Original Article

Treatment outcomes of Class II malocclusion cases treated with miniscrew-anchored Forsus Fatigue Resistant Device: *A randomized controlled trial*

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ABSTRACT

Objective: To evaluate the skeletal, dental, and soft tissue effects of the Forsus Fatigue Resistant Device (FRD) used with miniscrew anchorage and compare them with those of the conventional Forsus FRD.

Materials and Methods: This study was carried out on 38 patients. These patients were randomly allocated into three groups. The 14 patients in group 1 (aged 12.76 ± 1.0 years) were treated with the FRD appliance. In group 2, the 15 patients (aged 12.52 ± 1.12 years) received treatment with FRD using miniscrew anchorage, and the 9 patients in group 3 (aged 12.82 ± 0.9 years) received no treatment as a control group. Linear and angular measurements were made on lateral cephalograms before and immediately after Forsus treatment. Data were analyzed statistically using paired *t*-, ANOVA, and Tukey tests.

Results: Class I molar relationship and overjet correction were achieved in both treatment groups. Although mandibular growth was statistically nonsignificant, there was a significant headgear effect on the maxilla. Mandibular incisor proclination, maxillary incisor retroclination, and distalization of maxillary molars were significant in both treatment groups. However, no significant differences were found between the treatment groups.

Conclusions: Class II correction was mainly dentoalveolar in both treatment groups. Use of miniscrews with Forsus did not enhance mandibular forward growth nor prevent labial tipping of the mandibular incisors. (*Angle Orthod.* 2017;87:824–833.)

KEY WORDS: Forsus; Miniscrew; Fixed functional appliance; Class II malocclusion

INTRODUCTION

Class II malocclusion is one of the most commonly seen problems in daily orthodontic practice. McNamara[1] reported that mandibular retrusion is the main etiological factor in Class II malocclusion rather than maxillary protrusion. Therefore, several types of functional appliances have been advocated for the treatment of Class II malocclusion with mandibular retrusion, such as fixed functional devices that have the advantage of not depending upon patient cooperation. Moreover, they can be used simultaneously with orthodontic brackets.

The Forsus appliance produces continuous orthopedic forces that can be controlled by varying the pushrod size to the desired force level as well as by adding crimped stops, depending on the clinical application.[2] However, dentoalveolar side effects may limit skeletal correction.[3] Several studies have recently focused on minimizing these effects.[4–7]

Only two available studies[6,7] have shown the effects of using FRD with miniscrew anchorage. They reported that Class II correction was totally dentoalveolar, and unfortunately, miniscrew anchorage did not enhance mandibular forward growth. Both studies used different radiographic assessment methods. Moreover, there was controversy regarding some findings of these two

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studies, such as the exact effect on the maxilla, and only one study reported soft tissue changes. A recent systematic review[8] concluded that the use of skeletally anchored functional appliances can prevent mandibular incisor proclination; however, this finding should be interpreted with caution because of variability in the means of skeletal anchorage used in different studies with the FFA including miniscrews and miniplates, as well as variation in methods of indirect anchorage including thick steel wire, wire ligature, and elastic ligature. Pooling of results from different studies with such variation could be inappropriate. Moreover, a mean reduction of $-1.43°$ may not make enough clinical difference to encourage clinicians to use two miniscrews or miniplates with the FFA. The effect of using orthodontic miniscrews with the FRD were difficult to comprehend and, therefore, additional investigation is needed to analyze the skeletal, dental, and soft tissues changes associated with miniscrew-anchored FRD.

Specific Objective or Hypothesis

The aim of the present study was to evaluate the skeletal, dental, and soft tissue effects of the miniscrew-anchored FRD and compare it with conventional FRD. The null hypothesis was that there would be no difference in skeletal, dental, or soft tissue changes among treatment and control groups.

MATERIALS AND METHODS

Trial Design

This study was a single-center, randomized clinical trial. No changes occurred during the trial.

Participants, Eligibility Criteria, and Settings

The study design was approved by the Research Ethics Committee of Faculty of Dentistry, Tanta University, Egypt.

Patients were included according to following criteria:

1. Skeletal Class II malocclusion with mandibular retrognathia (ANB $>$ 4.5°, SNB $<$ 76°)
2. Normal vertical growth pattern (SN-MP angle in 25°–35° range)
3. Minimal or no crowding in the mandibular arch (0–5 mm), based on Little's irregularity index[9]
4. No extracted or missing permanent teeth (third molars excluded)
5. Undergoing circumpubertal phase of skeletal development (CVMI 2–4)
6. No medical history or systemic disease that could affect normal growth of the body or jaws.

The cervical vertebrae maturation index (CVMI) was used for patient selection. CVMI 2, 3, and 4 stages, which correspond to the circumpubertal growth period, were defined by lateral cephalometric radiographs.[10] Written informed consent and assent forms were obtained from the parents and children after we explained the treatment procedures in detail for all participants.

Sample Size Calculation

Sample size calculation was based on the ability to detect a clinically meaningful difference in mandibular length of 2 mm ($\pm$ 1.5 mm), with an alpha error of 0.05 and a test power of 80%. The calculation was carried out using software G* Power (Universität Düsseldorf, Germany). The recommended sample size was 12 patients in each group. To compensate for a possible dropout rate of 20% during the study period, 15 patients were included in each group.

Randomization

Patients were randomly assigned using a computer-generated random list. The patients were randomly allocated into three groups using sequentially numbered, opaque, sealed envelopes.

