Oral health–related quality of life of children before, during, and after anterior open bite correction: A single-blinded randomized controlled trial

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Introduction: One of the goals of malocclusion treatment is to improve the oral health–related quality of life (OHRQoL) of patients. The aim of this trial was to assess the OHRQoL of children before, during, and after anterior open bite (AOB) correction, compared with nontreated children, in a 2-arm parallel single-blind randomized controlled trial. **Methods:** Eighty children with AOB aged 8-10 years were randomly assigned to 2 groups (n = 40 each): a group treated with the use of fixed palatal crib (FPC; TG) and a control group (nontreated; CG). Randomization was performed with the use of BioEstat software. The outcome (OHRQoL) was assessed with the use of the validated Brazilian Portuguese version of the Child Perceptions Questionnaire (CPQ_{8-10}) applied before (baseline, phase 1), 3 months after FPC placement (phase 2), and 1 month after FPC removal (phase 3) in the TG. In the CG, CPQ_{8-10} was applied at baseline (phase 1), 3 months (phase 2), and 12 months (phase 3). Data were analyzed by means of a blinded statistic with the use of Friedman, Wilcoxon, and Mann-Whitney tests ($\alpha = 0.05$). **Results:** All participants finished the RCT, and demographic characteristics were similar between groups. In phase 1, the TG had lower scores for the "social well-being" domain ($P = 0.02$). In phase 2, the CG had higher scores than the TG for the "emotional well-being" and "social well-being" domains, but the opposite was observed for "oral symptoms" and "functional limitations" ($P < 0.001$). In phase 3, the TG showed a lower impact on OHRQoL than the CG in all domains and in the overall score ($P < 0.001$). In the 3 phases, the CG showed progressive increase (mean scores 70.37, 74.70, and 84.22, respectively; $P < 0.001$) and the TG a decrease (mean scores 70.20, 70.80, and 6.05, respectively; $P < 0.001$) in overall scores. The increase of scores in the CG was considered to represent a serious harm. **Conclusions:** Correction of AOB had a positive impact and failure to correct it had a negative impact on the OHRQoL of children. **Registration:** This trial was not registered. **Protocol:** The protocol was not published before trial commencement. (Am J Orthod Dentofacial Orthop 2019;156:303-11)

Oral health–related quality of life (OHRQoL) is related to the impact that oral health or disease has on activities of daily life and on general well-being, including physical, psychologic, and social aspects.[1] Malocclusion is a highly prevalent public health problem,[2,3] and many studies have shown its negative correlation with OHRQoL in patients of all ages.[4-7] Crowding, anterior crossbite, concave profile, and Angle Class III malocclusion are the major malocclusions associated with negative impacts on OHRQoL.[8]

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Assessment of quality of life, however, is a dynamic phenomenon, in which individuals modify their perceptions owing to changes that influence their physical and emotional development,[9] and malocclusion treatment is involved in this process.[8,10] Orthodontic treatment improves functional and esthetic aspects[8] and could affect how people perceive themselves and are perceived by society,[11] with a direct impact on their quality of life.[8]

Physical and psychosocial changes during childhood contribute to molding children's understanding. Around the age of 8 years, children begin to develop their self-perception of the appearance of their teeth and worry about what other people think about them, which eventually affects their self-esteem.[12] A recent systematic review showed that orthodontic treatment during childhood or adolescence moderately improves the emotional and social well-being domains of OHRQoL; however, this issue should be further investigated by studies of high methodologic quality, given that all of the studies included in the systematic review were observational, thus restricting the interpretation of their results.[5]

Among mixed dentition malocclusions, the prevalence of anterior open bite (AOB) could reach 46% and it is often associated with nonnutritive sucking habits.[13] It is widely known that AOB has a negative impact on children's OHRQoL,[6] but there is a paucity of studies on the impact of treatment of this malocclusion on the OHRQoL of pediatric patients.

