Original Article

Evaluation of the miniplate-anchored Forsus Fatigue Resistant Device in skeletal Class II growing subjects: *A randomized controlled trial*

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ABSTRACT

Objectives: To evaluate the use of direct miniplate anchorage in conjunction with the Forsus Fatigue Resistant Device (FFRD) in treatment of skeletal Class II malocclusion.

Materials and Methods: Forty-eight females with skeletal Class II were randomly allocated to the Forsus plus miniplates (FMP) group (16 patients, age 12.5 ± 0.9 years), Forsus alone (FFRD; 16 patients, age 12.1 ± 0.9 years), or the untreated control group (16 subjects, age 12.1 ± 0.9 years). After leveling and alignment, miniplates were inserted in the mandibular symphysis in the FMP group. The FFRD was inserted directly on the miniplates in the FMP group and onto the mandibular archwires in the FFRD group. The appliances were removed after reaching an edge-to-edge incisor relationship.

Results: Data from 46 subjects were analyzed. The effective mandibular length significantly increased in the FMP group only (4.05 ± 0.78). The mandibular incisors showed a significant proclination in the FFRD group (9.17 ± 2.42) and a nonsignificant retroclination in the FMP group (−1.49 ± 4.70). The failure rate of the miniplates was reported to be 13.3%.

Conclusions: The use of miniplates with the FFRD was successful in increasing the effective mandibular length in Class II malocclusion subjects in the short term. The miniplate-anchored FFRD eliminated the unfavorable mandibular incisor proclination in contrast to the conventional FFRD. (*Angle Orthod.* 2019;89:391–403.)

KEY WORDS: Class II malocclusion; Forsus; Miniplates; Anchorage; Growth; Fixed functional appliance

INTRODUCTION

Dimensional mandibular retrusion was shown to be the most common characteristic of skeletal Class II malocclusion.[1] The Forsus Fatigue Resistant Device (FFRD; 3M Unitek, Monrovia, Calif)[2] is an example of hybrid fixed functional appliances (FFAs), which are used for treatment of mandibular retrusion in growing subjects in which the factor of patient cooperation is controlled.

Recently, evidence[3,4] concluded that the skeletal effects of FFAs were minimal and of negligible clinical importance. Reduced skeletal correction was associated with the anchorage loss caused by these appliances that could also jeopardize the stability of the results. Several attempts were proposed to counteract the unwanted dentoalveolar side effects of FFAs, including the use of skeletal anchorage. Studies[5–7] showed that mini-screw anchorage reduced mandibular incisor proclination but was not able to enhance the skeletal changes.

Titanium miniplates were introduced for use in orthodontics in 1999.[8] They were shown to be well accepted by patients and became popular for use in various applications.[9–11] Recently, they were used for direct loading of FFRD for correction of skeletal Class II

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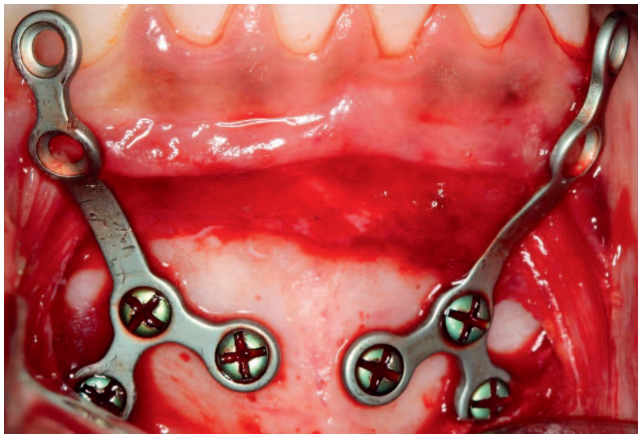

Figure 1. The miniplates inserted in the mandibular symphysis.

malocclusion. However, the available studies were either retrospective,[12] noncontrolled,[13] or nonrandomized.[14]

Cone-beam computed tomography (CBCT) has an advantage of improved visualization over conventional two-dimensional (2D) imaging techniques.[15] Shortcomings of 2D radiographic techniques have been thoroughly described in the literature.[16] Errors in landmark identification, visualization, and the superimposition of bilateral structures in 2D cephalograms have compromised the accuracy of their use in clinical research.

This study aimed to compare the skeletal and dental effects of FFRD alone or in conjunction with miniplates in the treatment of skeletal Class II malocclusion as compared with untreated Class II controls.

MATERIALS AND METHODS

Trial Design

This was a parallel-group, randomized, controlled trial with a 1:1:1 allocation ratio. The trial was registered at ClinicalTrials.gov with an identifier number of NCT02475785.

Table 1. Eligibility Criteria for the Study Participants

Inclusion Criteria	Exclusion Criteria
Chronologically; 10–13 y of age	Systemic diseases
Skeletally, the patients had to be in the cervical maturational stage 3 or 4 as detected by the lateral cephalometric radiograph	Facial asymmetry
Skeletal Angle Class II malocclusion with a deficient mandible (SNB $\leq$76°) and a horizontal or neutral growth pattern (MP/SN $\leq$ 39°)[a]	Any signs or symptoms or previous history of temporomandibular disorders
Class II division 1 incisor relation	Parafunctional habits
Increased overjet (minimum of 5 mm)	Extracted or missing upper permanent tooth/teeth (except for third molars)
Class II canine relationship. (minimum of half unit)	Class II division 2 incisor relation
Mandibular arch crowding less than 3 mm	Severe proclination or crowding that requires extractions in the lower arch

[a] Norms and cutoff values were set according to the Egyptian population.

Participants

The participants were recruited at the Faculty of Dentistry, Cairo University outpatient orthodontic clinic. All participants and parents were informed about the procedures and radiation exposures and signed informed consents. The methods of the study were approved by the Ethical Committee of the Faculty of Dentistry, Cairo University. The study was self-funded by the authors. The participants' eligibility criteria are mentioned in Table 1.

Interventions and Data Analysis

A passive, soldered transpalatal arch was cemented to the maxillary first permanent molars. MBT prescription brackets with 0.022-inch slots (3M Unitek) were bonded to both arches in the FFRD group and to the maxillary arch only in the miniplates (FMP) group. Leveling and alignment progressed until reaching 0.019×0.025-inch cinched-back stainless-steel wires.

