# Dentoskeletal changes in open bite treatment using spurs and posterior build-ups: A randomized clinical trial

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**Introduction:** This single-center 2-arm parallel randomized clinical trial aimed to compare the dentoskeletal effects of bonded spurs combined with posterior build-ups vs conventional bonded spurs in the treatment of anterior open bite malocclusion in the mixed dentition. **Methods:** Patients aged from 7 to 11 years with anterior open bite, recruited at a university orthodontic clinic, were randomly allocated into 2 groups. The experimental group consisted of patients treated with bonded spurs combined with posterior build-ups. The comparison group comprised patients treated with conventional bonded spurs. Lateral headfilms were obtained at pretreatment and after 12 months of treatment. The primary outcome was the change in the overbite. Randomization was performed using the Web site www.randomization.com. Sequentially numbered opaque and sealed envelopes were used for allocation concealment. Blinding was applicable for outcome assessment only. Intergroup comparisons were performed using *t* or Mann-Whitney U tests ($P < 0.05$). Mean difference (MD) and 95% confidence interval (CI) were obtained. **Results:** The experimental group included 24 patients (17 female, 7 male; mean age, 8.22 ± 1.06 years) and the comparison group comprised 25 patients (14 female, 11 male; mean age, 8.30 ± 0.99 years). Baseline demographic and cephalometric characteristics were similar between groups. After 12 months, all patients showed improvements. Both groups showed similar improvements of the overbite (MD, 0.00 mm; 95% CI, −0.92 to 0.91), similar slight decreases of the gonial (MD, 0.02°; 95% CI, −1.11 to 1.15) and mandibular plane (MD, 0.15°; 95% CI, −0.64 to 0.93) angles, and similar mandibular molar extrusion (MD, 0.14 mm; 95% CI, −0.27 to 0.56). The experimental group showed significantly smaller extrusion of the maxillary first molar than the comparison group (MD, −0.70 mm; 95% CI, −0.92 to −0.49). The other dentoskeletal variables showed similar changes without statistically significant intergroup differences. 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 significantly smaller extrusion of the maxillary molars, no greater counterclockwise rotation of the mandible than the comparison group was observed. **Registration:** This trial was registered at Clinicaltrials.gov (Identifier NCT03702881). **Protocol:** The protocol was not published. **Funding:** This trial was financed in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – Brasil (CAPES), Finance Code 001; and by grants: no. 2017/06440-3, no. 2018/05238-9 and no. 2018/24003-2, São Paulo Research Foundation (FAPESP). (Am J Orthod Dentofacial Orthop 2021;159:10-20)

Anterior open bite malocclusion is considered a challenge for orthodontists.[1,2] It affects esthetics and produces functional problems that could reflect in psychosocial issues.[2,3] Anterior open bite prevalence in the mixed dentition is approximately 17%[4] and has a multifactorial etiology involving the

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interaction of environmental and genetic factors.[2,4] Environmental factors include deleterious habits such as using a pacifier, thumb sucking, tongue thrusting, and mouth breathing.[4,5] The greater the influence of environmental factors, the better will be the treatment prognosis because the causal factors are eliminated.[2,5]

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

Anterior open bite is commonly related to a vertical growth pattern and an increase in the lower anterior face height.[4,5,13] Thus, some protocols have combined therapies that correct the habits and control the vertical dimension.[14-18] Bonded spurs combined with chincup demonstrated efficiency in open bite correction[16,17] and a significant decrease of the gonial angle.[16] However, chincup success depends on patient compliance.

The use of posterior build-ups combined with orthodontic fixed appliances for anterior open bite treatment in adults has been reported as a practical, efficient, and stable treatment option that provides counterclockwise rotation of the mandible because of the bite-block effect.[19] Therefore, the combination of bonded spurs with posterior build-ups can produce vertical control during anterior open bite early treatment. Nevertheless, no studies evaluating this combination has been reported.