Specific objectives or hypotheses

This study was designed to investigate children's OHRQoL before, during, and after AOB correction, compared with nontreated children, with the use of a single-blind randomized controlled trial (RCT) study design. The objective of this study was to compare AOB treatment and nontreatment in measurements of the patients' self-perceived OHRQoL.

METHODS

Trial design and any changes after trial commencement

The study was conducted as a prospective, parallel-group, randomized 2-arm parallel, single-blinded, nontreated-controlled clinical trial with a 1:1 allocation ratio. No changes to the study design were made after commencement.

This study followed the Consolidated Standards of Reporting Trials guidelines[14] and was revised and approved by the Research Ethics Committee of Universidade Estadual do Sudoeste da Bahia. At the beginning of the study, all parents and patients were asked to sign the free consent form and the patient information sheet, respectively, in full compliance with the Declaration of Helsinki.

Participants, eligibility criteria, and settings

Eighty children were recruited from the orthodontics clinic at Southwest Bahia State University, Jequié, Bahia, Brazil, from March 2014 to November 2017. Children aged 8-10 years with AOB caused by nonnutritive sucking, whose 4 incisors and upper first molars had already erupted, and who agreed to answer the questionnaire were eligible for the study. Patients with structural dental changes, missing anterior permanent teeth because of trauma, cleft lip or palate, as well as syndromic patients and patients who were uncooperative during treatment were excluded from the study.

The diagnosis of AOB was performed by measuring the open bite directly in the study model, determining the distance between the incisal edges of the superior incisor to the incisal edge of the inferior incisor.

Interventions

The patients' orthodontic records were analyzed and the sample was randomly split into 2 groups. In the group treated with fixed palatal crib (FPC; n = 40), the permanent first molars were banded and the bands were transferred to plaster molds, where a palatal arch and the FPC (5 cribs extending up to the incisal edge of lower incisors) were manufactured with 0.7-mm and 0.9-mm steel wires, respectively. The passive adaptation of the appliance was checked and the bands were cemented with the use of glass ionomer cement. The control group (n = 40) was not treated.

Patients in both groups were informed about the importance to give up the nonnutritive sucking habit and to have regular dental appointments to reinforce the recommendation for disrupting the habit, monitor the progress of treatment, underscore the importance of oral hygiene, and answer the questionnaire.

For ethical reasons, the control group was treated after 12 months of follow-up, regardless of the length of treatment necessary for the FPC group.

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

The primary outcome was OHRQoL. OHRQoL questionnaire (Child Perceptions Questionnaire for 8–10-year-olds [CPQ_{8-10}]) assesses quality of life in 4 domains: oral symptoms, functional limitations, emotional well-being, and social well-being. In addition to these 4 domains, the questionnaire contains questions on children's overall perception of their oral health and well-being (general well-being).

The CPQ_{8-10} validated for Brazilian Portuguese[15] was applied before orthodontic treatment (baseline), 3 months after FPC placement (phase 2, during the use of FPC), and 1 month after FPC removal (phase 3, after orthodontic correction of AOB) in the treated group, and at baseline (phase 1), 3 months (phase 2), and 12 months (phase 3) in the control group to detect possible changes in the scores over time, allowing us to assess how AOB treatment may influence children's OHRQoL. Patients' answers were scored and tabulated to obtain a frequency scale: score 0, "never"; 1, "once or twice"; 2, "sometimes"; 3, "many times"; and 4, "every day or almost every day." The scores for each domain, general questions, and overall scores were calculated by the sum of individual answers in each questionnaire.

The oral symptoms, functional limitations, and emotional well-being domains have 5 questions each and therefore the score in each of these domains ranges from 0 to 20. The social well-being domain has 10 questions and the score ranges from 0 to 40. Finally, the full CPQ_{8-10} has 25 questions, and scores range from 0 to 100. In all domains, and in the overall score, 0 indicates absence of impact by the oral condition (in this case, AOB) on OHRQoL and, as the score increases, the negative impact of the oral condition on OHRQoL also increases, with 100 indicating the maximum impact on children's OHRQoL.