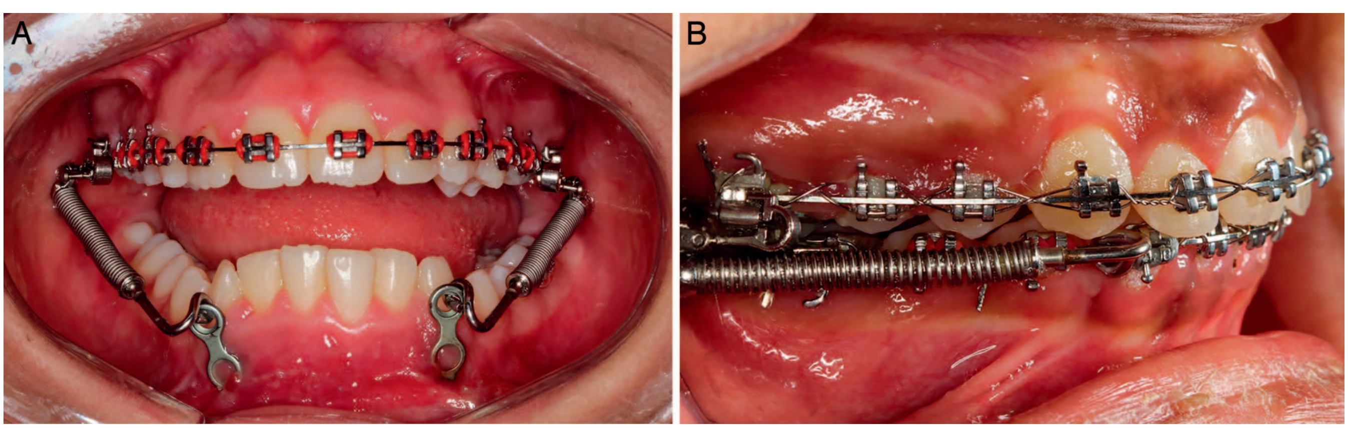

Figure 2. (A) FFRD insertion in the FMP group. (B) FFRD insertion in the FFRD group.

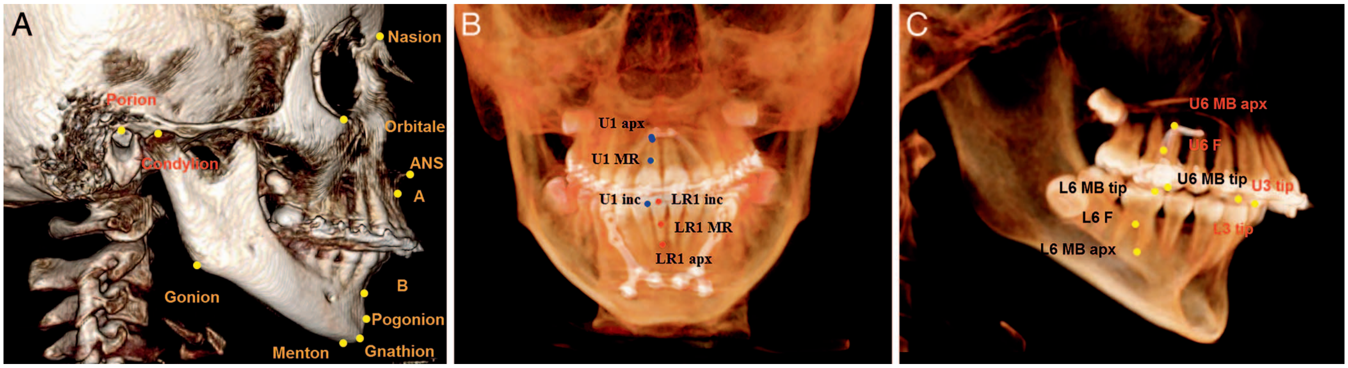

Figure 3. (A) The skeletal landmarks used in the CBCT analysis. (B, C) The dental landmarks used in the study.

The patients were then referred for the T1 CBCT scan. CBCT scanning was performed in maximum intercuspation with the next-generation i-CAT CBCT unit (Imaging Sciences International, Hatfield, Penn). The selected parameters were voxel dimension 0.3 mm, field of view 17 cm at 120 kV, and 18.54 mAs.

In the FMP group, surgical procedures were performed under local anesthesia. A single horizontal incision was made in the alveolar mucosa and the underlying muscle immediately below the mucogingival line from the mandibular canine on one side to that of the other using blade No. 15. Two long Y-shaped miniplates (Stryker, Leibinger, GmbH & Co, Freiburg, Germany) were adapted to the underlying bone (Figure 1). They were fixed by three titanium mini-screws (diameter 2 mm, lengths 8 and 10 mm). The flap was closed using resorbable (4/0) sutures, leaving the miniplate heads perforating the attached gingiva at the mandibular canine region. Postoperative anti-inflammatories and analgesics were prescribed; ice packs and soft diet were advised.

In both treatment groups, the proper FFRD size was selected according to the manufacturer's instructions. The pushrods were inserted onto the mandibular archwires distal to the mandibular canines in the FFRD group and into the miniplate heads in the FMP group (Figure 2a,b). Follow-up visits were every 4 weeks, during which the miniplates were checked for stability

Table 2. Definitions of the Included Measurements in the Study

Measurement	Definition
MP/SN	The angle between the line S-N and the mandibular plane
SNA	The angle between the points S, N, and A
A-FP	The linear distance between the A point and the frontal plane
Co-A	The linear distance between the condylion and A points indicating the effective maxillary length
SNB	The angle between the points S, N, and B
B-FP	The linear distance between the B point and the frontal plane
Co-Gn	The linear distance between the condylion and the gnathion points indicating the effective mandibular length
ANB	The angle between three landmarks: A, N, B
Gonial angle	The angle between the points Co, Go, and Me
Maxillary width	The linear distance between the right and left maxillaire points
Mandibular width	The linear distance between the right and left gonion points
U1 to A Pog	The horizontal distance between the incisal edges of the upper central incisors and the A pogonion line as viewed from the sagittal view
U1 vertical position	The linear distance from the mid-root of the upper incisors to the FHP as viewed from the sagittal view
U1/PP	The angle formed between the palatal plane and the upper central incisors long axes as viewed from the sagittal view
UR6 AP position	The linear distance between the mesiobuccal cusp tip of Upper first molar and the vertical plane as viewed from the sagittal view
U6 vertical position	The linear distance between the furcation area of the upper first molar to the FHP as viewed from the sagittal view
L1/MP	The angle formed between the mandibular plane and the lower central incisors long axes as viewed from the sagittal view
L1 to A Pog	The horizontal distance between the incisal edges of the lower central incisors and the A pogonion line as viewed from the sagittal view
L1 vertical position	The linear distance from the mid-root of the lower central incisors to the mandibular plane viewed from the sagittal view
L6 vertical position	The linear distance from the furcation points of the lower first molars to the mandibular plane as viewed from the sagittal view
L6 AP position	The linear distance between the mesiobuccal cusp tip of lower left first molar and the vertical plane as viewed from the sagittal view