Group 1 (12.76 $\pm$ 1.0 years): nine females and six males were treated with a conventional FRD. Group 2 (12.52 $\pm$ 1.12 years): 10 females and 5 males were treated with a miniscrew-anchored FRD. Group 3 (12.82 $\pm$ 0.9 years): untreated nine females and six males were used as a control group to compensate for the effects of growth on the treatment groups, as it was not possible to determine whether the skeletal changes were due to growth or treatment. The total observation period was about 6 months on average, and transition from one CVM stage to another generally takes at least 1 year. Thus, this observation period would not have affected the treatment plan for those patients. All control patients started their treatment immediately after termination of the observation period.

Interventions

All patients were treated with a nonextraction approach using 0.022-inch-slot MBT brackets (Ormco Corp, Orange, Calif) bonded to both arches. Mandibular canines were bonded with Damon 3MX brackets (Ormco), which have a square vertical slot (0.018 $\times$ 0.018-inch). Leveling was done until stainless steel archwires (0.019 $\times$ 0.025-inch) could be engaged passively in both arches. Both archwires were cinched back, teeth were figure-8 ligated, and anchorage was reinforced with a maxillary transpalatal arch to prevent buccal tipping of maxillary molars. In group 1, the FRD

Figure 1. Forsus used with miniscrews.

was selected and inserted following the manufacturer's instructions, that is, into the headgear tube of the maxillary molars; the pushrod was hooked onto the mandibular archwire distal to the canine brackets.

For group 2 patients, miniscrews (1.6 × 10 mm; MCT Tech, South Korea) were inserted bilaterally between the mandibular canine and first premolar roots at the level of the mucogingival junction. A segment of 0.016 × 0.016-inch stainless steel wire was shaped and inserted between the vertical slot of the mandibular canine bracket and the hole in the miniscrew neck to establish indirect anchorage (Figure 1).

Patients were observed every 4 weeks. During each follow-up visit, if the spring module was compressed more than 2.5 mm above the stop on the push rod, reactivation was performed by attaching a crimp onto the push rod to provide 1.5 mm of activation. The FRD and miniscrews were removed when an edge-to-edge incisor relationship had been achieved with a Class I or overcorrected Class I canine and molar relationship. This was achieved in a mean time of 6.06 ± 0.76 months in group 1 and 6.42 ± 1.04 months in group 2 (Figures 2 and 3). The fixed appliances were left in place using light Class II elastics to stabilize the results and avoid relapse. To settle the occlusion after FRD removal, light intermaxillary box elastics were used, and the mandibular archwire was replaced with a lighter, more flexible wire.

Outcomes

The main outcomes of the study were the skeletal and dentoalveolar changes. The secondary outcomes were the soft tissue changes after treatment.

Cephalometric Analysis

Lateral cephalometric radiographs were taken by a single technician on the same radiographic machine immediately before insertion (T1) and after removal of the FRD and miniscrews (T2) to compare treatment outcomes. All landmarks were digitized and measurements were recorded using Dolphin Imaging software version 11.8 (Dolphin Imaging, Chatsworth, Calif).

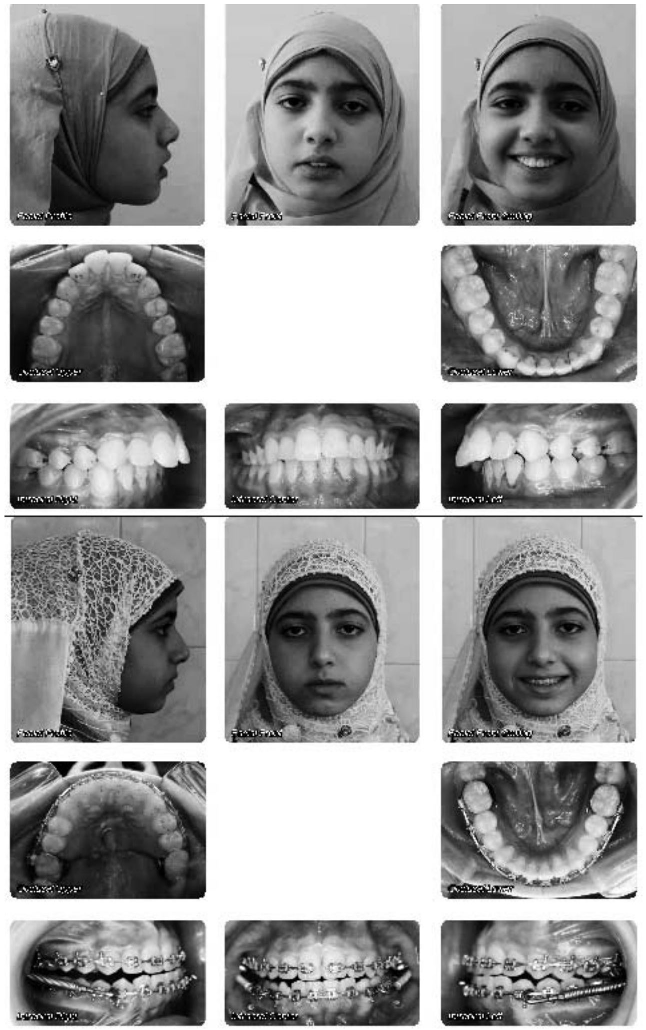

Figure 2. Intraoral and extraoral photos of a group 1 (Forsus) patient before and after treatment.

Reliability

To minimize any method error, all measurements were performed twice by the same investigator. The radiographs were remeasured after 1 month and the readings compared. A tolerance limit of 0.5 mm and 0.5° was established for the difference between the first and second observations of linear and angular measurements, respectively. If the limit was exceeded, a new tracing and measurement were made and the aberrant one discarded.

