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Randomized controlled trial

Dentoskeletal effects of the Bite-Jumping Appliance and the Twin-Block Appliance in the treatment of skeletal Class II malocclusion: a randomized controlled trial

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Summary

Objectives: The current parallel group, randomized controlled trial aimed to compare the dentoalveolar and skeletal changes resulting from treatment using two popular functional appliances: the Bite-Jumping Appliance (BJA) and the Twin-Block Appliance (TBA).
Study design: This study is designed as a parallel-group, randomized controlled trial.
Materials and methods: Patients were screened from the patients who were seeking treatment at the Department of Orthodontics, Al-Baath University. Eligibility criteria included skeletal Class II division 1 malocclusion resulting from the retrusion of the mandible. A computer-generated randomization list was used to randomly divide the patients into two equal groups to be treated with either the BJA or the TBA. Blinding was applicable for outcome assessment only. Forty-four patients (22 male and 22 female) aged 10.2–13.5 years were randomized in a 1:1 ratio to either the BJA or the TBA groups, and four patients were lost to follow-up (two from each group). Lateral cephalometric radiographs were obtained before treatment and after 12 months of active appliance therapy. Inter-group differences were evaluated with two-sample *t*-tests, and intra-group differences were assessed with paired-sample *t*-tests at the $P < 0.05$ level.
Results: Forty patients (20 in each group) were available for the statistical analysis. Baseline characteristics were similar between groups. Similar changes were observed in the sagittal plane, including a significant increase in the SNB angle. No significant changes were observed in the maxilla. The lower incisors were significantly proclined, and the upper incisors significantly retruded. In the vertical plane, BJA induced mandibular clockwise rotation, and the SN:MP angle increased by 2.14 2.97° ($P = 0.002$). Conversely, no significant changes took place in this angle in the TBA group 0.75 2.37° ($P = 0.096$). Similarly, Jarabak ratio decreased significantly in the BJA group by −1.78 0.85% ($P = 0.002$) and increased significantly in the TBA group by 1.26 0.76% ($P = 0.032$), with significant differences between the two groups ($P \leq 0.001$). No serious harm was observed.
Limitations: A limitation of this research is a lack of an untreated control group. However, the resulting differences between the two groups can be attributed to the appliance differences, which fulfil the aim of the current research.
Conclusions: Each of the two appliances is recommended for the functional treatment of skeletal Class II malocclusion resulting from the retrusion of the mandible. The BJA is recommended when clockwise rotation is desired, whereas the TBA is recommended to inhibit vertical development.

Registration: This trial was registered at the Department of Orthodontics, Al-Baath University, Number 16, on 6/25/2012.
Protocol: The protocol was not published before trial commencement.
Funding: No funding or conflict of interest to be declared.

Introduction

Class II malocclusion is one of the most prevalent orthodontic conditions throughout the world, and typically, these deformities are treated by using functional appliances (1, 2). At the beginning of the 20th century, extraoral forces were applied to the maxilla with headgear for the correction of Class II malocclusion. This therapeutic method was a reflection of the belief that prevailed during that era that the majority of skeletal Class II malocclusions are caused by the protrusion of the maxilla (3). However, subsequent studies indicated that the incidence of Class II division 1 malocclusion resulting from the protrusion of the maxilla does not exceed 20% of the total cases of Class II malocclusion, and the majority of these cases are significantly caused by mandibular retrusion, which prompted many researchers to use functional appliances that stimulate the growth of the mandible for the treatment of skeletal Class II malocclusion (4).

Many researchers have developed various functional appliances, such as the Monoblock developed by Robin, the Activator developed by Andresen, the Bionator developed by Balters, and the Function Regulator developed by Frankel (5).

In the 1950s, Martin Schwarz developed the Removable Double Plate Appliance (6, 7), which was later referred to as the Jumping-The-Bite Plate (8, 9), or Bite-Jumping Appliance (BJA) (10). This method and all its many variations depend on incorporated guide bars in a maxillary plate, which are guided by an inclined plane in a mandibular plate. This articulation leads the mandible forward when occlusion occurs (7–9).

The idea of the BJA led William Clark to develop the Twin-Block Appliance (TBA), which also consists of two separate plates overlapping with each another with inclined acrylic surfaces. This overlapping leads the mandible forward when it occludes (11). This appliance has also been subjected to many modifications, including torqueing spurs on the upper incisors (12), using Southend clasps (13), omitting the upper labial bow (14), and adding headgear (15).

