

Impact of Child Selected Customization of Twin Block Appliances on Acceptance and Compliance: A Pilot Randomized Clinical Trial

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ABSTRACT

Background: Treatment acceptance and compliance are critical determinants of successful Twin Block therapy. Child-centered customization of removable appliances may enhance treatment engagement; however, evidence regarding its influence on acceptance and compliance remains limited.

Aim: To evaluate the effect of child-selected customization of Twin Block appliances on treatment acceptance and self-reported compliance among children with Class II malocclusion.

Methods: This multicenter, two-arm, parallel pilot randomized clinical trial included 30 children aged 8–12 years presenting with Class II malocclusion requiring Twin Block therapy. Participants were randomly allocated to receive either a conventional Twin Block (n = 15) or a customized Twin Block incorporating child-selected aesthetic features (n = 15). Treatment acceptance was assessed using a validated child-reported questionnaire, while self-reported compliance was evaluated using a single-item Likert scale. Assessments were performed at 1 week, 3 months, and 6 months after appliance delivery.

Results: Children in the customized group demonstrated significantly higher acceptance scores than those in the conventional group at all follow-up periods ($p < 0.001$). Acceptance scores gradually decreased over time in both groups; however, the customized group maintained significantly higher acceptance throughout the study period. Self-reported compliance was significantly higher in the customized group at 1 week ($p = 0.006$), but no significant differences were observed at 3 months ($p = 0.185$) or 6 months.

Conclusions: Child-selected customization of Twin Block appliances significantly improved treatment acceptance and enhanced short-term compliance. Although the effect on compliance diminished over time, customized appliances consistently achieved higher acceptance scores than conventional appliances. Incorporating child-centered customization strategies may improve children's experiences during removable functional orthodontic treatment.

Keywords: *Twin Block; Class II malocclusion; appliance customization; treatment acceptance; compliance; pediatric orthodontics.*

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1. INTRODUCTION

Class II malocclusion is a common orthodontic problem in both children and adolescents and is frequently characterized by mandibular retrusion, increased overjet, and compromised facial esthetics ⁽¹⁾. Early intervention during the mixed dentition stage has been recommended to reduce severity of skeletal discrepancies, improve facial appearance, and reduce the risk of trauma to the anterior region due to protrusion of maxillary incisors ⁽²⁾.

The Twin Block appliance is among the most popular functional appliances for the treatment of Class II in growing children ^(3,4). Its value is owed to its effectiveness, and its capacity to permit normal mandibular function during treatment. However, the success of Twin Block therapy depends largely on patient cooperation and adherence to the prescribed wearing regimen. Inadequate compliance remains a major challenge and may compromise treatment outcomes ⁽⁵⁻⁷⁾.

Children undergoing orthodontic treatment often experience difficulties related to appliance wear, including speech impairment, discomfort, embarrassment, and social concerns. These factors may negatively affect treatment acceptance and reduce motivation to wear the appliance as instructed. Therefore, strategies aimed at improving children's engagement and acceptance of removable orthodontic appliances are of considerable clinical importance ^(8,9).

Recent advances in patient-centered healthcare have emphasized the value of involving children in treatment decisions whenever appropriate. Allowing children to participate in selecting colors, designs, or personalized features of their orthodontic appliances may enhance their sense of ownership and increase motivation toward treatment ^(10,11). Customization of healthcare products has been shown to improve user satisfaction and engagement in various pediatric settings. Nevertheless, limited evidence exists regarding the influence of appliance customization on the acceptance and compliance of children undergoing functional orthodontic treatment.

To date, most studies evaluating removable orthodontic appliances have focused on treatment effectiveness and clinical outcomes ⁽¹²⁻¹⁴⁾, while relatively few have investigated the psychosocial factors that influence children's willingness to wear these appliances ⁽¹⁵⁾. Furthermore, the impact of child-selected customization of Twin Block appliances on treatment acceptance has not been adequately explored.

Therefore, the purpose of the present investigation is to assess the viability and preliminary findings of child-customized Twin Block appliances with respect to acceptance and compliance among children with Class II malocclusion.

