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Dentoskeletal effects of aesthetic and conventional twin block appliances in the treatment of skeletal class II malocclusion: a randomized controlled trial

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Twin block appliances are commonly used to treat skeletal class II malocclusion. However, many adverse effects, such as lower incisor protrusion and a bulky nature, can be observed. To overcome these effects, a modified twin block was designed, which uses vacuum-formed hard plates (VFPs) instead of acrylic plates. This clinical trial evaluated the skeletal and dentoalveolar changes resulting from a modified twin block (aesthetic twin block) (ATB) in comparison with conventional twin block (CTB) in addition to levels of esthetics and discomfort. A two-arm parallel group randomized clinical trial was performed at the Department of Orthodontics, University of Damascus, Syria. Fifty-two patients (33 females and 19 males) aged 12.23 ± 0.77 years with skeletal class II division 1 malocclusion caused by mandibular retrognathism were included. The participants were randomly assigned to a study group according to a simple randomization method using a numbered and sealed envelope. The experimental group was treated with an aesthetic twin block, and the control group was treated with a conventional twin block. Sixteen angular variables and eleven seventeen linear variables (measured in millimeters) were evaluated before the treatment (T0) and at the end of the active phase of the treatment (T1) on lateral cephalometric radiographs and dental casts to study the skeletal and dentoalveolar changes, and a questionnaire was used to assess the levels of esthetic and discomfort. There was a statistically significant change in the ANB angle between the ATB group (−2.70 ± 0.84) and the CTB group (−1.92 ± 0.81°) ($P = 0{\cdot}002$) and between the SNB angle of the ATB group (2.72 ± 1.54°) and the CTB group (1.72 ± 1.41°) ($P = 0{\cdot}02$). The Jarabak ratio decreased significantly in the CTB group (−0.65 ± 1.37%) ($P = 0.02$) and increased significantly in the ATB group (0.84 ± 1.44%) ($P = 0.007$), with significant differences between the two groups ($P = 0.000$). The change in upper incisor angulation was statistically significant (−1.88 ± 1.48°) for the ATB group and (−3.5 ± 4.18°) for the CTB group ($P = 0{\cdot}001$). The change in lower incisor angulation was 1.34 ± 2.08° for the ATB group and 3.88 ± 2.47° for the CTB group, which was statistically significant ($P = 0{\cdot}000$). ATB had more control of vertical growth, lower incisor and upper incisor angulation and was more aesthetically acceptable.

Trial registration: (NCT05418413) (14/06/2022).

Keywords Twin block, Lower incisors, Skeletal changes, Functional treatment

Abbreviations

ATB	Aesthetic twin block appliance
CTB	Conventional twin block appliance
TB	Twin block appliance
VFPs	Vacuum-formed hard plates

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Class II malocclusion is considered one of the most prevalent orthodontic cases[1]. Cases of Class II malocclusion resulting from maxillary protrusion do not exceed 20% of the total Class II cases, while the majority are caused by mandibular retrognathism. This has led to the use of functional appliances, which stimulate mandibular growth[2,3]. Functional appliance therapy aims to improve relationships of dentofacial structures by addressing developmental factors and muscle function. Robin's monoblock is considered a precursor to modern functional appliances, while Andresen's Activator is often recognized as the first functional appliance. Since then, numerous modifications and new appliance systems have been developed[4]. The use of removable functional appliances is more common than the use of fixed functional appliances in the treatment of skeletal Class II malocclusion[5]. The twin block appliance (TB) is one of the most popular removable functional appliances because of its high patient compliance[5–7] and its ability to increase mandibular length[8,9]. Despite his satisfactory outcomes, some undesirable effects have been observed, especially mandibular incisor flaring, which leads to more dental correction than skeletal correction does[10], as well as negative effects on supporting periodontal tissues[11]. Several modifications have been made to TBs to control mandibular incisors and enhance skeletal effects, including capping the lower incisors[12], increasing the number of anterior ball clasps[13], and providing relief behind the lower incisors with an acrylic labial bow[14]. However, these methods have shown limited efficacy in controlling mandibular incisors or have an invasive nature, such as the use of mini implants[15]. With increasing patient demands, especially esthetics, reducing the size and costs of the appliance may improve patient compliance[16]. One of the latest modifications to the TB is the use of vacuum-formed hard plates (VFPs), which are better esthetics[17], instead of acrylic resin plates and wires as the main part of the appliance to make the aesthetic twin block appliance (ATB), which influences patient compliance and overcomes the drawbacks of the conventional twin block appliance (CTB)[18–20]. Previous studies reported significant advancement of the mandible with ATB more than with CTB[18,20] and control of lower incisor flaring[18,19], whereas other studies reported no significant changes in mandibular advancement[19] or lower incisor flaring[20] compared with CTB, suggesting that further clinical trials are needed to study the effects of ATB. This randomized clinical trial (RCT) aims to evaluate the dentoalveolar and skeletal changes resulting from the ATB appliance and compare them with those resulting from the CTB appliance via cephalometric and dental cast measurements and a questionnaire to assess the levels of aesthetics and discomfort at four assessment times.

Materials and methods

Study design

This study was conducted as a two-arm, parallel-group randomized controlled trial at the Department of Orthodontics, Faculty of Dentistry, University of Damascus, between June 6, 2022, and April 4, 2023.

Ethical consideration

The University of Damascus Local Research Ethics Committee approved this study (no. 1205-06-12-2021). All methods were performed in accordance with the relevant guidelines and regulations. Patients received information sheets, and written informed consent forms were collected after permission was obtained. ClinicalTrials.gov has filed this study under the number NCT05418413 (14/06/2022).

Sample size calculation and participants

G*power 3.1.9.7 software (Universität Düsseldorf, Düsseldorf, Germany) was used to calculate the sample size on the basis of the changes in ANB angular from a prior related study[21], with the following assumptions: a paired t test with a power of 90%, a significance level of 0.05, and an effect size of 0.83. Consequently, the required sample size was 24 patients for each group. However, with an assumed withdrawal rate of 10%, the required sample size was increased to 26 patients for each group.