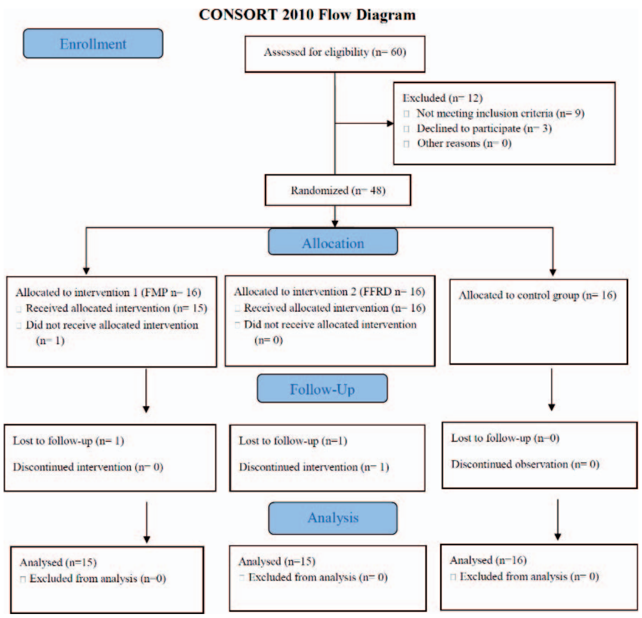

Figure 4. CONSORT 2010 flow diagram.

and the appliance for activation. The FFRD was planned to be removed either after 10 months or after reaching an edge-to-edge incisor relationship, whichever occurred first. T2 CBCT scan was obtained afterward.

The control group subjects were sent for the T1 CBCT after their random allocation. The observation period was 7.26 ± 1.74 months. Afterward, they were sent for the T2 CBCT that was considered their pretreatment record. Orthodontic treatment was then performed for all control patients.

CBCT analysis was done using Invivo Anatomage version 5.2 (San Jose, Calif). The landmarks and included measurements are described (Figure 3a–c; Table 2).

Table 4. Skeletal Maturational Stage for the Subjects in the Study Groups (Chi-Square Test)

	CV Stage 3	CV Stage 4	Row Totals	Chi-Square	*P* Value
FMP	9	6	15	1.867	.393
FFRD	6	9	15		
Control	10	6	16		
Column total	25	21	46 (grand total)		

Sample Size Calculation

Power and sample size calculation (PS) software (Vanderbilt University, Nashville, Tenn) was used. It was based on the work of Manni et al.,[17] who reported a 3.7 ± 2.26 mm difference in the mandibular length. When the power was set at 90%, the required sample size was found to be 11 subjects per group. To account for patient dropouts, a sample size of 16 patients was recruited in each group.

Randomization and Blinding

A random sequence table was generated at random.org. To ensure a 1:1:1 allocation ratio, randomization was made in blocks. Allocation concealment was achieved through opaque well-sealed envelopes. Because of the nature of the study, the operator and patients could not be blinded. However, the outcome assessors and the statistician were blinded.

Statistical Analysis

Statistical analysis was performed with IBM SPSS (SPSS Inc, IBM Corporation, Armonk, NY) version 20 for Windows. All bilateral variables were measured for the right and left sides, and for the sake of simplification, averages were statistically analyzed. The measurements were done by the same observer twice and

Table 3. Comparison Between the Mean Age and Duration of Treatment/Observation Between the Study Groups[a]

Parameter	Study Group	Mean	SD	95% Confidence Interval for Mean: Lower Bound	95% Confidence Interval for Mean: Upper Bound	*F*	*P* Value	*P* (FMP-FFRD)	*P* (FMP-Control)	*P* (FFRD-Control)
ANOVA										
Age	FMP	12.06	0.79	11.60	12.51	1.44	.25	NS	NS	NS
	FFRD	12.54	0.90	12.06	13.02					
	Control	12.13	0.86	11.67	12.58					
Duration	FMP	9.42	0.98	8.85	9.99	17.41	<.001*	<.001*	<.001*	NS
	FFRD	6.23	1.61	5.37	7.08					
	Control	7.26	1.74	6.33	8.19					
Multiple Bonferroni test										
Duration	FMP-FFRD	3.20	0.55				<.001*			
	FMP-Control	2.17	0.55				<.001*			
	FFRD-Control	−1.03	0.53				.1759			

[a] One-way analysis of variance (ANOVA) and multiple Bonferroni method tests. FFRD indicates Forsus alone group; FMP, Forsus and miniplates group; NS, nonsignificant; SD: standard deviation; Std Error, standard error.
* Significant when $P < .05$.

Table 5. Comparison of Baseline Characteristics Between the Study Groups[a]

