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Assessment of the condylar response of two differently anchored fixed functional appliances in class II malocclusion in young adult orthodontic patients: A randomized clinical trial

Mahmoud M. Fathy Abo-Elmahasen, Mohamed Elsaharty[1], Neven Fakhry Abotaha[1] and Ahmed Abdel Salam Mohamed[2]

Department of Orthodontics, Faculty of Dental Medicine (Cairo, Boys), Al-Azhar University, Cairo, Egypt, [1]Department of Orthodontics, Faculty of Dentistry, Tanta University, Egypt, [2]Department of Orthodontics, Faculty of Dentistry, Menofia University, Egypt

Address for correspondence: Dr. Mahmoud M. Fathy Abo-Elmahasen, Lecturer, Department of Orthodontics, Faculty of Dental Medicine (Cairo, Boys), Al-Azhar University, Cairo, Egypt. **Official Address:** Faculty of Dental Medicine, Al- Azhar University, in front of Conference Hall, Al Nasr Road, Nasr City, Cairo, Egypt. **Home address:** Building No. 5 (Building of Zahraa AL – Maadi Company) in front of Compound of Ashgar Darna, Al Saada Street, The Tenth Part, Zahraa AL – Maadi, Cairo, Egypt. E-mail: MahmoudFathy.209@azhar.edu.eg

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Abstract

OBJECTIVE: Measuring the condylar volume changes after treatment with skeletally anchored type IV Herbst appliance vs. Twin Force Bite Corrector (TFBC) in class II malocclusion in young adult patients.

MATERIALS AND METHODS: Twenty class II malocclusion participants were randomly involved in our randomized clinical study. They are divided equally into two groups: group I (10 patients with an age range of 16 to 18 years and a mean age of (17.15 ± 0.62) (five males and five females) with a mean Angle formed between (A) point and (Nasion) point and (B) point, to determine anteroposterior relation between maxilla and mandible (ANB) of 6.20 (1.03) and a mean mandibular length of 106.1 (1.7), who were treated by a skeletally anchored type IV Herbst appliance, supported at the mandible by two mini-plates fixed bilaterally at the mandibular symphysis; group II (10 patients with an age range of 15 to 18 years and a mean age of (16.85 ± 0.33) (six males and four females) with a mean ANB of 6.80 (0.89) and a mean mandibular length of 107.3 (2.36), who were treated by a TFBC that was installed just mesial to the tube of the maxillary first permanent molar and distal to the bracket of the lower canine for 4 months. According to the Index of Orthognathic Functional Treatment Need (IOFTN) index, the participants in both groups have grade 4 (great need for treatment) as they have excessive overjet (6–9 mm). Cone-beam computed tomography (CBCT) was taken just before installing fixed functional appliances and after the removal. The condylar volume was measured using Dolphin software. Parametric measurements were performed by the independent *t*-test, while non-parametric variables (percent change) were compared by the Mann-Whitney U–test.

RESULTS: On the right side, the Herbst group recorded a percent increase (median = 1.23%), while TFBC recorded a median percent decrease (-7.85%). This change is statistically significant ($P = 0.008$).

CONCLUSIONS: The difference in the condylar volume was significantly higher with the mini-plate anchored Herbst appliance than with the dentally anchored TFBC group.

Keywords:

Class II, condyle, fixed functional appliance, mini-plate anchored Herbst, TFBC

Introduction

One of the most prevalent orthodontic issues is skeletal class II malocclusion, which affects around thirty percent of the population.[1,2] Despite several skeletal and dental combinations that can lead to the development of class II, mandibular retrognathism is credited as the primary cause.[3,4]

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In patients with skeletal class II malocclusions, the mandible is typically too small and/or too retruded; hence, the goal of orthodontic and orthopedic treatment should be to move the jaw forward and stimulate the condyle growth and the glenoid fossa remodeling.[5-8]

Regarding class II malocclusion therapy, functional appliances are frequently used to correct class II malocclusion associated with mandibular retrognathism.[9-12] It was advised to use rigid fixed functional appliances (FFAs) such as the Herbst appliance and the Functional Mandibular Advancer rather than semi-rigid ones such as the power scope and the Forsus Fatigue Resistant Device (Forsus FRD).[13]

It was advised to use rigid FFAs such as the Herbst appliance and the Functional Mandibular Advancer rather than semi-rigid ones such as the power scope and the Forsus FRD.[13]

However, Jeff Rothenberg introduced the Twin Force Bite Corrector (TFBC) in 2004 as a new fixed appliance with a constant, integrated force for class II correction.[14] The TFBC consisted of two telescopic systems connected by internal coil springs. The appliance is screwed to the main orthodontic archwire mesial to the upper first molar tube and distal to the lower canine brackets to produce an average compression force of 210 g.[15,16]

Nonetheless, previous studies stated that the advancement of the mandible and downward and forward repositioning of the condyle cause adaptive remodeling of the condyle and glenoid fossa.[17,18] It has the potential to change the position of the articular disc.[19,20] It is critical to understand the treatment-induced changes in the Temporomandibular joint (TMJ) and its components to achieve the stability of treatment after mandibular advancement.[21-23]

The majority of the present research in this field, however, has concentrated on dentoalveolar changes assessed using a study model or lateral cephalometry. Robust evaluation of the morphology of the temporomandibular joints requires imaging techniques with increased power of penetration for the TMJ area, such as computed tomography (CT) and cone–beam computed tomography (CBCT).[24,25]

Mini-plate anchored Forsus FRD was introduced to overcome the dentoalveolar side effects of fixed functional appliances as the proclination of lower anterior teeth. Although the Herbst appliance is considered the best fixed functional appliance with successful skeletal and dentoalveolar effects, there are a few works of literature that discuss the efficacy of mini-plate anchored Herbst appliance.[26-28]

The skeletal effect of Herbst appliance was discussed in previous literature studies; Kevin O Brien reported that there is no difference in the skeletal effects between the twin block and the Herbst appliances[29] also, Kevin O Brien used skeletally anchored Herbst appliance to reduce harmful effects of dentally anchored one as proclination of the lower incisors was accompanied by gingival recession.[30]

Does the skeletally anchored Herbst appliance produce a different effect on the condylar volume than the TFBC due to the difference in nature of anchorage and rigidity of them, or do they have a similar effect? The scarcity of evidence related to this question in orthodontic research raised the need for this study.