Participants and eligibility criteria

The same orthodontist (M.N.A.) performed the treatments. Clinical examinations, intraoral and extraoral photographs, dental casts, and radiographic records were taken before orthodontic treatment was started for 93 patients referred to the Department of Orthodontics, University of Damascus, between June 2022 and August 2022, and 65 patients who fulfilled the inclusion criteria were identified. When the research project was presented to the patients, 57 agreed to participate. Consequently, 52 patients (19 males, 33 females) were randomly selected.

The inclusion criteria were as follows: skeletal class II division 1 relationship (ANB > 4°) with the retrognathic mandible (SNB < 78°), an overjet of 5–10 mm, a normal growth pattern (Bjork sum < 402°), and patients at the pubertal growth spurt peak (S or MP3cap) epiphyseal stages on hand wrist radiographs[22].

The exclusion criteria were as follows: previous orthodontic treatment, systemic diseases that may affect the treatment results; severe facial asymmetry; posterior crossbite or severe maxillary transverse deficiency; flared lower incisors (L1: MP > 97°); poor oral hygiene; and inability to close the lips and breathe from the nose due to respiratory disorders.

Randomization, allocation concealment, and blinding

A computer-generated randomization list was used to randomly divide the patients into two equal groups via Minitab® Version 19.1 (Minitab Inc., Pennsylvania, USA), which was created by one of the academic staff (not involved in this research) at the Department of Orthodontics.

The allocation sequence was concealed via sequentially numbered, opaque, closed envelopes. Patient and practitioner blinding was not feasible. Therefore, blinding was applied only for the outcome assessor while plaster-distributed casts and cephalometric radiographs were recorded with serial numbers to ensure blinding and avoid bias in the investigation. Additionally, patients were asked not to tell outcome assessors the treatment they received.

Treatment method

Fifty-two patients (33 females and 19 males) aged 12.23 ± 0.77 years were included in the trial and were randomly divided into 2 equal groups. The first group was the ATB group (experimental group). The 2nd group was the CTB group (control group). The CTB was designed according to Clark[23] and consists of 2 plates with no midline screw in the maxillary plate (Fig. 1).

The ATB consisted of two 1.5 mm vacuum-formed hard plates (VFPs) (3 A MEDES®, Easy-Vac Gasket, Gyeonggi-do, Republic of Korea) that were placed individually on a vacuum machine to form the base of the appliance. The models with the VFPs and the reconstruction bite were mounted in the hinge-type articulator, and then acrylic bite blocks with inclined planes at 70° to the occlusal plane were fabricated on the VFPs similar to the CTB (Fig. 1). The appliances used in both groups were fabricated in the same laboratory, and clear acrylic was used (Fig. 1).

Both groups had a reconstruction bite with a single-step mandibular advancement and an edge-to-edge incisal relationship with a 2–3 mm bite opening between the central incisors. In the ATB group, bite registration was performed while the VFPs were in the patient's mouth, accounting for the thickness of the plates.

Follow-up during treatment

All participants and parents received both oral and written information on the treatment, oral hygiene and maintenance of the appliance and were instructed to wear the appliance full time except for eating and brushing (nighttime included) and to breathe from the nose with closed lips while the appliance was put. The degree of compliance with appliance wear was measured via 'compliance charts', which were completed by the parents. Patients were recalled 1 week after appliance first fitting and then every 3 weeks to check from the appliance and monitor patient compliance, fill out the questionnaire and to measure the overjet clinically by using digital piacolis after applying mild pressure on the chin while closing to ensure that there was no fake bite [Sunday bite]. The process ends at the end of the active phase of the functional therapy when the overjet is reduced to (1–2.5 mm), and the occlusion settles into class I.

Outcome measures

Skeletal and dental changes

Lateral cephalometric radiographs and trimmed dental casts were obtained at T0 (before treatment) and T1 (at the end of the active phase). All cephalometric radiographs were taken with the same device, i.e., a PAX 400 (VATEH Co., Ltd., Hwaseong, Korea), with the same settings. Sixteen angular variables and eleven linear variables (measured in millimeters) were evaluated via lateral cephalometric radiographs, and six linear variables were used to study Arch Dimensions on dental casts, intracanine width, intramolar width and anterior arch length[24–26] (Figs. 2 and 3).

The questionnaire

To assess esthetic and discomfort levels during the treatment, a special questionnaire was used, which was derived and further modified from the questionnaire used by Sergl et al. [Sergl et al.., 1998; Sergl et al.., 2000]. It consists of four questions covering the following elements: pain, speech impairment, oral constraint and lack of confidence in the public[27].

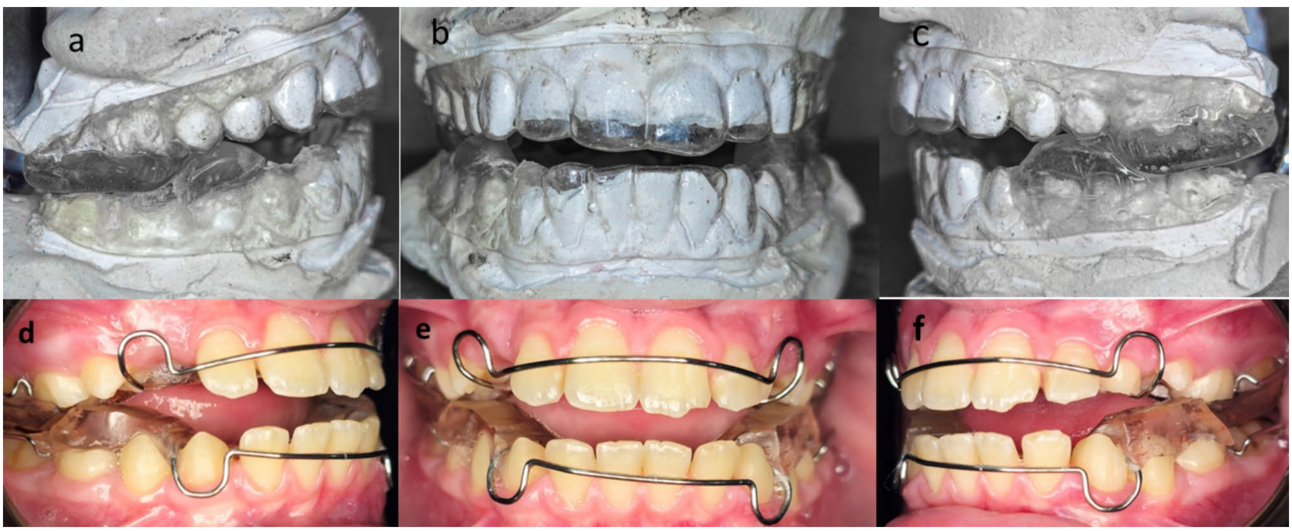

Fig. 1. (**a**) Right side view ATB. (**b**) Frontal view ATB. (**c**) Left side view of ATB. (**d**) Right side view of CTB. (**e**) Frontal view of the CTB. (**f**) Left side view of CTB.

