

EARLY ORTHODONTIC APPLIANCE ACCEPTANCE IN CHILDREN WITH ANTERIOR OPEN BITE: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Objective: To compare patient acceptance between fixed palatal cribs and bonded spurs in the early treatment of anterior open bite.

Methods: A total of 30 children aged 6 to 11 years with anterior open bite (≥ 1 mm) were enrolled in this randomized clinical trial. Participants were equally assigned to one of two treatment groups: fixed palatal crib ($n = 15$) or bonded spurs ($n = 15$). Patient acceptance was assessed through a questionnaire after one month of appliance use. For categorical data analysis, Fisher's exact test was applied, while continuous variables were analyzed using independent t-tests to compare the groups.

Results: Speech adaptation was significantly higher in the bonded spurs group (93.3%) compared to the fixed palatal crib group (40.0%) ($p < 0.01$). Adaptation time was also significantly shorter with bonded spurs, as 66.7% of patients adjusted within two days, whereas only 6.7% of the crib group achieved this adaptation within the same period ($p < 0.001$). While patient acceptance was higher for bonded spurs in terms of speech adaptation and quicker adjustment and eating comfort, aesthetics, or pain tolerance did not reveal any statistically significant variation between the two groups.

Conclusion: This study highlights how appliance design affects patient comfort and adaptation. The differences observed between bonded spurs and fixed palatal cribs suggest that patient comfort should be considered when choosing treatment. Ensuring a good balance between effectiveness and ease of adaptation can help improve patient experience and compliance.

KEYWORDS: Palatal crib, Bonded spurs, Anterior open bite, Patient acceptance.

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INTRODUCTION

Interceptive orthodontics refers to early interventions aimed at reducing the severity of malocclusions and simplifying future treatment¹. Early treatment plays a crucial role in maintaining arch length and promoting proper occlusal development, which may reduce the need for complex orthodontic procedures in later stages². In conditions like anterior open bite, timely intervention is particularly crucial, as addressing underlying etiological factors early can prevent worsening dental and skeletal discrepancies³.

Anterior open bite (AOB) is a multifactorial malocclusion influenced by genetic, skeletal, and environmental factors⁴. Non-nutritive sucking habits (NNSHs), such as thumb-sucking and pacifier use, exert prolonged pressure on the incisors, disrupting normal eruption patterns and leading to AOB¹. Additionally, tongue thrusting and mouth breathing alter tongue posture and maxillary growth, reinforcing the open bite⁵. In contrast, skeletal factors, including cranial base flexure, mandibular growth patterns, and maxillary rotation, often necessitate more complex treatment due to their influence on vertical facial height and occlusal development^{6,7,8}. In Egypt, AOB a prevalence of approximately 20.9% among children, highlighting its widespread occurrence and the importance of understanding its etiological factors to guide preventive strategies⁹.

Management of AOB includes various treatment approaches, ranging from behavioral modification and myofunctional therapy to orthodontic appliances, depending on the severity and underlying condition¹⁰. In cases where NNSHs and tongue thrusting contribute to AOB, fixed appliances such as fixed palatal cribs (FPC) and bonded spurs (BS) are commonly used to aid habit cessation and promote proper occlusal development^{11,12}, as FPC creates a physical barrier that prevents the tongue from exerting pressure on the incisors, promoting sponta-

neous bite closure^{12,13}. However, BS alters tongue positioning by providing proprioceptive feedback, encouraging a more favorable resting posture¹⁴.

The success of orthodontic treatment largely depends on patient acceptance, which plays a crucial role in compliance and overall satisfaction¹⁵. Discomfort and adaptation challenges associated with fixed appliances may affect cooperation and contribute to stress between patients and practitioners^{16,17,18}. While both FPC and BS are commonly used to manage AOB, limited research directly compares their impact on patient experience. This randomized clinical trial aimed to bridge this gap by evaluating adaptation, comfort, and compliance, offering clinically relevant insights to enhance treatment selection.

MATERIALS AND METHODS

Study Design:

The study was conducted as a randomized clinical trial using a parallel-group design with a 1:1 allocation ratio. Participants were randomly assigned to either the fixed palatal crib (FPC) group or the bonded spurs (BS) group.