2. SUBJECTS AND METHODS

Study Design

This study was designed as a multicenter, two-arm parallel pilot randomized clinical trial to evaluate the effect of child-selected customization of Twin Block appliances on its acceptance and compliance among children with Class II malocclusion. Participants were recruited from several dental clinics in Egypt. All eligible children were screened according to the study selection criteria and enrolled after obtaining informed consent from their parents or guardians.

Children aged 8–12 years with skeletal Class II malocclusion primarily due to mandibular retrusion, requiring Twin Block therapy, and in good general health were eligible for inclusion. Enrollment required that both the child and parent were able to understand study instructions and complete questionnaires. Exclusion criteria comprised a history of previous orthodontic intervention, the presence of maxillofacial anomalies or syndromes, chronic medical conditions, or cases requiring fixed functional appliances. Poor oral hygiene or active untreated dental disease.

Sample Size: this study was designed as a pilot study; a convenience sample of 30 participants were recruited. Fifteen children were allocated to each study group. The primary purpose was to evaluate feasibility, acceptability, and obtain preliminary estimates of effect size for future definitive trials.

Randomization and Allocation: Children who participated in this study were randomly assigned in a 1:1 ratio with the aid of computer-generation randomization. Concealment was achieved by using sequentially numbered opaque black sealed envelopes made by a researcher who wasn't involved in the recruiting or evaluation of participants.

Group 1 (Conventional twin block group): Children received a conventional Twin Block appliance fabricated according to the standard clinical protocol.

Group 2 (Customized twin block group): Children received a customized Twin Block appliance. Prior to appliance fabrication, each child was allowed to select preferred aesthetic features including acrylic color combinations, decorative designs, cartoon characters, sports logos, or personalized name labels incorporated within the appliance according to laboratory feasibility and safety requirements (figure 1).



Figure 1 Examples of customized Twin Block appliances with child-selected aesthetic features.

Appliance Fabrication

All Twin Block appliances were fabricated by the same dental laboratory using the same standardized construction principles and bite registration procedures. The only distinction between groups was the inclusion of child-selected customization features in Group II. Participants and their parents received standardized verbal and written instructions regarding appliance wear, oral hygiene measures, appliance cleaning, and storage.

Treatment and intervention

Complete orthodontic records were obtained for all participants before the start of treatment including clinical, radiographic examination, study casts, intra- and extra-oral photographs. The patients received treatment with a Twin Block appliance fabricated according to the protocol described by Clark et al. (2002) ⁽³⁾. All patients were advised both verbally and in writing to wear the appliance for a minimum of 12 hours daily.

Outcome Measures

Treatment Acceptance and compliance

Treatment acceptance was assessed using a child-reported questionnaire specifically developed for this study based on previously published measures of orthodontic treatment acceptance and patient satisfaction (Figure 2).

The questionnaire consisted of 9 items distributed across different domains such as aesthetic, satisfaction, ownership/personalization, treatment motivation, and overall acceptance. Answers were recorded using a Likert scale with 5 points ranging from 1 (strongly disagree) to 5 (strongly agree), with higher scores indicating greater acceptance of the appliance. Final acceptance score was the total of the scores from the first nine questions, which comprised a score range of 9 to 45. In addition, self-reported compliance was measured using a separate question (the 10th question) which was

aimed to evaluate child's adherence to the prescribed Twin Block wear instructions. Responses were recorded on a five-point scale, with score 5 indicating better compliance and 1 indicating lowest compliance.

The questionnaire items were generated following a review of the literature related to orthodontic treatment acceptance, patient satisfaction, treatment motivation, compliance, and patient-centered care. The first version of the questionnaire was reviewed by a committee of five professors (three pediatric dentists and two orthodontists) to analyze the item's relevance, comprehensibility, and clarity. According to their recommendations, modifications were made to improve the wording and suitability of the questionnaire for children aged 8–12 years. Ten children who met the study's eligibility requirements but weren't part of the final study sample were used for pilot testing to evaluate face validity. Slight changes were made in response to the children's feedback regarding the questionnaire items' comprehensibility and clarity. A five-point Likert scale, with 1 representing "strongly disagree" and 5 representing "strongly agree," was used to record responses.