Although some systematic reviews mentioned the need for well performed randomized clinical trials (RCT) on this topic,[6,8,9,20] only 2 RCT evaluated the effects of bonded spurs in the last years.[10,12] However, they did not include a combined therapy in their comparisons. Thus, the present study would bring information on the effectiveness of the proposed combined therapy for open bite early treatment.

## SPECIFIC OBJECTIVES OR HYPOTHESES

This study aimed to compare the dentoskeletal changes of bonded spurs combined with posterior build-ups vs conventional bonded spurs in anterior open bite early treatment. The null hypothesis tested was that both therapies produce similar dentoskeletal effects.

## METHODS

### Trial design and any changes after trial commencement

This project was a single-center RCT with 2 parallel arms and a 1:1 allocation ratio. This RCT followed the Consolidated Standards of Reporting Trials statement and guidelines,[21] 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, Bauru, Brazil (protocol no. 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, Bauru, Brazil, from June 2017 to April 2018. The selection criteria included patients aged between 7 and 11 years, anterior open bite >1 mm (clinically evaluated as the vertical distance between the incisal edges of the maxillary and mandibular central incisors), erupted permanent first permanent molars, with the maxillary and mandibular permanent central incisors fully erupted, without or with only mild crowding, and without the need of maxillary expansion. To differentiate between incomplete eruption and open bite for the younger patients, we considered the vertical relationship between lateral and central incisors. If the maxillary lateral incisors were closer to the occlusal plane than the maxillary central incisors and these central incisors still showed a negative overbite greater than 1 mm, the condition was classified as an open bite. This method was adopted on the basis of previous studies.[11,16,22] 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 recruitment.

### Interventions

Bonded spurs (Morelli Ortodontia, Sorocaba, São Paulo, Brazil) were installed at the cervical and incisal regions of the palatal and lingual surfaces of the maxillary and mandibular incisors, respectively. These regions were selected to prevent possible occlusal interferences during treatment.[11,16] The spurs were bonded using the Transbond XT light cure orthodontic adhesive (3M




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

Unitek, Monrovia, Calif). The spurs were sharpened with a carborundum disk before bonding.[14]

The experimental group comprised patients treated with bonded spurs combined with posterior build-ups. Posterior build-ups consisted of 2-3 mm resin blocks of light-cured orthodontic cement (Ortho Bite; FGM, Joinville, Santa Catarina, Brazil) bonded on the palatal cusps of all maxillary posterior teeth to maintain the natural occlusal force balance[19] (Fig 1, *A*). The maxillary molars were chosen on the basis of a previous study,[19] and because of the facility for relative isolation. Posterior build-ups wore down in a few patients (4 of 25) and were rebuilt only once during treatment. The comparison group comprised patients treated with only bonded spurs (Fig 1, *B*). The treatment follow-up was 12 months, as previously reported for similar studies.[10-12,15-17,23] Posterior build-ups were removed in the experimental group before obtaining the second digital lateral headfilms (which were taken on the same day). Bonded spurs were maintained as active retention in both groups.

Digital lateral headfilms were obtained using Orthophos XG 3D (Dentsply Sirona, Bensheim, Germany) 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 was considered as the primary outcome measurement.

Secondary outcome measurements included the changes in the gonial angle, mandibular plane angle, lower anterior face height, inclination/position/height of the maxillary and mandibular incisors, and maxillary and mandibular molar extrusion.

All measurements (Table I)[16] were performed using Dolphin Imaging software (version 11.5; Dolphin Imaging and Management Solutions, Chatsworth, Calif).

The anterior open bite was considered corrected when the overbite was equal or greater than 0 (0 meaning an end-to-end vertical incisor relationship),[23] cephalometrically confirmed as the distance in millimeters between the incisal edges of the maxillary and mandibular central incisors, perpendicular to the occlusal plane.[11,16] There were no outcome changes after trial commencement.

**Table I.** Cephalometric variables

| *Variables* | *Definition* |
|---|---|
| Vertical component | |
| Ar.Go.Me, ° | ArGo to GoMe angle |
| SN.GoGn, ° | SN to GoGn angle |
| LAFH, mm | 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 component | |
| 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 component | |
| 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.