The use of separate plates in these two methods helped patients increase their cooperation, in addition to maintaining the advantages of functional appliances. Consequently, these methods became common clinically (6). The effectiveness of both of the BJA (10, 16) and the TBA (13, 17) in the treatment of skeletal Class II malocclusion has been evaluated in many previous studies, but there is no study that compares the efficacy of these two appliances under the same conditions. The purpose of this randomized controlled trial (RCT) is to compare the short-term dentoalveolar and skeletal changes resulting from treatment with the BJA and the TBA.

Materials and methods

Trial design

The research was designed as a parallel-group, randomized controlled trial with a 1:1 allocation ratio.

Ethical considerations

The current study was ethically approved by the Ethical Committee of Al-Baath University.

Participants, eligibility criteria, and setting

The subjects were selected from the patients registered in the pending records of the Department of Orthodontics, Al-Baath University. The patients were selected using the following criteria: skeletal Class II division 1 malocclusion resulting from the retrusion of the mandible (SNB angle < 78°); convex facial profile; ANB angle >4°; good mouth health; no previous orthodontic treatments; pubertal growth spurt peak at the beginning of the treatment, which was assessed using hand-wrist radiographs according to the Fishman method (18).

After confirmation of the existence of the entry criteria among the subjects, the subjects' parents were informed about the research objectives and the trial method, and their written informed consent to participate in the study was obtained.

Interventions

All appliances were constructed by the same orthodontic technician using self-curing acrylic. The general design of both appliances consisted of two separate plates. The maxillary plate involved Adams clasps on the first permanent molars (0.7 mm stainless steel), a labial bow extending from canine to canine (0.7 mm stainless steel), and a midline screw that was turned once per week (0.2 mm). The mandibular plate involved Adams clasps on the first permanent molars (0.7 mm stainless steel), a labial bow extending from canine to canine (0.7 mm stainless steel), and acrylic extension that covered the incisal edges of the anterior teeth.

The anterior position during mandibular closing movement was achieved in the BJA group by adding advancing loops (1.2 mm stainless steel) consisting of two continuous long U loops with two lateral helixes to permit adjustments to the maxillary plate and an anterior inclined guiding plane to the mandibular plate that allows sliding against the advancing loops (Figure 1). The maxillary and mandibular plates of the TBA contained acrylic blocks with inclined guiding planes that slide against each other during mandibular closing movement to reach the anterior position (Figure 2).

A functional bite construction was recorded in the most comfortable anterior position, which allowed an overjet of up to 7 mm to be corrected with a single advancement. If additional correction was needed, the reactivation were performed by adjusting the advancing loops in the BJA group or by adding cold-cured acrylic to the upper blocks in the TBA group during treatment. The mandibular opening was 5 mm clinically measured at the central incisor segment.

The participants were instructed to wear the appliances at all times except meal time, and their parents were asked to control the appliance wears. They were reviewed at intervals of 4 weeks, and the upper midline expansion screw was turned 0.2 mm once a week until the necessary transverse expansion was achieved. An active appliance therapy period of 12 months was selected (14, 19), and all patients were treated by the same orthodontist (ASB).

Outcomes

Pre- and post-treatment digital lateral cephalometric radiograms were taken in central occlusion positions for every patient using the same equipment, PAX 400 (Vatech Co., Hawseong, Gyeonggi, Korea) with the

Figure 1. The BJA in the mouth. (A) Upper plate. (B) Lower plate. (C) Frontal view showing overlapping between plates.

Figure 2. The TBA in the mouth. (A) Upper plate. (B) Lower plate. (C) Lateral view showing overlapping between plates.

same settings. Cephalometric radiograms were evaluated by measuring 20 angular variables, 12 linear variables, and 1 proportion (Figure 3). The magnification factor was calculated, and all linear measurements were standardized to it (7.47 %). The dentoalveolar and skeletal effects resulting from both appliances were detected. Then, the changes resulting from treatment with the two appliances were compared.

Sample size calculation

To determine the appropriate sample size, the Minitab software (Minitab Inc., State College, Pennsylvania, USA) was used with two-sample t-tests, a selected study power of 80 %, a significance level of 0.05, and a detected difference of 1°. The used standard deviation (SD) of 1.09° was based on a pilot study of 10 cases (five in each group). The appropriate sample size was 20 patients in each group. This number was increased to 22 patients to compensate for the potential dropouts.