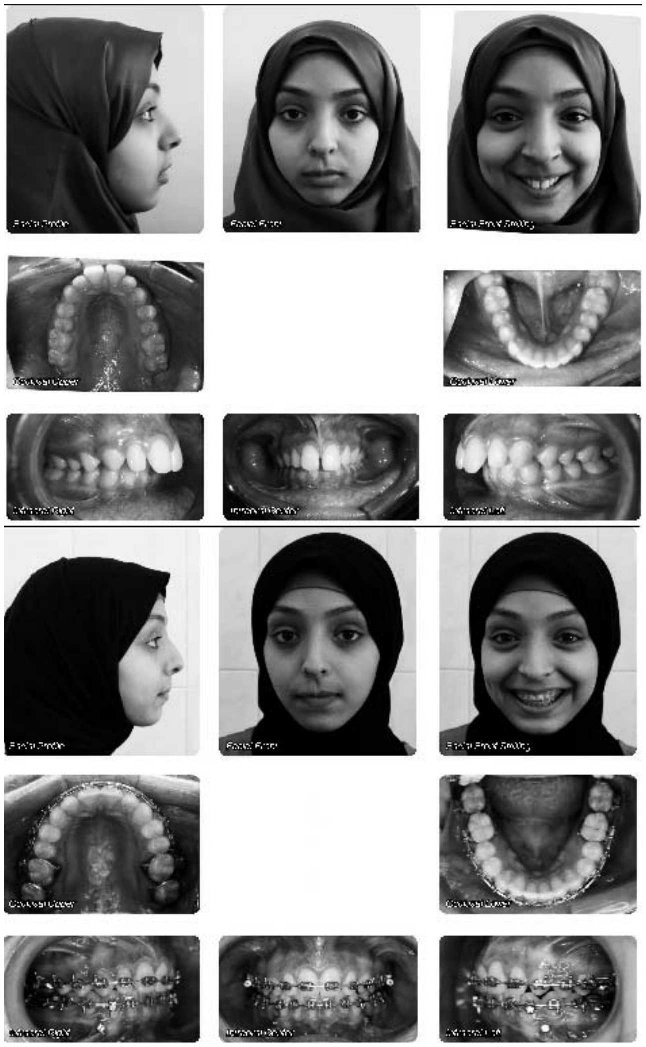

Figure 3. Intraoral and extraoral photos of a group 2 (Forsus with miniscrew) patient before and after treatment.

Blinding

Blinding of both patient and operator to the intervention was impossible. However, the investigator who analyzed the cephalograms was blinded regarding the origin of the films and the group to which the individual subjects belonged. All data were labeled with numbers and sent to the statistician, who was also blinded to the patients' groups. For the control group, it was impossible to be completely blinded as there were no appliances in the patients' mouths, but blinding was achieved regarding the time point of the cephalograms.

Statistical Analysis

Statistical analysis was performed with SPSS Version 21.0 (SPSS Inc, Chicago, Ill). The Shapiro-Wilk test showed that the data were normally distributed ($P > .05$), thus, parametric tests were used. Paired *t*-tests were performed to detect changes within each group. ANOVA was used for comparing mean changes among the three groups. If a statistically significant difference was found ($P < .05$), a Tukey multiple-comparison test was used to identify which groups were different.

RESULTS

Participants Flow and Patient Attrition

A CONSORT diagram is shown in Figure 4, demonstrating all patients recruited into the study.

Baseline Data

Groups were well matched regarding patient ages and treatment duration as there were no significant differences among all groups ($P > .05$; Table 1). There were no significant differences in male-to-female ratios in the treatment and control groups ($P > .05$), which excluded any potential effects of gender on craniofacial size and changes. There were no statistically significant differences among the three groups at T1 for any analyzed cephalometric parameters (Table 2). Skeletal, dental, and soft tissue changes between T1 and T2 for all groups are shown in Table 3. Comparisons among all groups are shown in Table 4.

Skeletal Measurements

In the anteroposterior dimension, there was a significant decrease in the SNA angle (0.51° $\pm$ 0.57°, $P < .05$; 0.79 $\pm$ 0.5, $P \leq .001$) and a highly significant decrease in the ANB angle (0.70° $\pm$ 0.62°, $P \leq .001$; 0.97° $\pm$ 0.65°, $P \leq .001$) for groups 1 and 2, respectively. Although there was an increase in SNB angle and mandibular length, this was not statistically significant ($P > .05$). Vertically, there was a significant increase in lower facial height (Group 1: –1.11 mm $\pm$ 1.43 mm, $P < .05$; Group 2: –1.45 mm $\pm$ 1.17 mm, $P \leq .001$). There were no statistically significant differences for any skeletal measurements between the treatment groups ($P > .05$; Table 4).

Dental Measurements

In groups 1 and 2, the maxillary incisors showed significant retrusion as evident from changes in U1-NA angle (6.89° $\pm$ 4.16°, $P \leq .001$; 2.56° $\pm$ 1.36°, $P \leq .001$, respectively). The mandibular incisors exhibited highly significant proclination; L1-NB angle (–6.0° $\pm$ 2.93°, $P \leq .001$; –4.70° $\pm$ 4.04°, $P \leq .001$) in groups 1 and 2, respectively. There was a significant reduction in overjet (4.48 $\pm$ 1.59 mm, $P < .05$; 5.53 $\pm$ 1.45, $P < .05$)