### Sample size calculation

The sample size was calculated 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 previously reported standard deviation of 1.69 mm.[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)

The randomization scheme was obtained by using the Web site Randomization.com (http://www.randomization.com).[24] This software generated the randomization list using random block sizes, ensuring equal distribution in both groups. Fifty patients were randomized before trial commencement.

Allocation concealment was achieved with sequentially numbered opaque and sealed envelopes containing the treatment allocation cards. Opacity was implemented by inserting the card with the assignment into the foil. The envelopes were prepared before the trial commencement. The patient's name and baseline information were written on the envelope before opening it. All envelopes were torn open instead of being unsealed. The envelopes were securely stored in a different location from the trial site.[25]

The generation of randomization lists, allocation concealment, and implementation (enrollment of participants/treatment assignment/deliver intervention) were performed independently by different persons.[25]

### Blinding

Blinding of either patient or operator was not possible because both knew the type of appliance installed. However, the assessment of the lateral radiographs was blinded.[26] All radiographs were unidentified before the assessor's evaluation, and all those taken at T2 showed the presence of bonded spurs and the absence of posterior build-ups.

### 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.

Normal distribution was tested using the Shapiro-Wilk test. Sex distribution was compared with the Fisher exact test. Intergroup comparisons regarding age and

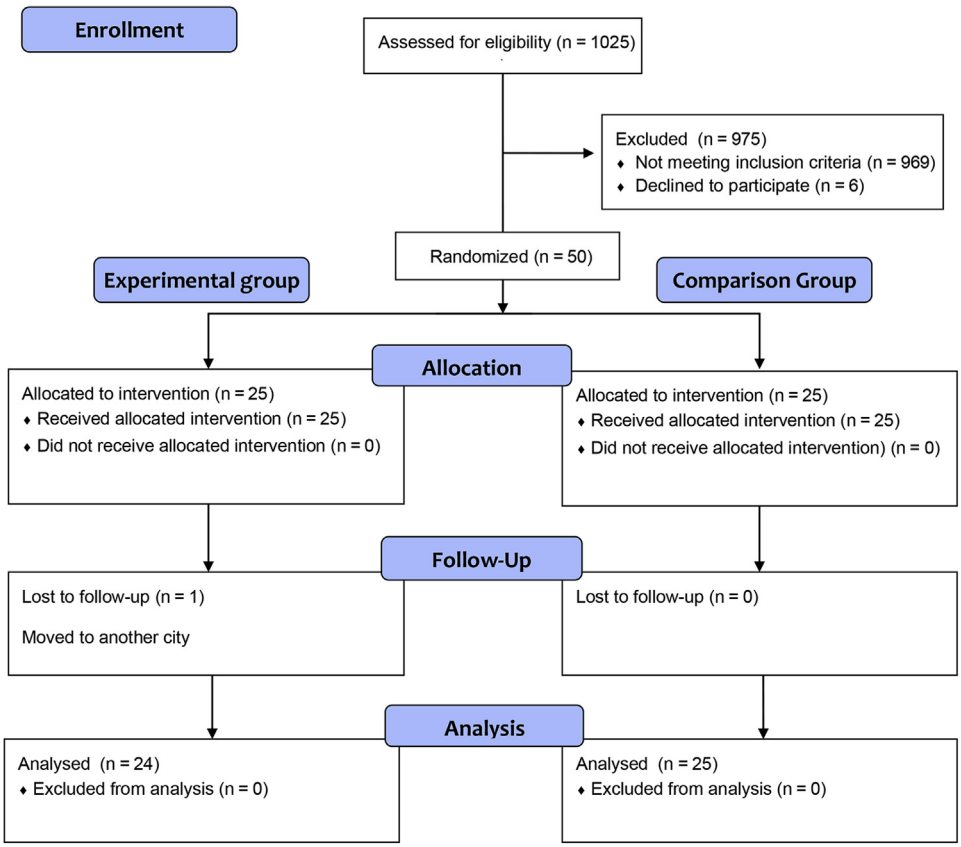



**Fig 2.** Consolidated Standards of Reporting Trials flow diagram.

cephalometric variables were performed with *t* or Mann-Whitney U tests, depending on normality. The influence of pretreatment predictor variables (Ar.Go.Me, SN.GoGn, LAFH, and the initial amount of anterior open bite) on the overbite change was evaluated with multiple linear regression analysis considering all patients. Statistical analyses were performed using SPSS software (version 25; IBM, Armonk, NY). Results were considered significant at $P < 0.05$.