Subjects and Methods

Study design

This is a prospective parallel randomized clinical study.

Study setting and population

This study was conducted on twenty young adult patients aged 15 to 18 years. The Herbst group (group I) included ten young adult patients treated by mini-plate anchored type IV Herbst appliance (Dentaurum GmbH and Co., KG, Germany), while the TFBC group (group II) included 10 young adult patients treated by dentally anchored TFBC (Ortho Organizer, Inc., 1822 Aston Avenue, HenryScheinOrtho.com, USA), and both group patients were selected from patients seeking orthodontic treatment at different orthodontic clinics.

Sample size calculation

The sample size calculation depended on the observed average effect size derived from the previous study.[15] Effect size (δ) is the standardized difference—the absolute difference Δ divided by the standard deviation σ. The calculation indicated that for a prospective randomized clinical study with an estimated effect size of 1.3678606, tail(s) =2, allocation ratio N2/N1 = 1, a power of 0.80, and an alpha of 0.05, a total sample of 20 patients are required (10 patients in each group).

Ethical consideration

This study was approved by the ethical committee of the regional institution related to the corresponding author's work. This study was registered on clinical trials.gov PRS with ID NCT05466344. All participants included in this study have signed an informed consent form that describes each step of treatment.

Inclusion criteria

Patients were selected according to the following criteria: (1) class II malocclusion due to mandibular retrusion with increased overjet angle formed between (S) point (Sella torcica) and (Nasion) point and (A) point, to determine Maxilla position to the cranium (SNA) (SNA = 82 ± 4, ANB = 5 – 9°) with age from 15 to 18 years; (2) lower arch with mild crowding; (3) all permanent dentitions are present; (4) good oral hygiene; (4) no presenting chronic disease that could affect the orthodontic treatment; and (5) no orthodontic work has been done in the past.

Groups' randomization

The patients involved in the study groups were randomly distributed through a simple online-generated randomization plan using online software found at the website http://www.graphpad.com/quickcalcs/index.cfm. The allocation ratio is 1:1.

Intervention (treatment steps)

As for Group I [Figure 1]

The Herbst appliance was held in place in the mandible, connecting directly to two mini-plates on the right and left sides that were placed between the cuspid and first bicuspid teeth, avoiding any dental loading. In contrast, the upper arch was connected to dental splints and bands.

The mini-plates (Universal Plates 2.3 mm, Four Holes, Stryker, USA) with the soldered Herbst base at the top hole of each plate were pre-bent and adapted to a 3D model of the patient that was printed by a 3D printer (Anycubic Chiron 3D Printer, China) using the patient's pre-cone beam.

Under local anesthesia, an envelope flap extending downward to the symphysis level was raised in the mandible to allow unrestricted installation of the mini-plate. As the mini-plates were manually pre-bended, their surgical placement was easy and did not take time. The mini-plates were placed between the lower cuspid and first bicuspid teeth on both sides and fixed to the bone directly by 2.3 screws (Stryker, USA) through drilling and screw tapping.

As for maxillary dental splints, ready-made bands for the cuspid, first bicuspid, and first and second molars were selected and fitted, an impression was taken, and the bands were repositioned in them and sent to the laboratory to construct the dental splint. The splint consists of wiring connecting the bands on each side from the palatal surface and two transpalatal arches connecting the bands across the palatal. All the wire connections were laser welded to ensure accuracy and cleanliness and to avoid two things: weakening of the bands through traditional soldering and solder bulkiness that may interfere with the lower dentition. A Herbst base was welded to the buccal surface on the first molar band on each side for Herbst attachment.

After 9 months, the appliances were removed, and the mini-plates were taken out during a second surgery. A CBCT was taken. Each patient's orthodontic treatment was finished with a fixed device to achieve a stable and reliable occlusion.

As for Group II [Figure 2]

As for anchorage preparation before the installation of the TFBC, a transpalatal arch and a passive lingual appliance were cemented to the upper and lower arches.

The upper and lower dental arches were leveled and aligned using a pre-adjusted straight wire bracket system (Ormco, Mini 2000, USA) with series Ni-Ti archwires (Ormco, USA) ended up with 0.0019 × 0.0025 inches of statistically significant (SS) archwire to which the TFBC appliance has been fixed just mesial to the tube of the maxillary first permanent molar and distal to the bracket of the lower canine. The upper and lower dental arches were tied by (eight pattern ligation) brass ligature wire (0.0010 Inch SS, Ormco, USA) under the SS archwire.

The TFBC appliance was retained for 4 months; during this stage, the patient had an edge-to-edge incisal bite.

