# Original Article

# Comparison between two bone anchored force systems for correction of skeletal Class II malocclusion in growing patients: a randomized controlled clinical trial, part 1: short-term skeletal changes

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#### **ABSTRACT**

**Objectives:** To compare the treatment effects of pushing or pulling force mechanics applied to bimaxillary miniplates with those of deferred treatment control patients to evaluate mandibular skeletal growth changes in growing patients with skeletal Class II malocclusion due to mandibular deficiency.

**Materials and Methods:** Thirty-nine patients (24 males, 15 females; mean age = 11.59  $\pm$  0.56 years) were equally and randomly assigned to one of three groups: Group A, skeletally anchored fixed-functional appliance (pushing mechanics); Group B, skeletally anchored Class II spring (pulling mechanics); and Group C, deferred treatment skeletal Class II control patients. Pretreatment and posttreatment cone-beam computed tomography scans were used for assessment of measurements (time interval: 11.52  $\pm$  0.32, 11.53  $\pm$  0.31, and 9.63  $\pm$  0.22 months for groups A, B, and C, respectively).

**Results:** Relative to the control group, both intervention groups showed significant increases in effective mandibular length (Co-Gn), with mean differences of  $5.08 \pm 2.25$  mm in Group A, and  $3.83 \pm 2.79$  mm in Group B. A significant improvement in the sagittal relationship was observed in both groups, with reductions in ANB angle by  $4.31^{\circ}$  in Group A, and  $5.5^{\circ}$  in Group B. The mandibular plane angle was increased significantly in Group B by  $1.83 \pm 0.72^{\circ}$ .

**Conclusion:** Mandibular growth was enhanced using either pushing or pulling skeletally anchored force mechanics. The use of pulling force mechanics, specifically, was associated with increases in lower facial height. (*Angle Orthod*. 2025;00:000–000.)

**KEY WORDS:** Developing Class II malocclusion; Miniplates; Fixed functional appliance; Class II springs; Skeletal anchorage

## INTRODUCTION

Skeletal Class II malocclusion is a common diagnosis in patients pursuing orthodontic intervention. <sup>1</sup> It was found that skeletal Class II malocclusion due to mandibular deficiency represented approximately 20–27%

among different samples in the Egyptian population.<sup>2,3</sup> Conventional functional appliances have been used for decades to treat mandibular deficiency in growing patients, despite the contentious evidence regarding their efficiency.<sup>4</sup> Authors of recent systematic reviews have revealed that functional tooth-borne appliances

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Table 1. Eligibility Criteria

Inclusion Criteria	Exclusion Criteria		
Chronological age 11–13 y	History of previous orthodontic treatment		
Cervical maturational stage 3 or 4 (circumpubertal growth stage)	Previous craniofacial surgeries		
Skeletal Class II malocclusion due to mandibular deficiency (SNB $\leq 76^{\circ}$ )	Chronic diseases, syndromes, growth problems that may affect bone		
Horizontal growth pattern (MP/SN ≤ 39°)	Temporomandibular disorders		
Angle Class II division 1 malocclusion (overjet $\geq$ 5 mm)	Parafunctional habits (for example, thumb sucking, tongue thrusting mouth breathing, nail biting, bruxism)		

were not able to achieve pure skeletal changes.  $^{5,6}$  Different trials have been conducted using miniplate anchorage for orthopedic correction of skeletal Class II malocclusion, and researchers reported skeletal increases in mandibular length of 3.03  $\pm$  0.81 mm within 8.45  $\pm$  1.15 months.  $^{7-13}$ 

However, authors of most previous studies used bone-borne anchorage in a single jaw and authors of only a few studies examined the use of bimaxillary skeletal anchorage in conjunction with either intermaxillary elastics or fixed functional appliances. 11-13 Authors of a recent systematic review aimed at evaluating the available evidence from studies in which

bimaxillary skeletal anchorage was used and found significant skeletal effects mainly due to mandibular protrusion. However, the conclusion was that low confidence in results exists and that a high-quality clinical trial was still needed. In the current study, we aimed at assessing the effect of two different force systems along with bimaxillary skeletal anchorage on the treatment of growing skeletal Class II subjects in comparison with the natural growth changes observed in a deferred treatment Class II control group. The null hypothesis of this study was that the use of direct bimaxillary miniplate anchorage with two different force systems would not yield statistically significant

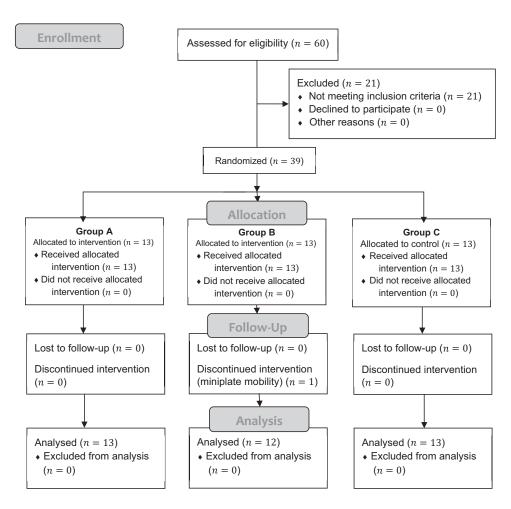
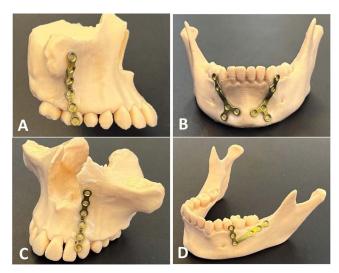


Figure 1. Consolidated Standards of Reporting Trials (CONSORT) diagram of the participants flow chart.



**Figure 2.** Miniplate adaptation over the three-dimensional (3D) printed skull models. (A) and (B) Over the zygomatic buttress and mandibular symphysis in Group A; (C) and (D) over the nasal buttress and the external oblique ridge in Group B.

skeletal mandibular growth effects in comparison with natural mandibular growth.

## **MATERIALS AND METHODS**

## **Trial Design**

This study was a three-parallel-arm randomized controlled clinical trial and was reported in compliance with the Consolidated Standards of Reporting Trials (CONSORT) statement.<sup>15</sup> This trial was registered at ClinicalTrials.gov with identifier NCT04884022.

## **Ethical Approval**

The study was conducted after obtaining ethical approval from the Institutional Review Board at the Faculty of Dentistry, Alexandria University (IRB:00010556–IORG:0008839 and Manuscript Ethics Committee 0219-02/2021). Prior to commencement, all guardians of the patients were apprised of the purpose of the study and associated risks and benefits, and signed informed consent was obtained.