The questionnaire was designed in English and translated into Arabic using a forward translation approach. The Arabic version was reviewed by the expert panel to ensure semantic equivalence, clarity, and cultural appropriateness for children aged 8–12 years. The translated questionnaire was then pilot tested. The internal consistency of the questionnaire was evaluated using Cronbach's alpha coefficient, which demonstrated good reliability (Cronbach's $\alpha = 0.94$).

The evaluation periods included in this study were: one week after insertion, three months after insertion, and six months after insertion. At each visit, the acceptance questionnaire was administered.

Statistical Analysis: Version 19 of the Statistical Package for Social Sciences (SPSS) program (IBM Corp., Armonk, NY, USA) was used to analyze the data. For every variable, descriptive statistics were computed. Categorical variables were presented as frequencies and percentages, while continuous data were expressed as means and standard deviations. Depending on the distribution of the data, either the independent t-test or the Mann-Whitney U test was used for inter-group comparisons. Repeated measures analysis was used to examine within-group variations over time. The threshold for statistical significance was set at $p < 0.05$.

3. RESULTS

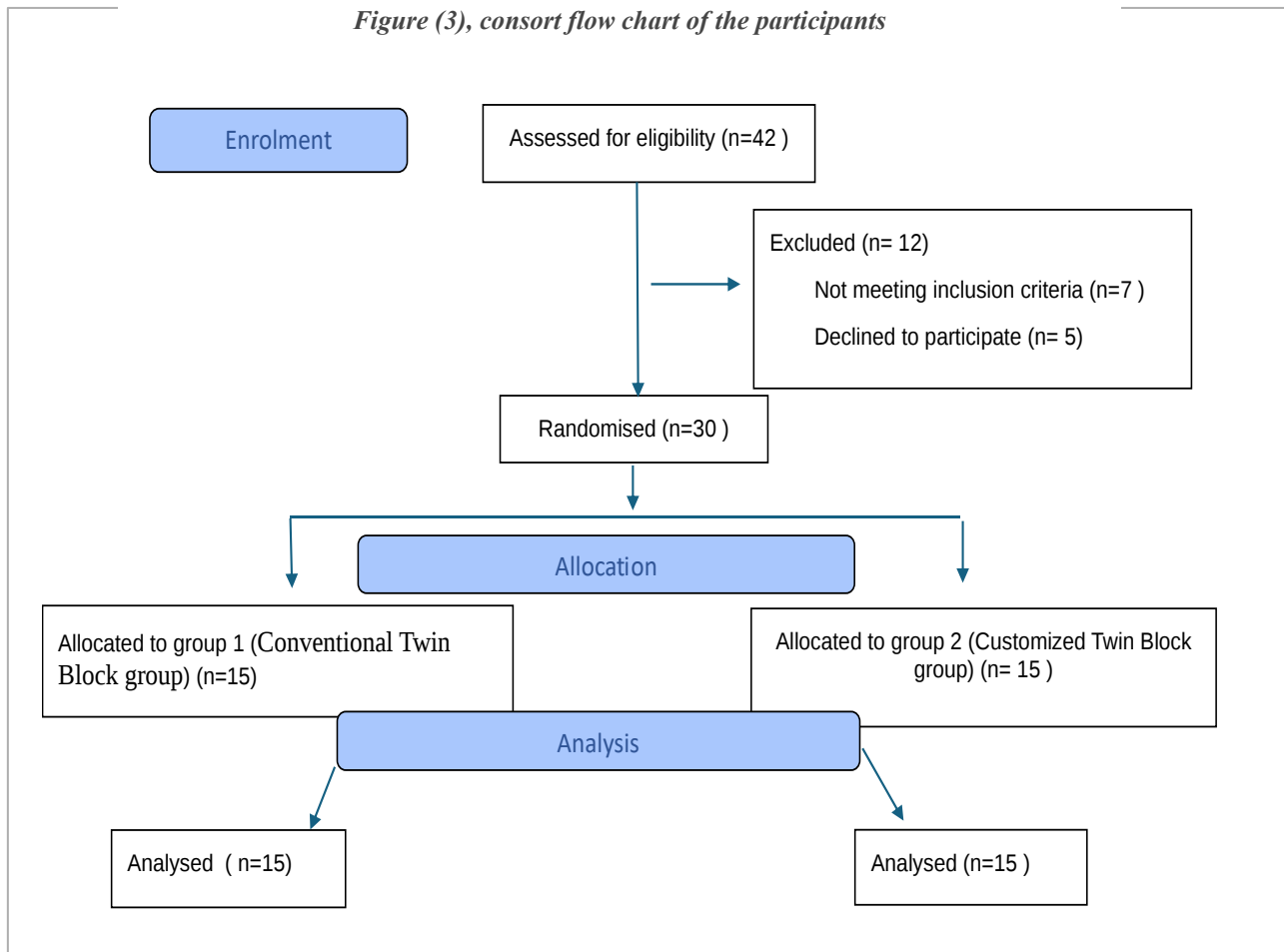
Participant Flow (Figure 3)