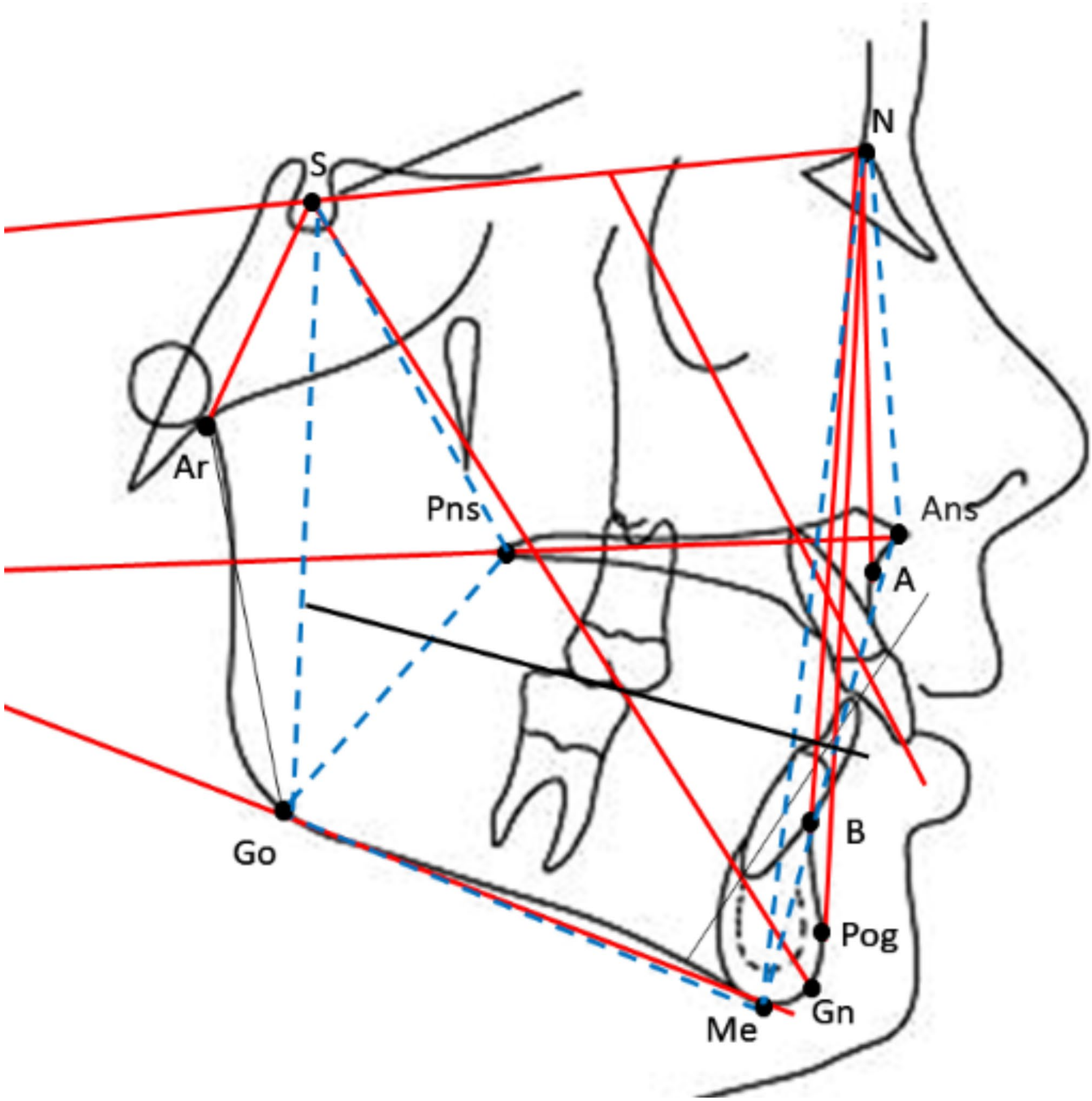

Fig. 2. Cephalometric measurements on the radiograms: *S* sella, *N* nasion, *A* A point, *B* B point, *NP* nasal plane, *MP* mandibular plane, *OP* occlusal plane, *Ar* articular, *Go* gonion, *Me* menton, *Gn* gnathion, *ANS* anterior nasal spine, *PNS* posterior nasal spine.

All questionnaires were completed by patients with the aid of their parents while the principal researcher (M.N.A.) was observing the procedure. Each subject completed the same questionnaire at the following times: 7 days (T1), 14 days (T2), three months (T3) and six months following initial appliance insertion (T4). The questions were answered on a four-point Likert scale: 1, not at all; 2, little; 3, much; and 4, very much.

Error of the method

Six weeks after the first measurement, fifteen random cephalograms and fifteen random dental casts were measured and analyzed again to determine method error. Reliability was evaluated via the intraclass correlation coefficient (ICC), which reflects strong intraexaminer reliability (ICC = 0.996).

The overall errors were calculated via the formula of Dahlberg. They do not exceed 0, 42 for the linear variable and 0,37 for the angular variable.

Fig. 3. Arches dimensions measurements on dental casts.

Statistical analysis

The statistical analysis was performed via SPSS for Windows (version 26.0; SPSS, Chicago, USA). The Shapiro–Wilk normality test was used to ensure the normal distribution of the data. The paired sample t test was used to study the significance of differences between the pre- and posttreatment variables in each group and to detect intragroup changes after the treatment. Independent t tests were used to compare the treatment results and find differences between the two groups. However, differences in the questionnaire results between the two groups were detected via the Mann‒Whitney U test. The level of significance was set at $p < 0.05$.