Aside from 25 questions, CPQ_{8-10} also includes 2 global indicators according to which children assess their oral health and the extent of the effects of their orofacial condition on their general well-being (oral health and general well-being). These 2 indicators, in question format, offer 4 answer choices, with scores from 0 to 3. Zero indicates that the oral condition has no impact on OHRQoL and 3 indicates the maximum impact of the oral condition on OHRQoL.

Demographic data (sex and age) were also collected by the questionnaire.

No changes to the study design were made after commencement.

Sample size calculation

Sample size was calculated in G*Power (version 3.1.9.2) with the use of data from a pilot study that followed the same procedures adopted in the present study. The impact of AOB treatment was adopted as the main outcome of this study and, the sample size was calculated for application of repeated-measures analysis of variance (ANOVA) with the data obtained from the total score obtained in the CPQ_{8-10} of the treated and control groups of the pilot study. The following parameters were used: effect size F = 0.25; α = 0.05 (5% error),-power = 0.90; number of groups = 2; number of measures = 3; correlation between repeated measures = 0.50; and nonsphericity correction = 0.5.

The minimum The sample was estimated to include 60 individuals. Considering the possible use of nonparametric statistics (Friedman test), an addition of 15% was used,[16] which increased the number of individuals to 69. Later, owing to possible losses, another 15% was added, totaling 80 individuals (40 per group).

Interim analyses and stopping guidelines

Not applicable.

Randomization

Randomization was performed by a researcher who did not participate in the study, taking into consideration population size and sample size for each group as well as the treatment used (yes or no). A random numbers table was built in BioEstat 5.0 (Civil Society Mamirauá, Amazonia, Brazil). Confidentiality was ensured by using 80 sequentially numbered brown envelopes containing the groups, following the order of the randomly drawn numbers, totaling 40 envelopes for the control group and 40 envelopes for the treated grouped. This procedure was also carried out by the researcher in charge of the randomization. The envelopes were opaque and the papers with designated group inside the envelopes were folded to prevent holding them to a bright light from revealing the contents. The envelopes were sealed and as the children were included in the study an envelope was used to assign the child to one of the groups. The envelopes were opened sequentially and only after the envelope had been irreversibly assigned to a participant.

Blinding

Blinding of treatment and application of the questionnaire were not possible. However, all data were blindly assessed, thereby endorsing the single-blind design of the study.

Statistical analysis

Descriptive statistics was used and the results were expressed as mean ± SD. Initially, the assumptions about the use of repeated-measures ANOVA, namely, homoscedasticity and normality, were checked. Homoscedasticity was assessed by Levene test and normality was evaluated by Shapiro-Wilk test. Because these assumptions were not accepted, nonparametric statistic