Thirty participants out of a total of 42 children were randomly allocated into two groups: the conventional Twin Block group ($n = 15$) and the customized Twin Block group ($n = 15$). All participants completed the study and were included in the final analysis.

Child Acceptance Questionnaire for Customized Twin Block Appliances						
Participant Information						
Participant Code: _____						
Age: _____ years						
Gender: ☐ Male ☐ Female						
Date of Appliance Delivery: ____ / ____ / ____						
Date of Assessment: ____ / ____ / ____						
Instructions						
Dear Child,						
Please read each statement carefully and choose the answer that best describes how you feel about your Twin Block appliance. There are no right or wrong answers. We are interested in your honest opinion.						
Questionnaire Items						
No.	Statement	1	2	3	4	5
1	I like the appearance of my appliance.	☐	☐	☐	☐	☐
2	The design of my appliance looks attractive.	☐	☐	☐	☐	☐
3	I feel that my appliance was made especially for me.	☐	☐	☐	☐	☐
4	The design of my appliance makes me more willing to wear it.	☐	☐	☐	☐	☐
5	The design of my appliance makes me excited about my treatment.	☐	☐	☐	☐	☐
6	I am willing to wear my appliance as instructed by my dentist.	☐	☐	☐	☐	☐
7	I try my best to wear my appliance every day.	☐	☐	☐	☐	☐
8	I would choose the same appliance again.	☐	☐	☐	☐	☐
9	Overall, I am satisfied with my appliance.	☐	☐	☐	☐	☐
Secondary Outcome: Self-Reported Compliance						
No.	Statement	1	2	3	4	5
10	I wear my Twin Block appliance as instructed by my dentist.	☐	☐	☐	☐	☐

Figure 2. the questionnaire used in the study

Figure (3), consort flow chart of the participants



4. BASELINE CHARACTERISTICS

The demographic data and baseline characteristics of the study participants are presented in Table (1). Thirty children were enrolled (n = 15 per group). The mean age was 10.40 ± 1.18 years in the conventional Twin Block group and 10.26 ± 1.22 years in the customized Twin Block group, with no statistically significant difference between the groups ($p > 0.05$). Similarly, gender distribution was comparable between the two groups. The conventional group consisted of 8 males (53.3%) and 7 females (46.7%), whereas the customized group included 7 males (46.7%) and 8 females (53.3%). No statistically significant differences were observed in baseline demographic characteristics, indicating that the two groups were comparable before the intervention.

Table (1). Demographic data and baseline characteristics of the study participants

Characteristic	Conventional Twin Block (n=15)	Customized Twin Block (n=15)	p-value
Age (years), Mean $\pm$ SD	10.40 $\pm$ (1.18)	10.26 $\pm$ (1.22)	> 0.05
Gender, N (%)			
Male	8 (53.3) %	7 (46.7) %	> 0.05
Female	7 (46.7) %	8 (53.3) %	

5. ACCEPTANCE QUESTIONNAIRE RESULTS

After 1-week results

The customized Twin Block group showed a significantly higher acceptance score than the conventional Twin Block group. The median acceptance score was 41 (IQR = 2) in the customized group compared with 23 (IQR = 5) in the conventional group. Mann–Whitney U test revealed a statistically significant difference between the two groups ($U = 0.000$, $Z = -4.688$, $p < 0.001$). (Table 2)

Table (2) Comparison of Total Acceptance Scores Between the Study Groups at week one.