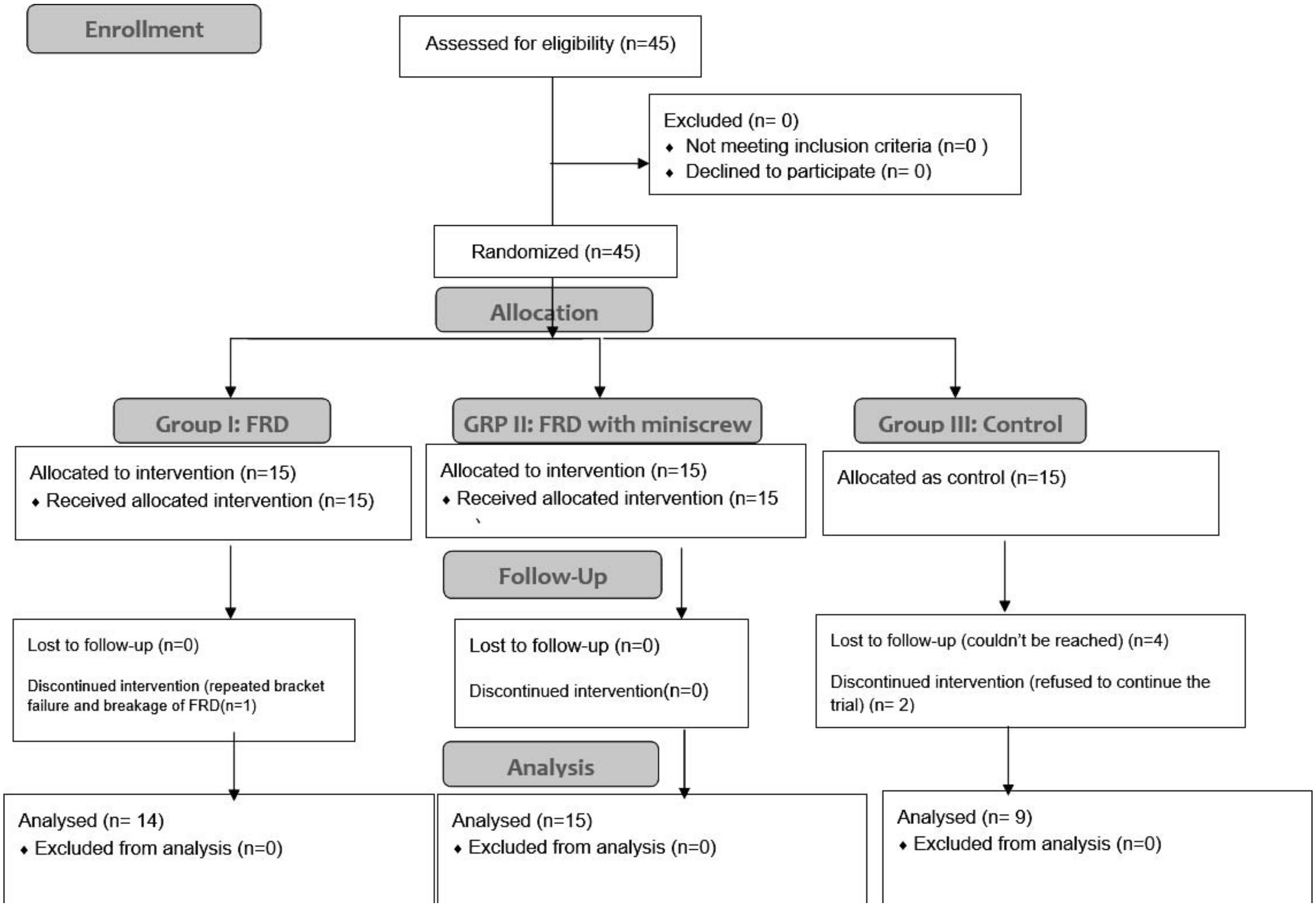

Figure 4. CONSORT diagram showing the flow of subjects in the study.

and overbite (1.8 $\pm$ 0.95, $P < .05$; 2.7 $\pm$ 1.98, $P < .05$). The maxillary molars exhibited highly significant distal movement; U6-PT mm (1.98 $\pm$ 1.44, $P \leq .001$; 1.94 $\pm$ 1.34, $P \leq .001$). For all dental measurements, there were no significant differences ($P > .05$) between the treatment groups (Table 4).

Soft Tissue Measurements

There was significant retraction of the upper lip in both treatment groups as demonstrated by upper lip to E-plane ($P < .05$). The lower lip did not show any significant change in relation to the E-plane ($P > .05$).

Harms

There was no looseness or mobility in the miniscrews of group 2; however, inflammation of gingival tissues near the miniscrews was reported in three cases.

DISCUSSION

Treatment was performed during the circumpubertal phases of skeletal development, which has been reported to be an optimal time for stimulation of mandibular growth.[11] Indirect anchorage was adopted for the present study to avoid direct orthopedic load on the miniscrews, which—originally designed to with-

Table 1. Comparison of the Mean Age and Treatment Duration Among Three Study Groups*

	Group 1 (n = 14)		Group 2 (n = 15)		Group 3 (n = 9)		ANOVA	
Variables	Mean	SD	Mean	SD	Mean	SD	F	P
Age	12.76	1.00	12.53	1.12	12.82	0.90	0.29	.750
Duration	6.06	0.76	6.42	1.04	6.07	0.25	0.88	.420

* $P > .05$ (Nonsignificant).