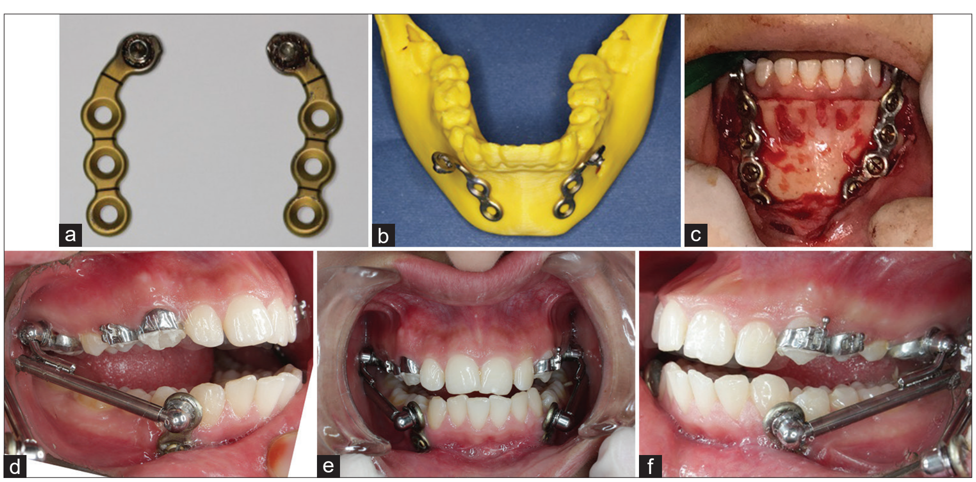


Figure 1: (a-f) Treatment steps using mini-plate anchored type IV Herbst appliance

After the TFBC device removal, another CBCT was taken. The patients were instructed to wear class II intraoral elastics for 2 months to achieve good adapted occlusal settling.

Outcomes

The primary outcome of this study is the amount of change in the condylar volume between both groups and within each group.

Records

CBCT scans (Planmeca ProMax® 3D Mid Imaging Unit, Ø200 × 170 mm, USA) were obtained just before installation and immediately after the removal of fixed functional appliances.

Error of the study

To evaluate reading reliability, ten CBCTs were randomly chosen, and then, the condylar volumes were re-assessed 2 months after the first evaluation. Reliability was assessed via intra-class correlation (ICC), which revealed excellent intra-examiner reliability (ICC ¼ 0.98), and the Dahlberg formula, which produced little error that had no effect on the final reading.

Assessment of the condylar volume [Figure 3]

Firstly, the pretreatment right condyle was separated. The condyle was cut inferiorly along a line with the same level as the Frankfort horizontal plane at the deepest point on the sigmoid notch, using the software's clipping and cutting features to mark and surround the part of the skull volume that was to be permanently removed from the screen and leave an isolated condyle.

The software was used to determine the condylar volume. For the left condyle, the same procedures were followed. All patients in both groups had their condylar volume measured at T1 (before the installation of a fixed functional device) and T2 (after fixed functional appliance removal).

Cephalometric skeletal and dental measurements

ANB angle, mandibular length, and lower incisors with mandibular plane angle were used to assess the skeletal effects of both appliances and their effects on lower anterior teeth.

IOFTN scores

All participants in both groups have been assessed according to the Index of Orthognathic Functional Treatment Need.

Assessment of the glenoid fossa relocation:

Superimposition was performed on pretreatment and posttreatment CBCT records using skeletal landmarks as guiding superimposition points, followed by automatic tuning to the two models to ensure accurate and precise superimposition, and a graduated color scale linear measurement was used to clarify the difference in position in the fossa location between the pretreatment and post-treatment records. To verify the results, axial sections containing the superimposed models were taken.

Statistical analysis

Statistical analysis was conducted by the Statistical Package for Social Sciences (SPSS) version 18. Measurements were tabled in additional terms of means and standard deviations. Readings were evaluated for normality of distribution using Kolmogorov-Smirnov and Shapiro-Wilk tests.

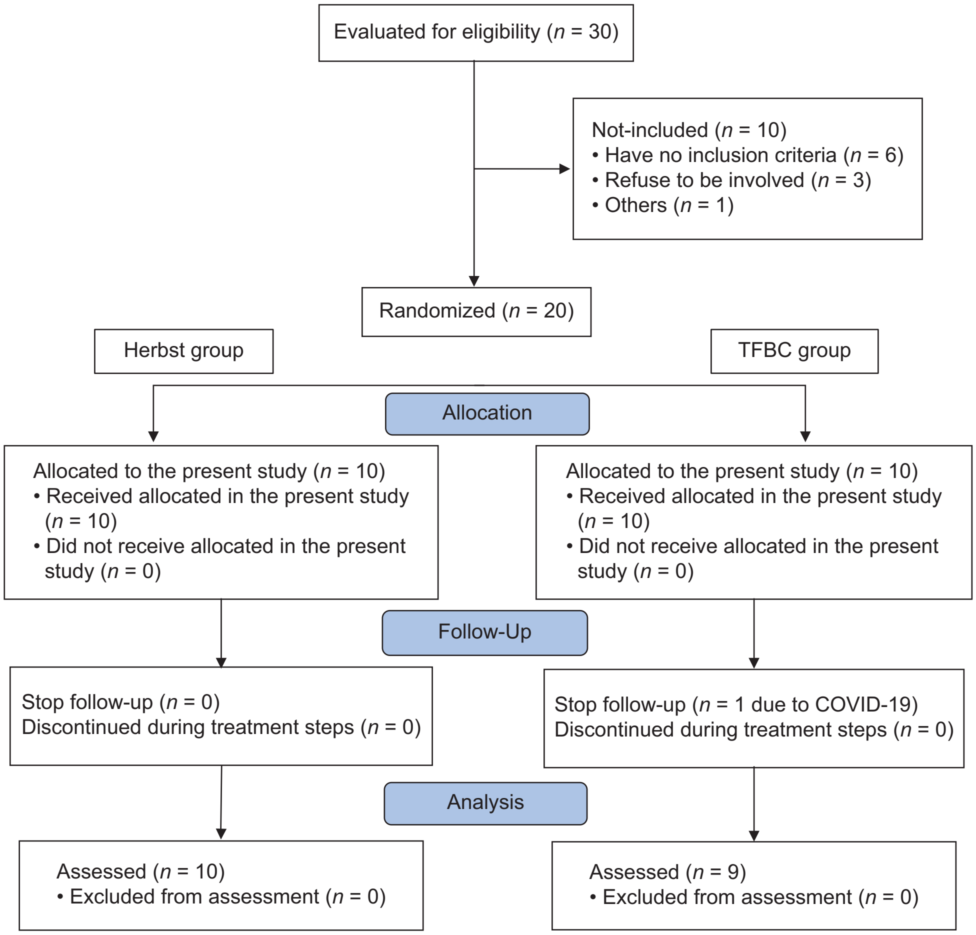
Comparisons of study groups were performed by an independent *t*-test, while non-parametric variables (percent change) were compared by the Mann-Whitney U-test. Comparisons between pre and post and between the right and left sides were made using the paired *t*-test and the Wilcoxon signed-rank test.