Randomization

A computer-generated randomization list was used to randomly divide the patients into two equal groups. Forty-four patients (22 male and 22 female) aged 10.2–13.5 years were randomized in a 1:1 ratio to either the BJA or the TBA groups.

Blinding

Blinding of either patient or operator was not possible; however, blinding of assessment was performed by (ASB) coding names of patients on pre- and post-treatment cephalograms, and tracing and measurements were performed by (FRN), so that the group each patient belonged to was unknown when the records were evaluated.

Method error

Re-demarcating and re-measuring of 10 cephalometric radiographs were performed after at least 1 month from the first measurement by (FRN). The results were recorded on separate forms, and then, the overall errors were calculated by using the formula of Dahlberg (20).

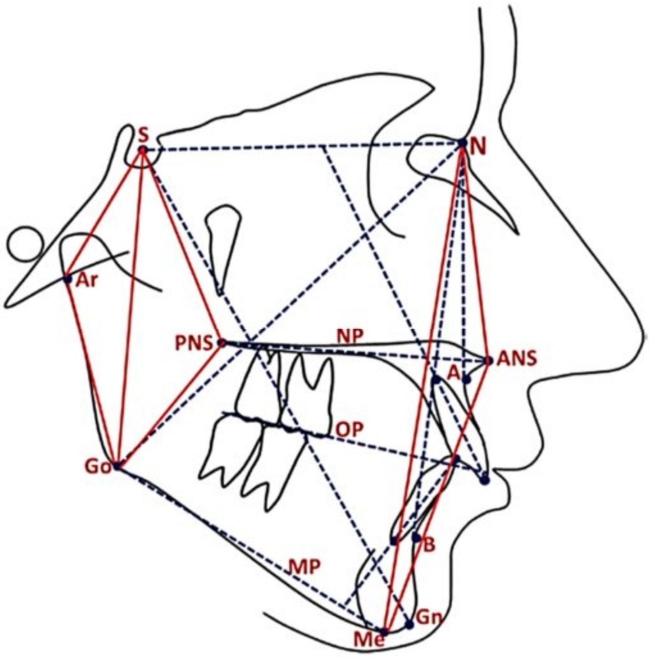

Figure 3. Cephalometric measurements on the radiograms: S, sella; N, nasion; A, A point; B, B point; NP, nasal plane; MP, mandibular plane; OP, occlusal plane; Ar, articular; Go, gonion; Me, menton; Gn, gnathion; ANS, anterior nasal spine; PNS, posterior nasal spine.

Statistical analysis

All variables were measured on pre- and post-treatment radiograms, and then, all of the data were entered into SPSS software, version 17.0(SPSS Inc., Chicago, Illinois, USA). After confirmation of the normal distribution of the variables, the pre-treatment variables differences between the two groups were detected by using two-sample *t*-tests; the effects of the treatment on the variables were detected by using paired-sample *t*-tests to compare the pre- and post-treatment variables in each group alone, and the effects of the used appliance on the changes in the studied variables were determined using two-sample *t*-tests to compare variable changes between the two groups.

Results

Participant flow

Forty-four patients (22 male and 22 female) were randomized in a 1:1 ratio to either the BJA or the BJA groups. Among them, four patients (two from each group) were lost to follow-up (Figure 4). A total of 40 patients (20 in each group) were available for the statistical analysis (Table 1). Patient recruitment commenced in June 2012 and ended in September 2012.

Baseline data

The patient initial ages were well matched between the two groups. The method errors revealed that the error of the various measurements did not exceed 0.5 mm and 0.7 degrees.

The mean initial mandibular advancement was 5.93 0.98 and 5.86 1.24 mm in the BJA and the TBA groups, respectively, with no significant differences between the two groups ($P = 0.709$). In addition, two-sample *t*-tests were performed to determine the significant differences between the two study groups before treatment. It was observed that the *P*-values were far greater than 0.05 for all studied variables; i.e. there were no significant differences between the two study groups before treatment at the 95% confidence level, which indicates that these groups were equivalent before treatment in terms of the values of the angular variables (Table 2) and linear variables (Table 3).