## Participants, Eligibility Criteria, and Settings

Patients were recruited from the outpatient clinic of the Department of Orthodontics, Faculty of Dentistry, Alexandria University, and were examined, considering the eligibility criteria listed in Table 1. A total of 60 individuals was assessed for eligibility, and participant flow during the trial is described in the CONSORT flow chart (Figure 1).



**Figure 3.** Surgical fixation of the miniplates in (A) and (B) pushing (Group A) and (C) and (D) pulling (Group B) groups.

## **Sample Size Calculation**

Sample size was estimated assuming a 5%  $\alpha$  error and 80% study power based on studies by Al-Dumaini et al., <sup>13</sup> ElKordy et al., <sup>7</sup> and Eissa et al., <sup>16</sup> who reported changes in mandibular length of 3.0  $\pm$  0.42 mm using pulling mechanics, 1.27  $\pm$  1.01 mm using pushing mechanics, and 2.63  $\pm$  2.7 mm in untreated cases, respectively. Using an analysis of variance (ANOVA) with a pooled SD = 1.37, the required sample size was determined to be 12 patients per group, subsequently augmented to 13 patients to account for potential attrition. The sample size was based on Rosner's method <sup>17</sup> and calculated by G\*Power 3.0.10 (http://www.gpower.hhu.de).



**Figure 4.** (A) Direct loading of SARA appliance, (B) CS coil spring to the miniplates (C) with 250g force measured using force gauge.

Table 2. Anatomical Landmarks and Reference Planes

Symbol	Name	Definition				
		Anatomical Landmarks				
S	Sella	The center of Sella turcica				
N	Nasion	The most anterior point of the nasofrontal suture				
Po	Porion	The most superior and outer point of the external auditory meatus				
Or	Orbitale	The lowest point on the inferior margin of the orbit				
A point	Subspinal	The deepest point in the concavity of the anterior maxilla between the ANS and alveolar crest				
B point	Supramental	The innermost point on the contour of the mandible between the incisor and alveolar bone				
Co	Condylion	The most superoposterior point on the curvature of the condylar head				
ANS	Anterior nasal spine	The apex of the spina nasalis anterior				
PNS	Posterior nasal spine	The most posterior point on the contour of the palate in the midsagittal plane				
Me	Menton	The deepest point of the mandibular symphysis				
Pog	Pogonion	The most prominent point on the chin				
Gn	Gnathion	The midpoint between Me and Pog				
Go	Gonion	The lowest point of the bony contour of the angle of the mandible				
		Reference planes				
FHP	Frankfort horizontal plane	Defined by 3 landmarks: right orbitale, left orbitale, and porion				
MSP	Midsagittal plane	Plane through Sella and nasion perpendicular to HRP				
SN	Sella-nasion plane	Plane joining nasion and Sella perpendicular to MSP				
OP	Occlusal plane	Plane joining the maxillary incisal edge with first molar mesial cusp tip				
PP	Palatal plane	Plane joining anterior nasal spine and posterior nasal spine perpendicular to the MSP				
MP	Mandibular plane	Plane joining gnathion and left and right gonion				
VR	Vertical plane	Plane through Sella perpendicular to Sella-nasion plane				

Table 3. Angular and Linear Skeletal Measurements

		Lin's	CCCa
Variable	Description	Intra	Inter
Angular			
measurements (°)			
SNA	Angle between the lines Sella-nasion and nasion—A point, which describes the anteroposterior position of maxillary base relative to the anterior cranial base	0.958	0.979
SNB	Angle between the lines Sella-nasion and nasion—B point, which describes the anteroposterior position of mandibular base relative to the anterior cranial base	0.965	0.965
ANB	Angle between the lines A point–nasion and nasion–B point, which describes the anteroposterior position of maxillary base to the mandibular base	0.925	0.916
NA-Pog	Angle between nasion-A point and A point-pogonion, which describes the angle of convexity	0.976	0.904
SN-PP	Angle between Sella-nasion and ANS-PNS, which describes the palatal plane angle	0.981	0.978
SN-MP	Angle between Sella-nasion and Go-Gn, which describes the mandibular plane angle	0.951	0.978
Gonial angle	The angle between the points Co, Go, and Me, which determines the direction of growth of the lower half of the face	0.952	0.919
SN-OP	Angle between Sella-nasion and occlusal plane, which describes the occlusal plane angle	0.911	0.813
Linear measurements (mm)			
Co-A	The linear distance between condylion and A point, which determines the effective maxillary length	0.967	0.930
Co-Gn	The linear distance between condylion and gnathion, which determines the effective mandibular length	0.981	0.978
A-VR	The linear distance between the A point and vertical plane, which determines the A-P maxillary position	0.931	0.932
B-VR	The linear distance between the B point and vertical plane, which determines the A-P mandibular position	0.980	0.976
Wits appraisal	Distance between A point perpendicular OP and B point perpendicular OP, which determines the position of the maxillary base relative to the mandibular base	0.944	0.961
Pog-VR	The linear distance between the Pog and vertical plane, which determines the A-P position of mandibular chin	0.915	0.909
Go-Pog	The linear distance between the Go and Pog points, which determines the mandibular body length	0.930	0.970
Co-Go	The linear distance between the Co and Go points, which determines the mandibular ramus length	0.961	0.963
AFH	The linear distance between ANS and Me points, which determines the anterior lower facial height	0.970	0.906
PFH	The linear distance between S and Go points, which determines the posterior facial height	0.944	0.966
A-FH	The linear distance between the A point and FH plane, which determines the maxillary vertical position	0.961	0.961
B-FH	The linear distance between the B point and FH plane, which determines the mandibular vertical position	0.927	0.933
Pog-FH	The linear distance between the Pog and FH plane, which determines the mandibular chin vertical position	0.978	0.975
A-SN	The linear distance between the A point and SN plane, which determines the maxillary vertical position	0.964	0.963
B-SN	The linear distance between the B point and SN plane, which determines the mandibular vertical position	0.944	0.968
Pog-SN	The linear distance between the Pog and SN plane, which determines the mandibular chin vertical position	0.902	0.967

 $<sup>^{\</sup>rm a}$  CCC indicates concordance correlation coefficient.