			95% Confidence Interval for Mean			
Measurement	Mean	SD	Lower Bound	Upper Bound	*F*	*P* Value
SNA						
Control	83.07	3.02	81.46	84.68	1.81	.176
FFRD	83.06	2.14	81.92	84.20		
FMP	81.23	3.75	79.07	83.40		
A-FP						
Control	2.86	2.16	1.71	4.02	1.84	.170
FFRD	2.73	2.86	1.21	4.26		
FMP	1.08	3.33	−0.85	3.00		
Co-A						
Control	80.93	4.16	78.72	83.15	2.32	.111
FFRD	83.92	3.32	82.15	85.69		
FMP	82.00	4.41	79.45	84.55		
SNB						
Control	75.53	2.32	74.29	76.76	6.81	.003*
FFRD	75.77	2.34	74.52	77.01		
FMP	72.75	2.73	71.17	74.32		
B-FP						
Control	−6.43	2.97	−8.02	−4.85	9.52	.001*
FFRD	−6.96	4.36	−9.29	−4.64		
FMP	−9.88	3.70	−12.02	−7.75		
Co-Gn						
Control	106.73	3.78	104.71	108.74	2.33	.109
FFRD	103.86	6.74	100.27	107.46		
FMP	107.68	4.11	105.31	110.05		
ANB						
Control	7.61	1.44	6.84	8.37	2.07	.139
FFRD	7.30	1.44	6.53	8.06		
FMP	8.45	1.90	7.35	9.54		
Gonial angle						
Control	124.59	3.60	122.67	126.51	0.02	.982
FFRD	124.92	8.15	120.58	129.26		
FMP	124.96	4.70	122.25	127.67		
MP/SN						
Control	36.58	4.32	34.28	38.88	3.52	.138
FFRD	36.12	6.32	32.75	39.49		
FMP	39.35	6.92	36.36	40.35		
Maxillary width						
Control	61.60	4.44	59.23	63.97	6.03	.005*
FFRD	58.95	2.26	57.75	60.15		
FMP	63.47	3.75	61.31	65.64		
Mandibular width						
Control	77.25	4.24	74.99	79.51	10.04	.001*
FFRD	84.52	4.48	82.13	86.90		
FMP	80.48	5.10	77.54	83.42		
Overjet						
Control	5.96	1.09	5.39	6.54	0.73	.49
FFRD	6.18	1.04	5.59	6.76		
FMP	6.43	1.06	5.81	7.05		
U1/PP						
Control	116.91	7.29	113.02	120.79	1.50	.234
FFRD	115.81	4.05	113.66	117.97		
FMP	113.03	7.02	108.98	117.08		
U1 to A Pog						
Control	10.64	1.64	9.76	11.52	2.61	.085
FFRD	9.38	2.08	8.27	10.49		
FMP	9.24	1.89	8.15	10.33		
U1 vertical position						
Control	36.04	3.25	34.31	37.77	8.87	.001*
FFRD	40.28	2.70	38.84	41.71		
FMP	39.59	3.14	37.77	41.40		
L1/MP						
Control	100.77	7.08	97.00	104.54	0.17	.842
FFRD	99.81	8.17	95.45	104.17		
FMP	99.29	5.39	96.18	102.40		
L1 A Pog						
Control	2.20	1.48	1.41	2.98	0.01	.99
FFRD	2.12	1.87	1.13	3.12		
FMP	2.13	1.80	1.09	3.16		
L1 vertical position						
Control	26.87	2.39	25.59	28.14	1.98	.15
FFRD	27.41	1.83	26.43	28.38		
FMP	28.59	2.96	26.89	30.30		
U6 AP position						
Control	39.51	2.61	38.12	40.91	5.57	.007*
FFRD	42.56	4.21	40.31	44.80		
FMP	38.63	3.22	36.78	40.49		
U6 vertical position						
Control	30.16	2.36	28.90	31.42	10.83	.001*
FFRD	34.34	2.80	32.85	35.84		
FMP	32.68	2.49	31.24	34.12		
L6 AP position						
Control	39.36	3.08	37.72	41.00	3.09	.056
FFRD	40.35	4.20	38.12	42.59		
FMP	36.93	4.21	34.50	39.36		
L6 vertical position						
Control	16.23	2.35	14.98	17.48	1.45	.247
FFRD	17.09	1.55	16.26	17.91		
FMP	17.41	2.00	16.26	18.57		

[a] One-way analysis of variance test. FFRD indicates Forsus alone group; FMP, Forsus and miniplates group; SD, standard deviation.
* Significant when $P < .05$.

by a second observer. Concordance correlation coefficients (CCCs) were calculated to detect the intra- and interexaminer reliability of the measurements.

Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests. Paired *t*-test was performed to compare between the pre- and posttreatment and/or observation measurements within the groups. One-way analysis of variance (ANOVA) was used for comparison of the baseline data and the mean changes between groups. This was followed by multiple-comparison Bonferroni test for the significant ANOVA variables.

RESULTS

Patient Flow and Dropouts

Sixteen patients were randomly allocated in each group (Figure 4; FFRD: 12.5 ± 0.9 years, FMP: 12.1 ± 0.9 years; and control: 12.1 ± 0.9 years). Two patients

Table 6. Concordance Correlation Coefficients (CCCs) for the Intraobserver and Interobserver Reliability of the Measurements Used in the Study

	Intraobserver Reliability Scores		Interobserver Reliability Scores	
Measurement	CCC	95% Confidence Limits	CCC	95% Confidence Limits
SNA	0.993	0.978–0.998	0.990	0.968–0.997
SNB	0.990	0.969–0.997	0.984	0.950–0.995
ANB	0.995	0.985–0.998	0.979	0.937–0.993
A-FP	0.992	0.976–0.997	0.983	0.948–0.994
B-FP	0.979	0.947–0.992	0.985	0.960–0.994
Co-A	0.993	0.978–0.998	0.963	0.896–0.987
Co-Gn	0.991	0.972–0.997	0.994	0.982–0.998
MP/SN	0.987	0.960–0.996	0.987	0.961–0.996
Gonial angle	0.969	0.888–0.992	0.981	0.953–0.992
Maxillary width	0.972	0.922–0.990	0.725	0.620–0.810
Mandibular width	0.988	0.963–0.996	0.995	0.984–0.998
U6 vertical position	0.931	0.815–0.975	0.940	0.835–0.979
U6 AP position	0.975	0.932–0.991	0.974	0.920–0.992
U1/PP	0.997	0.990–0.999	0.988	0.962–0.996
U1 vertical position	0.887	0.684–0.963	0.895	0.701–0.966
U1 to A Pog	0.990	0.968–0.997	0.972	0.915–0.991
L1/ MP	0.973	0.918–0.991	0.957	0.892–0.983
L1 A Pog	0.987	0.959–0.996	0.990	0.974–0.996
L1 vert	0.990	0.970–0.996	0.752	0.650–0.862
L6 AP position	0.968	0.911–0.988	0.974	0.922–0.991
L6 vert	0.982	0.946–0.994	0.921	0.778–0.973

were lost to follow-up; one each from the FMP and the FFRD groups. Thus, a total of 46 subjects were analyzed. Clinical examples of one patient of the FFRD and FMP groups are presented in Figures 5 and 6, respectively.