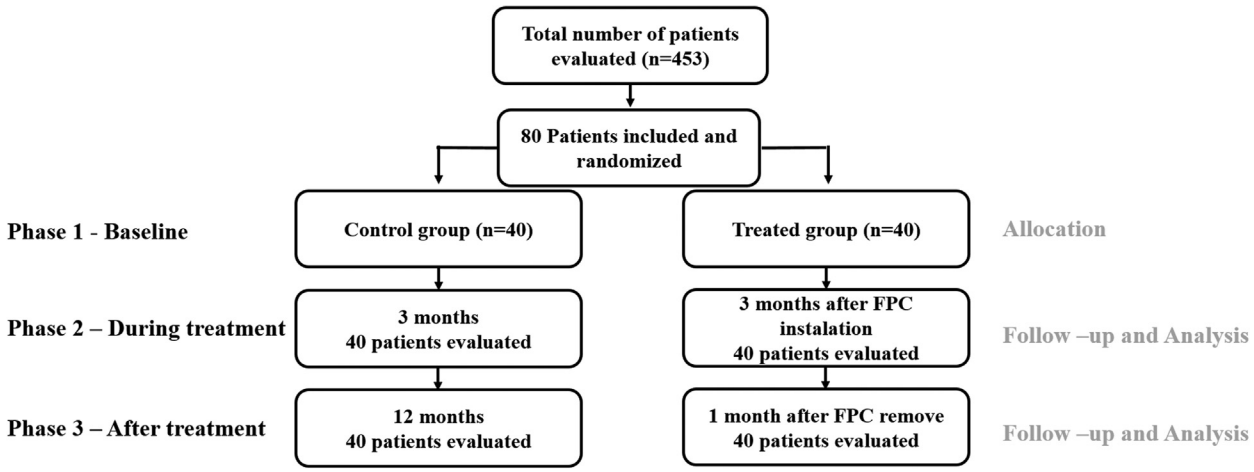

Fig 1. Diagram showing the study design. *FPC*, fixed palatal crib.

tests were used: Friedman test for within-group comparisons, Wilcoxon test for comparisons between pairs, and Mann-Whitney test for between-group comparisons. Effect-size statistics were calculated for changes between the baseline and after AOB correction in the CPQ_{8-10} overall score by dividing the mean of change scores by the SD of the pretreatment scores to give a dimensionless measure of effect. Effect-size statistics of 0.2-0.5 indicate a small clinically meaningful magnitude of change, 0.5-0.8 a moderate change, and >0.8 a large change.[17] The significance level was set at 5% ($\alpha = 0.05$). The data were tabulated and analyzed in IBM SPSS Statistics for Windows (IBM SPSS 21.0, 2012; Armonk, NY).

RESULTS

Participant flow

Eighty out of 453 children were selected and all of them completed the study (Fig 1).

Baseline data

The demographic characteristics of each group at baseline are presented in Table I. Both groups exhibited similar characteristics regarding sex and age. AOB was considered to be severe (4.3 ± 0.26 mm) and the mean duration of treatment of the AOB in the treated group was 13 months.

Numbers analyzed for each outcome, estimation, and precision

Table II presents the effects of the phase of the study (within-group factor) and of treatment (between-group factor) on CPQ_{8-10} scores among children subjected or not to orthodontic treatment for AOB correction.

Table I. Demographic characteristics of the groups in phase 1 (baseline)

	Control group	*Treated group*	
Variable	*n/median (%/IQR)*	*n/median (%/IQR)*	P *value**
Sex, n (%)			1.000
Male	19 (47.5)	19 (47.5)	
Female	21 (52.5)	21 (52.5)	
Age group, n (%)			0.811
8 years	20 (50.0)	19 (47.5)	
9 years	17 (42.5)	16 (40.0)	
10 years	5 (12.5)	5 (12.5)	
Age, y, median (IQR)	8.50 (1.00)	9.00 (1.00)	0.681

IQR, interquartile range.
*Chi-square test (sex), Fisher exact test (age group), and Mann-Whitney test (age).

Between-group comparisons revealed that the control and treated groups had different scores for social well-being at baseline (phase 1), with higher scores for the control group ($P = 0.02$). During the use of FPC (phase 2), the treated and control groups did not differ in general well-being, but the control group showed a stronger negative impact on quality of life (higher scores) in emotional well-being, social well-being, and overall ($P < 0.05$), as well as for oral health; whereas the treated group had a higher negative impact on quality of life (higher scores) in oral symptoms and functional limitations ($P < 0.05$). After orthodontic correction of AOB (phase 3), the treated group showed a smaller negative impact on quality of life (smaller scores) than the control group in all domains, as well as in the overall score and global indicators ($P < 0.001$).

Comparisons of percentage changes within and between groups of the scores obtained separately for

Table II. Mean ± SD and intergroup difference (95% CI) of Child Perceptions Questionnaire 8-10 scores among children before treatment (phase 1), after FPC placement (phase 2), and after AOB correction (phase 3)

	Phase of study			
Variable	*Phase 1—Baseline*	*Phase 2—During FPC treatment*	*Phase 3—After AOB correction*	P *value**
Overall perception indicators				
Oral health				
Control group	2.75 ± 0.44[a]	2.90 ± 0.30[b]	2.98 ± 0.16[b]	0.001
Treated group	2.78 ± 0.48[a]	2.50 ± 0.68[b]	0.30 ± 0.52[c]	<0.001
$\Delta_{control-treated}$ (95% CI)	−0.03 (−0.24 to 0.18)	0.40 (0.16 to 0.64)	2.68 (2.50 to 2.86)	
P value†	0.642	0.002	<0.001	
General well-being				
Control group	2.73 ± 0.45[a]	2.83 ± 0.39[b]	2.93 ± 0.27[c]	0.002
Treated group	2.80 ± 0.41[a]	2.90 ± 0.38[a]	0.25 ± 0.49[b]	<0.001
$\Delta_{control-treated}$ (IC95%)	−0.07 (−0.26 to 0.12)	−0.07 (−0.24 to 0.10)	2.68 (2.50 to 2.86)	
P value†	0.433	0.199	<0.001	
Domains				
Oral symptoms				
Control group	9.45 ± 3.23[a]	10.33 ± 2.31[b]	13.68 ± 2.12[c]	<0.001
Treated group	9.33 ± 3.66[a]	16.80 ± 3.00[b]	1.58 ± 0.81[c]	<0.001
$\Delta_{control-treated}$ (95% CI)	0.12 (−1.44 to 1.68)	−6.47 (−7.68 to −5.26)	15.10 (14.37 to 15.83)	
P value†	0.792	<0.001	<0.001	
Functional limitations				
Control group	16.00 ± 2.56[a]	16.83 ± 1.68[b]	18.40 ± 0.90[c]	<0.001
Treated group	15.80 ± 2.76[a]	17.70 ± 2.49[b]	1.55 ± 0.82[c]	<0.001
$\Delta_{control-treated}$ (95% CI)	0.20 (−1.01 to 1.41)	−0.87 (−1.83 to 0.09)	16.85 (16.46 to 17.24)	
P value†	0.557	<0.001	<0.001	
Emotional well-being				
Control group	16.60 ± 3.24[a]	17.40 ± 2.34[b]	19.33 ± 0.97[c]	<0.001
Treated group	16.65 ± 3.98[a]	11.67 ± 3.05[b]	0.95 ± 1.81[c]	<0.001
$\Delta_{control-treated}$ (95% CI)	−0.05 (−1.69 to 1.59)	5.73 (4.50 to 6.96)	18.39 (17.44 to 19.34)	
P value†	0.207	<0.001	<0.001	
Social well-being				
Control group	28.33 ± 5.44[a]	30.15 ± 3.01[b]	32.83 ± 1.68[c]	<0.001
Treated group	28.43 ± 7.71[a]	24.62 ± 5.16[b]	1.97 ± 1.49[c]	<0.001
$\Delta_{control-treated}$ (95% CI)	−0.10 (−3.12 to 2.92)	5.53 (3.62 to 7.44)	30.86 (30.14 to 31.58)	
P value†	0.020	<0.001	<0.001	
Overall score				
Control group	70.37 ± 13.69[a]	74.70 ± 8.25[b]	84.22 ± 3.89[c]	<0.001
Treated group	70.20 ± 17.48[a]	70.80 ± 10.78[a]	6.05 ± 1.93[b]	<0.001
$\Delta_{control-treated}$ (95% CI)	0.17 (−6.94 to 7.28)	3.90 (−0.45 to 8.25)	78.17 (76.78 to 79.56)	
P value†	0.100	0.002	<0.001	

AOB, anterior open bite; *FPC*, fixed palatal crib.
[a,b,c]Values with the same letters in the row are not statistically different ($P > 0.05$) according to Wilcoxon test.
*Friedman test; †Mann-Whitney test.

each domain, as well as the overall score, are presented in Figure 2 and Table III.

Looking at the change in the mean in CPQ_{8-10} overall score between phase 1 (baseline) and phase 3 (after orthodontic correction), it may be inferred that AOB correction improved the overall perception of OHRQoL by >90% (Δ = −91.4%; effect size = 3.7; effect size description = large), whereas the failure to treat AOB had a negative impact of ∼20% (Δ = 19.7%; effect size = 1.0; effect size description = large) on the outcome.

Harms

The increase of scores in the nontreated control group was considered to indicate a serious harm.

DISCUSSION

Main findings in the context of the existing evidence, interpretation

An association was previously demonstrated in observational studies between treatment of malocclusions and improvement in OHRQoL.[5] However, those findings are

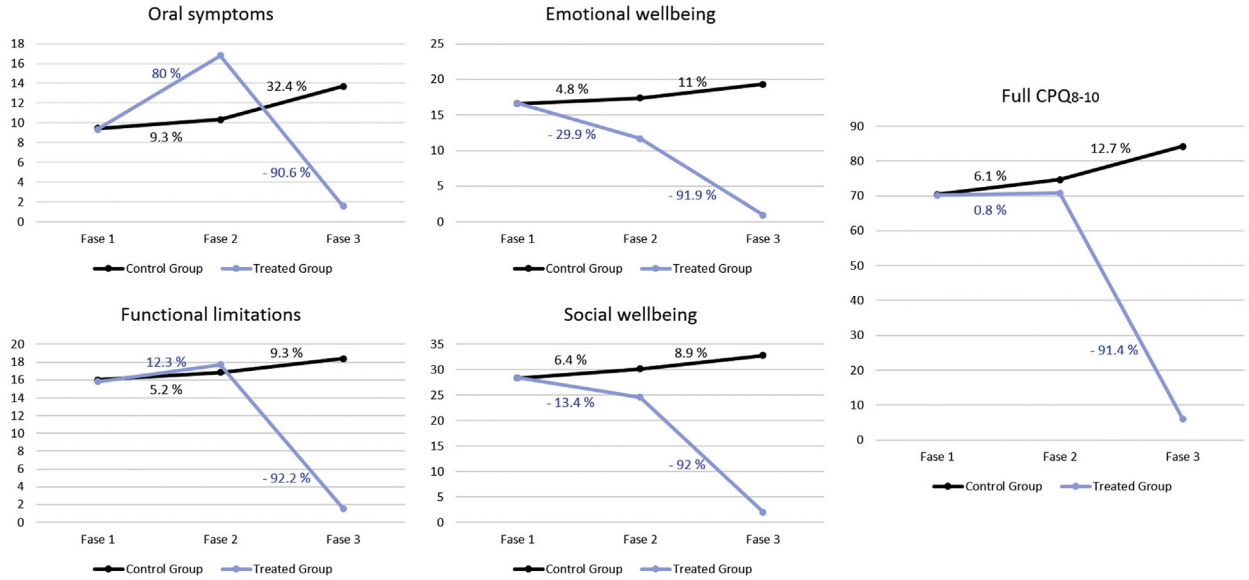

Fig 2. Tendency shown by the scores (change in means) in the 3 phases of the study (before, during, and after AOB correction), related to the CPQ_{8-10} domains and overall score.

limited because orthodontic treatment is an intervention and RCTs are the most suitable means to assess such outcomes. In addition, the information obtained from the first 3 months of orthodontic treatment is clinically relevant, because disturbances, pain, and limitations observed in this period could lead to treatment withdrawal.[18] Therefore, the present RCT assessed the impact of AOB correction with the use of FPC, and the impact of treatment phases, on children's OHRQoL. In general, the treated group had lower scores and less negative impact on OHRQoL after AOB correction, whereas the control group had higher scores and higher negative impact on OHRQoL at the end of the follow-up period.

The oral symptoms and functional limitations domains included questions that associated teeth with spontaneous pain or with cold foods, presence of oral wounds, food debris after meals, bad breath, and difficulty eating, speaking, and sleeping. The treated group showed higher scores and thus deterioration in OHRQoL in these domains after FPC placement (phase 2). This seems to be a logical finding because some pain is described as the major side-effect of orthodontic treatment,[19] along with soft tissue injuries.[20] According to the literature, some patients have had to change their diets to adapt to the pain caused by orthodontic treatment.[21] Mansor et al[21] assessed changes in OHRQoL after placement of fixed appliances and detected remarkable changes

Table III. Δ% and 95% CI of the score comparisons obtained separately for each domain as well as the overall score

	Δ% (95% CI)		
Domain	*Phase 1 – Phase 2*	*Phase 2 – Phase 3*	*Phase 1 – Phase 3*
Oral symptoms			
Control group	9.3	32.4	44.8
Treated group	80.0	−90.6	−83.1
$\Delta_{control-treated}$ (95% CI)	−70.7 (−85.7 to −54.4)	123.0 (94.9 to 150.6)	127.9 (98.7 to 156.6)
Functional limitations			
Control group	5.2	9.3	15.0
Treated group	12.0	−91.2	−90.2
$\Delta_{control-treated}$ (95% CI)	−6.8 (−26.7 to 11.7)	100.5 (77.5 to 123.0)	105.2 (81.4 to 128.8)
Emotional well-being			
Control group	4.8	11.1	16.5
Treated group	−29.9	−91.9	−94.3
$\Delta_{control-treated}$ (95% CI)	34.7 (16.3 to 54.0)	103.0 (79.5 to −126.1)	110.8 (85.5 to 135.7)
Social well-being			
Control group	6,4	8.9	15.9
Treated group	−13.4	−92.0	−93.1
$\Delta_{control-treated}$ (95% CI)	19.8 (1.5 to 38.5)	100.9 (77.8 to 123.5)	109.0 (84.1 to 133.4)
Overall score			
Control group	6.2	12.7	19.7
Treated group	0.9	−91.5	−91.4
$\Delta_{control-treated}$ (95% CI)	5.3 (−11.6 to 21.6)	104.2 (80.4 to 127.6)	111.1 (85.7 to 136.0)

associated with difficulty chewing, halitosis, impaired speech, oral discomfort while eating, ulcer, pain, avoidance of certain foods, oral hygiene difficulties, sleep disorders, and impaired concentration,[22] corroborating the findings of the present study.

After FPC removal, the scores for the previously mentioned domains were lower, demonstrating significant improvement in OHRQoL after treatment in terms of oral symptoms and functional limitations. This finding is related to malocclusion correction, with consequent positive effects on children's masticatory and swallowing functions,[23] as well as probably related to the removal of the orthodontic appliance.[19]

The emotional well-being and social well-being domains include questions that associate teeth with emotions (shame, sadness, worry), self-perception, daily school activities, and bullying. The treated group showed progressive improvement of OHRQoL in these domains and in the overall score in the 3 phases of treatment. These findings are possibly related to an improvement in facial and smile esthetics after orthodontic treatment having a positive impact on the factors assessed in these domains. Previous studies have shown that malocclusion is related to negative effects on self-esteem,[24] to bullying,[25] and to worse psychosocial judgments.[26] Children not affected by malocclusion are considered to be prettier, smarter, more desirable as friends, and less aggressive.[26] Hence, in the present study, AOB correction had a positive impact on emotional and social factors, as well as on quality of life, as previously described by Sheera et al.[27]