Table 1. The distribution of the sample

	Males		Females		Total	
Study sample	Size	Age (year)	Size	Age (year)	Size	Age (year)
BJA group	9	11.8 1.1	11	11.2 0.9	20	11.5 1.0
TBA group	13	11.9 0.7	7	11.7 1.2	20	11.8 0.9
Total Sample	22	11.9 0.9	18	11.4 1.0	40	11.6 1.0

Values are presented as the mean SD.

Numbers analyzed for each outcome

Paired-sample *t*-tests were used to determine the significant changes in BJA and TBA groups, and two-sample *t*-tests were used to detect the significant differences in changes between the two groups. The changes in the angular variables are shown in Table 4, and the changes in the linear variables are shown in Table 5.

Table 4 shows that many similar changes occurred in the two groups including the following: significant decrease in the value of the ANB angle, which was caused by significant increase of the SNB angle; anterior displacement of the temporomandibular joint, which was demonstrated through the significant decrease in the NSAr angle; and retrusion of the upper incisors. These desired effects were accompanied by protrusion of the lower incisors.

Conversely, many differences were observed between the two groups. The SN:MP angle was increased by 2.14 2.97° ($P = 0.002$) and 0.75 2.37° ($P = 0.096$) in the BJA group and TBA group, respectively. The increase was only significant in BJA group, and it was significantly larger in this group than in the TBA group ($P = 0.007$). The values of the Bjork sum, NSGn angle, and B angle

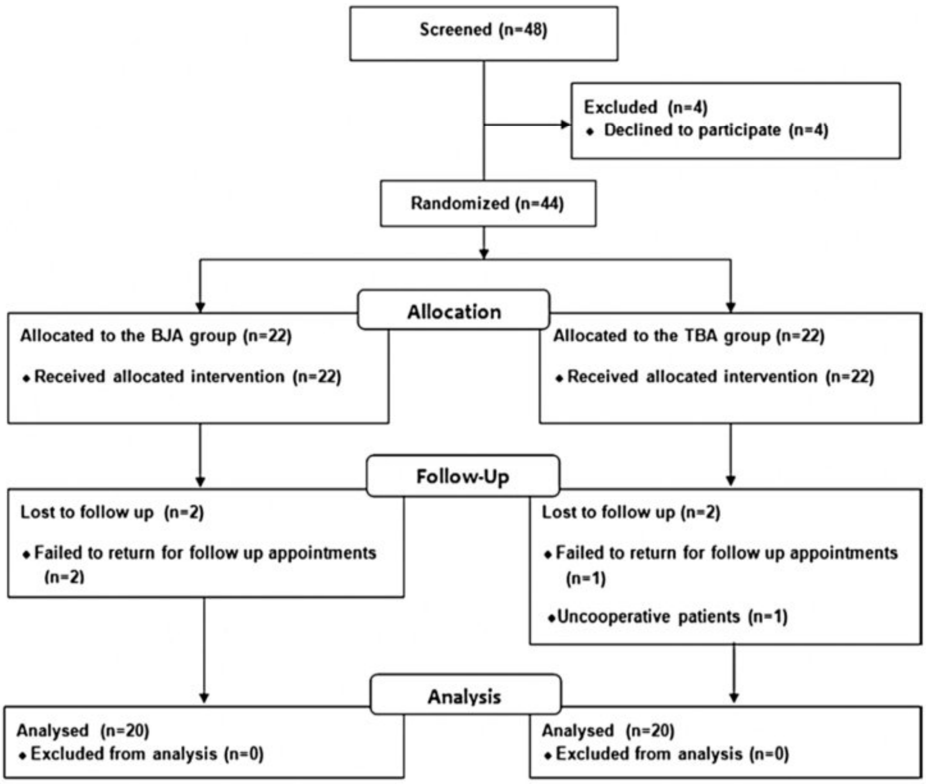

Figure 4. Patient flow diagram.