Table 4. Comparison of Mean Age and Sex Distribution Among the Study Groups at T1

			Age (y)			Gender		
	N	Mean ± SD	95% Cl <sup>a</sup> for Mean	<i>P</i> Value	Male, No. (%)	Female, No. (%)	<i>P</i> Value	
Group A	13	12.08 ± 0.76	11.62, 12.54	.159	8 (61.5)	5 (38.5)	.843	
Group B	12	$12.00 \pm 0.85$	11.46, 12.54		7 (53.8)	5 (38.5)		
Group C	13	$11.46 \pm 0.97$	10.88, 12.05		9 (69.2)	4 (30.8)		

<sup>&</sup>lt;sup>a</sup> CI indicates confidence interval.

#### **Randomization and Patient Allocation**

Eligible participants were equally and randomly assigned to either one of the intervention groups (Group A treated by pushing force mechanics or Group B treated by pulling force mechanics) or the deferred treatment control Group C, using a random sequence table (https://www.random.org). Randomization was made in blocks to ensure an equal allocation ratio. Each patient was assigned a number from consecutively numbered opaque sealed envelopes. The patients were, thereafter, assigned to one of the groups using a randomization table based on the numbers. 18

## **Blinding**

The operator obtaining the outcome data from concealed cone-beam computed tomographies (CBCTs) was blinded, as was the statistician who analyzed the data, which were labeled with randomized numbers. Due to the nature of the study, the participants and the main operator could not be blinded.

#### **Intervention Procedure**

Routine orthodontic records and CBCTs were taken at baseline (T1). CBCT scanning was performed in maximum intercuspation using a field of view of  $14.5 \times 13$  cm at 85 kVp, 15 mAs, 0.25 mm voxel dimension, with a SCANORA 3D device (Soredex, Milwaukee, Wisconsin, USA). Also, a three-dimensional (3D) printed skull model was obtained for each patient in the intervention groups for adaptation of the miniplates to the underlying bone in a standardized location prior to the surgical procedure. Segmentation was done using Bluesky Bio software (Grayslake, III), then printed with Fused Deposition Modeling (Figure 2).

## **Surgical Procedure**

For each patient in the intervention groups, four titanium miniplates (STEMA, Neuhausen ob Eck, Germany) were inserted in two surgical procedures under local anesthesia by the same surgeon. In Group A, two Y-shaped miniplates were fixed from one end in the mandibular symphysis, leaving the other end perforating the attached gingiva at the canine-premolar region, and two straight miniplates were fixed in the

zygomatic buttress, perforating the attached gingiva at the maxillary molar region (Figure 3A, B).

In Group B, two L-shaped miniplates were fixed in the external oblique ridge, perforating the attached gingiva at the mandibular molar region, and two straight miniplates were fixed in the nasal buttress, perforating the attached gingiva at the canine region (Figure 3C, D). In both groups, each miniplate was fixed by three titanium miniscrews (2  $\times$  10 mm), the last hole of the miniplate was opened to allow attachment of the appliance, and the miniplates were loaded directly with force from the appliance 3 weeks after placement.  $^{7,8,13}$ 

## **Orthopedic Treatment**

In Group A, 250 g of pushing force was applied using a fixed functional appliance (Sabbagh Advanced Repositioning Appliance (SARA); Forestadent, Pforzheim, Germany), measured using a force gauge (Figure 4). The proper pushrod of the SARA appliance was adjusted using split crimps (3 mm in length), and the molar tube part was removed (Figure 4A). In Group B, the same amount of pulling force was applied using a Class II Spring (CS Class II correction device coil spring [CS]: DynaFlex, Lake Saint Louis, Missouri, USA; Figure 4B). Follow-up appointments were scheduled every 4 weeks to check miniplate stability and to adjust the applied force. The appliances were removed after 9 months, while the miniplates were kept for an additional month before surgical removal to confirm correction of the skeletal relationship. A second set of orthodontic records and CBCT was taken after removal of the miniplates and after ending the 9-month observation period of the control group (T2).

#### **Outcome Assessment and Evaluation**

Analysis was done directly on the CBCT using InVivo-Dental Application version 5.3.1 (Anatomage Inc, Santa

**Table 5.** Cervical Vertebral Maturation Stages of the Subjects in the Three Study Groups at T1;  $\chi^2$  Test

	Stage 3	Stage 4	Total	P Value
Group A	9 (69.2%)	4 (30.8%)	13 (100.0%)	.605
Group B	7 (58.3%)	5 (41.7%)	12 (100.0%)	
Group C	10 (76.9%)	3 (23.1%)	13 (100.0%)	
Total	26 (68.4%)	12 (31.6%)	38 (100.0%)	

Table 6. Comparison of Baseline Characteristics of the Skeletal Variables Among the Study Groups; One-Way ANOVA<sup>a</sup>

Baseline data	N	Mean ± SD	95% CI for Mean	<i>P</i> Value
SNA (°)	,			.055
Group A	13	$80.54 \pm 1.66$	79.53, 81.54	
Group B	12	$81.75 \pm 0.87$	81.20, 82.30	
Group C	13	80.38 ± 1.71	79.35, 81.42	
SNB (°)			, -	.503
Group A	13	$73.77 \pm 1.24$	73.02, 74.52	
Group B	12	$74.08 \pm 0.79$	73.58, 74.59	
Group C	13	$73.54 \pm 1.33$	72.73, 74.34	
ANB (°)				.115
Group A	13	$6.62 \pm 1.61$	5.64, 7.59	
Group B	12	$7.83 \pm 0.94$	7.24, 8.43	
Group C	13	$6.85 \pm 1.77$	5.78, 7.92	
SNMP (°)			,	.207
Group A	13	$34.85 \pm 2.08$	33.59, 36.10	
Group B	12	$33.42 \pm 2.15$	32.05, 34.78	
Group C	13	34.69 ± 2.21	33.35, 36.03	
SNPP (°)			•	.308
Group A	13	$9.77 \pm 1.36$	8.95, 10.59	
Group B	12	$9.08 \pm 0.67$	8.66, 9.51	
Group C	13	$9.69 \pm 1.38$	8.86, 10.52	
SNOP (°)			,	.434
Group A	13	20.38 ± 1.39	19.55, 21.22	
Group B	12	$21.08 \pm 2.35$	19.59, 22.58	
Group C	13	$20.23 \pm 1.30$	19.44, 21.02	
PLMP (°)			,	.510
Group A	13	25.69 ± 1.44	24.82, 26.56	
Group B	12	$24.92 \pm 2.47$	23.35, 26.48	
Group C	13	25.62 ± 1.39	24.78, 26.45	
NAPog (°)			-,	.503
Group A	13	11.85 ± 2.12	10.57, 13.12	
Group B	12	11.08 ± 1.83	9.92, 12.25	
Group C	13	$12.00 \pm 2.20$	10.67, 13.33	
Yaxis (°)			,	.790
Group A	13	61.00 ± 1.22	60.26, 61.74	
Group B	12	$60.75 \pm 1.29$	59.93, 61.57	
Group C	13	61.08 ± 1.19	60.36, 61.79	
Gonial Angle (°)			·	.882
Group A	13	$116.69 \pm 1.97$	115.50, 117.89	
Group B	12	116.75 ± 2.22	115.34, 118.16	
Group C	13	$117.08 \pm 2.10$	115.81, 118.35	
COGN (mm)			,	.186
Group A	13	$98.46 \pm 2.22$	97.12, 99.80	
Group B	12	$100.17 \pm 3.13$	98.18, 102.15	
Group C	13	$98.54 \pm 2.22$	97.20, 99.88	
GOPog (mm)			,	.335
Group A	13	66.38 ± 1.80	65.29, 67.48	
Group B	12	67.08 ± 1.68	66.02, 68.15	
Group C	13	66.00 ± 1.96	64.82, 67.18	
CoGo (mm)			, <u>,</u>	.538
Group A	13	$48.77 \pm 1.30$	47.98, 49.56	
Group B	12	49.50 ± 2.71	47.78, 51.22	
Group C	13	48.77 ± 1.30	47.98, 49.56	
COA (mm)	. •		,	.431
Group A	13	79.00 ± 1.68	77.98, 80.02	
Group B	12	79.83 ± 2.66	78.15, 81.52	
Group C	13	78.85 ± 1.57	77.90, 79.80	
Wits (mm)		. 0.00 = 1.07		.476
Group A	13	$3.85 \pm 1.63$	2.86, 4.83	.470
Group B	12	3.65 ± 1.65 4.42 ± 1.51	3.46, 5.37	
Group C	13	4.46 ± 1.05	3.83, 5.10	