Baseline Data and Measurement Error

At baseline, age; cervical maturational stages (Tables 3 and 4); anteroposterior, vertical, and transverse jaw measurements; and overjet, maxillary, and mandibular incisor measurements; and first molar measurements were reported and compared (Table 5). Normality tests revealed the data were normally distributed. Regarding the measurement error, the CCC values ranged from 0.725–0.995, indicating good to excellent agreement (Table 6).

Follow-up

The mean follow-up period of the FMP, FFRD, and control groups were (in months) 9.42 ± 0.98, 6.23 ± 1.61, and 7.26 ± 1.74, respectively, with a significant difference between them (Table 3). Annualization of the data was performed to account for the difference in treatment/observation durations by calculating the change per year for every measurement.

Skeletal Changes

A significant increase was found in the effective mandibular length (4.05 ± 0.78), SNB, and B-FP in the FMP as compared with the FFRD and control groups, even after data annualization (Tables 7 and 8). The gonial angle was significantly decreased in the controls (–0.88 ± 0.76) and increased in the FMP group (1.15 ± 0.85). The effective maxillary length and A-FP showed no significant difference between groups. The ANB angle showed a significant decrease in the FMP group only (–1.62 ± 1.37), indicating the skeletal Class II improvement.

No significant differences were reported regarding the maxillary and mandibular widths. In the vertical plane, there was a significant increase in the MP/SN (2.06 ± 1.44), indicating a clockwise mandibular rotation in the FMP group, which was confirmed after data annualization.

Dental Changes

The maxillary incisors were significantly retroclined in the FFRD (–8.98 ± 2.55) and FMP (–10.03 ± 4.39) groups (Tables 7 and 8). In the FFRD group, the mandibular incisors showed significant proclination (9.17 ± 2.42) and advancement relative to the A-pogonion line (2.96 ± 0.95). The FMP and control groups showed no significant difference in the mandibular incisor position; retroclination (–1.49 ± 4.70) occurred in the FMP group. The FFRD also showed significant mandibular incisor intrusion (–1.76 ± 0.64), while the FMP showed significant extrusion (1.14 ± 1.52).

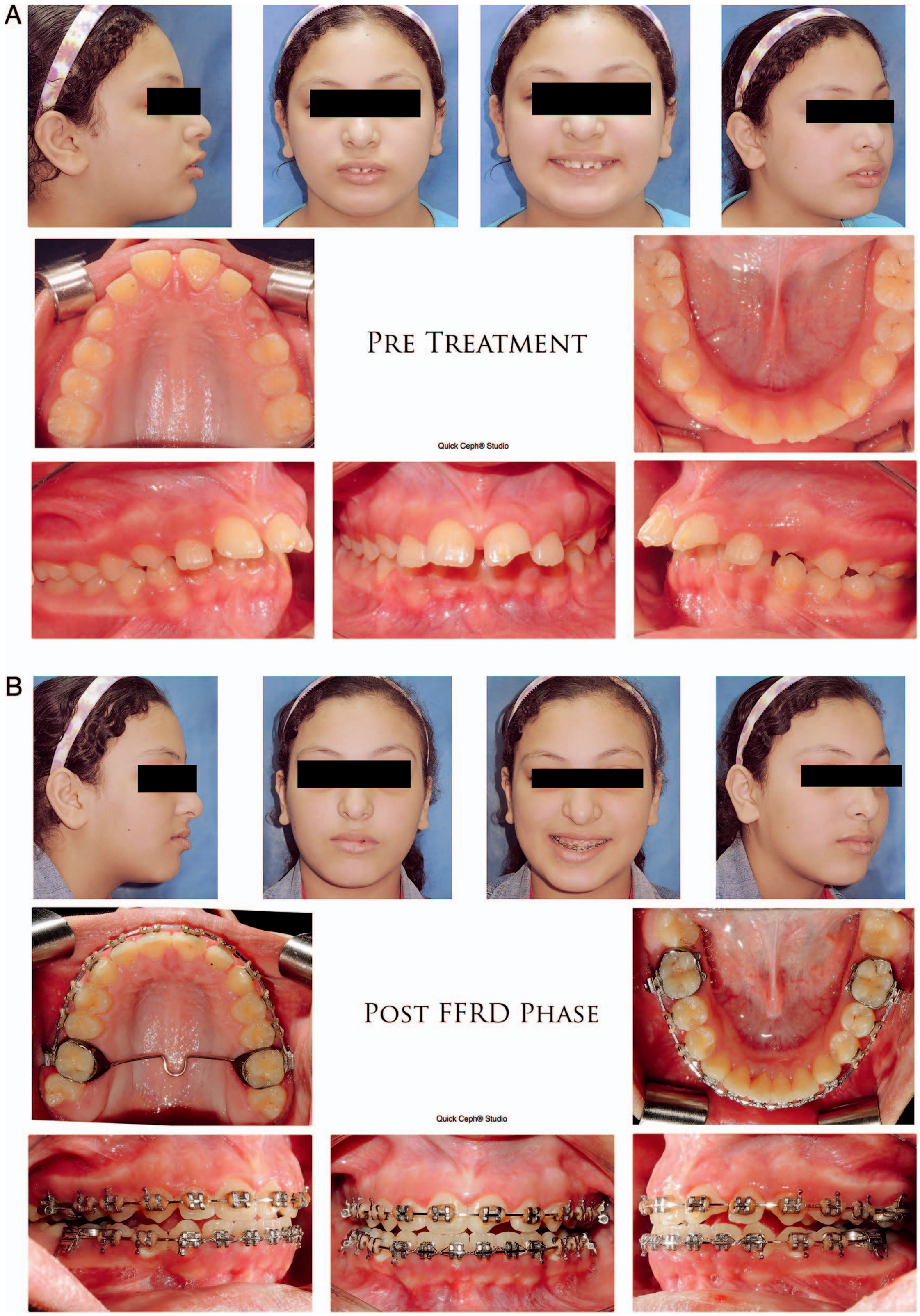

Figure 5. Extra- and intraoral photographs for a patient in the FFRD group: (A) before treatment, (B) after FFRD removal.