The percent change was calculated by the following formula: (value after-value before)/value before×100. All *P* values are bi-sided. *P* values ≤ 0.05 were considered significant.

Results

All twenty patients who met inclusion criteria had a complete analysis of the required CBCT condylar volume measurements before and after treatment with fixed functional appliances. Only one participant in the TFBC group has dropped out during follow-up due to coronavirus disease 2019 (COVID-19) (see participant flow diagram). Each participant has a follow-up every 3 weeks at the orthodontic clinic.

Figure 2: (a-c) Treatment steps by the dentally anchored Twin Force Bite Corrector appliance



Participants' flow diagram

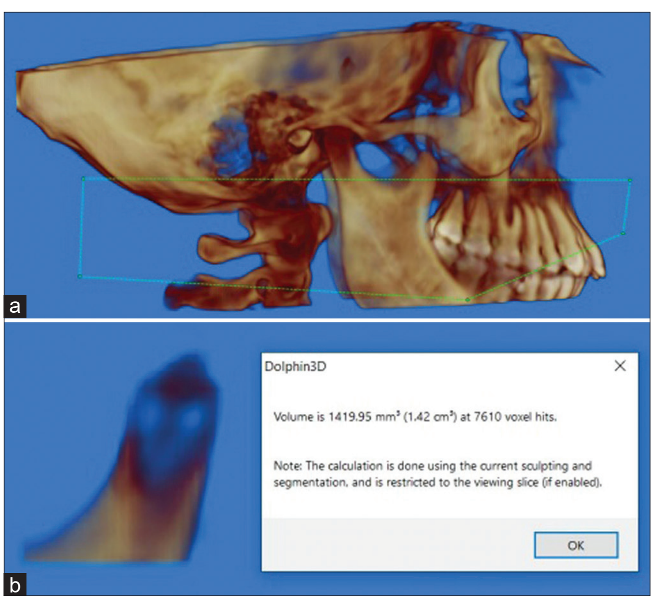


Figure 3: (a and b) Condylar volume measurement

For a comparison between the study groups, a paired *t*-test and the Mann-Whitney U–test were applied to determine the statistical significance of the outcome effect of either mini-plate anchored Herbst appliance or TFBC device.

By comparing the amount of change between the two groups, it revealed that on the right side, the Herbst group recorded a percent increase (median = 1.23%), while the TFBC group recorded a median percent decrease (-7.85%). This difference revealed a statistical significance (P = 0.008). On the left side, the Herbst group recorded a percent increase (median = 1.17%), while the TFBC group recorded a median percent decrease (-20.22%); however, this difference was not statistically significant (P = 0.065) [Table 1, Figure 4].

By comparing the pretreatment and posttreatment records within each group, it can be concluded that the Herbst group showed no significant difference between the pretreatment and posttreatment readings on both the right and left sides (P = 0.297, P = 0.434, respectively) and the TFBC group showed no significant difference between the pretreatment and posttreatment readings on both the right and left sides (P = 0.144, P = 0.129, respectively) [Table 1, Figure 5].

As for the mean condylar volume difference pre- and post-treatment and 95% confidence interval (CI) of the mean (standard deviation (SD)) volume differences within each group; the Herbst group revealed (Mean (SD) =50.40 (143.90) 95% CI = -52.54; 153.34) for the right side while it recorded (Mean (SD) =33.45 (129.29), 95% CI = -59.04; 125.94) for the left side. The TFBC group reported (Mean (SD) = -111.50 (206.69); 95% CI = -270.37; 47.38) for the right side and (Mean (SD) = -187.97 (332.95), 95% CI = -443.90; 67.96) for the left side. [Table 1].

Comparisons of pretreatment and posttreatment condylar volume measurements between the right and left sides were performed using a paired *t*-test and the Wilcoxon signed-rank test; the Herbst group showed no significant difference between the right and left sides values pretreatment ($P = 0.345$) and posttreatment ($P = 0.337$); also, the TFBC group showed no significant difference between the right and left sides values pretreatment ($P = 0.776$) and posttreatment ($P = 0.383$) [Table 2, Figure 5].

As for comparing the amount of change between the right and left sides, it can be summarized that in the Herbst group, both the right and left sides recorded a percent increase, with no significant difference between sides ($P = 0.646$), and also, in the TFBC group, both the right and left sides recorded a percent decrease, with no significant difference between sides ($P = 0.594$) [Table 2, Figure 4].

The effect of both appliances on the condylar volume was reflected in the advancement of the mandible and correction of class II malocclusion [Figures 6-9].