Table 6. Continued

Baseline data	N	$Mean \pm SD$	95% CI for Mean	P Value
PFH (mm)				.580
Group Á	13	$66.15 \pm 3.18$	64.23, 68.08	
Group B	12	$67.25 \pm 2.49$	65.67, 68.83	
Group C	13	66.15 ± 3.18	64.23, 68.08	
AFH (mm)				.646
Group Á	13	$56.92 \pm 1.61$	55.95, 57.89	
Group B	12	$57.67 \pm 2.90$	55.82, 59.51	
Group C	13	$57.08 \pm 1.50$	56.17, 57.98	
AVR (mm)				.931
Group A	13	$54.23 \pm 1.92$	53.07, 55.39	
Group B	12	$53.92 \pm 2.61$	52.26, 55.57	
Group C	13	54.15 ± 1.91	53.00, 55.31	
BVR (mm)				.951
Group A	13	$37.00 \pm 2.48$	35.50, 38.50	
Group B	12	$37.33 \pm 3.96$	34.82, 39.85	
Group C	13	$37.00 \pm 2.48$	35.50, 38.50	
PogVR (mm)				.867
Group A	13	$37.31 \pm 3.50$	35.19, 39.42	
Group B	12	$36.50 \pm 4.70$	33.51, 39.49	
Group C	13	$36.69 \pm 3.68$	34.47, 38.92	
ASN (mm)				.416
Group A	13	$50.08 \pm 6.81$	45.96, 54.19	
Group B	12	$53.08 \pm 6.07$	49.23, 56.94	
Group C	13	$49.85 \pm 7.08$	45.57, 54.13	
BSN (mm)				.668
Group A	13	$85.23 \pm 2.68$	83.61, 86.85	
Group B	12	$86.08 \pm 3.09$	84.12, 88.05	
Group C	13	$85.15 \pm 2.73$	83.50, 86.81	
PogSN (mm)				.501
Group A	13	$95.31 \pm 3.12$	93.42, 97.19	
Group B	12	$96.75 \pm 3.57$	94.48, 99.02	
Group C	13	$95.62 \pm 2.84$	93.90, 97.33	

<sup>&</sup>lt;sup>a</sup> ANOVA indicates analysis of variance; CI, confidence interval.

Clara, California, USA), after importing the DICOM files into the software. The landmarks and reference planes are described in Table 2. Angular and linear measurements are described in Table 3.

## **Statistical Analysis**

The data were analyzed using SPSS version 26 (SPSS, Chicago, III). The Shapiro-Wilk test was employed to assess normality, revealing that the data followed a normal distribution. Variables are presented using mean and standard deviation values. Paired t-test was used for intragroup comparisons between T1 and T2. Intergroup changes between T1 and T2 were analyzed using one-way ANOVA, followed by the least square difference (LSD) test. The significance level was established at a P-value of < .05.

#### **Measurement Error**

In this study, Lin's concordance correlation coefficient (CCC) was used to determine the intraexaminer and interexaminer reliability of measurements after

remeasuring 30% of the variables with a 2-week interval. Lin's CCC ranged from 0.813 to 0.981, indicating an accepted to excellent agreement within and between examiners.

## **RESULTS**

#### **Baseline Data**

The demographic characteristics for all groups are presented in Table 4. Baseline measurements were reported and compared among the three groups using one-way ANOVA (Tables 5 and 6). No significant difference was found among the groups at baseline. For all variables, independent-samples *t*-tests were used to confirm that no sex-based differences existed (Supplementary Table 1).

## **Patient Flow and Dropout**

One patient in the pulling group did not complete the intervention due to repeated mobility of the mandibular miniplates and inability to fix them for the third time. Thus, a total of 38 subjects was analyzed.

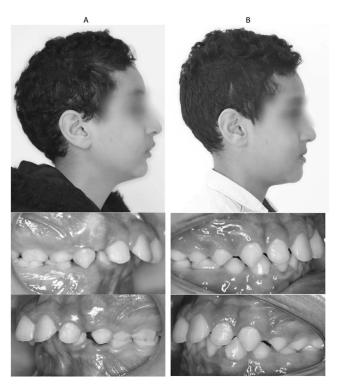


Figure 5. Photos of patient from the pushing group (A) pretreatment and (B) posttreatment.

Clinical examples of patient progress are presented in Figures 5 and 6.

## **Sagittal Skeletal Changes**

The intragroup sagittal skeletal changes between T1 and T2 are summarized in Table 7, while Table 8 demonstrates comparisons among the three study groups. A significant increase in Co-Gn was recorded of 5.08  $\pm$  2.25 mm for Group A, 3.83  $\pm$  2.79 mm for Group B, and 0.23  $\pm$  0.6 mm for Group C. The difference between groups A and B was not significant, while the difference between Group C and both intervention groups was significant. The linear measurement Go-Pog increased significantly in Group A  $(4.08 \pm 1.85 \text{ mm})$  and Group B  $(1.83 \pm 0.94 \text{ mm})$ . In addition, a significant increase was found in groups A and B of the two linear measurements B-VR (5.62  $\pm$ 2.93 mm and 5.83  $\pm$  2.95 mm) and Pog-VR (3.85  $\pm$ 0.9 mm and 4.17  $\pm$  0.83 mm) between T1 and T2, respectively. No significant difference was found in these measures between the two intervention groups.