Table 2. Pre-treatment angular variables

	BJA group		TBA group		
Angular variables (°)	Mean	SD	Mean	SD	*P* value
SNA	81.18	3.16	81.93	2.81	0.112
SNB	74.04	3.66	74.80	2.70	0.107
ANB	7.14	0.92	6.88	1.44	0.117
SN:MP	39.12	6.12	38.93	6.39	0.283
SN:NP	8.94	2.45	7.30	2.65	0.140
SN:OP	20.40	4.13	19.05	4.05	0.132
NSAr	129.24	4.72	128.30	4.03	0.381
SArGo	144.32	7.91	143.30	7.30	0.402
ArGoMe	127.64	6.59	130.30	5.83	0.222
Bjork sum	401.20	7.39	400.30	6.07	0.190
NSGn	72.12	3.98	71.18	4.16	0.242
NGoAr	49.62	4.02	52.78	5.44	0.373
NGoMe	77.56	6.24	77.43	5.38	0.254
B angle	29.10	5.78	30.28	5.80	0.910
OP:NP	12.42	4.52	11.78	3.94	0.153
OP:MP	17.98	3.42	18.28	4.49	0.422
U1:SN	104.70	6.05	105.56	5.79	0.206
U1:NP	66.08	5.89	67.56	4.76	0.178
L1:MP	98.24	4.64	99.80	5.05	0.206
U1:L1	118.86	8.19	120.05	7.90	0.106

Two-sample *t*-tests were used to compare pre-treatment angular variables between BJA and TBA groups. A, A point; Ar, articular; B, B point; BJA, Bite-Jumping Appliance; Gn, gnathion; Go, gonion; L1, lower central incisor; Me, menton; MP, mandibular plane; N, nasion; NP, nasal plane; OP, occlusal plane; S, sella; SD, standard deviation; TBA, Twin-Block Appliance; U1, upper central incisor.

Table 3. Pre-treatment linear variables

	BJA group		TBA group		
Linear variables (mm)	Mean	SD	Mean	SD	*P* value
S-N	71.05	2.60	70.22	2.76	0.502
S-Ar	44.55	4.33	43.13	3.05	0.110
Ar-Go	42.55	3.73	42.36	4.28	0.725
Go-Me	66.93	3.81	66.84	4.43	0.216
N-Me	119.30	6.37	117.25	7.23	0.135
N-ANS	56.05	3.54	54.36	3.12	0.488
ANS-Me	67.05	4.62	64.73	4.93	0.176
S-Go	73.30	4.99	69.54	6.14	0.170
S-PNS	42.43	3.80	41.52	2.64	0.098
PNS-Go	31.18	2.59	28.92	3.27	0.085
Jarabak ratio (%)	60.26	4.82	59.38	4.38	0.454
Overbite	3.63	1.46	3.39	1.94	0.097
Overjet	7.04	2.00	7.87	1.60	0.746

Two-sample *t*-tests were used to compare pre-treatment linear variables between BJA and TBA groups. ANS, anterior nasal spine; Ar; articulare; BJA, Bite-Jumping Appliance; Go, gonion; Me, menton; N, nasion; PNS, posterior nasal spine; S, sella; SD, standard deviation; TBA, Twin-Block Appliance.

increased significantly in the BJA group by 3.04 5.69° ($P = 0.005$), 2.01 1.54° ($P \leq 0.001$), and 1.08 2.32° ($P = 0.002$), respectively, whereas these values insignificantly decreased in the TBA group. These changes were significantly larger in the BJA group than in the TBA group ($P \leq 0.001$, $P \leq 0.001$ and $P = 0.021$, respectively). There was vertical growth in the BJA group but only insignificant changes in the TBA group.

Table 5 shows that many similar changes occurred in the two groups including a significant decrease in the overjet and an increase in the length and the height of the mandible. N-Me increased significantly by 1.72 0.44 mm ($P = 0.009$) and 1.31 1.04 mm ($P \leq 0.001$) in the BJA group and TBA group, respectively, but the differences were not significant between the two groups ($P = 0.311$).

Conversely, many differences were observed between the two groups. S-Go increased significantly by 1.19 0.37 mm ($P = 0.034$) and 2.21 0.76 mm ($P \leq 0.001$) in the BJA group and TBA group, respectively. The increase was significantly larger in the TBA group than in the BJA group ($P = 0.011$). The changes in N-Me and S-Go caused the Jarabak ratio to decrease significantly in the BJA group by −1.78 0.85% ($P = 0.002$) and to increase significantly in the TBA group by 1.26 0.76% ($P = 0.032$), with significant differences between the two groups ($P \leq 0.001$). There was vertical growth in the BJA group, but horizontal growth in the TBA group. Overbite decreased significantly in the BJA group by −1.25 1.32 mm ($P \leq 0.001$) and increased significantly in the TBA group by 0.58 1.39 mm ($P = 0.022$), with significant differences between the two groups ($P \leq 0.001$).

Harms

No serious harm was observed.