## RESULTS

### Participant flow

A total of 1025 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 initial cephalometric variables (Tables II and III; Fig 3, *A*).

### Number analyzed for each outcome, estimation, and precision

One out of 25 patients (4%) was lost during the follow-up in the experimental group because the patient moved to another city. 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 intraclass correlation coefficient values ranged from 0.905 (95% confidence interval, 0.802-0.955) to 0.996 (95% confidence interval, 0.991-0.998), demonstrating a very good intraexaminer reliability.[27]

**Table II.** Intergroup comparisons for age and sex

| *Variable* | *Experimental group (n = 24)* | *Comparison group (n = 25)* | P *value* |
|---|---|---|---|
| Age, y, mean (SD) | 8.22 (1.06) | 8.30 (0.99) | 0.787* |
| Sex, n (%) | | | |
| Female | 17 (70.8) | 14 (56.0) | 0.377† |
| Male | 7 (29.2) | 11 (44.0) | |

*SD,* Standard deviation.
**t* test; †Fisher exact test.

**Table III.** Pretreatment (T1) and posttreatment (T2) measurements

| | *Experimental group (n = 24)* | | | | | | *Comparison group (n = 25)* | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | *T1* | | | *T2* | | | *T1* | | | *T2* | | |
| *Variable* | *Mean* | *SD* | *Median* | *Mean* | *SD* | *Median* | *Mean* | *SD* | *Median* | *Mean* | *SD* | *Median* |
| Vertical component | | | | | | | | | | | | |
| Ar.Go.Me, ° | 129.95 | 6.01 | 129.05 | 129.29 | 6.29 | 127.50 | 131.48 | 5.20 | 131.90 | 130.80 | 5.15 | 130.70 |
| SN.GoGn, ° | 34.47 | 5.29 | 33.90 | 34.30 | 4.91 | 33.70 | 34.42 | 4.34 | 34.10 | 34.10 | 5.02 | 34.20 |
| LAFH, mm | 56.11 | 3.42 | 55.60 | 56.66 | 3.59 | 56.70 | 56.92 | 4.33 | 56.80 | 57.66 | 4.52 | 56.70 |
| Dental relationship | | | | | | | | | | | | |
| Overbite, mm | −4.45 | 1.49 | −4.05 | 0.39 | 1.42 | 0.35 | −4.36 | 1.65 | −4.30 | 0.48 | 1.57 | 1.00 |
| Maxillary dentoalveolar component | | | | | | | | | | | | |
| Mx1.NA, ° | 27.85 | 5.08 | 25.65 | 22.36 | 4.11 | 22.70 | 29.28 | 5.24 | 30.70 | 23.85 | 5.37 | 25.20 |
| Mx1-NA, mm | 4.54 | 1.81 | 4.25 | 4.30 | 1.54 | 4.10 | 5.46 | 2.12 | 5.50 | 5.10 | 2.38 | 5.20 |
| Mx1-PP, mm | 21.18 | 2.57 | 21.70 | 23.92 | 2.22 | 24.40 | 21.74 | 2.85 | 21.80 | 24.66 | 2.53 | 24.50 |
| Mx6-PP, mm | 16.96 | 1.64 | 17.05 | 17.08 | 1.70 | 17.40 | 17.10 | 2.65 | 16.70 | 17.92 | 2.73 | 17.70 |
| Mandibular dentoalveolar component | | | | | | | | | | | | |
| Md1.NB, ° | 27.84 | 4.32 | 27.15 | 24.78 | 4.08 | 24.70 | 29.60 | 5.84 | 30.60 | 26.48 | 6.70 | 27.50 |
| Md1-NB, mm | 4.82 | 1.36 | 4.75 | 4.94 | 1.47 | 4.60 | 5.56 | 1.84 | 5.60 | 5.62 | 1.83 | 5.70 |
| Md1-GoMe, mm | 31.56 | 2.20 | 31.15 | 33.96 | 2.32 | 34.00 | 32.31 | 2.54 | 31.90 | 34.56 | 2.32 | 34.50 |
| Md6-GoMe, mm | 24.37 | 2.12 | 24.25 | 24.88 | 2.37 | 25.00 | 24.50 | 1.99 | 24.20 | 24.86 | 2.11 | 25.00 |