Regarding the cephalometric skeletal and dental parameter changes, the lower incisor with mandibular plane angle (proclination of lower incisors) revealed that by comparing the pretreatment and post-treatment values within each group, there was no significant difference in the Herbst group ($P = 0.613$) (mean difference (SD) = 0.20 (1.21); 95% CI = -.66 to 1.06), while in the TFBC group a significantly higher value was recorded in post-treatment ($P = 0.000$) (mean difference (SD) = 8.35 (1.6), 95% CI = 7.21; 9.49). Comparing groups regarding the amount of difference revealed a significantly higher value in the TFBC group ($P = 0.000$) (mean difference (95% CI) = -8.2 (-9.5 – -6.8) [Table 3].

As for the mandibular length, the comparison of pre- and post-values within each group revealed a significantly higher value post-treatment in the Herbst group ($P = 0.000$) (mean difference (SD) = -2.70 (0.82), 95% CI = -3.29; -2.11) and the TFBC group ($P = 0.001$) (mean difference (SD) =1.3 (0.79) 95% CI = 0.74; 1.86). Comparing groups regarding the amount of difference revealed a significantly higher value in the Herbst group ($P = 0.004$) (mean difference (95% CI) = 1.3 (0.52 – 2.1) [Table 3].

ANB angle recorded that the comparison of pre- and post-values within each group revealed a significantly lower value post-treatment in the Herbst group ($P = 0.000$) (mean difference (SD) = -2.70 (0.82), 95% CI = -3.29; -2.11) and the TFBC group ($P = 0.000$) (mean (SD) = -2.30 (.59); 95% CI = -2.72; -1.88). Comparing groups regarding the amount of difference revealed no significant difference ($P = 0.302$) (mean difference (95% CI) = 0.40 (-0.27 – 1.1)) [Table 3].

According to the IOFTN index, the participants in both groups have grade 4 (great need for treatment) as they have excessive overjet (6–9 mm).

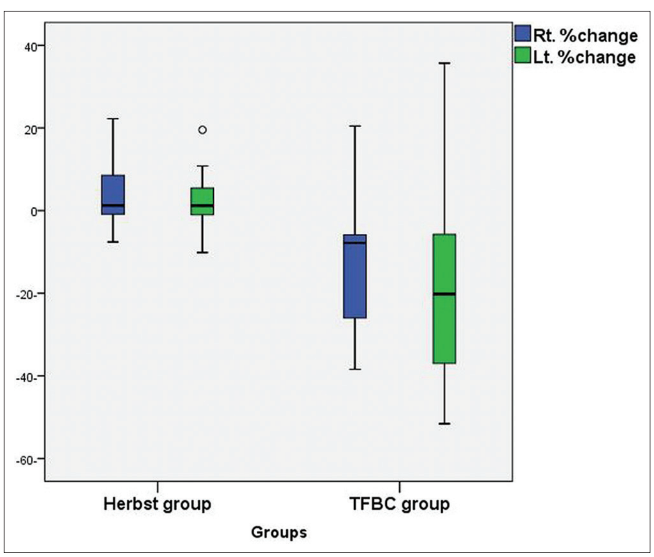


Figure 4: Box plot illustrating the median value of percent change (%) in the right and left sides in both groups

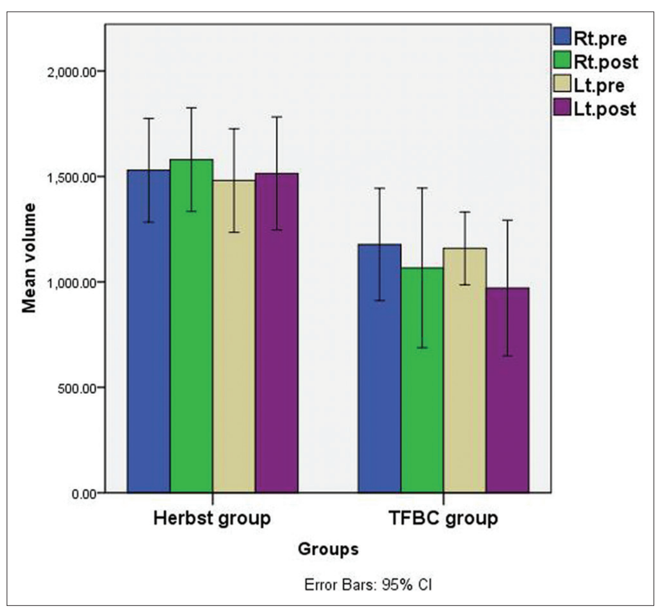


Figure 5: Bar chart illustrating the mean pre- and post-recorded values of the right and left condylar volumes in both groups

Table 1: Comparison of recorded values of condylar volume within the group (paired *t*-test), between groups (independent *t*-test), and difference and percent change (%) in the Herbst and TFBC groups (Mann-Whitney *U*-test)

Groups	Pre		Post		*P* within group
	Mean (SD)	95% CI (lower; upper)	Mean (SD)	95% CI (lower; upper)	
Right side					
Herbst	1529.33 (344.5)	1282.89; 1775.77	1579.73 (343.32)	1334.14; 1825.32	0.297 ns
TFBC	1177.64 (346.77)	911.09; 1444.19	1066.14 (492.56)	687.52; 1444.75	0.144 ns
P (bet.)	0.041*		0.016*		
Rt % change					
Herbst	Median=1.23, range= -7.61 to 22.26				
TFBC	Mean (SD)=3.61 (9.08); 95% CI=-2.89; 10.11				
	Median=-7.85, range=-38.44 to 20.47				
	Mean (SD)=-12.54 (17.75), 95% CI=-26.19; 1.11				
P (bet.)	0.008*				
Rt difference					
Herbst	Median=18.29, range=-167.74 to 349.11				
TFBC	Mean (SD)=50.40 (143.90), 95% CI=-52.54; 153.34				
	Median=-101.32, range=-343.62 to 348.67				
	Mean (SD)=-111.50 (206.69), 95% CI=-270.37; 47.38				
P (bet.)	0.017*				
Left side					
Herbst	1480.84 (343.46)	1235.14; 1726.53	1514.28 (374.71)	1246.23; 1782.33	0.434 ns
TFBC	1159.10 (224.65)	986.42; 1331.78	971.13 (418.88)	649.15; 1293.12	0.129 ns
P (bet.)	0.029*		0.008*		
Lt % change					
Herbst	Median=1.17, range=-10.15 to 19.53				
	Mean (SD)=2.29 (8.30), 95% CI=-3.65; 8.22				
TFBC	Median=-20.22, range=-51.59 to 35.71				
	Mean (SD)=-17.31 (28.61), 95% CI=-39.30; 4.68				
P (bet.)	0.065 ns				
Lt difference					
Herbst	Median=15.49, range=-172.22 to 280.19				
	Mean (SD)=33.45 (129.29), 95% CI=-59.04; 125.94				
TFBC	Median=-235.01, range=-687.43 to 395.24				
	Mean (SD)=-187.97 (332.95), 95% CI=-443.90; 67.96				
P (bet.)	0.043*				