Table 2. Pretreatment Mean Values of All Parameters in Each Group and Significance Values of the Differences Among the Three Groups*

Measurements	Group 1 (Forsus)		Group 2 (Forsus with Miniscrews)		Group 3 (Control)		ANOVA
	Mean	SD	Mean	SD	Mean	SD	Sig
SNA (°)	81.471	4.047	83.400	4.805	83.156	4.024	.460
SNB (°)	74.064	3.167	75.200	5.140	75.222	2.978	.704
ANB (°)	7.429	2.801	8.213	1.701	7.922	1.762	.628
MP-SN (°)	29.550	5.888	27.527	6.415	31.978	4.561	.200
LFH (ANS-Me) (mm)	63.279	5.344	62.573	4.107	59.267	5.062	.144
TFH (N-Me) (mm)	108.764	7.191	107.567	5.643	103.300	5.921	.132
Co-Gn (mm)	106.686	6.589	105.787	5.137	103.211	6.792	.410
LFH/TFH (%)	54.507	1.708	54.980	1.986	53.789	1.573	.302
Wits appraisal (mm)	7.082	2.157	6.923	1.258	7.211	1.650	.646
U1-NA (mm)	4.690	2.681	4.517	1.561	5.533	2.121	.054
U1-NA (°)	20.936	6.617	20.040	5.727	26.533	5.319	.058
L1-NB (mm)	7.529	3.003	6.127	1.665	5.522	2.103	.112
L1-NB (°)	32.114	5.372	30.527	4.169	29.878	7.550	.598
Overjet (mm)	6.543	1.266	7.980	1.292	10.033	2.993	.672
Overbite (mm)	4.210	1.031	4.400	1.829	5.733	1.708	.051
U6-PT vertical (mm)	16.093	3.625	16.847	3.603	14.222	5.119	.075
Lower lip to E-plane (mm)	3.036	2.542	2.807	3.265	2.200	2.845	.307
Upper lip to E-plane (mm)	0.221	2.566	1.160	2.488	1.378	2.877	.796
Nasolabial angle (Col-Sn-UL) (°)	108.000	11.539	113.733	10.610	109.178	7.628	.506

* $P > .05$ (Nonsignificant).

Table 3. Changes in Cephalometric Skeletal, Dental, and Soft Tissue Measurements in All Groups

Measurements	Treatment Time	Group 1 (Forsus)			Group 2 (Forsus With Miniscrews)			Group 3 (Control)		
		Mean	SD	Sig	Mean	SD	Sig	Mean	SD	Sig
SNA (°)	T1	81.47	4.04	.005*	83.4	4.8	<.001**	83.15	4.02	.148
	T2	80.95	3.97		82.6	4.62		83.72	3.91	
	T2−T1	−0.51	0.57		−0.79	0.504		0.56	1.06	
SNB (°)	T1	74.06	3.16	.242	75.2	5.14	.277	75.22	2.97	.145
	T2	74.22	3.17		75.37	5.01		75.8	2.68	
	T2−T1	0.15	0.48		0.17	0.593		0.57	1.07	
ANB (°)	T1	7.42	2.8	<.001**	8.21	1.7	<.001**	7.92	1.76	1
	T2	6.72	3.12		7.24	1.49		7.92	1.58	
	T2−T1	−0.7	0.62		−0.97	0.647		0	0.68	
MP-SN (°)	T1	29.55	5.88	.219	27.52	6.41	.067	31.97	4.56	.067
	T2	30.07	5.99		28.2	6.09		31.07	4.94	
	T2−T1	0.52	1.51		0.67	1.311		−0.9	1.27	
LFH (ANS-Me) (mm)	T1	63.27	5.34	.013*	62.57	4.1	<.001**	59.26	5.06	.149
	T2	64.38	4.95		64.02	4.06		59.88	4.14	
	T2−T1	1.1	1.43		1.45	1.173		0.62	1.16	
AFH (N-Me) (mm)	T1	108.76	7.19	.057	107.56	5.64	<.001**	103.3	5.92	.021*
	T2	110.06	6.23		109.86	5.39		105.34	4.47	
	T2−T1	1.3	2.32		2.29	1.729		2.04	2.13	
Co-Gn (mm)	T1	106.68	6.58	.417	105.78	5.13	.1	103.21	6.79	.019*
	T2	107.3	5.29		106.81	5.3		105.84	5.83	
	T2−T1	0.61	2.74		1.02	2.258		2.63	2.7	
LFH/AFH (%)	T1	54.5	1.7	.269	54.98	1.98	.779	53.78	1.57	.155
	T2	54.83	1.85		55.05	2.2		53.43	1.7	
	T2−T1	0.32	1.06		0.07	0.991		−0.35	0.67	
Wits appraisal (mm)	T1	7.08	2.15	<.001**	6.92	1.25	<.001**	7.21	1.65	.102
	T2	3.74	2.57		2.27	1.14		6.1	1.96	
	T2−T1	−3.33	2.23		−4.64	1.554		−1.11	1.8	
U1-NA (mm)	T1	4.69	2.68	.014*	4.51	1.56	.006*	5.53	2.12	.164
	T2	2.71	2.01		1.95	1.69		6.01	2.21	
	T2−T1	−1.98	2.06		−2.56	1.368		0.47	0.93	