*SD,* Standard deviation; *Mx1,* maxillary incisor; *Mx6,* maxillary first permanent molar; *Md1,* mandibular incisor; *Md6,* mandibular first permanent molar.

All patients in both groups showed a decrease of anterior open bite during follow-up (Table IV). The anterior open bite was corrected in 16 of 24 patients (66.7%) in the experimental group and 18 of 25 patients (72%) in the comparison group after 12 months of treatment.

Overall, both groups showed, numerically, similar changes after treatment (Table IV; Fig 3, *B*). For the primary outcome, both groups showed similar increases in the overbite. For the secondary outcomes; the groups showed similar decreases of the gonial and mandibular plane angles, maxillary incisor labial inclination and protrusion and mandibular incisor labial inclination (Table IV; Fig 3, *B*); and similar increases of the lower anterior facial height, maxillary incisor extrusion, mandibular incisor protrusion and extrusion, and mandibular molar extrusion. The experimental group showed significantly

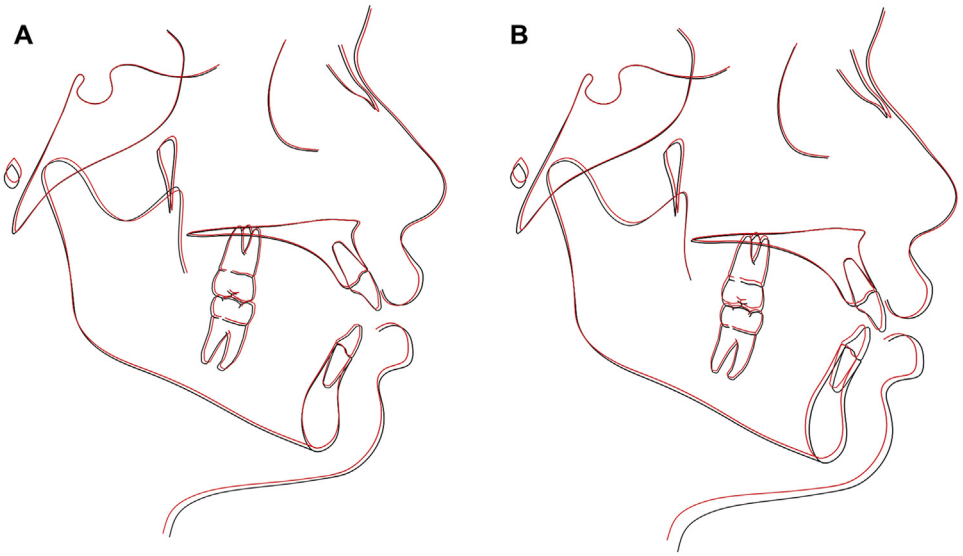



**Fig 3.** Superimposition of average cephalometric tracings of the experimental (*red color*) and comparison (*black color*) groups at pretreatment **(A)** and after 12 months of treatment **(B)**. The average cephalometric tracings were superimposed on the cranial base (Sella-Nasion) registered on Sella.

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

| | *Experimental group (n = 24)* | | | *Comparison group (n = 25)* | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| *Variable* | *Mean* | *SD* | *Median* | *Mean* | *SD* | *Median* | *Mean Difference* | *95% CI* | | P |
| Vertical component | | | | | | | | | | |
| Ar.Go.Me, ° | −0.66 | 2.19 | −0.30 | −0.68 | 1.73 | −1.30 | 0.02 | −1.11 | 1.15 | 0.970† |
| SN.GoGn, ° | −0.18 | 1.37 | −0.35 | −0.32 | 1.37 | 0.10 | 0.15 | −0.64 | 0.93 | 0.712† |
| LAFH, mm | 0.55 | 0.81 | 0.65 | 0.74 | 1.07 | 0.60 | −0.19 | −0.73 | 0.36 | 0.498† |
| Dental relationship | | | | | | | | | | |
| Overbite, mm | 4.84 | 1.76 | 4.40 | 4.84 | 1.41 | 4.60 | 0.00 | −0.92 | 0.91 | 0.865‡ |
| Maxillary dentoalveolar component | | | | | | | | | | |
| Mx1.NA, ° | −5.50 | 4.72 | −4.90 | −5.43 | 3.97 | −4.70 | −0.07 | −2.57 | 2.44 | 0.957† |
| Mx1-NA, mm | −0.24 | 1.17 | −0.30 | −0.36 | 1.13 | −0.20 | 0.12 | −0.54 | 0.78 | 0.720† |
| Mx1-PP, mm | 2.75 | 1.06 | 2.60 | 2.92 | 0.99 | 2.60 | −0.17 | −0.76 | 0.42 | 0.564† |
| Mx6-PP, mm | 0.12 | 0.38 | 0.10 | 0.82 | 0.37 | 0.90 | −0.70 | −0.92 | −0.49 | <0.001‡,* |
| Mandibular dentoalveolar component | | | | | | | | | | |
| Md1.NB, ° | −3.06 | 3.12 | −2.60 | −3.11 | 3.36 | −2.70 | 0.05 | −1.82 | 1.92 | 0.958† |
| Md1-NB, mm | 0.12 | 0.72 | 0.20 | 0.06 | 0.87 | 0.00 | 0.06 | −0.40 | 0.52 | 0.806† |
| Md1-GoMe, mm | 2.40 | 0.69 | 2.45 | 2.24 | 0.89 | 2.30 | 0.16 | −0.30 | 0.62 | 0.484† |
| Md6-GoMe, mm | 0.51 | 0.58 | 0.45 | 0.36 | 0.82 | 0.30 | 0.14 | −0.27 | 0.56 | 0.484† |

*T2*, Posttreatment; *T1*, pretreatment; *SD*, standard deviation; *Mx1*, maxillary incisor; *Mx6*, maxillary first permanent molar; *Md1*, mandibular incisor; *Md6*, mandibular first permanent molar.
*Statistically significant at $P < 0.05$; †*t* test; ‡Mann-Whitney U test.

lesser extrusion of the maxillary first molars than the comparison group.

The backward multiple linear regression analysis showed that the mandibular plane angle and the initial amount of open bite had negative and positive influences, respectively, on the anterior open bite correction (Table V). A greater mandibular plane angle at pretreatment would generate smaller open bite correction, whereas a greater initial amount of open bite would generate greater open bite correction.

## Harms

Few bonded spurs and build-ups were debonded accidentally during the evaluation period, showing breakdown rates of 2.5% and 5.3%, respectively. All of them were spitted out, as instructed before treatment, and bonded again as soon as possible. Occasionally, debonded spurs can be aspirated into the lungs or swallowed. It did not happen with any patient in this study. However, this should be informed to the patients before and during treatment.

No other serious harm was caused to the participants of this study other than plaque accumulation around the spurs. Patients were also instructed to maintain adequate oral hygiene during treatment. The benefits and collateral effects of the 2 protocols were already known from previous literature.[11,16,19] Patients with a remaining anterior open bite at T2 continued with the appliances after the evaluation period.