Results

Sample distribution

Fifty-two patients (33 females and 19 males) were included in the current trial. The ATB group comprised 26 patients (15 females and 11 males, with an average age of 12.41 ± 0.75), whereas the CTB group included 26 patients (18 females and 8 males, with an average age of 12.05 ± 0.76). The CONSORT flow diagram of patient recruitment, follow-up, and entry into the data analysis is given in (Fig. 4).

Baseline data

The basic sample characteristics are provided in (Table 1). The patients' initial ages were well matched between the two groups. Independent-sample t tests were performed to determine the significant differences between the two study groups before treatment. 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 and linear variables (Tables 2 and 3).

Dental and skeletal evaluation

The changes in the angular variables are shown in (Table 4). Table 4 shows a significant decrease in the ANB angle, which was caused by a significant increase in the SNB angle and SNPog angle. These changes were significantly greater in the ATB group than in the CTB group ($P = 0.002$, $P = 0.02$ and $P = 0.009$, respectively). These desired effects were accompanied by protrusions of the lower incisors of 1.34 ± 2.08° ($P = 0.004$) and 3.88 ± 2.47° ($P = 0.000$) in the ATB group and CTB group, respectively. The protrusions were significantly larger in the CTB group than in the ATB group ($P = 0.000$). The values of the U1:NP angle and U1:SN angle decreased significantly in the CTB group by -4.54 ± 3.25° ($P = 0.000$) and − 4.18 ± 3.34° ($P = 0.000$), respectively, whereas these values insignificantly decreased in the ATB group. These changes were significant between the CTB group and the ATB group ($P \leq 0.001$, $P \leq 0.008$, respectively). There was retraction of the upper incisors in the CTB group but only insignificant changes in the ATB group.

For the linear variables, Table 5 shows that similar changes occurred in the two groups, including a significant decrease in the overjet, overbite, and Wits values and a significant increase in the Go-Me and N-Me values. Conversely, many differences were observed between the two groups.

S-Go increased significantly by 2.57 ± 2.17 mm ($P = 0.000$) and 0.85 ± 1.99 mm ($P = 0.04$) in the ATB group and CTB group, respectively. The increase was significantly greater in the ATB group than in the CTB group ($P = 0.005$). The changes in N-Me and S-Go caused the Jarabak ratio to increase significantly in the ATB group by 0.84 ± 1.44% ($P = 0.007$) and to decrease significantly in the CTB group by -0.65 ± 1.37% ($P = 0.02$), with significant differences between the two groups ($P \leq 0.000$). There was vertical growth in the CTB group but horizontal growth in the ATB group.

S-Pns and N-Ans increased significantly in the CTB group (0.78 ± 1.52 mm ($P = 0.01$) and 1.27 ± 1.72 mm ($P = 0.001$), respectively), whereas these values insignificantly increased in the ATB group, with no significant difference between the two groups ($P = 0.102$) ($P = 0.425$).

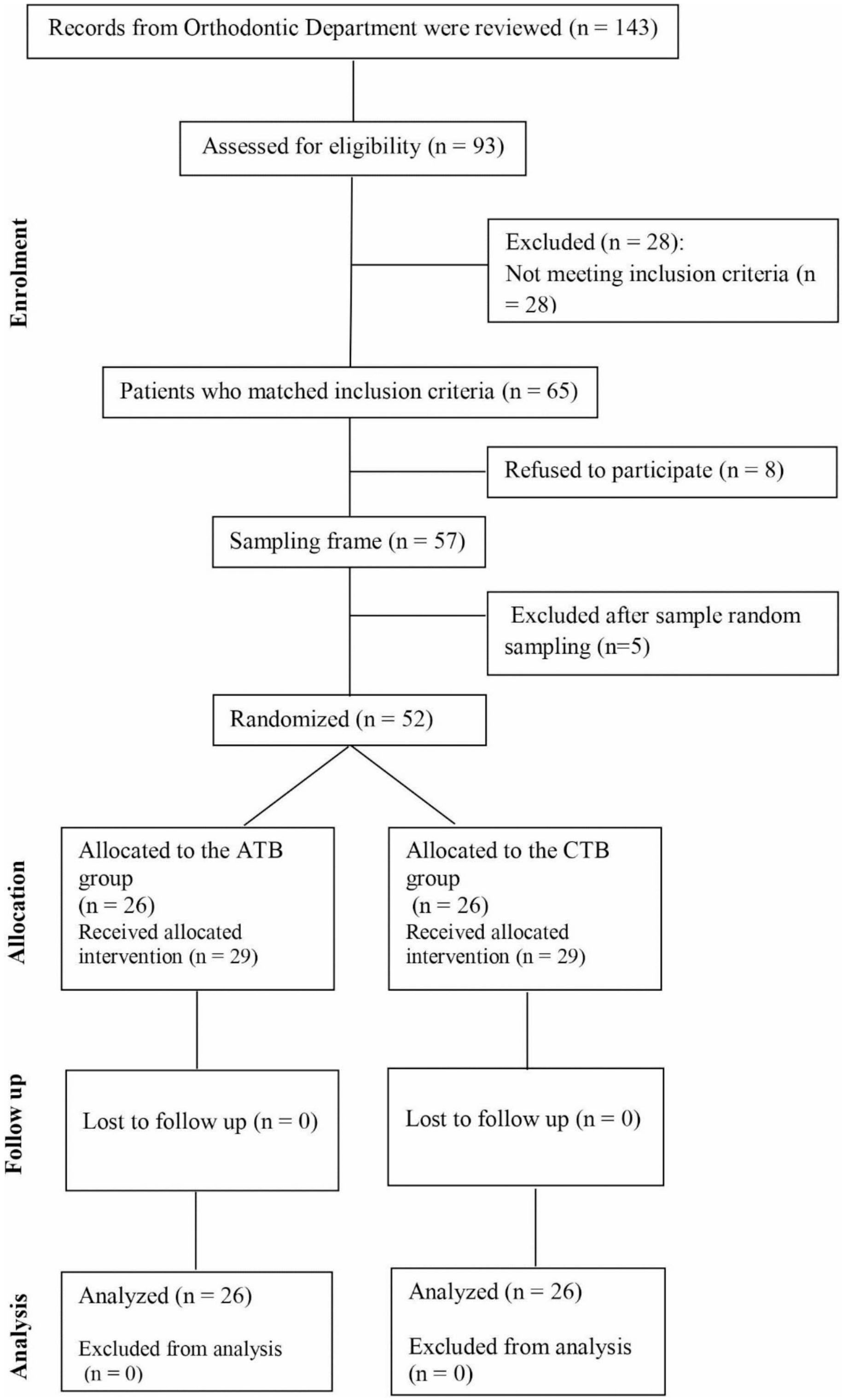

Fig. 4. CONSORT participant flow diagram.