Groups A and B demonstrated a significant increase in the SNB angle (4.38  $\pm$  0.65° and 4.17  $\pm$  0.58° for groups A and B, respectively). A statistically significant decrease in the SNA angle occurred in Group B only (1.33  $\pm$  0.98°). A significant decrease in ANB between T1 and T2 was seen in Group A (4.31  $\pm$  0.75°) and Group B (5.5  $\pm$  0.67°). Similarly, the NA-Pog angle



Figure 6. Photos of patient from the pulling group (A) pretreatment and (B) posttreatment.

decreased significantly in Group A (4.31  $\pm$  1.44°) and Group B (7.5  $\pm$  0.9°). Among the three study groups, a statistically significant difference was observed for several sagittal measures (Table 8). Also, a significant decrease was found in the Wits appraisal in Group A (4.31  $\pm$  1.44 mm) and Group B (7.5  $\pm$  0.9 mm).

## **Vertical Skeletal Changes**

The vertical skeletal changes within study groups from T1 to T2 are presented in Table 9. Comparison of changes among the groups are shown in Table 10. All the vertical measurements in groups A and C showed changes that were not statistically significant. However, in Group B, a statistically significant increase of 1.83  $\pm$  0.72° occurred in the mandibular plane angle, 3.25  $\pm$  1.71° in the palatal plane angle, 2.42  $\pm$  1.16° in the occlusal plane, and 3.00  $\pm$  1.04° in the Y-axis angle. The distances between SN plane and A, B, and Pog points significantly increased by 3.25, 4.42, and 7 mm, respectively. Also, the ramus length increased significantly by 4.75  $\pm$  0.87 mm. For PFH, a 6.83  $\pm$  1.34 mm increase was found, while AFH increased by 1.5  $\pm$  1.17 mm.

#### **Harms**

Miniplate mobility occurred in 14 of 156 miniplates (8.97%), and each of these was considered a miniplate failure. The surgical procedure was repeated to

**Table 7.** Mean Values of Sagittal Skeletal Measures at the Beginning (Pre) and End (Post) in the Study Groups; Paired *t*-Test

	Group .	A	Group	В	Group	С
	Mean ± SD	P Value	Mean ± SD	P Value	Mean ± SD	<i>P</i> Value
SNA (°)		.337		.001**		.19
T1 Č	$80.54 \pm 1.66$		$81.75 \pm 0.87$		$80.38 \pm 1.71$	
T2	$80.62 \pm 1.45$		$80.42 \pm 1.00$		$80.62 \pm 1.80$	
T2 - T1	$0.08 \pm 0.28$		$-1.33 \pm 0.98$		$0.24 \pm 0.60$	
SNB (°)	****	<.001**		<.001**		.082
T1 )	$73.77 \pm 1.24$		$74.08 \pm 0.79$		$73.54 \pm 1.33$	
T2	78.15 ± 1.07		$78.25 \pm 0.87$		73.77 ± 1.48	
T2 – T1	$4.38 \pm 0.65$		4.17 ± 0.58		$0.23 \pm 0.44$	
ANB (°)	= 0.00	<.001**	= 0.00	<.001**	0.20 = 0	.337
T1	$6.62 \pm 1.61$	1.001	$7.83 \pm 0.94$	1.001	$6.85 \pm 1.77$	.337
T2	2.31 ± 1.25		2.33 ± 1.07		$6.92 \pm 1.85$	.007
T2 – T1	$-4.31 \pm 0.75$		$-5.5 \pm 0.67$		$0.02 \pm 0.03$	
NAPog (°)	-4.51 ± 0.75	<.001**	-5.5 ± 0.07	<.001**	0.07 = 0.20	.137
T1	11.85 ± 2.12	<.001	11.08 ± 1.83	<.001	12 ± 2.20	.107
T2						
	$7.54 \pm 3.04$		$3.58 \pm 2.11$		12.38 ± 1.76	
T2 – T1	$-4.31 \pm 1.44$	<.001**	$-7.5 \pm 0.9$	.001**	$0.38 \pm 0.87$	10
COGN (°)	00.46 + 0.00	< .001	100 17 + 0 10	.001	00.54 + 0.00	.19
T1	98.46 ± 2.22		$100.17 \pm 3.13$		98.54 ± 2.22	
T2	$103.54 \pm 3.43$		104 ± 4.94		$98.77 \pm 2.24$	
T2 – T1	$5.08 \pm 2.25$		$3.83 \pm 2.79$		$0.23 \pm 0.60$	
GOPog (°)		<.001**		<.001**		.082
T1	$66.38 \pm 1.80$		$67.08 \pm 1.68$		$66 \pm 1.96$	
T2	$70.46 \pm 1.90$		$68.92 \pm 1.16$		$66.23 \pm 2.05$	
T2 – T1	$4.08 \pm 1.85$		$1.84 \pm 0.94$		$0.23 \pm 0.44$	
COA (°)		.219		.039		.165
T1	$79 \pm 1.68$		$79.83 \pm 2.66$		$78.85 \pm 1.57$	
T2	$79.31 \pm 1.70$		$80.17 \pm 2.92$		$79 \pm 1.63$	
T2 - T1	$0.31 \pm 0.85$		$0.34 \pm 0.49$		$0.15 \pm 0.38$	
Wits (°)		<.001**		<.001**		.337
T1	$3.85 \pm 1.63$		$4.42 \pm 1.51$		$4.46 \pm 1.05$	
T2	$1 \pm 0.82$		$1.33 \pm 0.89$		$4.54 \pm 0.97$	
T2 - T1	$-2.85 \pm 0.99$		$-3.09 \pm 1.44$		$0.08 \pm 0.28$	
AVR (°)		.111		.266		.165
T1	$54.23 \pm 1.92$		$53.92 \pm 2.61$		$54.15 \pm 1.91$	
T2	$54.69 \pm 2.21$		$53.58 \pm 2.54$		$54.31 \pm 1.89$	
T2 - T1	$0.46 \pm 0.97$		$-0.34 \pm 0.98$		$0.16 \pm 0.38$	
BVR (°)		<.001**		<.001**		.337
T1 Č	$37.00 \pm 2.48$		$37.33 \pm 3.96$		$37 \pm 2.48$	
T2	41.69 ± 2.87		41.75 ± 3.86		$37.08 \pm 2.47$	
T2 – T1	$4.69 \pm 0.95$		$4.42 \pm 0.90$		$0.08 \pm 0.28$	
PogVR (°)	= 0.00	<.001**	= 0.00	<.001**	0.00 = 0.20	.165
T1	$37.31 \pm 3.50$		$36.5 \pm 4.70$		$36.69 \pm 3.68$	
T2	41.15 ± 3.36		$40.67 \pm 4.70$		$36.85 \pm 3.83$	
T2 – T1	3.84 ± 0.90		4.17 ± 0.83		0.16 ± 0.38	