Participants:

The study included children aged 6 to 11 years with NNSHs and tongue thrusting, presenting with Angle Class I malocclusions and AOB of ≥ 1 mm, along with fully erupted maxillary and mandibular permanent central incisors. Exclusion criteria were children lacking permanent teeth due to trauma, caries, or congenital issues, those with dental crowding, maxillary constriction, posterior crossbite, prior orthodontic treatment, or craniofacial anomalies and syndromes. Data collection took place at the Outpatient Diagnostic Clinic of the Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University, between September 2022 and May 2023.

Participant recruitment spanned from September 2022 to May 2023. Of the 50 individuals initially assessed for eligibility, 20 failed to satisfy the eligibility requirements of the study and, therefore, were not included. The remaining 30 participants were assigned by randomization into two equal groups, with 15 assigned to the FPC group and 15 to the BS group. The intervention and follow-up process continued until May 2024, ensuring all participants completed the designated treatment protocol. The trial protocol was reviewed and approved by the Research Ethics Committee of the Faculty of Dentistry, Cairo University, in accordance with the Declaration of Helsinki. Written informed

consent was obtained from all parents or legal guardians before participation.

Sample size:

The sample size necessary to identify differences between the FPC and BS groups in managing AOB caused by NNSHs was determined through a power analysis. With an alpha level of 0.05, a power of 80%, and an effect size (d) of 1.23 obtained from previous research,¹² The final sample size was set at 30 participants. Each group included 15 participants, ensuring adequate statistical power while accounting for possible dropouts.



Fig. (1) The “I Can” chart and “Nim Nim” character were used to encourage habit cessation in young patients. The “I Can” chart visually tracked progress by marking clear fingers, while “Nim Nim” illustrated the oral health consequences of digit-sucking, including.

Interventions:

The preparatory phase prioritized optimal oral hygiene and caries prevention. Motivational tools were created to visually support habit cessation efforts as illustrated in **Figure 1**. The “I Can” chart used colored markers to track progress, motivating children to achieve “clear fingers,” symbolizing reduced habits. The “Nim Nim” character (Om Nom Cut the Rope Candy Monster, ZeptoLab, Vivid Toys Group Ltd, GU3 1LS, UK) incorporated cartoon illustrations to educate children on the effects of NNSHs in an engaging way.

Bonded spurs (Tongue Tamers®, Ortho Technology, Tampa FL) were positioned on the palatal cervical area of the upper central incisors and the lingual incisal portion of the lower central incisors to minimize occlusal interference and they were bonded using a light-cured adhesive (Transbond™ XT light cure orthodontic adhesive 3M Unitek, St. Paul, MN, USA) following acid etching for optimal retention^{12,14,19}. For the FPC was constructed by adapting bands (Ormco Corporation, Glendora, CA, USA) and soldering a 0.9 mm wire loop to span between the maxillary canines. Orthodontic separators ensured a secure fit before cementation, and glass ionomer cement (Medicime glass ionomer, Promedica Dental Material GmbH, Germany) was used for attachment¹². A clear clinical illustration of the FPC and BS used in the trial is presented in **Figure 2**, enhancing visual understanding of the evaluated appliances.

Outcome:

This trial primarily was assessed patient acceptance, evaluated a month post-appliance insertion by a qualified practitioner through a validated questionnaire²⁰. The questionnaire evaluated speech adaptation, eating difficulty, esthetics, pain, and adaptation time using a 3-point scale (1 = easy, 2 = neutral, 3 = difficult). The time required for patients to adjust to the appliances was also recorded, with response options ranging from ≤ 2 days to > 2 weeks **Figure 3**.

Randomization and blinding:

The randomization process was conducted using www.random.org, using a concealed allocation process with coded opaque envelopes to prevent prior knowledge of group assignments. Blinding was applied to the outcome assessors and the statistician; however, Due to the nature of the interventions, neither the operator nor the patients could be blinded.

Statistical methods:

Data analysis was conducted using SPSS software (version 20, IBM Corp., Armonk, NY, USA). The Kolmogorov-Smirnov and Shapiro-Wilk tests were utilized to verify data normality, confirming a parametric distribution. For categorical data, Fisher's exact test was applied, whereas comparisons between groups were performed using an independent t-test. A significance level of $P < 0.05$ was set for all statistical analyses.



Fig. (2) Illustrative intraoral photographs of the fixed palatal crib (A) and bonded spurs (B) appliances.