Discussion

Main findings

The current results revealed that both appliances are able to correct skeletal Class II malocclusion; that conclusion appears obvious from the significant decrease in the ANB angle and the overjet during the treatment. Although functional appliances should be electively prescribed to skeletal Class II patients with a retruded mandible, many previous RCTs did not consider mandibular features as inclusion criteria (14, 21). Functional appliances force the mandible to occlude anteriorly. The forced anterior position of the mandible usually associates with a neuromuscular adaptation with the new position (22). It was noticed in the present study that the forced anterior position of the mandible led to many changes in the mandible that contribute to the correction of mandibular retrusion, including the following criteria:

1. Forward motion of the mandible, which was demonstrated by significant increases in SNB angle by 2.88 1.32° ($P = 0.005$) and 3.13 1.86° ($P = 0.002$) in the BJA group and TBA group, respectively. The lower incisors in this study were significantly proclined in the two groups. Lingual movement of lower incisor roots may allow alveolar remodelling, lingual movement of point B, and reduction of the SNB angle. Thus, an increase in the SNB angle in these circumstances demonstrates significant improvement. These results are in agreement with other studies on TBAs (23) and BJAs (10).
2. Anterior movement of the temporomandibular joint, which was obvious from the significant decrease of in the NSAr angle by −1.80 0.56° ($P = 0.024$) and −1.53 1.16° ($P = 0.022$) in the BJA group and TBA group, respectively. Although many previous studies reported anterior movement of the temporomandibular joint as a significant finding after functional treatment (24), many studies have neglected this variable (10, 14, 25).
3. A significant increase in the dimensions of the mandible, including the length of the mandible by 3.13 1.20 mm ($P = 0.008$) and 2.42 1.45 mm ($P < 0.001$) in the BJA group and TBA group,

Table 4. Comparison of angular variables changes between the two groups

	BJA group			TBA group			Diff. between groups
Angular variables (°)	Mean	SD	*P* value	Mean	SD	*P* value	*P* value
SNA	−0.42	0.50	0.091	−1.03	0.15	0.064	0.311
SNB	2.88	1.32	0.005**	3.13	1.86	0.002**	0.121
ANB	−3.51	1.28	0.004**	−3.95	0.97	0.004**	0.298
SN:MP	2.14	2.97	0.002**	0.75	2.37	0.096	0.007**
SN:NP	0.05	0.53	0.078	0.53	1.11	0.151	0.345
SN:OP	0.21	2.97	0.224	0.98	1.87	0.164	0.389
NSAr	−1.80	0.56	0.024*	−1.53	1.16	0.022*	0.210
SArGo	3.32	2.10	0.002**	2.68	1.53	0.005**	0.324
ArGoMe	1.75	3.09	0.023*	−0.82	1.72	0.073	<0.001***
Bjork sum	3.04	5.69	0.005**	−1.12	4.35	0.095	<0.001***
NSGn	2.01	1.54	<0.001***	−0.92	1.79	0.061	<0.001***
NGoAr	0.21	1.10	0.251	−0.51	1.08	0.156	0.405
NGoMe	0.46	2.07	0.294	0.14	0.67	0.318	0.102
B angle	1.08	2.32	0.002**	−0.58	1.60	0.163	0.021*
OP:NP	0.30	1.50	0.392	−0.18	1.97	0.425	0.312
OP:MP	0.24	1.28	0.346	−0.42	2.34	0.334	0.303
U1:SN	−3.78	1.07	<0.001***	−4.12	1.83	0.005**	0.193
U1:NP	2.98	1.78	0.006**	2.61	1.29	0.006**	0.234
L1:MP	3.25	2.38	0.007**	3.63	1.62	0.002**	0.272
U1:L1	1.88	2.30	0.009**	1.39	2.53	<0.001***	0.291

Paired-sample *t*-tests were used to detect the changes in each group, and two-sample *t*-tests were used to detect the differences in changes between the two groups. A, A point; Ar, articular; B, B point; BJA, Bite-Jumping Appliance; Gn, gnathion; Go, gonion; L1, lower central incisor; Me, menton; MP, mandibular plane; N, nasion; NP, nasal plane; OP, occlusal plane; S, sella; SD, standard deviation; TBA, Twin-Block Appliance; U1, upper central incisor.

$^{*}P \le 0.05$, $^{**}P \le 0.01$, $^{***}P \le 0.001$.