Table 7. Mean Values of Parameters at the Beginning (Pre) and End (Post) and the Mean Difference (Post-Pre) of the Skeletal and Dental Measurements in the Three Study Groups[a]

		Control			FMP			FFRD		
Measurement	Time Point	Mean	SD	*P* Value	Mean	SD	*P* Value	Mean	SD	*P* Value
SNA	Pre	83.07	3.02	.20	81.23	3.75	.009*	83.06	2.14	.81
	Post	83.36	3.12		80.44	3.28		83.01	2.23	
	Post-Pre	0.30	0.88		−0.79	0.96		−0.05	0.85	
A-FP	Pre	2.86	2.16	.43	1.08	3.33	.26	2.73	2.86	.925
	Post	3.02	1.77		0.77	3.37		2.71	2.93	
	Post-Pre	0.16	0.78		−0.31	0.98		−0.02	0.86	
Co-A	Pre	80.93	4.16	.01*	82.00	4.41	.01*	83.92	3.32	.62
	Post	82.13	3.99		83.13	4.60		84.04	3.36	
	Post-Pre	1.20	1.74		1.13	1.48		0.12	0.99	
SNB	Pre	75.53	2.32	.80	72.75	2.73	.005*	75.77	2.34	.197
	Post	75.46	2.63		73.72	2.57		75.99	2.29	
	Post-Pre	−0.07	1.05		0.97	1.06		0.22	0.66	
B- FP	Pre	−6.43	2.97	.79	−9.88	3.70	.001*	−6.96	4.36	.43
	Post	−6.36	2.84		−7.68	4.42		−6.64	4.61	
	Post-Pre	0.07	1.03		2.20	1.96		0.33	1.62	
Co-Gn	Pre	106.73	3.78	<.001*	107.68	4.11	<.001*	103.86	6.74	<.001*
	Post	107.83	3.88		111.73	4.37		104.73	6.52	
	Post-Pre	1.11	0.74		4.05	0.78		0.86	0.79	
Gonial angle	Pre	124.59	3.60	<.001*	124.96	4.70	<.001*	124.92	8.15	.53
	Post	123.71	3.67		126.11	4.84		124.78	8.26	
	Post-Pre	−0.88	0.76		1.15	0.85		−0.14	0.89	
ANB	Pre	7.61	1.44	.79	8.45	1.90	<.001*	7.30	1.44	.053
	Post	7.66	1.23		6.83	1.55		7.02	1.53	
	Post-Pre	0.06	0.80		−1.62	1.37		−0.28	0.53	
MP/SN	Pre	36.58	4.32	.36	41.35	6.92	<.001*	36.12	6.32	.65
	Post	36.27	4.34		43.42	6.82		36.27	6.74	
	Post-Pre	−0.31	1.32		2.06	1.44		0.15	1.27	
Maxillary width	Pre	61.60	4.44	.07	63.47	3.75	.19	58.95	2.26	.007*
	Post	62.33	4.33		63.98	4.43		59.49	2.39	
	Post-Pre	0.73	1.48		0.51	1.36		0.54	0.69	
Mandibular width	Pre	77.25	4.24	.01*	80.48	5.10	.081	84.52	4.48	.019*
	Post	78.32	4.53		81.13	4.86		85.13	4.40	
	Post-Pre	1.06	0.86		0.65	1.28		0.61	0.92	
U1/PP	Pre	116.91	7.29	.014*	113.03	7.02	<.001*	115.81	4.05	<.001*
	Post	118.26	6.90		103.00	7.22		106.84	5.30	
	Post-Pre	1.35	1.96		−10.03	4.39		−8.98	2.55	
U1 to A Pog	Pre	10.64	1.64	.07*	9.24	1.89	<.001*	9.38	2.08	<.001*
	Post	11.00	1.52		5.47	1.66		6.87	1.80	
	Post-Pre	0.36	0.74		−3.77	0.98		−2.51	0.99	
U1 vert position	Pre	36.04	3.25	.03*	39.59	3.14	.009*	40.28	2.70	.145
	Post	36.86	3.12		40.67	3.24		40.73	3.15	
	Post-Pre	0.81	1.31		1.09	1.33		0.45	1.18	
U6 AP position	Pre	39.52	2.61	<.001*	38.64	3.22	<.001*	42.56	4.21	<.001*
	Post	40.70	2.68		36.87	3.79		41.04	4.66	
	Post-Pre	1.18	0.90		−1.77	1.02		−1.53	1.07	
U6 vert	Pre	30.16	2.36	<.001*	32.68	2.49	.011*	34.35	2.80	<.001*
	Post	31.40	2.63		31.60	2.67		33.14	3.11	
	Post-Pre	1.24	0.86		−1.09	1.38		−1.21	0.77	
L6 AP position	Pre	39.36	3.08	.036*	36.93	4.21	<.001*	40.36	4.20	<.001*
	Post	40.12	2.96		39.00	4.23		43.19	4.56	
	Post-Pre	0.76	1.31		2.08	1.26		2.83	1.31	
L6 vert	Pre	16.23	2.35	.004*	17.41	2.00	<.001	17.09	1.55	<.001*
	Post	16.73	2.17		20.16	2.00		18.35	1.61	
	Post-Pre	0.50	0.58		2.75	0.78		1.26	0.52	
L1/MP	Pre	100.78	7.08	.15	99.30	5.39	.258	99.81	8.17	<.001*
	Post	101.47	7.75		97.81	5.51		108.99	6.63	
	Post-Pre	0.69	1.81		−1.49	4.70		9.18	2.42	
L1 A Pog	Pre	2.20	1.48	.56	2.13	1.80	.16	2.13	1.87	<.001*
	Post	2.31	1.44		2.74	2.31		5.09	1.80	
	Post-Pre	0.11	0.74		0.61	1.54		2.96	0.95	

Table 7. Continued

Measurement	Time Point	Control			FMP			FFRD		
		Mean	SD	*P* Value	Mean	SD	*P* Value	Mean	SD	*P* Value
L1 vert	Pre	26.87	2.39	<.001*	28.59	2.96	.014*	27.41	1.83	<.001*
	Post	27.22	2.34		29.74	3.16		25.65	1.81	
	Post-Pre	0.35	0.27		1.15	1.52		−1.76	0.64	

[a] Paired *t*-test. FFRD indicates Forsus alone group; FMP, Forsus and miniplates group; SD, standard deviation.
* Significant when $P < .05$.

Maxillary molars were significantly distalized and intruded in the FFRD and FMP groups. Mandibular molars were mesialized and extruded in all groups. The highest mesialization was found in the FFRD group (2.83 ± 1.31), while the maximum extrusion was found in the FMP group (2.75 ± 0.78).

Harms

Excessive miniplate mobility was considered a sign of failure and occurred in 4 of 30 miniplates (13.3%). Loading was discontinued, and new miniplates were inserted.