<sup>\*</sup> P < 0.017 (due to Bonferroni correction); \*\* P < 0.001.

fix the mobile miniplates using new miniscrews. Clinical termination of 1 patient from the study was decided due to excessive miniplate mobility after refixing them. Repeated CS coil spring breakage in Group B was reported in 6 of 26 springs with a 23.07% failure rate, while only 1 SARA appliance failed in Group A (3.8%).

## **DISCUSSION**

The actual skeletal correction of Class II malocclusion due to mandibular deficiency presents a prevalent

therapeutic challenge in orthodontics, and authors of bimaxillary skeletal anchorage studies who used either pushing or pulling forces reported protrusive mandibular changes. However, no previous authors have compared the impact of altering the direction of orthopedic forces (pushing vs pulling) with bimaxillary skeletally anchored appliances on the correction of growing skeletal Class II subjects. In the present study, we compare the skeletal changes induced by using bimaxillary skeletal anchorage in conjunction with two different mechanical methods (pushing vs pulling).

**Table 8.** Comparison of the Mean Differences (T2 – T1) in the Sagittal Skeletal Measures Among the Study Groups; One-Way ANOVA and LSD Test<sup>a</sup>

					P Value	
	$Mean \pm SD$	95% CI for Mean	P Value	A-B	A-C	B-C
SNA (°)			<.001**	<.001**	.564	<.001**
Group A	$0.08 \pm 0.28$	-0.09, 0.24				
Group B	$-1.33 \pm 0.98$	-1.96, -0.71				
Group C	$0.23 \pm 0.60$	-0.13, 0.59				
SNB (°)		•	<.001**	.339	<.001**	<.001**
Group A	$4.38 \pm 0.65$	3.99, 4.78				
Group B	$4.17 \pm 0.58$	3.80, 4.53				
Group C	$0.23 \pm 0.44$	-0.03, 0.50				
ANB (°)		,	<.001**	<.001**	<.001**	<.001**
Group A	$-4.31 \pm 0.75$	-4.76, -3.85				
Group B	$-5.50 \pm 0.67$	-5.93, -5.07				
Group C	$0.08 \pm 0.28$	-0.09, 0.24				
NAPog (°)		,	<.001**	<.001**	<.001**	<.001**
Group A	$-4.31 \pm 1.44$	-5.18, -3.44				
Group B	$-7.50 \pm 0.90$	-8.07, -6.93				
Group C	$0.38 \pm 0.87$	-0.14, 0.91				
CoGn (°)		, , ,	<.001**	.144	<.001**	<.001**
Group A	$5.08 \pm 2.25$	3.72, 6.43				
Group B	$3.83 \pm 2.79$	2.06, 5.61				
Group C	$0.23 \pm 0.60$	-0.13, 0.59				
GoPog (°)		,	<.001**	<.001**	<.001**	.003*
Group A	$4.08 \pm 1.85$	2.96, 5.19				
Group B	$1.83 \pm 0.94$	1.24, 2.43				
Group C	$0.23 \pm 0.44$	-0.03, 0.50				
COA (°)		,	.728	.917	.526	.469
Group A	$0.31 \pm 0.85$	-0.21, 0.82				
Group B	$0.33 \pm 0.49$	0.02, 0.65				
Group C	$0.15 \pm 0.38$	-0.07, 0.38				
Wits (°)	****	,	<.001**	.560	<.001**	<.001**
Group A	$-2.85 \pm 0.99$	-3.44, -2.25				
Group B	$-3.08 \pm 1.44$	-4.00, -2.17				
Group C	$0.08 \pm 0.28$	-0.09, 0.24				
AVR (°)	0.00 = 0.20	0.00, 0.2	.065	.021	.346	.147
Group A	$0.46 \pm 0.97$	-0.12, 1.05		.02.		
Group B	$-0.33 \pm 0.98$	-0.96, 0.29				
Group C	$0.15 \pm 0.38$	-0.07, 0.38				
BVR (°)	0.10 = 0.00	0.07, 0.00	<.001**	.376	<.001**	<.001**
Group A	$4.69 \pm 0.95$	4.12, 5.26		.0.0		
Group B	$4.42 \pm 0.90$	3.84, 4.99				
Group C	$0.08 \pm 0.28$	-0.09, 0.24				
PogVR (°)	0.00 = 0.20	0.00, 0.2	<.001**	.285	<.001**	<.001**
Group A	$3.85 \pm 0.90$	3.30, 4.39				
Group B	$4.17 \pm 0.83$	3.64, 4.70				
Group C	$0.15 \pm 0.38$	-0.07, 0.38				
	0.10 = 0.00					

<sup>\*</sup> P < .017 (due to Bonferroni correction); \*\* P < .001.

It has been strongly recommended to include untreated Class II controls in studies to examine the effectiveness of treatment modalities relative to natural growth changes. A deferred treatment control group was recruited as part of the current study due to a shortage of contemporary growth studies and the absence of historical control data in the population participating in this study.<sup>7,16,19,20</sup>

The treatment intervention period was 9 months to allow analysis of the small changes induced by active

treatment and reduce the effect of normal growth.<sup>7–9</sup> In this study, for a comparable investigation of the effect of the appliances, force maintenance, and compliance avoidance, it was decided to use CS coil springs instead of intermaxillary elastics in the pulling group.<sup>21</sup>

CBCTs were needed in this study for surgical planning for miniplate placement and to take advantage of the better visualization and accuracy with less or equivalent radiation dose of one CBCT to the sum of

<sup>&</sup>lt;sup>a</sup> ANOVA indicates analysis of variance; CI, confidence interval; LSD, least significant difference.