1) How has it been adjusting to the appliance in terms of speaking?
☐ Easy ☐ Neutral ☐ Difficult

2) How has it been adjusting to the appliance when eating?
☐ Easy ☐ Neutral ☐ Difficult

3) How has it been adjusting to the appliance aesthetically?
☐ Easy ☐ Neutral ☐ Difficult

4) How has it been adjusting to it in terms of pain?
☐ Easy ☐ Neutral ☐ Difficult

5) How long did it take you to adjust to having the appliance?
☐ Two days or less ☐ One week ☐ Two weeks ☐ Have not adjusted yet

Additional comments? (optional)

Fig. (3) Patient acceptance questionnaire evaluating adaptation in speech, eating, aesthetics, pain, and adjustment time.

RESULTS

Baseline Data

Participants exhibiting NNSHs and tongue thrusting were randomly assigned into two equal groups, with 15 allocated to the FPC group and 15 to the BS group. The sample included an equal gender distribution, consisting of 33.3% males and 66.7% females. The mean age showed no significant difference observed ($P > 0.05$).

Numbers Analysed:

The patient acceptance questionnaire was administered one month after appliance placement to assess adaptation across five domains: speech, eating, aesthetics, pain, and adjustment time. The results revealed significant differences in speech adaptation ($P = 0.01$), with 93.3% of BS patients reporting smooth adaptation, whereas 40.0% of FPC patients experienced minimal difficulty, and 6.7% found it challenging. For eating, most participants in both groups adjusted well, with no significant difference observed ($P > 0.05$). Regarding aesthetics, all patients in both groups reported complete acceptance. Pain adaptation

did not show significant differences ($P > 0.05$), with all FPC patients experiencing no discomfort, whereas 26.7% of BS patients required some adjustment. A highly significant difference was observed in adjustment time ($P < 0.001$), as 66.7% of BS patients adapted within two days, whereas most FPC patients required one to two weeks. The merged response distribution and statistical findings for each question are detailed in (Tables 1–5).

Harms:

Patients in both groups experienced varying levels of adaptation challenges. In the FPC group, initial discomfort was reported due to the appliance's positioning, particularly its contact with the palate, which required a period of adjustment. In the BS group, patients faced difficulties related to appliance stability, as frequent debonding incidents were observed throughout the study. Additionally, maintaining oral hygiene around the appliances was a concern for some patients, which may have influenced their overall acceptance and compliance. Despite these challenges, most patients adapted over time, with differences in ease of adjustment between the two groups.

TABLE (1) Distribution of patient responses regarding speech adaptation and statistical comparison between the two groups.

Response to Q1	FPC (n, %)	BS (n, %)	FPC (Mean $\pm$ SD)	BS (Mean $\pm$ SD)	Fisher exact probability	P- Value
Easy	6 (40.0%)	14 (93.3%)				
Neutral	8 (53.3%)	1 (6.7%)	2.33 $\pm$ 0.72	2.87 $\pm$ 0.35	0.00520	< 0.01*
Difficult	1 (6.7%)	0 (0.0%)				

*: Significant at $P \leq 0.05$. CI indicates confidence interval.

TABLE (2) Distribution of patient responses regarding eating adaptation and statistical comparison between the two groups.

Response to Q2	FPC (n, %)	BS (n, %)	FPC (Mean $\pm$ SD)	BS (Mean $\pm$ SD)	Fisher exact probability	P- Value
Easy	11 (73.3%)	13 (86.7%)				
Neutral	4 (26.7 %)	2 (13.3%)	2.73 $\pm$ 0.46	2.87 $\pm$ 0.35	0.65130	> 0.05
Difficult	0 (0.0%)	0 (0.0%)				

*: Significant at $P \leq 0.05$. CI indicates confidence interval.

TABLE (3) Distribution of patient responses regarding aesthetic adaptation and statistical comparison between the two groups.

Response to Q3	FPC (n, %)	BS (n, %)	FPC (Mean $\pm$ SD)	BS (Mean $\pm$ SD)	Fisher exact probability	P- Value
Easy	15 (100.0%)	15 (100.0%)				
Neutral	0 (0.0%)	0 (0.0%)	3.00 $\pm$ 0.0	3.00 $\pm$ 0.0	1.0	> 0.05
Difficult	0 (0.0%)	0 (0.0%)				

*: Significant at $P \leq 0.05$. CI indicates confidence interval.

TABLE (4) Distribution of patient responses regarding pain adaptation and statistical comparison between the two groups.

