:29:45	Arón Aliaga Del Castillo	Aceito
Orçamento	Orcamento.pdf	18/05/2017 12:24:14	Arón Aliaga Del Castillo	Aceito
Cronograma	Cronograma.pdf	18/05/2017 12:21:55	Arón Aliaga Del Castillo	Aceito
Outros	Questionario_Tecnico.pdf	18/05/2017 12:21:24	Arón Aliaga Del Castillo	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_Doutorado_Aron.pdf	18/05/2017 12:18:13	Arón Aliaga Del Castillo	Aceito
TCLE / Termos de	Termo_de_Assentimento_Aron.pdf	18/05/2017	Arón Aliaga Del	Aceito

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Continuação do Parecer: 2.112.035

Assentimento / Justificativa de Ausência	Termo_de_Assentimento_Aron.pdf	12:07:57	Castillo	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_Aron.pdf	18/05/2017 12:07:41	Arón Aliaga Del Castillo	Aceito
Folha de Rosto	Folha_de_Rosto.pdf	18/05/2017 12:06:24	Arón Aliaga Del Castillo	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

BAURU, 09 de Junho de 2017

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

Endereço: DOUTOR OCTAVIO PINHEIRO BRISOLLA 75 QUADRA 9
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ANNEX B – Informed consent for children

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 **"Tratamento da mordida aberta anterior com esporão colado associado a build-ups versus esporão colado convencional: um ensaio clínico randomizado".** Essa pesquisa será realizada pelo Dr. Arón Aliaga Del Castillo, aqui na Faculdade de Odontologia de Bauru da Universidade de São Paulo (FOB-USP). 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 impedirá sua língua se interpor entre seus dentes da frente e ajudará a não mais utilizar chupeta ou chupar o dedo. Com isso, vamos corrigir a sua "mordida aberta".

Para fazer o seu tratamento, será necessário realizar 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). Quando começarmos o tratamento, vamos colar o aparelho (uns quadradinhos) na parte de trás dos dentes da frente e pode ser que coloquemos uns quadradinhos (resina) nos dentes de cima e de trás também. O aparelho é pequeno e você não sentirá desconforto enquanto coloca. Você deverá usar o aparelho por 12 meses. Não se preocupe que eu explicarei em detalhe para você e para o seu responsável tudo relacionado ao aparelho. Se você tiver alguma dúvida, pode me perguntar a qualquer momento. 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 "Tratamento da mordida aberta anterior com esporão colado associado a build-ups versus esporão colado convencional: um ensaio clínico randomizado**"**, 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 _____.

_____
Arón Aliaga Del Castillo
Pesquisador 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 – Informed consent for children´s legal guardians (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 **"Tratamento da mordida aberta anterior com esporão colado associado a build-ups versus esporão colado convencional: um ensaio clínico randomizado".** Essa pesquisa científica será realizada por Arón Aliaga Del Castillo, Doutorando 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 do esporão colado (aparelho fixo, dentro da boca, colado na parte de trás dos dentes anteriores) associado ou não a resinas nos dentes dentes póstero-superiores (de cima e de trás, de acordo com o grupo sorteado) em indivíduos dos 6 aos 11 anos de idade. O aparelho terá a função de impedir a língua se interpor entre os dentes da frente e auxiliará o menor a não mais utilizar chupeta ou chupar o dedo. A finalidade deste aparelho será proporcionar um bom relacionamento entre os arcos dentários, corrigindo a "mordida aberta anterior" presente. Correta higiene bucal e cuidados com alimentos duros serão importantes para a manutenção da saúde bucal e do aparelho em boas condições. Você e o menor sob sua responsabilidade serão orientados durante todo o tratamento sobre os cuidados necessários e sobre eventuais questionamentos.

Serão realizadas a documentação (registro) do menor ao início e após 12 meses de tratamento que consistirão 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. Por fim, durante todo o acompanhamento da terapia serão realizadas também algumas fotografias intrabucais (frontal, laterais e oclusais) e extrabucais (frente, lateral, e do sorriso), para complementar a avaliação acima descrita. 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.

O tempo total de tratamento será de 12 meses. Todos os procedimentos clínicos serão realizados pelo próprio pesquisador responsável, na clínica de Ortodontia da Faculdade de Odontologia de Bauru, Universidade de São Paulo. Ao participar desta pesquisa, o menor sob sua responsabilidade apresentará como benefícios a gratuidade do planejamento ortodôntico, do tratamento das suas más oclusões (posicionamento incorreto dos dentes), do acompanhamento clínico, e, caso apresentem a necessidade de algum outro tratamento bucal, serão encaminhados para o sistema de Triagem da Faculdade de Odontologia de Bauru para serem posteriormente encaminhados a outros Departamentos. Se houver suspeita de qualquer alteração médica ou psicológica, os responsáveis serão orientados a buscar tratamento e acompanhamento adequado para o menor. Ao final do estudo, os participantes terão garantido o acompanhamento e/ou tratamento ortodôntico complementar (se necessário) e estarão dispostos aos melhores métodos preventivos, diagnósticos e terapêuticos que se demonstrarem eficazes, por parte da Instituição patrocinadora. Não será oferecida remuneração, auxílio para alimentação ou transporte até o local nos dias de atendimento. É garantida a indenização em casos de danos que ocorram decorrentes dos procedimentos empregados nesta pesquisa.

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 alivia-o imediatamente.

Após a instalação do aparelho, o menor pode sentir algum tipo de desconforto, porém suportável, na região anterior da língua ou no dedo (se for o caso). Essa sensação é necessária pois é ela que reeducará o posicionamento da língua e/ou eliminará o hábito de sucção de chupeta ou do dedo. Adicionalmente, o menor poderá ou não relatar desconforto durante a mastigação durante a primeira semana de uso do aparelho que irá diminuindo a partir da segunda semana de tratamento. É importante que as orientações em relação à alimentação sejam levadas em consideração para diminuir dito desconforto.

É importante que você saiba que 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.

O **pesquisador** envolvido com a referida pesquisa é **Arón Aliaga Del Castillo** e com ele você poderá manter contato via **e-mail** (a_aliaga@hotmail.com) ou **telefone** (14) 997165983.

Rubrica do Participante da Pesquisa :

Rubrica do Pesquisador Responsável:

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 – Informed consent for children´s legal guardians (verso)

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 _____.

_____
Arón Aliaga Del Castillo
Pesquisador responsável

_____
Assinatura do responsável pelo menor

Rubrica do Participante da Pesquisa :

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

Rubrica do Pesquisador Responsável: