

**Dentoalveolar effects produced by different appliances on early treatment of anterior open bite:
A randomized clinical trial**

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ABSTRACT

Objectives: To compare different appliances for early anterior open bite (AOB) correction.

Materials and Methods: This was a parallel, randomized clinical trial. A prospective sample of patients with AOB was recruited consecutively. Eligibility criteria included angle class I malocclusion with AOB equal to or greater than 1 mm. Participants were allocated by simple randomization to 4 groups: bonded spurs, chin cup, fixed palatal crib, and removable palatal crib. Dentoalveolar changes among the groups were assessed by blinded observers by comparing lateral cephalograms taken before (T1) and 12 months after treatment (T2; analysis of variance followed by Tukey test). Of the measurements, 30% were reassessed for reliability (intraclass correlation coefficient and Bland-Altman agreement test; $\alpha = 5\%$; 95% confidence interval).

Results: A total of 99 patients with a mean AOB of 3.7 mm (mean age 8.4 ± 0.8 years, both genders) were recruited. Dropouts occurred in all the groups, yielding a final sample size of 81 analyzed individuals. Intergroup comparisons of differences (T2–T1) showed significant differences for the incisor positioning variables (1.1, 1-PP, 6-PP, IMPA, 1.NB and 1-GoMe). However, there was no significant difference in AOB reduction among the groups, with an average correction of 3.1 mm.

Conclusions: All of the tested devices promoted dental changes, especially in the anterior region, and contributed to AOB reduction during the study period. However, fixed palatal crib demonstrated greater impact on the positioning of the incisors. (*Angle Orthod.* 2018;88:684–691.)

KEY WORDS: Orthodontics; Open bite; Interceptive orthodontics

INTRODUCTION

Anterior open bite (AOB) is defined as the lack of vertical contact between opposing segments of teeth, causing great functional and esthetic impairment and affecting patient self-esteem, thus justifying its correction.¹ The prevalence of AOB is influenced by ethnicity

and age.^{2,3} In the primary dentition, it ranges from 31.1% to 36.8%,⁴ and decreases in the mixed dentition (13.5%–18.6%).² Self-correction can occur with discontinuation of habits and improved emotional development.³

AOB is one of the most difficult malocclusions to treat and maintain correction⁵ because mechanical approaches must be associated with personal motivation and the breaking of habits. Many authors^{2,5,6} recommended that the best time to treat AOB to achieve optimal results and stability is at the end of the primary dentition and the beginning of the mixed dentition.

Improvements in AOB in growing patients have been reported in several studies^{7–15} using orthodontic appliances alone or together with supplementary devices such as bonded spurs, banded spurs, bite blocks, bionators, Fränkel regulators, palatal cribs, and chin

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Accepted: April 2018. Submitted: October 2017.

Published Online: June 18, 2018

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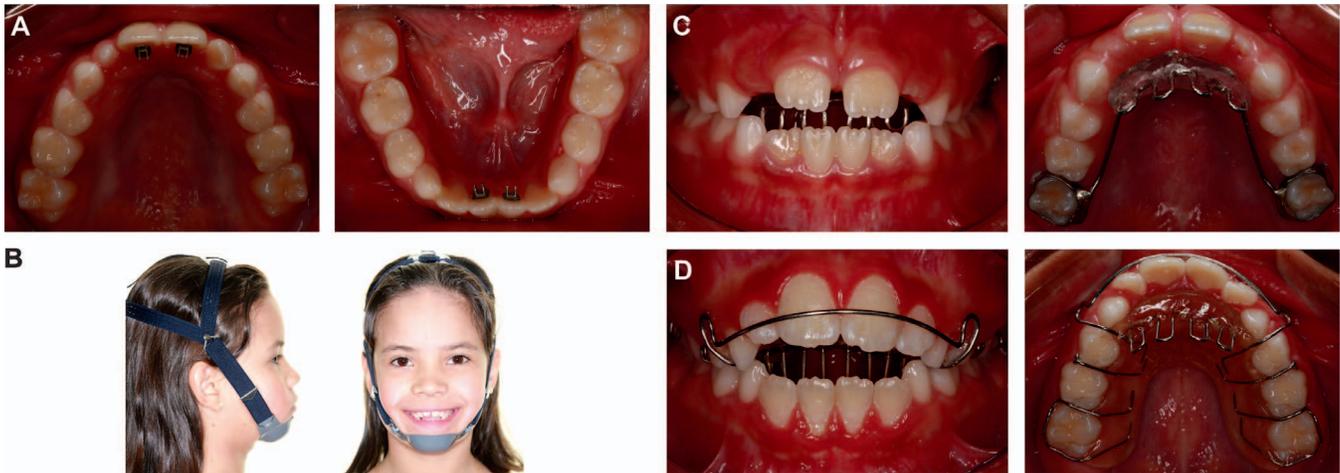


Figure 1. Appliances used: (A) bonded spurs (BS), (B) chin cup (CC), (C) fixed palatal crib (FPC), (D) removable palatal crib (RPC).

cups. Although AOB dentoalveolar characteristics may induce the orthodontist to choose among the several available orthodontic devices, there is scant data available from prospective randomized clinical trials. Each study often tests only one device, making it difficult to base any clinical decision on scientific findings.^{16,17} The purpose of this study, therefore, was to compare the following different devices during treatment in children with AOB and to determine the dentoalveolar effects produced by each: bonded spurs (BS), chin cup (CC), fixed palatal crib (FPC), and removable palatal crib (RPC).

MATERIALS AND METHODS

Trial Design

This study was a parallel, randomized, controlled clinical trial. Participants of each group were prospectively recruited and randomly divided into four study groups. No changes in the methods occurred after the trial began.

Participants

The sample for this prospective randomized clinical trial (RCT) was obtained from 4,563 students in public schools in the city of Londrina-Paraná, Brazil, with permission from their parents and school supervisors.

Patients were accepted in the study with the following criteria: between 7 and 10 years of age, angle class I malocclusion,¹⁸ AOB equal to or greater than 1 mm, and erupted maxillary and mandibular permanent central incisors. All patients presented nonnutritive sucking habits and/or tongue thrusting. Exclusion criteria were the following: missing permanent teeth, severe or moderate crowding, posterior crossbite, or prior orthodontic treatment.

The project was approved by The University of North Paraná Ethics Committee before trial commencement. Patients received treatment at The University of North Paraná Dental Clinic promptly after allocation to the groups. They were followed by two orthodontists who were overseen by an orthodontics professor with 15 years of experience.

Interventions

The participants were randomly allocated and followed up for 12 months in different treatment groups as follows:

- Nogueira lingual BS⁷ (Abzil, 3M Unitek, São José do Rio Preto, São Paulo, Brazil) were bonded on the palatal and lingual surfaces of the maxillary and mandibular central incisors, using Transbond (3M Unitek, Monrovia, Calif), preventing possible occlusal interferences (Figure 1A).
- A high-pull CC (Morelli, Sorocaba, São Paulo, Brazil) delivering 500 g of force per side was used and checked monthly with a dynamometer. The cap was individualized and adapted to each patient so that the resulting force vector passed 45° above the occlusal plane. All the participants were instructed to wear the CC 14 to 16 hours a day¹¹ (Figure 1B).
- The FPC, which included bands on the first permanent molars, was transferred to plaster models to allow welding of a palatal stainless-steel arch, measuring 0.9 mm. Palatal bars constructed of stainless steel and measuring 0.7 mm were added, extending the length of the cervical lingual aspect of the lower incisors (Figure 1C).
- The RPC was composed of a palatal crib with Adams' clasps on the maxillary permanent first molars, a labial archwire, and acrylic coverage on

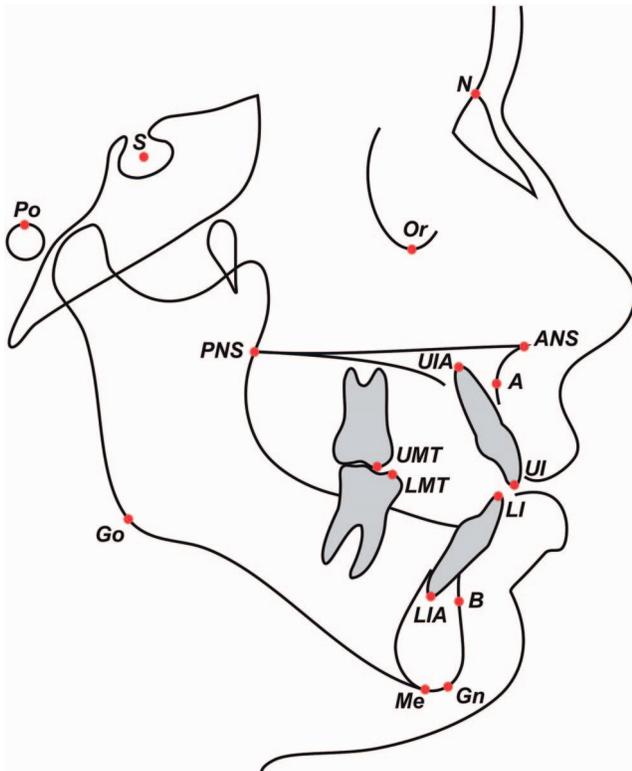


Figure 2. Cephalometric points: S indicates sella; N, nasion; Po, porion; Or, orbitale; A, subspinale; B, supramentale; Me, mentalis; Go, gonion; Gn, gnathion; ANS, anterior nasal spine; PNS, posterior nasal spine; UI, incisal edge of the maxillary incisor; UIA, apex of the maxillary incisor; LI, incisal edge of the mandibular incisor; LIA, apex of the mandibular incisor; UMT, mesiobuccal cusp of the maxillary first molar; LMT, mesiobuccal cusp of the mandibular first molar.

the palate in contact with the lingual aspect of all the teeth. Participants were instructed to wear the RPC full-time except during meals and oral hygiene (Figure 1D).

The patients who did not exhibit full AOB correction after the 12-month treatment period continued in treatment until an overbite of 1 mm was achieved. All volunteers were examined monthly for positive-negative reinforcement and the adjustment of appliances.

Outcomes

The primary outcome was overbite improvement. The secondary outcome was the tooth position in the different treatment modality groups.

Orthodontic records were taken for each patient at baseline (T1) and after 12 months (T2) of treatment. Cephalometric data were obtained from lateral cephalograms traced by one author using Dolphin Imaging Systems 11.7 (Chatsworth, Calif). A second author

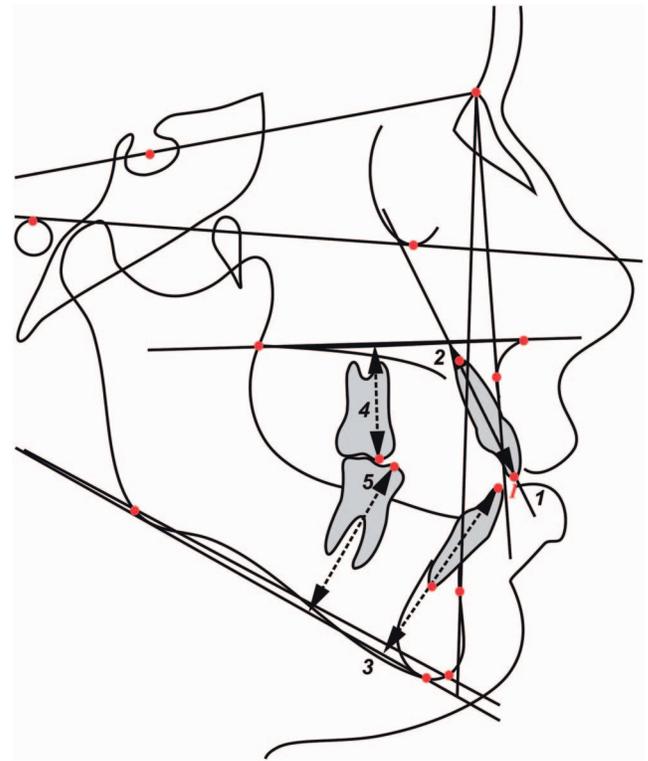


Figure 3. Less usual cephalometric variables. 1, overbite (distance between the incisal edges of the maxillary and mandibular central incisors, perpendicular to the occlusal plane); 2, U1-PP (perpendicular distance between the tip of maxillary central incisor and the palatal plane); 3, L1-GoMe (perpendicular distance from the tip of mandibular incisor to the GoMe line); 4, U6-PP (perpendicular distance from the maxillary first molar mesial point to the palatal plane); 5, L6-GoMe (perpendicular distance from the mandibular first molar mesial point to the GoMe line).

analyzed the landmarks (Figures 2 and 3) for agreement.

Sample Size

The sample size was calculated based on an α of 5% and a power of 80% to detect an overbite mean difference of 1.75 mm among the groups with a standard deviation of 1.69 mm.⁷ A total of 16 patients were needed in each group. The sample size for this study comprised 99 patients to compensate for potential dropouts.

Randomization

Simple randomization¹⁹ was computer generated by a software program (Excel 2007, Microsoft Windows, Microsoft, Chicago, IL, USA) in a 1:1 ratio by someone not involved in the study. Another person not involved in the study placed randomization codes in consecutively numbered, sealed, and opaque envelopes, ensuring concealed allocation into four groups. Participants were enrolled in the study and allocated to

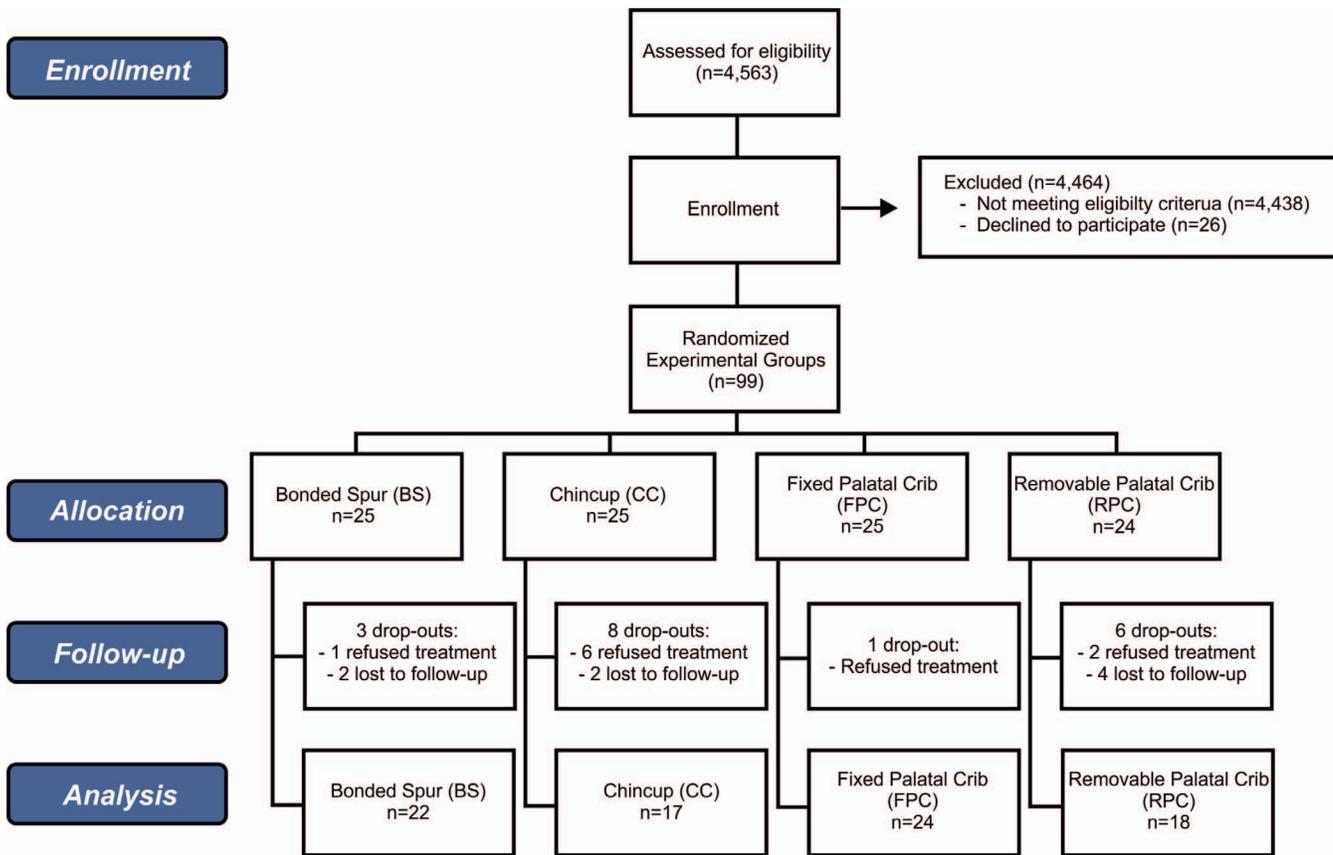


Figure 4. Consolidate Standards of Reporting Trials (CONSORT) diagram showing the flow of patients through the trial.

groups by an external researcher. This study was a single-blind RCT because both researchers were blinded during the cephalometric analyses (T1 and T2). There was no blinding during the treatment process.

Statistical Methods

Data distribution was analyzed by the Shapiro-Wilk normality test, described by means and standard deviation. The T1 and T2–T1 per-protocol comparisons among the groups were performed by one-way analysis of variance (ANOVA) with Tukey’s post hoc test. The χ^2 test was used to compare the ratio of genders among the groups.

Reliability was assessed by randomly selecting 25 patients and performing cephalometric measurements repeated after 30 days. The results were analyzed by using the intraclass correlation coefficient and the Bland-Altman agreement test according to the criteria described by Fleiss.²⁰

Statistical analysis was performed using IBM SPSS Statistics 18.0 software for Windows, New York, NY, USA and GraphPad Prism 5.0, GraphPad Software Inc, San Diego, USA. A confidence interval of 95% and

significance level of 5% ($P < .05$) was established for all the tests applied.

RESULTS

Participant Flow and Recruitment

Figure 4 presents the flow diagram of patients evaluated for enrollment in the study, randomization, and treatment allocation. Eligible participants were recruited from April 2012 to June 2012. A total of 125 participants met the inclusion criteria and were eligible for AOB treatment, although only 99 showed interest in receiving the treatment. Orthodontic records were taken in July 2012 (T1). The participants came to the clinic after randomization (baseline) to install devices and receive instructions in August 2012. Thereafter, they returned monthly for follow-up during a period of 12 months. Final orthodontic records were taken promptly after removal of devices in August 2013 (T2).

Baseline Data

Participants showed compatibility regarding initial variables (Tables 1 and 2). The final sample comprised

Table 1. Baseline (T1) Intergroup Comparisons for Age and Sex Ratio (χ^2 and Analysis of Variance Tests)^a

Variable	BS, n = 22	CC, n = 17	FPC, n = 24	RPC, n = 18	P
Gender; n (%)					
Boys	9 (40.9)	4 (23.5)	6 (25)	10 (55.6)	.1306 ^b
Girls	13 (59.1)	13 (76.5)	18 (75)	8 (44.4)	
Initial age					
Mean \pm SD	8.50 \pm 0.68	8.43 \pm 1.06	8.42 \pm 0.87	8.36 \pm 0.80	.9624 ^c

^a BS indicates bonded spurs; CC, chin cup; FPC, fixed palatal crib; RPC, removable palatal crib; SD, standard deviation.

^b $\chi^2 = 5.638$.

^c Analysis of variance.

81 patients with a mean age of 8.4 \pm 0.8 years and a mean AOB of 3.7 mm.

Outcome Data

AOB decreased by 3.1 mm on average to 0.6 mm after the follow-up period (Tables 2 and 3). The ANOVA of treatment changes (T2–T1) showed significant differences for the following dental variables: 1.1, 1-PP, 6-PP, IMPA, 1.NB, and 1-GoMe (Table 3). There were no statistically significant intergroup differences for overbite (Table 3) or for the following skeletal variables: SNA, SNB, ANB, FMA, and SN-GoGn.

Regarding intragroup results, the BS group showed a reduction in the initial open bite from –4.03 mm (Table 2) to –0.94 mm, with greater extrusion of the maxillary (1.50 mm) than the mandibular incisors (1.25 mm). There was an improvement in the interincisal relationship due to palatal inclination of the maxillary incisors (Table 3). The CC group exhibited a reduction in the initial open bite from –3.88 mm (Table 2) to –1.62 mm, with greater extrusion of the mandibular (1.25 mm) than the maxillary incisors (1.02 mm), but there was no restriction of the normal molar extrusion movement (0.7 mm). There was an improvement in

the interincisal relationship, resulting from a palatal inclination of the maxillary incisors and lingual inclination of the mandibular incisors (Table 3). The FPC group showed a correction of the initial open bite from –3.31 mm (Table 2) to 0.29 mm, with both maxillary (2.1 mm) and mandibular (2.05 mm) incisor extrusion. Only this group exhibited a positive mean overbite (0.29 mm), but it also had the smallest mean open bite at the beginning of treatment (3.31 mm), with no significant difference in this variable among the groups. There was no restriction of the normal extrusion movement of the maxillary (1.08 mm) or mandibular (0.47 mm) molars. However, there was an improvement in the interincisal relationship resulting from palatal inclination of the maxillary, and lingual inclination of the mandibular, incisors (Table 3). The RPC group showed a reduction in the initial open bite from –3.66 mm (Table 2) to –0.34 mm, with more extrusive movement of the mandibular (1.94 mm) than the maxillary (1.64 mm) incisors. There was no restriction of the normal extrusion movement of the maxillary molars (0.68 mm), but there was an improvement in the interincisal relationship, resulting from palatal inclination of the maxillary incisors (Table 3).

Table 2. Baseline Cephalometric Variables (T1): Descriptive Analysis, Mean (M), Standard Deviation (SD), and Analysis of Variance (P)^a

Variable	BS, n = 22		CC, n = 17		FPC, n = 24		RPC, n = 18		P
	M	SD	M	SD	M	SD	M	SD	
Overbite (mm)	–4.03	1.89	–3.88	2.01	–3.31	1.52	–3.66	1.80	.5637
SNA (°)	82.48	4.26	84.08	2.85	82.94	3.62	82.71	3.69	.5730
SNB (°)	78.01	3.39	78.98	3.04	77.67	3.29	76.89	3.18	.2951
ANB (°)	4.46	1.60	5.11	1.90	5.25	1.76	5.82	2.02	.1316
FMA (°)	28.30	3.99	28.85	5.22	28.92	4.91	29.81	4.08	.7819
SN-GoGn (°)	35.54	4.33	36.21	4.45	36.00	5.75	36.42	3.99	.9433
Interincisal (1.1) (°)	114.85	8.86	114.72	9.28	117.47	7.48	114.72	8.60	.6412
1.NA (°)	28.62	5.42	26.33	4.17	25.48	2.96	27.49	5.42	.1168
1-PP (°)	117.09	5.77	116.49	5.36	114.26	4.02	116.02	5.74	.2975
1-NA (mm)	4.85	2.15	4.11	1.12	3.85	1.16	4.08	1.86	.2097
1-PP (mm)	22.18	2.00	22.57	2.35	22.95	2.70	22.92	2.23	.6808
6-PP (mm)	16.19	1.67	16.86	1.11	16.00	1.74	16.30	1.63	.3747
IMPA (°)	95.69	6.18	95.76	5.78	95.23	6.44	95.82	5.80	.9877
1.NB (°)	32.05	5.26	33.84	6.58	31.79	5.98	31.96	5.58	.6950
1-NB (mm)	5.60	1.72	6.64	2.12	5.79	2.18	6.09	1.80	.3979
1-GoMe (mm)	33.92	2.30	34.52	1.99	34.07	2.67	34.39	2.36	.8473
6-GoMe (mm)	26.25	1.61	26.15	1.63	26.63	2.06	26.38	1.61	.8374

^a BS indicates bonded spurs; CC, chin cup; FPC, fixed palatal crib; RPC, removable palatal crib.

Table 3. Intergroup Comparison of Changes After Treatment (T2–T1): Mean (M), Standard Deviation (SD), ANOVA (*P*), and Tukey Post Hoc Test^a

Variable	BS, n = 22		CC, n = 17		FPC, n = 24		RPC, n = 18		95% CI	<i>P</i> ANOVA
	M	SD	M	SD	M	SD	M	SD		
Overbite (mm)	3.09	1.74	2.26	1.85	3.60	1.83	3.32	2.06	2.655, 3.474	.152
SNA (°)	-0.64	0.98	-0.57	1.24	-0.64	1.28	-0.77	1.67	-0.946, -0.362	.975
SNB (°)	0.18	1.10	0.00	0.83	-0.01	1.26	0.01	1.57	-0.230, 0.318	.947
ANB (°)	-0.82	0.84	-0.59	0.88	-0.62	1.02	-0.78	0.99	-0.912, -0.491	.828
FMA (°)	-0.16	1.29	0.11	3.10	-0.13	3.44	0.58	1.70	-0.440, 0.654	.791
SN-GoGn (°)	-0.53	1.49	-0.48	1.47	0.09	1.82	0.12	2.55	-0.620, 0.220	.541
Interincisal (1.1) (°)	3.34 ^A	7.32	4.25 ^{AC}	5.71	9.65 ^B	6.59	7.01 ^{BC}	9.47	4.486, 7.557	.024*
1-NA (°)	-1.18	4.74	-1.82	3.48	-3.43	4.74	-4.20	6.09	-3.723, -1.582	.183
1-PP (°)	-2.26	4.43	-2.16	3.58	-4.25	4.98	-4.13	5.73	-4.227, -2.140	.326
1-NA (mm)	0.52	1.47	0.23	1.41	0.26	1.79	-0.27	1.80	-0.171, 0.540	.498
1-PP (mm)	1.50 ^{AB}	1.00	1.02 ^A	1.27	2.10 ^B	1.08	1.64 ^{AB}	0.96	1.334, 1.794	.020*
6-PP (mm)	0.25 ^A	1.15	0.70 ^{AB}	0.83	1.08 ^B	0.91	0.68 ^{AB}	0.91	0.473, 0.892	.046*
IMPA (°)	-0.91 ^A	4.71	-1.25 ^A	3.76	-5.52 ^B	3.93	-2.00 ^A	5.13	-3.323, -1.503	.002*
1-NB (°)	-1.34 ^A	4.69	-1.85 ^A	3.23	-5.58 ^B	3.95	-2.02 ^A	5.15	-3.527, -1.808	.005*
1-NB (mm)	-0.01	0.79	-0.24	0.85	-0.73	1.08	-0.09	1.28	-0.481, -0.039	.082
1-GoMe (mm)	1.25	1.05	1.25	1.27	2.05	1.18	1.94	0.80	1.378, 1.867	.027*
6-GoMe (mm)	0.00	1.22	0.49	1.44	0.47	1.09	0.35	0.97	0.061, 0.587	.499

^a ANOVA indicates analysis of variance; BS, bonded spurs; CC, chin cup; FPC, fixed palatal crib; RPC, removable palatal crib; CI, confidence interval. Different uppercase letters show significant differences among the groups (Tukey).

* Significant at $P < .05$.

The reliability of measurement was considered excellent. Intraclass correlation coefficient for the cephalometric measurements ranged from 0.89 to 0.98 for angular variables (ANB and SNB) and from 0.79 to 0.99 for linear variables (overbite and 1-NA). The Bland-Altman analysis showed low degrees of bias for most repeated measurements with the Pearson correlation coefficient ranging from 0.90 (6-PP) to 0.99 (1-PP) and the confidence intervals ranging from -0.19 (SNA) to 2.73 (1.1) for the smallest limit, and 0.71 (1-NB) to 8.07 (1.1) for the greatest limit.

Harm Data

No serious harm was observed. All of the groups presented occurrences during the experimental period, such as loss of removable appliances, breakage of fixed and removable appliances, BS debonding, and other minor problems. It is important to emphasize that none of the damage affected the performance of the appliances because the patients were instructed to inform attendants immediately about the need for appliance repair.

DISCUSSION

Randomized clinical trials are preplanned experiments that aim at assessing the effects or benefits of treatment in humans and produce valid and precise estimates of treatment effects.²¹ Few controlled, randomized clinical trials have assessed the treatment outcomes of AOB.^{16,17} This study conformed to the Consolidate Standards of Reporting Trials (CON-

SORT) statement²² to obtain reliable evidence in determining the best treatment approach. Several authors have emphasized that AOB should be treated early in the mixed dentition.^{2,5-7,23} In the present study, the initial mean age of treated patients was 8.4 years, similar to that of other studies.^{7-10,24}

The interventions were performed in a quiescent period of growth (intertransitional period), thus allowing the use of fixed or removable devices without affecting the individual.⁵ Dentoalveolar changes in the anterior region are factors that often lead to AOB reduction.²⁵ In the present study, all of the groups showed dentoalveolar changes that contributed to reducing AOB. However, when comparing the intergroup T2–T1 differences, only six dental variables showed a statistically significant difference resulting from the various effects rendered by the different devices. The greatest impact was on the incisor position produced by the FPC.