**Table V.** Backward multiple linear regression analysis considering the overbite change (T2 − T1) as the dependent variable

| | *Unstandardized coefficients* | | | *95% CI* | |
|---|---|---|---|---|---|
| *Model* | *B* | *Standard error* | P | *Lower limit* | *Upper limit* |
| (Constant) | 5.454 | 1.400 | <0.001 | 2.635 | 8.272 |
| Initial SN.GoGn | −0.091 | 0.038 | 0.022* | −0.168 | −0.014 |
| Initial anterior open bite | 0.573 | 0.117 | <0.001* | 0.337 | 0.809 |

Note. $R = 0.616$, $R^2 = 0.380$; Adjusted $R^2 = 0.353$; $P < 0.001$.
*Statistically significant at $P < 0.05$.

## DISCUSSION

### Main findings in the context of the existing evidence and interpretation

Early treatment of anterior open bite malocclusion has been studied, and different protocols were reported to treat this condition.[10-12,14-17,23,28-30] However, RCT evaluating conventional and new associated protocols are still necessary.[6-9]

Previous studies have reported the efficiency of bonded spurs alone for early treatment of anterior open bite.[10-12] Bonded spurs combined with posterior build-ups could produce a combined effect of eliminating 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 3, *A*), eliminating the influence of any baseline factor on the treatment results. No differentiation between dental and skeletal open bites was 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.[1,31] All patients presented a history of at least 1 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 of treatment, 8 out of 24 patients in the experimental group and 7 of the 25 patients in the comparison group remained with an anterior open bite. This finding could be related to the persistence of some deleterious habits, to the follow-up period of 12 months that was not enough,[11,12,16] and to the divergent growth pattern and orofacial musculature characteristics of these patients.[2,6,18]

Both treatment protocols showed important improvements of the anterior open bite condition, clinically and cephalometrically (Table IV; Fig 3). The overbite improvement was expected because of the presence of bonded spurs that prevented the thumb sucking, anterior posture, and tongue thrusting, allowing vertical development of the anterior teeth without interferences.[10-12,16,17]

It has been reported that overbite increases from 1.43 to 2.08 mm for untreated open bite subjects followed for the same period.[11,16,17] This could lead to spontaneous anterior open bite correction in a few untreated patients. However, these increases are smaller than those observed for bonded spurs. Overbite increases ranging from 3.07[10,12] to 4.26 mm[11] and from 4.52[17] to 5.23 mm[16] have been reported when bonded spurs alone or bonded spurs combined with chincup were used, respectively. 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.

Maxillary and mandibular molar extrusion ranges from 0.64 to 0.90 mm and from 0.44 to 0.54 mm, respectively, in patients with untreated open bite patients with similar ages and follow-ups.[11,16,17] The comparison group showed maxillary molar extrusion within this range, whereas the experimental group showed significantly smaller extrusion (Table IV). Mandibular molar extrusion was similar to the expected range, and no significant difference was observed between groups. These outcomes show that posterior build-ups in children produced some vertical control of the maxillary molar and no vertical control of the mandibular molar. Contrary to the maxillary molar intrusion effect observed in adults,[19] no molar intrusion was present in this study. The extrusion of mandibular molars after the use of build-ups was also reported for adults,[19] and could be related to some compensatory effect of these teeth. Molar extrusion could be expected in this study because patients were growing children, as evidenced by the increase observed in the lower anterior facial height. Even when patients are treated with bonded spurs combined with vertical chincup,[16,17] or with bite blocks associated with vertical chincup,[18] some extrusion of molars is observed because of the growth potential that children present. Furthermore, some differences in the dimensional changes of the dental arches may have influenced these results. However, dental cast analysis should be further evaluated to confirm this speculation.

The experimental and comparison groups showed similar slight decreases of the gonial angle (0.66° and 0.68°, respectively) and mandibular plane angle (0.18° and 0.32°, respectively) with no intergroup differences (Table IV). This study showed that a slight decrease in the gonial and mandibular plane angles could be expected after using bonded spurs, with or without the association of posterior build-ups. This effect has been reported in other studies using bonded spurs.[11,12] Similar amounts of mandibular plane angle decrease (0.1° to 0.50°) have been reported for untreated open bite subjects with similar ages and followed by a similar period.[11,16,17] Contrarily, only 1 study showed an important increase in the mandibular plane angle after bonded

spurs therapy.[10] This could be related to the inherent characteristics of their sample.