Table 3. Continued

Measurements	Treatment Time	Group 1 (Forsus)			Group 2 (Forsus With Miniscrews)			Group 3 (Control)		
		Mean	SD	Sig	Mean	SD	Sig	Mean	SD	Sig
U1-NA (°)	T1	20.93	6.61	<.001**	20.04	5.72	<.001**	26.53	5.31	.062
	T2	14.05	5.92		11.94	4.95		28.36	3.94	
	T2−T1	−6.88	4.15		−8.1	4.47		1.83	2.53	
L1-NB (mm)	T1	7.529	3	<.001**	6.12	1.66	<.001**	5.52	2.1	.101
	T2	9.02	3.18		7.42	1.62		5.83	2.25	
	T2−T1	1.5	0.97		1.29	1.069		0.31	0.5	
L1-NB (°)	T1	32.11	5.37	<.001**	30.52	4.16	.001**	29.87	7.55	.919
	T2	38.11	7.52		35.22	4.06		29.95	8	
	T2−T1	6	2.96		4.7	4.047		0.07	2.22	
Overjet (mm)	T1	6.54	1.26	<.001**	7.98	1.29	<.001**	10.03	2.99	.126
	T2	2.06	1.17		2.42	0.7		10.56	2.54	
	T2−T1	−4.47	1.59		−5.55	1.453		-0.53	0.93	
Overbite (mm)	T1	4.21	1.03	<.001**	4.4	1.82	<.001**	5.73	1.7	.963
	T2	2.41	0.94		1.69	0.97		5.71	2.36	
	T2−T1	−1.8	0.95		−2.7	1.985		−0.02	1.39	
U6-PT Vertical (mm)	T1	16.09	3.62	<.001**	16.84	3.6	<.001**	14.22	5.11	.185
	T2	14.1	3.87		14.9	4.19		14.88	5.06	
	T2−T1	−1.98	1.44		−1.94	1.348		0.66	1.38	
Lower lip to E-Plane (mm)	T1	3.03	2.54	.968	2.8	3.26	.688	2.2	2.84	.443
	T2	3.01	2.96		2.58	3.06		2.8	3.94	
	T2−T1	−0.02	1.99		−0.22	2.142		0.6	2.23	
Upper lip to E-Plane (mm)	T1	0.22	2.56	.012*	1.16	2.48	<.001**	1.37	2.87	.222
	T2	−0.74	2.64		−0.84	2.13		2.31	2.61	
	T2−T1	−0.96	1.23		−2	1.45		0.93	2.11	
Nasolabial angle (Col-Sn-UL) (°)	T1	108	11.53	.021*	113.73	10.61	<.001**	109.17	7.62	.863
	T2	113.68	8.84		124.38	7.99		109.47	6.76	
	T2−T1	5.68	8.12		10.653	8.84		0.28	4.85	

$P > .05$ (nonsignificant).
* $P \leq .05$ (significant).
** $P \leq .001$ (highly significant).

stand routine orthodontic forces—could increase the risk of of miniscrew failure.[12]

Skeletal Changes

Both treatment groups showed a significant decrease in the SNA angle that could be attributed to posteriorly directed forces acting on the maxilla (headgear effect) that may effectively restrict maxillary forward growth. This result is in agreement with previous studies that have reported similar findings.[3,13,14] However, other studies reported that FRD had no significant effect on maxillary growth. Oztoprak et al.[15] and Aslan et al.[6] explained this controversy by variance in treatment age, different treatment mechanics, or treatment duration.

Mandibular size in both treatment groups exhibited no significant increases, indicating that the FRD did not stimulate forward mandibular growth. This finding was in accordance with those of other studies which reported little or no effect on mandibular growth.[3,6,13,15,16] In contrast, several studies concluded that significant mandibular growth could be achieved by the use of this appliance.[4,13,17,18] This difference might be attributed to treatment duration (6 months), which may be not enough for mandibular growth to take place.[6,13,14,19] Both treatment groups exhibited a significant reduction in ANB, which can be attributed to a reduction in SNA. Similar findings of a decrease in ANB were reported in several studies.[7,15,20]

Although the treatment groups exhibited posterior mandibular rotation, this change was not statistically significant. Similarly, Aslan et al.[6] reported nonsignificant changes in the mandibular plane angle in both treatment groups. On the contrary, several studies reported significant mandibular rotation with the skeletally anchored FRD appliance.[5,17,21] This contradiction might be related to differences in the sample groups, different treatment durations, or different treatment mechanics. There was a significant increase in lower facial height in both treatment groups. Similar findings have been reported.[5,17,18] This may be attributed to downward and forward forces from the appliance which resulted in a new mandibular position that enhanced vertical condylar growth and, subsequently, increased lower facial height.[17] Contradictory to the findings of the present study, Oztoprak et al.[15] found no significant change in facial height, postulating that this was due to

Table 4. Comparison of Cephalometric, Skeletal, Dental, and Soft Tissue Mean Changes Among Groups 1, 2, and 3

	ANOVA		Tukey's Post Hoc Tests					
			Gps 1 & 2		Gps 1 & 3		Gps 2 & 3	
Measurements	F	P	Diff	P	Diff	P	Diff	P
SNA (°)	11.284	<.001**	−0.279	.532	1.081	.002*	1.360	<.001**
SNB (°)	1.195	.315	0.016	.998	0.421	.348	0.404	.366
ANB (°)	6.428	.004*	−0.273	.500	.700	.042*	.973	.003*
MP-SN (°)	4.101	.025*	0.152	.953	−1.421	.054	−1.573	.028*
LFH (ANS-Me) (mm)	0.441	.647	0.423	.659	0.050	.996	−0.373	.777
N-Me (mm)	1.475	.243	0.800	.544	1.460	.226	0.660	.723
Co-Gn (mm)	4.278	.022*	1.550	.206	2.957	.018*	1.407	.357
LFH/TFH (%)	1.111	.341	−0.110	.950	−0.594	.332	−0.484	.467
Wits appraisal (mm)	20.080	<.001**	0.366	.836	4.341	<.001**	3.975	<.001**
U1-NA (mm)	17.892	<.001**	−0.960	.210	2.777	<.001**	3.737	<.001**
U1-NA (°)	19.226	<.001**	−1.214	.693	8.719	<.001**	9.933	<.001**
L1-NB (mm)	4.801	.014*	−0.207	.823	−1.188	.014*	−.982	.045*
L1-NB (°)	9.213	.001**	−1.300	.546	−5.922	.001**	−4.622	.006*
Overjet (mm)	55.688	<.001**	−1.075	.115	5.011	<.001**	6.086	<.001**
Overbite (mm)	8.551	.001**	−0.971	.221	1.713	.035*	2.684	.001**
U6-PT vertical (mm)	12.238	<.001**	0.046	.996	2.652	<.001**	2.606	<.001**
Lower lip to E-plane (mm)	0.443	.645	−0.205	.963	0.621	.771	0.827	.625
Upper lip to E-plane (mm)	9.784	<.001**	−1.036	.194	1.897	.021*	2.933	<.001**
Nasolabial angle (Col-Sn-UL)	5.019	.012*	4.968	.216	−5.397	.253	−10.36	.009*