There was a progressive increase in the scores of all domains and in the overall score in the 3 phases of treatment in the control group, indicating a stronger negative impact and deterioration of OHRQoL, with no direct intervention (aside from instructions) actually made. This may be related to an attempt to obtain feedback and trying to increase its level of priority at baseline, as suggested by other studies.[28,29] Another possibility could be the realization of symptoms, limitations, and perceptions by the children after the first application of CPQ_{8-10} (phase 1), which had gone unnoticed until then. Thus, in the subsequent phases (phases 2 and 3), the children were "more aware" of the factors they were asked about in the questionnaire, increasing the incidence of answers that indicate higher frequencies. However, this hypothesis could not be confirmed.

The authors of the present study understand the importance of RCTs in gathering scientific evidence, but the findings herein should raise a red flag about the development of studies with untreated control groups. Patients in such groups should be monitored regularly and treated as soon as possible to avoid deterioration in their OHRQoL. The authors of the present study make clear that despite the progressive negative impact on the OHRQoL of children included in the control group, AOB did not increase during the study period. Furthermore, all children in this group were treated immediately after the last evaluation of their OHRQoL, following the same treatment protocol of the treated group.

Using validated and reliable instruments to assess the impact of oral disorders on people's quality of life is of paramount importance, ensuring the reliability of the results. CPQ_{8-10} is a questionnaire that evaluates OHRQoL of children aged 8-10 years in a general fashion, and it was used in this study because of its verifiable psychometric properties and because of its validation in several languages, including Brazilian Portuguese.[15] The questionnaire contains a component targeted at parents that assesses the OHRQoL of children or adolescents (Parental-Caregiver Perceptions Questionnaire [P-CPQ]). That component was not applied in the present RCT, because Abreu et al[29] demonstrated strong agreement between adolescents and their parents or caregivers regarding the classification of the adolescents' OHRQoL with the use of CPQ and P-CPQ during orthodontic treatment.[30] Only the component applicable to children was used in the present study.

Given that quality of life is influenced by many factors besides the presence or treatment of malocclusion,[9] some extra caution was exercised when applying the CPQ_{8-10} in this RCT. The questionnaire was applied 3 months after FPC placement and 1 month after FPC removal. Therefore, there were not long periods between the phases of treatment and the assessment, which could play down the impact of AOB treatment on OHRQoL, as suggested by Palomares et al.[29]

To avoid biases related to questionnaire-based studies, because the results rely on participants' honesty and on the accuracy of their answers, participants in this study were given fully detailed explanations about the scoring system used. Also, the questionnaire was self-administered to avoid obtaining answers by any kind of coercion. In addition, a prior pilot study was carried out with a methodology similar to the one used in the present study to calculate the most appropriate sample size.

The improvements in OHRQoL for the treatment group indicate that treatment of AOB with the use of FPC should be performed as soon as possible during childhood, even considering that the generality and applicability of the findings can be influenced by context, culture, values, and preferences.[31] The comparison of the 2 groups in this RCT shows that not treating this malocclusion is negatively related to OHRQoL. This finding should be taken into account in future studies with nontreated control groups, where the OHRQoL

should be evaluated during the course of these studies along with the primary outcomes.

Generalizability

Because of the selection of participants from a single state-run university located in southwest Bahia, a state in northeastern Brazil, and the small age range used, the results cannot be generalized to other regions and age ranges. Prospective clinical trials with other populations should be conducted to make valid generalizations.

Limitations

One limitation of the study was that the facial growth pattern was not used as a factor of eligibility. The craniofacial growth pattern alters the way open bite is treated as well as affect quality of life outcomes.

CONCLUSIONS

AOB treatment of children aged 8-10 years had a positive impact on their OHRQoL, whereas the failure to treat this condition had a negative impact. Orthodontists and pediatric dentists play a key role in properly diagnosing and treating AOB early in the years of growth and development to improve the quality of life of the affected children.

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