Significance level $P \leq 0.05$, * significant, ns=non-significant, P (bet.)=between groups, Rt=right, Lt=left

Figure 6: (a-f) Pretreatment photographs, lateral cephalometry, and progressive intraoral photographs of the Herbst group patient

Figure 7: (a-f) Posttreatment photographs and lateral cephalometry of the Herbst group patient

Figure 8: (a-f) Pretreatment photographs, lateral cephalometry, and progressive intraoral photographs of the TFBC group patient

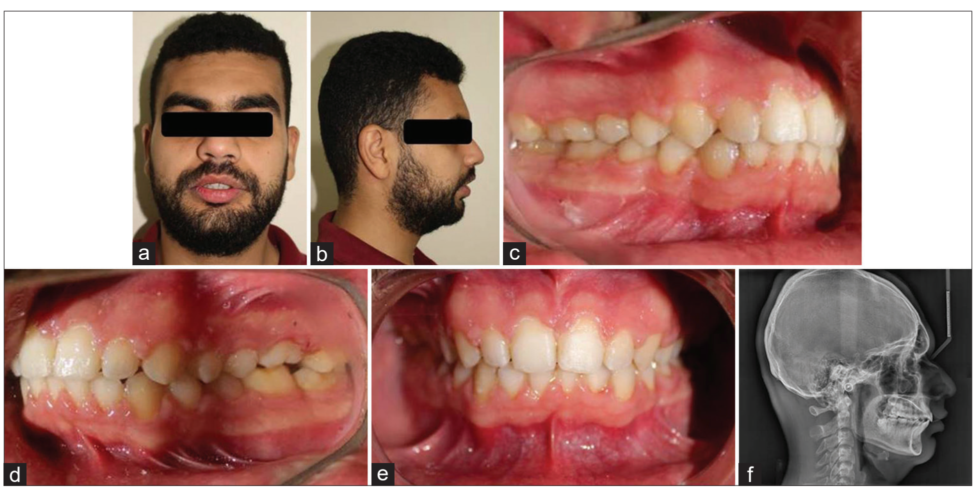


Figure 9: (a-f) Posttreatment photographs and lateral cephalometry of the TFBC group patient

As for the glenoid fossa relocation, the graduated color scale linear measurement that was used to clarify the difference in position in the fossa location between the pretreatment and post-treatment records showed that there was no color change (with in the green zone), indicating that the fossa stayed without any relocation in its position in both groups. Also, to verify the previous results, axial sections containing the superimposed models were taken, indicating the same results [Figure 10].

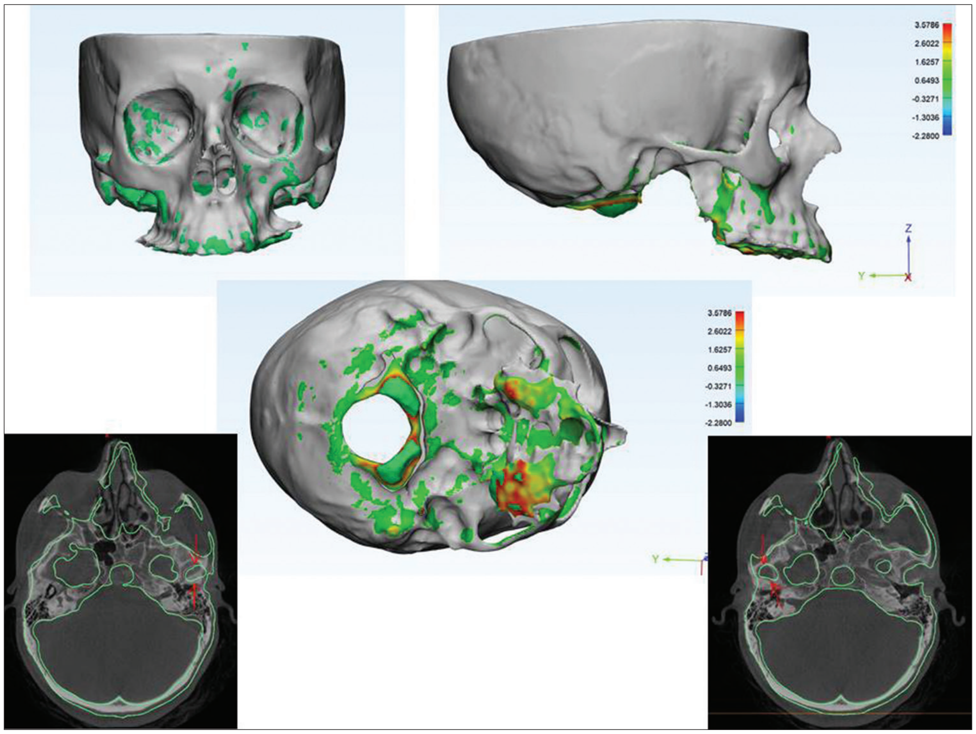


Figure 10: Assessment of the glenoid fossa relocation

Table 2: Comparison of recorded values for condylar volume in the left and right sides (paired *t*-test) and comparison of difference and percent change (%) in the right and left sides within the same group (Wilcoxon signed-rank test)