Pns-Go and Ans-Me increased significantly in the ATB group (1.52 ± 2.62 mm ($P = 0.008$) and 1.98 ± 1.52 mm ($P = 0.000$), respectively), whereas these values insignificantly increased in the CTB group, with no significant difference between the two groups ($P = 0.107$) ($P = 0.237$).

There were no significant changes in the intracanine or intramolar width of the arches in either group. However, there was a significant decrease in upper anterior arch length in the CTB group by -0.94 ± 0,20 ($P = 0.000$) and in the ATB group by -0.42 ± 0,50 ($P = 0.000$), with a significant difference between the two groups

Variable/group		ATB ($n=26$)	CTB ($n=26$)	*P* value	Significance
Gender	Male	11	8	0.66†	NS
	Female	15	18		
Age (in years): mean ± SD		12.41(0.75)	12.05(0.76)	0.56‡	NS

Table 1. The basic sample sample characteristics. *ATB* aesthetic twin block appliance; *CTB* conventional twin block appliance. *NS* non significant at $P>0.05$. †Chi-Square; ‡Independent-samples to test.

	ATB T0 ($n=26$)	CTB T0 ($n=26$)		
Variable	Mean (SD)	Mean (SD)	P value†	Significance
SNA	80.94) 3.28)	82.10 (3.83)	0.115	NS
SNB	74.38 (3.77)	75.64 (3.70)	0.109	NS
ANB	6.56 (1.37)	6.50 (1.56)	0.880	NS
SNPog	74.92 (3.75)	75.98 (3.58)	0.107	NS
SN: NP	9.20 (3.23)	8.60 (2.75)	0.144	NS
SN: MP	37.14 (4.41)	37.44 (3.55)	0.792	NS
B	25.94 (3.91)	26.84 (2.84)	0.286	NS
NSAr	128.80 (6.06)	126.90 (7.59)	0.339	NS
SArGo	139.16 (5.73)	139.72 (7.97)	0.771	NS
ArGoMe	127.48 (6.14)	130.28 (4.81)	0.088	NS
Bjork Su	395.44 (5.25)	396.92 (3.67)	0.258	NS
NSGn	71.80 (3.55)	70.20 (3.28)	0.178	NS
U1:NP	115.72(7.10)	115.04 (6.80)	0.731	NS
U1:SN	104.52 (7.18)	106.90 (5.28)	0.188	NS
L1:MP	93.6 (2.38)	93.00 (3.24)	0.577	NS
U1:L1	117.70 (9.23)	117.54 (8.30)	0.932	NS

Table 2. Comparison of pretreatment cephalometric angular variables. *A* A point, *Ar* articular, *ATB* aesthetic twin block appliance, *B* B point, *CTB* conventional twin block appliance, *Gn* gnathion, *Go* gonion, *L1* lower central incisor, *Me* menton, *MP* mandibular plane, *N* nasion, *NP* nasal plane, *S* sella, *U1* upper central incisor, *SD* standard deviation, *NS* non significant at $P>0.05$. †Independent-samples t test.

($P=0.000$), and a significant increase in lower anterior arch length in the CTB group by 0.89 ± 0,40 ($P=0.000$) and in the ATB group by 0.37 ± 0,38 ($P=0.001$), with a significant difference between the two groups ($P=0.000$).

Esthetic and discomfort evaluation

When the children were asked if the appliance had been painful or not, the answers revealed that ATB and CTB caused mild levels of pain, and this sensation decreased at all assessment times, with no significant differences between the two groups. The most disturbing complaint with CTB was speech impairment; speech impairment was significantly greater in the CTB group than in the ATB group at T2, T3 and T4. The two appliances caused a mild amount of oral constraint and little constriction to the lower jaw movements, which decreased in both groups during assessment times. There were no significant differences between the two groups. The CTB caused a high degree of 'lack of confidence in public', whereas the ATB caused a small amount of lack of confidence, and the differences between the two groups were significant at T1 and T2 (Table 6; Fig. 5).

Harms

No serious harm was observed.

Discussion

The ATB appliance is a modification of a twin block using VFPs as the base of the appliance (as in our study). Reports have reported different results in terms of skeletal and dentoalveolar changes with ATB[18–20]. This RCT suggested the study of the effects of ATB. In the present study, a 1.5 mm VFPs and clear acrylic were used. All patients were at the peak of the pubertal growth spurt to ensure the best effects of the treatment. The cephalometric changes were evaluated at the end of the active phase of functional treatment. The degree of compliance with appliance wear was good at least 16 h a day, which was confirmed by the use of 'compliance charts', which were completed by the parents.

Skeletal changes

In both groups, SNA was minimally decreased, but this decrease was not significant. This might be due to the distal force on the maxilla (headgear effect). Therefore, it could be assumed that some restriction of maxillary

Variable	ATB T0 (*n*=26) Mean (SD)	CTB T0 (*n*=26) Mean (SD)	P value†	Significance
Overjet	7.38) (1.24)	6.91 (1.26)	0.195	NS
Overbite	4.67 (1.02)	4.04 (1.21)	0.065	NS
Wits	1.75 (2.79)	1.36 (2.35)	0.595	NS
S_Go	67.11 (6.09)	66.88 (4.27)	0.876	NS
N_Me	109.51 (5.28)	107.28 (6.30)	0.186	NS
Jarabak ratio (%)	61.28 (4.68)	62.38 (2.78)	0.328	NS
S_Pns	42.04 (3.04)	42.21 (3.23)	0.843	NS
Pns_Go	38.93 (4.64)	37.69 (3.74)	0.304	NS
N_Ans	50.84 (3.23)	49.02 (3.34)	0. 478	NS
Ans_Me	61.79 (4.72)	62.92 (4.57)	0.392	NS
Go_Me	63.74 (5.01)	63.02 (4.84)	0.608	NS
UIC	34.06 (1.96)	33.80 (1.62)	0.602	NS
LIC	26.12 (1.18)	26.89 (1.43)	0.064	NS
UIM	44.93 (1.45)	44.67 (2.78)	0.686	NS
LIM	45.58 (1.86)	45.25 (2.77)	0.614	NS
UAL	18.90 (1.75)	19.30 (1.19)	0.356	NS
LAL	16.41 (1.42)	16.22 (1.11)	0.606	NS