**Table 9.** Mean Vertical Skeletal Measures at T1 and T2 in the Groups; Paired t-Test

	Group A	A	Group	В	Group	С
	Mean ± SD	P Value	Mean ± SD	P Value	Mean ± SD	P Value
SNMP (°)		.190		<.001**		.082
T1	$34.85 \pm 2.08$		$33.42 \pm 2.15$		$34.69 \pm 2.21$	
T2	$35.08 \pm 2.10$		$35.25 \pm 2.05$		$34.92 \pm 2.22$	
T2 - T1	$0.23 \pm 0.60$		$1.83 \pm 0.72$		$0.23 \pm 0.44$	
SNPP (°)		.273		<.001**		.337
T1 `	$9.77 \pm 1.36$		$9.08 \pm 0.67$		$9.69 \pm 1.38$	
T2	$10.00 \pm 1.63$		12.33 ± 1.61		$9.85 \pm 1.28$	
T2 - T1	$0.23 \pm 0.73$		$3.25 \pm 1.71$		$0.16 \pm 0.55$	
SNOP (°)		.337		<.001**		.337
T1 (	$20.38 \pm 1.39$		$21.08 \pm 2.35$		$20.23 \pm 1.30$	
T2	$19.92 \pm 1.32$		$23.5 \pm 2.20$		$20.31 \pm 1.25$	
T2 - T1	$-0.46 \pm 1.66$		$2.42 \pm 1.16$		$0.08 \pm 0.28$	
PLMP (°)		.068		.089		.165
T1	$25.69 \pm 1.44$		$24.92 \pm 2.47$		$25.62 \pm 1.39$	
T2	26.23 ± 1.36		24.33 ± 2.23		25.77 ± 1.42	
T2 – T1	$0.54 \pm 0.97$		$-0.59 \pm 1.08$		$0.15 \pm 0.38$	
Yaxis (°)		.337		<.001**		.337
T1	$61.00 \pm 1.22$		$60.75 \pm 1.29$		$61.08 \pm 1.19$	
T2	60.92 ± 1.12		$63.75 \pm 1.48$		61.23 ± 1.17	
T2 - T1	$-0.08 \pm 0.28$		$3.00 \pm 1.04$		$0.15 \pm 0.55$	
Gonial Angle (°)	****	.190		.144		.190
T1	116.69 ± 1.97		116.75 ± 2.22		117.08 ± 2.10	
T2	116.92 ± 2.22		$117.67 \pm 3.52$		117.31 ± 1.97	
T2 – T1	$0.23 \pm 0.60$		$0.92 \pm 2.02$		$0.23 \pm 0.60$	
CoGo (mm)	0.20 = 0.00	.096	0.02 = 2.02	<.001**	0.20 = 0.00	.337
T1	$48.77 \pm 1.30$	.000	$49.5 \pm 2.71$	1.001	$48.77 \pm 1.30$	.007
T2	$49.54 \pm 2.37$		$54.25 \pm 2.70$		48.85 ± 1.28	
T2 – T1	$0.77 \pm 1.54$		$4.75 \pm 0.87$		$0.08 \pm 0.28$	
PFH (mm)		.104	0 = 0.0.	<.001**	0.00 = 0.20	.082
T1	66.15 ± 3.18		$67.25 \pm 2.49$		66.15 ± 3.18	
T2	66.77 ± 3.30		$74.08 \pm 2.71$		66.38 ± 3.12	
T2 – T1	$0.62 \pm 1.26$		$6.83 \pm 1.34$		$0.23 \pm 0.44$	
AFH (mm)	0.02 =20	.096	0.00 = 1.01	.001**	0.20 = 0	.165
T1	56.92 ± 1.61	.000	$57.67 \pm 2.90$		57.08 ± 1.50	
T2	57.69 ± 2.02		$59.17 \pm 3.21$		58.62 ± 3.57	
T2 – T1	$0.77 \pm 1.54$		1.50 ± 1.17		$1.54 \pm 3.76$	
ASN (mm)	0.77 = 1.01	.054	1.00 = 1.17	<.001**	1.01 = 0.70	.190
T1	50.08 ± 6.81		$53.08 \pm 6.07$	1.001	$49.85 \pm 7.08$	
T2	50.46 ± 6.54		$56.33 \pm 5.84$		$50.08 \pm 6.99$	
T2 – T1	$0.38 \pm 0.65$		$3.25 \pm 0.97$		$0.23 \pm 0.60$	
BSN (mm)	0.00 = 0.00	.053	0.20 = 0.07	<.001**	0.20 = 0.00	.337
T1	85.23 ± 2.68	.000	$86.08 \pm 3.09$	1.001	85.15 ± 2.73	.007
T2	85.69 ± 2.75		$90.50 \pm 4.03$		$85.23 \pm 2.74$	
T2 – T1	$0.46 \pm 0.78$		4.42 ± 1.68		$0.08 \pm 0.28$	
PogSN (mm)	0.40 = 0.70	.053	T.TL = 1.00	<.001**	0.00 _ 0.20	.190
T1	95.31 ± 3.12	.000	96.75 ± 3.57	<u01< td=""><td>95.62 ± 2.84</td><td>.130</td></u01<>	95.62 ± 2.84	.130
T2	95.77 ± 3.06		103.75 ± 3.86		95.85 ± 2.64	
T2 – T1	$0.46 \pm 0.78$		$7.00 \pm 1.95$		$0.23 \pm 0.60$	
12 - 11	U.4U ± U.70		7.00 ± 1.95		U.23 ± U.0U	

<sup>\*</sup> P < .017 (due to Bonferroni correction); \*\* P < .00.

panoramic and lateral cephalometric x-rays together. The success rate of the miniplates was 91.03%, which was similar to that previously reported, ranging between 86.7 and 97%. The success rate of the miniplates was 91.03%, which was similar to that previously reported, ranging between 86.7 and 97%.