Response to Q4	FPC (n, %)	BS (n, %)	FPC (Mean $\pm$ SD)	BS (Mean $\pm$ SD)	Fisher exact probability	P- Value
Easy	15 (100.0%)	11 (73.3%)				
Neutral	0 (0.0%)	4 (26.7%)	3.00 $\pm$ 0.0	3.00 $\pm$ 0.46	0.09960	> 0.05
Difficult	0 (0.0%)	0 (0.0%)				

*: Significant at $P \leq 0.05$. CI indicates confidence interval.

TABLE (5) Distribution of patient responses regarding overall adjustment time and statistical comparison between the two groups.

Response to Q5	FPC (n, %)	BS (n, %)	FPC (Mean $\pm$ SD)	BS (Mean $\pm$ SD)	Fisher exact probability	P- Value
2 Days or Less	1 (6.7%)	10 (66.7%)				
One Week	9(60.0%)	5 (33.5%)	1.80 $\pm$ 0.56	1.33 $\pm$ 0.49	0.00068	< 0.001*
Two Weeks	5 (33.3%)	0 (0.0%)				

*: Significant at $P \leq 0.05$. CI indicates confidence interval.

DISCUSSION

Patient acceptance is a critical factor in orthodontic treatment, as it directly influences patient compliance and the likelihood of successful outcomes ²¹. A systematic review found that common early-treatment appliances, such as BS and palatal cribs (fixed or removable), produce similar improvements in overbite correction ²². The choice between appliances often depends on patient comfort and tolerance rather than efficacy alone, as discomfort or difficulty adapting to an appliance may reduce adherence and ultimately impact treatment success.¹¹ . This trial assessed patient acceptance through a questionnaire evaluating five key domains: speech, eating, aesthetics, pain, and adjustment time, offering one of the few direct comparisons between FPC and BS in a randomised clinical trial.

Previous studies have independently assessed the tolerability of different orthodontic appliances, but direct comparisons between BS and FPC remain limited. McRae ²⁰ , Canuto et al. ¹¹, and Aliaga-Del Castillo et al. ²³ reported quicker adaptation, fewer reported difficulties, and greater comfort among BS users compared to bulkier appliances. Specifically, Canuto et al. ¹¹ noted higher acceptance of BS compared to conventional lingual spurs appliances, particularly in chewing and speech-related adaptation. Similarly, McRae ²⁰ Aliaga-Del Castillo et al. ²³ observed faster adjustment periods and lower discomfort levels among BS users,

reinforcing their preference over more obstructive orthodontic devices.

Conversely, previous research has consistently highlighted greater adaptation challenges with cribs. Iqbal et al. ²⁴ and Pithon et al. ²⁵ highlighted that FPC users faced greater difficulty in speech adaptation, tongue discomfort, and oral hygiene challenges, which aligns with this trial. The observed variations may be linked to the larger size and structural design of FPC, which extends from the roof of the palate to the floor of the mouth, mechanically restricting tongue movement. This restriction prolongs the adjustment period, particularly for speech and eating, whereas BS, being smaller, allows for proprioceptive feedback rather than a rigid blockade. Consequently, the size and design of the appliance significantly influence patient comfort and adaptability. Future studies should examine whether adaptation to BS and FPC remains stable over a longer follow-up period. Additionally, using objective methods to assess patient adaptation rather than relying solely on self-reports could provide more accurate insights. Expanding the sample size and including a wider range of participants would also help confirm these findings.

Limitations:

This trial provides meaningful insight into short-term patient-reported adaptation to FPC and BS. Nevertheless, certain limitations should be acknowledged. First, the reliance on patient and caregiver reports may introduce some degree

of subjectivity, as perceptions of discomfort and adaptation can vary individually. Second, while the questionnaire was intentionally administered one month after appliance insertion to allow for initial adaptation, the use of multiple assessment timepoints (e.g., 3 days, 1 week, and 1 month) in future studies could offer a more detailed understanding of the adaptation process. Third, the limited follow-up period did not permit evaluation of long-term stability or compliance. Lastly, speech adaptation was based on caregiver observation rather than clinical evaluation. Future trials would benefit from incorporating objective assessments by speech-language pathologists to enhance data robustness.

CONCLUSIONS

This study highlights how appliance design affects patient comfort and adaptation. The differences observed between BS and FPC suggest that patient comfort should be considered when choosing treatment. Ensuring a good balance between effectiveness and ease of adaptation can help improve patient experience and compliance.

Other information:

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Trial registration: This study was registered at clinical trial.gov, ID: NCT05313399.

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