Table 5. Comparison of linear variables changes between the two groups

	BJA group			TBA group			Diff. between groups
Linear variables (mm)	Mean	SD	*P* value	Mean	SD	*P* value	*P* value
S-N	0.64	0.50	0.173	0.51	0.32	0.165	0.076
S-Ar	0.45	0.32	0.135	0.62	0.27	0.189	0.091
Ar-Go	2.63	1.28	0.006**	2.52	1.63	<0.001***	0.063
Go-Me	3.13	1.20	0.008**	2.42	1.45	<0.001***	0.461
N-Me	1.72	0.44	0.009**	1.31	1.04	<0.001***	0.311
N-ANS	0.41	0.64	0.081	0.65	0.09	0.218	0.119
ANS-Me	1.29	0.37	0.026*	0.23	0.54	0.082	0.019*
S-Go	1.19	0.37	0.034*	2.21	0.76	<0.001***	0.011*
S-PNS	0.48	1.86	0.198	0.69	0.41	0.161	0.116
PNS-Go	1.14	1.03	0.044*	2.11	1.38	<0.001***	0.041*
Jarabak ratio (%)	−1.78	0.85	0.002**	1.26	0.76	0.032*	<0.001***
Overbite	−1.25	1.32	<0.001***	0.58	1.39	0.022*	<0.001***
Overjet	−4.36	1.50	<0.001***	−4.75	1.47	<0.001***	0.261

Paired-sample *t*-tests were used to detect the changes in each group, and two-sample *t*-tests were used to detect the differences in changes between the two groups. ANS, anterior nasal spine; Ar; articular; BJA, Bite-Jumping Appliance; Go, gonion; Me, menton; N, nasion; PNS, posterior nasal spine; S, sella; SD, standard deviation; TBA, Twin-Block Appliance.

$^{*}P \le 0.05$, $^{**}P \le 0.01$, $^{***}P \le 0.001$.

respectively, and of the height of the mandible by 2.63 1.28 mm ($P = 0.006$) and 2.52 1.63 mm ($P < 0.001$) in the BJA group and the TBA group, respectively. Martina *et al.* referred to a significant increase in the length of the mandible but an insignificant increase in the height of the mandible with the BJA. They made the initial wax bite registration with the mandible advanced by only 4 mm (10), whereas the initial advancement of the mandible in the current study was 7 mm. Conversely, Baysal and Uysal reported a significant increase in the height of the mandible but an insignificant increase in the length of the mandible with TBA. They used a modified Hawley appliance with an anterior inclined plane after TBA and had post-treatment records after 4–6 months of occlusal settling and retention (25). Thus, the differences in the results between their study and the current study can be attributed to the differences in working methods.

No significant changes were observed in the maxilla in the sagittal plane. No significant changes were observed in the SNA angle in both study groups. This finding, with some caution, may indicate that the two appliances were able to restrict the growth of the maxilla. The upper incisors in this study were significantly proclined in the two groups. The root apices might have moved anteriorly, and point A might have been advanced as a result of alveolar bone reshaping. The SNA angle did not increase under these circumstances, so it could be assumed that some restriction of maxillary growth had occurred. Studies of O'Brien *et al.*, and Tumer and Gultan displayed restriction of the maxilla (17, 26), whereas the study of Baysal and Uysal did not (25). The differences in results between their study and the current study could be attributed as mentioned before to the differences in working methods.

The lower incisors in this study were significantly proclined by 3.25 2.38° (P = 0.007) and 3.63 1.62° (P = 0.002) in the BJA group and the TBA group, respectively. Lund and Sandler and Mills and McCulloch reported significant lower incisor proclination during functional treatment by 7.9° and 5.2°, respectively (27, 28). It can be noticed that although all of these studies mentioned significant lower incisor proclination, the lower incisor proclination in the current study is less than that in the above-mentioned studies. In the present study, an acrylic cover for lower incisors was used, which provides rigid retention in the lower labial segment, whereas Lund and Sandler and Mills and McCulloch used ball clasps and labial bows, respectively, and could not keep the lower incisor stable (27, 28), which potentially justifies the differences in results. Conversely, Martina *et al.* mentioned that no significant lower incisor proclination occurred when they used acrylic cover for lower incisors (10). A single mandibular advancement of up to 7mm was permitted in the current study, whereas the most single mandibular advancement in the study of Martina *et al.* was only 4mm (10). The overjet was not completely corrected in their study sample, which might justify the differences.