Significant improvement in the intermaxillary anteroposterior relationship was observed in both intervention groups due to an increase in effective mandibular length in response to direct transfer of orthopedic forces to the bone. In Group A, mandibular length increased by  $5.08\pm2.25$  mm, in agreement with previous studies in which similar pushing mechanics was used with miniplate anchorage. This was mainly due to increase in the mandibular body length by 4.08 mm, in agreement with Kochar et al., who showed Go-Pog increased by 3.29 mm. However, using pulling mechanics in Group B increased the

**Table 10.** Comparison of Mean Changes (T2 - T1) in the Vertical Skeletal Measures Among the Study Groups; One-Way ANOVA and LSD Test<sup>a</sup>

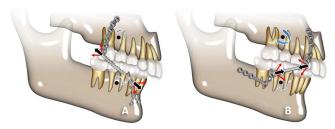
					P Value	
	$Mean \pm SD$	95% CI for Mean	P Value	A-B	A-C	B-C
SNMP (°)			<.001**	<.001**	1	<.001**
Group A	$0.23 \pm 0.60$	-0.13, 0.59				
Group B	$1.83 \pm 0.72$	1.38, 2.29				
Group C	$0.23 \pm 0.44$	-0.03, 0.50				
SNPP (°)		•	<.001**	<.001**	.859	<.001**
Group A	$0.23 \pm 0.73$	-0.21, 0.67				
Group B	$3.25 \pm 1.71$	2.16, 4.34				
Group C	$0.15 \pm 0.55$	-0.18, 0.49				
SNOP (°)		•	<.001**	<.001**	.254	<.001**
Group A	$-0.46 \pm 1.66$	-1.47, 0.54				
Group B	$2.42 \pm 1.16$	1.68, 3.16				
Group C	$0.08 \pm 0.28$	-0.09, 0.24				
PLMP (°)		•	.009*	.002*	.262	.039
Group A	$0.54 \pm 0.97$	-0.05, 1.12				
Group B	$-0.58 \pm 1.08$	-1.27, 0.11				
Group C	$0.15 \pm 0.38$	-0.07, 0.38				
Yaxis (°)		,	<.001**	<.001**	.399	<.001**
Group A	$-0.08 \pm 0.28$	-0.24, 0.09				
Group B	$3.00 \pm 1.04$	2.34, 3.66				
Group C	$0.15 \pm 0.55$	-0.18, 0.49				
Gonial Angle (°)		,	.295	.175	1	.175
Group A	$0.23 \pm 0.60$	-0.13, 0.59				
Group B	$0.92 \pm 2.02$	-0.37, 2.20				
Group C	$0.23 \pm 0.60$	-0.13, 0.59				
CoGo (mm)		3112, 3123	<.001**	<.001**	.097	<.001**
Group A	$0.77 \pm 1.54$	-0.16, 1.70				
Group B	$4.75 \pm 0.87$	4.20, 5.30				
Group C	$0.08 \pm 0.28$	-0.09, 0.24				
PFH (mm)		,	<.001**	<.001**	.371	<.001**
Group A	$0.62 \pm 1.26$	-0.15, 1.38				
Group B	$6.83 \pm 1.34$	5.98, 7.68				
Group C	$0.23 \pm 0.44$	-0.03, 0.50				
AFH (mm)	0.20 = 0	3.33, 3.33	.675	.464	.431	.969
Group A	$0.77 \pm 1.54$	-0.16, 1.70	.07.0			
Group B	1.50 ± 1.17	0.76, 2.24				
Group C	$1.54 \pm 3.76$	-0.73, 3.81				
ASN (mm)		3.7 3, 3.8 .	<.001**	<.001**	.604	<.001**
Group A	$0.38 \pm 0.65$	-0.01, 0.78	1.001	1.001	.00 1	1.001
Group B	$3.25 \pm 0.97$	2.64, 3.86				
Group C	$0.23 \pm 0.60$	-0.13, 0.59				
BSN (mm)	0.20 = 0.00	0.10, 0.00	<.001**	<.001**	.360	<.001**
Group A	$0.46 \pm 0.78$	-0.01, 0.93	1.001	V.001	.000	<.001
Group B	4.42 ± 1.68	3.35, 5.48				
Group C	$0.08 \pm 0.28$	-0.09, 0.24				
PogSN (mm)	0.00 = 0.20	0.00, 0.24	<.001**	<.001**	.637	<.001**
Group A	$0.46 \pm 0.78$	-0.01, 0.93	<.001	<.001	.007	<.001
Group B	$7.00 \pm 1.95$	5.76, 8.24				
Group C	$0.23 \pm 0.60$	-0.13, 0.59				
Group C	0.23 ± 0.60	-0.13, 0.39				

<sup>\*</sup> P < .017 (due to Bonferroni correction); \*\* P < .001.

mandibular length by 3.83  $\pm$  2.79 mm, in agreement with previous studies,  $^{12,13}$  but this increase was mainly due to an increase in ramal length of 4.75 mm, in agreement with a previous study.  $^{13}$  The disparity in growth patterns between the two groups may be attributed to the differing orientations of the force vectors

applied relative to the condyles. Additionally, mandibular position improved significantly (SNB increased by  $4.38\,\pm\,0.65^\circ$  and  $4.17\,\pm\,0.58^\circ$  for groups A and B, respectively), in agreement with previous, similar studies in which bimaxillary miniplate anchorage was used.  $^{11,13}$ 

<sup>&</sup>lt;sup>a</sup> ANOVA indicates analysis of variance; CI, confidence interval; and LSD, least significant difference.



**Figure 7.** A schematic diagram showing the miniplates and appliance settings in the (A) pushing and (B) pulling groups, with the distribution of expected force vectors and moments around the centers of resistance of the maxilla and mandible.

On the other hand, restriction of maxillary growth in both groups was found in comparison with the control group. The pulling group showed a significant reduction in SNA by 1.33° and a change of the A-point position, in agreement with Al-Dumiani et al., 13 indicating a J-hook headgearlike effect. Also, the pulling group showed more opening rotation of the mandible, in agreement with Ozbilek et al. 12 This could be explained by the point of application of force in the pulling mechanics being much more anterior to the maxillary center of resistance, leading to maxillary clockwise rotation, followed by the mandible. This obvious change in condylar and ramal growth pattern, along with an increase in the palatal and mandibular plane angles in the pulling group, explains the increase in lower facial height that was observed. Both mechanics theoretically can cause clockwise rotation; however, due to the increased distance of the point of force application in the pulling mechanics setup, the moment of force was greater than the negligible moment in the pushing mechanics setup (Figure 7).

#### Limitations

The main limitation of this study was the short-term evaluation period. However, a future publication is planned to report long-term follow-up after the fixed orthodontic phase is completed to validate the findings of the current study and determine stability of the treatment effects. The technique used in this study was considered invasive, as at least two surgeries were required for the insertion and removal of the miniplates.

## **CONCLUSIONS**

- Both force mechanics (pushing and pulling) used in conjunction with bimaxillary miniplate anchorage similarly promote correction of skeletal Class II malocclusion, mainly through a skeletal increase of the mandibular length.
- Pulling force mechanics affect the mandibular growth pattern, causing more vertical effects. Therefore, use

of these mechanics should be limited to horizontally growing patients.

## **SUPPLEMENTAL DATA**

Supplemental Tables 1 is available online. **Supplementary Table 1.** Measures at T1 and T2 by sex for each group; independent-samples t-test.

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