	Pre		Post		Percent change			Difference		
	Mean (SD)	95% CI	Mean (SD)	95% CI	Median and range	Mean (SD)	95% CI	Median and range	Mean (SD)	95% CI
Herbst										
Right	1529.33 (344.5)	1282.89; 1775.77	1579.73 (343.32)	1334.14; 1825.32	1.23 (-7.61-22.26)	3.61 (9.08)	-2.89; 10.11	18.29 (-167.74-349.11)	50.40 (143.90)	-52.54; 153.34
Left	1480.84 (343.46)	1235.14; 1726.53	1514.28 (374.71)	1246.23; 1782.33	1.17 (-10.15-19.53)	2.29 (8.30)	-3.65; 8.22	15.49 (-172.22-280.19)	33.45 (129.29)	-59.04; 125.94
$P^{\#}$	0.345 ns		0.337 ns		0.646 ns			0.646 ns		
TFBC										
Right	1177.64 (346.77)	911.09; 1444.19	1066.14 (492.56)	687.52; 1444.75	-7.85 (-38.44-20.47)	-12.54 (17.75)	-26.19; 1.11	-101.32 (-343.62-348.67)	-111.50 (206.69)	-270.37; 47.38
Left	1159.10 (224.65)	986.42; 1331.78	971.13 (418.88)	649.15; 1293.12	-20.22 (-51.59-35.71)	-17.31 (28.61)	-39.30; 4.68	-235.01 (-687.43-395.24)	-187.97 (332.95)	-443.90; 67.96
$P^{\#}$	0.776 ns		0.383 ns		0.594 ns			0.515 ns		

Significance level $P \leq 0.05$, *Significant, ns=non-significant, $P^{\#}$=between the right and left sides

Discussion

The purpose of using fixed functional appliances in the treatment of skeletal class II malocclusion in young adult patients is to stimulate the condylar growth that affects the growth of the mandible by its advancement to treat the skeletal class II anteroposterior discrepancy.[7,12,22] As for the efficacy of these fixed functional appliances with their different types and rigidity in stimulating condylar and mandibular growth after their cessation, many kinds of literature have demonstrated successful corrections of skeletal class II in young adult patients using these appliances.[17]

The previous studies showed that using mini-screws combined with fixed functional appliances reveals doubtful skeletal effects, while the installation of mini-plates with these appliances leads to great successful skeletal effects in the correction of skeletal class II malocclusion.[28, 31]

In the current study, we used two fixed functional appliances different from each other in nature of the anchorage and rigidity due to the following reasons:

Table 3: Comparison of recorded values of ANB, mandibular length, and proclination of lower incisors within the group (paired *t*-test), between groups (independent *t*-test), and comparison of difference in the Herbst and TFBC groups (Mann-Whitney *U*-test)

	Pre		Post		*P* within group
	Mean (SD)	95% CI (lower; upper)	Mean (SD)	95% CI (lower; upper)	
ANB					
Herbst	6.20 (1.03)	5.46; 6.94	3.50 (.71)	2.99; 4.01	0.000*
TFBC	6.80 (.89)	6.16; 7.44	4.50 (.82)	3.92; 5.08	0.000*
P (bet.)	0.181 ns		0.009*		
ANB difference					
Herbst	Median=-2.50, range=-4 to-2				
TFBC	Mean (SD)=-2.70 (0.82), 95% CI=-3.29; -2.11				
	Median=-2.25, range=-3 to-2				
	Mean (SD)=-2.30 (.59), 95% CI=-2.72; -1.88				
P (bet.)	0.302 ns				
	Mean diff (bet.) (95% CI)=0.40 (-0.27 – 1.1)				
Mandibular length					
Herbst	106.1 (1.7)	104.89; 107.31	108.7 (1.23)	107.82; 109.58	0.000*
TFBC	107.3 (2.36)	105.61; 108.99	108.6 (2.04)	107.14; 110.06	0.001*
P (bet.)	0.208 ns		0.896 ns		
Mandibular length difference					
Herbst	Median=2.50, range=1.5 to 4.5				
TFBC	Mean (SD)=2.60 (.88), 95% CI=1.97; 3.23				
	Median=1.50, range=0 to 2.5				
	Mean (SD)=1.3 (0.79), 95% CI=0.74; 1.86				
P (bet.)	0.004*				
	Mean diff (bet.) (95% CI)=1.3 (0.52 – 2.1)				
Proclination of lower incisors					
Herbst	88.4 (1.76)	87.14; 89.66	88.6 (1.43)	87.58; 89.62	0.613 ns
TFBC	88.75 (2.44)	87.00; 90.50	97.1 (1.79)	95.82; 98.38	0.000*
P (bet.)	0.717 ns		0.000*		
Proclination of lower incisor difference					
Herbst	Median=-0.25, range=-1.00 to2.00				
TFBC	Mean (SD)=0.20 (1.21), 95% CI=-0.66 to 1.06				
	Median=8.00, range=6 to 11				
	Mean (SD)=8.35 (1.6), 95% CI=7.21; 9.49				
P (bet.)	0.000*				
	Mean diff (bet.) (95% CI)=-8.2 (-9.5 – -6.8)				

Significance level $P \leq 0.05$, *significant, ns=non-significant. P (bet.)=between groups, mean diff (bet.)=mean difference in amount of change between groups

-Firstly, as we know that rigid and semi-rigid fixed functional appliances have the same mechanism of action, also their effect in the correction of class II malocclusion is approximately similar to each other (mainly dentoalveolar effect with little skeletal effect)[32] in addition to some of the studies referred to that the acceptance of the patient to the type of fixed functional appliance affect the end result of orthodontic treatment,[33] so in the current study we selected the most type of the dentally anchored fixed functional appliance accepted by the patients regardless its rigidity to obtain final clear results. Therefore, we used the TFBC appliance as a dentally anchored fixed functional appliance in comparison with the skeletally anchored Herbst appliance.