$P > .05$ (nonsignificant).
* $P \leq .05$ (significant).
** $P \leq .001$ (highly significant).

their study sample being in the postpeak growth period. Similarly, other researchers found no significant changes in facial height.[22,23]

Dental Changes

The distally directed force of the FRD transmitted through the heavy archwire to the maxillary incisors in both treatment groups could have caused their significant retrusion.[17] This finding is in accordance with those of previous Forsus studies.[6,17,24,25] Liu et al.[26] reported that upper anterior tooth retrusion would result in backward movement of A point with a consequent decrease in SNA°.

Both treatment groups showed significant mandibular incisor protrusion which is still one of the major disadvantages of FRD that could result in early correction of the overjet and, consequently, limit skeletal correction.[17] Contradictory to other studies,[6,7] which reported that the miniscrew-anchored FRD could limit mandibular incisor protrusion, we observed no significant difference between treatment groups; hence, the use of miniscrew anchorage did not minimize this unfavorable outcome. This difference may be attributed to the size of the wire segment used for connecting the miniscrew with the mandibular canine bracket. In the present study, a segment of 0.016×0.016-inch stainless steel was used because it was the largest wire size that could be inserted in the vertical slot (0.018×0.018-inch) of the mandibular canine bracket. Elkordy et al.[7] used a 0.019×0.025-inch stainless steel wire segment connected to the miniscrew and bonded to the labial surface of the mandibular canines. Whereas Aslan et al.[6] established indirect anchorage by using an 0.018×0.025-inch stainless steel wire between the vertical slot of the mandibular canine bracket and the miniscrew slot.

Significant reduction in overjet and overbite was evident in both treatment groups, which was related to the maxillary incisor retroclination and mandibular incisor proclination, suggesting total dentoalveolar effects of the appliance. This finding is in agreement with other studies.[6,7,25] In accordance with other studies,[3,7,18] the maxillary molar exhibited significant distal movement in both treatment groups, which can be attributed to the distal vector of force of the appliance.

Comparison of mean differences between groups 1 and 2 revealed no significant differences in any dental parameters, indicating that miniscrews did not prevent or even limit the dentoalveolar effects of the FRD. This finding is in disagreement with that of other studies reporting that the miniscrew-anchored Forsus limited mandibular incisor proclination[6,7] and increase maxillary molar distal movement.[7]

Soft Tissue Changes

Significant upper lip retrusion was observed in both treatment groups as measured by upper lip to the E-plane. This was in accordance with previous studies[5,13,15,17] and can be attributed to the heavy distal forces acting on the maxillary arch and subsequent retrusion of the maxillary incisors.[17] In contrast to some studies[4–6,27] that reported significant lower lip protrusion, we found nonsignificant lower lip protrusion. This was in accordance with other studies,[15,17] which reported similar findings. Turkkahraman et al.[17] suggested that the variation among studies might be due to differences in soft tissue reference lines and measurements. Possible contributors to the lower lip position are mandibular position, which did not show any significant forward movement, and the maxillary incisors, which showed significant retrusion. The nasolabial angle was significantly increased in both treatment groups. This may be attributed to retrusion of the maxillary incisors, allowing the upper lip to move posteriorly.[27] These treatment outcomes confirm those reported by other studies[15,28] that found similar soft tissue changes.

Limitations

The results of the present study should be interpreted with caution. The small sample size together with patient attrition could have affected the accuracy of the results. Moreover, the treatment duration of FRD (6 months) may be not enough for mandibular growth to take place and may be considered as a drawback of the FRD.

Generalizability

Despite the limited sample size, the results of this study could be applied to similar patients with Class II malocclusion.

CONCLUSIONS

- The Forsus FRD effectively corrected Class II malocclusion in both the conventional and miniscrew-anchored treatment groups, mainly through dentoalveolar changes. Due to the short treatment duration of the FRD (6 months), which may be not enough for mandibular growth to take place, a longer use of the appliance might have resulted in more skeletal effects.
- The use of miniscrews as a means of anchorage with FRD did not enhance forward mandibular growth or limit proclination of the lower incisors.