Outcome	Conventional Group Median (IQR)	Customized Group Median (IQR)	p-value
Total Acceptance Score	23 (21–26)	41 (40–42)	<0.001*

After 3 months results

After the 3rd month, children in the customized Twin Block group demonstrated significantly higher acceptance scores than those in the conventional group. The mean acceptance score was 37.87 ± 2.20 in the customized group compared with 24.33 ± 1.99 in the conventional group. Independent samples t-test revealed a statistically significant difference between the two groups ($t = -17.678$, $df = 28$, $p < 0.001$). [Table .3]

Table (3). Comparison of Total Acceptance Scores Between the Study Groups at the 3-Month Follow-up

Variable	Conventional Twin Block Group (n = 15)	Customized Twin Block Group (n = 15)	p-value
Total Acceptance Score (Mean $\pm$ SD)	24.33 ± 1.99	37.87 ± 2.20	<0.001*

*Independent samples t-test; statistically significant at $p < 0.05$.

At 6 months

After 6 months the customized Twin Block group continued to demonstrate significantly higher acceptance scores than the conventional group. The mean acceptance score was 33.00 ± 3.23 in the customized group compared with 24.20 ± 2.24 in the conventional group. Independent samples t-test revealed a statistically significant difference between the two groups (table 4)

Table (4) Comparison of Total Acceptance Scores Between the Study Groups at the 6-Month Follow-up

Variable	Conventional Twin Block Group (n = 15)	Customized Twin Block Group (n = 15)	p-value
Total Acceptance Score (Mean $\pm$ SD)	24.20 ± 2.24	33.00 ± 3.23	<0.001*

*Independent samples t-test; statistically significant at $p < 0.05$.

Comparison of Total Acceptance Scores Between the Study Groups Throughout the Study Period

Table (5) presents the comparison of total acceptance scores between the conventional and customized Twin Block groups at different follow-up periods. At all assessment visits, children in the customized Twin Block group demonstrated significantly higher acceptance scores than those in the conventional group. One week after appliance delivery, the customized group showed markedly greater acceptance than the conventional group ($p < 0.001$). This difference remained statistically significant at both the 3-month and 6-month follow-up visits ($p < 0.001$). Although acceptance scores in the customized group showed a gradual decline over time, they remained consistently higher than those observed in the conventional group throughout the study period.

Table (5) presents the comparison of total acceptance scores between the conventional and customized Twin Block groups throughout the study period.

Follow-up Period	Conventional Group (Mean $\pm$ SD)	Customized Group (Mean $\pm$ SD)	p-value
1 Week	24.20 ± 3.84	41.47 ± 1.41	<0.001
3 Months	24.33 ± 1.99	37.87 ± 2.20	<0.001
6 Months	24.20 ± 2.24	33.00 ± 3.23	<0.001

Compliance results

• Comparison of Self-Reported Compliance Between the Study Groups at the 1-Week Follow-up

The comparison of the compliance scores between the study groups at the 1-week follow-up is presented in Table (6). Children in the customized Twin Block group demonstrated significantly higher compliance scores than those in the conventional Twin Block group (table 6).

Table (6). Comparison of Self-Reported Compliance Scores Between the Study Groups at the 1-Week Follow-up

Variable	Conventional Twin Block Group (n = 15)	Customized Twin Block Group (n = 15)	p-value
Self-Reported Compliance Score, Median (IQR)	4 (1)	5 (1)	0.006*

*Mann–Whitney U test; statistically significant at $p < 0.05$.

• **Comparison of Self-Reported Compliance Between the Study Groups at the 3-Month Follow-up**

The comparison of self-reported compliance scores between the study groups at the 3-month follow-up is presented in Table (7). Although children in the customized Twin Block group demonstrated higher compliance scores than those in the conventional group, the difference was not statistically significant ($p = 0.185$).