Table 3. Comparison of pretreatment cephalometric linear variables. *ANS* anterior nasal spine, *ATB* aesthetic twin block appliance, *Go* gonion, *LAL* lower anterior length, *LIC* lower intracanines width, *LIM* lower intramolars width, *Me* menton, *N* nasion, *PNS* posterior nasal spine, *S* sella, *CTB* conventional twin block appliance, *UAL* upper anterior length, *UIC* upper intracanines width, *UIM* upper intramolars width. †Independent-samples t test; *SD* standard deviation, *NS* non significant at *P*>0.05.

	ATB T1-T0 (*n*=26)		CTB T1-T0 (*n*=26)		ATB/CTB T1-T0
Variable	Mean (SD) T1-T0	P value†	Mean (SD) T1-T0	P value†	P value‡
SNA	−0.10 (1.33)	0.712	−0.20 (1.51)	0.514	0.802
SNB	2.72 (1.54)	*0.000***	1.72 (1.41)	*0.000***	**0.02***
ANB	−2.70 (0.84)	*0.000***	−1.92 (0.81)	*0.000***	**0.002****
SNPog	2.72 (1.33)	*0.000***	1.65 (1.5)	*0.000***	**0.009****
SN: NP	0.16 (1.49)	0.594	0.36 (1.81)	0.334	0.676
SN: MP	0.26 (2.52)	0.616	0.04 (2.3)	0.698	0.744
B	0.10 (2.62)	0.855	−0.32 (2.37)	0.503	0.553
NSAr	0.08 (3.27)	0.904	−1.24 (4.51)	0.186	0.242
SArGo	−0.12 (4.04)	0.906	0.40 (4.96)	0.693	0.718
ArGoMe	0.92 (3.14)	0.157	0.92 (2.75)	0.108	1.006
Bjork Su	0.88 (3.87)	0.266	0.08 (4.11)	0.923	0.487
NSGn	−0.06 (1.63)	0.855	−0.20 (1.42)	0.494	0.744
U1:NP	−1.88 (1.48)	0.647	−4.54 (3.25)	*0.000***	**0.001****
U1:SN	−2.00 (2.02)	0.716	−4.18 (3.34)	*0.000***	**0.008****
L1:MP	1.34 (2.08)	*0.004***	3.88 (2.47)	*0.000***	**0.000****
U1:L1	−1.48 (6.23)	0.246	1.38 (5.86)	0.255	0.109

Table 4. Comparison of the angular variables changes between the 2 groups. *A* A point, *Ar* articular, *ATB* aesthetic twin block appliance, *B* B point, *CTB* conventional twin block appliance, *Gn* gnathion, *Go* gonion, *L1* lower central incisor, *Me* menton, *MP* mandibular plane, *N* nasion, *NP* nasal plane, *S* sella, *U1* upper central incisor, *SD* standard deviation. *significant at *P*>0.05; **significant at *P*>0.01. †Paired-samples t test. ‡Independent-samples t test.

growth has occurred. Studies by Tripathi et al.. and Singh et al.. revealed restrictions of the maxilla[18,20], whereas the study of Golfeshan et al.. did not reveal restrictions in the ATB[19]. The differences in results between their study and the current study could be attributed to the differences in working methods. A significant increase in mandibular length (GO-Pog) was observed in both groups, with no significant difference between the 2 groups ($p=0.13$). This result agrees with the studies of Tripathi et al.. and Golfeshan et al. on the affected mandibles[18,19]. This increase in both groups was greater than that in other removable functional appliances and may be due

Variable	ATB T1-T0 (*n* = 26)		CTB T1-T0 (*n* = 26)		ATB/CTB T1-T0
	Mean (SD) T1-T0	P value†	Mean (SD) T1-T0	P value†	P value‡
Overjet	−3.92 (1.15)	*0.000***	−3.88 (1.11)	*0.000***	0.895
Overbite	−1.74 (0.89)	*0.000***	−1.46 (1.01)	*0.000***	0.373
Wits	−2.76 (2.16)	*0.000***	−2.67 (1.6)	*0.000***	0.865
S_Go	2.57 (2.17)	*0.000***	0.85 (1.99)	*0.04**	**0.005****
N_Me	2.92 (3.10)	*0.000***	2.51 (3.07)	*0.000***	0.633
Jarabak ratio (%)	0.84 (1.44)	*0.007***	−0.65 (1.37)	*0.02**	**0.000****
S_Pns	0.01 (1.89)	0.967	0.78 (1.52)	*0.01**	0.102
Pns_Go	1.52 (2.62)	*0.008***	0.34 (2.38)	0.485	0.107
N_Ans	0.83 (2.13)	0.062	1.27 (1.72)	*0.001***	0.425
Ans_Me	1.98 (1.52)	*0.000***	0.77 (2.18)	0.095	0.237
Go_Me	3.35 (1.53)	*0.000***	2.30 (1.47)	*0.000***	0.132
UIC	0.01 (0.25)	0.75	0.03 (0.08)	0. 214	0.596
UIC	−0.05 (0.16)	0.13	−0.04 (0.18)	0.195	0.984
UIM	−0.02 (0.25)	0.64	−0.08 (0.67)	0.525	0.666
LIM	−0.01 (0.14)	0.55	0.04 (0.20)	0.337	0.258
UAL	−0.42 (0.50)	*0.000***	−0.94 (0.56)	*0.000***	**0.001****
LAL	0.37 (0.38)	*0.001***	0.89 (0.40)	*0.000***	**0.000****

Table 5. Comparison of the linear variables changes between the 2 groups. *ANS* anterior nasal spine, *ATB* aesthetic twin block appliance, *Go* gonion, *LAL* lower anterior length, *LIC* lower intracanines width, *LIM* lower intramolars width, *Me* menton, *N* nasion, *PNS* posterior nasal spine, *S* sella, *CTB* conventional twin block appliance, *UAL* upper anterior length, *UIC* upper intracanines width, *UIM* upper intramolars width, *SD* standard deviation. *Significant at $P > 0.05$; **Significant at $P > 0.01$. †Paired-samples t test; ‡Independent-samples t test.