The mean AOB reduction was 3.1 mm, similar to that described by Cozza et al.¹⁰ (3.6 mm). However, even after 12 months, this vertical correction led to a positive overlap in only 47% of the participants, in agreement with the results of Torres et al.⁸ and Leite et al.¹² Presumably, the results of this study can be attributed to the shorter treatment time and greater severity of AOB at the beginning of the treatment (-3.72 mm) compared to the studies by Cozza et al.¹⁰ (-2.5 mm) and Leite et al.¹² (-2.17 mm). Nevertheless, even though complete correction of negative overbite was not attained, the improvements were greater than the mean spontaneous AOB reduction observed in the

untreated control groups in Erbay et al.²⁴ (1.4 mm), Cozza et al.¹⁰ (0.8 mm), Torres et al.⁸ (1.9 mm), Pedrin et al.⁹ (1.38 mm), Cassis et al.⁷ (1.38 mm), and Leite et al.¹² (2.33 mm).

All of the study groups exhibited improvement in the interincisal ratio (1.1), although to different degrees, with the groups treated with FPC and RPC showing the greatest changes (Table 3). These findings are in agreement with those of Pedrin et al.,⁹ indicating that the axial inclination changes may be attributed to the labial archwire of the RPC. Although this archwire was left passive in the present study, it could have had a role in improving the palatal inclination of the maxillary incisors achieved because of the design. The change in the inclination of the mandibular incisors was found to be significantly different among the groups, where the FPC group showed better correction of the 1.NB variable when compared with the other groups.

In this study, vertical dentoalveolar development of the mandibular molars (6-PP) showed a significant intergroup difference. The molars in the CC, FPC, and RPC groups exhibited extrusion. This result was similar to that shown by Pedrin et al.,⁹ where participants were treated with a RPC combined with a vertical CC. However, the current findings for the BS group were similar to those of the untreated control group in the Pedrin et al.⁹ study. These findings reinforce the results obtained by Cassis et al.,⁷ namely, that the CC was not effective for vertical control. However, it should be considered that the short, 1-year period of use may not have been long enough for this device to produce the desired effect.

Limitations

One limitation of this study was the lack of an untreated control group, a problem observed in several other studies.¹⁶ In such studies, it may not be ethical to have the control group go untreated, a situation in which participants would be exposed to needless radiation and kept for a year without treatment despite their need for immediate intervention.²¹ In addition, the short-term follow-up period and the absence of blinding for participants and operators were limitations of this study. However, although the latter factor is an inherent issue in this kind of study, it is very unlikely that this source of bias could have influenced the results.

The possible failure in AOB reduction in some patients could be attributed to persistent sucking habits, anterior tongue thrusting, or posture. Despite efforts made to resolve habits and secure patient cooperation, such issues may be inherent to each individual and were beyond control.⁸ Two of the devices used in this study were removable (CC and

RPC) and thus completely dependent on patient cooperation, whereas two others were fixed (BS and FPC), thus facilitating the correction of the malocclusion. Although the BS were fixed, there were recurrent debonded attachments in this group, a factor that should be considered at the time of appliance selection.¹⁴

It is also important to emphasize that the current study included only class I open-bite patients. Future investigations including other malocclusions such as posterior crossbites, crowding, angle class II, and class III malocclusions could produce different clinical results.

Interpretation

It is up to the professional to consider respective cost-benefit ratios and indicate what device should be used to achieve the best results for individual patients. In this regard, either fixed or removable devices may be used, and each device has its own advantages and disadvantages. Therefore, if removable devices are chosen, a RPC could be appropriate. If the patient is not compliant or if a fixed appliance is the best choice, the choice between a FPC and a BS should be based on the steps required for execution. The FPC requires procedures such as band adaptation, impressions, laboratory steps, and clinical mounting, whereas installing a BS requires only simple clinical procedures. The CC can be used in conjunction with any of the devices mentioned to provide a combined treatment effect.¹¹

In light of the current findings, further investigations are needed to evaluate the results of longer treatment durations and treatment stability. An analysis of the cost and side effects of the various interventions would also be beneficial.²⁶

CONCLUSIONS

- All of the tested treatment protocols (BS, CC, FPC, and RPC) were effective in reducing AOB in 97.5% of the class I children, although they resulted in positive overbite in only 47% of the participants after 12 months. AOB reduction occurred as a result of dentoalveolar changes especially in the anterior region, with incisor extrusion and correction of the incisor inclination, which contributed to a mean increase of 3.1 mm in overbite.
- FPC produced the greatest impact on incisor position and was a good choice for early AOB correction.

ACKNOWLEDGMENTS

Supported by Fundação Nacional de Desenvolvimento do Ensino Superior Particular (FUNADESP) (process no. 2009/

17622-9). This trial has not been registered. The protocol was not published before trial commencement.

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