DISCUSSION

Undesirable tooth movements and anchorage loss complicate the treatment outcomes of FFAs. Skeletal anchorage was suggested to overcome the dentoalveolar side effects.[6,7,12–14] Results of the current randomized trial showed that miniplate-anchored FFRD yielded favorable skeletal effects over the conventional FFRD and untreated controls and eliminated the unwanted mandibular anchorage loss in the short term.

The current study sample included only subjects with Class II division 1 incisor relationship with exclusion of Class II division 2. This was because they have been shown to be different in almost all of their skeletal and dental features.[18] Molar relation was not considered during patient inclusion because it was reported that Angle classification does not match the jaw base relationships in one of every three individuals.[19] Gender restriction to females was adopted because of the documented variations in growth timing, pattern, and rate between males and females,[20] rendering the validity of combination of their skeletal outcomes questionable.

Skeletal age is superior to chronological age in determination of the growth status[21]; thus, the cervical vertebral maturational stage method according to Baccetti et al.[22] was elected for use in subject selection. Subjects were selected to be in stages 3 or 4, and there were no significant differences between groups, indicating similar growth potentials. Inclusion of untreated skeletal Class II controls was based on previous recommendations to separate the treatment effects from the growth changes.[23] Lack of growth studies in the population involved in this study resulted in the absence of historical control data; thus, prospective controls were recruited.

Miniplates were used for directly anchoring the FFRD without bonding the mandibular arch, in accordance with previous studies,[12–14] because they provide more reliable anchorage over mini-screws upon application of orthopedic forces.[10]

Normal growth yielded a modest increase in the mandibular length in the controls that was almost the same as in the FFRD group. This confirmed the evidence that FFAs could not induce additional skeletal changes.[3,4] On the contrary, miniplate-anchored FFRD (FMP) showed an increase of 4.05 mm in the Co-Gn measurement, which could have been due to the direct application of orthopedic forces to the bone that transmitted a downward and forward force vector to the condyles. Annualizing the data did not change this fact, so the difference was not due to the duration discrepancy between groups. The B point was significantly more retruded at baseline in the FMP group, which could be attributed to a random allocation error that might occur in randomized trials.[24]

Clockwise mandibular rotation was noted to be significantly higher in the FMP group, in accordance with previous studies.[12–14] It could be explained by the application of the force more anterior to the mandibular center of resistance. This posterior rotation masked the increase in the SNB, which was shown previously to be an indicator of mandibular positional change rather than a change of its size.[25] In addition, the increased gonial angle in the FMP group could indicate a change in the mandibular morphology because of bone bending following the directly applied downward and forward forces.

The maxillary skeletal changes showed no difference among all groups, in agreement with previous studies.[12–14] The ANB angle showed limited improvement in the skeletal Class II in the FMP group only (1.6° ± 1.37°). This reduced magnitude could be attributed to the previously mentioned backward mandibular

Table 8. Comparison of the Mean Differences (T2–T1) in the Skeletal and Dental Measurements Among the Three Study Groups[a]

				95% Confidence Interval for Mean			Actual Study Data				Annualized Data			
Measurement	Study Group	Mean	SD	Lower Bound	Upper Bound	*F*	*P* Value	*P* (Control-FFRD)	*P* (Control-FMP)	*P* (FFRD-FMP)	*P* Value	*P* (Control-FFRD)	*P* (Control-FMP)	*P* (FFRD-FMP)
SNA	Control	0.30	0.88	−0.18	0.77	5.62	.007*	NS	.05*	NS	.057	NS	NS	NS
	FFRD	−0.05	0.85	−0.51	0.40									
	FMP	−0.79	0.96	−1.35	−0.23									
A-FP	Control	0.16	0.78	−0.25	0.57	1.08	.348	NS	NS	NS	.47	NS	NS	NS
	FFRD	−0.02	0.86	−0.48	0.44									
	FMP	−0.31	0.98	−0.88	0.26									
Co-A	Control	1.20	1.74	0.27	2.12	2.75	.075*	NS	NS	NS	.167	NS	NS	NS
	FFRD	0.12	0.99	−0.40	0.65									
	FMP	1.13	1.48	0.27	1.99									
SNB	Control	−0.07	1.05	−0.63	0.49	4.84	.013*	NS	.01*	NS	.04*	NS	.04*	NS
	FFRD	0.22	0.66	−0.13	0.57									
	FMP	0.97	1.06	0.36	1.59									
B- FP	Control	0.07	1.03	−0.48	0.62	8.10	.001*	NS	.001*	.006*	.01*	NS	.016*	NS
	FFRD	0.33	1.62	−0.53	1.19									
	FMP	2.20	1.96	1.07	3.33									
Co-Gn	Control	1.11	0.74	0.71	1.50	77.96	<.001*	NS	<.001*	<.001*	<.001*	NS	<.001*	<.001*
	FFRD	0.86	0.79	0.44	1.29									
	FMP	4.05	0.78	3.60	4.50									
ANB	Control	0.06	0.80	−0.37	0.48	13.06	<.001*	NS	<.001*	<.001*	<.001*	NS	<.001*	.01*
	FFRD	−0.28	0.53	−0.56	0.00									
	FMP	−1.62	1.37	−2.41	−0.83									
Gonial angle	Control	−0.88	0.76	−1.29	−0.48	22.68	<.001*	.045*	<.001*	<.001*	<.001*	.05*	<.001*	.02*
	FFRD	−0.14	0.89	−0.61	0.33									
	FMP	1.15	0.85	0.66	1.64									
MP/SN	Control	−0.31	1.32	−1.01	0.39	12.94	<.001*	NS	<.001*	<.001*	.002*	NS	.002*	.03*
	FFRD	0.15	1.27	−0.53	0.82									
	FMP	2.06	1.44	1.23	2.89									
Maxillary width	Control	0.73	1.48	−0.07	1.52	0.15	.863	NS	NS	NS	.588	NS	NS	NS
	FFRD	0.54	0.69	0.17	0.90									
	FMP	0.51	1.36	−0.28	1.29									
Mandibular width	Control	1.06	0.86	0.61	1.52	0.96	.389	NS	NS	NS	.297	NS	NS	NS
	FFRD	0.61	0.92	0.12	1.10									
	FMP	0.65	1.28	−0.09	1.38									
U1/PP	Control	1.35	1.96	0.31	2.39	65.17	<.001*	<.001*	<.001*	NS	<.001*	<.001*	<.001*	.03*
	FFRD	−8.98	2.55	−10.34	−7.62									
	FMP	−10.03	4.39	−12.57	−7.49									
U1 to A Pog	Control	0.36	0.74	−0.03	0.76	82.72	<.001*	<.001*	<.001*	.001*	<.001*	<.001*	<.001*	NS
	FFRD	−2.51	0.99	−3.04	−1.98									
	FMP	−3.77	0.98	−4.34	−3.21									
U1 vertical position	Control	0.81	1.31	0.11	1.51	0.94	.397	NS	NS	NS	NS	NS	NS	NS
	FFRD	0.45	1.18	−0.18	1.08									
	FMP	1.09	1.33	0.32	1.85									
L1/MP	Control	0.69	1.81	−0.28	1.66	49.56	<.001*	<.001*	NS	<.001*	<.001*	<.001*	NS	<.001*
	FFRD	9.17	2.42	7.89	10.46									
	FMP	−1.49	4.70	−4.20	1.23									
L1 A Pog	Control	0.11	0.74	−0.28	0.50	29.99	<.001*	<.001*	NS	<.001*	<.001*	<.001*	NS	<.001*
	FFRD	2.96	0.95	2.45	3.47									
	FMP	0.61	1.54	−0.28	1.50									
L1 vertical position	Control	0.35	0.27	0.20	0.49	39.69	<.001*	<.001*	NS	<.001*	<.001*	<.001*	NS	<.001*
	FFRD	−1.76	0.64	−2.09	−1.42									
	FMP	1.14	1.52	0.27	2.02									
U6 AP position	Control	1.18	0.90	0.70	1.66	41.90	<.001*	<.001*	<.001*	NS	<.001*	<.001*	<.001*	NS
	FFRD	−1.52	1.07	−2.09	−0.96									
	FMP	−1.76	1.02	−2.35	−1.18									
U6 vertical position	Control	1.24	0.85	0.78	1.69	28.86	<.001*	<.001*	<.001*	NS	<.001*	<.001*	<.001*	NS
	FFRD	−1.21	0.77	−1.62	−0.80									
	FMP	−1.08	1.38	−1.88	−0.29									