REFERENCES

1. McNamara JA Jr. Components of Class II malocclusion in children 8–10 years of age. *Angle Orthod*. 1981;51:177–202.
2. El-Sheikh MM, Godfrey K, Manosudprasit M, Viwattanatipa N. Force-deflection characteristics of the fatigue-resistant device spring: an in vitro study. *World J Orthod*. 2007;8:30–36.
3. Jones G, Buschang PH, Kim KB, Oliver DR. Class II non-extraction patients treated with the Forsus fatigue resistant device versus intermaxillary elastics. *Angle Orthod*. 2008;78:332–338.
4. Celikoglu M, Buyuk SK, Ekizer A, Unal T. Treatment effects of skeletally anchored Forsus FRD EZ and Herbst appliances: a retrospective clinical study. *Angle Orthod*. 2016;86:306–314.
5. Unal T, Celikoglu M, Candirli C. Evaluation of the effects of skeletal anchoraged Forsus FRD using miniplates inserted on mandibular symphysis: a new approach for the treatment of Class II malocclusion. *Angle Orthod*. 2015;85:413–419.
6. Aslan BI, Kucukkaraca E, Turkoz C, Dincer M. Treatment effects of the Forsus fatigue resistant device used with miniscrew anchorage. *Angle Orthod*. 2014;84:76–87.
7. Elkordy SA, Abouelezz AM, Fayed MM, Attia KH, Ishaq RA, Mostafa YA. Three-dimensional effects of the mini-implant-anchored Forsus fatigue resistant device: a randomized controlled trial. *Angle Orthod*. 2016;86:292–305.
8. Elkordy SA, Aboelnaga AA, Salah Fayed MM, AboulFotouh MH, Abouelezz AM. Can the use of skeletal anchors in conjunction with fixed functional appliances promote skeletal changes? A systematic review and meta-analysis. *Eur J Orthod*. 2016;38:532–545.
9. Little RM. The irregularity index: a quantitative score of mandibular anterior alignment. *Am J Orthod*. 1975;68:554–563.
10. Baccetti T, Franchi L, McNamara JA. The cervical vertebral maturation (CVM) method for the assessment of optimal treatment timing in dentofacial orthopedics. *Semin Orthod*. 2005;11:119–129.
11. Singh S, Singh M, Saini A, Misra V, Sharma VP, Singh GK. Timing of myofunctional appliance therapy. *J Clin Pediatr Dent*. 2010;35:233–240.
12. Luzi C, Verna C, Melsen B. Guidelines for success in placement of orthodontic mini-implants. *J Clin Orthod*. 2009;43:39–44.
13. Franchi L, Alvetro L, Giuntini V, Masucci C, Defraia E, Baccetti T. Effectiveness of comprehensive fixed appliance treatment used with the Forsus fatigue resistant device in Class II patients. *Angle Orthod*. 2011;81:678–683.
14. Giuntini V, Vangelisti A, Masucci C, Defraia E, McNamara JA Jr, Franchi L. Treatment effects produced by the Twin-block appliance vs the Forsus fatigue resistant device in growing Class II patients. *Angle Orthod*. 2015;85:784–789.
15. Oztoprak MO, Nalbantgil D, Uyanlar A, Arun T. A cephalometric comparative study of Class II correction with Sabbagh universal spring (SUS(2)) and Forsus FRD appliances. *Eur J Dent*. 2012;6:302–310.
16. Cacciatore G, Ghislanzoni LT, Alvetro L, Giuntini V, Franchi L. Treatment and posttreatment effects induced by the Forsus appliance: a controlled clinical study. *Angle Orthod*. 2014;84:1010–1017.
17. Turkkahraman H, Eliacik SK, Findik Y. Effects of miniplate anchored and conventional Forsus fatigue resistant devices in the treatment of Class II malocclusion. *Angle Orthod*. 2016;86:1026–1032.
18. Karacay S, Akin E, Olmez H, Gurton AU, Sagdic D. Forsus nitinol flat spring and Jasper Jumper corrections of Class II Division 1 malocclusions. *Angle Orthod*. 2006;76:666–672.
19. Phan KL, Bendeus M, Hagg U, Hansen K, Rabie AB. Comparison of the headgear activator and Herbst appli-

ance—effects and post-treatment changes. *Eur J Orthod*. 2006;28:594–604.

20. Cacciatore G, Alvetro L, Defraia E, Ghislanzoni LT, Franchi L. Active-treatment effects of the Forsus fatigue resistant device during comprehensive Class II correction in growing patients. *Korean J Orthod*. 2014;44:136–142.
21. Celikoglu M, Unal T, Bayram M, Candirli C. Treatment of a skeletal Class II malocclusion using fixed functional appliance with miniplate anchorage. *Eur J Dent*. 2014;8:276–280.
22. Pancherz H. The mechanism of Class II correction in Herbst appliance treatment. A cephalometric investigation. *Am J Orthod*. 1982;82:104–113.
23. Covell DA Jr, Trammell DW, Boero RP, West R. A cephalometric study of Class II Division 1 malocclusions treated with the Jasper Jumper appliance. *Angle Orthod*. 1999;69:311–320.
24. Heinig N, Goz G. Clinical application and effects of the Forsus spring. a study of a new Herbst hybrid. *J Orofac Orthop*. 2001;62:436–450.
25. Gunay EA, Arun T, Nalbantgil D. Evaluation of the immediate dentofacial changes in late adolescent patients treated with the Forsus FRD. *Eur J Dent*. 2011;5:423–432.
26. Liu YH, Ding WH, Liu J, Li Q. Comparison of the differences in cephalometric parameters after active orthodontic treatment applying mini-screw implants or transpalatal arches in adult patients with bialveolar dental protrusion. *J Oral Rehabil*. 2009;36:687–695.
27. Upadhyay M, Yadav S, Nagaraj K, Uribe F, Nanda R. Mini-implants vs fixed functional appliances for treatment of young adult Class II female patients. *Angle Orthod*. 2012;82:294–303.
28. Kuroda S, Yamada K, Deguchi T, Kyung HM, Takano-Yamamoto T. Class II malocclusion treated with miniscrew anchorage: comparison with traditional orthodontic mechanics outcomes. *Am J Orthod Dentofacial Orthop*. 2009;135:302–309.