Table (7). Comparison of Self-Reported Compliance Scores Between the Study Groups at the 3-Month Follow-up

Variable	Conventional Twin Block Group (n = 15)	Customized Twin Block Group (n = 15)	p-value
Self-Reported Compliance Score, Median (IQR)	4 (1)	5 (1)	0.185

*Mann–Whitney U test.

• **Comparison of Self-Reported Compliance Between the Study Groups at the 6-Month Follow-up**

The comparison of self-reported compliance scores between the study groups at the 6-month follow-up is presented in Table X. No statistically significant difference was observed between the conventional and customized Twin Block groups regarding self-reported compliance scores ($p = 0.228$).

Table (8). Comparison of Self-Reported Compliance Scores Between the Study Groups at the 6-Month Follow-up

Variable	Conventional Twin Block Group (n = 15)	Customized Twin Block Group (n = 15)	p-value
Self-Reported Compliance Score, Median (IQR)	5 (1)	5 (1)	0.228

*Mann–Whitney U test.

• **Comparison of Self-Reported Compliance Between the Study Groups Throughout the Study Period**

The comparison of self-reported compliance scores between the conventional and customized Twin Block groups throughout the study period is presented in Table X. Children in the customized group demonstrated significantly higher compliance scores at the 1-week follow-up ($p = 0.006$). However, no statistically significant differences were observed between the study groups at the 3-month ($p = 0.185$) or 6-month ($p = 0.228$) follow-up visits. (table 9).

Table (9). Comparison of Self-Reported Compliance Scores Between the Study Groups Throughout the Study Period

Follow-up Period	Conventional Twin Block Group (n = 15)	Customized Twin Block Group (n = 15)	p-value
1 Week	4 (1)	5 (1)	0.006*
3 Months	4 (1)	5 (1)	0.185
6 Months	5 (1)	5 (1)	0.228

Values are presented as Median (IQR).

*Mann–Whitney U test; statistically significant at $p < 0.05$.

6. DISCUSSION

The present trial was conducted to assess the effect of child-selected customization of Twin Block appliances on treatment acceptance and self-reported compliance among children undergoing functional orthodontic treatment. To the best of our knowledge, limited evidence exists regarding the influence of appliance customization and child participation in appliance design on the acceptance of removable functional appliances. Therefore, this study aimed to investigate whether allowing children to select the appearance and decorative features of their Twin Block appliances could positively influence their perceptions of treatment and their willingness to wear the appliance.

The results demonstrated that children who received customized Twin Block appliances reported significantly higher acceptance scores than those who received conventional appliances throughout the study period. Although acceptance scores declined in both groups over time, the customized group consistently maintained significantly higher acceptance levels at all follow-up visits.

The greater acceptance noted in the customized group may be explained by the principles of patient-centered care and shared decision-making, which emphasize the importance of involving children in treatment-related decisions whenever developmentally appropriate ⁽¹⁵⁾. Allowing children to participate in selecting the appearance and design of their Twin Block appliances may have enhanced their sense of ownership, autonomy, and engagement with treatment. Furthermore, these findings support previous evidence suggesting that appliance appearance, material characteristics, and opportunities

for personalization can positively influence children's preferences for appliances, treatment acceptance, and overall orthodontic treatment experience^(7,17–19).

The current findings are also consistent with those reported by Walton et al⁽²⁰⁾, who showed that children and adolescents assigned higher attractiveness and acceptability ratings to orthodontic appliances incorporating personalized and visually appealing features, such as colored elastomeric ties and shaped brackets. The authors concluded that customization and aesthetic enhancement positively influence children's perceptions of orthodontic appliances and increase their willingness to accept treatment. These observations support the present findings and suggest that providing children with opportunities for personalization may enhance their overall treatment experience and acceptance of removable orthodontic appliances. Similarly, the findings of the present study are in agreement with those reported by Krishnakumar and Kalaskar (21), who evaluated children's attitudes toward both conventional removable appliances and customized "Vivid Pado Appliances." The authors demonstrated significantly greater acceptance and compliance among children receiving customized appliances incorporating colors, stickers, and decorative elements selected based on the child's preferences. Similar to the present findings, they suggested that the enhanced aesthetic appeal and active involvement of children in the customization process contributed to more positive treatment perceptions and a greater willingness to wear the appliance. Together, these findings support the concept that personalization of removable orthodontic appliances can improve children's treatment experiences and increase acceptance of orthodontic treatment.