Table 8. Continued

Measurement	Study Group	Mean	SD	95% Confidence Interval for Mean		F	Actual Study Data				Annualized Data			
				Lower Bound	Upper Bound		P Value	P (Control-FFRD)	P (Control-FMP)	P (FFRD-FMP)	P Value	P (Control-FFRD)	P (Control-FMP)	P (FFRD-FMP)
L6 AP position	Control	0.76	1.31	0.06	1.46	10.44	<.001*	<.001*	<.001*	NS	<.001*	<.001*	NS	.002*
	FFRD	2.83	1.31	2.13	3.53									
	FMP	2.07	1.26	1.34	2.80									
L6 vertical position	Control	0.50	0.58	0.19	0.81	49.02	<.001*	.004*	<.001*	<.001*	<.001*	<.001*	<.001*	NS
	FFRD	1.26	0.52	0.98	1.54									
	FMP	2.75	0.78	2.30	3.19									

[a] One-way analysis of variance and multiple Bonferroni method tests. FFRD indicates Forsus alone group; FMP, Forsus and miniplates group; NS, nonsignificant; SD, standard deviation.
* Significant when $P < .05$.

rotation. Previous studies showed no significant difference in the ANB change between the FFRD and the FFRD with miniplates.[12,14]

The current FFRD group results confirmed previous reports that FFRD resulted in a large amount of mandibular incisor proclination, reaching 9°–10°.[6,26] However, the association between this and the inability of the mandible to surpass its normal growth amount is not fully understood. In the current study, mandibular incisor retroclination occurred in the FMP group, similar to previous studies evaluating the same technique,[12–14] and it is considered favorable in Class II subjects. Vertically, the FFRD group showed significant mandibular incisor intrusion due to the downward and forward forces applied to the mandibular teeth by the conventional FFRD. In contrast, the FMP showed mandibular incisor extrusion. The maxillary incisors were similarly retroclined in the FFRD and FMP groups, consistent with the study by Turkkahraman et al.[14]

Regarding the mandibular molars, mesialization and extrusion were evident in all groups. Noteworthy of mention is that the FMP group showed almost double the molar extrusion of the FFRD group. This could be compensatory to the clockwise mandibular rotation and emphasizes the importance of vertical control during miniplate-anchored FFRD therapy.

The increase achieved in the mandibular length must be interpreted with caution, because it was evaluated only in the short term. Long-term follow-up could diminish the difference in mandibular growth between groups and reveal it was a temporary acceleration of growth. Celikoglu et al.[12] achieved almost the same amount of mandibular lengthening that occurred in the current FMP group with both the skeletally anchored FFRD and the Herbst appliance. Concomitant with the invasiveness of the miniplate procedure, the Herbst appliance could be a more efficient tool to choose. The main difference between both appliances was the incisor proclination that was associated only with the Herbst appliance. This could limit the indications for the miniplate-anchored FFRD to those severe Class II subjects whose lower incisors were already proclined.

Limitations and Generalizability

The technique investigated in this study suffered from several limitations. A minimum of two surgeries were needed for miniplate insertion and removal. The additional cost is also an important disadvantage, rendering a cost-benefit analysis mandatory. Engagement of this modality as an integral part of treatment for Class II growing patients still needs further investigation in future studies to show the stability of its long-term outcomes. Another limitation in this study was the different experimental periods between the FFRD and FMP groups, which was managed by annualizing the data. Despite being performed in a university setting that received patients with rural and urban backgrounds, the generalizability of the results might be reduced due to gender restriction. Bigger trials including males and females with subgroup analysis are thus recommended.

CONCLUSIONS

- The addition of miniplates to the FFRD (FMP group) enhanced the skeletal outcome of Class II malocclusion treatment in the short term.
- Miniplate-anchored FFRD (FMP) resulted in a significant lengthening of the mandible that was coupled with clockwise mandibular rotation, reducing the apparent sagittal correction.
- In contrast to the conventional FFRD, miniplate-anchored FFRD (FMP) showed retroclination of the mandibular incisors and no anchorage loss.

Figure 6. Extra- and intraoral photographs for a patient in the FMP group: (A) before treatment, (B) after FFRD removal.

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