SenSation	T1	T2	T3	T4
Pain	0.093	0.150	0.209	0.933
Speech impairment	0.098	*0.013**	*0.004***	*0.001***
Oral constriction	0.205	0.098	0.585	0.308
Lack of confidence in public	*0.002***	*0.001***	0.32	0.195

Table 6. Significance of differences in the comparisons made between the two groups at each assessment time. P- Values from Mann-Whitney U tests when evaluating differences between the two groups at the four assessment times (*)Significant differences at $P < 0.05$, (**)Significant differences at $P < 0.01$.

to the difference in the variable (Co_Pog instead of Go_Me)[9]. The forward motion of the mandible, which was demonstrated by significant increases in SNB and SNPog angles, has been reported in several studies[28,29]; the ATB shows a significantly greater increase in SNB and SNPog angles, leading to significantly greater decreases in the ANB angle, which is in agreement with previous studies[18,20]. In addition, this change was greater than that of other removable functional appliances (i.e., activator, bionator, and Frankel)[30]. The results of the current study indicate that both appliances were effectively able to correct skeletal Class II malocclusion, as evidenced by a significant decrease in the ANB angle, overjet, and Wits value during the treatment period, with the superiority of ATB.

Burhan et al., Mills, and McCulloch reported that CTB might be able to prevent any increase in the vertical dimension[29,31]. In our study, the 2 groups showed no significant changes in most vertical measurements except the jarabak ratio. The ratio increased significantly in the ATB group because of a significant increase in posterior face height. The reason for this might be the complete coverage of the dental arch by the VFPs and its thickness combined with bite block height, which leads to a greater opening of the Leeway space in addition to closing the lips and thus further promoting molars intrusion and inhibiting vertical growth (Fig. 6). Singh et al.. and Golfeshan et al. reported similar results[19,20]. This could suggest that ATB could be more beneficial in class II patients with vertical growth patterns.

Dental changes

In the CTB group, lower incisor angulation increased by 3.88° ±2.47. Ehsani et al. reported significantly lower incisor proclination during functional treatment with CTB[10]. The degree of lower incisor proclination in the present study was lower than that reported in most studies in the abovementioned systematic review with CTB. In the present study, 97° of the maximum angle was taken before treatment, which provides more bone anchorage in the lower labial segment, potentially explaining the differences in results. In the ATB group, the lower incisor

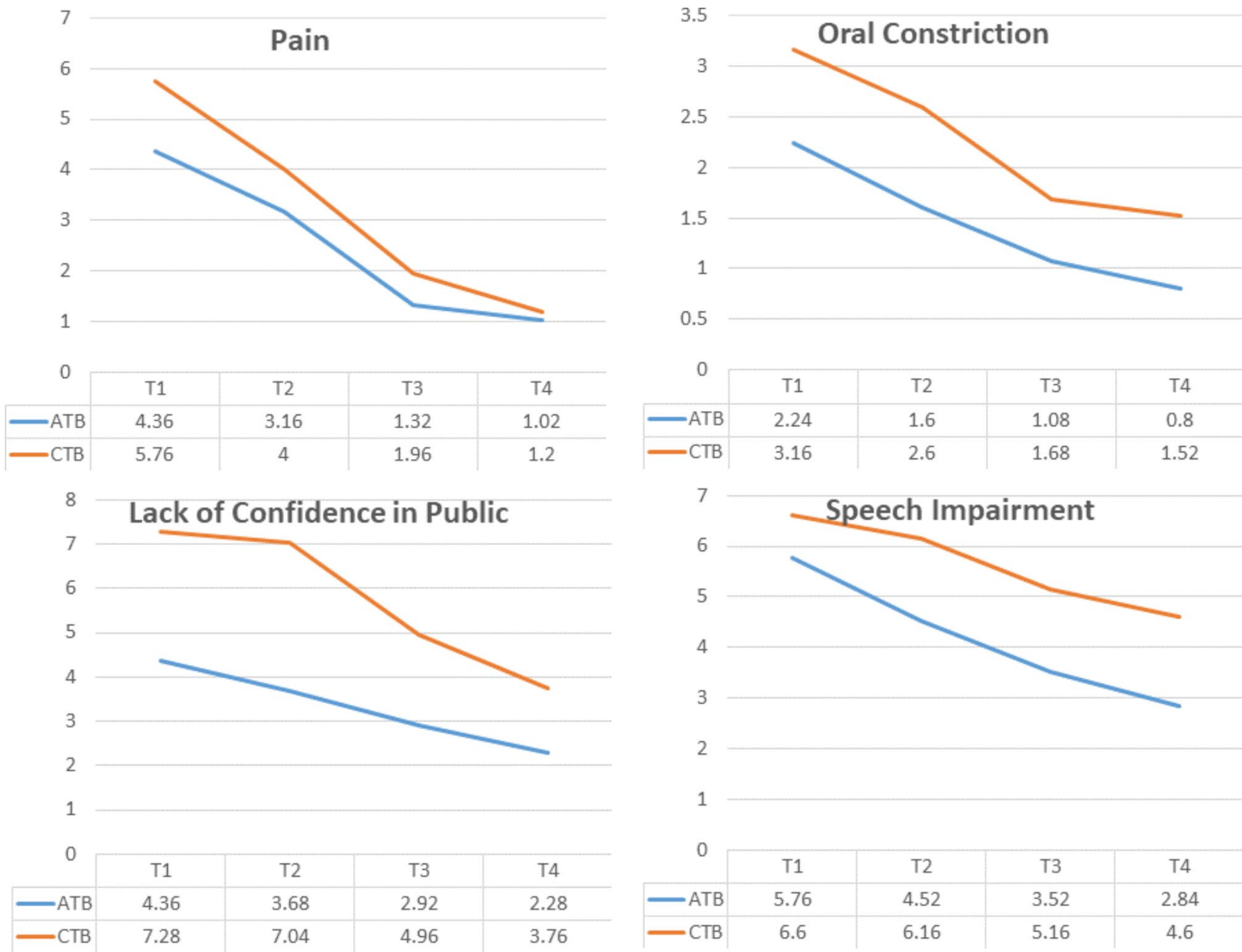

Fig. 5. Changes in esthetic and discomfort levels.