-Secondly, the TFBC appliance is the most commonly used type of fixed functional appliance that can be accepted by patients without any complaints related to breakage of the appliance, interfering with speech, or slippage from its attachment. However, the Herbst appliance is a bulky rigid intraoral appliance that is not accepted by the patients, and consequently, this will affect the end results of orthodontic treatment because the patients try to remove or break it. Therefore, the current study aimed to evaluate whether this bulky rigid appliance (Herbst appliance) produces a significantly greater effect than the semi-rigid, simple one (TFBC) or whether the two types have the same effect on the condylar volume and consequently skeletal correction of class 2 malocclusion in young adult patients.

-Thirdly, the TFBC and almost many types of semi-rigid fixed functional appliances have hex nuts at their two ends, were designed to be directly attached to the main rectangular orthodontic archwire, and are not suitable to be soldered into the surgical mini-plate, so it is very difficult to obtain skeletally anchored TFBC. Therefore, in the current study, we use the rigid Herbst appliance because one of its ends is suitable to be soldered to the surgical mini-plate.

A 3D measurement tool, CBCT, was used in the current study rather than using magnetic resonance imaging (MRI) to avoid any limitations of the two-dimensional method; also, CBCT provides an accurate assessment of changes in the condylar volume with a low dose of radiation.

In the present study, we used a three-dimensional method for the evaluation of changes in the condylar volume on both sides, which was described by Yildirim. E, as it is an accurate method and allows the superimposition property of pretreatment and posttreatment condylar images for both sides.[34]

It is noteworthy that, by comparing the pretreatment and posttreatment readings of the right and left sides for both groups, it recorded non-statistically significant difference, so the right and left sides were considered the same (($P = 0.646$, ($P = 0.594$), respectively).

As for a comparison of the amount of change between the two groups, it revealed that the Herbst group recorded a significant increase in the condylar volume after treatment (median = 1.23%) ($P = 0.008$) in comparison with the TFBC group, thus pointing to the completion of the remodeling process of the temporomandibular joint that ends in bone addition at the outer surface of the condyle, and this result is concomitant with previous studies.[20,21] While the TFBC group recorded a significant decrease in the condylar volume after removal of the fixed functional appliance in comparison with the Herbst group (median = -7.85%) ($P = 0.008$), this indicates an incomplete remodeling process of the TMJ (only bone resorption occurred around the outer surface of the condyle, which is the first stage of bone remodeling), so this led to decrease in the condylar volume.

However, the comparison of the pretreatment and posttreatment condylar readings within each group revealed a non-statistical significant difference, and this result was due to high differences in the pretreatment values within each group, but this cannot change the fact that the mini-plate anchored Herbst appliance produced a great skeletal effect due to its significant efficacy on the condylar volume in contrast to the TFBC group, which had a weak effect on the condylar volume that reflected on the advancement of the mandible.

In previous literature that depended on MRI in the assessment of TMJ remodeling after using fixed functional orthodontic appliances in patients with class 2 malocclusion, these studies revealed that remodeling of the mandibular condyle and glenoid fossa and the new position of the condyle within the fossa were associated with autorotation and forward and advancement of the mandible. According to these studies, although these remodeling changes occurred, however, MRI cannot calculate the amount or direction of these changes.[22,23]

By assessment, the glenoid fossa relocation revealed that there was no change in the position of the glenoid fossa, so the mini-plate anchored Herbst appliance resulted only in increasing condylar volume without any effect on the glenoid fossa position.

As the skeletally anchored Herbst appliance resulted in significant increase in the condylar volume, it consequently led to great skeletal correction of class II malocclusion, and this can be proven in the current study by the significant increase in the ANB angle and the effective mandibular length more than the TFBC appliance. It is worth to be mentioned that mini-plate anchored Herbst appliance does not affect the angulation of lower incisors other than the TFBC appliance that leads to proclination of lower anterior teeth.

Regarding the IOFTN index[35] score for all participants of both groups, they recorded grade 4 that entitled great need for treatment, and this is what brings us to the conclusion that using skeletally anchored fixed functional appliances can decrease the need for orthognathic surgeries in many class II malocclusion in young adult patients.

Limitations and recommendations

Limited mouth opening and severe gingival and periodontal diseases are the main complaints of young adult orthodontic patients that can interfere with and limit the end results of orthodontic treatment with the mini-plate anchored Herbst appliance, so we recommend careful diagnosis to obtain study participants with good oral health and normal mouth opening before starting the research work.

Conclusion

The current study can be concluded that

1- The skeletally anchored Herbst appliance can significantly increase the condylar volume reflecting on great skeletal correction of the major class II skeletal cases that need orthognathic surgery without proclination of lower anterior teeth.

2- The TFBC appliance has a weak effect on the condylar volume that impressed on its dentoalveolar correction of class II malocclusion with the main disadvantage of proclination of lower incisors.

Ethical approval

The ethical approval was obtained from the Ethical Committee of Faculty of Dental Medicine, Cairo Boys, Al-Azhar University, by code 603/307. This study was registered on clinical trials.gov PRS with ID NCT05466344.

Patient releases

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and that due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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