While Krishnakumar and Kalaskar evaluated acceptance and compliance using a simple questionnaire administered immediately after appliance delivery and at short-term follow-up, the present study assessed acceptance longitudinally across three follow-up time points using a validated multidimensional questionnaire. Despite these methodological differences, both studies consistently demonstrated positive influence of appliance customization on children's acceptance of removable orthodontic appliances.

Interestingly, acceptance scores in the customized group declined over time, despite remaining significantly higher than those of the conventional group. This finding may reflect the diminishing influence of the novelty effect. During the initial stages of treatment, children may experience excitement and enthusiasm toward a newly customized appliance. However, as treatment progresses and appliance wear becomes integrated into daily routines, the initial excitement may gradually diminish. Nevertheless, the persistence of significantly higher acceptance scores throughout the study period suggests that the benefits of customization extend beyond the initial novelty phase.

Similar observations have been reported by Schott and Menne⁽²²⁾, who demonstrated that patient-selected colors did not prevent the general decline in wear time as treatment progressed. In the present study, a gradual reduction in acceptance scores was also observed over time, suggesting that the initial positive effect of appliance customization may be partly attributable to a novelty effect that diminishes as children become accustomed to appliance wear.

Regarding self-reported treatment compliance, children in the customized group demonstrated significantly higher compliance scores during the first week following appliance delivery; however, this difference was not maintained at the 3- and 6-month follow-up visits. These findings suggest that the positive influence of customization on compliance may be most pronounced during the early stages of treatment.

The findings related to compliance are partially supported by those reported by Frilund et al.⁽²³⁾, who objectively assessed Twin Block wear using embedded microensors. The authors observed a gradual decline in wear time throughout treatment despite regular follow-up visits and found that increasing the frequency of review appointments did not significantly improve compliance. Collectively, these findings suggest that long-term compliance with removable functional appliances is influenced by multiple behavioral and environmental factors beyond the initial attractiveness of the appliance.

One possible explanation is that compliance with removable orthodontic appliances is influenced by factors extending beyond appliance appearance, including parental supervision, treatment motivation, daily routines, comfort, and adaptation to appliance wear. Consequently, although customization may enhance initial enthusiasm and short-term compliance, its effect may diminish over time as these additional factors become more important determinants of long-term appliance use. The present study has several strengths. First, the randomized clinical trial design reduced selection bias and enhanced the validity of group comparisons. Second, both treatment acceptance and self-reported treatment compliance were evaluated across multiple follow-up periods, allowing evaluation of changes over time. Third, the study-specific validated questionnaire demonstrated excellent internal consistency, supporting the reliability of the collected data.

Study limitations

The study was conducted as a pilot trial with a relatively small sample size, which may limit the generalizability of the findings. In addition, compliance was assessed using self-reported measures rather than objective wear-time monitoring devices, making the results susceptible to recall and social desirability bias. Furthermore, the study focused on a specific

removable functional appliance (Twin Block), and the findings may not be generalizable to other removable orthodontic appliances.

Recommendations

- It is recommended to conduct further studies with larger sample sizes and extended follow-up durations to validate the current findings.
- Further research should also investigate the effects of appliance customization on objectively measured wear time, treatment outcomes, oral health-related quality of life, and patient satisfaction. Additionally, evaluating customization across different types of removable orthodontic appliances may provide further insight into its role in pediatric orthodontic care.

7. CONCLUSION

In conclusion, child-selected customization of Twin Block appliances significantly improved treatment acceptance throughout the study period and enhanced self-reported compliance during the early stages of treatment. Although the effect on compliance diminished over time, customized appliances consistently achieved higher acceptance scores than conventional appliances. These findings support the incorporation of child-centered customization strategies as a simple and practical approach for improving children's experiences with removable orthodontic treatment.

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