The upper incisors were significantly retruded by −3.78 1.07° (P < 0.001) and −4.12° 1.83° (P = 0.005) in the BJA group and TBA group, respectively. The retrusion of the upper incisors is a consistent finding in many previous studies (10, 14, 25). This finding can be interpreted as a posterior reaction resulting from the anterior advancing of the mandible. The labial bow of maxillary plates in both study groups was not activated to avoid the upper incisor retrusion and consequently to avoid a dental constraint on mandibular growth stimulation (10).

A comparison between the two study groups revealed no significant differences in the changes in the sagittal plane. This may be because of the similar mechanism of action in the sagittal plane for both appliances. Both appliances depend on the forced advancement of the mandible either through the advancing loops in the BJA group or by inclined guiding planes in the TBA group. No previous study comparing these two appliances was found in the literature.

It has been suggested that the Class II orthopaedic correction may be influenced by vertical craniofacial features (29). Increases in lower anterior and posterior face heights are consistent findings after functional therapy, but the proportional increase in anterior and posterior height may define rotation direction (10, 25).

The BJA induced mandibular clockwise rotation and motivated vertical growth. These changes can be diagnosed by the increase in the angle of the mandible with the anterior skull base by 2.14 2.97° (P = 0.002), in the total sum of Bjork by 3.04 5.69° (P = 0.005), and in the facial axis angle by 2.01 1.54° (P < 0.001) in addition to the decrease of the proportion of Jarabak by −1.78 0.85% (P = 0.002). These changes can be attributed to the anterior acrylic bite block, which covers the lower incisors.

However, it appears that the acrylic bite block covering the posterior teeth in a TBA appliance prevented the vertical growth motivation, and no significant changes occurred in the angle of the mandible with the anterior skull base, in the total sum of Bjork, or in the facial axis angle. Conversely, it appears that these surfaces were able to induce some mandibular counterclockwise rotation, which presented as a significant increase in the proportion of Jarabak by 1.26 0.76% (P = 0.032), and, with some interpretive precaution, as a significant increase in the overbite by 0.58 1.39mm (P = 0.022). Baysal and Uysal reported that acrylic contouring during Twin-Block appliance treatment should be taken into account when the increase in the lower anterior face height is evaluated. They trimmed acrylic upper bite blocks in deep-bite patients to increase the vertical dimension and reported that the TB appliance may inhibit vertical development if acrylic upper bite blocks not trimmed (25).

Martina *et al.* found no clockwise mandibular rotation during treatment with the BJA. They attributed this finding to the forward position of the prongs and to their inclination (60°) (10). Although the prongs in the current study had similar characteristics, some clockwise mandibular rotation was observed after using the BJA. The most single mandibular advancement in the study of Martina *et al.* was only 4mm (10), which might make the full occlusion in their sample easier than that of the current sample. A single mandibular advancement of up to 7mm was permitted in the current study, which may justify the differences in the study results.

Limitations

A limitation of this research is a lack of an untreated control group, which means that the resulting changes can't be attributed to the treatment only, but also to ordinary growth. However, the resulting differences between the two groups can be attributed to the appliance differences, which fulfil the aim of the current research.

Generalizability

Chronological age may differ by gender, race, and geographical regions. A limitation of many previous RCTs may be the use of chronological age as an inclusion criterion (14) as there may be an issue of inappropriate functional treatment timing given that functional appliances are more effective when used close to the pubertal growth peak (30). Patients in the current study were in the pubertal growth spurt peak at the beginning of the treatment, which was assessed based on hand-wrist radiographs. The interventions were implemented for both sexes. The proportion of allocated participants who refused to follow-up the trial as indicated on the flow diagram may indicate acceptability of the tested appliances. These factors emphasize the generalizability of the current research findings.

Conclusions

Both the BJA and the TBA are recommended for the functional treatment of skeletal Class II malocclusion resulting from the retrusion of the mandible. The two appliances produce similar changes in the sagittal plane, including significant advancing of the mandible, no significant changes in the maxilla, lower incisor proclination, and upper incisor retrusion. Significant differences in the vertical plane were observed. The BJA motivated mandibular clockwise rotation, whereas the TBA induced fewer changes in the vertical plane. Likewise, some variables, the proportion of Jarabak, for example, indicated that the TBA motivated some mandibular counterclockwise rotation.

It is recommended the BJA be used when clockwise rotation is desired, whereas it is recommended the TBA be used to inhibit vertical development.

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