Although less extrusion of the maxillary molar was observed in the experimental group, no significant greater reduction of the gonial angle and counterclockwise rotation of the mandible was observed compared with the spurs only group. A different outcome was found in a previous study reporting that bonded spurs combined with vertical chincup therapy produced a greater reduction of the gonial angle than untreated patients, as an effect of the vertical chincup.[16]

Greater and significant decreases on the gonial and mandibular plane angles have been reported after the use of vertical chincup 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 0.54°.[12] This may be related to the mainly dentoalveolar origin of the open bite in the included patients and the lack of patient compliance using chincup.[16]

Regarding the other cephalometric variables, no statistically significant differences were observed between groups (Table IV). Dentoalveolar variables showed that the improvement of the overbite in the experimental and comparison groups was associated with palatal inclination, retrusion, and extrusion of maxillary incisors; and with lingual inclination, extrusion, and slight protrusion of the mandibular incisors, as previously reported with these kinds of therapies.[10-12,16,17]

The regression analysis showed that a greater mandibular plane angle at pretreatment would generate smaller open bite correction and that a greater initial amount of anterior open bite would generate a greater open bite correction. These findings were expected. If the anterior open bite has a greater vertical skeletal component, the open bite correction is more challenging.[2,5,8] Regarding the initial amount of open bite, if a patient shows a greater open bite at pretreatment mainly caused by deleterious habits, a greater open bite closure would be expected if the habits are interrupted with the appliances. It does not mean that the open bite would be completely closed after 12 months of follow-up. It might be expected that a greater initial amount of open bite needs more time to be corrected, especially in the presence of a skeletal component. However, this speculation should be further confirmed.

The results of this study showed that the association of bonded spurs with posterior build-ups was not capable of producing a greater counterclockwise rotation of the mandible in children with an anterior open bite when compared with bonded spurs alone. The lack of the orthopedic effect may be related to the short-term evaluation period. Further studies with longer follow-up periods, including various phases comparisons and evaluating the dentoskeletal effects of bonded spurs combined with posterior build-ups, bonded spurs combined with chincup, and bonded spurs alone, should be performed to complement the understanding of the effects of these therapies. In addition, this study shows an interim report of 12 months of treatment. Long-term stability must be evaluated.

## Limitations

Open bite patients with greater vertical skeletal characteristics should be included. However, at this age range, the anterior open bite malocclusion has mainly a dentoalveolar origin, limiting the selection of an ideal sample.

Although the inclusion of an untreated control group would be ideal to compare treatment and normal growth changes, it was not plausible because of ethical concerns in exposing participants to needless radiation and maintain them without treatment for a year, despite their need for immediate intervention.[8,12,20,32] In contrast, the use of a historical control group was not possible because of the RCT design that only considered 2 experimental groups and because of the possible bias related to the use of historical controls.[33,34]

Although improvements were observed in all patients, some patients in both groups remained with a negative overbite at T2. This finding could be attributed to the 12-month follow-up period, which was not enough to close the anterior open bite in all patients. In addition, the persistence of deleterious habits and lack of cooperation of some patients may also have played a role.

It might be criticized that the trial is not adequately powered to detect small or moderate clinically relevant effects between treatments, except very large ones. However, this is not seen that often. This should be considered as a limitation of the study. Further studies with greater samples should be performed to confirm our results.

## Generalizability

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

## CONCLUSIONS

1. Both treatment protocols produced similar overbite increases and showed similar dentoskeletal changes after 12 months of treatment.
2. Although the bonded spurs combined with posterior build-ups showed significantly smaller extrusion of the maxillary molars, no greater counterclockwise rotation of the mandible was observed in comparison with conventional bonded spurs alone in the short term.

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