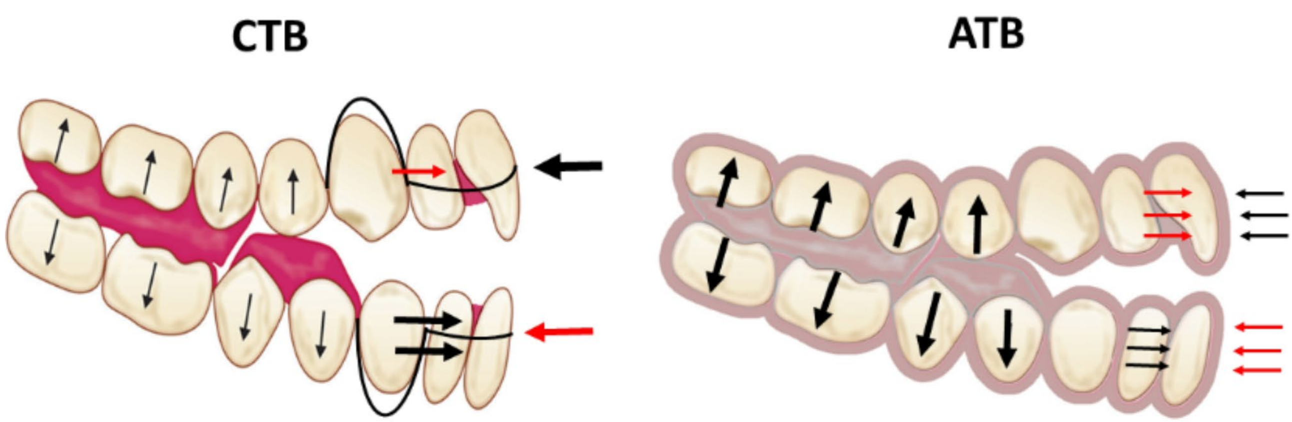

Fig. 6. Forces while using CTB and ATB.

angulation increased by 1.34° ±2.08, which was significantly less than that in the CTB group, which agreed with the findings of Golfeshan et al.. and Tripathi et al.[18,19]. This may be due to the complete coverage of the buccal surface cervically of the lower incisors by VFP and its rigidity, which limits the effect of the mesial forces resulting from the appliance and reinforced anchorage, providing greater stability in the sagittal dimension. Unlike Singh et al., *a* 1 mm VFP thickness (less than ours) was used, and the small number of patients could be the reason for this difference[20]. In addition, the increase in the length of the lower anterior arch length was less common in the ATB group, which reinforces this result (Fig. 6). This flaring in the ATB group was greater than that in the frankel appliance group and less than that in the activator and bionator groups[30]. The results of the present study support the idea that the ATB provides more control to lower incisors and potentially enhances skeletal correction.

The upper incisor angulation in this study significantly decreased in the CTB group, possibly because the distal force resulting from the appliance being concentrated in the labial bow area led to uncontrolled tilting, unlike in the ATB group, where the buccal and palatal surfaces were completely covered, which limits the effect of this tilting and leads to insignificant retraction. The significant decrease in the upper anterior arch length in the CTB group compared with the ATB group supports this effect (Fig. 6). Tripathi et al.[18] reported a significant decrease in upper incisors in ATB groups, which may be due to a reduction in rigidity caused by the splitting of the appliance by the expansion screw and the use of thinner VFPs[18]. This retraction in the ATB group was less than that in the other removable functional appliance groups (i.e., activator, bionator, frrankel)[30].

There were no significant changes in the transverse dimensions of the canines or molars, possibly due to the absence of an expansion screw in either appliance.

Esthetics and discomfort

The two appliances caused a little amount of pain during the short term at T1 and T2, which then decreased gradually because of the patient's adaptation to pain and discomfort when the treatment progress agreed with that of Alhayek et al.[32]. The CTB caused a greater level of speech impairment, which may be due to its design, in which the acrylic base extends and covers more palatal rugae and had wire elements, such as the labial bow and clasps. These results agreed with those of Idris et al..'s study, which noted that speech impairment was greater with Trainer T4k™, which had more extension than did the activator[27].

The 'oral constraint' was not a problem a little amount stated by participants in this study for both appliances at all assessment times, possibly because the two appliances consisted of two plates, which provided more freedom during jaw movement. The ATB had an aesthetic appearance with no wire elements and a clear color; however, the CTB had wire elements and caused greater speech impairment, which is likely one of the reasons for the greater level of acceptance of the ATB than the CTB. These previous factors may lead to greater compliance with ATB.

Limitation

A limitation of this research is the lack of an untreated control group with which to study neutral growth changes for ethical reasons. However, the resulting differences between the two groups can be attributed to appliance differences, which fulfill the aim of the current research. Blinding was applied only for the outcome assessor when the casts and cephalometric radiographs were recorded. This might be considered a limitation of this study, but this was not possible owing to the clarity of the appliances.

Conclusions

Both the CTB and the ATB can lead to the correction of skeletal Class II malocclusion resulting from the retrusion of the mandible, with some advantages of the ATB in mandibular advancement, control of lower and upper incisor angulation, and vertical growth development. Compared with CTB, ATB was superior in terms of aesthetics and discomfort, which may lead to better compliance. ATB is preferred for mandibular advancement in Class II growing patients.

Data availability

The data used and analyzed during the current research are available from the corresponding author upon request.

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Author contributions
M.N.A. contributed in collection of data; data analysis/interpretation and writing of the manuscript.M.Y. contributed in study design, data analysis and writing of the manuscript.

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Declarations

Competing interests
The authors declare no competing interests.

Ethics approval and consent to participate
The institutional review board and the ethical review committee of Damascus University (No. 1205–06–12–2021) approved this study. Written informed consent was obtained from each patient.

Additional information
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